HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. BESLUIT

Op 16 september 2014 is van

UPL Europe Ltd.
1st Floor, The Centre, Birchwood Park
WARRINGTON, Cheshire WA3 6YN
GROOT-BRITTANNIE

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

Betasana SE

op basis van de werkzame stof fenmedifam.

HET COLLEGE BESLUIT tot toelating van de aangevraagde wijziging van het Wettelijk Gebruiksvoorschrift voor het 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 conform de geldende regelgeving op of bij de verpakking te worden vermeld:

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

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

1.4 Aflever- en opgebruiktermijn (respijtperiode)

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

2. WETTELIJKE GRONDSLAG

Besluit	Artikel 45 van de Verordening (EG) 1107/2009
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Conform Bgb en Rgb d.d. 16 december 2011 en Evaluation Manual Zonaal 2.0.

3. BEOORDELINGEN

Voor de beoordeling van de aangevraagde wijziging is uitgegaan van de laatste volledige beoordeling;

3.1 Fysische en chemische eigenschappen

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

3.2 Analysemethoden

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

3.3 Risico voor de mens

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

3.4 Risico voor het milieu

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

3.5 Werkzaamheid

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

Bezwaarmogelijkheid

Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 8030, 6710 AA, EDE. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Wageningen, 23 december 2015

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

2.1 Aanvraaginformatie

Aanvraagnummer:	20146195 NLWG
Type aanvraag:	aanvraag tot wijziging van nationaal addendum
Middelnaam:	Betasana SE
Verzenddatum aanvraag:	15 september 2014
*Formele registratiedatum: **	16 oktober 2014
Datum in behandeling name:	
Datum compliance check:	nvt

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

2.2 Stofinformatie

Werkzame stof	Gehalte
fenmedifam	160G/L

Fenmedifam is per 1 maart 2005 opgenomen in Bijlage I van Richtlijn 91/414/EEC .
De stof is goedgekeurd onder Verordening 1107/2009 (nummer 88).
Bij Reg No 1197/2012 is de toelatingstermijn verlengd tot 31/07/2017.

2.3 Toelatingsinformatie

Toelatingsnummer:	13234 N
Expiratiedatum:	1 september 2019
Afgeleide parallel of origineel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel

W-coderingen en aflever- en opgebruiktermijnen:

- *W-codering professioneel gebruik:* 3
- *Vorige w-codering professioneel gebruik:* 2
- *Aflevertermijn professioneel gebruik:* onbeperkt
- *Opgebruiktermijn professioneel gebruik:* onbeperkt

2.4 Verpakkingsinformatie

Aard van het preparaat:
Suspo-emulsie

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BIJLAGE II Etikettering van het middel Betasana 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. H410 Zeer 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.
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

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BIJLAGE III WG van het middel

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

Toepassing	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]	8x per teeltcyclus	8 l/ha per teeltcyclus	7
			1-1,5 l/ha	8x per teeltcyclus		
			2-2,5 l/ha	4x per teeltcyclus		
	Rijenbehandeling na opkomst	Eenjarige breedbladige onkruiden	0,25-0,37 l/ha [1]	8x per teeltcyclus		
			0,5-0,75 l/ha	8x per teeltcyclus		
			1-1,25 l/ha	8x per teeltcyclus		
Aardbei (onbedekte teelt)	Voor bloei, na oogst of na uitplanten	Eenjarige breedbladige onkruiden	4-8 l/ha	2x per 12 maanden	8 l/ha per 12 maanden	10

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

Toepassingsvoorwaarden

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.

Resistentiemanagement
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 Onderbouwing

Contents

1. Identity of the plant protection product

1.1 Applicant
UPL Europe Ltd.
1st floor, The Centre, Birchwood Park
Warrington WA3 6YN
United Kingdom

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

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

1.4 Function
Herbicide.

1.5 Uses applied for
See GAP (Appendix I).

1.6 Background to the application
Label amendment.
By the transposal from WGGA to WG, a maximum number of applications was incorporated in the WG. Application was made to change this number of applications in strawberry and beets in line with the common practice. The total maximum quantity will not increase as a result of this change.

1.7 Packaging details
Packaging details remain the same.

2. Physical and chemical properties

Physical and chemical properties remain the same

3. Methods of analysis

Physical and chemical properties remain the same.

4. Mammalian toxicology

No changes occur concerning mammalian toxicology.

5. Residues

No changes occur concerning residues.

6. Environmental fate and behaviour

Strawberry

The adjusted use of Betasana SE applied for in strawberry has an equal or lower risk for persistence in soil and emission to surface water and sediment as the already authorised use.
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.

Beets
The adjusted uses of Betasana SE applied for in beets have an equal risk for persistence in soil, emission to surface water and sediment as the already authorised use.
The adjusted use of Betasana SE applied for in beets do not have an equal risk for leaching to groundwater as the already authorised use. For this aspect a separate risk assessment is required.

Risk assessment leaching to groundwater
As for the original risk assessment of Betasana SE (20040042 TG), the List of Endpoints used for the evaluation of the leaching behaviour of the substance regarding the application for adjustment of the label is taken from the Review Report dd 13-02-2004 (SANCO/4060/2001 – final).

List of Endpoints Fate/behaviour (Review Report phenmedipham)

Route of degradation

Aerobic:

Mineralization after 100 days:	CO_2 evolved: 13.3 – 16.5 % of AR within 120 days, AP ^{14}C-labelled, low temperature/low moisture (n=1) 9.7 – 11.3 % of AR within 120 days, phenoxy ring – U-^{14}C labelled (n=3)
Non-extractable residues after 100 days:	63.6 – 64.1 % of AR within 120 days, AP ^{14}C-labelled, low temperature/low moisture (n=1) 71.3 – 73.8 % of AR within 120 days phenoxy ring –U-^{14}C labeled (n=3)
Major metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	MHPC max 14 % of AR at day 14 (n=1) APMP max 4 % of AR after 56 days (n=1) (label position AP) MHPC max 54 % at day 5 (n=1, ring-U-labelled)

Supplemental studies

Anaerobic:	CO_2 evolved 6.6 % of AR, NER 74.3 % of AR after 97 days, MHPC max 19 % of AR after 32 days (label position AP, n=1)
Soil photolysis:	DT_{50} 79 hours on irradiated soil photochemical products: 3-aminophenol and 3-methoxycarbonylaminophenol max 17.8 % of AR (sum of all polar products) after 105 hours of irradiation (n=1)
Remarks:	None

Rate of degradation

Laboratory studies

DT_{50}lab (20 °C, aerobic):	26, 42, 43 d, mean=37 days (n=3, r^2 = 0.932 - 0.953) *MHPC: 12, <3, <3 d, mean= 6 d*
DT_{90}lab (20 °C, aerobic):	85, 138, 143 days (n=3, r^2 = 0.932 – 0.953)
DT_{50}lab (10 °C, aerobic):	27 days
DT_{50}lab (20 °C, anaerobic):	15 days (n=1, r^2 = 0.934)

Field studies (country or region)

DT_{50f} from soil dissipation studies:	first order kinetics, DT_{50f}: Germany, bare soil, four sites: 5.8 days at pH 5.0, 9.0 days at pH 6.9, 15.7 days at pH 7.1, 39.9 days at pH 6.0, mean 17.6 days (n=4, r^2 not available, 1st order) USA, California, one site: sandy loam, on red beet stage 4-6 leaf: 13.3 days at pH 7.0 (n=1, r^2 not available, 1st order) metabolites: no DT_{50} values calculated in the field studies
DT_{90f} from soil dissipation studies:	DT_{90f}: Germany, sites described above: range 30 - 133 days, mean 82 days (n=4 , r^2 not available, 1st order)
Soil accumulation studies:	no data submitted nor required
Soil residue studies:	no data submitted nor required

Remarks: e.g. effect of soil pH on degradation rate	no clear pH dependence

Adsorption/desorption

K_f / K_{oc}: PMP	K_{oc}: PMP: 657, 934, 1072, mean = 888, 1/n = 0.821, 0.865, 0.854 (soil samples, n = 3, equilibrium time 2.5 hours) 469, 728, mean = 599, 1/n = 0.82, 0.84 (sediments, n=2, equilibrium time 3 hours)
MHP	K_{oc}: MHPC: 212, 138, 58, 470, mean = 220, 1/n = 0.515, 0.699, 0.949, 0.805 (n = 4, one outlier excluded) K_d: MHPC: 0.57 - 4.8
pH dependence:	Yes, due to the hydrolysis processes which indirect affect the adsorption of parent. No dependence for the metabolites. For FOCUS gw modelling with FOCUS_PEARL v. 1.1.1 following median K_{om} values were used: PMP: 422, 1/n = 0.84

	MHPC: 101, 1/n = 0.752

Mobility

Laboratory studies:

Column leaching:	1) Guideline: US EPA subdiv. N, para 163.1 Precipitation: 920 ml corresponding to 50.8 cm rainfall in 10 days (92 ml/d) Soils: 2 soils, label positions AP and T Use rate: 0.825 kg/ha (AP) and 1.1 kg/ha (T) Leachate: total residue 0.33 - 0.45 % of AR in leachates, not characterized further Soil columns: total residue 88.1 – 92.6 % of AR in soil columns (mainly in the top 5 cm), NER 43.1 – 53.1 % and 34.9 – 60.4 % extractable of it Volatiles 3.72 – 7.27 % of AR during the leaching period. 2) Guideline: US EPA subdiv. N, para 163.1 Precipitation: 560 mm in 5 days Soil: 2 soils, label positions AP and T Use rate 1.65 kg/ha Leachate: total residue 0.6 - 2.3 % of AR in leachates, not characterized further Soil columns: total residue 89.5 – 95.4 % of AR in soil columns (mainly in the top 10 cm), extractable 26 – 64 % of it, mainly unchanged parent Volatiles not trapped. 3) Guideline: BBA Precipitation: 200 ml/day for 2 days Soils: 3 soils, label position AP Use rate: 1.5 kg/ha Leachate: total residue <0.5 % of AR in leachates, not characterized further
Aged residue leaching:	1) Guideline: BBA Soils: 1 soil, German standard soil 2.1 Use rate: 960 g/ha, label position T Aged at 20 degrees C, 40 % MWHC, for 33 days Precipitation: 2 days irrigation of 200 mm Leachate: 0.48 % of AR was found in the leachate, not characterized further Soil column: 96.2 % of AR remained in soil, mainly in the top 10 cm Volatiles: 5.7 % of AR. 2) Guideline: EPA Vol 40, No 123, Part II, 1975 Soils: 2 soils, German standard soils 2.2 and 2.3 Use rate: 1.25 kg/ha, label position AP Aged at 25-30 degrees C, 70 % MWHC, for 30 days Precipitation: 45 days irrigation of 125 mm/day Leachate: 0.58 and 1.66 % of AR was found in the leachates, not characterized further Soil column: 99.1 – 112.9 % of AR remained in the soil, mainly in the top 6 cm. The aged soil was not analysed further

	for the metabolites. 3) Guideline: EPA Vol 40, No 123, Part II, 1975 Soils: 2 soils, German standard soils 2.2 and 2.3 Use rate: 1.65 kg/ha on soil 2.2 and 1.25 kg/ha on soil 2.3, label position T Aged at 25-30 degrees C, 75 % MWHC, for 30 days Precipitation: 45 days irrigation of 125 mm/day Leachate: 1.37 - 1.83 % of AR was found in the leachates, not characterized further Soil column: 72.9 – 88.7 % of AR remained in the soil, mainly in the top 5 cm. The aged soil was not characterized further for the metabolites.
Field studies: Lysimeter/Field leaching studies:	1) Location: UK Study type: lysimeter Soils: loamy sand, low content of organic matter Number of applications: one single application of 0.942 kg/ha in the first year, study continued over 2 years Crops: sugar beet + wheat Average annual rainfall: 757 mm (1st year), 948 mm (2nd year) Average annual leachate volume: 200 mm/ first year (25 % of the precipitation), 445 mm/ second year (47 % of the precipitation) % radioactivity in the leachate (max/year): after 2 years totally 0.8 - 1.1 % of AR was leached Peak annual average concentrations: total radioactive residues 1.28 – 1.9 µg/l in the first year, 1.1 – 1.33 µg/l in the second year (40 % of AR in leachate attributed to humic acid type fragments and up to 27 % incorporated with naturally occurring compounds), MHPC 0.006 µg/l, PMP could not be detected in any of the samples (LOD = 0.03 µg/l Phenmedipham a.s.equivalents). 2) Location: Germany Study type: lysimeter Soils: loamy sand with low organic matter content Number of applications: 1.0 kg/ha either once or in two successive years, study continued for up to 3 years Crops: sugar beet (1 or 2 successive years) + wheat Average annual rainfall: 860 mm/year (cumulative sum of 2582 mm within 3 years) Average annual leachate volume: 428 mm % radioactivity in the leachate (max/year): after 2 years totally 0.22 - 0.32 % of AR was leached Peak annual average concentrations: total radioactive residues 0.314 – 0.805 µg/l (water soluble humic acid-type components, due to the low radioactivity the further characterization was not possible). MHPC was calculated as <0.01 µg as equivalents/l. (LOQ = 0.017 µg/l for PMP and 0.010 µg/l for MHPC).
Remarks:	No groundwater contamination expected

Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:

DT_{50}	DT_{90}	r^2
pH 4: 259 d	861 d	-0.9726
pH 5: 47 d	156 d	-0.9958
pH 7: 12 h	39 h	-0.9922
pH 9: 7 min	24 min	-0.9860

(25 °C, 1st order kinetics)

Major metabolites: MHPC

Photolytic degradation: no degradation (artificial light source, λ > 290 nm)

Major metabolites: None

Biological degradation

Readily biodegradable: no

Water/sediment study:

DT_{50} water: 0.1 – 0.3 days (√t/1st order, r^2 = 0.989, 0.544, n=2)

DT_{90} water: 0.6 – 3.4 days (√t/1st order, r^2 = 0.989, 0.544, n=2)

DT_{50} whole system: 0.11, 0.12, 0.18 days (1st order kinetics, r^2 = 0.942 – 0.978, n=3)
MCPA: 20-22 days (n=3, taken from monograph)

DT_{90} whole system: 0.38, 0.40, 0.60 days (1st order kinetics, r^2 = 0.942 – 0.978, n=3)

Distribution in water / sediment systems (active substance): 1 - 2 % of AR in water phase and
51 - 55 % in sediment after 126 days
(non-sterilised samples, 2 label positions, 2 systems),
44 - 51 % of AR in water and
39 - 44 % in sediment after 126 days (sterilised samples, 1 label position, 2 systems).

Distribution in water / sediment systems (metabolites): MHPC: 60 - 70 % of AR within 1 - 2 days
1 % of AR after 126 days

Accumulation in water and/or sediment: Due to quite rapid degradation of PMP and MHPC no accumulation is expected

Degradation in the saturated zone: no data submitted nor required

Remarks: *Rapid hydrolysis of PMP in neutral and alkanline pH to MHPC*

Fate and behaviour in air

Volatility

Vapour pressure: 7×10^{-10} Pa at 25 °C

Henry's law constant: 5×10^{-8} Pa x m^3 x mol^{-1}

Photolytic degradation

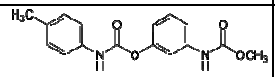
Direct photolysis in air:	not studied, no data required
Photochemical oxidative degradation in air DT_{50}:	6.7 hours derived by the Atkinson method of calculation
Volatilisation:	from plant surfaces: no data from soil surface: no data

Remarks:

PECair considered negligible

Appendix A: Metabolite names, codes and other relevant information of the plant protection product Betasana SE with active substance phenmedipham.

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

Compound name	IUPAC name	Structural formula	Structure	Molecular Weight [g/mol]	Observed in study (% of occurrence / formation)
phenmedipham	[3- (methoxy carbonylamino)phenyl] N-(3-methylphenyl)carbamate	$C_{16}H_{16}N_2O_2$		300.31	Parent substance
MHPC				167.27	soil aeroob: max. 54%

6.1.2 Leaching to shallow groundwater

The leaching potential of the active substance phenmedipham and metabolite MHPC is calculated in the first tier using Pearl 2.2.2 in line with the original assessment of Betasana SE and the FOCUS Kremsmünster scenario. Input variables are the actual worst-case application rate of 0.64 kg a.s./ha, the crop strawberry and an interception value appropriate to the crop stage of 0.2 (in line with original assessment). First date of yearly application is May 25th (default). For metabolites all available data concerning substance properties are regarded. Metabolite MHPC has been included in the calculations. 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:

PEARL:

<u>Active substance phenmedipham:</u>
Mean DT_{50} for degradation in soil (20°C): 37 days
Mean K_{om} (pH-independent): 522 L/kg
1/n: 0.9 (default)

Saturated vapour pressure: 7.0 E-10 Pa (25^0C)
Solubility in water: 1.8 mg/L (20^0C)
Molecular mass: 300.3 g/mol

Plant uptake factor: 0 (default)
Q10: 2.2

Metabolite MHPC:
Mean DT_{50} for degradation in soil (20°C): 6 days
Mean K_{om} (pH-independent): 129 L/kg
1/n: 1 (default)

Saturated vapour pressure: 7.0 E-10 Pa (25^0C, parent value)
Solubility in water: 0.0018 g/L (20^0C, parent value)
Molecular mass: 167.27 g/mol

Maximum occurrence: 54%

Plant uptake factor: 0 (default)
Q10: 2.2

Other parameters: standard settings of PEARL 2.2.2

The following concentrations are predicted for the a.s. phenmedipham following the realistic worst case GAP, see Table M.1a.

Table M.1 Leaching of active substance phenmedipham as predicted by PEARL 2.2.2, following spring application.

Use	Substance	Rate substance [kg/ha]	Frequency	Interval [days]	Fraction Intercepted *	PEC groundwater [µg/L]
Strawberry	phenmedipham	0.64	2	10	0.2	<0.001
	MHPC	**				<0.001

* interception value used for PEARL 2.2.2 calculations is taken from the risk assessment of the original application of Betasana SE.
** calculations using transformation scheme

Results of Pearl 2.2.2 using the Kremsmünster scenario are examined against the standard of 0.01 µg/L. This is the standard of 0.1 µg/L with an additional safety factor of 10 for vulnerable groundwater protection areas (NL-specific situation).

From Table M.1 it reads that the expected leaching based on the PEARL-model calculations for the active substance phenmedipham and metabolite MHPC is smaller than 0.01 µg/L for all proposed applications. Hence, the applications meet the standards for leaching as laid down in the RGB.

Lysimeter/field leaching studies
No lysimeter/ field leaching studies standardized to NL conditions are available.

Monitoring data
There are no data available regarding the presence of the substance phenmedipham in groundwater.

Conclusions
The proposed application of the product Betasana SE complies with the requirements laid down in the UB concerning leaching to groundwater.

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

See List of Endpoints.

6.5 Data requirements

-

The following restriction sentences were proposed by the applicant:

-

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

-

6.6 Overall conclusions fate and behaviour

The adjusted use of Betasana SE applied for in strawberry has an equal or lower risk for persistence in soil and emission to surface water and sediment as the already authorised use.
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.

The adjusted use of Betasana SE applied for in beets have an equal risk for persistence in soil, leaching to groundwater and emission to surface water and sediment as the already authorised use.

7. Ecotoxicology

The risk of the applied use in strawberries and sugar and fodder beets is equal to or lower than the risk of the authorised uses with regard to the environment for the aspects birds and mammals, aquatic organisms, bees, non-target arthropods, soil organisms, non-target plants and activated sludge.

8. Efficacy

Betasana SE is currently authorised for control of annual broadleaved weeds in beets at three dose rate ranges (0.5-0.75, 1-1,5 and 2-2,25 l/ha) and in strawberry at 4-8 l/ha with a total maximum of 8 l/ha. In beets up to three applications are allowed and in strawberry one application.

The applicant has applied for an extension of the label, on the new label in beets up to eight applications can be applied and in strawberry two applications. The total maximum dose of 8 l/ha is unchanged, the new label will allow more flexibility in spray programmes, and will allow longer spray programmes, especially at low dose rates, for example, under the low dosage system (LDS).

8.1 Efficacy evaluation

Beets
The applied dose rates, interval and the maximum total dose are unchanged. Therefore effectiveness has already been proven in the previous evaluation of the authorised product.

Strawberry
The applied dose rate and the maximum total dose are unchanged. Therefore effectiveness has already been proven in the previous evaluation of the authorised product.

Conclusion
The evaluation complies with the Uniform Principles, article 2.1.

8.2 Harmful effects

8.2.1 Phytotoxicity
Beets
The applied dose rates and the maximum total dose are unchanged. The spray programme changes, but it is not expected that this will lead to a higher risk for phytotoxicity. Therefore crop safety has already been proven at the previous evaluation of the authorised product.

Strawberry
The applied dose rates and the maximum applied dose rate per season remain the same. The current authorisation is expected to be worst case for phytotoxicity compared to the split application, where the product is applied at lower dose rates, and over a longer time frame.

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

8.3 Resistance
The current label does not have a resistance management warning.
According to the new label, more applications at a lower dose rate are possible. Therefore a higher resistance risk is expected. A resistance management sentence has to be placed on the label:

> *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.*

Conclusion
The evaluation complies with the Uniform Principles, article 2.1.3. The level of control on the long term is not influenced by the use of this product because of the possible build up of resistance.

Data requirements
None

Restriction sentences
The following restriction sentences have to be placed on the legal instructions (WG) additionally or alternatively to the sentences provided by the applicant, according to the efficacy evaluation:

> *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.*

9. Conclusion

The proposed application of the product Betasana SE complies with the requirements laid down in the Uniform Principles UB.

10. Classification and labelling

Classification and labelling does not change.

Restriction sentences
The following restriction sentences have to be placed on the legal instructions (WG) additionally or alternatively to the sentences provided by the applicant, according to the efficacy evaluation:

> *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**.***

Appendix 1 Table of authorised 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)	kg, L product / ha	g, kg as/ha	Water L/ha min / max		
1	NL	Sugar Beet and Fodder Beet	F	Annual dicotyledonous weeds	Broadcast spray	After crop emergence or weed re-emergence Weeds. BBCH 10-11	8 (7-10)	0.5-0.75 l/ha	0.08-012	150-300	-	LDS, applied with other herbicides Per crop a maximum of 8 L product/ha (1.28 kg fenmedifam/ha)
2	NL	Sugar Beet and Fodder Beet	F	Annual dicotyledonous weeds	Row treatment	After crop emergence or weed re-emergence Weeds. BBCH 10-11	8 (7-10)	0.25-0.37 l/ha	0.04-0.06	150-300	-	LDS, applied with other herbicides Per crop a maximum of 8 L product/ha (1.28 kg fenmedifam/ha)
3	NL	Sugar Beet and Fodder Beet	F	Annual dicotyledonous weeds	Broadcast spray	After crop emergence or weed re-emergence Weeds. BBCH 11-12	8 (7-10)	1-1.5 l/ha	0.16-0.24	150-300	-	Per crop a maximum of 8 L product/ha (1.28 kg fenmedifam/ha)
4	NL	Sugar Beet and Fodder Beet	F	Annual dicotyledonous weeds	Row treatment	After crop emergence or weed re-emergence Weeds. BBCH 11-12	8 (7-10)	0.5-0.75	0.08-0.12	150-300	-	Per crop a maximum of 8 L product/ha (1.28 kg fenmedifam/ha)
5	NL	Sugar Beet and Fodder Beet	F	Annual dicotyledonous weeds	Broadcast spray	Weeds: BBCH>12	4 (7-10)	2-2.5 l/ha	0.32-0.40	150-300	-	Per crop a maximum of 8 L product/ha (1.28 kg fenmedifam/ha)
6	NL	Sugar Beet and Fodder Beet	F	Annual dicotyledonous weeds	Row treatment	Weeds: BBCH>12	8 (7-10)	1-1.25 l/ha	0.16-0.20	150-300	-	Per crop a maximum of 8 L product/ha (1.28 kg fenmedifam/ha)
7	NL	Strawberry	F	Annual dicotyledonous weeds	Overall spray over crop	april-mei, juli-aug	2 (10-14)	4-8 l/ha*	0.64-1.28	600-1000	-	Apply before flowering and after harvest *total volume per 12 months 8l/ha (1.28 kg fenmedifam/ha)

Appendix 2 Reference list

No new studies were submitted.