



## HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

### 1. **BESLUIT**

Op 16 september 2016 is van

ADAMA Registrations B.V.  
Postbus 355  
3830 AK LEUSDEN

een aanvraag tot wijziging van het Wettelijk Gebruiksvoorschrift als bedoeld in artikel 45 Verordening (EG) 1107/2009 (verder te noemen: de Verordening) ontvangen voor het gewasbeschermingsmiddel

#### **Goltix SC**

op basis van de werkzame stof metamitron.

De aangevraagde wijziging betreft het wegnemen van het voorschrift tot het gebruik van luchtondersteuning in de restrictie ter bescherming van niet-doelwit planten. Hiertoe heeft aanvrager voor enkele toepassingen een verlaging van de dosis voorgesteld en heeft aanvrager de intervallen tussen de opeenvolgende voor, tijdens en na opkomst toepassingen in hetzelfde gewas gespecificeerd. Deze wijzigingen in de GAP zijn beoordeeld voor de aspecten Ecotoxicologie en Werkzaamheid, uitgaande van de beoordeling van de herregistratie (Collegebesluit van 31 augustus 2016). Voor de overige aspecten is geen beoordeling uitgevoerd, omdat de aangevraagde wijzigingen vallen binnen de risico-envelop van de herregistratie (Collegebesluit van 31 augustus 2016).

**HET COLLEGE BESLUIT** tot honorering van de aangevraagde wijzigingen van het Wettelijk Gebruiksvoorschrift.

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. In afwijking van gebruikelijk is de onderbouwing niet in de vorm van een nationaal addendum maar in de vorm van een nationale beoordeling. Hierin wordt zoveel mogelijk verwezen naar de Core.

**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 volgens het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.

**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.
- De classificatie die overeenkomstig het toelatingsbesluit is vastgesteld, moet volgens de voorschriften op de verpakking worden vermeld, zoals beschreven in bijlage II.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in bijlage III.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.

**1.4 Aflever- en opgebruiktermijn (respijtperiode)**

Bij dit besluit wordt het Wettelijk Gebruiksvoorschrift aangepast. Daarom wordt het volgnummer van het etiket verhoogd van W.3 naar W.4. Omdat het niet alleen een uitbreiding (minder strikte driftreducerende maatregelen) maar ook een beperking (verlaging van dosering) betreft ten opzichte van het oude etiket, dienen respijttermijnen te worden vastgesteld.

Aanvrager heeft echter laten weten dat geen verpakkingen met het vorige etiket met volgnummer 3 op de markt zijn gebracht en dat respijttermijnen daarom niet nodig zijn.

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	Rgb d.d. 13 juni 2011 en Evaluation Manual 1.1

**3. BEOORDELINGEN****3.1 Fysische en chemische eigenschappen**

Niet beoordeeld. Er zijn geen wijzigingen ten opzichte van het besluit op de herregistratie d.d. 31 augustus 2016.

**3.2 Analysemethoden**

Niet beoordeeld. Er zijn geen wijzigingen ten opzichte van het besluit op de herregistratie d.d. 31 augustus 2016.

**3.3 Risico voor de mens**

Niet beoordeeld. Er zijn geen wijzigingen ten opzichte van het besluit op de herregistratie d.d. 31 augustus 2016.

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### **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.*

Ede, 30 december 2016

HET COLLEGE VOOR DE TOELATING VAN  
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw  
Voorzitter

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## BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

### 2.1 Aanvraaginformatie

*Aanvraagnummer:* 20161415 NLWG  
*Type aanvraag:* aanvraag tot wijziging van nationaal addendum  
*Middelnaam:* Goltix SC  
*Verzenddatum aanvraag:* 15 september 2016  
*Formele registratiedatum: \** 27 september 2016  
*Datum in behandeling name:*

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

### 2.2 Stofinformatie

Werkzame stof	Gehalte
metamitron	700G/L

De stof metamitron is per 1 september 2009 geplaatst op Annex I van Richtlijn 91/414/EEG (Dir 2008/125/EC d.d. 19 december 2008) en vervolgens bij Uitvoeringsverordening (EU) 540/2011 d.d. 25 mei 2011 goedgekeurd. De goedkeuring van deze werkzame stof expireert op 31 augustus 2019.

### 2.3 Toelatingsinformatie

*Toelatingsnummer:* 12629 N  
*Expiratiedatum:* 1 september 2026  
*Afgeleide parallel of origineel:* n.v.t.  
*Biocide, gewasbeschermingsmiddel of toevoegingsstof:* Gewasbeschermingsmiddel  
*Gebruikers:* Professioneel

W-coderingen en aflever- en opgebruiktermijnen:

- *W-codering professioneel gebruik:* 4
- *Vorige w-codering professioneel gebruik:* 3
- *Aflevertermijn professioneel gebruik:* Geen
- *Opgebruiktermijn professioneel gebruik:* Geen

### 2.4 Verpakkingsinformatie

*Aard van het preparaat:* Suspensie concentraat

## BIJLAGE II Etikettering van het middel Goltix SC

Professioneel gebruik

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

Metamitron

Pictogram	GHS07 GHS09
Signaalwoord	WAARSCHUWING
Gevarenaanduidingen	H302 Schadelijk bij inslikken. H410 Zeer giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P102 Buiten het bereik van kinderen houden. P270 Niet eten, drinken of roken tijdens het gebruik van dit product. P280C Beschermende handschoenen en beschermende kleding dragen. 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.

**HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN**
**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 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	Minimum interval tussen toepassingen in dagen.
Bieten	voor opkomst	eenjarige breedbladige onkruiden en straatgras <sup>1</sup>	1,5-3 L/ha <sup>2</sup>	1 per teeltcyclus	5 L/ha	-
	rond opkomst	eenjarige breedbladige onkruiden en straatgras <sup>1</sup>	2 L/ha <sup>3</sup>	1 per teeltcyclus		14 <sup>7</sup>
	na opkomst	eenjarige breedbladige onkruiden en straatgras <sup>1</sup>	0,5-1 L/ha <sup>4</sup>	6 per teeltcyclus		5 <sup>8</sup>
Afrikaantjes ( <i>Tagetes</i> ) als groenbemester	na opkomst	eenjarige breedbladige onkruiden en straatgras <sup>1</sup>	0,5-2 L/ha <sup>2</sup>	5 per teeltcyclus	5 L/ha	7
Rode biet	voor opkomst	eenjarige breedbladige onkruiden en straatgras <sup>1</sup>	1,5-3 L/ha <sup>2</sup>	1 per teeltcyclus	5 L/ha	-
	rond opkomst	eenjarige breedbladige onkruiden en straatgras <sup>1</sup>	2 L/ha <sup>3</sup>	1 per teeltcyclus		14 <sup>7</sup>
	na opkomst	eenjarige breedbladige onkruiden en straatgras <sup>1</sup>	0,5-1 L/ha <sup>4</sup>	6 per teeltcyclus		5 <sup>8</sup>
Bloembol- en bloemknolgewassen m.u.v. lelie (onbedekte teelt)	rond opkomst en na opkomst	eenjarige breedbladige onkruiden en straatgras <sup>1</sup>	2 L/ha	2 per teeltcyclus	4 L/ha	7

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	Minimum interval tussen toepassingen in dagen.
Lelie (onbedekte teelt)	rond opkomst of na opkomst	eenjarige breedbladige onkruiden en straatgras <sup>1</sup>	2 L/ha	1 per teeltcyclus	5 L/ha	7
	na opkomst	eenjarige breedbladige onkruiden en straatgras <sup>1</sup>	0,5-1 L/ha <sup>5</sup>	10 per teeltcyclus		
Lelie (bedekte teelt)	rond opkomst en na opkomst	eenjarige breedbladige onkruiden en straatgras <sup>1</sup>	1-2 L/ha <sup>6</sup>	2 per 12 maanden	4 L/ha	7

<sup>1</sup> Straatgras (*Poa annua*)

<sup>2</sup> Dosering afhankelijk van de grondsoort.

<sup>3</sup> In combinatie met 2 liter per ha minerale of plantaardige olie.

<sup>4</sup> LDS in combinatie met toegelaten middelen

<sup>5</sup> LDS in combinatie met 5 liter per ha minerale of plantaardige olie.

<sup>6</sup> De lage dosering in combinatie met toegelaten middelen.

<sup>7</sup> Het minimum interval tussen de rond opkomst behandeling en de voorgaande voor opkomst behandeling is 14 dagen.

<sup>8</sup> Het minimum interval tussen de eerste na opkomst behandeling en de voorgaande rond opkomst behandeling en tussen na opkomst behandelingen onderling is 5 dagen.

### Toepassingsvoorwaarden

Om de zoogdieren te beschermen is toepassing in de onbedekte teelt van lelies uitsluitend toegestaan voor het kappen van het gewas of voor volledige bloei (uiterlijk tot BBCH 65).

Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing in onbedekte teelten uitsluitend toegestaan wanneer gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen en kantdoppen.

Mislukt een bietengewas door welke oorzaak dan ook (bijv. vorstschade of insectenvraat) en is Goltix SC toegepast dan zijn de mogelijkheden voor een volggewas beperkt:

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- zonder grondbewerking kunnen bieten of krotten worden gezaaid;
- na ploegen kunnen maïs en aardappelen worden geteeld;

#### Resistentiemanagement

Dit middel bevat de werkzame stof met amitron. Met amitron behoort tot de triazonen. 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.



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

**BIJLAGE IV**

**RISKMANAGEMENT**

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## 1. Identity of the plant protection product

### 1.1 Applicant

ADAMA Registrations B.V.  
Arnhemseweg 87  
3832 GK LEUSDEN

### 1.2 Identity of the active substance

Common name	Metamitron
Name in Dutch	Metamitron
Chemical name	4-amino-4,5-dihydro-3-methyl-6-phenyl-1,2,4-triazin-5-one
CAS no	41394-05-2
EC no	255-349-3

The active substance was included in Annex I of Directive 91/414/EEC on 1 September 2009. From 14 June 2011 onwards, 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

Name	Goltix SC
Formulation type	SC
Content active substance	700 g/L metamitron

The formulation is comparable to that assessed for the inclusion in Annex I of Directive 91/414/EEC / approval under Reg. (EC) No 1107/2009.

### 1.4 Function

herbicide

### 1.5 Uses applied for

See GAP (Appendix IA).

### 1.6 Background to the application

This application concerns an amendment of the Legal Instructions for Use . The applicant applied for removing the prescription for use of air assisted spraying techniques for drift reduction for the protection of non-target plants from the label. For this aim, the applicant proposed reductions of the maximum dose for selected uses and provided statements on minimum realistic intervals between the subsequent pre-emergence, during emergence and post emergence treatments. (See Efficacy section for details). As these are considered minor changes of national aspects of the label, the application is handled on a national level. Only those aspects affected by the changes applied for are adapted; i.e. non-target plants and efficacy. For the other aspects is referred to the evaluation of the reregistration as decided on by the Board of Ctgb on 31 August 2016.

### 1.7 Packaging details

#### 1.7.1 Packaging description

<b>Material:</b>	<b>Professional use:</b> HDPE/EVOH (1L), HDPE (5L), co-extruded HDPE (10L), HDHMWPE (20L)
<b>Capacity:</b>	<b>Professional use:</b>

	1L, 5L, 10L, 20L
<b>Type of closure and size of opening:</b>	46 mm-63 mm Screw cap or K60+gasket+security ring
<b>Other information</b>	UN/ADR compliant

### 1.7.2 Detailed instructions for safe disposal

No particular recommendations.

### 2. Physical and chemical properties

No changes; please refer to the evaluation of the reregistration as decided on by the Board of Ctgb on 31 August 2016.

### 3. Methods of analysis

No changes; please refer to the evaluation of the reregistration as decided on by the Board of Ctgb on 31 August 2016.

### 4. Mammalian toxicology

No changes; please refer to the evaluation of the reregistration as decided on by the Board of Ctgb on 31 August 2016.

### 5. Residues

No changes; please refer to the evaluation of the reregistration as decided on by the Board of Ctgb on 31 August 2016.

### 6. Environmental fate and behaviour

No changes; please refer to the evaluation of the reregistration as decided on by the Board of Ctgb on 31 August 2016.

## 7. Ecotoxicology

### List of Endpoints Ecotoxicology

Metamitron is an existing substance that has been placed on Annex I per 09/01/2008 (2008/125/EC). For the risk assessment, the final list of endpoints (LoEP d.d. 09/29/2008) as given in the EFSA Scientific Report on metamitron (2008) 185; 1-95 (d.d. 29 September 2008) is used.

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

Species	Test substance	Time scale	End point (mg a.s. or metabolite /kg bw /day)	End point (mg a.s. /kg feed)
Birds ‡				
Japanese quail ( <i>Coturnix coturnix japonica</i> )	Technical metamitron	Acute	LD50 (male) = 1358 LD50 (female) = 1302	-
Bobwhite quail ( <i>Colinus virginianus</i> )	Technical metamitron	Short-term	LD50 = >904	LC50 >5000 mg a.s. /kg diet
Mallard duck ( <i>Anas platyrhynchos</i> )	Technical metamitron	Short-term	LD50 = >1586	LC50 >5000 mg a.s. /kg diet
Bobwhite quail ( <i>Colinus virginianus</i> )	Technical metamitron	Long-term	NOAEL = 81.5	NOAEC 1000
Mammals ‡				
Rat	Technical metamitron	Acute	LD50 (male) = 1183 LD50 (female) = 1482	-
Mouse	Technical metamitron	Acute	LD50 (male) = 691 LD50 (female) = 644	-
Rat	'Goltix SC 700'	Acute	LD50 = 200-2000 (precise value not calculable)	-
Rat	Desaminometamitron	Acute	LD50 = 4325	-
Rat	Technical metamitron	Long-term	Ecological NOAEL = 36.4 (male) & 53.8 (female)	Ecological NOAEC = 500

## Additional higher tier studies ‡

**Foliar residue studies:** Details for a UK foliar residue decline field study indicate that following a spray application of 'Goltix SC 700' metamidron residues declined rapidly. The apparent short foliar half-life of metamidron is also supported by the results of four German residue field studies in which, following spray applications of formulated metamidron, the high initial (day 0) measured residues of metamidron were found to be reduced to non-significant levels (i.e.  $\leq 0.1$  mg/kg) at the subsequent analysis made in each trial 14-16 days after treatment. The evidence is considered sufficient to support use of a DT50 of 1.9 days in the refined risk assessment (in place of a default '1<sup>st</sup> tier' value of 10 days). Based on the available 'day 0' (initial) metamidron foliar residue data from one UK site and from five sites in Germany, the generic acute and long-term residue per unit dose values (RUDs) used in the first tier risk assessment can also be refined. Using these data, the 'refined' acute RUD is 74 (based on maximum residue levels) and the long-term RUD is 48 (based on mean residue levels). The 21 day time averaged  $C_{res}$  level is calculated to be 21.53 mg a.s./kg foliage. The long term risk assessment for herbivorous birds and mammals can be refined using this refined exposure value.

**Various published studies on bird behaviour and feeding preferences:** The evidence is sufficient to support the assumption that in relation to the long-term consumption of invertebrates, the invertebrate component of the diet for the skylark and yellowhammer will consist (by weight) of approximately 75% 'large' invertebrates (>4mm body length) and 25% 'small' invertebrates ( $\leq 4$ mm body length). For the yellow wagtail, the evidence supports a long-term consumption estimate of 50% (by weight) of 'large' invertebrates and 50% of 'small' invertebrates.

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg a.s. /L unless indicated otherwise)
Laboratory tests ‡				
Fish				
<i>Oncorhynchus mykiss</i> (rainbow trout)	Technical metamidron (>98% purity)	96 hr (static), acute.	Mortality, EC <sub>50</sub>	>190 (nominal)
<i>Oncorhynchus mykiss</i> (rainbow trout)	Technical metamidron (>98% purity)	21 d (semi- static with daily renewal), prolonged toxicity test.	Growth NOEC	7.0 (nominal)
<i>Oncorhynchus mykiss</i> (rainbow trout)	'Goltix SC 700' (690g /l metamidron)	96 hr (static)	Mortality, EC <sub>50</sub>	>200 mg product /l ≡ >114 a.s. /l (nominal)
<i>Oncorhynchus mykiss</i> (rainbow trout)	Desamino- metamidron (99.5% purity)	96 hr (static)	Mortality, EC <sub>50</sub>	>1000 mg (nominal)

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg a.s. /L unless indicated otherwise)
Aquatic invertebrates				
<i>Daphnia magna</i>	Technical metamitron (99% purity)	48 h (static)	Immobilisation, EC <sub>50</sub>	5.7 (mean measured)
<i>Daphnia magna</i>	Technical metamitron (99% purity)	21 d (semi-static, renewal 3 times per week), reproductive toxicity test	Reproduction, NOEC	10 (nominal)
<i>Daphnia magna</i>	Goltix SC 700 (57.4 w/w metamitron)	48 h (static)	Immobilisation, EC <sub>50</sub>	170 mg product /l ≡ 97.6 mg a.s./l (nominal)
<i>Daphnia magna</i>	Desamino-metamitron (99% purity)	48 h (static)	Mortality, EC <sub>50</sub>	745 mg metabolite / l (nominal)
Sediment dwelling organisms				
<i>Chironomus riparius</i> (dipteran midge)	Desamino-metamitron (99.5% purity)	28 d (static spiked water) emergence & development study.	NOEC	100 mg metabolite /l (initial nominal)
Algae				
<i>Pseudokirchneriella subcapitata</i> formerly <i>Selenastrum capricornutum</i> (green alga)	Metamitron (technical: purity 99.3%)	72 h (static) Growth inhibition	Biomass E <sub>b</sub> C <sub>50</sub> Growth rate E <sub>r</sub> C <sub>50</sub>	0.4 (initial measured) 1.8 (initial measured)
<i>Pseudokirchneriella subcapitata</i> formerly <i>Selenastrum capricornutum</i> (green alga)	'Goltix SC 700' (724.1 g/l metamitron)	72 h (static) Growth inhibition	Biomass E <sub>b</sub> C <sub>50</sub> Growth rate E <sub>r</sub> C <sub>50</sub>	0.82 mg product/l ≡ 0.49 mg a.s./l (nom.) 3.38 mg product/l ≡ 2.01 mg a.s./l (nom.)
<i>Pseudokirchneriella subcapitata</i> formerly <i>Selenastrum capricornutum</i> (green alga)	Desamino-metamitron (99% purity)	72 h (static) Growth inhibition	Biomass E <sub>b</sub> C <sub>50</sub> Growth rate E <sub>r</sub> C <sub>50</sub>	25.1 mg metabolite /l (nominal) 73.5 mg metabolite /l (nominal)

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg a.s. /L unless indicated otherwise)
Higher plant				
<i>Lemna gibba</i>	a.s. (technical: purity 98.8%)	7 day (semi- static with renewal on days 3 & 5) Growth inhibition	Biomass E <sub>b</sub> C <sub>50</sub>  Growth rate E <sub>r</sub> C <sub>50</sub>	0.4 mg a.s./l (mean measured) 0.8 mg a.s./l (mean measured)
<i>Lemna minor</i>	a.s. (technical: purity 98.6%)	14 day (semi- static with renewal on days 2, 5, 7, 9, & 12) Growth inhibition	Biomass E <sub>b</sub> C <sub>50</sub>  FronD no. EC <sub>50</sub>	0.38 mg a.s./l (mean measured) 0.45 mg a.s./l (mean measured)

Microcosm or mesocosm tests:

After a single application of 'Goltix SC 700' to outdoor mesocosm enclosures containing phytoplankton, zooplankton and macrophyte communities, significant treatment related effects were observed at the 2 highest test concentrations (i.e. 1120 and 4480 µg a.s./L), but only for physical-chemical endpoints related to the community metabolism (pH and dissolved oxygen concentration), with these effects at 1120 µg a.s./L being slight and transient (day 2 reductions of 0.5 in pH & of 30% in oxygen levels, with no effects when next assessed on day 5). No consistent treatment-related effects on structural endpoints of phytoplankton (species composition, densities, chlorophyll-a level), periphyton (chlorophyll-a level) and macrophytes (% cover, final biomass, growth of *Myriophyllum spicatum* in *in situ* bioassays) were obtained at up to the highest test concentration. In addition, densities of the major zooplankton groups appeared to be unaffected. Only the more pronounced effects on oxygen and pH levels at 4480 µg a.s. /L (i.e. reductions on day 2 compared with day 0 in oxygen levels by 80% and a pH drop from 9.2. to 7.5, with recovery by day 15) are considered to be ecologically relevant, and on this basis the **study NOAEC** (no observed ecologically adverse effect concentration) is 1120 µg a.s. /L or 1.12 mg a.s. /l (nominal).

It is noted that exposure in the study differs from the proposed use in not including repeat exposure. However, given the low level and rapid reversibility of effects at the NOAEC, the effects of metamitron exposure at or below this concentration are considered unlikely to be significant increased by repeat exposure. Although effects on a wide range of aquatic invertebrates and algae species were assessed in the study, effects on only three species of higher aquatic plants were assessed – which may not be fully representative of the range of sensitivity of higher aquatic plants to metamitron. To take account of the uncertainty involved in extrapolating the results of the mesocosm study to the field situation, an uncertainty factor of 3 has been applied by the RMS to the study NOAEC.

Bioconcentration		
	Metamitron	Desamino-metamitron
logP <sub>ow</sub>	0.85-0.96	1.43-2.46
Bioconcentration factor (BCF) <sup>1</sup>	-	-

<sup>1</sup> only required if  $\log P_{ow} > 3$ .

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

Test substance	Acute oral toxicity (48h LD <sub>50</sub> µg a.s. /bee)	Acute contact toxicity (48h LD <sub>50</sub> µg a.s./bee)
Metamitron ‡	>97.2	> 100.0
'Goltix SC 700' (690g a.s./l) ‡ #	123.3	> 200.0

# Toxicity of 'Goltix 700 SC' expressed in terms of levels of active substance exposure

#### Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

##### Laboratory tests with standard sensitive species:

Species	Test Substance	End point	Effect (LR <sub>50</sub> )
<i>Typhlodromus pyri</i> ‡	'Goltix SC 700'	Mortality	LR50 = > 21 litres product /ha (≡ > 14383 g a.s./ha)
<i>Aphidius rhopalosiphi</i> ‡	'Goltix SC 700'	Mortality	LR50 = > 21 litres product /ha (≡ > 14383 g a.s./ha)

##### Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	ESCORT 2 Trigger value
<i>Pardosa</i> spp	Adult	'Goltix SC 700'; quartz sand; 14 day exposure.	5 litres product /ha (exposure to initial residues)	Corrected mortality (%) Feeding activity (% reduction)	0% mortality 8% reduction	50 % (at in-field exposure rate)
<i>Coccinella septempunctata</i>	Larvae	'Goltix SC 700' # glass plate substrate, exposure up to adult emergence	2.0-6.1 litres product /ha (exposure to initial residues)	% corrected mortality (M) & % reduction in reproduction (R) 2.0 l product /ha 5.1 l product /ha 6.1 l product /ha	12(M), 32(R) 5(M), 33(R) 10(M), 68(R)	50 % (at in-field exposure rate)

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7):



Test organism	Test substance	Time scale	End point
<b>Earthworms</b>			
<i>Eisenia fetida</i>	Technical metamitron (99% purity) ‡	Acute, 14 days	LC <sub>50</sub> 914 mg a.s./kg d.w. soil
<i>Eisenia fetida</i>	Desamino-metamitron (99.4% purity) ‡	Acute, 14 days	LC <sub>50corrected</sub> > 500 mg a.s. /kg d.w. soil <sup>1</sup>
<i>Eisenia fetida</i>	'Goltix SC 700' (690.2 g metamitron / litre) ‡	Chronic, 8 weeks (reproductive toxicity study)	NOEC 28 mg a.s. /kg d.w. soil <sup>2</sup>
<b>Other soil macro-organisms</b>			
<i>Folsomia candida</i> , (Collembola)	Desamino-metamitron (99.4% purity) ‡	Chronic, 28 days (reproductive toxicity study)	NOEC 100
<b>Soil micro-organisms</b>			
Nitrogen mineralisation	'Goltix SC 700' (690 g/L metamitron)‡	28 day study	Effects on nitrogen transformation processes by day 28 at 19.5 mg a.s./kg d.w. soil < ±25% of the control <sup>3</sup>
Nitrogen mineralisation	Desamino-metamitron (99.4% purity). ‡	56 day study	Effects by day 42 on nitrogen transformation at 21.73 mg metabolite /kg dw soil <±25% of the control <sup>3</sup>
Carbon mineralisation	'Goltix SC 700' (690 g/L metamitron)‡	28 day study	Effects on soil respiration at 19.5 mg a.s./kg d.w. soil throughout the study < ±25% of the control <sup>3</sup>
<b>Field studies</b>			
Not required			

<sup>1</sup> Since the maximum estimated Log P<sub>OW</sub> values of desamino-metamitron is above 2 and testing was conducted in an artificial soil containing 10% organic matter, an EPO correction factor of 2 was applied to the toxicity endpoint

<sup>2</sup> Calculated from the applied rate per unit area - considering a soil depth of 5 cm and a density of 1.5 g/cm<sup>3</sup>

<sup>3</sup> Test doses compares with maximum soil PECs from the proposed use of 3.74 mg a.s. /kg dw soil and 0.62 mg desamino-metamitron /kg dw soil.

#### Effects on non-target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data:

Not required for herbicides
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Laboratory dose response tests:

Most sensitive species	Test substance	ER <sub>50</sub> Post-emergence exposure	ER <sub>50</sub> Pre-emergence Exposure
Lettuce (based on post-emergence exposure effects in vegetative vigour test) ‡	'Goltix 700 SC'	171.6 g a.s./ha (effects on shoot fresh weight – the most sensitive measured effect)	-
Rape (based on pre-emergence exposure effects in seedling emergence & growth test) ‡	'Goltix 700 SC'	-	54.9 g a.s./ha (effects on shoot fresh weight – the most sensitive measured effect)

**Effects on biological methods for sewage treatment (Annex IIA 8.7)**

Test type/organism	End point
Activated sludge bacterial respiratory inhibition study with technical metamitron (98.4% purity)	EC50 6400 mg a.s. /litre

The following data is taken from the core assessment of AG-MA-700 SC (Goltix SC) from the zonal RR evaluated by CRD (UK) November 2012

**Effects on aquatic organisms**

AG-M4-700 SC #	<i>Daphnia magna</i>	48 h (static)	EC50	>136.1 (prod.) > 77.4 (a.s.) [Nominal]	Ref. IIIA 10.2.2.2/02: Juckeland, D. (2011)
AG-M4-700 SC #	<i>P. subcapitata</i>	72 h (static)	EyC50 ErC50	0.231 (a.s.) 0.886 (a.s.) [Mean measured]	Ref. IIIA 10.2.2.3/02: Juckeland, D. (2011)
AG-M4-700 SC #	<i>Lemna minor</i>	7 d (semi-static)	ErC50 EyC50	1.03 (a.s.) 0.491 (a.s.) [Mean measured]	Ref. IIIA 10.8.2.1/01: Juckeland, D. (2011)

**Effects on earthworms**

AG-M4-700 SC	<i>Eisenia fetida</i>	14 d	LC <sub>50</sub>	> 575	Ref. IIIA 10.6.2/01: Meisner, P. (2001)
AG-M4-700 SC	<i>Eisenia fetida</i>	56 d	NOEC	28	Ref. IIIA 10.6.3/01: Heimbach, F. (1999)

					[EU agreed endpoint: EFSA Review Report (2008) 185]
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### Effects on non-target plants

Reference	IIA 8.6.1/01; Fiebig, S. (2000) <sup>1</sup> IIA 8.6.1/02; Spatz, B.; Wever, B. (2002) <sup>2</sup>	IIA 8.6.1/03; Spatz, B.; Schmitzer, S. (2002)
Test system:	Vegetative vigour test (post-emergence); Single spray application on the plant and leaf surfaces (GS = 2-4 leaf stage) Test rates: 35 - 3520 g a.s./ha Exposure period: 14 days	Seedling emergence and growth test (pre-emergence); Single spray application onto the soil surface following seed sowing Test rates: 14.33 - 3500 g a.s./ha Exposure period: 21 days
Test substance:	GOLTIX SC 700	GOLTIX SC 700
Test method:	OEDC 208 B (draft 2000)	OEDC 208 A (draft 2000)
	Rate and parameter used for establishing the endpoint	
Species	ER <sub>50</sub> [g a.s./ha]	ER <sub>50</sub> [g a.s./ha]
Oat	2323 B	427.6 C
Onion	> 3520 a, b	272.6 c
Maize	> 3520 a, b	469.3 c
Rape	1035 B	<b>54.9</b> c
Carrot	725 B	63.0 c
Soya bean	> 3520 a, b	3428.0 c
Lettuce	<b>171.6</b> C	66.8 c

<sup>1</sup> tests in oat, onion, maize, rape, carrot, Soya bean; <sup>2</sup> test in lettuce

**Bold letters:** most sensitive ER<sub>50</sub>

a = shoot height; b = dry weight; c = fresh weight

#### 7.1 Effects on birds

No changes: Applied for changes are less worst case and are covered by the evaluation of the reregistration as decided on by the Board of Ctgb on 31 August 2016.

#### 7.2 Effects on aquatic organisms

No changes: Applied for changes are less worst case and are covered by the evaluation of the reregistration as decided on by the Board of Ctgb on 31 August 2016.

#### 7.3 Effects on terrestrial vertebrates other than birds

No changes: Applied for changes are less worst case and are covered by the evaluation of the reregistration as decided on by the Board of Ctgb on 31 August 2016.

#### 7.4 Effects on bees

No changes: Applied for changes are less worst case and are covered by the evaluation of the reregistration as decided on by the Board of Ctgb on 31 August 2016.

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

##### 7.5.1 Effects on non-target arthropods

No changes: Applied for changes are less worst case and are covered by the evaluation of the reregistration as decided on by the Board of Ctgb on 31 August 2016.

### 7.5.2 Earthworms

No changes: Applied for changes are less worst case and are covered by the evaluation of the reregistration as decided on by the Board of Ctgb on 31 August 2016.

#### 7.5.2.2 Other soil macro-organisms

No changes: Applied for changes are less worst case and are covered by the evaluation of the reregistration as decided on by the Board of Ctgb on 31 August 2016.

### 7.5.3 Effects on soil micro organisms

No changes: Applied for changes are less worst case and are covered by the evaluation of the reregistration as decided on by the Board of Ctgb on 31 August 2016.

### 7.5.4 Effects on activated sludge

No changes: Applied for changes are less worst case and are covered by the evaluation of the reregistration as decided on by the Board of Ctgb on 31 August 2016.

### 7.5.5 Effects on non-target-plants

The risk assessment for non-target plants is based on an off-crop situation with a drift percentage of 4.7. The exposure thus equals  $0.047 * \text{the application rate} * \text{MAF}$  (in case of multiple application). MAF-values are taken from ESCORT 2.

The effects of formulated met amitron on non-target plants were evaluated within the framework of two vegetative vigour tests and a seedling emergence test conducted with AG-M4-700 SC, the formulation for which authorisation is sought. The dose-response tests were performed with 7 representative plant species: oat, carrot, onion, lettuce, rape, corn and soya bean. The studies were previously submitted and reviewed as part of the EU inclusion process for met amitron.

In summary, it is evident that the risk assessment is not driven by exposure via foliage but by exposure via soil, indicated by the results of the corresponding studies: the lowest  $ER_{50}$  value (171.58 g a.s./ha) derived from the two vegetative vigour tests is much higher than the lowest  $ER_{50}$  value (54.86 g a.s./ha) derived from the seedling emergence test.

A TER is calculated with the lowest  $EC_{50}$  value from a laboratory test with higher plants and the exposure concentration. The lowest  $EC_{50}$  is 54.86 g a.s./ha for all 7 species tested. See table E.22 for TER calculation.

Comment Ctgb:

Ctgb does agree with the argument that the risk based on seedling emergence is worst-case compared to the vegetative vigour. However it should be kept in mind, that both effects were also found in vegetative vigour tests and that the risk should also be acceptable for established plants.

**Table E.22 Overview of exposure concentrations and TERs for non-target plants**

Use	Substance	Dose [kg a.s. /ha]	MAF	Drift% (off-field exposure)	Exposure (kg a.s./ha)	$EC_{50}$ [kg a.s./ha]	TER	Trigger value
All	Formulation*	3.5	1	4.7	0.16	0.05	<b>0.31</b>	5

\* AG-MA-700SC

The ratio between the lowest  $EC_{50}$  (derived from the seedling emergence) and the exposure concentration is < 5. Therefore, the risk for non-target plants is considered to be high.

The applicant proposes drift reducing measures in the NL addendum. However, crop free zones of 5m are suggested in addition to drift reducing nozzles. However, these crop free zones are not standard in the Netherlands and corresponding drift values need to be confirmed by Plant Research International (PRI). Based on what is realistic and applicable in practice, no additional crop free zones > 3 m are accepted in arable crops in The Netherlands (many small parcels on which larger crop-free zones are not realistic (not accepted by the farmers). This means that at maximum a crop-free zone of 3.0 m, measured from the middle of the last crop row to the border of the parcel (off-field evaluation zone distance (1m wide) is then 3.5 – 4.5 m) is accepted. In addition, the GAP used for the calculations is different than the proposed GAP for the current authorisation. However, in this case a HR5 is available. The following is taken from the EFSA conclusion:

Furthermore, the applicant also presented a probabilistic risk assessment in the DAR, taking into account the species sensitivity distribution for the 7 plant species tested. The 5<sup>th</sup> percentile (Hazard Rate HR<sub>5</sub>) was 35 g a.s./ha.

**Table E.23 Overview of exposure concentrations and TERs for non-target plants**

Use	Substance	Dose [kg a.s./ha]	MAF	Drift% (off-field exposure)	Exposure (kg a.s./ha)	HR <sub>5</sub> [kg a.s./ha]	TER	Trigger value
All	Formulation*	3.5	1	4.7	0.16	0.035	<b>0.22</b>	1

\* AG-MA-700SC

As seen in table E.23 the TER is still below the trigger, therefore the risk for non-target plants is still unacceptable.

*Additional information from the applicant and altered by Ctgb:*

In the following, a more realistic risk assessment is presented based on a HR<sub>5</sub> calculation and in consideration of application scenarios actually supported in the Netherlands. For this purpose, the applicant already presented a probabilistic risk assessment in the DAR, taking into account the species sensitivity distribution for the 7 plant species tested in the most sensitive test system, i.e. in the seedling emergence test with AG-M4-700 SC. In summary, the 5<sup>th</sup> percentile (Hazard Rate HR<sub>5</sub>) was determined to be 35 g a.s./ha.

The table with data of the species sensitivity distribution for the 7 plant species tested with AG-M4-700 SC taken from the corresponding DAR:

Reference	IIA 8.6.1/01; Fiebig, S. (2000) <sup>1</sup> IIA 8.6.1/02; Spatz, B.; Wever, B. (2002) <sup>2</sup>	IIA 8.6.1/03; Spatz, B.; Schmitzer, S. (2002)
Test system:	Vegetative vigour test (post-emergence); Single spray application on the plant and leaf surfaces (GS = 2-4 leaf stage) Test rates: 35 - 3520 g a.s./ha Exposure period: 14 days	Seedling emergence and growth test (pre-emergence); Single spray application onto the soil surface following seed sowing Test rates: 14.33 - 3500 g a.s./ha Exposure period: 21 days
Test substance:	Goltix SC 700	Goltix SC 700
Test method:	OEDC 208 B (draft 2000)	OEDC 208 A (draft 2000)
	Rate and parameter used for establishing the endpoint	
Species	ER <sub>50</sub> [g a.s./ha]	ER <sub>50</sub> [g a.s./ha]
Oat	2323 B	427.6 C
Onion	> 3520 a, b	272.6 c

Maize	> 3520 a, b	469.3 c
Rape	1035 B	<b>54.9</b> c
Carrot	725 B	63.0 c
Soya bean	> 3520 a, b	3428.0 c
Lettuce	<b>171.6</b> C	66.8 c
<b>HC5</b>	<b>101*</b>	<b>17.8</b>

\* Indicative number because only four values are to be used. HC5 is only used for a comparison in sensitivity between seedling emergence and vegetative vigour.

Comment Ctgb: The RMS of the DAR has not checked the appropriateness or accuracy of calculations performed by the Notifier in the probabilistic assessment to derive the HR5 value and this should be done if it is to form the basis behind a further risk assessment. Ctgb used ETX 2.0 to recalculate the HR5 and found different numbers, that is 17.8.

From an exposure point of view, the level of soil exposure considered as the crucial exposure media may be increased by multiple applications, because the active substance seems to be less stable on foliage than in soil. Therefore, a Multiple Application Factor (MAF) was taken into account for uses with more than one application (GAP **Appendix 1B**). Considering the lower endpoint for seedling emergence and the lower dissipation in soil, the risk assessment based on seedling emergence can be considered worst-case compared to risk assessment based on vegetative vigour.

Max. application rate for sugar beet etc. (GAP **Appendix 1B**)

**Application rates, timing:** 1<sup>st</sup> application: 2100 g a.s./ha pre-emergence, 14 days before last application  
2<sup>nd</sup> application: 1400 g a.s./ha

**MAF:** 1<sup>st</sup>-2<sup>nd</sup> application: 1.64 (i = 14 d, DT<sub>50</sub> = 22 d)

**MAF adjusted application rate:** (1.64-1)× 2100 + 1× 1400 g a.s./ha = **2751 g a.s./ha**

**Application rates, timing:** 1<sup>st</sup> application: 1400 g a.s./ha during emergence, 15 days before last application  
2<sup>nd</sup> – 4<sup>th</sup> application post-emergence: 700 g a.s./ha, interval 5 days

**MAF:** 1<sup>st</sup>-4<sup>th</sup> application: 1.62 (i = 15 d, DT<sub>50</sub> = 22 d); 2<sup>nd</sup>-4<sup>th</sup> application: 1.73 (i=10d, DT<sub>50</sub> = 22 d); 3<sup>rd</sup>-4<sup>th</sup> application: 1.85 (i=5d, DT<sub>50</sub> = 22 d)

**MAF adjusted application rate:** (1.62-1)× 1400 + (1.73-1)× 700 + (1.85-1)× 700 + 1× 700 g a.s./ha = **2682 g a.s./ha**

Max. application rate for bulbflowers, flower bulbs, iris, narcis, tulp (GAP **Appendix 1B**)

**Application rates, timing:** 1<sup>st</sup> application: 1400 g a.s./ha, 7 days before last application  
2<sup>nd</sup> application: 1400 g a.s./ha

**MAF:** 1<sup>st</sup> application: 1.8 (2 applications, interval = 7 d, DT<sub>50</sub> = 22 d)

**MAF adjusted application rate:**  $(1.8-1) \times 1400 + 1 \times 1400 \text{ g a.s./ha} = 2523 \text{ g a.s./ha}$

Max. application rate for lily (GAP Appendix 1B)

**Application rates, timing:** 5× 700 g a.s./ha, application interval = 7 days

**MAF:** 3.38 (5 applications, interval = 7 d,  $DT_{50} = 22 \text{ d}$ )

**MAF adjusted application rate:**  $3.38 \times 700 \text{ g a.s./ha} = 2363 \text{ g a.s./ha}$

**Application rates, timing:** 1<sup>st</sup> application: 1400 g a.s./ha, 21 days before last application; 2<sup>nd</sup> application: 700 g a.s./ha, 14 days before last application; 3<sup>rd</sup> application: 700 g a.s./ha, 7 days before last application; 4<sup>th</sup> application: 700 g a.s./ha.

**MAF:** 1st-4<sup>th</sup> application: 1.52 (i=21d,  $DT_{50} = 22 \text{ d}$ ); 2<sup>nd</sup>-4<sup>th</sup> application: 1.64 (i=14d,  $DT_{50} = 22 \text{ d}$ ); 3<sup>rd</sup>-4<sup>th</sup> application: 1.80 (i=7d,  $DT_{50} = 22 \text{ d}$ )

**MAF adjusted application rate:**  $(1.52-1) \times 1400 + (1.64-1) \times 700 + (1.80-1) \times 700 + 1 \times 700 \text{ g a.s./ha} = 2434 \text{ g a.s./ha}$

According to SANCO/10329/2002 (2002), non-target plants are defined as *non-crop plants located outside the treatment area*. Therefore, exposure of non-target plants to AG-M4-700 SC expressed as predicted environmental rates (PER) has only to be assessed for the off-field area.

Spray drift is the most important route of exposure of plants in the off-field area. Consequently, the exposure assessment was based on spray drift following application of AG-M4-700 SC considering a distance of 1 m from the edges of the parcel (off-field evaluation zone of 0.5 - 1.5 m) and appropriate risk mitigation measures, i.e. the use of drift reducing spray techniques. For the predicted exposure of the off-field area, drift deposition was considered by applying the spray drift values as given in the Dutch "Evaluation Manual for the Authorisation of Plant Protection Products and Biocides" (Chapter 7 - Ecotoxicology: terrestrial; non-targets; version 2.0; January 2014).

Furthermore, as already justified above it is considered that exposure via soil is more relevant with respect to adverse effects on terrestrial non-target plants. In this case, interception by the off-crop vegetation is taken into account in order to assess a more realistic exposure of non-target plants which is in general in line with the recommendations of the "Evaluation Manual for the Authorisation of Plant Protection Products and Biocides" (Chapter 7 - Ecotoxicology: terrestrial; non-targets; version 2.0; January 2014). Taking the actual spraying period of AG-M4-700 SC into consideration (i.e. April to July), the vegetation of the non-sprayed area outside the field is well developed. According to "Evaluation Manual for the Authorisation of Plant Protection Products and Biocides" (Chapter 7 - Ecotoxicology: terrestrial; non-targets; version 1.0; January 2010) interception by off-field plants is between 40 % and 50 % at this timing. Accordingly, a deposition factor of 0.6 was used as worst-case.

PER<sub>off-field</sub> and TER values are summarised in the table below.

## Comment Ctgb:

Based on the LoEP and the fate risk assessment, the PEC soil is 22 days. Thus the calculations should be adapted accordingly. Furthermore, applications of Goltix can start already in March, or even in February for Lily. Corresponding deposition values for those months are 0.7 and 0.8 respectively.

Considering vegetative vigour, it should be made clear if the risk assessment for seedling emergence will also protect the risk based on vegetative vigour. Not all refinement options are also valid for vegetative vigour tests. A DT50 of 1.9 days has been established for beets. However this value cannot be extrapolated to all foliage, but it is clear that the dissipation will be much faster than from soil and that the calculated MAF for seedling emergence will certainly be worst-case for vegetative vigour. However, interception is not relevant for vegetative vigour.

Ctgb therefor added Table E - 25

**Table E – 24: TER values for non-target plants, considering the HR<sub>5</sub> (derived from the seedling emergence)**

HR <sub>5</sub> [g a.s./h a]	A <sub>MAF</sub> [g a.s./h a]	f <sub>dep</sub>	Drift scenario	f <sub>drift</sub> <sup>#</sup>	PER [g a.s./ha]	TER	TER trigg er
<b>GAP Appendix 1B no 01: Sugar beet etc. supported in the Netherlands:</b>							
1× 2100 g a.s./ha, pre-emergence (BBCH 00-09), i = 5 d DT <sub>50</sub> =22							
17.8	2100	0.7	Standard flat fan	0.047 / 0.019	69.09/27.9 3	<b>0.26/0.64</b>	1
			Low drift nozzle	0.017 / 0.012	24.99/17.6 4	<b>0.71/1.01</b>	
			Low drift nozzle + end nozzle	0.015 / 0.009	22.05/13.2 3	<b>0.81/1.35</b>	
			75% drift reducing nozzle	0.01 / 0.009	14.7/13.23	1.21/1.35	
			75% drift red. nozzle + end nozzle	0.009 / 0.007	13.23/10.2 9	1.35/1.73	
<b>GAP Appendix 1Bno 01: Sugar beet etc. supported in the Netherlands:</b>							
1× 2100, pre-emergence (BBCH 00-09) + 1× 1400 g a.s./ha, post-emergence (BBCH 10-39), i = 14 d DT <sub>50</sub> =22							
17.8	2751	0.7	Standard flat fan	0.047 / 0.019	90.51/36.5 9	<b>0.20/0.49</b>	1
			Low drift nozzle	0.017 / 0.012	32.74/23.1 1	<b>0.54/0.77</b>	
			Low drift nozzle + end nozzle	0.015 / 0.009	28.89/17.3 3	<b>0.62/1.03</b>	
			75% drift reducing nozzle	0.01 / 0.009	19.26/17.3 3	<b>0.92/1.03</b>	
			75% drift red. nozzle + end nozzle	0.009 / 0.007	17.33/13.4 8	1.03/1.32	



HR <sub>5</sub> [g a.s./h a]	A <sub>MAF</sub> [g a.s./h a]	f <sub>dep</sub>	Drift scenario	f <sub>drift</sub> <sup>#</sup>	PER [g a.s./ha]	TER	TER trigg er
<b>GAP Appendix 1B no 04: Ornamental flowers supported in the Netherlands:</b> 1× 1400 + 1× 1400 g a.s./ha, during emergence/early post-emergence (BBCH 09-39), i = 7 d DT <sub>50</sub> =22							
17.8	2523	0.7	Standard flat fan	0.047 / 0.019	83.01/33.5 6	<b>0.21/0.53</b>	1
			Low drift nozzle	0.017 / 0.012	30.02/21.1 9	<b>0.59/0.84</b>	
			Low drift nozzle + end nozzle	0.015 / 0.009	26.49/15.8 9	<b>0.67/1.12</b>	
			75% drift reducing nozzle	0.01 / 0.009	17.66/15.8 9	1.01/1.12	
			75% drift red. nozzle + end nozzle	0.009 / 0.007	15.89/12.3 6	1.12/1.44	
<b>GAP Appendix 1B no 06: Lily supported in the Netherlands:</b> 1× 1400 + 1× 700 + 1× 700 g a.s./ha, during emergence/early post-emergence (BBCH 09-79), i = 7 d DT <sub>50</sub> =22							
17.8	2434	0.8	Standard flat fan	0.047 / 0.019	91.53/37.0 0	<b>0.19/0.48</b>	1
			Low drift nozzle	0.017 / 0.012	33.11/23.3 7	<b>0.54/0.76</b>	
			Low drift nozzle + end nozzle	0.015 / 0.009	29.21/17.5 3	<b>0.61/1.02</b>	
			75% drift reducing nozzle	0.01 / 0.009	19.47/17.5 3	<b>0.91/1.02</b>	
			75% drift red. nozzle + end nozzle	0.009 / 0.007	17.53/13.6 3	1.02/1.31	

bold: below the corresponding trigger value

# without/with air assistance

In conclusion, based on a probabilistic approach, a safe use (with respect to an acceptable risk for non-target plants) can be identified for each of the GAP uses proposed for AG-M4-700 SC in the Netherlands, provided that appropriate risk mitigation measures are applied (see below).

**Table E - 26: Proposed risk mitigation measures, by the applicant, for the GAP uses of AG-M4-700 SC supported in the Netherlands**

GAP no.	Crop	Worst-case application scenario	Proposed risk mitigation measures
<b>Protection of terrestrial non-target plants</b>			
01	<i>Beta vulgaris</i>	a) Pre-emergence (BBCH 00-09), 1× 2100 g a.s./ha	- 75% drift reducing nozzle + end nozzle

GAP no.	Crop	Worst-case application scenario	Proposed risk mitigation measures
	<b>vulgaris</b> <b>var.:</b> Sugar beet, fodder beet, beetroot	b) Pre-/Post-emergence (BBCH 00-39), 1× 2100 + 1× 1400 g a.s./ha, i = 14d	- 75% drift reducing nozzle + end nozzle
02	<b>Ornamental flowers:</b> Bulbflowers, flowerbulbs, iris, narcis, tulp, lily, tagetes etc.	a) Pre-/early post-emergence (BBCH 09-39), 1× 1400 + 1× 1400 g a.s./ha, i = 7d	- 75% drift reducing nozzle + end nozzle
		b) Pre-/Post-emergence (BBCH 09-79, only for lily), 1x 1400 + 3× 700 g a.s./ha, i = 7d	- 75% drift reducing nozzle + end nozzle

Comment Ctgb:

Table 24 leads to the following restriction sentences are relevant per crop and scenario:

GAP no.	Crop	Worst-case application scenario	Proposed risk mitigation measures
<b>Protection of terrestrial non-target plants</b>			
01	<b>Beta vulgaris vulgaris</b> <b>var.:</b> Sugar beet, fodder beet, beetroot	a) Pre-emergence (BBCH 00-09), 1× 2100 g a.s./ha	- 75% drift reducing nozzle + end nozzle
		b) Pre-/Post-emergence (BBCH 00-39), 1× 2100 + 1× 1400 g a.s./ha, i = 14d	- 75% drift reducing nozzle + end nozzle
02	<b>Ornamental flowers:</b> Bulbflowers, flowerbulbs, iris, narcis, tulp, lily, tagetes etc.	a) Pre-/early post-emergence (BBCH 09-39), 1× 1400 + 1× 1400 g a.s./ha, i = 7d	- 75% drift reducing nozzle + end nozzle
		b) Pre-/Post-emergence (BBCH 09-79, only for lily), 1x 1400 + 3× 700 g a.s./ha, i = 7d	- 75% drift reducing nozzle + end nozzle

For the clarity of the label the following restriction sentence is proposed:

*Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing in onbedekte teelten uitsluitend toegestaan wanneer gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen en kantdoppen.*

### Conclusions any other organisms

The product does comply with the RGB for the aspect non-target plants, provided drift mitigating measures are applied.

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

See List of End-points.

### 7.7 Data requirements

None.

## 7.8 Restriction sentences

The following restriction sentences were proposed by the applicant:

*None.*

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

In the WG (legal instructions):

- *Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing in onbedekte teelten uitsluitend toegestaan wanneer gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen en kantdoppen.*

## 7.9 Overall conclusions regarding ecotoxicology

It can be concluded that:

By adjusting the GAP in comparison to the reregistration as decided on by the Board of Ctgb on 31 August 2016 and applying the above proposed mitigation measures the product is assessed to have an acceptable risk. The product complies with the ecotoxicological Uniform Principles.

## 8. Efficacy

Authorisation is sought for modification of the label of Goltix SC. Evaluation of efficacy is based on the evaluation of the re-registration of Goltix SC (dossier number 20120427 THG), Board decision 31 August 2016).

The proposed changes concern lowering the dose applied and a changed time interval between applications.

In beet pre-emergence, around emergence and post-emergence applications are claimed that can be combined up to a maximum of 5 L/ha in total per cultivation cycle.

The claim is 1 pre-emergence application at a dose rate of 1.5-3 L/ha, depending on the type of soil.

The claim for around emergence application at 2 L/ha + oil is changed, a minimum time interval of 14 days between pre-emergence application and application during emergence is added.

The claim for post-emergence application is split into a maximum of 6 applications (with 5 days interval) at a dose rate of 0.5-1 L/ha under the low dosage system (LDS) in combination with oil.

Currently a dose rate of 0.5-2 L/ha is authorized in LDS with 0.5-1 L oil per hectare .

The same label claims are made for beetroot.

The claim in field grown flower bulbs and tubers (excluding lily) is for one or two around/post emergence application at a dose rate of 2 L/ha, depending on the type of soil. Currently, one or two post emergence applications for flower bulbs and tubers application is registered at a dose rate of 2-3 L/ha.

The claim in lily (open field) is for one application around emergence or post emergence at a dose rate of 2 L/hectare. Currently a dose rate of 2-3 L/hectare and 1 or 2 applications are registered. The dose rate of the post-emergence LDS treatment in lily remains unchanged at 0.5-1.0 L/ha. The amount of mineral oil to be added is 5 L/ha and the maximum number of applications is 10.

The claims for Tagetes and Lily-protected use did not change and will not be further discussed.

### 8.1 Efficacy evaluation

Effectiveness

### Beet/Beetroot

#### Pre-emergence/emergence

The claim for the minimum interval between a pre-emergence application and an emergence application is 14 days. Currently no minimum interval is mentioned on the WG/label. The interval of 14 days is now specified for reason of the environmental assessment. According to information from IRS (Instituut voor Rationale Suikerproductie) 50% emergence will be reached around two weeks after planting seeds. A claim for a minimum interval of 14 days between pre-emergence and emergence is therefore acceptable.

#### *Post-emergence application*

The claim in beet is a maximum of 6 post-emergence applications at a dose rate of 0.5-1 L/ha in LDS in combination with oil up to a maximum of 5 L/ha. Currently 6 post-emergence applications at 0.5-2 L/ha in LDS in combination with oil up to a maximum of 5 L/ha are registered.

According to the applicant a dose rate of 0.5-1 L/ha in LDS is acceptable because it was the authorised use before the re-registration. However the WG/label before the re-registration mentions that 0.5-1 L/ha is possible in LDS in combination with other authorised products in beet. Therefore, based on the pre-reregistration use the WG/label should mention that a dose rate of 0.5-1 L/ha is only possible in combination with other authorised products.

A total of 8 trials were submitted for trials at a low rate (0.8-0.85 L/ha) with oil. These trials do not cover a range of 0.5-1L/ha and can therefore not be accepted.

The use in beetroot is acceptable if with the restriction that LDS is possible in combination with other authorised products. Beetroot is sown with a higher density and therefore extrapolation is possible from beet to beetroot.

### Flower bulbs

No new data is presented on the control of weeds in flower bulb and blub flower crops. The claim in these crops has changed in relation to the currently authorised use.

The claim in field grown flower bulbs and tubers (excl. lily) is 2 around/post emergence application at a dose rate of 2 L/ha. Currently, two post emergence or around/post emergence application is registered at a dose rate of 2-3 L/ha with a maximum of 5 L/ha per 12 months.

A dose rate of 0.5-2 L/ha (depending on soil type) is present on the current WG/label for Tagetes. According to expert judgement it possible to extrapolate for weed control from Tagetes to flower bulbs and tubers. Therefore 2 around/post emergence application at a dose rate of 2 L/ha is acceptable.

### Lily

No new data is presented on the control of weeds in lily (field uses). The claim for lily has changed in relation to the currently authorised use.

The claim in field grown lily is 1 around/post emergence application at a dose rate of 2 L/ha. Currently, two post emergence or around/post emergence application is registered at a dose rate of 2-3 L/ha with a maximum of 5 L/ha per 12 months.

A dose rate of 0.5-2 L/ha (depending on soil type) is present on the current WG/label for Tagetes. According to expert judgement it is possible to extrapolate for weed control from Tagetes to lily. Therefore an around/post emergence application at a dose rate of 2 L/ha is acceptable.

An around/post emergence application can be combined with LDS treatment like in beet. Therefore a reduction from 2 to 1 around/post emergence treatment is acceptable.

### **Conclusion**

The evaluation complies with the Uniform Principles, article 2.1.

The product controls annual broadleaved weeds and annual meadow grass (*Poa annua*) in beets, field grown flower bulbs and tubers and in protected lily.

## **8.2 Harmful effects**

### **8.2.1 Phytotoxicity**

Please refer to the evaluation of re-registration of Goltix SC (20120427 THG), Board decision of 31 August 2016.

### **8.2.2 Yield**

Please refer to the evaluation of re-registration of Goltix SC (20120427 THG), Board decision of 31 August 2016.

### **8.2.3 Effects on succeeding crops or substitution crops**

Please refer to the evaluation of re-registration of Goltix SC (20120427 THG), Board decision of 31 August 2016.

### **8.2.4 Effects on plants or plant products to be used for propagation**

Please refer to the evaluation of re-registration of Goltix SC (20120427 THG), Board decision of 31 August 2016.

### **8.2.5 Effects on adjacent crops**

The maximum applied rate of Goltix SC are lowered compared to the current label.

No negative effects on adjacent crops are expected.

### **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**

Please refer to the evaluation of re-registration of Goltix SC (20120427 THG), Board decision of 31 August 2016.

### **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.

The changes in application details in the GAP proposed by the applicant have been assessed to lead to an acceptable use with less stringent drift reducing measures as compared to the reregistration by Board decision d.d. 31 August 2016. Efficacy is considered to be sufficiently proven for the applied for changes in the GAP, except that for the LDS use with the reduced dose rate of 0.5-1.0 L/ha in beets and beetroot should be stated that this is in combination with other authorized products.

**The restriction on the current label:**

*Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing in onbedekte teelten uitsluitend toegestaan wanneer gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen met luchtondersteuning en kantdoppen.*

**Can therefore be replaced by :**

*Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing in onbedekte teelten uitsluitend toegestaan wanneer gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen en kantdoppen.*

All other restrictions resulting from the reregistration (Board decision 31 August 2016) remain in place.

The evaluation is in accordance with the Uniform Principles laid down in appendix VI of Directive 91/414/EEC. The evaluation has been carried out on basis of a dossier that meets the criteria of appendix III of the Directive.

**10. Classification and labelling**

Please refer to the evaluation of the reregistration as decided on by the Board of Ctgb on 31 August 2016

## Appendix 1A; Table of authorized uses; Goltix SC – metamitron 700 g/l

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 Method / Kind	Timing / Growth stage of crop & season	Number / (min. Interval between applications)	Application rate per treatment kg, L product / ha	kg as/ha	Water L/ha min / max	PHI (days)	Remarks: 1. max. no. of applications per crop and season 2. Maximum product rate per season 3. additional remarks
Changed uses												
1	NL	Beet	F	annual broadleaved weeds and <i>Poa annua</i>	Downward spraying	Pre-emergence (BBCH 00 - 09) Mar-May	1	1,5 – 3 L/ha	1,05 – 2,1	200- 400	-	2. Max. 5 L product/ha/season  <i>During emergence:</i> 3. In combination with mineral- or vegetable oil 2 L/ha
						During emergence (BBCH 09 - 10) Mar – May	1 (14 days after pre- emergence application)	2 L/ha	1,4	200- 400	-	3. LDS in combination with mineral- or vegetable oil 2 L/ha
						Post-emergence (BBCH 10 - 39) Mar-Jul	1-6 (5 days)	0,5 –1 L/ha	0,35 – 0,7	200- 400	-	<i>Post-emergence:</i> 3. LDS in combination with authorised products 0,5-1 oil per hectare.
3	NL	Beetroot	F	annual broadleaved weeds and <i>Poa annua</i>	Downward spraying	Pre-emergence (BBCH 00 - 09) Mar – May	1	1,5 – 3 L/ha	1,05 – 2,1	200- 400	-	2. Max. 5 L product/ha/season  <i>During emergence:</i> 3. In combination with mineral- or vegetable oil 2 L/ha.
						During emergence (BBCH 09 - 10) Mar- May	1 (14 days after pre- emergence appl.)	2 L/ha	1,4	200- 400	-	3. LDS in combination with mineral- or vegetable oil 2 L/ha.
						Post-emergence (BBCH 10 - 39) Mar - Jul	1-6 (5 days)	0,5 – 1 L/ha	0,35 – 0,7	200- 400	-	<i>Post-emergence:</i> 3. LDS in combination with authorised products
4	NL	Flower bulb and flower corm crops excluding lily	F	annual broadleaved weeds and <i>Poa annua</i>	Downward spraying	During and/or post- emergence (BBCH 09 - 19) Feb- Jul	1-2 (7 days)	2 L/ha	1,4	200- 500	-	2. Max. 4 L product/ha/season
6	NL	Lily	F	annual broadleaved weeds and <i>Poa annua</i>	Downward spraying	During and/or post- emergence (BBCH 09 - 19) Feb- Jul	1	2 L/ha	1,4	200- 500	-	2. Max. 5 L product/ha/season
					Downward spraying	LDS post emergence (BBCH 10 - 79) Apr - Sep	1-10 (7 days)	0,5 – 1 L/ha	0,35 – 0,7	200- 500	-	2. Max. 5 L product/ha/season 3. In combination with 5 l/ha mineral or vegetable oil

Only changed uses compared to the reregistration (board decision 31 August 2016) are included in this GAP.