10319 N

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

Oblix 500 SC

op basis van de werkzame stof ethofumesaat.

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

De wijziging betreft de toevoeging van een Laag Doserings Systeem (LDS) in de toepassing van bieten.

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)

De toevoeging van de toepassing middels het Laag Doserings Systeem geeft een wijziging van het gebruiksvoorschrift, maar heeft geen beperkend effect. De W-codering van het etiket dient daarom te worden opgehoogd naar W.10, maar er is geen grond om het afleveren en opgebruik van verpakkingen met etiket W.9 te beperken.

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	HTB 0.2

3. BEOORDELINGEN

Voor de beoordeling van de aangevraagde wijziging is uitgegaan van de laatste volledige beoordeling; besluit tot herregistratie d.d. 23 februari 2007.

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. De wijziging betreft het toevoegen van een Laag Doserings Systeem (LDS) bij de toepassing in bieten.

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 217, 6700 AE WAGENINGEN. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Wageningen, 1 mei 2015

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20146197 NLWG
Type aanvraag:	aanvraag tot wijziging van nationaal addendum
Middelnaam:	Oblix 500 SC
Verzenddatum aanvraag:	15 september 2014
*Formele registratiedatum: **	16 oktober 2014
Datum in behandeling name:	9 april 2015

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

2 Stofinformatie

Werkzame stof	Gehalte
ethofumesaat	500G/L

- De bestaande werkzame stof ethofumesaat is per 1 maart 2003 geplaatst op Annex I (Richtlijn 2002/37/EG d.d. 3 mei 2002) van gewasbeschermingsrichtlijn 91/414/EEG. De stof is goedgekeurd krachtens Verordening (EG) No 1107/2009 (Uitvoeringsverordening (EU) No 540/2011 d.d. 25 mei 2011). Bij Uitvoeringsverordening (EU) No 823/2012 d.d. 14 september 2012 is de plaatsing verlengd tot 31 juli 2016.

3 Toelatingsinformatie

Toelatingsnummer:	10319 N
Expiratiedatum:	31 juli 2016
Afgeleide parallel of origineel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel
W-codering professioneel gebruik:	10

Aflever- en opgebruiktermijnen voor oude etiket:

- *Vorige w-codering professioneel gebruik:* 9
- *Aflevertermijn professioneel gebruik:* onbeperkt
- *Opgebruiktermijn professioneel gebruik:* onbeperkt

4 Verpakkingsinformatie

Aard van het preparaat:
Suspensie concentraat

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BIJLAGE II Etikettering van het middel Oblix 500 SC

De etikettering is niet gewijzigd ten opzichte van het vorige besluit d.d. 15 augustus 2014.

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

Pictogram		
Signaalwoord		
Gevarenaanduidingen	H412	Schadelijk voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P273	Voorkom lozing in het milieu.
	P501	Inhoud/verpakking afvoeren naar ....
	SP 1	Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
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.

Toepassingsgebied	Type	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 onkruiden	0,6 l/ha[1]	2 per teeltcyclus	1,6 l/ha per teeltcyclus	10
			1 l/ha[2]	1 per teeltcyclus		-
			0,2 - 0,4 l/ha[3]	8 per teeltcyclus		7
Graszaadteelt van Engels- en Italiaans raaigras	over het gewas	eenjarige onkruiden	3-4 l/ha	1 per 12 maanden	4 l/ha per 12 maanden	-

[1] In combinatie met 3,5 l/ha fenmedifam (160 g/l).
[2] In combinatie met 5 l/ha fenmedifam (160 g/l).
[3] In LDS-systeem met toegelaten middelen.

Het gebruik in de graszaadteelt (met uitzondering van Engels en Italiaans raaigras) en de graszodenteelt is op basis van een “vereenvoudigde uitbreiding”. Er is voor deze uitbreiding 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.

Het gebruik in de teelt van cichorei is beoordeeld conform artikel 51 EG 1107/2009. Er is voor deze toepassing geen werkzaamheids- en fytotoxiciteitonderzoek uitgevoerd. Er wordt daarom aangeraden een proefbespuiting uit te voeren, voordat het middel gebruikt wordt. Gebruik van dit middel in dit toepassingsgebied, komt voor risico en verantwoordelijkheid van de gebruiker.

Toepassingsgebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassigen per teeltcyclus of per 12 maanden	Maximaal aantal liter middel per ha per teeltcyclus of per 12 maanden	Minimum interval tussen toepassingen in dagen

Graszaadteelt met uitzondering van Engels en Italiaans raaigras	over het gewas	Duist, windhalm, straatgras, muur en herderstasje	3-4 l/ha	1 per 12 maanden	4 l/ha per 12 maanden	-
Graszodenteelt	over het gewas	Duist, windhalm, straatgras, muur en herderstasje	3-4 l/ha	1 per 12 maanden	4 l/ha per 12 maanden	-
Cichorei	na opkomst	eenjarige onkruiden	0,1-0,2 l/ha[1]	4 per teeltcyclus	0,4 l/ha per teeltcyclus	7

[1] In LDS-systeem met toegelaten middelen.

Toepassingsvoorwaarden
Dit middel dient te worden toegepast 200-300 liter water per ha.

Na gebruik in de graszaadteelt het gras/hooi niet vervoederen.

De totale dosering in één seizoen mag niet hoger zijn dan 2 kg ethofumesaat (als werkzame stof) per hectare.

Om niet tot de doelsoorten behorende planten te beschermen is toepassing in de graszaadteelt en graszodenteelt uitsluitend toegestaan indien gebruikt wordt gemaakt van driftarme spuitdoppen.

Voor bieten geldt dat tijdelijk enige gewasbeschadiging op kan treden, vooral bij kleine bietenplantjes.

Om schade te voorkomen als gevolg van eventuele residuen van ethofumesaat in de grond moet voor het zaaien of planten eerst kerend worden geploegd, bijvoorbeeld bij een nateelt van wintergranen of bij een mislukte teelt. Bij mislukken van een gewas waarin dit middel werd toegepast kunnen de volgende gewassen na kerend ploegen gezaaid of geplant worden: suiker- en voederbieten, maïs, bruine bonen, tuinbonen, raaigrassen, erwten, spinazie, knolselderij, wortelen, zaai- en plantuien.

BIJLAGE IV

Risk Management

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1. Identity of the plant protection product

1.1 Applicant
UPL Europe Ltd.
1st Floor, The Centre, Birchwood Park
WARRINGTON, Cheshire WA3 6YN
Great Britain

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
The addition of the use in a Low Dose System (LDS) to the label. The current label states a maximum of 4 applications. In the LDS the frequency will be up to 8 times, without changing the total maximum rate.

1.6 Background to the application
An application is done for a label amendment.

1.7 Packaging details
Packaging details remain the same.

2. Physical and chemical properties

Physical and chemical properties remain the same

3. Methods of analysis

No changes occur in the methods of analysis.

4. Mammalian toxicology

No changes occur concerning mammalian toxicology.
The addition of the Low Dose System on the label for beets is covered by the risk envelope of the existing authorisation.

5. Residues

No changes occur concerning residues.

6. Environmental fate and behaviour
As for the original risk assessment of Oblix 500 SC (20050073 THG), 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 monograph.

List of Endpoints Fate/behaviour (monograph active substance ethofumesate)

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

Mineralization after 100 days	Range 6 - 13%; median 8.7%; n=5
Non-extractable residues after 100 days	Range 16 - 34%; median 31%; n=5
Relevant metabolites - name and/or code, % of applied (range and maximum)	All less than 6%

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation	Not relevant because of very slow transformation
Soil photolysis	In one study: maximum conc. of NC8493 30%

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

Method of calculation	9 of 10 calculated according to 1st order kinetics, 1 of 10 calculated according to 1.5 order kinetics
Laboratory studies (range or median, with n value, with r^2 value)	DT_{50lab} (20°C, aerobic, 40 - 75% WHC): Range 47 – 211 days; mean 97 days; median 84 d n=10
	DT_{90lab} (20°C, aerobic, 40 - 75% WHC): Range 210 – 701 days; median 331 days; n=10
	DT_{50lab} (10°C, aerobic): No study. Calculation of DT_{50} at 10°C carried out on eight DT_{50} laboratory tests (20-21°C, aerobic) using Q_{10}=2.2. Results: DT_{50}, (10°C, aerobic): 198 days.
	DT_{50lab} (20°C, anaerobic): Very slow transformation: 90-100% unaltered after 60d.
	Degradation in the saturated zone: No study
Soil photolysis	DT_{50}, two studies: 14 d; ≥290 nm, 24 h light 1.5 kg as/ha. 65 days; 300-800 nm, light 12 h per day, 15 mg as/kg.
Field studies (state location, range or median with n value)	DT_{50f}: Germany: One dose range 0.8 - 6.5 kg as/ha: range 15 - 250 days; median 65 days; n=10. Not dose related

	UK: One dose 1.5 kg as/ha: 36 and 56 days; mean 46 days; n=2 California, USA: 2.1 kg as/ha: 75 days; n=1 Calculated mean of all = 77 d; median = 56 d; n=13
	DT_{90f}: Germany: One dose range 0.8 - 6.5 kg as/ha: range 3 months - >3 years; median ca.11 months; n=11 UK: One dose 1.5 kg as/ha: 4 and 4.6 months, mean 4.3 months; n=2
Soil accumulation and plateau concentration	No relevant data. Accumulation calculated based on a field DT_{50} = 119 days assuming 5.0 cm incorporation a) Application of 1.0 kg as/ha and year, a plateau concentration of 114% of maximum PECsoil reached after 3 years. Plateau concentration 1.5 mg as/kg soil. b) Application 1.0 kg as/ha each third year new GAP dec. 1999). There was no significant accumulation. Three years after applic. 0.1% of dose remained.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} K_d pH dependence (yes / no) (if yes type of dependence)	Koc = range 97 - 245; mean = 147; median 132; n=11 Kd = range 0.73 – 6.2; mean = 2.7; median 2.3; n=11 Not pH dependent
Koc sediment	Koc = 267 and 449; mean 358, n=2 Kd = 6.1 and 19.4; mean 12.8, n=2

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

Column leaching	According to BBA Guideline: 200 mm over 2 days: n.d.-2.9% as; n=9 Other method, 508 mm over 15-20 d.: 4.2-67% of applied radioactivity; n=4
Aged residues leaching	Three different methods: n.d.-4.2% of applied initial radioactivity; n=5
Lysimeter/ field leaching studies	Two studies according to BBA guideline: Two lysimeters per study: 1. Three lysimeters with loamy sand soil. Lysimeter surface area 0.5 m^2 and 1.0 m depth. One dose of 1.25 kg as/ha applied pre-emergence to sugar beet in April 1992. Rainfall of ca. 857 mm/year. Terminated after 2 years. LOD = 0.1 µg/L 2. Two lysimeters with a sandy soil.Lysimeter surface area 1.0 m^2 and 1.2m depth. One dose of 1.5 kg as/ha applied to fodder beet on both lysimeters in May year 1 and additionally to one lysimeter in May year 2. Total rainfall (4 years) 3280 mm. Terminated after 3 years. LOD = 0.01 µg/L <u>Results</u>: No detectable amount active substance or metabolite in leachate in any of the lysimeters.

Model calculations (Annex IIA 7.2.4)

Maximum/Average concentration	1) PELMO: Two studies by two different model users (Feinchemie and AgrEvo). Totally about 17 runs: Varying input parameters, DT_{50} (50 to 114 days), Koc (99 to 207) and weather (dry to wet). Dose 1.0 to 1.25 kg as/ha applied to soil sandy soil and loamy soil, bare soil application. Date of application and crop not specified. Great difference in result: no leaching (13 runs) to significant leaching >0.1 µg/l in 4 runs. 2) a) MACRO (MACRO_DB) (simulation by KemI): Input: low dose, 0.2 kg/ha pre-emergence and highest recommended dose, 2.0 kg as/ha pre-emergence + 1.5 kg post-emergence first year. Crop all years was sugar beet. DT_{50} = 84 days (lab data) and log Kow = 2.7 (Koc≅182). Four years simulation on a sandy loam over sand with a mean precipitation of 740 mm. Judged to be a realistic worse case scenario. Results: Significant leaching at both recommended doses (2.0 + 1.5 kg as/ha) and at a low dose (0.2 kg as/ha). b) MACRO version 4.1 (simulation by AgrEvo): Input: 1.0kg as/ha once per year each third year 30 days post-emergence on sugar beet. Half-life 113 days (worse case lab. data) and Koc = 157 (mean). Simulation over a period 20 x 3 years on a silty clay loam with a mean precipitation of about 648 mm. Mean temperature appr. 10°C. Results: Mean concentrations calc. over periods of three years in the water passing 100-120 cm were <0.1µg/L, but highest values were close to 0.1 µg/L.

PEC (soil) (Annex IIIA, point 9.1.3)

Method of calculation	First order kinetics Realistic worst case field DT_{50} = 120 days
Application rate	1. Single application: 2.0 kg as/ha pre-emergence. Incorporated in the top 5 cm. 2. Two applications: 2.0 + 1.5 kg as/ha pre- and post-emergence application (45 days interval) (assumed 50% soil covered by plants at second application) Incorporated in the top 5 cm. Initial conc. calculated directly after second application.

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) (20°C)	pH___5.0___: Negligible
	pH___7.0___: Negligible
	pH___9.2___: Negligible
Photolytic degradation of active substance and relevant metabolites	Artificial light: (greatly variable results) 37-62d (summer, 40-60°N) 4.6 d (on a year basis) / 2.6 d (for month May)

Readily biodegradable (yes/no)	Not readily biodegradable; n=3
Degradation in water/sediment -DT_{50} water - DT_{90} water - DT_{50} whole system - DT_{90} whole system	Calculations: 3 out of 5 according to first order kinetics, 2 out of 5 according to 1.5th order kinetics Study 1: 13 days, n=1 (1st order) Study 2: 11 and 19 days, n=2 (1st and 1.5th order, resp.) Study 3: 7 and 50 days, n=2 (root of 1st order) Study 1: - Study 2: 121 and 212 days, n=2 Study 3: - Study 1: 125 days, n=1, (1st order) Study 2: 105 and 153 days, n=2 (1st and 1.5th order, resp.) Study 3: 242 and 285 days, n=2 (root of 1st order Study 1: - Study 2: 507 and 550 days, n=2 Study 3: -
Distribution in water / sediment systems (as) Metabolites	Study 1: After 84 days, 14% of applied radioactivity as parent compound in water/51% of in sediment, n=1. Maximum 53% parent compound in the sediment after 63 days of incubation. No DT50 could be calculated. Study 2: After 103 days, 13-18% of applied radioactivity as parent compound in water / 37-41% in sediment. Maximum 48 – 49 % of applied as parent compound in the sediment after 30 days of incubation. Thereafter DT50 in the sediment 170 – 270 days. Study 3: After 225 and 234 days, 21 and 1.5% of applied radioactivity as parent compound in water / 30 and 53% in sediment. Maximum of 4 unknown metabolites, altogether up to 17% of applied radioactivity.

PEC (surface water) (Annex IIIA, point 9.2.3)

Method of calculation	First order kinetics. Realistic worst case DT_{50} = 50 days. Water depth 0.3 m
Application rate	Single application: 2.0 kg as/ha (pre-emergence) Multiple applications: 2.0 kg+1.5 kg as/ha (post-emergence), 45 days interval between treatments
Main routes of entry	4% spray drift (1 m) + run-off

PEC (sediment)

Method of calculation sediment	Worst case initial PEC_{sed} in 0-2.5 cm top layer of sediment. Maximum 53% of applied ethofumesate in the sediment. DT50 220 days.
Application rate	Single application: 2.0 kg as/ha, spray-drift 1 m (4%) Multiple applications: 2.0 kg+1.5 kg as/ha, 45 days interval between treatments

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

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	1) Lysimeters (5 lysimeters in two studies). BBA-guideline. 2) Simulations with PELMO (n=17); MACRO (MACRO_DB) n=2 and MACRO 4.1 n=1 Different scenarios
Application rate	1) 1.2 - 3.0 kg as/ha 2) 0.2 - 3.5 kg as/ha, with differences between frequency of application

$PEC_{(gw)}$

Maximum concentration	1) Lysimeters: ethofumesate and metabolites not detected. LOD = 0.1 and 0.01 µg/l 2) Models: varying results: from <<0.1 µg/l (PELMO), ≤ 0.1 µg/L (MACRO 4.1) to significant concentrations >0.1 µg/l (PELMO and MACRO_DB)
Average annual concentration	1) Lysimeters: ethofumesate and metabolites were not detectable. LOD = 0.1 and 0.01 µg/l 2) Models: varying results from non predicted to significant concentrations >0.1 µg/l. Results from the simulation with MACRO 4.1 with GAP (dec. 1999) indicate conc. at 1 m <0.1 µg/l

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

Direct photolysis in air	No study. Not required.

Photochemical oxidative degradation in air (DT_{50})	2.1 h, calc. according to Meyland and Howard (AOP) 4.1 h, calc. According to Atkinson
Volatilisation	From plant surfaces: 22% lost from plant surface during 24 hours
	From soil: 15% lost from soil surface during the first 24 hours

PEC (air)

Method of calculation	Based on the volatilisation from soil and plant given above and assuming still air 10 m above soil surface

$PEC_{(a)}$

Maximum concentration	Initial calculated concentrations following application: pre-emergence: 2.0 kg as/ha: in air 3.0 µg/l post-emergence (100% plant cover): 1.5 kg as/ha: in air 3.3 µg/l. Using the oxidative chemical half-life calculated according to the Atkinson model PEC_{air} will be ≤0.4 µg/L air after one day (12 h of light). Measured concentration: Field study. After treatment of sugar beets a conc. of 8.5×10^{-4} µg as/l air was measured between 1 to 7.5 hours after treatment.

Definition of the Residue (Annex IIA, point 7.3)

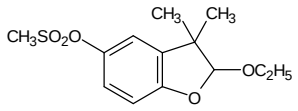
Relevant to the environment	Soil, water and sediment: Ethofumesate

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

Soil (indicate location and type of study)	No data
Surface water (indicate location and type of study)	1) Monitoring area: Vemmenhög a drained catchment area with intensive agriculture, Scania, south of Sweden : Samples collected during growing season, usually May to September in 1992-1998 in an open ditch receiving drainage water, 1991-1992 and at the outlet of culvert in 1992-1996. Range of applied dose 1991-1996 is 0.17 to 0.30 kg as/ha in cultivation of sugar beet, covering 10 to 19% of catchment area during the period. LOD = 0.1-0.2 µg/l. Reported TWMC(Time Weighted Mean Conc): a) 1991and 1992 (open ditch): No of samples 34 and 30; frequency of detection 53 and 37%; TWMC = 0.06 and 0.21 µg as/l, resp. b) 1992, 1993, 1994, 1995 and 1996 (outlet of culvert): No of samples 29, 25, 18, 22 and 22; frequency of detection 97, 87, 78, 77, and 68%; TWMC = 1.08, 0.39, 0.63, 0.14 and 0.10 µg as/l, resp. c) 1998: Low frequency of detection and low concentration. Decrease in frequency and concentrations during the sampling period has been explained by measures taken to minimise effects from bad management and surface run-off. 2) Monitoring area: East Anglia UK (Sugar beet growing area. A total number of 792 samples over a 5 years period. Results: 16 samples ≥0.1 µg/l; 42 samples <0.1µg/l but >LOD; LOD = 0.02-0,05 µg/l. Remark: No details on use of as regarding dose and freuency.
Ground water (indicate location and type of study)	1) East Anglia, UK. A sugar beet growing region. A tot. number of 78 samples from 43 different groundwater wells over a 5 year period. Results: 1 sample = 0.2 µg/l; 6 samples <0.1 µg/l >LOD; LOD = 0.02-0,05 µg/l. Remark: No details on use of as regarding dose and freuency.
Air (indicate location and type of study)	No data

Appendix A: Metabolite names, codes and other relevant information of the plant protection product Oblix 500 SC with active substance ethofumesate.

The compounds shown below were found in one or more studies involving the metabolism and/or environmental fate of active substance ethofumesate. The parent compound structure of ethofumesate 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)
ethofumesate	(±)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-ylmethanesulfonate	$C_{13}H_{18}O_5S$		286.3	Parent substance

6.1.2 Leaching to shallow groundwater

The leaching potential of the active substance ethofumesate is calculated in the first tier using Pearl 2.2.2 in line with the original assessment of Oblix 500 SC and the FOCUS Kremsmünster scenario. Input variables are the actual worst-case application rate, the crop sugarbeet and an interception value appropriate to the crop stage of 0.8. First date of yearly application is May 25th (default). For metabolites all available data concerning substance properties are regarded. No 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:

Active substance ethofumesate:
Mean DT_{50} for degradation in soil (20°C): 84 days
Mean K_{om} (pH-independent): 78 L/kg
1/n: 0.9 (default)

Saturated vapour pressure: 6.5 E-4 Pa (25^0C)
Solubility in water: 50 mg/L (25^0C)
Molecular mass: 286.3 g/mol

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. ethofumesate following the realistic worst case GAP, see Table M.1a.

Table M.1a Leaching of active substance ethofumesate as predicted by PEARL 2.2.2, following spring application. Values ≥0.1 µg/L are indicated in bold, values ≥0.01-<0.1 µg/L are underlined

Use	Substance	Rate substance [kg/ha]	Frequency	Interval [days]	Fraction Intercepted *	PEC groundwater [µg/L]
Beets	ethofumesate	0.2	8	7	0.8	**1.576**

* interception value used for PEARL 2.2.2 calculations is taken from the risk assessment of the original application of Oblix 500 SC in beets

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.1a it reads that the expected leaching based on the PEARL-model calculations for the active substance ethofumesate is equal to or larger than 0.1 µg/L. Therefore, further study into the leaching behaviour is necessary.

GeoPEARL
The leaching potential of substances to the shallow groundwater in the potential area of use within The Netherlands is calculated using the GeoPEARL model. The same input data as used in the first tier with Pearl 2.2.2 is employed. Additional input is the crop and the number of plots (minimum 250). In the risk assessment of the original authorisation of Oblix 500 SC, GeoPEARL 1.1.1 was used for refinement of the leaching assessment. As this model is not available anymore to Ctgb, GeoPEARL 2.2.2 has been used for PECgw calculations.
For results see Table M.1b.

Table M.1b Leaching of active substance ethofumesate as predicted by GeoPEARL 2.2.2. Values ≥0.1 µg/L are indicated in bold, values ≥0.01-<0.1 µg/L are underlined

Use	Substance	Rate a.s. [kg/ha]	Frequency	Interval [days]	Fraction Intercepted*	PEC groundwater [µg/L]
Beets	ethofumesate	0.2	8	7	0.8	**0.906**

* interception value used for GeoPEARL 2.2.2 calculations is taken from the risk assessment of the original application of Oblix 500 SC in beets

GeoPEARL calculations show that the predicted leachate concentrations equal to or are larger than 0.1 µg/L. Therefore, the proposed use of the active substance is not permissible.

Lysimeter/field leaching studies
The following paragraph is taken from the original risk assessment and adapted for the current application (label adjustment) in beets. Applicant has submitted a lysimeter study. In this study ethofumesate was not found in the leached water. An assessment to the vulnerability of the soil, according to Verschoor et al., (2001), the soil profile was more vulnerable than the Dutch standard soil. The amount of precipitation and irrigation was comparable. However, due to a higher soil temperature, the lysimeters were less vulnerable. Also the amount of water leached, was lower.
The lysimeter study was standardised according to Verschoor (2001). The standardisation resulted in a simulation error of 2×10^{-12}. This error is irrelevant for risk assessment. Results for the PEARL calculation can therefore not be corrected for the simulation error.

It can be concluded that the lysimeter was not vulnerable enough for the Dutch situation. Therefore, the proposed use of the active substance is not permissible. Monitoring data or a lysimeter study comparable to the Dutch situation is required.

A second lysimeter study has been submitted together with a standardisation according to Verschoor (2001). Also in this lysimeter no ethofumesate was found in the leachate. However the same argumentation with regard to vulnerability as above is true. Furthermore, according to the report by Verschoor a quantitative vulnerability assessment can only be sufficient if a lysimeter study was triggered by a slight exceedance of the trigger concentration by the model calculations.
Standardisation of the lysimeters on the basis of the standard dossier data according to Verschoor revealed a simulation error of 0.75. For the lysimeter soil a preliminary sorption

test was performed that resulted in a Kom value of 106 L/kg. This value can be used for the standardisation calculation. If the value is used together with the worst case DT50 value of 47 days a simulation error of 262 is calculated. If the simulation error is used as correction factor on the model results the estimated concentration in the groundwater is <0.01 µg/L.
In the lysimeters during the experiment the concentration ethofumesate was measured in the top layers of the soil. There are 3 timepoints available. From these measurements a half-life in the lysimeter topsoil can be estimated.
From these calculations a lysimeter half-life of 29.4 days was derived. Standardisation using the lysimeter specific DT50 and Kom value revealed a simulation error of 14.5.

Furthermore, several studies were provided by applicant regarding the re-registration of Oblix 500 SC. The following was mentioned in the risk assessment:

1. *Ethofumesate Calibration of lysimeter study 836695, Dr. H.J.M. Verhaar, Environ Document: 77AC-LYS2-20070002, 12 July 2007*
2. *Degradation of ^{14}C- Ethofumesate in one soil incubated under aerobic conditions, Dr. J. Hellstern, RCC Study No.: B01901, 4 July 2007*
3. *Adsorption/desorption of ^{14}C- Ethofumesate on soil - advanced test, Dr. J. Hellstern, RCC Study No.: B01912, 4 July 2007.*

Recently an extra lysimeter study has become available. This study is summarized and evaluated in RIVM report 11495A00.

4. *Diehl M. 2005. Ethofumesate: mobility and degradation in soil in outdoor lysimeters. Itingen, Switzerland: RCC Ltd. Report no. 836706. 118 pp. Data provided by AgriChem B.V. Confidential: Y.*
5. *Verhaar HJM. 2007. Ethofumesate - Calibration of lysimeter study 836706. Zeist, the Netherlands: Environ Netherlands B.V. Report no. 77AC-GRAS-20070048. 34 pp. Data provided by AgriChem B.V. Confidential: Yes.*

Reaction of Ctgb:

Study 1.
Ethofumesate Calibration of lysimeter study 836695, Dr. H.J.M. Verhaar, Environ Document: 77AC-LYS2-20070002, 12 July 2007

Environ Document 77AC-LYS2-20070002 shows based on the parallel studies with the lysimeter soil of ethofumesaat (respectively 60.5 days and 108 L/kg at 20 ℃) (RCC study no. 836695), a real SE of > 4513.

The study is considered complete and adequate. A calculation of the adjustment factor according to Van der Linden et al. based on the available SE values is lacking.

Study 2.
Degradation of ^{14}C- Ethofumesate in one soil incubated under aerobic conditions, Dr. J. Hellstern, RCC Study No.: B01901, 4 July 2007

GLP: Y Guide line: SETAC en OECD 307
1 soil: lysimeter soil, loamy sand
DT_{50} value of 60,5 days.

DT50 value is recalculated according to Guidance Document on Estimating Persistence and Degradation Kinetics FOCUS (2005)[1][1].
DT50: 58.8 d (χ^2: 5.9)

The study is considered complete and adequate.

Study 3.
Adsorption/desorption of ^{14}C- Ethofumesate on soil - advanced test, Dr. J. Hellstern, RCC Study No.: B01912, 4 July 2007.

GLP: Y Guideline: OECD 106
Number of soils: 1 lysimeter soil, loamy sand

ethofumesaat

soil	type	rep	pH(CaCl2)	%OC	SLratio	KF	1/n	Pcrit	Koc-calc	Koc-dos	Kom-calc	kom-dos
lysimeter	loamy sand	1	6.67	1.41	0.33	2.634	0.93	0.86922	186.81	187	108.36	108.00
arithmetic mean							0.93	0.87	186.81	187.00	108.36	108.00

The soil used fulfills the p criterium (p > 0,1) and the same values are calculated.
The Kom value of the lysimeter soil is 108.4 L/kg.

The study is considered complete and adequate.

Study 4.
Third lysimeter study (Diehl)

Substance	Soil type[1]	Location	Dose [kg as/ha]	Month of application	OM[1] [%]	pH[1] [KCl]	Leached [%]	Ri
ethofumesate, 200 g/L EC	loamy sand	Itingen, Switzerland	2	October 10, 2001	3.0	5.6	0%	1
ethofumesate, 200 g/L EC	loamy sand	Itingen, Switzerland	2	October 10, 2001	3.0	5.6	0%	1

Table 1. [1]*in top 30 cm soil layer*

Test substance
Ethofumesate 200 g/L EC, containing ^{14}C-ethofumesate, purity 98.12%.

Soil
Undisturbed soil monoliths from agricultural land in Borstel/Neustadt a. R., Lower Saxony/Germany. For characteristics, see Table below.

1. 1. Characteristics of lysimeter soil

Parameter	Horizon 0-30 cm	Horizon 30-60 cm	Horizon 60-90 cm	Horizon 90-120 cm
Soil type (USDA)	loamy sand	sand	sand	sand
pH (KCl)	5.60	5.36	4.95	5.09
OC (%)	1.77	0.30	0.08	0.00
CEC (meq/ 100g dry soil)	7.12	3.16	0.93	0.68

Planting details
Crop: Grass, sown on September 7, 2001, sowing density 33 g/m^2, cutting of grass on March 20, May 22, July 17, August 15, September 27 in 2002 and on June 6, 2003.

Results

Application
Application losses amounted to about 2 and 3%.

Environmental conditions

Precipitation

In the first year (days 0-384), the natural precipitation amounted to 1055.6 mm. In May, July and October 2002, the monthly amounts of precipitation were clearly much higher compared to the long-term average (147 to 218%). Additional irrigation was not performed.
In the second year (days 385-737), the precipitation amounted to 853 mm. In November 2002 and October 2003, 221 and 145% of the long-term average precipitation was recorded. Additional irrigation was performed in June and July 2003 to assure proper plant growth.

Temperature

The annual average temperatures were slightly higher than the long-term average (1961-1990) of 9.7 °C and reached values of 10.3 °C in 20 01 and 11.0 °C in 2002.

Leachate collected

During the first year the quantity of leachate amounted to 588 and 604 L for lysimeter 1 and 2, respectively. These values represent about 56-57% of the precipitation within this period. During the second year the quantity of leachate amounted to 422 and 442 L, respectively. These values represent about 46 and 48% of the precipitation and irrigation within this time period.

Distribution of radioactivity

Leachates

radioactivity collected in the lachates is given in the table below

2. 2. Radioactivity in the leachates

	Lysimeter 1		**Lysimeter 2**	
	Year 1	*Year 2*	*Year 1*	*Year 2*
radioactivity (% applied)	*1.7*	*0.7*	*1.5*	*0.6*
mean concentration (µg parent equiv./L)	*5.51*	*3.26*	*4.45*	*2.34*

In the leachates, $^{14}CO_2$ amounted to 0.09 and 0.08% of AR, corresponding to 3.8% of the radioactivity in the leachates. This indicates that degradation and mineralisation of the test compound occurred in the monolith. Upon characterisation of non-volatile radioactivity in the leachates, the first TLC chromatograms showed polar radioactivity that was smearing over the plate or not moving at all i.e. remaining at the origin of the plate or smearing through the HPLC column. Consequently, part of the radioactivity in the leachates was bound to water dissolved organic matter and a good chromatography was not possible. Several HPLC methods were tested in order to obtain well separated peaks, but peak separation was impossible. It could be shown, however, that none of the available reference items, i.e. ethofumesate nor 2-ketoethofumesate, were present in the leachates. In order to confirm this, an additional analysis was performed for determination of the parent. Aliquots of yearly pool leachates were pooled and radioactivity was determined by LSC. The whole aliquot was partitioned into dichloromethane, but no radioactivity was determined in the organic phase. In a procedural recovery with spiked control leachate (0.07 and 0.65 µg/L), recovery in the organic phase was 105 and 107%.

Soil

Radioactivity in soil layers approximately 2 years after last application is reported in the following table.

3. 3. Distribution of radioactivity in lysimeter soil

Layer no.	Soil layer depth [cm]	Total radioactive residue (parent equivalents)					
		Lysimeter 1			Lysimeter 2		
		[mg/kg]	[mg]	[% of AR]	[mg/kg]	[mg]	[% of AR]
1	0-15	0.214	37.58	20.03	0.257	50.51	27.18
2	15-24	0.042	4.11	2.19	0.032	3.98	2.14
3	25-34	0.026	3.16	1.69	0.021	3.01	1.62
4	35-44	0.024	3.25	1.73	0.018	2.67	1.44
5	45-54	0.018	2.71	1.44	0.015	2.18	1.17
6	55-64	0.012	1.90	1.02	0.010	1.60	0.86
7	65-74	0.008	1.24	0.66	0.008	1.27	0.68
8	75-84	0.006	0.96	0.51	0.006	0.96	0.52
9	85-94	0.007	1.09	0.58	0.004	0.72	0.39
10	94-104	0.006	1.00	0.53	0.005	0.90	0.49
11	105-114	0.005	0.77	0.41	0.005	0.80	0.43
12	115-125	0.007	1.21	0.64	0.005	0.79	0.42
Total			58.97	**31.43**		69.38	**37.33**
Total >65 cm			3.33	**3.3**		2.92	**2.9**

Radioactivity released by extraction of the upper most layer amounted to 5.6 and 6.7% of the radioactivity in that layer, indicating that about 95% of the radioactivity was present as bound residues.
Organic matter fractionation of the non-extractable residues in layer 1 indicated that the majority of the radioactivity present in the layer (about 64%) was bound to the immobile humic acids and humin fraction of the soil. The major part of the non-extractable radioactivity was bound to the immobile humic acids and humin fraction amounting to 66.9 and 67.8% of the non-extractable radioactivity present in layer 1 of lysimeters 1 and 2, respectively. The corresponding radioactivity associated with the more mobile fulvic acids was 33.1% and 32.2% of the non-extractable radioactivity in lysimeters 1 and 2, respectively.
Crops
Radioactive residues in the crop are given in the table below.

4. 4. Radioactive residues in crops

Crop	Radioactivity (% applied)	
	Lysimeter 1	Lysimeter 2
grass	0.01	0.02

The mass balance at the end of the experimental period showed that about 3 and 39% of AR was recovered in lysimeter 1 and 2, respectively. Apparently, 66% and 61% were lost to the atmosphere by volatilisation for lysimeters 1 and 2, respectively.

Remarks
It is reported that irrigation was performed in June and July 2003 to assure proper plant growth. No daily irrigation values were available. Irrigation was pooled per month. However, according to Verschoor et al. (2001), irrigation should not exceed 20 mm/day. By reporting the monthly irrigation it can not be verified if irrigation at exceeded 20 mm/day at one point in time. However, since the maximum irrigation per month did not exceed 45 mm, this is considered unlikely. The results of the study, that none of the available reference items (i.e. ethofumesate nor 2-ketoethofumesate), were present in the leachates, can be used for risk assessment.

Study 5.

Calibration of field lysimeter (836706)

Results

After a first SWAP simulation was run, using the lysimeter characteristics as described above, the estimated leaching for this run showed a leaching profile that was in good agreement with the recorded leaching from the two lysimeters, but with a significantly lower percolation during most of the simulation period than actually measured. Adjustment of the soil water retention parameters did not appreciably influence the simulated leaching pattern, or the cumulative amout leached. Therefore, the crop factor for the lysimeter crops was decreased to simulate lower evapotranspiration. The crop factor for grass was set to 0.8. No adjustment was made to the crop factor for bare soil, since there was a continuous crop during the entire study period. With this crop factor, the simulated leaching follows the actual leaching very well, with only a slight deviation during the final month, which is not particularly relevant for the evaluation of the leaching behaviour considering the DT_{50} value of ethofumesate. The author states that the areic mass leached from the two lysimeters in the lysimeter study can be derived form the concentration of ethofumesate in the individual leachate fractions, and the size of these fractions. However, since the concentration of ethofumesate in the leachate fractions was below the LOD at all times, it is only possible to give an upper limit on the amount that may have leached. The upper limit concentration was set to 15.33 pg/L (LOD of the TLC phospor-imager is 20 dpm, which equals 92 pg ^{14}C-ethofumesate. A total of 3 L of the pooled percolate was submitted to the ultrafiltration/TLC analysis approach. No parent compound was detected in the percolate in this analysis, setting the maximum amount present to half of the LOD, or 46 pg in 3 L). Combined with the average amount of leachate recovered form the two lysimeters of 1027.7 L, the upper limit on the amount of leached ethofumesate can be set to < 15.8 ng. The areic mass leached from the lysimeters therefore is < 15.8 ng/m^2 or < $158*10^{-9}$ kg/ha. The author states that the total accumulated areic mass leached from the PEARL lysimeter simulation, performed with the default lysimeter calibration settings, expressed in the variable AmaLea, for the soil profile is 6.68×10^{-3} kg/ha. This leads to a simulation error of > 42280. It can be concluded that PEARL greatly overestimates the leaching potential of ethofumesate. With this simulation error applied to default (Kremsmuenster scenario) PEARL calculations, all foreseen applications of ethofumesate in grass fulfil the requirements for leaching to the upper groundwater.

Remarks

Conclusion: Using the soil-specific, parallel K_{om} and DT_{50} values for ethofumesate for the lysimeter soil, PEARL estimates the leaching and the results (simulation error > 42280) can be used for risk assessment.

Based on this second lysimeter (grass), including calibration, a second SE has become available. This SE has a value of > 42280.

From the final degradation and sorption studies with the lysimetersoil a lysimeter half-life of 58.8 days and a Kom value 108.4 L/kg were derived. Standardisation using the lysimeter specific DT50 and Kom value revealed a simulation error of 4513.

Standardisation using the third lysimeter (grass) specific DT50 and Kom value revealed a simulation error of > 42280.

Simulation errors for ethofumesaat were calculated for the two soil types of the three lysimeter soils. In principle the simulation errors of all lysimeters can be used for the risk assessment for deriving the adjustment factor. Nevertheless the very low simulation error is excluded because this value is not relevant for risk assessment.

Calculated values and conclusions for leaching including lysimeter data are given in Table M.1c. According to Van der Linden et al., the adjustment factor for leaching estimations in the authorisation procedure is 4513 (2 experiment2, 1 number of lysimeter soils).

As a result the adjusted estimate for the concentration in groundwater is as reported in table M.1c.

Table M.1c Adjusted estimate leaching of active substance ethofumesate

Use	Substance	Rate a.s. [kg/ha]	Frequency	Interval [days]	PEC groundwater spring [µg/L]
Beets	Ethofumesate	0.2	8	7	< 0.001*

* Adjusted PEC groundwater results using an $f_{adjustment}$ of 4513.

The adjusted estimate shows that the predicted leachate concentrations for ethofumesate are smaller than 0.01 µg/L. Hence, the active substance meets the standards laid down in the Regulation of Uniform Principles for Plant protection products (BUBG) for the proposed application.

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

See List of Endpoints.

6.5 Data requirements

None.

The following restriction sentences were proposed by the applicant:

-

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

-

6.6 Overall conclusions fate and behaviour

It can be concluded that:
the proposed application of the active substance ethofumesate meets the standards for leaching to the shallow groundwater as laid down in the BUGB.

7. Ecotoxicology

The risk of the applied use in beets in LDS 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

Oblix 500 SC is currently authorised for control of annual weeds in beets at three dose rates (0.6, 1 and 0.2-0.4 l/ha) with a total maximum of 2 l/ha. When applied at 0.2-0.4 l/ha four applications are allowed.

The applicant has applied for an extension of the label, on the new label in beets up to eight applications can be applied when applied at 0.2-0.4 l/ha (low dosage system application,

LDS). The total maximum dose is 1.6 l/ha. The new label will allow more flexibility in spray programmes, and will allow longer spray programmes under (LDS).

8.1 Efficacy evaluation

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.

Conclusion

The evaluation complies with the Uniform Principles, article 2.1.

8.2 Harmful effects

8.2.1 Phytotoxicity

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.

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. A higher resistance risk is expected. As the LDS application of Oblix 500 SC is applied in combination with other authorised products the resistance risk is low. Therefore a resistance management sentence is not necessary.

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.

9. Conclusion

The product complies with the Uniform Principles.

10. Classification and labelling

Classification and labelling does not change.

Appendix 1 GAP-Table authorised uses

Only the uses that are changed are presented.

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	Beets	F	Annual grasses and dicotyledonous weeds	Tractor mounted boom spray	BBCH 10-12 of the weeds March-June	8 / (7)	0,2-0,4 L/ha	0,1-0,2 kg as/ha	200-300	n.a.	In combination with approved products

Appendix 2 Reference list

No new studies were submitted.