

REGISTRATION REPORT

Part A

Risk Management

Product code: SAP 480H

Product name(s): GRANADA 48 SC

Active Substance(s):

Metribuzin, 480 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: SAPEC AGRO France

Date: 28/03/2018 (Decision)

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PART A – Risk Management

The company SAPEC AGRO France has requested marketing authorisation in France for the product GRANADA 48 SC (SAP 480H), containing 480 g/L metribuzin for use as an 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 GRANADA 48 SC (SAP 480H) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of GRANADA 48 SC (SAP 480H) have been made using endpoints agreed in the EU peer review of metribuzin.

This document describes the specific conditions of use and labelling required for France for the registration of GRANADA 48 SC (SAP 480H).

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 SAPEC AGRO France's application to market GRANADA 48 SC (SAP 480H) in France as an 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

Metribuzin

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 metribuzin for uses other than in post-emergence selective herbicide in potatoes 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 metribuzin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006 shall be taken into account.

In this overall assessment Member States:

— must pay particular attention to the protection of algae, aquatic plants, non-target plants outside the treated field and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures.

— must pay particular attention to the operator safety and ensure that conditions of use prescribe the application of

adequate personal protective equipment.

The Member States concerned shall request the submission of further data to confirm the risk assessment for groundwater. They shall ensure that the notifiers at whose request metribuzin has been included in this Annex provide such studies to the Commission within two years from the approval.

An EFSA conclusion is available (EFSA Scientific report (2006) 88, 1-74).

A Review Report is available (SANCO/10051/2006 rev 1, 21 November 2011).

1.3 Regulatory approach

The present application (2013-1217) 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.

The French Order of 4th May 2017³ 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 1107/2009⁴, 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 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁶ 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,

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

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

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/AGRGI1407093A/jo>

mainly based on the EU document on residue data extrapolation⁷ 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 GRANADA 48 SC (SAP 480H), 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.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity


Product name (code)	GRANADA 48 SC (SAP 480H)
Authorisation number	None (marketing authorisation refused)
Function	herbicide
Applicant	SAPEC AGRO France
Composition	480 g/L metribuzin
Formulation type (code)	Suspension concentrate (SC)
Packaging	HDPE bottle (0,5 L, 1 L) HDPE canister (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	–
Environmental hazards	Aquatic Acute 1; Aquatic Chronic 1
Hazard pictograms	

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

Signal word	Warning	
Hazard statements	H400	H400 Very toxic to aquatic life
	H410	H410 Very toxic to aquatic life with long lasting effects
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH 208	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

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: The product is not authorised in France

2.2.4 Other phrases linked to the preparation

N/A: The product is not authorised in France

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.

PPP (product name/code) **GRANADA 48 SC/ SAP 480H**
active substance 1 **metribuzin**
active substance 2 -
active substance 3 -
safener safener
synergist -
Applicant: **SAPEC AGRO S.A.**
Zone(s): **southern**
Verified by MS: **yes/no**

Formulation type: **SC**
Conc. of as 1: **480 g/L**
Conc. of as 2: -
Conc. of as 3: -
Conc. of safener: **conc.**
Conc. of synergist: **conc.**
professional use ☒
non professional use ☐

GAP rev. , date: 2018-03-28

Crop and/or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Potato	FR	SAP480H	F	Annual broad-leaf and grasses	SC	480	Soil broadcast spray	BBCH 00-08	1	--	0.075-0.132	400-700	0.528	N/A	Not acceptable (risk for aquatic organisms)
Tomato	FR	SAP480H	F	Annual broad-leaf and grasses	SC	480	Soil broadcast spray	BBCH 00-07 (seeded tomato) or BBCH 17-19 (transplanted tomato)	1	--	0.075-0.132	400-700	0.528	N/A	Not acceptable (lack of residue trials ; risk for aquatic organisms) Not finalised (selectivity)

-
- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
 - (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
 - (f) All abbreviations used must be explained
 - (g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at 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
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) 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 GRANADA 48SC (SAP 480H) is a suspension concentrate formulation. 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 liquid, with a characteristic odor. It is not explosive and has no oxidizing properties. The product is not flammable and no flash point was observed before the boiling point at 87°C. It has a self-ignition temperature is superior of 350°C. In 1% aqueous solution, it has a pH value 6.4 at 24.8°C. 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. As the formulation is a SC formulation with water as solvent, all the packaging can be considered as acceptable. Its technical characteristics are acceptable for a SC formulation.

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

A minimum of 2 rinses should be noted on the label.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical method for the determination of active substance in the formulation is available and validated. As the active substance metribuzin does not contain relevant impurity, no analytical method is required.

3.1.2.2 Analytical methods for residues

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

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

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

GRANADA 48SC (SAP 480H) containing 480 g/L of metribuzin has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G ⁸	Equipment	Application rate L product/ha (g as/ha)	Spray dilution (L/ha)	Model
Tomato/potato	F	Tractor mounted/trailed boom sprayer: hydraulic nozzles	1.1 L/ha (528 g as/ha)	400-700	BBA

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

Crop	Equipment	PPE and/or working coverall	% AOEL metribuzin
Tomato/potato	Tractor mounted/trailed boom sprayer: hydraulic nozzles	Working coverall and gloves during mixing/loading and application	36

According to the model calculations, it can be concluded that the risk for the operator using GRANADA 48 SC (SAP 480H) is acceptable.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to 3.5 % of the AOEL of metribuzin.

It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to GRANADA 48 SC (SAP 480H).

3.1.3.4 Worker Exposure

GRANADA 48 SC (SAP 480H) 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.

For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

3.1.4 Residues and Consumer Exposure

The data available for potatoes are considered sufficient for risk assessment. An exceedance of the current MRL for metribuzin as laid down in Reg. (EU) 396/2005 is not expected.

The intended use on tomato cannot be supported.

The chronic and the short-term intakes of metribuzin residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern.

As far as consumer health protection is concerned, France agrees with the authorization of the proposed uses.

According to available data, no specific mitigation measures should apply.

The preparation GRANADA 48 SC (SAP 480H) is composed of metribuzin only.

⁸ Open field or glasshouse

Summary for metribuzin

Use- No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported ?	Sample storage covered by stability data?	MRL compliance Reg (EC) N° 149/2008	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	Potato	Yes	Yes (21)	Yes	Yes	Yes	No	No	/
/	Tomato	Yes	No (2)	No	No	/	/	/	(1)

(1) Use not acceptable because of a lack of residue trials and metabolites not measured in the 2 available residue trials.

As residues of metribuzin 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 taking into account the specific circumstances of the cGAP uses being considered here. 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.

Summary for GRANADA 48 SC (SAP 480H)

Crop	PHI for GRANADA 48 SC (SAP 480H) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for GRANADA 48 SC (SAP 480H) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Metribuzin		
Potato	F** BBCH 00-08	Yes	F** BBCH 00-08	/

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

Not relevant.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs for the active substance and its 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 metribuzin and its 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 review or agreed in the assessment based on new data provided.

PEC soil and PEC_{sw} derived for the active substance and its metabolites are used for the eco-toxicological risk assessment, and mitigation measures are proposed.

PEC_{gw} for metribuzin and its metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000⁹ for application every other year every year on potatoes and every year on tomatoes.

Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses when applied in these conditions.

Based on vapour pressure, information on volatilisation from plants and soil, and DT₅₀ calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

3.1.6.1 Effects on Terrestrial Vertebrates

The risk assessment for birds and mammals is carried out according to the 'EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)^[1] and considering the EU agreed endpoints of metribuzin.

The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk, indicating that the risk to birds and mammals^[2] is acceptable following use of GRANADA 48 SC (SAP 480H) according to the proposed use patterns.

3.1.6.2 Effects on Aquatic Species

The risk assessment for aquatic organisms is carried out according to the Guidance Document on Aquatic Ecotoxicology (EFSA Journal 2013;11(7):3290) and considering the EU agreed endpoints of metribuzin, its metabolites and data on the formulation GRANADA 48 SC (SAP 480H).

The TER values metribuzin using FOCUS PEC_{SW} STEP 4 - 20 m buffer zone with 20 m vegetated buffer strip are below the relevant trigger value for some scenarios (D6 and R4 for potatoes use; R4 for tomatoes uses) to algae. Therefore, an unacceptable risk for aquatic organism is demonstrated for potatoes and tomatoes uses (see, III 10.2.1.11).

It should also be noted, that for potatoes use, a risk mitigation measure may be required at national level (SPe2) to protect effects on aquatic organisms on drained soils.

3.1.6.3 Effects on Bees and Other Arthropod Species

Bees

The risk assessment for bees is carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the EU agreed endpoints of metribuzin and the formulation GRANADA 48 SC (SAP 480H).

All hazard quotients for GRANADA 48 SC (SAP 480H) and metribuzin are less than 50, indicating that the risk to bees is acceptable following use of metribuzin according to the proposed use pattern.

Other non-target arthropods

The risk assessment for non-target arthropods is carried out according to the Guidance Document ESCORT 2 and considering the EU agreed endpoints of the formulation GRANADA 48 SC (SAP 480H).

The in-field and off-field HQ values are below the trigger value indicating that the risk to in-field and off-field non-target arthropods is acceptable following use of GRANADA 48 SC (SAP 480H) according to the proposed use patterns.

⁹ Guidance document on the assessment of the relevance of metabolites in groundwater of substance regulated under Council directive 94/414/EEC. Sanco/2000-rev10-final, 25 February 2003

^[1] European Food Safety Authority; Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA. EFSA journal 2009; 7(12):1438. [139 pp.]

^[2] from direct dietary exposure, drinking water and secondary poisoning.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

The risk assessment is carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the EU agreed endpoints of metribuzin, its metabolites and the formulation GRANADA 48 SC (SAP 480H).

The acute and chronic TER values for GRANADA 48 SC (SAP 480H), metribuzin and its metabolites are greater than the triggers of 10 and 5 respectively, indicating that the risk to earthworms is acceptable following use of GRANADA 48 SC (SAP 480H) according to the proposed use pattern.

3.1.6.6 Effects on Soil Non-target Micro-organisms

The risk of GRANADA 48 SC (SAP 480H) to soil micro-organisms was evaluated by comparison of no-effect concentrations, derived from laboratory tests, with PEC_S .

The no effect levels exceed the relevant PEC_S values, indicating that the risk to soil micro-organisms is acceptable following use of GRANADA 48 SC (SAP 480H) according to the proposed use pattern.

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna)

The risk assessment for non-target plants is carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the EU agreed endpoints of the formulation GRANADA 48 SC (SAP 480H).

The risk to non-target plants is acceptable following use of GRANADA 48 SC (SAP 480H) according to the proposed use patterns with a 5 m buffer zone.

3.1.7 Efficacy

Considering the data submitted:

- ✓ the efficacy of GRANADA 48 SC (SAP480H) is considered as satisfying for all the intended uses,
- ✓ the selectivity of GRANADA 48 SC (SAP480H) is considered as acceptable on potato, but some specific varietal toxicity are known on potato. It should be mention on label. For tomato the selectivity of GRANADA 48 SC (SAP480H) is considered as acceptable when applied in pre emergence. Dose rate reduction is proposed for application in post emergence/ transplanted tomato to 0.7 L/ha and additional selectivity trials should be provided on tomato.
- ✓ The risk of negative impact (yield, quality, transformation processes, propagation) is considered as negligible.
- ✓ the risk of negative impact on adjacent and succeeding is considered as acceptable with the some recommendations of use.
- ✓ the risk of resistance development or appearance is considered as low.

Comments on the recommendations of use

- It is recommended not to suggest the use of GRANADA 48 SC (SAP480H) in post emergence of potato.
- It is recommended to sow potato or tomato only in case of accidental destruction of crops treated with GRANADA 48 SC (SAP480H)
- Post authorization data : it is recommended to carry on specific selectivity trials on tomato to validate the selectivity of the product when applied in post emergence at 0.7 L/ha. The trials results and their analysis should be provided in 2 years.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation cannot be granted. 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



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 **GRANADA 48 SC***

de la société SAPEC AGRO France

enregistrée sous le n°2013-1217

Vu les conclusions de l'évaluation de l'Anses du 29 novembre 2017,

Considérant que l'estimation de l'exposition, liée à l'utilisation du produit GRANADA 48 SC, pour les usages revendiqués, entraîne un risque inacceptable pour les organismes aquatiques,

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.



Informations générales sur le produit	
Nom du produit	GRANADA 48 SC
Type de produit	Produit de référence
Titulaire	SAPEC AGRO France 2/12 Chemin des Femmes Immeuble l'Odyssée -A-3° 91300 MASSY France
Formulation	Suspension concentrée (SC)
Contenant	480 g/L - métribuzine
Numéro d'intrant	9903-2013.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usages	Professionnel

A Maisons-Alfort, le 28 MARS 2018
28 MARS 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)



Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15655901 Pomme de terre*Désherbage	1,1 L/ha	1/an	F
Motivation du refus : L'usage revendiqué est refusé en raison d'un risque inacceptable pour les organismes aquatiques.			
16955901 Tomate*Désherbage	1,1 L/ha	1/an	F
Motivation du refus : L'usage revendiqué en plein champ est refusé en raison d'un risque inacceptable pour les organismes aquatiques, d'un nombre insuffisant d'essais résidus permettant de s'assurer que les limites maximales seront respectées et de données de sélectivité incomplètes pour une application en post-levée/post plantation.			

GRANADA 48 SC
AMM n°:

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

HERBICIDE

GRANADA® 48 SC

Suspension Concentrée (SC)

contenant 480 g/l de métribuzine

Herbicide Pomme de terre et Tomate

Autorisation de Mise sur le Marché n° XXXXXX

« RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL »

Homologué par:

SAPEC AGRO S.A.

Avenida do Rio Tejo - Herdade das Praias

2910-440 SETÚBAL - PORTUGAL

Tel: +351 265710100

Lot N°.....

Date de fabrication :



GRANADA 48 SC®

Suspension Concentrée contenant 480 g/l de métribuzine
AMM n° XXXXXX

ATTENTION



SGH09

H410 Très toxique pour les organismes aquatiques, entraîne des effets à long terme.

P102 Tenir hors de portée des enfants.
P270 Ne pas manger, boire ou fumer en manipulant ce produit.
P273 Éviter le rejet dans l'environnement.
P501 Éliminer le contenu/récipient conformément à la réglementation nationale.

Conditions d'emploi

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

- Délai de rentrée des travailleurs sur la parcelle: 6 heures après traitement
- SP1- Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.
- SPE3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres comportant un dispositif végétalisé de 20 mètres en bordure des points d'eau.
- SPE3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone adjacente non cultivée.

Distributeur :

La fiche de données de sécurité est disponible sur demande chez votre fournisseur de produits phytopharmaceutiques et elle est également téléchargeable et imprimable à partir des sites www.sapcagro.fr et www.quickfds.com.

En cas d'urgence **appelez le n° 15 ou le Centre Anti-poison** (Paris : 01 40 05 48 48) puis signalez vos symptômes au réseau Phyt'attitude, n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Fabriqué au PORTUGAL

Contenu : XX L e

GRANADA® 48 SC -Marque déposée par SAPEC AGRO
SAPEC AGRO, S.A. Avenida do Rio Tejo - Herdade das Praias, 2910-440 Setúbal - Portugal

GRANADA 48 SC
480 g/l de métribuzine

PRESENTATION ET MODE D'ACTION

GRANADA 48 SC est un herbicide avec un effet foliaire et racinaire efficace contre un large spectre d'adventices annuelles.

USAGES, DOSES, SPECIFICATIONS D'USAGE, DELAI AVANT RECOLTE (DAR), ZONE NON TRAITEE (ZNT) ET MENTIONS ABEILLES.

Culture	Cibles & Usages	Dose (L/ha)	Nombre d'applications	Stade d'application	ZNT (en m)	Délai réentrée (heures)
Pomme de terre	Désherbage (dicotylédones annuelles et graminées annuelles)	1.1	1	BBCH 00-08	20	6
Tomate	Désherbage (dicotylédones annuelles et graminées annuelles)	1.1	1	BBCH 00-07 (tomates semées) BBCH 17-19 (plants)	20	

Les limites maximales de résidus sont disponibles sur le site : http://ec.europa.eu/sanco_pesticides/public/index.cfm

RECOMMANDATION D'UTILISATION

PREPARATION DE LA BOUILLIE

Remplir la cuve au 2/3 du volume d'eau nécessaire.

Mettre l'agitation en marche avant de verser la quantité nécessaire de **GRANADA 48 SC** puis compléter avec de l'eau jusqu'au volume final.

Mettre l'agitateur en marche

Maintenir l'agitation durant le remplissage et la pulvérisation

Dans tous les cas, il est préférable réaliser une application immédiate

Dans le cadre des bonnes pratiques agricoles, rincer 3 fois les emballages et verser l'eau de rinçage dans la cuve du pulvérisateur.

Laisser l'agitateur en fonctionnement pendant le trajet et jusqu'à la fin de la pulvérisation.

Protection de l'utilisateur lors de la préparation de la bouillie :

Gants en nitrile ou néoprène (EN 374), lunettes de sécurité, bottes de protection marquage S5 ou P5, vêtements de travail de niveau de protection 4.

APPLICATION

Sur Pomme de terre

GRANADA 48 SC peut être appliqué tant en pré-émergence qu'en post-émergence. Dans tous les cas appliquez sur une butte stabilisée et suffisamment affinée. L'absence de vent lors du traitement permettra de répartir uniformément l'herbicide sur les deux côtés de la butte. Ensuite, l'efficacité de l'herbicide dépendra de l'humidité du sol. - Pré-émergence

Traiter sur des buttes bien stabilisées et après le buttage définitif avant l'émergence des pommes de terre. Dose: 0,75 à 1,1 L/ha.

Pommes de terre de conservation, de féculerie, de semence; Dose autorisée : 1,1 L/ha

Pommes de terre primeur; Dose maximale : 0,88 L/ha

Pommes de terre primeur plantées à plat (Bretagne); Dose maximale : 0,75 L/ha

- Application fractionnée

Cette technique consiste à effectuer un traitement de pré-émergence suivi d'un traitement de post-émergence. Peut être utile pour des champs fortement infestés de mauvaises herbes. Dose: 2/3 de la dose en pré-levée jusqu'à 0,75 L/ha. 1/3 de la dose en post-levée jusqu'à 0,35 L/ha.

- Post-émergence

En post-levée, cette application doit être considérée seulement comme un traitement de rattrapage car, dans ces conditions, **GRANADA 48 SC** peut parfois provoquer des phénomènes de phytotoxicité variables selon la sensibilité variétale, l'état sanitaire de la culture au moment de l'application, les conditions météorologiques (forte pluie après l'application), les conditions de traitement (application en mélange avec d'autres spécialités phytosanitaires).

Ne jamais dépasser le stade 5 cm de la pomme de terre et la dose de 0,44 L/ha.

- Sélectivité

GRANADA 48 SC peut s'utiliser sur la plupart des variétés de pommes de terre. Toutefois, ne pas appliquer sur les variétés Belle de Fontenay, Fambo, Frieslander, hermès, Lady Christl, Lyra, Morène, Concorde, pasha, Vitesse.

Ne pas dépasser la dose :

- de 0,75 L/ha en pré-levée sur les variétés Draga, Eva, Jetta, Lady Felicia, Lady Roseta, Logita, Multa, Osirène, Pansta, Pétra, Prima, Révy, Rubis, Scorbio, Sensor, Spartaan, Starlette, Stefano, Sybilla, Turbo, Vebeca, Vivaks.
- de 0,29 L/ha en post-levée sur les variétés Agata, Daisy, Innovator et Russet bank.

Volume de bouillie par hectare : 150 à 300 L/ha

Sur Tomate : **GRANADA 48 SC** peut être utilisé pour le désherbage des tomates repiquées quelques jours avant le repiquage sur sol humide de préférence, à la dose de 1,1 L/ha.

Ne pas utiliser en cultures de tomates sous serre ou sous abris.

Volume de bouillie par hectare :

- Pulvérisateur pneumatique : minimum 100 l/ha.
- Jet porté (aéroconvection) ou jet projeté : minimum 250 l/ha.

MELANGES

Les mélanges doivent être mis en œuvre conformément à la législation en vigueur et aux recommandations des guides de bonnes pratiques des officiels.

Consulter le site : <http://e-phy.agriculture.gouv.fr>

PRECAUTIONS D'EMPLOI

- Conserver **GRANADA 48 SC** dans son emballage d'origine et stocker le dans un local phytosanitaire conforme et fermé à clé. Conserver hors de porte des enfants, à l'écart des aliments et boissons y compris ceux pour animaux.
- Pendant la préparation de la bouillie et au cours de l'application :
 - Porter un vêtement de protection et des gants appropriés.

- Ne pas traiter les cours d'eau et fossés en eau. Appliquer la bouillie dans les cultures par temps calme, sans vent fort pour éviter toute dérive de pulvérisation vers les fossés, cours d'eau, chemins, abords de ferme ou bâtiments.
- Appliquer, après dilution, les fonds de cuve conformément à la législation en vigueur.
- Emballage :
 - Réemploi de l'emballage interdit ; rincer soigneusement le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur, ou dans la cuve de rinçage pour l'injection directe.
 - Éliminer les emballages vides via une collecte organisée par un 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.

Important

Respecter les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage. Elles ont été déterminées 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...

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 issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur.

Appendix 3 – Letter(s) of Access

Not applicable.