



## HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

### 1 BESLUIT

Op 27 augustus 2014 is van

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

een aanvraag tot kleine toepassingsuitbreiding van gewasbeschermingsmiddeltoelating ontvangen voor het middel

#### **Centurion Plus**

op basis van de werkzame stoffen clethodim.

**HET COLLEGE BESLUIT** tot toelating van bovenstaand middel.

Alle bijlagen vormen een onlosmakelijk onderdeel van dit besluit.

Voor nadere gegevens over deze toelating wordt verwezen naar de bijlagen:

- Bijlage I voor details van de aanvraag en toelating.
- Bijlage II voor de etikettering.
- Bijlage III voor wettelijk gebruik.
- Bijlage IV voor de onderbouwing.

#### **1.1 Samenstelling, vorm en verpakking**

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

#### **1.2 Gebruik**

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

#### **1.3 Classificatie en etikettering**

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

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- 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 (respijterperiode)**

Het nieuwe gebruiksvoorschrift en de nieuwe etikettering dienen bij de eerstvolgende aanmaak op de verpakking te worden aangebracht. Oude verpakkingen mogen worden opgemaakt.

## **2 WETTELIJKE GRONDSLAG**

Besluit	artikel 51 Verordening (EG) Nr. 1107/2009 en artikel 2.2 Rgb
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Beoordeling conform RGB (Hoofdstuk 2) en Evaluation Manual 1.0.

## **3 BEOORDELINGEN**

### **3.1 Fysische en chemische eigenschappen**

De identiteit en de fysische en chemische eigenschappen van het middel en de werkzame stof wijzigen niet.

### **3.2 Analysemethoden**

De analysemethoden voor de werkzame stoffen en het middel wijzigen niet. Voor de toegelaten toepassingen voldoen de vereiste residuanalysemethoden.

### **3.3 Risico voor de mens**

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

### **3.4 Risico voor het milieu**

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

### **3.5 Werkzaamheid**

Gelet op artikel 51 Verordening (EG) 1107/2009 is de aanvraag niet beoordeeld voor het aspect werkzaamheid (inclusief ftotoxiciteit).

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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 8030, 6710 AA, EDE. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.*

Ede, 4 december 2015

HET COLLEGE VOOR DE TOELATING VAN  
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw  
Voorzitter

**BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING****1 Aanvraaginformatie**

Aanvraagnummer:	20146056 NLKUGB
Type aanvraag:	aanvraag tot kleine toepassingsuitbreiding van gewasbeschermingsmiddeltoelating
Middelnaam:	Centurion Plus
Formele registratiedatum: *	13 oktober 2014
Datum in behandeling name:	20 maart 2015
Datum compliance check:	N.v.t.

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

**2 Stofinformatie**

<u>Werkzame stof</u>	<u>Gehalte</u>
clethodim	120G/L

De stof clethodim 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 of parallel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel
W-codering professioneel gebruik:	2

**4 Aflever- en opgebruiktermijnen voor oude etiket**

Vorige W-codering professioneel gebruik:	1
Aflevertermijn professioneel gebruik:	n.v.t.
Opgebruiktermijn professioneel gebruik:	n.v.t.

**5 Verpakkingsinformatie**

Aard van het preparaat:  
Emulgeerbaar concentraat

**BIJLAGE II Etikettering van het middel Centurion Plus**

Professioneel gebruik

de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:  
clethodim, nafta, zwaar aromatisch

Pictogram	GHS08	
	GHS09	
Signaalwoord	GEVAAR	
Gevarenaanduidingen	H304	Kan dodelijk zijn als de stof bij inslikken in de luchtwegen terechtkomt.
	H411	Giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P270	Niet eten, drinken of roken tijdens het gebruik van dit product.
	P273	Voorkom lozing in het milieu.
	P301 + P310	NA INSLIKKEN: Onmiddellijk een ANTIGIFCENTRUM/arts/... raadplegen.
	P331	GEEN braken opwekken.
	P391	Gelekte/gemorste stof opruimen.
	P501	Inhoud/verpakking afvoeren naar ....
	SP 1	Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
Aanvullende etiketelementen	EUH208	Bevat clethodim. Kan een allergische reactie veroorzaken.
	EUH401	Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.
Kinderveilige sluiting verplicht		Nee
Voelbare gevaarsaanduiding verplicht		Nee

**HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN**
**BIJLAGE III WG van het middel**
**Wettelijk Grbruiksvoorschrift**

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 <sup>1</sup>	2,5 l/ha	1	
Bieten	Eenjarige grasachtige onkruiden en stuifdek	1 l/ha	1	56
	Kweek <sup>1</sup>	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 <sup>1</sup>	2 l/ha	1	
Wortelen	Eenjarige grasachtige onkruiden	1 l/ha	1	48
	Kweek <sup>1</sup>	2 l/ha	1	
Zaaiui	Eenjarige grasachtige onkruiden	1 l/ha	1	56
	Kweek <sup>1</sup>	2 l/ha	1	
Eerstejaars plantui	Eenjarige grasachtige onkruiden	1 l/ha	1	56
	Kweek <sup>1</sup>	2 l/ha	1	
Tweedejaars plantui	Eenjarige grasachtige onkruiden	1 l/ha	1	56
	Kweek <sup>1</sup>	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 <sup>1</sup>	2 l/ha	1	
Knoflook	Eenjarige grasachtige onkruiden	1 l/ha	1	56
	Kweek <sup>1</sup>	2 l/ha	1	

<sup>1</sup> *Agropyron repens*

Het gebruik in de onbedekte teelt van blauwmaanzaad, karwij (oliehoudende zaden), zonnebloem (oliehoudende zaden), vezelgewassen, lupine (groenbemester), witlof (pennenteelt), cichorei, aardbei (vermeerdering, wachtbed en productie), bloemkoolachtigen, schorseneer, zilverui en picklers, maggi, engelwortel, bevernelwortel, wortelpeterselie, lelie, iris, dahlia, zantedeschia, hyacint, narcis, bloemisterijgewassen, vaste planten en bij de veredelingsteelt, bloemenzaadteelt, groentenzaadteelt en zaadteelt van kruiden, bieten, peulvruchten, oliehoudende zaden, vezelgewassen, groenbemestersgewassen, voedergewassen en witlof, cichorei, boekweit en meekrap is beoordeeld conform artikel 51 EG 1107/2009. Er is voor deze toepassingen geen werkzaamheids- en fytoxiciteitonderzoek uitgevoerd. Er wordt daarom aangeraden een proefbespuiting uit te voeren, voordat het middel gebruikt wordt. Gebruik van dit middel in deze toepassingsgebieden, komt voor risico en verantwoordelijkheid van de gebruiker.

Toepassings-gebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus of per 12 maanden	Maximaal aantal liter middel per ha per teeltcyclus of per 12 maanden	Veiligheidstermijn in dagen
Blauwmaanzaad	Voor en na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	1 l/ha per teeltcyclus	120
Karwij (oliehoudende zaden)	Voor en na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	1 l/ha per teeltcyclus	120
Lijnzaad	Voor en na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	1 l/ha per teeltcyclus	-
Zonnebloem (oliehoudende)	Voor en na opkomst	Eenjarige grasachtige	1 l/ha	1 per	2 l/ha per	100

zaden)		onkruiden		teeltcyclus	teeltcyclus	
		Kweek <sup>1</sup>	2 l/ha			
Vezelgewassen	Voor en na opkomst	Eenjarige grasachtige onkruiden en stuifdek	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	-
		Kweek <sup>1</sup>	2 l/ha			
Lupine (groenbemester)	Voor en na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	-
		Kweek <sup>1</sup>	2 l/ha			
Witlof (pennenteelt)	Na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2,5 l/ha per teeltcyclus	56
		Kweek <sup>1</sup>	2,5 l/ha			
Cichorei	Na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2,5 l/ha per teeltcyclus	56
		Kweek <sup>1</sup>	2,5 l/ha			
Aardbei vermeerdering en wachtbed (onbedekte teelt)	Na uitplanten	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	-
		Kweek <sup>1</sup>	2 l/ha			
Aardbei productie (onbedekte teelt)	Na uitplanten	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	30
		Kweek <sup>1</sup>	2 l/ha			
Bloemkoolachtigen (onbedekte teelt)	Voor en na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	28
		Kweek <sup>1</sup>	2 l/ha			
Schorseneer	Na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	1 l/ha per teeltcyclus	48
Zilverui	Na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	56
		Kweek <sup>1</sup>	2 l/ha			
Picklers	Na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	56
		Kweek <sup>1</sup>	2 l/ha			



Maggi	Na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	48
		Kweek <sup>1</sup>	2 l/ha			
Engelwortel	Na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	48
		Kweek <sup>1</sup>	2 l/ha			
Bevernelwortel	Na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	48
		Kweek <sup>1</sup>	2 l/ha			
Wortelpeterselie	Na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	48
		Kweek <sup>1</sup>	2 l/ha			
Lelie (onbedekte teelt)	Na opkomst	Eenjarige grasachtige onkruiden	0,5/ha <sup>2</sup>	4 per teeltcyclus	2 l/ha per teeltcyclus	-
		Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus		
		Kweek <sup>1</sup>	2 l/ha			
Dahlia (onbedekte teelt)	Na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	-
		Kweek <sup>1</sup>	2 l/ha			
Narcis (onbedekte teelt)	Na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	-
		Kweek <sup>1</sup>	2 l/ha			
Zantedeschia (onbedekte teelt)	Na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	-
		Kweek <sup>1</sup>	2 l/ha			
Iris (onbedekte teelt)	Na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	-
		Kweek <sup>1</sup>	2 l/ha			
Hyacint (onbedekte teelt)	Na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	-
		Kweek <sup>1</sup>	2 l/ha			

Bloemisterijgewassen (onbedekte teelt)	Voor en na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	-
		Kweek <sup>1</sup>	2 l/ha			
Vaste plantenteelt (onbedekte teelt)	Na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per 12 maanden	2 l/ha per 12 maanden	-
		Kweek <sup>1</sup>	2 l/ha			
Veredelingsteelt, bloemenzaadteelt, groentenzaadteelt en zaadteelt van kruiden, bieten, peulvruchten, oliehoudende zaden, vezelgewassen, groenbemestersgewassen, voedergewassen en witlof, cichorei, boekweit en meekrap (onbedekte teelt)	Voor en na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	-
		Kweek <sup>1</sup>	2 l/ha			

<sup>1</sup> *Agropyron repens*

<sup>2</sup> In LDS-systeem in combinatie met toegelaten middelen

### Toepassingsvoorwaarden

Behandeld lijnzaad niet voor menselijke of dierlijke consumptie bestemmen en/of in de handel brengen.

Behandelde vezelgewassen niet voor dierlijke consumptie bestemmen.

Toepassing van het middel in karwij is alleen toegestaan voor productie van karwij als oliehoudend zaad (niet als kruidenzaadgewas).

Toepassen in de teelt van bloemkoolachtigen voordat de oogstbare delen (bloemkool of broccoli) worden gevormd (voor BBCH 41).

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

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- 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 perceelgrens); 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.

**HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN**

**BIJLAGE IV**

**RISKMANAGEMENT**

**Contents**

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## 1. Identity of the plant protection product

### 1.1 Applicant

Arysta Life Sciences (S.A.S)  
Route d'Atrix – BP 80  
64150 Nogueres  
France

### 1.2 Identity of the active substance

The identity of the active substance does not change.

Common name	Clethodim
Name in Dutch	Clethodim
Chemical name	(5 <i>RS</i> )-2-{{(1 <i>EZ</i> )-1-[(2 <i>E</i> )-3-chloroallyloxyimino]propyl}-5-[(2 <i>RS</i> )-2-(ethylthio)propyl]-3-hydroxycyclohex-2-en-1-one (IUPAC)
CAS no	99129-21-2
EC no	Not available

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

### 1.3 Identity of the plant protection product

The identity of the plant protection product does not change.

Name	Centurion Plus
Formulation type	EC
Content active substance	120 g/L pure active substance

The formulation was not part of the assessment of the active substance for inclusion in Annex I of Directive 91/414/EEC.

### 1.4 Function

Herbicide.

### 1.5 Uses applied for

See GAP (Appendix I).

### 1.6 Background to the application

It concerns a simplified extension of the authorisation with minor uses.

### 1.7 Packaging details

Packaging details do not change.

## 2. Physical and chemical properties

The physical and chemical properties of the active substance and the formulation do not change.

### 3. Methods of analysis

#### 3.1 Analytical methods in technical material and plant protection product

The analytical methods for the technical material and the plant protection product do not change.

#### 3.2 Residue analytical methods

In the tables below the methods are presented, considered acceptable at the last full evaluation of Centurion Plus.

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)

Extraction with methanol/water and determination with LC-MS/MS: LOQ (clethodim, clethodim sulfoxide and clethodim sulfone, individually): 0.005 mg/kg (soybean, sugar beet roots and leaves, proteinaceous peas)

Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)

No method required, however the following method was submitted:  
After extraction conversion to sulfones, detection by LCMS/MS. LOQ (clethodim sulfoxide/clethodim sulfone as sum): 0.05 mg/kg (Beef meat, fat, liver, kidney and milk and chicken meat and eggs).

Based on the proposed extension for use, residue analytical methods for food/feed of plant origin are required for dry, watery and fat matrices.

Definition of the residue and MRLs for clethodim		
Matrix	Definition of the residue for monitoring	MRL
Food/feed of plant origin	Sum of clethodim, clethodim sulfoxide and clethodim sulfone expressed as clethodim	0.1 mg/kg or higher (fat, dry, water)
Food/feed of animal origin	No definition of the residue is proposed. No relevant residues are expected to occur in food/feed of animal origin.	

The residue analytical methods, included in the abovementioned List of Endpoints, are suitable for monitoring of the MRLs. Therefore, the intended extension for use is covered by the risk-envelope of the current authorisation.

Fat matrices are covered considering the methods for food/feed of plant origin were validated for soybean (soybean and soybean oil). Dry matrices are considered covered by proteinaceous peas (addendum to volume 3, September 2007).

The residue analytical methods for air, soil and water were accepted during the assessment of the original authorization of Centurion Plus. This simplified extension does not give rise to re-assess these residue analytical methods.

#### 3.3 Conclusion

The proposed extension for use is covered by the risk envelope of the existing authorisation for the section residue analytical methods.

#### 4. Mammalian toxicology

The proposed extension for use involves partly applications on crops for which the risk assessment can be extrapolated from the current authorisation based on the method of application and dosage (mechanical downward application with a maximum dosage of 2.5 L product/ha with a minimum spray volume of 200 L/ha). Therefore, this part of the proposed extension remains within the existing risk envelope for the section mammalian toxicology (operator, bystander and worker).

However, the proposed extension also involves applications on crops for which the risk assessment cannot be extrapolated from the current authorisation with respect to the method of application (manual downward), the bystander/resident exposure (because of the lower water application rate of 150 L/ha) and worker exposure (re-entry activities other than crop inspection). For these a risk assessment is performed.

#### List of Endpoints

Clethodim is an existing active substance, included in Annex I of Directive 91/414/EEC. The final List of Endpoints presented below is taken from the EFSA Scientific Report on clethodim (2011) 9(10); 2417 (d.d. 24 November 2011). Where relevant, some additional remarks/information are given in italics.

##### Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 6.1)

Rate and extent of oral absorption	88-95% based on urine, tissues, expired CO <sub>2</sub> , cage wash, and residual carcass within 168 h.
Distribution	Widely (0.2-0.7% in tissues); highest residues in adrenals, liver and kidneys.
Potential for accumulation	No evidence of accumulation
Rate and extent of excretion	Urinary: 80-86% in 24 h; faecal 8.5-14% in 24 h
Metabolism in animals	Extensively metabolised, >99% by oxidation to clethodim sulfoxide.
Toxicologically relevant compounds (animals and plants)	Parent compound
Toxicologically relevant compounds (environment)	Parent compound

##### Acute toxicity (Annex IIA, point 6.2)

Rat LD <sub>50</sub> oral	1133 mg a.s./kg bw	R22
Rat LD <sub>50</sub> dermal	> 4167 mg a.s./kg bw	
Rat LC <sub>50</sub> inhalation	> 3.25 mg a.s./L air/4h (whole body) (maximal attainable concentration)	
Skin irritation	Irritating	R38
Eye irritation	Non-irritant	
Skin sensitisation	Sensitizer (M&K test)	R43

**Short term toxicity (Annex IIA, point 6.3)**

Target / critical effect	Liver, red blood cells (rat, mouse, dog)	
Relevant oral NOAEL	21 mg a.s./kg bw/d (90-d and 1-yr dog) 25 mg a.s./kg bw/d (90-d rat) 74 mg a.s./kg bw/d (4-wk, range-finding, mouse)	
Relevant dermal NOAEL	83 mg a.s./kg bw/d (4-wk-rat)	
Relevant inhalation NOAEL	No data – not required	

**Genotoxicity (Annex IIA, point 6.4)**

Unlikely to be genotoxic.	
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**Long term toxicity and carcinogenicity (Annex IIA, point 6.5)**

Target/critical effect	Decreased body weight (rat) Liver: increased weight and associated histopathological findings (rat, mouse) Lungs: increased incidence of alveolar macrophages (mouse).	
Relevant NOAEL	16 mg a.s./kg bw/d (2-yr rat) 24 mg a.s./kg bw/d (18-month mouse)	
Carcinogenicity	No carcinogenic potential.	

**Reproductive toxicity (Annex IIA, point 6.6)****Reproduction toxicity**

Reproduction target / critical effect	Parental: decreased body weight and food consumption Pups: no adverse effects Reproductive: no adverse effects	
Relevant parental NOAEL	26.7 mg a.s./kg bw/d	
Relevant reproductive NOAEL	133.7 mg a.s./kg bw/d	
Relevant offspring NOAEL	133.7 mg a.s./kg bw/d	

**Developmental toxicity**

Developmental target / critical effect	Maternal: clinical signs, decreased body weight and food consumption (rat, rabbit), increased mortality at higher dose (rats) Developmental: reduced foetal weight, delayed ossification, increased post-implantation loss at higher dose (rats); no adverse effect in rabbits	
Relevant maternal NOAEL	83.3 mg a.s./kg bw/d (rat) 20.8 mg a.s./kg bw/d (rabbit)	
Relevant developmental NOAEL	83.3 mg a.s./kg bw/d (rat)	



250 mg a.s./kg bw/d (rabbit)	
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**Neurotoxicity/Delayed neurotoxicity (Annex IIA, point 6.7)**

No data, no indication from other studies.	
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**Other toxicological studies (Annex IIA, point 6.8)**

	<p>Studies with metabolite clethodim imine sulfone:</p> <ul style="list-style-type: none"> <li>- LD<sub>50</sub>, oral rat: &gt; 1400 mg/kg bw</li> <li>- no genotoxic potential (Ames, chrom. aberr. <i>in vitro</i>)</li> <li>- subacute toxicity, oral, rat: NOAEL 70.9 mg/kg bw/d</li> <li>- teratogenicity, oral, rat: NOAEL maternal toxicity 10 mg/kg bw/d, NOAEL developmental 100 mg/kg bw/d</li> </ul> <p>Studies with metabolite clethodim 5-OH sulfone:</p> <ul style="list-style-type: none"> <li>- LD<sub>50</sub>, oral rat: &gt; 1400 mg/kg bw</li> <li>- no genotoxic potential (Ames, chrom. aberr. <i>in vitro</i>)</li> <li>- subacute toxicity, oral, rat: NOAEL 5.94 mg/kg bw/d</li> <li>- teratogenicity, oral, rat: NOAEL maternal and developmental toxicity 100 mg/kg bw/d</li> </ul> <p>Studies with metabolite clethodim oxazole sulfone:</p> <ul style="list-style-type: none"> <li>- Unlikely to be genotoxic (<i>in vitro</i>: negative Ames test, positive chrom. aberr., equivocal gene mutation; <i>in vivo</i>: negative mouse micronucleus).</li> </ul> <p>Studies with clethodim sulfone:</p> <ul style="list-style-type: none"> <li>- genotoxicity: <i>in vitro</i> some positive result (Ames test, chrom. aberr.), <i>in vivo</i> negative (mouse liver UDS), <i>in vivo</i> equivocal (mouse micronucleus)</li> </ul> <p>Unlikely to be genotoxic.</p>
Plant metabolites	<p>Studies with metabolite M17R:</p> <ul style="list-style-type: none"> <li>- oral LD<sub>50</sub> &gt; 2000 mg/kg bw (rat)</li> <li>- 28-day oral NOAEL = 400 mg/kg bw/day (rat)</li> <li>- Ames test: negative</li> <li>- <i>In vitro</i> chromosome aberration test: negative</li> </ul> <p>Studies with metabolite M18R:</p> <ul style="list-style-type: none"> <li>- oral LD<sub>50</sub> &gt; 2000 mg/kg bw</li> <li>- Ames test: negative</li> </ul>

**Medical data (Annex IIA, point 5.9)**

No evidence of toxicological concern from medical surveillance of manufacturing plant personnel. No human cases of poisoning by clethodim reported.
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**Summary (Annex IIA, point 5.10)**

Value	Study	Safety factor
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14300 N

ADI	0.16 mg/kg bw/day	2-y rat	100
AOEL	0.2 mg/kg bw/day	90-d dog 1-yr dog	100
ARfD	Not necessary, not allocated		

### Dermal absorption (Annex IIIA, point 7.3)

Formulation: Select 2.0 EC\*

15% for the undiluted formulation and 42% for the spray dilution based on an *in vivo* dermal absorption in rats.

\* See 4.2 Dermal absorption

### Local effects

Clethodim produces local effects after a single exposure (skin irritation) and produces skin effects in a sensitisation study, but these effects are covered in the risk assessment/management by means of assignment of R- and S-phrases.

### Data requirements active substance

No additional data requirements are identified.

#### 4.1 Toxicity of the formulated product (IIIA 7.1)

The formulation Centurion Plus does not need to be classified on the basis of its acute oral ( $LD_{50}$  rat >2000 mg/kg bw), dermal ( $LD_{50}$  rat >2000 mg/kg bw), and inhalation toxicology ( $LC_{50}$  rat >5.51 mg/L).

The formulation Centurion Plus is considered not irritating to skin and eyes.

The formulation Centurion Plus does not have sensitising properties in a Maximisation test.

#### 4.1.1 Data requirements formulated product

No additional data requirements are identified.

#### 4.2 Dermal absorption (IIIA 7.3)

The applicant has submitted a new dermal absorption study for the formulation Centurion Plus. This study has previously been evaluated in accordance with the EFSA guidance on dermal absorption by the zRMS Lithuania for the Northern zone. Dermal absorption values of 3% for the concentrate and 7% for the dilution were derived. The tested spray dilution (0.25 g/L) corresponds to the dilution rate currently applied for (0.3 g/L). Therefore, the dermal absorption values are considered to be appropriate.

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

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

#### 4.4 Exposure/risk assessments

##### Overview of the intended uses

An application has been submitted for the minor use extension of the authorisation of the plant protection product Centurion Plus, a herbicide based on the active substance clethodim.

Centurion Plus is an EC formulation and contains 120 g/L clethodim.

#### 4.4.1 Operator exposure/risk

##### 4.4.1 Operator exposure/risk

According to the Dutch Plant Protection Products and Biocides Regulations the risk assessment is performed according to a tiered approach. There are four possible tiers:

Tier 1: Risk assessment using the EU-AOEL without the use of PPE

Tier 2: Risk assessment using the NL-AOEL without the use of PPE

Tier 3: Refinement of the risk assessment using new dermal absorption data

Tier 4: Prescription of PPE

##### Tier 1

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

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

Since the formulation is applied once or twice during the period January - October, a semi-chronic exposure duration is applicable for the operator (including contract workers). A semi-chronic AOEL is therefore derived.

Since clethodim is included in Annex I of 91/414/EEC, the (semi-)chronic EU-AOEL of 0.2 mg/kg bw/day (= 14 mg/day for a 70-kg operator), based on the 90-day and 1-year study in dogs is used for the risk assessment (see List of Endpoints).

##### Exposure/risk

Exposure to clethodim during mixing and loading and application of Centurion Plus is estimated with models. The exposure is estimated for the unprotected operator. In general, mixing and loading and application is performed by the same person. Therefore, for the total exposure, the respiratory and dermal exposure during mixing/loading and application have to be combined.

In the Table below the estimated internal exposure is compared with the systemic EU-AOEL.

**Table T.1 Internal operator exposure to clethodim and risk assessment for the use of Centurion Plus**

	Route	Estimated internal exposure <sup>a</sup> (mg /day)	Systemic EU-AOEL (mg/day)	Risk-index <sup>b</sup>
<i>Manual downward spraying on the intended crops, max. 2.5 L product/ha (chicory roots, 150 L water/ha) (uncovered)</i>				
Mixing/ Loading <sup>c</sup>	Respiratory	<0.01	14	<0.01
	Dermal	1.08	14	0.07
Application <sup>d</sup>	Respiratory	0.24	14	0.02
	Dermal	14.28	14	1.02
	Total	15.60	14	1.11

a Internal exposure was calculated with:

- biological availability via the dermal route: 3% (concentrate) and 7% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

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

c External exposure is estimated with EUROPOEM (dermal) / NL-model (respiratory).

d External exposure is estimated with UK POEM.

Since the EU-AOEL is exceeded without the use of PPE, a tier 2 assessment has to be performed using the NL-AOEL.

## **Tier 2**

### **Calculation of the NL-AOEL**

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

The calculation of the systemic AOEL for semi-chronic / chronic exposure is based on the NOAEL of 25 mg/kg bw/day in the 90-day study with the rat. Calculations from other studies result in higher AOELs.

Safety factors are used to compensate for the uncertainties, which arise, for example, from extrapolation from the tested species to humans and the differences between experimental circumstances, and to ensure that at the acceptable exposure level no adverse health effects will occur.

Used factors are:

- extrapolation rat → human on basis of caloric demand 4
- other interspecies differences: 3
- intraspecies differences: (professional use) 3
- biological availability via oral route: 100%\*
- weight of professional operator/worker: 70 kg

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

$$AOEL_{\text{systemic}}: 25 \times 100\% \times 70 / (4 \times 3 \times 3) = 48.6 \text{ mg/day}$$

## **Exposure/risk**

**Table T.2 Internal operator exposure to clethodim and risk assessment for the use of Centurion Plus**

	Route	Estimated internal exposure <sup>a</sup> (mg/day)	Systemic NL-AOEL (mg/day)	Risk-index <sup>b</sup>
<i>Manual downward spraying on the intended crops, max. 2.5 L product/ha (chicory roots, 150 L water/ha) (uncovered)</i>				
Mixing/ Loading <sup>c</sup>	Respiratory	<0.01	48.6	<0.01
	Dermal	1.08	48.6	0.02
Application <sup>c</sup>	Respiratory	0.24	48.6	<0.01
	Dermal	14.28	48.6	0.29
	Total	15.60	48.6	0.32

a Internal exposure was calculated with:

- biological availability via the dermal route: 15% (concentrate) and 75% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

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

c External exposure is estimated with EUROPOEM (dermal) / NL-model (respiratory).

d External exposure is estimated with UK POEM.

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

#### 4.4.2 Bystander exposure/risk

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

**Table T.3 Internal bystander exposure to clethodim and risk assessment during application of Centurion Plus**

Route	Estimated internal exposure <sup>a</sup> (mg /day)	Systemic EU-AOEL (mg/day)	Risk-index <sup>b</sup>
<i>Bystander exposure during application in the intended uses (max. 2.5 L product/ha , 150 L water/ha)</i>			
Respiratory	0.08	14	0.01
Dermal	0.02	14	<0.01
Total	0.10	14	0.01

a External exposure was estimated with EUROPOEM II. Internal exposure was calculated with:

- biological availability via the dermal route: 7% (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

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

Bystanders and residents may be exposed via the dermal route to spray drift deposits or by inhalation of vapour drift within or directly adjacent to an application area (bystander), or in the vicinity of the application (resident). The internal bystander and resident exposure is calculated in addition to the internal bystander exposure and risk assessment calculated with EUROPOEM II above, which is intended to estimate the work-related bystander exposure. Two different methods are used: 1) the German model which calculates the total exposure for adults, and children, and considers for the latter also the oral exposure via hand-to-mouth or object-to-mouth transfer; and 2) the UK method which calculates the total bystander exposure for adults, and separately the respiratory and dermal/oral route for resident children. In the table below the estimated internal exposure values from these methods are compared with the systemic AEL.

**Table T.4 Internal bystander and resident exposure to clethodim and risk assessment for the application of Centurion Plus**

Route	Estimated internal exposure <sup>a</sup> (mg /day)	Systemic AEL (mg/day) <sup>b</sup>	Risk-index <sup>c</sup>
<i>Bystander exposure during application in representative uses according to the German model</i>			
Child Total	0.01	3.23	<0.01
Adult Total	0.06	12.00	<0.01
<i>Resident exposure during application in all representative uses according to the German model</i>			
Child Total	0.01	3.23	<0.01
Adult Total	0.02	12.00	<0.01
<i>Bystander exposure during application in representative uses according to the UK method</i>			
Adult Total	0.01	12.00	<0.01
<i>Resident exposure during application in representative uses according to the UK method</i>			
Child Respiratory	0.01	3.00	<0.01
Dermal+Oral	<0.01	3.00	<0.01

- a External exposure was estimated according to 1) the German guidance paper for exposure and risk assessment for bystanders and residents (Martin *et al.* 2008, *J. Verbr. Lebensm.* 3: 272-281), and 2) the UK method. Internal exposure was calculated with:
- biological availability via the respiratory route: 100% (worst case)
  - biological availability via the dermal route: 7% (see 4.2)
  - biological availability via the oral route: 100% (see List of End Points)
- b From the systemic AOEL of 0.2 mg/kg bw/day a specific AEL is derived assuming a body weight of 16.15 or 15 kg for children in the German model or UK method, respectively, and of 60 kg for adults.
- c The risk-index is calculated by dividing the internal exposure by the systemic AEL.

Based on the calculated risk indexes for clethodim, the resident exposure of children and adults living next to a field treated with Centurion Plus is considered to be safe.

#### 4.4.3 Worker exposure/risk

##### Tier 1

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

**Table T.5 Internal worker exposure to clethodim and risk assessment after application of Centurion Plus**

Route	Estimated internal exposure <sup>a</sup> (mg /day)	Systemic EU-AOEL (mg/day)	Risk-index <sup>b</sup>
<i>Re-entry activities in the intended uses (max. 2.5 L product/ha)</i>			
Respiratory	-	14	-
Dermal	0.95	14	0.07
Total	0.95	14	0.07

a External exposure was estimated with EUROPOEM II. Internal exposure was calculated with:

- biological availability via the dermal route: 7% (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

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

#### 4.4.4 Re-entry

See 4.4.3 Worker exposure/risk.

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

The product complies with the Uniform Principles.

##### Operator exposure

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

##### Bystander exposure

Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected bystander, nor for nearby non-work related bystanders and residents, due to exposure to clethodim during application of Centurion Plus in the intended uses.

##### Worker exposure

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

#### 4.5 Appropriate mammalian toxicology and operator exposure end-points relating to the product and approved uses

See List of Endpoints.

#### 4.6 Data requirements

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

#### 4.7 Combination toxicology

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

#### 4.8 Mammalian toxicology classification and labelling

##### Proposal for the classification and labelling of the formulation concerning health

Classification and labelling of the formulation does not change.

## 5. Residues

### List of Endpoints

The list of endpoints presented below is taken from: The peer review of the pesticide risk assessment of the active substance clethodim (EFSA Journal 2011;9 (10):2417).

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

Plant groups covered	Root vegetables (carrot) Pulses and oilseeds (soybean and cotton)
Rotational crops	Carrot, lettuce and wheat
Metabolism in rotational crops similar to metabolism in primary crops?	Yes, clethodim extensively metabolised
Processed commodities	No study provided and not required
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Soil metabolites oxazole sulfoxide and oxazole sulfone observed in rotational crops but not in primary crops.
Plant residue definition for monitoring	Root/tuber vegetable and Oilseeds/Pulses group: Sum of clethodim, clethodim sulfoxide and clethodim sulfone expressed as clethodim
Plant residue definition for risk assessment	Root/tuber vegetables and Oilseeds/Pulses groups: Sum of clethodim, clethodim sulfone, clethodim sulfoxide and metabolites M15R, M17R and M18R expressed as clethodim
Conversion factor (monitoring to risk assessment)	2.5 for Root/tuber vegetables and Oilseeds/Pulses

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

Animals covered	Goat, hen.
Animal residue definition for monitoring	Not proposed and not required for sugar beet use, since residues in food of animal origin were assessed to be insignificant and MRLs were not proposed.
Animal residue definition for risk assessment	Not proposed and not required for sugar beet use, since residues in food of animal origin were assessed to be insignificant and MRLs were not proposed.
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No



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

TRR (mg equivalent/kg) in rotational crops following application to bare soil at 1100 g a.s./ha (2.9N).			
<b>Plant back interval</b>	<b>30</b>	<b>120</b>	<b>366 days</b>
carrot leaf:	0.340	0.420	0.053
carrot root:	0.021	0.019	0.005
lettuce:	0.084	0.045	0.016
wheat straw:	0.480	0.650	0.420
wheat grain:	0.025	0.012	0.021
Individual compound not expected to be present in significant levels (above 0.01 mg/kg) in rotational crops when clethodim is applied according to the cGAP.			

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

Clethodim is stable up to 9 and 11 months in sugar beet tops and sugar beet roots, when stored at -20°C and analysed as DME (dimethyl ester sulfone) using the common moiety method. No information is provided on the stability of the individual compounds (clethodim, clethodim sulfoxide and clethodim sulfone) included in the residue definition for monitoring (data gap).
Clethodim (measured as DME), S-methyl clethodim sulfoxide (measured as S-methyl-DME) and 5-OH clethodim sulfone (measured as DME-OH) were stable during storage at -18°C for approximately 2 months in egg, for at least 6 weeks in gizzard, liver (poultry), muscle (poultry) and fat (poultry), and for approximately 5 months in bovine milk, fat, kidney, liver and muscle.

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

	<b>Ruminant:</b>	<b>Poultry:</b>	<b>Pig:</b>
Expected intakes by livestock $\geq$ 0.1 mg/kg diet (dry weight basis) yes/no (if yes, specify the level)	Yes <sup>1</sup> 1.36/1.54 mg/kg DM Dairy/Beef cattle	Yes <sup>1</sup> 0.13 mg/kg DM	Yes <sup>1</sup> 1.35 mg/kg DM
Potential for accumulation (yes/no):	No	No	No
Metabolism indicate potential residues $\geq$ 0.01 mg/kg in edible tissues (yes/no)	No	No	No
Feeding studies	Dairy cattle: (1 mg clethodim + 19 mg clethodim sulfoxide/kg feed) ca. 10/14 N study (beef/dairy cattle) Poultry: 0.74 mg clethodim + 11 mg clethodim sulfoxide/kg feed) ca. 90 N study Residue levels in matrices: Max. values (mg/kg), analysed as DME/S-meth-DME/DME-OH using a		

	common moiety method2		
Liver	0.059/<0.05/<0.05	<0.05/<0.05/<0.05	-
Kidney	0.051/<0.05/<0.05	-	-
Muscle	<0.05/<0.05/<0.05	<0.05/<0.05/<0.05	-
Fat	<0.05/<0.05/<0.05	<0.05/<0.05/<0.05	-
Milk	<0.0125/<0.0125/0.0125		
Eggs		<0.05/<0.05/<0.05	

<sup>1</sup>:Animal intakes calculated using HR values of 0.05 mg/kg and 0.25 mg/kg for sugar beet roots and leaves, respectively, and a correction factor of 2.5.

<sup>2</sup>:Samples analysed according to the common moiety method RM-26A where:

- Clethodim and clethodim-like metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one moiety are converted to DME,
- 5-OH clethodim and 5-OH clethodim like metabolites containing the 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moiety are converted to DME-OH,
- S-methyl-clethodim and S-methyl like metabolites are converted to S-methyl-DME, the residues being expressed as clethodim equivalents.

Based on these feeding studies it was concluded that no residues are expected to be present at significant levels in animal matrices, and no residue definitions and MRLs were proposed for products of animal origin.

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

Crop/processed crop	Number of studies	Transfer factor		Amount transferred (%)
		Transfer factor	Yield factor	
No acceptable data (residue level in sugar beet root (RAC) <LOQ)				

#### Comments on/additions to List of Endpoints

No comments

#### 5.1 Summary of residue data

The following assessment is based on:

the peer review of the pesticide risk assessment of the active substance clethodim (EFSA Journal 2011;9 (10):2417);

Evaluation Report in the framework of Article 12 review (Regulation (EC) 396/2005) and 20146056 Evaluation Report, Ctgb 2015.

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

##### 5.1.1 Metabolism in plants

Metabolism in clethodim was investigated in root vegetables (carrot, two studies) and pulses and oilseed (soybean and cotton), metabolism of data was also generated in shoots of this crops. The studies were evaluated in the DAR (carrot, soybean and cotton) and in the Additional Report (carrot). It was concluded that the metabolism is similar in these crop groups. The main metabolites were: clethodim, clethodim sulfoxide, clethodim sulfone and bases on later submitted carrot study, metabolites: M15R, M17R and M18R.

##### 5.1.2 Metabolism in livestock

Metabolism studies in goats and hen were evaluated during the peer review (see List of Endpoints).

##### 5.1.3 Residue definition (plant and animal)

Pesticide Peer Review Experts discussed clethodim and toxicity of its metabolites in the Teleconferences TC 60 and TC 61. As conclusion residue definitions were set:

For monitoring: sum of clethodim, clethodim sulfoxide, clethodim sulfone expressed as clethodim

For risk assessment: sum of clethodim, clethodim sulfoxide, clethodim sulfone and metabolites M15R, M17R, M18R expressed as clethodim.

Conversion factor of 2.5 was proposed from monitoring to risk assessment for root and tuber vegetables and oilseed and pulses groups.

No residue definition for animals was set during the peer review, since it was considered not necessary for the use on sugar beet only.

#### 5.1.4 Stability of residues

Stability of clethodim residues was evaluated during the peer review and during the assessment for the existing authorisation of the product Centurion Plus.

Storage stability of the sum of clethodim, clethodim sulfoxide and clethodim sulfone is sufficiently proven in watery matrices for a period of 11 months.

A storage stability study with clethodim, clethodim sulfoxide and clethodim sulfone in oil seed rape (fatty matrix) showed that all three metabolites are stable when stored frozen for a period up to 6 months in fatty matrices.

#### 5.1.5 Supervised residue trials

*Poppy seed (cGAP-NL: 1x 120 g as/ha, PHI=120 days, BBCH 00-30)*

In the existing authorisation of Centurion Plus, the use of clethodim in oilseed rape is authorised according to a similar cGAP. Extrapolation of residue data is possible from oilseed rape to poppy seed. Eight trials with oilseed rape are available. Clethodim residues were in range from <0.014 to 0.039 mg/kg. The current EU-MRL for clethodim in poppy seed is 0.1 mg/kg and the intended use is covered by the EU-MRL, based on the trials in oilseed rape..

*Caraway as oil-bearing seed (cGAP-NL: cGAP-NL: 1x 120 g as/ha, PHI=120 days, BBCH 00-30)*

In the existing authorisation of Centurion Plus, the use of clethodim in oilseed rape is authorised according to a similar cGAP. An extrapolation of residue data is possible from oilseed rape to caraway as oil-bearing seed. Eight trials with oilseed rape are available. Clethodim residues were in range from <0.014 to 0.039 mg/kg. The current EU-MRL for clethodim in oilseeds, others is 0.1 mg/kg and the intended use is covered by the EU-MRL, based on the trials in oilseed rape.

Caraway as “seed herb” cannot be authorised based on this extrapolation. For the sake of clarity the following restriction is included in the directions of use: “Caraway treated with Centurion Plus can be used as oil-bearing seed only.”

*Linseed (cGAP-NL: 1x120 g as/ha, PHI =70 days)*

Four supervised residue trials were submitted for this application. The trials were evaluated nationally by Ctgb (20146056 Evaluation Report, Ctgb 2015).

The trials were performed according to the proposed cGAP-NL. In the treated samples residues of clethodim and clethodim sulfoxide were not detected (below LOD: 0.002 mg/kg). Residues of clethodim sulfone were below LOQ (0.005 mg/kg) in all the trials. However, in the submitted study report there is no clear indication of storage timeline of the samples.

From the study schedule it is concluded that samples were analysed until July 2007 (experimental completion date of analytical phase), therefore 11 months after last sampling (August 2006). Therefore, the available stability data (see point 5.1.4) does not cover storage time from this study and the trials are not acceptable. Extrapolation of residue data from

oilseed rape to linseed is not possible since the PHI significantly deviates from the oilseed rape GAP. The use Centurion Plus on linseed is therefore restricted to production of linseed that is not used for human and/or animal consumption.

*Sunflower (cGAP-NL: 1x240 g as/ha, PHI=100 days )*

Eight supervised residue trials with clethodim in sunflower are available. The trials were performed with more critical cGAP (1x 480 g as/ha). The trials were evaluated by Ctgb in the Evaluation Report within the framework of Article 12 Review (Regulation (EC)396/2005). At the PHI of 100 days, residues of clethodim (sum of clethodim, clethodim sulfoxide and clethodim sulfone) were in range from <0.014 mg/kg to 0.030 mg/kg. The current EU-MRL in clethodim in sunflower seed is 0.5 mg/kg. The intended use is covered by the current EU-MRL.

*Fiber crops (cGAP: 1x 240 g as/ha)*

Fiber crops are not used for human consumption. However, part of the crop can be used as feed for animals. To prevent the possible exposure of animals to clethodim residues via feed, a restriction should be included in the directions of use: Fiber crops may not be used as livestock feed.

*Lupin (cGAP: 1x 120g as/ha)*

Lupin as a green manure crop is not intended for human and animal consumption, therefore no residue trials are required.

*Witloof chicory roots (cGAP: 1x300 g as/ha, PHI = 56 days)*

In the existing authorisation of Centurion Plus, the use of clethodim in sugar beet is authorised according to the same cGAP. According to the document SANCO 7525/VI/95 rev 9, extrapolation is possible from sugar beets to chicory roots. Eight trials with sugar beets are available, where residues were in range from <0.015 to 0.05 mg/kg. MRLs apply to products of plant and animal origin to be used as food or feed and therefore do not apply to witloof chicory roots, but to chicory witloof shoots. The current EU-MRL for clethodim in chicory witloof shoots is 0.5 mg/kg. Taking into account the residue levels in roots up to 0.05 mg/kg, residues in witloof shoots resulting from the production of forced witloof are not expected to exceed the existing MRL.

*Wild chicory (large-rooted cichory) (cGAP: 1x300 g as/ha, PHI = 56 days)*

In the existing authorisation of Centurion Plus, the use of clethodim in sugar beet is authorised according to the same cGAP. According to the document SANCO 7525/VI/95 rev 9, extrapolation is possible from sugar beets to chicory roots. Eight trials with sugar beets are available, where residues were in range from <0.015 to 0.05 mg/kg. The current EU-MRL for clethodim in chicory roots is 0.1 mg/kg and the intended use is covered by the EU-MRL.

*Strawberry – propagation, waiting bed (cGAP: 1x240 g as/ha, PHI = 30 days)*

*Strawberry – fruit production (cGAP: 1x 240 g as/ha, PHI = 30 days)*

Eight trials with clethodim in strawberries are available in Northern Europe. The trials were evaluated by Ctgb in the Evaluation Report within Article 12 review (Regulation (EC)396/2005). The residues ranged from <0.015 mg/kg to 0.22 mg/kg. The current EU-MRL in strawberries is 0.5 mg/kg and the intended use is covered by the current EU-MRL.

*Grapes (wine and table) (cGAP: 1x240 g as/ha, PHI=21 days)*

Two trials with clethodim in grapes in Northern Europe and two in Southern Europe are available. The trials were evaluated by Ctgb in the Evaluation Report within Article 12 review (Regulation (EC)396/2005). The trials were performed with a more critical GAP (1x480 g as/ha), than the proposed cGAP-NL. In both trials residues of clethodim (and metabolites) at the proposed PHI of 21 days were not detected, all metabolites were <0.005 mg/kg. The zero-residue situation is also confirmed in the trials in southern Europe, which is supportive

information. Grapes are major crops, therefore eight trials are required. However, since the residues were not detected in grapes, two trials are considered acceptable for this application. The current EU-MRL in grapes is 1 mg/kg for table grapes and 0.5 mg/kg for wine grapes and based on the available trials the intended use is covered by the current EU-MRLs.

*Cauliflower, broccoli (cGAP: 1x240 g as/ha, BBCH 12-41, PHI=28 days)*

In the existing authorisation of Centurion Plus, the use of clethodim in head cabbage is authorised. Eight trials with young head cabbage, performed according to the same cGAP are available. Since the intended application time for cauliflower and broccoli is on early growing stage (BBCH 12-41); it was agreed that for this national application extrapolation from the available eight trials in young head cabbage is acceptable. However, it should be included in the direction of use (WG) that the application in cauliflower and broccoli can be done until BBCH 41.

The residues found in the trials with head cabbage were from 0.047 mg/kg to 0.349 mg/kg. The current EU-MRL for clethodim in cauliflower and broccoli is 0.5 mg/kg and the intended uses are covered by the current EU-MRL, based on the available trials in head cabbage.

*Black salsify (cGAP: 1x 120 g as/ha, PHI 48 days)*

In the existing authorisation of Centurion Plus, the use of clethodim in carrot is authorised according to the same cGAP. Extrapolation of residue data is possible from carrot to black salsify. Eight trials with carrot, performed with more critical cGAP are available. Clethodim residues ranged from <0.014 mg/kg to 0.12 mg/kg. The current EU-MRL for clethodim in black salsify is 0.5 mg/kg and the intended use is covered by the EU-MRL, based on the available trials in carrot.

*Silverskin, pickles (cGAP: 1x 240 g as/ha, PHI = 56 days)*

In the existing authorisation of Centurion Plus, the use of clethodim in bulb onions is authorised according to the same cGAP. Extrapolation of residue data is possible from onions to silverskin and pickles. Eight trials with onion are available. Clethodim residues ranged from <0.014 – 0.049 mg/kg. Silverskin and pickles belong to the same crop group as onion, therefore the same EU-MRL apply. The intended uses are covered by the current EU-MRL, based on the available trials in onions.

*Aromatic root crops: Lovage root, Angelica, Burnet Saxifrage root, Hamburg root parsley (cGAP: 1x 240 g as/ha, PHI = 48 days)*

In the existing authorisation of Centurion Plus, the use of clethodim in carrot is authorised according to the same cGAP. Extrapolation of residue data is possible from carrot to Lovage root, Angelica, Burnet Saxifrage root, Hamburg root parsley. Eight trials with carrot are available, where clethodim residues were in range from <0.014 mg/kg to 0.12 mg/kg. The current EU-MRL for clethodim in the mentioned above aromatic root crops is 0.5 mg/kg and the intended use is covered by the EU-MRL, based on the available trials in carrot.

#### **5.1.6 Residues in succeeding crops**

During the peer review it was concluded that clethodim residues are not expected to be present in significant levels in rotational crops.

#### **5.1.7 Residues from livestock feeding studies**

Linseed and sunflower meal can be used as feed in animals. However, since the dietary burden calculated in the framework of the Article 12 Review covers the intended uses, no new dietary burden is calculated for this application. Residues in livestock are covered by the existing authorisation.

#### **5.1.8 Processing factors**

No processing data is required, since for the intended uses the TMDI is lower than 10% of the ADI.

### 5.1.9 Calculation of the ADI and the ARfD

#### *Calculation of the ADI*

The ADI is based on the NOAEL of 1.6 mg/kg bw/d in the 2 year rat study. Application of a safety factor for inter- and intraspecies differences of 100 results in an ADI of 0.16 mg/kg bw/day (see the List of Endpoints for mammalian toxicology).

The ADI applies to clethodim parent as well as metabolites clethodim sulfoxide, clethodim sulfone, M15R, M17R and M18R.

#### *Calculation of the ARfD*

No ARfD is derived, since clethodim has no acute toxic properties.

### 5.2 Maximum Residue Levels

Temporary EU-MRLs are present in Annex III of Regulation (EC) 396/2005. The product complies with the MRL Regulation.

### 5.3 Consumer risk assessment

#### *Input values*

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

**Table R2: Input values for the consumer risk assessment**

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Root and tuber vegetables, oilseed group	EU-MRL*CF	During the peer review a conversion factor of 2.5 was proposed	No ARfD is derived, since clethodim has no acute toxic properties	
All commodities	EU-MRLs	-		

#### *Risk assessment for chronic exposure through diet*

A calculation of the Theoretical Maximum Daily Intake (TMDI) was carried out using EFSA PRIMo rev. 2.0, containing all available Member State diets, and the temporary EU-MRLs (including the conversion factor of 2.5 for root and tuber and oilseed and pulses crops). The maximum TMDI is 21% of the ADI for WHO Cluster Diet B. The TMDI is 12.9% and % 5.8 of the ADI for the Dutch general population and Dutch children ages 1-6, respectively.

As no ARfD was derived for clethodim a risk assessment for acute exposure was not performed.

### Conclusion

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

The following restrictions need to be included in the directions of use:

- Fiber crops treated with Centurion Plus and by products may not be used as livestock feed

“Behandelde vezelgewassen niet voor dierlijke consumptie bestemmen.”

- Application of Centurion Plus on cauliflower and broccoli can be done until growing stage: BBCH 41 (Cauliflower or broccoli heads begin to form; width of growing tip > 1 cm3. )

“Toepassen in de teelt van bloemkoolachtigen voordat de oogstbare delen (bloemkool of broccoli) worden gevormd (voor BBCH 41).”

- Linseed treated with Centurion Plus may not be used for human consumption or as livestock feed.

“Behandeld lijnzaad niet voor menselijke of dierlijke consumptie bestemmen en/of in de handel brengen.”

- Caraway treated with Centurion Plus can be used as oil-bearing seed only.

“Toepassing van het middel in karwij is alleen toegestaan voor productie van karwij als oliehoudend zaad (niet als kruidenzaadgewas).”

#### 5.4 Data requirements

None

## 6. Environmental fate and behaviour

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

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, published 21 October 2011.

The final list of endpoints from the EFSA conclusion (Nov, 2011) is used for risk assessment.

### List of Endpoints Fate/behaviour clethodim

#### Fate and Behaviour in the Environment

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

Mineralization after 100 days  
% refers to the applied radioactivity

Soil Sandy loam I (d380)	<b>Propyl label</b> 47% AR (d124), 55%
Soil Sandy loam II Clay loam Loam Loamy sand	<b>Allyl label, Ring label</b> 45%-57% AR (d125-121) 34.2%-63.6% AR (d119-57) 45.4%-57% AR (d119-57) 36%-58.4% AR (d119-57):

Non-extractable residues after 100 days  
% refers to the applied radioactivity

Soil	<b>Propyl label</b>
Sandy loam I (d380)	17% AR (d124), 16% AR
Soil	<b>Allyl label, Ring label</b>
Sandy loam II	13%-29% AR (d119-125)
Clay loam	53.3%-27.6% AR (d119-57)
Loam	45%-27.3% (AR d119-57)
Loamy sand	49.9%-19.3% AR (d119-57)

Major metabolites – name and/or code, % of  
Applied radioactivity (range and maximum)

<b>Clethodim sulfoxide:</b>	
Sandy loam I : max 63% AR at day 7 (Propyl label)	
Soil	Allyl label, Ring label
Sandy loam II :	max 65%-73% AR at day 7-3
Clay loam :	max 59.6%-72% AR at day 1-2
Loam :	max 65.2%-67.5% AR at day 1-2
Loamy sand :	max 53.8% AR at day 1-2
<b>Clethodim sulfone:</b>	
Sandy loam I : max 11% AR at day 61 (Propyl label)	
Soil	Allyl label, Ring label
Sandy loam II :	max 15%-16% AR at day 30
Clay loam :	max 25.8%-33.3% AR at day 7-14
Loam :	max 20.9%-24.4% AR at day 11-14
Loamy sand :	max 11.9%-12.6% AR at day 7
<b>Clethodim oxazole sulfone :</b>	
Sandy loam I : max 10% AR at day 380 (propyl label)	
Sandy loam II : max 8.6% AR at day 121 (ring label)	
Loamy sand : max 7.5% AR at 57 days (ring label)	

Anaerobic degradation

Mineralisation maximum 6.8% AR at 31 d
Non-extractable residues maximum 22% AR at 62 d
Metabolites
clethodim sulfoxide, maximum 79% AR at 1 d
clethodim imine, maximum 44% AR at 31 d
clethodim imine sulfoxide, maximum 14% AR at 31 d
[ring-4,6- <sup>14</sup> C] (n=1)

Soil photolysis

Clay loam, 20 ± 1°C
<b>Clethodim :</b>
max DT <sub>50</sub> = 0.16 days (irradiated samples)
max DT <sub>50</sub> = 2.88 days (dark samples)
<b>Major metabolites :</b>
<b>Clethodim sulfoxide: (allyl – ring labels)</b>
max 60.4%- 53.7% at d 1 (irradiated)
max 89.2%- 88.1% at d 15-10 (dark)
max DT <sub>50</sub> : 1.55 days (irradiated-ring label)
stable in dark

% refers to the applied radioactivity



**Trans-3-chloroacrylic acid:** max 18.1% at d 3 (irr)  
DT<sub>50</sub> : 6.49 days (irradiated-allyl label)

**2-[3-chloroallyloxyimino]butanoic acid isomers :**  
max 18.7% at the end of irradiation period (irr)  
No DT<sub>50</sub> value

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

Method of calculation

First order kinetics; integrated fit. Normalisation according to temperature (ref 20°C) and moisture content (pF2) using a Walker equation coefficient of 0.7 and Q10 of 2.58.  
Field: no reliable data available

<b>Clethodim</b>						
Soil type	label	pH	t. °C / % MWHC	DT <sub>50</sub> /DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20°C pF2/10kPa	Chi <sup>2</sup>
Sandy loam	Propyl	7.1	25°C / 75% FC	2.55/8.50	3.04	9.3
Sandy loam	Allyl	7.5	20°C / 75% FC	1.08/3.59	1.28	14.3
	Ring	7.5	20°C / 75% FC	1.18/3.92	1.40	14.5
geometric mean					1.34	
Clay loam	Allyl	7.3	20°C / 40-50% MWC	0.23/0.76	0.17	11.8
	Ring	7.3	20°C / 40-50% MWC	0.36/1.20	0.27	113.1 <sup>#</sup>
geometric mean					0.21	
Loam	Allyl	6.8	20°C / 40-50% MWC	0.38/1.26	0.28	11.8
	Ring	6.8	20°C / 40-50% MWC	0.36/1.21	0.26	108 <sup>#</sup>
geometric mean					0.27	
Loamy sand	Allyl	5.7	20°C / 40-50% MWC	0.40/1.33	0.48	21.4
	Ring	5.7	20°C / 40-50% MWC	0.52/1.73	0.62	67.8 <sup>#</sup>
geometric mean					0.55	
Geometric mean/median					0.66/0.55	

<sup>#</sup> The high chi2 values for the ring-labelled studies in the Mamouni study are due to inaccurate study design on sampling times (first sampling point after time zero was after 2 days which is a too long period for such a fast degrading substance). Nevertheless, because the results in DT<sub>50</sub> are very similar between the allyl and the ring-labelled studies, overall the results are acceptable.

pH dependence ‡  
(yes / no) (if yes type of dependence)

No

<b>Clethodim sulfoxide</b>						
Soil type	label	pH	t. °C / % MWHC	DT <sub>50</sub> /DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20°C pF2/10kPa <sup>#</sup>	ff
Sandy loam	Propyl	7.1	25°C / 75% FC	22.14/73.55	26.26	80.99
Sandy loam	Allyl	7.5	20°C / 75% FC	15.92/52.89	18.18	87
	Ring	7.5	20°C / 75% FC	16.42/54.55	19.47	89.3
geometric mean DT <sub>50</sub> , arithmetic mean ff					18.81	88.15
Clay loam	Allyl	7.3	20°C / 40-50% MWC	3.67/12.19	2.71	83.22
	Ring	7.3	20°C / 40-50% MWC	3.58/11.89	2.64	100
geometric mean DT <sub>50</sub> , arithmetic mean ff					2.67	91.61
Loam	Allyl	6.8	20°C / 40-50% MWC	7.82/25.98	5.66	91.76
	Ring	6.8	20°C / 40-50% MWC	5.42/18.00	3.93	91.61
geometric mean DT <sub>50</sub> , arithmetic mean ff					4.72	91.69
Loamy sand	Allyl	5.7	20°C / 40-50% MWC	3.7/12.29	4.42	100
	Ring	5.7	20°C / 40-50% MWC	5.04/16.74	6.01	67.89
geometric mean DT <sub>50</sub> , arithmetic mean ff					5.15	83.95
Geometric mean/median DT <sub>50</sub> ; arithmetic mean ff					7.97/5.15	87.28

<sup>#</sup> For Chi2 values reference is made to the table of clethodim.

<b>Clethodim sulfone</b>						
Soil type	label	pH	t. °C / % MWHC	DT <sub>50</sub> /DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20°C pF2/10kPa <sup>#</sup>	Ff
Sandy loam	Propyl	7.1	25°C / 75% FC	22.14/73.55	35.32	27.46
Sandy loam	Allyl	7.5	20°C / 75% FC	15.92/52.89	55.92	31.8
	Ring	7.5	20°C / 75% FC	16.42/54.55	31.62	40.5
geometric mean DT <sub>50</sub> , arithmetic mean ff					42.05	36.15
Clay loam	Allyl	7.3	20°C / 40-50% MWC	3.67/12.19	9.29	66.9
	Ring	7.3	20°C / 40-50% MWC	3.58/11.89	9.23	40.92
geometric mean DT <sub>50</sub> , arithmetic mean ff					9.26	53.91
Loam	Allyl	6.8	20°C / 40-50% MWC	7.82/25.98	8.52	54.99
	Ring	6.8	20°C / 40-50% MWC	5.42/18.00	10.47	50.54
geometric mean DT <sub>50</sub> , arithmetic mean ff					9.44	52.77
Loamy sand	Allyl	5.7	20°C / 40-50% MWC	3.7/12.29	5.49	15

	Ring	5.7	20°C / 40-50% MWC	5.04/16.74	2.89	79.78
	geometric mean DT <sub>50</sub> , arithmetic mean ff				3.98	47.39
Geometric mean/median DT <sub>50</sub> ; arithmetic mean ff					13.89/9.44	43.54

# For Chi2 values reference is made to the table of clethodim.

<b>Clethodim oxazole sulfone</b>							
Soil type	label	pH	t. °C / % MWHC	DT <sub>50</sub> /DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20°C pF2/10kPa	Chi <sup>2</sup>	ff
Sandy loam	§	6.4	20°C / 40-60% MWC	20/66	20	8.5	*
Loamy sand	§	5.4	20°C / 40-60% MWC	24/79	24	6.4	*
Clay	§	7.2	20°C / 40-60% MWC	68/227	68	7.3	*
Geometric mean					32		16.95#

§ cold study

\* applied as test compound

# based on ring label loamy sand study (pH 5.7)

**Data gap** identified for experimental degradation rates in soil of the two soil photolysis metabolites 2-[3-chloroallyloxyimino]butanoic acid and *trans*-3-chloroacrylic acid.

Field studies (state location, range or median with n value)

No acceptable field study.  
DT<sub>50f</sub>: no reliable data submitted  
DT<sub>90f</sub>: no reliable data submitted

Soil accumulation and plateau concentration

No accumulation is expected for clethodim, clethodim sulfoxide, clethodim sulfone or clethodim oxazole sulfone.  
No accumulation study was conducted.

**Soil adsorption/desorption (Annex IIA, point 7.1.2)**

<b>Clethodim</b>							
Soil Type	OC %	Soil pH (CaCl <sub>2</sub> )	K <sub>d</sub> (mL/g)	K <sub>oc</sub> (mL/g)	K <sub>F</sub> (mL/g)	K <sub>Foc</sub> (mL/g)	1/n
Sandy loam	2.3	5.6	-	-	0.993	43.17	1.04
Loam	1.28	7.4	-	-	0.065	5.08	0.97
Clay loam	4.13	7.5	-	-	0.112	2.71	0.98
Silt loam	2	5.4	-	-	0.794	39.7	1.05
Arithmetic mean						22.7	1.01
pH dependence, Yes or No				Yes. Although a very narrow range of soil pH was tested for clethodim, a higher adsorption was observed for the acidic soils.			

K<sub>F</sub>K<sub>oc</sub>K<sub>d</sub> = (K<sub>oc</sub> × % o.c.)

pH dependence (yes/No) if yes, type of dependence

**Clethodim sulfoxide**K<sub>Foc</sub> = 24/14/2 L/kg (arithmetic mean = 13.3 L/kg)K<sub>F</sub> = 0.550/0.184/0.072

1/n = 0.71/0.78/1.02 (arithmetic mean = 0.83)

No effect of pH

**Clethodim sulfone**K<sub>Foc</sub> = 16/11/5 L/kg (arithmetic mean = 10.7 L/kg)K<sub>F</sub> = 0.366/0.146/0.194

1/n = 0.77/0.87/0.74 (arithmetic mean = 0.79)

No effect of pH

**Clethodim oxazole sulfoxide**K<sub>doc</sub> = 26/58/130 L/kg (arithmetic mean = 71.3 L/kg)K<sub>d</sub> = 0.6/1.66/2.4

1/n = no data

No effect of pH

**Clethodim oxazole sulfone**K<sub>Foc</sub> = 12/96/43 L/kg (arithmetic mean = 50.3 L/kg)K<sub>F</sub> = 0.277/1.249/1.779

1/n = 1.09/1.00/1.01 (arithmetic mean = 1.03)

No effect of pH

K<sub>oc</sub> and 1/n used for FOCUS PEC<sub>gw</sub> modeling:Clethodim: worst-case K<sub>Foc</sub> = 4 L/kg for all the FOCUS scenarios and 1/n = 0.975 (agreed in PRAPeR 78) (geometric mean of KFoc values at alkaline pH)Arithmetic mean K<sub>oc</sub> (L/kg) / 1/n

Clethodim sulfoxide: 13 / 0.83

Clethodim sulfone: 11 / 0.79

Clethodim oxazole sulfone: 51 / 1.03

**Data gap** identified for experimental soil adsorption values of the two soil photolysis metabolites 2-[3-chloroallyloxyimino]butanoic acid and *trans*-3-chloroacrylic acid.

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

Column leaching

Guideline: BBA IV, 4-2  
 Precipitation: 200 mm  
 Time period: 2 d  
 Leachate: 30-68% of applied; parent 2.4-7.1%,  
 clethodim sulfoxide 26-59%, clethodim sulfone  
 1.6-5.3%, clethodim oxazole sulfoxide, clethodim  
 oxazole sulfone <2.4%; soil concentrations not  
 determined.  
 [unlabelled clethodim]

Aged residues leaching

Guideline: BBA IV, 4-2  
 Precipitation: 200 mm  
 Time period: 2 d  
 Leachate: parent, clethodim sulfoxide, clethodim  
 sulfone, clethodim oxazole sulfoxide, clethodim  
 oxazole sulfone: all <1.8%; soil concentrations not  
 determined.  
 [unlabeled clethodim]

Lysimeter/ field leaching studies

No data submitted.

**PEC (soil) (Annex IIIA, point 9.1.3)**

Method of calculation

First order kinetics with a normalized max  $DT_{50}$  of  
 3.04 days  
 Bulk density of soil : 1.5 g/cm<sup>3</sup>  
 Depth of the soil layer : 5 cm

Application data

Crop: sugar beet  
 Northern Europe:  
 90 g a.s./ha about BBCH 40\* (GAP 300 with 70 %  
 foliar interception)

Southern Europe:  
 116.7 g a.s./ha at BBCH 40\* (GAP 384 with 70 %  
 foliar interception)

\*Based on the intended uses as originally  
 proposed by the applicant in the resubmission  
 dossier, the correct GAPs should be as follows:

**NORTHERN EUROPE**  
 GAP 300: 1 application of 300 g a.s./ha (BBCH  
 31-39); effective application rate 90 g a.s./ha  
 GAP 240: 1 application of 240 g a.s./ha (BBCH  
 12-39); effective application rate 192 g a.s./ha  
 GAP 180: 1 application of 180 g a.s./ha (BBCH  
 12-39); effective application rate 144 g a.s./ha

**SOUTHERN EUROPE**  
 GAP 384: 1 application of 384 g a.s./ha (BBCH  
 31-39); effective application rate 115.2 g a.s./ha  
 GAP 2x192: 2 applications of 192 g a.s./ha at 21 d  
 interval (BBCH 11-39); effective application rate  
 153.6 g a.s./ha  
 GAP 192: 1 application of 192 g a.s./ha (BBCH  
 11-19); effective application rate 153.6 g a.s./ha

Metabolites – parameters used for PECs calculation

GAP 300, 384 with 70 % foliar interception  
GAP 240, 2x192, 192, 180 with 20 % foliar interception.

The corresponding PEC<sub>soil</sub> calculations for clethodim and its soil metabolites can be found in the Additional Report (November 2009) (The Netherlands, 2009).

The max. initial PEC<sub>soil</sub> value for clethodim is **0.256 mg/kg** as a result of the calculations for the GAP 240. This value has been properly used in the risk assessment for soil organisms.

**Clethodim sulfoxide**

Molar mass = 375.9 g/mol  
Laboratory -SFO- DT<sub>50</sub> = 26.26 days (worst-case normalised)  
Formation fraction = 100%

**Clethodim sulfone**

Molar mass = 391.9 g/mol  
Laboratory -SFO- DT<sub>50</sub> = 42.05 days  
Formation fraction = 79.78% (highest of 2 replicates)

**Clethodim oxazole sulfone**

Molar mass = 299.4 g/mol  
Laboratory -SFO- DT<sub>50</sub> = 121.15 days  
Formation fraction = 16.95%  
The DT<sub>50</sub> for clethodim oxazole sulfone has been determined in a new study and has been shown to be 68 days as opposed to 121.15 days. Revised short-term and long-term PECs have not been calculated, as the existing values are worst case. Moreover, PEC<sub>max</sub> is used for risk assessment. PEC accumulation is not relevant.

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

Hydrolysis of active substance and relevant metabolites (DT<sub>50</sub>) (state pH and temperature)

propyl-label pH 5: 28 d at 25 °C (1st order, r2=0.99) allyl-label pH 5: 54 d at 25 °C (1st order, r2=0.94)
propyl-label pH 7: 300 d at 25 °C (1st order, r2=0.96) allyl-label pH 7: 499 d at 25 °C (1st order, r2=0.82)
propyl-label pH 9: 310 d at 25 °C (1st order, r2=0.96)
propyl-label: the major hydrolysis product oxazole RE-47365 (maximum levels recorded after 32 days: 50.5, 6.8 and 4.9% at pH 5, 7 and 9, respectively). allyl-label, the major hydrolysis product was chloroallyl alcohol (RE-46261; maximum levels recorded after 30 days were 30.7 and 4.3% at pH 5 and 7, respectively).

Photolytic degradation of active substance and relevant metabolites % refers to the applied radioactivity

Not sensitised:  
 pH 5: DT<sub>50</sub> = 1.49 - 1.71 (25°C)  
 pH 7: DT<sub>50</sub> = 4.05 - 6.84 (25°C)  
 pH 9: DT<sub>50</sub> = 6.0 - 9.57 (25°C)  
 Sensitised (with acetone)  
 pH 5: DT<sub>50</sub> = 0.20 - 0.94 (25°C)  
 pH 7: DT<sub>50</sub> = 0.61 - 1.22 (25°C)  
 pH 9: DT<sub>50</sub> = 0.33 - 0.52 (25°C)

DME sulfoxide: maximum 48.9%  
 clethodim imine sulfoxide: maximum 23.0%  
 clethodim imine: maximum 18.2%  
 clethodim sulfoxide: maximum 14.2%  
 imine ketone: maximum 11.8%  
 clethodim oxazole sulfoxide: maximum 6.9%  
 clethodim oxazole: maximum 5.5%  
 chloroallyl alcohol: maximum 31.3%  
 3-chloropropenal: maximum 31.3%

The maximum amounts of a.s. in the dark control samples at the end of the study are 88.8%, 94.5% and 85.7% at pH 5, 7 and 9.

Readily biodegradable (yes/no)

Yes

Degradation in water/sediment

- DT<sub>50</sub> water  
 - DT<sub>90</sub> water

Clethodim – Water Phase					
River			Pond		
Ring	Allyl	geomean	Ring	Allyl	geomean
8.9	5.5	7.0	13.2	9.2	11.0
29.4	18.3	-	44.0	30.4	-

- DT<sub>50</sub> total system  
 - DT<sub>90</sub> total system

Clethodim – Total System					
River			Pond		
Ring	Allyl	geomean	Ring	Allyl	geomean
11.1	7.38	9.0	15.0	13.6	14.3
36.8	25.9	-	49.9	45.2	-

- DT<sub>50</sub> total system  
 - DT<sub>90</sub> total system

Clethodim sulfoxide– Total System					
River			Pond		
Ring	Allyl	geomean	Ring	Allyl	geomean
31.3	27.4	29.3	24.5	13.3	18.1
104	91	-	83	44	-



- DT<sub>50</sub> total system
- DT<sub>90</sub> total system

Clethodim imine		Clethodim imine sulfoxide		Clethodim sulfone	
Total System		Total System		Total System	
River	Pond	River	Pond	River	Pond
50.0*	46.9*	41.5*	34.5*	360*	---
166*	156*	138*	156*	1196*	---

\* mean from both labels

Mineralization (allyl-ring labels)  
 River : 32.3-34.7% of AR at d 174  
 Pond I : 26.8-43.7% of AR at d 174  
 Pond II : 18.3% of AR at d 196 (ring)

Non-extractable residues (allyl-ring labels)  
 River : 22.1-24.4% at d 174  
 Pond I : 27.7-32.9% at d 174  
 Pond II : 32.5% at d 196

Distribution in water / sediment systems (active substance)  
River : at day 0, 96.1% of AR in water, less than 2% from d 42  
Pond I : at day 0, 96.5% of AR in water, less than 4% from d 56  
Pond II : at day 0, 70.5% of AR in water, less than 5% from day 103  
 Maximum observed in sediment  
River : 10.8-11.1% of AR at d 7-14 (ring-allyl)  
Pond I : 8.6-12% of AR at d 2-7 (ring-allyl)  
Pond II : 2.6% of AR at d 28 (ring)

Distribution in water / sediment systems (relevant metabolites) % AR.  
 Water:  
 Clethodim sulfoxide: max 57.8% day 14 (allyl-river)  
 Clethodim sulfone: max 10.4% at day 68 (allyl-pond)  
 Clethodim imine sulfoxide: max 7.1 % at day 33 (ring-river)  
 Clethodim imine: <2.1%  
 Sediment:  
 Clethodim sulfoxide: < 5.3%  
 Clethodim sulfone: < 3.1%  
 Clethodim imine: max 35.8% at day 33 (ring-pond)  
 Clethodim imine sulfoxide: max 15.5% at d 61(ring-pond)

**PEC (surface water) (Annex IIIA, point 9.2.3) and PEC sediment**

Method of calculation	STEPS 1-2 in FOCUS, STEP 3 in FOCUS Only highest tier in LOEP. All tiers are presented in the addendum.
Application rate	<p>Crop: sugar beet</p> <p>NORTHERN EUROPE  GAP 300: 1 application of 300 g a.s./ha  GAP 240: 1 application of 240 g a.s./ha  GAP 180: 1 application of 180 g a.s./ha</p> <p>SOUTHERN EUROPE  GAP 384: 1 application of 384 g a.s./ha  GAP 2x192: 2 applications of 192 g a.s./ha at 14 d* interval  GAP 192: 1 application of 192 g a.s./ha</p> <p>GAP 300, 384 with 70 % foliar interception  GAP 240, 2x192, 192, 180 with 20% foliar interception</p> <p>*14 d interval was used in the risk assessment instead of the representative 21 d interval, however, this was considered acceptable as it represents a more worst case.</p>
Main routes of entry	<p>Drift, drainage and run-off.</p> <p>Active substance: Clethodim  Molecular mass 359.92 g/mol  Water solubility 5450 mg/L  Mean DT<sub>50</sub> soil 0.56 days  Koc 4 mL/g (worst case)  Max DT<sub>50</sub> water 19.7 days (conservative)  Max DT<sub>50</sub> total system 23 days (conservative 14.3 days could have been used)  DT<sub>50</sub> sediment 1000 days</p>

Metabolites	Clethodim sulfoxide	Clethodim sulfone	Clethodim oxazole sulfone	Clethodim imine	Clethodim imine sulfoxide
Molecular mass (g/mol)	375.9	391.9	299.4	269	285
Solubility (mg/L)	73	46.43	1468	0.6644	103.13
Max formed in total system (%)	61.5	13.5	-	36.3	21.7
Max formed in soil (%)	73	33.3	10	Not detected in soil	Not detected in soil
Mean DT <sub>50</sub> soil (days)	7.01	12.53	&121.15	Not detected in soil	Not detected in soil
Koc (mL/g)	9	9.66	&55	240*	49.9*
Max DT <sub>50</sub> water (days)	31.3	360	1000 default value	50	46
Max DT <sub>50</sub> total system (days)	31.3	360	Not major in water sediment study	50	46
Max DT <sub>50</sub> sed (days)	1000	1000	1000 default value	1000	1000

\* Values very different but conservative compared to the 32 days and 71 mL/g that could have been selected.

\* EPIWIN v3.11 estimation

DT<sub>50</sub> (days) used in FOCUS PECsw modeling for the both compartments in STEP 1 and the water compartment in STEP 2 and 3 (sediment compartment default of 1000 days for STEP 2/3):  
 Clethodim: 23 d for STEP 1, 19.7 d for STEP 2/3 (worst-case values)  
 Clethodim sulfoxide: 31.3 d  
 Clethodim sulfone: 360 d  
 Clethodim imine: 50 d  
 Clethodim imine sulfoxide: 46 d

### PEC (sediment)

See tables above for input values

**PEC (ground water) (Annex IIIA, point 9.2.1)**

Method of calculation and type of study (e.g. modelling, monitoring, lysimeter)

Modelling by FOCUS PEARL 3.3.3 and FOCUS PELMO 3.3.2, calculations, locations: Châteaudun, Hamburg; Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, and Thiva.

For FOCUS PEC<sub>gw</sub> modelling

Geometric mean DT<sub>50lab</sub> (20°C, aerobic, moisture corrected):

clethodim: 0.56 d (the correct values to use would be 0.66 d)

clethodim sulfoxide: 7.01 d and mean ff 87.45%

(the correct values to use would be 13.89 d and mean ff 43.54)

clethodim sulfone: 7.97 d and mean ff 87.28%

(the correct values to use would be 13.89 d and mean ff 43.54)

clethodim oxazole sulfone: 32 d and mean ff

16.95%

Koc and 1/n used for FOCUS PEC<sub>gw</sub> modeling:

Arithmetic mean Koc (L/kg) / 1/n

Clethodim: 4 (conservative value agreed in PRAPeR 78) / 0.975

Clethodim sulfoxide: 13 / 0.83

Clethodim sulfone: 11 / 0.79

Clethodim oxazole sulfone: 51/ 1.03

Plant uptake factor: 0.5 (for metabolites a plant uptake factor of 0 should have been used; however, it is expected not to have substantial impact on the groundwater modelling results).

Application rate

Crop: sugar beet

192 g a.s./ha about BBCH 12-39 (GAP 240 with 20 % foliar interception)

115.2 g a.s./ha at BBCH 31-39 (GAP 384 with 70 % foliar interception)

2 x 153.6 g a.s./ha at BBCH 11-39 with a 21-day interval (GAP 2x192 with 20 % foliar interception)

**Data gap** identified in PRAPeR 78 for a groundwater assessment for the two soil photolysis metabolites 2-[3-chloroallyloxyimino]butanoic acid and *trans*-3-chloroacrylic acid.

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

Direct photolysis in air

NA

Quantum yield of direct photo-transformation

No data

Photochemical oxidative degradation in air

Latitude: no data Season: no data

DT<sub>50</sub>: Atkinson calculation

for reaction with OH-radical: 0.827 h [Cis-isomer], 0.818 h [Trans-isomer], (1.5x10<sup>6</sup> OH/cm<sup>3</sup>)

for reaction with ozone: 22.566 h [Cis-isomer], 21.154 h [trans-isomer], (7x10<sup>11</sup> mol/cm<sup>3</sup>)

Volatilization

from plant surfaces: NA

from soil: NA

**PEC (air)**

Method of calculation

Not calculated. Taking into consideration the very low vapour pressure of clethodim:  $2.1 \cdot 10^{-6}$  Pa at 20°C, and the Henry's law constant  $1.40 \cdot 10^{-7}$  (Pa.m<sup>3</sup>/mol) at 20°C, respectively, contamination of the air is very unlikely to occur.

For the metabolites the following vapour pressures are available (EPIWIN):

Clethodim sulfoxide: 2.14E-12 mmHg  
 Clethodim sulfone: 8.24E-13 mmHg  
 Imine sulfoxide: 9.69E-11 mmHg  
 Oxazole: 6.24E-06 mmHg  
 Oxazole sulfoxide: 3.38E-07 mmHg  
 Oxazole sulfone: 1.49E-07 mmHg

As these values are considered to be low, none of the identified metabolite of clethodim was considered relevant for air and no PEC<sub>air</sub> was calculated.

**Residues requiring further assessment** (Annex IIA, point 7.3)

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which a groundwater exposure assessment is triggered

**Soil:**

clethodim, clethodim sulfoxide, clethodim sulfone, clethodim oxazole sulfone, 2-[3-chloroallyloxyimino] butanoic acid (soil photolysis), *trans*-3-chloroacrylic acid (soil photolysis)

**Ground water:**

provisionally clethodim, clethodim sulfoxide, clethodim sulfone, clethodim oxazole sulfone, 2-[3-chloroallyloxyimino] butanoic acid, *trans*-3-chloroacrylic acid; however, a data gap was identified for the characterization of the chromatographic peak M20 found in a soil metabolism study in order to support the exclusion of the content of this peak from the overall quantification of metabolite clethodim oxazole sulfoxide. In case that this fraction is part (one of the isomers) of clethodim oxazole sulfoxide and the quantitative determination makes the metabolite occurring more than 5% at 2 consecutive time points, then a groundwater assessment would be needed for clethodim oxazole sulfoxide.

**Surface water:**

clethodim, clethodim sulfoxide, clethodim sulfone, clethodim oxazole sulfone

**Sediment:**

clethodim, clethodim oxazole sulfone, clethodim imine sulfoxide, clethodim imine

**Air:**

clethodim

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

Soil (indicate location and type of study)  
 Surface water (indicate location and type of study)  
 Ground water (indicate location and type of study)  
 Air (indicate location and type of study)

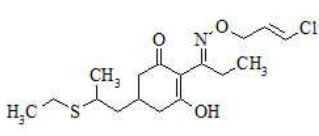
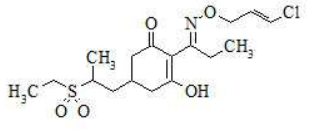
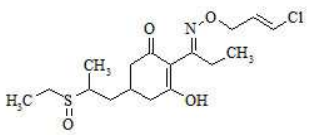
No data
No data
No data
No data

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

No classification proposed.
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**Appendix A: Metabolite names, codes and other relevant information of the plant protection product Centurion Plus with active substance clethodim.**

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

Compound name	IUPAC name	Structural formula	Structure	Molecular Weight [g/mol]	Observed in study (% of occurrence / formation)
Clethodim		C <sub>17</sub> H <sub>26</sub> ClNO <sub>3</sub> S		359.9	Parent substance
Clethodim-sulfone	(5 <i>RS</i> )-2-[( <i>E</i> )-1-[(2 <i>E</i> )-3-chloroallyloxyimino]propyl]-5-[(2 <i>RS</i> )-2-(ethylthio)propyl]-3-hydroxycyclohex-2-en-1-one	C <sub>17</sub> H <sub>26</sub> ClNO <sub>5</sub> S		391.9	Soil (33.3%) Water and sediment (10.4 %, day 14)
Clethodim-sulfoxide	2,6-diethyl- <i>N</i> -methoxymethyl-2-sulfoacetanilide	C <sub>17</sub> H <sub>26</sub> ClNO <sub>4</sub> S		375.9	Soil (73%) Water 57.8% (day 14) and sediment
Clethodim-				299.4	Soil (0.10)

Compound name	IUPAC name	Structural formula	Structure	Molecular Weight [g/mol]	Observed in study (% of occurrence / formation)
oxazole-sulfone					
Clethodim-imine				269	Water and sediment (15.5 % (day 61))
Clethodim-imine-sulfoxide				285	Water and sediment (35.8% (day 33))

## 6.1 Fate and behaviour in soil

### 6.1.2 Leaching to shallow groundwater

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

The leaching potential of the active substance clethodim and metabolites is calculated in the first tier using Pearl 4.4.4 and the FOCUS Kremsmünster scenario. Input variables are the actual worst-case application rate ranging 120-300 g/ha, the crop [see Table 2.a] and an interception value appropriate to the crop stage ranging 0-0.4. Date of yearly application is September 30st for applications applied for up to and including October, and November 1<sup>st</sup> for applications applied for up to and including December. For metabolites all available data concerning substance properties are regarded. For active substance clethodim and metabolite clethodim-sulfoxide, the DT<sub>50</sub> is < 10 days and the K<sub>om</sub> is < 10 L/kg. Therefore, the first tier prediction using PEARL 4.4.4 is skipped and leaching behaviour is directly modelled using GeoPEARL 3.3.3. For metabolites clethodim – sulfone, clethodim – oxazole-sulfone leaching behaviour is predicted using PEARL 4.4.4. Moreover, because clethodim and clethodim sulfoxide are predecessors of clethodim – sulfone and clethodim – oxazole – sulfone, these two substance are included in the PEARL 4.4.4 calculation. No other metabolites occurred above > 10 % of AR, > 5 % of AR at two consecutive sample points or had an increasing tendency.

Only the autumn scenario has been accounted for in leaching calculations.

The following input data are used for the calculation:

#### PEARL and GeoPEARL:

##### Active substance clethodim:

Geometric mean normalised DT<sub>50</sub> for degradation in soil (20°C): 0.66 days (n=5)  
 Conservative K<sub>om</sub> (pH-independent): 2.32 L/kg (agreed in PRAPeR 78, see LoEP).  
 Arithmetic mean 1/n: 0.975

Saturated vapour pressure: 2.08 x 10<sup>-6</sup> Pa (20°C)  
 Solubility in water: 5450 mg/L (20°C)  
 Molecular mass: 359.9 g/mol

Plant uptake factor: 0.5  
 Q10: 2.58

Metabolite clethodim - sulfoxide:Geometric mean DT<sub>50</sub> for degradation in soil (20°C): 7.97 days (n=5)Arithmetic mean K<sub>om</sub> (pH-independent): 7.71 L/kg

Arithmetic mean 1/n: 0.83

Formation fraction: 0.87 (from parent)

Saturated vapour pressure: 2.14 x 10<sup>-9</sup> Pa (20°C)

Solubility in water: 73 mg/L (20°C)

Molecular mass: 375.9 g/mol

Plant uptake factor: 0.0

Q10: 2.58

Metabolite clethodim - sulfone:Geometric mean DT<sub>50</sub> for degradation in soil (20°C): 13.9 days (n=5)Arithmetic mean K<sub>om</sub> (pH-independent): 6.21 L/kg

Arithmetic mean 1/n: 0.79

Formation fraction: 0.43 (from clethodim-sulfoxide)

Saturated vapour pressure: 8.24 x 10<sup>-10</sup> Pa (20°C)

Solubility in water: 46.43 mg/L (20°C)

Molecular mass: 391.9 g/mol

Plant uptake factor: 0.0

Q10: 2.58

Metabolite clethodim-oxazole sulfone:Geometric mean DT<sub>50</sub> for degradation in soil (20°C): 32 days (n=3)Arithmetic mean K<sub>om</sub> (pH-independent): 29.4 L/kg

Arithmetic mean 1/n: 1.03

Formation fraction: 0.17 (from clethodim-sulfone)

Saturated vapour pressure: 2.08 x 10<sup>-6</sup> Pa (20°C, parent value)

Solubility in water: 1468 mg/L (20°C)

Molecular mass: 299.4 g/mol

Plant uptake factor: 0.0

Q10: 2.58

Other parameters: standard settings of PEARL 4.4.4

The following concentrations are predicted for the metabolites clethodim-sulfone and clethodim-oxazole sulfone following the realistic worst case GAP, see Table M.1a.



**Table M.1a Leaching of active substance clethodim and metabolites clethodim-sulfone and clethodim-oxazole sulfone as predicted by PEARL 4.4.4, autumn scenario. (Values  $\geq 0.1 \mu\text{g/L}$  are indicated in bold, values  $\geq 0.01$ - $< 0.1 \mu\text{g/L}$  are underlined)**

Use	Substance	PEARL scenario	Rate substance parent [kg/ha]	Freq. / Int. [days]	Fraction Intercepted *	PEC groundwater [ $\mu\text{g/L}$ ]
Strawberry propagation, waiting bed, Strawberry production	clethodim -sulfone -oxazole sulfone	Strawberry	120	1 / -	$0.30^{1,2}$	<b>0.2698</b> <b>0.2213</b>
	clethodim -sulfone -oxazole - sulfone		240	1 / -	$0.30^{1,2}$	<b>0.7135</b> <b>0.4640</b>
Grapes wine and table	clethodim -sulfone -oxazole – sulfone	Vines	120	1 / -	$0^3$	<b>0.6255</b> <b>0.2897</b>
	clethodim -sulfone -oxazole – sulfone		240	1 / -	$0^3$	<b>0.5465</b> <b>0.2975</b>
Cauliflower, Broccoli	clethodim -sulfone -oxazole – sulfone	Winter cereals	120	1 / -	$0.25^{4,5}$	<b>0.3159</b> <b>0.2464</b>
	clethodim -sulfone -oxazole – sulfone		240	1 / -	$0.25^{4,5}$	<b>0.8382</b> <b>0.5120</b>
Black salsify	clethodim -sulfone -oxazole – sulfone	Winter cereals	120	1 / -	$0.20^6$	<b>0.3465</b> <b>0.2639</b>
Lilium	clethodim -sulfone -oxazole – sulfone	Winter cereals	60	4 / 7	$0.10^7$	<b>1.0826</b> <b>0.6411</b>
	clethodim -sulfone -oxazole – sulfone		120	1 / -	$0.10^7$	<b>0.4097</b> <b>0.2989</b>
	clethodim -sulfone -oxazole – sulfone		240	1 / -	$0.10^7$	<b>1.0775</b> <b>0.6199</b>
Lilium, Dahlia, Zantedeschia, Daffodils	clethodim -sulfone -oxazole – sulfone	Winter cereals	120	1 / -	$0.10^8$	<b>0.4097</b> <b>0.2989</b>
	clethodim -sulfone		240	1 / -	$0.10^8$	<b>1.0775</b>

Use	Substance	PEARL scenario	Rate substance parent [kg/ha]	Freq. / Int. [days]	Fraction Intercepted *	PEC groundwater [µg/L]
	-oxazole – sulfone					<b>0.6199</b>
Iris	clethodim -sulfone	Winter cereals	120	1 / -	0.40 <sup>9</sup>	<b>0.2291</b>
	-oxazole – sulfone					<b>0.1932</b>
	clethodim -sulfone		240	1 / -	0.40 <sup>9</sup>	<b>0.6145</b>
	-oxazole – sulfone					<b>0.4049</b>
Floricultural crops, Plant breeding crops, flower seed crops and seed production for vegetable crops, herbs, beets, pulses, oil-bearing seeds, fibre crops, green fertilisers, fodder crops, chicory (roots), wild chicory, buckwheat, common madder	clethodim -sulfone	Winter cereals	120	1 / -	0 <sup>10</sup>	<b>0.4755</b>
	-oxazole – sulfone					<b>0.3341</b>
	clethodim -sulfone		240	1 / -	0 <sup>10</sup>	<b>1.2443</b>
	-oxazole – sulfone					<b>0.6920</b>
Perennials	clethodim -sulfone	Winter cereals	120	1 / -	0.15 <sup>11</sup>	<b>0.3777</b>
	-oxazole – sulfone					<b>0.2814</b>
	clethodim -sulfone		240	1 / -	0.15 <sup>11</sup>	<b>0.9962</b>
	-oxazole – sulfone					<b>0.5838</b>

\* interception values derived from Table 1.5 and 1.6 in Generic Guidance for Tier 1 FOCUS Ground Water Assessments. (FOCUS, 2011). <sup>1,2</sup> An interception of 0.3 is appropriate for strawberries from growth stage BBCH 11 onwards. <sup>3</sup> An interception of 0 is appropriate for Vines from growth stage BBCH 00 onwards. <sup>4,5</sup> An interception of 0.25 is appropriate for cauliflower and broccoli from growth stage BBCH 12 onwards (based on the interception values of cabbage). <sup>6</sup> An interception of 0.2 is appropriate for black salsify at growth stage BBCH 11-12 (based on the interception values of sugar beets). <sup>7,8</sup> An interception value of 0.1 is appropriate for liliium and lilium, dahlia, zanthedeschia and daffodils from growth stage BBCH 11 onwards (based on the interception values of onions). <sup>9</sup> An interception of 0.4 is appropriate for Iris from BBCH growth stage 71 onwards (based on the interception values of onions).

<sup>10</sup> An interception of 0 is appropriate for floricultural crops and plant breeding crops, flower seed crops and seed production for vegetable crops, herbs, beets, pulses, oil-bearing seeds, fibre crops, green fertilizers, fodder crops, chicory (roots), wild chicory, buckwheat, common madder from growth stage BBCH 00 onwards (based on the interception values of beans). <sup>11</sup> An interception value of 0.15 is appropriate for perennials from growth stage BBCH 11 onwards (based on the interception values of potatoes).

Results of Pearl 4.4.4 using the Kremsmünster scenario are examined against the standard of 0.01 µg/L. This is the standard of 0.1 µg/L with an additional safety factor of 10 for vulnerable groundwater protection areas (NL-specific situation).

From Table M.1a it reads that the expected leaching based on the PEARL-model calculations for the metabolites clethodim-sulfone and clethodim-oxazole-sulfone is equal to or larger than 0.1 µg/L for all applications.

Therefore, further study into the leaching behaviour is necessary.

In the next section a higher tier modelling is presented.

### GeoPEARL

The leaching potential of substance clethodim and metabolites clethodim-sulfone, clethodim-sulfoxide and clethodim-oxazole-sulfone to the shallow groundwater in the potential area of use within The Netherlands is calculated using the GeoPEARL model. The same input data as used in the first tier with Pearl 4.4.4 is employed. Additional input is the crop and the number of plots (minimum 250). For results see Table M.1b. Only the worst case applications, based on application rate, interception and scenario, are calculated.

**Table M.1b Leaching of active substance clethodim and metabolites clethodim-sulfone, clethodim-sulfoxide and clethodim-oxazole-sulfone as predicted by GeoPEARL 3.3.3., autumn scenario. Values  $\geq 0.1$  µg/L are indicated in bold, values  $\geq 0.01$ -<0.1 µg/L are underlined.**

Use	Substance	GeoPEARL scenario	Rate a.s. [kg/ha]	Freq./ Int. [days]	Fraction Intercepted*	PEC groundwater [µg/L]
1. Strawberry propagation, wating bed; Strawberry production	clethodim	Strawberries	0.240	1 / -	0.3	< 0.001
	clethodim					<u>0.094</u>
	-sulfoxide					<b>0.607</b>
	-sulfone					<b>0.385</b>
2. Grapes wine and table	clethodim	Fruit culture	0.240	1 / -	0	< 0.001
	clethodim					<b>0.155</b>
	-sulfoxide					<b>0.680</b>
	-sulfone					<b>0.517</b>
3. Cauliflower, Broccoli, Black Salsify	clethodim	Leaf vegetables	0.240	1 / -	0.2	< 0.001
	clethodim					<u>0.058</u>
	-sulfoxide					<b>0.438</b>
	-sulfone					<b>0.395</b>
4. Liliium, Liliium, Dahlia, Zantedeschia,	clethodim	Flower bulbs	0.240	1 / -	0.1	< 0.001
	clethodim					<b>0.970</b>

Use	Substance	GeoPEARL scenario	Rate a.s. [kg/ha]	Freq./ Int. [days]	Fraction Intercepted*	PEC groundwater [µg/L]
Daffodils, Iris	-sulfone -oxazole-sulfone					<b>2.330</b> <b>0.646</b>
5. Floricultural crops	clethodim clethodim-sulfoxide -sulfone -oxazole-sulfone	Floriculture	0.240	1 / -	0	< 0.001  <b>0.334</b> <b>1.393</b> <b>0.655</b>
6. Perennials, Plant breeding crops, flower seed crops and seed production for vegetable crops, herbs, beets, pulses, oil-bearing seeds, fibre crops, green fertilizers, fodder crops, chicory (roots), wild chicory, buckwheat, common madder	clethodim clethodim-sulfoxide -sulfone -oxazole-sulfone	Grass	0.240	1 / -	0	< 0.001  <u>0.080</u> <b>0.498</b> <b>0.476</b>

\* interception values derived from Table 1.5 in Generic Guidance for Tier 1 FOCUS Ground Water Assessments. (FOCUS, 2011). For explanation of the interception values used for GeoPEARL calculations, please refer to footnote of Table M.1a

GeoPEARL calculations show that the predicted leachate concentrations for clethodim are smaller than 0.1 µg/L. Hence, the active substance meets the standards laid down in the RGB for the proposed applications.

Metabolite clethodim-sulfoxide exceeds the threshold of 0.01 µg/L for the proposed uses 1 (strawberry group), 3 (cauliflower group) and 6 (perennial group) and exceed the threshold of 0.1 µg/L for the proposed uses 2 (grape wine and table), 4 (lilium group) and 5 (floricultural crops). Furthermore metabolites clethodim-sulfone and clethodim-oxazole-sulfone exceed the threshold of 0.1 µg/L for all proposed uses. However, metabolites clethodim-sulfoxide, clethodim-sulfone and clethodim-oxazole sulfone were subjected to a non-relevance assessment according to the Guidance Document<sup>1</sup> on the assessment of the relevance of metabolites in groundwater.

Based on this assessment metabolites clethodim-sulfoxide, clethodim-sulfone and clethodim-oxazole-sulfone are considered non-relevant with regard to groundwater for the proposed uses (with the exception of the intended uses 4 and 5) and therefore do not need to comply with the standards for leaching as laid down in the RGB. For the intended uses 4 (lilium group) the predicted leachate concentration for metabolites clethodim-sulfoxide, clethodim-sulfone exceed the trigger of 0.75 µg/L and for the intended uses in 5 (floricultural crops) metabolite clethodim-sulfone exceeds the trigger of of 0.75 µg/L and therefore a consumer exposure assessment according to the Guidance Document<sup>1</sup> is applicable (see below).

### Consumer risk exposure assessment

#### Clethodim-sulfoxide:

Following the SANCO guidance document, a refined risk assessment considering all the contributions to the diet has been performed since clethodim-sulfoxide concentrations in groundwater were predicted to be higher than the threshold of concern of 0.75 µg/L.

As clethodim is extensively metabolized in animals into clethodim sulfoxide, it is concluded that the ADI of the parent can be safely used for clethodim-sulfoxide.

The highest groundwater concentration of clethodim-sulfoxide given by the model was 0.970 µg/L. Since the ADI of the parent is used the concentration equivalent to the parent should be used. The molecular weight of clethodim is 359.92 and the MW of clethodim sulfoxide is 375.92.  $(0.970 \text{ µg/L} / 375.92) * 359.92 = 0.929 \text{ µg/L}$

**Table 1c: Assessment of clethodim-sulfoxide contribution to the diet via drinking water**

	Weight (kg)	Water Consumption (L/day)	Uptake (µg/ kg bw/day)	% of ADI (ADI = 160 µg/kg bw/day)
Adult	65.8	2	0.028	0.018%
Children	18.4	1	0.050	0.031%
Infants	10.2	0.75	0.068	0.043%

The contribution of clethodim-sulfoxide through the diet has been compared with the ADI of the parent compound clethodim. The ADI given in the List of Endpoints for clethodim is 0.16 mg/kg bw/day.

As shown in Table 1c, it is evident that the highest estimated exposure via the drinking water is 0.043 % of the ADI, which is below the allocation factor of 20% set in the WHO Guidance for drinking-water quality by and is therefore considered acceptable. With respect to combination toxicology, this is also applicable to the sum of highest estimated exposure values, i.e. the added percentages of the ADI of clethodim-sulfoxide and clethodim-sulfone:  $0.043\% + 0.098\% = 0.141\%$ .

#### Clethodim-sulfone:

Following the SANCO guidance document, a refined risk assessment considering all the contributions to the diet has been performed since clethodim-sulfone concentrations in groundwater were predicted to be higher than the threshold of concern of 0.75 µg/L.

As clethodim is extensively metabolized in animals into clethodim-sulfoxide and further oxidized into clethodim-sulfone, it is concluded that the ADI of the parent can be used for clethodim-sulfone as well.

The highest groundwater concentration of clethodim-sulfone given by the model was 2.330 µg/L. Since the ADI of the parent is used the concentration equivalent to the parent should be used. The molecular weight of clethodim is 359.92 and the MW of clethodim-sulfone is 391.92.  $(2.330 \text{ µg/L} / 391.92) * 359.92 = 2.140 \text{ µg/L}$

**Table 1d: Assessment of clethodim sulfone contribution to the diet via drinking water**

	Weight (kg)	Water Consumption (L/day)	Uptake ( $\mu\text{g}/\text{kg bw}/\text{day}$ )	% of ADI (ADI = 160 $\mu\text{g}/\text{kg bw}/\text{day}$ )
Adult	65.8	2	0.065	0.041%
Children	18.4	1	0.116	0.073%
Infants	10.2	0.75	0.157	0.098%

The contribution of clethodim-sulfone through the diet has been compared with the ADI of the parent compound clethodim. The ADI given in the List of Endpoints for clethodim is 0.16 mg/kg bw/day.

As shown in Table 1d, it is evident that the highest estimated exposure via the drinking water is 0.098 % of the ADI, which is below the allocation factor of 20% set in the WHO Guidance for drinking-water quality by and is therefore considered acceptable. With respect to combination toxicology, this is also applicable to the sum of highest estimated exposure values, i.e. the added percentages of the ADI of clethodim-sulfoxide and clethodim-sulfone: 0.043% + 0.098% = 0.141%.

## Conclusions

The proposed applications of the product Centurion Plus comply with the requirements laid down in the RGB concerning leaching to shallow groundwater.

Metabolites clethodim-sulfoxide, clethodim-sulfone and clethodim-oxazole sulfone have been declared non-relevant with regard to groundwater for the proposed uses according to the Guidance Document on the assessment of the relevance of metabolites in groundwater.

## 6.2 Fate and behaviour in water

### 6.2.1 Rate and route of degradation in surface water

#### *Drinking water criterion*

Article 2.10b of the *Plant Protection Products and Biocides Regulations* (RGB) describes the use of the 90<sup>th</sup> percentile.

It follows from the decision of the Court of Appeal on Trade and Industry of 19 August 2005 (Awb 04/37 (General Administrative Law Act)) that when considering an application, the Ctgb should, on the basis of the scientific and technical knowledge and taking into account the data submitted with the application, also judge the application according to the drinking water criterion 'surface water intended for drinking water production'.

The assessment methodology followed is developed by the WG implementation drinking water criterion and outlined in Alterra report 1635<sup>1</sup>.

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

- For new substances, a preregistration calculation is performed.
- For existing substances, the assessment is based on monitoring data of VEWIN (drinking water board).
  - o If for an existing substance based on monitoring data no problems are expected by VEWIN, Ctgb follows this VEWIN assessment.

<sup>1</sup> Adriaanse et al. (2008). Development of an assessment methodology to evaluate agricultural use of plant protection products for drinking water production from surface waters - A proposal for the registration procedure in the Netherlands. Alterra-Report 1635

- If for an existing substance based on monitoring data a potential problem is identified by VEWIN, Ctgb assesses whether the 90<sup>th</sup> percentile of the monitoring data meet the drinking water criterion at each individual drinking water abstraction point.

As clethodim is a new active substance, there are no data available regarding its presence in surface water at drinking water abstraction points.

The decision tree as outlined in Alterra report 1635 (2010) should be followed. The tool DROPLET (described in Alterra report 2020, 2010) to calculate concentrations on drinking water abstraction points is available at Ctgb and is used since it represents the current scientific insight.

The following data are used for the assessment:

#### **Input in SWASH:**

##### **Substance input parameters:**

Molecular mass:	359.9 g/mol
Saturated vapour pressure:	$2.08 \times 10^{-6}$ Pa (20 °C)
Solubility in water:	5450 mg/L (20 °C)
Arithmetic mean Kom:	2.32 L/kg
Arithmetic mean 1/n:	0.975
Factor plant uptake:	0.5
Geometric mean DT50 Water (DT50 system):	11.34 d
Geometric mean lab DT50 Soil:	0.66 d
DT50 Sediment:	1000 d (default)
DT50 Crop (default 10 d)	

##### **Scenario (Focus wizard):**

Selected crop: Vegetables, bulb; Pome/stone fruit, early application; Vegetables, leafy  
 Selected scenario: D3  
 Input in FOCUS-TOXSWA: NL Drift value 1%

##### **Input in DROPLET:**

Selected crop: strawberries, cabbage, vegetables leafy, floriculture, root vegetable, leafy beans, field beans

$f_{\text{market}}$ : 0.4

$f_{\text{additional dilution}}$ : 1 for all abstraction points, except for Andijk: 0.17

Other parameters: standard settings SWASH 2.1 and DROPLET 1.0

See Table M.2 for results for each drinking water abstraction point.

**Table M.2 Predicted concentrations of active substance clethodim at drinking water abstraction points in The Netherlands as calculated by DROPLET 1.0**

Drinking water abstraction point	FOCUS D3 crop	$f_{\text{useintensity}}$ (-)	Relative Cropped Area (-)	PEC <sub>drinking water abstraction point</sub> ( $\mu\text{g/L}$ ) *
De Punt	Pome/Stone Fruit, early appl	0.000014	0.000071	0.010
	Vegetables, leafy	0.000142	0.000710	
	Cabbage	0.000004	0.000018	
	Floriculture	0.000082	0.000409	
Andijk	Vegetables, bulb	0.000078	0.003899	0.001
	Pome/Stone Fruit, early appl	0.000013	0.000064	
	Vegetables, leafy	0.000074	0.000370	
	Strawberries	0.000018	0.000089	
	Cabbage	0.000096	0.000478	
	Floriculture	0.000104	0.000519	
Nieuwegein	Pome/Stone Fruit, early appl	0.000180	0.000899	0.002
	Vegetables, leafy	0.000042	0.000211	
	Strawberries	0.000099	0.000493	
	Cabbage	0.000088	0.000438	
	Floriculture	0.000239	0.001196	
Heel	Vegetables, bulb	0.000147	0.000735	0.010
	Pome/Stone Fruit, early appl	0.000326	0.001628	
	Vegetables, leafy	0.000725	0.003624	
	Strawberries	0.000082	0.000410	
	Cabbage.	0.000279	0.001397	
	Floriculture	0.000055	0.000273	
A'dam Rijnkanaal	Pome/Stone Fruit, early appl	0.000134	0.000668	0.002
	Vegetables, leafy	0.000085	0.000424	
	Strawberries	0.000073	0.000366	
	Cabbage	0.000066	0.000331	
	Floriculture	0.000201	0.001005	
Brakel	Vegetables, bulb	0.000485	0.002424	0.007
	Pome/Stone Fruit, early appl	0.000175	0.000874	
	Vegetables,	0.000427	0.002136	



Drinking water abstraction point	FOCUS D3 crop	$f_{\text{useintensity}}$ (-)	Relative Cropped Area (-)	PEC <sub>drinking water abstraction point</sub> ( $\mu\text{g/L}$ ) *
	leafy Strawberries Cabbage Floriculture	0.000377 0.000226 0.000470	0.001884 0.001129 0.002350	
Petrusplaat	Vegetables, bulb Pome/Stone Fruit, early appl Vegetables, leafy Strawberries Cabbage Floriculture	0.000446 0.000164 0.000461 0.000389 0.000256 0.000459	0.002229 0.000822 0.002304 0.001946 0.001279 0.002294	0.005
Twentekanaal	Strawberries Cabbage Floriculture	0.000010 0.000010 0.000149	0.000050 0.000050 0.000746	< 0.001
Scheelhoek	Vegetables, bulb Pome/Stone Fruit, early appl Vegetables, leafy Strawberries Cabbage Floriculture	0.000329 0.000153 0.000473 0.000298 0.000473 0.000389	0.001643 0.000763 0.002367 0.001490 0.002365 0.001943	0.006
Bommelerwaard (subarea of Brakel)	Vegetables, bulb Pome/Stone Fruit, early appl Vegetables, leafy Strawberries Cabbage Floriculture	0.000012 0.000074 0.000062 0.000420 0.000272 0.001136	0.000062 0.000370 0.000309 0.002099 0.001358 0.005679	0.001

\* Cumulative PEC<sub>drinking water abstraction point</sub> for all crops, including the crops assessed at the original risk assessment of Centurion Plus (14300 N).

Results show that for all drinking water abstraction points the predicted concentrations are below 0.1  $\mu\text{g/L}$ .

Therefore, the application of Centurion Plus is not expected to exceed the drinking water criterion. The standards for surface water destined for the production of drinking water as laid down in the RGB are met.

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

See List of Endpoints.

#### **6.5 Data requirements**

-

The following restriction sentences were proposed by the applicant:

-

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

-

#### **6.6 Overall conclusions fate and behaviour**

It can be concluded that:

***Conclusion for environmental aspects persistence in soil and leaching to groundwater, emission to surface water and sediment, drinking water criterion and monitoring data***

*The new uses of Centurion Plus applied for have an equal or lower risk for persistence in soil and emission to surface water and sediment as the already authorised uses.*

1. all proposed applications of the active substance clethodim meet the standards for leaching to the shallow groundwater as laid down in the RGB.
2. Metabolites clethodim-sulfoxide, clethodim-sulfone and clethodim-oxazole sulfone can be considered non-relevant with regard to groundwater for the proposed uses according to the Guidance Document on the assessment of the relevance of metabolites in groundwater and need not comply with the standards for leaching to shallow groundwater..
3. all proposed applications of the active substance clethodim meet the standards for surface water destined for the production of drinking water as laid down in the RGB

## **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 January 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 October 2011.

The final list of endpoints from the EFSA conclusion (November 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

### Ecotoxicology

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

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

SFO 1<sup>st</sup> order DT<sub>50</sub> for residue decline of clethodim on treated crops

(summarized 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				
<i>Salmo gairdneri</i>	clethodim	96 h	Mortality, EC <sub>50</sub>	25 <sup>(A)</sup>
<i>Oncorhynchus mykiss</i>		21 d	NOEC	3.9 <sup>(A)</sup>
<i>Daphnia magna</i>		48 h	Immobility, EC <sub>50</sub>	>100 <sup>(B)</sup>
<i>Daphnia magna</i>		21 d	Reproduction, NOEC	49 <sup>(B)</sup>
<i>Selenastrum capricornutum</i>		72 h	Biomass, growth rate, EC <sub>50</sub>	>12 <sup>(A)</sup>
<i>Lemna gibba</i>		14 d	Fronds, EC <sub>50</sub>	1.9 <sup>(C)</sup>
<i>Oncorhynchus mykiss</i>	Select 240 EC	96 h	Mortality, EC <sub>50</sub>	3.4 <sup>(B)</sup>
<i>Oncorhynchus mykiss</i>	Select + oily adjuvant	21 d	NOEC	0.29 <sup>(A)</sup>
<i>Oncorhynchus mykiss</i>	TM-20016	21 d	NOEC	1.1 <sup>(B)</sup>
<i>Daphnia magna</i>	Select 2 EC	48 h	Immobility, EC <sub>50</sub>	5.1 <sup>(A)</sup>
<i>Daphnia magna</i>	Select + oily adjuvant	21 d	Reproduction, NOEC	0.00084 <sup>(B)</sup>
<i>Daphnia magna</i>	TM-20016	21 d	Reproduction, NOEC	0.51 <sup>(B)</sup>
<i>Scenedesmus subspicatus</i>	Select + oily adjuvant	72 h	Biomass, growth rate, EC <sub>50</sub>	1.5 <sup>(A)</sup>
<i>Scenedesmus subspicatus</i>	Select 2 EC	72 h	growth rate, EC <sub>50</sub>	3.2 <sup>(A)</sup>
<i>Lemna gibba</i>	Select 240 EC + oily adjuvant	14 d	Fronds, EC <sub>50</sub>	4.52 <sup>(B)</sup>
<i>Lemna gibba</i>	Select 2 EC	14 d	Fronds, EC <sub>50</sub>	69 <sup>(A)</sup>
<i>Desmodesmus subspicatus</i>	clethodim sulfoxide	72 h	Biomass, EC <sub>50</sub>	>100 <sup>(B)</sup>
<i>Lemna gibba</i>	clethodim sulfoxide	7 d	Biomass, EC <sub>50</sub>	88 <sup>(B)</sup>
<i>Oncorhynchus mykiss</i>	clethodim sulfoxide	96 h	Mortality, EC <sub>50</sub>	> 100 <sup>(B)</sup>
<i>Chironomus riparius</i>	clethodim imine	28 d	Emergence, NOEC	10 <sup>(D)</sup>
Microcosm or mesocosm tests				

Not available
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\* 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)

Annex VI Trigger for the bioconcentration factor

Clearance time (CT<sub>50</sub>)

(CT<sub>90</sub>)

Level of residues (%) in organisms after the 14 day depuration phase

Clethodim: 2.1
1000 for readily biodegradable compounds
4.9 d (allyl-label) and 0.23 d (ring-label)
16 d (allyl-ring) and 0.76 d (ring-label)
≤ 30% after 14 d depuration

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

Acute oral toxicity

LD<sub>50</sub> >43 µg a.s./bee (Select 240 EC)

LD<sub>50</sub> 55 µg a.s./bee (Select + adjuvant)

Acute contact toxicity

LD<sub>50</sub> >51 µg a.s./bee (Select 240 EC)

LD<sub>50</sub> 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 <sub>50</sub> (g a.s./ha)	Annex VI /Escort II Trigger
<b>Laboratory tests</b>						
<i>Aphidius rhopalosiphi</i>	Laboratory, sprayed plants	Select + Adjuvant	9.6 240	mortality/reproduction	0 / 5 0 / 5	50%
<i>Typhlodromus pyri</i>	Extended laboratory <sup>(A)</sup>	Select + Adjuvant	9.6	mortality/reproduction	>240 g a.s./ha	50%
				LR <sub>50</sub> , ER <sub>50</sub>	82 / 51	
<i>Typhlodromus pyri</i>	Extended laboratory <sup>(A)</sup>	Select + Adjuvant	0.6 1.2 2.4 4.8 9.6	mortality/reproduction	<9.6 g a.s./ha	50%
				LR <sub>50</sub> , ER <sub>50</sub>	1 / 10 4 / 0.2 16 / 14 73 / 33 100 / n.a. <sup>(B)</sup>	
				LR <sub>50</sub>	3.6 g a.s./ha	
				ER <sub>50</sub>	>4.8 g a.s./ha	
<i>Typhlodromus pyri</i>	Extended laboratory	Select 240 EC	0, 11 and 384	Fresh residues:	LR <sub>50</sub> <384 ER <sub>50</sub> >11	50%
				4, 7 & 14 d aged:	LR <sub>50</sub> >384 ER <sub>50</sub> >384	

<i>Poecilus cupreus</i>	Laboratory, sand	Select + Adjuvant	256	mortality /food consumption LR <sub>50</sub>	3.3 / +3.1 >256 g a.s./ha	50%
<i>Poecilus cupreus</i>	Laboratory, sand	Select 240 EC	221	mortality /food consumption LR <sub>50</sub>	3.4 / 10 >221 g a.s./ha	50%
<i>Aleochara bilineata</i>	Laboratory, sand	Select 240 EC	259	parasitic capacity ER <sub>50</sub>	2.6 >259 g a.s./ha	50%
<i>Aleochara bilineata</i>	Laboratory, natural soil	Select 240 EC + Adjuvant	386	parasitic capacity ER <sub>50</sub>	1.9 >386 g a.s./ha	50%
<i>Chrysoperla carnea</i>	Extended laboratory <sup>(C)</sup>	Select 240 + Adjuvant	384	mortality/repr odution LR <sub>50</sub> , ER <sub>50</sub>	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

<b>clethodim sulfoxide</b> LC <sub>50</sub> >1000 mg/kg (500 mg a.s./kg <sup>(A)</sup> ) <b>Select 240 EC</b> LC <sub>50</sub> 129 mg a.s./kg (65 mg a.s./kg <sup>(A)</sup> )
--

Reproductive toxicity

<b>clethodim oxazole sulfone</b> NOEC 10 mg/kg (5 mg a.s./kg <sup>(A)</sup> )
--

(A) corrected for organic content of OECD 207 substrate

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

Acute toxicity

<b>TM-5403 (120 g a.s./L EC formulation):</b> LC <sub>50</sub> 27.3 mg a.s./kg (13.7 mg a.s./kg <sup>(A)</sup> )
---

(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

<b>Clethodim</b> Up to 2.741 mg a.s./kg: effects <25% <b>Select EC 240</b> 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) (2 <sup>nd</sup> soil) <b>Select + Para Sommer</b> (= oily adjuvant) Up to 1.7 mg a.s./kg: effects <25% (2 soils) <sup>(A)</sup> . <b>Clethodim oxazole sulfone</b> Up to 0.10 mg a.s./kg: effects <25%
--

Carbon mineralization

<b>Clethodim</b>
------------------

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)

<b>Collembola</b>					
Clethodim oxazole sulfoxide: NOEC 100 mg a.s./kg soil ( <i>F. candida</i> ) (NOEC 50 mg a.s./kg soil corrected for organic content of OECD 207 substrate)					
<b>Non-target terrestrial plants</b>					
<u>Screening data with Select 2 EC-H and Para Sommer</u>					
Species	treatment	survival (kg a.s./ha)		biomass production (kg a.s./ha)	
		NOEC	ER <sub>50</sub>	NOEC	ER <sub>50</sub>
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

	<b>Rate response for seedling emergence</b>	<b>Rate response for vegetative vigour (plant dry weight)</b>
	<b>EC<sub>50</sub> (g a.s./ha)</b>	<b>EC<sub>50</sub> (g a.s./ha)</b>
Ryegrass ( <i>L. perenne</i> )		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 ( <i>E. crus-galli</i> )		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 ( <i>Glycine max</i> )	Select: > 0.28 kg a.s./ha (all species)	Select: > 0.28 kg a.s./ha (all species)
Lettuce ( <i>Lactuca sativa</i> )		
Carrot ( <i>Daucus carota</i> )		
Tomato ( <i>Lycopersicon esculentum</i> )		
Cucumber ( <i>Cucumis sativus</i> )		
Cabbage ( <i>Brassica oleracea</i> )		
Oat ( <i>Avena sativa</i> )	Select: 54 g a.s./ha	Select: 20 g a.s./ha
Perennial ryegrass ( <i>Lolium perenne</i> )	Select: 67 g a.s./ha	Select: 6.7 g a.s./ha
Corn ( <i>Zea mays</i> )	Select: 25 g a.s./ha	Select: 13 g a.s./ha
Onion ( <i>Allium cepa</i> )	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

<b>clethodim</b> EC <sub>50</sub> > 95 mg/L <b>Select H EC24</b> EC <sub>50</sub> 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
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**Studies submitted with present application for Centurion Plus (20110591 TG) (report 120801 by EPP Consultancy):**

**Toxicity data for aquatic species**

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

(A) Based on analytically confirmed nominal concentrations.

**Effects on bees**

Acute oral toxicity

LD <sub>50</sub> >14 µg a.s./bee (Select 120)
---

Acute contact toxicity

LD <sub>50</sub> >14 µg a.s./bee (Select 120)
---

**Effects on other arthropod species**

Species	Test type and exposure scenario	Test Substance	Dose (g a.s./ha)	Endpoint	L(E)R <sub>50</sub> (g a.s./ha)	Annex VI /Escort II Trigger
<b>Laboratory tests</b>						
<i>Aphidius rhopalosiphi</i>	Extended laboratory (barley seedlings)	Select 120 <sup>(A)</sup>	0.033 - 325.5 g a.s./ha	mortality/reproduction	LR <sub>50</sub> , ER <sub>50</sub> : >330 g a.s./ha	50%
<i>Typhlodromus pyri</i>	Extended laboratory (leaf discs)	Select 120 <sup>(A)</sup>	1.96 - 35 g a.s./ha	mortality/reproduction	LR <sub>50</sub> : 3.7 g a.s./ha ER <sub>50</sub> : >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**

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

**Additional studies on bioaccumulation in earthworms (summarised and evaluated by Ctgb (11/2013))****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<sup>2</sup> at 1DAA. The mean abundance, calculated from samplings at 1DAA and 14DAA, was 80 earthworms/m<sup>2</sup>. 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<sup>2</sup> before application, and 50.9, 76.7, 28.0, 35.8, 38.2 and 23.7 g/m<sup>2</sup> 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		0.313		0.011	
	Tb	0.045	0.072	0.226	0.325	0.016	0.016
	Tc	0.103		0.272		0.017	
	Td	0.100		0.489		0.020	
28/04/2012 2DAA	Ta	0.006 <sup>a)</sup>		0.207		0.020	
Tb	0.012	0.018	0.329	0.297	0.025	0.027	
Tc	0.021		0.280		0.024		
Td	0.032		0.372		0.039		
30/04/2012 4DAA	Ta		n.d.		0.102		0.027
Tb	n.d.	n.d.	0.085	0.125	0.017	0.027	
Tc	n.d.		0.171		0.029		
Td	n.d.		0.141		0.033		
03/05/2012 7DAA	Ta		n.d.		0.042		0.011
Tb	n.d.	n.d.	0.047	0.048	0.016	0.016	
Tc	n.d.		0.056		0.017		
Td	n.d.		0.048		0.020		
10/05/2012 14DAA	Ta		n.d.		0.011		0.004 <sup>a)</sup>
Tb	n.d.	n.d.	0.010	0.012	0.004 <sup>a)</sup>	0.005 <sup>a)</sup>	
Tc	n.d.		0.012		0.005 <sup>a)</sup>		
Td	n.d.		0.014		0.006 <sup>a)</sup>		
24/05/2012 28DAA	Ta		n.d.		n.d.		n.d.
Tb	n.d.	n.d.	n.d.	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)

<sup>a)</sup> < LOQ (0.01 mg/kg)

DT<sub>50</sub> and DT<sub>90</sub> 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<sup>2</sup> 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<sub>50</sub>, DT<sub>90</sub>, Chi<sup>2</sup>, and estimated M(0) for elimination of clethodim, clethodim sulfoxide and clethodim sulfone in earthworms**

Calculated for residues for	Kinetic model	DT <sub>50</sub> (days)	DT <sub>90</sub> (days)	Chi <sup>2</sup> 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:  $\leq 10\%$  mortality (no mortality in the control and 0.625% mortality in the treatment) and  $\leq 20\%$  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  $\text{Chi}^2$  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  $1.0438 \text{ day}^{-1}$  (standard deviation 0.25, p-value  $<0.001$ ).

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

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  $1.0438 \text{ day}^{-1}$ , 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  $0.9943 \text{ day}^{-1}$  (optimization error 0.287) and the elimination rate constant ( $k_e$ ) was  $2.4223 \text{ day}^{-1}$  (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.

### Risk assessment

The risk of the applied use in (blue) poppy seed, caraway, linseed, sunflower, fiber crops, lupin, chicory roots, strawberry propagation, waiting bed, strawberry production, cauliflower, broccoli, black salsify, silverskin and picklers, Lovage root, Angelica, Burnet Saxifrage root, Hamburg root parsley, liliium, dahlia, zantedeschia, daffodils, iris, hyacinth, floricultural crops, perennials, plant breeding crops, flower seed crops and seed production for vegetable crops, herbs, beets, pulses, oil-bearing seeds, fibre crops, green fertilisers, fodder crops, chicory (roots), wild chicory, buckwheat, common madder is equal to or lower than the risk of the authorised uses with regard to the environment for all ecotoxicological aspects.

For grape the following was concluded:

<b>Environmental aspect</b>	<b>Point of interest</b>	<b>Equal or lower risk</b>	<b>Argumentation</b>
Aquatic organisms		Y	See conclusion emission to surface water and sediment and STP
remarks			
Birds and mammals	Dose rate	Y	Equal/lower
	Frequency	Y	Equal
	Interval	Y	Equal
	Time of application (interception and season)	Y	Equal / different
	Focal species and RUD (PD, PT, DT50)	N	The grape wine and table grapes fall under the category "orchard/vines/hops". The birds 'indicator species are similar as for the "leafy crops". The mammals indicator species, however, are different. The indicator species for leafy crops is medium herbivorous mammal while the one for vines is the small herbivorous mammal. The RUDs and FIR/bw of the later are higher than for medium herbivorous mammal. No acute risk to small mammals is expected. A long-term dietary risk, however it is expected for small herbivorous mammal.
	Bioaccumulation : PEC soil and PEC water (see fate)	Y	Equal

	Remarks	The previous applications in leafy crops were intended from BBCH 12-45. For many of the current crops the applications are from BBCH 00, which means applications on bare soil. The active substance is systemic and therefore the risk to herbivorous B&Ms must be addressed. As said above, the crop category is "leafy crops" and the herbivorous B&Ms included are "medium herbivorous" birds and mammal. Thus the risk from application on bare soil is covered by the current indicator species. For the small herbivorous mammal, however, the risk is not covered.	
Bees and bumblebees	Dose rate	Y	Equal
	Exposure route (e.g. spray drift, dust drift)	Y	Equal
	Other relevant species (e.g. bumblebees?)	Y	Equal
remarks			
Non-target-arthropods	Dose rate	Y	Equal
	Frequency	Y	Equal
	Interval	Y	Equal
	Drift rate	Y	Lower
	Exposure route (e.g. spray, seed treatment)	Y	Equal
remarks		The current application is as herbicide spraying under the vines. For this situation the drift is 2.2%. In the risk assessment of the original application the off-field risk to NTAs was considered acceptable if the drift is maximum 2.5%. This was achieved with the additional drift reducing nozzles. Therefore the restriction sentence placed on the label of the authorized uses is valid here as well.	
Earthworms		Y	See conclusion persistence and emission to soil
remarks			
Soil micro-organisms		Y	See conclusion persistence and emission to soil
remarks			
Activated sludge		Y	See conclusion emission to surface water and sediment and STP
remarks			
Non-target plants	Dose rate	Y	Equal
	Frequency	Y	Equal
	Interval	Y	Equal
	Drift rate	Y	Lower

remarks	The current application is as herbicide spraying under the vines. For this situation the drift is 2.2%. In the risk assessment of the original application the off-field risk to NTPs was considered acceptable if the drift is maximum 0.38%. This was achieved with the additional drift reducing nozzles. Therefore the restriction sentence placed on the label of the authorized uses is valid here as well.
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Thus a risk assessment for mammals is provided below.

### 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  $\geq 10$  and TER for chronic exposure should be  $\geq 5$ . 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 <sub>50</sub>	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). Orchard/vine/hops. 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
Grape	Orchard/vine/hops	small herbivorous 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.1a Acute risk for mammals**

Substance	FIR / bw	RUD	Applica- tion rate  (kg a.s./ha)	MAF	Acute ETE  (mg/kg bw/d)	LD50 (mg/kg bw/d)	TER  (trigger 10)
<b>small herbivorous mammal</b>							
clethodim	1.39	142	0.240	-	47.4	1133	24

**Table E.1b Long-term risk for mammals**

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)
<b>Small herbivorous mammal</b>								
clethodim	1.39	76	0.240	-	0.53	13.4	16	<b>1.2</b>

Taking the results in Table E.1a-b. into account, it appears that a long-term risk cannot be excluded. In the DAR a refinement for DT50 is available. However this DT50 value was determined on carrot and sugar beets and this cannot be extrapolated to grasses. Thus no refinement is available.

The table above shows that the Sanco GD indicates a risk. Ctgb has decided to perform a first tier risk assessment based on the new GD (EFSA Journal 2009; 7(12):1483) which is the state of the art in the risk assessment guidance. Considering that the product is a herbicide, only the EFSA Tier 1 scenarios "application ground directed" will be presented. The results are presented in the table below:

**Table E.2 Reproductive risk for mammals – Tier 1 assessment**

Scenario	Generic focal species	Applica- tion rate [kg a.s./ha]	SV <sub>mean</sub>	MAF <sub>m</sub> * ftwa	DDD [mg a.s./kg bw/d]	NOEL [mg a.s./kg bw/d]	TER	trigger
<b>Crop (grape 1 x0.24 kg/ha)</b>								
Vineyard, application ground directed	Large herbivorous mammal "lagomorph"	0.24	11.1	0.53	1.41	16	11.3	5
Vineyard, application ground directed	Small herbivorous mammal "vole"	0.24	72.3	0.53	9.2	16	<b>1.7</b>	5
Vineyard, application ground directed	Small omnivorous mammal "mouse"	0.24	7.8	0.53	0.99	16	16	5

Table E.2 shows that also according to a more up-to-date guidance, the TER is still below the trigger of 5 for the small herbivorous mammal. No refinements are available. For the other focal species, the long-term risk is acceptable. A further refined risk assessment is required for the chronic risk to small herbivorous mammals in grape.

The application for the use of Centurion Plus in grapes is withdrawn by the applicant.

#### ***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 (0.240 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 covered by the risk assessment for the parent.

#### **7.7 Data requirements**

None

#### **7.8 Restriction sentences**

##### **Based on the current assessment, the following has to be stated in the GAP/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% driftreducerende 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 perceelgrens); 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

Note: these restrictions are already included on the label and are also relevant for the new extensions.

#### **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**

The uses applied for are minor uses. According article 51 of Regulation no.1107/2009 no efficacy data is needed.

## **9. Conclusion**

The product complies with the Uniform Principles.

## **10. Classification and labelling**

Classification and labelling of the formulation does not change.

## Appendix 1 Table of authorised extensions

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation	F G or I	Pests or Group of pests controlled	Application			Application rate per treatment			PHI (days)	Remarks: a) max. no. of applications per crop and season b) Maximum product rate per season c) additional remarks
					Method / Kind	Timing / Growth stage of crop & season	Number / (min. Interval between applications)	L product / ha	g as/ha	Water L/ha min / max		
Minor uses according to article 51												
1	NL	(Blue) poppy seed, caraway (oil-bearing seed)	F	Annual grasses	Spraying	BBCH 00-30 April-June	1 / NA	1	120	150-400	120	a) 1 application per crop. 1 crop per season b) 1 l/ha per season
2	NL	Linseed*	F	Annual grasses	Spraying	BBCH 00-30 April-June	1 / NA	1	120	150-400	-	a) 1 application per crop. 1 crop per season b) 1 l/ha per season *Not for human and/or animal consumption
3	NL	Sunflower (oil bearing seed)	F	Annual grasses	Spraying	BBCH 00-19 April-June	1 / NA	1	120	150 - 400	100	a) 1 application per crop. 1 crop per season b) 2 l/ha per season
4	NL		F	Quack grass ( <i>agropyron repens</i> )	Spraying	BBCH 00-19 April-June		2	240	150-240	100	
5	NL	Fibre crops	F	Annual grasses	Spraying	BBCH 00-41 April-June	1 / NA	1	120	150-400	-	a) 1 application per crop. 1 crop per season b) 2 l/ha per season
6	NL		F	Quack grass ( <i>Agropyron repens</i> )	Spraying	BBCH 00-41 April-June		2	240	150-400	-	
7	NL	Lupin	F	Annual grasses	Spraying	BBCH 00-41 April-June	1 / NA	1	120	150-400	-	a) 1 application per crop. 1 crop per season b) 2 l/ha per season
8	NL		F	Quack grass ( <i>Agropyron repens</i> )	Spraying	BBCH 00-41 April-June		2	240	150-400	-	

9	NL	Chicory roots	F	Annual grasses	Spraying	BBCH 12-33 May-July	1 / NA	1	120	150-400	56	a) 1 application per crop. 1 crop per season b) 2.5 l/ha per season
			F	Quack grass ( <i>Agropyron repens</i> )	Spraying	BBCH 12-33 May-July		2.5	300	150-400	56	
10	NL	Wild chicory	F	Annual grasses	Spraying	BBCH 12-33 May-July	1 / NA	1	120	150-400	56	a) 1 application per crop. 1 crop per season b) 2.5 l/ha per season
				Quack grass ( <i>Agropyron repens</i> )				2.5	300			
11	NL	Strawberry propagation, waiting bed	F	Annual grasses	Spraying	BBCH 11-97 January - october	1 / NA	1	120	150-800	-	a) 1 application per crop. 1 crop per season b) 2 l/ha per season
12	NL		F	Quack grass ( <i>Agropyron repens</i> )	Spraying	BBCH 11-97 January - october		2	240	150-800	-	
13	NL	Strawberry production	F	Annual grasses	Spraying	BBCH 11-59 BBCH 91-93 April-September	1 / NA	1	120	150-800	30	a) 1 application per crop. 1 crop per season b) 2 l/ha per season
14	NL		F	Quack grass ( <i>Agropyron repens</i> )	Spraying	BBCH 11-59 BBCH 91-93 April-September		2	240	150-800	30	
15	NL	Cauliflower	F	Annual grasses	Spraying	BBCH 12-41 April-October	1 / NA	1	120	150-600	28	a) 1 application per crop. 1 crop per season b) 2 l/ha per season
16	NL		F	Quack grass ( <i>Agropyron repens</i> )	Spraying	BBCH 12-41 April-October		2	240	150-600	28	
17	NL	Broccoli	F	Annual grasses	Spraying	BBCH 12-41 April-October	1 / NA	1	120	150-600	28	a) 1 application per crop. 1 crop per season b) 2 l/ha per season
18	NL		F	Quack grass ( <i>Agropyron repens</i> )	Spraying	BBCH 12-41 April-October		2	240	150-600	28	
19	NL	Black salsify	F	Annual grasses	Spraying	BBCH 11-12 April-October	1 / NA	1	120	150-600	48	a) 1 application per crop, 1 crop per season b) 1 l/ha per season
20	NL	Silverskin onions and picklers	F	Annual grasses	Spraying	BBCH 12-45 March-July	1 / NA	1	120	150-600	56	a) 1 application per crop. 1 crop per season b) 1 l/ha per season

21	NL		F	Quack grass ( <i>Agropyron repens</i> )	Spraying	BBCH 12-45 March-July	1 / NA	2	240	150-600	56	a) 1 application per crop. 1 crop per season b) 2 l/ha per season	
22	NL	Aromatic root crops: Lovage root, Angelica, Burnet Saxifrage root, Hamburg root parsley	F	Annual grasses	Spraying	BBCH 12-45 April-July	1 / NA	1	120	150-600	48	a) 1 application per crop. 1 crop per season b) 2 l/ha per season	
23	NL		F	Quack grass ( <i>Agropyron repens</i> )	Spraying	BBCH 12-45 April-July		1	240	150-600	48		
24	NL	Lilium	F	Annual grasses	Spraying LDS applicatio n	BBCH 11-99 April-September	4 / (7d)	0.5	60	150-500	-	a) a) Up to maximal 4 applications per crop b) b) Maximum application rate per season 2.0 L/ha c) row 24: LDS application in combination with other authorised products.	
25	NL		F	Annual grasses	Spraying	BBCH 11-99 April-September		1 / NA	1	120	150-500		-
26	NL		F	Quack grass ( <i>Agropyron repens</i> )	Spraying	BBCH 11-99 April-September		2	240	150-500	-		
27	NL	Lilium, Dahlia, Zantedeschia, Daffodils	F	Annual grasses	Spraying	BBCH 11-99 April-September	1 / NA	1	120	150-500	-	a) 1 application per crop. 1 crop per season b) 2 l/ha per season	
28	NL		F	Quack grass ( <i>Agropyron repens</i> )	Spraying	BBCH 11-99 April-September		2	240	150-500	-		
29	NL	Iris	F	Annual grasses	Spraying	BBCH 71-99 April-September	1 / NA	1	120	150-500	-	a) 1 application per crop. 1 crop per season b) 2 l/ha per season	
30	NL		F	Quack grass ( <i>Agropyron repens</i> )	Spraying	BBCH 71-99 April-September		2	240	150-500	-		
31	NL	Hyacinth	F	Annual grasses	Spraying	BBCH 71-99 April-July	1 / NA	1	120	150-500	-	a) 1 application per crop. 1 crop per season b) 2 l/ha per season	
32	NL		F	Quack grass ( <i>Agropyron repens</i> )	Spraying	BBCH 71-99 April-July		2	240	150-500	-		
33	NL	Floricultural crops	F	Annual grasses	Spraying	BBCH 00-99 April-September	1 / NA	1	120	150-800	-	a) 1 application per crop. 1 crop per season b) 2 l/ha per season	
34	NL		F	Quack grass ( <i>Agropyron repens</i> )	Spraying	BBCH 00-99 April-September		2	240	150-800	-		
35	NL	Perennials	F	Annual grasses	Spraying	BBCH 11-99 April-September	1 / NA	1	120	300-800	-	a) 1 application per crop. 1 crop per season	

36	NL		F	Quack grass ( <i>Agropyron repens</i> )	Spraying	BBCH 11-99 April-September		2	240	300-800	-	b) 2 l/ha per season
37	NL	Plant breeding crops, flower seed crops and seed production for vegetable crops, herbs, beets, pulses, oil-bearing seeds, fibre crops, green fertilisers, fodder crops, chicory (roots), wild chicory, buckwheat, common madder	F	Annual grasses	Spraying	BBCH 00-99 May - September	1 / NA	1	120	200-400	-	a) 1 application per crop. 1 crop per season b) 2 l/ha per season
38	NL		F	Quack grass ( <i>Agropyron repens</i> )	Spraying	BBCH 00-99 May - September		2	240	200-400	-	

**Appendix 2 Reference list**

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner
IIIA 7.6.1/01	2013	<i>In vitro</i> human skin penetration of <sup>14</sup> C-clethodim Eurofins Agrosience Services Chem SAS, Vergéze, France Study No. S13-02302 Arysta LifeScience S.A.S GLP, Unpublished	Y	ALS

This appendix serves only to give an indication of which data have been used for decision making for the first time; as a result of concurring applications for authorisations, the data mentioned here may have been used for an earlier decisions as well. Therefore, no rights can be derived from this overview.

Deze appendix geeft een indicatief overzicht van de gegevens die voor het eerst gebruikt zijn ten behoeve van een besluit; het kan echter voorkomen dat (onder andere) door een samenloop van aanvragen, de hier opgenomen gegevens al eens eerder gebruikt zijn. Aan dit overzicht kunnen dan ook geen rechten ontleend worden.