



HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 BESLUIT

Op 27 oktober 2015 is van

ADAMA Registrations B.V.
Postbus 355
3830 AK LEUSDEN

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

Goltix Queen

op basis van de werkzame stoffen metamitron en quinmerac.

HET COLLEGE BESLUIT tot uitbreiding van bovenstaand middel.

Alle bijlagen vormen een onlosmakelijk onderdeel van dit besluit.

Voor nadere gegevens over deze toelating wordt verwezen naar de bijlagen:

- Bijlage I voor details van de aanvraag en toelating.
- Bijlage II voor de etikettering.
- Bijlage III voor wettelijk gebruik.
- Bijlage IV voor de onderbouwing.

1.1 Samenstelling, vorm en verpakking

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

1.2 Gebruik

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

1.3 Classificatie en etikettering

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

14298 N

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

1.4 Aflever- en opgebruiktermijn (respijtperiode)

Het nieuwe gebruiksvoorschrift en de nieuwe etikettering dienen bij de eerstvolgende aanmaak op de verpakking te worden aangebracht. Oude verpakkingen mogen worden opgemaakt.

2 WETTELIJKE GRONDSLAG

Besluit	artikel 51 Verordening (EG) Nr. 1107/2009 en artikel 2.2 Rgb
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Rgb d.d. 13 juni 2011 en Evaluation Manual 1.1

3 BEOORDELINGEN

3.1 Fysische en chemische eigenschappen

De identiteit en de fysische en chemische eigenschappen van het middel en de werkzame stof wijzigen niet.

3.2 Analysemethoden

De analysemethoden voor de werkzame stoffen en het middel wijzigen niet. Voor de toegelaten toepassingen voldoen de vereiste residuanalysemethoden.

3.3 Risico voor de mens

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

3.4 Risico voor het milieu

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

3.5 Werkzaamheid

Gelet op artikel 51 Verordening (EG) 1107/2009 is de aanvraag niet beoordeeld voor het aspect werkzaamheid (inclusief ftotoxiciteit).

14298 N

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, 7 oktober 2016

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:	20151719 NLKUG
Type aanvraag:	aanvraag tot uitbreiding kleine toepassing van gewasbeschermingsmiddeltoelating
Middelnaam:	Goltix Queen
Formele registratiedatum: *	4 november 2015
Datum in behandeling name:	2 maart 2016
Datum compliance check:	N.v.t.

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

2 Stofinformatie

Werkzame stof	Gehalte
metamitron	525G/L
quinmerac	40G/L

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

De stof quinmerac is per 1 mei 2011 geplaatst op Annex I van Richtlijn 91/414/EEG (2010/89/EU) en vervolgens bij Uitvoeringsverordening (EU) 540/2011 d.d. 25 mei 2011 goedgekeurd. De goedkeuring van deze werkzame stof expireert op 30 april 2021.

3 Toelatingsinformatie

Toelatingsnummer:	14298 N
Expiratiedatum:	30 november 2020
Afgeleide of parallel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel
W-codering professioneel gebruik:	2

4 Aflever- en opgebruiktermijnen voor oude etiket

Vorige W-codering professioneel gebruik:	1
Aflevertermijn professioneel gebruik:	nvt
Opgebruiktermijn professioneel gebruik:	nvt

5 Verpakkingsinformatie

Aard van het preparaat:
Suspensie concentraat

BIJLAGE II Etikettering van het middel Goltix Queen

Professioneel gebruik

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

Pictogram	GHS09
Signaalwoord	-
Gevarenaanduidingen	H411 Giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P102 Buiten het bereik van kinderen houden. P501 Inhoud/verpakking afvoeren naar SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
Aanvullende etiketelementen	EUH208 Bevat 1,2-benzisothiazol-3(2H)-on. Kan een allergische reactie veroorzaken. EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.

BIJLAGE III WG van het middel

WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het professionele gebruik als onkruidbestrijdingsmiddel door middel van een na opkomst behandeling in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.0, Ctgb juni 2011) onder de vermelde toepassingsvoorwaarden

Toepassingsgebied	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus	Minimum interval tussen toepassingen
Bieten	Eenjarige breedbladige onkruiden	2 L/ha	3	10 dagen

Het gebruik in de teelt van lelie, gladiool en pioen is beoordeeld conform artikel 51 EC 1107/2009. Er is voor deze toepassingen geen werkzaamheids- en fytoxiciteitonderzoek uitgevoerd. Er wordt daarom aangeraden een proefbespuiting uit te voeren, voordat het middel gebruikt wordt. Gebruik van dit middel in deze toepassingsgebieden, komt voor risico en verantwoordelijkheid van de gebruiker.

Toepassingsgebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassing en per teeltcyclus	Minimum interval tussen toepassing en
Lelie (vermeerderingsteelt, onbedekt)	Na-opkomst	Eenjarige breedbladige onkruiden	0,7 – 1 L/ha	6	5 dagen
Gladiool (vermeerderingsteelt, onbedekt)	Na-opkomst	Eenjarige breedbladige onkruiden	0,7 – 1 L/ha	6	5 dagen
Pioen (snijbloemen, onbedekt)	Na-opkomst, onder het gewas	Eenjarige breedbladige onkruiden	1,5 L/ha	3	5 dagen

Toepassingsvoorwaarden

Draag beschermende kleding en handschoenen tijdens het handmatig spuiten in lelie en gladiool (vermeerderingsteelt) en pioen.

Om het grondwater te beschermen mag dit product in de teelt van lilies en gladiolen in de periode 1 september tot 1 maart niet worden gebruikt in grondwaterbeschermingsgebieden

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

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

14298 N

- na ploegen en een wachttijd van 2 maanden na de laatste toepassing kunnen raaigras en klaver worden geteeld.

Resistentiemanagement

Dit middel bevat de werkzame stoffen metamitron en quinmerac.

Metamitron behoort tot de triazinonen de Hrac code is C1, Quinmerac behoort tot de quinolinecarboxylic-zuren de Hrac code is O.

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.

14298 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE IV

RISKMANAGEMENT

Art. 51
Extension of authorisation for minor uses

DRAFT
REGISTRATION REPORT
Part A

Risk Management

Product name: Goltix Queen
Active Substances:
metamitron 525 g/L and quinmerac 40 g/L

COUNTRY: The Netherlands

NATIONAL ASSESSMENT

Applicant: ADAMA Registrations B.V.

Date: additional questions April 2016

Table of Contents

PART A – Risk Management	8
1 Details of the application.....	8
1.1 Application background	9
1.2 Approval	9
1.3 Regulatory approach.....	10
1.3.1 Uses applied for and registration decision.....	10
1.3.2 Public interest and minor use.....	11
1.4 Data protection claims	11
1.5 Letters of Access	11
2 Details of the authorisation.....	11
2.1 Product identity	11
2.2 Classification and labelling.....	11
2.2.1 Classification and labelling under Directive 99/45/EC or Regulation (EC) No 1272/2008	11
2.2.2 R and S phrases under Regulation (EC) No 547/2011	12
2.2.3 Other phrases	12
2.2.3.1 Restrictions linked to the PPP	Fout! Bladwijzer niet gedefinieerd.
2.2.3.2 Specific restrictions linked to the intended uses.....	13
3 Risk management	14
3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles	14
3.1.1 Physical and chemical properties	14
3.1.2 Methods of analysis.....	14
3.1.2.1 Analytical method for the formulation	14
3.1.2.2 Analytical methods for residues	14
3.1.3 Mammalian Toxicology	14
3.1.4 Residues and Consumer Exposure	22
3.1.5 Environmental fate and behaviour.....	22
Metamitron	23
Quinmerac	24
3.1.6 Ecotoxicology.....	25
3.1.7 Efficacy.....	29
3.2 Conclusions	29
3.3 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation.....	31
Appendix 1 – Reference to the product authorisation	31
Appendix 2 – Copy of the product label	31
Appendix 3 – Letter of Access	32
IIIA 9 FATE AND BEHAVIOUR IN THE ENVIRONMENT.....	Fout! Bladwijzer niet gedefinieerd.
IIIA 9.1 Rate of Degradation in Soil	Fout! Bladwijzer niet gedefinieerd.
IIIA 9.1.1 Aerobic degradation of the preparation in soil.....	Fout! Bladwijzer niet gedefinieerd.
IIIA 9.1.2 Anaerobic degradation of the preparation in soil... ..	Fout! Bladwijzer niet gedefinieerd.
IIIA 9.2 Field Studies.....	Fout! Bladwijzer niet gedefinieerd.
IIIA 9.2.1 Soil dissipation testing on a range of representative soils.....	Fout! Bladwijzer niet gedefinieerd.
IIIA 9.2.2 Soil residue testing.....	Fout! Bladwijzer niet gedefinieerd.
IIIA 9.2.3 Soil accumulation testing	Fout! Bladwijzer niet gedefinieerd.
IIIA 9.2.4 Aquatic (sediment) field dissipation	Fout! Bladwijzer niet gedefinieerd.
IIIA 9.2.5 Forestry field dissipation.....	Fout! Bladwijzer niet gedefinieerd.

- IIIA 9.3 Mobility of the Plant Protection Product in Soil **Fout! Bladwijzer niet gedefinieerd.**
- IIIA 9.3.1 Column leaching..... **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.3.2 Lysimeter studies **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.3.3 Field leaching studies **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.3.4 Volatility – laboratory study..... **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.3.5 Volatility – field study **Fout! Bladwijzer niet gedefinieerd.**
- IIIA 9.4 Predicted Environmental Concentrations in Soil (PECs) for the Active Substance.....**Fout! Bladwijzer niet gedefinieerd.**
- IIIA 9.4.1 Initial PECs values..... **Fout! Bladwijzer niet gedefinieerd.**
 - Active substance metamidon **Fout! Bladwijzer niet gedefinieerd.**
 - Active substance quinmerac..... **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.4.2 Short-term PECs values (1-4 days after last application) **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.4.3 Long-term PECs values (from 7-100 days after last application) ... **Fout! Bladwijzer niet gedefinieerd.**
- IIIA 9.5 Predicted Environmental Concentrations in Soil (PECs) for Relevant Metabolites.....**Fout! Bladwijzer niet gedefinieerd.**
- IIIA 9.5.1 Initial PECs values..... **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.5.2 Short-term PECs values (1-4 days after last application) **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.5.3 Long-term PECs values (from 7-100 days after last application) ... **Fout! Bladwijzer niet gedefinieerd.**
- IIIA 9.6 Predicted Environmental Concentrations in Ground Water (PECgw) **Fout! Bladwijzer niet gedefinieerd.**
- Metamidon **Fout! Bladwijzer niet gedefinieerd.**
 - Quinmerac **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.6.1 Active substance **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.6.2 Relevant metabolites **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.6.3 Additional field testing **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.6.4 Information on impact on water treatment procedures **Fout! Bladwijzer niet gedefinieerd.**
- IIIA 9.7 Predicted Environmental Concentrations in Surface Water (PECsw) for the Active Substance **Fout! Bladwijzer niet gedefinieerd.**
- IIIA 9.7.1 Initial PECsw value for static water bodies **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.7.2 Initial PECsw value for slow moving water bodies.. **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.7.3 Short-term PECsw values for static water bodies (1-4 days after last application) .**Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.7.4 Short-term PECsw values for slow moving water bodies (1-4 days after last application) **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.7.5 Long-term PECsw values for static water bodies (7-42 days after last application) **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.7.6 Long-term PECsw values for slow moving water bodies (7-42 days after last application) **Fout! Bladwijzer niet gedefinieerd.**
- IIIA 9.8 Predicted Environmental Concentrations in Surface Water (PECsw) for Metabolites.....**Fout! Bladwijzer niet gedefinieerd.**
- IIIA 9.8.1 Initial PECsw value for static water bodies **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.8.2 Initial PECsw value for slow moving water bodies.. **Fout! Bladwijzer niet gedefinieerd.**
 - IIIA 9.8.3 Short-term PECsw values for static water bodies 1-4 days after last application) ..**Fout! Bladwijzer niet gedefinieerd.**

IIIA 9.8.4	Short-term PECsw values for slow moving water bodies 1-4 days after last application)	Fout! Bladwijzer niet gedefinieerd.
IIIA 9.8.5	Long-term PECsw values for static water bodies 7-42 days after last application)	Fout! Bladwijzer niet gedefinieerd.
IIIA 9.8.6	Long-term PECsw values for slow moving water bodies 7-42 days after last application)	Fout! Bladwijzer niet gedefinieerd.
IIIA 9.9	Fate and Behaviour in Air	Fout! Bladwijzer niet gedefinieerd.
IIIA 9.9.1	Spray droplet size spectrum – laboratory studies ..	Fout! Bladwijzer niet gedefinieerd.
IIIA 9.9.2	Drift – field evaluation	Fout! Bladwijzer niet gedefinieerd.
IIIA 9.10	Other/Special Studies	Fout! Bladwijzer niet gedefinieerd.
IIIA 9.10.1	Laboratory studies	Fout! Bladwijzer niet gedefinieerd.
IIIA 9.10.2	Field studies	Fout! Bladwijzer niet gedefinieerd.
Appendix 1:	List of data submitted in support of the evaluation	Fout! Bladwijzer niet gedefinieerd.
Appendix 3:	Additional information provided by the applicant.	Fout! Bladwijzer niet gedefinieerd.
IIIA 10	RISK ASSESSMENT	Fout! Bladwijzer niet gedefinieerd.
IIIA 10.1	Effects on Birds	Fout! Bladwijzer niet gedefinieerd.
IIIA 10.1.1	Acute toxicity exposure ratio (TER_A)	Fout! Bladwijzer niet gedefinieerd.
IIIA 10.1.2	Long-term toxicity exposure ratio (TER_{ST})	Fout! Bladwijzer niet gedefinieerd.
IIIA 10.2	Effects on Aquatic Organisms	Fout! Bladwijzer niet gedefinieerd.
IIIA 10.3	Effects on Terrestrial Vertebrates Other Than Birds	Fout! Bladwijzer niet gedefinieerd.
IIIA 10.3.1	Toxicity exposure ratios	Fout! Bladwijzer niet gedefinieerd.
IIIA 10.3.1.1	Acute toxicity exposure ratio (TER_A)	Fout! Bladwijzer niet gedefinieerd.
IIIA 10.3.1.3	Long-term toxicity exposure ratio (TER_{LT})	Fout! Bladwijzer niet gedefinieerd.
IIIA 10.4	Effects on Bees	Fout! Bladwijzer niet gedefinieerd.
IIIA 10.5	Effects on Arthropods Other Than Bees	Fout! Bladwijzer niet gedefinieerd.
IIIA 10.6	Effects on Earthworms and Other Soil Non-target Macro-organisms	Fout! Bladwijzer niet gedefinieerd.
IIIA 10.7	Effects on Soil Microbial Activity	Fout! Bladwijzer niet gedefinieerd.
IIIA 10.8	Effects on Non-Target Plants	Fout! Bladwijzer niet gedefinieerd.
IIIA 10.9	Other Non-Target Species (Flora and Fauna)	Fout! Bladwijzer niet gedefinieerd.
IIIA 10.10	Other/Special Studies	Fout! Bladwijzer niet gedefinieerd.
IIIA 10.11	Summary and Evaluation of Points 10.1-10.10	Fout! Bladwijzer niet gedefinieerd.

PART A – Risk Management

This document describes the acceptable use conditions required for extension of the registration of Goltix Queen containing met amitron 525 g/L and quinmerac 40 g/L in The Netherlands.

The risk assessment conclusions are based on the already existing registration of the Goltix Queen in The Netherlands (risk envelope approach). The following sections of Registration Report, Part B were prepared on basis of new data (see also table below):

Assessments for the safe use of Goltix Queen have been made using the current versions of endpoints agreed in the EU reviews of met amitron and quinmerac.

Risk envelope overview:

section	worst case critical GAP used	covered by risk envelope (decision)	remarks
1 Identity, physical and chemical	not relevant for extension of authorisation according Article 51.	yes	
2 analytical methods	formulation: not relevant for extension of authorisation according Article 51.	yes	for residues see: 3.1.2.2
3 mammalian toxicology	Peony, handheld spray application 2 L/ha	no	See Part a, 3.1.3 for this section
4 metabolism and residues	covered by the main authorisation	yes	
5 environmental fate	Lily, Gladiolus and Peony	no	see special Part B (5) and section 3.1.5
6 ecotoxicological studies	Peony	no	see special Part B (6) and section 3.1.6
7 efficacy data	Not relevant	Not applicable	
8 relevance of metabolites in groundwater	metabolites BH 518-2 and BH 518-5	yes	see special Part B (5)

1 Details of the application

This application was submitted by ADAMA Registrations B.V. in October 2015.

An extension is asked of the already registered product Goltix Queen, an suspension concentrate

containing 525 G/L metamitron and 40 G/L quinmerac. More specifically, the extensions applied for are the field uses in Lily (propagation), Gladiolus (propagation) and peony (cut flowers). The application is intended for use in The Netherlands only.

1.1 Application background

Details on applicant and application

Plant protection product	Goltix Queen
Type of application	National application according to Article 51
Registration number	14298 N
Applicant	ADAMA Registrations B.V.
Authorisation holder	Arnhemseweg 87 3832 GK LEUSDEN The Netherlands
Function	herbicide
Type of formulation	suspension concentrate
Expiration of authorisation	2020-11-30

1.2 Approval

The active substances included in the plant protection product are approved according Regulation (EC) No 1107/2009. The present application is in line with the provisions of the approvals.

Active substance(s)

Metamitron

Content in PPP	525 g/l
Approval status	approved according Regulation (EC) No 1107/2009
Approval	Regulation (EC) No 540/2011
Expiration of approval	31/08/2019

Quinmerac

Content in PPP	40 g/l
Approval status	approved according Regulation (EC) No 1107/2009
Approval	Regulation (EC) No 540/2011
Expiration of approval	30/04/2021

1.3 Regulatory approach

The PPP is already registered in The Netherlands according to Directive 91/414/EEC or Reg.(EC) No. 1107/2009 taking into account the Uniform Principles of Reg.(EC) No. 546/2011. Therefore the evaluation of the current application is limited to the points not covered by the existing registration.

1.3.1 Uses applied for and registration decision

See 2.5 Product uses for extension (minor uses) and 3.2 Conclusions

1.3.2 Public interest and minor use

According to Article 51 (2) a and c of the Regulation (EC) No 1107/2009 extensions of authorisation are only possible if the intended use applied for is minor in nature and in public interest.

1.4 Data protection claims

See original application

1.5 Letters of Access

No letters of Access are needed

2 Details of the authorisation

2.1 Product identity

Product name	Goltix Queen
Authorisation number	14298N
Composition	Metamitron 525 g/L Quinmerac 40 g/L
Type of formulation	suspension concentrate (SC)
Function	Herbicide
Authorisation holder	Arnhemseweg 87 3832 GK LEUSDEN The Netherlands

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC or Regulation (EC) No 1272/2008

Proposal for the classification and labelling of the formulation concerning health

Based on the profile of the substance, the provided toxicology of the preparation, the characteristics of the co-formulants, the method of application and the risk assessment for the operator, as mentioned above, the following labeling of the preparation is proposed:

The identity of all substances in the mixture that contribute to the classification of the mixture *:

-	
Pictogram:	GHS09 Signal word: -
H-statements:	H411 Toxic to aquatic life with long lasting effects.
P-statements:	P273 Avoid release to the environment. P501 Dispose of contents/container to ...

Supplemental Hazard information:

EUH401 To avoid risks to human health and the environment, comply with the instructions for use

EUH208 Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

SP1 Do not contaminate water with the product or its container.

Child-resistant fastening obligatory? not applicable
Tactile warning of danger obligatory? not applicable

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

2.2.2 R and S phrases under Regulation (EC) No 547/2011

None

2.2.3 Other phrases

None

2.2.3.1 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions (mandatory labelling):

See 2.3 (Product uses)

2.3 Product uses for extension minor uses applied for

GAP-Table

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	MS	Crop and/or situation	F G or I	Pests or Group of pests controlled	Application			Application rate per treatment			PHI (day s)	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	Maximum number / (min. Interval between applications)	L product / ha a) per application b) max per crop	kg as/ha a) max per application b) max per crop	Water L/ha min / max		
Minor uses according to article 51												
	NL	Propagation of Lily	F	Annual, broadleaved . weeds	Spraying	BBCH 12 – 39 (Apr - Sept)	6 (5 days)	a) 0.7 – 1 b) 6	a) 0.525 MET+0.04 QUI b) 3.15 MET+0.24 QUI	150 – 500	-	
	NL	Propagation of Gladiolus	F	Annual , broadleaved . weeds	Spraying	BBCH 12 – 39 (Apr - Sept)	6 (5 days)	a) 0.7 – 1 b) 6	a) 0.525 MET+0.04 QUI b) 3.15 MET + 0.04 QUI	150 – 500	-	
	NL	Peony (cut flowers)	F	Annual, broadleaved . weeds	Spraying	BBCH 12 – 39 (Apr- Jun)	3 (5 days)	a) 1.5 b) 4.5	a) 0.7875 MET + 0.06 QUI b) 2.3625 MET + 0.18 QUI	150 – 800	-	'Under-crop' treatment.

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

Not relevant for extension of authorisation according Article 51.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Not relevant for extension of authorisation according Article 51.

3.1.2.2 Analytical methods for residues

The new uses fall within the risk envelope for the section residue analytical methods.

The new uses comprise of ornamentals exclusively. Therefore, residue analytical methods for food/feed of plant and animal origin are not required. The methods for soil, water and air do not need to be re-evaluated for this application.

3.1.3 Mammalian Toxicology

3.1.3.1 Toxicity of the formulated product

See current authorisation:

Table 3.1.3-1: Acute toxicological data obtained with Goltix Queen

Parameter [Reference]	Species	Result mg/kg bw or mg/L or effect	Classification according to Directive 67/548/EEC or Reg. (EC) 1272/2008
Oral route	Rat	LD ₅₀ > 2000 mg/kg bw 2/6 animals died prematurely	None
Percutaneous route	Rat	LD ₅₀ > 2000 mg/kg bw No mortality	None
Inhalation route	Rat	LC ₅₀ > 5.57 mg/L (4 h) No mortality	None
Skin irritation	Rabbit	Non-irritating	None
Eye irritation	Rabbit	Non-irritating	None

Parameter [Reference]	Species	Result mg/kg bw or mg/L or effect	Classification according to Directive 67/548/EEC or Reg. (EC) 1272/2008
Skin sensitisation	Guinea pig	Not sensitising	None

Data requirements formulated product

No additional data requirements are identified.

3.1.3.2 Dermal absorption

Metamitron

Agreed EU endpoints for metamitron (EFSA Scientific Report (2008) 185, 1-95, Conclusion on the peer review of metamitron)

endpoint	metamitron
Dermal penetration*	Concentrate: 1% Spray dilutions: 20%
AOEL	0.036 mg/kg bw/d

* based on *in vitro* dermal absorption study on human skin with 700 g Metamitron/L SC (Goltix 700 SC)

Quinmerac

Agreed EU endpoints for quinmerac (EFSA Journal 2010; 8(3):1523, Conclusion on the peer review of quinmerac)

endpoint	quinmerac	
	EU agreed endpoints*	endpoints used in risk assessment**
Dermal penetration	Concentrate: 2% Spray dilution: 5%	Concentrate: 0.96% Spray dilution: 1.38%
AOEL	0.08 mg/kg bw/d	

* based on an *in vivo* dermal absorption study in rats with a 12.5% SC formulation;

** Please see Point IIIA 7.6.2 Dermal Absorption (core assessment).

3.1.3.3 Available toxicological data relating to non-active substances (IIIA 7.4)

The available toxicological data relating to non-active substances will be taken into account in the classification and labelling of the formulated product.

3.1.3.4 Exposure/risk assessments

Overview of the intended uses

An application has been submitted for the simplified extension of the authorisation of the plant protection product Goltix Queen.

The product Goltix Queen is a suspension concentrate (SC) formulation containing 525 g/L metamitron and 40 g/L quinmerac, intended as a herbicide against mono- and dicotyledonous weeds in several ornamental crops, including peony. for which manual spray application by operators cannot be excluded. In the current authorisation, only mechanical application was assessed.

Goltix Queen is intended to be applied up to three times per year with a maximum application rate of 2 L/ha corresponding to 1.05 kg a.s./ha metamitron and 0.08 kg a.s./ha quinmerac.

Operator exposure/risk

According to the Dutch Plant Protection Products and Biocides Regulations the risk assessment is performed according to a tiered approach. There are four possible tiers:

Tier 1: Risk assessment using the EU-AOEL without the use of PPE

Tier 2: Risk assessment using the NL-AOEL without the use of PPE

Tier 3: Refinement of the risk assessment using new dermal absorption data

Tier 4: Prescription of PPE

Metamitron

Tier 1

Exposure to metamitron during mixing and loading and application of Goltix Queen is estimated with models. The exposure is estimated for the unprotected operator. In general, mixing and loading and application is performed by the same person. Therefore, for the total exposure, the respiratory and dermal exposure during mixing/loading and application have to be combined. In the Table below the estimated internal exposure is compared with the systemic EU-AOEL.

Table 3.1.3-2 Internal operator exposure to metamitron and risk assessment for the use of Goltix Queen

	Route	Estimated internal exposure ^a (mg/day)	Systemic EU-AOEL ^b (mg/day)	Risk-index ^c
<i>Manual downward spraying on peony (1.5 L/ha, uncovered)</i>				
Mixing/ Loading ^d	Respiratory	<0.01	2.52	<0.01
	Dermal	0.95	2.52	0.38
Application ^e	Respiratory	0.63	2.52	0.25
	Dermal	107.1	2.52	42.5
	Total	109	2.52	43

a Internal exposure was calculated with:

- biological availability via the dermal route: 1% (concentrate), 20% (spray dilution)
- biological availability via the respiratory route: 100% (worst case)

b Assuming a body weight of 70 kg.

c The risk-index is calculated by dividing the internal exposure by the systemic AOEL.

d External exposure is estimated with EUROPOEM (dermal) and NL-model (respiratory).

e External exposure is estimated with UK POEM.

Since the EU-AOEL is exceeded without the use of PPE, a tier 2 assessment has to be performed using the NL-AOEL.

Tier 2

Calculation of the NL-AOEL

The risk index calculated with the EU-AOEL is >1. Therefore, the Plant Protection Products and Biocides Regulations (NL: Rgb) prescribes the calculation of the risk with an AOEL based on allometric extrapolation (known as the NL-AOEL). This method takes into account the caloric demand of the species studied and results in a more specific value than the EU-AOEL for which a standard factor of 100 is applied.

The calculation of the systemic AOEL for semi-chronic exposure is based on the NOAEL of 7.3 mg/kg bw/day in the two generation reproduction study in rats. Calculations from other studies result in higher AOELs.

Safety factors are used to compensate for the uncertainties, which arise, for example, from extrapolation from the tested species to humans and the differences between experimental circumstances, and to ensure that at the acceptable exposure level no adverse health effects will occur.

Used factors are:

- extrapolation rat → human on basis of caloric demand 4
- other interspecies differences: 3
- intraspecies differences: (professional use) 3
- biological availability via oral route: 100%*
- weight of professional operator/worker: 70 kg
- If the absorbed dose is significantly lower (<80%) than the administered dose, this is adjusted by a correction factor equal to the percentage absorption.

$$AOEL_{\text{systemic}}: 7.3 \times 1 \times 70 / (4 \times 3 \times 3) = 14.20 \text{ mg/day}$$

Table 3.1.3-3 Internal operator exposure to metamitron and risk assessment for the use of Goltix Queen

	Route	Estimated internal exposure ^a (mg/day)	Systemic NL-AOEL ^b (mg/day)	Risk-index ^c
<i>Manual downward spraying on peony (1.5 L/ha, uncovered)</i>				
Mixing/ Loading ^d	Respiratory	<0.01	14.20	< 0.01
	Dermal	0.95	14.20	0.07
Application ^e	Respiratory	0.63	14.20	0.04
	Dermal	107	14.20	7.5
	Total	109	14.20	7.7

a Internal exposure was calculated with:

- biological availability via the dermal route: 1% (concentrate), 20% (spray dilution)
- biological availability via the respiratory route: 100% (worst case)

- b Assuming a body weight of 70 kg.
- c The risk-index is calculated by dividing the internal exposure by the systemic AOEL.
- d External exposure is estimated with EUROPOEM (dermal) and NL-model (respiratory).
- e External exposure is estimated with UK POEM.

Since the NL-AOEL is exceeded without the use of PPE, a tier 3 assessment has to be performed.

Tier 3

Since the results of acceptable dermal absorption studies were already used in tier 1 and 2, a further refinement with additional dermal absorption data is not considered relevant and a tier 4 assessment will be performed.

Tier 4

Table 3.1.3-4 Internal operator exposure to metamitron and risk assessment for the use of Goltix Queen including PPE

	Route	Estimated internal exposure ^a (mg /day)		Systemic NL-AOEL (mg/day) ^b	Risk-index ^c	
		without PPE	with PPE		without PPE	with PPE
<i>Manual downward spraying on peony (1.5 L/ha, uncovered)</i>						
Mixing/ Loading ^d	Respiratory	<0.01	(<0.01)	14.20	<0.01	(<0.01)
	Dermal	0.95	(0.95)	14.20	0.07	(0.07)
Application ^e	Respiratory	0.63	(0.63)	14.20	0.04	(0.04)
	Dermal	107	10.7	14.20	7.5	0.75
	Total	109	11.4	14.20	7.7	0.87 ^f

a Internal exposure was calculated with:

* biological availability via the dermal route: 1% (concentrate), 20% (spray dilution)

* biological availability via the respiratory route: 100% (worst case)

b Assuming a body weight of 70 kg.

c The risk-index is calculated by dividing the internal exposure by the systemic AOEL.

d External exposure is estimated with EUROPOEM (dermal) and NL-model (respiratory).

e External exposure is estimated with UK POEM.

f PPE: gloves and coverall during application

Quinmerac

Tier 1

Exposure to quinmerac during mixing and loading and application of Goltix Queen is estimated with models. The exposure is estimated for the unprotected operator. In general, mixing and loading and application is performed by the same person. Therefore, for the total exposure, the respiratory and dermal exposure during mixing/loading and application have to be combined. In the Table below the estimated internal exposure is compared with the systemic EU-AOEL.

Table 3.1.3-5 Internal operator exposure to quinmerac and risk assessment for the use of Goltix Queen

	Route	Estimated internal exposure^a (mg/day)	Systemic EU-AOEL^b (mg/day)	Risk-index^c
<i>Manual downward spraying on peony (1.5 L/ha, uncovered)</i>				
Mixing/ Loading ^d	Respiratory	< 0.01	5.60	< 0.01
	Dermal	0.07	5.60	0.01
Application ^e	Respiratory	0.05	5.60	0.01
	Dermal	0.56	5.60	0.10
	Total	0.69	5.60	0.12

a Internal exposure was calculated with:

* biological availability via the dermal route: 0.96% (concentrate), 1.38% (spray dilution)

* biological availability via the respiratory route: 100% (worst case)

b Assuming a body weight of 70 kg.

c The risk-index is calculated by dividing the internal exposure by the systemic AOEL.

d External exposure is estimated with EUROPOEM (dermal) and NL-model (respiratory).

e External exposure is estimated with UK POEM.

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

Bystander exposure/risk

For bystanders, the proposed extension in lily, gladiolus and peony can be extrapolated from the current authorisation. Therefore, the proposed extension remains within the existing risk envelope for bystanders.

Worker exposure/risk

For workers, the proposed extension in lily, gladiolus and peony can be extrapolated from the current authorisation. Therefore, the proposed extension remains within the existing risk envelope for workers.

Re-entry

See Worker exposure/risk.

Overall conclusion of the exposure/risk assessments of operator, bystander, and worker

The product complies with the Uniform Principles.

Operator exposure

For the unprotected operator, adverse health effects after dermal/respiratory exposure to metamidon as a result of the application of Goltix Queen in peony, lily and gladiolus cannot be excluded. Correct use of personal protective equipment will reduce the dermal exposure and results in a sufficient reduction of the exposure to metamidon for the application of Goltix Queen in peony, lily and gladiolus.

The following restriction needs to be included in the directions of use:

Draag beschermende kleding en handschoenen tijdens het handmatig spuiten in lelie en gladiool (vermeerderingsteelt) en pioen.

Bystander exposure

For bystanders, the proposed extension in lily, gladiolus and peony can be extrapolated from the current authorisation. Therefore, the proposed extension remains within the existing risk envelope for bystanders.

Worker exposure

For workers, the proposed extension in lily, gladiolus and peony can be extrapolated from the current authorisation. Therefore, the proposed extension remains within the existing risk envelope for workers.

3.1.3.5 Appropriate mammalian toxicology and operator exposure end-points relating to the product and approved uses

See List of Endpoints.

3.1.3.6 Data requirements

Based on this evaluation, no additional data requirements are identified.

3.1.3.7 Combination toxicology

See current authorization:

For the active substance metamidon the relevant NOAEL in dogs was set at 3.6 mg/kg bw/day and was derived from changes in clinical chemistry in a 90-day study. Long term studies identified the liver as target organ of toxicity in the rat, mouse and dog.

For the active substance quinmerac, the main effect was a reduction in red blood cell parameters in dogs in short-term toxicity studies with a relevant NOAEL of 7.9 mg/kg bw/day. The relevant NOAEL for long-term toxicity is 31 mg/kg bw/day (based on reduced body weight gain in a 18-month mouse study).

Neither active was carcinogenic, neurotoxic nor teratogenic; reproduction toxicity was observed only at higher dose levels.

Since both actives have different target organs of toxicity combination effects are considered unlikely.

3.1.4 Residues and Consumer Exposure

The proposed extension for use involves non-edible crops (lily, gladiolus and peony), therefore the evaluation of metabolism and residue data is not relevant to this submission. However, in the Netherlands lilies and gladiolus after propagation can be grown in rotation with consumable crops. Maximum requested dose in this application is the same dose as already evaluated in existing authorisation. Therefore, it can be concluded that with respect to evaluation of rotational crops the proposed extension remains within the existing risk envelope for the section residues.

3.1.5 Environmental fate and behaviour

The new use of Goltix Queen applied for in Propagation of Lily and Gladiolus has an equal risk for persistence in soil and emission to surface water and sediment as the already authorised uses. The new use of Goltix Queen applied for in peony has an equal risk for emission to surface water and sediment as the already authorised uses.

The drinking water criterion is met.

The available and most recent monitoring data in groundwater and surface water have been reviewed and have no consequences for the proposed uses.

The new uses of Goltix Queen applied for in Propagation of Lily and Gladiolus do not have an equal (or lower) risk for leaching to groundwater as the already authorised uses. Furthermore, the risk of the use in Peony applied for is not included in the risk envelope for the aspects persistence in soil and groundwater. A separate risk assessment was performed in the NL Addendum, Part B.5.

PECsoil

The PEC_{soil} calculations were performed with the standard Excel calculation sheet, using the input parameters from the Core dossier of the original authorization of Goltix Queen.

PECs values for active substance metamitron and its metabolite desamino-metamitron and active substance quinmerac and its metabolites BH 518-2 and BH 518-5 for the application in peony can be found in Tables 3.1.5-1 and 3.1.5-2.

Table 3.1.5-1: Results of PECsoil calculation for active substance metamitron and its metabolite desamino-metamitron for use in Peony (soil bulk density 1.5 g/cm³. soil depth 5 cm)

use:		Peony				
Number of applications/intervall		3 / 5d				
application rate:		3x 1050 g/ha				
crop interception:		0 % (under-crop treatment)				
active substance/preparation	soil relevant application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa 21 d} (mg/kg)	tillage depth (cm)	PEC_{bkgd} (mg/kg)	PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)
Metamitron	1050	3.618 (after 3 rd)	2.646	20	-	-

		application)				
Desamino-metamitron	0.166 *	0.611	0.511	20	0.0003	0.6112

* parent application rate multiplied with formation fraction and molecular weight ratio

Table 3.1.5-2: Results of PEC_{soil} calculation for active substance quinmerac and its metabolites BH 518-2 and BH 518-5 for use in Peony (soil bulk density 1.5 g/cm⁻³, soil depth 5 cm)

use:		Peony				
Number of applications/intervall		3 applications, 5 days				
application rate:		3 × 80 g Quinmerac/ha,				
crop interception:		0 %				
active substance/preparation	soil relevant application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa} 21 d (mg/kg)	tillage depth (cm)	PEC_{bkgd} (mg/kg)	PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)
Quinmerac	3 × 80	0.302	0.267	20	-	-
BH 518-2	0.505*	0.150	0.142	20	0.006	0.156
BH 518-5	0.391*	0.116	0.111	20	0.007	0.124

* parent application rate multiplied with formation fraction and molecular weight ratio

Leaching to shallow groundwater

In the National Addendum document for the Netherlands, the risk of ground water contamination is assessed by following the currently agreed approaches described in the CTGB Manual for the Authorisation of Pesticides¹ in the Netherlands.

PEC_{gw} calculations were performed for the autumn use in Propagation of Lily and Gladiolus, and the spring use in Peony.

Metamitron

Groundwater contamination by direct leaching of the active substance and its metabolites, degradation or reaction products through soil is generally assessed by groundwater model calculations.

The PEC of Metamitron and its metabolites in ground water have been assessed with FOCUS scenario Kremsmünster, relevant for the Netherlands, to obtain outputs from the FOCUS PEARL 4.4.4. and additionally GeoPEARL 3.3.3.

¹ Evaluation manual for the authorisation of plant protection products and biocides. NL part. Plant protection products. Chapter 6 Fate and behaviour in the environment: behaviour in soil; leaching; version 1.0; January 2010

In the core dossier PEC_{gw} calculations were performed for metabolite M3. In the Addendum Confirmatory Data (May 2014), it was concluded by RMS UK that metabolite M3 most likely is an artefact of the reaction of a.s. metamitron with acetone as solvent.

Still PEC_{gw} calculations were added to the Addendum Confirmatory Data after the commenting round, using a DT₅₀ of 6.6 days proposed by EFSA and various K_{oc} values (default worst case of 0 L/kg; 8.64 L/kg (1/10 of parent) and 86.4 L/kg (parent value)). No definite conclusions regarding the necessity of modelling the metabolite M3 were drawn in the Addendum.

In the Final Review Report for a.s. metamitron (SANCO/208/08 final; 20 March 2015), it is concluded that *no impact of the soil metabolite M3 on groundwater is expected*.

Based on the conclusions of RMS in the Addendum Confirmatory Data indicating that the metabolite most likely is an artefact, and the conclusion in the Review Report that no impact on groundwater is expected, NL concludes that no groundwater leaching assessment should be performed for metabolite M3. The calculations for this metabolite performed in the Core dossier of the original authorization of Goltix Queen (that pre-dates the finalisation of the assessment of the confirmatory data on EU level) are deemed not relevant for the NL Addendum.

Corresponding with the risk assessment of the original authorization, PEC_{gw} calculations have been performed assuming biennial application. Furthermore, annual application has been accounted for as well.

GeoPEARL calculations show that the predicted leachate concentrations for active substance metamitron and metabolite desamino-metamitron for the spring use in peony are smaller than 0.1 µg/L. Hence, the active substance metamitron meets the standards laid down in the RGB for the proposed applications.

However, as the predicted concentration for active substance metamitron and metabolite desamino-metamitron for the annual autumn use in Propagation in Lily and Propagation in Gladiolus is larger than 0.01 µg/L, a restriction on the use in groundwater protection areas should be placed on the label:

Om het grondwater te beschermen mag dit product in de teelt van lelies en gladiolen in de periode 1 september tot 1 maart niet worden gebruikt in grondwaterbeschermingsgebieden.

Quinmerac

Groundwater contamination by direct leaching of the active substance and its metabolites, degradation or reaction products through soil is generally assessed by groundwater model calculations.

The PEC of Quinmerac and its metabolites in ground water have been assessed with FOCUS scenario Kremsmünster, relevant for the Netherlands, to obtain outputs from the FOCUS PEARL 4.4.4..

The expected leaching based on the biennial PEARL-model calculations for the active substance quinmerac is smaller than 0.01 µg/L for all proposed applications (i.e.: 0.005 µg/L for the autumn use in Lily and Gladiolus, and <0.001 µg/L for the spring use in Peony). Hence, the applications meet the standards for leaching as laid down in the RGB.

It is expected that the leaching concentrations for a.s. quinmerac will increase slightly with annual use, but as the product already has a restriction sentence on the autumn use in Lily and Gladiolus based on the expected leaching for metabolite desamino-metamitron, and no exceedance of the 0.1 µg/L is expected, no additional annual leaching concentrations have been calculated.

For the metabolites BH 518-2 and BH 518-5, FOCUS PEARL modelling predicts that PEC_{GW} concentrations are above the trigger of 0.1 µg/L for the uses in Propagation of Lily and propagation of Gladiolus, and

equal to or larger than 0.01 µg/L for the use in Peony. However, these metabolites have undergone a non-relevance assessment according to SANCO/221/2000 rev. 10², the results of which demonstrate that both metabolites are considered as non-relevant metabolites (for further details, please refer to the core assessment of AG-QMM1-565 SC dRR, Part B, Section 5 for Central Zone).

3.1.6 Ecotoxicology

The risk for the proposed use of Goltix Queen for use in Lily, Gladiolus and Peony fall within the existing risk envelope for use in beets for the aspects aquatic organisms, bees, non-target arthropods, non-target plants and birds and mammals via secondary poisoning.

For the aspects birds and mammals, direct exposure and soil organisms a risk assessment has been performed.

For birds acute and chronic TER values were above the relevant triggers of 10 and 5 after first tier assessment for the use in Lily and Gladiolus. For the use in Peony, the acute risk was acceptable after first tier risk assessment. For the chronic risk, the TER omnivorous birds and insectivorous birds is above the trigger of 5, however, for granivorous birds the TER is 3.7, which is below the trigger of 5. A further refinement is required.

See table 3.1.6-1

Table 3.1.6-1 Long-term risk (TER_{LT}) to birds from metamitron, quinmerac and the combination

Crop	Scenario	Generic focal species	Substance	DDD [mg a.s./kg bw/day]	NOEL [mg a.s./kg bw/day]	TER
Lily and gladiolus, 6 x 1L						
Bulbs & onion like crops	BBCH 10 - 39	Small granivorous bird "finch"	Metamitron	9.52	81.5	8.6
			Quinmerac	0.725	11	15
			Combination			5.5
	BBCH 10 - 39	Small omnivorous bird "lark"	Metamitron	9.10	81.5	9.0
			Quinmerac	0.693	11	16
			Combination			5.7
	BBCH 10 - 19	Small insectivorous bird "wagtail"	Metamitron	9.43	81.5	8.6
			Quinmerac	0.719	11	15
			Combination			5.5
	BBCH ≥ 20	Small insectivorous bird "wagtail"	Metamitron	8.10	81.5	10
			Quinmerac	0.617	11	18
			Combination			6.4
Peony, 3x 2L						
Ornamentals/nursery	Application to plant - exposure to underlying ground	Small insectivorous/ worm feeding species "thrush"	Metamitron	6.98	81.5	12
			Quinmerac	0.532	11	21
			Combination			7.5
Ornamentals/nursery	Bare soil	Small granivorous bird "finch"	Metamitron	14.0	81.5	5.84
			Quinmerac	1.06	11	10.3

² Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000, rev. 10, February 25, 2003)

			Combination			3.73
	Bare soil	Small omnivorous bird "lark"	Metamitron	10.0	81.5	8.12
Quinmerac			0.765	11	14.4	
Combination			5.19			

The TER_{LT} values for the active substances are all greater than the Annex VI trigger of 5. However, for the formulation, the TER for small granivorous birds is below the relevant trigger of 5 for the use in Peony. Therefore a chronic risk to birds cannot be excluded for the use in peony. For the use in Lily and Gladiolus, the risk is considered to be acceptable.

Refined risk assessment

During the assessment the applicant changed to dose rate in Peony to 3 x 1.5 L/ha, equivalent to 3 x 0.7875 kg metamitron/ha and 0.06 kg quinmerac/ha. The chronic risk to granivorous bird has been recalculated below.

The TER values are shown in Table 3.1.6-2.

Table 3.1.6-2 Long-term risk (TER_{LT}) to birds from metamitron, quinmerac and the combination

Crop	Scenario	Generic focal species	Substance	DDD [mg a.s./kg bw/day]	NOEL [mg a.s./kg bw/day]	TER
Peony, 3x 1.5L						
Ornamentals/nursery	Bare soil	Small granivorous bird "finch"	Metamitron	10.5	81.5	7.8
			Quinmerac	0.80	11	14
			Combination			5.0

The risk to granivorous birds is acceptable with the lower application rate.

For mammals, acute and chronic TER values are all above the relevant triggers of 10 for all proposed uses. For the chronic risk, the TER was above the trigger of 5 for the use in gladiolus and Lily, but for peony a refinement was required.

See tables below

Table 3.1.6-3 Tier I long-term risk (TER_{LT}) to mammals from metamitron, quinmerac and the combination

Crop	Scenario	Generic focal species	Substance	DDD [mg a.s./kg bw/day]	NOEL [mg a.s./kg bw/day]	TER
Lily and gladiolus, 6 x 1L						
Bulbs & onion like crops	BBCH 10-19	Small insectivorous mammal "shrew"	Metamitron	3.51	36.4	10

	BBCH ≥ 20	Small insectivorous mammal "shrew"	Quinmerac	0.267	100	374	
			Combination			10	
			Metamitron	1.59	36.4	23	
	BBCH 10 - 39	Small omnivorous mammal "mouse"	Quinmerac	0.121	100	828	
			Combination			22	
			Metamitron	6.51	36.4	5.6	
	Peony, 3 x 2 L						
	Ornamentals/nursery	Application to plant - exposure to underlying ground	Small insectivorous mammal "shrew"	Metamitron	5.02	36.4	7.3
				Quinmerac	0.382	100	261
Combination						7.1	
Application crop directed BBCH 10-49		Small omnivorous mammal "mouse"	Metamitron	9.55	36.4	3.8	
			Quinmerac	0.728	100	137	
			Combination			3.7	

For the use in lily and gladiolus, all TER_{LT} values are greater than the Annex VI trigger of 5, indicating acceptable long-term risk to mammals.

For the use in peony, the TER_{LT} values for metamitron and the combination are below the Annex VI trigger of 5 for small omnivorous mammals represented by the mouse at BBCH 10-49. The risk assessment needs to be refined for this generic focal species. As the TER for quinmerac is considerable above the trigger of 5, the contribution to toxicity to mammals for this substance is considered to be negligible.

The applicant refined the risk with a DT₅₀ of 1.9 days (derived from beet leaves), in order to adapt the Ftwa and MAF for the weed part of the risk assessment. However as the presence of weeds in this crop is questionable, the refinement is questionable as well.

The diet of the woodmouse can be corrected for the weed component. As a diet of 75% seeds in this type of crops is considered to be unlikely; a ratio of 50:50% is taken; which is similar as the diet for omnivorous birds.

The refined risk assessment for small omnivorous mammals is shown in the table below.

Table 3.1.6-3 Refined long-term risk (TER_{LT}) to small omnivorous mammals from metamitron, for the use on peony

Crop / scenario /	Substance	Food	PD	RUD	Application	MAF * TWA	FIR/ bw	DDD [mg]	NOEL [mg]	TER
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generic focal species					rate [kg a.s./ha]			a.s./kg bw]	a.s./kg bw]	
Peony, 3 x 2 L										
Ornamentals / nursery	Metamitron	Weed seeds	0.5	40.2	1.05	2.2*0.53	0.24	5.91	-	-
Application crop directed BBCH 10-49		Ground arthropods	0.450	7.5*	1.05	2.2*0.53	0.24	1.10		
Small omnivorous mammal "mouse"		Total diet	1					7.01	36.4	5.2

* RUD value for ground dwelling invertebrates without interception

** Adjusted shortcut value based on RUD for ground invertebrates without interception

The refined TER_{LT} value for small omnivorous mammals for the application on peony at BBCH 10-49 is above the trigger of 5

Uncertainty analysis

Source of Uncertainty	conservativeness adjustment	Explanation
Focal species	?	Unknown. No information is available. Wood mouse is considered to be reasonable worst-case
Weeds	?	There is an assumption that no grasses or weeds are present. Usually the presence of weeds lead to a higher risk. However in this case, with a DT50 of 1.9 days on foliage, the not taking into account of weeds is can even be worst-case
Diet of woodmouse	-	Best case, considering correction in favor of arthropod diet and not on seeds.
DT50	+	No DT50 refinements are included. Considering the fast dissipation of metamidon, the default DT50 of 10 days for arthropods and seeds is worst-case
PT	+	No PT refinement is given. The risk assessment is worst-case assuming 100% consumption in treated fields
Conclusion	Most refinements options of the risk assessment are still worst-case. However there are still some uncertainties considering focal species and diet.	

As the TER in the refined risk assessment is above the trigger of 5 and as the refinements in risk assessment are neither extremely worst-case or best case, the risk is considered to be acceptable.

For soil organisms all TER values are above the relevant triggers.

3.1.7 Efficacy

According to Article 51 of the Regulation (EC) No 1107/2009 the requirements for approval concerning the sufficient effect and any unacceptable effects on plants and plant products does not need to be checked.

3.2 Conclusions

Goltix Queen is already registered in The Netherlands according to Reg. (EC) No. 1107/2009 taking into account the Uniform Principles of Reg. (EC) No. 546/2011.

The intended use is minor in nature and the extension of authorisation is in public interest. No additional effects are anticipated because of the extension of uses.

Considering an application in accordance with the evaluated use pattern and good agricultural practise as well as strict observance of the conditions of use no harmful effects are to be expected. An authorisation can therefore be granted, when the following sentences are placed on the label:

“Draag beschermende kleding en handschoenen tijdens het handmatig spuiten in lelie en gladiool (vermeerderingsteelt) en pioen.”

“Om het grondwater te beschermen mag dit product in de teelt van lelies en gladiolen in de periode 1 september tot 1 maart niet worden gebruikt in grondwaterbeschermingsgebieden.”

3.3 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

None

None Appendix 1 – Reference to the product authorisation

The final product authorisation in The Netherlands is found on the Ctgb website : www.ctgb.nl > chose English > “pesticides database” > “Filter by name” Goltix Queen.

Appendix 2 – Copy of the product label

WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het professionele gebruik als onkruidbestrijdingsmiddel door middel van een na opkomst behandeling in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.0, Ctgb juni 2011) onder de vermelde toepassingsvoorwaarden

Toepassingsgebied	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus	Minimum interval tussen toepassingen
Bieten	Eenjarige breedbladige onkruiden	2 L/ha	3	10 dagen

Het gebruik in de teelt van lelie, gladiool en pioen is beoordeeld conform artikel 51 EC 1107/2009. Er is voor deze toepassingen geen werkzaamheids- en fytoxiciteitonderzoek uitgevoerd. Er wordt daarom aangeraden een proefbespuiting uit te voeren, voordat het middel gebruikt wordt. Gebruik van dit middel in deze toepassingsgebieden, komt voor risico en verantwoordelijkheid van de gebruiker.

Toepassingsgebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassing per teeltcyclus	Minimum interval tussen toepassingen
Lelie (vermeerderingsteelt, onbedekt)	Na-opkomst	Eenjarige breedbladige onkruiden	0,7 – 1 L/ha	6	5 dagen
Gladiool (vermeerderingsteelt, onbedekt)	Na-opkomst	Eenjarige breedbladige onkruiden	0,7 – 1 L/ha	6	5 dagen
Pioen (snijbloemen, onbedekt)	Na-opkomst, onder het gewas	Eenjarige breedbladige onkruiden	1,5 L/ha	3	5 dagen

Toepassingsvoorwaarden

Draag beschermende kleding en handschoenen tijdens het handmatig spuiten in lelie en gladiool (vermeerderingsteelt) en pioen.

Om het grondwater te beschermen mag dit product in de teelt van lelie en gladiolen in de periode 1 september tot 1 maart niet worden gebruikt in grondwaterbeschermingsgebieden

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

- zonder grondbewerking kunnen bieten of krotten worden gezaaid;
- na ploegen kunnen maïs en aardappelen worden geteeld;
- na ploegen en een wachttijd van 2 maanden na de laatste toepassing kunnen raaigras en klaver worden geteeld.

Resistentiemanagement

Dit middel bevat de werkzame stoffen metamitron en quinmerac.

Metamitron behoort tot de triazinonen de Hrac code is C1, Quinmerac behoort tot de quinolinecarboxylic-zuren de Hrac code is O.

Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen.

Appendix 3 – Letter of Access

No letter of access necessary.

Appendix 4 – Reference list

N.A.