ctgb

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 HERREGISTRATIE TOELATING

Gelet op de aanvraag d.d. 9 maart 2011 (20110285 THG) van

ISK Biosciences Europe N.V.
De Kleetlaan 12 B
1831 DIEGEM
BELGIË

tot herregistratie van de toelating als bedoeld in artikel 80, vijfde lid Verordening (EG) 1107/2009 juncto artikel 28, eerste lid, Wet gewasbeschermingsmiddelen en biociden voor het gewasbeschermingsmiddel, op basis van de werkzame stof flonicamid

TEPPEKI

gelet op artikel 39, eerste lid, Wet gewasbeschermingsmiddelen en biociden,

BESLUIT HET COLLEGE als volgt:

1.1 Herregistratie toelating

1. De toelating van het gewasbeschermingsmiddel TEPPEKI, welke expireert op 30 juni 2014 wordt voor de in bijlage I genoemde toepassingen verlengd onder nummer 12757. Voor de gronden van dit besluit wordt verwezen naar bijlage II bij dit besluit.
2. De toelating geldt tot 1 mei 2024.

1.2 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

1.3 Gebruik

Het middel mag slechts worden gebruikt met inachtneming van hetgeen in bijlage I bij dit besluit is voorgeschreven.

1.4 Classificatie en etikettering

Gelet op artikel 31 en artikel 65 van de Verordening EG/1107/2009 worden voorschriften gegeven.

Dit leidt tot de volgende voorschriften:

De aanduidingen, welke moeten worden vermeld, worden hierbij vastgesteld als volgt:

aard van het preparaat: Water dispergeerbaar granulaat

werkzame stof:	*gehalte:*
flonicamid	50 %

de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:
-

PICTOGRAM(MEN)

pictogram:
GHS07-schadelijk

SIGNAALWOORD

Waarschuwing

Gevarenaanduidingen

H319	Veroorzaakt ernstige oogirritatie.

Voorzorgsmaatregelen

SP 1	Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.

Aanvullende etiketelementen

EUH401	Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.

Behalve de voorgeschreven aanduidingen en vermeldingen moeten op de verpakking voorkomen:

a. letterlijk en zonder enige aanvulling:
het wettelijk gebruiksvoorschrift
De tekst van het wettelijk gebruiksvoorschrift is opgenomen in Bijlage I.

b. bij het toelatingsnummer een cirkel met daarin de aanduiding W.6.

1.5. Aflever- en opgebruiktermijn (respijtperiode)

De nieuwe etikettering met W-codering W.6. dient bij de eerstvolgende aanmaak op de verpakking te worden aangebracht. Oude verpakkingen met W-codering W.5. mogen onbeperkt worden afgeleverd en opgebruikt.

2 DETAILS VAN DE AANVRAAG EN TOELATING

2.1 Aanvraag
De toelating van het gewasbeschermingsmiddel TEPPEKI (besluit d.d. 16 december 2005) is laatstelijk bij besluit d.d. 13 december 2013 verlengd tot 30 juni 2014. Het betreft een aanvraag tot herregistratie van de toelating van het middel TEPPEKI (12757 N), een middel op basis van de werkzame stof flonicamid. De herregistratie wordt aangevraagd voor de toelating als insectenbestrijdingsmiddel in de teelt van aardappelen, wintertarwe, triticale, spelt, zomertarwe, pitvruchten, bloembol- en bloemknolgewassen, bloemisterijgewassen, boomkwekerijgewassen, vaste plantenteelt, bloemenzaadteelt, veredelingsteelt en basis zaadproductie van akkerbouw- en groentegewassen (bedekte teelt), openbaar groen en vruchtbomen en struiken van pitvruchten. Bij de herregistratie zijn de volgende uitbreidingen opgenomen ten opzichte van de bestaande toelating:

- spelt
- de toepassingen in bedekte teelt van bol- en knolbloemen en de onbedekte teelt van bloembollen en bloemknollen is nu uitgebreid naar bloembol- en bloemknolgewassen welke bedekte en onbedekte teelt van zowel bloembollen en –knollen als van bol- en knolbloemen omvat.
- de toepassingen in appel en peer en vruchtbomen en –struiken van appel en peer in de huidige toelating zijn geëxtrapoleerd naar pitvruchten in het algemeen.

2.2 Informatie met betrekking tot de stof
De werkzame stof flonicamid is bij Richtlijn 2010/29/EG d.d. 28 april 2010 van de Europese Commissie van de Europese Gemeenschappen opgenomen in Bijlage I van Richtlijn 91/414/EEG en is goedgekeurd krachtens Verordening (EG) No 1107/2009 (Uitvoeringsverordening (EU) No 540/2011 d.d. 25 mei 2011) en geplaatst als stof 305 in de bijlage.

2.3 Karakterisering van het middel
Teppeki is een wateroplosbaar granulaat (WG) dat 500 g per kg van de werkzame stof flonicamid bevat. Het is een systemisch insecticide met een translaminaire werking. Flonicamid remt de aminozuursynthese en blokkeert de voeding. Bladluizen kunnen zich niet meer voeden en gaan dood door uithongering binnen een tot vier dagen.
Het middel is in meerdere Europese landen toegelaten, waaronder in Nederland.

2.4 Voorgeschiedenis
De aanvraag is op 9 maart 2011 ontvangen; op 16 september 2011 zijn de verschuldigde aanvraagkosten ontvangen.

3 RISICOBEOORDELINGEN

3.1 Toetsingskader
Het toetsingskader dat gebruikt is voor de beoordeling van de aanvraag voor herregistratie van Teppeki is weergegeven in de RGB (Hoofdstuk 2) en de Evaluation Manual 1.1.

3.2 Fysische en chemische eigenschappen
De aard en de hoeveelheid van de werkzame stoffen en de in humaan-toxicologisch en ecotoxicologisch opzicht belangrijke onzuiverheden in de werkzame stof en de hulpstoffen zijn bepaald. De identiteit van het middel is vastgesteld. De fysische en chemische eigenschappen van het middel zijn vastgesteld en voor juist gebruik en adequate opslag van het middel aanvaardbaar geacht.

3.3 Analysemethoden
De geleverde analysemethoden voldoen aan de vereisten om de residuen te kunnen bepalen die vanuit humaan-toxicologisch en ecotoxicologisch oogpunt van belang zijn, volgend uit geoorloofd gebruik.

3.4 Risico voor de mens
Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor de mens verwacht.

3.5 Risico voor het milieu
Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor het milieu verwacht.

3.6 Werkzaamheid
Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften verwacht dat het werkzaam is.

3.6 Eindconclusie
Bij gebruik volgens het Wettelijk Gebruiksvoorschrift/Gebruiksaanwijzing is het middel TEPPEKI op basis van de werkzame stof flonicamid voldoende werkzaam en heeft het geen schadelijke uitwerking op de gezondheid van de mens en het milieu.

Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 217, 6700 AE WAGENINGEN. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Wageningen, 2 mei 2014

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

ir. J.F. de Leeuw
voorzitter

Dit middel is uitsluitend bestemd voor professioneel gebruik

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I bij het besluit d.d. 2 mei 2014 tot herregistratie van de toelating van het middel TEPPEKI, toelatingnummer 12757 N

Wettelijk Gebruiksvoorschrift
Toegestaan is uitsluitend het professionele gebruik als insectenbestrijdingsmiddel door middel van een gewasbehandeling in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.0, Ctgb juni 2011) onder de vermelde toepassingsvoorwaarden

Toepassings-gebied	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus of per 12 maanden	Minimum interval tussen toepassingen in dagen	Veiligheidstermijn in dagen
Aardappelen	bladluis[1]	0,16 kg/ha	2 per teeltcyclus	21	14
Wintertarwe	bladluis	0,14 kg/ha	2 per teeltcyclus	21	28
Triticale	bladluis	0,14 kg/ha	2 per teeltcyclus	21	28
Spelt	bladluis	0,14 kg/ha	2 per teeltcyclus	21	28
Zomertarwe	bladluis	0,14 kg/ha	2 per teeltcyclus	21	28
Pitvruchten	bladluis	0,14 kg/ha	3 per 12 maanden	21	21
Bloembol- en bloemknolgewassen	bladluis	0,14 kg/ha	3 per 12 maanden	21	-
Bloemisterijgewassen	bladluis	0,14 kg/ha	3 per 12 maanden	21	-
Boomkwekerijgewassen	bladluis	0,14 kg/ha	3 per 12 maanden	21	-
Vaste plantenteelt	bladluis	0,14 kg/ha	3 per 12 maanden	21	-
Bloemenzaadteelt	bladluis	0,14 kg/ha	3 per 12 maanden	21	-
Veredelingsteelt en basiszaadproductie van akkerbouw- en groentegewassen (bedekte teelt)	bladluis	0,14 kg/ha	3 per 12 maanden	21	-
Openbaar groen	bladluis	0,14 kg/ha	3 per 12 maanden	21	-
Vruchtbomen en struiken van pitvruchten	bladluis	0,14 kg/ha	3 per 12 maanden	21	-

[1] wegedoornluis *(Aphis nasturtii),* groene perzikluis *(Myzus persicae)*, aardappeltopluis *(Macrosiphum euphorbiae),*
vuilboomluis *(Aphis frangulae)*

Toepassingsvoorwaarden
Voor zaadteelten geldt dat aangeraden wordt om op kleine schaal te toetsen of het middel van invloed is op de kiemkracht van het gewas of ras.

Dit middel bevat de werkzame stof flonicamid. Flonicamid behoort tot de pyridinecarboxamiden. De Irac code is 9. Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen.

Dit middel is schadelijk voor niet-doelwit arthropoden in bedekte teelten. Vermijd onnodige blootstelling.

Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen mag u dit product op in bloei staande gewassen of op niet-bloeiende gewassen wanneer deze actief bezocht worden door bijen en hommels alleen toepassen na zonsondergang.

Gebruik is wel toegestaan op bloeiende planten in de kas mits er geen bijen of hommels in kas actief naar voedsel zoeken.”

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 2 mei 2014 tot herregistratie van de toelating van het middel TEPPEKI, toelatingnummer 12757 N

Contents

1. Identity of the plant protection product

1.1 Applicant

ISK Biosciences Europe N.V
De Kleetlaan 12B
1831 DIEGEM
België

1.2 Identity of the active substance

Common name	Flonicamid
Name in Dutch	Flonicamid
Chemical name	*N*-cyanomethyl-4-trifluoromethylnicotinamide [IUPAC]
CAS no	158062-67-0
EC no	not allocated

The active substance was included in Annex I of Directive 91/414/EEC on September 1st, 2010. From 14 June 2011 forward, according to Reg. (EU) No 540/2011 the substance is approved under Reg. (EC) No 1107/2009, repealing Directive 91/414/EEC.

1.3 Identity of the plant protection product

Name	TEPPEKI
Formulation type	WG
Content active substance	500 g/kg pure flonicamid

The formulation is identical to that assessed for the inclusion of the active substance in Annex I of Directive 91/414/EEC.

1.4 Function

Insecticide.

1.5 Uses applied for

See GAP (Appendix I).
In addition: In the project WGGA to WG extrapolation has been done from apple and pear into pomes (pitvruchten). Therefore pomes will also be on the final label of the reregistration (WG), instead of apple and pear. With the reregistration the applicant applied for extensions with the use in spelt, for the open field use in bulb flowers, and for the use in protected cultivation of flower bulbs and –corms.

1.6 Background to the application

It concerns an application for re-registration.

1.7 Packaging details

1.7.1 Packaging description

Material:	HDPE
Capacity:	1L, 3L or 275 mL (500g, 2 kg, or 100/140g)
Type of closure and size of opening:	(tamper evident) cap 63, 63, 50 mm Seal type: Induction heat sealing
Other information	Not applicable (not subject to ADR requirements, because it is not classified as a dangerous good for transport)

1.7.2 Detailed instructions for safe disposal

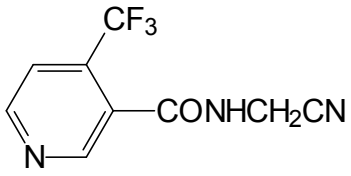
No particular recommendations.

2. Physical and chemical properties

2.1 Active substance: flonicamid

Data on the identity and the physical and chemical properties is taken from the List of Endpoints. The final List of Endpoints presented below is taken from the EFSA Scientific report on flonicamid (2010 8(1); 1445). Where relevant, some additional remarks/information are given in italics.

Identity

Chemical name (IUPAC) ‡	*N*-cyanomethyl-4-(trifluoromethyl)nicotinamide
Chemical name (CA) ‡	*N*-(cyanomethyl)-4-(trifluoromethyl)-3-pyridincarboxamide
CIPAC No ‡	763
CAS No ‡	158062-67-0
EC No (EINECS or ELINCS) ‡	not allocated
FAO Specification (including year of publication) ‡	No FAO specification is available
Minimum purity of the active substance as manufactured ‡	minimum 960 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Toluene max 3 g/kg
Molecular formula ‡	$C_9H_6F_3N_3O$
Molecular mass ‡	229.16 g/mol
Structural formula ‡	

Physical-chemical properties

Melting point (state purity) ‡	157.5°C (99.7%)
Boiling point (state purity) ‡	No boiling point observed (99.7%)
Temperature of decomposition (state purity)	306-320°C (99.7%)
Appearance (state purity) ‡	PAI : off white: Solid powder, odourless TGAI : Light beige (21°C), solid powder (24.9°C)
Vapour pressure (state temperature, state purity) ‡	2.55×10^{-6} Pa at 25°C 9.43×10^{-7} Pa at 20°C (99.7%)

Henry's law constant ‡	4.2×10^{-8} (20°C) (99.7%) calculation based
Solubility in water (state temperature, state purity and pH) ‡	5.2 g/L at 20°C (99.7%)

Solubility in organic solvents ‡ (state temperature, state purity)

	PAI (99.7%) g/L at 20°C	TGAI (98.7%) g/L at 20°C
Acetone	163.5	157.1
Ethyl acetate	34.2	34.9
Methanol	104.3	89.0
Dichloromethane	4.5	4.0
Toluene	0.55	0.30
Hexane	0.0002	0.0003
n-Octanol	3.0	2.6
Acetonitrile	132.8	111.4
Isopropyl alcohol	18.7	14.7

Surface tension ‡ (state concentration and temperature, state purity)	47.3 mN/m at 25±1°C 47.0 mN/m at 40±1°C Concentration tested 90 % of water solubility. Although the concentration tested is not correct as it is greater than 1 g/L it is clear that the material is surface active. Surface active (98.7%)
Partition co-efficient ‡ (state temperature, pH and purity)	Log P_{ow} = -0.24 at 20°C (pH not measured) (calculated value)
Dissociation constant (state purity) ‡	pKa = 11.6 at 20 ±1°C (99.7%)
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	λmax — ε (L/(cm x mol)) 265 nm in neutral solution (99.7%) — 3870 266 nm in acidic solution — 3890 204 and 270 nm in basic solution — 13200 and 4190 No significant absorption above 290 nm
Flammability ‡ (state purity)	Not highly flammable (98.7%)
Explosive properties ‡ (state purity)	Not explosive (expert statement)
Oxidising properties ‡ (state purity)	Not oxidizing (expert statement)

EFSA Journal 2010;8(5):1445 stated the following data requirement: "*New technical material specification or a justification and quality data support the available technical specification (relevant for all representative uses evaluated; identified by RMS, confirmed by PRAPeR*". The applicant submitted to RMS France five batch analysis data from three commercial production sites. The RMS France has evaluated the data and confirmed the technical equivalence of the commercial production sites. The assessment by the RMS was included in addenda to the DAR.

2.2 Plant protection product: TEPPEKI

Data about plant protection product are taken from the DAR.
The range of the application concentration of the plant protection product is 0.01 - 0.094%

Section (Annex point)	Study	Guidelines and GLP	Findings	Evaluation and conclusion
B.2.2.1	Appearance:	GLP	Solid, free flowing cylindrical	Acceptable

Section (Annex point)	Study	Guidelines and GLP	Findings	Evaluation and conclusion
(IIIA 2.1)	physical state	Visual	granules	
B.2.2.2 (IIIA 2.1)	Appearance: colour	GLP Visual	Brown	Acceptable
B.2.2.3 (IIIA 2.1)	Appearance: odour	GLP Visual	Slight odour of ammonia	Acceptable
B.2.2.4 (IIIA 2.2)	Explosive properties	Theoretical assessment and DSC analysis	Not explosive (DSC: < 500 J/g decomposition energy)	Acceptable
B.2.2.5 (IIIA 2.2)	Oxidising properties	Theoretical assessment	Not oxidising	Acceptable
B.2.2.6 (IIIA 2.3)	Flammability	Theoretical assessment	Not highly flammable, based on the individual properties of the product components.	Acceptable
B.2.2.7 (IIIA 2.3)	Auto-flammability	Theoretical assessment	Not self-igniting, based on the individual properties of the product components.	Acceptable
B.2.2.8 (IIIA 2.3)	Flash point		Not applicable	
B.2.2.9 (IIIA 2.4)	Acidity / alkalinity		Not applicable	
B.2.2.10 (IIIA 2.4)	pH	GLP CIPAC MT75.2	pH = 8.3 at 22 ^{o}C (1% dispersion)	Acceptable
B.2.2.11 (IIIA 2.5)	Surface tension		Not applicable	
B.2.2.12 (IIIA 2.5)	Viscosity		Not applicable	
B.2.2.13 (IIIA 2.6)	Relative density		Not applicable	
B.2.2.14 (IIIA 2.6)	Bulk (tap) density	GLP CIPAC MT169	Density: 0.543 g/ml Tapped density: 0.582 g/ml	Acceptable
B.2.2.14 (IIIA 2.7)	Storage stability	GLP	Stable for 2 weeks at 54 ^{o}C in HDPE Properties determined before and after storage: appearance, packaging stability, a.i. content, pH, tap density, foam persistence, suspensibility, spontaneity of dispersion, wet sieve residue, particle size distribution, dust content, attrition resistance. No significant changes were observed after storage.	Acceptable. Determination of the impurity toluene before and after storage is not required since formation of this impurity during storage is unlikely to occur. Wettability was not determined after storage. This is considered acceptable, based on the

Section (Annex point)	Study	Guidelines and GLP	Findings	Evaluation and conclusion
				overall stability of the product during storage.
B.2.2.15 (IIIA 2.7)	Shelf life	GLP	Stable for 3 years at ambient temperatures in HDPE. Properties determined before and after storage: appearance, packaging stability, a.i. content, pH, tap density, foam persistence, suspensibility, spontaneity of dispersion, wet sieve residue, particle size distribution, dust content, attrition resistance. No significant changes were observed after storage.	Acceptable. Determination of the impurity toluene before and after storage is not required since formation of this impurity during storage is unlikely to occur.
B.2.2.16 (IIIA 2.8)	Wettability	GLP CIPAC MT 53.3.1	1 second	Acceptable
B.2.2.17 (IIIA 2.8)	Persistent foaming	GLP CIPAC MT47.2	0.16% in CIPAC D water: 60 mL after 1 minute.	Acceptable
B.2.2.18 (IIIA 2.8)	Suspensibility	GLP CIPAC MT168	In CIPAC D water: 0.008%: 100% 0.16%: 99.8%	Acceptable
B.2.2.19 (IIIA 2.8)	Spontaneity of dispersion	GLP CIPAC MT174	84.6%	Acceptable No information concerning the type of water used was presented in the DAR. The CIPAC handbook requires the use of CIPAC D water for this test. It is therefore assumed the test was performed in CIPAC D water.
B.2.2.20 (IIIA 2.8)	Dilution stability		Not applicable	
B.2.2.21	Dry sieve test		Not applicable	

Section (Annex point)	Study	Guidelines and GLP	Findings	Evaluation and conclusion
(IIIA 2.8)				
B.2.2.22 (IIIA 2.8)	Wet sieve test	GLP CIPAC MT167	0.02% w/w on a 75 micron sieve	Acceptable
B.2.2.23 (IIIA 2.8)	Particle size distribution	GLP CIPAC MT170	x1 = 250 µm (where R_x >= 90%) x2 = 850 µm (where R_x =< 10%)	Acceptable
B.2.2.24 (IIIA 2.8)	Content of dust/fines	GLP CIPAC MT171	9.2 mg Nearly dust free	Acceptable
B.2.2.25 (IIIA 2.8)	Attrition and friability	GLP CIPAC MT178	97.1%	Acceptable During the EU evaluation it was noted that no additional risk for the operator is expected, because the product is not toxic by inhalation, an irritant or sensitizer.
B.2.2.26 (IIIA 2.8)	Emulsifiability, re-emulsifiability and emulsion stability		Not applicable	
B.2.2.27 (IIIA 2.8)	Stability of dilute emulsion		Not applicable	
B.2.2.28 (IIIA 2.8)	Flowability	GLP CIPAC MT172	% test material retained on the test sieve after 5 liftings: 0% w/w 10 liftings: 0%w/w	Acceptable
B.2.2.29 (IIIA 2.8)	Pourability (rinsibility)		Not applicable	
B.2.2.30 (IIIA 2.8)	Dustability		Not applicable	
B.2.2.31 (IIIA 2.8)	Adherence and distribution to seeds		Not applicable, since the application is for seed production and not for seed treatment.	
2.9.1	Physical compatibility with other products		Not applicable	
2.9.2	Chemical compatibility with other products		Not applicable	

Conclusion
The physical and chemical properties of the active substance and the plant protection product are sufficiently described by the available data. Neither the active substance nor the product has any physical or chemical properties, which would adversely affect the use according to the proposed use and label instructions.

In the GAP/instructions for use the following has to be stated:
None.

2.3 Data requirements
None.

3. Methods of analysis

Description and data on the analytical methods is taken from the List of Endpoints. The final List of Endpoints presented below is taken from the EFSA Scientific report on flonicamid ((2010) 8(1); 1445). Where relevant, some additional remarks/information are given in italics.

3.1 Analytical methods in technical material and plant protection product

Technical as (analytical technique)	HPLC/UV
Impurities in technical as (analytical technique)	HPLC/UV, GC/FID and Karl Fisher titration
Plant protection product (analytical technique)	*HPLC/UV(flonicamid)* *GC/MS (toluene)*

Conclusion
The analytical methods have been assessed and are considered to be acceptable.

3.2 Residue analytical methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS LOQ : 0.01 mg/kg (wheat grain, tomatoes and apples) and 0.02 mg/kg in wheat straw for each compound (flonicamid and its metabolites TFNG, TFNA and TFNA-AM) And HPLC-MS/MS LOQ : 0.05 mg/kg (peach and potatoes) and 0.10 mg/kg (wheat straw) for each compound (flonicamid and its metabolites TFNG, TFNA and TFNA-AM)

Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS (an enforcement method is not required due to the fact that no MRLs are proposed) LOQ: 0.01 mg/L for milk LOQ: 0.01 mg/kg for bovine, poultry tissues and poultry eggs LOQ: 0.025 mg/kg for the other ruminant tissues for each compound (flonicamid and its metabolites OH-TFNA-AM, TFNA AND TFNA-AM)
Soil (analytical technique and LOQ)	HPLC-MS/MS LOQ: 0.005 mg/kg (flonicamid, TFNG, TFNG-AM, TFNA, TFNA-AM and TFNA-OH)
Water (analytical technique and LOQ)	HPLC-MS/MS LOQ: 0.1 µg/L (flonicamid, TFNA, TFNG, TFNA-AM, TFNA-OH and TFNG-AM in drinking water and surface water)
Air (analytical technique and LOQ)	HPLC-UV LOQ: 1.5 µg/m^3 (flonicamid)
Body fluids and tissues (analytical technique and LOQ)	Not required; the active substance is not classified as toxic or very toxic.

Based on the proposed use of the plant protection product (potato, cereals, apple, pear), analytical methods for determination of residues in food/feed of plant origin are required for dry and watery matrices.

Definition of the residue and MRLs for flonicamid		
Matrix	**Proposed definition of the residue for monitoring**	**Proposed MRL**
Food/feed of plant origin	flonicamid, TFNA and TFNG expressed as flonicamid	EU MRL: 0.05* mg/kg and above
Food/feed of animal origin	flonicamid and TFNA-AM expressed as flonicamid	EU MRL: 0.02* mg/kg (fat, milk), 0.03 mg/kg (meat, liver, kidney, offal), 0.05 mg/kg (egg), 0.03* mg/kg (others)
		Required LOQ
Soil	flonicamid	0.05 mg/kg (default)
Drinking water	flonicamid	0.1 µg/L (drinking water guideline)
Surface water	flonicamid	0.1 µg/L (HTB 1.0)
Air	flonicamid	7.5 µg/m^3 (derived from the AOEL according to SANCO/825/00)
Body fluids and tissues	The active substance is not classified as (very) toxic thus no definition of the residue is proposed.	

The residue analytical methods, included in the above List of Endpoints, are suitable for monitoring of the proposed MRLs. A method for hop was submitted for this application but since analytical methods were available for dry and watery matrices, this is not considered relevant here.

The residue analytical methods for water, soil and air, evaluated in the DAR, are acceptable and suitable for monitoring of residues in the environment.

Conclusion
The submitted analytical methods meet the requirements. The methods are specific and sufficiently sensitive to enable their use for enforcement of the MRLs and for monitoring of residues in the environment.

3.3 Data requirements
None.

4. Mammalian toxicology

List of Endpoints

The final List of Endpoints presented below is taken from the EFSA Journal on flonicamid (2010) 8(5); 1445. Where relevant some additional remarks/information are given in italics.

Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 5.1)

Rate and extent of absorption ‡	Rapid and extensive > 80% within 24 h Tmax = 0.4 h at low dose (2 mg/kg)
Distribution ‡	Extensive with peak tissue concentrations ≤ peak blood concentrations except in liver, kidney, adrenals, thyroid and GI tract.
Potential for accumulation ‡	None
Rate and extent of excretion ‡	Rapid mostly via urine 70 – 80% within 24 h; low biliary excretion (~ 5% AD).
Metabolism in animals ‡	Proceeds in the rat by nitrile & amide hydrolysis, N-oxidation, hydroxylation of pyridine ring Main component in urine, faeces and bile: IKI-220 (up to 70% AD); main metabolite in urine and bile: TFNA-AM (up to 27% AD); minor metabolites: TFNA and conjugates, TFNG-AM, TFNA-AM N oxide conjugate, OH-TFNA-AM, TFNG
Toxicologically relevant compounds (animals and plants) ‡	Parent substance
Toxicologically significant compounds (environment) ‡	Parent substance, impurity toluene

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	884 – 1768 mg/kg bw (m – f) **Xn, R22**
Rat LD_{50} dermal ‡	> 5000 mg/kg (m/f)

Rat LC_{50} inhalation ‡	> 4.9 mg/L (4 h, nose-only aerosol) (MMAD 4.8 µm)
Skin irritation ‡	non irritant
Eye irritation ‡	non irritant
Skin sensitization (test method used and result) ‡	not sensitising (M & K test)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	kidney (rat, dog), liver (mouse, rat), haematopoietic system (mouse, dog)
Relevant oral NOAEL ‡	8 mg/kg bw/d (dog 90-d and 52 w) 60 mg/kg bw/d (rat, 90-d) 15.3 mg/kg bw/d (mouse, 90-d)
Relevant dermal NOAEL ‡	1000 mg/kg bw/d (rat, 28-day study)
Relevant inhalation NOAEL ‡	no study – not required

Genotoxicity (Annex IIA, point 5.4) ‡	No genotoxic potential

The genotoxic potential of flonicamid was investigated in vitro in an Ames test, a mammalian cell gene mutation assay using L5178Y mouse lymphoma cells and a mammalian cytogenetic assay using Chinese hamster CHL cells. All these in vitro studies gave negative results.
Regarding in vivo data, a micronucleus study with mice, an UDS assay with rats and a Comet assay with mice were negative.

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Rat: kidneys, liver, anaemia Mouse: lungs, liver, haematopoietic system
Lowest relevant NOAEL / NOEL ‡	7.32 mg/kg bw/d (rat, 2-yr) 10 mg/kg bw/d (mouse, 18-month)
Carcinogenicity ‡	Rat: nasal tumours not considered relevant for humans. Mouse: strain- and species-specific lung tumours of unknown relevance to humans.

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	Reproduction: no adverse effect on reproductive parameters Parents: kidneys lesions, reduced ovary/adrenal weights Offspring: delayed vaginal opening and reduced uterus weight in F1 weanlings
Relevant parental NOAEL ‡	18 mg/kg bw/d
Relevant reproductive NOAEL ‡	109 mg/kg bw/d (highest dose tested)
Relevant offspring NOAEL ‡	30 mg/kg bw/d

Developmental target / critical effect ‡	Development (rat): increased placental weight, increased skeletal variations (cervical ribs)

	Development (rabbit): increased visceral anomalies without maternal toxicity Parental: liver and kidney (rat), reduced weight gain and food consumption (rabbit)
Relevant maternal NOAEL ‡	Rat: 100 mg/kg bw/d Rabbit: 7.5 mg/kg bw/d
Relevant developmental NOAEL ‡	Rat: 100 mg/kg bw/d **Repro Cat. 3, R63?** Rabbit: 2.5 mg/kg bw/d

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7) ‡

Acute neurotoxicity ‡	NOAEL 600 mg/kg bw (rat)
Repeated neurotoxicity ‡	NOAEL >625 mg/kg bw/day (rat, 90-day)
Delayed neurotoxicity ‡	No study – Not required

Other toxicological studies (Annex IIA, point 5.8) ‡

Mechanism studies ‡	Lung cell cycle analysis (BrdU index): dose response relationship in the mouse (NOEL 12.3 mg/kg bw/d); reversibility study; comparative study in the rat and the mouse Lung cell cycle analysis (BrdU index) with TFNG, TFNA, TFNA-AM: no effect on BrdU index after a 3 or 7-d treatment at 318-402 mg/kg bw/d Comparison of lung cell cycle analysis after flonicamid or isoniazid dietary exposure in 3 mouse strains: BrdU index increased in CD-1 mouse strain only after flonicamid and no strain specificity after isoniazid.
Studies performed on metabolites or impurities ‡	Acute oral toxicity of metabolites TFNA oral LD_{50}: >2000 mg/kg. No clinical signs TFNA-AM oral LD_{50}: >2000 mg/kg. No clinical signs TFNA-OH oral LD_{50}: >2000 mg/kg. No clinical signs TFNG oral LD_{50}: >2000 mg/kg. No clinical signs TFNG-AM oral LD_{50}:>2000 mg/kg. No clinical signs Genotoxicity testing of metabolites Bacterial reverse mutation assays: negative for TFNA; TFNA-AM; TFNA-OH; TFNG and TFNG-AM 90-day toxicity studies on metabolites TFNA: NOAEL 136 mg/kg bw/d TFNG: NOAEL 135 mg/kg bw/d

Medical data (Annex IIA, point 5.9) ‡

Not applicable. Flonicamid has not been marketed. No adverse health effects have been reported in manufacturing plant personnel.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.025 mg/kg bw	Rabbit developmental	100
AOEL ‡	0.025 mg/kg bw	Rabbit developmental	100
ARfD (acute reference dose) ‡	0.025 mg/kg bw	Rabbit developmental	100

Dermal absorption (Annex IIIA, point 7.3) ‡

TEPPEKI® 50% WG	concentrate: 7.46 %; spray dilution: 13 %

Local effects
Flonicamid does not produce local effects, neither after a single nor repeated exposure.

Data requirements active substance
No additional data requirements are identified.

4.1 Toxicity of the formulated product (IIIA 7.1)

The formulation does not need to be classified on the basis of its acute oral (LD_{50} rat >2000 mg/kg bw), dermal (LD_{50} rat >2000 mg/kg bw) and inhalation toxicology (LC_{50} rat >5.36 mg/L).
The formulation is considered not irritating to skin.
The formulation is considered irritating to eyes and needs to be classified as H319 ‘Causes serious eye irritation’.
The formulation does not have sensitising properties in a LLNA and two Buehler tests.

4.1.1 Data requirements formulated product

No additional data requirements are identified.

4.2 Dermal absorption (IIIA 7.3)

One *in vitro* study was presented in the DAR (with TEPPEKI (manufacturer's code number: IKI-220 50% WG, IKI-220 50WG, IBE 3894)). A field use dilution of 0.4 g flonicamid/L was tested with human skin samples and gave a dermal absorption value of 7.46%. Results from a new *in vitro* study with the representative formulation were provided in addendum 2 to B.6 (France, 2009), showing a value of 13% with human skin samples when a field use dilution of 0.07 g flonicamid/L was tested. Therefore it was agreed to use dermal absorption values of 7.46% for the concentrate and 13% for the dilution in the DAR.

The spray dilution range specified in the GAP table for this application is 0.05 - 0.47 g flonicamid/L. As in general a lower field concentration results in a higher dermal absorption percentage, using a dermal absorption value of 7.46% for the concentrate (obtained with a field use dilution of 0.4 g flonicamid/L) and a value of 13% for the spray dilution (obtained with the formulation containing 0.07 g flonicamid/L) for the current application is considered acceptable.

4.3 Available toxicological data relating to non-active substances (IIIA 7.4)

The available toxicological data relating to non-active substances will be taken into account in the classification and labelling of the formulated product.

4.4 Exposure/risk assessments

Overview of the intended uses

An application has been submitted for the reregistration of the plant protection product TEPPEKI, an insecticide based on the active substance flonicamid.

TEPPEKI is a WG (water dispersible granule) formulation and contains 500 g/kg flonicamid.

4.4.1 Operator exposure/risk

According to the Dutch Plant Protection Products and Biocides Regulations the risk assessment is performed according to a tiered approach. There are four possible tiers:
Tier 1: Risk assessment using the EU-AOEL without the use of PPE
Tier 2: Risk assessment using the NL-AOEL without the use of PPE
Tier 3: Refinement of the risk assessment using new dermal absorption data
Tier 4: Prescription of PPE

Tier 1

Calculation of the EU-AOEL / Tolerable Limit Value (TLV)

For flonicamid no TLV has been set. The AOEL will be used for the risk assessment.

Since the formulation is applied 1-3 times during the cultivation period, a semi-chronic exposure duration is applicable for the operator (including contract workers).

Since flonicamid is included in Annex I of 91/414/EEC, the semi-chronic EU-AOEL of 0.025 mg/kg bw/day (= 1.75 mg/day for a 70-kg operator), based on the developmental toxicity study with rabbits, is used for the risk assessment (see List of Endpoints).

Exposure/risk

Exposure to flonicamid during mixing and loading and application of TEPPEKI is estimated with models. The exposure is estimated for the unprotected operator. In general, mixing and loading and application is performed by the same person. Therefore, for the total exposure, the respiratory and dermal exposure during mixing/loading and application have to be combined.
In the Table below the estimated internal exposure is compared with the systemic EU-AOEL.

Table T.1 Internal operator exposure to flonicamid and risk assessment for the use of TEPPEKI

	Route	Estimated internal exposure [a] (mg/day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Mechanical downward spraying on potatoes, winter wheat, summer wheat, triticale, spelt, flower bulb and flower corm crops, floriculture crops, flower seed crops, perennials and public green spaces (uncovered, 0.16 kg/ha)				
Mixing/ Loading[c]	Respiratory	0.01	1.75	< 0.01
	Dermal	0.08	1.75	0.04
Application[d]	Respiratory	0.01	1.75	< 0.01
	Dermal	0.31	1.75	0.18
	Total	0.40	1.75	0.23

	Route	Estimated internal exposure [a] (mg/day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Mechanical upward spraying on apple, pear, fruit trees and shrubs of apple and pear (includes rootstocks) and tree nursery crops (uncovered, 0.14 kg/ha)				
Mixing/ Loading[c]	Respiratory	0.01	1.75	< 0.01
	Dermal	0.08	1.75	0.04
Application[d]	Respiratory	0.01	1.75	0.01
	Dermal	4.15	1.75	2.37
	Total	4.25	1.75	2.43
Manual upward spraying on apple, pear, fruit trees and shrubs of apple and pear (includes rootstocks) and tree nursery crops (uncovered, 0.14 kg/ha)				
Mixing/ Loading[c]	Respiratory	< 0.01	1.75	< 0.01
	Dermal	0.04	1.75	0.02
Application[e]	Respiratory	0.08	1.75	0.05
	Dermal	5.06	1.75	2.89
	Total	5.18	1.75	2.96
Manual up- and downward spraying on flower bulb and flower corm crops, floriculture crops, flower seed crops, tree nursery crops, perennials and basic seed production and plant breeding crops of vegetables and arable crops (covered, 0.07 kg a.s./ha)				
Mixing/ Loading and application[f]	Respiratory	0.07	1.75	0.04
	Dermal	1.82	1.75	1.04
	Total	1.89	1.75	1.08

a Internal exposure was calculated with:
- biological availability via the dermal route: 7.46% (concentrate) and 13% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AOEL.
c External exposure is estimated with the NL-model.
d External exposure is estimated with EUROPOEM.
e External exposure is estimated with the German model (90th percentile).
f External exposure is estimated with the Dutch greenhouse model.

Since the EU-AOEL is exceeded without the use of PPE for uncovered mechanical and manual upward spraying and covered manual up- and downward spraying, a tier 2 assessment has to be performed using the NL-AOEL.

Tier 2

Calculation of the NL-AOEL
The risk index calculated with the EU-AOEL is >1. Therefore, the Plant Protection Products and Biocides Regulations (NL: Rgb) prescribes the calculation of the risk with an AOEL based on allometric extrapolation (known as the NL-AOEL). This method takes into account the caloric demand of the species studied and results in a more specific value than the EU-AOEL for which a standard factor of 100 is applied.

The calculation of the systemic AOEL for semi-chronic exposure is based on the NOAEL of 2.5 mg/kg bw/day in the developmental toxicity study with rabbits. Calculations from other studies result in higher AOELs.
Safety factors are used to compensate for the uncertainties, which arise, for example, from extrapolation from the tested species to humans and the differences between experimental circumstances, and to ensure that at the acceptable exposure level no adverse health effects

will occur.

Used factors are:
- extrapolation rabbit → human on basis of caloric demand 2.4
- other interspecies differences: 3
- intraspecies differences: (professional use) 3
- biological availability via oral route: >80%*
- weight of professional operator/worker: 70 kg

* If the absorbed dose is significantly lower (<80%) than the administered dose, this is adjusted by a correction factor equal to the percentage absorption.

$AOEL_{systemic}$: 2.5 x 1 x 70 / (2.4 x 3 x 3) = 8.10 mg/day

Exposure/risk

Table T.2 Internal operator exposure to flonicamid and risk assessment for the use of TEPPEKI

	Route	Estimated internal exposure [a] (mg/day)	Systemic NL-AOEL (mg/day)	Risk-index [b]
Mechanical upward spraying on apple, pear, fruit trees and shrubs of apple and pear (includes rootstocks) and tree nursery crops (uncovered, 0.14 kg/ha)				
Mixing/ Loading[c]	Respiratory	0.01	8.10	< 0.01
	Dermal	0.08	8.10	0.01
Application[d]	Respiratory	0.01	8.10	< 0.01
	Dermal	4.15	8.10	0.51
	Total	4.25	8.10	0.52
Manual upward spraying on apple, pear, fruit trees and shrubs of apple and pear (includes rootstocks) and tree nursery crops (uncovered, 0.14 kg/ha)				
Mixing/ Loading[c]	Respiratory	< 0.01	8.10	< 0.01
	Dermal	0.04	8.10	< 0.01
Application[e]	Respiratory	0.08	8.10	0.01
	Dermal	5.06	8.10	0.62
	Total	5.18	8.10	0.63
Manual up- and downward spraying on flower bulb and flower corm crops, floriculture crops, flower seed crops, tree nursery crops, perennials and basic seed production and plant breeding crops of vegetables and arable crops (covered, 0.07 kg a.s./ha)				
Mixing/ Loading and application[f]	Respiratory	0.07	8.10	0.01
	Dermal	1.82	8.10	0.22
	Total	1.89	8.10	0.23

a Internal exposure was calculated with:
- biological availability via the dermal route: 7.46% (concentrate) and 13% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AOEL.
c External exposure is estimated with the NL-model.
d External exposure is estimated with EUROPOEM.
e External exposure is estimated with the German model (90th percentile).
f External exposure is estimated with the Dutch greenhouse model.

Since the NL-AOEL is not exceeded without the use of PPE, a higher tier assessment is not required.

4.4.2 Bystander exposure/risk

Uncovered use

The exposure is estimated for the unprotected bystander. In Table T.3 the estimated internal exposure is compared with the systemic EU-AOEL.

Table T.3 Internal bystander exposure to flonicamid and risk assessment during application of TEPPEKI

Route	Estimated internal exposure [a] (mg/day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Bystander exposure during downward application			
Respiratory	0.02	1.75	0.01
Dermal	0.01	1.75	0.01
Total	0.03	1.75	0.01
Bystander exposure during upward application			
Respiratory	0.01	1.75	0.01
Dermal	0.27	1.75	0.16
Total	0.28	1.75	0.16

a External exposure was estimated with EUROPOEM II. Internal exposure was calculated with:
- biological availability via the dermal route: 13% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AOEL.

Covered use

During spraying operations there should be no bystanders present in the greenhouse. No exposure to bystanders is therefore expected.

For residents living near greenhouses, the exposure is estimated using the Lee Side Turbulence model. In many cases the exposure of nearby residents is low. Therefore, a two step approach is used.

Step 1:
Is the ADI or other reference value (in µg/kg bw/day) divided by the application rate (in kg a.s./ha) > 2.14?

For flonicamid the ADI is 0.025 mg/kg bw/day. The highest application rate of flonicamid for TEPPEKI is 0.08 kg a.s./ha:

25 / 0.08 = 313.

Thus, safe use for residents nearby greenhouses can be concluded.

4.4.3 Worker exposure/risk

Uncovered use

<u>Tier 1</u>

Shortly after application it is possible to perform re-entry activities during which intensive contact with the treated crop will occur. Therefore, worker exposure is calculated.
The exposure is estimated for the unprotected worker. In Table T.4 the estimated internal exposure is compared with the systemic EU-AOEL.

Table T.4 Internal worker exposure to flonicamid and risk assessment after application of TEPPEKI

Route	Estimated internal exposure [a] (mg/day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Re-entry activities in apple and pear, floriculture, perennials			
Respiratory	-[c]	1.75	-[c]
Dermal	0.82	1.75	0.47
Total	0.82	1.75	0.47

a External exposure was estimated with EUROPOEM II. Internal exposure was calculated with:
- biological availability via the dermal route: 13% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AOEL.
c No model is available to calculate the respiratory internal exposure. However, the respiratory internal exposure can be considered negligible in view of the fact that the uses concern field activities (outdoors) and no spraying of the product occurs during re-entry activities.

Covered use

Shortly after application it is possible to perform re-entry activities during which intensive contact with the treated crop will occur. Therefore, worker exposure is calculated.
The exposure is estimated for the unprotected worker. In Table T.5 the estimated internal exposure is compared with the systemic EU-AOEL.

Table T.5 Internal worker exposure to flonicamid and risk assessment after application of TEPPEKI

Route	Estimated internal exposure [a] (mg/day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Re-entry activities in flower bulb and flower corm crops, floriculture crops, flower seed crops, tree nursery crops, perennials and basic seed production and plant breeding crops of vegetables and arable crops			
Respiratory	0.02	1.75	0.01
Dermal	0.82	1.75	0.47
Total	0.84	1.75	0.48

a External exposure was estimated with EUROPOEM II. Internal exposure was calculated with:
- biological availability via the dermal route: 13% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AOEL.

Since the EU-AOEL is not exceeded without the use of PPE, a higher tier assessment is not required.

4.4.4 Re-entry

For the possible re-entry activities on public green spaces in the Table below the estimated internal exposure as a result of dermal exposure is compared with the systemic AEL. There is no model available to estimate respiratory exposure, but it is expected that this will be negligible. Oral exposure (in case of infants) is estimated as a result from hand-to-mouth exposure.

Table T.6 Internal re-entry exposure to flonicamid and risk assessment after application of TEPPEKI

	Route	Estimated internal exposure [a] (mg/day)	Systemic AEL (mg/day) [b]	Risk-index [c]
Re-entry in public green spaces				
Infant (10.5 months)	Oral [d]	0.04	0.22	0.17
	Dermal	0.04	0.22	0.20
	Total	0.08	0.22	0.37
Child (4 year)	Dermal	0.14	0.38	0.36
Adult (lying)	Dermal	0.18	1.58	0.11
Adult (sporter)	Dermal	0.27	1.58	0.17

a External exposure was estimated by the 'RIVM re-entry model'. Internal exposure was calculated with:
- biological availability via the dermal route: 13% (see 4.2)
- biological availability via the oral route: 100% (see List of Endpoints).

b From the systemic AEL of 0.025 mg kg/bw day a specific AEL is derived for children of 10.5 month (8.7 kg bw) and 4 year (15 kg bw) and for adults (63 kg bw).

c The risk-index is calculated by dividing the internal exposure by the systemic AEL.

d For crawling children (10.5 months), also oral exposure via hand-mouth contact is included.

Overall conclusion of the exposure/risk assessments of operator, bystander, and worker

The product complies with the Uniform Principles.

Operator exposure

Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected operator after respiratory and dermal exposure to flonicamid as a result of the application of TEPPEKI in the intended crops.

Bystander exposure

Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected bystander due to exposure to flonicamid during application of TEPPEKI in the intended crops.

Worker exposure

Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected worker after respiratory and dermal exposure during re-entry activities in the intended crops due to exposure to flonicamid after application of TEPPEKI.

Re-entry exposure

Based on the risk assessment, it can be concluded that no adverse health effects are expected for unprotected adults, children and infants during re-entry activities on public green spaces due to exposure to flonicamid after application of TEPPEKI on public green spaces.

4.5 Appropriate mammalian toxicology and operator exposure endpoints relating to the product and approved uses

See List of Endpoints.

4.6 Data requirements

Based on this evaluation, no additional data requirements are identified.

4.7 Combination toxicology

TEPPEKI contains only one active substance and it is not described that it should be used in combination with other formulations.

5. Residues

List of Endpoints

The list of Endpoints presented below is taken from the EFSA scientific Report: Conclusion on the peer review of the pesticide risk assessment of the active substance flonicamid, EFSA Journal 2010; 8 (5): 1445.

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Cereals (wheat), Root vegetable (potato) and Fruit crop (peach, pepper)
Rotational crops	none
Plant residue definition for monitoring	Option 1: Flonicamid Option 2: Flonicamid+TFNG+TFNA expressed as flonicamid
Plant residue definition for risk assessment	Flonicamid+TFNG+TFNA expressed as flonicamid
Conversion factor (monitoring to risk assessment)	Option 1: Yes, 2.5 apple/pear, 1.6 peach, 3.0 potato and 17.5 wheat grain Option 2: None

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Goat and hen
Animal residue definition for monitoring	Flonicamid+TFNA-AM expressed as Flonicamid
Animal residue definition for risk assessment	Flonicamid+TFNA-AM expressed as Flonicamid
Conversion factor (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Study not required

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

Stable for at least a period of 18 months on crops (apple, potato, wheat) and for at least 15 months on cereal products (bread) Stable for a period of at least 8 month in poultry matrices (meat, eggs, fat) and at least 9 month in goat matrices (meat, milk, fat)

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes 0.46 and 0.64 mg/kg DM (dairy&beef cattle)	Yes 0.33 mg/kg DM Poultry	Yes 0.37mg/kg DM Pig
Potential for accumulation (yes/no):	No	No	Not applicable
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No	No	Not applicable
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices (flonicamid +TFNA-AM) : Mean (max) mg/kg		
Muscle	<0.025 (4 N)	0.050	Not required
Liver	<0.025 (4 N)	0.058 (8 N)	Not required
Kidney	<0.025 (4 N)	-	Not required
Fat	<0.005 (6 N)	0.0226 (8 N)	Not required
Milk	<0.01* (5 N)		
Eggs		0.0735 (8 N)	

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/processed crop	Number of studies	Transfer factor
Wheat:bread (whole meal)	4	0.28 – 0.86 (mean: 0.58)
Plum/Prune	1	2.5

Calculated on the basis of distribution in the different portions. parts. or products as determined through balance studies.

Comments on/additions to List of Endpoints
No comments

5.1 Summary of residue data

The following assessment is based on the EFSA conclusion (2010), the Draft Assessment Report for flonicamid and available addenda, (France, 2005), EFSA Reasoned Opinion on the modification of the existing MRLs for flonicamid in various crops (EFSA Journal 2010; 8(5): 1610), Ctgb report (Ctgb, November 2013).

5.1.1 Metabolism in plants

Metabolism of flonicamid was investigated in wheat, potato, peach and pepper. The metabolism was shown to be comparable in all the investigated crops. In the wheat straw and chaff extract the major identified compound was parent flonicamid (41-50% TRR), in grain extract the majority of the TRR was metabolite TFNG (39%). Metabolites TFNA, TFNA-AM and N-oxide of TFNA-AM were also detected, however they were <10% TRR in straw, chaff or grain.
In the potato tuber surface, the total residues were very low (<0.5%TRR). In the potato tubers (unwashed) the majority of TRR was comprised of metabolites TFNG (39.3%TRR) and TFNA (34.4% TRR). The parent compound was present in a lower amount of 5.6% TRR. The proportion of metabolites found in surface washed tubers was comparable.
In the fruit crop (peach) the parent compound was the major contributor to the TRR in mature peach fruits, foliage and surface wash, metabolite TFNA was dominant in the fruits (juice and pomace).
The residues of concern for consumers should be defined as the parent compound flonicamid, metabolite TFNG and TFNA in food of plant origin.

5.1.2 Metabolism in livestock

Metabolism of flonicamid was investigated in lactating goats and laying hens. In the goat study, the animals were treated with a dose of 15 mg flonicamid (10 mg/kg based on feed) for 5 consecutive days. The test material was rapidly metabolised and excreted. The levels of the residue detected were very low in milk (1% of total administered dose) and in the organs and tissues (10% of total administered dose). Metabolite TFNA-AM was identified as a major metabolite in goat organs (29% of TRR in liver, 31-41% in kidney), tissues (74% of TRR in fat, 42-50% of TRR in muscle) and milk (97% of TRR). TFNA (as free acid and an unstable conjugate) was the major metabolite in urine (56-59% of TRR) and in faeces (82-88%). The unchanged parent compound was either not detected or in very low amounts (5.5%TRR).
In the laying hens study, the animals were treated with a dose of 1.12 mg flonicamid (10 mg/kg in diet) for 5 consecutive days. The residue levels detected were very low: 2,4% of administered dose in eggs, 5.9% in organs and tissues, 67.2% in excreta and 5.2% in a cage wash. Metabolite TFNA-AM was the main residue detected in eggs (96% of TRR in egg white, 94.7% TRR in egg yolk), organs (92.9% of TRR in liver, 76.4% of TRR in kidney) and tissues (96.8% of TRR in breast muscle, 96.4% of TRR in skin and 94.7% in fat). The unchanged parent compound was detected in very low amounts (2.5-3.8% of TRR in eggs, 0.3-0.4% TRR in organs, 0.4-0.7% of TRR in tissues, 7.5% of TRR in excreta). Metabolite TFNA-AM is the major residue in products of animal origin.
No significant differences in metabolic pattern in the goat compared to rat was found, therefore a metabolism study in pigs was not required.

5.1.3 Residue definition (plant and animal)

In plants, the residue definition for the risk assessment is defined as the sum of flonicamid, TFNA and TFNG expressed as flonicamid. The residue definition for monitoring in plants was discussed during the PRAPeR 70 experts meeting (2009). Two definitions were proposed:

1. parent compound flonicamid only (with conversion factors monitoring to risk assessment 2.5, 1.6; 3.0; 17.5 for apple, peach, potato and wheat grain respectively)
2. sum of flonicamid, TFNA and TFNG expressed as flonicamid

In products of animal origin the residue definition is for risk assessment and monitoring is defined as the sum of flonicamid and TFNA-AM expressed as flonicamid.

5.1.4 Stability of residues

The residues of flonicamid and its metabolites were shown to be stable in apple, potato (high water matrix), wheat grain and wheat straw (dry matrix) for 18 months under frozen conditions (≤-18°C).

5.1.5 Supervised residue trials

Pome fruits (apple/pears)
(cGAP-NL: 3x 70 g as/ha, interval 21d, PHI=21 days)
Eleven residue trials are available in the DAR with pome fruits (ten with apples and one in pears) in Northern Europe. The application rate in the trials is according with the proposed cGAP-NL.
Apples and pears are a major crop, therefore eight trials is required, a sufficient number of trials is available.
The current EU-MRL of flonicamid in apple and pears is 0.2 mg/kg and it is covered by the available trials.

Potato
(cGAP-NL: 2x 0.08 kg as/ha, interval=21 days, PHI=14 days)
Twelve residues trials are evaluated and available in the DAR with flonicamid in potatoes in Northern Europe. The application rate in the trials is slightly lower (2x 0.07 kg as/ha) than the proposed cGAP-NL, however within 25% difference.
Potatoes are a major crop, therefore eight trials is required, a sufficient number of trials is available.
The current EU-MRL of flonicamid in potatoes is 0.1 mg/kg and it is covered by the available trials.

Wheat (summer, winter), triticale, spelt
(cGAP-NL: 2x 0.07 kg as/ha, interval=21 days, PHI= 28 days))
Twelve residues trials are evaluated and available in the DAR with flonicamid in winter wheat in Northern Europe (residues in straw were measured in 11 trials). The application rate in the trials is according to proposed cGAP-NL (2x 0.07 kg as/ha). Wheat is a major crop, therefore eight trials is required, a sufficient number of trials is available. The current EU-MRL of flonicamid in wheat is 2 mg/kg and it is covered by the available trials.
The residue data from trials in wheat can be extrapolated to spelt and triticale. Current EU-MRL of flonicamid in spelt and triticale is 2 mg/kg and it is covered by the available trials in wheat.

The residue levels selected for MRL setting and risk assessment are presented in table R1.

Table R1: Selected residue levels from trials with flonicamid (sum of flonicamid, TFNA and TFNG expressed as flonicamid)

Crop	Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)
Apple/Pear	<0.03; <0.03; <0.04; <0.05; <0.06; <0.07;0.11; 0.115; 0.12; 0.14; 0.17	0.07	0.17
Potatoes	9x<0.03; <0.04; 2x<0.05	0.03	0.05
Wheat (grain) → spelt, triticale	<0.08<0.14;<0.16; <0.17; <0.23; 0.24; 0.36;<0.48; <0.55; <0.59 <0.62; 1.2;	0.3	1.2
Wheat (straw) → spelt, triticale	<0.06;<0.06;<0.06;<0.07; <0.13; <0.11; <0.15;< 0.17; <0.17; 0.43; <0.48	0.13	0.48

→: extrapolation

5.1.6 Residues in succeeding crops

A study on flonicamid residues in succeeding crops is not required. The active substance flonicamid and its metabolites were shown to be rapidly degraded in soils. The residues in succeeding crops are not excepted.

5.1.7 Residues from livestock feeding studies

Flonicamid can be applied to crops which can possibly be used as feed for animals. In the DAR feeding studies with flonicamid in laying hens and dairy cows are available. In the study with dairy cows, the animals were fed 0.086, 0.252 and 0.839 mg/kg bw (which corresponds to 1x, 3x and 10x dose) for 28 consecutive days.
In milk the residues of flonicamid and metabolites TFNG and TFNA were below the LOQ (0.01 mg/kg) in all test groups. Metabolite TFNA-AM was below the LOQ (0.01 mg/kg) in the 1x dose group, and ranged from <0.01-0.089 mg/kg in the 3x and 10x dose groups.
Parent compound flonicamid was not detected in any samples of muscles or tissues. Metabolite TFNA was <0.02 mg/kg in all tissues in all dose groups, except in kidney where the residues were <0.01-0.14 mg/kg, with the highest residues in the 10x dose group. Metabolite TFNA-AM was above the LOQ in the milk, muscle, liver and kidney of 3x and 10x dose groups and in one sample of fat in 10x dose group.
Based on dietary burden calculation (EFSA Journal 2010; 8(5): 1610, Modification of the existing MRLs for flonicamid in various crops) maximum dietary burden for dairy ruminants is 0.014 mg/kg bw/d, which is lower than the dose group 1x (0.086 mg/kg bw). Therefore, it can be concluded that no significant residues are expected in the product of animal (ruminants) origin after application flonicamid according to proposed GAP.
In the study with laying hens, the animals were fed 0.23 mg/kg as dry feed (0.1x dose), 2.3 mg/kg dry feed (1x dose), 6.9 mg/kg dry feed (3x dose), 23.26 mg/kg dry feed (10x dose) for 28 consecutive days. Based on dietary burden calculation (EFSA Journal 2010; 8(5): 1610)) maximum dietary burden for poultry is 0.33 mg/kg dry feed. Residues of parent compound flonicamid were below 0.01 mg/kg (LOQ) in eggs, muscles and other tissues in dose groups 0,1x and 1x. In eggs metabolite TFNA-AM was <0.015 mg/kg in dose group 0,1x and ranged up to 0.0985 mg/kg in 1x dose group. In other tissues metabolite TFNA-AM was not found in dose group 0.1x. The dose group 0.1x (0.23 mg/kg dry feed) is slightly lower than the maximum dietary burden calculation for poultry, however since the residues of the parent compound and metabolite TFNA-AM were below the LOQ level (0.01 m/kg) it can be concluded that no significant residues are expected in the product of animal (poultry) origin after application flonicamid according to proposed GAP.

5.1.8 Processing factors

A hydrolysis study was submitted with this application and was summarised by Ctgb (November 2013). Very limited degradation of flonicamid was observed in aqueous buffer solutions under all the conditions used (pasteurisation, baking and boiling, sterilization), with no significant degradation product being formed.
In the DAR, studies with processed wheat, peaches and plums are available to establish processing factors. For the processing factors, refer to the List of Endpoints presented above.

5.1.9 Calculation of the ADI and the ARfD

Calculation of the ADI
The ADI is based on the NOAEL of 2.5 mg/kg bw/d in the rabbit developmental study. Application of a safety factor for inter- and intraspecies differences of 100 results in an ADI of 0.025 mg/kg bw/day (see the List of Endpoints for mammalian toxicology).

Calculation of the ARfD

The ARfD is based on the NOAEL of 2.5 mg/kg bw/d in the rabbit developmental study. Application of a safety factor for inter- and intraspecies differences of 100 results in an ARfD of 0.025 mg/kg bw/day (see the List of Endpoints for mammalian toxicology).

5.2 Maximum Residue Levels

Temporary EU-MRLs are present in Annex IIIA of Regulation (EC) 396/2005.
The product complies with the MRL Regulation. Notification of MRLs is not necessary.

5.3 Consumer risk assessment

The consumer risk assessment was calculated based on the residue definition for monitoring: flonicamid+ TFNG+TFNA expressed as flonicamid.

Risk assessment for chronic exposure through diet
A calculation of the Theoretical Maximum Daily Intake (TMDI) was carried out using EFSA PRIMo rev. 2.0, containing all available Member State diets, and the temporary EU-MRLs. The maximum TMDI is 83.1% of the ADI for WHO Cluster diet B. The TMDI is 22.4% and 53.9% of the ADI for the Dutch general population and Dutch children ages 1-6, respectively.

Risk assessment for acute exposure through diet
A calculation of the Estimated Short Term Intake (ESTI) was carried out using EFSA PRIMo rev. 2.0 and the previously mentioned temporary EU-MRLs and accompanying HR for wheat. The highest percentage of the ESTI is 78.4 % of the ARfD for apple for the UK infant . ESTI values for the other commodities in all other consumer diets are all lower.

Conclusion
Based on the assessment for residues, no risk for the consumer due to the exposure to flonicamid is currently expected. The product complies with the Uniform Principles

5.4 Data requirements

No data requirements were identified.

6. Environmental fate and behaviour

Risk assessment is done in accordance with Chapter 2 of the RGB published in the Government Gazette (Staatscourant) 188 of 28 September 2007, including the updates of 20 October 2009 (which came into effect on 1 January 2010) and 18 April 2011 (which came into effect on 23 April 2011).

Flonicamide is an approved active substance. The LoEP of flonicamide from the EFSA conclusion (2010) is used for the assessment (EFSA Journal 2010; 8(5):1445).

List of Endpoints Fate/behaviour flonicamid (EFSA Journal 2010; 8(5):1445)

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days	47-56.6 % after 30 d (4 soils)
Non-extractable residues after 100 days	29.6-43.3 % after 30 d (4 soils)
Relevant metabolites - name and/or code, % of applied (range and maximum)	TFNA : 12.2-36.4 % after 1-3 d TFNA-OH : 12.1-21.3 % after 2-7 d TFNG-AM : 7.8-10.2 % after 0.3-2 d TFNG : < 3.9 % TFNA-AM : 7.6 % after 7 d

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation	No data provided, not required (April-July applications)
Soil photolysis	DT_{50} : 53 d (dark) and 22 d (continous artificial light) on dry soil TFNG-AM : 13.8 % (dark), 29.5 % (light) after 15 d Negligible role of photodegradation

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	1st order, $R^2 > 0.94$
Laboratory studies (range or median, with n value, with r^2 value)	DT_{50lab} (20°C, aerobic): Flonicamid : 0.7-1.8 d (mean 1.1 d), 4 soils (pH 6.2-7.2) TFNA : 0.29-0.46 d (mean 0.4 d), 3 soils (pH 5.7-6.8) TFNA-OH : 1.0-2.6 d (mean 1.6 d), 3 soils (pH 5.7-6.8) TFNG-AM : 0.2-1.0 (mean 0.5 d), 3 soils (pH 6.2-7.0) TFNG : 0.1-1.1 d (mean 0.5 d), 3 soils (pH 5.7-6.8) TFNA-AM : 1.0-2.6 d (mean 1.6 d), 3 soils (pH 6.2-7.0)
	DT_{90lab} (20°C, aerobic): Flonicamid : 2.3-6.0 d (mean 3.5 d) TFNA : 1.0-1.5 d (mean 1.3 d) TFNA-OH : 3.4-8.7 d (mean 5.4 d) TFNG-AM : 0.6-3.3 (mean 1.6 d) TFNG : 0.4-3.5 d (mean 1.5 d) TFNA-AM : 3.4-8.5 d (mean 5.2 d)
	DT_{50lab} (10°C, aerobic): Flonicamid : 2.4 d TFNA : 0.99 d TFNA-OH : 4.5 d TFNG-AM : 0.7 d TFNG : 0.3 d TFNA-AM : 4.8 d
	DT_{50lab} (20°C, anaerobic): No data, not required (April-July applications)
	degradation in the saturated zone:
Field studies (state location, range or median with n value)	DT_{50f}: : no data, not required
	DT_{90f}: : no data, not required
Soil accumulation and plateau concentration	No data, not required

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} K_d pH dependence (yes / no) (if yes type of dependence)	Flonicamid	Kd : 0.03-0.17 L/kg Kdoc : 2.5-8.7 L/kg (mean 5.9) 4 soils (pH 6.5-7.6)
	TFNA	Kd : < 0.02 L/kg Kdoc : < 3.0 L/kg (mean ±2.0)

	4 soils (pH 5.7-7.2)
TFNA-OH	Kd : < 0.06 L/kg Kdoc : < 4.4 L/kg (mean ± 3.0) 4 soils (pH 5.7-7.2)
TFNG-AM	Kd : 0.04-0.32 L/kg Kdoc : 5.5-13.2 L/kg (mean 9.2) 4 soils (pH 5.6-7.2)
TFNG	Kd : < 0.03 L/kg Kdoc : < 4.0 L/kg (mean ± 1.6) 4 soils (pH 5.7-7.2)
TFNA-AM	Kd : 0.03-0.20 L/kg Kdoc : 2.8-12.1 L/kg (mean 6.2) 9 soils (pH 5.6-8.1)
No pH dependence for flonicamid or its metabolites.	

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching	No data provided, not required
Aged residues leaching	No data provided, not required
Lysimeter/ field leaching studies	No data provided

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 4 : flonicamid and TFNA are stable
	pH 7: flonicamid and TFNA are stable
	pH 9 : DT_{50} 204 d (25° C), 17.1 d (40° C), 9.0 d (50° C) TFNG-AM : 65.1 % after 20 d at 50° C TFNG : 85.7 % after 120 d at 50° C TFNA : stable
Photolytic degradation of active substance and relevant metabolites	pH 7 , 23° C : stable (dark), DT_{50} 267 d (continous artifical light). Negligible role of photodegradation (Φ = 0.000319)
Readily biodegradable (yes/no)	No
Degradation in water/sediment - DT_{50} water - DT_{90} water - DT_{50} whole system - DT_{90} whole system	30.3-37.3 d (1st order) 100.5-123.8 d 35.7-43.6 d (1st order) 118.7-144.8 d
Mineralization	15.6-59.1 % (136-145 d)
Non-extractable residues	38.4-75.4 % (136-145 d)

Distribution in water / sediment systems (active substance)	Max. 17.8-43.7 % after 3 d due to high sediment:water ratio (1:4) and to high OC content up to 10.2 % (DT_{50} 41-69 d)
Distribution in water / sediment systems (metabolites)	TFNA : max. 9.6 % in water after 30 d (apparent DT_{50} 60 d) and 9.2 % in sediment after 42 d (apparent DT_{50} 59 d). TFNA-OH : max. 12.5 % in water after 42 d (apparent DT_{50} 49 d) and < 2.2 % in sediment. TFNG : < 3.7 % in water and < 2.7 % in sediment.

	TFNA-AM : < 0.9 % in water and < 1.1 % in sediment.

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air	Not available. not required
Quantum yield of direct phototransformation	Not applicable
Photochemical oxidative degradation in air	DT_{50} ..13.7 d (12 h day) for K_{OH} 0.779 x 10^{-12} cm^3 $molecule^{-1}$ sec^{-1} and [OH] 1.5 x 10^6 radicals per cm^3
Volatilization	from plant surfaces: no data provided
	from soil: no data provided

PEC (air)

Method of calculation	Expert judgement based on physico chemical properties

PEC (a)

Maximum concentration	Flonicamid has a low vapour pressure (9.43 x 10-7 Pa at 20° C) and a low Henry law constant (4.2 x 10-8 Pa m3 mole-1). Accordingly negligible concentrations are expected in air despite slow photo-oxidation in air.

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	Soil : flonicamid, TFNA, TFNA-OH, TFNG-AM, TFNG, TFNA-AM residue for monitoring : flonicamid Groundwater : flonicamid. TFNA. TFNA-OH. TFNG-AM. TFNG, TFNA-AM. residue for monitoring : flonicamid Surface water : flonicamid, TFNA, TFNA-OH residue for monitoring : flonicamid Sediment : flonicamid Air : flonicamid

Monitoring data, if available (Annex IIA, point 7.4)

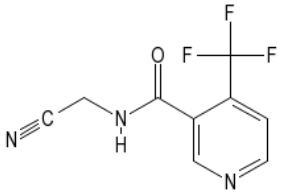
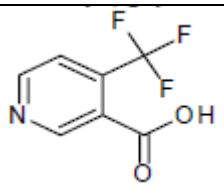
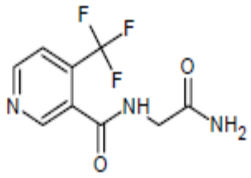
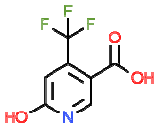
Soil (indicate location and type of study)	No data
Surface water (indicate location and type of study)	No data
Ground water (indicate location and type of study)	No data
Air (indicate location and type of study)	No data

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	R53

Appendix A: Metabolite names, codes and other relevant information of the plant protection product TEPEKKI with active substance flonicamid

The compounds shown below were found in one or more studies involving the metabolism and/or environmental fate of active substance flonicamid. The parent compound structure of flonicamid is shown first in this list and followed by degradate or related compounds.

Compound name	IUPAC name	Structural formula	Molecular Weight [g/mol]		Observed in study (% of occurrence/ formation)
flonicamid		$C_9H_6F_3N_3O$	229.16		
TFNA	4-trifluoromethylnicotinic acid	$C_7H_4F_3NO_2$	191.11		Max 36.4% (soil); max 9.6% (water)
TFNG-AM	N-(4-trifluoromethyl-nicotinoyl) glycinamide	$C_9H_8F_3N_3O_2$	242.11		Max 10.2% (soil);
TNFA-OH	6-hydroxy-4-trifluoro-methylnicotinic acid	$C_7H_4F_3NO_3$	207.11		TFNA-OH 21.3% (soil); max 12.5% (water)

6.1 Fate and behaviour in soil

6.1.1 Persistence in soil

Article 2.8 of the *Plant Protection Products and Biocides Regulations* (RGB) describes the authorisation criterion persistence. If for the evaluation of the product a higher tier risk assessment is necessary, a standard is to be set according to the MPC-INS[1] method. Currently this method equals the method described in the Technical Guidance Document (TGD). Additional guidance is presented in RIVM[2]-report 601782001/2007[3].

Preceding the harmonisation of the persistence assessment in The Netherlands with regulation 1107/EG, the EU approach for persistence assessment is followed.

For the current application this means the following:

Active substance flonicamid

The following laboratory DT_{50} values are available for the active substance flonicamid: 1.0., 0.7, 0.7, 1.8 days (geomean: 0.97 days). The mean DT_{50}-value of the active substance can

[1] INS: international and national quality standards for substances in the Netherlands.

[2] RIVM: National institute of public health and the environment.

[3] 601782001/2007: P.L.A. van Vlaardingen and E.M.J. Verbruggen, Guidance for the derivation of environmental risk limits within the framework of 'International and national environmental quality standards for substances in the Netherlands' (INS). Revision 2007'.

thus be established to be < 90 days. Furthermore it can be excluded that after 100 days there will be more than 70% of the initial dose present as bound (non-extractable) residues together with the formation of less than 5% of the initial dose as CO_2.
In this way, the standards for persistence as laid down in the RGB are met.

For the metabolite TFNA the following DT_{50}-values are available: 0.46, 0.29 and 0.45 days (geomean 0.4 days).
For the metabolite TFNA-OH the following DT_{50}-values are available: 1.3, 1.0 and 2.6 days (geomean 1.5 days).
For the metabolite TFNG-AM the following DT_{50}-values are available: 0.2, 0.3 and 1.0 days (geomean 0.4 days).
Based on the above, the standards for persistence as laid down in the RGB are met.

PECsoil

The concentration of the active substance flonicamid and metabolites TFNG-AM, TFNA and TFNA-OH in soil is needed to assess the risk for soil organisms (earthworms, micro-organisms). The PECsoil is calculated for the upper 5 cm of soil using a soil bulk density of 1500 kg/m^3.

As the logPow of the substance is < 3 (-0.24), a PEC_{21days} is not needed for the assessment of secondary poisoning of birds and mammals through the consumption of earthworms.

For the glasshouse uses 'flower bulb and flower corm crops', 'floriculture crops', flower seed crops', 'tree nursery crops', 'perennials' and 'basic seed production and plant breeding crops of vegetables and arable crops' exposure of soil organisms is not considered relevant.

The following input data are used for the calculation:

PEC soil:

Active substance flonicamid:
Maximum lab DT_{50} for degradation in soil: 1.8 days
Molecular mass: 229.2 g/mol

Metabolite TFNA:
Maximum lab DT_{50} for degradation in soil (20°C): 0.46 days
Molecular mass: 190.2 g/mol
Correction factor: 0.364 (maximum observed percentage) x 0.83 (relative molar ratio = M metabolite/M parent) = 0.302

Metabolite TFNA-OH:
Maximum lab DT_{50} for degradation in soil (20°C): 2.6 days
Molecular mass: 206.3 g/mol
Correction factor: 0.213 (maximum observed percentage) x 0.90 (relative molar ratio = M metabolite/M parent) = 0.192

Metabolite TFNG-AM:
Maximum lab DT_{50} for degradation in soil (20°C): 1.0 days
Molecular mass: 247.5 g/mol
Correction factor: 0.102 (maximum observed percentage) x 1.08 (relative molar ratio = M metabolite/M parent) = 0.110

See Table M.1 for other input values and results.

Table M.1 PECsoil calculations for active substance flonicamid and metabolites TFNA, TFNA-OH and TFNG-AM (5 cm)

Use	Substance	Rate [kg a.s./ha]	Freq.	Interval [days]	Fraction intercepted *	$PIEC_{soil}$ [mg a.s./kg] (5 cm)
Potatoes (F)	Flonicamid TFNA TFNA-OH TFNG-AM	0.080 0.024 0.015 0.009	2	21	0.15; 0.15	0.091 0.027 0.017 0.010
winter wheat, summer wheat, triticale, spelt (F)	Flonicamid TFNA TFNA-OH TFNG-AM	0.070 0.021 0.013 0.008	2	21	0.90; 0.90	0.009 0.003 0.002 0.001
Apple (F); Pear (F)	Flonicamid TFNA TFNA-OH TFNG-AM	0.070 0.021 0.013 0.008	3	21	0.65; 0.70; 0.80	0.033 0.010 0.006 0.004
Fruit trees and shrubs of apple and pear (includes rootstocks) (F)	Flonicamid TFNA TFNA-OH TFNG-AM	0.070 0.021 0.013 0.008	3	21	0.25; 0.25; 0.40	0.070 0.021 0.013 0.008
Flower bulb and flower corm crops (F);	Flonicamid TFNA TFNA-OH TFNG-AM	0.070 0.021 0.013 0.008	3	21	0.10; 0.10; 0.25	0.084 0.025 0.016 0.010
Floriculture crops (F)	Flonicamid TFNA TFNA-OH TFNG-AM	0.070 0.021 0.013 0.008	3	21	0.25; 0.25; 0.40	0.070 0.021 0.013 0.008
Flower seed crops (F);	Flonicamid TFNA TFNA-OH TFNG-AM	0.070 0.021 0.013 0.008	3	21	0.15; 0.15; 0.50	0.079 0.021 0.015 0.009
Tree nursery crops (F);	Flonicamid TFNA TFNA-OH TFNG-AM	0.070 0.021 0.013 0.008	3	21	0.25; 0.25; 0.40	0.070 0.021 0.013 0.008
Perennials (F)	Flonicamid TFNA TFNA-OH TFNG-AM	0.070 0.021 0.013 0.008	3	21	0.15;0.15; 0.50	0.079 0.021 0.015 0.009
Public green spaces.	Flonicamid TFNA TFNA-OH TFNG-AM	0.070 0.021 0.013 0.008	3	21	0.40; 0.40; 0.60	0.056 0.017 0.010 0.006

* interception values derived from Table 1.6 in “generic guidance for FOCUS groundwater scenarios”.

For potatoes, potatoes was taken as a representative crop. An interception value of 15% and was used for potatoes, corresponding to the earliest indicated BBCH code (11) as specified in the GAP as worst case.
For wheat, summer wheat, triticale and spelt, winter cereals was taken as a representative crop. An interception value of 90% was used, corresponding to the earliest indicated BBCH code (49) as specified in the GAP.
For apple and pear, apples was taken as a representative crop. Interception values of 65%, 70% and 80% were used, corresponding to the earliest indicated BBCH code (69) as specified in the GAP.
For fruit trees and shrubs of apple and pear (includes rootstock), cabbage was taken as a representative crop. An interception value of 25% was used for the first two applications, and 40% for the third application, corresponding to the earliest indicated BBCH code (BBCH 11).
For flower bulb and flower corm crops, onions was taken as a representative crop. An interception value of 10% was used for the first two applications, and 25% for the third application, corresponding to the earliest indicated BBCH code (BBCH 11).
For floriculture crops, beans (field+vegetable) was taken as a representative crop. An interception value of 25% was used for the first two applications, and 40% for the third application, corresponding to the earliest indicated BBCH code (BBCH 11).
For flower seed crops, potatoes was taken as a representative crop. An interception value of 25% was used for the first two applications, and 50% for the third application, corresponding to the earliest indicated BBCH code (BBCH 11).
For tree nursery crops, cabbage was taken as a representative crop. An interception value of 25% was used for the first two applications, and 40% for the third application, corresponding to the earliest indicated BBCH code (BBCH 11).
For perrenials, potatoes was taken as a representative crop. An interception value of 15% was used for the first two applications, and 50% for the third application, corresponding to the earliest indicated BBCH code (BBCH 11).
For public green spaces, grass was taken as a representative crop. An interception value of 40% was used for the first two applications, and 60% for the third application, corresponding to the earliest indicated BBCH code (BBCH 11).

These exposure concentrations are examined against ecotoxicological threshold values in section 7.5.

6.1.2 Leaching to shallow groundwater

Article 2.9 of the *Plant Protection Products and Biocides Regulations* (RGB) describes the authorisation criterion leaching to groundwater.

The leaching potential of the active substance flonicamid and its metabolites is normally calculated in the first tier using Pearl 4.4.4 and the FOCUS Kremsmünster scenario. Input variables are the actual worst-case application rates, the crop, an interception value appropriate to the crop stage and date of application.

However, the active substance flonicamid and its metabolites TFNA, TFNA-OH and TFNG-AM have a mean DT_{50} and a mean K_{om} smaller than 10 L/kg. Because of this, PEARL is not a suitable model for the active substance and its metabolites. Therefore, the leaching of the active substance flonicamid and metabolites TFNA, TFNA-OH and TFNG-AM will be calculated directly with the spatial distribution model GeoPEARL 3.3.3.

Input variables are the actual worst-case application rate (0.07-0.08 kg a.s./ha depending on the crop), the crop scenario potatoes for the use ‘potatoes’; the crop scenario winter cereals for the uses ‘winter wheat, summer wheat, triticale and spelt’ and ‘public green spaces’ (default scenario); the crop scenario fruit culture for the uses ‘apple and pear’; the crop scenario ‘tree nursery’ for the uses ‘fruit trees and shrubs of apple and pear (includes rootstock)’ and ‘tree nursery crops’; the crop scenario flower bulbs for the use ‘flower bulb and flower corm crops’; the crop scenario floriculture for the use ‘floriculture crops’ and ‘flower seed crops’; and the crop scenario vegetables for ‘basic seed production and plant breeding crops of vegetables and arable crops’.

First date of yearly application is May 25th (default date for modelling and in line with GAP) for the uses ‘potatoes’, ‘winter wheat, summer wheat, triticale, spelt’, ‘apple’, ‘pear’, ‘fruit trees and shrubs of apple and pear (inclusing rootstocks), ‘flower bulb and flower corm crops’, ‘floriculture crops’, ‘flower seed crops’, ‘tree nursery crops’, ‘perrenials’, ‘basic seed

production and plant breeding crops of vegetables and arable crops' and 'public green spaces'.

Additional autumn scenario calculations are performed for the proposed use on potatoes with date of yearly application September 9th (in line with GAP) and for the proposed uses on 'flower bulb and flower corm crops' and 'floriculture crops', 'flower seed crops', 'tree nursery crops', 'perrenials' and 'public green spaces' with date of yearly application September 19th (in line with GAP).

For metabolites all available data concerning substance properties are regarded. Metabolites TFNA, TFNA-OH and TFNG-AM are included in the calculations. No other metabolites occurred above > 10 % of AR, > 5 % of AR at two consecutive sample points or had an increasing tendency.

GeoPEARL
The leaching potential of substances to the shallow groundwater in the potential area of use within The Netherlands is calculated using the GeoPEARL model. The same input data as would have beed used in the first tier with Pearl 4.4.4. Additional input is the crop and the number of plots (minimum 250). For results see Table M.2.

The following input data are used for the calculation:

GeoPEARL:

Active substance flonicamid:
Geometric mean laboratory DT_{50} for degradation in soil (20°C): 1.0 days (n=4)
Arithmetic mean K_{om} (pH-independent): 5.9 L/kg
1/n: 0.9 (default, based on K_d)

Saturated vapour pressure: 9.43 x 10^{-7} Pa (20°C)
Solubility in water: 5.2mg/L (20°C)
Molecular mass: 229.2 g/mol

Plant uptake factor: 0.5 (systemic mode of action)
Q10: 2.2

Metabolite TFNA:
Geometric mean laboratory DT_{50} for degradation in soil (20°C): 0.4 days (n=3)
Arithmetic mean K_{om} (pH-independent): 2.0 L/kg
1/n: 1.0 (default for metabolites, based on K_d)

Saturated vapour pressure: 9.43 x 10^{-7} Pa (20°C; parent value)
Solubility in water: 5.2mg/L (20°C; parent value)
Molecular mass: 190.2 g/mol
Correction factor: 0.364 (formation fraction metabolite) x 0.83 (relative molar ratio = M metabolite/M parent) = 0.302

Plant uptake factor: 0.0
Q10: 2.2

Metabolite TFNA-OH:
Geometric mean laboratory DT_{50} for degradation in soil (20°C): 1.5 days (n=3)
Arithmetic mean K_{om} (pH-independent): 3.0 L/kg
1/n: 1.0 (default for metabolites, based on K_d)

Saturated vapour pressure: 9.43 x 10^{-7} Pa (20°C; parent value)
Solubility in water: 5.2mg/L (20°C; parent value)
Molecular mass: 206.3 g/mol
Correction factor: 0.213 (formation fraction metabolite) x 0.90 (relative molar ratio = M metabolite/M parent) = 0.192

Plant uptake factor: 0.0
Q10: 2.2

Metabolite TFNG-AM:
Geometric mean laboratory DT_{50} for degradation in soil (20°C): 0.4 days (n=3)
Arithmetic mean K_{om} (pH-independent): 6.2 L/kg
1/n: 1.0 (default for metabolites, based on K_d)

Saturated vapour pressure: 9.43 x 10^{-7} Pa (20°C; parent value)
Solubility in water: 5.2 mg/L (20°C; parent value)
Molecular mass: 247.5 g/mol
Correction factor: 0.102 (formation fraction metabolite) x1.08 (relative molar ratio = M metabolite/M parent) = 0.110

Plant uptake factor: 0.0
Q10: 2.2

Other parameters: standard settings of GeoPEARL 4.4.4

Table M.2 Leaching of active substance flonicamid and metabolites TFNA, TFNA-OH and TFNG-AM as predicted by GeoPEARL 3.3.3

Use	Substance	Rate substance [kg/ha]	Frequency	Interval [days]	Fraction Intercepted *	PEC groundwater [µg/L]	
						spring	autumn
Potatoes (F)	Flonicamid TFNA TFNA-OH TFNG-AM	0.08	2	21	0.15; 0.15	<0.001 <0.001 <0.001 <0.001	<0.001 <0.001 <0.001 <0.001
winter wheat, summer wheat, triticale, spelt (F)	Flonicamid TFNA TFNA-OH TFNG-AM	0.07	2	21	0.90; 0.90	<0.001 <0.001 <0.001 <0.001	n.c.
Apple (F); Pear (F)	Flonicamid TFNA TFNA-OH TFNG-AM	0.07	3	21	0.65; 0.70; 0.80	<0.001 <0.001 <0.001 <0.001	n.c.
Fruit trees and shrubs of apple and pear (includes rootstocks);	Flonicamid TFNA TFNA-OH TFNG-AM	0.07	3	21	0.25; 0.25; 0.40	<0.001 <0.001 <0.001 <0.001	n.c.
Flower bulb and flower corm crops (F);	Flonicamid TFNA TFNA-OH TFNG-AM	0.07	3	21	0.10; 0.10; 0.25	<0.001 <0.001 <0.001 <0.001	<0.001 <0.001 0.0018 <0.001

Use	Substance	Rate substance [kg/ha]	Frequency	Interval [days]	Fraction Intercepted *	PEC groundwater [µg/L]	
						spring	autumn
Floriculture crops (F)	Flonicamid TFNA TFNA-OH TFNG-AM	0.07	3	21	0.25; 0.25; 0.40	<0.001 <0.001 <0.001 <0.001	<0.001 <0.001 <0.001** <0.001
Flower seed crops (F)	Flonicamid TFNA TFNA-OH TFNG-AM	0.07	3	21	0.15;0.15; 0.50	<0.001 <0.001 <0.001 <0.001	<0.001 <0.001 <0.001** <0.001
Tree nursery crops;	Flonicamid TFNA TFNA-OH TFNG-AM	0.07	3	21	0.25; 0.25; 0.40	<0.001 <0.001 <0.001 <0.001	<0.001 <0.001 <0.001** <0.001
Perennials (F)	Flonicamid TFNA TFNA-OH TFNG-AM	0.07	3	21	0.15;0.15; 0.50	<0.001 <0.001 <0.001 <0.001	<0.001 <0.001 <0.001** <0.001
Public green spaces	Flonicamid TFNA TFNA-OH TFNG-AM	0.07	3	21	0.40; 0.40; 0.60	<0.001 <0.001 <0.001 <0.001	<0.001 <0.001 <0.001** <0.001

* interception values derived from Table 1.6 in “generic guidance for FOCUS groundwater scenarios”.
For potatoes, potatoes was taken as a representative crop. An interception value of 15% and was used for potatoes, corresponding to the earliest indicated BBCH code (11) as specified in the GAP as worst case.
For wheat, summer wheat, triticale and spelt, winter cereals was taken as a representative crop. An interception value of 90% was used, corresponding to the earliest indicated BBCH code (49) as specified in the GAP.
For apple and pear, apples was taken as a representative crop. Interception values of 65%, 70% and 80% were used, corresponding to the earliest indicated BBCH code (69) as specified in the GAP.
For fruit trees and shrubs of apple and pear (includes rootstock), cabbage was taken as a representative crop. An interception value of 25% was used for the first two applications, and 40% for the third application, corresponding to the earliest indicated BBCH code (BBCH 11).
For flower bulb and flower corm crops, onions was taken as a representative crop. An interception value of 10% was used for the first two applications, and 25% for the third application, corresponding to the earliest indicated BBCH code (BBCH 11).
For floriculture crops, beans (field+vegetable) was taken as a representative crop. An interception value of 25% was used for the first two applications, and 40% for the third application, corresponding to the earliest indicated BBCH code (BBCH 11).
For flower seed crops, potatoes was taken as a representative crop. An interception value of 25% was used for the first two applications, and 50% for the third application, corresponding to the earliest indicated BBCH code (BBCH 11).
For tree nursery crops, cabbage was taken as a representative crop. An interception value of 25% was used for the first two applications, and 40% for the third application, corresponding to the earliest indicated BBCH code (BBCH 11).
For perrenials, potatoes was taken as a representative crop. An interception value of 15% was used for the first two applications, and 50% for the third application, corresponding to the earliest indicated BBCH code (BBCH 11).
For public green spaces, grass was taken as a representative crop. An interception value of 40% was used for the first two applications, and 60% for the third application, corresponding to the earliest indicated BBCH code (BBCH 11).
n.c.: not calculated
** the PEC of metabolite TFNA-OH that was calculated for the proposed use flower bulbs covers for the PECgroundwater value for the proposed use (given that the scenario for flower bulbs is the most vulnerable for leaching and the interception of this proposed use is higher).

For glasshouse uses no scenario is available in GeoPEARL. For the glasshouse use in ‘flower bulb and flower corm crops’, ‘floriculture crops’, ‘flower seed crops’, ‘tree nursery crops’ and

'perennials', the risk for leaching is considered to be covered by the respective field use. No respective field use is available for the glasshouse use for 'basic seed production and plant breeding crops of vegetables and arable crops'. However as various scenarios are included in the GeoPEARL calculations and from those results no risk are identified (PEC groundwater < 0.001 µg/L), Ctgb considers the glasshouse use for 'basic seed production and plant breeding crops of vegetables and arable crops' covered as well.

Results of GeoPearl 3.3.3 are examined against the standard of 0.01 µg/L. This is the standard of 0.1 µg/L with an additional safety factor of 10 for vulnerable groundwater protection areas (NL-specific situation).

From Table M.2 it reads that the expected leaching based on the GeoPEARL-model calculations for the active substance flonicamid and metabolites TFNA, TFNA-OH and TFNG-AM is smaller than 0.01 µg/L for all proposed applications. Hence, all applications meet the standards for leaching as laid down in the RGB.

Monitoring data
Article 2.10b of the *Plant Protection Products and Biocides Regulations* (RGB) describes the use of the 90th percentile.

There are no data available regarding the presence of the substance flonicamid or its metabolites in groundwater.

Conclusions
The active substance flonicamid and metabolites TFNA, TFNA-OH and TFNG-AM comply with the requirements laid down in the RGB concerning persistence in soil.

All proposed applications of the product complies with the requirements laid down in the RGB concerning leaching in soil.

6.2 Fate and behaviour in water

6.2.1 Rate and route of degradation in surface water
Article 2.10c of the *Plant Protection Products and Biocides Regulations* (RGB) prescribes the use of Dutch specific drift percentages.

The exposure concentrations of the active substance flonicamid and metabolites TFNA and TFNA-OH in surface water have been estimated for the various proposed uses using calculations of surface water concentrations (in a ditch of 30 cm depth), which originate from spray drift during application of the active substance. The spray drift percentage depends on the use.

Concentrations in surface water are calculated using the model TOXSWA. The following input data are used for the calculation:

TOXSWA:
Active substance flonicamid:
Geometric mean DT_{50} for degradation in water at 20°C: 39.5 days (n=2)
DT_{50} for degradation in sediment at 20°C: 1000 days (default).

Arithmetic mean K_{om} for suspended organic matter: 5.9 L/kg (n=4)
Arithmetic mean K_{om} for sediment: 5.9 L/kg (n=4)
1/n: 0.9 (default, based on K_d)

Saturated vapour pressure: 9.43 x 10^{-7} Pa (20°C)

Solubility in water: 5.2 mg/L (20°C)
Molecular mass: 229.2 g/mol
Q10: 2.2

Metabolite TFNA-OH:
Geometric mean DT_{50} for degradation in water at 20°C: 49 days
DT_{50} for degradation in sediment at 20°C: 1000 days (default).

Arithmetic mean K_{om} for suspended organic matter: 3.0 L/kg (n=4)
Arithmetic mean K_{om} for sediment: 3.0 L/kg (n=4)
1/n: 1.0 (default for metabolites, based on K_d)

Saturated vapour pressure: 9.43 x 10^{-7} Pa (20°C;parent value)
Solubility in water: 5.2 mg/L (20°C;parent value)
Molecular mass: 207.11 g/mol
Correction factor: 0.125 (max. % observed) * 0.90 (relative molar ratio = M metabolite/ M parent) = 0.1125
Q10: 2.2

Other parameters: standard settings TOXSWA

When no separate degradation half-lives (DegT50 values) are available for the water and sediment compartment (accepted level P-II values), the system degradation half-life (DegT50-system, level P-I) is used as input for the degrading compartment and a default value of 1000 days is to be used for the compartment in which no degradation is assumed. This is in line with the recommendations in the FOCUS Guidance Document on Degradation Kinetics.

For metabolites, the level M-I values are used (system DegT50 value) only, since level M-II criteria have not been fully developed under FOCUS Degradation Kinetics.

For all proposed applications a standard drift percentage of 1% was used with the exception of the proposed applications on ‘apple’, ‘pear’ for which a standard drift percentage of 17% was used (fruit crops without leaves; until 1 May) and 7% (fruit crops with leaves, from 1 May onwards).

For glasshouse applications an emission percentage of 0.1% is applicable. No calculations were performed for glasshouse applications in case these are covered by the field applications.
No respective field use is available for the glasshouse use ‘basic seed production and plant breeding crops of vegetables and arable crops’, however given the similar application rate and interval compared to (for example) the field use ‘flower seed crops’, the PECsurfacewater of this use is covered by the other proposed field uses.

In Table M.3**,** the calculated surface water concentrations for the active substance flonicamide its metabolite TFNA-OH is presented.

Table M.3. Overview of surface water concentrations for active substance flonicamid and its metabolite TFNA-OH in the edge-of-field ditch following spring application

Use	Substance	Rate a.s. [kg/ha]	Freq.	Inter-val	Drift [%]	PIEC [µg/L] spring	PEC21 [µg/L] spring	PEC28 [µg/L] spring
Potatoes	Flonicamid	0.08	2	21	1	0.6785	0.4694	0.4303
	TFNA-OH	0.009				0.0776	0.0542	0.0496

Use	Substance	Rate a.s. [kg/ha]	Freq.	Inter-val	Drift [%]	PIEC [µg/L] spring	PEC21 [µg/L] spring	PEC28 [µg/L] spring
Winter wheat, summer wheat, triticale, spelt;	Flonicamid TFNA-OH	0.07 0.0079	2	21	1	0.5937 0.0681	0.4107 0.0475	0.3765 0.0436
Apple; Pear	Flonicamid TFNA-OH	0.07 0.0079	3	21	17	10.260 1.176	7.0730 0.8174	7.6160 0.8793
Apple; Pear	Flonicamid TFNA-OH	0.07 0.0079	3	21	7	4.2230 0.4841	2.9120 0.3366	3.1350 0.3621
Fruit trees and shrubs of apple and pear (includes rootstocks); Flower bulb and flower corm crops; Floriculture crops; Flower seed crops; Perrenials; Public green spaces.	Flonicamid TFNA-OH	0.07 0.0079	3	21	1	0.6030 0.0692	0.4157 0.0481	0.4475 0.0517
Tree nursery crops;	Flonicamid TFNA-OH	0.07 0.0079	3	21	2.8	1.689 0.194	1.164 0.135	1.253 0.145

* calculated according to TOXSWA

The exposure concentrations in surface water are compared to the ecotoxicological threshold values in section 7.2.

Monitoring data
Article 2.10b of the *Plant Protection Products and Biocides Regulations* (RGB) describes the use of the 90th percentile.

The Pesticide Atlas on internet (www.pesticidesatlas.nl, www.bestrijdingsmiddelenatlas.nl) is used to evaluate measured concentrations of plant protection products and biocides in Dutch surface water, and to assess whether the observed concentrations exceed threshold values. Dutch water boards have a well-established programme for monitoring surface waters. In the Pesticide Atlas, these monitoring data are processed into a graphic format accessible on-line and aiming to provide an insight into measured concentrations of Dutch surface waters against environmental standards.
The current version 2.0 of the Pesticide Atlas does not contain a land use correlation analysis, which may indicate probable or causal relationships with land use. Instead a link to the land use analysis performed in version 1.0 is made, in which the analysis is made on the basis of data aggregation based on grid cells of either 5 x 5 km or 1 x 1 km.

Data from the Pesticide Atlas are used to evaluate potential exceeding of the authorisation threshold and the MPC (*ad-hoc* or according to INS) threshold.
For examination against the drinking water criterion, another database (VEWIN) is used, since the drinking water criterion is only examined at drinking water abstraction points. For the assessment of the proposed applications regarding the drinking water criterion, see next section.

Active substance flonicamid

The active substance flonicamid was observed in the surface water (most recent data from 2012). In Table M.4, the number of observations in the surface water are presented.

In the Pesticide Atlas, surface water concentrations are compared to the authorisation threshold value and to the indicative Maximum Permissible Concentration (MPC) of 120 µg/L as presented in the Pesticide Atlas.

No authorisation threshold is included for flonicamid in the Pesticide Atlas. However, based on the ecotoxicology data, the authorisation threshold is 310 µg/L [0.1 x $NOEC_{daphnia}$]. As this is more than a factor 2.5 higher than the MPC, the MPC can be regarded as conservative. As there are no exceedings of the MPC, there are also no exceedings of the authorisation threshold.

Currently, this MPC value is not harmonised, which means that not all available ecotoxicological data for this substance are included in the threshold value. In the near future and in the framework of the Water Framework Directive, new quality criteria will be developed which will include both MPC data as well as authorisation data.
The currently available MPC value is reported here for information purposes. Pending this policy development, however, no consequences can be drawn for the proposed applications.

Table M.4. Monitoring data in Dutch surface water (from www.pesticidesatlas.nl, version 2.0)

Total no of locations (2012)	*n* > authorisation threshold	*n* > indicative/ad hoc MPC threshold	*n* > MPC-INS threshold *
342*	-	0	n.a

* n.a.: no MPC-INS available. < : exceeding expected to be lower than with indicative/ad hoc MPC value; > : exceeding expected to be higher than with indicative/ad hoc MPC value
** the number of observations at each location varies between 1 and 30, total number of measurements is 2.298 in 2012.

As there are no exceedings of thresholds, the monitoring data have no consequences for the proposed uses of the product.

Drinking water criterion
Article 2.10b of the *Plant Protection Products and Biocides Regulations* (RGB) describes the use of the 90th percentile.

It follows from the decision of the Court of Appeal on Trade and Industry of 19 August 2005 (Awb 04/37 (General Administrative Law Act)) that when considering an application, Ctgb should, on the basis of the scientific and technical knowledge and taking into account the data submitted with the application, also judge the application according to the drinking water criterion 'surface water intended for drinking water production'.
The assessment methodology followed is developed by the WG implementation drinking water criterion and outlined in Alterra report 1635[4].

Substances are categorized as new substances on the Dutch market (less than 3 years authorisation) or existing substances on the Dutch market (authorised for more than 3 years).

- For new substances, a preregistration calculation is performed.

[4] Adriaanse et al. (2008). Development of an assessment methodology to evaluate agricultural use ofplant protection products for drinking water production from surface waters - A proposal for the registration procedure in the Netherlands. Alterra-Report 1635

- For existing substances, the assessment is based on monitoring data of VEWIN (drinking water board).
    - If for an existing substance based on monitoring data no problems are expected by VEWIN, Ctgb follows this VEWIN assessment.
    - If for an existing substance based on monitoring data a potential problem is identified by VEWIN, Ctgb assesses whether the 90th percentile of the monitoring data meet the drinking water criterion at each individual drinking water abstraction point.

Active substance flonicamid has been on the Dutch market for > 3 years (authorised since 16-12-2005). This period is sufficiently large to consider the market share to be established. From the general scientific knowledge collected by Ctgb about the product and its active substance, Ctgb concludes that there are in this case no concrete indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. Ctgb does under this approach expect no exceeding of the drinking water criterion. The standards for surface water destined for the production of drinking water as laid down in the RGB are met.

The standards for surface water destined for the production of drinking water as laid down in the RGB are met.

6.3 Fate and behaviour in air

Route and rate of degradation in air

Flonicamid:
The vapour pressure is 9.43 x 10^{-7} Pa at 20°C. The Henry constant is 4.2 x 10^{-8} at 20°C. The half-life in air is 13.7 days. Based on the vapour pressure flonicamid would be classified under the national scheme of The Netherlands as very slightly volatile. The Henry's law constant of 4.2x10^{-8} also indicates negligible volatilisation potential from water / soil water. These physico chemical properties indicate volatilisation losses after spraying operations have finished would be expected to be negligible. An atmospheric half life estimated at 13.7 days indicates that any applied flonicamid that did volatilise (for example if aerosols were formed during application), would be expected to be subject to long range atmospheric transport.

The half-life exceeds the $DT_{50,air}$ trigger that has been set at a value of 2 days by the FOCUS Working Group on Pesticides in Air[5]. The trigger is not a measure of risk in itself but indicates the need to consider the potential for long-range transport.

Since at present there is no clear framework how to assess fate and behaviour in air of plant protection products, for the time being this issue is not taken further into consideration.

6.4 Appropriate fate and behaviour end-points relating to the product and approved uses

See List of End-points.

6.5 Data requirements

None

The following restriction sentences were proposed by the applicant:
None.

[5] FOCUS, 2008. "Pesticides in Air: Considerations for Exposure Assessment". Report of the FOCUS Working Group on Pesticides in Air, EC Document Reference SANCO/10553/2006 Rev 2 June 2008. 327 pp.

Based on the current assessment, the following has to be stated in the GAP/legal instructions for use (WG):
None.

6.6 Overall conclusions fate and behaviour

It can be concluded that:

1. the active substance flonicamid meets the standards for persistence in soil as laid down in the RGB.
2. metabolites TFNA, TFNA-OH and TFNG-AM of flonicamid meet the standards for persistence in soil as laid down in the RGB.
3. all proposed applications of the active substance flonicamid and its metabolites TFNA, TFNA-OH, TFNG-AM meet the standards for leaching to the shallow groundwater as laid down in the RGB.
4. all proposed applications of the active substance flonicamid meet the standards for surface water destined for the production of drinking water as laid down in the RGB.

7. Ecotoxicology

E.M. 1.1: Risk assessment is done in accordance with Chapter 2 of the RGB published in the Government Gazette (Staatscourant) 188 of 28 September 2007, including the updates of 20 October 2009 (which came into effect on 1 January 2010) and 18 April 2011 (which came into effect on 23 April 2011).

Flonicamid is an existing active substance listed on Annex I of 91/414/EEC (COMMISSION DIRECTIVE 2010/29/EU of 27 April 2010). An EFSA conclusion is available (EFSA Journal 2010; 8(5) 1445. [63 pp.]). RMS is France. The List of Endpoints was taken from the EFSA conclusion as approved in the Review Report (SANCO/10479/2010 final, dd. 12/04/2010). Additionally, for the current risk assessment of TEPPEKI, the original notification in the Netherlands (20040125 TG, notification number 12757N) and the most recent Dutch risk assessment in connection with an extension of the existing authorisation in the Netherlands (20100478 UG) were taken into consideration. Comments made by Ctgb (NL) are included in italic.

According to EFSA's review report, " **Member States must pay particular attention to … the risk to bees".**

List of Endpoints Ecotoxicology

TEPPEKI (IKI-220 50% WG) is a water dispersible granule (WG) containing 50% flonicamid. Relevant metabolites in soil and/or surface water are: TFNA, TFNA-OH, TFNA-AM, TFNG and TFNG-AM

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Toxicity to mammals	Short-term LD50 = 884 mg a.s./kg bw Long-term NOEL (teratogenicity) = 25 mg a.s./kg bw/d
Acute toxicity to birds	LD50 (quail. boths sexes) > 2000 mg a.s./kg bw LD50 (duck. male) = 2621 mg a.s./kg bw LD50 (duck. female) = 1591 mg a.s./kg bw
Dietary toxicity to birds	LD50 (quail) > 411 mg a.s./kg bw/d LD50 (duck) > 301.8 mg a.s./kg bw/d
Reproductive toxicity to birds	NOEL (quail) = 90 mg a.s./kg bw/d NOEL (duck) = 59 mg a.s./kg bw/d

Toxicity data for aquatic species (Annex IIA. point 8.2. Annex IIIA. point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/L)
Laboratory tests				
O. mykiss	a.s.	acute	LC50-96 h	> 100 mg a.s./L
O. mykiss	IKI-220 50%WG	acute	LC50-96 h	> 51 mg a.s./L
L. macrochirus	a.s.	acute	LC50-96 h	> 100 mg a.s./L
P. promelas	a.s.	chronic	NOEC-33 d	10 mg a.s./L
D. magna	a.s.	acute	EC50-48 h	> 100 mg a.s./L
D. magna	IKI-220 50%WG	acute	EC50-48 h	> 51 mg a.s./L
D. magna	a.s.	chronic	NOEC-21 d	3.1 mg a.s./L
Ps. subcapitata	a.s.		EbC50-72 h ErC50-72 h	> 100 mg a.s./L > 100 mg a.s./L
Ps. subcapitata	IKI-220 50%WG		EbC50-72 h ErC50-72 h	43 mg a.s./L > 51 mg a.s./L
L. gibba	a.s.		EC50 biomass and growth-7 d	119 mg a.s./L
C. riparius	a.s.	acute	LC50-48 h	> 200 mg a.s./L
C. riparius	a.s.	chronic	NOEC-28 d	25 mg a.s./L
O. mykiss	TFNA	acute	LC50-96 h	> 100 mg a.s./L
D. magna		acute	EC50-48 h	> 100 mg a.s./L
Ps. subcapitata			EbC50-72 h ErC50-72 h	> 100 mg a.s./L > 100 mg a.s./L
O. mykiss	TFNA-OH	acute	LC50-96 h	> 100 mg a.s./L
D. magna		acute	EC50-48 h	> 100 mg a.s./L
Ps. subcapitata			EbC50-72 h ErC50-72 h	29 mg a.s./L > 100 mg a.s./L
O. mykiss	TFNA-AM	acute	LC50-96 h	> 100 mg a.s./L
D. magna		acute	EC50-48 h	> 100 mg a.s./L
Ps. subcapitata			EbC50-72 h ErC50-72 h	> 100 mg a.s./L > 100 mg a.s./L
O. mykiss	TFNG-AM	acute	LC50-96 h	> 100 mg a.s./L
D. magna		acute	EC50-48 h	> 100 mg a.s./L
Ps. subcapitata			EbC50-72 h ErC50-72 h	> 100 mg a.s./L > 100 mg a.s./L

Bioconcentration

Bioconcentration factor (BCF)	logPow = 0.3 (i.e.. < 3)
Annex VI Trigger:for the bioconcentration factor	
Clearance time (CT_{50}) (CT_{90})	
Level of residues (%) in organisms after the 14 day depuration phase	

Effects on honeybees (Annex IIA. point 8.3.1. Annex IIIA. point 10.4)

Acute oral toxicity	> 104.3 mg IKI-220 50% WG (TEPPEKI) / bee *i.e.*. > 53.3 mg a.s./bee
Acute contact toxicity	> 100.0 mg IKI-220 50% WG (TEPPEKI) / bee *i.e.*. > 51.1 mg a.s./bee

Effects on other arthropod species (Annex IIA. point 8.3.2. Annex IIIA. point 10.5)

Laboratory tests:

Species	Stage	Test Substance[1]	Dose (g a.s./ha)	Endpoint	Adverse effect[2]	Annex VI Trigger
Laboratory tests						
A. rhopalosiphi (standard test)	adults	IKI-220 50% WG	80 210	mortality	22.2% 55.5%	30%
T. pyri (standard test)	protonymphs		80 210	mortality	100% 100%	30%
C. 7-punctata (standard test)	larvae		80 210	mortality	30% 30%	30%

Tier 2 studies:

Species	Stage	Test Substance[1]	Dose (g a.s./ha)	Endpoint	Adverse effect[2]	Annex VI Trigger
Extended laboratory tests						
A. rhopalosiphi (ext[d] test)	adults		85	mortality reproduction	4.4% 9.5% *	30%
T. pyri (ext[d] test)	protonymphs		85	mortality reproduction	23.3% 5.5% *	30%
C. 7-punctata (ext[d] test)	larvae		85	mortality reproduction	6.1% 14.3%	30%
C. carnea (ext[d] test)	larvae		85	mortality reproduction	18.8% - 18.5% *	30%
P. cupreus (standard test)	adults		45	mortality food consumption	3.3% - 0.8% *	30%
E. balteatus (ext[d] test)	larvae		85	mortality reproduction	2.3% 30.2%	30%
O. laevigatus (lab test)	2[nd] stage nymph		161 (dry residues)	mortality reproduction	22% 11%	30%
Field or semi-field tests: no data.						

* reduction.

[1] *Test substance IKI-220 50% WG = TEPPEKI = 50% flonicamid*

[2] *Adverse effect means:*
x % effect on mortality = x % increase of mortality compared to control
y % effect on a sublethal parameter = y % decrease of sublethal paramether compared to control
(sublethal parameters are e.g. reproduction, parasitism, food consumption)

When effects are favourable for the test organisms, a + sign is used for the sublethal effect percentages (i.e. increase of e.g. reproduction) and a – sign for mortality effect percentages (i.e. decrease of mortality).

Effects on earthworms (Annex IIA. point 8.4. Annex IIIA. point 10.6)

Acute toxicity	flonicamid > 1000 mg a.s./kg soil TFNA > 100 mg a.s./kg soil TFNA-OH > 100 mg a.s./kg soil TFNG-AM > 100 mg a.s./kg soil TFNA-AM > 100 mg a.s./kg soil
Reproductive toxicity	not required

Effects on soil micro-organisms (Annex IIA. point 8.5. Annex IIIA. point 10.7)

Nitrogen transformation	0.105 kg a.s./ha: no effect > 25%
Carbon mineralization	0.105 kg a.s./ha: no effect > 25%

Effects on terrestrial plants (Annex IIA 8.6; Annex IIIA 10.8)

Foliar treatment	Eleven species. No effect in a screening test
Soil treatment	Seventeen species. No effect in a screening test

It can be concluded that IKI 220-50WG at the practical use rate of 100 g a.i/ha has no effect to 11 species of adjacent crops. At 300 g a.i./ha, IKI 220-50WG has no effect to 17 species of succeeding crops.

Effects on biological methods for sewage treatment *(taken from the DAR, …200x)*
EC_{50} > 1000 mg/L = > 500 mg a.s./L
NOEC = 1000 mg/L.

Classification and proposed labelling (Annex IIA. point 10)

with regard to ecotoxicological data	not classified

Other studies

Two field studies in honey bees were submitted and summarized/evaluated by Wageningen UR (reports dated November 2012, revised February 2013).

Study 1
The first study was performed by RCC (study number B47520) and tested the impact of one application of 80 g a.s./ha TEPPEKI (IKI-220 50% WG), sprayed after bee foraging activity on flowering *Phacelia tanacetefolia,* on the acute mortality, colony strength, brood development and foraging activity of honey bees. The exposure duration was 7 days.

The study was conducted on two test plots. The test plot measured of 2808 m^2 (EPPO 1/170 (3) guideline recommend 1500 m^2, EPPO 1/170 (4) update 2010, recommends 2500 m^2), the control plot measured 1984 m^2 . The test and control sites were located approximately 3 km from each other.
The parameters flight density to assess exposure and adult bee mortality were recorded daily at 3 days before and 7 days after the application of TEPPEKI. The colony strength was recorded 2 days before application and 25 days after application. Mortality of the brood was recorded up to 22 days after application and the development of the brood, starting with eggs, young larvae and old larvae started 1 day before application and was completed 22 days after application. EPPO 1/170 (3) recommends brood check up to 28 days.

Exposure to the crop by means of checking pollen income with a pollen was not carried out. The parameters provide sufficient information to evaluate the short term effect TEPPEKI on a honeybee colony.

The test design meets the EPPO guideline which provides a reasonable foraging conditions and exposure for the honeybee colonies. The smaller control plot does not meet the 2010 guideline but does meet the EPPO 2000 guideline, it is large enough to compare colony development as result of foraging on *Phacelia tanacetifolia*.

In the study report, the number of foragers per m^2 on the test site is adjusted with a factor 1.42 to account for the difference between control (1984 m^2) and test site (2808 m^2) before statistical analysis. However, this is incorrect as the total number of bees per field is not the

parameter but the number of foraging bees per m^2. The same goes for in field mortality in which number of dead bees per 5 *1 m^2 (observation time per recording :15 seconds) is the parameter and not the assessed in-field mortality of the entire field. Therefore, the results were recalculated by the reviewer, as follows:

Mean flight density
pre-treatment (day -3 to -1): test mean (sd): 7.5 (5.7), control mean 5.7 (10.0) F = 43.16, P < 0.01 df res/tot = 13/14
post treatment day 0 to day 7: test mean (sd): 5.1 (4.9), control mean 8.3 (6.5) F = 34.52, P < 0.01 df res/tot = 68/69

mean in field mortality
pre-treatment (day -3 to -1): test mean (sd): 0.11 (0.33), control mean 1.8 (3.1) F = 21.76, P = 0.002 df res/tot = 7/8
post treatment day 0 to day 7: test mean (sd): 0.14 (0.35), control mean 2.4 (2.69) F = 0.52, P = 0.47 df res/tot = 40/41

mean flight density on day 1
test mean (sd): 1.1 (2.05), control mean 5.6 (4.2) F = 14.96, P < 0.01 df res/tot = 20/21

mean flight density on day 2
test mean (sd): 9.7 (7.5), control mean 15.9 (4.2) F = 6.18, P = 0.025 df res/tot = 15/16

The recording times were correct to assess foraging activity. The number of foraging bees, recorded at subsequent intervals 1 and 2 days after application and once a day till 7 days after application, on the sprayed crop was sufficient to provide exposure although the mean flight density was significant lower on the test plot compared to the control plot on day 1 and 2. The number of four colonies per test site meets the requirement of the EPPO guideline 170 (3). The number of bees per colony, required according to the guideline, at least 10 000 bees is not specifically recorded. A fully occupied frame (Swiss format hives (36 x 30 cm is occupied by approximately 2 x 1300 = 2600 bees. The number of occupied bee ways (gap between 2 frames) was recorded. Each completely occupied bee ways contains about 2600 bees. The number occupied bee ways exceeded 4 meaning that the colonies met the requirement of colony strength. The brood was recorded in detail by assessing the percentage coverage by brood. Simultaneously the percentage coverage of the frames by pollen, nectar, honey and vacant cells were assessed. The number of frames containing brood met the requirements.
Mortality was recorded in the traps placed in front of the hives and on three, 5 m^2 linen sheets in the field, both test site and control site. In the traps the number of dead bees the total of 3 days (-2, -1, 0) before application was 102 and 47 for the control- and test site respectively. After application these numbers, collected from day 1 to day 22, were 250 and 219. Before application no dead larvae and pupae were found in the traps. After application the mean numbers of dead pupae collected from day 1 till day 22 was 4.4 and 2.25 in the control- and test colonies. At the control site 2 larvae were found. Overall there was no statistically significant difference in in-hive adult bee mortality in the colonies placed at the control- and test sites. The success of brood development in the control was 92.6% in the control colonies (n = 4) and 89.0% in the test colonies (n = 4). This is within the range of normal development.
The statistics applied are applicable for the evaluation of the brood development parameters. The statistics applied for flight density and in field mortality are applicable but adjusting the data to account for the test and control site area is not correct. Recalculation of the original data shows significant differences between in field flight density before and after TEPPEKI application both during the entire study period as during day 1 and 2 following the TEPPEKI application. In field mortality was not significant different after TEPPEKI application.

In the study there was no positive control (known toxic). Although a positive control provides information about foraging activity and exposure it is not required for field tests (EPPO PP 170 (3). No specific checks were done to show that the bees foraged on *Phacelia tanacetifolia* by counting the incoming colour of the pollen pellets. However the recording of the foraging activity in the fields, the placement of the colonies and the surface of the control- and test plot assure foraging of the bees to the plots.

Based on the data reported and statistical methods applied to evaluate the results, the conclusion of the report that there are no adverse effects on honeybee colonies under field conditions is not justifiable for flight density. There are significant differences between the test and control site. The argument mentioned in the discussion that there were other colonies around does not justify this differences as there is no recording of these colonies nor of competing crops near the sites. Based on the data and GLM analysis, flight density after TEPPEKI application is significantly reduced.

Based on the data reported and statistical methods applied to evaluate the results, the conclusion of the report that there are no adverse effects on honeybee colonies under field conditions is justifiable for brood development, in hive mortality and field mortality.

Study 2

The second was performed by IBacon (project 36061040) and tested the impact of one application of 80 g a.s./ha TEPPEKI (IKI-220 50% WG), sprayed after bee foraging activity on flowering *Phacelia tanacetefolia,* on the acute mortality, colony development and foraging activity of honey bees. The exposure duration was 7 days.

The study was conducted on two test plots of 2300 m^2 (EPPO guideline recommend 1500 m^2) located 5 km from each other. The parameters flight density to assess exposure, pollen income to verify where the bees foraged on and adult bee mortality were recorded daily at 3 days before and 7 days after the application of TEPPEKI. The colony status was recorded one day before and 7 and 21 days after the application of TEPPEKI.
The parameters provide sufficient information to evaluate the short term effect TEPPEKI on a honeybee colony.

The test design meets the EPPO guideline which provides a reasonable foraging conditions and exposure for the honeybee colonies.

The mean number of bees foraging on 1 m^2 around noon was approximately 22.5 in the control site and 27.3 in the test site. The day after spraying, the mean number of foraging bees on 1 m^2 around noon was approximately 30. The recordings were sufficient to assess foraging activity. The number of foraging bees on the sprayed crop was sufficient to provide a good exposure. The number of four colonies per test site meets the requirement of the EPPO guideline 170 (3). The number of bees per colony, required according to the guideline, at east 10 000 bees is not specifically recorded. However the number of occupied gaps between the frames was recorded. A fully occupied frame (Deutsch Normalmass (22 x 37 cm is occupied by approximately 800 - 900 bees. A gap between two frames can contain about 1600 bees. As the number of gaps between the frames at the start of the test was about 15, the number of bees met the guideline. The number of frames containing brood met the requirements.
Mortality was recorded in the traps and on gauze placed in front of the hives. The mean number of daily mortality before application on the gauze strips was 1.7 and 4 for the control- and test site respectively. After application these numbers were 0.6 and 0.6. In the traps, the mean number of daily mortality before application was 20.1 and 20.3 for the control- and test site respectively. After application these numbers were 12.8 and 3.5. The number of dead bees in the traps after TEPPEKI application varied significantly in the control traps and was rather stable in the traps in front of the test colonies. Overall there was no statistically

significant difference in adult bee mortality in the colonies placed at the control- and test sites. The variation of daily mortality in the traps in front of the hives at the control sites can be considered as normal variation.

Flight density and adult mortality were recorded up to 7 days after TEPPEKI application. After 7 days, foraging activity decreased, which was also seen in the pollen storage check on day 7 and day 21. During the 7 days after TEPPEKI application exposure to the crop was demonstrated by the ratio of blue (*Phacelia*) pollen of 46 - 66% of the pollen flow. A 7-day exposure is the minimum exposure duration in field trials according to the European and Mediterranean Plant Protection Organization PP 1/170 (3); the revised guideline EPPO 1/170 (4) updated 2010-09 recommends assessments of the adult mortality up to 14 days.
The duration of 21 days is a minimal one, to evaluate worker brood development as the brood cycle of the honey bee brood lasts 21 days. The recommended period post treatment for the evaluation of brood effect according to both the EPPO 1/170(3) and 1/170(4) guideline mentioned above is 28 days. Possible delayed effects of brood starting after the beginning of the exposure can be less evaluated as the checks were not continued up till 28 days.

Although recordings of mortality met the minimum requirement (EPPO 1/170(3) of the exposure (mortality 7 days) and recording of brood development was shorter than de recommended period, the recordings provide sufficient sound data to evaluate the acute impact of dried residue of TEPPEKI on honeybee colonies.

The statistics applied are applicable for the evaluation of the parameters:

In the study there was no positive control (known toxic). Although a positive control provides information about foraging activity and exposure it is not required for field tests (EPPO PP 170 (3)), checking the foraging activity by recording and determining the botanic origin (microscope or colour) of the pollen income is a simple way to evaluate foraging activity and exposure of the pollen foragers. There is no minimal requirement of fraction incoming pollen loads to assess the exposure recommended in EPPO 1/170 (3) and (4). The contribution of approximately 50% of pollen from the treated plot demonstrates exposure of at least half of the pollen collecting bees. No data are required about the fraction nectar collecting bees in the guidelines mentioned above.

Based on the data reported and statistical methods applied to evaluate the results the conclusion of the report, that there was no impact of TEPPEKI applied in the evening after bee foraging at 80 g a.i./ ha is justifiable. Taken into account: exposure 7 days, exposure of approximately half of the pollen foragers and brood check 21 days after start exposure which meet, except the last brood check on day 28, the requirements of the EPPO guideline 1/170(3) the most recent EPPO guideline at the time of testing.

7.1 Effects on birds

Birds can be exposed to the active substance flonicamid via natural food (sprayed insects, seeds, leafs), drinking water and as a result of secondary poisoning.

The threshold value for birds is based on the trigger from the RGB. This means that Toxicity-Exposure Ratio's (TERs) for acute and short-term exposure should be ≥ 10 and TER for chronic exposure should be ≥ 5.
Table E.1 presents an overview of toxicity data.

Table E.1 Overview of toxicity data for birds

	Endpoint	Value
Acute toxicity to birds:	LD_{50}	1591 mg a.s./kg bw

	Endpoint	Value
Dietary toxicity to birds:	LC_{50}	>301.8 mg a.s./kg bw/d
Reproductive toxicity to birds:	NOEL	59 mg a.s./kg bw/d

7.1.1 Natural food and drinking water

Sprayed products
The risk assessment from the applicant is based on the revised guidance for birds and mammals (EFSA Journal 2009; 7(12):1483). Since this guidance has passed the SCoFCAH (standing committee) per 13-07-12, Ctgb will perform the risk assessment below based on EFSA (2009).

For the risk assessment below, tables and/or texts from the dRR of the applicant are used where necessary or practical. This is not explicitly indicated; the risk assessment below should be considered as Ctgb risk assessment.

- **Acute dietary risk assessment: screening step for sprayed products**

For the application in bare soils and hop, the indicator species is a small granivorous bird, for applications in cereals, potatoes, bulbs and onion like crops, the indicator species is a small omnivorous bird, for applications in orchards and ornamentals/nursery the indicator species is a small insectivorous bird, and for applications in grassland the indicator species is a large herbivorous bird. For uses with frequency > 1, a MAF (Multiple Application Factor) may be applicable. MAF values are taken from Table 7 of the EFSA guidance (2009) with the following adaptation: As this document only gives acute MAF-values up to an interval of 14 days, but all TEPPEKI applications concern intervals of 21 days, for calculation of the acute DDDm, MAF-values for 14-d interval were used as a worst case, with assuming a default DT_{50} of 10 days on vegetation.

The DDD_m is calculated as application rate * shortcut value * MAF_{90}. The DDD_m is compared to the relevant toxicity figure. TER should be above the trigger (10) for an acceptable risk. The screening assessment is shown in Table E.2.

Table E.2 Acute risk for birds (screening assessment)

Crop	Substance	Indicator species	LD_{50} [mg a.s./kg bw]	DDD			DDD_m [mg a.s./ kg bw/d]	TER_A	Trigger
				Appl. rate [kg a.s./ha]	SV_{90}	MAF_{90}			
Bare soils and hop	Flonicamid	Small granivorous bird	1591	3x0.07	24.7	1.3	2.2	708	10
Potatoes, cereals*	Flonicamid	Small omnivorous bird	1591	2x0.08	158.8	1.2	15.2	104	10
Bulbs and onion like crops	Flonicamid	Small omnivorous bird	1591	3x0.07	158.8	1.3	14.5	110	10
Orchards and ornamentals/nursery	Flonicamid	Small insectivorous bird	1591	3x0.07	46.8	1.3	4.3	374	10
Grassland	Flonicamid	Large	1591	3x0.07	30.5	1.3	2.8	573	10

Crop	Substance	Indicator species	LD_{50} [mg a.s./kg bw]	DDD			DDD_m [mg a.s./ kg bw/d]	TER_A	Trigger
				Appl. rate [kg a.s./ha]	SV_{90}	MAF_{90}			
		herbivorous bird							

* 2 x 0.08 kg a.s./ha (potatoes) covers the cereals application rate (2x0.07 kg a.s./ha)

Taking the results in Table E.2 into account, it appears that all proposed uses meet the standards laid down in the RGB.

Acute risk for birds through drinking water

Leaf scenario

The leaf scenario is not relevant for any of the proposed applications, and is therefore not assessed.

Puddle scenario

The exposure of birds to drinking water from puddles formed on the field after rainfall is relevant for all proposed field uses of flonicamid.

According to EFSA (2009) the puddle scenario is relevant for the acute (this section) and reproduction scenario (see below). Generic focal species is a small granivorous bird (body weight 15.3 g) with a DWR (daily drinking water rate) of 0.46 L/kg bw/d.
According to EFSA Guidance Document for Birds and Mammals (2009), no specific calculations are necessary when the ratio of effective application rate (in g a.s./ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc <500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥500 L/kg). The Koc of flonicamid is 5.9 L/kg. The highest ratio of application rate to acute endpoint is 80.02 g a.s./ha / 1591 mg a.s./kg bw = 0.05. This ratio does not exceed the trigger of 50.The risk due to exposure to drinking water from puddles is concluded to be acceptable.

- **Chronic dietary risk assessment: screening step for sprayed products**

For the application in bare soils and hop, the indicator species is a small granivorous bird, for applications in cereals, potatoes, bulbs and onion like crops, the indicator species is a small omnivorous bird, for applications in orchards and ornamentals/nursery the indicator species is a small insectivorous bird, and for applications in grassland the indicator species is a large herbivorous bird. For uses with frequency > 1, a MAF (Multiple Application Factor) may be applicable. Since a MAF value for application interval of 21 days is not presented in Table 11 of the EFSA guidance (2009), MAF values for the next lower application interval were chosen, i.e. 14 day application interval. NOEC was chosen as endpoint in the reproductive screening assessment as this value was lower than LD_{50}/10.

The DDD_m is calculated as application rate * shortcut value * MAF_{mean}* TWA. The DDD_m is compared to the relevant toxicity figure. TER should be above the trigger (5) for an acceptable risk. The screening assessment is shown in Table E.3.

Table E.3 Chronic risk for birds (screening assessment)

Crop	Substance	Indicator species	NOEC [mg	DDD	DDD_m [mg	TER_{LT}	Trigger

			a.s./kg bw]	Appl. rate [kg a.s./ha]	SV_{mean}	MAF_m	TWA	a.s./ kg bw/d]		
Bare soils and hop	Flonicamid	Small granivorous bird	59	3x0.07	11.4	1.5	0.53	0.63	93	5
Potatoes, cereals*	Flonicamid	Small omnivorous bird	59	2x0.08	64.8	1.4	0.53	3.85	15	5
Bulbs and onion like crops	Flonicamid	Small omnivorous bird	59	3x0.07	64.8	1.5	0.53	3.37	16	5
Orchards and ornamentals/nursery	Flonicamid	Small insectivorous bird	59	3x0.07	18.2	1.5	0.53	1.01	58	5
Grassland	Flonicamid	Large herbivorous bird	59	3x0.07	16.2	1.5	0.53	0.90	65	5

Taking the results in Table E.3 into account, it appears that all proposed uses meet the standards laid down in the RGB.

Metabolites
(copied from the core dRR, d.d. 28 February 2011):
In the plant metabolism studies carried out in wheat, potato and peach, two major metabolites, i.e. TFNG and TFNA, were found (please refer to DAR 2005, Volume 3, 9.1.7.4). TFNG was the major metabolite found in wheat grain (39 - 44 % of the total radioactive residue (TRR)) and TFNA was the most significant metabolite found in mature peach fruits (17 - 49 % of TRR in juice and pomace). Accordingly, birds might be exposed to either TFNG or TFNA when feeding on wheat grains or mature fruits.
In the metabolism study with laying hens (please refer to DAR 2005, Volume 3, 9.1.7.4) TFNA was mainly excreted (11.3 % TRR) and small amounts were determined in kidney (1.4 % TRR) and thigh muscle (0.1 % TRR). TFNG was not detected in the hens. A poultry feeding study was conducted where the parent compound and TFNG was fed in a 1:1 mixture to laying hens up to a concentration of 23 mg/kg feed. This dose level highly exceeded the maximum residue level in wheat grains (at least by a factor of 10). No residues (≥ 0.01 mg/kg) of both TFNG and TFNA were found in the hens at any dose level or sampling time.
In conclusion, no risk from plant metabolites is to be expected when birds are exposed to metabolites of Flonicamid.

Ctgb agrees with this evaluation.

Chronic risk for birds through drinking water
Leaf scenario
The leaf scenario is not relevant for chronic risk assessment.

Puddle scenario
The exposure of birds to drinking water from puddles formed on the field after rainfall is relevant for all proposed field uses of flonicamid.

According to EFSA (2009) the puddle scenario is relevant for the acute (this section) and reproduction scenario (see below). Generic focal species is a small granivorous bird (body weight 15.3 g) with a DWR (daily drinking water rate) of 0.46 L/kg bw/d.
According to EFSA Guidance Document for Birds and Mammals (2009), no specific calculations are necessary when the ratio of effective application rate (in g a.s./ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc <500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥500 L/kg). The Koc of flonicamid is 5.9 L/kg. The highest ratio of application rate to chronic endpoint is 80.02 g a.s./ha / 59 mg a.s./kg bw/d = 1.4. This ratio does not exceed the trigger of 50. The risk due to exposure to drinking water from puddles is concluded to be acceptable.

Risk for birds through drinking water according to Dutch requirments
The risk from exposure through drinking surface water is calculated for a small bird with body weight 10 g and a DWI (daily water intake) of 2.7 g/d. Surface water concentrations are calculated using TOXSWA (see paragraph 6.2.1). In the first instance, acute exposure is taken into account. The highest $PIEC_{water}$ is 10.26 µg/L. It follows that the risk of drinking water is (LD50 * bw) / (PIEC*DWI) = (1591 * 0.010) / (10.26 * 0.0027) = 5.75 x 10^5.
Since TER > 10, the risk is acceptable.

7.1.2 Secondary poisoning
The risk as a result of secondary poisoning is assessed based on bioconcentration in fish and worms.
Since the log Kow of flonicamid < 3 (-0.24), the potential for bioaccumulation is considered low and no further assessment is deemed necessary.

Conclusions birds
The product complies with the RGB.

7.2 Effects on aquatic organisms

7.2.1 Aquatic organisms
The risk for aquatic organisms for the various uses of the active substance flonicamid and metabolites TFNA and TFNA-OH is assessed by comparing toxicity values with surface water exposure concentrations from section 6.2. Risk assessment is based on toxicity-exposure ratio's (TERs).
Toxicity data for aquatic organisms for the active substance flonicamid, metabolites TFNA and TFNA-OH and the formulation TEPPEKI are presented in Table E.4. In view of the toxicity of flonicamid to daphnids, acute and chronic toxicity studies with the aquatic insect species *Chironomus riparius* were performed as well.

Table E.4 Overview toxicity endpoints for aquatic organisms

Substance	Organism	Lowest		Toxicity value
		$L(E)C_{50}$ [mg/L]	NOEC [mg/L]	[µg/L]
Flonicamid [a.s.]	*Acute*			
	Algae (*Ps. Subcapitata*)	> 100		> 100000
	Invertebrates (*D. magna*)	> 100		> 100000
	Chironomids	> 200		> 200000
	Fish (*O. mykiss*)	> 100		> 100000
	Macrophytes (*L. gibba*)	119		119000
	Chronic			
	Invertebrates (*D. magna*)		3.1	3100
	Fish (*P. promelas)*		10	10000
	Chironomids		25	25000

Substance	Organism	Lowest		Toxicity value
		L(E)C_{50} [mg/L]	NOEC [mg/L]	[µg/L]
TFNA [metabolite]	*Acute*			
	Algae (*Ps. Subcapitata*)	> 100		> 100000
	Invertebrates (*D. magna*)	> 100		> 100000
	Fish (*O. mykiss*)	> 100		> 100000
TFNA-OH [metabolite]	*Acute*			
	Algae (*Ps. Subcapitata*)	29		29000
	Invertebrates (*D. magna*)	> 100		> 100000
	Fish (*O. mykiss*)	> 100		> 100000
TEPPEKI* [formulation] (expressed as a.s.)	*Acute*			
	Algae (*Ps. Subcapitata*)	43		43000
	Invertebrates (*D. magna*)	> 51		> 51000
	Fish (*O. mykiss*)	> 51		> 51000

* In the LoEP it is presented as IKI-220 50% WG. This is the same as TEPPEKI WG (500g flonicamid/L)

These toxicity values are compared to the surface water concentrations calculated in section 6.2. Trigger values for acute exposure are 100 for invertebrates and fish (0.01 times the lowest L(E)C_{50}-value) and 10 for algae and macrophytes (0.1 times the lowest EC_{50}-value). Trigger values for chronic exposure are 10 for invertebrates and fish (0.1 times the lowest NOEC-values).
For acute and chronic risk, the initial concentration for the worst-case use in apples and pears (17% drift) is used (PIEC) for TER calculation. In tables E.5 and E.6 TER values for aquatic organisms are shown.

Table E.5 TER values for active substance flonicamid, metabolites, and formulation for the worst-case use in Apple and Pear: acute

Use	Substance	PECsw [µg a.s./L][1]	TER_{st} (trigger 10) Algae	TER_{st} (trigger 100) Invertebrates	TER_{st} (trigger 100) Fish	TER_{st} (trigger 10) Macrophytes
Apple; pear	Flonicamid (a.s)	10.26	>9747	>9747 [2] >19493 [3]	>9747	11598
	TFNA (m.)	0.843	>118624	>118624	>118624	-
	TFNA-OH (m.)	0.9584	30259	>104341	>104341	-
	TEPPEKI (f.)	10.26	4191	>4971	>4971	-

[1] PIECsw calculated for 17% drift
[2] : based on *D. magna* data
[3] : based on *Ch. riparius* data

Table E.6 TER values for the worst-case use in Apple and Pear: chronic

Use	Substance	PECsw [µg a.s./L]	TER_{lt} (trigger 10) Invertebrates	TER_{lt} (trigger 10) Fish
Apple; pear	Flonicamid (a.s)	10.26	302 [1] 2437 [2]	975

[1] : based on *D. magna* data
[2] : based on *Ch. riparius* data

Taking the results in Tables E.5 and E.6 into account, the acute TERs for fish and invertebrates are above the relevant Annex VI triggers of 100 and the acute TERs for algae and *Lemna* are above the relevant Annex VI triggers of 10. The chronic TERs for fish and

invertebrates are above the relevant Annex VI triggers of 10. Thus, it appears that for the active substance flonicamid the proposed uses meet the standards for aquatic organisms as laid down in the RGB.

7.2.2 Risk assessment for bioconcentration

Since log Kow of flonicamid is < 3, experimental data are not required. A BCF-value of 0.25 L/kg can be calculated from log Kow -0.24.

Since this value is below 100 L/kg, the risk for bioconcentration is small. Therefore the active substance flonicamid meets the standards for bioconcentration as laid down in the RGB.

7.2.3 Risk assessment for sediment organisms

None of the metabolites is found in sediment at levels > 10% after 14 days.

The water–sediment study indicates that over 10% of flonicamid is found in the sediment after 14 days. The NOEC for daphnids, however, is above 0.1 mg/L and therefore, there is no potential risk for sediment organisms.

Nevertheless, there is data available regarding the toxicity of flonicamid to the sediment organisms (water spiked).

The NOEC value for *Chironomus* is 25000 µg/L. When this value is examined against the highest PIEC in water, the TER value is 2437 and the trigger value of 10 is met. Therefore, the active substance flonicamid meets the standards for sediment organisms as laid down in the RGB.

Conclusions aquatic organisms

The proposed applications meet the standards for aquatic organisms.

7.3 Effects on terrestrial vertebrates other than birds

Mammals can be exposed to the active substance flonicamid via natural food (sprayed insects, seeds, leafs), drinking water and as a result of secondary poisoning.

The threshold value for mammals is based on the trigger from the RGB. This means that the Toxicity-Exposure Ratio (TER) for acute exposure should be ≥ 10 and TER for chronic exposure should be ≥ 5. Dietary toxicity is not taken into account for mammals.
Table E.7 presents an overview of toxicity data.

Table E.7 Overview of toxicity data for mammals

	Endpoint	Value
Acute toxicity to mammals:	LD_{50}	884 mg a.s./kg bw
Reproductive toxicity to mammals:	NOEL	25 mg a.s./kg bw/d

7.3.1 Natural food and drinking water

Sprayed products

The risk assessment from the applicant is based on the revised guidance for birds and mammals (EFSA Journal 2009; 7(12):1483). Since this guidance has passed the SCoFCAH (standing committee) per 13-07-12, Ctgb will perform the risk assessment below based on EFSA (2009).

For the risk assessment below, tables and/or texts from the dRR of the applicant are used where necessary or practical. This is not explicitly indicated; the risk assessment below should be considered as Ctgb risk assessment.

- **Acute dietary risk assessment: screening step for sprayed products**

For the application in cereals, potatoes, bulbs and onion like crops, as well as grassland, orchards and ornamentals/nursery, the indicator species is a small herbivorous mammal. For uses with frequency > 1, a MAF (Multiple Application Factor) may be applicable. MAF values are taken from Table 7 of the EFSA guidance (2009) with the following adaptation: As this document only gives acute MAF-values up to an interval of 14 days, but all TEPPEKI applications concern intervals of 21 days, for calculation of the acute DDDm, MAF-values for 14-d interval were used as a worst case, with assuming a default DT_{50} of 10 days on vegetation.

The DDD_m is calculated as application rate * shortcut value * MAF_{90}. The DDD_m is compared to the relevant toxicity figure. TER should be above the trigger (10) for an acceptable risk. The screening assessment is shown in Table E.8.

Table E.8 Acute risk for mammals (screening assessment)

Crop	Substance	Indicator species	LD_{50} [mg a.s./kg bw]	DDD			DDD_m [mg a.s./ kg bw/d]	TER_A	Trigger
				Appl. rate [kg a.s./ha]	SV_{90}	MAF_{90}			
Potatoes, cereals*	Flonicamid	Small herbivorous mammal	884	2x0.08	118.4	1.2	11.4	78	10
Bulbs and onion like crops	Flonicamid	Small herbivorous mammal	884	3x0.07	118.4	1.3	10.8	82	10
Grassland, orchards and ornamentals/nursery	Flonicamid	Small herbivorous mammal	884	3x0.07	136.4	1.3	12.4	71	10

* 2 x 0.08 kg a.s./ha (potatoes) covers the cereals application rate (2x0.07 kg a.s./ha)

Taking the results in Table E.8 into account, it appears that all proposed uses meet the standards laid down in the RGB.

Acute risk for mammals through drinking water

Leaf scenario

The leaf scenario is not relevant for any of the proposed applications, and is therefore not assessed.

Puddle scenario

The exposure of mammals to drinking water from puddles formed on the field after rainfall is relevant for all proposed field uses of flonicamid.

According to EFSA (2009) the puddle scenario is relevant for the acute (this section) and reproduction scenario (see below). Generic focal species is a small granivorous mammal (body weight 21.7 g) with a DWR (daily drinking water rate) of 0.24 L/kg bw/d.
According to EFSA Guidance Document for Birds and Mammals (2009), no specific calculations are necessary when the ratio of effective application rate (in g a.s./ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc <500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥500 L/kg). The Koc of flonicamid is 5.9 L/kg. The highest ratio of application rate to acute endpoint is 80.02 g

a.s./ha / 884 mg a.s./kg bw = 0.09. This ratio does not exceed the trigger of 50. The risk due to exposure to drinking water from puddles is concluded to be acceptable.

- **Chronic dietary risk assessment: screening step for sprayed products**

For the application in cereals, potatoes, bulbs and onion like crops, as well as grassland, orchards and ornamentals/nursery, the indicator species is a small herbivorous mammal. For uses with frequency > 1, a MAF (Multiple Application Factor) may be applicable. Since a MAF value for application interval of 21 days is not presented in Table 11 of the EFSA guidance (2009), MAF values for the next lower application interval were chosen, i.e. 14 day application interval. NOEC was chosen as endpoint in the reproductive screening assessment as this value was lower than $LD_{50}/10$.

The DDD_m is calculated as application rate * shortcut value * MAF_{mean}* TWA. The DDD_m is compared to the relevant toxicity figure. TER should be above the trigger (5) for an acceptable risk. The screening assessment is shown in Table E.9.

Table E.9 Chronic risk for birds (screening assessment)

Crop	Substance	Indicator species	NOEC [mg a.s./kg bw]	DDD				DDD_m [mg a.s./ kg bw/d]	TER_{LT}	Trigger
				Appl. rate [kg a.s./ha]	SV_{mean}	MAF_m	TWA			
Potatoes, cereals*	Flonicamid	Small herbivorous mammal	25	2x0.08	48.3	1.4	0.53	2.87	8.7	5
Bulbs and onion like crops	Flonicamid	Small herbivorous mammal	25	3x0.07	48.3	1.5	0.53	2.69	9.3	5
Grassland, orchards and ornamentals/nursery	Flonicamid	Small herbivorous mammal	25	3x0.07	72.3	1.5	0.53	4.02	6.2	5

Taking the results in Table E.9 into account, it appears that all proposed uses meet the standards laid down in the RGB.

Metabolites
(copied from the cord RR, d.d. 28 February 2011):
In the plant metabolism studies carried out in wheat, potato and peach, two major metabolites, i.e. TFNG and TFNA, were found (please refer to DAR 2005, Volume 3, 9.1.7.4). TFNG was the major metabolite found in wheat grain (39-44% of the total radioactive residue (TRR)) and TFNA was the most significant metabolite found in mature peach fruits (17-49% of TRR in juice and pomace). Accordingly, terrestrial vertebrates other than birds might be exposed to either TFNG or TFNA when feeding on wheat grains or mature fruits.
In conclusion, no risk from plant metabolites is to be expected when terrestrial vertebrates other than birds are exposed to metabolites of Flonicamid.

The applicant provided no sound justification in the core dRR for the above conclusion, i.e. that terrestrial vertebrates other than birds are not at risk from plant metabolites, however, in the EFSA conclusion it was stated that “Some metabolites identified in the rat metabolism were tested and considered of lower toxicity than flonicamid.” TFNG and TFNA were

amongst the tested metabolites. The conclusion on metabolites is therefore accepted by the Ctbg.

Chronic risk for birds through drinking water
Leaf scenario
The leaf scenario is not relevant for chronic risk assessment.

Puddle scenario
The exposure of birds to drinking water from puddles formed on the field after rainfall is relevant for all proposed field uses of flonicamid.

According to EFSA (2009) the puddle scenario is relevant for the reproduction scenario. Generic focal species is a small granivorous mammal (body weight 21.7 g) with a DWR (daily drinking water rate) of 0.24 L/kg bw/d.
According to EFSA Guidance Document for Birds and Mammals (2009), no specific calculations are necessary when the ratio of effective application rate (in g a.s./ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc <500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥500 L/kg). The Koc of flonicamid is 5.9 L/kg. The highest ratio of application rate to chronic endpoint is 80.02 g a.s./ha / 25 mg a.s./kg bw/d = 3.2. This ratio does not exceed the trigger of 50. The risk due to exposure to drinking water from puddles is concluded to be acceptable.

Risk for mammals through drinking water according to Dutch requirments
The risk from exposure through drinking from surface water is calculated for a small mammal with body weight 10 g and a DWI (daily water intake) of 1.57 g/d. Surface water concentrations are calculated using TOXSWA (see paragraph 6.2.1). In the first instance, acute exposure is taken into account. The highest $PIEC_{water}$ is 10.26 µg/L. It follows that the risk of drinking water is (LD50 * bw) / (PIEC*DWI) = (884* 0.010) / (10.26* 0.00157) = 5.49 x 10^5.
Since TER > 10, the risk is acceptable.

7.3.2 Secondary poisoning
The risk as a result of secondary poisoning is assessed based on bioconcentration in fish and worms.
Since the log Kow of flonicamid < 3 (-0.24), the potential for bioaccumulation is considered low and no further assessment is deemed necessary.

Conclusions mammals
The product complies with the RGB.

7.4 Effects on bees
The risk assessment for bees is based on the Hazard Quotient (HQ), the ratio between the highest single application rate and toxicity endpoint (LD_{50} value). An overview of the risk at the proposed uses is given in Table E.10.

Table E.10 In-field risk for bees

Use	Substance	Application rate	LD_{50}	HQ (Rate/LD_{50})	Trigger value
		[g a.s./ha]	[µg/bee]		
potatoes	flonicamid	80	>51.1	<1.57	50

The first-tier HQ values for acute oral and contact exposure of bees were far below the trigger of 50 indicating a low risk. However, adverse effects on bees were observed in some of the additionally submitted tunnel tests e.g. altered feeding behaviour (avoidance) and

increased mortality of bees when bees were present during spraying. Therefore the RMS of the DAR suggested to restrict the use to periods of no flowering for uses in apples/pears and peaches and additional information may be required (bee brood feeding study) if other authorizations e.g. in oilseed-rape are granted at MS's level.

Since the proposed use is in flowering crops during the flowering period, exposure to bees cannot be excluded based on the Tier 1 assessment. The applicant submitted two field studies in honey bees. A detailed summary and evaluation of these studies can be found in the LoE section above, under "Other studies". From these field studies it can be concluded that application of TEPPEKI in the evening, after bee foraging, does not have a short term effect on bee mortality or bee colony development or strength. The mode of action of flonicamid is unknown, and appears to be a novel mechanism. It has been shown to inhibit the feeding of aphids, but the method by which this is accomplished is unknown. Since there is no indication from insecticides with a similar mode of action of long-term harm to bee populations, Ctgb considers the very low HQ value in acute studies and the lack of effect in short-term field studies to be sufficient to show that the current application of TEPPEKI meets the standards laid down in the RGB, provided that the following restriction is placed on the label for outdoor uses:

"*Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen mag u dit product op in bloei staande gewassen of op niet-bloeiende gewassen wanneer deze actief bezocht worden door bijen en hommels alleen toepassen na zonsondergang*."

Furthermore, bees can be exposed off-field, in flowering margins and/or bordering fields. An off-field risk assessment is necessary if the in-field risk assessment indicates a risk. Since the in-field risk was concluded to be acceptable if application is done after bee foraging, the off-field risk is expected to be acceptable as well.

<u>Risk from exposure to contaminated nectar or pollen</u>
Due to its possible systemic nature, the a.s. may be taken up by the crop. Potatoes, apple, pear, fruit trees and floriculture crops are supposed to flower during cultivation, so exposure via nectar or pollen can take place.
The new EPPO scheme for risk assessment for bees (EPPO 2010) includes a risk assessment method for this exposure route.

No risk is expected from substances with an LD50 > 10 µg/bee. As both the acute oral LD50 and the acute contact LD50 are >50 µg a.s./bee, no risk is expected from the proposed applications of flonicamid.

<u>Exposure via honeydew</u>
Lastly, the risk from exposure via honeydew from aphids should be assessed.

The risk to honeybees foraging on honeydew of treated crops is expected to be low as the oral acute LD50 > 10 µg a.s./bee and because the DAR states that *"it was demonstrated that aphids stop producing honeydew within two hours after application"* of the product. In view of proposed application of the product after bee foraging, potential contamination of honeybees via honeydew is expected to be very limited, and therefore no risk is expected from the proposed applications of flonicamid.

Honeybees and bumble bees are important pollinators also in glasshouses. Taking the above assessment into consideration, the following restriction sentence should therefore be included on the label for indoor uses:

Gebruik is wel toegestaan op bloeiende planten in de kas mits er geen bijen of hommels in de kas actief naar voedsel zoeken.

Conclusions bees
The product complies with the RGB, provided that restriction sentences are placed on the label.

7.5 Effects on any other organisms (see annex IIIA 10.5-10.8)

7.5.1 Effects on non-target arthropods
The risk for non-target arthopods is assessed by calculating Hazard Quotients. For this, Lethal Rate values (LR_{50}) are needed. Based on LR_{50}-values from studies with the two standard species *Aphidius rhopalosiphi* and *Typhlodromus pyri* an in-field and an off-field Hazard Quotient (HQ) can be calculated according to the assessment method established in the SETAC/ESCORT 2 workshop and described in the Evaluation Manual. Hazard Quotients should be below the trigger value of 2 to meet the standards. The resulting Hazard Quotients are presented in Table E11. The risk assessment is based on the worst case application rate of 0.08 kg a.s./ha (potatoes; see Table M.0, overview of intended uses) and covers the lower application rate for all other uses (*i.e.* 0.07 kg a.s./ha).

Table E.11 HQ-values for *A. rhopalosiphi* and *T. pyri*

	Application rate (kg a.s./ha)	MAF[1]	Drift fraction / Vegetation factor[2]	Safety factor[2]	LR_{50} (kg a.s./ha)	HQ
In-field						
A. rhopalosiphi	0.08	1	-	-	0.08< LR50 <0.210	0.38 - 1.0
T. pyri	0.08	1	-	-	<0.080	>1
Off-field						
A. rhopalosiphi	0.08	1	0.01 (=0.1/10)	10	0.08< LR50 <0.210	0.038 - 0.1
T. pyri	0.08	1	0.01 (=0.1/10)	10	<0.080	>0.1

[1]: Multiple Application Factor is set to 1 because the max. DT50 of flonicamid in soil is 1.8 days and therefore, with the interval of 21 days between applications, no accumulation of the a.s. is expected.
[2]: off-field: drift fraction = 10% (thus 0.1), vegetation distribution factor = 10, safety factor = 10 (default values)

As the above table shows, both in- and off-field HQ values for *A. rhopalosiphi* values are below the trigger value of 2. For *T. pyri* an in-field risk cannot be excluded. Higher tier studies are therefore required.

Additional studies with *A. rhopalosiphi*, *T.pyri* , *C. septempunctata, C. carnea, P cupreus, E. balteatus* and *O. laevigatus* are available. In extended laboratory tests, adverse effects on mortality and reproduction were <50% on *A. rhopalosiphi, T. pyri, C. septempunctata*, *C. carnea* and *E. balteatus* at application rates of 85 g a.s./ha. Because the test rate is higher than the application rate for the field uses, the risk for non-target arthropods is considered acceptable in-field and as well off-field.

For greenhouse uses, however, in-field trigger values are lower as compared to field uses, *i.e.* 25% adverse effects for extended laboratory studies. If the trigger is not met, a warning sentence should be placed on the label. Off-field exposure does not occur for uses inside the glasshouse.

In extended laboratory tests, adverse effects were <25% on *A. rhopalosiphi, T. pyri, C. septempunctata* and *C. carnea* at application rates of 80-85 g a.s./ha. However, in an

extended laboratory test with *E. balteatus*, reproduction decreased with 30.2% at an application rate of 85 g a.s./ha. Mortality was not affected This means that an in-field risk for this beneficial arthropod cannot be excluded in greenhouse uses and a warning sentence should be placed on the label and/or instructions for use:
"Dit middel is schadelijk voor niet-doelwit arthropoden in bedekte teelten. Vermijd onnodige blootstelling"

The proposed application of the product therefore meets with the standards as laid down in the RGB, provided that a warning sentence is placed on the label for IPM uses.

7.5.2 Earthworms

For glasshouse uses, management practice includes regular sterilisation of the soil, which prevents the formation of a natural soil organism community within glasshouses. Exposure to natural soils is not expected. Therefore no risk assessment is performed for soil organisms for glasshouse uses.

For field uses, the acute risk for earthworms is calculated as TER-value (trigger value 10). Since the log Pow of the active substance flonicamid and the metabolites < 2, no correction to the reference soil containing 4.7 % organic matter is necessary. The toxicity value for earthworms based on the 14-day LC_{50} of the active substance and metabolites amounts therefore >1000 mg/kg for flonicamid and >100 mg/kg for the most relevant metabolites in soil with formation rates > 10%, i.e. TFNA, TFNA-OH and TFNG-AM. Exposure is expressed as the initial PEC_{soil} which is calculated in section 6.1.1. Table E.12 presents endpoints, PEC_{soil} and TER values for the active substance flonicamid and its metabolites TFNA, TFNA-OH and TFNG-AM for the worst-case field application in potatoes.

Table E.12 Overview of soil concentrations and acute TERs for earthworms for the worst-case use in potatoes

Use	Substance	Application rate [kg a.s./ha]	$LC50_{corr}$ [mg/kg]	PIECsoil [mg a.s./kg] (5 cm)	TER	Trigger value
Potatoes	Flonicamid (a.s.)	0.08	> 1000	0.091	>10989	10
	TFNA (m.)		> 100	0.027	>3704	10
	TFNA-OH (m.)		> 100	0.017	>5882	10
	TFNG-AM (m.)		> 100	0.010	>10000	10

In view of the results presented in Table E.12, a low acute risk for earthworms is expected at the worst-case proposed use.

Sublethal studies are not required because the TER values are > 10 and the DT90 is below 365 days.

The proposed applications of the product therefore meet the standards as laid down in the RGB.

7.5.3 Effects on soil micro-organisms

For glasshouse uses, management practice includes regular sterilisation of the soil, which prevents the formation of a natural soil organism community within glasshouses. Exposure to natural soils is not expected. Therefore no risk assessment is performed for soil microorganisms.

In the tested soils no effects are observed on nitrogen transformation and carbon respiration processes at relevant application rates of 0.105 kg a.s./ha with the formulation TEPPEKI. This tested rate is above the current highest application rate of 0.08 kg a.s./ha. Since the

reduction percentage is below 25% after 28 days, the standards from the RGB regarding soil micro-organisms are met.

7.5.4 Effects on activated sludge

Exposure to activated sludge is expected from indoor uses and from outdoor uses on hardened surfaces. Models to calculate the exposure concentration in the sewage treatment plant (STP) are currently available for hardened surfaces, for indoor cultivations of mushrooms and for the potato processing industry. For other indoor uses, models are not available. For the proposed application this means the following:

For the proposed field uses no exposure of activated sludge is expected. Therefore, the proposed applications comply with the standards for activated sludge as laid down in the RGB.

For the proposed indoor uses exposure of activated sludge is expected. However, to date there is no module available to calculate influent concentrations in the sewage treatment plant (STP) for these application types. Therefore, the proposed greenhouse applications cannot be examined against the standard for activated sludge as laid down in the RGB. For the time being this issue is not taken into consideration.

7.5.5 Effects on non-target plants

For protected uses, no exposure to non-target plants is expected and no risk assessment is performed.

For field uses, the risk assessment for non-target plants is based on an off-crop situation with a drift percentage depending on the crop. A MAF must be applied for multiple applications, see also 7.1 (birds). The exposure thus equals drift %/100 * the application rate * MAF (in case of multiple application). MAF-values are taken from ESCORT 2.

A TER is calculated with the lowest EC_{50} value from a laboratory test with higher plants and the exposure concentration. The lowest EC_{50} is > 100 g a.s./ha (11 plant species tested). See table E.13 for TER values for the different field uses of TEPPEKI.

Table E.13 Overview of exposure concentrations and TERs for non-target plants

Use	Dose [kg a.s. /ha]	MAF	Drift% (off-field exposure)	Exposure (kg a.s./ha)	EC_{50} [kg a.s./ha]	TER	Trigger value
Potatoes	0.08	1.2	4.7%	0.00451	> 0.100	> 22	5
Winter wheat, summer wheat, triticale, spelt	0.07	1.2	4.7%	0.00395	> 0.100	> 25	5
Apple; Pear	0.07	1.3	17%	0.01547	> 0.100	> 6.5	5
Fruit trees and shrubs of apple and pear (includes rootstocks) (before May 1st)	0.07	1.3	36.8%	0.0335	> 0.100	> **3.0**	5
Fruit trees and shrubs of apple and pear (includes rootstocks) (after May 1st)	0.07	1.3	14.7%	0.0134	> 0.100	> 7.4	5
Flower bulb and flower corm crops; Floriculture crops; Flower seed crops; Tree nursery crops[1], Perennials; Public green	0.07	1.3	4.7%	0.00428	> 0.100	> 23	5

[1] "Spillen" and "opzetters" have lower drift percentages (1.8 and 6.3%, respectively) and are therefore not mentioned separately.

The ratio between EC_{50} and the exposure concentration for most field uses is > 5 indicating an acceptable risk for non-target plants after multiple application of TEPPEKI. For fruit trees treated before May 1st, the ratio between EC_{50} and the exposure concentration is < 5. In view of the low DT50 of flonicamid in soil (1.8 d) and the relatively long interval between applications (21 days), no accumulation of the a.s. in plants is expected, and hence the MAF could also be set to 1. In such case the TER would be closer to the trigger value. Also, the risk for non-target plants is considered to be low because the tests showed no effects on eleven species of adjacent crops at a rate of 100 g a.s./ha, which is above the highest proposed application rate. The EC_{50} is thus expected to be higher than 100 g a.s./ha. The low risk statement is supported by results from other tests with seventeen species of succeeding crops, where no effects were found at 300 g a.s./ha. Therefore, the risk for non-target plants is considered to be low for all applications of TEPPEKI.

The product complies with the RGB.

Conclusions any other organisms
The product does comply with the RGB for the aspects earthworms, soil micro-organisms, activated sludge and non-target plants. The product therefore meets with the standards for non-target arthropods as laid down in the RGB, provided that a warning sentence is placed on the label for IPM uses.

Considering the acceptable risk of flonicamid for earthworms, soil macro-organisms, soil micro-organisms and non-target plants, flonicamid meets the standards for persistence.

7.6 Appropriate ecotoxicological end-points relating to the product and approved uses

See List of End-points.

7.7 Data requirements

None.

7.8 Restriction sentences

The following restriction sentences were proposed by the applicant:

Voor geïntegreerde teelten (waaronder begrepen alle kasteelten, boomteelt en fruitteelt): Dit middel is schadelijk voor niet-doelwit arthropoden. Vermijd onnodige blootstelling.

Based on the current assessment, the following has to be stated in the GAP/legal instructions for use:

In the WG (legal instructions):

"Dit middel is schadelijk voor niet-doelwit arthropoden in bedekte teelten. Vermijd onnodige blootstelling"

"*Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen mag u dit product op in bloei staande gewassen of op niet-bloeiende gewassen wanneer deze actief bezocht worden door bijen en hommels alleen toepassen na zonsondergang*.

Gebruik is wel toegestaan op bloeiende planten in de kas mits er geen bijen of hommels in kas actief naar voedsel zoeken."

7.9 Overall conclusions regarding ecotoxicology

It can be concluded that:

1. all proposed applications of the active substance flonicamid meet the standards for persistence as laid down in the RGB.
2. all proposed applications of the active substance flonicamid meet the standards for birds as laid down in the RGB.
3. all proposed applications of the active substance flonicamid meet the standards for aquatic organisms as laid down in the RGB.
4. the active substance flonicamid meets the standards for bioconcentration as laid down in the RGB.
5. all proposed applications of the active substance flonicamid meet the standards for mammals as laid down in the RGB.
6. the proposed applications of the active substance flonicamid meet the standards for bees as laid down in the RGB when applied only after bee foraging.
7. all proposed applications of the active substance flonicamid meet the standards for non-target arthropods as laid down in the RGB.
8. all proposed applications of the active substance flonicamid meet the standards for earthworms as laid down in the RGB.
9. all proposed applications of the active substance flonicamid meet the standards for soil micro-organisms as laid down in the RGB.
10. all proposed applications of the active substance flonicamid meet the standards for activated sludge as laid down in the RGB *or* cannot be examined against the standards as laid down in the RGB; for the time being this issue is not taken into consideration.
11. all proposed applications of the active substance flonicamid meet the standards for non-target plants as laid down in the RGB

8. Efficacy

This evaluation is partly based on the summary and evaluation of TEPPEKI prepared by the Plant Protection Service (NVWA) on behalf of Ctgb (report numberCs13TEPPEKI).

8.1 Efficacy evaluation

This application concerns a re-registration. Dose rates claimed for the re-registration are the same as de currently authorised dose rate for potato, winter wheat, summer wheat, triticale, apple, pear (including shrubs of apple and pear), floriculture crops (indoor/outdoor), flower seed crops (indoor/outdoor), tree nursery crops (indoor/outdoor), perennials (indoor/outdoor), basic seed production and plant breeding crops of vegetables and arable crops (indoor) and public green spaces.
The application in spelt is new in this re-registration.
At the moment TEPPEKI is authorized in bulb flower and corm flower, indoor. (Dutch: bedekte teelt van bol- en knolbloemen) and in flowerbulbs and flower corms, outdoor (onbedekte teelt van bloembollen en bloemknollen). For this re-registration the whole group of flower bulb and flower corn corps (bloembol- en bloemknolgewassen) indoor and outdoor is claimed.

Dose justification

The applicant submitted 3 trials in potato, 11 trials in wheat, eight trials in apple, and 14 trials in ornamentals. The data submitted have been evaluated for this re-registration.
The results of the trials with different dose rates in potato, winter wheat, apple and ornamentals confirm the proposed dose rate claimed for re-registration.

Effectiveness

A total of 104 trials were carried out to evaluate the efficacy of TEPPEKI for the control of aphids in potato, wheat, apple, pear and ornamentals. The results in the efficacy trials are presented for each specific crop-aphid combination.
Based on all submitted data, enough information was available to support the claim of aphid control in potato, winter wheat, apple, pear, and ornamentals (indoor).
Further the following extrapolations are possible:

According to the extrapolation document version 2.0 (the Netherlands), it is possible to extrapolate the effectiveness against English grain aphid (MACSAV) from winter wheat to summer wheat, triticale, spelt. Also extrapolation is possible for the effectiveness against English grain aphid to Rose-grain aphid (METODR). Therefore it can be concluded, that 0.14 kg/ha TEPPEKI is effective in controlling these aphids in winter wheat, summer wheat, triticale and spelt.

According to the extrapolation document version 2.0 (the Netherlands), it is possible to extrapolate for the effectiveness against aphids in potted chrysanthemum to the protected culture of floriculture crops, the protected plant breeding crops and basic seed production for arable, vegetable and fruit crops, herbs and ornamental crops. The effectiveness of TEPPEKI is also evaluated positive for several outdoor crops. For this reason extrapolation to unprotected floriculture crops is possible. Therefore it can be concluded, that 0.14 kg/ha TEPPEKI is effective in controlling aphids in protected and unprotected culture of floriculture crops, the protected plant breeding crops and basic seed production for arable, vegetable and fruit crops, herbs and ornamental crops.

According to the extrapolation document version 2.0 (the Netherlands), it is possible to extrapolate the effectiveness against rosy apple aphid (DYSAPL), green apple aphid (APHIPO), and pear aphid from apple and pear to fruit trees and fruit tree rootstocks. Therefore it can be concluded, that 0.14 kg/ha TEPPEKI is effective in controlling aphids in fruit trees and fruit tree rootstocks.

The effectiveness of the proposed use of TEPPEKI is evaluated positive for several outdoor crops such as apple, pear and for floricultural crops grown under protection. For this reason and the practical experience during the authorized period, extrapolation to tree nursery crops, perennials and public green spaces is possible.

No information (trials) is available for the evaluation of TEPPEKI against aphids in flower bulb and flower corn crops (indoor/outdoor), but based on expert judgement , on the results of the submitted trials for other crops and the fact that TEPPEKI is currently authorized in bulb flower and corm flower(indoor) and flower bulbs and flower corms(outdoor), it can be concluded that TEPPEKI at a dose rate of 0.14 kg/ha will be effective in controlling aphids in the whole group of flower bulbs and flower corn crops, indoor and outdoor.

Further, data submitted have been evaluated for the re-registraton of TEPPEKI. TEPPEKI is authorized in the Netherlands for many years in the Netherlands and other European countries. Efficacy have been evaluated for the first authorization. To date, the effectiveness of Tepekki have been good and consistent. Trials submitted, confirm this.

Conclusion
The product complies with the Uniform Principles because it does in accordance with article 2.1 control different aphids species in:
- potato,
- winter wheat, summer wheat, triticale and spelt
- apple, pear, and fruit trees and shrubs of apple and pear (including rootstocks)
- flower bulbs and flower corn crops (indoor/outdoor)
- floriculture crops (indoor/outdoor)

- flower seed crops (indoor/outdoor)
- tree nursery crops (indoor/outdoor)
- perennial (indoor/outdoor)
- basic seed production and plant breeding crops of vegetables and arable crops (indoor)
- public green spaces.

8.2 Harmful effects

8.2.1 Phytotoxicity

The available information was sufficient for the evaluation of the phytotoxicity of TEPPEKI.

Potato

There are 13 phytotoxicity trials in several potato varieties available to evaluate the effect of TEPPEKI. Two spray applications were made with an interval of 16 to 22 days. The trials were conducted with the single and double dose for TEPPEKI and the single and double dose of the reference product based on pirimicarb. One trial showed white spots on the leaf surface two days after the first application of both TEPPEKI and the reference product. This symptom was temporary. In none of the other 12 phytotoxicity trials, TEPPEKI or the reference product showed any phytotoxicity in potato.

Wheat

There are 13 phytotoxicity trials in several winter wheat varieties available to evaluate the effect of TEPPEKI. Two spray applications were made with an interval of 6 to 24 days. The trials were conducted with the single and double dose for TEPPEKI and the single and double dose of the reference products based on pirimicarb, or deltamethrin. In none of the trials, TEPPEKI or the references products showed any phytotoxicity in winter wheat.

Apple

There are eight phytotoxicity trials in several apple varieties available to evaluate the effect of TEPPEKI. Three spray applications were made with an interval of 21 or 22 days. The trials were conducted with the single and double dose for TEPPEKI and the single and double dose of the reference products based on pirimicarb, or imidacloprid. In none of the trials, TEPPEKI or the references products showed any phytotoxicity in apple.

Pear

There are eight phytotoxicity trials in several pear varieties available to evaluate the effect of TEPPEKI. Three spray applications were made with an interval of 21 or 22 days. The trials were conducted with the single and double dose for TEPPEKI and the single and double dose of the reference products based on pirimicarb, or imidacloprid. In none of the trials, TEPPEKI or the references products showed any phytotoxicity in pear.

Ornamentals

Cutflowers

There are 15 phytotoxicity trials, conducted in a dark season, available to evaluate the effect of TEPPEKI. The trials were carried out with various cultivars chrysanthemum (five trials), gerbera (five trials) and rose (five trials). Three spray applications were made with an interval of seven days. The trials were conducted with the 1.4N and 2.8N dose for TEPPEKI and the N and 2N dose for the reference product based on imidacloprid. Assessments were done on the occurrence of phytotoxic symptoms on the leaves around the second and third application and 2, 7, 14 and 21 days after the third application. Crop vigour and visible residue were also examined. In none of the trials, TEPPEKI or the reference product showed any phytotoxicity.

Potted plants

There are six phytotoxicity trials, conducted in a dark season, available to evaluate the effect of TEPPEKI. The trials were carried out with various cultivars Ficus benjamina (two trials), begonia (two trials) and Saintpaulia (two trials). Three spray applications were made with an interval of seven days. The trials were conducted with the 1.4N and 2.8N dose for TEPPEKI and the N and 2N dose for the reference product based on imidacloprid. Assessments were done on the occurrence of phytotoxic symptoms on the leaves around the second and third application and 7-8, 13-14 and 20-21 days after the third application. Crop vigour and visible residue were also examined. In none of the trials TEPPEKI or the reference product showed any phytotoxicity. In the effectiveness trials in potted chrysanthemum no phytotoxicity was seen either.

Extrapolation possibilities

According to the extrapolation document version 2.0 (the Netherlands), it is possible to extrapolate for phytotoxicity from:

consumption potatoes to starch potatoes. Therefore it can be concluded, that 0.16 kg/ha TEPPEKI is safe in potato.

winter wheat to summer wheat, triticale, spelt. Therefore it can be concluded, that 0.14 kg/ha TEPPEKI is safe in winter wheat, summer wheat, triticale and spelt.

apple and pear to fruit trees and fruit tree rootstocks. Therefore it can be concluded, that 0.14 kg/ha TEPPEKI is safe in fruit trees and fruit tree rootstocks.

at least three species of cut flowers and three species of potted plants to other floriculture crops, nursery crops and perennials and public green (protected and unprotected conditions), breeding and seed growing of arable and vegetable crops (protected conditions) and seed growing of flowers.

No phytotoxicity information (trials) is available for the evaluation of TEPPEKI in flower bulb and flower corn crops (indoor/outdoor), but based on expert judgement , on the results of the submitted trials for other crops and the fact that TEPPEKI is currently authorized in bulb flower and corm flower(indoor) and flower bulbs and flower corms(outdoor), it can be concluded that TEPPEKI is safe in flower bulb and flower corn crops (indoor/outdoor)

Conclusion phytotoxicity

The available information is sufficient for the evaluation of the phytotoxicity of TEPPEKI in potato, winter wheat, summer wheat, triticale, spelt, apple, pear, fruit trees and shrubs of apple and pear (includes rootstocks), flower bulb and flower corm crops, floriculture crops, flower seed crops, tree nursery crops and perennials, basic seed production and plant breeding crops of vegetable and arable crops.
It can be concluded that the proposed uses of TEPPEKI in potato, winter wheat, summer wheat, triticale, spelt, apple, pear, fruit trees and shrubs of apple and pear (includes rootstocks), flower bulb and flower corm crops, floriculture crops, flower seed crops, tree nursery crops and perennials, basic seed production and plant breeding crops of vegetable and arable crops is safe.

8.2.2 Yield

TEPPEKI have been authorized in a wide range of crops during some years. Negative effects on yield have never been reported. The proposed dose rates have prove to be safe.

8.2.3 Effects on succeeding crops or substitution crops

Seedling trials with sixteen different crops are available to evaluate the effect of a pre-emergence application with 300 g/ha flonicamid. None of the crops showed any phytotoxicity. Further, no phytotoxic effects have been reported in any of the of the conducted studies, as a consequence it is assumed that TEPPEKI does no gave adverse effects on succeeding crops/replacement crops. In addition, TEPPEKI has been authorised during the past years. The proposed dose rates have proven to be safe for succeeding crops/replacement crops.

8.2.4 Effects on plants or plant products to be used for propagation

Potato

There are 11 phytotoxicity trials in several potato varieties available to evaluate the effect of TEPPEKI on sprouting. Two spray applications were made with an interval of 16 to 22 days. The trials were conducted with the single and double dose for TEPPEKI and the single and double dose of the reference product based on pirimicarb. After harvest the tubers were stored for 28 days at 3-5˚C followed with 28 days at 10-12˚C. In none of the trials, TEPPEKI or the reference product showed a negative effect on sprouting of potato.

No additional information is available for the re-registration for crops for seed production. On the current label of TEPPEKI the following warning sentence is mentioned for crops for seed production: “voor zaadteelten geldt dat aangeraden wordt om op kleine schaal te toetsen of het middel van invloed is op de kiemkracht van het gewas of ras”. This sentence should be put on the label (WG) again.

8.2.5 Effects on adjacent crops

There are trials available with ten different crops which were treated with 0.2 kg/ha and 0.4 kg/ha TEPPEKI. The applied dose is higher compared to the proposed use of resp. 0.14 kg/ha or 0.16 kg/ha. None of the crops showed a negative effect of TEPPEKI.

Conclusion

The product complies with the Uniform Principles because it does not, in accordance with article 2.2., induce any unacceptable side effects on plants or plant products, when used and applied in accordance with the proposed label.

8.3 Resistance

Flonicamid is an insecticide which belongs to group 9 of the IRAC MoA Classification Version: 7.2. Flonicamid acts as a selective homopteran feeding blocker.

The following resistance management strategy is presented by the applicant on the WGGA:

- ‘ Om resistentieopbouw te voorkomen mag u dit product of andere producten die flonicamid bevatten, niet vaker gebruiken dan twee keer per teelt voor aardappel en granen en drie keer per seizoen in alle overige teelten. ‘
- ‘ To prevent the development of resistance the number of applications per season with this product or other products based on flonicamid is limited to a maximum of 2 for potato and cereals, and 3 for all other crops. ‘

During the re-registration the WGGA is converted to a WG (within the project WGGA to WG). Because in the Netherlands a standardized resistance management sentence is available, above mentioned sentences should be replaced by the following sentence:
“Dit middel bevat de werkzame stof flonicamid. Flonicamid behoort tot de pyridinecarboxamiden. De Irac code is 9. Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen.
Further in the table on the WG the number of applications is mentioned.

This proposal for resistance management includes recommendations proposed by the Insecticide Resistance Action Comity (IRAC).

Conclusion
The product complies with the Uniform Principles, article 2.1.3 as the level of control on the long term is not influenced by the use of this product because of the possible build up of resistance.

8.4 For vertebrate control agents: impact on target vertebrates
Because no vertebrates are controlled, this point is not relevant.

8.5 Any other relevant data / information / Data requirements
None.

Restriction/warning sentences
The following restriction/warning sentences have to be placed on the legal instructions (WG) additionally or alternatively to the sentences provided by the applicant, according to the efficacy evaluation:

“Voor zaadteelten geldt dat aangeraden wordt om op kleine schaal te toetsen of het middel van invloed is op de kiemkracht van het gewas of ras

“Dit middel bevat de werkzame stof flonicamid. Flonicamid behoort tot de pyridinecarboxamiden. De Irac code is 9. Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen.

9. Conclusion

The product complies with the Uniform Principles.

The evaluation is in accordance with the Uniform Principles laid down in appendix VI of Directive 91/414/EEC. The evaluation has been carried out on basis of a dossier that meets the criteria of appendix III of the Directive.

10. Classification and labelling

Proposal for the classification and labelling of the formulation

Based on the profile of the substance, the provided toxicology of the preparation, the characteristics of the co-formulants, the method of application and the risk assessments, the following labelling of the preparation is proposed:

The identity of all substances in the mixture that contribute to the classification of the mixture *:		
-		
Pictogram:	GHS07	Signal word: Warning
H-statements:	H319	Causes serious eye irritation.
P-statements:	-	-
Supplemental Hazard information:	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.
	SP1	Do not contaminate water with the product or its container.

Child-resistant fastening obligatory?	not applicable
Tactile warning of danger obligatory?	not applicable

Explanation:	
Pictogram:	GHS07 should be assigned as the results of the eye irritation study with the formulation triggers classification with H319 according to the CLP criteria.
H-statements:	H319 should be assigned as the results of the eye irritation study with the formulation triggers classification with H319 according to the CLP criteria.
P-statements:	-
Other:	-

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

Based on the current assessment, the following has to be stated in the GAP/legal instructions for use:

In the WG (legal instructions):

“Voor zaadteelten geldt dat aangeraden wordt om op kleine schaal te toetsen of het middel van invloed is op de kiemkracht van het gewas of ras

“Dit middel bevat de werkzame stof flonicamid. Flonicamid behoort tot de pyridinecarboxamiden. De Irac code is 9. Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen.

“Dit middel is schadelijk voor niet-doelwit arthropoden in bedekte teelten. Vermijd onnodige blootstelling”

“*Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen mag u dit product op in bloei staande gewassen of op niet-bloeiende gewassen wanneer deze actief bezocht worden door bijen en hommels alleen toepassen na zonsondergang*.

Gebruik is wel toegestaan op bloeiende planten in de kas mits er geen bijen of hommels in kas actief naar voedsel zoeken.”

Appendix 1 Table of authorised uses

Date advice:		28.02.2011		20110258															
Product:		Teppeki																	
Active ingredient:		flonicamid																	
Crop and/or situation	**Member State or Country**	**Product name**	**F G or I**	**Pests or Group of pest controlled ©**	**Formulation**		**Application**					**Application rate per treatment**						**PHI days (days)**	**Remarks:**
(a)	(NL)	(a)	(b)		Type (d-f)	Conc. Of as g/kg (i)	method kind (f-h)	growth stage & season (j)	number (k)		interval between applications (days)	kg as/hL		water L/ha		kg as/ha		(l)	(m)
									min	max		min	max	min	max	min	max		
Existing uses																			
potatoes	NL	Teppeki	F	aphids	WG	500	spraying	BBCH 11-89 May till September	1	2	21	0.020	0.040	200	400	0.08	0.08	14	
winter wheat, summer wheat, triticale, spelt	NL	Teppeki	F	aphids	WG	500	spraying	BBCH 49-89 May till July	1	2	21	0.018	0.035	200	400	0.07	0.07	28	
apple	NL	Teppeki	F	aphids	WG	500	spraying	BBCH 69-89 March till August	1	3	21	0.005	0.014	500	1500	0.07	0.07	21	
pear	NL	Teppeki	F	aphids	WG	500	spraying	BBCH 69-89 March till August	1	3	21	0.006	0.014	500	1200	0.07	0.07	21	
fruit trees and shrubs of apple and pear (includes rootstocks)	NL	Teppeki	F	aphids	WG	500	spraying	BBCH 69-89 March till August	1	3	21	0.007	0.014	500	1000	0.07	0.07	-	
Flower bulb and flower corm crops	NL	Teppeki	G	aphids	WG	500	spraying	At aphid infestation. Jan-Dec	1	3	21	0.007	0.014	500	1000	0.07	0.07	-	AVI: Vanaf BBCH 11 (i.o.m. werkzaamheid)
Flower bulb and flower corm crops	NL	Teppeki	F	aphids	WG	500	spraying	At aphid infestation. February till October	1	3	21	0.018	0.047	150	400	0.07	0.07	-	AVI: Vanaf BBCH 11 (i.o.m. werkzaamheid)

floriculture crops	NL	Teppeki	F	aphids	WG	500	spraying	At aphid arrival. February till October	1	3	21	0.007	0.014	500	1000	0.07	0.07	-	AVI: Vanaf BBCH 11 (i.o.m. werkzaamheid)
floriculture crops	NL	Teppeki	G	aphids	WG	500	spraying	At aphid arrival. February till October	1	3	21	0.007	0.014	500	1000	0.07	0.07		AVI: Vanaf BBCH 11 (i.o.m. werkzaamheid)
Flower seed crops	NL	Teppeki	F	aphids	WG	500	spraying	At aphid arrival. February till October	1	3	21	0.007	0.014	500	1000	0.07	0.07	-	AVI: Vanaf BBCH 11 (i.o.m. werkzaamheid)
Flower seed crops	NL	Teppeki	G	aphids	WG	500	spraying	At aphid arrival. Jan-Dec	1	3	21	0.007	0.014	500	1000	0.07	0.07	-	AVI: Vanaf BBCH 11 (i.o.m. werkzaamheid)
tree nursery crops	NL	Teppeki	F	aphids	WG	500	spraying	At aphid infestation. February till October	1	3	21	0.007	0.014	500	1000	0.07	0.07	-	AVI: Vanaf BBCH 11 (i.o.m. werkzaamheid)
tree nursery crops	NL	Teppeki	G	aphids	WG	500	spraying	At aphid infestation. Jan-Dec	1	3	21	0.007	0.014	500	1000	0.07	0.07		AVI: Vanaf BBCH 11 (i.o.m. werkzaamheid)
perennials	NL	Teppeki	F	aphids	WG	500	spraying	At aphid infestation. February till October	1	3	21	0.007	0.014	500	1000	0.07	0.07		AVI: Vanaf BBCH 11 (i.o.m. werkzaamheid)
perennials	NL	Teppeki	G	aphids	WG	500	spraying	At aphid infestation. Jan-Dec	1	3	21	0.007	0.014	500	1000	0.07	0.07		AVI: Vanaf BBCH 11 (i.o.m. werkzaamheid)
Basic seed production and Plant breeding crops of vegetables and arable crops	NL	Teppeki	G	aphids	WG	500	spraying	At aphid infestation. Jan-Dec	1	3	21	0.007	0.014	200	1000	0.07	0.07	-	AVI: Vanaf BBCH 11 (i.o.m. werkzaamheid)
Public green spaces	NL	Teppeki	F	aphids	WG	500	spraying	At aphid infestation. February till October	1	3	21	0.007	0.007	1000	1000	0.07	0.07	-	AVI: Vanaf BBCH 11 (i.o.m. werkzaamheid)

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Appendix 2 Reference list

This appendix serves only to give an indication of which data have been used for decision making for the first time; as a result of concurring applications for authorisations, the data mentioned here may have been used for an earlier decisions as well. Therefore, no rights can be derived from this overview.
Deze appendix geeft een indicatief overzicht van de gegevens die voor het eerst gebruikt zijn ten behoeve van een besluit; het kan echter voorkomen dat (onder andere) door een samenloop van aanvragen, de hier opgenomen gegevens al eens eerder gebruikt zijn. Aan dit overzicht kunnen dan ook geen rechten ontleend worden.

Part A - List of Annex II data submitted in support of the evaluation

Annex point	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or Unpublished**	**Data protection claimed Y/N**	**Owner**	**Application number***	**Date of submission***
IIA, 6.0/01	2003	Freezer storage stability of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM on various crops Battelle, Report no. A-22-00-03, September 15, 2003 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.0/02 = IIA, 6.5/03	2003	Freezer storage stability of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM on bread Battelle, Report no. A-22-01-17, July 10, 2003 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.1/01	2002	Metabolism of [^{14}C] IKI-220 by wheat Ricerca LLC, report no. 010416-1, March 5, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.1/02	2002	Metabolism of [^{14}C] IKI-220 by potato Ricerca LLC, report no. 010424-1, March 5, 2002	Y	ISK	20110285	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
		GLP, unpublished				
IIA, 6.2/01	2002	Metabolism of [^{14}C] IKI-220 in lactating goats report no. 011048-1, April 17, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.2/02	2002	Metabolism of [14C] IKI-220 in laying hens Report no. 011750-1, May 17, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/01 220/SOLTU 05/F/00	2002	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in potatoes after two treatments of IKI-220 50% WG (IBE 3880 and IBE 3894) (Italy, Spain, Germany, France and United Kingdom-Season 2000) Battelle, report no. A-22-01-09, August 13, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
	2001	Study to generate crop specimens for analysis of IKI-220 residues in the raw agricultural commodity potato resulting from a sequential application of IBE 3894 or IBE 3880 in Southern France, Northern France and the UK, during 2000 Agrisearch, AF/5173/IB, March 1st 2001 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/02 220/SOLTU 07/GB/00	2002	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in potatoes after two treatments of IKI-220 50% WG (IBE 3880 and IBE 3894) (Italy, Spain, Germany, France and United Kingdom-Season 2000) Battelle, report no. A-22-01-09, August 13, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
	2001	Study to generate crop specimens for analysis of IKI-220 residues in the raw agricultural commodity potato resulting from a sequential application of IBE 3894 or IBE 3880 in Southern France, Northern France and the UK, during 2000 Agrisearch, report no. AF/5173/IB, March 1st 2001 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/03 220/SOLTU 04/D/00	2002	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in potatoes after two treatments of IKI-220 50% WG (IBE 3880 and IBE 3894) (Italy, Spain, Germany, France and United Kingdom-Season 2000) Battelle, report no. A-22-01-09, August 13, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
	2001	Residue Decline curve of IKI 220 in potatoes following two treatments with IBE 3880 and IBE 3894 in Germany during 2000 Versuchswesen Pflanzenschutz, Report no. VP00-1-10, January 25, 2001 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/04 220/SOLTU 11/FR/01	2002	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in early potatoes after two treatments of IKI-220 50% WG (IBE 3894) (Greece, North and South of France and United Kingdom - season 2001) Battelle, report no. A-22-01-15 GLP, unpublished	Y	ISK	20110285	05.04.2004
	2002	Study to generate crop specimens for	Y	ISK	20110285	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
		analysis of IKI-220 residues in potato resulting from 2 sequential applications of IBE 3894 in S France, N France and the UK, during 2001 Agrisearch, report no. AF/5733/IB/1, April, 29, 2002 GLP, unpublished				
IIA, 6.3/05 220/SOLTU 15/GB/01	2003	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in early potatoes after two treatments of IKI-220 50% WG (IBE 3894) (Greece, North and South of France and United Kingdom - season 2001) Battelle, report no. A-22-01-15, March 25, 2003 GLP, unpublished	Y	ISK	20110285	05.04.2004
	2002	Study to generate crop specimens for analysis of IKI-220 residues in potato resulting from 2 sequential applications of IBE 3894 in S France, N France and the UK Agrisearch, report no. AF/5733/IB/5, April, 29, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/06 220/SOLTU 17/D/01	2003	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in ware potatoes after two treatments of IKI-220 50% WG (IBE 3894) (Italy, Spain, Germany and South of France - season 2001) Battelle, report no. A-22-01-14, March 25, 2003 GLP, unpublished	Y	ISK	20110285	05.04.2004
	2001	Residue decline curve of IKI-220 in	Y	ISK	20110285	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
		potatoes following two treatments with IBE 3894 in Germany 2001 Versuchswesen Pflanzenschutz, report no. VP01-1-21, January 25, 2001 GLP, unpublished				
IIA, 6.3/07 220/SOLTU 16/D/01	2003	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in ware potatoes after two treatments of IKI-220 50% WG (IBE 3894) (Italy, Spain, Germany and South of France - season 2001) Battelle, report no. A-22-01-14, March 25, 2003 GLP, unpublished	Y	ISK	20110285	05.04.2004
	2002	Residue at harvest of IKI-220 in potatoes following two treatments with IBE 3894 in Germany 2001 Versuchswesen Pflanzenschutz, report no. VP01-1-22, January 31, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/08 220/SOLTU 01/F/99	2003	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in potatoes after two treatments of IKI-220 50% WG (IBE 3880) (France - season - 1999) Battelle, report no. A-22-01-04, March 25, 2003 GLP, unpublished	Y	ISK	20110285	05.04.2004
	2000	Study to generate specimens of potatoes for residue analysis following two overall applications of IBE 3880 in Northern France, during 1999 Agrisearch, report no. AF/4759/IB, May 8, 2000	Y	ISK	20110285	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
		GLP, unpublished				
	2000	Generation of specimens of potato tubers Raw Agricultural Commodity (RAC) following a program of foliar sprays of two IKI-220 formulations (coded IBE 3880 and IBE 3894 Recerca Agrícola, report no. IK-0052-I/G, July 21, 2000 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/18 220/TRAZW 03/F/00	2002	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in winter wheat after two treatments of IKI-220 50% WG (IBE 3880 or IBE 3894) (North and South of France and Germany - season 2000) Battelle, report no. A-22-01-10, September 3, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
	2000	To generate crop specimens for analysis of IKI-220 residues in the RAC winter wheat and processed fractions resulting from a sequential application of IBE 3894 or IBE 3880 in S. France and N. France during 2000 Agrisearch, report no. AF/5174/IB, November 24, 2000 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/19 220/TRAZW 04/F/00	2002	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in winter wheat after two treatments of IKI-220 50% WG (IBE 3880 or IBE 3894) (North and South of France and Germany - season 2000) Battelle, report no. A-22-01-10,	Y	ISK	20110285	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
		September 3, 2002 GLP, unpublished				
	2000	To generate crop specimens for analysis of IKI-220 residues in the RAC winter wheat and processed fractions resulting from a sequential application of IBE 3894 or IBE 3880 in S. France and N. France during 2000 Agrisearch, report no. AF/5174/IB, November 24, 2000 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/20 /D/00	2002	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in winter wheat after two treatments of IKI-220 50% WG (IBE 3880 or IBE 3894) (North and South of France and Germany - season 2000) Battelle, report no. A-22-01-10, September 3, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
	2001	Residues of IKI-220 in winter wheat following two treatments with IBE 3880 and IBE 3894 in Germany 2000 Versuchswesen Pflanzenschutz, report no. VP00-1-9, January 25, 2001 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/21 220/TRAZW 12/F/01	2002	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in winter wheat after two treatments of IKI-220 50% WG (IBE 3894) (Italy, spain, North and South of France, Germany and United Kingdom - season 2001) Battelle, report no. A-22-01-16, August 26, 2002	Y	ISK	20110285	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
		GLP, unpublished				
	2002	To generate crop specimens for analysis of IKI-220 residues in the RAC winter wheat resulting from a sequential application of IBE 3894 in S France, N France and UK during 2001 Agrisearch, report no. AF/5731/IB, August 6, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/22 220/TRAZW 13/F/01	2002	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in winter wheat after two treatments of IKI-220 50% WG (IBE 3894) (Italy, spain, North and South of France, Germany and United Kingdom - season 2001) Battelle, report no. A-22-01-16, August 26, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
	2002	To generate crop specimens for analysis of IKI-220 residues in the RAC winter wheat resulting from a sequential application of IBE 3894 in S France, N France and UK during 2001 Agrisearch, report no. AF/5731/IB, August 6, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/23 220/TRAZW 16/GB/01	2002	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in winter wheat after two treatments of IKI-220 50% WG (IBE 3894) (Italy, spain, North and South of France, Germany and United Kingdom - season 2001) Battelle, report no. A-22-01-16, August 26, 2002	Y	ISK	20110285	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
		GLP, unpublished				
	2002	To generate crop specimens for analysis of IKI-220 residues in the RAC winter wheat resulting from a sequential application of IBE 3894 in S France, N France and UK during 2001 Agrisearch, report no. AF/5731/IB, August 6, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/24 220/TRAZW 17/D/01	2002	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in winter wheat after two treatments of IKI-220 50% WG (IBE 3894) (Italy, spain, North and South of France, Germany and United Kingdom - season 2001) Battelle, report no. A-22-01-16, August 26, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
	2001	Residue decline curve of IKI-220 in winter wheat following two treatments with IBE 3894 in Germany 2001 Versuchswesen Pflanzenschutz, report no. VP01-1-20, January 30, 2001 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/25 220/TRAZW 01/D/99	2002	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in winter wheat after two treatments of IKI-220 50% WG (IBE 3880) (Germany - season 1999) Battelle, report no. A-22-01-05, June 5, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
	2000	Residues of IKI-220 in winter wheat following two treatments with IBE 3880 in	Y	ISK	20110285	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
		Germany 1999 Versuchswesen Pflanzenschutz, report no. VP99-1-17, april 1st, 2000 GLP, unpublished				
IIA, 6.3/35 220/MABSD 06/D/00	2002	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in apples after three treatments of IKI-220 50% WG (IBE 3880 and IBE 3894) (Spain, Italy, France and Germany - season 2000) Battelle, report no. A-22-01-06, June 4, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
	2001	Residues decline curve ok IKI-220 in apples following three treatments with IBE 3880 and IBE 3894 in Germany 2000 Versuchswesen Pflanzenschutz, report no. VP00-1-19, March 25, 2001 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/36 220/MABSD 07/F/00	2002	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in apples after three treatments of IKI-220 50% WG (IBE 3880 and IBE 3894) (Spain, Italy, France and Germany - season 2000) Battelle, report no. A-22-01-06, June 4, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
	2000	Determination of the residue level of the active ingredient of the formulations IBE 3880 and IBE 3894 insecticide on apple trees Prestagro, report no. ISK-00-041-IF, October 18, 2000	Y	ISK	20110285	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
		GLP, unpublished				
IIA, 6.3/37 220/MABSD 09/F/00	2002	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in apples after three treatments of IKI-220 50% WG (IBE 3880 and IBE 3894) (Spain, Italy, France and Germany - season 2000) Battelle, report no. A-22-01-06, June 4, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
	2000	Determination of the residue level of the active ingredient of the formulations IBE 3880 and IBE 3894 insecticide on apple trees Prestagro, report no. ISK-00-042-IF, October 18, 2000 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/38 220/MASBD 10/F/01	2003	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in apples after three treatments of IKI-220 50% WG (IBE 3894) (Germany and North of France - Season 2001) Battelle, report no. A-22-01-12, February 13, 2003 GLP, unpublished	Y	ISK	20110285	05.04.2004
	2001	Determination of the evolution of the residue levels of the active ingredient of the formulations IBE 3894 insecticide on apple trees Prestagro, report no. ISK-01-016IF, February 19, 2001 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/41 220/MASBD	2003	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-	Y	ISK	20110285	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
12/D/01		AM in apples after three treatments of IKI-220 50% WG (IBE 3894) (Germany and North of France - Season 2001) Battelle, report no. A-22-01-12, February 13, 2003 GLP, unpublished				
	2002	Two residue decline curves of IKI-220 in Apples following three treatments with IBE 3894 in Germany 2001 Versuchswesen Pflanzenschutz, report no. VP01-1-8D2, January, 31, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.3/42 220/MABSD 01/F/99	2002	Determination of residues of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM in apples after three treatments of IKI-220 50%WG (IBE 3880) (Italy -France - Season 1999) Battelle, report no. A-22-01-03, January 22, 2002 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.4/01	2003	IKI-220 ruminant feeding study: residues of IKI-220 in milk and edible tissues of cattle RCC Ltd, report no. 826154, 14 January 2003 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.4/02	2003	Poultry feeding study: Residue of IKI-220 in eggs and edible tissues of laying hens. RCC Ltd., report no. 835064, January 14, 2003 GLP, unpublished	Y	ISK	20110285	05.04.2004
IIA, 6.5/01	2003b	Wheat processing study for IKI-220 residues after treatment with IBE 3894. Battelle, report no. P-22-00-01, July 14,	Y	ISK	20110285	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
		2003 GLP, unpublished				
IIA, 6.5/02	2003c	Processing study for determination of IKI-220 and its metabolites TFNG, TFNA and TFNA-AM on peaches after two treatments of IKI-220 50% WG (IBE 3894) - Southern Europe - Season-2001). Battelle, report no. P-22-01-02, November 10, 2003 GLP, unpublished	Y	ISK	20110285	05.04.2004

* in case of an earlier submission (for an earlier application)

Part B - List of Annex III data submitted in support of the evaluation

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
OECD IIIA, 6.1.1/01	2003	GABA Gated C1 Channel - Flonicamid Mode of action. FMC Corporation, Report no. F-1, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/02	2003	Voltage-gated Sodium Channel – Flonicamid Mode of Action Studies. FMC Corporation, Report no. F-2, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/03	2003	Energy Metabolism – Flonicamid Mode of Action Studies.	Y	ISK	20110285 THG	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
		FMC Corporation, Report no. F-3, Non GEP / Unpublished				
OECD IIIA, 6.1.1/04	2002	IKI-220's spectrum of activity. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/05	2002	Insecticidal activity of IKI-220 against nine species of aphid. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-02, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/06	2002	Residual activity of IKI-220 under summer spray conditions. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-04, non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/07	2002	Systemic and translaminar activity of IKI-220. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-05, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/08	2002	Effects of IKI-220 against feeding behavior of green peach aphid, Myzus persicae. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-09, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/09	2002	Effects of IKI-220 on acetylcholinseterase of housefly. Ishihara Sangyo Kaisha Ltd. , Report no. AL0201-I-12, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/10	2002	Effect of IKI-220 on alpha-BGTX specific binding to nAChRs on honeybee head membranes. Ishihara Sangyo Kaisha Ltd., Report no.	Y	ISK	20110285 THG	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
		AL0201-I-13, Non GEP / Unpublished				
OECD IIIA, 6.1.1/11	2002	Insecticidal activity of IKI-220 against green peach aphid (Myzus persicae) selected with pymetrozine. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-15, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/12	2002	Rainfastness of IKI-220 in pot tests. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-07, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/01	1998	Field biological evaluation –IBE 3880 Aphids on apple trees Prestagro, Report no. 98-002-I-F-51, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/02	1998	Efficacy agains aphids on apple tree Stage, Report no. 98-002-I-F-52, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/03	1998	Evaluate efficacy of insecticides against Aphids on Apple trees Staphyt, Report no. 98-002-I-F-53, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/04	1998	Evaluate efficacy of insecticides against Aphids on Apple trees Staphyt, Report no. 98-002-I-F-54, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/05	1999	Insecticide efficacy against aphids on apple tree Stage, Report no. 99-005-I-F-03, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/06	1999	Field study – IBE 3880 Aphids on apple trees Prestagro, Report no. 99-005-I-F-51,	Y	ISK	20110285 THG	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
		GEP / Unpublished				
OECD IIIA, 6.1.2/07	1999	Evaluate efficacy of insecticides against aphids on apple trees Staphyt, Report no. 99-005-I-F-52, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/08	1999	Evaluate efficacy of insecticides against aphids on apple trees Staphyt, Report no. 99-006-I-F-51, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/09	1999	Determination of effective rate, knockdown effect and persistence of treatment with IBE 3880 for Dysaphis plantaginea (or Aphis pomi) control on apple Agricola 2000 , Report no. 99-003-I-I-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/25	2000	Efficacy evaluation of insecticide products against aphids (Dysaphis plantaginea) in apple trees orchard Staphyt, Report no. 00-014-I-F-52, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/04	2001	Efficacy of IBE 3894 for aphid control on apple trees – Control of aphids (Dysaphis plantaginea) in apple De Bredelaar , Report no. 01-001-I-NL-04 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/05	2003	Insecticides and acaricides RSF – Research Station of Gorsem, Report no. 01-001-I-B-02 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/07	2002	Efficacy of IBE 3894 for aphid control on apple trees – Control of aphids (Dysaphis plantaginea) in apple De Bredelaar , Report no. GAT02-EF01-NL01	Y	ISK	20110285 THG	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
		GEP / Unpublished				
OECD IIIA, 6.1.3/08	2002	Efficacy of IBE 3894 for aphid control on apple trees – Control of aphids (Dysaphis plantaginea) in apple De Bredelaar , Report no. GAT02-EF01-NL02 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/14	2002	Field test to evaluate the efficacy of IBE 3894 against aphids on apple trees Technisches Büro für Landwirtschaft Adolf Hiebler , Report no. GAT02-EF01-AU03 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/15	2002	Field test to evaluate the efficacy of IBE 3894 against aphids on apple trees, Technisches Büro für Landwirtschaft Adolf Hiebler , Report no. GAT02-EF01-AU04 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/16	2002	Blattläuse in Obstbau PSD Bonn, Report no. GAT02-EF01-DE02 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/17	2002	Blattläuse/Apfel LPP Mainz, Report no. GAT02-EF01-DE03 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/18	2004	Efficacy of IBE 3894 for aphid control on apple trees – Open field efficacy study 2002 Field Research Support , Report no. GAT02-EF01-DE06 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/19	2002	Efficacy of IBE 3894 for aphid control on apple trees Agrostat , Report no. GAT02-EF01-DE08 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/20	2004	Efficacy of IBE 3894 for aphid control on apple trees	Y	ISK	20110285 THG	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
		BioChem Agrar , Report no. GAT02-EF01-DE09 GEP / Unpublished				
OECD IIIA, 6.1.3/21	2004	Efficacy of IBE 3894 for aphid control on apple trees Versuchswesen Pflanzenschutz Dr. Paul Reh , Report no. GAT02-EF01-DE12 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/22	2004	An evaluation of the efficacy of IBE 3894 for aphid control in apple in Germany 2003 Versuchswesen Pflanzenschutz Dr. Paul Reh , Report no. GAT03-EF01-DE01 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/23	2004	Efficacy of IBE 3894 for aphid control on apple trees – Open field efficacy study 2002 Field Research Support, Report no. GAT03-EF01-DE02 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/24	2003	Efficacy of IBE 3894 for aphid control on apple trees Martin Feldversuchswesen , Report no. GAT03-EF01-DE03 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/25	2002	Control of possible phytotoxicity effects on pear, RSF-Research Station of Gorsem npo, Report no. GPT02-EF01-BE01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/26	2004	Efficacy of IBE 3894 for aphid control on apple trees – Open field efficacy study 2003 Field Research Support, Report no GPT03-EF01-DE04, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA,	2004	Efficacy of IBE 3894 for aphids control on	Y	ISK	20110285 THG	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
6.1.3/27		pear trees, Agrartest, Report no. GPT04-EF11-DE01, GEP / Unpublished				
OECD IIIA, 6.1.3/28	2003	Determine levels of efficacy of IBE 3894 at different rates and compare to standard for control of Aphids on Pear trees, AgroSoler, Report no. 01-019-I-E-03, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/29	2002	Efficacy of IBE 3894 for aphids control on pear trees, Agricola 2000, Report no. 01-019-I-I-02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/30	2000	Efficacy of IBE 3894 for aphids control on pear trees, Staphyt, Report no. 00-019-I-F-51 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/31	2001	Efficacy evaluation of aphids products against Dysaphis pyri in pear trees orchard under natural condition, Staphyt, Report no. 01-019-I-F-51 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/32	2002	Determine levels of efficacy of IBE 3894 at different rates and compare to standard for control of Dysaphis pyri on Pear trees, Staphyt, Report no. GPT02-EF01-FR51, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/33	2002	Efficacy of IBE 3894 for aphids control on pear trees, Prestagro, Report no. GPT02-EF01-FR52, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/34	2002	IBE 3894 To determine the efficacy of IBE 3894 for control of aphids on apple trees: Spray Volume incidence, Inveresk Research, Report no. 00-027-I-E-	Y	ISK	20110285 THG	05.04.2004

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		02, GEP / Unpublished				
OECD IIIA, 6.1.3/35	2003	Determine levels of efficacy of IBE 3894 at different rates and compare to standard for control of Aphids on Apple trees AgroSoler, Report no. 01-011-I-E-03, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/36	2001	Efficacy of IBE 3894 for aphids control on apple trees, Agri2000, Report no. 01-011-I-I-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/37	2001	Efficacy of IBE 3894 for aphids control on apple trees, Agri2000, Report no. 01-011-I-I-02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/38	2001	Efficacy of IBE 3894 for aphids control on apple trees, Agricola 2000, Report no. 01-011-I-I-03, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/39	2000	IBE-3894 Efficacy for aphid control on apple trees, S.P.F. GAB Italia, Report no. 00-011-I-I-04, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/42	2000	Field study – IBE 3880 Aphids on apple trees Prestagro, Report no. 00-012-I-F-52, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/43	2000	Efficacy of IBE 3894 for aphids control on apple trees, Stage, Report no. 00-014-I-F-51, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/45	2000	Efficacy of IBE 3894 for aphids control on apple trees: Spay Volume incidence, Prestagro, Report no. 00-015-I-F-52,	Y	ISK	20110285 THG	05.04.2004

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		GEP / Unpublished				
OECD IIIA, 6.1.3/46	2000	Determine levels of efficacy of IBE 3894 at different rates and compare to standard for control of Dysaphis plantaginea on apple trees, Solevi, Report no. 00-015-I-F-51, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/47	2001	Efficacy of IBE 3894 for aphids control on apple trees: Spay Volume incidence, Prestagro, Report no. 01-011-I-F-51, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/48	2001	Determine levels of efficacy of IBE 3894 at different rates and compare to standard for control of Dysaphis plantaginea on apple trees, Solevi, Report no. 01-011-I-F-52, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/49	2001	Efficacy evaluation of aphids products against Dysaphis plantaginea in apple trees orchard under natural infestation, Staphyt, Report no. 01-011-I-F-53 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/01	2000	Measure incidence on apple trees of repeated applications of IBE 3894, Solevi, Report no. 00-016-I-F-52, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/02	2000	Crop safety of IBE 3894 on apple trees, Agricola2000, Report no. 00-028-I-I-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/03	2000	IBE 3894 Crop safety on apple trees, S.P.F. GAB Italia, Report no. 00-028-I-I-02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/07	2001	Crop safety of IBE 3894 on apple trees, Bredelaar Research Group, Report no. 01-	Y	ISK	20110285 THG	05.04.2004

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		002-I-NL-01, GEP / Unpublished				
OECD IIIA, 6.2.1/08	2001	Crop safety of IBE 3894 on apple trees, Bredelaar Research Group, Report no. 01-002-I-NL-02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/09	2001	Crop safety of IBE 3894 on apple trees: fruit setting, Agri2000, Report no. 01-013-I-I-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/10	2001	Crop safety of IBE 3894 on apple trees, Recerca Agrícola, Report no. 01-013-I-E-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/11	2001	Crop safety of IBE 3894 WG on apple trees, S.P.F. GAB Italia, Report no. 01-002-I-I-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/12	2001	Crop safety of IBE 3894 on apple trees, Recerca Agrícola, Report no. 01-002-I-E-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/13	2001	Crop safety of IBE 3894 on apple trees, TrialCamp, Report no. 01-002-I-E-02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/14	2001	Control of possible phytotoxicity effects on apple, RSF – Research Station of Gorsem npo, Report no. 01-002-I-B-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/15	2002	Control of possible phytotoxicity effects on apple, RSF – Research Station of Gorsem npo, Report no. GAT02-SE01-BE01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA,	2002	Crop safety of IBE 3894 WG on apple trees,	Y	ISK	20110285 THG	05.04.2004

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6.2.1/16		De Bredelaar B.V. , Report no. GAT02-SE01-NL01, GEP / Unpublished				
OECD IIIA, 6.2.1/17	2002	Crop safety of IBE 3894 WG on apple trees, De Bredelaar B.V. , Report no. GAT02-SE01-NL02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/18	2002	Measure incidence on apple trees of repeated applications of IBE 3894 used at maximum and double rates and with maximum proposed number of sprays, Ingenieurbüro Andreas Hetterich, Report no. GAT02-SE01-DE01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/19	2002	Evaluation of the selectivity of IBE 3894 in apple in Germany 2002, Versuchswesen Pflanzenschutz Dr. Paul Reh, Report no. GAT02-SE01-DE02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/20	2003	Insecticides and acaricides RSF – Research Station of Gorsem, Report no. 01-004-I-B-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/21	2001	Crop safety of IBE 3894 on pear trees De Bredelaar , Report no. 01-004-I-NL-01 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/22	2001	Crop safety of IBE 3894 on pear trees De Bredelaar , Report no. 01-004-I-NL-02 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/23	2003	Insecticides RSF – Research Station of Gorsem, Report no. GPT02-SE01-BE01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA,	2002	Crop safety of IBE 3894 on pear trees: Yield	Y	ISK	20110285 THG	05.04.2004

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6.2.1/24		and effects on fruits S.P.F. GAB Italia, Report no. GPT02-SE01-IT01, GEP / Unpublished				
OECD IIIA, 6.2.1/25	2002	Crop safety of IBE 3894 on pear trees in Spain Recerca Agricola, Report no. GPT02-SE01-ES01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/26	2002	Crop safety of IBE 3894 on pear trees: Yield and effects on fruits De Bredelaar, Report no. GPT02-SE01-NL01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/27	2002	Crop safety of IBE 3894 on pear trees: Yield and effects on fruits De Bredelaar, Report no. GPT02-SE01-NL02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/28	2003	Evaluation of the selectivity of IBE 3894 in pear in Germany 2002 Versuchswesen Pflanzenschutz Dr. Paul Reh, Report no. GPT02-SE01-DE01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/40	2001	Measure incidence on apple trees of repeated applications of IBE 3894 used at maximum and double rates and with maximum proposed number of sprays, Solevi, Report no. 01-012-I-F-51, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/41	2001	Evaluate the efficacy against aphids (Dysaphis plantaginea) and the crop sensitivity, Prestagro, Report no. 01-012-I-F-52,	Y	ISK	20110285 THG	05.04.2004

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		GEP / Unpublished				
OECD IIIA, 6.2.1/46	2003	Crop safety of IBE 3894 on pear trees: Yield and effects on fruits Ingenieurbüro Andreas Hetterich, Report no. GPT02-SE01-DE02 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/01	1999	Pommier – Effets non intentionnels sur Typhlodromus Pyri. S.P.V. , Report no. 99-008-I-F-51, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/02	1999	Rapport d'expérimentation sur les effets non intentionnels des produits codés IBE 3887 (fongicide) et IBE 3880 (insecticide) sur Typhlodromus Pyri au laboratoire. ENSA-INRA Montpellier, Report no. 99-009-I-F-01 Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/03	2000	Evaluation des effets non intentionnels d'IBE 3894 sur Typhlodromus Pyri en verger. Testapi, Report no. 00-018-I-F-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/04	2000	Unintended effects of the insecticide IBE 3894 on Predatory Mites in orchards in Southern France. Viti R&D, Report no. 00-018-I-F-52, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/05	2001	Define selectivity in the field of the aphicide IBE-3894 on beneficial arthropods. S.P.F. GAB Italia, Report no. 01-031-I-I-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.7/01	2002	Impact of IKI-220 50WG (IBE-3894) on Adjacent Crops and on Succeeding Crops. Ishihara Sangyo Kaisha Ltd., Report no.	Y	ISK	20110285 THG	05.04.2004

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		AL0201-I-08, Non GEP / Unpublished				
OECD IIIA, 6.2.8/01	1999	Sensibilité de diverses souches de pucerons, au nouvel aphicide IKI220 de la société ISK Biosciences. UPMC-INRA Versailles, Report no. 98-005-I-F-01 Non GEP / unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/02	2000	Sensibilité d'Aphis frangulae (kaltenbach) et Aphis nasturtii (kaltenbach) au nouvel aphicide IKI-220. F.R.E.D.EC., Report no. 99-030-I-F-01, non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/03	2000	Evaluation de l'efficacité de la molécule IKI-220 sue des populations de Sitobion avenae et Aphis nasturtii. F.R.E.D.E.C., Report no. 00-030-I-F-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/04	2001	Evaluation de l'efficacité de la molécule IKI-220 sue des populations de Sitobion avenae et Aphis nasturtii. F.R.E.D.E.C., Report no. 01-030-I-F-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/05	2001	Evaluation de l'efficacité de la molécule IKI-220 sur des populations de Sitobion avenae et Aphis nasturtii. F.R.E.D.E.C., Report no. 01-029-I-F-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/06	2001	Efficiency of the test substance IBE 3894 on 3 strains of Aphis Gossypii. Enigma , Report no. 01-008-I-F-02, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/07	2001	Efficiency of the test substance IBE 3894 on 2 strains of Myzus persicae.	Y	ISK	20110285 THG	05.04.2004

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		Enigma, Report no. 01-008-I-F-03, Non GEP / Unpublished				
OECD IIIA, 6.2.8/08	2002	Evaluation de l'efficacité de la molécule IKI-220 sue des populations de Sitobion avenae et Aphis nasturtii. F.R.E.D.E.C., Report no. GWW02-RS01-FR01 / GPO02-RS01-FR01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/09	2002	Baseline sensitivity of IKI-220 against Aphis gossypii and Myzus persicae in Japan. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-06, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/10	2002	Efficiency of the test substance IBE 3894 on 3 strains of Myzus persicae. Enigma, Report no. GLB02-RS01-FR01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/11	2002	Efficiency of the test substance IBE 3894 on 3 strains of Dysaphis plantaginea, Enigma, Report no. GLB02-RS02-FR01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/12	2001	Efficiency of the test substance IBE 3894 on 3 strains of Dysaphis plantaginea, Enigma, Report no. 01-008-I-F-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/01	2003	GABA Gated C1 Channel - Flonicamid Mode of action. FMC Corporation, Report no. F-1, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/02	2003	Voltage-gated Sodium Channel – Flonicamid Mode of Action Studies. FMC Corporation, Report no. F-2, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA,	2003	Energy Metabolism – Flonicamid Mode of	Y	ISK	20110285 THG	05.04.2004

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6.1.1/03		Action Studies. FMC Corporation, Report no. F-3, Non GEP / Unpublished				
OECD IIIA, 6.1.1/04	2002	IKI-220's spectrum of activity. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/05	2002	Insecticidal activity of IKI-220 against nine species of aphid. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-02, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/06	2002	Residual activity of IKI-220 under summer spray conditions. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-04, non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/07	2002	Systemic and translaminar activity of IKI-220. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-05, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/08	2002	Effects of IKI-220 against feeding behavior of green peach aphid, Myzus persicae. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-09, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/09	2002	Effects of IKI-220 on acetylcholinseterase of housefly. Ishihara Sangyo Kaisha Ltd. , Report no. AL0201-I-12, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/10	2002	Effect of IKI-220 on alpha-BGTX specific binding to nAChRs on honeybee head membranes.	Y	ISK	20110285 THG	05.04.2004

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		Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-13, Non GEP / Unpublished				
OECD IIIA, 6.1.1/11	2002	Insecticidal activity of IKI-220 against green peach aphid (Myzus persicae) selected with pymetrozine. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-15, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/12	2002	Rainfastness of IKI-220 in pot tests. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-07, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/01	1999	Efficacy of IKI-220 for aphid control in wheat – Insecticide IKI-220 for aphid control in winter wheat. Redebel s.a., Report no. 99-020-I-B-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/02	1998	Efficacy of IKI-220 for aphid control in wheat – To test IBE 3880 in a aprogram of treatment against aphids / winter wheat. SARL Entreprise Decarsin, Report no. 98-004-I-F-01 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/03	1998	Efficacy of IKI-220 for aphid control in wheat – To test IBE 3880 in a aprogram of treatment against aphids / winter wheat SARL Entreprise Decarsin, Report no. 98-004-I-F-02 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/04	1998	Evaluate efficacy of new insecticides against aphids on Cereals Staphyt , Report no. 98-004-I-F-03 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004

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OECD IIIA, 6.1.2/05	1998	Efficacy of IKI-220 for aphid control in wheat – IBE 3880 Aphids on cereals (ears) Prestagro, Report no. 98-004-I-F-04 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/06	1998	Efficacy of IKI-220 for aphid control in wheat – IBE 3880 Aphids on cereals (ears) Prestagro, Report no. 98-004-I-F-05 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/07	1998	Efficacy of IKI-220 for aphid control in wheat – IBE 3880 Aphids on cereals (ears) Prestagro, Report no. 98-004-I-F-51 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/08	1999	Efficacy of IKI-220 for aphid control in wheat – Evaluate IKI-220 for aphid control on Winter Wheat. SARL Entreprise Decarsin, Report no. 99-020-I-F-01 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/09	1999	Crop safety and yield – Homogeneous crop (IBE 3880 for aphid control on Winter Wheat). SARL Entreprise Decarsin , Report no. 99-020-I-F-02 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/10	1999	Crop safety and yield homogeneous crop (IBE 3880 for aphid control on winter wheat) SARL Entreprise Decarsin, Report no. 99-021-I-F-01 GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/11	1999	Field study to evaluate the efficacy of IKI-220 for the control of aphids on winter wheat Agrisearch UK , Report no. 99-020-I-GB-02	Y	ISK	20110285 THG	05.04.2004

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OECD IIIA, 6.1.2/12	1999	Crop safety, yield, germination test and taint tests on winter wheat – An evaluation of the selectivity of IKI-220 when applied to winter wheat Oxford Agricultural Trials Ltd. / 99-021-I-GB-01 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/01	2000	Efficacy of IKI-220 for aphid control in wheat. Redebel s.a., Report no. 00-020-I-B-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/02	2000	Efficacy of IKI-220 for aphid control in wheat . Solevi, Report no. 00-020-I-F-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
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OECD IIIA, 6.1.3/04	2000	Evaluation of the efficacy of IKI-220 for aphid control in wheat. Staphyt , Report no. 00-020-I-F-03, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/05	2000	Evaluation of the efficacy of IKI-220 for aphid control in wheat. Staphyt , Report no. 00-020-I-F-04 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/10	2000	To evaluate the efficacy of IBE 3880 (IKI-220) and IBE 3894 (IKI-220) against aphids on winter wheat. Inveresk Research , Report no. 00-020-I-GB-05 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA,	2001	Efficacy and selectivity of IKI-220 for the	Y	ISK	20110285 THG	05.04.2004

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6.1.3/11		control of ear aphids in cereals. Solevi , Report no. 01-020-I-F-01 , GEP / Unpublished				
OECD IIIA, 6.1.3/12	2001	Efficacy and selectivity of IKI-220 for the control of ear aphids in cereals. Solevi , Report no.01-020-I-F-02 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/13	2001	Evaluation of the efficacy of new insecticide products against aphids on ears. Staphyt , Report no. 01-020-I-F-03 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/14	2001	Efficacy of IKI-220 for aphid control in wheat. S.P.V. , Report no. 01-023-I-F-01 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/19	2001	Efficacy of IKI-220 for aphid control in wheat – An evaluation of the efficacy of IBE 3894 (IKI-220) for aphid control in winter wheat. Oxford Agricultural Trials Ltd. , Report no. 01-020-I-GB-03 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/20	2001	Efficacy of IKI-220 for aphid control in wheat – An evaluation of the efficacy of IBE 3894 (IKI-220) for aphid control in winter wheat. Oxford Agricultural Trials Ltd. , Report no. 01-020-I-GB-04 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/21	2001	Efficacy of IKI-220 for aphid control in wheat – An evaluation of the efficacy of IBE 3894 (IKI-220) for aphid control in winter wheat. Oxford Agricultural Trials Ltd. , Report no. 01-020-I-GB-01, 02, 03, 04 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA,	2001	Field study to evaluate the efficacy and crop	Y	ISK	20110285 THG	05.04.2004

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
6.1.3/22		safety of IKI-220 for the control of aphids on winter wheat. Agrisearch UK , Report no. 01-020-I-GB-05 , GEP / Unpublsihed				
OECD IIIA, 6.1.3/23	2001	Field study to evaluate the efficacy and crop safety of IKI-220 for the control of aphids on winter wheat. Agrisearch UK / 01-020-I-GB-06 , GEP / Unpublsihed	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/24	2001	Field study to evaluate the efficacy and crop safety of IKI-220 for the control of aphids on winter wheat. Agrisearch UK , Report no.01-020-I-GB-07 , GEP / Unpublsihed	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/25	2001	Field study to evaluate the efficacy and crop safety of IKI-220 for the control of aphids on winter wheat. Agrisearch UK , Report no. 01-020-I-GB-08 , GEP / Unpublsihed	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/26	2001	Field study to evaluate the efficacy and crop safety of IKI-220 for the control of aphids on winter wheat. Agrisearch UK , Report no. 01-020-I-GB-05, 06, 07, 08 , GEP / Unpublsihed	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/27	2001	Efficacy of IKI-220 against aphids in ears of winter wheat. Ingenieurbüro Andreas Hetterich , Report no. 00-060-I-D-01 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/28	2001	Efficacy of IKI-220 against aphids in ears of winter wheat.	Y	ISK	20110285 THG	05.04.2004

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		Ingenieurbüro Andreas Hetterich , Report no. 00-060-I-D-02 , GEP / Unpublished				
OECD IIIA, 6.1.3/29	2001	Evaluation of the efficacy of IKI-220 for Aphid control in winter wheat in Germany 2000. Versuchswesen Pflanzenschutz Dr. Paul Reh , Report no./ 00-060-I-D-03 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/30	2000	Efficacy of IKI-220 against aphids in ears of winter wheat. LWK Weser-Ems , Report no. 00-060-I-D-05 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/31	2000	Efficacy of IKI-220 against aphids in ears of winter wheat. Agroplan , Report no. 00-060-I-D-06 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/32	2001	Blattlausbekämpfung in Winterweizen. LWK Hannover , Report no. 01-020-I-D-03, 04 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/35	2002	Efficacy of IKI-220 for aphid control in wheat – Evaluate efficacy and selectivity of IKI-220 for registration purposes. Ingenieurbüro Andreas Hetterich , Report no. GWW02-EF01-DE03 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/36	2003	Evaluation of the efficacy of IKI-220 for Aphid control in winter wheat in Germany 2002. Versuchswesen Pflanzenschutz Dr. Paul Reh , Report no. GWW02-EF01-DE04 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA,	2003	Efficacy of IKI-220 for aphid control in	Y	ISK	20110285 THG	05.04.2004

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6.1.3/37		wheat. Agro-check, Report no. GWW02-EF01-DE05 , GEP / Unpublished				
OECD IIIA, 6.1.3/38	2003	Efficacy of IKI-220 for aphid control in wheat. Agrostat, Report no. GWW02-EF01-DE06 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/39	2002	Evaluation of the efficacy of a new insecticide product used against aphids in a winter wheat crop. Staphyt , Report no. GWW02-EF01-FR01 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/40	2002	Evaluation of the efficacy of a new insecticide product used against aphids in a cereal crop / Staphyt , Report no. GWW02-EF01-FR02 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/41	2002	Evaluation of the efficacy of a new insecticide product used against aphids in a cereal crop / Staphyt , Report no. GWW02-EF01-FR03 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/01	2001	Field study to evaluate the crop safety of two sequential applications of IBE 3894 on winter wheat and the subsequent viability of the seed, and to generate winter wheat specimens suitable for taint testing in Northern France. Agrisearch France , Report no. 00-021-I-F-01, 02 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/02	2000	Crop safety, yield, germination test and taint tests on winter wheat – An evaluation of the	Y	ISK	20110285 THG	05.04.2004

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		selectivity of IKI-220 when applied to winter wheat. Oxford Agricultural Trials Ltd. , Report no. 00-021-I-GB-01 , GEP / Unpublished				
OECD IIIA, 6.2.1/03	2002	Field study to evaluate the crop safety of two sequential applications of IBE 3894 on winter wheat and the subsequent viability of the seed, and to generate winter wheat specimens suitable for taint testing in France. Agrisearch France , Report no. 01-021-I-F-01, 02 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/04	2002	Crop safety, yield, germination test and taint tests on winter wheat - An evaluation of the selectivity of IBE 3894 (IKI-220) in winter wheat for registration purposes. Oxford Agricultural Trials Ltd. , Report no. 01-021-I-GB-01 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/05	2000	Crop safety, yield, germination test and taint tests on winter wheat. Agro-check , Report no. 00-061-I-D-01 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/06	2003	Crop safety, yield and germination test on winter wheat. Agro-check , Report no. GWW02-SE01-DE01 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/07	2003	Crop safety, yield and germination test on winter wheat. Ingenieurbüro Andreas Hetterich , Report no. GWW02-SE01-DE02 , GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004

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OECD IIIA, 6.2.1/08	2003	Selectivity of IBE 3894 in winter wheat - Open field efficacy study. Field Research Support , Report no. GWW02-SE01-DE03 , GEP / Unpublished	Y	ISK	20110285 THG	
OECD IIIA, 6.2.1/09	2002	Evaluation of the influence of an insecticide product on the quality of bread making. Staphyt, Report no. GWW02-SE02-FR01, 02, 03, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/01	1999	Pommier – Effets non intentionnels sur Typhlodromus Pyri. S.P.V. , Report no. 99-008-I-F-51, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/02	1999	Rapport d'expérimentation sur les effets non intentionnels des produits codés IBE 3887 (fongicide) et IBE 3880 (insecticide) sur Typhlodromus Pyri au laboratoire. ENSA-INRA Montpellier, Report no. 99-009-I-F-01 Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/03	2000	Evaluation des effets non intentionnels d'IBE 3894 sur Typhlodromus Pyri en verger. Testapi, Report no. 00-018-I-F-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/04	2000	Unintended effects of the insecticide IBE 3894 on Predatory Mites in orchards in Southern France. Viti R&D, Report no. 00-018-I-F-52, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/05	2001	Define selectivity in the field of the aphicide IBE-3894 on beneficial arthropods. S.P.F. GAB Italia, Report no. 01-031-I-I-01,	Y	ISK	20110285 THG	05.04.2004

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		Non GEP / Unpublished				
OECD IIIA, 6.2.7/01	2002	Impact of IKI-220 50WG (IBE-3894) on Adjacent Crops and on Succeeding Crops. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-08, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/01	1999	Sensibilité de diverses souches de pucerons, au nouvel aphicide IKI220 de la société ISK Biosciences. UPMC-INRA Versailles, Report no. 98-005-I-F-01 Non GEP / unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/02	2000	Sensibilité d'Aphis frangulae (kaltenbach) et Aphis nasturtii (kaltenbach) au nouvel aphicide IKI-220. F.R.E.D.EC., Report no. 99-030-I-F-01, non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/03	2000	Evaluation de l'efficacité de la molécule IKI-220 sue des populations de Sitobion avenae et Aphis nasturtii. F.R.E.D.E.C., Report no. 00-030-I-F-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/04	2001	Evaluation de l'efficacité de la molécule IKI-220 sue des populations de Sitobion avenae et Aphis nasturtii. F.R.E.D.E.C., Report no. 01-030-I-F-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/05	2001	Evaluation de l'efficacité de la molécule IKI-220 sur des populations de Sitobion avenae et Aphis nasturtii. F.R.E.D.E.C., Report no. 01-029-I-F-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/06	2001	Efficiency of the test substance IBE 3894 on 3 strains of Aphis Gossypii.	Y	ISK	20110285 THG	05.04.2004

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		Enigma , Report no. 01-008-I-F-02, Non GEP / Unpublished				
OECD IIIA, 6.2.8/07	2001	Efficiency of the test substance IBE 3894 on 2 strains of Myzus persicae. Enigma, Report no. 01-008-I-F-03, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/08	2002	Evaluation de l'efficacité de la molécule IKI-220 sue des populations de Sitobion avenae et Aphis nasturtii. F.R.E.D.E.C., Report no. GWW02-RS01-FR01 / GPO02-RS01-FR01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/09	2002	Baseline sensitivity of IKI-220 against Aphis gossypii and Myzus persicae in Japan. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-06, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/10	2002	Efficiency of the test substance IBE 3894 on 3 strains of Myzus persicae. Enigma, Report no. GLB02RS01-FR01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/01	2003	GABA Gated C1 Channel - Flonicamid Mode of action. FMC Corporation, Report no. F-1, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/02	2003	Voltage-gated Sodium Channel – Flonicamid Mode of Action Studies. FMC Corporation, Report no. F-2, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/03	2003	Energy Metabolism – Flonicamid Mode of Action Studies. FMC Corporation, Report no. F-3, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA,	2002	IKI-220's spectrum of activity.	Y	ISK	20110285 THG	05.04.2004

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6.1.1/04		Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-01, Non GEP / Unpublished				
OECD IIIA, 6.1.1/05	2002	Insecticidal activity of IKI-220 against nine species of aphid. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-02, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/06	2002	Residual activity of IKI-220 under summer spray conditions. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-04, non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/07	2002	Systemic and translaminar activity of IKI-220. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-05, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/08	2002	Effects of IKI-220 against feeding behavior of green peach aphid, Myzus persicae. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-09, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/09	2002	Effects of IKI-220 on acetylcholinseterase of housefly. Ishihara Sangyo Kaisha Ltd. , Report no. AL0201-I-12, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/10	2002	Effect of IKI-220 on alpha-BGTX specific binding to nAChRs on honeybee head membranes. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-13, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA,	2002	Insecticidal activity of IKI-220 against green	Y	ISK	20110285 THG	05.04.2004

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6.1.1/11		peach aphid (Myzus persicae) selected with pymetrozine. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-15, Non GEP / Unpublished				
OECD IIIA, 6.1.1/12	2002	Rainfastness of IKI-220 in pot tests. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-07, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/01	2003	Efficacy of IKI-220 against aphids on ornamentals – Control of Aphis Gossypii in Chrysanthemum Research Company for Plant Protection "De Bredelaar" B.V., Report no. GOM02-EF01-NL01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/02	2003	Efficacy of IKI-220 against aphids on ornamentals – Control of Aphis Gossypii in Chrysanthemum Research Company for Plant Protection "De Bredelaar" B.V. , Report no. GOM02-EF01-NL02, GEP/ Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/03	2003	Selectivity of IKI-220 against aphids on ornamentals – Selectivity in protected Chrysanthemum Research Company for Plant Protection "De Bredelaar" B.V., Report no. GOM02-SE01-NL01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/04	2003	Selectivity of IKI-220 against aphids on ornamentals – Selectivity in Gerbera Research Company for Plant Protection "De Bredelaar" B.V., Report no. GOM02-SE01-	Y	ISK	20110285 THG	05.04.2004

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		NL02, GEP / Unpublished				
OECD IIIA, 6.1.2/05	2003	Selectivity of IKI-220 against aphids on ornamentals – Selectivity in Rose Research Company for Plant Protection "De Bredelaar" B.V., Report no. GOM02-SE01-NL03, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/03	2003	Efficacy of IKI-220 against aphids on ornamentals – Control of Aphids in protected Chrysanthemum Research Company for Plant Protection "De Bredelaar" B.V., Report no. GOM03-EF11-NL01, GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.1.3/04	2003	Efficacy of IKI-220 against aphids on ornamentals – Control of Aphids in protected Chrysanthemum / Research Company for Plant Protection "De Bredelaar" B.V., Report no. GOM03-EF11-NL02, GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.1.3/05	2003	Efficacy of IKI-220 against aphids on ornamentals – Control of Aphids in protected Chrysanthemum / Research Company for Plant Protection "De Bredelaar" B.V., Report no. GOM03-EF11-NL03, GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.1.3/06	2003	Efficacy of IKI-220 against aphids on ornamentals – Control of Aphids in protected Chrysanthemum / Research Company for Plant Protection "De Bredelaar" B.V., Report no. GOM03-EF11-	Y	ISK	20110285 THG	18.07.2006

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		NL04, GEP/ Unpublished				
OECD IIIA, 6.1.3/07	2003	Efficacy of IKI-220 against aphids on ornamentals – Control of Aphids in protected Chrysanthemum Research Company for Plant Protection De Bredelaar B.V. , Report no. GOM03-EF11-NL05, GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.1.3/08	2003	Efficacy of IKI-220 against aphids on ornamentals – Control of Aphids in protected Chrysanthemum Research Company for Plant Protection De Bredelaar B.V. , Report no. GOM03-EF11-NL06, GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.1.3/09	2005	Efficacy of IKI-220 against aphids on ornamentals – Control of Aphids in protected Chrysanthemum Research Company for Plant Protection De Bredelaar B.V., Report no. GOM04-EF11-NL01, GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.1.3/10	2005	Efficacy of IKI-220 against aphids on ornamentals – Control of Aphids in protected Chrysanthemum Research Company for Plant Protection De Bredelaar B.V., Report no. GOM04-EF11-NL02, GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.1.3/11	2005	Efficacy of IKI-220 against aphids on ornamentals – Control of Aphids in protected Chrysanthemum Research Company for Plant Protection De	Y	ISK	20110285 THG	18.07.2006

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		Bredelaar B.V., Report no. GOM04-EF11-NL03, GEP/ Unpublished				
OECD IIIA, 6.1.3/12	2005	Efficacy of IKI-220 against aphids on ornamentals – Control of Aphids in protected Chrysanthemum Research Company for Plant Protection De Bredelaar B.V., Report no. GOM04-EF11-NL04, GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.1.3/13	2005	Efficacy of IKI-220 against aphids on ornamentals – Control of Aphids in protected Chrysanthemum Research Company for Plant Protection De Bredelaar B.V., Report no. GOM04-EF11-NL05, GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.1.3/14	2005	Efficacy of IKI-220 against aphids on ornamentals – Control of Aphids in protected Chrysanthemum Research Company for Plant Protection De Bredelaar B.V., Report no. GOM04-EF11-NL06, GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.2.1/01	2003	Selectivity of IKI-220 against aphids on ornamentals – Selectivity in protected Chrysanthemum Research Company for Plant Protection “De Bredelaar” B.V., Report no. GOM02-SE01-NL01, GEP / Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.2.1/05	2004	Selectivity of IKI-220 on ornamentals (Roses, Chrysantemum, Gerbera) Selectivity in protected Chrysanthemum	Y	ISK	20110285 THG	18.07.2006

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		Research Company for Plant Protection "De Bredelaar" B.V., Report no. GOM03-SE11-NL02, GEP/ Unpublished				
OECD IIIA, 6.2.1/06	2004	Selectivity of IKI-220 on ornamentals (Roses, Chrysantemum, Gerbera) Selectivity in protected Rose Research Company for Plant Protection "De Bredelaar" B.V., Report no. GOM03-SE11-NL03, GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.2.1/07	2004	Selectivity of IKI-220 on ornamentals (Roses, Chrysantemum, Gerbera) Selectivity in protected Rose Research Company for Plant Protection "De Bredelaar" B.V., Report no. GOM03-SE11-NL04, GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.2.1/08	2004	Selectivity of IKI-220 on ornamentals (Roses, Chrysantemum, Gerbera) Selectivity in protected Gerbera Research Company for Plant Protection "De Bredelaar" B.V., Report no. GOM03-SE11-NL05, GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.2.1/09	2004	Selectivity of IKI-220 on ornamentals (Roses, Chrysantemum, Gerbera) Selectivity in protected Gerbera Research Company for Plant Protection "De Bredelaar" B.V., Report no. GOM03-SE11-NL06, GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.2.1/10	2004	Selectivity of IKI-220 on ornamentals (Roses, Chrysantemum, Gerbera)	Y	ISK	20110285 THG	18.07.2006

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Application number*	Date of submission*
		Phytotoxicity in protected Chrysanthemum Research Company for Plant Protection “De Bredelaar” B.V., Report no. GOM04-SE11-NL01, GEP/ Unpublished				
OECD IIIA, 6.2.1/11	2004	Selectivity of IKI-220 on ornamentals (Roses, Chrysantemum, Gerbera) Phytotoxicity in protected Chrysanthemum Research Company for Plant Protection “De Bredelaar” B.V., Report no. GOM04-SE11-NL02 , GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.2.1/12	2004	Selectivity of IKI-220 on ornamentals (Roses, Chrysantemum, Gerbera) Phytotoxicity in protected Rose Research Company for Plant Protection “De Bredelaar” B.V. , Report no. GOM04-SE11-NL03, GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.2.1/13	2004	Selectivity of IKI-220 on ornamentals (Roses, Chrysantemum, Gerbera) Phytotoxicity in protected Rose Research Company for Plant Protection “De Bredelaar” B.V., Report no. GOM04-SE11-NL04 , GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.2.1/14	2004	Selectivity of IKI-220 on ornamentals (Roses, Chrysantemum, Gerbera) Phytotoxicity in protected Gerbera / Research Company for Plant Protection “De Bredelaar” B.V., Report no. GOM04-SE11-NL05, GEP/ Unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA,	2004	Selectivity of IKI-220 on ornamentals	Y	ISK	20110285 THG	18.07.2006

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6.2.1/15		(Roses, Chrysantemum, Gerbera) Phytotoxicity in protected Gerbera Research Company for Plant Protection “De Bredelaar” B.V., Report no. GOM04-SE11-NL06, GEP/ Unpublished				
OECD IIIA, 6.2.1/16	2006	Selectivity of IBE 3894 on potted plants (foliar applications) Proeftuin Zwaagdijk, Report no. GOM06-SE11-NL01, 02, 03, 04, 05, 06 , GEP/ unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.2.1/17	2006	Selectivity of IBE 3894 on potted plants (foliar applications) Proeftuin Zwaagdijk, Report no. GOM06-SE11-NL01 , GEP/ unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.2.1/18	2006	Selectivity of IBE 3894 on potted plants (foliar applications) Proeftuin Zwaagdijk, Report no. GOM06-SE11-NL02 , GEP/ unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.2.1/19	2006	Selectivity of IBE 3894 on potted plants (foliar applications) Proeftuin Zwaagdijk, Report no. GOM06-SE11-NL03, GEP/ unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.2.1/20	2006	Selectivity of IBE 3894 on potted plants (foliar applications) Proeftuin Zwaagdijk, Report no. GOM06-SE11-NL04, GEP/ unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.2.1/21	2006	Selectivity of IBE 3894 on potted plants (foliar applications) Proeftuin Zwaagdijk, Report no. GOM06-	Y	ISK	20110285 THG	18.07.2006

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		SE11-NL05, GEP/ unpublished				
OECD IIIA, 6.2.1/22	2006	Selectivity of IBE 3894 on potted plants (foliar applications) Proeftuin Zwaagdijk, Report no. GOM06-SE11-NL06, GEP/ unpublished	Y	ISK	20110285 THG	18.07.2006
OECD IIIA, 6.2.4/01	1999	Pommier – Effets non intentionnels sur Typhlodromus Pyri. S.P.V. , Report no. 99-008-I-F-51, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/02	1999	Rapport d'expérimentation sur les effets non intentionnels des produits codés IBE 3887 (fongicide) et IBE 3880 (insecticide) sur Typhlodromus Pyri au laboratoire. ENSA-INRA Montpellier, Report no. 99-009-I-F-01 Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/03	2000	Evaluation des effets non intentionnels d'IBE 3894 sur Typhlodromus Pyri en verger. Testapi, Report no. 00-018-I-F-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/04	2000	Unintended effects of the insecticide IBE 3894 on Predatory Mites in orchards in Southern France. Viti R&D, Report no. 00-018-I-F-52, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/05	2001	Define selectivity in the field of the aphicide IBE-3894 on beneficial arthropods. S.P.F. GAB Italia, Report no. 01-031-I-I-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.7/01	2002	Impact of IKI-220 50WG (IBE-3894) on Adjacent Crops and on Succeeding Crops.	Y	ISK	20110285 THG	05.04.2004

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		Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-08, Non GEP / Unpublished				
OECD IIIA, 6.2.8/01	1999	Sensibilité de diverses souches de pucerons, au nouvel aphicide IKI220 de la société ISK Biosciences. UPMC-INRA Versailles, Report no. 98-005-I-F-01 Non GEP / unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/02	2000	Sensibilité d'Aphis frangulae (kaltenbach) et Aphis nasturtii (kaltenbach) au nouvel aphicide IKI-220. F.R.E.D.EC., Report no. 99-030-I-F-01, non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/03	2000	Evaluation de l'efficacité de la molécule IKI-220 sue des populations de Sitobion avenae et Aphis nasturtii. F.R.E.D.E.C., Report no. 00-030-I-F-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/04	2001	Evaluation de l'efficacité de la molécule IKI-220 sue des populations de Sitobion avenae et Aphis nasturtii. F.R.E.D.E.C., Report no. 01-030-I-F-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/05	2001	Evaluation de l'efficacité de la molécule IKI-220 sur des populations de Sitobion avenae et Aphis nasturtii. F.R.E.D.E.C., Report no. 01-029-I-F-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/06	2001	Efficiency of the test substance IBE 3894 on 3 strains of Aphis Gossypii. Enigma , Report no. 01-008-I-F-02, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA,	2001	Efficiency of the test substance IBE 3894 on	Y	ISK	20110285 THG	05.04.2004

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6.2.8/07		2 strains of Myzus persicae. Enigma, Report no. 01-008-I-F-03, Non GEP / Unpublished				
OECD IIIA, 6.2.8/08	2002	Evaluation de l'efficacité de la molécule IKI-220 sue des populations de Sitobion avenae et Aphis nasturtii. F.R.E.D.E.C., Report no. GWW02-RS01-FR01 / GPO02-RS01-FR01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/09	2002	Baseline sensitivity of IKI-220 against Aphis gossypii and Myzus persicae in Japan. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-06, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/10	2002	Efficiency of the test substance IBE 3894 on 3 strains of Myzus persicae. Enigma, Report no. GLB02-RS01-FR01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/01	2003	GABA Gated C1 Channel - Flonicamid Mode of action. FMC Corporation, Report no. F-1, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/02	2003	Voltage-gated Sodium Channel – Flonicamid Mode of Action Studies. FMC Corporation, Report no. F-2, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/03	2003	Energy Metabolism – Flonicamid Mode of Action Studies. FMC Corporation, Report no. F-3, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/04	2002	IKI-220's spectrum of activity. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004

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OECD IIIA, 6.1.1/05	2002	Insecticidal activity of IKI-220 against nine species of aphid. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-02, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/06	2002	Residual activity of IKI-220 under summer spray conditions. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-04, non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/07	2002	Systemic and translaminar activity of IKI-220. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-05, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/08	2002	Effects of IKI-220 against feeding behavior of green peach aphid, Myzus persicae. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-09, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/09	2002	Effects of IKI-220 on acetylcholinseterase of housefly. Ishihara Sangyo Kaisha Ltd. , Report no. AL0201-I-12, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/10	2002	Effect of IKI-220 on alpha-BGTX specific binding to nAChRs on honeybee head membranes. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-13, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.1/11	2002	Insecticidal activity of IKI-220 against green peach aphid (Myzus persicae) selected with pymetrozine. Ishihara Sangyo Kaisha Ltd., Report no.	Y	ISK	20110285 THG	05.04.2004

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		AL0201-I-15, Non GEP / Unpublished				
OECD IIIA, 6.1.1/12	2002	Rainfastness of IKI-220 in pot tests. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-07, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/01	1998	Efficacy of IKI-220 against aphids in potato – Essai d'efficacité d'insecticides sur la transmission de virus – Enroulement et virus Y. Bretagne-Plants, Report no.98-024-I-F-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/02	1998	Efficacy of IKI-220 against aphids in potato. SARL Entreprise Decarsin, Report no.98-024-I-F-02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/03	1998	Efficacy of IKI-220 against aphids in potato. SARL Entreprise Decarsin, Report no.98-024-I-F-03, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/04	1999	Efficacy of IKI-220 against aphids in potato – The efficacy and selectivity of IKI-220 for control of Aphids in potatoes / Oxford Agricultural Trials Ltd., Report no.99-024-I-GB-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/05	1999	IKI-220 Crop safety, yield, germination test and taint tests on potatoes. SARL Entreprise Decarsin, Report no. 99-025-I-F-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.2/06	2000	IKI-220 Crop safety, yield, germination test and taint tests on potatoes – An evaluation of the crop safety of IBE 3880 when applied	Y	ISK	20110285 THG	05.04.2004

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		to potatoes. Oxford Agricultural Trials Ltd., Report no. 99-025-I-GB-01, GEP / Unpublished				
OECD IIIA, 6.1.3/01	2000	Evaluation of IKI-220 (IBE 3894, IBE 3880) used in potato crop for aphid control. Redebel S.A., Report no. 00-024-I-B-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/02	2000	Evaluation of IKI-220 (IBE 3894, IBE 3880) used in potato crop for aphid control. Redebel S.A., Report no. 00-024-I-B-02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/03	2000	Efficacy of IKI-220 against aphids in potato. Redebel S.A., Report no. 00-024-I-B-03, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/04	2000	Efficacy of IKI-220 against aphids in potato – Evaluation of the efficacy of IKI-220 for aphid control in potatoes. Staphyt, Report no. 00-024-I-F-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/05	2000	Efficacy of IKI-220 against aphids in potato – Evaluation of the efficacy of IKI-220 for aphid control in potatoes. Staphyt, Report no. 00-024-I-F-02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/06	2000	Evaluation of IKI-220 for aphid control on potato. SARL Entreprise Decarsin, Report no. 00-024-I-F-03, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/07	2000	Evaluation of IKI-220 for aphid control on potato. SARL Entreprise Decarsin, Report no. 00-024-I-F-04,	Y	ISK	20110285 THG	05.04.2004

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		GEP / Unpublished				
OECD IIIA, 6.1.3/08	2000	Efficacy of IKI-220 against aphids in potato. Essais +, Report no. 00-024-I-F-05, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/09	2000	Efficacy of IKI-220 against aphids in potato – An evaluation of the efficacy and crop selectivity of IKI-220 for the control of aphid in potato, Report no. 00-024-I-GB-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/10	2001	Efficacy of IKI-220 against aphids in potato / Agrisearch UK, Report no. 01-024-I-GB-04, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/11	2001	Efficacy of IKI-220 against aphids in potato / Agrisearch UK, Report no. 01-024-I-GB-05, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/12	2001	Efficacy of IKI-220 against aphids in potato / Agrisearch UK, Report no. 01-024-I-GB-04,05, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/13	2001	Evaluate efficacy and selectivity of IKI-220 for registration purposes. Ingenieurbüro Andreas Hetterich, Report no. 00-040-I-D-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/14	2001	Evaluate efficacy and selectivity of IKI-220 for registration purposes. Ingenieurbüro Andreas Hetterich, Report no. 00-040-I-D-02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/15	2000	Efficacy of IKI-220 for control of aphids in potato. Agroplan, Report no. 00-040-I-D-05, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/16	2001	Blattlausbekämpfung in Kartoffeln. Landwirtschaftskammer Hannover, Report	Y	ISK	20110285 THG	05.04.2004

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		no. 01-013-I-D-04, GEP / Unpublished				
OECD IIIA, 6.1.3/17	2001	Blattlausbekämpfung in Kartoffeln . Landwirtschaftskammer Hannover, Report no. 01-013-I-D-05, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/18	2001	Blattläuse an Kartoffeln. Landwirtschaftskammer Weser-Ems, Report no. 01-013-I-D-07, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/19	2001	Report no. 01-013-I-D-13, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/20	2002	Blattläuse an Kartoffeln Landwirtschaftskammer Hannover, report no. GPO02-EF01-DE01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/21	2002	PP 1/24 (2) BBA Blattläuse an Kartoffeln Landwirtschaftskammer Weser-Ems, report no. GPO02-EF01-DE02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/22	2002	PP 1/24 (2) BBA Blattläuse an Kartoffeln Landwirtschaftskammer Westfalen-Lippe, report no. GPO02-EF01-DE03, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/23	2003	Efficacy of IKI-220 against aphids in potato. Ingenieurbüro Andreas Hetterich, report no. GPO02-EF01-DE04, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/24	2003	Evaluation of the efficacy of IKI-220 for aphid control in potatoes in Germany 2002. Versuchswesen pflanzenschutz Dr. Paul Reh, report no. GPO02-EF01-DE05, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA,	2003	Efficacy of IKI-220 against aphids in potato.	Y	ISK	20110285 THG	05.04.2004

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6.1.3/25		Agrostat GmbH, report no. GPO02-EF01-DE06, GEP / Unpublished				
OECD IIIA, 6.1.3/26	2002	Efficacy of IKI-220 against aphids in potato. Staphyt / GPO02-EF01-FR02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.3/27	2002	Efficacy of IKI-220 against aphids in potato – control of aphids in ware potatoes. De Bredelaar N.V., report no. GPO02-EF01-NL01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.4.2/01	2000	IKI-220 Crop safety, yield, germination test and taint tests on potatoes. Agrisearch, Report no. 00-025-I-F-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.4.2/02	2000	IKI-220 Crop safety, yield, germination test and taint tests on potatoes. Oxford Agricultural Trials Ltd., Report no. 00-025-I-GB-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.4.2/03	2000	IKI-220 Crop safety, yield, germination test and taint tests on potatoes. Oxford Agricultural Trials Ltd., Report no. 00-025-I-GB-02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.4.2/04	2001	Sensory evaluation of potatoes (fresh, quick-frozen and canned) treated with IBE 3894 WG (a.i. IKI-220). CCFRA Technology Ltd., Report no. 00-025-I-GB -01, 02 taint tests, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.4.2/05	2002	IKI-220 Crop safety, yield, germination test and taint tests on potatoes. Oxford Agricultural Trials Ltd., Report no.	Y	ISK	20110285 THG	05.04.2004

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		01-025-I-GB-01, GEP / Unpublished				
OECD IIIA, 6.1.4.2/06	2002	IKI-220 Crop safety, yield, germination test and taint tests on potatoes. Oxford Agricultural Trials Ltd., Report no. 01-025-I-GB-02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.4.2/07	2002	Sensory evaluation of potatoes treated with IBE 3894 Insecticide. CCFRA Technology Ltd. , Report no. 01-025-I-GB-01, 02 taint tests, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.4.2/08	2003	IKI-220 Crop safety, yield, germination test on potatoes - Evaluate selectivity of IKI-220 in potato for registration purposes. Ingenieurbüro Andreas Hetterich, Report no. GPO02-SE01-DE01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.4.2/09	2003	IKI-220 Crop safety, yield, germination test and taint tests on potatoes. Oxford Agricultural trials Ltd., Report no. GPO02-SE01-GB01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.4.2/10	2003	IKI-220 Crop safety, yield, germination test and taint tests on potatoes – Evaluation of the non intentional effects of a new insecticide product in a potato crop. Staphyt, Report no. GPO02-SE02-FR01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.4.2/11	2003	IKI-220 Crop safety, yield, germination test and taint tests on potatoes – Evaluation of the non intentional effects of a new insecticide product in a potato crop. Staphyt, Report no. GPO02-SE02-FR02,	Y	ISK	20110285 THG	05.04.2004

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		GEP / Unpublished				
OECD IIIA, 6.1.4.2/12	2002	Evaluation sensorielle de “Pomme de terre”. Coopagri Bretagne, Report no. GPO02-SE02-FR01, 02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.1.4.2/13	2002	Sensory evaluation of potatoes (fresh, canned and quick-frozen) treated wirh IBE 3894 insecticide (a.i. IKI-220). CCFRA Technology Ltd., Report no. GPO02-SE01-GB01 taint tests / GPO02-SE11-GB01, 02 taint tests, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/01	2000	IKI-220 Crop safety, yield, germination test and taint tests on potatoes. Agro-check, Report no. 00-042-I-D-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/02	2001	IKI-220 Crop safety, yield, germination test and taint tests on potatoes. Ingenieurbüro Andreas Hetterich, Report no. 00-042-I-D-02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/03	2000	IKI-220 Crop safety, yield, germination test and taint tests on potatoes. Agrisearch, Report no. 00-025-I-F-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/04	2000	IKI-220 Crop safety, yield, germination test and taint tests on potatoes. Oxford Agricultural Trials Ltd., Report no. 00-025-I-GB-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/05	2000	IKI-220 Crop safety, yield, germination test and taint tests on potatoes. Oxford Agricultural Trials Ltd., Report no. 00-025-I-GB-02,	Y	ISK	20110285 THG	05.04.2004

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		GEP / Unpublished				
OECD IIIA, 6.2.1/06	2000	IKI-220 Crop safety, yield, germination test and taint tests on potatoes. Oxford Agricultural Trials Ltd., Report no. 00-025-I-GB-01, 02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/07	2002	IKI-220 Crop safety, yield, germination test and taint tests on potatoes / Oxford Agricultural Trials Ltd., Report no. 01-025-I-GB-01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/08	2002	IKI-220 Crop safety, yield, germination test and taint tests on potatoes. Oxford Agricultural Trials Ltd., Report no. 01-025-I-GB-02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/09	2002	IKI-220 Crop safety, yield, germination test and taint tests on potatoes. Oxford Agricultural Trials Ltd., Report no. 01-025-I-GB-01, 02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/10	2002	Evaluation of the crop safety of two applications of IBE 3894 on potatoes and the subsequent viability of the daughter tubers / Agrisearch France, Report no. 01-025-I-F-02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/11	2003	IKI-220 Crop safety, yield, germination test on potatoes - Evaluate selectivity of IKI-220 in potato for registration purposes. Ingenieurbüro Andreas Hetterich, Report no. GPO02-SE01-DE01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA,	2003	IKI-220 Crop safety, yield, germination test	Y	ISK	20110285 THG	05.04.2004

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6.2.1/12		on potatoes. Agrisearch UK, Report no. GPO02-SE01-FR01, GEP / Unpublished				
OECD IIIA, 6.2.1/13	2003	IKI-220 Crop safety, yield, germination test and taint tests on potatoes. Oxford Agricultural trials Ltd., Report no. GPO02-SE01-GB01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/14	2003	IKI-220 Crop safety, yield, germination test and taint tests on potatoes – Evaluation of the non intentional effects of a new insecticide product in a potato crop. Staphyt, Report no. GPO02-SE02-FR01, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.1/15	2003	IKI-220 Crop safety, yield, germination test and taint tests on potatoes – Evaluation of the non intentional effects of a new insecticide product in a potato crop. Staphyt, Report no. GPO02-SE02-FR02, GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/01	1999	Pommier – Effets non intentionnels sur Typhlodromus Pyri. S.P.V. , Report no. 99-008-I-F-51, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/02	1999	Rapport d'expérimentation sur les effets non intentionnels des produits codés IBE 3887 (fongicide) et IBE 3880 (insecticide) sur Typhlodromus Pyri au laboratoire. ENSA-INRA Montpellier, Report no. 99-009-I-F-01 Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/03	2000	Evaluation des effets non intentionnels d'IBE 3894 sur Typhlodromus Pyri en verger.	Y	ISK	20110285 THG	05.04.2004

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		Testapi, Report no. 00-018-I-F-01, Non GEP / Unpublished				
OECD IIIA, 6.2.4/04	2000	Unintended effects of the insecticide IBE 3894 on Predatory Mites in orchards in Southern France. Viti R&D, Report no. 00-018-I-F-52, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.4/05	2001	Define selectivity in the field of the aphicide IBE-3894 on beneficial arthropods. S.P.F. GAB Italia, Report no. 01-031-I-I-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.7/01	2002	Impact of IKI-220 50WG (IBE-3894) on Adjacent Crops and on Succeeding Crops. Ishihara Sangyo Kaisha Ltd., Report no. AL0201-I-08, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/01	1999	Sensibilité de diverses souches de pucerons, au nouvel aphicide IKI220 de la société ISK Biosciences. UPMC-INRA Versailles, Report no. 98-005-I-F-01 Non GEP / unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/02	2000	Sensibilité d'Aphis frangulae (kaltenbach) et Aphis nasturtii (kaltenbach) au nouvel aphicide IKI-220. F.R.E.D.EC., Report no. 99-030-I-F-01, non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/03	2000	Evaluation de l'efficacité de la molécule IKI-220 sue des populations de Sitobion avenae et Aphis nasturtii. F.R.E.D.E.C., Report no. 00-030-I-F-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/04	2001	Evaluation de l'efficacité de la molécule IKI-220 sue des populations de Sitobion	Y	ISK	20110285 THG	05.04.2004

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		avenae et Aphis nasturtii. F.R.E.D.E.C., Report no. 01-030-I-F-01, Non GEP / Unpublished				
OECD IIIA, 6.2.8/05	2001	Evaluation de l'efficacité de la molécule IKI-220 sur des populations de Sitobion avenae et Aphis nasturtii. F.R.E.D.E.C., Report no. 01-029-I-F-01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/06	2001	Efficiency of the test substance IBE 3894 on 3 strains of Aphis Gossypii. Enigma , Report no. 01-008-I-F-02, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/07	2001	Efficiency of the test substance IBE 3894 on 2 strains of Myzus persicae. Enigma, Report no. 01-008-I-F-03, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/08	2002	Evaluation de l'efficacité de la molécule IKI-220 sue des populations de Sitobion avenae et Aphis nasturtii. F.R.E.D.E.C., Report no. GWW02-RS01-FR01 / GPO02-RS01-FR01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/09	2002	Baseline sensitivity of IKI-220 against Aphis gossypii and Myzus persicae in Japan / Ishihara Sangyo Kaisha Ltd. / AL0201-I-06 / GEP: NO / Unpublished	Y	ISK	20110285 THG	05.04.2004
OECD IIIA, 6.2.8/10	2002	Efficiency of the test substance IBE 3894 on 3 strains of Myzus persicae. Enigma, Report no. GLB02-RS01-FR01, Non GEP / Unpublished	Y	ISK	20110285 THG	05.04.2004

- in case of an earlier submission (for an earlier application)