14300 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. BESLUIT

Op 15 augustus 2014 is van

Arysta LifeScience S.A.S.
Route d'Artix - BP 80
F-64150 NOGUERES
FRANKRIJK

een aanvraag tot wijziging van het Wettelijk Gebruiksvoorschrift ontvangen voor het middel

Centurion Plus

op basis van de werkzame stof clethodim.

HET COLLEGE BESLUIT tot toelating van de aangevraagde wijziging van het Wettelijk Gebruiksvoorschrift voor het bovenstaand middel.

Het middel Centurion Plus is bij besluit 4 april 2014 toegelaten. De wijziging betreft een toevoeging van een restrictiezin voor de toepassingsvoorwaarden.

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 conform de geldende regelgeving op of bij 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)

Het nieuwe gebruiksvoorschrift en de nieuwe etikettering dienen bij de eerstvolgende aanmaak op de verpakking te worden aangebracht. De te hanteren w-coderingen en aflever- en opgebruiktermijnen voor oude verpakkingen staan vermeld onder “toelatingsinformatie” in bijlage I.

2. WETTELIJKE GRONDSLAG

Besluit	Artikel 45 van de Verordening (EG) 1107/2009
Classificatie en etikettering	Artikel 31 en Artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Deze beoordeling is conform RGB (Hoofdstuk 2) en Evaluation Manual 1.0.

3. BEOORDELINGEN

Voor de beoordeling van de aangevraagde wijziging is uitgegaan van de laatste volledige beoordeling; besluit tot toelating d.d. 4 april 2014.

3.1 Fysische en chemische eigenschappen

Gelet op de aard van het verzoek is dit aspect niet beoordeeld. De fysische en chemische eigenschappen wijzigen niet.

3.2 Analysemethoden

Gelet op de aard van het verzoek is dit aspect niet beoordeeld.

3.3 Risico voor de mens

Gelet op de aard van het verzoek is dit aspect niet beoordeeld.

3.4 Risico voor het milieu

Op basis van de geleverde gegevens kan worden vastgesteld dat de risico’s van de gewenste wijziging aanvaardbaar zijn voor het milieu. De wijziging betreft het toevoegen van de restrictie dat het middel toepast mag worden indien gebruik gemaakt wordt van een conventionele spuit in combinatie met 75% driftreducerende spuitdoppen + kantdop + 2,75 meter teeltvrije zone (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelgrens).

3.5 Werkzaamheid

Gelet op de aard van het verzoek is dit aspect niet beoordeeld.

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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, 3 april 2015

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

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BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20145907 NLWG
Type aanvraag:	aanvraag tot mineure wijziging WG nationaal
Middelnaam:	Centurion Plus
*Formele registratiedatum: **	19 september 2014
Datum in behandeling name:	

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

2 Stofinformatie

Werkzame stof	Gehalte
clethodim	120G/L

De stof is per 1 juni 2011 geplaatst op Annex I van Richtlijn 91/414/EEG (Richtlijn 2011/21/EU van 2 maart 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:	14300 N
Expiratiedatum:	1 maart 2024
Afgeleide parallel of origineel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel

W-coderingen en aflever- en opgebruiktermijnen:

- *W-codering professioneel gebruik:* 1
- *Vorige w-codering professioneel gebruik:* 0
- *Aflevertermijn professioneel gebruik:* Onbeperkt
- *Opgebruiktermijn professioneel gebruik:* Onbeperkt

4 Verpakkingsinformatie

Aard van het preparaat:
Emulgeerbaar concentraat

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BIJLAGE II Etikettering van het middel Centurion Plus

De etikettering is niet gewijzigd ten opzichte van het vorige besluit d.d. 4 april 2014.

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BIJLAGE III WG van het middel

Wettelijk Gebruiksvoorschrift
Toegestaan is uitsluitend het professionele gebruik als onkruidbestrijdingsmiddel door middel van een na opkomst behandeling of behandeling na uitplanten in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.0, Ctgb juni 2011) onder de vermelde toepassingsvoorwaarden

Toepassings-gebied	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus	Veiligheidstermijn in dagen
Aardappelen	Eenjarige grasachtige onkruiden	1 l/ha	1	56
	Kweek [1]	2,5 l/ha	1	
Bieten	Eenjarige grasachtige onkruiden en stuifdek	1 l/ha	1	56
	Kweek [1]	2,5 l/ha	1	
Winterkoolzaad	Eenjarige grasachtige onkruiden en graanopslag	1 l/ha	1	120
Boon met peul (onbedekte teelt)	Eenjarige grasachtige onkruiden	1 l/ha	1	30
Erwt met peul (onbedekte teelt)	Eenjarige grasachtige onkruiden	1 l/ha	1	30
Sluitkoolachtigen	Eenjarige grasachtige onkruiden	1 l/ha	1	28
	Kweek [1]	2 l/ha	1	
Wortelen	Eenjarige grasachtige onkruiden	1 l/ha	1	48
	Kweek [1]	2 l/ha	1	
Zaaiui	Eenjarige grasachtige onkruiden	1 l/ha	1	56
	Kweek [1]	2 l/ha	1	
Eerstejaars plantui	Eenjarige grasachtige onkruiden	1 l/ha	1	56
	Kweek [1]	2 l/ha	1	
Tweedejaars plantui	Eenjarige grasachtige onkruiden	1 l/ha	1	56
	Kweek [1]	2 l/ha	1	

Toepassings-gebied	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus	Veiligheidstermijn in dagen
Sjalotten	Eenjarige grasachtige onkruiden	1 l/ha	1	56
	Kweek [1]	2 l/ha	1	
Knoflook	Eenjarige grasachtige onkruiden	1 l/ha	1	56
	Kweek [1]	2 l/ha	1	

[1] *Agropyron repens*

Toepassingsvoorwaarden

Om niet tot de doelsoorten behorende geleedpotigen/ insecten en niet tot de doelsoorten behorende planten te beschermen is toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van de onderstaande maatregelen:
- Lage spuitboomhoogte (30 cm boven de top van het gewas) in combinatie met minimaal 50% drift reducerende spuitdoppen + kantdop + luchtondersteuning; of
- Lage spuitboomhoogte (30 cm boven de top van het gewas) in combinatie met Venturidop + kantdop + 1,0 meter teeltvrije zone (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelsgrens); of
- Conventionele spuit in combinatie met 75% driftreducerende spuitdoppen + kantdop + 2,75 meter teeltvrije zone (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelgrens); of
- Sleepdoek in combinatie met minimaal 50% driftreducerende spuitdoppen; of
- Overkapte beddenspuit

Met name de gewassen maïs en granen zijn zeer gevoelig voor de stof clethodim. Met deze gewassen in de directe nabijheid dient bij bespuiting van het te behandelen perceel elke mate van drift naar genoemde gewassen te worden vermeden.

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BIJLAGE IV Onderbouwing

Contents

1. Identity of the plant protection product

1.1 Applicant
Arysta LifeScience S.A.S.
Route d'Artix
BP80
64150 Nogueres, France

1.2 Identity of the active substance
In accordance with the identity in the original authorization.

1.3 Identity of the plant protection product
In accordance with the identity in the original authorization.

1.4 Function
Herbicide.

1.5 Uses applied for
Not applicable.

1.6 Background to the application
An application is done for a label amendment and concerns an additional drift reducing measure.

1.7 Packaging details
Packaging details remain the same.

2. Physical and chemical properties
Physical and chemical properties remain the same.

3. Methods of analysis
No changes occur in the methods of analysis.

4. Mammalian toxicology
No changes occur concerning mammalian toxicology.

5. Residues
No changes occur concerning residues.

6. Environmental fate and behaviour
No changes occur concerning fate and behaviour.

7. Ecotoxicology

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

Clethodim was included in Annex I van Richtlijn 91/414 on 1 June 2011 (Directive 201/21/EC of 2 March 2011), date of expiry 31 May 2021. The applicant is notifier of the dossier and RMS is The Netherlands. For the active substance a review report is available: SANCO/13456/2010 final 28 januari 2011; a revision is published: SANCO/13456/2010 final, 9 december 2011. EFSA conclusion, including final LoEP, is available: EFSA Journal 2011; 9(10):2417, date of publication 21 oktober 2011.

The final List of Endpoints from the EFSA conclusion (Oct, 2011) is used for risk assessment. In addition, studies on ecotoxicity of formulations to environmental organisms were evaluated by EPP Consultancy and have been used in the assessment (Report 120801).

Centurion Plus is also known under the names Select Super and Centurion Max, and under the code TM-20015.

List of Endpoints Ecotoxicology

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

Acute toxicity to birds	LD_{50} >1640 mg/kg bw (bobwhite quail)
Dietary toxicity to birds	LC_{50} >851 mg/kg bw/day (mallard duck)
Reproductive toxicity to birds	NOEL 17 mg/kg bw/day (bobwhite quail)
Acute toxicity to mammals	LD_{50} 1133 g/kg bw (rat)
Reproductive toxicity to mammals	NOEL 16 mg/kg bw/day (rat, 2-year chronic toxicity and carcinogenicity study)

SFO 1st order DT_{50} for residue decline of clethodim on treated crops *(summarised in the "Evaluation report by RMS Netherlands" dated 05 January 2012 (report available on confidential EFSA website))*	*Carrot leaves:* *<2.6 & <2.8 days (2 trials)* *Carrot root:* *2.8 & <2.9 days (2 trials)* *Potato haulm:* *4.6, 1.7, 3.6 & 1.6 days (4 trials)* *Wine grape:* *3.7 days (1 trials)* *Sugar beet leaves:* *5.8 & 2.8 days (2 trials)* *Overall arithmetic mean: 3.3 days*

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance*	Time-scale	Endpoint	Toxicity (mg a.s./l)**
Laboratory tests				
Salmo gairdneri	clethodim	96 h	Mortality, EC_{50}	25 (A)
Oncorhynchis mykiss		21 d	NOEC	3.9 (A)
Daphnia magna		48 h	Immobility, EC_{50}	>100 (B)
Daphnia magna		21 d	Reproduction, NOEC	49 (B)
Selenastrum capricornutum		72 h	Biomass, growth rate, EC_{50}	>12 (A)
Lemna gibba		14 d	Fronds, EC_{50}	**1.9** (C)
Oncorhynchus mykiss	Select 240 EC	96 h	Mortality, EC_{50}	**3.4** (B)
Oncorhynchus mykiss	Select + oily adjuvant	21 d	NOEC	**0.29** (A)
Oncorhynchus mykiss	TM-20016	21 d	NOEC	1.1 (B)
Daphnia magna	Select 2 EC	48 h	Immobility, EC_{50}	**5.1** (A)
Daphnia magna	Select + oily adjuvant	21 d	Reproduction, NOEC	**0.00084** (B)

Daphnia magna	TM-20016	21 d	Reproduction, NOEC	0.51 (B)
Scenedesmus subspicatus	Select + oily adjuvant	72 h	Biomass, growth rate, EC_{50}	**1.5** (A)
Scenedesmus subspicatus	Select 2 EC	72 h	growth rate, EC_{50}	3.2 (A)
Lemna gibba	Select 240 EC + oily adjuvant	14 d	Fronds, EC_{50}	4.52 (B)
Lemna gibba	Select 2 EC	14 d	Fronds, EC_{50}	69 (A)
Desmodesmus subspicatus	clethodim sulfoxide	72 h	Biomass, EC_{50}	>100 (B)
Lemna gibba	clethodim sulfoxide	7 d	Biomass, EC_{50}	88 (B)
Oncorhynchis mykiss	clethodim sulfoxide	96 h	Mortality, EC_{50}	> 100 (B)
Chironomus riparius	clethodim imine	28 d	Emergence, NOEC	10 (D)
Microcosm or mesocosm tests				
Not available				

* Formulations Select and Select 2 EC are identical, but differ from Select 240 EC in solvent content. Select 240 = 240 g clethodim/L. Select and Select 2EC = 256 g clethodim/L. TM-20016 is a 240 g/L clethodim formulation without oily adjuvant.

**endpoint given in bold are used in risk assessment. Since the formulation is more toxic than the active substance by one order of magnitude or more (except for *L. gibba*), the data on the product should be used for risk assessment. This is in line with section 2.5.3 from the aquatic guidance document. Furthermore, endpoints from the formulation studies including the oily adjuvant should be used, since the endpoints with Select with the oily adjuvant are worst case and the GAP as submitted with the dossier contained applications with oily adjuvant only. However, formulated clethodim could also be used without oily adjuvant. Selection of the relevant endpoint should therefore be taken at Member State level, depending on the proposed use.

(A) Based on mean measured concentrations.
(B) Based on analytically confirmed nominal concentrations.
(C) Based on nominal concentrations (analytically confirmed for initial concentrations).
(D) Based on measured initial concentrations.

Bioconcentration

Bioconcentration factor (BCF)	Clethodim: 2.1
Annex VI Trigger for the bioconcentration factor	1000 for readily biodegradable compounds
Clearance time (CT_{50}) (CT_{90})	4.9 d (allyl-label) and 0.23 d (ring-label) 16 d (allyl-ring) and 0.76 d (ring-label)
Level of residues (%) in organisms after the 14 day depuration phase	≤ 30% after 14 d depuration

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

Acute oral toxicity	LD_{50} >43 µg a.s./bee (Select 240 EC) LD_{50} 55 µg a.s./bee (Select + adjuvant)
Acute contact toxicity	LD_{50} >51 µg a.s./bee (Select 240 EC) LD_{50} 68 µg a.s./bee (Select + adjuvant)
Field or semi-field tests Not required	

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

Species	Test type and exposure scenario	Test Substance	Dose (g as/ha)	Endpoint	Adverse effect (%)* or $L(E)R_{50}$ (g a.s./ha)	Annex VI /Escort II Trigger
Laboratory tests						
Aphidius rhopalosiphi	Laboratory, sprayed plants	Select + Adjuvant	9.6 240	mortality/reproduction LR_{50}, ER_{50}	0 / 5 0 / 5 >240 g a.s./ha	50%
Typhlodromus pyri	Extended laboratory(A)	Select + Adjuvant	9.6	mortality/reproduction	82 / 51	50%

				LR_{50}, ER_{50}	<9.6 g a.s./ha	
Typhlodromus pyri	Extended laboratory(A)	Select + Adjuvant	0.6 1.2 2.4 4.8 9.6	mortality/reproduction LR_{50} ER_{50}	1 / 10 4 / 0.2 16 / 14 73 / 33 100 / n.a.(B) 3.6 g a.s./ha >4.8 g a.s./ha	50%
Typhlodromus pyri	Extended laboratory	Select 240 EC	0, 11 and 384	Fresh residues: 4, 7 & 14 d aged: 	LR_{50} <384 ER_{50} >11 LR_{50} >384 ER_{50} >384	50%
Poecilus cupreus	Laboratory, sand	Select + Adjuvant	256	mortality /food consumption LR_{50}	3.3 / +3.1 >256 g a.s./ha	50%
Poecilus cupreus	Laboratory, sand	Select 240 EC	221	mortality /food consumption LR_{50}	3.4 / 10 >221 g a.s./ha	50%
Aleochara bilineata	Laboratory, sand	Select 240 EC	259	parasitic capacity ER_{50}	2.6 >259 g a.s./ha	50%
Aleochara bilineata	Laboratory, natural soil	Select 240 EC + Adjuvant	386	parasitic capacity ER_{50}	1.9 >386 g a.s./ha	50%
Chrysoperla carnea	Extended laboratory(C)	Select 240 + Adjuvant	384	mortality/reproduction LR_{50}, ER_{50}	2.2 / 19 >384 g a.s./ha	50%

* Effects are adverse effects, i.e. X% effect on mortality means X% more mortality and Y% effect on reproduction means Y% less reproduction compared to control. When effects are favourable for the test organisms, a + sign is used for the sublethal effect percentages and a – sign for mortality effect percentages.
(A) Exposure to dry residues on laboratory treated *Phaseolus vulgaris* leaves.
(B) n.a. = not applicable (insufficient survivors from initial phase to assess reproduction).
(C) Exposure to dry residues in conjunction with esterified rape seed oil (1.0 L/ha) on laboratory treated apple leaves.

Field or semi-field tests
Not provided

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

Acute toxicity	**clethodim sulfoxide** LC_{50} >1000 mg/kg (500 mg a.s./kg(A)) **Select 240 EC** LC_{50} 129 mg a.s./kg (65 mg a.s./kg(A))
Reproductive toxicity	**clethodim oxazole sulfone** NOEC 10 mg/kg (5 mg a.s./kg(A))

(A) corrected for organic content of OECD 207 substrate

Study submitted with present application 20110591 TG (report 120801 by EPP Consultancy):

Acute toxicity	***TM-5403 (120 g a.s./L EC formulation):*** *LC_{50} 27.3 mg a.s./kg (13.7 mg a.s./kg(A))*

(A) corrected for organic content of OECD 207 substrate

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

Nitrogen mineralization	**Clethodim** Up to 2.741 mg a.s./kg: effects <25% **Select EC 240** Up to 2.7 mg a.s./kg: effects <25% (1 soil) At 0.53 and 2.7 mg a.s./kg: effects >25% after 28 and 42 days (= end of test) (2nd soil) **Select + Para Sommer**(= oily adjuvant) Up to 1.7 mg a.s./kg: effects <25% (2 soils)(A). **Clethodim oxazole sulfone** Up to 0.10 mg a.s./kg: effects <25%
Carbon mineralization	**Clethodim** Up to 2.741 mg a.s./kg: effects <25% **Select EC 240** Up to 2.7 mg a.s./kg: effects <25% (2 soils). **Select + Para Sommer**(= oily adjuvant) Up to 1.7 mg a.s./kg: effects <25% (2 soils). **Clethodim oxazole sulfone** Up to 0.10 mg a.s./kg: effects <25%

(A) Study not suitable to evaluate effects of metabolites.

Effects on other non-target organisms (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Collembola					
Clethodim oxazole sulfoxide: NOEC 100 mg a.s./kg soil (*F. candida*) (NOEC 50 mg a.s./kg soil corrected for organic content of OECD 207 substrate)					
Non-target terrestrial plants					
Screening data with Select 2 EC-H and Para Sommer					
Species	treatment	survival (kg a.s./ha)		biomass production (kg a.s./ha)	
		NOEC	ER_{50}	NOEC	ER_{50}
Oat	post-emergence	0.016	0.024	0.0040	0.099
Corn	post-emergence	0.0040	0.0081	0.25	0.25
Onion	post-emergence	0.76	>0.76	0.76	>0.76
Rape	post-emergence	0.76	>0.76	0.063	>0.76
Carrot	post-emergence	0.76	>0.76	0.063	0.23
Red clover	post-emergence	0.76	>0.76	0.76	>0.76

Seedling emergence and vegetative vigour tests with active substance clethodim, metabolites and formulation Select

	Rate response for seedling emergence	**Rate response for vegetative vigor (plant dry weight)**
	EC_{50} (g a.s./ha)	**EC_{50} (g a.s./ha)**
Ryegrass *(L. perenne)*		clethodim: 6.7 g a.s./ha clethodim sulfoxide: 25 g a.s./ha clethodim sulfone: 23 g a.s./ha clethodim oxazole sulfone: >320 g a.s./ha
Cockspurr grass *(E. crus-galli)*		clethodim: 3.4 g a.s./ha clethodim sulfoxide: 16 g a.s./ha clethodim sulfone: 12 g a.s./ha clethodim oxazole sulfone: >320 g a.s./ha
Soybean (*Glycine max*)		
Lettuce (*Lactuca sativa*)		
Carrot (*Daucus carota*)		

Tomato (*Lycopersicon esculentum*)	Select: > 0.28 *k*g a.s./ha (all species)	Select: > 0.28 *k*g a.s./ha (all species)
Cucumber (*Cucumis sativus*)		
Cabbage (*Brassica oleracea*		
Oat (*Avena sativa*)	Select: 54 g a.s./ha	Select: 20 g a.s./ha
Perennial ryegrass (*Lolium perenne*)	Select: 67 g a.s./ha	Select: 6.7 g a.s./ha
Corn (*Zea mays*)	Select: 25 g a.s./ha	Select: 13 g a.s./ha
Onion (*Allium cepa*)	Select: > 280 g a.s./ha	Select: > 280 g a.s./ha

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

Respiratory rate	**clethodim** EC_{50} > 95 mg/L **Select H EC24** EC_{50} 162 mg a.s./L

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

Compartment	
soil	Parent
water	Parent
sediment	Parent
groundwater	Parent
air	Parent

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	No classification is proposed

<u>Studies submitted with present application for Centurion Plus (20110591 TG) (report 120801 by EPP Consultancy):</u>

Toxicity data for aquatic species

Group	*Test substance*	*Time-scale*	*Endpoint*	*Toxicity (mg a.s./l)*
Laboratory tests				
Oncorhynchis mykiss	*TM-20015 (Centurion Plus)*	*96 h*	*Mortality, LC_{50}*	*1.21(A)*
Daphnia magna	*TM-20015 (Centurion Plus)*	*48 h*	*Immobility, EC_{50}*	*3.97(A)*
Pseudokirchneriella subcapitata	*TM-20015 (Centurion Plus)*	*72 h*	*ErC_{50}* *EbC50*	*>1.35(A)* *0.77(A)*
Anabaena flos aquae	*TM-20015 (Centurion Plus)*	*72 h*	*ErC_{50}* *EbC50*	*2.15(A)* *1.0(A)*
Lemna gibba	*TM-20015 (Centurion Plus)*	*7 d*	*ErC_{50}* *EbC50*	*14.0(A)* *1.60(A)*

(A) Based on analytically confirmed nominal concentrations.

Effects on bees

Acute oral toxicity	*LD_{50} >14 µg a.s./bee (Select 120)*
Acute contact toxicity	*LD_{50} >14 µg a.s./bee (Select 120)*

Effects on other arthropod species

Species	*Test type and exposure scenario*	*Test Substance*	*Dose (g as/ha)*	*Endpoint*	*L(E)R_{50} (g a.s./ha)*	*Annex VI /Escort II Trigger*
Laboratory tests						
Aphidius rhopalosiphi	*Extended laboratory (barley seedlings)*	*Select 120*(A)	*0.033 - 325.5 g a.s./ha*	*mortality/ reproduction*	*LR_{50}, ER_{50}: >330 g a.s./ha*	*50%*
Typhlodromus pyri	*Extended laboratory (leaf discs)*	*Select 120*(A)	*1.96 - 35 g a.s./ha*	*mortality/reproduction*	*LR_{50}: 3.7 g a.s./ha ER_{50}: >3.5 g a.s./ha*	*50%*

(A) No information was submitted to confirm that Select 120 is identical to Centurion Plus.

Soil micro-organisms

Nitrogen mineralization	***TM-20015 (Centurion Plus)*** *Up to 2.05 mg a.s./kg: effects <25% after 56 days (= end of test) (1 soil)*
Carbon mineralization	***TM-20015 (Centurion Plus)*** *Up to 2.05 mg a.s./kg: effects <25% after 62 days (= end of test) (1 soil)*

Non-target terrestrial plants

	Seedling emergence performed with Centurion Pro (135.2 g clethodim/L)(A)	***Vegetative vigor performed with Centurion Pro (135.2 g clethodim/L (A)***
	ER_{50} (g a.s./ha)	***ER_{50} (g a.s./ha)***
Oat (Avena sativa)	*>270 g a.s./ha*	*10.8 g a.s./ha*
Onion (Allium cepa)	*>270 g a.s./ha*	*>270 g a.s./ha***
Maize (Zea mays)	*>270 g a.s./ha*	***4.73 g a.s./ha***
Radish (Raphanus sativus)	*>270 g a.s./ha*	*>270 g a.s./ha*
Carrot (Daucus carota)	*>270 g a.s./ha*	*>270 g a.s./ha*
Soybean (Glycine max)	*>270 g a.s./ha*	*>270 g a.s./ha*

(A) No information was submitted to confirm that Centurion Pro is identical to Centurion Plus.

***49% inhibition at 271 g a.s./ha*

<u>Additional studies on bioaccumulation in earthworms (summarised and evaluated by Ctgb (11/2013)</u>

Hamberger A., 2012 TM-20015 (Clethodim 120 g/L): a field study to evaluate residues of clethodim in earthworms following an application on bare soil in southern Germany

A field study was conducted in South Germany to determine the residues of clethodim and its metabolites clethodim sulfoxide, clethodim sulfone, clethodim oxazole sulfoxide and clethodim oxazole sulfone in earthworms collected from fields treated with TM-20015 (clethodim 120 g/L EC) at a nominal rate of 324 g a.s./ha.

Four plots of 12x19 m each were established in the field. Each plot was surrounded by a guard row of at least 5 m between adjacent plots and/or the edge of the field. The test item was applied to bare soil with a calibrated boom sprayer on 26 April 2012, at an intended application rate of 324 g a.s./ha. This test rate was equivalent to 0.432 mg a.s./kg soil dw (assuming an even incorporation over a depth of 5 cm).

The soil was characterised as a silty clay, pH was 5.12, 1.1% organic carbon.
Earthworms for residue analysis were sampled from two randomly selected 100 cm x 100 cm sampling areas per plot on each sampling occasion. The earthworm samples from each plot were pooled to give a single sample per plot. Samples were taken before application and at 1, 2, 4, 7, 14 and 28 days after application. Earthworms were not purged.

Results
On the day of application, only clethodim and clethodim sulfoxide were found in the soil. Measured concentrations were expressed as mg/kg soil w.w. while the target concentration was calculated for soil dry weight (and based on the nominal a.s. content of the product). Soil samples were reported to contain 19% water. The reviewer recalculated the soil concentrations to mg/kg soil dw. Mean measured concentrations in soil represented 71% of the target concentration.

The report stated that the deviation of the measured mean precipitation to the long term average was -31.2 mm in May, which was compensated by irrigation. However, after compensation for irrigation the deviation was still -26.2 mm. The deviation in April was -65.6 mm. Total earthworm biomass decreased during the study (see below), which indicates that precipitation may have been low.Lower precipitation may have led to reduced exposure of earthworms.

Earthworm abundance was 93 earthworms/m^2 at 1DAA. The mean abundance, calculated from samplings at 1DAA and 14DAA, was 80 earthworms/m^2. The dominant endogeic species was *A. caliginosa* (11.3% of total earthworms), the dominant anecic species was *L. terrestris* (5.0% of total earthworms) and the dominant epigeic species was *L. rubellus* (15.6% of total earthworms). 66.3% of the earthworms collected were juveniles.

Earthworm biomass was 51.5 g/m^2 before application, and 50.9, 76.7, 28.0, 35.8, 38.2 and 23.7 g/m^2 at 1DAA, 2DAA, 4DAA, 7DAA, 14DAA and 28DAA, respectively.

Residues in earthworms
The results concerning residues determined in earthworms are summarised in the Tables below. Residues in earthworms collected before the first treatment were all below the LOQ (<0.01 mg/kg w.w.). After 28 days, concentrations of clethodim and its metabolites were all below the limit of detection.

Residues of clethodim and its metabolites in earthworms sampled in plots treated with TM-20015 (clethodim 120 g/L EC) (concentrations in mg/kg earthworm w.w.)

Date	Replicate	Residues [mg/kg]					
		Clethodim		Clethodim Sulfoxide		Clethodim Sulfone	
			Mean		Mean		Mean
27/04/2012 1DAA	Ta	0.040	0.072	0.313	0.325	0.011	0.016
	Tb	0.045		0.226		0.016	
	Tc	0.103		0.272		0.017	
	Td	0.100		0.489		0.020	
28/04/2012 2DAA	Ta	0.006[a)]	0.018	0.207	0.297	0.020	0.027
	Tb	0.012		0.329		0.025	
	Tc	0.021		0.280		0.024	
	Td	0.032		0.372		0.039	
30/04/2012 4DAA	Ta	n.d.	n.d.	0.102	0.125	0.027	0.027
	Tb	n.d.		0.085		0.017	
	Tc	n.d.		0.171		0.029	
	Td	n.d.		0.141		0.033	
03/05/2012 7DAA	Ta	n.d.	n.d.	0.042	0.048	0.011	0.016
	Tb	n.d.		0.047		0.016	
	Tc	n.d.		0.056		0.017	
	Td	n.d.		0.048		0.020	
10/05/2012 14DAA	Ta	n.d.	n.d.	0.011	0.012	0.004[a)]	0.005[a)]
	Tb	n.d.		0.010		0.004[a)]	
	Tc	n.d.		0.012		0.005[a)]	
	Td	n.d.		0.014		0.006[a)]	
24/05/2012 28DAA	Ta	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	Tb	n.d.		n.d.		n.d.	
	Tc	n.d.		n.d.		n.d.	
	Td	n.d.		n.d.		n.d.	

DAA days after application
n.d. = not detectable (< 30 % of LOQ, i.e. below 0.003 mg/kg)
a) < LOQ (0.01 mg/kg)

DT_{50} and DT_{90} values were calculated from the residue data of clethodim, clethodim sulfoxide and clethodim sulfone. The results were analysed according to FOCUS (2006) by a single first order (SFO) model, based on individual replicate values, where the first value <LOQ was taken to be half the LOQ. The SFO fit was acceptable for all three substances, with acceptable visual fits and acceptable Chi^2 errors (all <15%). There was no evidence of a biphasic decline. Degradation rate constants were all significantly different from 0 (p-values all <0.001).

DT_{50}, DT_{90}, Chi^2, and estimated M(0) for elimination of clethodim, clethodim sulfoxide and clethodim sulfone in earthworms

Calculated for residues for	Kinetic model	DT_{50} (days)	DT_{90} (days)	Chi^2 error (%)	Visual fit	Estimated M(0) (mg/kg earthworm w.w.)
Clethodim	SFO	0.4966	1.6497	0.8848	Acceptable	0.29071
Clethodim sulfoxide	SFO	2.3304	7.7415	11.93	Acceptable	0.46601
Clethodim sulfone	SFO	5.9057	19.618	11.13	Acceptable	0.029070

The Estimated M(0) represents a worst-case assuming that concentrations in earthworms were highest at t = 0 and declined from day 1 onward, while in reality accumulation still had to take place at t = 0.

The report presented calculations for the 28-day TWA concentrations for clethodim, clethodim sulfoxide and clethodim sulfone. The calculations were not in agreement with Focus 2006 and were recalculated, but are not reported in the summary, as the risk assessment will be based on the worst-case, in order to take into account the uncertainty due to dry weather.

Schöbinger U., 2012 Clethodim: a laboratory study to evaluate bioaccumulation in earthworms

A study according to OECD 317 was conducted to determine the residue levels of clethodim and its metabolites in earthworms (*Eisenia fetida*), exposed under laboratory conditions to natural soil (pH 5.12) treated with clethodim at 0.65 mg a.s./kg soil d.w., during a period of 21 days, followed by a 21-day elimination period. The soil came from the treated field use in the field study described above.

The validity criteria were satisfied: ≤10% mortality (no mortality in the control and 0.625% mortality in the treatment) and ≤20% weight loss (a weight gain was observed between day 1 and 21). Clethodim residues in soil and earthworms were highest at test start and decreased below detection at day 7. Clethodim sulfoxide reached maximum levels at day 2 and then decreased until the end of the exposure phase. Residues of clethodim sulfone were detectable in soil from day 2, and in earthworms from day 10. These concentrations increased during the exposure phase. Clethodim oxazole sulfoxide and clethodim oxazole sulfone were only detected at low levels in soil but not in earthworms. At all sampling times, concentrations of clethodim sulfoxide and clethodim sulfone in earthworms were lower than those in soil. In the elimination phase, residues of clethodim sulfoxide and clethodim sulfone in earthworms decreased to below 50% of the initial residue within 4 days. The lipid content in untreated earthworms was 1.65% of wet mass before test start.

A steady state was not reached for clethodim or any of its metabolites. The author of the report therefore calculated a kinetic BAF for clethodim from the soil uptake rate constant (k_s) and the elimination rate constant (k_e). However, it is not correct to calculate a kinetic BAF for each sampling time. Furthermore, the guideline states that in cases where a significant decrease of the test substance in soil is observed over time during the uptake phase, the degradation rate constant in soil (k_0) should be considered in the calculations. This is the case for clethodim. Therefore, the reported BAF values (0.47-2.19 on days 1-7, mean 1.20) are not accepted.

The reviewer calculated the degradation rate constant in soil from the reported residue values, using SFO modelling with KinGUI 1.1, where the first values <LOQ were taken to be half the LOQ. The visual fit was good. Therefore, even though the Chi^2 error for the SFO fit was >15% (i.e. 31%), the fit was considered acceptable. The degradation rate constant in soil (k_0) was estimated to be 1.0438 day^{-1} (standard deviation 0.25, p-value <0.001).

The kinetic BAF for clethodim, calculated as k_s/k_e is thus 0.9943/2.4223 = 0.410 kg soil d.w./kg earthworm w.w.. Based on the lipid content of the earthworms in the study (1.65% of wet weight), the BAF is equivalent to 24.9 kg soil d.w./kg lipid w.w..

The uptake and elimination rate constant in earthworms were then calculated using equation 6 in the test guideline (for the uptake phase):

$C_a = \frac{k_s}{k_e - k_0} \times (e^{-k_0 t} - e^{-k_e t})$, where k_s is the uptake rate constant in earthworms, k_e is the elimination rate from earthworms, and k_0 is the degradation rate in soil (taken to be 1.0438 day^{-1}, from SFO). Modelmaker version 4.0 was used to optimize k_s and k_e. The fit was considered to be acceptable, with r^2 = 0.948. The uptake rate constant (k_s) was 0.9943 day^{-1} (optimization error 0.287) and the elimination rate constant (k_e) was 2.4223 day^{-1} (optimization error 0.689).

For clethodim sulfoxide and clethodim sulfone, BAF values were not derived. However, it can be concluded that the BAF values for these metabolites are <1, as concentrations in earthworms were always lower than those in soil. Furthermore, concentrations of total clethodim equivalents in earthworms (calculated after correction for molecular weights) were always lower than concentrations of total clethodim equivalents in soil. This indicates that clethodim and its metabolites do not accumulate in earthworms.

7.1 Effects on birds

Birds can be exposed to the active substance clethodim via natural food (sprayed insects, seeds, leaves), 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 Ratios (TERs) for acute and short-term exposure should be ≥ 10 and TER for chronic exposure should be ≥ 5. Table E.1 presents an overview of toxicity data.

Table E.1 Overview of toxicity data for birds

	Endpoint	Value
Acute toxicity to birds:	LD_{50}	>1640 mg a.s./kg bw
Dietary toxicity to birds:	LC_{50}	>851 mg a.s./kg bw/d
Reproductive toxicity to birds:	NOEL	17 mg a.s./kg bw/d

7.1.1 Natural food and drinking water

Sprayed products

Procedures for risk assessment for birds comply with the recommendations in the Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC (Sanco/4145/2000).

For the current application, uses can be categorized as leafy crops. Depending on the crop category, different indicator species are chosen. Table E.2 shows which indicator species are relevant for which uses.

Table E.2 Indicator species per use

Use	Crop	Indicator species
All	leafy	medium herbivorous and insectivorous

Table E.3a-c show the TER values for birds for the worst case use. The estimated daily uptake values (ETE, Estimated Theoretical Exposure) for acute, short-term and long-term exposure are calculated using the Food Intake Rate of the indicator species (FIR) divided by the body weight of the indicator species (bw), the Residue per Unit Dose (RUD), a time-weighted-average factor (f_{TWA}, only for long term) and the application rate. For uses with frequency > 1, a MAF (Multiple Application Factor) may be applicable. The ETE is calculated as application rate * (FIR/bw) * RUD * MAF [* $f_{TWA,}$ only for long term]. The ETE is compared to the relevant toxicity figure. TER should be above the trigger for an acceptable risk.

Table E.3a Acute risk for birds

Substance	FIR / bw	RUD	Application rate (kg a.s./ha)	MAF	Acute ETE (mg/kg bw/d)	LD50 (mg/kg bw/d)	TER (trigger 10)
medium herbivorous bird							
clethodim	0.76	87	0.3	-	19.8	>1640	83

					Acute ETE		TER
insectivorous bird							
clethodim	1.04	52	0.3	-	16.2	>1640	101

Table E.3b Short-term risk for birds

Substance	FIR / bw	RUD	Applica-tion rate (kg a.s./ha)	MAF	Short-term ETE (mg/kg bw/d)	LC50 (mg/kg bw/d)	TER (trigger 10)
medium herbivorous bird							
clethodim	0.76	40	0.3	-	9.1	>851	93
insectivorous bird							
clethodim	1.04	29	0.3	-	9.0	>851	94

Table E.3c Long-term risk for birds

Substance	FIR / bw	RUD	Applica-tion rate (kg a.s./ha)	MAF	ftwa	Long-term ETE (mg/kg bw/d)	NOEL (mg/kg bw/d)	TER (trigger 5)
medium herbivorous bird								
clethodim	0.76	40	0.3	-	0.53	4.8	17	**3.5**
insectivorous bird								
clethodim	1.04	29	0.3	-	-	9.0	17	**1.9**

Taking the results in Table E.3a-c into account, it appears that the acute and short-term risk of the proposed uses to birds is low, but that a long-term risk to birds cannot be excluded.

Refinement of the long-term risk to herbivorous birds

Refinement of the risk to herbivorous birds is possible by considering the short life-time of clethodim on the treated crops. Information on the decline of clethodim is available from plant metabolism studies summarised in the Draft Assessment Report (DAR) of Clethodim. Based on the metabolism studies for clethodim in carrots (two studies), the calculated DT_{50} was <2.6 and <2.8 days (carrot leaves) and 2.8 and <2.9 days (carrot root). Together wit the present application for registration, residue trials in the crops for which auhorisation is requested were submitted, which are summarised in the "Evaluation report by RMS Netherlands" dated 05 January 2012 (report available on confidential EFSA website). This report includes a few residue decline trials which may be used for estimation of the rate of declined of clethodim residues on treated crops. The following data are available (all from trials in Europe-North):

- potato haulm: 2.3/4.4 mg/kg after 0/11 days; 8.01/<0.1 mg/kg after 0/11 days; 7.02/1.02 mg/kg after 0/10 days; 11.99/0.25 mg/kg after 0/9 days; first order DT50 4.6, 1.7, 3.6 and 1.6 days, respectively.
- wine grape: 0.14/<0.005 mg/kg after 3/21 days; first order DT50 3.7 days.
- sugar beet leaves: 3.74/0.70 mg/kg after 0/14 days; 3.63/0.12 mg/kg after 0/14 days; first order DT50 5.8 and 2.8 days, respectively.

The overall mean first order DT50 of the above underlined values is 3.3 days. Calculation of the f_{twa} based on a DT50 of 3.3 days and a 21-day time window gives a f_{twa} value of 0.22. Centurion Plus is applied only once per season. Based on ftwa = 0.22, the long-term ETE is

2.0 and TER is 8.5, which is above the trigger of 5. Hence the long-term risk to herbivorous birds is acceptable for the proposed uses.

Refinement of the long-term risk to insectivorous birds
Revised arthropod residue data became available when the Guidance Document for Birds and Mammals (Sanco 4145/2000) was revised. The new GD has now officially been implemented in the Netherlands. However, this was after the submission of the current application for authorisation. Therefore the risk assessment of Centurion Plus was based on SANCO/4145/2000, in the first tier. The revised RUD values for arthropods are given in Table E.4 below. Furthermore, it was determined that a generic DT_{50} of 10 days can be used for arthropods. Based on this value, an f_{twa} of 0.53 can be used for clethodim.

Table E.4 Revised RUD values for arthropods

Crop/category of insects	Crop stage	mean	90th percentile
Ground dwelling invertebrates without interception[1]	ground directed applications	7.5	13.8
Ground dwelling invertebrates with interception[2]	applications directed to crop canopies	3.5	9.7
Insects (foliar dwelling invertebrates[3])	whole season	21.0	54.1

[1] applications on bare soil, or ground directed applications up to principle growth stage 3, ground directed applications in orchards/vines (e.g. herbicides)
[2] applications directed to crop canopies (orchards/vines), ground directed applications on top of crops with principle growth stage of 4 or greater
[3] no data are available for canopy dwelling invertebrates in winter or before the leaves appear (interception would be less)

The ETE and TER based on a RUD value of 21.0 and f_{twa} of 0.53 are presented in Table E.5 below.

Table E.5 Long-term risk for insectivorous birds (refinement based on EFSA (2009))

Substance	FIR / bw	RUD	Application rate (kg a.s./ha)	MAF	ftwa	Long-term ETE (mg/kg bw/d)	NOEL (mg/kg bw/d)	TER (trigger 5)
insectivorous bird								
clethodim	1.04	21	0.3	-	0.53		17	**4.9**

Taking the results in Table E.5 into account, it appears that a long-term risk to insectivorous birds for the proposed uses cannot be excluded as TER is just below the trigger of 5. However, the above assessment is conservative as it assumes that both PT and PD are 1. Since in practice this will not be the case, the long-term risk to insectivorous birds is considered to be acceptable.

drinking water
The risk from exposure through drinking surface water is calculated for a small bird with body weight 10 g and a DWI (daily water intake) of 2.7 g/d. Surface water concentrations are calculated using TOXSWA (see paragraph 6.2.1). In the first instance, acute exposure is taken into account. The highest $PIEC_{water}$ is 1.429 µg/L. It follows that the risk of drinking water is (LD50 * bw) / (PIEC*DWI) = (>1640 * 0.010) / (0.001429 * 0.0027) = $>4.3 \times 10^6$. Since TER > 10, the risk is acceptable.

Risk of metabolites of clethodim

Clethodim sulfoxide and clethodim imine sulfoxide are major (>10%) metabolites in plants. In the DAR a risk assessment was performed for exposure of birds to these plant metabolites at a treatment rate (0.384 kg a.s./ha) which is higher than the worst case treatment rate of the present application (0.3 kg a.s./ha). This risk assessment, which was based on the maximum formation of the metabolite in plants and the toxicity of parent clethodim, demonstrated that the risk of both metabolites to birds through consumption of contaminated plants is acceptable. Therefore the risk of both metabolites to birds through consumption of contaminated plants following the proposed uses of the present application is considered to be low.

7.1.2 Secondary poisoning

The risk as a result of secondary poisoning is assessed based on bioconcentration in fish and worms. Examination takes place against the threshold value for chronic exposure of 0.2 times the NOEC value. This means that the TER should be ≥ 5.

Fish

Clethodim

For clethodim a BCF of 2.1 L/kg is available. The highest $PEC_{water(21)}$ (taken from paragraph 6.2.1.) is reached for the use in sugar and fodder beets and potato and is 1.076 µg/L = 0.001076 mg/L.

Indicator species is a 1000-g bird eating 206 g fresh fish per day.

The TER is then calculated as NOEL / ($PEC_{water(21)}$ * BCF_{fish} * (FIR/bw) = 17 / (0.001076 * 2.1 * 0.21 = 35826. Since this is > 5, the risk for birds as a result of consumption of contaminated fish is considered to be small.

Earthworms

Clethodim

Since there are no experimental data the bioconcentration factor for earthworms (BCF_{worm}) is calculated according to the following formula: BCF = (0.84 + 0.01 * Kow) / f_{oc} * K_{oc}.

The $logK_{ow}$ of clethodim is 4.22, and the worst Koc (4.0 L/kg) is used, which leads to a BCF_{worm} = 2085 kg soil/kg worm.

The highest $PEC_{soil(21)}$ (taken from paragraph 6.1.1) is reached at the use in potato and is 0.070 mg/kg soil. Indicator species is a 100-g bird eating 113 g fresh worms per day.

The risk is then calculated as NOEL / $PEC_{soil(21)}$ * BCF_{worm} * (FIR/bw) = 17 / (0.070 * 2085 * 1.1) = 0.11. Since this is < 5, the risk for birds as a result of consumption of contaminated worms is considered to be high.

Refinement of the risk to earthworm eating birds

The above risk assessment uses a mean Koc and is based on the assumption that clethodim exists in soil in the non-dissociated form. Clethodim however has pKA 4.47, and at environmental pH the dissociated form of clethodim is relevant. It can be assumed that per pH unit above pKa, the amount of non-dissociated form decreases with a factor of 10. However, this non-dissociated fraction remains the relevant fraction to take into account for the risk assessment for bioaccumulation, because that is the speciation of clethodim that will enter the earthworms (since it is the non-polar, lipophilic speciation). The amount of dissociated clethodim that will enter earthworms will be negligible as compared to the amount of non-dissociated clethodim (the logKow of the dissociated fraction is about a factor of 3 lower, which will result in a BCF 1000 times lower, so even with the PECsoil of the dissociated fraction 10 times higher than the PECsoil of the non-dissociated fraction, the PECworm for the dissociated fraction will be a factor of 100 lower).

The risk assessment may be based on the 21d twa PECsoil of the non-dissociated fraction, together with a BCF based on Kow for the non-dissociated fraction. Based on the above, and the pH dependent Koc values, new BCF and TER values can be calculated: see Table E.6 below. Koc = 4 L/kg for soils with pH > 6.47 and 41.5 L/kg for soils with pH < 6.47.

BCFworm = 2085 or 201 for soils with pH >6.47 or < 6.47 respectively. For soil pH 4.5, 5.5 and 6.6, 100%, 10% and 1% of the worst case 21-day TWA PECsoil is used (0.070, 0.007 and 0.0007 mg/kg dry weight respectively). In addition, for soils of pH 4.5, TER for the best case use will be calculated ($PEC_{TWA,21d}$ is 0.020 mg/kg soil d.w.). This risk assessment is in line with that performed in the EU Addendum for Clethodim dated September 2007.

Table E.6 Refined long-term risk for earthworm eating birds

appln.	**Dose (kg as/ha)**	**NOEC (mg/kg bw/d)**	**Route**	**PEC_{FEED} (mg/kg wwt)**	**ETE (mg/kg bw/d)**	**TERlt**
potato (worst case)						
soil pH 4.5 *Koc 41.5 L/kg*	0.30	17	Earthworms	14.1	15.5	**1.1**
soil pH 5.5 *Koc 41.5 L/kg*	0.30	17	Earthworms	1.4	1.5	11.0
soil pH 6.5 *Koc 4 L/kg*	0.30	17	Earthworms	1.5	1.6	10.6
oil seed rape (best case)						
soil pH 4.5 *Koc 41.5 L/kg*	0.12	17	Earthworms	4.0	4.4	**3.8**

The TER values in the above table are below the trigger value of 5 for soils with pH 4.5 for all uses. TER values for soils with pH 5.5 and 6.5 are above the trigger of 5. Therefore, a safe use for earthworm eating birds is demonstrated for soils of pH 5.5 and higher. For soils with pH < 5.5 further refinement is necessary, for example measured residues in earthworms or an experimentally derived BCFworm.

Further refinement

The applicant submitted two news studies (see detailed description in the LoEP). One was a field study on a soil with pH 5.12, in which residues in earthworms were measured. Although there are some concerns on the draught during the study, which could lead to a lower exposure to earthwoms, the study shows that only low concentrations of clethodim and its metaboilites can be found in earthworms. Maximum calculated concentration were 0.29 mg/kg wwt for clethodim, which is almost a factor of 50 lower thant the calculated PEC feed (including a PEC $soil_{twa}$) of 14.1 mg/kg, and would lead to TERs far above the trigger of 5.

Furthermore, with the same soil an earthworm BCF study was performed. From the study a BAF of 0.41 mg/kg can be calculated for clethodim; which is more than a factor of 5000 times lower than the calculated BCF. For clethodim sulfoxide and clethodim sulfone, BAF values were not derived. However, it can be concluded that the BAF values for these metabolites are <1, as concentrations in earthworms were always lower than those in soil. Furthermore, concentrations of total clethodim equivalents in earthworms (calculated after correction for molecular weights) were always lower than concentrations of total clethodim equivalents in soil. This indicates that clethodim and its metabolites do not accumulate in earthworms (see also below).

Risk of metabolites of clethodim

Clethodim sulfoxide, clethodim sulfone and clethodim oxazole sulfone are major metabolites in soil. Clethodim sulfoxide, clethodim sulfone, clethodim imine and clethodim imine sulfoxide are major metabolites in water. The logKow of clethodim sulfoxide (2.07), clethodim imine (1.38) and clethodim imine sulfoxide (-0.76) is < 3. Clethodim sulfone is more polar than

clethodim sufoxide hence its logKow is <2.07. The logPow value of clethodim oxazole sulfone was estimated by the applicant to be <3.0 using EPA EPI Suite software, and by the RMS to be 1.73 using Pallas 3.0 (DAR clethodim). Hence for all metabolites the potential for bioaccumulation is considered to be low and no further assessment is deemed necessary

Conclusions birds
The product complies with the RGB.

7.2 Effects on aquatic organisms

7.2.1 Aquatic organisms

The risk for aquatic organisms is assessed by comparing toxicity values with surface water exposure concentrations from section 6.2. Risk assessment is based on toxicity-exposure ratios (TERs).
Toxicity data for aquatic organisms are presented in Table E.7. Because the application for authorisation concerns a herbicide, also the effects on macrophytes (aquatic plants) are evaluated.

Table E.7 Overview toxicity endpoints for aquatic organisms

Substance	Organism	Lowest		Toxicity value
		L(E)C_{50} [mg/L]	**NOEC [mg/L]**	**[µg/L]**
clethodim	*Acute*			
	Algae	>12		>12000
	Invertebrates	>100		>100000
	Fish	25		25000
	Macrophytes	1.9		1900
	Chronic			
	Invertebrates		49	49000
	Fish		3.9	3900
Clethodim sulfoxide	*Acute*			
	Algae	>100		>100000
	Invertebrates			
	Fish	>100		>100000
	Macrophytes	88		88000
TM-20015 (Centurion Plus)	*Acute*			
	Algae	0.77		770
	Invertebrates	3.97		3970
	Fish	1.21		1210
	Macrophytes	1.60		1600

These toxicity values are compared to the surface water concentrations calculated in section 6.2. Trigger values for acute exposure are 100 for invertebrates and fish (0.01 times the lowest L(E)C_{50}-value) and 10 for algae and macrophytes (0.1 times the lowest EC_{50}-value). Trigger values for chronic exposure are 10 for invertebrates and fish (0.1 times the lowest NOEC-values).
For acute and chronic risk, the initial concentration is used (PIEC) for TER calculation.
In table E.8a-b TER values for aquatic organisms are shown for the worst case use.

Table E.8a TER values: acute

Use	Substance	PECsw [µg a.s./L]	TER_{st} (trigger 10) Algae	TER_{st} (trigger 100) Invertebrates	TER_{st} (trigger 100) Fish	TER_{st} (trigger 10) Macrophytes
Sugar/fodder beets and potato (worst case)	Clethodim	1.429	>8397	>69979	17495	1330
	Clethodim-sulfoxide	0.919	>108814	-	>108814	95756
	Centurion Plus	1.429	539	2778	847	1120

Table E.8b TER values: chronic

Use	Substance	PECsw [µg a.s./L]	TER_{lt} (trigger 10) Invertebrates	TER_{lt} (trigger 10) Fish
Sugar/fodder beets and potato (worst case)	clethodim	1.429	34290	2729

Taking the results in Table E.8a-b into account, the acute TERs for fish and invertebrates are above the relevant Annex VI triggers of 100 and the acute TERs for algae and *Lemna* are above the relevant Annex VI triggers of 10. The chronic TERs for fish and invertebrates are above the relevant Annex VI triggers of 10. Thus, it appears that for the active substance clethodim, the metabolite clethodim sulfoxide and the formulation Centurion Plus the proposed uses meet the standards for aquatic organisms as laid down in the RGB.

No data on toxicity of the major water metabolites clethodim sulfone and clethodim imine sulfoxide are available. Considering however the very large safety margins calculated for parent clethodim and the even larger safety margins calculated for metabolite clethodim sulfoxide, and the fact that the PIEC of clethodim sulfone and clethodim imine sulfoxide is a factor of 5.8-6.8 lower than that of clethodim, the risk of these metabolites to aquatic organisms is considered to be acceptable.

7.2.2 Risk assessment for bioconcentration

For the active substance a BCF-value of 2.1 L/kg is available.
Since this value is below 100 L/kg, the risk for bioconcentration is small. Therefore the active substance clethodim meets the standards for bioconcentration as laid down in the RGB.

Metabolites

Since logKow of the metabolite clethodim sulfoxide is <3, experimental data are not required. A BCF-value of 11 L/kg can be calculated from logKow 2.07. Since this value is below 100 L/kg, the risk for bioconcentration is small. Therefore the metabolite clethodim sulfoxide meets the standards for bioconcentration as laid down in the RGB.
The metabolites clethodim sulfone and clethodim imine sulfoxide are of comparable or higher polarity than clethodim sulfoxide, hence their partition coefficient, and therefore their BCF, will be comparable to or lower than that of clethodim sulfoxide (hence <11 L/kg). Since this value is below 100 L/kg, the risk for bioconcentration is small. Therefore the metabolites clethodim sulfone and clethodim imine sulfoxide meet the standards for bioconcentration as laid down in the RGB.

7.2.3 Risk assessment for sediment organisms

The water–sediment study indicated that over 10% of the metabolites clethodim imine (max 35.8%) and clethodim imine sulfoxide (max 15.5%) is found in the sediment after 14 days, and no data on chronic toxicity of these metabolites for daphnids is available. The NOEC value of clethodim imine for *Chironomus* is 10000 µg/L. When this value is examined against the worst case PIEC in water, the TER value is 6998 and the trigger value of 10 is not exceeded. Therefore, the metabolite clethodim imine meets the standards for sediment organisms as laid down in the RGB. Considering the structural similarity of clethodim imine and clethodim imine sulfoxide, it is anticipated that the toxicity of these two metabolites to sediment dwelling organisms will be comparable. Taking into account further that the PIEC of clethodim imine sulfoxide is lower than that of clethodim imine, and the large safety margin calculated for clethodim imine, the risk of clethodim imine sulfoxide to sediment dwelling organisms is also considered to be low.

Conclusions aquatic organisms

The proposed applications meet the standards for aquatic organisms.

7.3 Effects on terrestrial vertebrates other than birds

Mammals can be exposed to the active substance clethodim via natural food (sprayed insects, 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.9 presents an overview of toxicity data.

Table E.9 Overview of toxicity data for mammals

	Endpoint	Value
Acute toxicity to mammals:	LD_{50}	1133 mg a.s./kg bw
Reproductive toxicity to mammals:	NOEL	16 mg a.s./kg bw/d

7.3.1 Natural food and drinking water

Sprayed products

Procedures for risk assessment for mammals comply with the recommendations in the Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC (Sanco/4145/2000).
For the current application, uses can be categorized as leafy crops. Depending on the crop category different indicator species are chosen. Table E.10 shows which indicator species are relevant for which uses.

Table E.10 Indicator species per use

Use	Crop	Indicator species
all	Leafy crop	Medium herbivorous mammal / insectivorous mammal

Table E.11a-b show for the worst case use the estimated daily uptake values (ETE, Estimated Theoretical Exposure) for acute and long-term exposure, using the Food Intake Rate of the indicator species (FIR) divided by the body weight of the indicator species (bw), the Residue per Unit Dose (RUD), a time-weighted-average factor (f_{TWA}, only for long term) and the application rate. For uses with frequency of > 1, a MAF (Multiple Application Factor) may be applicable. The ETE is calculated as application rate * (FIR/bw) * RUD * MAF [* $f_{TWA,}$

only for long term]. The ETE is compared to the relevant toxicity figure. TER should be above the trigger for an acceptable risk.

Table E.11a Acute risk for mammals

Substance	FIR / bw	RUD	Application rate (kg a.s./ha)	MAF	Acute ETE (mg/kg bw/d)	LD50 (mg/kg bw/d)	TER (trigger 10)
Medium herbivorous mammal							
clethodim	0.28	87	0.3	-	7.3	1133	155
insectivorous mammal							
clethodim	0.63	14	0.3	-	2.6	1133	428

Table E.11b Long-term risk for mammals

Substance	FIR / bw	RUD	Application rate (kg a.s./ha)	MAF	ftwa	Long-term ETE (mg/kg bw/d)	NOEL (mg/kg bw/d)	TER (trigger 5)
Medium herbivorous mammal								
clethodim	0.28	40	0.3	-	0.53	1.8	16	9.0
insectivorous mammal								
clethodim	0.63	5.1	0.3	-	-	1.0	16	17

Taking the results in Table E11a-b. into account, it appears that all proposed uses meet the standards laid down in the RGB.

drinking water

The risk from exposure through drinking surface water is calculated for a small mammal with body weight 10 g and a DWI (daily water intake) of 1.57 g/d. Surface water concentrations are calculated using TOXSWA (see paragraph 6.2.1). In the first instance, acute exposure is taken into account. The highest $PIEC_{water}$ is 1.429 µg/L. It follows that the risk of drinking water is (LD50 * bw) / (PIEC*DWI) = (1133 * 0.010) / (0.001429 * 0.00157) = $5x10^6$. Since TER > 10, the risk is acceptable.

Risk of metabolites of clethodim

Clethodim sulfoxide and clethodim imine sulfoxide are major (>10%) metabolites in plants. In the DAR a risk assessment was performed for exposure of mammals to these plant metabolites at a dose level (0.384 kg a.s.ha) which is higher than the worst case dose of the present application (0.3 kg a.s./ha). This risk assessment, which was based on the maximum formation of the metabolite in plants and the toxicity of parent clethodim, demonstrated that the risk of both metabolites to mammals through consumption of contaminated plants is acceptable. Therefore the risk of both metabolites to mammals through consumption of contaminated plants following the proposed uses of the present application is considered to be low.

7.3.2 Secondary poisoning

The risk as a result of secondary poisoning is assessed based on bioconcentration in fish and worms. Examination takes place against the threshold value for chronic exposure of 0.2 times the NOEC value. This means that the TER should be ≥ 5.

Fish

Clethodim

For clethodim a BCF of 2.1 L/kg is available. The highest $PEC_{water(21)}$ (taken from paragraph 6.2.1.) is reached for the use in sugar and fodder beets and potato and is 1.076 µg/L = 0.001076 mg/L. Indicator species is a 3000-g mammal eating 390 g fresh fish per day. The TER is then calculated as NOEL / ($PEC_{water(21)}$ * BCF_{fish} * (FIR/bw) = 16 / (0.001076 * 2.1 * 0.13) = $5x10^4$. Since this is > 5, the risk for mammals as a result of consumption of contaminated fish is considered to be small.

Earthworms

Clethodim

Since there are no experimental data the bioconcentration factor for earthworms (BCF_{worm}) is calculated according to the following formula: BCF = (0.84 + 0.01 * Kow) / f_{oc} * K_{oc}.
The $logK_{ow}$ of clethodim is 4.22, and the worst Koc (4.0 L/kg) is used, which leads to a BCF_{worm} = 2085 kg soil/kg worm.
The highest $PEC_{soil(21)}$ (taken from paragraph 6.1.1) is reached at the use in potato and is 0.070 mg/kg soil. Indicator species is a 10-g mammal eating 14 g fresh worms per day.
The risk is then calculated as NOEL / $PEC_{soil(21)}$ * BCF_{worm} * (FIR/bw) = 16 / (0.070 * 2085 * 1.4) = 0.078. Since this is < 5, the risk for mammals as a result of consumption of contaminated worms is considered to be high.

Refinement of the risk to earthworm eating mammals

The above risk assessment uses a mean Koc and is based on the assumption that clethodim exists in soil in the non-dissociated form. Clethodim however has pKA 4.47, and at environmental pH the dissociated form of clethodim is relevant. It can be assumed that per pH unit above pKa, the amount of non-dissociated form decreases with a factor of 10. However, this non-dissociated fraction remains the relevant fraction to take into account for the risk assessment for bioaccumulation, because that is the speciation of clethodim that will enter the earthworms (since it is the non-polar, lipophilic speciation). The amount of dissociated clethodim that will enter earthworms will be negligible as compared to the amount of non-dissociated clethodim (the logKow of the dissociated fraction is about a factor of 3 lower, which will result in a BCF 1000 times lower, so even with the PECsoil of the dissociated fraction 10 times higher than the PECsoil of the non-dissociated fraction, the PECworm for the dissociated fraction will be a factor of 100 lower).
The risk assessment may be based on the 21d twa PECsoil of the non-dissociated fraction, together with a BCF based on Kow for the non-dissociated fraction. Based on the above, and the pH dependent Koc values, new BCF and TER values can be calculated: see Table E.12 below. Koc = 4 L/kg for soils with pH > 6.47 and 41.5 L/kg for soils with pH < 6.47. BCFworm = 2085 or 201 for soils with pH >6.47 or < 6.47 respectively. For soil pH 4.5, 5.5 and 6.6, 100%, 10% and 1% of the worst case 21-day TWA PECsoil is used (0.070, 0.007 and 0.0007 mg/kg dry weight respectively). In addition, for soils of pH 4.5, TER for the best case use will be calculated ($PEC_{TWA,21d}$ is 0.020 mg/kg soil d.w.). This risk assessment is in line with that performed in the EU Addendum for Clethodim dated September 2007.
In addition, in the Addendum to the DAR (September, 2007), the RMS considered that the NOAEL from the 2-generation reproduction study with rat of 26.7 mg a.s./kg bw/d would be acceptable as a refinement of the endpoint from the 2-year toxicity study (NOAEL 16 mg a.s./kg bw/d). The assessment below uses the refined NOAEL of 26.7 mg a.s./kg bw/d.

Table E.12 Refined long-term risk for earthworm eating mammals

appln.	Dose (kg as/ha)	NOEL (mg/kg bw/d)	Route	PEC_{FEED} (mg/kg wwt)	ETE (mg/kg bw/d)	TERlt
potato (worst case)						
soil pH 4.5 *Koc 41.5 L/kg*	0.30	26.7	Earthworms	14.1	19.7	**1.4**
soil pH 5.5 *Koc 41.5 L/kg*	0.30	26.7	Earthworms	1.4	2.0	13.6
soil pH 6.5 *Koc 4 L/kg*	0.30	26.7	Earthworms	1.5	2.0	13.1
oil seed rape (best case)						
soil pH 4.5 *Koc 41.5 L/kg*	0.12	26.7	Earthworms	4.0	5.6	**4.7**

The TER values in the above table are below the trigger value of 5 for soils with pH 4.5 for all uses. TER values for soils with pH 5.5 and 6.5 are above the trigger of 5. Therefore, a safe use for earthworm eating mammals is demonstrated for soils of pH 5.5 and higher. For soils with pH <5.5 further refinement is necessary, for example measured residues in earthworms or an experimentally derived BCFworm.

Further refinement

The applicant submitted two news studies (see detailed description in the LoEP). One was a field study on a soil with pH 5.12, in which residues in earthworms were measured. Although there are some concerns on the draught during the study, which could lead to a lower exposure to earthwoms, the study shows that only low concentrations of clethodim and its metaboilites can be found in earthworms. Maximum calculated concentration were 0.29 mg/kg wwt for clethodim, which is almost a factor of 50 lower thant the calculated PEC feed (including a PEC $soil_{twa}$) of 14.1 mg/kg, and would lead to TERs far above the trigger of 5.
Furthermore, with the same soil an earthworm BCF study was performed. From the study a BAF of 0.41 mg/kg can be calculated for clethodim; which is more than a factor of 5000 times lower than the calculated BCF. For clethodim sulfoxide and clethodim sulfone, BAF values were not derived. However, it can be concluded that the BAF values for these metabolites are <1, as concentrations in earthworms were always lower than those in soil. Furthermore, concentrations of total clethodim equivalents in earthworms (calculated after correction for molecular weights) were always lower than concentrations of total clethodim equivalents in soil. This indicates that clethodim and its metabolites do not accumulate in earthworms (see also below).

Risk of metabolites of clethodim

Clethodim sulfoxide, clethodim sulfone and clethodim oxazole sulfone are major metabolites in soil. Clethodim sulfoxide, clethodim sulfone, clethodim imine and clethodim imine sulfoxide are major metabolites in water. The logKow of clethodim sulfoxide (2.07), clethodim imine (1.38) and clethodim imine sulfoxide (-0.76) is < 3. Clethodim sulfone is more polar than clethodim sufoxide hence its logKow is <2.07. The logPow value of clethodim oxazole sulfone was estimated by the applicant to be <3.0 using EPA EPI Suite software, and by the RMS to be 1.73 using Pallas 3.0 (DAR clethodim). Hence for all metabolites the potential for bioaccumulation is considered to be low and no further assessment is deemed necessary

Conclusions mammals

The product complies with the RGB.

7.4 Effects on bees

The risk assessment for bees is based on the ratio between the highest single application rate and toxicity endpoint (LD_{50} value). The toxicity endpoint is the lowest available value from tests with EC formulations containing clethodim. An overview of the risk at the proposed uses is given in Table E.13.

Table E.13 Risk for bees

Use	Substance	Application rate	LD_{50}	Rate/LD_{50}	Trigger value
		[g a.s./ha]	[µg/bee]		
Potato and sugar and fodder beet (worst case)	Clethodim	300	>14	<21	50

Since the ratio rate/LD_{50} is below 50, the risk for bees is considered to be low. Hence, all proposed uses meet the standards for bees as laid down in the RGB.

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

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 HTB (v 1.0). Since only data from extended laboratory studies are available, hazard Quotients should be below the trigger value of 1 to meet the standards. The toxicity data used are those obtained with the 120 g a.s./L EC formulation Select 120. The resulting Hazard Quotients for the worst case use are presented in Table E.14. These HQs also cover effects on reproduction since mortality was equally or more critical.

Table E.14 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	0.3	1	-	-	>0.33	<0.91
T. pyri	0.3	1	-	-	0.0037	**81**
Off-field						
A. rhopalosiphi	0.3	1	0.1	5	>0.33	<0.45
T. pyri	0.3	1	0.1/10	5	0.0037	**4.0**

[1]: Multiple Application Factor

[2]: off-field: drift fraction = 0.1, vegetation distribution factor = 10 for *T. pyri* (2d-testing) but not used for *A. rhopalosiphi* (3-D testing), safety factor = 5 (extended laboratory testing)

As the above table shows, the in- and off-field HQ values for *A. rhopalosiphi* are below the trigger value of 1, but those for *T. pyri* are above the trigger value of 1. It should be noted that the off-field HQ for *T. pyri* at the lowest proposed application rate (0.12 kg a.s./ha) is 1.6, and hence also above the trigger of 1. Therefore a refinement is necessary for *T. pyri* for all of the proposed uses.

In addition to the data for the two standard species, studies were submitted with three additional species. In extended laboratory studies, the LR50 and/or ER50 of Select 240 EC with adjuvant to *Chrysoperla carnea* was >384 g a.s./ha, and to *Aleochara bilineata* >386 g a.s./ha. These LR50 values are above the maximum field rate of the proposed uses (300 g a.s./ha), and therefore the risk of the proposed uses to *C. carnea* and *A. bilineata* is considered to be acceptable. These two studies satisfy the requirement for testing of two additional species. Laboratory tests on sand substrate with Select 240 EC with and without adjuvant gave LR50 values for *Poecilus cupreus* of >221 and >256 g a.s./ha. Although the highest tested rates in the studies with *P. cupreus* do not cover all of the proposed uses (highest rate 300 g a.s./ha), the results do not indicate that a risk would exist.

Refinement for T. pyri
Refinement of the in-field risk to *T. pyri* may be based on the extended laboratory study with exposure to aged residues performed on Select 240 EC, where the LR50 was >384 g a.s./ha following exposure to 4-, 7- and 14-day aged residues. This indicates that affected in-field populations of *T. pyri* will recover within 4 days after exposure to clethodim following the proposed uses. Hence the in-field risk to *T. pyri* is considered to be acceptable. However, the aged residue study is considered to be insufficient to address the off-field risk.

Off-field areas are usually not large nature areas, but consist mainly of vegetational strips along the agricultural field. Therefore it is not considered self-evident that non-flying insects can easily recolonise the off-field area (too many barriers). Furthermore the off-field population may consist of slow reproducing species that are not adapted to pesticides, which makes the potential for recovery within an ecologically acceptable period not self-evident from an aged residue test in the laboratory (tested species may not be representative). Therefore it is not considered sufficient to demonstrate a potential recovery with an aged residue test when the off-field threshold for non-flying species is exceeded, and studies demonstrating actual recovery have to be provided.

The off-field risk will be acceptable if the drift is maximum 2.5%.
The applicant proposes to prescribe the following additional drift reducing nozzles.
To address the off field risk to *T. pyri* the following drift mitigation measures are proposed:

- the use of an *air assisted low boom sprayer with 50% drift reducing nozzles* when applying Centurion Plus resulting in 1.8% drift at 0.5-1.5 m distance from the last nozzle according to *Van de Zande et al. (2007)*[1]
- the use of a *Släpduk* and 50% drift reducing nozzles when applying Centurion Plus resulting in 2.5% drift at 0.5-1.5 m distance from the last nozzle
- the use of an *air assisted low boom sprayer with Venturi nozzles and endnozzle with an additional crop-free zone of 50 cm* when applying Centurion Plus resulting in 0.7% drift at 1 m distance.
- the use of a *tunnel* when applying Centurion Plus resulting in 0.2% drift at 0.5-1.5 m distance from the last nozzle

The proposed drift reduction measures are acceptable and lead to an acceptable off-field risk.

Hence, the standards for non-target arthropods as laid down in the RGB are met, provided that the following restriction sentences will be placed on the label:

Om niet tot de doelsoorten behorende geleedpotigen/ insecten te beschermen is toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van de onderstaande maatregelen:

[1] Van de Zande, J.C., J.M.G.P. Michielsen & H. Stallinga., Spray drift and off-field evaluation of agrochemicals in the Netherlands, Report 149, July 2007

- *Lage spuitboomhoogte (30 cm boven de top van het gewas) in combinatie met minimaal 50% drift reducerende spuitdoppen+ kantdop + luchtondersteuning*
- *Lage spuitboomhoogte (30 cm boven de top van het gewas) in combinatie met Venturidop + kantdop* + 1.0 meter teeltvrije zone (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelsgrens)

- *Conventionele spuit met minimaal 50% driftreducerende spuitdoppen in combinatie met een teeltvrije zone van 1,5 meter, gemeten vanaf het hart van de planten in de buitenste rij of de buitenste plant in de rij waarop geen gewas of niet hetzelfde gewas als op de rest van het perceel wordt geteeld.*

- *Sleepdoek in combinatie met minimaal 50% driftreducerende spuitdoppen;*

- *Overkapte beddenspuit*

The applicant requested to add the following drift reducing measure (application 20145907 NLWG):

- Conventionele spuit in combinatie met 75% driftreducerende spuitdoppen+ kantdop + 1,75 meter teeltvrije zone (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelgrens)

However, the zone which is mentioned in the sentence is not the right one. The zone of 1.75 m is an additional zone. The standard zone from the middle of the last crop row to the border of the parcel is 1 meter. Hence, the total zone becomes 2.75 m (measured from the middle of the last crop row to the border of the parcel). Hence, the sentence should be:

- Conventionele spuit in combinatie met 75% driftreducerende spuitdoppen+ kantdop + 2,75 meter teeltvrije zone (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelgrens)

This measure is sufficient to reduce the risk to non-target arthropods to an acceptable level (drift is ca. 0.7%, while 2.5% is needed).

7.5.2 Earthworms

The acute risk for earthworms is calculated as TER-value (trigger value 10). Since the logPow of the active substance and clethodim sulfoxide is >2, a correction to the reference soil containing 4.7 % organic matter is necessary. Exposure is expressed as the initial PEC soil. PEC soil is calculated in section 6.1.1. Table E.15 presents endpoints, PECsoil and TER values for the worst case use.

Table E.15 Overview of soil concentrations and acute TERs for earthworms

Use	Substance	$LC50_{corr}$ [mg/kg]	PIECsoil	TER	Trigger value
Potato	Clethodim as TM-5403 (120 g a.s./L EC formulation	13.7	0.340	40	10
	Clethodim sulfoxide	500	0.118	4237	10

In view of the results presented in Table E.15, a low acute risk for earthworms is expected at all proposed uses following exposure to clethodim and clethodim sulfoxide.

No studies were supplied for the other two major soil metabolites, clethodim sulfone and clethodim oxazole sulfone. Based on the structural similarity between clethodim sulfone and clethodim sulfoxide, and the large safety margin calculated for clethodim sulfoxide, the acute risk of clethodim sulfone to earthworms is considered to be acceptable. The PIEC of clethodim oxazole sulfone is a factor of 12 lower than that of clethodim. The TER for clethodim oxazole sulfone would be <10 if the LC50 of clethodim oxazole sulfone would be a factor of 48 higher than that of parent clethodim. Based on structural considerations, this is considered unlikely and the acute risk of clethodim oxazole sulfone to earthworms is considered to be acceptable.

Subletal studies with clethodim, clethodim sulfoxide and clethodim sulfone are not required because multiple applications (3 or more) of the plant protection product will not be made and the mean DT90 of clethodim, clethodim sulfoxide and clethodim sulfone is ≤100 days. Sublethal toxicity data is available for the metabolite clethodim oxazole sulfone, which has a maximum $DT_{90,lab}$ of 227 days. The logPow value of clethodim oxazole sulfone was estimated by the applicant to be <3.0 using EPA EPI Suite software, and by the RMS to be 1.73 using Pallas 3.0 (DAR clethodim). Since these are estimations, and the estimated values is close to the trigger of logKow 2, in a conservative approach $NOEC_{corr}$ will be used.

In the subchronic risk assessment for earthworms, a long-term TER-value is calculated. Examination of the PIEC takes place against the trigger of 0.2*NOEC. See Table E.16.

Table E.16 Overview of soil concentrations and chronic TERs for earthworms

Use	Substance	$NOEC_{corr}$ [mg/kg]	PIECsoil [mg/kg]	TER	Trigger value
Potato	clethodim oxazole sulfone	5	0.028	179	5

The TER value for earthworms resulting from exposure to the metabolite clethodim oxazole sulfone meets the trigger. The proposed applications of the product therefore meet the standards as laid down in the RGB.

7.5.2.2 Other soil macro-organisms

Also for other soil macro-organisms data are available. A long-term TER-value is calculated. Examination of the PIEC takes place against the trigger of 0.2 * NOEC. See Table E.17 (worst case use.

Table E.17 Overview of soil concentrations and chronic TERs for other soil macro-organisms

Use	Substance	Organism	$NOEC_{corr}$ [mg/kg]	PIECsoil [mg/kg]	TER	Trigger value
Potato	clethodim oxazole sulfoxide	Collembola	50	0.270	185	5

The TER value for other soil macro-organisms resulting from exposure to the metabolite clethodim oxazole sulfoxide meets the trigger of 5.

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 formulation Centurion Plus and the metabolite clethodim oxazole sulfone. Since the reduction percentage is below 25% after 28-62 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 authorisation 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 applications comply 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). MAF-values are taken from ESCORT 2.
A TER is calculated with the lowest ER_{50} value from a laboratory test with higher plants and the exposure concentration. The lowest ER_{50} is 3.4 g a.s./ha for cockspurr grass. See table E.18 for TER calculation. TER is calculated for 3 application rates 1, 2 and 3 (120, 240 and 300 g a.s./ha, respectively).
The applicant used a lowest ER50 of 5.4 g a.s./ha based on data obtained with Centurion Pro (135.2 g/L clethodim). However, it was not further substantiated why Centurion Pro is a more relevant formulation than Select (240 g/L clethodim).

Table E.18 Overview of exposure concentrations and TERs for non target plants

Use	Substance	Dose [kg a.s. /ha]	MAF	Drift% (off-field exposure)	Exposure (kg a.s./ha)	ER_{50} [kg a.s./ha]	TER	Trigger value
1	clethodim	0.12	1	4.7	0.0056	0.0034	**0.60**	5
2	clethodim	0.24	1	4.7	0.011	0.0034	**0.30**	5
3	clethodim	0.3	1	4.7	0.014	0.0034	**0.24**	5

The ratio between ER_{50} and the exposure concentration is <5. Therefore, a risk for non-target plants is considered to be present.

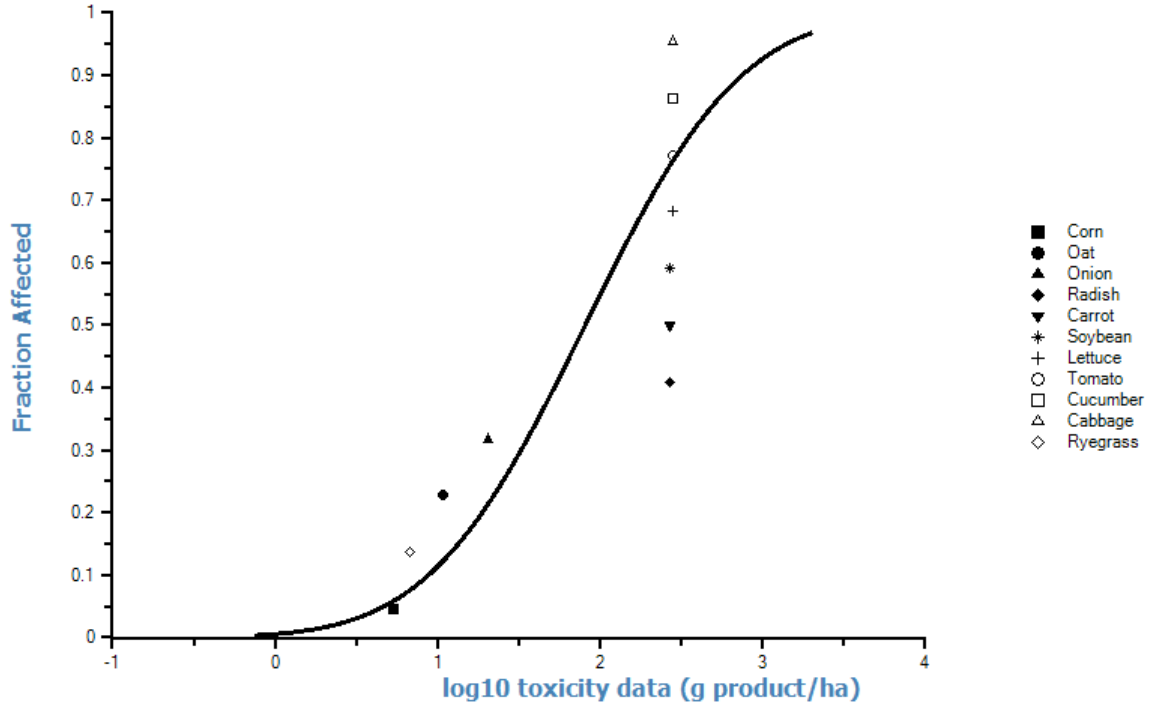
Refined risk assessment, proposed by the applicant

Probabilistic Risk Assessment

In accordance with the recommendations made in the Terrestrial Ecotoxicology Guidance Document (SANCO/10329/2002 rev. 2 (final, 17 October 2002), a probabilistic approach to the risk assessment can also be considered. The vegetative vigour study with clethodim 120 g/L included three monocot species (corn, oat, onion) and three dicot species (radish, carrot, soybean). Effects were only observed for the monocot species tested. No effects were observed for the dicot species at the maximum rate tested of 270.4 mg a.s/ha. In addition studies have also been conducted with the comparable formulation clethodim 240 g/L also with soybean, carrot, oat, onion and corn and the additional species lettuce, tomato, cucumber, cabbage and ryegrass.
The results reported with clethodim 240 g/L were similar to those with clethodim 120 g/L with no effects reported for the dicot species (soybean, lettuce, carrot, tomato, cucumber, cabbage) at the maximum concentration tested of 280 g a.s/L. For the monocot species oat, ryegrass and corn ER_{50} values of 20, 6.7 and 13 g a.s/ha were reported respectively. Due to the similarity of the two formulations the data points for the additional species tested (lettuce, carrot, tomato, cucumber and cabbage) with clethodim 240 g/L were also considered relevant and so were included for the probabilistic risk assessment to provide 11 data points in total. The concentration representing the 5^{th} percentile of normally distributed toxicity data (HC_5) was calculated for vegetative vigour using the using the ETX 2.0 program developed

by RIVM. The species sensitivity distribution (SSD's) calculated for vegetative vigour is presented in the figure below.

Figure 10.8.1-1: Species sensitivity distribution for representative non-target plant species



The subsequent HC_5 value calculated from the SSD's was 4.28 g a.s/ha for vegetative vigour. The data however was not shown to be normally distributed due to the skew of no effects being observed for the majority of the species tested.

Reaction Ctgb.
The endpoints mentioned by the applicant and additional endpoints from the a.s. are given below:

Species	Centurion PRO	Selekt	Clethodim (a.s.)	
Oat (Avena sativa)	*10.8*	20		
Onion (Allium cepa)	*270**	>280		
Maize (Zea mays)	***4.73***	13		
Radish (Raphanus sativus)	*>270*			
Carrot (Daucus carota)	*>270*	>280		
Soybean (Glycine max)	*>270*	>280		
Lettuce (*Lactuca sativa*)		>280		

Tomato (*Lycopersicon esculentum*)		>280		
Cucumber (*Cucumis sativus*)		>280		
Cabbage (*Brassica oleracea*		>280		
Perennial ryegrass (*Lolium perenne*)		6.7	6.7	
Cockspurr grass *(E. crus-galli)*			3.4	

* No EC50 was determined but 49% inhibition was found at 270 g a.s./ha

It is not clear how the HC5 from the applicant has been derived. However it seems that all '> 'values have been included in this calculation, which is not allowed. Furthermore, the data is not normally distributed. A clear distinction can be found between the grasses and the other plants. Therefore a HC5 is of no use. However the large dataset should not be neglected and just taking the lowest value is considered too much of worst-case.

Since grasses are clearly the most sensitive, only the data of the grasses are considered. From these four datapoints a geometric mean will be used in risk assessment.
As it is not clear if the formulations of Selekt and centurion pro are really similar in toxic effects to non-target plants, the lowest value is taken for the geometric mean.

Table E.19 Geometric mean used for risk assessment

Species	EC50 (g a.s./ha)
Oat (Avena sativa)	10.8
Maize (Zea mays)	4.73
Perennial ryegrass (*Lolium perenne*)	6.7
Cockspurr grass *(E. crus-galli)*	3.4
Geometric mean	5.84

The result of the risk assessment using the geometric mean without additional drift reduction is given below in table E.20

Table E.20 Overview of exposure concentrations and TERs for non-target plants

Use	Substance	Dose [kg a.s. /ha]	MAF	Drift% (off-field exposure)	Exposure (kg a.s./ha)	ER_{50} [kg a.s./ha]	TER	Trigger value
1	clethodim	0.12	1	4.7	0.0056	0.0058	**1.03**	5
2	clethodim	0.24	1	4.7	0.011	0.0058	**0.53**	5
3	clethodim	0.3	1	4.7	0.014	0.0058	**0.41**	5

Based on the calculation presented above additional drift reduction is required. A maximum drift of 0.96-0.38 is allowed. A drift of 0.9% can be achieved by prescribing 75% drift reducing nozzles.
For non-target arthopods, also additional drift reducing nozzles are prescribed (see section 7.5). However as the evaluation zone is different (normally 50-150 cm for non-target arthropods and 150-250 cm for non-target plants, drift rates are also different. In the evaluation manual drift deposition on 50-150 cm and 150-250 cm are reported. For non-target arthopods, the following drift reducing measures are prescribed:

- the use of an *air assisted low boom sprayer with 50% drift reducing nozzles* when applying Centurion Plus resulting in 1.8% drift at 0.5-1.5 m distance from the last nozzle according to *Van de Zande et al. (2007)*[2]
- implementation of a *buffer zone 1 meter wide*, in combination with the use of a *sprayer with 50% drift reducing nozzles* when applying Centurion Plus resulting in 1.7% drift at 1.5-2.5 m distance from the last nozzle according to *Van de Zande et al. (2007)*[5]

The first restriction would obtain a drift deposition of 0.3% in the evaluation zone of 150-250 m, which is relevant for plants. Thus with these measures the risk for non-target plants would also be acceptable. However, the second proposed restriction sentence cannot be implemented because it is not known what is the additional drift reduction of the proposed additional crop-free zone of 1 meter for non-target plants. It is expected that the needed drift percentage of 0.38% will not be reached with this additional 1 meter crop-free zone. Hence, only the first proposed restriction sentence will be accepted by Ctgb.
Thus the risk to non-target plants is acceptable, provided that the following restriction sentence is given on the label:

Om niet tot de doelsoorten behorende planten te beschermen is toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van de onderstaande maatregelen:

- Lage spuitboomhoogte (30 cm boven de top van het gewas) in combinatie met minimaal 50% drift reducerende spuitdoppen + kantdop + luchtondersteuning
Also the following additional measures are possible:
- *Lage spuitboomhoogte (30 cm boven de top van het gewas) in combinatie met Venturidop + kantdop* + 1.0 meter teeltvrije zone (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelsgrens)[1]
- *Sleepdoek in combinatie met minimaal 50% driftreducerende spuitdoppen;*
- *Overkapte beddenspuit*

[1]Note: for non-target arthropods this measure is only allowed with an additional cropfree zone of 0.5 m included. This will also lower the drift for non-target plants.

The applicant requested to add the following drift reducing measure (application 20145907 NLWG):

- Conventionele spuit in combinatie met 75% driftreducerende spuitdoppen + kantdop + 1,75 meter teeltvrije zone (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelgrens)

However, the zone which is mentioned in the sentence is not the right one. The zone of 1.75 m is an additional zone. The standard zone from the middle of the last crop row to the border of the parcel is 1 meter. Hence, the total zone becomes 2.75 m (measured from the middle of the last crop row to the border of the parcel). Hence, the sentence should be:

- Conventionele spuit in combinatie met 75% driftreducerende spuitdoppen + kantdop + 2,75 meter teeltvrije zone (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelgrens)

This measure is also sufficient to reduce the risk to non-target arthropods to an acceptable level (drift is ca. 0.7%, while 2.5% is needed).

[2] Van de Zande, J.C., J.M.G.P. Michielsen & H. Stallinga., Spray drift and off-field evaluation of agrochemicals in the Netherlands, Report 149, July 2007

Based on what is stated above the restriction sentences are as follows:

Om niet tot de doelsoorten behorende geleedpotigen/ insecten en niet tot de doelsoorten behorende planten te beschermen is toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van één van de onderstaande maatregelen:
- *Lage spuitboomhoogte (30 cm boven de top van het gewas) met minimaal 50% drift reducerende spuitdoppen en een kantdop in combinatie met luchtondersteuning;*
- *Lage spuitboomhoogte (30 cm boven de top van het gewas) met Venturidoppen en een kantdop in combinatie met een teeltvrije zone van minimaal 1,0 meter (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelsgrens);*
- *Sleepdoek in combinatie met minimaal 50% driftreducerende spuitdoppen;*
- *Overkapte beddenspuit;*
- *Conventionele spuit met minimaal 75% driftreducerende spuitdoppen en een kantdop in combinatie met een teeltvrije zone van minimaal 2,75 meter (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelgrens).*

The product complies with the RGB, provided that a restriction sentence is included on the label.

Risk of metabolites
ER50 values of clethodim sulfoxide, clethodim sulfone and clethodim oxazole sulfone (16, 12 and >320 g a.s./ha, respectively) were determined for the most sensitive species cockspurr grass. These ER50 values are a factor of at least 3.5 higher than those of clethodim in cockspur grass (3.4 g a.s./ha), and the exposure to metabolites will be lower than that to clethodim. Therefore the risk of metabolites to non-target plants is considered to be covered by the assessment for clethodim.

Conclusions any other organisms
The product complies with the RGB for the aspects earthworms, soil micro-organisms and activated sludge. The product complies with the RGB for the aspect non-target arthropods and non-target plants, provided that a restriction sentence is placed on the label.

7.6 Appropriate ecotoxicological endpoints relating to the product and approved uses
See List of Endpoints.

7.7 Data requirements
None.

7.8 Restriction sentences

Based on the current assessment, the following has to be stated in the legal instructions for use:
Om niet tot de doelsoorten behorende geleedpotigen/ insecten en niet tot de doelsoorten behorende planten te beschermen is toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van één van de onderstaande maatregelen:
- *Lage spuitboomhoogte (30 cm boven de top van het gewas) met minimaal 50% drift reducerende spuitdoppen en een kantdop in combinatie met luchtondersteuning;*
- *Lage spuitboomhoogte (30 cm boven de top van het gewas) met Venturidoppen en een kantdop in combinatie met een teeltvrije zone van minimaal 1,0 meter (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelsgrens);*
- *Conventionele spuit met minimaal 75% driftreducerende spuitdoppen en een kantdop in combinatie met een teeltvrije zone van minimaal 2,75 meter (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelgrens).*

- *Sleepdoek in combinatie met minimaal 50% driftreducerende spuitdoppen;*
- *Overkapte beddenspuit;*

7.9 Overall conclusions regarding ecotoxicology

It can be concluded that:

1. all proposed applications of the active substance clethodim meet the standards for birds as laid down in the RGB.
2. all proposed applications of the active substance clethodim meet the standards for aquatic organisms as laid down in the RGB.
3. the active substance clethodim meets the standards for bioconcentration as laid down in the RGB.
4. all proposed applications of the active substance clethodim meet the standards for mammals as laid down in the RGB.
5. all proposed applications of the active substance clethodim meet the standards for bees as laid down in the RGB.
6. all proposed applications of the active substance clethodim meet the standards for non-target arthropods as laid down in the RGB, provided that a restriction sentence is placed on the label.
7. all proposed applications of the active substance clethodim meet the standards for earthworms as laid down in the RGB.
8. all proposed applications of the active substance clethodim meet the standards for soil micro-organisms as laid down in the RGB.
9. all proposed applications of the active substance clethodim meet the standards for activated sludge as laid down in the RGB.
10. all proposed applications of the active substance clethodim meet the standards for non-target plants as laid down in the RGB, provided that a restriction sentence is placed on the label.

8. Efficacy

No changes occur concerning efficacy.

9. Conclusion

The product complies with the Uniform Principles.

10. Classification and labelling

Classification and labelling does not change.

Based on the assessments for Centurion Plus, the following has to be stated in the legal instructions for use:

Om niet tot de doelsoorten behorende geleedpotigen/ insecten en niet tot de doelsoorten behorende planten te beschermen is toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van de onderstaande maatregelen:

- Lage spuitboomhoogte (30 cm boven de top van het gewas) in combinatie met minimaal 50% drift reducerende spuitdoppen + kantdop + luchtondersteuning; of
- Lage spuitboomhoogte (30 cm boven de top van het gewas) in combinatie met Venturidop + kantdop + 1,0 meter teeltvrije zone (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelsgrens); of
- Conventionele spuit in combinatie met 75% driftreducerende spuitdoppen + kantdop + 2,75 meter teeltvrije zone (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelgrens); of
- Sleepdoek in combinatie met minimaal 50% driftreducerende spuitdoppen; of

- Overkapte beddenspuit

Met name de gewassen maïs en granen zijn zeer gevoelig voor de stof clethodim. Met deze gewassen in de directe nabijheid dient bij bespuiting van het te behandelen perceel elke mate van drift naar genoemde gewassen te worden vermeden.

Appendix 1 Table of authorised uses

Please refer to the original authorization.

Appendix 2 Reference list

No studies submitted for this application.