REGISTRATION REPORT

Part A

Risk Management

Product code: AG-QMM2-410 SC

Product name(s): GOLTIX SILVER

Active Substance(s):

Metamitron, 350 g/L

Quinmerac, 60 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: **ADAMA France SAS**

Date: **19/01/2018**

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PART A – Risk Management

The company ADAMA FRANCE SAS has requested marketing authorisation in France for the product GOLTIX SILVER (AG-QMM2-410 SC), containing 350 g/L metamitron and 60 g/L quinmerac for use as a herbicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to GOLTIX SILVER (AG-QMM2-410 SC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of GOLTIX SILVER (AG-QMM2-410 SC) have been made using endpoints agreed in the EU peer review of both metamitron and quinmerac.

This document describes the specific conditions of use and labelling required for France for the registration of GOLTIX SILVER (AG-QMM2-410 SC).

Appendix 1 of this document provides a copy of the French Decision.

Appendix 2 of this document is a copy of the draft product label as proposed by the applicant.

Appendix 3 of this document is a copy of the letter(s) of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of ADAMA FRANCE SAS's application to market GOLTIX SILVER (AG-QMM2-410 SC) in France as a herbicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Metamitron

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of Regulation (EU) No 540/2011 were as follows : PART A Only uses as herbicide may be authorised. PART B In assessing applications to authorise plant protection products containing metamitron for uses other than on root crops, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metamitron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of personal protective equipment where appropriate; — the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions; — the risk to birds and mammals, and non-target terrestrial plants.

Conditions of authorisation shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of further information on the impact of soil metabolite M3 on groundwater, on residues in rotational crops, on the long-term risk to insectivorous birds and the specific risk to birds and mammals that may be contaminated by the intake of water in field. They shall ensure that the notifiers at whose request metamitron has been included in this Annex provide such information to the Commission by 31 August 2011 at the latest.
An EFSA conclusion is available (EFSA Scientific Report (2008) 185, 1-95). A Review Report is available (SANCO/208/08 final, 6 January 2009).

Quinmerac

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of Regulation (EU) No 540/2011 were as follows : PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on quinmerac, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions; — the dietary exposure of consumers to residues of quinmerac (and its metabolites) in succeeding rotational crops — the risk to aquatic organisms and the long term risk for earthworms. Conditions of use shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of information as regards: — the potential of plant metabolism to result in an opening of the quinoline ring; — residues in rotational crops and the long term risk for earthworms due to the metabolite BH 518-5. They shall ensure that the applicant provides such confirmatory data and information to the Commission by 30 April 2013.
An EFSA conclusion is available (EFSA Journal 2010; 8(3): 1523). A Review Report is available (SANCO/12192/2010 final, 7 December 2010).

1.3 Regulatory approach

The present application (2013-0790) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

[1] French Food Safety Agency, Afssa, before 1 July 2010

[2] SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

The French Order of 4th May 2017[3] provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, drift buffer zones may be reduced under some circumstances as explained in Appendix 3 of the above-mentioned French Order.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[4], implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[6] provides that:

- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[7] is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of GOLTIX SILVER (AG-QMM2-410 SC), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

Not necessary: the applicant has provided sufficient data to show that access is not required.

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3 Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

4 REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

5 COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

6 http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

7 SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	GOLTIX SILVER (AG-QMM2-410 SC)
Authorisation number	None (no marketing autorisation)
Function	herbicide
Applicant	ADAMA France SAS
Composition	350 g/L metamitron 60 g/L quinmerac
Formulation type (code)	Suspension concentrate (SC)
Packaging	Bottles HDPE (1 L) Canisters HDPE (5 L, 10 L, 20 L)

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

2.2.2 Classification and labelling in accordance with Regulation (EC) No1272/2008

Physical hazards	-	
Health hazards	Sensitisation — Skin, Hazard Category 1-	
Environmental hazards	Hazardous to the aquatic environment — Chronic Hazard, Category 2-	
Hazard pictograms	- 	
Signal word	Warning-	
Hazard statements	H317-	May cause an allergic reaction-
	H411-	Toxic to aquatic life with long lasting effects.-
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	Contains 1,2-benzisothiazol-3(2H)-one.-	

See Part C for justifications of the classification and labelling proposals.

2.2.3 Other phrases in compliance with Regulation (EU) No 547/2011

N/A

2.2.4 Other phrases linked to the preparation

N/A

2.3 Product uses

Please note:
When the conclusion is "not acceptable" the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 1, date: 2018-01-19

PPP (product name/code)	**GOLTIX SILVER** (AG-QMM2-410 SC)	**Formulation type:**	**SC**
active substance 1	**metamitron**	**Conc. of as 1:**	**350 g/L**
active substance 2	**quinmerac**	**Conc. of as 2:**	**60 g/L**
active substance 3	-	**Conc. of as 3:**	-
safener	-	**Conc. of safener:**	-
synergist	-	**Conc. of synergist:**	-
Applicant:	**ADAMA FRANCE SAS**	**professional use**	☒
Zone(s):	**southern**	**non professional use**	☐
Verified by MS:	**yes**		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		e.g. g safener/synergist per ha [f]
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	France	Sugar beet	F	Broad leaf weeds and grasses	Foliar spray	BBCH 00 to 09	a) 1 b) 1	-	a) 4 L/ha b) 4 L/ha	a) 0.240+1.4 b) 0.240+1.4	80-400	**90**	**Not acceptable (risk operator)**
2	France	Sugar beet	F	Broad leaf weeds and grasses	Foliar spray	BBCH 09 to 37	a) 3-5 b) 3-5	6	a) 0.8-1.33 L/ha b) 4 L/ha	a) 0.048-0.080 + 0.280-0.4667 b) 0.240 + 1.400	80-400	**90**	**Not acceptable (risk operator)**
3	France	Fodder beet	F	Broad leaf weeds and grasses	Foliar spray	BBCH 00 to 09	a) 1 b) 1	-	a) 4 L/ha b) 4 L/ha	a) 0.240 + 1.4 b) 0.240 + 1.4	80-400	**90**	**Not acceptable (risk operator)**
4	France	Fodder beet	F	Broad leaf weeds and grasses	Foliar spray	BBCH 09 to 37	a) 3-5 b) 3-5	6	a) 0.8-1.33 L/ha b) 4 L/ha	a) 0.048-0.080 + 0.280-0.4667 b) 0.240 + 1.400	80-400	**90**	**Not acceptable (risk operator)**

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

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

The formulation GOLTIX SILVER (AG-QMM2-410 SC) is Suspension Concentrate (SC). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of off-white homogenous suspension, with a characteristic odour. It is not explosive and has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 505°C. In aqueous solution (1%), it has a pH value 3.6 at ambient temperature. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C; neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE bottle. Its technical characteristics are acceptable for a Suspension Concentrate (SC) formulation.

The formulation is not classified for the physical-chemical part.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of active substances in the formulation are available and validated. As the active substances metamitron and quinmerac do not contain relevant impurity, no analytical method is required.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the monograph/this dossier and validated for the determination of residues of metamitron and quinmerac in plants (high water), food of animal origin, soil, water (surface and drinking) and air.

To update the dossier, an ILV of the analytical method (Weber (2009)) is required for the determination of metamitron in meat, liver, kidney or eggs.

The active substances are neither toxic nor very toxic hence no analytical method is required for the determination of resides in biological fluids and tissues.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment:

Active Substance: Metamitron			
ADI	0.03 mg kg bw/d		EU 2009
ARfD	0.1 mg/kg bw		
AOEL	0.036 mg/kg bw/d		
Dermal absorption	Based on an *in vitro* human study performed on formulation or on a similar formulation according to guidance on dermal absorption (EFSA 2012), according to guidance on dermal absorption (EFSA 2012):		
		Concentrate (used in formulation) 350 g/L	Spray dilution (used in formulation) 0.7 g/L
	Dermal absorption endpoints %	**2**	**55**

Active Substance: Quinmerac

ADI	0.08 mg kg bw/d		EU 2011
ARfD	0.3 mg/kg bw		
AOEL	0.08 mg/kg bw/d		
Dermal absorption	Based on an *in vitro* human study performed on formulation or on a similar formulation according to guidance on dermal absorption (EFSA 2012), according to guidance on dermal absorption (EFSA 2012):		
		Concentrate (used in formulation) 60 g/L	Spray dilution (used in formulation) 0.12 g/L
	Dermal absorption endpoints %	**4**	**14**

3.1.3.1 Acute Toxicity

GOLTIX SILVER (AG-QMM2-410 SC) containing 350 g/L metamitron and 60 g/L quinmerac has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye. However, study provided to assess skin sensitisation was not judged valid, the formulation is considered as a skin sensitiser by calculation method.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G	Equipment	Application rate	Spray dilution (L/ha)	Model
Beet	F	Tractor mounted/trailed boom sprayer, hydraulic nozzles	4 L/ha (1.4 kg metamitron/ha; 240 g quinmerac/ha)	80-400	BBA

Considering proposed use, operator systemic exposure was estimated using the German BBA model:

Crop	Equipment	PPE and/or working coverall	% AOEL metamitron	% AOEL quinmerac
Beet	Tractor mounted/trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	168	4.1

According to the model calculations, it can be concluded that the risk for the operator using GOLTIX SILVER (AG-QMM2-410 SC) is **unacceptable** even if a working coverall (90% protection factor) and gloves during mixing/loading and application are worn.

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to 17 % of the AOEL of metamitron and 0.5 % of quinmerac.
It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to GOLTIX SILVER (AG-QMM2-410 SC).

3.1.3.4 Worker Exposure

GOLTIX SILVER (AG-QMM2-410 SC) is used as herbicidal treatment on several crops where there is no need to re-enter the treated area after application. Worker exposure is considered not relevant.

3.1.4 Residues and Consumer Exposure

Critical GAP(s) and overall conclusion

Overall conclusion
The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.2 mg/kg for metamitron and 0.5 mg/kg for quinmerac as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of both active substances residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, France agrees with the authorization of the intended use(s).

According to available data, the following specific mitigation measures are recommended:

Due to metamitron
- tops should not be fed to livestock when GOLTIX SILVER (AG-QMM2-410 SC) is applied between BBCH 18 and BBCH 37.
- tops should not be fed after thinning or crop failure.

Data required in post-authorization : /

Summary of the evaluation

Summary for metamitron

Use-No.	**Crop**	**Plant metabolism covered?**	**Sufficient residue trials?**	**PHI sufficiently supported?**	**Sample storage covered by stability data?**	**MRL compliance Reg. (EC) No 149/2008**	**Chronic risk for consumers identified?**	**Acute risk for consumers identified?**	**Comments**
1	Sugar beet (pre-emergence)	Yes	Yes	Yes	Yes	Yes	No	No	
2	Sugar beet (post-emergence)	Yes	Yes	Yes	Yes	Yes		No	
3	fodder beet (pre-emergence)	Yes	Yes	Yes	Yes	Yes		No	Extrapolation from sugar beet
4	fodder beet (post-emergence)	Yes	Yes	Yes	Yes	Yes		No	

As residues of metamitron do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary. However as no information is available on residue levels of conjugates metamitron, tops should not be fed to livestock. Moreover, on the basis of the results of metabolism study in sugar beet and acceptable residue trials (residues in leaves below LOQ for PHI ≥103 days), tops should not be fed after thinning or

crop failure.

Chronic consumer exposure resulting from the uses proposed in the framework of this application was calculated. Based on EFSA PRIMo (rev2), chronic and acute exposures were considered as acceptable for all groups of consumers.

Summary for quinmerac

Use-No.*	**Crop**	**Plant metabolism covered?**	**Sufficient residue trials?**	**PHI sufficiently supported?**	**Sample storage covered by stability data?**	**MRL compliance Reg. (EC) No 149/2008**	**Chronic risk for consumers identified?**	**Acute risk for consumers identified?**	**Comments**
1	Sugar beet (pre-emergence)	Yes	Yes	Yes	Yes	Yes	No	No	
2	Sugar beet (post-emergence)	Yes	Yes	Yes	Yes	Yes		No	
3	Fodder beet (pre-emergence)	Yes	Yes	Yes	Yes	Yes		No	Extrapolation from sugar beet
4	fodder beet (post-emergence)	Yes	Yes	Yes	Yes	Yes		No	

Summary for GOLTIX SILVER (AG-QMM2-410 SC)

Information on GOLTIX SILVER (AG-QMM2-410 SC)

Crop	**BBCH for GOLTIX SILVER (AG-QMM2-410 SC) proposed by applicant**	**BBCH/ Withholding period* sufficiently supported for**		**BBCH for GOLTIX SILVER (AG-QMM2-410 SC) proposed by zRMS**	**zRMS Comments (if different BBCH proposed)**
		Metamitron	**quinmerac**		
Sugar beet (pre-emergence)	BBCH 00-09	Yes	Yes	BBCH 00-09	
Sugar beet (post-emergence)	BBCH 09-37	Yes	Yes	BBCH 09-37	
Fodder beet (pre-emergence)	BBCH 00-09	Yes	Yes	BBCH 00-09	
fodder beet (post-emergence)	BBCH 09-37	Yes	Yes	BBCH 09-37	

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			**Overall waiting period proposed by zRMS for GOLTIX SILVER (AG-QMM2-410 SC)**
Crop group	**Led by metamitron**	**Led by quinmerac**	
NR	NR	NR	

NR: not relevant

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substances and their metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC of metamitron, quinmerac and their respective metabolites desamino-metamitron, BH 518-2 and BH 518-5 in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.
PEC soil and PECsw derived for the active substances and their metabolites are used for the ecotoxicological risk assessment.
PECgw for metamitron, quinmerac and their metabolites desamino-metamitron and BH 518-2 and BH 518-5 respectively do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[8] for an application of the preparation GOLTIX SILVER (AG-QMM2-410 SC) every third year. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses on sugar beet for an application every third year.
Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

The risk assessment of GOLTIX SILVER (AG-QMM2-410 SC) was based on toxicity studies performed with AG-QMM1-565 SC containing 525 g metamitron/L and 40 g quinmerac/L. The changes concerned an higher volume of water and a slightly increased amount of quinmerac in AG-QMM1-565 SC. The bridging of the toxicity studies was considered acceptable.

A risk assessment was performed to assess the effects of GOLTIX SILVER (AG-QMM2-410 SC) on birds and mammals, when applied to sugar beet crops according to the instructions of use. The risk assessment was performed according to guidance document on Birds and Mammals of EFSA (2010). Additionally, exposure through drinking water was assessed and an acceptable risk was found in the puddle water scenario.
Based on EC_{50} of 380 mg/L from Lemna study and PEC Step 3, the risk is acceptable for aquatic organisms.
The risk to bees was considered acceptable for contact and oral toxicity (HQ_C and $HQ_O < 50$), if GOLTIX SILVER (AG-QMM2-410 SC) is applied according to the instructions for use.
The effects of AG-QM1-565 SC on the species *Aphidius rhopalosiphi* and *Typhlodromus pyri* have been investigated in extended laboratory test designs with freshly dried residues, No significant effect on mortality and reproduction were observed when assuming one application of 4 L/ha (worst-case exposure).

[8] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

For acute as well as long-term risk to earthworms, the criteria as set out in Regulation (EC) n°. 1107/2009 are met (TER_a > 10 and TER_{lt}> 5). It is concluded that there is no unacceptable acute/short-term, or long-term risk to earthworm populations if GOLTIX SILVER (AG-QMM2-410 SC) is used according to the instructions for use.
The risk to soil micro-organisms was evaluated by comparison of no-effect concentrations derived from laboratory tests with the relevant PEC_S. When a realistic scenario is considered, i.e. the rotation for the sugar/fodder beet is taken into account, the trigger values indicate an acceptable risk to soil microflora from the proposed uses of GOLTIX SILVER (AG-QMM2-410 SC) for applications every 2nd year.
The risk assessment for non-target terrestrial plants showed an acceptable risk based on vegetative vigour and seedling emergence test conducted with the preparation GOLTIX SILVER (AG-QMM2-410 SC).

3.1.7 Efficacy

Considering the data submitted:

- the efficacy of GOLTIX SILVER (AG-QMM2-410 SC) is considered as satisfying,
- the selectivity of GOLTIX SILVER (AG-QMM2-410 SC) is considered as acceptable,
- the risk of negative impact on plants and plants products is considered as acceptable,
- the risk of resistance development or appearance is considered as low.

Crop	Pest	Method and timing of application	Dose of use (L/ha)	Dose max / crop (L/ha)	Max nb of appl. per use	Max nb of appli. Per crop	Opinion of France for efficacy section	Comments (e.g. monitoring …) / additional demands
Sugar beet	Broad leaf weeds and grasses	Foliar spray Pre emergence or early post emergence by spray	4.0	4.0	1 in pre-emergence or 3-5 in post-emergence	5	Acceptable	
Fodder beet	Broad leaf weeds and grasses	Foliar spray Pre emergence or early post emergence by spray	4.0	4.0	1 in pre-emergence or 3-5 in post-emergence	5	Acceptable	

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation cannot be granted (unacceptable risk for the operator)**. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

N/A: authorisation not granted in France.

3.4.2 Post-authorisation data requirements

N/A: authorisation not granted in France.

3.4.3 Label amendments

N/A: authorisation not granted in France.

Appendix 1 – Copy of the French Decision

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Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

Vu la demande d'autorisation de mise sur le marché et les demandes associées du produit phytopharmaceutique ***GOLTIX SILVER***

de la société	*ADAMA FRANCE SAS*
enregistrées sous les	*n°2013-0790 ; 2013-0792 ; 2015-0333 et 2015-6495*

Vu les conclusions de l'évaluation de l'Anses du 30 octobre 2017,

Considérant que l'exposition de l'opérateur à la métamitrone est supérieure au niveau acceptable d'exposition de l'opérateur lors d'une application avec un pulvérisateur à rampe,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

GOLTIX SILVER
AMM n°-

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Informations générales sur le produit	
Noms du produit	GOLTIX SILVER TORNADO GOLD
Type de produit	Produit de référence
Titulaire	ADAMA FRANCE SAS 33 rue de Verdun 92156 SURESNES FRANCE
Formulation	Suspension concentrée (SC)
Contenant	350 g/L - métamitrone 60 g/L - quinmérac
Numéro d'intrant	905-2013.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usages	Professionnel

A Maisons-Alfort, le 19 JAN. 2018

Françoise WEBER
Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

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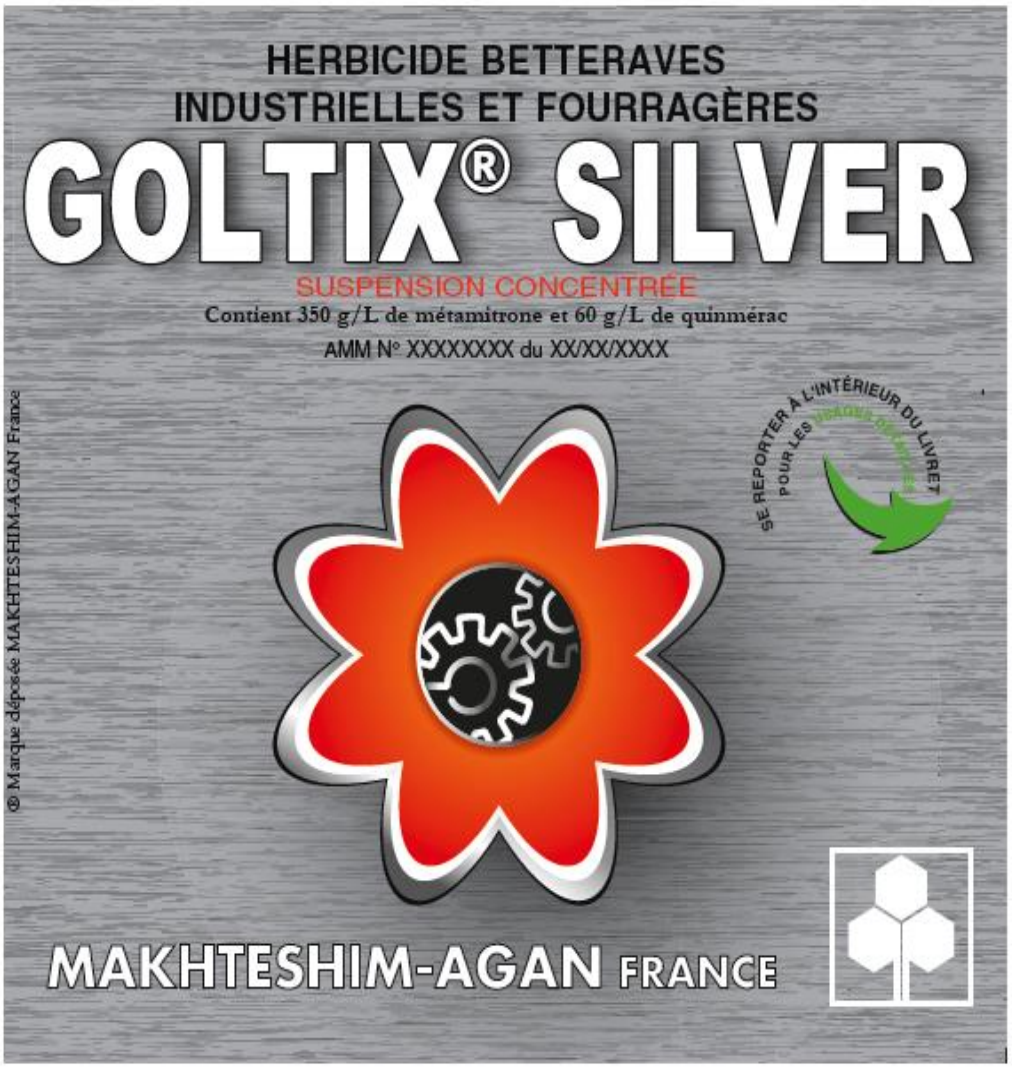
Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15055911 Betterave industrielle et fourragère*Désherbage	4 L/ha	1 /an	90
	Motivation du refus : L'usage est refusé en raison d'un risque sanitaire inacceptable pour l'opérateur.		

Appendix 2 – Copy of the draft product label as proposed by the applicant



MODE D'ACTION - PROPRIÉTÉS :

GOLTIX® SILVER est un herbicide à base de métamitrone, de la famille chimique des triazinones et de quimérac de la famille des acides quinoléïnes carboxyliques. Il est sélectif des cultures de betteraves sucrières et fourragères.
Absorbé par les racines et le feuillage des mauvaises herbes, il agit en inhibant la photosynthèse. Il est actif sur un grand nombre de dicotylédones annuelles et quelques graminées (matricaire, renouées, chénopodes, morelles, amarantes, repousses de colza, éthuses, ammi majus, gaillet...).

MODE D'EMPLOI :

Usages et doses homologués :

Pour un désherbage sur :	Dose homologuée	DAR*
Betterave industrielle	4 L/ha	90 jours
Betterave fourragère		

* Délai Avant Récolte

Les Limites Maximales de Résidus sont consultables sur le site Internet de la Commission - Direction Générale Santé et protection du Consomateur à l'adresse suivante :http://ec-europa.eu/sanco_pesticides/public/index.cfm

Conditions d'emploi :

GOLTIX® SILVER s'applique en pré-levée ou en post-levée de la culture sur des adventices non levées ou déjà présentes lors du traitement.
Les applications de post-levée doivent être réalisées sur des betteraves saines, en bon état végétatif.

Préconisations :

En pré-levée : 4 L/ha
ou
En post-levée : fractionnement possible de 3 à 5 applications à la dose de 1,3 L/ha à 0,8 L/ha sans dépasser la dose cumulée de 4 L/ha.

Ne pas appliquer **GOLTIX® SILVER** :
- à la levée des betteraves,
- si de fortes amplitudes thermiques sont prévues dans les heures suivant l'application.

La meilleure efficacité de **GOLTIX® SILVER** est observée en conditions humides.

Pour obtenir une efficacité globale sur l'ensemble de la flore adventice sur betterave, **GOLTIX® SILVER** s'utilise en programme de traitements fractionnés, associé à d'autres spécialités*.

Délai de rentrée des travailleurs sur la parcelle :
6h après traitement, conformément à l'arrêté du 12 septembre 2006 relatif à la mise sur le marché et à l'utilisation des produits visés à l'article L-253-1 du Code Rural.

Préparation de la bouillie : Verser **GOLTIX® SILVER**, présenté sous forme de solution concentrée, dans la cuve du pulvérisateur à demi remplie d'eau, le système d'agitation étant en marche pour obtenir une bonne mise en suspension. Compléter avec la quantité d'eau nécessaire à l'application en maintenant l'agitation.
GOLTIX® SILVER s'utilise sans problème aux volumes/ha de bouillies habituellement employés en désherbage des betteraves (80 à 400 L/ha).
L'application de **GOLTIX® SILVER** sera généralement distincte de celle d'engrais liquides et d'oligo éléments. De tels mélanges ne peuvent être réalisés que sous la responsabilité de l'utilisateur en raison de la multiplicité des formules et d'éventuelles incompatibilités.

Mélange avec du bore : Compte tenu de la multiplicité des formulations des produits à base de bore, avant de faire le mélange, s'assurer au préalable de la compatibilité des produits en faisant un test dans un petit récipient à part.
* Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques officiels. Consultez le site : http://e-phy.agriculture.gouv.fr

Culture suivante : dans le cas d'une rotation normale, après une betterave désherbée avec **GOLTIX® SILVER**, il n'y a pas de restriction sur les cultures suivantes.

Culture de remplacement : en cas d'accident nécessitant le remplacement d'une culture de betterave désherbée avec **GOLTIX® SILVER**, il est possible d'implanter, après un labour :
- immédiatement : betterave, pomme de terre.
- après un délai de 6 semaines : maïs, pois, féverole, orge de printemps.

Les cultures de colza et graminées fourragères sont déconseillées avant un délai de 3 mois après applications.
La culture du lin est déconseillée en culture de remplacement.

PRÉCAUTIONS GÉNÉRALES :

DANS LE CADRE DES BONNES PRATIQUES AGRICOLES :

Gestion du risque de résistance :
L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation.
Emballages vides : réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et rincer le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Eliminer les emballages vides
via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR ou tout autre
service de collecte spécifique.
Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.
Nettoyage de l'équipement : ne pas laisser de bouillie prête à l'emploi dans le pulvérisateur. Eliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur.
Eviter toute contamination des mares, puisards, ruisseaux, eaux souterraines ou de distribution ou de
tout autre point d'eau, par le produit, la bouillie de pulvérisation et les eaux de rinçage des emballages
et équipements de traitement.
Conditions de stockage : Stocker fermé à température ambiante. Protéger de l'humidité. Eviter les fortes chaleurs.

Premiers soins :
- En cas d'inhalation, éloigner la victime de la zone dangereuse, transporter la victime à l'air frais et selon les symptômes, consulter le médecin.
- En cas de contact avec la peau, laver soigneusement à l'eau et au savon, le cas échéant consulter le médecin.
- En cas de contact avec les yeux, rincer abondamment à l'eau pendant plusieurs minutes. Si nécessaire, consulter le médecin.
- En cas d'ingestion, ne pas provoquer de vomissement, faire boire abondamment de l'eau, consulter immédiatement le médecin.

Mesures d'urgence : en cas d'urgence, appeler le 15 ou le centre antipoison le plus proche de votre
domicile puis signalez vos symptômes au réseau Phyt'attitude, n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

RECOMMANDATIONS : "Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces, la pression parasitaire... Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture. Compte-tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées protégées ou issues de cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur. Makhteshim-Agan ne saurait être tenu en aucun cas responsable des conséquences inhérentes à toute copie (totale ou partielle) de cette étiquette, à sa diffusion ou son utilisation non autorisée".

N - Dangereux pour l'environnement

GOLTIX® SILVER

AMM N°XXXXXXX

SC - Suspension concentrée

360 g/L de métamitrone + 60 g/L de quinmérac

R51/53 **Toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique.**

Délai de rentrée des travailleurs sur la parcelle : 6h après traitement.

S2	Conserver hors de la portée des enfants.
S13	Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.
S20/21	Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.
S29/35	Ne pas jeter les résidus à l'égout. Ne se débarrasser de ce produit et de son emballage qu'en prenant toutes précautions d'usage.
S57	Utiliser un récipient approprié pour éviter toute contamination du milieu ambiant.
S60	Éliminer le produit et son récipient comme un déchet dangereux.
S61	Éviter le rejet dans l'environnement. Consulter les instructions spéciales/la fiche de données de sécurité.

Respectez les instructions d'utilisation afin d'éviter les risques pour l'homme et l'environnement.

SP1 Ne pas polluer l'eau avec le produit ou son emballage.

PRODUIT POUR LES PROFESSIONNELS : RESPECTER LES CONDITIONS D'EMPLOI.
Lire les instructions ci-jointes avant emploi.

La fiche de données de sécurité peut être obtenue gratuitement sur Internet www.quickfds.com ou à partir de www.ma-france.com ou en écrivant à fds@ma-france.com ou par courrier à l'adresse postale de Makhteshim Agan France.

Responsable de l'emballage :
Agan Chemical Manufacturers Ltd
P.O.B. 262, Northern Industrial Zone
Ashdod 77102
Israël

Produit fabriqué en Israël

Voir emballage

N° de lot et date de fabrication

Volume net : **5 L**

Distribué par :
MAKHTESHIM-AGAN France
2, rue Troyon
92316 Sèvres Cedex
Tél. : 01 41 90 16 96
Fax : 01 46 42 71 17

Appendix 3 – Letter(s) of Access

Not applicable.