HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 BESLUIT

Op 27 mei 2013 is van

Sumi Agro France
25 Blvd de l'Amiral Bruix
F-75016 PARIS
FRANKRIJK

een aanvraag ontvangen tot herregistratie van de toelating van het gewasbeschermingsmiddel

TACHIGAREN 70 WP

op basis van de werkzame stof hymexazool.

HET COLLEGE BESLUIT tot toelating van bovenstaand middel.

Alle bijlagen vormen een onlosmakelijk onderdeel van dit besluit.

Voor nadere gegevens over deze toelating wordt verwezen naar de bijlagen:
- Bijlage I voor details van de aanvraag en toelating.
- Bijlage II voor de etikettering.
- Bijlage III voor wettelijk gebruik.
- Bijlage IV voor de onderbouwing.

1.1 Samenstelling, vorm en verpakking

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

1.2 Gebruik

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

1.3 Classificatie en etikettering

Mede gelet op de onder “wettelijke grondslag” vermelde wetsartikelen, dienen alle volgende aanduidingen en vermeldingen op de verpakking te worden vermeld:

- De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder “verpakkingsinformatie” in bijlage I bij dit besluit.

- Het toelatingsnummer met een cirkel met daarin de aanduiding van de W-codering zoals vermeld onder “toelatingsinformatie” in bijlage I bij dit besluit.
- De etikettering zoals opgenomen in bijlage II bij dit besluit.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in bijlage III bij dit besluit.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.

1.4 Aflever- en opgebruiktermijn (respijtperiode)

Bij de herregistratie wordt de W-codering van het etiket verhoogd van W.1 naar W.2. De etiketten met W-codering W.1 hebben nog een WG/GA format. Op de etiketten met W.2 wordt alleen het WG vermeld en er wordt een nieuwe restrictiezin voor de bescherming van vogels op het etiket opgenomen. Bovendien wordt na de herregistratie niet langer de combinatie van het gebruik van TACHIGAREN 70 WP in combinatie met een Thiram houdend middel voorgeschreven.
Vanwege de beperkingen in de toepassingsvoorwaarden wordt de respijttermijn voor het afleveren en opgebruiken van bestaande voorraden beperkt. Omdat aanvrager heeft bevestigd dat het middel tussen de datum van dit besluit (1 mei 2015) en eind juli 2015 niet wordt aangewend voor zaadcoating, is er ook geen sprake van risico voortvloeiend uit het gebruik volgens het oude etiket. Het Ctgb stelt daarom respijttermijnen vast tot 1 augustus 2015 zodat aanvrager en gebruikers de tijd hebben om de bestaande voorraden om te labelen.

Het nieuwe gebruiksvoorschrift en de nieuwe etikettering dienen bij de eerstvolgende aanmaak op de verpakking te worden aangebracht. Oude verpakkingen met W-codering W.1 mogen worden afgeleverd en worden opgebruikt tot 1 augustus 2015.

2 WETTELIJKE GRONDSLAG

Besluit	artikel 80, vijfde lid Verordening (EG) 1107/2009 juncto artikel 28, eerste lid, Wet gewasbeschermingsmiddelen en biociden
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Rgb d.d. 13 juni 2011 en Evaluation Manual 1.1

3 BEOORDELINGEN

3.1 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.

3.2 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.

3.3 Risico voor de mens

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

3.4 Risico voor het milieu

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

3.5 Werkzaamheid

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

Bezwaarmogelijkheid

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, 1 mei 2015

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

8733 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20130724 THG
Type aanvraag:	aanvraag tot herregistratie van de toelating van het gewasbeschermingsmiddel
Middelnaam:	TACHIGAREN 70 WP
Formele registratiedatum: *	27 mei 2013
Datum in behandeling name:	18 september 2014
Datum compliance check:	17 februari 2012

* Datum waarop zowel de aanvraag is ontvangen als de aanvraagkosten zijn voldaan.

2 Stofinformatie

Werkzame stof	Gehalte
hymexazool	70%

De stof hymexazool is per 1 juni 2011 geplaatst op Annex I van Richtlijn 91/414/EEG (Directive 2011/5/EC d.d. 20 januari 2011) en vervolgens bij Uitvoeringsverordening (EU) 540/2011 d.d. 25 mei 2011 goedgekeurd. De goedkeuring van deze werkzame stof expireert op 31 mei 2021.

3 Toelatingsinformatie

Toelatingsnummer:	8733 N
Expiratiedatum:	1 mei 2025
Afgeleide of parallel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel
W-codering professioneel gebruik:	2

4 Aflever- en opgebruiktermijnen voor oude etiket

Vorige W-codering professioneel gebruik:	1
Aflevertermijn professioneel gebruik:	1 augustus 2015
Opgebruiktermijn professioneel gebruik:	1 augustus 2015

5 Verpakkingsinformatie

Aard van het preparaat:
Spuitpoeder

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BIJLAGE II Etikettering van het middel TACHIGAREN 70 WP

Professioneel gebruik
de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel: hymexazool

Pictogram	GHS02 GHS05 GHS08 GHS09
Signaalwoord	GEVAAR
Gevarenaanduidingen	H228 Ontvlambare vaste stof. H318 Veroorzaakt ernstig oogletsel H361d Wordt ervan verdacht het ongeboren kind te schaden. H411 Giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P210 Verwijderd houden van warmte, hete oppervlakken, vonken, open vuur en andere ontstekingsbronnen. Niet roken. P273 Voorkom lozing in het milieu. P280 Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen. P305 + P351 + P338 + P310 BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk. Blijven spoelen. Onmiddellijk een ANTIGIFCENTRUM/arts/... raadplegen. P501 Inhoud/verpakking afvoeren naar .... SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
Aanvullende etiketelementen	EUH208 Bevat hymexazool. Kan een allergische reactie veroorzaken. EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.
Kinderveilige sluiting verplicht	n.v.t.
Voelbare gevaarsaanduiding verplicht	n.v.t.

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BIJLAGE III WG van het middel

Wettelijk Gebruiksvoorschrift

Toegestaan is uitsluitend het professionele gebruik als schimmelbestrijdingsmiddel door middel van een zaadbehandeling in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.0. Ctgb juni 2011) onder de vermelde toepassingsvoorwaarden.

Toepassingsgebied	Te bestrijden organisme	Dosering (middel) per toepassing
Suikerbiet	Kiemplantenziekten[1,2]	40 g per eenheid zaad (100.000 zaden)

[1] *Aphanomyces spp.*
[2] *Pythium spp.*

Toepassingsvoorwaarden

Om vogels te beschermen moet blootstelling aan zaden geminimaliseerd worden. Om dit te bereiken dienen bij het uitzaaien van het behandelde zaad specifieke instructies gevolgd te worden die vermeld staan op de zakken behandeld zaad.

Het volgende moet worden vermeld op de zakken met behandeld zaad:

Bij het zaaien
Om de vogels te beschermen moet het behandelde zaad volledig in de bodem worden ondergewerkt; zorg ervoor dat het behandelde zaad ook aan het voorend is ondergewerkt.
Om vogels te beschermen moet u gemorste zaden verwijderen.

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE IV

RISKMANAGEMENT

Contents **Page**

1. Identity of the plant protection product

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FRANKRIJK

1.2 Identity of the active substance

Common name	Hymexazol
Name in Dutch	Hymexazol
Chemical name	5-methylisoxazol-3-ol (or 5-methyl-1,2-oxazol-3-ol)
CAS no	10004-44-1
EC no	233-000-6

The active substance was included in Annex I of Directive 91/414/EEC on 1 June 2011. 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	TACHIGAREN 70 WP
Formulation type	WP
Content active substance	700 g/kg pure active substance

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

1.4 Function

Fungicide.

1.5 Uses applied for

Seed treatment in sugar beet. See GAP in appendix I.

1.6 Background to the application

The application for TACHIGAREN 70 WP concerns a reregistration of the present authorization. However, the present authorization prescribes a combined application of TACHIGAREN 70 WP and a product based on thiram. In the reregistration only solo application of TACHIGAREN 70 WP is applied for with an increased dose.

1.7 Packaging details

1.7.1 Packaging description

Material:	PE bag in a cardboard/fibre drum
Capacity:	25 kg
Type of closure and size of opening:	Lid sealed with metal band
Other information	UN/ADR compliant

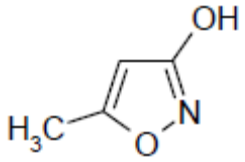
1.7.2 Detailed instructions for safe disposal

No particular recommendations.

2. Physical and chemical properties

The final List of Endpoints presented below is taken from the EFSA Scientific report on hymexazol EFSA Journal (2010) 8(8); 1653 (d.d. 4 November 2010), also taking into account the final review report on hymexazol (SANCO/13057/2010 – final, d.d. 25 November 2010). Where relevant, some additional remarks/information are given in italics.

Identity

Active substance (ISO Common Name)	Hymexazol
Chemical name (IUPAC)	5-methylisoxazol-3-ol (or 5-methyl-1,2-oxazol-3-ol)
Chemical name (CA)	5-methyl-3 (2H)-isoxazolone
CIPAC No	528
CAS No	10004-44-1
EEC No (EINECS or ELINCS)	233-000-6
FAO Specification (including year of publication)	Not available
Minimum purity of the active substance as manufactured (g/kg)	985 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	None
Molecular formula	$C_4H_5NO_2$
Molecular mass	99.15
Structural formula	

Physical-chemical properties

Melting point (state purity)	83.9 - 84.9 ℃ (99.1 %)
Boiling point (state purity)	Hymexazol decomposes before boiling. (99.9 %)
Temperature of decomposition	Decomposes above 180℃ . (99.9 %)
Appearance (state purity)	Yellowish white crystalline solid (99.1 %)
Relative density (state purity)	Density: 0.551 g/ml at 22℃
Surface tension	72.1 mN/m at 20 ℃ , 1 g/l solution (99.96 %)
Vapour pressure (in Pa, state temperature)	0.182 Pa at 25℃ (99.75 %) (extrapolated from measurements at 303 – 323 ℃)
Henry's law constant (in $Pa \cdot m^3 \cdot mol^{-1}$)	1.4×10^{-4} Pa · m^3 · mol^{-1} water solubility (99.1 %): 65.1 g/l at 20 ℃ vapour pressure (99.75 %): 0.0925 Pa at 20 ℃
Solubility in water (in g/l or mg/l, state temperature)	65.1 g/l at 20 ℃, unbuffered water (99.1 %) 58.2 g/l at 20 ℃, pH 3 (99.1 % tech.) 67.8 g/l at 20 ℃, pH 9 (99.1 % tech.)

Solubility in organic solvents (in g/l or mg/l, state temperature)	Solvent: Solubility: acetone 730 g/l at 20 ℃ (99.1 %) dichloromethane 602 g/l at 20 ℃ (99.1 %) ethyl acetate 437 g/l at 20 ℃ (99.1 %) hexane 12.2 g/l at 20 ℃ (99.1 %) methanol 968 g/l at 20 ℃ (99.1 %) toluene 176 g/l at 20 ℃ (99.1 %)
Partition co-efficient (log P_{ow}) (state pH and temperature)	pH 4: log Pow = 1.01 at 25 ℃ (99.8 %) pH 7: log Pow < 0.3 at 25 ℃ (99.8 %) pH 9: log Pow < 0.3 at 25 ℃ (99.8 %)
Hydrolytic stability (DT_{50}) (state pH and temperature)	pH 5: > 1 year at 25 ℃ (not calculated due to insufficient hydrolysis) No hydrolysis products comprising >10 % at 25-50 ˚C pH 7: > 1 year at 25 ℃ (not calculated due to insufficient hydrolysis) No hydrolysis products comprising >10 % at 25-50 ℃ pH 9: > 1 year at 25 ℃ (not calculated due to insufficient hydrolysis No hydrolysis products comprising >10 % at 25-50 ℃)
Dissociation constant	pKa = 5.92 at 20 ℃ (99.75 %)
UV/VIS absorption (max.) (if absorption >290 nm state ε at wavelength)	UV/VIS absorption measured in neutral, acidic and basic water solutions at room temperature. (99.8 %) Maximum absorption at neutral, pH 6.5: λmax = 205.6 nm ε = 6796.4 l · mol^{-1} · cm^{-1} acidic, pH 1.7: λmax = 201.9 nm ε = 10344 l · mol^{-1} · cm^{-1} basic, pH 12.1: λmax = 212.9 nm ε = 5077 l · mol^{-1} · cm^{-1}
Photostability (DT_{50}) (aqueous, sunlight, state pH)	DT_{50} : >1 year (Xenon lamp, spectral intensity of the light was informed to give a good approximation to natural sunlight) No photodegradation products exceeding 10 % of applied levels
Quantum yield of direct photo-transformation in water at λ > 290 nm	Hymexazol was shown to be photolytically stable so quantum yield was not measured.
Photochemical oxidative degradation in air	DT_{50} of 0.6 hrs derived by the Atkinson calculation (AOPWIN ver. 1.86).
Flammability	Not highly flammable. (99.96 %)
Auto-flammability	The test material did not self-ignite on heating to 120 ℃.
Oxidising properties	Not oxidizing. (99.96 %)
Explosive properties	Not explosive. (99.96 %)

2.2 Plant protection product: TACHIGAREN 70 WP

Data on the plant protection product is taken from the DAR (21 June 2007).

There is no significant dilution of the plant protection product, only sufficient water is used to prepare a slurry.

Section (Annex point)	Study	Guidelines and GLP	Findings	Evaluation and conclusion
B.2.2.1 (IIIA 2.1)	Appearance: physical state	GLP: N Visual assessment EPA OPPTS 830.6303	Free flowing powder	Acceptable
B.2.2.2 (IIIA 2.1)	Appearance: colour	GLP: N Visual assessment EPA OPPTS 830.6303	White	Acceptable
B.2.2.3 (IIIA 2.1)	Appearance: odour	GLP: N Organoleptic EPA OPPTS 830.6304	Odourless	Acceptable
B.2.2.4 (IIIA 2.2)	Explosive properties	GLP: N EEC A.14	'TACHIGAREN' 70 WP is not explosive in respect of thermal sensitivity (effect of flame), mechanical sensitivity (shock) and mechanical sensitivity (friction).	Acceptable
		GLP: Y EPA guidel. 63-16	Not explosive.	Acceptable
B.2.2.5 (IIIA 2.2)	Oxidising properties	Statement	Not oxidising	Acceptable
B.2.2.6 (IIIA 2.3)	Flammability	GLP : Y EEC A.10 EEC A.12	The test substance can be considered as highly flammable. The test substance does not react with water and is not considered hazardous.	Acceptable
B.2.2.7 (IIIA 2.3)	Auto-flammability	GLP:Y EEC A.16	No self-ignition was observed below 400 ˚C.	Acceptable
B.2.2.8 (IIIA 2.3)	Flash point	GLP :Y ASTM D56 Tag closed cup	189 ˚C	Acceptable
B.2.2.9 (IIIA 2.4)	Acidity / alkalinity	GLP:Y CIPAC MT31	Acidity 26.4 % w/w (as equivalent sulphuric acid) at 20 ˚C.	Acceptable
B.2.2.10 (IIIA 2.4)	pH	GLP:Y CIPAC 75	1 % w/v dispersion in water at 20 ˚C. pH 3.51	Acceptable
B.2.2.11 (IIIA 2.5)	Surface tension		Not applicable	
B.2.2.12 (IIIA 2.5)	Viscosity		Not applicable	

Section (Annex point)	Study	Guidelines and GLP	Findings	Evaluation and conclusion
B.2.2.13 (IIIA 2.6)	Relative density		Not applicable	
B.2.2.14 (IIIA 2.6)	Bulk (tap) density	GLP:Y equivalent to CIPAC MT 33	Tap density: 0.319 g/ml	Acceptable
B.2.2.15 (IIIA 2.7)	Storage stability	GLP:Y CIPAC Mt 46	14 days at 54˚C, no packaging specified. The following properties were determined before and after storage: Appearance, particle size distribution, pH and content a.i.. No significant changes occurred.	Acceptable The packaging has not been specified. Since an acceptable shelf life has been assessed, the accelerated storage stability study is not required.
B.2.2.16 (IIIA 2.7)	Shelf life	GLP:Y CropLife technical monograph No. 17	2 years at 10 – 30 ˚C in LDPE/cardboard The following properties were determined before and after storage: Appearance, particle size distribution, pH and content a.i.. No significant changes occurred.	Acceptable
B.2.2.17 (IIIA 2.8)	Wettability	GLP:Y CIPAC MT 53.3	26 seconds without swirling After 24 months at RT wettability times in CIPAC water D 7 seconds with swirling	Acceptable
B.2.2.18 (IIIA 2.8)	Persistent foaming	Statement	The product is applied as a seed treatment to sugar beet as a slurry in small volumes of water and/or other plant protection seed treatments and inert materials. There is no significant dilution of the product, only sufficient water is used to prepare a slurry. Not applicable for solid preparation.	Acceptable
B.2.2.19 (IIIA 2.8)	Suspensibility	Statement	The product is applied as a seed treatment to sugar beet as a slurry in small volumes of water and/or other plant protection seed treatments and inert materials.	Acceptable

Section (Annex point)	Study	Guidelines and GLP	Findings	Evaluation and conclusion
			There is no significant dilution of the product, only sufficient water is used to prepare a slurry. Not applicable for solid preparation.	
B.2.2.20 (IIIA 2.8)	Spontaneity of dispersion		Not applicable	
B.2.2.21 (IIIA 2.8)	Dilution stability		Not applicable	
B.2.2.22 (IIIA 2.8)	Dry sieve test		Not applicable	
B.2.2.23 (IIIA 2.8)	Wet sieve test	GLP:Y CIPAC MT 59.3	After 24 months at RT the test substance all passed through a 38 µm test sieve.	Acceptable
B.2.2.24 (IIIA 2.8)	Particle size distribution	GLP:Y CIPAC MT 59.1	(% of recovered sample) 850 – 250 µm 3.32 % 250 – 150 µm 96.90 % 150 µm 100 %	Acceptable
B.2.2.25 (IIIA 2.8)	Content of dust/fines		Not applicable	
B.2.2.26 (IIIA 2.8)	Attrition and friability		Not applicable	
B.2.2.27 (IIIA 2.8)	Emulsifiability, re-emulsifiability and emulsion stability		Not applicable	
B.2.2.28 (IIIA 2.8)	Stability of dilute emulsion		Not applicable	
B.2.2.29 (IIIA 2.8)	Flowability		Not applicable	
B.2.2.30 (IIIA 2.8)	Pourability (rinsibility)		Not applicable	
B.2.2.31 (IIIA 2.8)	Dustability		Not applicable	
B.2.2.32 (IIIA 2.8)	Adherence and distribution to seeds	GLP:Y CIPAC MT 175 MT147	The initial hymexazol loading of the treated seed was 91% of nominal. Adhesion testing showed no change in the mean concentration of hymexazol (91 %) on the treated seeds	Acceptable

Section (Annex point)	Study	Guidelines and GLP	Findings	Evaluation and conclusion
			following the test. Uniformity of loading testing showed individual seed loadings of 260 - 667 µg with a mean of 417 µg/seed (85 % of nominal) and a RSD value of 19 %.	
2.9.1	Physical compatibility with other products		No mixing proposed	
2.9.2	Chemical compatibility with other products		No mixing proposed	

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

The final List of Endpoints presented below is taken from the EFSA Scientific report on hymexazol EFSA Journal (2010) 8(8); 1653 (d.d. 4 November 2010). Where relevant, some additional remarks/information are given in italics.

3.1 Analytical methods in technical material and plant protection product

Technical as (principle of method)	HPLV-UV at 240.
Impurities in technical as (principle of method)	Titration, selective electrodes, ion chromatography and atomic emission spectroscopy
Preparation (principle of method)	HPLV-UV at 240.

Conclusion
The analytical methods regarding the technical active substance and the preparation have been assessed in the DAR and are considered to be acceptable.

3.2 Residue analytical methods

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	LC-MS/MS 0.05 mg/kg for hymexazol in sugar beet (roots and tops) and tomato (fruit)
Food/feed of animal origin	No residue definition is established,

(principle of method and LOQ for methods for monitoring purposes)	no analytical method is required.
Soil (principle of method and LOQ)	LC-MS/MS 0.05 mg/kg for hymexazol
Water (principle of method and LOQ)	LC-MS/MS 0.1 µg/l for hymexazol in drinking and surface water
Air (principle of method and LOQ)	LC-MS/MS 2 µg/m^3 for hymexazol
Body fluids and tissues (principle of method and LOQ)	Hymexazol is not classified as toxic or very toxic, no analytical method is required.

Based on the proposed use of the plant protection product analytical methods for determination of residues in food/feed of plant origin are required for matrices with a high water content (sugar beets).

Definition of the residue and MRLs for hymexazol		
Matrix	**Definition of the residue for monitoring**	**MRL**
Food/feed of plant origin	hymexazol	0.1 mg/kg (sugar beet)
Food/feed of animal origin	None	None
		Required LOQ
Soil	hymexazol	0.05 mg/kg (default)
Drinking water	hymexazol	0.1 µg/L (drinking water guideline)
Surface water	hymexazol a data gap needs to be filled before it can be concluded if RMH-1915 can be excluded from the definition or not	0.1 µg/L
Air	hymexazol	51 µg/m^3 (derived from the AOEL of 0.17 mg/kg bw/d 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 abovementioned List of Endpoints, are suitable for monitoring of the MRLs.

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 Conclusion on the peer review of the pesticide risk assessment of the active substance hymexazol (EFSA Journal 2010; 8(7): 1653). Where relevant, some additional remarks/information are given in italics.

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Rapid and extensive (>95% within 24h) based on excretion in urine. Maximum blood concentration reached at 0.5 h after low dose administration.
Distribution ‡	Small amount found in carcass (0.3 %) and in all other tissues combined (less than 0.01 %) 168 h after administration.
Potential for accumulation ‡	No evidence of accumulation.
Rate and extent of excretion ‡	>95 % excreted in urine and 1 % in faeces within 24 h. Slightly lower excretion rate at high dose level and in females.
Metabolism in animals ‡	Extensively metabolised, mainly by conjugation with sulphuric acid and glucuronic acid to form hymexazol-O-sulfate (TOS, about 50 % at the low dose level) and hymexazol-O-glucuronide (TOGL, about 40 % at the low dose level). Another minor pathway involves enzymatic reduction to form 3-hydroxybutamide and 3-hydroxybutyric acid.
Toxicologically relevant compounds ‡ (animals and plants)	Hymexazol
Toxicologically relevant compounds ‡ (environment)	Hymexazol

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	1600 mg/kg bw	**R22**
Mouse LD_{50} oral	1700 mg/kg bw	
Rabbit LD_{50} dermal ‡	> 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 0.65 mg/l/4 h (highest attainable concentration, aerosol, whole body)	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Severe corneal opacity with hyperaemic blood vessels.	**R41**
Skin sensitisation ‡	Sensitising (Magnusson-Kligman maximisation test)	**R43**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Liver: blood biochemical changes and centrilobular hepatocyte enlargement (rat, mouse); increased weight (dog) Decreased body weight (rat).	
Relevant oral NOAEL ‡	Rat: 371 mg/kg bw/d (90-d) Mouse: 55 mg/kg bw/d (90-d) Dog: 17 mg/kg bw/d (1-year)	
Relevant dermal NOAEL ‡	No data, not required	
Relevant inhalation NOAEL ‡	No data, not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

Slightly clastogenic at high dose level in an *in vivo* chromosome aberration test in rats. No genotoxic potential in an *in vivo* micronucleus test in mice. Unlikely to be genotoxic in humans	

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

Target/critical effect ‡	Reduced body weight (gain) (rat, mouse) **Liver**: increased weight (rat, mouse), blood biochemical changes (rat), centrilobular hepatocyte enlargement (rat), granulomatous inflammation and necrosis (mouse) **Thyroid**: increased weight (rat) **Kidney**: increased weight (mouse)	
Relevant NOAEL ‡	Rat: 99 mg/kg bw/d (2-yr) Mouse: 355 mg/kg bw/d (91-wk)	
Carcinogenicity ‡	No evidence of a tumorigenic effect at the high doses tested (532 mg/kg bw/d in rats; 2994 mg/kg bw/d in mice)	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental and offspring: no adverse effects Reproduction: slightly extended gestation length, increased post-implantation loss and reduced litter size (days 1 to 4 post-partum)	
Relevant parental NOAEL ‡	159 mg/kg bw/d (2500 ppm)	
Relevant reproductive NOAEL ‡	31 mg/kg bw/d	
Relevant offspring NOAEL ‡	159 mg/kg bw/day (2500 ppm)	

Developmental toxicity

Developmental target / critical effect ‡	**Maternal**: no adverse effect (rat); mortalities and clinical signs, decreased body weight during early gestation (rabbits) **Developmental**: reduced foetal weight (rat, rabbit), increased post-implantation loss (rabbit), skeletal variations (rat), heart/great vessels malformations (incomplete inferior vena cava, rabbit)	**Repr Cat 3** **R63**
Relevant maternal NOAEL ‡	Rat: 500 mg/kg bw/d Rabbit: 150 mg/kg bw/d	
Relevant developmental NOAEL ‡	Rat: 100 mg/kg bw/d Rabbit: 50 mg/kg bw/d	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available. No concern from other studies.
Repeated neurotoxicity ‡	No data available. No concern from other studies.
Delayed neurotoxicity ‡	No data available. No concern from other studies.

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data available. Not required.

Medical data ‡ (Annex IIA, point 5.9)

	No evidence of adverse effects to workers of manufacturing plants, agricultural workers and consumers.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.17 mg/kg bw/d	1-yr dog	100
AOEL ‡	0.17 mg/kg bw/d	1-yr dog	100
ARfD ‡	0.5 mg/kg bw	dev tox, rabbit	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

In vitro, human; study performed with the active substance	In the absence of study with the representative formulations (TACHIGAREN 30L and TACHIGAREN 70W): 100 % dermal absorption for the concentrate and the dilution (default).

Local effects
Hymexazol produces local effects after a single exposure (eye irritation and skin sensitisation), but these local effects are covered in the risk assessment/management by means of assignment of H- and P-statements. Hymexazol does not produce local effects after repeated exposure.

Data requirements active substance
No additional data requirements are identified.

4.1 Toxicity of the formulated product (IIIA 7.1)
The formulation TACHIGAREN 70 WP does not need to be classified on the basis of its acute oral (LD_{50} rat ≥ 2800 mg/kg bw), dermal (LD_{50} rat >2000 mg/kg bw), and inhalation toxicology (LC_{50} rat > 4.53 mg/L).

The formulation TACHIGAREN 70 WP is considered not irritating to skin.

The formulation TACHIGAREN 70 WP is considered severely irritating to eyes and needs to be classified as H318 ‘Causes serious eye damage’.

The formulation TACHIGAREN 70 WP does not have sensitising properties in a Maximisation and Buehler test.

4.1.1 Data requirements formulated product
No additional data requirements are identified.

4.2 Dermal absorption (IIIA 7.3)
The applicant provided an in vitro dermal absorption study using human skin membranes with TACHIGAREN 70 WP. The applicant derived a dermal absorption value of 16% for the 350 g/kg preparation, 16% for a 350 g/L solution, and 62% for a 21 g/L solution. Dermal delivery values (exposed skin after tape stripping + receptor fluid + receptor rinse + receptor wash) were taken as >75% of the dose was absorbed after half of the study duration. However, according to the 2012 EFSA guidance on dermal absorption, which is applicable to the current application, these values should be increased by the SD as it is > 25%, and corrected for the recovery values as they are <95%. This would results in (rounded) dermal absorption values of 28% ((15.92+8.55)*100/88.98), 24% ((16.31+6.01)*100/91.46), and 104% ((62.04+16.43)*100/75.12) for the 350 g/kg preparation, 350 g/L solution and 21 g/L solution, respectively. According to OECD 428 studies with recoveries <90% are not acceptable if the low recovery cannot be explained. Hymexazol is a volatile substance and the losses in recovery could be related to the volatility. Nonetheless the dilution value is not

accepted since the recovery deviates to much from the 90% and the other two values are corrected for the recovery according to the EFSA guidance on dermal absorption. This results in (rounded) dermal absorption values of 28% ((15.92+8.55)*100/88.98) and 24% ((16.31+6.01)*100/91.46), for the 350 g/kg preparation and 350 g/L solution, respectively.

Potential exposure would be to concentrated product and therefore 28% is used as a dermal absorption value in the current application.

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

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

Since hymexazol is included approved under Regulation (EC) No 1107/2009, the (semi-)chronic EU-AOEL of 0.17 mg/kg bw/day (= 11.9 mg/day for a 70-kg operator), based on the 1-yr study in dog is used for the risk assessment (see List of Endpoints).

The formulation TACHIGAREN 70 WP is applied as a seed treatment, in which seeds are treated in a closed system in an industrial setting, and the seeds are planted mechanically. Exposure during seed treatment is considered to be covered by the Risk Inventarisation & Evaluation (RI&E) of the facility.

4.4.2 Bystander exposure/risk

No bystander presence is anticipated during professional seed coating treatment.

4.4.3 Worker exposure/risk

Worker exposure can occur when seeds are sown in the field. Farmers handle treated seeds when loading the hopper of the sowing equipment and performing the sowing operations. For the scenario loading and sowing of seeds no EU-wide accepted model is available.

For these operations, the applicant did not provide exposure estimates; according to the applicant TACHIGAREN 70 WP is contained within the hard film coating covering pelleted sugar beet seeds and pelleted sugar beet seeds are generally recognised to release minimal dust; therefore, worker dermal and inhalation exposure from sowing seeds is expected to be negligible. Below, however, in table 1, worker exposure is estimated for both loading and sowing procedures using SeedTROPEX. As the estimations are based on a study exposure from grain, without the hard covering film, the scenario can be considered as a worst case for the worker exposure to hymexazol as a result of the application of TACHIGAREN 70 WP.

Table T.1 Internal worker exposure to hymexazol and risk assessment after application of TACHIGAREN 70 WP

Route	Estimated internal exposure [a] (mg /day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Loading and sowing of sugar beet seeds			
Respiratory	0.16	11.9	0.01
Dermal	3.31	11.9	0.28
Total	3.47	11.9	0.29

a External exposure was estimated with [SeedTROPEX. Internal exposure was calculated with:
- Geometric mean; an 8 hour working day
- biological availability via the dermal route: 28% (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.

Shortly after seeding it is not necessary to perform any re-entry activities during which intensive contact with the treated crop will occur. Therefore no worker exposure for re-entry is calculated.

4.4.4 Re-entry

See 4.4.3 Worker exposure/risk.

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

The product complies with the Uniform Principles.

Operator exposure

The coating of seeds in the Netherlands is a highly technological process which is not expected to be performed by agricultural operators but only in closed industrial systems. This industrial process is under control of industrial safety authorities and agricultural professional associations. This guarantees that both the production plants themselves and the way they are run correspond to modern standards, and that safety measures are maintained. It is assumed that these plants periodically perform the proper RI&E (Risk Inventory and Evaluation) assessments.

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 hymexazol during application of TACHIGAREN 70 WP in the seed treatment of sugar beet seeds.

Worker exposure

Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected worker after dermal and respiratory exposure during re-entry activities in the seed treatment of sugar beet seeds due to exposure to hymexazol after application of TACHIGAREN 70 WP.

Shortly after seeding it is not necessary to perform any re-entry activities during which intensive contact with the treated crop will occur. Therefore no worker exposure for re-entry is calculated.

4.5 Appropriate mammalian toxicology and operator exposure end-points 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
TACHIGAREN 70 WP 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 obtained from the EFSA peer review (EFSA Journal 2010 8(8):1653).

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

Plant groups covered	Tomato (F)
Rotational crops	None studied
Metabolism in rotational crops similar to metabolism in primary crops?	No studies available on identification
Processed commodities	Tomato
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes under simulated pasteurisation conditions. The residue pattern under simulated baking, brewing, boiling and sterilization is not known.
Plant residue definition for monitoring	Hymexazol
Plant residue definition for risk assessment	Hymexazol and glucoside conjugates (hymexazol-O-monoglucoside, hymexazol-O-diglucoside and hymexazol-N-monoglucoside) expressed as hymexazol.
Conversion factor (monitoring to risk assessment)	8 (tomato)

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

Animals covered	Not required. Significant consumption of tomatoes by livestock is considered unlikely.
Time needed to reach a plateau concentration in milk and eggs	Not relevant
Animal residue definition for monitoring	Not relevant
Animal residue definition for risk assessment	Not relevant
Conversion factor (monitoring to risk assessment)	Not relevant
Metabolism in rat and ruminant similar (yes/no)	Not relevant
Fat soluble residue: (yes/no)	No, $\log_{ow}$ not higher than 1.01.

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

In soil below-LOQ-situation was reached for hymexazol only at 4 weeks in the southern EU test site after two treatments with 'TACHIGAREN' 30 equivalent to 5.4 kg hymexazol/ha and intervals of 0, 14, 21, 28, 42, and 70 days. On this basis an interval of at least six weeks after the final application of 'TACHIGAREN' 30 L was set.

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

In tomato 9 months at -20℃. Residues are not stable in sugar beet. After one month 11% remained.

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)	No	No	No
Potential for accumulation (yes/no):			
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Not submitted	Not submitted	Not submitted
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	-	-	-
Liver	-	-	-
Kidney	-	-	-
Fat	-	-	-
Milk	-		
Eggs		-	

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Tomato, puree	~~4~~ 2	2.7		
Tomato, juice	~~4~~ 2	0.8		
Tomato, canned fruit	~~4~~ 2	0.7		

Comments on/additions to List of Endpoints
No comments.

5.1 Summary of residue data

The following assessment is based on the EFSA peer review (EFSA Journal 2010 8(8):1653), the DAR (2007) and its addendum (2010), and the Addendum containing confirmatory data (revised version of February 2014).

Only points that are not covered by the List of Endpoints or that need clarification are discussed below.

5.1.1 Metabolism in plants

The PRAPeR Expert Meeting TC 29 concluded that the submitted sugar beet metabolism study was not considered acceptable due to significant concerns about the storage stability of hymexazol and uncertainty regarding the application rate and method of application. Therefore, during the peer review, the nature of the residues in root crops has not been confirmed and the risk assessment for this use could not be concluded upon. Confirmatory information was requested. The confirmatory study has now been submitted and evaluated in an Addendum (Circabc, revised version of February 2014). It has also been peer reviewed. The metabolism study addresses the data gap. The sugar beet seed treatments resulted in low residue levels (TRR <0.01 mg/kg), and no further identification was required.

5.1.2 Metabolism in livestock

During the peer review, animal metabolism studies were not required, since no significant animal intake was expected from tomatoes. Also for the current application for authorization, animal metabolism studies are not required (see 5.1.7).

5.1.3 Residue definition (plant and animal)

The plant residue definition for monitoring has been confirmed for root crops: hymexazol parent only. No clear conclusion is available in the Addendum on the plant residue definition for risk assessment for root crops. However, since the TRR was <0.01 mg/kg, it was concluded for this application, that the plant residue definition for monitoring can also be applied for risk assessment.

During the peer review no residue definition for animals has been established.

5.1.4 Stability of residues

It has been concluded in the peer review that residues in sugar beet are not stable. After one month only 11% of the residues remained. However, samples from the supervised residue trials were not stored, but analyzed as quickly as possible, immediately after harvest. Therefore, storage stability is not relevant for the samples from these trials.

5.1.5 Supervised residue trials

Sugar beet, cGAP-NL: 1x 42 g as/ha, 28 g as/100.000 seeds, seed treatment (based on a maximum seed rate of 1.5 unit/ha and a concentration of 28 g as./unit seeds (1 unit = 100,000 seeds))
Six supervised residue trials are available in NEU, and have been evaluated in the DAR. Only in the trials from 2003, analysis was performed as quickly as possible and, therefore, only these four trials are acceptable. The trials were performed according to a more critical GAP, because the applied dose rate was 44 g as/100,000 seeds. However, since there is a zero residues situation, this is considered acceptable. Residues in both sugar beet roots and leaves were <0.05 mg/kg. Sugar beet is a major crop, therefore, eight trials are required. Four trials are available. However, since in all four trials the residues were below the LOQ (0.05 mg/kg), four trials are sufficient.

The current EU-MRL in sugar beet is 0.1 mg/kg. Based on the available trials the intended use is covered by the current EU-MRL.

5.1.6 Residues in succeeding crops

No studies in rotational crops with hymexazol are available. However, in the DAR residue levels in different soils after soil drench application (5.4 kg as/ha) in Southern Europe were evaluated. No hymexazol residues above the LOQ were found in the soils 42 days after the application.
In this study the application rate was much more critical that the proposed cGAP for sugar beet seed treatment (0.042 kg as/ha). Therefore, it was concluded in the DAR that residues of hymexazol are not expected in the soil after harvest of sugar beet after the seed treatment with hymexazol.

5.1.7 Residues from livestock feeding studies

For the current application, the residue levels measured in the sugar beet metabolism study have been used to calculate the dietary burden, since these levels (<0.01 mg/kg in both roots and leaves) provide a more realistic calculation than using the residue values from the supervised residue trials (<0.05 mg/kg). The trigger of 0.1 mg/kg DM is not exceeded. Therefore, animal metabolism studies as well as livestock feeding studies are not required.

5.1.8 Processing factors

Not required, since residues in sugar beets are below the trigger value of 0.1 mg/kg.

5.1.9 Calculation of the ADI and the ARfD

Calculation of the ADI
The ADI is based on the NOAEL of 17 mg/kg bw/d in the 1 year dog study. Application of a safety factor for inter- and intraspecies differences of 100 results in an ADI of 0.17 mg/kg bw/day (see the List of Endpoints for mammalian toxicology).

Calculation of the ARfD
The ARfD is based on the NOAEL of 50 mg/kg bw/d in the developmental tox study in rabbits. Application of a safety factor for inter- and intraspecies differences of 100 results in an ARfD of 0.5 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

Input values
The following input values were used for the consumer risk assessment.

Table R1: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Tomatoes	8	MRL x conversion factor (1 x 8)	-	
Sugar beet	0.1	MRL	0.1	MRL
All other commodities	MRLs		-	

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, including the conversion factor for tomatoes. The maximum TMDI is 15.8 % of the ADI for WHO Cluster diet B. The TMDI is 2.6 % and 4.8 % 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 temporary EU-MRL for sugar beets. The percentage of the ESTI is 1.3 % of the ARfD for sugar beets for UK children aged 4-6 years.

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

5.4 Data requirements
No data requirements were identified.

6. Environmental fate and behaviour

The underlying risk assessment is based on the final list of endpoints (LoEP) from the EFSA conclusion for hymexazol (EFSA Journal, 2010, 8(7): 1653).

List of Endpoints Fate/behaviour (EFSA Journal 2010; 8(7):1653)

Fate and behaviour in the environment

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

Mineralization after 100 days ‡	-65.3% after 50 d (25℃, 75% FMC 1/3 bar moisture), [^{14}C-isoxazole]-label (n[1]= 1) -58.7-69.6% after 90 d and 59.3-73.5% after 120 d (20℃, pF 2 moisture), [^{14}C-isoxazole]-label (n= 3)
Non-extractable residues after 100 days ‡	-28.0% after 50 d (25℃, 75% FMC 1/3 bar moisture), [^{14}C-isoxazole]-label (n= 1) -15.7- 26.9% after 90 d and 14.8-25.7% after 120 d (20℃, pF 2 moisture), [^{14}C-isoxazole]-label (n= 3)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	No major metabolites observed (i.e. ≥ 10% of applied radioactivity), [^{14}C-isoxazole]-label

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

Anaerobic degradation ‡	
Mineralization after 100 days	23.6 % after 60 d,[^{14}C-isoxazole]-label (n= 1)
Non-extractable residues after 100 days	22.8 – 27.3 % throughout the anaerobic phase of incubation (0 - 60 d), [^{14}C-isoxazole]-label (n= 1)
Metabolites that may require further	Two components observed at levels ≥ 10%:

[1] n corresponds to the number of soils.

consideration for risk assessment - name and/or code, % of applied (range and maximum)	-Acetoacetamide: maximum 27.8% after 3 d flooded conditions, declined to 2.1% after 60 d flooded conditions -Crotonic acid: maximum 18.3% after 14 d flooded conditions, declined to 2.6% after 60 d flooded conditions. [^{14}C-isoxazole]-label (n= 1)

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No major metabolites were observed (i.e. ≥ 10% of applied radioactivity). [^{14}C-isoxazole]-label (n= 1)

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	org. C[2] (%)	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam	0.84	7.9	25 °C / 75 %	7.9 / 26.2	6.6[1]	0.953	SFO
Sandy loam	3.9	5.6	20 °C / 100 %	15.1 / 50.2	15.1	0.991	SFO
Sandy loam	1.1	8.4	20 °C / 100 %	15.4 / 51.1	15.4	0.859	SFO
Loamy sand	0.8	7.1	20 °C / 100 %	31.5 / 104.5	31.5	0.971	SFO
Loamy sand	0.8	7.1	10 °C / 100 %	101 / 335	n.a.[2]	0.984	SFO
Geometric mean					14.8 (n=4)		

1 = Normalisation assumed a Q10 of 2.58 and Walker equation coefficient of 0.7

2 = The study was conducted using the loamy sand soil presented above, but the degradation rate was not recalculated as an incubation at 20 °C was available for this soil.

No significant degradation products observed

[2] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	Data range (d)[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
Sandy clay loam	ES	0 - 28	NA	20	11.1	36.8	0.991	-	Day length adjustm.
Geometric mean/median								-	

NA = Not available

pH dependence ‡ (yes / no) (if yes type of dependence)	Hymexazol degradation in soil is not pH dependant.
Soil accumulation and plateau concentration ‡	Due to the rapid degradation of hymexazol observed in laboratory studies no studies have been performed nor required.

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	org. C[3] (%)	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam	0.84	7.9	25 °C /75 %	11.4 41.8	n.a.	1.00	Aerobic phase SFO
Sandy loam	0.84	7.9	25 °C /n.a.	1.64 5.43	n.a.	0.80	Anaerobic phase 1 (0-3 d) SFO
Sandy loam	0.84	7.9	25 °C /n.a.	76.8 255	n.a.	0.98	Anaerobic phase 2 (3-60 d) SFO
Geometric mean/median							

Acetoacetamide	Anaerobic conditions							
Soil type	Org. C[1] (%)	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam	0.84	7.9	25 °C /n.a.	4.0 13.0		n.a.		Estimated visually
Geometric mean/median								

[3] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Crotonic acid	Anaerobic conditions							
Soil type	Org. C[1] (%)	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam	0.84	7.9	25 °C /n.a.	14.0 46.0		n.a.		Estimated visually
Geometric mean/median								

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam	1.3	5.7	1.10-2.14		1.29	99	0.87
Silty clay loam	2.5	6.4	2.86-4.31		3.09	124	0.93
Clay loam	1.7	7.4	0.24-0.61		0.34	20	0.79
Clay loam 2	3.1	7.8	0.57-1.99		0.85	27	0.75
Sandy loam	1.3	8.0	0.11-0.36		0.15	12	0.74
Arithmetic mean						56.5	0.816
pH dependence, Yes or No			Hymexazol adsorption to soil is pH dependant, adsorption is weaker in alkaline soil.				

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

Column leaching ‡	No studies submitted nor required
Aged residues leaching ‡	Aged for (d): 3 d Time period (d): 2 d Eluation (mm): 200 mm
	Analysis of soil residues post ageing (soil residues pre-leaching): 21 % active substance
	Leachate: 26 % total residues/radioactivity in leachate (19.6 % CO_2, remaining 3.2 % consisted of a single component of intermediate polarity, not either hymexazol or acetoacetamide) 53.7 % total residues/radioactivity retained in top 6 cm
Lysimeter/ field leaching studies ‡	No studies submitted nor required

PEC (soil) (Annex IIIA, point 9.1.3) 'TACHIGAREN' 30 L

Parent Method of calculation	DT_{50} (d): 31.5 days Kinetics: SFO Field or Lab: representative worst case from laboratory studies.
Application data	Crop: tomato Depth of soil layer: 20cm Soil bulk density: 1.5g/cm^3 % plant interception: soil drench application therefore no crop interception Number of applications: 3 Interval (d): 14 d Application rate(s):0.54, 0.72 and 0.72 kg as/ha

PEC (soil) (Annex IIIA, point 9.1.3) 'TACHIGAREN' 70 WP

Parent Method of calculation	DT_{50} (d): 31.5 days Kinetics: SFO Field or Lab: representative worst case from laboratory studies.
Application data	Crop: sugar beet dressing Depth of soil layer: 5 cm Soil bulk density: 1.5g/cm^3 % plant interception: seed dressing therefore no crop interception Number of applications: 1 Interval (d): 365 d Application rate(s):72.45 g as/ha

No major metabolites were found in the aerobic degradation studies.

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: > 1 year at 25 ℃ (not calculated due to insufficient hydrolysis) No hydrolysis products comprising >10 % at 25-50 ^oC pH 7: > 1 year at 25 ℃ (not calculated due to insufficient hydrolysis) No hydrolysis products comprising >10 % at 25-50 ^oC pH 9: > 1 year at 25 ℃ (not calculated due to insufficient hydrolysis No hydrolysis products comprising >10 % at 25-50 ^oC)

Photolytic degradation of active substance and metabolites above 10 % ‡	DT_{50} : >1 year (Xenon lamp, spectral intensity of the light was informed to give a good approximation to natural sunlight) No photodegradation products exceeding 10 % of applied levels
Quantum yield of direct phototransformation in water at Σ > 290 nm	Hymexazol was shown to be photolytically stable so quantum yield was not measured.
Readily biodegradable ‡ (yes/no)	Not readily biodegradble

Degradation in water / sediment

Parent	Distribution: Max in water 92 % of ARA after 0.25 d, 60-67 % after 2 d. Declined to 1-2 % after 28 d. Max. sed 1-3 % after 1-2 d. (NL systems) Max in water 25.66 % of ARA after 7 d, 6.46 % after 14 d. (UK system)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calcul.
TNO, NL (clay loam)	8.9	7.3	20	2.4 – 8.0	0.981	2.3 – 7.8	0.983	-		1st order kinetics
Kromme Rijn, NL (sandy loam)	6.8	7.5	20	3.1 – 10.1	0.995	3.0 – 9.8	0.995	-		1st order kinetics
(Emperor lake, Derbyshire, UK)	6.7	6.2	20	not calculated		not calculated		not calculated		-
Geometric mean/median (n=2)				2.7 - 9		2.7 – 8.8		-		

Metabolites	
Acetoacetic acid	Distribution: max in water 4 % after 1 d. Max. sed 2 % after 1-7 d. (NL systems)
unknown met. 1	Distribution: max in water 14 % after 14 d. Max. sed 2 % after 2-7 d. (NL systems)
unknown met. 2	Distribution: max in water 4 % after 2-14 d. Max. sed 5 % after 7 d. (NL systems)
RMH-1915 = 5-methyl-2(3H)-oxazolone	Distribution: max in water 17.19 % after 14 d. (UK system)

unidentified A (multiple components)	Distribution: max in water 16.27 % after 14 d. (UK system)
unidentified B (dissolved CO_2)	Distribution: max in water 19.21 % after 7 d. (UK system)

Mineralization and non extractable residues

Water / sediment system	pH water phase	pH sed	Mineralization	Non-extractable residues in sed. (maximum)	Non-extractable residues in sed. (end of the study)
TNO, NL (clay loam)	8.9	7.3	CO_2 52.2 % of ARA after 105 d.	40.2 % of ARA after 63 d.	39.3 % of ARA after 105 d.
Kromme Rijn, NL (sandy loam)	6.8	7.5	CO_2 74.0 % of ARA after 105 d.	29.5 % of ARA after 28 d.	21.5 % of ARA after 105 d.
Emperor lake, Derbyshire, UK	6.7	6.2	CO_2 72 % of ARA after 42 d.	23 % of ARA after 14 d.	16 % of ARA after 105 d.

PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3) 'TACHIGAREN' 30 L (outdoor use)

Parent Parameters used in FOCUSsw step 1 and 2	FOCUS surface water guidelines, SANCO/4802/2001-rev 2. Steps 1 and 2. Molecular weight: 99.15 g/mol Water solubility: 65100 mg/l Koc: 20 mL/g for alkaline soils, 112 mL/g for neutral/acidic soils DT50 soil: 17.4 d (laboratory data, 20 °C) DT50 water: 2.7 d DT50 sediment: 17.4 d (soil, laboratory data) DT50 combined: 2.8 d Crop interception %: no interception, no drift Main route of entry: runoff, drainage
Parameters used in FOCUSsw step 3 (if performed)	FOCUS surface water guidelines, SANCO/4802/2001-rev 2. Step 3. Vapour pressure: 0.182 Pa (25 °C) Koc: 20 mL/g for alkaline soils, 112 mL/g for neutral/acidic soils 1/n: 0.76 for alkaline soils, 0.90 for neutral/acidic soils Soil incorporation 10 cm (uniform) FOCUS scenarios: D6, R2, R3, R4 Simulations used a Q10 of 2.2 and Walker equation coefficient 0.7
Application rate	Crop: Southern EU soil drench application on **tomato seedlings after transplantation into the field**

	Crop interception: no interception Number of applications: 3 Interval (d):14 d Application rate(s): 720 g as/ha Application window: March – May
Metabolite RMH-1915 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 99.15 g/mol Water solubility: Not available Koc: Not available DT50 soil: Not available DT50 water: Not available DT50 sediment: Not available DT50 combined: Not available Crop interception %: no interception, no drift Main route of entry: runoff, drainage Maximum in soil: Not observed Maximum in water/sediment: 17 %
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Crop: Southern EU soil drench application on **tomato seedlings after transplantation into the field** Crop interception: no interception Number of applications: 3 Interval (d):14 d Application rate(s): 720 g as/ha Application window: March – May

PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3) 'TACHIGAREN' 30 L (indoor use)

Parent Parameters used in FOCUSsw step 1 and 2	FOCUS surface water guidelines, SANCO/4802/2001-rev 2. Step 2. Molecular weight: 99.15 g/mol Water solubility: 65100 mg/l Koc: 20 mL/g (worst case) DT50 soil: 14.8 d (laboratory data, 20 ^{o}C) DT50 water: 2.7 d DT50 sediment: 1000 d (default value) DT50 combined: 2.8 d Crop interception %: no interception Main route of entry: spray drift (2.7590 %) modified o an emission of 0.1 % Runoff, drainage: No runoff & drainage
Parameters used in FOCUSsw step 3 (if performed)	Step 3 calculations were not performed
Application rate	Crop: Southern and Northern EU, highest individual treatment for **tomatoes, indoors**

	Crop interception: no interception Number of applications: 1 Interval (d):365 d Application rate(s): 5400 g as/ha Application window: March – May

PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3) 'TACHIGAREN' 70 WP

Parent Parameters used in FOCUSsw step 1 and 2	FOCUS surface water guidelines, SANCO/4802/2001-rev 2. Steps 1 and 2. Molecular weight: 99.15 g/mol Water solubility: 65100 mg/l Koc: 20 mL/g for alkaline soils, 112 mL/g for neutral/acidic soils DT50 soil: 17.4 d (laboratory data, 20 ^{o}C) DT50 water: 2.7 d DT50 sediment: 17.4 d (soil, laboratory data) DT50 combined: 2.8 d Crop interception %: no interception, no drift
Parameters used in FOCUSsw step 3 (if performed)	Step 3 modellings were not performed
Application rate	Crop: **Sugar beet** (seed dressing) Crop interception: no interception Number of applications: 1 Interval (d): 365 d Application rate(s): 72.45 g as/ha Application window: March – May

Metabolite RMH-1915 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 99.15 g/mol Water solubility: Not available Koc: Not available DT50 soil: Not available DT50 water: Not available DT50 sediment: Not available DT50 combined: Notavailable Maximum in soil: Not observed Maximum in water/sediment: 17 %
Parameters used in FOCUSsw step 3 (if performed)	Step 3 modellings were not performed
Application rate	Crop: **Sugar beet** (seed dressing) Crop interception: no interception Number of applications: 1 Interval (d): 365 d Application rate(s): 72.45 g as/ha Application window: March – May

PEC (ground water) (Annex IIIA, point 9.2.1) 'TACHIGAREN' 30 L

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	FOCUS groundwater guidelines, SANCO/321/2000 rev 2. Models used: FOCUS PELMO 3.3.2. and FOCUS PEARL 3.3.3. Scenarios: Piacenza, Porto, Sevilla and Thiva. Crop: Tomatoes (outdoor, S EU). Soil DT_{50} : 14.8 days (laboratory data 20°C) Soil adsorption parameters (soil pH, K_{FOC}, 1/n): alkaline soils: 7.4, 20, 0.76 Acidic/neutral soils: 5.7, 112, 0.90 No significant metabolites. Simulations used a Q10 of 2.58 and Walker equation coefficient of 0.7
Application rate	1 x 0.54 kg a.s./ha (10 % carry over from seed bed treatment) + 1 x 0.54 and 2 x 0.72 kg a.s./ha (post transplant treatment). Default emergence date used as the transplant date (scenario specific). Applications made 14 and 4 days prior to transplantation and 4, 18 and 32 days following transplantation. Crop interception: 0 %

PEC (ground water) (Annex IIIA, point 9.2.1) 'TACHIGAREN' 70 WP

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	FOCUS groundwater guidelines, SANCO/321/2000 rev 2. Model used: FOCUS PELMO 3.3.2. and FOCUS PEARL 3.3.3. Scenarios: All nine scenarios. Crop: Sugar beet seed treatment. Soil DT_{50} : 14.8 days (laboratory data 20°C) Soil adsorption parameters (soil pH, K_{FOC}, 1/n): alkaline soils: 7.4, 20, 0.76 Acidic/neutral soils: 5.7, 112, 0.90 No significant metabolites.
Application rate	Single treatment of 72.45 g a.s./ha each year on default planting date for each scenario location (scenario specific). Crop interception: 0 %.

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

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	Not applicable. Phototransformation DT_{50} value >1 year.
Photochemical oxidative degradation in air ‡	DT50 of 0.6 hrs derived by the Atkinson calculation (AOPWIN ver. 1.86).
Volatilisation ‡	Worst-case 7.4% (estimated worst-case) from soil within 24 hours of planting.

Metabolites	None

PEC (air)

Method of calculation	Expert judgement, based on vapour pressure, dimensionless Henry's Law Constant and information on volatilisation from plants and soil.

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which a groundwater exposure assessment is triggered.	Soil: hymexazol only. Groundwater: hymexazol only. Water: hymexazol RMH-1915. Sediment: hymexazol only. Air: hymexazol only.

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

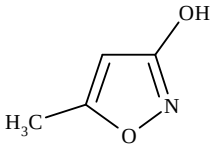
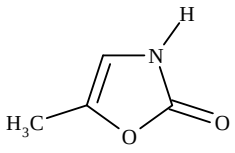
Soil (indicate location and type of study)	No monitoring data available.
Surface water (indicate location and type of study)	No monitoring data available.
Ground water (indicate location and type of study)	No monitoring data available.
Air (indicate location and type of study)	No monitoring data available.

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

Not readily biodegradable (candidate for R53)

Appendix A: Metabolite names, codes and other relevant information of the plant protection product TACHIGAREN 70 WP with active substance hymexazol.

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

Compound name	IUPAC name	Structural formula	Structure	Molecular Weight [g/mol]	Observed in study (% of occurrence/ formation)
Hymexazol	3-Hydroxy-5-methylisoxazole	($C_4H_5NO_2$)		99.15	Parent substance
RMH 1915	5-methyl-2(3H)-oxazolone	($C_4H_5NO_2$)		99.15	Water: 17.2 %

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[4] method. Currently this method equals the method described in the Technical Guidance Document (TGD). Additional guidance is presented in RIVM[5]-report 601782001/2007[6].

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:

<u>hymexazol</u>
The following laboratory non-normalised DT_{50} values carried out at 20 ℃ are available for the active substance hymexazol: 7.9, 15.1, 15.4, 31.5 days (geometric mean 15.5 days, n=4). The geometric mean DT50-value of the a.s. can 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 CO2.
Only a non-representative field study is available (Spain, DT50 of 11.1 days) however field data are not triggered.
In this way, the standards for persistence as laid down in the RGB are met.

There are no major metabolites under aerobic conditons.

PECsoil
The concentration of the active substance hymexazol 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.

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

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

[6] 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'. RIVM report 601782001.

As the logPow of the substance is < 3 (1.01 at pH 4 and < 0.3 at pH 7), a PEC_{21days} is not needed for the assessment of secondary poisoning of birds and mammals through the consumption of earthworms.

No major metabolites are formed in soil from hymexazol.

The following input data are used for the calculation:

PEC soil:

Active substance hymexazol:
Maximum non-normalised lab DT_{50} for degradation in soil: 31.5 days
Molecular mass: 99.15 g/mol

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

Table M.1 PECsoil calculations for active substance hymexazol (5 cm)

Use	Substance	Rate [kg a.s./ha]	Freq.	Interval [days]	Fraction intercepted *	$PIEC_{soil}$ [mg a.s./kg] (5 cm)
Sugarbeet	hymexazol	0.042	1	n.r.**	0	0.056

* For seed treatments interception is irrelevant, so the interception fraction is set to zero (the full dosage reaches the soil).
** n.r. = not relevant

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 hymexazol is calculated in the first tier using Pearl 4.4.4 and the FOCUS Kremsmünster scenario. Input variables are the actual worst-case application rate, the crop sugarbeet and no interception, as it is a seed treatment. As the sowing period is March- April, the date of yearly application is set to April 1 (in line with GAP). The seeding depth varies between 2 and 4 cm. For the application of hymexazol the application method is set to incorporation into the soil with an incorporation depth of 5 cm. No metabolites occurred above > 10 % of AR, > 5 % of AR at two consecutive sample points or had an increasing tendency.
The following input data are used for the calculation:

PEARL:

Active substance hymexazol:
Geometric mean DT_{50} for degradation in soil (20°C): 14.8 days (n=4)
$K_{om\text{-}base}$: 11.6 L/kg (average K_{om} of 3 values for alkaline soils, based on the final addendum to Additional report by RMS Finland)
1/n: 0.76 (corresponding to the average K_{om} of 3 values for alkaline soils, based on the final addendum to Additional report by RMS Finland)

Saturated vapour pressure: 0.182 Pa (25°C)
Solubility in water: 65100 mg/L (20°C)
Molecular mass: 99.15 g/mol

Plant uptake factor: 0.0
Q10: 2.58

Other parameters: standard settings of PEARL 4.4.4

The following concentrations are predicted for the a.s. hymexazol following the realistic worst case GAP, see Table M.2.

Table M.2 Leaching of active substance hymexazol as predicted by PEARL 4.4.4.

Use	Substance	Rate substance [kg/ha]	Frequency	Interval [days]	Fraction Intercepted*	PEC groundwater [µg/L]
Sugarbeet	hymexazole	0.042	1	n.r.**	0	< 0.001

* For seed treatments interception is irrelevant, so the interception fraction is set to zero (the full dosage reaches the soil). An incorporation depth of 5 cm is applicable for treated beet seeds.
** n.r. = not relevant

Results of Pearl 4.4.4 using the Kremsmünster scenario 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 PEARL-model calculations for the active substance hymexazol is smaller than 0.01 µg/L for all proposed applications. Hence, the applications meet the standards for leaching as laid down in the RGB.

Lysimeter/field leaching studies
No lysimeter studies are available nor required.

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 hymexazol in groundwater.

Conclusions
The active substance hymexazol complies with the requirements laid down in the RGB concerning persistence in soil.

The proposed application of the product TACHIGAREN 70 WP 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 proposed application of hymexazol is a seed treatment for sugarbeet. As for seed treatments no spray drift occurs, no exposure concentrations of the active substance hymexazol and its metabolite RMH-1915 in surface need to be estimated.

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

In 2014, version 3 of the Pesticide Atlas was launched, which includes a statistical correlation analysis between concentrations, threshold exceedance and land use, which may indicate probable relationships. In this version also the correlation analysis of land use with the environmental quality standards (EQS) of the Water Framework Directive (WFD) is included.

Data from the Pesticide Atlas are used to evaluate potential exceedances of the authorisation threshold and environmental quality standards (MKN in Dutch, data source http://www.rivm.nl/rvs/Normen). These environmental quality standards consist either of the harmonised WFD thresholds derived according to the Fraunhofer methodology[7] (AA-EQS and MAC-EQS) or of an MPC value (which is usually derived on the basis of outdated guidance). When EQS values according to the Water Framework Directive are available, the MPC value is not used further in the analysis of monitoring data for the purpose of the registration.

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.

<u>hymexazol</u>
The active substance hymexazol was observed in the surface water (most recent data from 2012). In Table M 3 the number of observations in the surface water are presented.
There is no authorisation threshold available in the Pesticide Atlas since the only authorised use of hymexazol is a seed treatment, for which no aquatic risk assessment is done currently.

The relevant EQS for this substance is the MPC and equals 8.8 µg/L.
The currently available MPC value is reported here for information purposes when no EQS values are available.

[7] 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'. RIVM report 601782001.

Table M 3 Monitoring data in Dutch surface water for hymexazol (from www.pesticidesatlas.nl, version 3.0)

Total no of locations (2012)	*n* > authorisation threshold	*n* > EQS		
		MAC-EQS	AA-EQS	MPC (ad-hoc/indicative)
69*	n.a.**	n.a.**	n.a.**	0

* the number of observations at each location varies between 1 and 100, total number of measurements is 430 in 2012.
** n.a. not available

As there is no exceedance of thresholds, the monitoring data have no consequences for the proposed use 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[8].

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.
- 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 hymexazol has been on the Dutch market for > 3 years (authorised since 07-12-1993. 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

[8] 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

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.

6.3 Fate and behaviour in air

Route and rate of degradation in air
hymexazol
The vapour pressure is 0.182 Pa at 25°C. The Henry constant is 1.4 x 10^{-4} at 25°C. The half-life in air is 0.64 hours.

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 framework to assess fate and behaviour in air of plant protection products, for the time being this issue is not taken 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.

6.6 Overall conclusions fate and behaviour

It can be concluded that:

1. the active substance hymexazol meets the standards for persistence in soil as laid down in the RGB.
2. the proposed application of the active substance hymexazol meets the standards for leaching to the shallow groundwater as laid down in the RGB.
3. the proposed application of the active substance hymexazol meets the standards for surface water destined for the production of drinking water as laid down in the RGB

7. Ecotoxicology

For the risk assessment the final List of Endpoints taken from the EFSA Journal 2010 8(8): 1653, 1-63 (also taking into account the final review report on hymexazol (SANCO/13057/2010 final - d.d. 23 November 2010) is used.

The representative formulated products during EU review of hymexazol were TACHIGAREN 30 L and TACHIGAREN 70 WP.

Extra information available from the DAR (and related addenda) and relevant for the risk assessment is added by Ctgb in *italic* to the List of Endpoints.

List of Endpoints Ecotoxicology (EFSA Journal 2010; 8(7):1653)

TACHIGAREN 70 WP is a water dispersible powder for slurry seed treatment (WS) containing the active substance hymexazol (700 g/kg).
TACHIGAREN 30 L is a a soluble concentrate (SL) containing 360 g/l hymexazol.

Effect on terrestrial vertebrates (Annex IIA, Point 8.1; Annex IIIA, Points 10.1 and 10.3)

Acute oral toxicity to mammals:	LD_{50} = 1390 mg a.s./kg bw (rat)
Short-term toxicity to mammals:	No recommended endpoint
Reproductive toxicity to mammals:	NOEL = 500 mg a.s./kg diet (equivalent to 37 mg a.s./kg bw/day, 2-generation study with the rat)
Acute oral toxicity to birds:	LD_{50} > 1085 mg/kg bw (Japanese quail)
Dietary toxicity to birds:	LC_{50} > 5200 mg/kg diet; (equivalent to > 1473 mg/kg bw/day, Bobwhite quail)
Reproductive toxicity to birds:	NOEC = 1000 mg/kg diet; (equivalent to 86.5 mg/kg bw/day, Bobwhite quail)

Toxicity data for aquatic species (most sensitive endpoint and species of each group) (Annex IIA, Point 8.2; Annex IIIA, Point 10.2)

Findings: Group	**Findings:** Test substance	**Findings:** Time-scale	**Findings:** End point	**Findings:** Toxicity (mg/L)
Findings: Laboratory tests				
Fish (rainbow trout)	Hymexazol	96-hours	LC_{50}	> 100
	Hymexazol	28-days	NOEC	> 100
Invertebrates *(Daphnia magna)*	Hymexazol	48-hours	EC_{50}	28
	Hymexazol	21-days	NOEC (no. live juveniles) EC_{10}	0.8 0.4
Algae *(Scenedesmus subspicatus)*	Hymexazol	72-hours	E_bC_{50} and E_rC_{50}	32
Algae *(Selenastrum capricornutum)*	Hymexazol	72-hours	E_bC_{50} and E_rC_{50}	32
Aquatic plants (*Lemna gibba*)	Hymexazol	14-days	IC_{50}	9.4
Sediment dweller (*Chironomus riparius*)	Hymexazol	28-days	EC_{50} NOEC	> 1.6 1.6
Microcosm or mesocosm tests				
Not submitted nor required.				

Hymexazol is very toxic to aquatic organisms. The experts in the PRAPeR 75 discussed the relevant chronic end-point for Daphnia magna and agreed to use the EC_{10} =0.4 mg /L, instead of the NOEC = 0.8 mg/L (see Evaluation Table for Hymexazol, expert consultation 5.5).

Bioconcentration (Annex IIA, Point 8.2.3)

Log Po/w	pH 4: 1.01 pH 7: <0.3 pH 9: <0.3
Bioconcentration factor (BCF):	Residues in fish not detected at limit of detection of 1.1 µg/g following exposure to a mean measured concentration of 0.182 and 1.87 mg hymexazol/L.
Annex VI trigger for the BCF:	1000
Clearance time (CT_{50}): (CT_{90}):	Residues not detected.
Level of residues (%) in organisms after the 14 day depuration phase:	Residues not detected.

Effects on honey bees (Annex IIA, Point 8.3.1; Annex IIIA, Point 10.4)

Acute oral toxicity:	LD_{50} > 100 µg/bee (hymexazol technical)
Acute contact toxicity:	LC_{50} > 100 µg/bee (hymexazol technical)
Field or semi-field tests:	No data submitted nor required.

Effects on other arthropod species (Annex IIA, Point 8.3.2; Annex IIIA, Point 10.5)

Species	Stage	Test substance	Dose (kg a.s./ha)	Endpoint
Laboratory tests				
Poecilus cupreus	Adults, 5 weeks old	'Tachigaren' 70 WP on sugar beet seeds	0.208	No mortality or effects on feeding rate
Poecilus cupreus	Adults, 3-4 weeks old	'Tachigaren' 70 WP on sugar beet seeds	Not calculated (39 g a.s./ kg seed, one seed per 234 cm^2)	No mortality or effects on feeding rate
Aloeochara bilineata	Adults, 3 days old	'Tachigaren' 70 WP on sugar beet seeds	0.276	No significant decrease in parasitisation rate
Aloeochara bilineata	Adults, 1-7 days old	'Tachigaren' 70 WP on sugar beet seeds and 'Tachigaren' 30 L	0.216 and 10.8	No significant effects on fecundity relative to blank control
Poecilus cupreus;	Adults, 3-4 weeks old	'Tachigaren' 30 L	10.8	No mortality or effects on feeding rate
Typhlodromus pyri	Protonymphs, ≤ 3 days old	'Tachigaren' 30 L	0.01 to 4.00	LR_{50} = 1107 g a.s./ha NOEC (eggs/female) = 400 g a.s./ha
Aphidius rhopalosiphi	Adults, < 48 hours old	'Tachigaren' 30 L	0.01 to 2.00	LR_{50} = 1426 g a.s./ha NOEC (mummies/female) = 400 g a.s./ha

Field or semi-field tests
No data submitted nor required.

Effects on earthworms (Annex IIA, Point 8.4; Annex IIIA, Point 10.6)

Acute toxicity:

Hymexazol technical	14-day LC_{50} = 281.9 mg a.i./kg dry weight soil
'Tachigaren' 30 L	14-day LC_{50} = 243.3 mg a.i./kg dry weight soil
'Tachigaren' 70 WP	14-day LC_{50} = 238.9 mg a.i./kg dry weight soil

Not triggered.

Reproductive toxicity:

Effects on soil micro-organisms (Annex IIA, Point 8.5; Annex IIIA, Point 10.7)

Nitrogen mineralisation: Carbon mineralisation:	Application of hymexazol to soil at rates of 14.4 and 72.0 mg/kg dry soil (ca 5 and 25 x the highest use rate of 'Tachigaren' 30 L) suppressed respiration and stimulated nitrification by the indigenous soil microflora. These effects were transient and the differences between rates measured in the presence and absence of the test substance had diminished to less than 25% within 71 days. Hymexazol had no permanent effect on carbon or nitrogen oxidation processes in soil at the concentrations applied.

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g a.i./ha) vegetative vigor	ER_{50} (g a.i./ha) emergence	Exposure [1] (g/ha)
Brassica oleracea	Hymexazol technical		450 000 (emergence)	720
			131 000 (seedling growth)	720
Lycopersicon esculentum	Hymexazol technical	103 000		720

[1] exposure has been estimated as soil drench application

Additional studies (e.g. semi-field or field studies)

No further studies submitted nor required

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Hymexazol technical

Test type /organism	End point	3-hour EC_{50}
Activated sludge	Respiration inhibition	217 mg/L

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	Comounds
soil	Hymexazol
water	Hymexazol and a data gap needs to be filled before RMH-1915 can be excluded as being relevant.
sediment	Hymexazol
groundwater	Hymexazol

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

ECB voted, published in the Official Journal of the European Communities in 1999 (Commission Directive 98/98/EC)

Active substance	R52 Harmful to aquatic organisms R53 May cause long-term adverse effects in the aquatic environment (ECB)
'TACHIGAREN' 30 L	R52 Harmful to aquatic organisms R53 May cause long-term adverse effects in the aquatic environment (RMS proposal)
'TACHIGAREN' 70 WP	R52 Harmful to aquatic organisms R53 May cause long-term adverse effects in the aquatic environment

Hymexazol confirmatory data – addendum to DAR (RMS: Finland) February 2014

This study was not yet evaluated by the RMS (Finland) at the time of this evaluation. Thus, an evaluation was performed by Ctgb residues expert.

Uptake in Sugar Beet (IIA 6.1.1)

Report:	*KIIIA 8.9/01 → KIIA 6.10/01, Piskorski R., 2012b*
Title:	*[^{14}C]Hymexazol: Uptake in Sugar Beet (amended report)*
Document No:	*20120019*
Guidelines:	*OECD Guideline for Testing of Chemicals, 501, Metabolism in Crops (January 2007)* *US-EPA Residue Chemistry Test Guideline OPPTS 860.1300 Nature of the Residues – Plant, Livestock* *EU Guidelines for the generation of the data concerning residues as provided in Annex II, Part A Section 6 and Annex III, Part A, Section 8 of the Directive 91/414/EEC concerning the placing of plant protection products on the market. Appendix A, Document 7028/VI/95 rev.3, July 1997, Metabolism and Distribution in Plant.*
GLP	*yes*

Executive Summary:

The uptake of hymexazol in sugar beet was investigated at early growth stage indoors under controlled conditions following seed application. The purpose of this plant uptake study was:

- *To investigate the uptake of [^{14}C]hymexazol in sugar beet plants at an early growth stage*
- *To quantify the total radioactive residue levels in appropriate crop parts.*

The total application rate was 28.54 g a.i./kg naked seeds (corresponding to 32.82 g a.i./100,000 seeds), which is slightly higher than the maximum GAP (24.35 g a.i./kg naked seeds corresponding to 28 g a.i./100,000 seeds) applicable for this re-registration submission.
The sugar beet seeds were treated on the day of sowing with a mixture of unlabelled and labelled hymexazol (80:20) applied in methanol solution at the rate of 6.55 g [^{14}C]hymexazol/100,000 seeds. Cultivation and husbandry of sugar beet was carried out according to common agricultural practice under greenhouse conditions.

Treated sugar beet plants were sampled at 2-4-leaf stage (BBCH 12-14, at treatment to sampling interval, TSI, 25 d). The aerial parts of the plants were harvested, homogenized and TRR determined by combustion and LSC analysis.
The TRR in leaves of the treated sugar beet plants amounted to 2.783 mg parent equivalent per kg fresh weight, which corresponded to 6.026 µg parent equivalent per plant and thus represented 9.21% of the applied radioactivity. The results showed that only <10% of the test item applied to the seeds could be recovered from the plant material already after 25 days of plant growth.

7.1 Effects on birds

Birds can be exposed to the active substance hymexazol via natural food (seeds, leaves), granules as food and/or grit, 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 exposure should be ≥ 10 and TER for chronic exposure should be ≥ 5.
Tables E.1a-b present an overview of toxicity data.

Table E.1a Overview of toxicity data for birds for active substance hymexazol

	Endpoint	Value
Acute toxicity to birds:	LD_{50}	>1085 mg a.s./kg bw
Dietary toxicity to birds:	LC_{50}	> 1473 mg a.s./kg bw/d
Reproductive toxicity to birds:	NOEL	86.5 mg a.s./kg bw/d

Table E.1b Overview of toxicity data for birds for TACHIGAREN 70 WP

	Endpoint	Value
Acute toxicity to birds:	LD_{50}	1698 mg a.s./kg bw (male) 1737 mg a.s./kg bw (female)

7.1.1 Natural food and drinking water

treated seed
The risk assessment for seed treatment is based on the new guidance of the 'European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals' (EFSA Journal 2009; 7(12):1438).

According to this guidance, for pelleted seeds risk assessment should be performed for 'birds ingesting granules as grit', and for 'birds feeding on crop seedlings'. For treated seeds a screening step is not required, thus risk assessment starts at Tier 1.

Risk of secondary poisoning has not been assessed, as the active substance hymexazol has a log Pow < 3.0.

Acute toxicity exposure ratio (TER_A)
For potential 'consumers' in bird populations the scenario represented by a seed treatment resembles a bare-soil scenario.
Herbivorous birds are not considered to be attracted to fields immediately after treated seed has been drilled. However it is possible that birds may consume seedlings that contain residues of the active substance or consume the seedling and the remaining seed.

Pelleted sugar beet seeds have a diameter of 3.5-4.75 mm, and thus are considered large granules.

The acute risk to birds for products used as seed treatment is calculated as follows:

- Grit eating birds

$$TER_A = \frac{LD_{50}}{DGritD_{acute} \text{ (large granules)}}$$

With: $DGritD_{acute}$ (large granules) = (2453 x ($G_{density}$/(71 + $G_{density}$)) x $G_{loading}$)/ BW[9]

Where:

$DGritD_{acute}$ = acute daily grit dose

$G_{density}$ = 15 seeds/m^2 (assuming no incorporation, i.e. worst case)

$G_{loading}$ = 0.28 mg a.s./seed

BW = 0.3 kg (medium-sized bird)

- birds eating newly emerged crop shoots

$$TER_A = \frac{LD_{50}}{\text{Short-cut value}}$$

According to the EFSA guidance (2009), the short-cut value (daily dietary dose (DDD)) for small omnivorous birds is 0.5 × NAR/5.

The short-cut values assume that root, seed and seedling are ingested by the animal and that all of the applied substance remains available.

Tables E.2a and E.2b present acute TER values for the grit and seedling scenarios, respectively. The lowest available LD_{50} value was used in calculations.

Table E.2a Acute first tier risk assessment for granivorous birds eating grit according to EFSA guidance (2009)

Crop scenario	Indicator species	DGritD [mg as/kg bw/d]	LD_{50} [mg/kg bw]	TER (10)
Pelleted sugar beet seeds/ large granules	Medium-size granivorous bird	399	>1085	**>2.7**

Table E.2b Acute first tier risk assessment for birds feeding on sugar beet seedlings according to EFSA guidance (2009)

Crop scenario	Indicator species	NAR [mg a.s./kg seeds]	FIR/bw	DDD [mg as/kg bw/d]	LD_{50} [mg/kg bw]	TER (10)
Sugar beet seedlings	Small omnivorous bird	24350*	0.5	2435	>1085	**>0.45**

* NAR was calculated based on loading data presented in a seedling residue study: 28.54 g a.s./kg naked seed corresponds with 32.82 g a.i./100 000 seeds → 28 g a.s./100 000 seeds corresponds with 24.35 g a.s./ kg naked seed.

[9] The formula in the EFSA guidance is incorrect as the body weight is not taken into account. This has been corrected in the current evaluation.

Taking the results in Tables E.2a and E.2b into account, it appears that an acute risk to birds for the proposed use as seed treatment cannot be excluded, since TER_A values are below the trigger of 10. Hence, it must be demonstrated by means of an adequate risk assessment that there are no unacceptable effects under field conditions after the plant protection product has been applied according to the proposed GAP, for example when the percentage of incorporated seed or active substance residues in seedlings are taken into account.

Refinement for grit eating birds
The applicant states that "sugar beet seeds are sown by precision drilling, a method which leaves minimal quantities of sugar beet seed present at the surface". The applicant also refers to a DEFRA report[10] (study PS2334) which assessed the availability of seeds at the surface following drilling. The report statest that "Maize and sugar beet each had mean numbers of surface seeds per square metre that were generally below one and these were similar whether measured on headlands or on the main field.". The number of sugar beet seeds on the surface in-field was derived as 0.2 seeds/m^2 (90^{th} percentile), and in the headland as 1.26 seeds/m^2 (90^{th} percentile). The applicant used the DEFRA seed density data in the refinement for the risk to grit eating birds, which is acceptable. Refined TER values are presented in Table E.2.c.

In the case of precision drilling, Ctgb considers that 0.5% of the drilled seeds remain on the surface (midland). At a seed density of 15 seeds/m^2, this corresponds with 0.075 seeds/m^2. Since this value is lower than the seed density values presented by DEFRA, which concern seeds in the headland, i.e. a worst-case scenario, TER values taking the midland scenario into account are not presented in detail. The acute TER value according to Ctgb approach is 449, thus well above the trigger of 10.

Table E.2c Refined acute risk for medium (300 g) granivorous birds based on 1.26 seeds/m^2 remaining at the soil surface after precision drilling

Crop scenario	Indicator species	DGritD [mg as/kg bw/d]	LD_{50} [mg/kg bw]	TER (10)
Pelleted sugar beet seeds/ large granules	Medium-size granivorous bird	39.9	>1085	>27

Taking the results in Table E.2c into account, it appears that the acute risk to birds ingesting pelleted treated sugar beet seeds is acceptable provided the following:

A restriction sentence should thus appear on the Dutch WG:

Om vogels te beschermen moet blootstelling aan zaden geminimaliseerd worden. Om dit te bereiken dienen bij het uitzaaien van het behandelde zaad specifieke instructies gevolgd te worden die vermeld staan op de zakken behandeld zaad.

Het volgende moet worden vermeld op de zakken met behandeld zaad:

Bij het zaaien
Om de vogels te beschermen moet het behandelde zaad volledig in de bodem worden ondergewerkt; zorg ervoor dat het behandelde zaad ook aan het voorend is ondergewerkt. Om vogels te beschermen moet u gemorste zaden verwijderen.

[10] Assessment of the availability of seed on the soil surface after drilling. 2009. DEFRA Project PS2334 Final Report. CSL, UK.

Refinement for birds eating newly emerged crop shoots

The applicant refers to available data on active substance residues in sugar beet seedlings to refine the daily dietary dose (DDD) of small omnivorous birds. Residues were determined in seedlings harvested at BBCH 12-14 (2-4-leaf stage; at treatment to sampling interval, TSI, 25 d). The total application rate was 28.54 g a.i./kg naked seeds (corresponding to 32.82 g a.i./100,000 seeds), corresponding to a mixture of unlabelled and labelled hymexazol (80:20) applied in methanol solution at the rate of 6.55 g [^{14}C]hymexazol/100,000 seeds. The TRR in leaves of the treated sugar beet plants amounted to 2.783 mg parent equivalent per kg fresh weight, which corresponded to 6.026 µg parent equivalent per plant and thus represented 9.21% of the applied radioactivity. Since the applied application rate of active substance in the test was higher than the proposed application rate of the current submission, the derived residue value in seedlings can be seen as worst case.

According to the EFSA guidance (2009), it is assumed that the applied amount of plant protection product is contained in a total mass of seedling that is five times the weight of the original seed. In the study report there is no information presented on the weight of a single seed, nor on the weight of a seedling at BBCH 12-14. However, information on growth stages of sugar beet shows that shoots ermerge through the soil surface at BBCH 9 and that first leaves are visible from BBCH 10.[11] It may be expected that it is only after leaves start to develop that birds feed on the seedlings. Therefore it is acceptable to take residues in seedlings at BBCH 12-14 into account for refinement of the DDD.

The short-cut value (daily dietary dose (DDD)) for small omnivorous birds is now calculated from FIR/bw × seedling residue at BBCH 12-14.

Table E.2d Refined acute first tier risk assessment for birds feeding on sugar beet seedlings according to EFSA guidance (2009)

Crop scenario	Indicator species	Seedling residue [mg a.s./kg seeds]	FIR/bw	DDD [mg as/kg bw/d]	LD_{50} [mg/kg bw]	TER (10)
Sugar beet seedlings	Small omnivorous bird	2.783	0.5	1.39	>1085	>780

Taking the results in Table E.2d into account, it appears that the risk to birds feeding on sugar beet seedlings emerged from treated sugar beet seeds is acceptable.

Short-term toxicity exposure ratios (TER_{ST})

According to the EFSA Guidance (2009), only acute and reproductive risk assessments for birds due to the use of sprayed products are considered. Therefore, no short-term risk assessment was conducted for the current seed treatment use. It is covered by the long-term risk assessment.

Long-term toxicity exposure ratios (TER_{LT})

For potential 'consumers' in bird populations the scenario represented by a seed treatment resembles a bare-soil scenario.

Pelleted sugar beet seeds have a diameter of 3.5-4.75 mm, and thus are considered large granules.

[11] BBCH monograph, 2nd edition, 2001 (German Federal Biological Research Centre for Agriculture and
Forestry (BBA))

The long-term risk for products used as seed treatment is calculated as follows:

- Grit eating birds

$$TER_{repro} = \frac{NOEL}{DGritD_{repro} \text{ (large granules)}}$$

With: $DGritD_{repro}$ (large granules) = (1306 x $G_{density}$/(71 + $G_{density}$) x $G_{loading}$) x f_{TWA}/ BW[12]

Where:

$DGritD_{repro}$ = daily grit dose

$G_{density}$ = 15 seeds/m^2 (assuming no incorporation, i.e. worst case)

$G_{loading}$ = 0.28 mg a.s./seed

BW = 0.3 kg (medium-sized bird)

f_{TWA} = 1 (in absence of degradation/dissipation data of the active substance on pelleted seeds)

- birds eating newly emerged crop shoots

$$TER_{LT} = \frac{NOEL}{\text{Short-cut value}}$$

According to the EFSA guidance (2009), the short-cut value (daily dietary dose (DDD)) for small omnivorous birds is 0.5 × NAR/5 x f_{TWA}. In absence of degradation/dissipation data of the active substance on pelleted seeds f_{TWA} is set to 1.

The short-cut values assume that root, seed and seedling are ingested by the animal and that all of the applied substance remains available.

Tables E.2e and E.2f present long-term TER values for the grit and seedling scenarios, respectively.

Table E.2e Long-term first tier risk assessment for granivorous birds eating grit according to EFSA guidance (2009)

Crop scenario	Indicator species	DGritD [mg as/kg bw/d]	NOEL [mg/kg bw/d]	TER (5)
Pelleted sugar beet seeds/ large granules	Medium-size granivorous bird	213	86.5	**0.41**

[12] The formula in the EFSA guidance is incorrect as the body weight is not taken into account. This has been corrected in the current evaluation.

Table E.2f Long-term first tier risk assessment for birds feeding on sugar beet seedlings according to EFSA guidance (2009)

Crop scenario	Indicator species	NAR [mg a.s./kg seeds]	FIR/bw	DDD [mg as/kg bw/d]	NOEL [mg/kg bw/d]	TER (5)
Sugar beet seedlings	Small omnivorous bird	24350*	0.5	2435	86.5	**0.036**

* NAR was calculated based on loading data presented in a seedling residue study: 28.54 g a.s./kg naked seed corresponds with 32.82 g a.i./100 000 seeds → 28 g a.s./100 000 seeds corresponds with 24.35 g a.s./ kg naked seed.

Taking the results in Tables E.2e and E.2f into account, it appears that a chronic risk to birds for the proposed use as seed treatment cannot be excluded, since TER_{LT} values are below the trigger of 5. Hence, it must be demonstrated by means of an adequate risk assessment that there are no unacceptable effects under field conditions after the plant protection product has been applied according to the proposed GAP, for example when the percentage of incorporated seed or active substance residues in seedlings are taken into account.

Refinement for grit eating birds
The same approach as for acute risk to grit eating birds was applied by the applicant to refine the chronic risk, except that for chronic exposure the mean headland number of sugar beet seeds was used in calculations, i.e. 0.41 seeds/m^2 (DEFRA report PS2334). This is acceptable. Refined TER values are presented in Table E.2.g.

In the case of precision drilling, Ctgb considers that 0.5% of the drilled seeds remain on the surface (midland). At a seed density of 15 seeds/m^2, this corresponds with 0.075 seeds/m^2. Since this value is lower than the seed density values presented by DEFRA, which concern seeds in the headland, i.e. a worst-case scenario, TER values taking the midland scenario into account are not presented in detail. The long-term TER value according to Ctgb approach is 67, thus wel above the trigger of 5.

Table E.2g Refined long-term risk for medium (300 g) granivorous birds based on 0.41 seeds/m^2 remaining at the soil surface after precision drilling

Crop scenario	Indicator species	DGritD [mg as/kg bw/d]	NOEL [mg/kg bw/d]	TER (5)
Pelleted sugar beet seeds/ large granules	Medium-size granivorous bird	7.0	86.5	12

Taking the results in Table E.2c into account, it appears that the chronic risk to birds ingesting pelleted treated sugar beet seeds is acceptable provided the following:

A restriction sentence should thus appear on the Dutch WG:

Om vogels te beschermen moet blootstelling aan zaden geminimaliseerd worden. Om dit te bereiken dienen bij het uitzaaien van het behandelde zaad specifieke instructies gevolgd te worden die vermeld staan op de zakken behandeld zaad.

Het volgende moet worden vermeld op de zakken met behandeld zaad:

Bij het zaaien
Om de vogels te beschermen moet het behandelde zaad volledig in de bodem worden ondergewerkt; zorg ervoor dat het behandelde zaad ook aan het voorend is ondergewerkt. Om vogels te beschermen moet u gemorste zaden verwijderen.

Refinement for birds eating newly emerged crop shoots
The same approach as for acute risk to birds feeding on newly emerged crop shoots was applied by the applicant to refine the chronic risk, which is acceptable.
The TRR in leaves of the treated sugar beet plants was 2.783 mg parent equivalent per kg fresh weight and is used in TER calculations as the appropriate exposure estimate.

The short-cut value (daily dietary dose (DDD)) for small omnivorous birds is now calculated from FIR/bw × seedling residue at BBCH 12-14 x PD x PT x f_{TWA}, where PD, PT and f_{TWA} are all set to 1.

Table E.2h Refined long-term first tier risk assessment for birds feeding on sugar beet seedlings according to EFSA guidance (2009)

Crop scenario	Indicator species	Seedling residue [mg a.s./kg seeds]	FIR/bw	DDD [mg as/kg bw/d]	NOEL [mg/kg bw/d]	TER (5)
Sugar beet seedlings	Small omnivorous bird	2.783	0.5	1.39	86.5	62

Taking the results in Table E.2h into account, it appears that the chronic risk to birds feeding on sugar beet seedlings emerged from treated sugar beet seeds is acceptable.

Overall, when taking the results in Tables E.2c, E.2d, E.2g and E.2h into account, it appears that the proposed use of hymexazol as seed treatment meets the standards for birds laid down in the RGB provided that a warning sentence is placed on the label..

drinking water
The EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009) states for treated seeds: Significant contamination of drinking water after the use of a plant protection product as seed treatment seems equally unlikely to be a critical route or to lead to TER greater than direct dietary consumption. Furthermore, the Dutch assessment only takes exposure of surface water via drift into account. Since for seed treatments no spray drift occurs, no exposure concentrations of the active substance hymexazol were calculated in section 6.2. Also, no exposure via dust-drift is expected. Therefore, assessment for surface water was not performed.

However, exposure of birds to contaminated drinking water via puddles on soil may occur. In first instance, the ratio of effective application rate (in g/ha) to acute and long-term endpoint (in mg/kg bw/d) was calculated to evaluate if specific calculations of exposure and TER are necessary. In case the ratio does not exceed 50 (K_{OC} ≤ 500 L/kg) or 3000 (K_{OC} ≥ 500), as specified in the EFSA Guidance Document (2009), further actions are not needed. In Table E.3 relevant data are presented.

Table E.3 Ratios of effective application rate to endpoints for hymexazol following the use of TACHIGAREN 70 WP

Test substance	K_{OC} [1] [L/kg]	AR_{eff} [g a.s./ha]	Endpoint [mg/kg bw]	Ratio of application rate to endpoint	Ratio trigger
Hymexazol	56.5	42	LD_{50} > 1085	> 0.039	50
			NOEL = 86.5	0.49	

AR_{eff} = effective application rate
1 = mean K_{foc} taken from EFSA LoEP

Since the ratio of effective application rate (in g/ha) to acute and long-term endpoint (in mg/kg bw/d) does not exceed 50 (K_{OC} ≤ 500 L/kg), no specific calculations of exposure and TER are necessary. Also, there is no risk for birds resulting from exposure to contaminated drinking water via puddles on soil, because the ratio trigger is below 50.

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 hymexazol is < 3 (<0.3 at pH 7 and 25℃), the potential for bioaccumulation is considered low and no further assessment is deemed necessary.

Conclusions birds

The product complies with the RGB provided that a restriction sentence is included in the legal instruction.

7.2 Effects on aquatic organisms

7.2.1 Aquatic organisms

The risk for aquatic organisms 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 are presented in Table E.4.

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]
Hymexazol	***Acute***			
	Algae	32		32000
	Invertebrates	28		28000
	Fish	>100		100000
	Macrophytes	9.4		9400
	Chronic			
	Invertebrates		0.4	400
	Fish		>100	100000

* Hymexazol is very toxic to aquatic organisms. The experts in the PRAPeR 75 discussed the relevant chronic endpoint for *Daphnia magna* and agreed to use the EC10 =0.4 mg /L, instead of the NOEC = 0.8 mg/L (see Evaluation Table for Hymexazol, expert consultation 5.5)

These toxicity values should be compared to the surface water concentrations, however, since for seed treatments no spray drift occurs, no exposure concentrations of the active substance hymexazol were calculated in section 6.2.

Thus, it appears that for the active substance hymexazol the proposed use meets the standards for aquatic organisms as laid down in the RGB.

7.2.2 Risk assessment for bioconcentration

Since logKow of hymexazol is < 3 (<0.3 at pH 7), experimental data are not required. A BCF-value of <-2.2 L/kg can be calculated from logKow.

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

7.2.3 Risk assessment for sediment organisms

The water–sediment study indicates that over 10% of the metabolite RMH 1915 (5-methyl-2(3H)-Oxazolone) is found in the sediment after 14 days. However, there are no data regarding the toxicity of the metabolite RMH 1915 for sediment organisms.

The NOEC value for *Chironomus* is 1600 µg/L (parent: hymexazol). In view of the proposed application of hymexazol as seed treatment, no exposure concentrations of the active substance hymexazol and its metabolite RMH 1915 were calculated in section 6.2, since for seed treatments no spray drift occurs.

Thus, it appears that for the active substance hymexazol and its metabolite RMH 1915 the proposed use meets the standards for sediment organisms as laid down in the RGB.

Conclusions aquatic organisms

The proposed application meets the standards for aquatic organisms.

7.3 Effects on terrestrial vertebrates other than birds

Mammals can be exposed to the active substance hymexazol via natural food (seeds, leaves), 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.5 presents an overview of toxicity data.

Table E.5 Overview of toxicity data for mammals

	Endpoint	Value
Acute toxicity to mammals:	LD_{50}	1390 mg a.s./kg bw
Reproductive toxicity to mammals:	NOEL	37 mg a.s./kg bw/d

7.3.1 Natural food and drinking water

treated seed

The risk assessment for seed treatment is based on the new guidance of the 'European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals' (EFSA Journal 2009).

According to this guidance, for treated seeds a screening step is not required, thus risk assessment starts at Tier 1. Additionally, for pelleted seeds a risk assessment for mammals is not required, yet assessment for 'mammals feeding on crop seedlings' is needed.

Risk of secondary poisoning has not been assessed, as the active substance hymexazol has a log Pow < 3.0.

Acute toxicity exposure ratio (TER_A)

For potential 'consumers' in mammal populations the scenario represented by a seed treatment resembles a bare-soil scenario.
Herbivorous mammals are not considered to be attracted to fields immediately after treated seed has been drilled. Furthermore, although pelleted seeds may be consumed by small omnivorous mammals (e.g. wood mice) the risk may be reduced due to animals cracking and discarding the pellet with most of the residue before ingesting the seed. Therefore assessment of seed consumption is not needed.

However it is possible that mammals may consume seedlings that contain residues of the active substance or consume the seedling and the remaining seed.

Pelleted sugar beet seeds have a diameter of 3.5-4.75 mm, and thus are considered large granules.

The acute risk to mammals for products used as seed treatment is calculated for mammals eating newly emerged crop shoots as follows:

$$TER_A = \frac{LD_{50}}{\text{Short-cut value}}$$

According to the EFSA guidance (2009), the short-cut value (daily dietary dose (DDD)) for small omnivorous mammals is 0.24 × NAR/5.

The short-cut values assume that root, seed and seedling are ingested by the animal and that all of the applied substance remains available.

Table E.6a Acute first tier risk assessment for mammals feeding on sugar beet seedlings according to EFSA guidance (2009)

Crop scenario	Indicator species	NAR [mg a.s./kg seeds]	FIR/bw	DDD [mg as/kg bw/d]	LD_{50} [mg/kg bw]	TER (10)
Sugar beet seedlings	Small omnivorous mammal	24350*	0.24	1169	1390	**1.2**

* NAR was calculated based on loading data presented in a seedling residue study: 28.54 g a.s./kg naked seed corresponds with 32.82 g a.i./100 000 seeds → 28 g a.s./100 000 seeds corresponds with 24.35 g a.s./ kg naked seed.

Taking the result in Table E.6a into account, it appears that an acute risk to mammals for the proposed use as seed treatment cannot be excluded, sinthe ce TER_A value is below the trigger of 10. Hence, it must be demonstrated by means of an adequate risk assessment that there are no unacceptable effects under field conditions after the plant protection product has been applied according to the proposed GAP, for example when the percentage of incorporated seed or active substance residues in seedlings are taken into account.

Refinement for mammals eating newly emerged crop shoots

The applicant refers to available data on active substance residues in sugar beet seedlings to refine the daily dietary dose (DDD) of small omnivorous mammals. Residues were determined in seedlings harvested at BBCH 12-14 (2-4-leaf stage; at treatment to sampling interval, TSI, 25 d). The total application rate was 28.54 g a.i./kg naked seeds (corresponding to 32.82 g a.i./100,000 seeds), corresponding to a mixture of unlabelled and labelled hymexazol (80:20) applied in methanol solution at the rate of 6.55 g [^{14}C]hymexazol/100,000 seeds. The TRR in leaves of the treated sugar beet plants amounted to 2.783 mg parent equivalent per kg fresh weight, which corresponded to 6.026 µg parent equivalent per plant and thus represented 9.21% of the applied radioactivity. Since the applied application rate of active substance in the test was higher than the proposed application rate of the current submission, the derived residue value in seedlings can be seen as worst case.

According to the EFSA guidance (2009), it is assumed that the applied amount of plant protection product is contained in a total mass of seedling that is five times the weight of the original seed. In the study report there is no information presented on the weight of a single

seed, nor on the weight of a seedling at BBCH 12-14. However, information on growth stages of sugar beet shows that shoots ermerge through the soil surface at BBCH 9 and that first leaves are visible from BBCH 10.[13] It may be expected that it is only after leaves start to develop that birds feed on the seedlings. Therefore it is acceptable to take residues in seedlings at BBCH 12-14 into account for refinement of the DDD.

The short-cut value (daily dietary dose (DDD)) for small omnivorous mammals is now calculated from FIR/bw × seedling residue at BBCH 12-14.

Table E.6b Refined acute first tier risk assessment for mammals feeding on sugar beet seedlings according to EFSA guidance (2009)

Crop scenario	Indicator species	Seedling residue [mg a.s./kg seeds]	FIR/bw	DDD [mg as/kg bw/d]	LD_{50} [mg/kg bw]	TER (10)
Sugar beet seedlings	Small omnivorous mammal	2.783	0.24	0.67	1390	2081

Taking the result in Table E.6b into account, it appears that the risk to small omnivorous mammals feeding on sugar beet seedlings emerged from treated sugar beet seeds is acceptable.

Short-term toxicity exposure ratios (TER_{ST})

According to the EFSA Guidance (2009), only acute and reproductive risk assessments for mammals due to the use of sprayed products are considered. Therefore, no short-term risk assessment was conducted for the current seed treatment use. It is covered by the long-term risk assessment.

Long-term toxicity exposure ratios (TER_{LT})

For potential 'consumers' in bird populations the scenario represented by a seed treatment resembles a bare-soil scenario.

Pelleted sugar beet seeds have a diameter of 3.5-4.75 mm, and thus are considered large granules.

The long-term risk to mammals for products used as seed treatment is calculated for mammals eating newly emerged crop shoots as follows:

$$TER_{LT} = \frac{NOEL}{\text{Short-cut value}}$$

According to the EFSA guidance (2009), the short-cut value (daily dietary dose (DDD)) for small omnivorous mammals is 0.24 × NAR/5 x f_{TWA}. In absence of degradation/dissipation data of the active substance on pelleted seeds f_{TWA} is set to 1.

The short-cut values assume that root, seed and seedling are ingested by the animal and that all of the applied substance remains available.

Table E.6c presents the long-term TER value for the seedling scenario.

[13] BBCH monograph, 2nd edition, 2001 (German Federal Biological Research Centre for Agriculture and
Forestry (BBA))

Table E.6c Long-term first tier risk assessment for mammals feeding on sugar beet seedlings according to EFSA guidance (2009)

Crop scenario	Indicator species	NAR [mg a.s./kg seeds]	FIR/bw	DDD [mg as/kg bw/d]	NOEL [mg/kg bw/d]	TER (5)
Sugar beet seedlings	Small omnivorous mammal	24350*	0.24	1169	37	**0.032**

* NAR was calculated based on loading data presented in a seedling residue study: 28.54 g a.s./kg naked seed corresponds with 32.82 g a.i./100 000 seeds → 28 g a.s./100 000 seeds corresponds with 24.35 g a.s./ kg naked seed.

Taking the result in Table E.6c into account, it appears that a chronic risk to mammals for the proposed use as seed treatment cannot be excluded, since the TER_{LT} value is below the trigger of 5. Hence, it must be demonstrated by means of an adequate risk assessment that there are no unacceptable effects under field conditions after the plant protection product has been applied according to the proposed GAP, for example when the percentage of incorporated seed or active substance residues in seedlings are taken into account.

Refinement for mammals eating newly emerged crop shoots
The same approach as for acute risk to mammals feeding on newly emerged crop shoots was applied by the applicant to refine the chronic risk, which is acceptable.
The TRR in leaves of the treated sugar beet plants was 2.783 mg parent equivalent per kg fresh weight and is used in TER calculations as the appropriate exposure estimate.

The short-cut value (daily dietary dose (DDD)) for small omnivorous mammals is now calculated from FIR/bw × seedling residue at BBCH 12-14 x PD x PT x f_{TWA}, where PD, PT and f_{TWA} are all set to 1.

Table E.6d Refined long-term first tier risk assessment for mammals feeding on sugar beet seedlings according to EFSA guidance (2009)

Crop scenario	Indicator species	Seedling residue [mg a.s./kg seeds]	FIR/bw	DDD [mg as/kg bw/d]	NOEL [mg/kg bw/d]	TER (5)
Sugar beet seedlings	Small omnivorous mammal	2.783	0.24	0.67	37	55

Taking the result in Table E.6d into account, it appears that the chronic risk to mammals feeding on sugar beet seedlings emerged from treated sugar beet seeds is acceptable.

Overall, when taking the results in Tables E.6b and E.6d into account, it appears that the proposed use of hymexazol as seed treatment meets the standards for mammals laid down in the RGB.

drinking water
The EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009) states for treated seeds: Significant contamination of drinking water after the use of a plant protection product as seed treatment seems equally unlikely to be a critical route or to lead to TER greater than direct dietary consumption. Furthermore, the Dutch assessment only takes exposure of surface water via drift into account. Since for seed treatments no spray drift occurs, no exposure concentrations of the active substance hymexazol were calculated in section 6.2. Also, no exposure via dust-drift is expected. Therefore, assessment for surface water was not performed.

However, exposure of mammals to contaminated drinking water via puddles on soil may occur. In first instance, the ratio of effective application rate (in g/ha) to acute and long-term endpoint (in mg/kg bw/d) was calculated to evaluate if specific calculations of exposure and TER are necessary. In case the ratio does not exceed 50 (K_{OC} ≤ 500 L/kg) or 3000 (K_{OC} ≥ 500), as specified in the EFSA Guidance Document (2009), further actions are not needed. In Table E.7 relevant data are presented.

Table E.7 Ratios of effective application rate to endpoints for hymexazol following the use of TACHIGAREN 70 WP

Test substance	K_{OC}[1] [L/kg]	AR_{eff} [g a.s./ha]	Endpoint [mg/kg bw]	Ratio of application rate to endpoint	Ratio trigger
Hymexazol	56.5	42	LD_{50} = 1390	0.030	50
			NOEL = 37	1.14	

AR_{eff} = effective application rate
1 = mean K_{foc} taken from EFSA LoEP

Since the ratio of effective application rate (in g/ha) to acute and long-term endpoint (in mg/kg bw/d) does not exceed 50 (K_{OC} ≤ 500 L/kg), no specific calculations of exposure and TER are necessary. Also, there is no risk for mammals resulting from exposure to contaminated drinking water via puddles on soil, because the ratio trigger is below 50.

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 hymexazol is < 3 (<0.3 at pH 7 and 25℃), the potential for bioaccumulation is considered low and no further assessment is deemed necessary.

Taking the results for secondary poisoning through fish and earthworms into account, the proposed use does not meet the standards for secondary poisoning as laid down in the RGB.

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.8.

Table E.8 In-field risk for bees

Use	Substance	Application rate	LD_{50}	HQ (Rate/LD_{50})	Trigger value
		[g a.s./ha]	[µg/bee]		
Sugar beet seed treatment	Hymexazol	42	>100	<0.42	50

Since the HQ is below 50, the risk for bees is considered to be low. Additionally, there is no exposure of bees following the proposed use of the product, i.e. treatment of sugar beet seeds. Hence, the proposed use meets the standards for bees as laid down in the RGB.

Risk from dust drift from treated seeds.

The risk that dust from the seed coating reaches neighbouring crops or other flowering plants and in that way exposes bees to the a.s., depends on the type of coating in combination with

the type of sowing. According to the 'Dust drift matrix' (version of 15/09/2010, see Ctgb website, bee evaluation manual 2.0), the formation of dust is not relevant due to pelleting (and mechanical drilling).
Therefore, a risk can be excluded.

Risk from exposure to contaminated nectar or pollen
Due to its systemic nature, the a.s. can be taken up by the crop. Sugar beet is supposed to flower during cultivation, so exposure via nectar or pollen can take place. In a residue study with sugar beet seedlings it was shown that at early growth stage (BBCH 12, 2 leaves, unfolded[14]) very low amount of the active substance hymexazol was present in the seedlings, so it may be expected that at flowering stage (>BBCH 60) the amount of residue in plants is even lower, if present at all. Therefore, the risk to bees from exposure to contaminated nectar or pollen is deemed to be low.

Exposure via honeydew
In a seedling residue study it was shown that at early growth stage (BBCH 12) very low amount of the active substance hymexazol was present in sugar beet seedlings. Although sugar beet leaves may be infested with aphids already at early BBCH stages (3-4 leaves, ≥BBCH 14) it is not considered likely that any produced honeydew will contain high amounts of hymexazol, mainly in view of the low levels of residue found in seedlings at BBCH 12.

Conclusions bees
The product complies with the RGB.

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

7.5.1 Effects on non-target arthropods

Species	Stage	Test Substance [1]	Dose [kg a.s./ha]	Endpoint
Laboratory tests				
T. pyri	Protonymph	TACHIGAREN 30 L	0.01-4.00	Mortality: LR50 = 1107 g a.s./ha Reproduction: NOEC (eggs/female) = 400 g a.s./ha
A. rhopalosiphi	Adult	TACHIGAREN 30 L	0.01-2.00	Mortality: LR50 = 1426 g a.s./ha beneficial capacity[2]: NOEC (mummies/female) = 400 g a.s./ha

[1] Test substance TACHIGAREN 30 L = 30.4 % (w/w) hymexazol
[2] Beneficial capacity = parasitism

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 E.9.

Table E.9 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	0.042	1	-	-	1.426	0.03
T. pyri	0.042	1	-	-	1.107	0.04

[14] http://www.bba.de/veroeff/bbch/bbcheng.pdf ; choose 'beet'

	Application rate (kg a.s./ha)	MAF[1]	Drift fraction / Vegetation factor[2]	Safety factor[2]	LR_{50} (kg a.s./ha)	HQ
Off-field						
A. rhopalosiphi	0.042	1	n.a.	10	1.426	n.d.
T. pyri	0.042	1	n.a.	10	1.107	n.d.

[1]: Multiple Application Factor
[2]: off-field: drift fraction = not applicable for seed treatments, vegetation distribution factor = 10, safety factor = 10 (default values)
n.a.: not applicable
n.d.: not determined

As the above table shows, the in-field HQ values are well below the trigger value of 2. Since no spray drift occurs in seed treatments, the off-field HQ was not calculated due to lack of a drift fraction value. Furthermore, in view of the proposed application as seed treatment an off-field risk to ground-dwelling arthropods is not expected.

Thus, it appears that for the active substance hymexazol the proposed use meets the standards for non-target arthropods as laid down in the RGB.

7.5.2 Earthworms

The acute risk for earthworms is calculated as TER-value (trigger value 10). Since the logPow of the active substance < 2, no correction to the reference soil containing 4.7 % organic matter is necessary. Exposure is expressed as the initial PECsoil. The PECsoil is calculated in section 6.1.1. Table E.10 presents endpoints, PECsoil and TER values.

Table E.10 Overview of soil concentrations and acute TERs for earthworms

Use	Substance	LC50 [mg a.s./kg]	PIECsoil [mg a.s./kg]	TER	Trigger value
Sugar beet seed treatment	Hymexazol	281.9	0.056	5034	10
	Tachigraen 70 WP	238.9	0.056	4266	10

In view of the results presented in Table E.10, a low acute risk for earthworms is expected at the proposed use.

Sublethal studies are not required because the TER values are > 10, the DT90 is below 365 days and the use concerns a single application per year.

Thus, for the active substance hymexazol the proposed use meets the standards for earthworms as laid down in the RGB.

7.5.2.2 Other soil macro-organisms

No data for other soil macro-organisms are available, nor are such data required.

7.5.3 Effects on soil micro-organisms

In the tested soils no effects are observed on nitrogen transformation and carbon respiration processes at relevant application rates with the active substance hymexazol. Since the reduction percentage is below 25% after 71 days, the standards from the RGB regarding soil micro-organisms are met.

7.5.4 Effects on activated sludge

Article 2.10a of the Plant Protection Products and Biocides Regulations (RGB) describes the authorization criterion STP.

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 uses no exposure of activated sludge is expected. Therefore, the proposed application complies with the standards for activated sludge as laid down in the RGB.

7.5.5 Effects on non target-plants

The risk assessment for non-target plants is based on an off-crop situation with a drift percentage of 4.7%. The exposure thus equals [0.047] * the application rate * MAF (in case of multiple application). As the proposed use concerns the treatment of sugar beet seeds, no spray drift occurs and calculation of TER values is deemed not necessary.

Thus, it appears that the product does comply with the RGB.

Conclusions any other organisms

The product does comply with the RGB for the aspects non-target arthropods, earthworms, soil micro-organisms, activated sludge and non-target plants.

Considering the acceptable risk of hymexazol for earthworms, soil macro-organisms, soil micro-oranisms and non-target plants, hymexazol 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

No restriction sentences were proposed by the applicant.

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

In the WG (legal instructions):

Om vogels te beschermen moet blootstelling aan zaden geminimaliseerd worden. Om dit te bereiken dienen bij het uitzaaien van het behandelde zaad specifieke instructies gevolgd te worden die vermeld staan op de zakken behandeld zaad.

Het volgende moet worden vermeld op de zakken met behandeld zaad:

Bij het zaaien

Om de vogels te beschermen moet het behandelde zaad volledig in de bodem worden ondergewerkt; zorg ervoor dat het behandelde zaad ook aan het voorend is ondergewerkt. Om vogels te beschermen moet u gemorste zaden verwijderen.

7.10 Overall conclusions regarding ecotoxicology

It can be concluded that:

1. all proposed applications of the active substance hymexazol meet the standards for persistence as laid down in the RGB.
2. all proposed applications of the active substance hymexazol meet the standards for birds as laid down in the RGB, provided that a restriction sentence is included on the label.

3. all proposed applications of the active substance hymexazol meet the standards for aquatic organisms as laid down in the RGB.
4. the active substance hymexazol meets the standards for bioconcentration as laid down in the RGB.
5. all proposed applications of the active substance hymexazol meet the standards for mammals as laid down in the RGB.
6. all proposed applications of the active substance hymexazol meet the standards for bees as laid down in the RGB.
7. all proposed applications of the active substance hymexazol meet the standards for non-target arthropods as laid down in the RGB.
8. all proposed applications of the active substance hymexazol meet the standards for earthworms as laid down in the RGB.
9. all proposed applications of the active substance hymexazol meet the standards for soil micro-organisms as laid down in the RGB.
10. all proposed applications of the active substance hymexazol meet the standards for activated sludge as laid down in the RGB.
11. all proposed applications of the active substance hymexazol meet the standards for non-target plants as laid down in the RGB

8. Efficacy

TACHIGAREN 70 WP is a fungicide containing 700 g/kg hymexazol and is formulated as a wettable powder (WP). In the Netherlands TACHIGAREN 70 WP is authorized in the culture of sugar beets as a seed treatment against fungal diseases for more than 20 years. Under the current authorisation the product has to be used in combination with the active substance thiram.
This submission of TACHIGAREN 70 WP is considered a re-registration for the Netherlands. The proposed dose rate is almost doubled and the combination with the active substance thiram is no longer required.

Table 8-1: Details of the active substance and the product

Product name	TACHIGAREN 70 WP
Formulation	WP
Active substance	hymexazol
Concentration	700 g/kg
Chemical group	isoxazoles
Mode of action	Interferes DNA/RNA synthesis

Mode of action:
Hymexazol is a systemic soil and seed fungicide. It is rapidly translocated and has local systemic distribution properties. It also exhibits moderate apoplastic (xylem-mediated) transport properties, but has no symplastic (phloem-mediated) transport properties. Hymexazol belongs to the chemical group of isoxazoles, part of the group heteroaromatics. The proposed mode of action is interference with DNA/RNA synthesis.

The plant protection product
TACHIGAREN 70 WP is a wettable powder containing 700 g/kg hymexazol. The product is authorized in various countries of all three EU registration zones. A large part of the sugar beet seeds drilled in Europe are treated with TACHIGAREN 70 WP.
For the Netherlands, the existing authorization of TACHIGAREN 70 WP is 21 gram product/ unit of seeds + 8 gram thiram 50% per unit of seeds. In the re-registration process, the claim of TACHIGAREN 70 WP is changed to a dose rate of 40 gram TACHIGAREN 70 WP (28 g a.s./unit seed). The combination with thiram is no longer required.

Table 8-2: Simplified table of registered uses and requested uses for TACHIGAREN 70 WP

Uses		Member State	Dose rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Existing use (current registered dose rate)				
Sugar beets	damping-off diseases	NL	14.7 g a.s./unit seed + 4 g thiram	
New use (proposed dose rate)				
Sugar beets	damping-off diseases	NL	28 g a.s./unit seed	

The data presented in this dRR are intended to support the label claim for TACHIGAREN 70 WP for the control of the damping-off diseases, caused by *Aphanomyces* spp. and *Pythium* spp. in sugar beets.

Description of the target pests

Table 8-3: Glossary of pests mentioned in the dossier

EPPO code	Scientific name	Common name
APHASP	*Aphanomyces* spp.	Damping-off disease
PYTHSP	*Pythium* spp.	Damping-off disease

Aphanomyces spp.
An important root disease in sugar beet production is caused by the soil borne oomycete *Aphanomyces cochlioides*. *A. cochlioides* is well recognized as a pathogen wherever sugar beet is grown worldwide. The acute seedling phase of the disease is commonly referred to as black root. The chronic root rot phase occurs on plants infected earlier in the season or from new infections on older plants, and is more common than the acute phase in many production areas. The disease is initiated when soils become warm and wet. Under these conditions, the overwintering resting spores (oospores) germinate and can infect plants directly, or through the production of zoospores. These spores can swim independently through soil water.

Pythium spp.
Pythium sp. are soil borne and common soil pathogens. *Pythium* spp, like *Aphanomyces* spp. belong to the oomycetes. *Pythium* occurs in all fields and wet conditions are favourable for infection of seeds or seedlings. *Pythium* infected seeds rot before or while they germinate. *Pythium* can cause seed rot depending on conditions, or may slow or delay emergence. These conditions include temperature, deep sowing, and excessive soil moisture. Under wet conditions, *Pythium* also causes damping-off, usually within the first week of emergence. Symptoms of *Pythium* include a brown, water-soaked discoloration of the seedlings before or just after emergence. Overwintering resting spores (oospores) germinate and can infect plants directly, or through the production of zoospores. These spores can swim independently through soil water. In some species no oospores are formed and dispersal takes place exclusively by zoospores.

Table 8-4: Major/ minor status of intended uses

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Sugar beets	NL	-	*Aphanomyces* spp.	NL	-
			Pythium spp.	NL	-

The information in this dRR is summarised from the core Biological Assessment Dossier of TACHIGAREN 70 WP, made by LKC UK Ltd, may 2013.

Trials were carried out by contractors and research institutes, that are recognized by the authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

Information on trial methodology of the minimum effective dose trials and the effectiveness trials is presented in table 8-5.

Table 8-5: Overview of the details of the trials (Minimum effective dose, effectiveness and phytotoxicity)

Guidelines	General guidelines	EPPO PP 1/181(3): Conduct and reporting of efficacy evaluation trials including good experimental practice EPPO PP 1/152 (3): Design and analysis of efficacy evaluation trials EPPO PP 1/135(3): Phytotoxicity assessment EPPO PP 1/226 (2): Number of efficacy trials
	Specific guidelines	EPPO PP 1/125 (3): Seeds treatments against seedling diseases (trials under controlled conditions) CEB MG 02: Principes généraux d'étude en conditions de culture de l'efficacité pratique de préparations destinées à protéger les plantes et les produits végétaux contre les maladies
Experimental design	Plot design	RCBD
	Plot size field trials	20-27 m^2
	Pot t trials	Plant growth rooms
	Number of replications	4-8
Crop	Varieties field trials	Effectiveness: Cetus, Julietta Phytotoxicity: Cetus, Etna, Harpoon, Julietta, Kujawska, Lubelska, Manhattan,
	Varieties laboratory trials	Effectiveness: Sandra, Koala Phytotoxicity: Harpoon, Koala, Kujawska, Lubelska, Sandra
	Sowing period	Between and 22-3 / 14-5
Application	Crop stage (BBCH) at application	BBCH 00; Seed treatment
	Number of applications	1
Assessment	Assessment types	early plant emergence (after1-3 weeks) (number or %) late plant emergence (3-8 weeks) (number or %) infected plants (% or infection score on scale 0-4)
Other relevant information	Soil type field trials	Sandy clay, sandy silt, clay loam, loamy soil.
	Plant growth rooms	Infected field soil

Reference products

In the Netherlands, no suitable reference products against damping-off diseases in sugar beets are available, because no other seed treatment products are authorized. Therefore the results of the seed treatment with TACHIGAREN 70 WP are compared with the untreated seeds. No comparison was made between the new claimed dose rate of 28 g a.s./unit seeds and the authorized dose rare of 14.7 g a.s./unit seeds in combination with 4 g thiram.

8.1 Efficacy evaluation

8.1.1 Preliminary tests

No preliminary range findings tests were conducted. TACHIGAREN 70 WP has been used for more than 30 years through Europe, and the uses are known.

8.1.2 Dose justification

To determine the minimum effective dose of TACHIGAREN 70 WP, seventeen trials with different dose rates are available; eleven in plant growth rooms and six under field

conditions. The growth medium for the trials in the plant growth rooms was taken from infected fields.
In three trials only one disease was present, in the other trials both diseases were present.

In table 8.6 and 8.7 an overview of the results with different dose rates in plant growth rooms is given. In table 8.6 the percentage emerged plants 2-4 weeks after drilling is given. Table 8.7 gives an overview of the percentage infected plants 3-7 weeks after drilling.

Table 8.6: Percentage of emerged plants in plant growth room from seeds treated with different dose rates of TACHIGAREN 70 WP

		Percentage emerged plants (number of trials)				
	Disease	untreated	0.25N	0.5N	1.0N	2.0N
Mean	P	53.6 (1)	57.6 (1)	70.0 (1)	90 (1)	92.4 (1)
Mean	P+A	97.0 (8)	98.5 (8)	98.6 (8)	99.0 (8)	98.2 (8)
Range		91.3-101.3	94.8-101.0	93.5-102	93.5-102.5	87.3-103.5

P= *Pythium* spp.; A=*Aphanomyces* spp.

Table 8.7: Percentage of infected plants in plant growth rooms from seeds treated with different dose rates of TACHIGAREN 70 WP

		Percentage emerged plants (number of trials)				
	Disease	untreated	0.25N	0.5N	1.0N	2.0N
Mean	P	56.6 (2)	48.8 (1)	29.4 (2)	15.8 (2)	8 (1)
Range		49.2-64	48.8	26.7-32.0	12.8-18.7	8
Mean	A	2.6* (1)	0.7* (1)	0.2* (1)	0.0* (1)	0.3* (1)
Mean	P+A	58.0 (8)	28.5 (8)	21.1 (8)	9.3 (8)	2.9 (8)
Range		18.2-96-7	1.0-93.4	0.0-63.0	0.2-26.7	0-11.7

P= *Pythium* spp.; A=*Aphanomyces* spp.
*= assessment made with an infection score on a scale 0-4

In most trials, a small increase of the percentage of emerged seeds was visible by increasing the dose rate of TACHIGAREN 70 WP. In the trials, with different dose rates, the increase from 0.25N to 0.5N was significant in 3 trials; from 0.5N to 1.0N in 2 trials and in none of the trials a significant increase was visible when the dose rate was increased from 1.0N to 2.0N.

The effect of increasing the dose rate on the percentage infected plants was more clear. In all trials a significant difference between the untreated seeds and the seeds treated with the proposed use of TACHIGAREN 70 WP was visible. The increase from 0.25N to 0.5N was significant in 3 trials; from 0.5N to 1.0N in 3 trials and in one of the trials a significant increase was visible when the dose rate was increased from 1.0N to 2.0N.

In six field trials the dose rates 0.5N, 1.0N and 1.5N were tested. In table 8.8 an overview of the results with different dose rates in the field trials is given.

Table 8.8. Increasing percentage of emerged plants from seeds treated with different dose rates of TACHIGAREN 70 WP under field conditions

	Increasing of emerged plants from seeds treated with TACHIGAREN 70 WP compared to untreated seeds in % (number of trials)		
Dose rate	0.5N	1.0N	1.5N
Mean	3.60 (6)	10.6 (6)	10.3 (6)
Range	-14.2-10.9	3.1-19.8	1.0-17.0

In all field trials, a positive effect of the treatment with TACHIGAREN 70 WP was visible. The effect of 1.0N and 1.5N were comparable. The results of the field trials were in line with the trials in plant growth rooms.

In general, the proposed dose rate to control *Pythium* sp. and *Aphanomyces* sp. is confirmed in the trials.

Summary and conclusions on the minimum effective dose

The information is sufficient to evaluate the minimum effective dose rate of TACHIGAREN 70 WP against damping-off diseases in sugar beets. In eleven trials conducted in plant growth rooms and in six field trials different dose rates of TACHIGAREN 70 WP were tested. According to the presented results, the dose rate of 40 gram TACHIGAREN 70 WP/unit seed (=28 g hymexazol/ unit seed) provided the optimum overall control and should be considered as the minimum effective dose rate for control of *Pythium* spp. and *Aphanomyces* spp.

Effectiveness

To evaluate the effectiveness of TACHIGAREN 70 WP against damping-off diseases seventeen trials are available. The trials were carried out in plant growth rooms (eleven trials) in The Netherlands, United Kingdom and France and under field conditions (six trials) in France and Denmark in 2012 and 2013. In table 8.5 an overview of the details of the trials is given.

In the Netherlands, no suitable reference products against damping-off diseases in sugar beets are available, because no other seed treatment products against these diseases are authorised. Therefore the results of the seed treatment with TACHIGAREN 70 WP are compared with the untreated control. In table 8.9 an overview of the results in plant growth rooms is given.

Table 8.9: Percentage of emerged and infected plants in plant growth room

		Percentage emerged plants (number of trials)		Percentage infected plants (number of trials)	
	Disease	Untreated control	40 g TACHIGAREN 70 WP/ unit seed	Untreated control	40 g TACHIGAREN 70 WP/ unit seed
Mean	P	53.6 (1)	90 (1)	56,6 (2)	15,75 (2)
Range		-	-	49.2-64	12.8-18.7
Mean	A	-	-	2.6* (1)	0.0* (1)
Range				-	-
Mean	P+A	97.0 (8)	99.0 (8)	50.9 (8)	7.3 (8)
Range		91.3-101.3	93.5-102.5	18.2-96.7	0.2-26.7

P= *Pythium* spp.; A=*Aphanomyces* spp.

Eleven trials from plant growth rooms are available. In five trials, there were no significant differences in the percentage of emerged plants in the untreated control and seeds treated with the proposed use of TACHIGAREN 70 WP. In three trials the percentage of emerged plants was significantly higher when the seeds were treated with TACHIGAREN 70 WP. In all trials the percentage of infected plants was lower after a treatment with TACHIGAREN 70 WP. In eight trials this effect was significant.

Six field trials are available to evaluate the effectiveness of a seed treatment with TACHIGAREN 70 WP. In all trials the number of emerged plants was determined and the difference between the emergence in untreated control and the emergence of treated seeds was calculated (percentage).. In four trials the percentage of infected plants was determined. In table 8.10 an overview of the results in the field trials is given.

Table 8.10: Percentage of emerged and infected plants in field trials

	Calculated difference between the emergence in untreated control and the emergence of treated seeds in %. (number of trials)	Percentage infected plants (number of trials)	
		untreated control	40 g TACHIGAREN 70 WP/unit seed
Mean	10.6 (6)	6.7 (4)	1.8 (4)
Range	3.1-17.9	3-14.6	0-4

In one trial the number of emerged seeds treated with TACHIGAREN 70 WP was lower compared to the number of emerged seeds in the untreated control. In one trial the number of emerged seeds was comparable and in four trials the number of emerged seeds was higher compared to the untreated control. In none of the trials the differences were significant. In four trials the percentage of infected plants was determined. In one trial no clear effect of the treatment with TACHIGAREN 70 WP was visible; in three trials the percentage of infected plants was lower compared to the untreated control. The differences were not significant. The results of trials conducted on the field were in line with the results from the trials conducted in plant growth rooms.

Summary and conclusion of the effectiveness trials

The applicant submitted a large number of trials that were performed under controlled conditions (plant growth rooms). Under normal circumstances efficacy trials should be performed under field conditions if the proposed use is a field use.
In the case of seed treatments it is often difficult to have sufficiently challenging conditions in field trials. The field trials indeed show a relatively low infestation in the untreated controls. The trials under controlled conditions can, in this case be used as additional data.

The information to evaluate the effectiveness of TACHIGAREN 70 WP against damping-off diseases in sugar beets is sufficient.
Eleven trials in plant growth rooms and six trials under field conditions are available. In general, the percentage of emerged plants was increased and the percentage of infected plants was decreased by a seed treatment with TACHIGAREN 70 WP against damping-off disease in sugar beets.

The evaluation complies with the Uniform Principles, article 2.1
The product effectively controls damping off caused by *Pythium* spp*.* and *Aphanidermatum* spp*.*

8.2 Harmful effects

To evaluate the phytotoxicity of TACHIGAREN 70 WP.trials in absence of diseases are available. These trials were conducted under different conditions in different countries. In the minimum effective dose and effectiveness trials assessments on phytotoxicity were also made. Data from field trials and trials in plant growth rooms are available. In total, 60 trials from different countries are available; 41 field trials and 19 plant growth room trials. Several aspects were assessed in the trials: sugar, sodium, potassium and N-amino content in sugar beets at harvest time; visual phytotoxic symptoms (i.e. malformation, chlorosis, yellowing and toxic spot); plant vigour; influence on germination of the seeds.

In table 8.11 an overview of the trials used to evaluated the adverse effects of a seed treatment with TACHIGAREN 70 WP on sugar beets is given.

Table 8.11: Number of the trials used for evaluating phytotoxicity

Country	Number of trials	Range of dose rates g TACHIGAREN 70 WP /unit seed	Sugar content	Na, K, N-amino content	Yield	Germination	Phytotoxicity symptoms	Period
Field trials								
Denmark	4	20-60	x	x	x			2012
Denmark	27	25	x	x	x			2002-2008
France	1	20-50	x		x			2012
Germany	1	5-60					x	2012
Poland	2	17-34					x	2005
Sweden	3	20-60	x	x	x			2012

Sweden	3	5-60					x	2012
Plant growth room trials								
France	1	10-40				x	x	2012
Germany	3	5-60					x	2012-2013
Netherlands	4	5-60				x	x	2012-2013
Poland	2	17-34				x	x	2005
Spain	1	20-60				x	x	2012
Sweden	8	5-60					x	2012-2013

8.2.1 Phytotoxicity

Phytotoxitic symptoms
In none of the trials, visual phototoxic symptoms (i.e. malformation, chlorosis, yellowing, toxic spot and so on) were visible.

Germination
In two trials in plant growth room rooms slow germination especially at higher dose rates (1.5N and 2.0N) were found, but full recovery was observed at the time of full emergence. Germination capacity was assessed in one plant growth room trial with dose rates between 0.25N and 2.0N. The criterion adopted by the sugar beet inter-professional association is that the lots which are sown must emerge at 75% after 96 hours, and at 89% after 7 days, in absence of any infestation. All seeds tested had a good germination value, above the minimum requirements at 96 hours

No phytotoxicity symptom caused by TACHIGAREN 70 WP at the proposed dose rate of 40 g/unit seed was recorded in the trials.

8.2.2 Yield

In general fungicides would be expected to have no or low adverse effects on the target plants. In 35 trials yield at harvest of the crop was assessed. There were no significant differences between the untreated and treated plots. This could be due to the fact that with a lower number of plants, but spread well over the plots, still a reasonable harvest is possible. In some trials, yield was assessed in the absence of pest. In these trials no effect of TACHIGAREN 70 WP was visible.

In none of the trials, TACHIGAREN 70 WP at the proposed label rate of 40 g/seed unit had a negative effect on the yield of sugar beets.

Effects on the quality of plants or plant products
Based on the results of the effectiveness and phytotoxicity trials no negative effects on quality of plants or plant products is expected. In 35 trials yield at harvest of the crop was assessed. In 35 trials the content of sugar in the sugar beets was assessed and in 34 trials the content of sodium, potassium and N-amino. There were no significant differences between the untreated and treated plots.

In none of the trials, TACHIGAREN 70 WP at the proposed label rate of 40 g/seed unit had any effect on the content of sugar, sodium, potassium and N-amino in the sugar beets.

Effects on transformation processes
No information on the effects of TACHIGAREN 70 WP on the transformation process of sugar beets is available. No residues of hymexazol (the relevant residue in sugar beet) above the limit of quantification have been found in supervised residue trials carried out over several seasons. The use of TACHIGAREN 70 WP is known for 30 years and no negative effects of the treatment are known. No negative effects on transformation processes are expected. Therefore no further information is needed.

8.2.3 Effects on succeeding crops or substitution crops

No significant phytotoxicity with a negative impact on sugar beet was recorded when TACHIGAREN 70 WP was used as a seed treatment. TACHIGAREN 70 WP is a fungicide and is therefore not expected to have any significant impact on succeeding crops.
It can be concluded that the use of product TACHIGAREN 70 WP does not lead to unacceptable risk for succeeding crops when applied according to the recommendations.

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

Not relevant for the claim. The proposed use of TACHIGAREN 70 WP is for the protection of the culture of sugar beets. Therefore, there is no requirement for the evaluation of effects on plants for propagating purposes.

8.2.5 Effects on adjacent crops

Adverse effects of a seed treatment on other plants, including adjacent crops, are not expected by normal use due to good agricultural practice. For this reasons negative effects of TACHIGAREN 70 WP on other plants including adjacent crops are not expected.

Conclusion adverse effects

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

8.3 Resistance

The active substance of TACHIGAREN 70 WP, hymexazol, belongs to the group of the heteroaromatics with FRAC code 32. The target site of active substances from this group is the DNA/RNA synthesis.
Because:

- according to the FRAC resistance in this group is not known;
- the proposed use of TACHIGAREN 70 WP in sugar beets as a seed treatment is one application per year;
- the proposed use of TACHIGAREN 70 WP in sugar beets is preventive application against soil borne diseases and;
- sugar beets are grown in a wide crop rotation (at least 3 years);

the risk of resistance for damping-off diseases to hymexazol in sugar beets is regarded as low.

Conclusion

The evaluation complies with the Uniform Principles, article 2.1.3.
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. Resistance management sentences on the label are not required.

8.5 Any other relevant data / information / Data requirements

No other or special studies have been carried out.

Data requirements

None.

Restriction sentences

None.

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 assessment for the operator, as mentioned above, the following labeling of the preparation is proposed:

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
hymexazol			
Pictogram:	GHS02 GHS05 GHS08 GHS09	Signal word:	Danger
H-statements:	H228	Flammable solid.	
	H318	Causes serious eye damage.	
	H361d	Suspected of damaging the unborn child.	
	H411	Toxic to aquatic life with long lasting effects	
P-statements:	P210	Keep away from heat/sparks/open flames/hot surfaces. – No smoking.	
	P273	Avoid release to the environment.	
	P280	Wear protective gloves/protective clothing/eye protection/face protection.	
	P305+P351+P338+P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.	
	P501	Dispose of contents/container to hazardous or special waste collection point.	
Supplemental Hazard information:	EUH208	Contains hymexazol. May produce an allergic reaction.	
	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.	
SP 1-statement: (gewas)	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:	Based on assigned H-statements.
H-statements:	H318 based on the formulation study H361d based on the classification of the active substance a determined during the EU review of hymexazol. H411: Based on chronic toxicity of hymexazol to aquatic invertebrates
P-statements:	The selected P-statements are (highly) recommended with the assigned H-statements and were also proposed by the applicant.
Other:	EUH401: All plant protection products subject to 1107/2009/EC shall also include this phrase. SP1 according to Reg. (EU) No 547/2011

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

The following restriction sentence needs to be placed on the legal instructions for use (WG):

Om vogels te beschermen moet blootstelling aan zaden geminimaliseerd worden. Om dit te bereiken dienen bij het uitzaaien van het behandelde zaad specifieke instructies gevolgd te worden die vermeld staan op de zakken behandeld zaad.

Het volgende moet worden vermeld op de zakken met behandeld zaad:

Bij het zaaien
Om de vogels te beschermen moet het behandelde zaad volledig in de bodem worden ondergewerkt; zorg ervoor dat het behandelde zaad ook aan het voorend is ondergewerkt.
Om vogels te beschermen moet u gemorste zaden verwijderen.

Appendix 1 Table of authorized uses; TACHIGAREN 70 WP; hymexazol 700 g/kg.

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/or situation (crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled**	**Application**			**Application rate**			**PHI** (days)	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	g product / 100.000 seeds a) max. rate per appl. b) max. total rate per crop/season	g as/100.000 seeds a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha		
1	All Zones	Sugar beets	I/F	Damping-off, caused by *Aphanomyces* spp and *Pythium* spp	Seed treatment	Pre-sowing (Sowing = march-april)	1	40 g	28 g	42 g a.i./ha	-	Based on a maximum seed rate of 1.5 unit/ha and a concentration of 28 g a.i./unit seeds (1 unit = 100,000 seeds).

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.

Annex point/ reference number	**Year**	**Title** **Source (where different from company)** **Report no.** **GLP or GEP status (where relevant)** **Published or not**	**Data Protection Claimed Y/N**	**Owner**
IIA 6.2.1/03 IIIA 8.2/01	2012	[14C] Hymexazol: Metabolism in Sugar Beet Innovative Environmental Services, Switzerland Report No: 20110054 Date: 02 April 2012 GLP, unpublished	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 0	2013	Biological Assessment Dossier of Tachigaren 70WP	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 3	2002	Dossier according to Directive 91/414/EEC, Summary and Assessment Document M-III (Tier II), Point 6: Efficacy Data	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 4	2012	Fungicide seed treatment in sugar beet Tachigaren and Thiram Mitsui Chemical Agro, Ltd. Nordic Beet Research, Report 423-2012 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.

Annex point/ reference number	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
III A 6/Annex 5	2012	Rapport d'essai Sumi Agro/ITB Fungicide en traitements de semences, Efficacité du Tachigaren Institut Technique de la Betterave, Report 2012ITB03 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 6	2012	Rapport d'essai Sumi Agro/ITB Fungicide en traitements de semences, Efficacité du Tachigaren Institut Technique de la Betterave, Report 2012ITB02 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 7	2012	Rapport d'essai Sumi Agro/ITB Fungicide en traitements de semences, Efficacité du Tachigaren Institut Technique de la Betterave, Report 2012ITB01 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 8	2013	Effectiveness of the fungicide Tachigaren to control damping off caused by Pythium sp. Agrene GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 9	2012	Report on the efficacy of hymexazol seed treatment to control *Aphanomyces cochlioides* under climate room conditions in sugar beet in 2012 Instituut voor Rationele Suikerproductie (IRS), Report 12V05 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 10	2012	Report on the efficacy of hymexazol seed treatment to control Phytium ultimum under climate room conditions in sugar beet in 2012 Instituut voor Rationele Suikerproductie (IRS), Report 12V03 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.

Annex point/ reference number	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
III A 6/Annex 11	2005	Badania nad biologiczna ocean srodka Tachigaren 70WP zastosowanego w dawce 1500 I 3000 g/100 kg ziarna w terminie BBCH 00 w zwalczaniu chorob grzybowych buraka cukrowego odmiany Instytut Ochrony Roslin, Sosnicowice, Report 52F/2005 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 12	2005	The evaluation of the biological efficacy and selecticvity of seed treatment Tachigaren 70 WP in sugar beet Akadamia Rolnicza IM. Augusta Cieszkowskiego w Poznaniu, Report 47/rej/43/05/Pr GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 13	1994	Agrochemical Efficacy Test, Sugar Beet, Fungicides, Aphanomyces cochlioides. Oak Park Research Centre Carlow, Irland Report OP/PP/19/94 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 14	2012	Study of the activity and selectivity of the fungicide Tachigaren 70WP in seed dressing in sugar beet in Northern Spain AIMCRA, Report 2606107412 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 15	2007	New seed treatmens against soil borne fungi in sugar beet Sockernäringens Betodlings Utveckling (SBU), Report 2007-1-2-487 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 16	2004	New seed treatmens against soil borne fungi in sugar beet Sockernäringens Betodlings Utveckling (SBU), Report 2004-1-2-487 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 17	2005	New seed treatmens against soil borne fungi in sugar beet Sockernäringens Betodlings Utveckling (SBU), Report 2005-1-2-487 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 18	2005	New seed treatmens against soil borne fungi in sugar beet Sockernäringens Betodlings Utveckling (SBU), Report 2006-1-2-487 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.

Annex point/ reference number	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
III A 6/Annex 19	2008	Seed treatments against soil borne fungi in sugar beets 2008 Nordic Beet Research, Report 2008-424 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 20	2013	Aphanomyces screen, Final Report Broom's Barn Suffolk GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 21	2004	Fungicide Seed Dressing in Sugar Beet Alstegaard Sugar Beet Research Foundation, Report 2004-2-4-460 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 22	2003	Fungicide Seed Dressing in Sugar Beet Alstegaard Sugar Beet Research Foundation, Report 2003-2-4-460 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 23	2001	Fungicide Seed Dressing in Sugar Beet Alstegaard Sugar Beet Research Foundation, Report 2001-2-4-484 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 24	2005	Fungicide Seed Dressing in Sugar Beet Alstegaard Sugar Beet Research Foundation, Report 2005-2-4-460 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 25	2006	Fungicide Seed Dressing in Sugar Beet Alstegaard Sugar Beet Research Foundation, Report 2006-2-4-460 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 26	2007	Fungicide Seed Dressing in Sugar Beet Alstegaard Sugar Beet Research Foundation, Report 2007-2-4-460 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 27	2008	Fungicide Seed Dressing in Sugar Beet Tachigaren and Thiram Mitsui Chemical Agro, Ltd. Nordic Beet Research, Report 2008-2-4-423 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.

Annex point/ reference number	**Year**	**Title** **Source (where different from company)** **Report no.** **GLP or GEP status (where relevant)** **Published or not**	**Data Protection Claimed Y/N**	**Owner**
III A 6/Annex 28	2012	PP 1/125(3) Seed treatments against seedling diseases LWK Niedersachsen PSA Hannover, Report 12744FZR127 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 29	2013	Research on the efficacy of hymexazol seed treatment to control *Aphanomyces cochlioides* under climate room conditions in sugar beet in 2013 Instituut voor Rationele Suikerproductie (IRS), Report 12V03 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 30	2001	New seed treatmens against fungi in sugar beet Sockernäringens Betodlings Utveckling (SBU), Report 2001-1-2-482 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 31	2002	New seed treatmens against fungi in sugar beet Sockernäringens Betodlings Utveckling (SBU), Report 2002-1-2-484 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 32	1982	Damping-off sugar beet in Finland: Causal agents and some factors affecting the disease. Dpr of Plant Pathology, University of Helsinki Not GEP, Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 33	1981	Lutte contre le pythium de la betterave avec le Tachigaren, France 1981 Schell Chimie/Agrishell Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 34	2000	Sugar Beet Trials, Italy Agronomica GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 35	2013	Hymexazol against *Pythium* in sugar beet (high infestation) LWK Niedersachsen PSA Hannover, Report 4F12SUD066 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 36	2013	PP 1/125(3) Hymexazol against *Pythium* in sugar beet (Incrustation, medium infestation) LWK Niedersachsen PSA Hannover, Report 4F12SUD070 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.

Annex point/ reference number	**Year**	**Title** **Source (where different from company)** **Report no.** **GLP or GEP status (where relevant)** **Published or not**	**Data Protection Claimed Y/N**	**Owner**
III A 6/Annex 37	2013	Hymexazol against seedling diseases in sugar beet LWK Niedersachsen PSA Hannover, Report 4F12SUD077 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 38	2013	Efficacy testing of hymexazol in sugar beets, Sweden 2013 (Experiment 1-8) Nordic Beet Research, Report 424-2013 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 39	2013	Efficacy testing of hymexazol in sugar beets, Sweden 2013 (Experiment 9-16) Nordic Beet Research, Report 424-2013 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 40	2013	Efficacy testing of hymexazol in sugar beets, Sweden 2012 Nordic Beet Research, Report 424-2012 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.
III A 6/Annex 41	2013	Research on the efficacy of hymexazol seed treatment to control Pythium ultimum under climate room conditions in sugar beet in 2013 Instituut voor Rationele Suikerproductie (IRS), Report 13V07 GEP, Not Published	Y	Mitsui Chemicals Agro, Inc.