REGISTRATION REPORT Part A Risk Management

Product code: CA2272

Product name: CREDIT

Chemical active substance:

glyphosate, 540 g/L

Southern Zone
Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE (authorisation renewal according to art. 43)

Applicant: NUFARM SAS

Date: 29 December 2021

Table of Contents

1	Details of the application	4
1.1	Application background	4
1.2	Letters of Access	
1.3	Justification for submission of tests and studies	5
1.4	Data protection claims	
2	Details of the authorisation decision	5
2.1	Product identity	5
2.2	Conclusion	
2.3	Substances of concern for national monitoring	
2.4	Classification and labelling	
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	
2.4.2	Standard phrases under Regulation (EU) No 547/2011	
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) N 1107/2009)	0
2.5	Risk management	
2.5.1	Restrictions linked to the PPP	
2.5.2	Specific restrictions linked to the intended uses	
2.6	Intended uses (only NATIONAL GAP)	
3	Background of authorisation decision and risk management	12
3.1	Physical and chemical properties (Part B, Section 2)	12
3.2	Efficacy (Part B, Section 3)	
3.3	Methods of analysis (Part B, Section 5)	13
3.3.1	Analytical method for the formulation	
3.3.2	Analytical methods for residues	13
3.4	Mammalian toxicology (Part B, Section 6)	13
3.4.1	Acute toxicity	13
3.4.2	Operator exposure	13
3.4.3	Worker exposure	
3.4.4	Bystander exposure	
3.4.5	Resident exposure	
3.5	Residues and consumer exposure (Part B, Section 7)	15
3.6	Environmental fate and behaviour (Part B, Section 8)	16
3.7	Ecotoxicology (Part B, Section 9)	16
3.8	Relevance of metabolites (Part B, Section 10)	17
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	
5	Further information to permit a decision to be made or to support review of the conditions and restrictions associated with the authorisation	

CA2272 / CREDI Part A - National		
FRANCE DEPR		
5.1.1	Post-authorisation monitoring	18
5.1.2	Post-authorisation data requirements	18
Appendix 1	Copy of the product authorisation	19
Appendix 2	Copy of the product label	24

PART A RISK MANAGEMENT

1 Details of the application

The company NUFARM SAS has requested a marketing authorisation in France for the product CREDIT (CA2272) (formulation code: SL), containing 540 g/L glyphosate¹ as a 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).

Appendix 3 of this document is the list of data considered for national authorisation.

1.1 Application background

The present registration report concerns the evaluation of NUFARM SAS's application submitted on 19/02/2018 to market CREDIT (CA2272) 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 re-registration of authorisation after the renewal of approval of the active substance glyphosate of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2018-0579) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², 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 CREDIT (CA2272) has been made using endpoints agreed in the EU peer review of glyphosate. It also includes assessment of data and information related to CREDIT (CA2272) 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 546/2011⁴, 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 registration of CREDIT (CA2272).

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2324 of 12 December 2017, renewing the approval of the active substance glyphosate in accordance with Regulation (EC) N°1107/2009 of the European Parliament and the Council concerning the placing of plant protection products on the market, and amending the Annex to commission Implementing Regulation (EU) N°540/2011.

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

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

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

1.2 Letters of Access

NUFARM SAS is part of the Glyphosate Task Force so NUFARM SAS is co-owner of the protected Glyphosate data used in this application. A letter of acces from Monsanto dated on 23 November 2017 has been provided and is available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: "Product specific data in line with the requirements of Regulation (EC) No. 284/2013 (formulation) were submitted to support this application. Please refer to Appendix 4 for further details."

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of CREDIT (CA2272), 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	CA2272
Product name in MS	CREDIT
Authorisation number	2100206
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	NUFARM SAS
Active substance (incl. content)	glyphosate, 540 g/L
Formulation type	Soluble concentrate [SL]
Packaging	HDPE ⁵ (5 L, 10 L, 20 L)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

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⁵ High density polyethylene

The evaluation of the application for CREDIT (CA2272) resulted in the decision to withdraw 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

N/A: marketing authorisation withdrawn

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

N/A: marketing authorisation withdrawn

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

N/A: marketing authorisation withdrawn.

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 2017⁶ 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.

Moreover, for glyphosate-based products, the official statement⁷ of 8 October 2004 provides specific restrictions (applied doses and/or conditions of use) for uses on crops, in non-agricultural or industrial areas or in forestry.

Finally, the French Order of 26 March 2014⁸ provides that:

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, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

Avis du 8 octobre 2004 à tous les détenteurs d'autorisations de mise sur le marché pour des spécialités commerciales à base de glyphosate, https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT000000445445

⁸ http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

- 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 extrapolation⁹ 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: marketing authorisation withdrawn

2.5.2 Specific restrictions linked to the intended uses

N/A: marketing authorisation withdrawn.

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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 12 April 2021 (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" or "not finalised", 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: 2021/12/29

PPP (product name/code): CREDIT / CA2272 Formulation type: SL (a, b)

Active substance 1: glyphosate Conc. of a.s. 1: 540 g/L (c)

 Applicant:
 NUFARM SAS
 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-	Member	Crop and/		Pests or Group of		Applicati	ion		Ap	plication rate		РНІ	Remarks:
No.	state(s)	or situation (crop destination/purpose of crop) d or outdoor uses, certain	Fpn G, Gn, Gpn or I	pests controlled (additionally: developmental stages of the pest or pest group) of protected crops)	Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	product/ha a) max. rate per appl. b) max. total	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	L/ha	(days)	e.g. g safener/synergist per ha
1	FR	Presowing, Pre-planting (Including arable crops, vegetable crops, industrial crops, forest)	F	Annual graminaceous weeds	Overall Spray	Jan-Dec due to vegetable crops	a) 1 b) 1			a) 1.080 b) 1.080	100-300	-	Not acceptable (genotoxic potential)
2	FR	Presowing, Pre-planting (Including arable crops, vegetable crops, industrial crops, forest)	F	Annual and biennial dicotyledonous weeds	Overall Spray	Jan-Dec due to vegetable crops	a) 1 b) 1		/	a) 2.160 b) 2.160	100-300	-	Not acceptable (genotoxic potential)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-	Member	Crop and/		Pests or Group of		Applicati	ion		Ap	plication rate		PHI	Remarks:
No. (e)	state(s)	or situation (crop destination/purpose of crop)	Fpn	pests controlled (additionally: developmental stages of the pest or pest group)	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	a) max. rate per appl.	Water L/ha min/max	(days)	e.g. g safener/synergist per ha (f)
3	FR	Presowing, Pre-planting (Including arable crops, vegetable crops, industrial crops, forest)	F	Perennial weeds	Overall Spray	Jan-Dec due to vegetable crops	a) 1 b) 1	-	a) 4.6 b) 4.6	a) 2.484 b) 2.484	100-300	-	Not acceptable (MRL (exept forestry), genotoxic potential)
4	FR	Post harvest (Including arable crops, vegetable crops, industrial crops, forest)	F	Annual graminaceous weeds	Overall Spray	July-November	a) 1 b) 1	-	a) 2.0 b) 2.0	a) 1.080 b) 1.080	100-300	-	Not acceptable (genotoxic potential)
5	FR	Post harvest (Including arable crops, vegetable crops, industrial crops, forest)	F	Annual and biennial dicotyledonous weeds	Overall Spray	July-November	a) 1 b) 1	-	a) 4.0 b) 4.0	a) 2.160 b) 2.160	100-300	-	Not acceptable (genotoxic potential)
6	FR	Post harvest (Including arable crops, vegetable crops, industrial crops, forest)	F	Perennial weeds	Overall Spray	July-November	a) 1 b) 1	-	a) 4.6 b) 4.6	a) 2.484 b) 2.484	100-300	-	Not acceptable (MRL (exept forestry), genotoxic potential)
7	FR	General treatment Cereals. Including winter soft wheat, durum wheat, winter and spring barley. Excluding: seed production, wheat bread, malting and brewing barley.	F	All weeds	Overall Spray	June - August	a) 1 b) 1	-	a) 4.0 b) 4.0	a) 2.160 b) 2.160	100-300	7	Not acceptable (MRL, genotoxic potential) Preharvest weed control Excluding: seed production, wheat bread, malting and brewing barley.
8	FR	Orchards. Excluding stones fruits, kiwi and bananas	F	Annual graminaceous weeds	Overall Spray	February- November	a) 2 b) 2	60	a) 2.6 b) 5.2	a) 1.404 b) 2.808	100-300	21 (except for olives tree: 7)	Not acceptable (genotoxic potential)
9	FR	Orchards. Excluding stones fruits, kiwi and bananas	F	Annual and biennial dicotyledonous weeds	Overall Spray	February- November	a) 1 b) 1	-	a) 4.0 b) 4.0	a) 2.160 b) 2.160	100-300	21 (except for olives tree: 7	Not acceptable (genotoxic potential)

CA2272 / CREDIT Part A - National Assessment

FRANCE DEPR version

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-	Member	Crop and/		Pests or Group of		Applicati	on		Ap	plication rate		PHI	Remarks:
No. (e)	state(s)	or situation (crop destination/purpose of crop)	Fpn	pests controlled (additionally: developmental stages of the pest or pest group)	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	a) max. rate per appl.	Water L/ha min/max	(days)	e.g. g safener/synergist per ha (f)
10	FR	Orchards. Excluding stones fruits, kiwi and bananas	F	Perennial weeds	Spot treatment	February- November	a) 1 b) 1	-		a) 2.862 b) 2.862	100-300	21 (except for olives tree: 7	Not acceptable (genotoxic potential)
11	FR	Vine	F	Annual graminaceous weeds Perennial weeds	Overall Spray	February - August	a) 2 b) 2	60		a) 1.404 b) 2.808	100-300	21	Not acceptable (MRL, genotoxic potential)
12	FR	Vine	F	Annual and biennial dicotyledonous weeds	Overall Spray	February - August	a) 1 b) 1	-		a) 2.160 b) 2.160	100-300	21	Not acceptable (MRL, genotoxic potential)
13	FR	Vine	F	Perennial weeds	Spot treatment	February - August	a) 1 b) 1	-		a) 2.862 b) 2.862	100-300	21	Not acceptable (MRL, genotoxic potential)
14	FR	Vine	F	Annual and biennial dicotyledonous weeds	Local Spray	February - August	a) 3 b) 3	60		a) 2.862 b) 2.862	100-300	21	Not acceptable (MRL, genotoxic potential)
15	FR	Vine	F	Perennial weeds	Spot treatment	February - August	a) 3 b) 3	60		a) 2.862 b) 2.862	100-300	21	Not acceptable (MRL, genotoxic potential)

CA2272 / CREDIT

Part A - National Assessment

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Kemarks
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

Remarks columns:

- Numeration necessary to allow references
- 2 Use official codes/nomenclatures of EU Member States
- 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)
- 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
- 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.
- 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.

- (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.
- 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
- 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
- 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)

The appearance of the product is that of yellow-beige viscous liquid, with a specific odour. It is not explosive, has no oxidising properties. The product is not flammable. In aqueous solution, it has a pH value around 4.6 at 22 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. Needles are observed at the low temperature. In consequence, in the label, it should be indicated "protect from frost". The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in *PE-HD flask*. Its technical characteristics are acceptable for a soluble liquid formulation.

The intended concentration of use is 1.75% to 3.3%.

The active substance glyphosate contains the relevant impurities formaldehyde and N-nitrosoglyphosate. The relevant impurity formaldehyde is considered as a by-product of the manufacturing process for glyphosate and as such cannot hence be formed by during the storage of storage of the formulation. The monitoring of this impurity in the storage studies is not necessary.

Concerning the relevant impurity N-nitrosoglyphosate, based on the conditions of formation of this impurity, it is unlikely that this impurity is formed during the formulation and storage of the preparation.

Nevertheless, in order to demonstrate the absence of formation of NNG during the storage, a monitoring of the concentration of this impurity during storage of the preparation has been provided. The concentration of this impurity during storage of the preparation is below the acceptable limit.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

The efficacy level of CREDIT (CA2272) is considered satisfactory for all the claimed uses.

Glyphosate having an herbicidal activity on all types of plants (known as "total weed killer"), the preparation CREDIT (CA2272) cannot therefore be considered selective. Given the foliar penetration of glyphosate, the preparation should not be directed to the green parts of crops.

For all claimed uses except specific cases of weed control for cereals at the stage of maturity before harvest the risks of negative impact on yield, quality and propagation are considered negligible.

In the absence of data allowing the assessment of the risk of negative impact on the bread-making process, the malting/brewing process and on cereal seed production, the preparation should not be used on cereals intended for bread-making/brewing processes and for seed production.

The risk of negative impact on succeeding crops is considered negligible.

The risk of negative impact on adjacent crops is considered acceptable, as long as the preparation does not reach the green parts of adjacent crops. Specific attention should be paid to the spraying conditions close to adjacent crops.

There is a risk of resistance development or appearance to glyphosate for ryegrass (Lolium multiflorum, Lolium perenne and Lolium rigidum), fleabanes (Conyza sp.), and common ragweed (Ambrosia artemisiifolia) requiring a survey of resistance.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods are available for the determination of glyphosate and relevant impurities in the formulation.

3.3.2 Analytical methods for residues

Ananalytical methods are available for the determination of glyphosate in plants, animals and environmental matrices are available.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

CREDIT (CA2272) containing 540 g/L glyphosate 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.

In the EC review report for glyphosate (SANTE/10441/2017 Rev 2), the following toxicity studies were requested:

"As outlined in the EFSA conclusion on glyphosate, the peer review recognised that some genotoxicity studies on formulations presented positive results, and therefore, that the genotoxic potential of formulations should be addressed during renewal or first authorisation of plant protection products."

These studies have not been submitted in this dossier. In this context, the genotoxic potential of CREDIT (CA2272) could not be evaluated. Therefore, the genotoxic potential of the preparation cannot be finalised.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Minimum Equipment volume wa-Maximum application rate F/G^{10} Crop type kg as /ha ter Application method (L/ha) Vehicle mounted/ Manual Hand held Orchards F 2.862 100 Downward

-

¹⁰ Open field or glasshouse

Considering proposed			

Crop	Equipment	PPE and/or working coverall	% AOEL glyphosate
orchards	Vehicle mounted	Working coverall and gloves during mixing/loading and application	1.02
	Hand held	Working coverall and gloves during mixing/loading and application	20.46

According to the model calculations, it can be concluded that the risk for the operator using CREDIT (CA2272) 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/irrigation activities. Therefore, estimation of worker exposure was calculated according to AOEM model.

The worst case of exposure is taken into account, application dose 2.862 kg as/ha:

Exposure is estimated to 6.01 % of the AOEL of glyphosate with PPE.

It is 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.

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."

3.4.5 Resident exposure

Residential exposure was assessed according to EFSA model¹². An acceptable risk was determined for residents (adult and/or child) when mitigation measures such as a buffer zone of 3 meters are taken: The worst case of exposure is taken into account, Orchards, application dose 2.862 kg as/ha:

Model (AOEM) - All pathways (mean)	% AOEL Glyphosate
Resident (children)	17.35

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

14

¹² EFSA Journal 2014;12(10):3874

Resident (adults) 5.78

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

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs (Reg 293/2013) for glyphosate as laid down in Reg. (EU) 396/2005 is not expected providing the application of the mitigation measures for pre-sowing/pre-planting use, for wheat (except for France), and for orchards.

Intended use is not supported by available data and compliance with current MRLs cannot be performed for barley.

Intended use is not supported by available data for grape.

In accordance with the available residue data, a maximum application dose of 4 L/ha/year is retained for presowing/preplanting use.

The chronic and the short-term intakes of glyphosate residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France authority, as zRMS agrees with the authorization of the intended presowing/preplanting uses and orchards.

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

- For uses in orchards and olives: "Use application material or agricultural practices to avoid edible parts contact with active substance or with soil treated with active substance"

Summary for CREDIT (CA2272)

Сгор	PHI for CREDIT (CA2272) pro- posed by appli- cant	PHI/Witholding period* sufficiently supported for glyphosate	PHI for CREDIT (CA2272) pro- posed by zRMS	zRMS Comments (if different PHI proposed)
Presowing/pre- planting	-	Yes	Before sowing or before planting	
Cereals (Winter soft wheat, durum wheat, winter and spring Barley. Excluding: seed production, wheat bread, malting and brewing barley)	7	No		This use is not recommended in France, considering a possibil-ity of exceedance of the current MRL on grain in NEU and on livestock commodities.
Orchards (Excluding stones fruits, Kiwi and bananas)	21	Yes	21	
Grapes (table and wine)	21	No		This use is not recommended in France as not sufficient residue trials are available.

The results of the rotational crop study have shown that neither glyphosate nor AMPA show a potential

uptake into follow crops. No specific waiting period is thus required.

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 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 glyphosate and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC soil and PECsw derived for glyphosate and its metabolites are used for the ecotoxicological risk assessment.

PECgw for glyphosate and its metabolite do not occur at levels exceeding those mentioned in regulation EC 1107/2009. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

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.

3.7 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 substance and its 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.

For the chronic risk assessment to birds, the intended use in cereals pre-harvest, the scenario 'BBCH 71-89' - small insectivorous bird "passerine" do not meet the trigger value of 5. Therefore the risk for the insectivorous birds following applications of CA2272 for pre-harvest weed control in cereals cannot be finalised.

Consequently, for the intended use in cereals zRMS proposed to not apply CA2272 at pre-harvest (BBCH 71-89). Indeed application in cereals could be considered in pre-planting of crops or post-sowing / pre-emergence of crop at application rate of 3.59 kg a.s, since an acceptable risk is demonstrated.

Concerning the risk assessment to bees and other pollinators, for the intended uses with down-ward application at full dose, the EFSA GD 2013 tier 1 trigger values are not exceeded for application at dose rate lower and equal to 2.28 kg a.s./ha.

For intended uses in spot applications (<10% of the area), in this case where no effects have been observed in the available limit tests, oral and contact assessment is not required.

Concerning the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions (Regulation (EU) 2017/2324), no new information has been provided by the notifier to

assess this risk compared to the UE review (EFSA Journal 2015;13(11):4302; Pesticides Peer Review Meeting 128; Renewal Assessment Report).

Risk mitigation measures are required in order to protect aquatic organisms, bees and non-target plants.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

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

In accordance with article 50.2 of Regulation No 1107/2009, a comparative assessment was implemented for plant protection products containing the active substance glyphosate.

Only five main uses of glyphosate in France were considered, in compliance with available informations: uses in "inter crops" for field crops, uses on grapevines, orchards and forest and non-agricultural uses (railways, public areas, etc.). This work was performed in cooperation with:

- INRAE (french Institute for agricultural and environmental research), for uses on field crops, orchards and grapevine
- CGAEER/CGEDD (general councils respectively for agriculture and for environment) for non agricultural uses
- ONF/CNPF (National Forest Office and Private Forest Center), for uses in forest

Based on all this information, Anses produced four comparative assessment reports (available on Anses web site https://www.anses.fr/fr).

For the uses on other crops (tropical crops, vegetables, etc.), substitution is not considered, because of a lack of information on practical and economical characteristics of non-chemical weed control alternatives.

Field crops

Among the application of glyphosate in field crops, the main use is inter-crop application.

In case of control of regulated organisms, **substitution will not be considered**, and there is no restriction of use.

In case of perennial and invasive weeds, **substitution can be considered**. Ploughing can be an alternative way of controlling weeds, except in the situation of installed spring crops after a summer or a beginning of autumn plough in hydromorphic soils. Furthermore, a **reduction in the maximal dose of application**, from 2280 g/ha to **1080** g/ha/year of glyphosate, was proposed.

Grapevine:

Today the only non-chemical alternative to glyphosate is ground working. Groundwork is not possible in some situations: steep slope, stony ground, etc. In these conditions, no limitation of glyphosate uses is proposed.

In the other agronomical situations, groundwork is only possible between the rows but material adapted to "under the row" groundwork is not always available. So a reduction of glyphosate rate is proposed considering that 20% of the total surface is treated, then resulting in a **reduction of the maximal dose of application**, from 2280 g/ha to **450** g/ha/year of glyphosate.

Orchards:

The situation in orchards is quite similar to the one in grapevine as the only non-chemical alternative to glyphosate is ground working. Groundwork is also not possible in same situations: steep slope, stony ground, etc. In these conditions, no limitation of glyphosate uses is proposed.

"Whole surface treating" is also a need in situations where fruits are harvested on the soil (tree nuts, cider apples, some olives, etc.). In the other agronomical situations, groundwork or permanent grass growing is possible between the rows but "under the row" groundwork is not always possible (because of irrigation system) and material adapted to "under the row" groundwork is not always available. So a reduction of glyphosate rate is proposed considering that 40% of the total surface is treated, then resulting a **reduction** in the maximal dose of application, from 2280 g/ha to 900 g/ha/year of glyphosate.

<u>For the non-agricultural uses</u>, Anses considered that, based on CGAEER/CGEDD report, the comparative assessment **cannot be implemented**. Moreover, these uses are considered as minor uses in France.

Forest uses:

Non-chemical alternatives for the <u>use on devitalization</u> are considered as widely used and without practical or economical disadvantage, so **substitution will be considered for this use**.

For the <u>uses on clearance</u> (weed control in forest), an **important restriction is proposed**, allowing the application during the first years of the forest implementation only (tree height less than 3 meters). **Substitution will not be considered** for:

- <u>weed control in forest nursery and seed orchards in forest production</u> because as there is no non-chemical alternative.
- <u>weed control before planting (or forest regeneration)</u> because of the lack non-chemical method to control perennial grasses and practical or economical disadvantages for landlords and forest managers.

As a result of this assessment, a withdrawal of use for devitalization of forest trees, and changes in registered conditions of uses of glyphosate based products are proposed in France.

For further information, French comparative assessment reports for glyphosate uses are available on the Anses website https://www.anses.fr/en/content/glyphosate-anses-publishes-results-its-comparative-assessment-available-non-chemical.

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: marketing authorisation withdrawn

5.1.2 Post-authorisation data requirements

N/A: marketing authorisation withdrawn

Appendix 1 Copy of the product authorisation

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Décision relative à une demande de renouvellement de l'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 règlement d'exécution (UE) 2017/2324 de la Commission du 12 décembre 2017 renouvelant l'approbation de la substance active «glyphosate» conformément au règlement (CE) no 1107/2009 du Parlement européen et du Conseil concernant la mise sur le marché des produits phytopharmaceutiques et modifiant l'annexe du règlement d'exécution (UE) no 540/2011 de la Commission,

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 de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active glyphosate, du produit phytopharmaceutique CREDIT

de la société NUFARM SAS

enregistrée sous le n°2018-0579

Vu les rapports de l'INRA de juillet 2019 sur les alternatives au glyphosate en viticulture, de l'INRAE de février 2020 sur les alternatives au glyphosate en arboriculture, de l'INRAE de juin 2020 sur les alternatives au glyphosate en grandes cultures et la note de synthèse sur les solutions alternatives au glyphosate d'AXEMA du 30 juin 2020,

Vu les procès-verbaux des réunions du comité de suivi des AMM en date des 26 septembre 2019, 30 janvier 2020, 4 juin 2020 et du 9 juillet 2020,

Vu les rapports des évaluations comparatives réalisées par l'Anses conformément à l'article 50.2 du règlement susvisé pour les usages en viticulture, arboriculture, forêt et grandes cultures en date du 15 septembre 2020,

Vu le procès-verbal de la réunion du comité de suivi des AMM du 17 décembre 2020,

Vu les conclusions de l'évaluation de l'Anses du 4 novembre 2021,

Considérant que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit,

Considérant qu'un effet génotoxique ne peut être exclu,

Considérant que les conditions mentionnées à l'article 29 du règlement (CE) n°1107/2009 ne sont donc pas respectées,

Considérant par ailleurs que les rapports des évaluations comparatives susvisés conduisent à proposer, pour plusieurs usages, une restriction des conditions d'emploi des produits à base de glyphosate,

Considérant qu'il apparaît donc nécessaire de prendre en compte ces restrictions pendant le délai accordé pour l'utilisation des stocks,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas renouvelée** en France, et les stocks existant devront être utilisés conformément aux conditions d'emploi précisées en annexe à la présente décision.

CREDIT AMM n°2100206

Page 1 sur 5

DocuSign Envelope ID: 216BE146-D58C-440D-B438-F1B91F1E7CCA



Liberté Égalité Fraternité



Informations générales sur le produit				
Nom du produit	CREDIT			
Type de produit	Produit de référence			
Titulaire	NUFARM SAS Immeuble West Plaza 11 rue du Débarcadère 92700 COLOMBES France			
Formulation	Concentré soluble (SL)			
Contenant	540 g/L - glyphosate			
Numéro d'intrant	2060034			
Numéro d'AMM	2100206			
Fonction	Herbicide			
Gamme d'usage	Professionnel			

A Maisons-Alfort, le 29/12/2021

—pocusigned by: Charlotte Grastilleur

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

CREDIT AMM n°2100206

Page 2 sur 5

DocuSign Envelope ID: 216BE146-D58C-440D-B438-F1B91F1E7CCA





ANNEXE : Conditions de mise sur le marché demandées

Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	Délai accordé pour la vente et la distribution	Délai accordé pour le stockage et l'utilisation des stocks		
2,6 L/ha	1/an	21	6 mois à compter de la présente décision	12 mois à compter de la présente décision		
Motivation du retrait : L'usage est retiré au motif que les données disponibles ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également retiré aux doses de 4 L/ha et 5,3 L/ha au même motif.						
2 L/ha	1/an	-	6 mois à compter de la présente décision	12 mois à compter de la présente décision		
Motivation du retrait: L'usage, évalué comme les usages 11015935 Traitements généraux*Désherbage*Intercultures, jachères et destruction de cultures e 00401013 et Forêt*Désherbage*Avt Plantation, est retiré au motif que les données disponibles ne permettent pas d'évaluer le potentie génotoxique du produit. L'usage est également retiré aux doses de 4 L/ha et 4,6 L/ha au même motif. L'usage à la dose de 4,6 L/ha est également retiré en raison d'un risque de dépassement des limites maximales de résidus.						
4 L/ha	1/an	7	6 mois à compter de la présente décision	12 mois à compter de la présente décision		
	2,6 L/ha Motivation du retrait : L'usage est retiré au motif L'usage est également ret 2 L/ha Motivation du retrait : L'usage, évalué comme 00401013 et Forêt*Déshe génotoxique du produit. L'usage est également ret L'usage à la dose de 4,6 L	Dose d'emploi d'applications 2,6 L/ha 1/an Motivation du retrait : L'usage est retiré au motif que les données disponibles L'usage est également retiré aux doses de 4 L/ha et 5,3 2 L/ha 1/an Motivation du retrait : L'usage, évalué comme les usages 11015935 Traite 00401013 et Forèt "Désherbage"Avt Plantation, est ret génotoxique du produit. L'usage est également retiré aux doses de 4 L/ha et 4,6 L'usage à la dose de 4,6 L/ha est également retiré en n	Dose d'emploi d'applications (jours) 2,6 L/ha 1/an 21 Motivation du retrait : L'usage est retiré au motif que les données disponibles ne permettent pas d'évalue L'usage est également retiré aux doses de 4 L/ha et 5,3 L/ha au même motif. 2 L/ha 1/an - Motivation du retrait : L'usage, évalué comme les usages 11015935 Traitements généraux*Désherba 00401013 et Forêt*Désherbage*Avt Plantation, est retiré au motif que les donné génotoxique du produit. L'usage est également retiré aux doses de 4 L/ha et 4,6 L/ha au même motif. L'usage à la dose de 4,6 L/ha est également retiré en raison d'un risque de dépass	### Activation du retrait: L'usage est également retiré aux doses de 4 L/ha et 4,6 L/ha au même motif. #### Activation du retrait: L'usage est également retiré aux doses de 4 L/ha et 5,3 L/ha au même motif. ###################################		

CREDIT

AMM n°2100206 Page 3 sur 5

DocuSign Envelope ID: 216BE146-D58C-440D-B438-F1B91F1E7CCA







Liste des usages retirés								
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	Délai accordé pour la vente et la distribution	Délai accordé pour le stockage et l'utilisation des stocks			
	2,6 L/ha	1/an	21	6 mois à compter de la présente décision	12 mois à compter de la présente décision			
12705902 Vigne"Désherbage" Cult. Installées	Motivation du retrait: L'usage est rétiré aux motifs que les données disponibles ne permettent pas d'évaluer le potentiel génotoxique du produit et en raison d'un risque de dépassement des limites maximales de résidus. L'usage est également retiré aux doses de 4 L/ha et 5,3 L/ha au même motif.							

CREDIT AMM n°2100206

Page 4 sur 5

DocuSign Envelope ID: 216BE146-D58C-440D-B438-F1B91F1E7CCA



Liberté Égalité Fraternité

Conditions d'emploi du produit applicables pendant le délai accordé pour l'utilisation des stocks :

Pour les utilisations correspondant au désherbage des cultures fruitières installées :

Dans les situations de terrains non mécanisables (vergers en pente, en terrasses, sur buttes, sols très caillouteux/rocheux) ou de récolte mécanique des fruits au sol (fruits à coques, pommes à cidres, prunes « à pruneaux », etc.), ne pas dépasser la dose annuelle de 2160 g de glyphosate par hectare.

Dans toutes les autres situations, ne pas appliquer entre les rangs, ne pas appliquer sur plus de 40 % de la surface de la parcelle et ne pas dépasser la dose annuelle de 900 g de glyphosate par hectare.

Pour les utilisations correspondant au désherbage des vignes installées :

Dans les situations non mécanisables (vignes installées en fortes pentes ou en terrasses, sols caillouteux, vignes-mères de porte-greffes), ne pas dépasser la dose annuelle de 2160 g de glyphosate par hectare.

Dans toutes les autres situations, ne pas appliquer entre les rangs et ne pas dépasser la dose annuelle de 450 g de glyphosate par hectare.

Pour les utilisations correspondant au désherbage des intercultures, jachères et destruction de cultures intermédiaires et CIPAN :

Ne pas appliquer en situation de labour effectué avant l'implantation de la culture, à l'exception des cultures de printemps installées après un labour d'été ou de début d'automne en sols hydromorphes et ne pas dépasser la dose annuelle de 1080 g de glyphosate par hectare.

Dans le cadre d'une lutte réglementée, ne pas dépasser la dose annuelle de 2880 g de glyphosate par hectare.

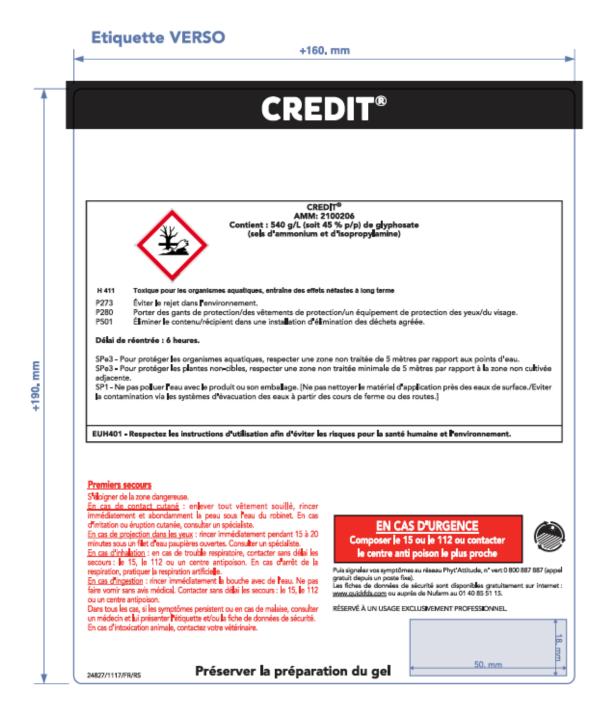
Pour les utilisations correspondant au dégagement ou à la dévitalisation en forêt :

Ne pas utiliser pour l'entretien des forêts, à l'exception de la période d'installation du peuplement (hauteur inférieure à 3 mètres), et ne pas utiliser pour dévitaliser les souches.

CREDIT AMM n°2100206

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.





FACE A - Livret page 2

+158, mm

CREDIT®

RECOMMANDATIONS D'EMPLOI

Conditions d'application
CREDIT® s'utilise du printemps à l'automne en tenant compte des

CREDIT® sutilise du printemps à l'automne en tenant compte des remarques suivantes:

L'efficacité est favorisée par une température poussante (5°C) et une bonne hygromètrie lors du traitement (en période chaude et sèche intervenir platôt le matin ou en fin de journée. Dens la mesure où l'application s'est réalisée en bonnes conditions, des températures basses (inférieures à 0°C) avant ou après n'abèrent pes l'efficacité. Ne pas traiter sur plantes gelées.

Pour la fibre annuelle (véronique, mouron, pâturin, levée de ray-grass...) germant dans l'hiver il est préférable d'intervenir au démarage de la végétation à des stades allant du tallage/rosette foliaire à la montaison.

Pour la fibre annuelle germant au printemps/ésté (morelle, amarante, chénopode, digitaire, repousses de cultures...) il est souhaitable d'intervenir lorsque l'ansemble des levées s'est effectué.

Pour la fibre basnnuelle (pissentit, carotte, érodium...) le stade le plus favorable se trouve au printemps en début de montaison lorsque la couverture foliaire est maximale.

Pour la vivace (chiendent, liseron, chardon, rumex...) cu pérenne (ronce, potentiles...) il convient d'intervenir lorsque l'ensemble des parties aériennes est développé (pour assurer la melleure systémie et troucher au mieux les organes souterrains). La systémie est renforcée en période automnale de descarte de sève.

Précautions d'emploi

Précautions d'emploi Éviter tout traitement à be nt à base de glyphosate sur les fossés en eau ou

Evine tout transment a case de grypnosate sur les noses en eau ou à proximité.
 Dans le cadre des bonnes pratiques d'utilisation, l'usage de buses à dérive limitée et/ou d'adjuvants appropriés possident la mention l'imitation de dérive" est recommande. Dans de cas, veiller à n'utiliser que des adjuvants sans effets antagonistes sur l'efficacité du

n'utiliser que des adjuvants sans effets antagonistes sur l'efficaché du plephosete.

Dans le cas de traitement en culture pérenne, éviter toutes projections sur les parties vertes ou non acutées de la culture.

Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.

Traiter per temps culme, sans vent pour éviter toute dérive sur les cultures adjucentes. C'est à l'opérateur de décider si le publification est adapté à l'application envisagée et s'il est bien régle. S'essurer de l'absence de dérive lu incombe également.

Eviter toute contamination des saux souterraines, de surface ou de distribution lois du remplissage, de la publiérisation ou du rinçage des emballages et équipements de traitement.

Pour assurer la SECURITÉ PÉRSONNELLE des MANIPULATEURS et UTILISATEURS, observer soigneusement les précautions d'emploi de cette également.

Mélanges extemporanés
Les mélanges extemporanés doivent être mis en œuvre conformément à la réglementation en vigueur.

Préparation de la bouille

Ajouter la quantité voulue de CREDIT® dans la cuve du pulvérisateur à moitié remplie d'eau et l'agistation en route, complèter avec la quantité d'eau nécessaire. Maintenir l'agistation pardant le trahement. Appliquer dans un volume d'eau compris entre 100 et 300 Lhs. Respecter un volume de bouille supérieur ou égal à 200 Lhs pour des applications avec un pulvérisateur à dos ou une lance.

Il est recommandé d'utiliser une eau de faible dureté (inférieur à 30° th)—sus consules.

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 ayent le même mode d'action, pout conduire à l'apparition d'organismes résistants. Pour réduire ce résque, l'utilisateur doit raisonner en premier lieu les protiques agronomiques et respecter les conditions d'emploi du produit. Il est conseilé d'abamer ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tantau cours d'une saison culturale que dans la rotation. En dépit du respect de ces règles, on ne peut pas exdure une altériation de l'efficaché de cette préparation lée à ces phémomèmes de résistance. De ce fait, NUFARM SAS, décine toute responsabilité quant à d'éventuelles conséquences qui poursient être dues à de telles résistances.

MISE EN ŒUVRE RÉGLEMENTAIRE ET BONNES PRATIQUES

Stockage du produit

Conserver le produit uniquement dans son embalage d'origine, dans un local phytophamaccutique conforme à la réglementation en vigueur, à l'écart des alments et boissons, y compris ceux pour animeux. Conserver hors de la portée des enfants et dies personnes non autorisées.

Protection de l'opérateur et du travailleur Se laver les mains acrès toute manipulation/utilisation/intervention dans une parculle présibblement vaités. Ne pes manger, boine, siléghoner ou fumer lors de l'utilisation du produit.

Il convient de rappeler que l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituer la première mesure de prévention contre les risques professionnels, avant la mise en place de protections complémentaires comme les protections individuelles.

En tout état de cause, le port de combinaison de traveil dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex: lavage des mains, douche en fin de traitement) et à un comportement rigorieux (ex: : procédure d'habillagoi/deshabillagoi. Les modalités de rentoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à eur notice d'utilisation.

Rapporter les équipements de protection individuelle (EPI) usagés dans un sactranslucide, a votre distributour partenaire ECO EPI ou faire appel à une entreprise habilitée pour la collecte et l'elimination de produits dangereux.

Nettoyage du pulvérisateur et gestion des fonds de cuve

A la fin de la période d'application du produit, l'intégralité de l'appareil (ouve, mmpe, circuit, buses...) doit être nincée à l'eau chire. Le ninçage du putérisation. L'épandage ou le vidange du fond de cuve et l'éfamination des offluents doivent être réalisés conformément à la réglamentation on

E +188

