



## HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

### BESLUIT

Op 8 juni 2016 is van

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

een aanvraag tot uitbreiding met kleine toepassing van een gewasbeschermingsmiddeltoelating ontvangen voor het middel

#### **Centurion Plus**

op basis van de werkzame stof clethodim.

**HET COLLEGE BESLUIT** tot toelating van de aanvraag tot uitbreiding 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. Samenstelling, vorm en verpakking**

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

##### **1.1. Gebruik**

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

#### **Classificatie en etikettering**

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

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

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- 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.

#### Aflever- en opgebruiktermijn (respijtperiode)

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	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 fytotoxiciteit).

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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, 3 maart 2017

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:	20160906 NLKUG
Type aanvraag:	aanvraag tot uitbreiding met kleine toepassing van een gewasbeschermingsmiddeltoelating
Middelnaam:	Centurion Plus
Formele registratiedatum: *	11 augustus 2016
Datum in behandeling name:	
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 (2011/21/EU, d.d.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:	3

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

Vorige W-codering professioneel gebruik:	2
Aflevertermijn professioneel gebruik:	nvt
Opgebruiktermijn professioneel gebruik:	nvt

**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

A.  
WETTELIJK GEBRUIKSVOORSCHRIFT

WG-format 2.0 WG professioneel gebruik

**Wettelijk Gebruiksvoorschrift**

Het middel is uitsluitend toegelaten als onkruidbestrijdingsmiddel voor het professionele gebruik door middel van een na opkomst behandeling of behandeling na uitplanten in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.1 Ctgb juni 2015) onder de hierna vermelde toepassingsvoorwaarden.

**Toepassingsvoorwaarden:**

Toepassings-gebied	Werkzaamheid getoetst op	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

Toepassings- gebied	Werkzaamheid getoetst op	Dosering* middel per toepassing	Maximaal aantal toepassingen per teeltcyclus	Veiligheidstermijn in dagen
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	
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	

\*Verlaging van de dosering is toegestaan, maar van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken.

Werkzaamheid is bij lagere dosering niet aangetoond.

<sup>1</sup> Kweek (*Agropyron repens*)

Het gebruik in de onbedekte teelt van blauwmaanzaad, karwij (oliehoudende zaden), zonnebloem (oliehoudende zaden), vezelgewassen, lupine (groenbemester), Afrikaantjes, witlof (pennenteelt), cichorei, aardbei (vermeerdering, wachtbed en productie), bloemkoolachtigen, schorseneer, zilverui en picklers, maggi, engelwortel, bevernelwortel, wortelpeterselie, lelie, iris, dahlia, zantedeschia, hyacint, narcis, bloemisterijgewassen, boomkwekerijgewassen, 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 fytotoxiciteitonderzoek 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.

Toepassingsgebied	Type toepassing	Werkzaamheid getoets op	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	Veiligheids termijn 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 zaden)	Voor en na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	100
		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			
Afrikaantjes (groenbemesters)	Na opkomst	Eenjarige grasachtige onkruiden	1 l/ha	1 per teeltcyclus	2 l/ha per teeltcyclus	-
		Kweek <sup>1</sup> en straatgras <sup>2</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			



Toepassings- gebied	Type toepassing	Werkzaamheid getoets op	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	Veiligheids- termijn in dagen
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

Toepassings- gebied	Type toepassing	Werkzaamheid getoets op	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	Veiligheids- termijn in dagen
		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 l/ha <sup>3</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	1 l/ha	1 per teeltcyclus	2 l/ha per	-

Toepassings- gebied	Type toepassing	Werkzaamheid getoets op	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	Veiligheids- termijn in dagen
		onkruiden			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			
Boomkwekerijgewassen (grondgebonden, onbedekte teelt)	Voor en na opkomst <sup>4</sup> , rijenbehandeling	Straatgras <sup>2</sup>	2 l/ha	1 per 12 maanden	2 l/ha per 12 maanden	-
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			

\*Verlaging van de dosering is toegestaan, maar van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken.

<sup>1</sup> Kweek (*Agropyron repens*)

<sup>2</sup> Straatgras (*Poa annua*)

<sup>3</sup> In LDS-systeem in combinatie met toegelaten middelen

<sup>4</sup> Toepassen met gebruikmaking van afschermkappen om het gewas niet te raken

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**Overige 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% 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.

Met name de gewassen mais 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.

**BIJLAGE IV**

**RISKMANAGEMENT**

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## 1 Identity of the plant protection product

### 1.1 Applicant

Arysta LifeScience S.A.S.  
Route d'Artix - BP 80  
F-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	(5RS)-2-{{(1EZ)-1-[(2E)-3-chloroallyloxyimino]propyl}-5-[(2RS)-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 clethodim

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 authorization 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**

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

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

#### **Residue analytical methods**

The proposed extension for use of Centurion Plus in tagetes and tree nursery crops does not include crops intended for human consumption and/or as food/feed for livestock. Therefore, residue analytical methods for food/feed of plant and animal origin are not required.

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

#### **Conclusion**

The proposed extension for use does not include crops intended for human consumption and/or as food/feed for livestock. Therefore, assessment of coverage of the risk envelope of the existing authorisation for the section residue analytical methods is not required.

### **4 Mammalian toxicology**

The proposed extension for use involves an application tagetes and tree nursery crops for which the risk assessment can be extrapolated from the current authorisation based on the method of application and dosage (manual and mechanical downward spray application with a maximum dosage of 2.5 kg product/ha with a minimum spray volume of 150 L/ha). Therefore, the proposed extension remains within the existing risk envelope for the section mammalian toxicology (operator and bystander).

For the worker the risk assessment can only be partly extrapolated from the current authorisation based on the dosage and duration of re-entry activities. For the current application a higher transfer coefficient (TC) of 0.5 m<sup>2</sup>/h is considered relevant for the re-entry activities in tree nursery crops compared to the TC value used for the current application (0.25 m<sup>2</sup>/h). However, considering the relatively low % AOEL of 7% obtained for the current authorisation, the lower application rate intended to be used for the current application and that Centurion Plus is a herbicide that is not sprayed directly on the crops, an undue risk is not to be expected. Therefore, a risk assessment is not considered necessary and this part of the proposed extension remains within the existing risk envelope for the section mammalian toxicology (worker).

### **5 Residues**

The proposed extension for use involves application on non-edible crops (green manure crop, specifically tagetes, and tree nursery crops). No assessment of residue data is necessary for this application. No risk for the consumer is expected.

## 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).

Clethodim is per 1 juni 2011 geplaatst op Annex I van richtlijn 91/414 (Richtlijn 2011/21/EU van 2 maart 2011) expiratedatum 31 mei 2021. The applicant is notifier of the dossier and RMS is The Netherlands. For the active substance a review report is available: SANCO/13456/2010 final 28 januari 2011; a revision is published: SANCO/13456/2010 final, 9 december 2011. EFSA conclusion, including final LoEP, is available: EFSA Journal 2011; 9(10):2417, publicatiedatum 21 oktober 2011.

The final list of endpoints from the EFSA conclusion (Oct, 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	<b>Propyl label</b>
Sandy loam I	47% AR (d124), 55% (d380)
Soil	<b>Allyl label, Ring label</b>
Sandy loam II	45%-57% AR (d125-121)
Clay loam	34.2%-63.6% AR (d119-57)
Loam	45.4%-57% AR (d119-57)
Loamy sand	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)



	<p>Soil                    Allyl label, Ring label</p> <p>Sandy loam II : max 15%-16% AR at day 30</p> <p>Clay loam :        max 25.8%-33.3% AR at day 7-14</p> <p>Loam :                max 20.9%-24.4% AR at day 11-14</p> <p>Loamy sand :    max 11.9%-12.6% AR at day 7</p> <p><b>Clethodim oxazole sulfone :</b></p> <p>Sandy loam I : max 10% AR at day 380 (propyl label)</p> <p>Sandy loam II : max 8.6% AR at day 121 (ring label)</p> <p>Loamy sand : max 7.5% AR at 57 days (ring label)</p>
Anaerobic degradation	<p>Mineralisation maximum 6.8% AR at 31 d</p> <p>Non-extractable residues maximum 22% AR at 62 d</p> <p>Metabolites</p> <p>clethodim sulfoxide, maximum 79% AR at 1 d</p> <p>clethodim imine, maximum 44% AR at 31 d</p> <p>clethodim imine sulfoxide, maximum 14% AR at 31 d</p> <p>[ring-4,6-<sup>14</sup>C] (n=1)</p>
Soil photolysis	<p>Clay loam, 20 ± 1°C</p> <p><b>Clethodim :</b></p> <p>max DT<sub>50</sub> = 0.16 days (irradiated samples)</p> <p>max DT<sub>50</sub> = 2.88 days (dark samples)</p> <p><u>Major metabolites :</u></p> <p><b>Clethodim sulfoxide: (allyl – ring labels)</b></p> <p>max 60.4%- 53.7% at d 1 (irradiated)</p> <p>max 89.2%- 88.1% at d 15-10 (dark)</p> <p>max DT<sub>50</sub> : 1.55 days (irradiated-ring label)</p> <p>stable in dark</p> <p><b>Trans-3-chloroacrylic acid:</b> max 18.1% at d 3 (irr)</p> <p>DT<sub>50</sub> : 6.49 days (irradiated-allyl label)</p> <p><b>2-[3-chloroallyloxyimino]butanoic acid isomers :</b></p> <p>max 18.7% at the end of irradiation period (irr)</p> <p>No DT<sub>50</sub> value</p>
% refers to the applied radioactivity	
<b>Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)</b>	
Method of calculation	<p>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.</p> <p>Field: no reliable data available</p>

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<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
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<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

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	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

# 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>	DT <sub>50</sub> (d)	Chi <sup>2</sup>	ff

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				(d)	20°C pF2/10kPa		
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)

Clethodim							
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> x % 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)

<p><math>K_f = 0.366/0.146/0.194</math>  <math>1/n = 0.77/0.87/0.74</math> (arithmetic mean = 0.79)                  No effect of pH</p> <p><b>Clethodim oxazole sulfoxide</b>  <math>K_{doc} = 26/58/130</math> L/kg (arithmetic mean = 71.3 L/kg)  <math>K_d = 0.6/1.66/2.4</math>  <math>1/n =</math> no data                  No effect of pH</p> <p><b>Clethodim oxazole sulfone</b>  <math>K_{Foc} = 12/96/43</math> L/kg (arithmetic mean = 50.3 L/kg)  <math>K_f = 0.277/1.249/1.779</math>  <math>1/n = 1.09/1.00/1.01</math> (arithmetic mean = 1.03)                  No effect of pH</p> <p><u>Koc and 1/n used for FOCUS PECgw modeling:</u>                  Clethodim: worst-case <math>K_{Foc} = 4</math> L/kg for all the FOCUS scenarios and <math>1/n = 0.975</math> (agreed in PRAPeR 78) (geometric mean of <math>K_{Foc}</math> values at alkaline pH)                  Arithmetic mean Koc (L/kg) / 1/n                  Clethodim sulfoxide: 13 / 0.83                  Clethodim sulfone: 11 / 0.79                  Clethodim oxazole sulfone: 51 / 1.03</p>
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**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

<p>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 &lt;2.4%; soil concentrations not determined.                  [unlabelled clethodim]</p>
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Aged residues leaching

<p>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 &lt;1.8%; soil concentrations not determined.                  [unlabeled clethodim]</p>
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Lysimeter/ field leaching studies

<p>No data submitted.</p>
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**PEC (soil) (Annex IIIA, point 9.1.3)**

Method of calculation

First order kinetics with a normalized max DT<sub>50</sub> 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

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

The corresponding PECsoil calculations for clethodim and its soil metabolites can be found in the Additional Report (November 2009) (The Netherlands, 2009).

The max. initial PECsoil 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.

Metabolites – parameters used for PECs calculation

**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, PECmax is used for risk assessment. PEC accumulation is not relevant.

**Max. iniPECsoil for metabolites:**

Clethodim sulfoxide: 0.291 mg/kg (GAP 2x192)

Clethodim sulfone: 0.160 mg/kg (GAP 2x192)

Clethodim oxazole sulfone: 0.024 mg/kg (GAP 2x192)

**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).
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)

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

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

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

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*	---



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	166*	156*	138*	156*	1196*	---
- DT <sub>50</sub> total system - DT <sub>90</sub> total system	* 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)	<u>River</u> : at day 0, 96.1% of AR in water, less than 2% from d 42 <u>Pond I</u> : at day 0, 96.5% of AR in water, less than 4% from d 56 <u>Pond II</u> : at day 0, 70.5% of AR in water, less than 5% from day 103  Maximum observed in sediment <u>River</u> : 10.8-11.1% of AR at d 7-14 (ring-allyl) <u>Pond I</u> : 8.6-12% of AR at d 2-7 (ring-allyl) <u>Pond II</u> : 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	Crop: sugar beet  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

Main routes of entry

<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>
Drift, drainage and run-off.
<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

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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 PEC<sub>sw</sub> 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 point 1.5.8

### 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):

Application rate

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).

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.

PEC<sub>(gw)</sub>

Maximum concentration

FOCUS PELMO 3.3.2

80<sup>th</sup> percentile annual average:

Clethodim: 0.000 µg/L

Clethodim sulfoxide: 0.021 µg/L

Clethodim sulfone: 0.113 µg/L

Clethodim oxazole sulfone: 0.356 µg/L

PEARL 3.3.3

80<sup>th</sup> percentile annual average:

Clethodim: 0.000 µg/L

Clethodim sulfoxide: 0.5663 µg/L

Clethodim sulfone: 1.0905 µg/L

Clethodim oxazole sulfone: 0.5264 µg/L

FOCUSPELMO 3.3.2 results: 80<sup>th</sup> percentile annual average

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**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 10 <sup>-6</sup> Pa at 20°C, and the Henry's law constant 1.40 10 <sup>-7</sup> (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.
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**PEC<sub>(a)</sub>**

Maximum concentration	Not calculated.
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**Residues requiring further assessment (Annex IIA, point 7.3)**

Environmental occurring metabolite requiring further assessment by other disciplines	<b>Soil:</b> clethodim, clethodim sulfoxide, clethodim
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(toxicology and ecotoxicology) or for which a groundwater exposure assessment is triggered

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)

No data

Surface water (indicate location and type of study)

No data

Ground water (indicate location and type of study)

No data

Air (indicate location and type of study)

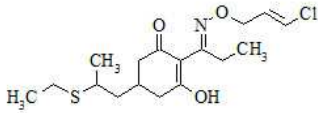
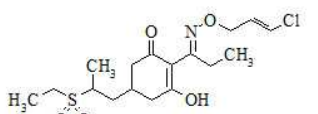
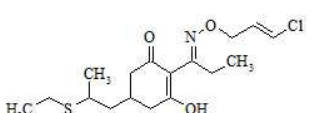
No data

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

No classification proposed.

**Appendix A: Metabolite names, codes and other relevant information of the pesticide Centurion Plus with active substance clemathodim**

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

Compound name	IUPAC name	Structural formula	Structure	Molecular Weight [g/mol]	Observed in study (maximum observed)
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-oxazole-sulfone				299.4	Soil (0.10)
Clemathodim-imine				269	Water and sediment (15.5 % (day 61)
Clemathodim-imine-sulfoxide				285	Water and sediment (35.8% (day 33))

**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 (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 of 0.240 kg/ha, the crop winter cereals and an interception value appropriate to the crop stage of 0. Date of yearly application is May 25<sup>th</sup> for spring application, and November 1<sup>st</sup> for autumn application. For metabolites all available data concerning substance properties are regarded.

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For active substance clethodim and metabolite clethodim-sulfoxide, the  $DT_{50}$  is < 10 days and the  $K_{om}$  is < 10 L/kg. Therefore, the first tier prediction using PEARL 4.4.4 is skipped and leaching behaviour is directly studied 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.

The following input data are used for the calculation:

**(Geo)PEARL:**

Active substance clethodim:

Geometric mean normalised  $DT_{50}$  for degradation in soil (20°C): 0.66 days (n=5)

Conservative  $K_{om}$  (pH-independent): 2.32 L/kg (agreed in PRAPeR 78, see LoEP).

Arithmetic mean  $1/n$ : 0.975

Saturated vapour pressure:  $2.08 \times 10^{-6}$  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  $DT_{50}$  for degradation in soil (20°C): 7.97 days (n=5)

Arithmetic mean  $K_{om}$  (pH-independent): 7.71 L/kg

Arithmetic mean  $1/n$ : 0.83

Formation fraction: 0.87 (from parent)

Saturated vapour pressure:  $2.14 \times 10^{-9}$  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  $DT_{50}$  for degradation in soil (20°C): 13.9 days (n=5)

Arithmetic mean  $K_{om}$  (pH-independent): 6.21 L/kg

Arithmetic mean  $1/n$ : 0.79

Formation fraction: 0.43 (from clethodim-sulfoxide)

Saturated vapour pressure:  $8.24 \times 10^{-10}$  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  $DT_{50}$  for degradation in soil (20°C): 32 days (n=3)



Arithmetic mean  $K_{om}$  (pH-independent): 29.4 L/kg

Arithmetic mean 1/n: 1.03

Formation fraction: 0.17 (from clethodim-sulfone)

Saturated vapour pressure:  $2.08 \times 10^{-6}$  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 active substance clethodim and the metabolite 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 the metabolite clethodim – sulfone, clethodim – sulfoxide and clethodim – oxazole - sulfone as predicted by PEARL 4.4.4**

Use	Substance	Rate substance [kg/ha]	Freq./ Interval [days]	Fraction Intercepted *	PEC groundwater [µg/L]	
					spring	autumn
Tree nursery crops	Clethodim	0.240	1 / -	0	<0.001	<0.001
	-sulfone**				<b>0.420</b>	<b>1.340</b>
	-oxazole sulfone**				<b>0.492</b>	<b>0.756</b>

\* interception values derived from Table 1.6 in “generic guidance for FOCUS groundwater scenarios”. An interception of 0 is considered appropriate for Tree nursery crops at BBHC growth stage 00-99 (worst case possibility in line with GAP).

\*\* Calculated according to transformation scheme: clethodim → -sulfoxide → - sulfone → -oxazole sulfone

Results of Pearl 4.4.4 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 active substance clethodim is smaller than 0.01 µg/L for the proposed application. Hence, the applications meet the standards for leaching as laid down in the RGB.

PEARL 4.4.4 calculations show that the predicted leachate concentrations for metabolites clethodim-sulfone and clethodim-oxazole sulfone are larger than 0.1 µg/L. Therefore, the leaching concentration of the active substance clethodim and metabolites clethodim – sulfone, clethodim – sulfoxide and clethodim oxazole sulfone will be calculated using GeoPEARL.

### GeoPEARL

The leaching potential of the active substance clethodim and metabolites clethodim sulfoxide, clethodim sulfone and clethodim oxazole sulfone to the shallow groundwater in the potential area of use within The Netherlands is calculated using the GeoPEARL 3.3.3 model. The input data as described in the input box above and used in the first tier with Pearl 4.4.4 is employed. Additional

input is the crop tree nursery crops and the number of plots (minimum 250). For results see Table M.1b.

**Table M.1b. Leaching of active substance clethodim and metabolites clethodim-sulfoxide and clethodim-oxazole-sulfone as predicted by GeoPEARL 3.3.3.**

Use	Substance	Rate a.s. [kg/ha]	Freq./ Interval [days]	Fraction Intercepted*	PEC groundwater [µg/L]	
					spring	autumn
Tree nursery crops	Clethodim	0.240	1 / -	0	< 0.001	< 0.001
	-sulfoxide				< 0.001	<b>0.202</b>
	-sulfone				<u>0.028</u>	<b>0.820</b>
	-oxazole sulfone				<b>0.236</b>	<b>0.559</b>

\* interception values derived from Table 1.6 in “generic guidance for FOCUS groundwater scenarios”. Interception values are appropriate for the BBCH stages; interception value for onions is used for use in garlic and shallots.

\*\* Calculated according to transformation scheme: clethodim → -sulfoxide → - sulfone → -oxazole sulfone

GeoPEARL calculations show that the predicted leachate concentrations for active substance clethodim (both spring and autumn scenario) and metabolite clethodim – sulfoxide (spring scenario) are smaller than 0.1 µg/L. Hence, the active substance meets the standards laid down in the RGB for the proposed applications.

An assessment of the toxicological relevance of groundwater metabolites according to the ‘Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater’ (Sanco 221/2000 – rev. 10- final, Feb, 2003) has to be performed for the three metabolites clethodim sulfoxide, clethodim sulfone and clethodim oxazole sulfone. According to the Guidance, several steps should be performed.

Firstly, the genotoxicity and toxicity of the metabolites should be assessed to determine if the metabolites can be considered to be non-relevant. In the additional report to the DAR (March 2010) the non-relevance of the groundwater metabolites is described:

*“The predicted concentrations in groundwater of some of the metabolites exceeded 0.1 µg/L and the toxicological relevance of the metabolites has been considered. The metabolite oxazole **sulfoxide** is a major rat metabolite and the toxicological profile is considered to have been covered by the toxicology studies conducted with parent material. The metabolites clethodim **sulfone** and clethodim **oxazole sulfone** are only minor metabolites in the rat therefore the genotoxicity of these metabolites has been investigated. The studies showed no significant genotoxicity activity and although these metabolites could possibly exceed 0.1 µg/L in groundwater they can be considered toxicologically non relevant.”*

Moreover, in the EFSA conclusion, the following table is included (EFSA conclusion, 6.2).

<b>Compound (name and/or code)</b>	<b>Pesticidal activity</b>	<b>Toxicological relevance</b>	<b>Ecotoxicological activity</b>
clethodim sulfoxide	no	Major rat metabolite Not relevant	No
clethodim sulfone	No	Unlikely to be genotoxic Not relevant	No

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<i>clethodim oxazole sulfone</i>	<i>No</i>	<i>Unlikely to be genotoxic Not relevant</i>	<i>No</i>
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Based on these findings, all three metabolites can be considered to be non-relevant and pass into stage 4 of the Guidance.

In stage 4, a threshold of concern approach is taken. For metabolites present in the groundwater below 0.75 µg/L, further assessment is not required. Both metabolites clethodim sulfoxide and clethodim oxazole sulfone are present in groundwater below 0.75 µg/L and can therefore be considered as non-relevant.

Metabolite clethodim sulfone is present in the groundwater above the threshold of concern, therefore a stage 5 refined risk assessment is required.

#### Stage 5: refined risk assessment

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.

In the EFSA conclusion on clethodim it is stated that the reference values of the parent apply to this metabolite. Therefore the ADI of the parent clethodim can be used for this refined risk assessment for the metabolite clethodim sulfone.

The highest groundwater concentration of clethodim sulfone given by the model was 0.820 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 g/mol and the MW of clethodim sulfone is 391.9 g/mol.  
 $(0.820 \mu\text{g/L} / 391.9) * 359.92 = 0.75 \mu\text{g/L}$

**Table 2: Assessment of clethodim sulfone 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	0.023	0.01
Children	18.4	1	0.041	0.03
Infants	10.2	0.75	0.055	0.03

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 2, it is evident that the highest estimated exposure via the drinking water is 0.03% 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.

#### Conclusions

The proposed application of the product Centurion Plus complies with the requirements laid down in the RGB concerning leaching to 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.

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

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See List of End-points.

## 6.5 Data requirements

*none*

**The following restriction sentences were proposed by the applicant:**

*none*

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

*none*

## 6.6 Overall conclusions fate and behaviour

It can be concluded that:

1. 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 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.

## 7 Ecotoxicology

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

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

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

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

### List of Endpoints Ecotoxicology 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)

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

(summarised in the "Evaluation report by RMS Netherlands" dated 05 January 2012 (report available on confidential EFSA website))

Carrot leaves:	<2.6 & <2.8 days (2 trials)
Carrot root:	2.8 & <2.9 days (2 trials)
Potato haulm:	4.6, 1.7, 3.6 & 1.6 days (4 trials)
Wine grape:	3.7 days (1 trials)
Sugar beet leaves:	5.8 & 2.8 days (2 trials)
Overall arithmetic mean: 3.3 days	

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

Group	Test substance*	Time-scale	Endpoint	Toxicity (mg a.s./l)**
Laboratory tests				
<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>	<b>1.9</b> <sup>(C)</sup>
<i>Oncorhynchus mykiss</i>	Select 240 EC	96 h	Mortality, EC <sub>50</sub>	<b>3.4</b> <sup>(B)</sup>
<i>Oncorhynchus mykiss</i>	Select + oily adjuvant	21 d	NOEC	<b>0.29</b> <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>	<b>5.1</b> <sup>(A)</sup>
<i>Daphnia magna</i>	Select + oily adjuvant	21 d	Reproduction, NOEC	<b>0.00084</b> <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>	<b>1.5</b> <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				

\* 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

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submitted with the dossier contained applications with oily adjuvant only. However, formulated clethodim could also be used without oily adjuvant. Selection of the relevant endpoint should therefore be taken at Member State level, depending on the proposed use.

(A) Based on mean measured concentrations.

(B) Based on analytically confirmed nominal concentrations.

(C) Based on nominal concentrations (analytically confirmed for initial concentrations).

(D) Based on measured initial concentrations.

### Bioconcentration

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

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

Acute oral toxicity	LD <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
Laboratory tests						
<i>Aphidius rhopalosiphi</i>	Laboratory, sprayed plants	Select + Adjuvant	9.6 240	mortality/reproduction LR <sub>50</sub> , ER <sub>50</sub>	0 / 5 0 / 5 >240 g a.s./ha	50%
<i>Typhlodromus pyri</i>	Extended laboratory <sup>(A)</sup>	Select + Adjuvant	9.6	mortality/reproduction LR <sub>50</sub> , ER <sub>50</sub>	82 / 51 <9.6 g a.s./ha	50%
<i>Typhlodromus pyri</i>	Extended laboratory <sup>(A)</sup>	Select + Adjuvant	0.6 1.2 2.4 4.8 9.6	mortality/reproduction LR <sub>50</sub> ER <sub>50</sub>	1 / 10 4 / 0.2 16 / 14 73 / 33 100 / n.a. <sup>(B)</sup> 3.6 g a.s./ha >4.8 g a.s./ha	50%

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<i>Typhlodromus pyri</i>	Extended laboratory	Select 240 EC	0, 11 and 384	Fresh residues: 4, 7 & 14 d aged:	LR <sub>50</sub> <384 ER <sub>50</sub> >11  LR <sub>50</sub> >384 ER <sub>50</sub> >384	50%
<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/reproduction 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> )
---

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(A) corrected for organic content of OECD 207 substrate

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

Nitrogen mineralization

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

Carbon mineralization

**Clethodim**  
Up to 2.741 mg a.s./kg: effects <25%  
**Select EC 240**  
Up to 2.7 mg a.s./kg: effects <25% (2 soils).  
**Select + Para Sommer**(= oily adjuvant)  
Up to 1.7 mg a.s./kg: effects <25% (2 soils).  
**Clethodim oxazole sulfone**  
Up to 0.10 mg a.s./kg: effects <25%

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

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

<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

	Rate response for seedling emergence	Rate response for vegetative vigor (plant dry weight)
	EC <sub>50</sub> (g a.s./ha)	EC <sub>50</sub> (g a.s./ha)
Ryegrass ( <i>L. perenne</i> )		clethodim: 6.7 g a.s./ha clethodim sulfoxide: 25 g a.s./ha



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		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

#### clethodim

EC<sub>50</sub> > 95 mg/L

#### Select H EC24

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

#### **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)
Laboratory tests				

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<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 as/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 &lt;25% after 56 days (= end of test) (1 soil)

Carbon mineralization

**TM-20015 (Centurion Plus)**

Up to 2.05 mg a.s./kg: effects &lt;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

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Soybean ( <i>Glycine max</i> )	>270 g a.s./ha	>270 g a.s./ha
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(A) No information was submitted to confirm that Centurion Pro is identical to Centurion Plus.

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

**Risk envelope analysis****Table E.1 Overview of risks of points of interest of the use in tagetes and tree nursery crop, compared to the already allowed uses**

<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
	Frequency	Y	Equal
	Interval	Y	Equal
	Time of application (interception and season)	Y	Equal
	Focal species and RUD (PD, PT, DT50)	Y/N	See remarks
	Bioaccumulation : PEC soil and PEC water (see fate)	Y	Equal/lower/higher
	Remarks	In reregistration risk assessment was performed according to sanc0; including herbivorous and insectivorous birds; and medium herbivorous and insectivorous mammals. These focal species are relevant for the cropping groups bare soil and leafy crops. Tagetes fall in the cropping group 'leafy crops' and therefore falls within the risk envelope. 'tree nursery' includes a wide range of crops and can also include crops with grass strips in-between, such as lane trees. For this group, the orchard scenario is more relevant, which would trigger the small herbivorous mammals. As the application is against grasses, it is unlikely that the application is ment to be on the green strips, but this is not specified. In case the application is only on the blacks, an off-crop risk assessment needs to be performed for small herbivorous mammals. In cases application is general in tree nursery crops, a full risk assessment for small herbivorous mammals needs to be performed. Applicant is requested to specify the group 'tree nursery'.	
Bees and bumblebees	Dose rate	Y	Equal
	Exposure route (e.g. spray drift, dust drift)	Y	Equal
	Other relevant species	Y	Equal
remarks			
Non-target-	Dose rate	Y	Equal

arthropods			
	Frequency	Y	Equal
	Interval	Y	Equal
	Drift rate	Y	Equal
	Exposure route (e.g. spray, seed treatment)	Y	Equal
	remarks	A general restriction sentence is included on the label. This is also applicable for current extensions	
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
	Frequency	Y	Equal
	Interval	Y	Equal
	Drift rate	Y	Equal
	remarks	A general restriction sentence is included on the label. This is also applicable for current extensions	

### Conclusion with respect to comparability

The risk of the applied use in tagetes is equal to or lower than the risk of the authorised uses with regard to the environment for all aspects addressed above.

The risk of the use applied for in tree nursery crops is not included in the risk envelope for the aspects mammals, since this cropping group can include trees with grass strips in-between. For this aspect a separate risk assessment might be required. There are 3 options:

- 1) Tree nursery crops in which black- and green strips are possible (such as lane trees) should be excluded. In that case no risk assessment is required
- 2) It should be specified that the application in tree nursery crops in which black- and green strips are possible should only be made on the black strips. In that case, only an off-crop risk assessment for small herbivorous mammals is required.
- 3) Without any further specification of the exact intended application, a full risk assessment for small herbivorous mammals is required.

The applicant restricted the label and application on grass strips is not allowed. A restriction sentences is included on the label.

Therefore only a risk assessment for the black strips and an off-field assessment for grass inbetween the rows is relevant.

### 7.1 Effects on birds

All uses applied for fall within the existing risk envelope.

#### Conclusions birds

The product complies with the RGB.

### 7.2 Effects on aquatic organisms

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All uses applied for fall within the existing risk envelope.

### Conclusions aquatic organisms

The proposed applications meet the standards for aquatic organisms.

### 7.3 Effects on terrestrial vertebrates other than birds

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

The threshold value for mammals is based on the trigger from the RGB. This means that the Toxicity-Exposure Ratio (TER) for acute exposure should be  $\geq 10$  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).

The use in tagetes falls within the existing risk envelope. Fost uses in the category 'tree nurseries' also fall within the existing risk envelope, with exception the crops with possible grass strips in-between the rows (lane trees). For this use a risk assessment is required. As the use is applied for on the black strips, risk assessment should be performed for bare soil scenario, and an off-crop risk assessment for the grassland scenario.

**Table E.10 Indicator species per use**

Use	Crop	Indicator species
Tree nurseries (lane trees)- black strips	Bare soil	insectivorous mammal
Tree nurseries (lane trees) grass off-crop	Grassland (off-crop)	Small herbivorous mammal

As the exposure to the grass strips is indirect, an off-field assessment using 10% drift will be performed and therefore the application rate is 0.025 kg a.s./ha.

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

**Table E.11a Acute risk for mammals**

Substance	FIR / bw	RUD	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	144	0.024	-	4.80	1133	236
<b>insectivorous mammal</b>							
clethodim	0.63	14	0.24	-	2.11	1133	537

**Table E.11b 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>Medium herbivorous mammal</b>								
clethodim	1.39	76	0.024	-	0.53	1.3	16	12
<b>insectivorous mammal</b>								
clethodim	0.63	5.1	0.24	-	-	0.77	16	21

Taking the results in Table E11a-b. into account, it appears that all proposed uses meet the standards laid down in the RGB, provided that application on grass strips is excluded.

The exclusion for application on grass strips and the usability of a proposed restriction sentence was checked with the nVWA. According to the nVWA it is not common practice to use a herbicide like Centurion for application on grass strips.

Therefore an additional restriction sentence for exclusion of application on grass strips is not necessary.

### Conclusions mammals

The product complies with the RGB.

### 7.4 Effects on bees

All uses applied for fall within the existing risk envelope.

### Conclusions bees

The product complies with the RGB.

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

All uses applied for fall within the existing risk envelope. The restriction sentences already on the label also apply for the uses applied for.

### Conclusions any other organisms

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

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

See List of End-points.

## 7.7 Data requirements

-

## 7.8 Restriction sentences

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:

-

The following restriction sentences are currently on the label and also apply for the new uses:

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

## 7.9 Overall conclusions regarding ecotoxicology

It can be concluded that:

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

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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 labeling 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		
<b>New minor uses according to article 51</b>												
1	NL	<i>Tagetes</i> (green manure crop)	F	Annual grasses Annual Meadow grass ( <i>Poa annua</i> ) >BBCH29 and Quack grass ( <i>Agropyron repens</i> )	Spraying	BBCH 11-99 (April-Sept)	1/NA	1	120	150-400	-	a) 1 application per crop. 1 crop per season b) Maximal allowed dose rate in <i>Tagetes</i> per 12 month: 2.0 L/ha
								2	240			

2	NL	Tree nursery crops, soilbound, row treatment	F	Annual Meadow grass ( <i>Poa annua</i> ) >BBCH29	Spraying	BBCH 00-99 (April-Sept)	1/NA	2	240	300-800	-	<p>a) 1 application per crop. 1 crop per season</p> <p>b) Maximal allowed dose rate in Tree nursery crops per 12 month: 2.0 L/ha</p> <p>Soil bound crops, use of covered nozzles</p> <p>Don't apply product on grass vegetation strip</p>
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## **Appendix 2 Reference list**

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

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

Not applicable.