REGISTRATION REPORT

Part A

Risk Management

Product code: AG-QMM2-410 SC

Product name: GOLTIX SILVER

Chemical active substances:

Metamitron, 350 g/L
Quinmerac, 60 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: ADAMA France S.A.S.

Finalisation date: May 2021

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PART A
RISK MANAGEMENT

1 Details of the application

The company ADAMA France S.A.S. has requested a marketing authorisation in France for the product GOLTIX SILVER (formulation code: AG-QMM2-410 SC), containing 350 g/L metamitron[1] and 60 g/L quinmerac[1] as an herbicide for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

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

1.1 Application background

The present registration report concerns the evaluation of ADAMA France S.A.S.'s application submitted on 13/06/2019 to market GOLTIX SILVER (AG-QMM2-410 SC) in France (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 Member States (MSs) of the Southern zone.

The present application (2019-4464) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[2], the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[3]. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of GOLTIX SILVER (AG-QMM2-410 SC) have been made using endpoints agreed in the EU peer reviews of metamitron and quinmerac. It also includes assessment of data and information related to GOLTIX SILVER (AG-QMM2-410 SC) where those data have not been considered in the EU peer review process.

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 risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the

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1 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

2 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

3 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

4 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

registration of GOLTIX SILVER (AG-QMM2-410 SC).

1.2 Letters of Access

The applicant has provided letters of access for active substances metamitron and quinmerac. These letters of access are available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: « All studies and data provided with this application are requested by current guidelines for authorisation or re-authorisation of a plant protection product (here: AG-QMM2-410 SC) in EU countries. ».

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.

2 Details of the authorisation decision

2.1 Product identity

Product code	AG-QMM2-410 SC
Product name in MS	GOLTIX SILVER
Authorisation number	N/A : no marketing authorisation granted
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	ADAMA France S.A.S.
Active substance(s) (incl. content)	Metamitron, 350 g/L Quinmerac, 60 g/L
Formulation type	Suspension concentrate [SC]
Packaging	N/A : no marketing authorisation granted
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion DAMM

The evaluation of the application for GOLTIX SILVER (AG-QMM2-410 SC) resulted in the decision **to refuse** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 2
Hazard pictograms:	 SGH09
Signal word:	none
Hazard statement(s):	H400: Very toxic to aquatic life H411: Toxic to aquatic life with long lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the existing legislation***
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	EUH208: Contains 1,2-benzisothiazolin-3-one (CAS No. 2634-33-5). May produce an allergic reaction.

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

2.4.2 Standard phrases under Regulation (EU) No 547/2011

N/A : no marketing authorisation granted

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

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

The French Order of 4 May 2017 [5] provides that:
- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

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

Finally, the French Order of 26 March 2014[6] provides that:
- an authorisation granted for a "reference" crop applies also for "related" crops, unless formally stated in the Decision
- the "reference" and "related" 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 "related" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those "related" 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.

2.5.1 Restrictions linked to the PPP

N/A : no marketing authorisation granted

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

[5] 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

[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

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2021/05/10

PPP (product name/code):	GOLTIX SILVER / AG-QMM2-410 SC	Formulation type:	SC [a, b]
Active substance 1:	Metamitron	Conc. of a.s. 1:	350 g/L [c]
Active substance 2:	Quinmerac	Conc. of a.s. 2:	60 g/L [c]
Safener:	--	Conc. of safener:	--
Synergist:	--	Conc. of synergist:	--
Applicant:	ADAMA France s.a.s	Professional use:	☒
Zone(s):	Southern Zone [d]	Non-professional use:	☐
Verified by MS:	**Yes**		

Field of use: Herbicide

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:** e.g. g safener/synergist per ha [f]
					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 a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													

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:** e.g. g safener/synergist per ha [f]
					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 a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	FR	Sugar beet (BEAVA)	F	Broad leaf weeds and grasses	Soil spray or incorporation	BBCH 00 to 09	a) 1 b) 1	n.a.	a) 4 L/ha b) 4 L/ha	a) 1400 g/ha metamitron, 240 g/ha quinmerac b) 1400 g/ha metamitron, 240 g/ha quinmerac	80 - 300	80	**Not** acceptable (risk for aquatic organisms, bees) Pre-emergence pre-sowing application (incorporation) Or pre-emergence post-sowing application
2	FR	Sugar beet (BEAVA)	F	Broad leaf weeds and grasses	Foliar spray	BBCH 10 to 37	a) 3-5 b) 3-5	6	a) 0.8 – 1.33 L/ha b) 4 L/ha	a) 280 – 466.7 g/ha metamitron, 48 - 80 g/ha quinmerac b) 1400 g/ha metamitron, 240 g/ha quinmerac	80 - 300	80	**Not** acceptable (risk for aquatic organisms, bees) Maximum 4.0 L/ha product in total split into 3 to 5 applications
3	FR	Fodder beet (BEAVC)	F	Broad leaf weeds and grasses	Soil spray or incorporation	BBCH 00 to 09	a) 1 b) 1	n.a.	a) 4 L/ha b) 4 L/ha	a) 1400 g/ha metamitron, 240 g/ha quinmerac b) 1400 g/ha metamitron, 240 g/ha quinmerac	80 - 300	80	**Not** acceptable (risk for aquatic organisms, bees) Pre-emergence pre-sowing application (incorporation) Or pre-emergence post-sowing application

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, 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:** e.g. g safener/synergist per ha [f]
					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 a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
4	FR	Fodder beet (BEAVC)	F	Broad leaf weeds and grasses	Foliar spray	BBCH 10 to 37	a) 3-5 b) 3-5	6	a) 0.8 – 1.33 L/ha b) 4 L/ha	a) 280 – 466.7 g/ha metamitron, 48 - 80 g/ha quinmerac b) 1400 g/ha metamitron, 240 g/ha quinmerac	80 - 300	80	**Not** acceptable (risk for aquatic organisms, bees) Maximum 4.0 L/ha product in total split into 3 to 5 applications

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 authorisation 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 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

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 an off-white homogenous suspension with a characteristic odour. The product GOLTIX SILVER (AG-QMM2-410 SC) is not explosive, not flammable, and not oxidising. The pH is 4.4 for the neat formulation and 3.6 for the 1 % solution. The product GOLTIX SILVER (AG-QMM2-410 SC) is surface active. All other relevant physical-chemical properties indicate that GOLTIX SILVER (AG-QMM2-410 SC) is a non-hazardous product. It is stable for a period of at least 14 days at 54 °C, 24 months at ambient temperature and 7 days at low temperature. Neither the active substances's 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 containers. The technical characteristics are acceptable for a suspension concentrate.

The formulation is not classified for the physico-chemical aspect.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:
- The efficacy of the product GOLTIX SILVER (AG-QMM2-410 SC) applied in pre-emergence and post-emergence is considered satisfactory to control broadleaved weeds in sugar and fodder beets;
- The level of selectivity of the product GOLTIX SILVER (AG-QMM2-410 SC) is considered acceptable for the claimed uses;
- The risks of negative impact on yield, quality and multiplication are considered acceptable;
- The risks of negative impact on succeeding crops are considered acceptable. Nevertheless, specific attention should be paid to susceptible succeeding crops;
- The risks of negative impact on adjacent crops are considered acceptable;
- There is a risk of resistance development or appearance to metamitron requiring a survey of resistance.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

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

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR) and are validated for the determination of residues of quinmerac and metamitron in plants (high water, high acid, dry and high oil content), food of animal origin, soil, water (surface and drinking) and air.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

The product GOLTIX SILVER (AG-QMM2-410 SC) has a low acute oral, inhalational and dermal toxicity. It is not irritating to the rabbit skin or eye and is not a skin sensitiser.

Active substance(s) (incl. content)	**Metamitron** 350 g/L	**Quinmerac** 60 g/L
AOEL systemic	0.036 mg/kg bw/d	0.08 mg/kg bw/d
AAOEL	None	None
Inhalation absorption	100 %	100 %
Vapour pressure	7.44×10^{-7} Pa at 25°C	$< 1 \times 10^{-10}$ Pa at 20°C
Oral absorption	> 80% (noted 100 % in EFSA model)	> 80% (noted 100 % in EFSA model)
Reference	EFSA Scientific Report (2008) 185, 1-95 SANCO/208/08 final 6 January 2009 (revised 20 March 2015)	EFSA Journal (2010) 8(3):1523 SANCO/12192/2010 — rev. 11 18 May 2017
Dermal absorption	Concentrate: 0.063 % Dilution 1 (4.7 g/L): 1.5 % Dilution 2 (0.93 g/L): 8.0 % [Based on product AG-QMM2-410 SC; Hassler, S., 2019b]	Concentrate: 0.9 % Dilution 1 (0.8 g/L): 2.3 % (3) Dilution 2 (0.16 g/L): 2.3 % (3) [Based on product AG-QMM2-410 SC; Hassler, S., 2019a]

(3) The maximum rate (determined for the fisrt dilution) was used for both dilutions.

3.4.2 Operator exposure

Considering the proposed uses, operator systemic exposure was estimated using the EFSA model[8]:

Estimated operator exposure, considering critical use 1 x 4 L prod./ha:

		Metamitron		**Quinmerac**	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL(1)**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL(2)**
Tractor mounted boom spray application outdoors to bare soil Application rate: 1 x 4 L prod/ha (1 x 1.400 kg metamitron/ha, 1 x 0.240 kg quinmerac/ha)					
EFSA calculator (75^{th} percentile, long-term exposure) Body weight: 60 kg	Work wear (3) during mixing and loading and application and gloves	0.0006	1.8	0.0004	0.54

(1) AOEL (RVNAS) of metamitron: 0.036 mg/kg bw/day
(2) AOEL (RVNAS) of quinmerac: 0.08 mg/kg bw/day
(3) Work wear – arms, body and legs covered

[8] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

It can be noted that the application rate of 4 L/ha on low crops (bare soil) is a worst case scenario when compared to the soil incorporation (operator is exposed only during mixing/loading).

Estimated operator exposure, considering critical use 3 x 1.33 L prod./ha

		Metamitron		Quinmerac	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL(1)**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL(2)**
Tractor mounted boom spray application outdoors to low crops (root and tuber vegetables) Application rate: 3 x 1.33 L prod/ha (3 x 0.466 kg metamitron/ha, 3 x 0.080 kg quinmerac/ha)					
EFSA calculator (75th percentile, long-term exposure) Body weight: 60 kg	Work wear (3) and gloves during mixing and loading and application.	0.0008	2.1	0.0002	0.29

(1) AOEL (RVNAS) of metamitron: 0.036 mg/kg bw/day
(2) AOEL (RVNAS) of quinmerac: 0.08 mg/kg bw/day
(3) Work wear – arms, body and legs covered

It can be noted that the application rate of 3 x 1.33 L/ha on low crops (root and tuber vegetables) is a worst case scenario when compared to the other scenarios proposed by the applicant (4 x 1 L/ha and 5 x 0.8 L/ha).

According to the model calculations, it may be concluded that the risk for the operator using GOLTIX SILVER (AG-QMM2-410 SC) is acceptable with a working coverall and gloves during mixing/loading and application.

3.4.3 Worker exposure

Workers may have to enter treated areas after treatment for crop inspection and/or irrigation tasks. Therefore, estimation of worker exposure was calculated according to EFSA model. Exposure is summarized in table below:

Estimated worker exposure, considering critical use 3 x 1.33 L prod./ha:

		Metamitron		Quinmerac	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL(1)**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL(2)**
Inspection, irrigation Outdoor Work rate: 2 hours/day DT50: 30 days DFR: 3 µg/cm2/kg a.s./ha Interval between treatments: 6 days					
Number of applications and appl. rate:		3 x 0.466 kg a.s./ha		3 x 0.080 kg a.s./ha	
EFSA calculator Body weight: 60 kg	Potential exposure TC: 12500 cm^2/person/h (3)	0.1225	340	0.0060	7.6
	Work wear TC: 1400 cm^2/person/h (4)	0.0137	38	0.0007	0.85

(1) AOEL (RVNAS) of metamitron: 0.036 mg/kg bw/day
(2) AOEL (RVNAS) of quinmerac: 0.08 mg/kg bw/day
(3) Potential exposure: no clothing
(4) Work wear – arms, body and legs covered, but no gloves

It can be noted that the application rate of 3 x 1.33 L/ha on low crops (root and tuber vegetables) is a worst case scenario when compared to the other scenarios proposed by the applicant (4 x 1 L/ha and 5 x 0.8 L/ha).

No treated foliage needs to be considered during bare-soil application. Therefore, no exposure via entry into treated crops is expected. It is not necessary to estimate worker exposure by considering a single total application of 4 L prod/ha.

It may be concluded that there is no unacceptable risk anticipated for the worker.

3.4.4 Bystander exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[9].

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure*."

[9] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

3.4.5 Resident exposure

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and child) with a buffer zone of 2-3 meters and without drift reduction technology:

Estimated resident exposure, considering critical use 1 x 4 L prod./ha:

		metamitron		quinmerac	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL(1)**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL(2)**
Tractor mounted boom spray application outdoors to low crops (bare soil) Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha					
Number of applications and application rate		1.4 kg a.s./ha		0.24 kg a.s./ha	
Resident child Body weight: 10 kg	**Sum (mean)**	0.0091	25	0.0031	3.9
Resident adult Body weight: 60 kg	**Sum (mean)**	0.0027	7.6	0.0009	1.1

(1) AOEL (RVNAS) of metamitron: 0.036 mg/kg bw/day
(2) AOEL (RVNAS) of quinmerac: 0.08 mg/kg bw/day

Estimated Resident exposure, considering critical use 3 x 1.33 L prod./ha:

		metamitron		quinmerac	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL(1)**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL(2)**
Tractor mounted boom spray application outdoors to low crops (root and tuber vegetables) Buffer zone: 2-3 (m) Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 6 days					
Number of applications and application rate		3 x 0.466 kg a.s./ha		3 x 0.08 kg a.s./ha	
Resident child Body weight: 10 kg	**Sum (mean)**	0.0230	64	0.0023	2.8
Resident adult Body weight: 60 kg	**Sum (mean)**	0.0095	26	0.0007	0.86

(1) AOEL (RVNAS) of metamitron: 0.036 mg/kg bw/day
(2) AOEL (RVNAS) of quinmerac: 0.08 mg/kg bw/day

It can be noted that the application rate of 3 x 1.33 L/ha on low crops (root and tuber vegetables) is a worst case scenario when compared to the other scenarios proposed by the applicant (4 x 1 L/ha and 5 x 0.8 L/ha).

3.4.6 Combined exposure

Currently no EU-harmonised guidance is available on the risk assessment of combined exposure to multiple active substances. Most assessment approaches employed up to now make use of the Hazard Index (HI) concept. It is therefore suggested to use this as a first tier assessment.

A cumulative assessment for operators, bystanders/residents and workers has been performed. At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.

Hazard quotients (HQ) for each active substance and the HI (sum of hazard quotients) are:

		Critical use: max. 1 x 4 L product/ha in a minimum water volume of 80 L/ha	**Critical use: max. 3 x 1.33 L product/ha in a minimum water volume of 80 L/ha; 6-day interval between each application**
Application scenario	**Active Ingredient**	**Estimated exposure / AOEL (HQ)(4)**	**Estimated exposure / AOEL (HQ)(4)**
Operators – tractor-mounted downward spraying wearing work wear(1) and gloves during M/L and A(2).	metamitron	0.0176	0.0213
	quinmerac	0.0054	0.0029
	Cumulative risk Operators (HI)(5)	**0.023**	**0.024**
Workers – inspection and irrigation wearing work wear (no PPE)	metamitron	Not relevant*	0.3811
	quinmerac		0.0085
	Cumulative risk Workers (HI)(5)		**0.39**
Resident - Child (all pathways) (3)	metamitron	0.2534	0.639
	quinmerac	0.0385	0.0282
	Cumulative risk Resident - Child (HI)(5)	**0.29**	**0.67**
Resident - Adult (all pathways) (3)	metamitron	0.0759	0.2632
	quinmerac	0.0111	0.0086
	Cumulative risk Resident - Adult (HI)(5)	**0.087**	**0.27**

(1) Work wear – arms, body and legs covered
(2) M = Mixing, L = Loading, A = Application
(3) For the resident combined toxicity assessment, the worst-case sub-scenario is considered
(4) Hazard Quotients, equivalent to the predicted exposure as % of systemic AOEL converted to decimal
(5) Hazard Index (HI) = sum of the individual HQs
* No treated foliage needs to be considered during bare-soil application. Therefore, no exposure via entry into treated crops is expected.

The Hazard Index is < 1. Thus combined exposure to all active substances in the product GOLTIX SILVER (AG-QMM2-410 SC) is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

3.5 Residues and consumer exposure (Part B, Section 7)

3.5.1 Residues

The data available are considered sufficient for risk assessment purposes. Any exceedance of the current MRL of 0.2 mg/kg for metamitron and 0.5 mg/kg for quinmerac as laid down in Regulation (EC) No 149/2008[10] is not expected.

3.5.2 Consumer exposure

The chronic and short-term intakes of metamitron and quinmerac residues are unlikely to present a public health concern. As far as consumer health protection is concerned, France as zRMS agrees with the authorisation of the intended uses.

3.6 Environmental fate and behaviour (Part B, Section 8)

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 values of metamitron, quinmerac and their metabolites 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.

PECsoil and PECsw values derived for the active substances and their metabolites are used for the ecotoxicological risk assessment.

PECgw values for metamitron and its metabolite do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009.
PECgw values for quinmerac and its metabolites cannot be considered acceptable since the geomean of Koc values were not considered for the active substance and its metabolite BH 518-5. Considering that, this deviation could have a significant impact on the outcome of the groundwater risk assessment, thus the groundwater risk assessment cannot be finalized.

Based on vapour pressures, information on volatilisation from plants and soil, and DT_{50} calculations, no significant contamination of the air compartment is expected for the intended uses.

[10] Commission Regulation (EC) No 149/2008 of 29 January 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substances and their metabolites were used 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.

Based on the guidance documents, the risks for birds, aquatic organisms, mammals non-target arthropods other than bees, earthworms, other soil macro and micro-organisms and terrestrial plants are acceptable for the intended uses.

For bees, the toxicity test on larva provided by the applicant is based on measurement of mortality at 8 day after repeated exposure. **No information is available to assess the effect on emergence at 22 days in accordance with Regulation (EU) No. 284/2013**. Thus, the risk assessment for bees can not be finalized.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to 3.6 for conclusion on the risk of groundwater contamination.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substances metamitron and quinmerac are not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

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

When the conclusions of the assessment is « Not acceptable », please refer to relevant summary under point 3 “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

N/A : no marketing authorisation granted

5.1.2 Post-authorisation data requirements

None.

Appendix 1 Copy of the product authorisation DAMM

RÉPUBLIQUE FRANÇAISE
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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 réglementaire,

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

de la société	*ADAMA FRANCE SAS*
enregistrée sous le	*n°2019-4464*

Vu les conclusions de l'évaluation de l'Anses du 14 avril 2021,

Considérant qu'un risque inacceptable de contamination des eaux souterraines, lié à l'utilisation du produit, ne peut être exclu,

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.

RÉPUBLIQUE FRANÇAISE
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Informations générales sur le produit	
Nom du produit	GOLTIX SILVER
Type de produit	Produit de référence
Titulaire	ADAMA FRANCE SAS 33 rue de Verdun 92156 SURESNES France
Formulation	Suspension concentrée (SC)
Contenant	60 g/L - quinmérac 350 g/L - métamitrone
Numéro d'intrant	9996-2019.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 10 mai 2021 :

RÉPUBLIQUE FRANÇAISE
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AGENCE NATIONALE DE SÉCURITÉ SANITAIRE de l'alimentation, de l'environnement et du travail

ANNEXE : Conditions de mise sur le marché demandées

Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
15055911 Betterave industrielle et fourragère* Désherbage	0,8 L/ha	5/an	80
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque inacceptable de contamination des eaux souterraines.		

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

ADAMA

GOLTIX® SILVER

AMM N°XXXXXXXX
SC - Suspension concentrée
Métamitrone 350 g/L (31.25%) + quinmérac 60 g/L (5.36%)
Contient de la 1,2 benzisothiazol-3(2H)-one.

Attention

H411 : Toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
EUH401 : Respecter les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.

Délai de rentrée des travailleurs sur la parcelle : 48h après traitement.
P102 : Tenir hors de portée des enfants.
P280 : Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/ du visage.
P501 : Éliminer le contenu/récipient dans un centre de collecte des déchets dangereux ou spéciaux.

SP1 : Ne pas polluer l'eau avec le produit ou son emballage.
SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres en bordure des points d'eau.

RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL.
Consulter le livret avant toute utilisation.

RÉEMPLOI DE L'EMBALLAGE INTERDIT.

JT 407B/02

Produit fabriqué en Israël

N° de lot	VOIR SUR L'EMBALLAGE
Date de fabrication	

3 700249 112065

5 L

PREMIERS SECOURS

Inhalation : Transporter la victime à l'air frais. En cas de respiration irrégulière ou d'absence de respiration, pratiquer la respiration artificielle. Consulter un médecin.

Contact cutané : Rincer immédiatement au savon et à grande eau en retirant les chaussures et vêtements contaminés. Consulter un médecin.

Contact avec les yeux : Rincer immédiatement et abondamment avec de l'eau. Après le rinçage initial, retirer les éventuelles lentilles de contact et continuer à rincer pendant au moins 15 minutes. Maintenir l'œil grand ouvert pendant le rinçage. Si les symptômes persistent, consulter un médecin.

Ingestion : Rincer la bouche. Boire beaucoup d'eau. Si les symptômes persistent, consulter un médecin.

EN CAS D'URGENCE
Composer le 15 ou le 112 ou contacter le centre antipoison le plus proche.

Puis signalez vos symptômes au réseau Phyt'attitude, N° Vert : 0 800 887 887 (appel gratuit depuis un poste fixe).

DESCRIPTIF DU PRODUIT

Tableau des usages autorisés

Libellé de l'usage	Nombre maximal d'applications	Dose autorisée	Délai avant récolte
Betterave industrielle et fourragère*Désherbage	1 en pré-levée	4 L/ha	80 jours
Betterave industrielle et fourragère*Désherbage	3 à 5 en post-levée	4L fractionnée entre 0.8 et 1.3 L/ha par application	

ADAMA France ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées dans le tableau ci-dessus et, à ce titre, décline toute responsabilité concernant l'élargissement de son utilisation à d'autres cultures et cibles telles que prévues par le catalogue des usages fixé par l'arrêté du 26 mars 2014.

Ainsi, l'attention de l'utilisateur est attirée sur les risques éventuels de non-conformité de cet élargissement permis par ce catalogue.

Délai de rentrée des travailleurs sur la parcelle cultivée : 48 heures après traitement, conformément à l'arrêté du 4 mai 2017.

Limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse : http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database.

Mode d'action

Goltix® Silver est un herbicide à base de métamitrone (de la famille chimique des triazinones) et de quinmérac (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 à la fois, en inhibant la photosynthèse (métamitrone), et en perturbant leur croissance et l'assimilation des nutriments (quinmérac).

Spectre d'efficacité

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, vulpin, pâturin...).

RECOMMANDATIONS D'EMPLOI

Conditions d'application

- Applications en pré ou en post-levée.
- Application au plus tard au stade BBCH 37.
- En post-levée, fractionnement entre 3 à 5 applications aux doses de 0.8 L/ha à 1.3 L/ha, sans dépasser la dose totale de 4L/ha par saison.

Précautions d'emploi

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.

Mélanges extemporanés

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur selon l'arrêté du 7 avril 2010 modifié par l'arrêté du 12 juin 2015.

En cas d'utilisation en mélange, contacter un représentant d'ADAMA France ou votre distributeur pour valider la possibilité d'association.

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.

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).

Cultures 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.

Cultures suivantes

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.

PRÉVENTION ET GESTION DE LA RÉSISTANCE

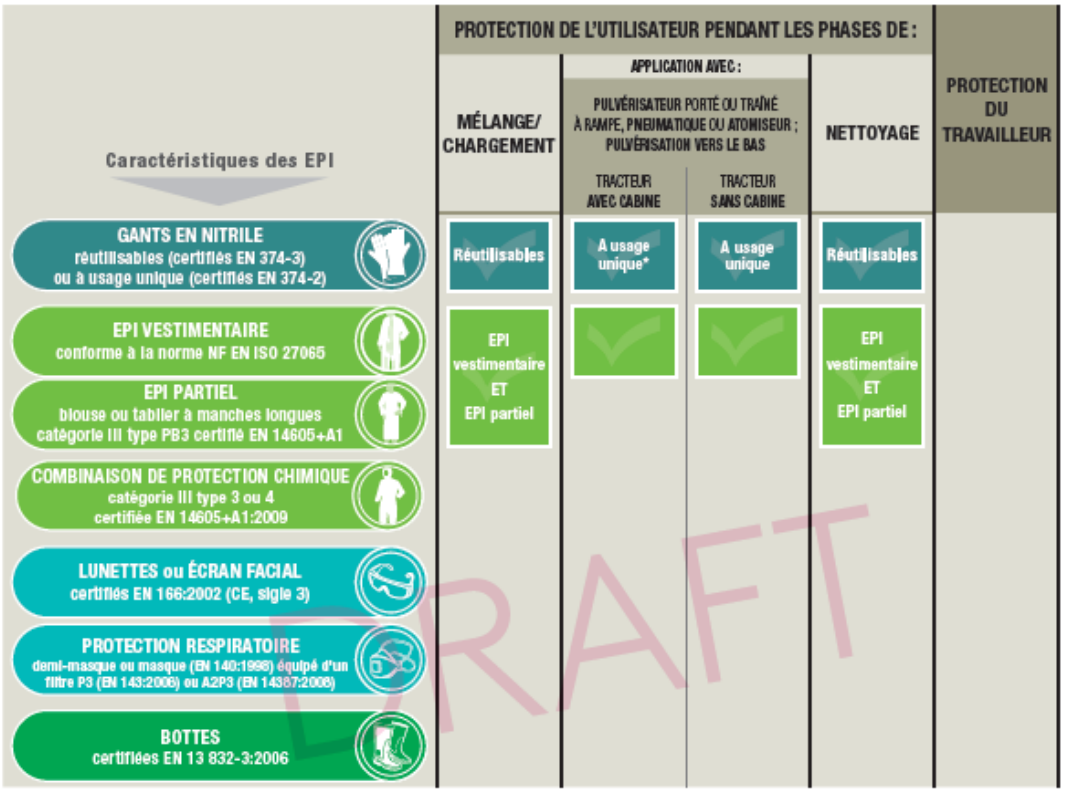
L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations 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.

MISE EN ŒUVRE RÉGLEMENTAIRE ET BONNES PRATIQUES

Stockage du produit

Conserver le produit dans son emballage d'origine, stocker dans un local réservé à cet usage, dans un endroit frais sec et bien ventilé à l'abri de la chaleur et de l'humidité.

Protection de l'opérateur et du travailleur



Caractéristiques des EPI	PROTECTION DE L'UTILISATEUR PENDANT LES PHASES DE : MÉLANGE/ CHARGEMENT	APPLICATION AVEC : PULVÉRISATEUR PORTÉ OU TRAÎNÉ À RAMPE, PNEUMATIQUE OU ATOMISEUR ; PULVÉRISATION VERS LE BAS — TRACTEUR AVEC CABINE	APPLICATION AVEC : PULVÉRISATEUR PORTÉ OU TRAÎNÉ À RAMPE, PNEUMATIQUE OU ATOMISEUR ; PULVÉRISATION VERS LE BAS — TRACTEUR SANS CABINE	NETTOYAGE	PROTECTION DU TRAVAILLEUR
GANTS EN NITRILE réutilisables (certifiés EN 374-3) ou à usage unique (certifiés EN 374-2)	Réutilisables	A usage unique*	A usage unique	Réutilisables	
EPI VESTIMENTAIRE conforme à la norme NF EN ISO 27065	EPI vestimentaire ET EPI partiel	✓	✓	EPI vestimentaire ET EPI partiel	
EPI PARTIEL blouse ou tablier à manches longues catégorie III type PB3 certifié EN 14605+A1					
COMBINAISON DE PROTECTION CHIMIQUE catégorie III type 3 ou 4 certifiée EN 14605+A1:2009					
LUNETTES ou ÉCRAN FACIAL certifiés EN 166:2002 (CE, sigle 3)					
PROTECTION RESPIRATOIRE demi-masque ou masque (EN 140:1998) équipé d'un filtre P3 (EN 143:2006) ou A2P3 (EN 14387:2008)					
BOTTES certifiées EN 13 832-3:2006					

* EN CAS D'INTERVENTION À L'EXTÉRIEUR ; DANS CE CAS, LES GANTS DOIVENT ÊTRE STOCKÉS ET PORTÉS À L'EXTÉRIEUR DE LA CABINE.

Nettoyage du pulvérisateur et gestion des fonds de cuve

Ne pas laisser de bouillie prête à l'emploi dans le pulvérisateur. Éliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur. Éviter 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.

Élimination du produit, de l'emballage

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. Éliminer 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.

En cas de déversement accidentel

Se protéger (EPI) et sécuriser la zone.

Prévenir les pompiers (18 ou 112) en cas de danger immédiat pour l'environnement que vous ne pouvez gérer avec vos propres moyens.

Collecter tout ce qui a pu être en contact avec le produit, terre souillée incluse. Nettoyer le site et le matériel utilisé, en prenant soin de confiner les effluents générés par l'opération de nettoyage. Les éliminer selon la réglementation en vigueur.

AVERTISSEMENT

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.

Conduire sur ces bases 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 au permis d'expérimentation. 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. ADAMA 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.


GOLTIX® SILVER
Cultures
Betteraves industrielles et fourragères.
Mode d'action HRAC
C1-0
voir verso
La fiche de données de sécurité peut être obtenue gratuitement sur Internet www.quickfds.com ou en écrivant à fds@adama.com ou par courrier à l'adresse postale d'ADAMA France s.a.s ou en scannant le flashcode avec votre téléphone mobile.
Matières actives : Métamitrone 350 g/L + quinmérac 60 g/L
Formulation : SC - Suspension concentrée
AMM N°XXXXXXX
Titulaire de l'AMM :
ADAMA France s.a.s
33 rue de Verdun
92156 Suresnes Cedex
Tél. : 01 41 47 33 33
® Marque enregistrée par une société du groupe ADAMA
STOCKER ENTRE
35°
0°
5 L
HERBICIDE
Pré-levée et post-levée
ADAMA
JS407A/02


ADAMA
GOLTIX® SILVER
AMM N°XXXXXXXX
SC - Suspension concentrée
Métamitrone 350 g/L (31.25%) + quinmérac 60 g/L (5.36%)
Contient de la 1,2 benzisothiazol-3(2H)-one.
Attention
H411 : Toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
EUH401 : Respecter les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.
Délai de rentrée des travailleurs sur la parcelle : 48h après traitement.
P102 : Tenir hors de portée des enfants.
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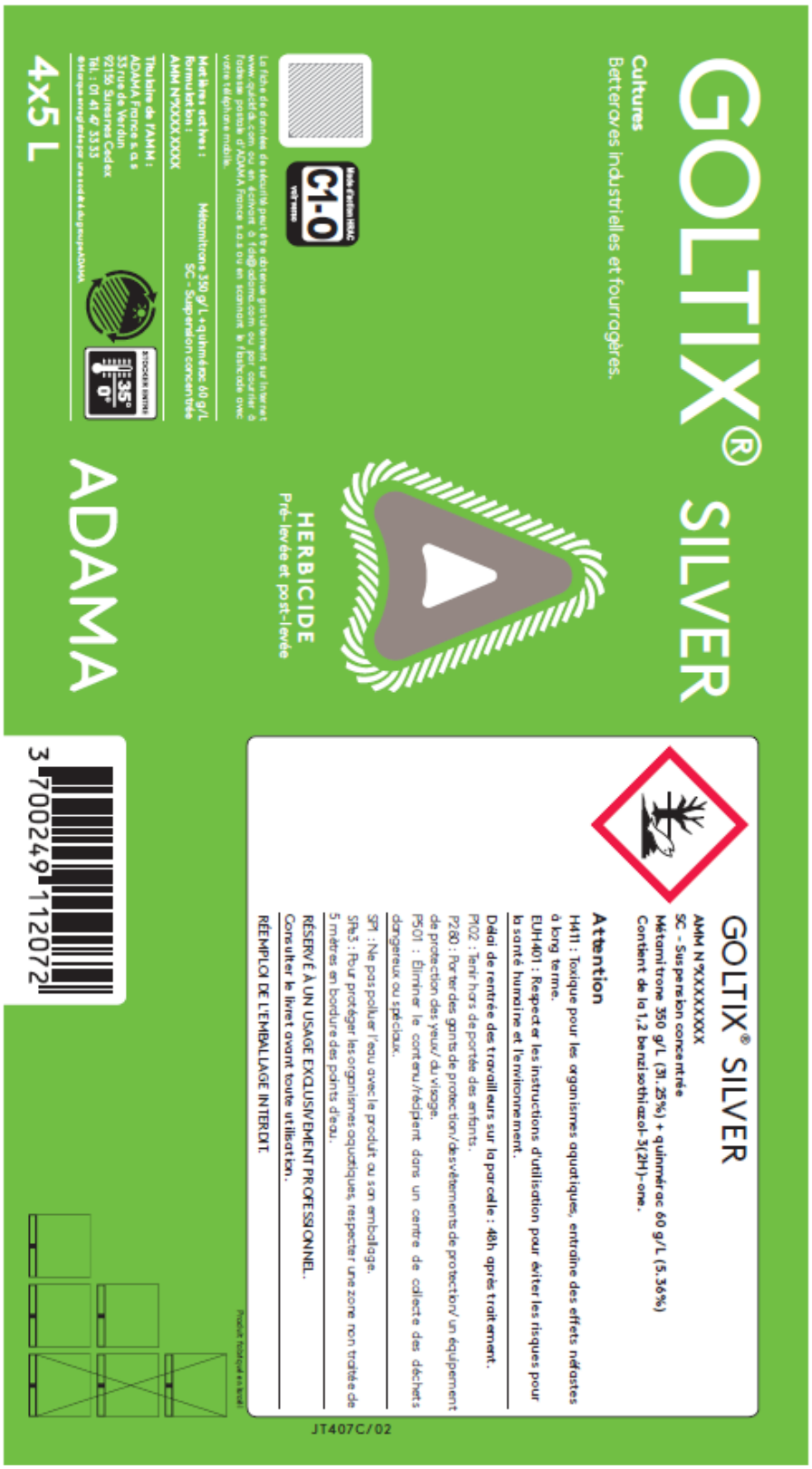
SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres en bordure des points d'eau.
RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL.
Consulter le livret avant toute utilisation.
RÉEMPLOI DE L'EMBALLAGE INTERDIT.
JT 407 B/02
Produit fabriqué en Israël
N° de lot
Date de fabrication
VOIR SUR L'EMBALLAGE
3 700249 112065
5 L

AG-QMM2-410 SC / GOLTIX SILVER
Part A - National Assessment
FRANCE version



Appendix 3 Lists of data considered for national authorisation DAMM

Not applicable.