HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 BESLUIT

Op 10 mei 2016 is van

UPL Europe Ltd.
The Centre, 1st Floor
Birchwood Park
WA3 6YN WARRINGTON Cheshire
United Kingdom

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

Corzal SE

op basis van de werkzame stof fenmedifam.

HET COLLEGE BESLUIT 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.

1.1 Samenstelling, vorm en verpakking

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

1.2 Gebruik

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

1.3 Classificatie en etikettering

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

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

1.4 Aflever- en opgebruiktermijn (respijtperiode)

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	HTB 0.2

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).

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, 1 september 2017

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20160695 NLKUG
Type aanvraag:	aanvraag tot uitbreiding met kleine toepassing van een gewasbeschermingsmiddeltoelating
Middelnaam:	Corzal SE
Formele registratiedatum: *	24 oktober 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

Werkzame stof	Gehalte
fenmedifam	160G/L

De stof fenmedifam is per 1 maart 2005 geplaatst op Annex I van Richtlijn 91/414/EEG (04/58/EC d.d. 23 April 2004) en vervolgens bij Uitvoeringsverordening (EU) 540/2011 d.d. 25 mei 2011 goedgekeurd. De goedkeuring van deze werkzame stof expireert op 31 juli 2018.

3 Toelatingsinformatie

Toelatingsnummer:	13234 N
Expiratiedatum:	1 september 2019
Afgeleide of parallel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel
W-codering professioneel gebruik:	4

4 Aflever- en opgebruiktermijnen voor oude etiket

Vorige W-codering professioneel gebruik:	3
Aflevertermijn professioneel gebruik:	nvt
Opgebruiktermijn professioneel gebruik:	nvt

5 Verpakkingsinformatie

Aard van het preparaat:
Suspensie concentraat

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BIJLAGE II Etikettering van het middel Corzal SE

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

Pictogram	GHS07 GHS09
Signaalwoord	WAARSCHUWING
Gevarenaanduidingen	H317 Kan een allergische huidreactie veroorzaken. H319 Veroorzaakt ernstige oogirritatie. H411 Giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P261 Inademing van stof/rook/gas/nevel/damp/spuitnevel vermijden. P273 Voorkom lozing in het milieu. P280 Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen. P333 + P313 Bij huidirritatie of uitslag: een arts raadplegen. P337 + P313 Bij aanhoudende oogirritatie: een arts raadplegen. P501 Inhoud/verpakking afvoeren naar ....
Aanvullende etiketelementen	EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.

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BIJLAGE III WG van het middel Corzal SE

Wettelijk Gebruiksvoorschrift

Toegestaan is uitsluitend het professionele gebruik als onkruidbestrijdingsmiddel in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.0, Ctgb juni 2011) onder de vermelde toepassingsvoorwaarden

Toepassingsgebied	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	Minimum interval tussen toepassingen in dagen
Bieten	Na opkomst	Eenjarige breedbladige onkruiden	0,5-0,75 l/ha [1]	8 per teeltcyclus	8 l/ha per teeltcyclus	7
			1-1,5 l/ha	8 per teeltcyclus		
			2-2,5 l/ha	4 per teeltcyclus		
	Rijenbehandeling na opkomst	Eenjarige breedbladige onkruiden	0,25-0,37 l/ha [1]	8 per teeltcyclus		
			0,5-0,75 l/ha	8 per teeltcyclus		
			1-1,25 l/ha	8 per teeltcyclus		
Aardbei (onbedekte teelt)	Voor bloei, na oogst of na uitplanten	Eenjarige breedbladige onkruiden	4-8 l/ha	2 per 12 maanden	8 l/ha per 12 maanden	10

[1] in LDS-systeem in combinatie met toegelaten middelen

Het gebruik in de teelt van aardbei, spinazie, snijbiet, gezaaide boomkwekerijgewassen, bloemisterijgewassen, veredeling en zaadteelt van akkerbouwgewassen (m.u.v. aardappel, maïs, granen en graszaadteelt, hop en olifantsgras), groenten- en fruitgewassen, kruiden en sierteeltgewassen en rode bieten 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	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	Minimum interval tussen toepassingen in dagen
Aardbei (onbedekte teelt)	Voor bloei, na oogst of na uitplanten	Eenjarige breedbladige onkruiden	0.5-3 l/ha	12 per teeltcyclus	6 l/ha per teeltcyclus	5
Spinazie (onbedekte teelt)	Na opkomst	Eenjarige breedbladige onkruiden	1-2 l/ha	2 per teeltcyclus	2 l/ha per teeltcyclus	5
Snijbiet (onbedekte teelt)	Na opkomst	Eenjarige breedbladige onkruiden	1-2 l/ha	2 per teeltcyclus	2 l/ha per teeltcyclus	5
Boomkwekerijgewassen (gezaaid) (onbedekte teelt)	Na opkomst	Eenjarige breedbladige onkruiden	1-3 l/ha	6 per 12 maanden	6 l/ha per 12 maanden	5
Bloemisterijgewassen (onbedekte teelt)	Na opkomst	Eenjarige breedbladige onkruiden	1-3 l/ha	6 per 12 maanden	6 l/ha per 12 maanden	5
Veredeling en zaadteelt van akkerbouwgewassen (m.u.v. maïs, granen en graszaadteelt, hop en olifantsgras), groenten- en fruitgewassen, kruiden en sierteeltgewassen (onbedekte teelt)	Na opkomst	Eenjarige breedbladige onkruiden	1-3 l/ha	6 per 12 maanden	6 l/ha per 12 maanden	5
Rode biet (onbedekte teelt)	Na opkomst	Eenjarige breedbladige onkruiden	0,5-0,75 l/ha [1]	6 per teeltcyclus	6 l/ha per teeltcyclus	7
			1-1,5 l/ha	6 per teeltcyclus		
			2-2,5 l/ha	3 per teeltcyclus		

[1] in LDS-systeem in combinatie met toegelaten middelen

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Toepassingsvoorwaarden
In de onbedekte teelt van aardbei maximaal 8 l/ha per 12 maanden toepassen.In de onbedekte teelt van boomkwekerijgewassen alleen toepassen in het eerste groeiseizoen.

Om in het water levende organismen te beschermen is de toepassing in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien gebruikt wordt gemaakt van minimaal 75% driftreducerende spuitdoppen.

Dit middel is gevaarlijk voor niet-doelwit arthropoden. Vermijd onnodige blootstelling.

Bij het gebruik in bieten, het middel toepassen voor het sluiten van het gewas.
Dit middel bevat de werkzame stof fenmedifam. Fenmedifam behoort tot de fenylcarbamaten. De Hrac code is C1. Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen**.**

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BIJLAGE IV

RISKMANAGEMENT

1. Identity of the plant protection product

1.1 Applicant

UPL Europe Ltd
1st Floor, The Centre, Birchwood Park
WA3 6 YN Warrington
United Kingdom

1.2 Identity of the active substance

The identity of the active substance(s) does not change.

Common name	Phenmedipham
Name in Dutch	Fenmedifam
Chemical name	methyl 3-(3-methylcarbaniloyloxy)carbanilate; 3-methoxycarbonylaminophenyl 3´-methylcarbanilate
CAS no	13684-63-4
EC no	EINECS: 2371990

The active substance was included in Annex I of Directive 91/414/EEC on 1 March 2005.
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	Corzal SE
Formulation type	SC
Content active substance	160 g/L

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 Extensions applied for

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	Strawberries	F	Annual dicotyledonous weeds	Broadcast spray	BBCH 00-59 (April-May) and BBCH 91-97 (July-August)	12 (5)	0.5-3 L/ha	80-480 g a.s./ha	200/400	-	b) Maximum 6 L/ha
2	NL	Spinach family except garden orache	F	Annual dicotyledonous weeds	Broadcast spray	BBCH 10-40 (March-May)	2 (5)	1-2 L/ha	160-320 g a.s./ha	200/400	28	b) Maximum 2 L/ha/crop cycle
3	NL	Tree nursery (sown)	F	Annual dicotyledonous weeds	Broadcast spray	BBCH 10-20 (March-June)	6 (5)	1-3 L/ha	160-480 g a.s./ha	200/400	-	b) Maximum 6 L/ha c) apply only in first planting season
4	NL	Ornamental crops (floriculture crops)	F	Annual dicotyledonous weeds	Broadcast spray	BBCH 10-30 (March-June)	6 (5)	1-3 L/ha	160-480 g a.s./ha	200/400	-	b) Maximum 6 L/ha
5	NL	Plant breeding crops and seed production for arable (except maize, cereals, grass seed, hop and elephant grass), vegetable and fruit crops, herbs and ornamental crops	F	Annual dicotyledonous weeds	Broadcast spray	BBCH 10-40 (March-June)	6 (5)	1-3 L/ha	160-480 g a.s./ha	200/400	-	b) Maximum 6 L/ha
6	NL	Red beet	F	Annual dicotyledonous weeds	Broadcast spray	BBCH 10-40 (March-June)	6 (5)	0.5-2.5 L/ha	80-400 g a.s./ha	200/400	-	b) Maximum 6 l/ha

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.

1. Physical and chemical properties

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

2. 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 involves application on crops that can be extrapolated from the current authorisation of Corzal SE based on their crop group (matrix) and their MRL. Therefore, the proposed extension remains within the existing risk envelope for the section residue analytical methods for food/feed of plant and animal origin.

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

Conclusion

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

Physical-chemical classification and labelling

Proposal for the classification and labelling of the formulation concerning physical chemical properties

Classification and labelling of the formulation does not change.

3. Mammalian toxicology

List of Endpoints
The final list of endpoints presented below is taken from the final review report on phenmedipham (SANCO/4060/2001-final, d.d. 13 February 2004). Where relevant, some additional remarks/information are given in italics.

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Rapid. 85%, based on urinary excretion in 24 –30 h
Distribution:	Widely distributed, highest residues in blood (methylphenyl ring label)
Potential for accumulation:	Low potential for accumulation
Rate and extent of excretion:	Rapid. Over 90% within 24- 30 h
Toxicologically significant compounds:	Parent compound and metabolites. 3-aminophenol and 3-aminotoluene may be of special toxicological concern
Metabolism in animals:	Extensively metabolised. Oxidative/hydrolytic cleavage of parent molecule, hydroxylation of aromatic ring structures, acetylation of amino groups and further oxidation of methyl groups

Acute toxicity

Rat LD_{50} oral	>8000 mg/kg
Rat LD_{50} dermal	>2000 mg/kg
Rat LC_{50} inhalation	>7.0 mg/l (nose only)
Skin irritation	Non irritant
Eye irritation	Non irritant
Skin sensitization (test method used and result)	Not sensitising (M & K)

Short term toxicity

Target / critical effect	Effects on red blood cells (methemoglobinemia and hemolytic anemia) and related effects (hemosiderin deposition in spleen, liver and kidneys)
Lowest relevant oral NOAEL / NOEL	150 ppm (13 mg/kg bw/day) (90-day, rat)
Lowest relevant dermal NOAEL / NOEL	No data. Not required
Lowest relevant inhalation NOAEL / NOEL	No data. Not required

Genotoxicity	Clastogenic *in vitro*. Non-genotoxic *in vivo* (mouse bone marrow: negative for chromosome aberrations and micronuclei induction; mouse spermatogonial cells: negative for induction of chromosomal aberrations) [1]

[1] *The genotoxic potential of phenmedipham was investigated in 13 in vitro studies (Ames test, mammalian cell gene mutation test in Chinese hamster lung fibroblasts V79 and mouse lymphoma cells, mammalian cytogenetic test in Chinese hamster ovary cells) and 5 in vivo studies (micronucleus test in mouse bone marrow and chromosome aberration test in NMRI mouse spermatogonial cells).*

Long term toxicity and carcinogenicity

Target/critical effect	Effects on red blood cells (methemoglobinemia and hemolytic anemia) and related histophatological effects in spleen, liver and kidneys (increased weight, hemosiderosis, extramedullar hematopoiesis)
Lowest relevant NOAEL / NOEL	60 ppm (3 mg/kg bw/day) 2-year, rat)
Carcinogenicity	No carcinogenic potential

Reproductive toxicity

Target / critical effect – Reproduction:	Reduced pup weight at parentally toxic dose levels
Lowest relevant reproductive NOAEL / NOEL	25 mg/kg bw/day (two-generation, rat) [2]
Target / critical effect Developmental	Retarded ossification in rats and rabbits at maternally toxic dose levels
Lowest relevant developmental NOAEL / NOEL	Rabbit: 225 mg/kg bw/day [3]

[2] *The NOAELs for paternal and maternal toxicity were respectively 75 and 25 mg/kg bw/day based on reduced body weight.*

[3] *Also maternal NOAEL*

Delayed neurotoxicity	No data. Not required.
Other toxicological studies	No data. Not required.
Medical data	Four different studies were supplied which reported cases of allergic dermatitis, photoallergic dermatosis, allergic rhinitis and toxic hepatitis in pesticide operators and field workers who had applied Betanal or Betamix formulations of phenmedipham

Summary	Value	Study	Safety factor
ADI:	0.03 mg/kg bw/day	2-year rat study	100
AOEL systemic:	0.13 mg/kg bw/day	90-day rat study	100
ARfD (acute reference dose)	Not allocated, not necessary		

Dermal absorption

	1% (based on an absorption study *in vivo* in rat, and comparative *in vitro* penetration studies with rat and human skin).[4]

[4] *The dermal absorption studies are performed with an EC formulation with 75 g/L phenmedipham (in the DAR the term OF (oil flowable) was used for this formulation). From the available studies it can be concluded that there was hardly any difference between the dermal absorption of the undiluted formulation (0.9%) and the 1:50 spray dilution (0.2%). Therefore, the dermal absorption will be considered 1% (worst case).*

Local effects

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

Data requirements active substance

No additional data requirements are identified.

3.1 Toxicity of the formulated product (IIIA 7.1)

The formulation Corzal SE does not need to be classified on the basis of its acute oral (LD_{50} rat >2000 mg/kg bw) and dermal (LD_{50} rat >4000 mg/kg bw) toxicology.
The formulation Corzal SE is considered irritating to eyes and needs to be classified as H319 'Causes serious eye irritation'.
The formulation Corzal SE is not classifiable as a skin irritant.
The formulation Corzal SE is positive in a Maximisation test for skin sensitisation and needs to be classified as H317 'May cause an allergic skin reaction'.

3.1.1 Data requirements formulated product

No additional data requirements are identified.

3.2 Dermal absorption (IIIA 7.3)

For the current authorisation of the product Corzal SE, the dermal absorption value of 1% was used in the risk assessment. This value was based on the value in the List of Endpoints, derived from a dermal absorption study *in vivo* in rat and *in vitro* with rat and human skin.
Since this considers an application for minor use extension, the same dermal absorption value will be used as was used in the current authorisation (1% for concentrate and spray dilution).

3.3 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.

3.4 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 Corzal SE, a herbicide based on the active substance phenmedipham.

Corzal SE is a SC formulation and contains 160 g/L phenmedipham.

3.4.1 Operator exposure/risk

The formulation Corzal SE is authorised for beet and strawberry. For this minor use extension, several crops are applied for: strawberries (LDS), spinach family, tree nursery, ornamental crops, plant breeding crops and seed production, and red beet. Since the product Corzal SE is a herbicide, only downwards spraying is applicable. For mechanical downward spraying, the minor uses applied for are within the risk envelope of the current authorisation based on the method of application and dose. However, for the minor uses applied for, manual downward spray application cannot be excluded. Therefore, a risk assessment is performed for manual downward spraying in these crops.

Calculation of the EU-AOEL / Tolerable limit value (TLV)

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

Since the formulation is applied 1 - 12 times during the period March – August, a chronic exposure duration cannot be excluded for the operator. A chronic AOEL is therefore derived.

The EU-AOEL in the List of Endpoints is based on the 90-day rat study, which does not cover chronic exposure. Therefore, the chronic AOEL will be based on the NOAEL of 3 mg/kg bw/day in the 2-year rat study, with a safety factor of 100. No correction for oral absorption is necessary, as >80% of phenmedipham is orally absorbed. The chronic AOEL is 0.03 mg/kg bw/day (= 2.1 mg/day for a 70 kg operator).

Exposure/risk

Exposure to phenmedipham during mixing and loading and application of Corzal SE 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 phenmedipham and risk assessment for the use of Corzal SE

	Route	Estimated internal exposure [a] (mg/day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Manual downward spraying on the intended uses (uncovered, 480 g a.s./ha)				
Mixing/	Respiratory	0.48	2.10	0.23

	Route	Estimated internal exposure [a] (mg/day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Loading and application[c]	Dermal	0.96	2.10	0.46
	Total	1.44	2.10	0.69

a Internal exposure was calculated with:
- biological availability via the dermal route: 1% (concentrate) and 1% (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 NL model.

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

3.4.2 Bystander exposure/risk

The formulation Corzal SE is authorised for use as a herbicide in beet and strawberry. The uses applied for in this minor use extension are within the risk envelope of the existing authorisation based on the method of application and dose already authorised (downward spraying, max. 1.28 kg a.s./ha). Therefore, it is not necessary to perform a risk assessment for this minor use extension.

3.4.3 Worker exposure/risk

The formulation Corzal SE is authorised for use as a herbicide in beet and strawberry. The uses applied for in this minor use extension are within the risk envelope of the existing authorisation. Therefore, it is not necessary to perform a risk assessment for this minor use extension.

3.4.4 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 respiratory and dermal exposure to phenmedipham as a result of the application of Corzal SE in the intended uses.

Bystander exposure

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 phenmedipham during application of Corzal SE.

Worker exposure

It can be concluded that no adverse health effects are expected for the unprotected worker after respiratory and dermal exposure during re-entry activities in the intended uses due to exposure to phenmedipham after application of Corzal SE.

The current classification and labelling of the formulation can be maintained.

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

See List of Endpoints.

3.6 Data requirements

No additional data required.

3.7 Combination toxicology

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

4. Residues

List of Endpoints

The evaluation of Corzal SE is based on the most recent List of Endpoints of phenmedipham on residues (October 22nd, 2003)

List of Endpoints

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

Plant groups covered	Root vegetables (sugar beet), leafy crops (spinach), fruits (strawberry), pulses (pea)
Rotational crops	-
Plant residue definition for monitoring	phenmedipham
Plant residue definition for risk assessment	phenmedipham
Conversion factor (monitoring to risk assessment)	-

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

Animals covered	Cow and hen
Animal residue definition for monitoring	MHPC expressed as phenmedipham
Animal residue definition for risk assessment	phenmedipham and MHPC
Conversion factor (monitoring to risk assessment)	1*
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	potential to accumulate

** Phenmedipham was included in the residue definition for unclear reasons since it was not found in animal tissue. A conversion factor of 1 is used in the EU.*

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

-

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

Parent compound is stable at –10 °C for at least 5 months in processed commodities of sugar beets (cosettes, dry pulp and molasses). Parent compound is stable at –20 °C for at least 24 months in sugar beets.

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

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: Yes	Poultry: Yes	Pig: no studies
Muscle	-	4 ng/g (skeletal muscle) 3 ng/g (skeletal muscle/ breast)	-

Liver	112 ng/g (MPC label) 150 ng/g (PC label)	16 ng/g	-
Kidney	140 g/g (MPC label) 150 ng/g (PC label)	-	-
Fat	-	7 ng/g (peritoneal fat)	-
Milk	8 ng/g (MPC label) 18 ng/g (PC label)	-	-
Eggs	-	16 ng/g	-

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

Crop/processed crop	Number of studies	Transfer factor	% Transference
Sugar beet/ sugar	4		
Sugar beet/ molasses	1		
Sugar beet/ wet pulp	2		
Sugar beet/ dry pulp	2		
Sugar beet/ pulp	2		
Sugar beet/ thick juice	2		
Sugar beet/ thin juice	2		
Sugar beet/ diffusion juice	2		
Sugar beet/ lime cake	2		
Sugar beet/ cosettes	1		
Sugar beet/ mother lye	1		
Sugar beet/ cuts	1		
Strawberry/ jam	1		

Comments on/additions to List of Endpoints
No comments

4.1 Summary of residue data
The following assessment is based on the Draft Assessment Report for phenmedipham (Finland, 1999-2003) and Review of the existing MRLs for phenmedipham (EFSA Journal 2014;12(8)3807).

4.1.1 Metabolism in plants
In the DAR, metabolism studies were performed with root vegetables (sugar beet), leafy crops (spinach), fruits (strawberry) and pulses (pea). Phenmedipham has been defined as the major residue.

4.1.2 Metabolism in livestock
In the DAR, metabolism studies were performed with phenmedipham in lactating goats and laying hens. Phenmedipham has been extensively metabolised in ruminant matrices. Metabolites MHPC, 3-aminophenol and 3-acetamidophenol have been identified as major compounds. In hens studies phenmedipham has been the major metabolite.

4.1.3 Residue definition (plant and animal)
The current residue definition for monitoring and risk assessment of plant products is phenmedipham for both plant and animal matrices (EFSA Journal 2014;12(8):3807).

4.1.4 Stability of residues

See the List of Endpoints

4.1.5 Supervised residue trials

Strawberry (cGAP-NL: 12x 480 g as/ha, interval 5 days, BBCH 00-59 and BBCH 91-97)
The proposed treatment is before the edible crops are present (BBCH 00-59) and at BBCH 91-97, when the edible part is not present anymore. No residue assessment is required for the proposed growing stages. Moreover, the use on strawberries is already authorised for product Corzal SE, according to a more critical GAP. Therefore, the proposed use falls within the risk envelope of the existing authorisation.

Red beet (cGAP-NL:6x 400 g as/ha, BBCH 10-40, max. 6L/ha, which corresponds to max. 960 g as/ha)
The use on sugar beet is already authorised for the product Corzal SE, according to a more critical GAP. Therefore, the proposed use falls within the risk envelope of the existing authorisation.
Residue data from sugar beet can be extrapolated to red beet.
No exceedance of the current EU-MRL in red beet (0.15 mg/kg) is expected based on the residue data in sugar beet.

Spinach family, except garden orache (cGAP-NL: 2x 160-320 g as/ha, interval 5 days, PHI= 28 days, max. 2L/ha, which corresponds to max. 320 g as/ha).

To support the use of Corzal SE on spinach, the applicant refers to four residue trials with phenmedipham on spinach. The trials have been performed with a more critical GAP (2 x 0.310-0.346 kg as/ha, PHI 12-26 days) than the cGAP requested for Corzal SE. Residues in spinach have been: 2x 0.07, 0.13; 0.20 mg/kg. The current EU-MRL of phenmedipham in spinach is 0.3 mg/kg.

The applicant did not submit trials compliant with the cGAP requested for Corzal SE in spinach, only worst case trials with regard to number of application are available. Applying proportionality is, therefore, not possible. Normally overdosed trials are considered acceptable for national authorisation only if the residue levels demonstrate compliance with the existing MRL. However, in this case, based on the available trials on spinach an MRL of 0.5 mg/kg would be required.

With regard to residues, the national authorisation of proposed extension for minor use of Corzal SE on spinach is accepted in this particular case for the following reasons:

- The cGAP requested for Corzal SE is covered by the EU-GAP evaluated for MRL setting (EFSA Journal 2014;12(8):3807).
- Although the trials submitted by applicant result in an MRL proposal of 0.5 mg/kg, exceedance of the existing MRL of 0.3 mg/kg is not expected since the trials are worst case with regard to total seasonal application rate and the highest residue of 0.2 mg/kg was still lower than the current MRL.
- No unacceptable risk for consumers is identified.

Spinach family, except garden orache has been requested within this application. According to Dutch definition list of permitted uses spinach family includes: spinach, chard, garden orache and purslane. Garden orache has not been requested within this application. The current EU-MRL in purslane is 0.01* mg/kg, therefore, based on the available data in spinach MRL exceedance cannot be excluded. Hence, no authorisation of purslane is possible. The current EU-MRL in chard is 0.3 mg/kg and it can be supported based on the residue trials on spinach and argumentation above.

Authorisation on spinach and chard can be granted for this application.

4.1.6 Residues in succeeding crops
See the List of Endpoints

4.1.7 Residues from livestock feeding studies
No new uses contributing to the dietary burden have been requested within this application. Therefore, the assessment of residues in livestock falls within the existing authorisation.

4.1.8 Processing factors
See the List of Endpoints

4.1.9 Calculation of the ADI and the ARfD
The ADI is based on the NOAEL of 3 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 0.03 mg/kg bw/day (see the List of Endpoints for mammalian toxicology).

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

4.2 Maximum Residue Levels
EU-MRLs are present in Annex II of Regulation (EC) 396/2005.

4.3 Consumer risk assessment

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, during most recent Review of the existing MRLs for phenmedipham (EFSA Journal 2014;12(8):3807).

The maximum TMDI is 8.4% of the ADI for UK infant. The TMDI is 1.5% and 5.7% of the ADI for the Dutch general population and Dutch children ages 1-6, respectively.

Risk assessment for acute exposure through diet
As no ARfD was derived for phenmedipham 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 phenmedipham is currently expected. The requested uses on strawberry, spinach and chard can be authorised within this application. The current EU-MRL in purslane is 0.01* mg/kg, therefore, based on the available data in spinach MRL exceedance cannot be excluded. Hence, no authorisation of purslane is possible.

5. Environmental fate and behaviour

The new uses of Betasana SC applied for in a range of new uses have an equal (or lower) risk for persistence in soil, leaching to groundwater, and emission to surface water and sediment as the already authorised uses. The drinking water criterion is met.
The available and most recent monitoring data in groundwater and surface water have been reviewed and have no consequences for the proposed uses.

6. Ecotoxicology

The *Plant Protection Products and Biocides Regulations* (RGB) published in the Government Gazette (Staatscourant) 188 of 28 September 2007 came into effect on 17 October 2007, while repealing the *Uniform Principles Decree on Plant Protection Products* (BUBG) and the *Regulation elaborating the uniform principles for plant protection products* (RUUBG).

For applications for formulations received and taken into the assessment procedure before 17-10-2007 containing only active substances of the following category

- existing active substances which have not (yet) been placed on Annex I of directive 91/414/EEC
- new active substances or active substances which have already been placed on Annex I of directive 91/414/EEC, **only in the case where the date of taking into the assessment procedure lies before 01-09-2006**

risk assessment is done in accordance with HTB 0.2.

This means that for the current application of Corzal SE, risk assessment is done in accordance with HTB 0.2.

List of Endpoints Ecotoxicology

Ecotoxicology

Terrestrial Vertebrates

Acute toxicity to mammals:	rat: LD50 >8000 mg a.i./kg body weight (formulation >2000 mg/kg)
Acute toxicity to birds:	mallard duck: LD50 and NOEL >2100 mg/kg body weight mallard duck & japanese quail: LD50 >2500 mg/kg body weight, NOEL 2500 mg/kg as in the first study with mallard no effects were found, the higher NOEL value from the last study could be used in the risk assessment
Dietary toxicity to birds:	mallard duck : NOEC 2000 mg/kg feed bobwhite quail: NOEC 5000 mg/kg feed
Reproductive toxicity to birds:	bobwhite quail: NOEC 1200 mg/kg feed
Reproductive toxicity to mammals:	2-generation rat study: NOAEL 100 mg/kg corresponding to 6.8 mg PMP/kg b.w./day

Aquatic Organisms

PMP

	Species	Time scale	Endpoints	Toxicity (mg a.s./l) (unless mentioned differently)
Acute toxicity fish:	Rainbow trout	96 hours	LC50	1.71
	Rainbow trout	96 hours	LC50	6.9 (formulation) 1.1
Long term toxicity fish:	Rainbow trout	21 days	NOEC	0.32
Bioaccumulation fish:	Rainbow trout	64 hours	BCF	165
Acute toxicity	Daphnia magna	48 hours	EC50	0.41

invertebrate:				
	Daphnia magna	48 hours	EC50	5.7 (formulation) 0.9
Chronic toxicity invertebrate:	*Daphnia magna*	21 days	NOEC	0.061
	Daphnia magna	21 days	NOEC	0.025
Acute toxicity algae:	*Selenastrum capricornutum* green alga	72 hours	EbC50 (based on nominal values due to unclear reporting in original study, used in risk assessment as being lowest value)	0.086
Chronic toxicity sediment dwelling organism:	*Chironomus riparius*	28 days	NOEC	0.37
Acute toxicity aquatic plants:	*Lemna minor*	14 days	EbC50 NOEC	0.23 0.028

MHPC

	Species	Time scale	Endpoint	Toxicity (mg/ l)
Acute toxicity fish:	Rainbow trout	96 hours	LC50	75
Acute toxicity invertebrate:	Daphnia magna	48 hours	EC50	14
Acute toxicity algae:	*Pseudokirchneriella subcapitata*	96 hours	EbC50	30

Honeybees

Acute oral toxicity:	>100 µg/bee (product containing 160 g PMP/l) >16 µg/bee (a.i., calculated based on the PMP-content of the product)
Acute contact toxicity:	50 µg/bee

Other arthropod species

Test species	stage	dose	Eadverse effect[1]	Adverse effects[1]

Test species	stage	dose	Eadverse effect[1]	Adverse effects[1]
Typhlodromus pyri	proto-nymphs	480 g PMP/ha 960 g PMP/ha	mortality mortality	0 % 0 %
Aphidius rhopalosiphi	adults on glass plate	480 g PMP/ha 960 g PMP/ha	mortality mortality	63 % 43 %
	extended, adults on barley seedlings	480 g PMP/ha 960 g PMP/ha	mortality fecundity mortality fecundity	7 % + 2 % 0 % 35 %
Poecilus cupreus	adults	480 g PMP/ha 960 g PMP/ha	mortality feeding activity mortality feeding activity	0 % + 15 % 0 % 15 %
Chrysoperla carnea	larvae	480 g PMP/ha 960 g PMP/ha	mortality + fecundity mortality + fecundity	- 12.96 % - 6.18 %
Syrphus corollae	larvae – develop-ment	4.375 % corresp. to 2800 g PMP/ha	mortality	- 38 %
Coccinella septempunctata	larvae	4.3 % corresp. to ca. 2800 g PMP/ha	predatory behaviour	33 %
Erigone atra spiders	adults	1440 g PMP/ha	mortality behaviour feeding	0 % 0 % + 5 %
Chrysopa carnea	larvae - development	2.25 % corresp. to ca. 1400 g PMP/ha	mortality development	0 % 0 %
Tricho-gramma cacoeciae	adults	2.25 % corresp. to ca. 1400 g PMP/ha	parasiting behaviour	29 %
Poecilus cupreus	adults	1430 g/ha	mortality	0 %
Bembidion lampros	adults	1440 g/ha	mortality	0 %
4 species of ground dwelling spiders	adults	0.5 % corresp. to ca. 314 g PMP/ha	mortality	0 %
Aleochara bilineata	adults	1400 g/ha	parasiting behaviour	+ 10 %

[1] *Adverse effect means:*
x % effect on mortality = x % increase of mortality compared to control

y % effect on a sublethal parameter = y % decrease of sublethal parameter compared to control
(sublethal parameters are e.g. reproduction, parasitism, food consumption)

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

Earthworms

Acute toxicity:	LC_{50} = 244 mg/kg (TOP 2 frame formulation), corresponding to 36 mg/kg PMP
Reproductive toxicity:	NOEC = 5 kg PMP/ha, corrected by the factor of 2 for the organic carbon content of the substrate -> 2.5 kg PMP/ha, corresponding to 3.33 mg a.i./kg soil (standard soil bulk density)→ refined NOEC 10.35 mg a.i./kg soil (actual application amount and actual soil bulk density)

Soil micro-organisms

Nitrogen mineralization:	In a lab study no effects with the normal and 10 x maximum field use rate (corresponding to soil concentration of ca. 1.3 and 13 mg PMP/kg soil) compared to control in two soils. In a field study the nitrification rate was in one soil 43 to 30 % lower in the treated soil compared to the unsprayed soil after 2 weeks and at harvesting, when PMP formulation (1 kg PMP/ha) was sprayed as a tank mixture with ethofumesate (0.75 kg/ha). In the other soil the nitrification rate was 58 % higher in the treated soil compared to control. The use rate in this study corresponds to soil concentration of ca. 1.3 mg PMP/kg soil.
Carbon mineralization:	In the previous study slight reversible effects (ca 20 %) on soil respiration was observed with a normal field use rate (1 kg pmp/ha) when sprayed as a tank mixture with ethofumesate. Soil biomass was 28 - 38 % lower in the treated samples at harvesting.

Formulation Data

Acute toxicity to birds

formulation	organism	LD_{50} [mg a.s./kg b.w.]	Remarks
Betasana SC	*Colinus virginianus*	>318	No mortality

Acute toxicity to daphnids

formulation	organism	48-h LC_{50} [mg a.s./L]	Remarks
Betasana SC	*Daphnia magna*	16.2	Based on phenmedipham + metabolite MHPC

Acute toxicity to bees

formulation	organism	LD_{50} [µg a.s./bee]	Remarks
Betasana SC	*Apis mellifera*	>200 (oral) >153 (contact)	None None

Toxicity to non-target arthropods

formulation	Species	Method	Dose [L/ha]	Dose [kg as/ha]	Parameter	Adverse effects [%]	LR_{50} [kg as/ha]
Betasana SC	*Typhlodromus pyri*	Lab.test	7.0	1.12	Mortality Reproduction	61 96	
Betasana SC	*Typhlodromus pyri*	Ext. Lab.test	1.25-20.0	0.20-3.24	Mortality		0,403
Betasana SC	*Aphidius rhopalosiphi*	Lab.test	7.0	1.12	Mortality	92	
Betasana SC	*Aphidius rhopalosiphi*	Ext. Lab.test	7.1	1.15	Mortality Reproduction	2,5 45	
Betasana SC	*Aphidius rhopalosiphi*	Ext. Lab.test	14.2	2.3	Mortality Reproduction	2,5 38	

Acute toxicity to earthworms

formulation	organism	14-day LC_{50} [mga.s./kg]	remarks
Betasana SC	*Eisenia fetida*	76.14	none

It concerns an application for simplified extension of Betasana SC as a herbicide.
The risk of the applied uses is equal to or lower than the risk of the authorised uses with regard to the aspects birds, bees, soil organisms. For aquatic organisms the following restriction sentence is placed on the label, which also applies for the proposed extended uses:

Om in het water levende organismen te beschermen is de toepassing in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien gebruikt wordt gemaakt van minimaal 75% driftreducerende spuitdoppen.

For non-target arthropods an in-field risk could not be excluded in the original authorization. However the guidance of the original authorization stated that the uses could be authorized, if the following warning sentence is included on the label:

Dit middel is gevaarlijk voor niet-doelwit arthropoda. Vermijd onnodige blootstelling.

For non-target plants no risk assessment has been performed in the original authorization. As the formulation under assessment concerns a herbicide, non-target plants are probably at risk. However as this aspect was not included of the original authorization, this has not been assessed.

The risk of the use in spinach is included in the risk envelope for the aspect mammals. The risk of the other uses applied for is not included in the risk envelope for the aspect mammals. Therefore, for all new uses except spinach, a separate risk assessment for mammals is required.

6.1 Effects on birds

The risk for the uses applied for fall within the existing risk envelope. Please refer to the original authorization.

Conclusions birds
The proposed application of the product complies with the RGB.

6.2 Effects on aquatic organisms

The risk for the uses applied for fall within the existing risk envelope. For aquatic organisms the following restriction sentence is placed on the label, which also applies for the proposed extended uses:

Om in het water levende organismen te beschermen is de toepassing in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien gebruikt wordt gemaakt van minimaal 75% driftreducerende spuitdoppen.

Please refer to the original authorization.

Conclusions aquatic organisms
The proposed applications meet the standards for aquatic organisms, provided that a restriction sentence is included on the label.

6.3 Effects on terrestrial vertebrates other than birds

The risk of the use in spinach is included in the risk envelope for the aspect mammals.

The risk of the other uses applied for is not included in the risk envelope for the aspects mammals. For this aspect a separate risk assessment is required for ~~exposre~~exposure via food. For exposure via secondary poisoning or drinking water, all proposed uses fall within the existing risk envelope.

Thus, a risk assessment for mammals via food is presented here for the following uses:

Crop	**Field (F)/ Glasshouse (G)**	**Application rate a.s. [kg/ha]**	**Freq./Int. [days]**	**Time of application**
Strawberries	F	0.080-0.480	12 (5)	BBCH 00-59 (April-May) and BBCH 91-97 (July-August) Maximum 6 L/ha (= 0.96 kg/ha)
Tree nursery (sown)	F	0.160-0.480	6 (5)	BBCH 10-20 (March-June) Maximum 6 L/ha (= 0.96 kg/ha)
Ornamental crops (floriculture crops)	F	0.160-0.480	6 (5)	BBCH 10-30 (March-June) Maximum 6 L/ha (= 0.96 kg/ha)
Plant breeding crops and seed production for arable crops (except maize, cereals, grass seed, hop and elephant grass),	F	0.160-0.480	6 (5)	BBCH 10-40 (March-June) Maximum 6 L/ha (= 0.96 kg/ha)

vegetable and fruit crops, herbs and ornamental crops				
Red beet	F	0.080-0.400	6 (5)	BBCH 10-40 (March-June) Maximum 6 L/ha (= 0.96 kg/ha)

The risk is assessed based on HTB 0.2 (Handboek toelating bestrijdingsmiddelen version 0.2, 2002) as this was also used for the original authorization of the product.

Mammals can be exposed to the active substance phenmedipham by natural food (sprayed insects, seeds, leafs).
The threshold value for mammals is based on the trigger from the RGB. The threshold value for acute exposure is set to 0.1 times the LD_{50} value, and the threshold value for chronic exposure is set to 0.2 times the NOEC. Dietary toxicity is not taken into account for mammals.
Table E.1 presents an overview of toxicity data and resulting threshold values.
In the risk assessment a small mammal with a body weight (BW) of 6 gram (i.e., a mouse), a daily food intake (DFI) of 1.025 g/day and a daily water intake (DWI) van 1.8 g is chosen. For grasslands, cereals and orchards a lagomorph with a body ~~weigth~~weight (BW) of 1200 gram (rabbit) and a intake (DFI) of 500 g/day is chosen.

Table E.1 Overview of threshold values for mammals

Substance	Exposure		Endpoint	Safety factor	Threshold value
			[mg/kg bw]		**[mg/kg bw]**
phenmedipham	Acute	LD_{50}	>8000	10	>800*
			[mg/kg food]		**[mg/kg food]**
	Long term	NOEC	100	5	20

* corrected for indicator species, the acute threshold values are ≥4.8 mg/mammal for a 6 g mammal and ≥960 mg/mammal for a 1.2 kg mammal

6.3.1 Natural food

The initial concentration in food is calculated using the residu-per-unit-dose relationship of Luttik (2001) *et al.* for leafs, leafy crops, fodder crop and small seeds and insects as 25 * application rate* number of applications, and for short grass as 62* application rate* number of applications. A maximum of three applications is summed. In first instance, acute and long term exposure is examined against the $PIEC_{food}$, without taking decline of the residue between applications into account.

Table E.2 presents an overview of the calculated concentrations of the active substance phenmedipham in food.

Table E.2 Overview concentrations in food

Use	Relevant food type	Substance	Rate	RUD *	Max. freq.**	$PIEC_{food}$
			[kg/ha]			**[mg/kg]**
All uses	Leafy crops	phenmedipham	0.96***	25	1	24
Tree nursery	Short grass	phenmedipham	0.96***	62	1	60

Use	Relevant food type	Substance	Rate	RUD *	Max. freq.**	$PIEC_{food}$
			[kg/ha]			[mg/kg]
(avenue/lane trees), plant breeding crops and seed production for fruit crops						

* residue per unit dose according to HTB 0.2
** calculation based on a maximum of 3 applications, but since the maximum total dose rate is used, the maximum frequency is set at 1 in this calculation.
***The dose rate is 0.08-0.48 for strawberries and other uses, and 0.16-0.48 kg/ha for plant breeding crops and production for fruit crops, but for all crops the maximum annual application is set at 0.96 kg/ha. Therefore, the worst case exposure is calculated from a single exposure of 0.96 kg/ha.

Table E.3 presents the threshold exceeding factors at exposure to food. Values > 1 indicate a potential risk.

Table E.3 Threshold exceeding factors for natural food

Use	Substance	Threshold exceeding factors	
		food, acute PIEC*DFI/ $0.1*LD_{50target\ species}$	food, long term PIEC/ 0.2*NOEC
Strawberries and other uses	phenmedipham	<0.0051	**1.2**
Tree nursery (avenue / lane trees), plant breeding crops and seed production for fruit crops	phenmedipham	<0.013	**3.0**

Since the long term exposure is larger than the threshold value, a refinement of the risk assessment is carried out, taking residue decline on the crop in between applications into account. Since the half-life of the formulation on plant material is unknown, a default DT_{50} value of 10 days is used as a first approach (as implied in HTB 0.2 in the formula for MAF calculation). In determining the $PIEC_{food}$ a MAF (Multiple Application Factor) can be applied, if the DT50 value is known, but the maximum MAF that can be applied is 3. The $PEC_{food, long}$ is calculated as time-weighted average over a period of 28 days or interval between applications (if frequency * interval > 28 days). Since the interval*frequency is >28 days for all uses, the ftwa is calculated over the interval in all cases. See Table E.4 for results.

Table E.4 Overview of concentrations in food, taking residue decline on the crop into account

Use	Substance	Rate	RUD *	Max. freq.	interval	MAF	FTwa	$PEC_{food, long}$
		[kg/ha]						[mg/kg]
Strawberries and other uses: exposure via dicotyl plants	phenmedipham	0.96***	25	6-12	5	1**	0.85	20.4

Tree nursery (avenue / lane trees), plant breeding crops and seed production for fruit crops: exposure via short grass	phenmedipham	0.96***	62	6	5	1**	0.85	50.6

* residue per unit dose according to Luttik
** calculation based on a maximum of 3 applications, but since the maximum total dose rate is used, the maximum frequency is set at 1 in this calculation.
***The dose rate is 0.08-0.48 for strawberries and other uses, and 0.16-0.48 kg/ha for plant breeding crops and production for fruit crops, but for all crops the maximum annual application is set at 0.96 kg/ha. Therefore, the worst case exposure is calculated from a single exposure of 0.96 kg/ha.

Table E.5 presents the threshold exceeding factors at exposure to food taking residue decline in account.

Table E.5 Threshold exceeding factors for natural food, taking residue decline on the crop into account

Use	**Substance**	**Threshold exceeding factors**
		food, long term $PEC_{food, long}$ / 0.2*NOEC
Strawberries and other uses: exposure via dicotyl plants	phenmedipham	**1.02**
Tree nursery (avenue / lane trees), plant breeding crops and seed production for fruit crops: exposure via short grass	phenmedipham	**2.53**

Taking the results in Table E.5 into account, it appears that all proposed uses still exceed the threshold. For most uses (strawberry, ornamental crops, redbeets and scenarios for tree nurseries and plant breeding and seed production for crops without grass underground vegetation), the threshold exceeding level is only 1.02. Considering that phenmedipham is a carbamate, which dissipates quickly from the environment (see also Sanco 2000 guidance and EFSA 2009 guidance), the exposure will probably be lower, and the risk is considered to be acceptable. For orchard-like uses such as avenue trees, lane trees and fruit crops (which may have a grassy underground vegetation), the threshold exceeding level is 2.5 and a risk cannot be excluded.
Hence, for those uses that pose a risk it must be demonstrated by means of an adequate risk assessment that there are no unacceptable effects under field conditions after application of the plant protection product according to the proposed GAP, for example a study into the actual decline of the residue on the crop.

Refined risk assessment
The applicant has made a GAP change: 3 applications with 0.32 kg a.s./ha, and an interval of 12 days. Since the frequency has been reduced to a maximum of 3, a 28d twa can be used.

Table E.4 Overview of concentrations in food, taking residue decline on the crop into account

Use	Substance	Rate	RUD *	Max. freq.	interval	MAF	FTwa	$PEC_{food, long}$
		[kg/ha]						[mg/kg]
Tree nursery (avenue / lane trees), plant breeding crops and seed production for fruit crops: exposure via short grass	phenmedipham	0.96***	62	3	12	1**	0.44	26.2

Table E.5 Threshold exceeding factors for natural food, taking residue decline on the crop into account

Use	Substance	Threshold exceeding factors
		food, long term $PEC_{food, long}$ / 0.2*NOEC
Tree nursery (avenue / lane trees), plant breeding crops and seed production for fruit crops	phenmedipham	**1.31**

Based on the calculations given above, the threshold is still exceeded. However it should be taken into account that the total annual dose rate is summed, without taking into account the dissipation between applications.

If, as a realistic worst-case, a MAF is calculated with a worst-case DT50 of 10 day, and an interval period of 12 days is taken into account, the risk will be as follows:

Table E.6 Overview of concentrations in food, taking residue decline on the crop into account

Use	Substance	Rate	RUD *	Max. freq.	interval	MAF	FTwa	$PEC_{food, long}$
		[kg/ha]						[mg/kg]
Tree nursery (avenue / lane trees), plant breeding crops and seed production for fruit crops: exposure via short grass	phenmedipham	0.32	62	3	12	1.6	0.44	13.97

Table E.7 Threshold exceeding factors for natural food, taking residue decline on the crop into account

Use	Substance	Threshold exceeding factors
		food, long term $PEC_{food, long}$ / 0.2*NOEC
Tree nursery (avenue / lane trees), plant breeding crops and seed production for fruit crops	phenmedipham	0.7

The threshold exceeding value in table E.7 is below 1, indicating acceptable risk under the relevant framework for risk assessment, which is the evaluation manual of 2002 (HTB 0.2). The Ctgb notes that the risk assessment for mammals described in HTB 0.2 is outdated and much less conservative than more recent guidances (Sanco 4145/2000 and EFSA 2009), especially in the long term. Based on these newer guidances, a long-term risk is indicated for mammals in crops with grassy underground (with threshold exceeding factors ca.5, meaning that the expected exposure is five time as high as the acceptable exposure).

Conclusions mammals
The proposed application of the product complies with the RGB for the application in tree nursery and plant breeding crops and seed production for fruit crops.

6.4 Effects on bees

The risk for the uses applied for fall within the existing risk envelope. Please refer to the original authorization.

Conclusions bees
The product complies with the RGB.

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

6.5.1 Effects on non-target arthropods

The risk for the uses applied for fall within the existing risk envelope. A risk cannot be excluded. The following warningsentences has been included on the label:
Dit middel is gevaarlijk voor niet-doelwit arthropoda. Vermijd onnodige blootstelling.
Please refer to the original authorization.

6.5.2 Earthworms

The risk for the uses applied for fall within the exsisting risk envelope. Please refer to the original authorization.

6.5.3 Effects on soil micro-organisms

The risk for the uses applied for fall within the existing risk envelope. Please refer to the original authorization.

6.5.4 Effects on activated sludge

The risk for the uses applied for fall within the existing risk envelope. Please refer to the original authorization.

6.5.5 Effects on non target-plants

For non-target plants no risk assessment has been performed in the original authorization. As the formulation under assessment concerns a herbicide, non-target plants are probably at risk. However as this aspect was not included in the original authorization, this has not been assessed.

Conclusions any other organisms

The product does comply with the RGB for the aspects earthworms, soil micro-organisms and activated sludge. For non-target arthropods an in-field risk could not be excluded in the original authorizaiton. The following warning sentence has been included on the label: *Dit middel is gevaarlijk voor niet-doelwit arthropoda. Vermijd onnodige blootstelling.*
For non-target plants no risk assessment has been performed in the original authorization. As the formulation under assessment concerns a herbicide, non-target plants are probably at risk. However as this aspect was not included of the original authorization, this has not been assessed.

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

See List of End-points.

6.7 Data requirements

None

6.8 Restriction sentences (already on the label)

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

Om in het water levende organismen te beschermen is de toepassing in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien gebruikt wordt gemaakt van minimaal 75% driftreducerende spuitdoppen.

Dit middel is gevaarlijk voor niet-doelwit arthropoda. Vermijd onnodige blootstelling.

6.9 Overall conclusions ecotoxicology

It can be concluded that:

1. all proposed applications of the formulated product Corzal SE meet the standards for birds as laid down in the RGB.
2. all proposed applications of the the formulated product Corzal SE meet the standards for aquatic organisms as laid down in the RGB, provided that a restriction sentence is placed on the label.
3. the active substance phenmedipham meets the standards for bioconcentration as laid down in the RGB.
4. The proposed applications of the formulated product Corzal SE meet the standards for mammals as laid down in the RGB.
5. all proposed applications of the the formulated product Corzal SE meet the standards for bees as laid down in the RGB.
6. all proposed applications of the the formulated product Corzal SE meet the standards for non-target arthropods as laid down in the RGB , provided that the following warning sentence is included on the label: *Dit middel is gevaarlijk voor niet-doelwit arthropoda. Vermijd onnodige blootstelling*
7. all proposed applications of the formulated product Corzal SE meet the standards for earthworms as laid down in the RGB.
8. all proposed applications of the formulated product Corzal SE meet the standards for soil micro-organisms as laid down in the RGB.
9. all proposed applications of the active substance phenmedipham meet the standards for activated sludge as laid down in the RGB
10. For non-target plants no risk assessment has been performed in the original authorization. As the formulation under assessment concerns a herbicide, non-target plants are probably at risk. However as this aspect was not included of the original authorization, this has not been assessed.

7. Efficacy

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

8. Conclusion

During the assessment the applicant requested to change the GAP. The product complies with the Uniform Principles, when the following restriction sentences are stated on the label (already stated on the label):

“Om in het water levende organismen te beschermen is de toepassing in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien gebruikt wordt gemaakt van minimaal 75% driftreducerende spuitdoppen.”

“Dit middel is gevaarlijk voor niet-doelwit arthropoda. Vermijd onnodige blootstelling.”

9. Classification and labelling

The classification and labelling does not change.

Appendix 1 Table of new authorised minor uses

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	Strawberries	F	Annual dicotyledonous weeds	Broadcast spray	BBCH 00-59 (April-May) and BBCH 91-97 (July-August)	12 (5)	0.5-3 L/ha	80-480 g a.s./ha	200/400	-	b) Maximum 6 L/ha
2	NL	~~Spinach family except garden orache~~	~~F~~	~~Annual dicotyledonous weeds~~	~~Broadcast spray~~	~~BBCH 10-40 (March-May)~~	~~2 (5)~~	~~1-2 L/ha~~	~~160-320 g a.s./ha~~	~~200/400~~	~~28~~	~~b) Maximum 2 L/ha/crop cycle~~
	NL	Spinach	F	Annual dicotyledonous weeds	Broadcast spray	BBCH 10-40 (March-May)	2 (5)	1-2 L/ha	160-320 g a.s./ha	200/400	28	b) Maximum 2 L/ha/crop cycle
	NL	chard	F	Annual dicotyledonous weeds	Broadcast spray	BBCH 10-40 (March-May)	2 (5)	1-2 L/ha	160-320 g a.s./ha	200/400	28	b) Maximum 2 L/ha/crop cycle
3	NL	Tree nursery (sown)	F	Annual dicotyledonous weeds	Broadcast spray	BBCH 10-20 (March-June)	6 (5)	1-3 L/ha	160-480 g a.s./ha	200/400	-	b) Maximum 6 L/ha c) apply only in first planting season
4	NL	Ornamental crops (floriculture crops)	F	Annual dicotyledonous weeds	Broadcast spray	BBCH 10-30 (March-June)	6 (5)	1-3 L/ha	160-480 g a.s./ha	200/400	-	b) Maximum 6 L/ha
5	NL	Plant breeding crops and seed production for arable (except maize, cereals, grass seed, hop and elephant grass), vegetable and fruit crops, herbs and ornamental crops	F	Annual dicotyledonous weeds	Broadcast spray	BBCH 10-40 (March-June)	6 (5)	1-3 L/ha	160-480 g a.s./ha	200/400	-	b) Maximum 6 L/ha
6	NL	Red beet	F	Annual dicotyledonous weeds	Broadcast spray	BBCH 10-40 (March-June)	6 (5)	0.5-2.5 L/ha	80-400 g a.s./ha	200/400	-	b) Maximum 6 l/ha

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.

NA