REGISTRATION REPORT

Part A

Risk Management

Product code: glyphosate 20% + oxyfluorfen 3% SC

Product name(s): FLODEN

Active Substance(s):

Glyphosate 200 g/L

Oxyfluorfen 30 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: **LAINCO, S.A**

Date: **2019/11/29**

Table of Contents

PART A – Risk Management

The company LAINCO, S.A. has requested A marketing authorisation in France for the product FLODEN (product code: GLYPHOSATE 20% + OXYFLUORFEN 3% SC) containing 30 g/L oxyfluorfen and 200g/L glyphosate as a herbicide for professional uses.

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 FLODEN (GLYPHOSATE 20% + OXYFLUORFEN 3% SC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of FLODEN (GLYPHOSATE 20% + OXYFLUORFEN 3% SC) have been made using endpoints agreed in the EU peer review(s) of both oxyfluorfen and glyphosate

This document describes the specific conditions of use and labelling required for France for the registration of FLODEN (GLYPHOSATE 20% + OXYFLUORFEN 3% SC).

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

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

Appendix 3 of this document concerns letter(s) of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of LAINCO, S.A's application to market FLODEN (GLYPHOSATE 20% + OXYFLUORFEN 3% SC) in France as a herbicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Oxyfluorfen

Commission implementing Regulation (EU) 2017/359 of 28 February 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance oxyfluorfen.
The column 'Specific provisions' of row 11, oxyfluorfen, of Part B of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following: 'PART A Only uses as herbicide for banded applications close to ground from autumn to early spring may be authorised, at a rate not exceeding 150 g active substance per hectare, per year. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on oxyfluorfen, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed, shall be taken into account. In this overall assessment, Member States must pay particular attention to: — operator safety and ensure that conditions of use impose the application of adequate personal protective equipment where appropriate, — the risks to aquatic organisms, earthworm-eating mammals, soil-living macro-organisms, non-target arthropods and non-target plants.

Conditions of authorisation shall include risk mitigation measures such as no-spray buffer zones and drift reducing nozzles and shall provide for respective labelling of plant protection products. Those conditions shall include further risk mitigation measures, where appropriate.'
EFSA conclusions are available (EFSA Journal 2010,8(11):1906.. [78 pp.]. doi:10.2903/j.efsa.2010.1906. and EFSA Journal 2015; 13(8): 4205, 45 pp. doi: 10.2903/j.efsa.2015/4205). A Review Report is available (SANCO/11136/2011 rev 3 17 June 2011, 24 January 2017).

Glyphosate

Commission implementing regulation (EU) 2017/2324 of 12 December 2017 renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011
Only uses as herbicide may be authorised. 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 glyphosate, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: - the protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses, - the protection of operators and amateur users, - the risk to terrestrial vertebrates and non-target terrestrial plants, - the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions, - compliance of pre-harvest uses with good agricultural practices. Conditions of use shall include risk mitigation measures, where appropriate. Member States shall ensure that use of plant protection products containing glyphosate is minimised in the specific areas listed in Article 12(a) of Directive 2009/128/EC. Member States shall ensure equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the toxicological studies. Member States shall ensure that plant protection products containing glyphosate do not contain the co-formulant POE-tallowamine (CAS No 61791-26-2).
EFSA Conclusions are available (EFSA Journal 2015; 13(11): 4302. Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. doi:10.2903/j.efsa.2015.4302. and Conclusion on the peer review of the pesticide risk assessment of the potential endocrine disrupting properties of glyphosate. EFSA Journal 2017;15(9):4979, 20 pp. https://doi.org/10.2903/j.efsa.2017.4979) A Review report is available (SANTE/10441/2017 Rev 2, 9 November 2017).

1.3 Regulatory approach

The present application (2018-1030) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) 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")[1] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

[1] 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

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

The French Order of 4th May 2017[2] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[3], implementing regulations, and French regulations.

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

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

Moreover, for glyphosate-based products, the official statement[5] 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 2014[6] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

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

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

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of FLODEN (GLYPHOSATE

[2] 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

[3] 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

[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

[5] 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

[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

20% + OXYFLUORFEN 3% SC), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

The applicant has provided letter(s) of access for active substance glyphosate.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	FLODEN (GLYPHOSATE 20% + OXYFLUORFEN 3% SC)
Authorisation number	N/A : no marketing authorisation granted
Function	Herbicide Professional use
Applicant	LAINCO, S.A
Composition	30 g/L oxyfluorfen 200 g/L glyphosate
Formulation type (code)	suspension concentrate (SC)
Packaging	N/A : no marketing authorisation granted

2.2 Classification and labelling

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

N/A : not registered in France

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

N/A: no marketing authorisation granted

2.2.3 Other phrases linked to the preparation

N/A : not registered 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.

GAP rev. , date: 2019-11-29

PPP (product name/code)	**FLODEN**	**Formulation type:**	**SC**
active substance 1	**glyphosate**	**Conc. of as 1:**	**200 g/L**
active substance 2	**oxyfluorfen**	**Conc. of as 2:**	**30 g/L**
Applicant:	**INDUSTRIAS AFRASA SA**	**professional use**	☒
Zone(s):	**southern**	**non professional use**	☐
Verified by MS:	**yes**		

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled**	**Application**			**Application rate**			**PHI (days)**	**Remarks: Total rate (max) /season**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**L prod./ha a) max. rate per appl. b) max. total rate per crop/season**	**kg as/ha a) min/max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**		
1	FR	Grapes (table and wine)	F	Annual grasses, broadleaves	Tractor mounted with boom sprayer. Directed spray to ground (1)	Dormant BBCH: 00 (Autumn – Early Spring)	a) 1 b) 1	a) 4 b) 4	Glyphosate a) 0.8 a) 0.8 Oxyfluorfen a) 0.12 b) 0.12	250- 400	180	**Not acceptable (relevant impurities, MRL, genotoxic potential, aquatic organisms, bees, soil macro-organisms, efficacy, (*))**
2	FR	Olive (table and oil production)	F	Annual grasses, broadleaves	Tractor mounted with boom sprayer. Directed spray to ground (1)	BBCH: 00-80 (early spring to autumn)	a) 1 b) 1	a) 4 b) 4	Glyphosate a) 0.8 a) 0.8 Oxyfluorfen a) 0.12 b) 0.12	250- 400	28(2) 1(2)	**Not acceptable (relevant impurities, genotoxic potential, aquatic organisms, bees, soil macro-organisms, efficacy, (*))**

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled**	**Application**			**Application rate**			**PHI (days)**	**Remarks: Total rate (max) /season**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**L prod./ha a) max. rate per appl. b) max. total rate per crop/season**	**kg as/ha a) min/max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**		
3	FR	Pome fruits	F	Annual grasses, broadleaves	Tractor mounted with boom sprayer. Directed spray to ground (1)	Dormant BBCH: 00 (Autumn – Early Spring)	a) 1 b) 1	a) 4 b) 4	Glyphosate a) 0.8 a) 0.8 Oxyfluorfen a) 0.12 b) 0.12	250- 400	180	**Not acceptable (relevant impurities, genotoxic potential, aquatic organisms, bees, soil macro-organisms, efficacy, (*))**
4	FR	Stone fruits	F	Annual grasses, broadleaves	Tractor mounted with boom sprayer. Directed spray to ground (1)	Dormant BBCH: 00 (Autumn – Early Spring)	a) 1 b) 1	a) 4 b) 4	Glyphosate a) 0.8 a) 0.8 Oxyfluorfen a) 0.12 b) 0.12	250- 400	180	**Not acceptable (relevant impurities, genotoxic potential, aquatic organisms, bees, soil macro-organisms, efficacy, (*))**
5	FR	Citrus	F	Annual grasses, broadleaves	Tractor mounted with boom sprayer. Directed spray to ground (1)	(Autumn – Early Spring)	a) 1 b) 1	a) 4 b) 4	Glyphosate a) 0.8 a) 0.8 Oxyfluorfen a) 0.12 b) 0.12	250-400	21	**Not acceptable (relevant impurities, genotoxic potential, aquatic organisms, bees, soil macro-organisms, efficacy, (*))**

(1)Applied as a banded application to the soil below the crop row, and the area between the rows is not treated
(2)PHI: 28 days for olive oil, PHI: 1 day for olive table

(*) Risk to diversity and abundance of non-target terrestrial arthropods and vertebrates *via* trophic interactions.

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 product FLODEN (GLYPHOSATE 20% + OXYFLUORFEN 3% SC) is a suspension concentrate (SC). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a free flowing homogeneous liquid, light yellow in colour and no strong odour. It is not explosive, has no oxidising properties. The product has no flash point. It has a self-ignition temperature of > 368 °C. In aqueous solution (1%), it has a pH value of 5.0 at 20°C. It has a relative density of 1.1075 g/ml. 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. Its technical characteristics are acceptable for a suspension concentrate (SC) formulation.

The active substance glyphosate contains two relevant impurities, formaldehyde and N-nitrosoglyphosate (NNG).
Analytical methods for the determination of the active substance and the relevant impurities formaldehyde and N-nitrosoglyphosate in the formulation are available and validated

The relevant impurity formaldehyde is considered as a by-product of the manufacturing process for glyphosate and as such cannot be formed during storage of the formulation. **However, the content of formaldehyde in the product in the storage stability studies is higher than the allowed limit in the product (1 g/kg of active substance).**

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 of the preparation.. **However, limit of quantification of the analytical method for determination of the relevant impurity N-nitroglyphosate in the preparation is higher than the acceptable limit**
The active substance oxyfluorfen contains one relevant impurity, N,N-dimethylnitrosamine. This relevant impurity cannot be formed during storage of the formulation.

The preparation FLODEN (GLYPHOSATE 20% + OXYFLUORFEN 3% SC) does not contain POE-tallowamines (n° CAS 61791-26-2).

3.1.2 Methods of analysis

Analytical methods for the determination of the active substances (glyphosate and oxyfluorfen) in the formulation are available and validated.

Analytical methods for the determination of the active substance and the relevant impurities formaldehyde and N-nitrosoglyphosate in the formulation are available and validated. **However, limit of quantification of the analytical method for determination of the relevant impurity N-nitroglyphosate in the preparation is higher than the acceptable limit** A method for the determination of the relevant impurity N,N-dimethylnitrosamine of oxyfluorfen in the preparation was provided.

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of oxyfluorfen in plants (high water content, high acid content and high oil content matrices), food of animal origin, soil, water (surface and drinking) and air.
Analytical methods are available in the RAR/this dossier and validated for the determination of residues of glyphosate in plants (high water content, high acid content and high oil content matrices), food of animal origin, soil, water (surface and drinking), air, tissues and body fluids.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active Substance: **glyphosate**			
ADI	0.5 mg kg bw/d		EU (2017)
ARfD	0.5 mg/kg bw		
AOEL	0.1 mg/kg bw/d		
Dermal absorption	Based on an in vitro human study performed on formulation (*pro rata* correction) :		
		Concentrate (tested) 200 g/L	Diluted formulation (tested) 2.4 g/L
	In vitro (human) %	0.36	2
		Concentrate (used in formulation) 200 g/L	Spray dilution (used in formulation) 2 g/L
	Dermal absorption endpoints %	**0.36**	**44.4**
Oral absorption	**20%**		

Active Substance: **oxyfluorfen**			
ADI	0.003 mg kg bw/d		EU (2017)
ARfD	0.3 mg/kg bw		
AOEL	0.013 mg/kg bw/d		
Dermal absorption	Based on an in vitro human study performed on formulation (*pro rata* correction):		
		Concentrate (tested) 30 g/L	Diluted formulation (tested) 0.36 g/L
	In vitro (human) %	3	37
		Concentrate (used in formulation) 30 g/L	Spray dilution (used in formulation) 0.3 g/L
	Dermal absorption endpoints %	**3**	**44.4**
Oral absorption	**60%**		

3.1.3.1 Acute Toxicity

FLODEN (GLYPHOSATE 20% + OXYFLUORFEN 3% SC) has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin and is irritating to the rabbit eye and is not a skin sensitiser.Genotoxic potential

3.1.3.2 Genotoxic potential

In the EC review report for glyphosate (SANTE/10441/2017 Rev 2), the following toxicity studies were requested (see page 6 of the review report):
"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."

According to EFSA scientific opinion on genotoxicity testing strategies (EFSA Journal 2011; 9(9):2379), a combination of two tests is needed to "[fulfil] the basic requirements to cover the three genetic endpoints: the bacterial reverse mutation assay covers gene mutations and the in vitro micronucleus test covers both structural and numerical chromosome aberrations".

These studies have not been submitted in this dossier. In this context, the genotoxic potential of FLODEN (GLYPHOSATE 20% + OXYFLUORFEN 3% SC) could not be evaluated. Therefore, the genotoxic potential of the preparation cannot be finalised.

3.1.3.3 Operator Exposure

Summary of critical use patterns (worst cases):

Crop type	**F/G**[8]	**Equipment** *Application method*	**Maximum application rate kg as /ha**	**Minimum volume water (L/ha)**
grapes	F	Vehicle mounted *downward spraying*	0.8 kg glyphosate/ha 0.12 kg oxyfluorfen/ha	250 L/ha
orchards	F	Vehicle mounted *downward spraying*	0.8 kg glyphosate/ha 0.12 kg oxyfluorfen/ha	250 L/ha

Considering proposed uses, operator systemic exposure was estimated using the EFSA model[9]:

Crop	**Equipment**	**PPE and/or working coverall**	**% AOEL glyphosate**	**% AOEL oxyfluorfen**
grapes	Vehicle mounted *downward spraying*	Working coverall and gloves during mixing/loading and application	0.57	5.92
orchards	Vehicle mounted *downward spraying*	Working coverall and gloves during mixing/loading and application	0.57	5.92

According to the model calculations, it can be concluded that the risk for the operator using FLODEN (GLYPHOSATE 20% + OXYFLUORFEN 3% SC) is acceptable with a working coverall and gloves during mixing/loading and application.

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

[8] Open field or glasshouse
[9] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

3.1.3.4 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[10].
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*."

3.1.3.5 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. Exposure is estimated to 2.7 % of the AOEL of glyphosate with PPE and to 57.4 % of the AOEL of oxyfluorfen with PPE. It is concluded that there is no unacceptable risk anticipated for the worker.
For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

3.1.3.6 Resident Exposure

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and child) when drift reduction technology and mitigation measures such as a buffer zone of 2-3 meters are taken to reduce the resident exposure:

Model (AOEM) - All pathways (mean)	**% AOEL glyphosate**	**% AOEL oxyfluorfen**
Resident (children)	5	86
Resident (adults)	2	40

3.1.3.7 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:

Population groups and PPE		**Active ingredient**	**Estimated exposure / AOEL (HQ)**
Operators	Working coverall and gloves during mixing/loading and application	**glyphosate**	0.0057
		oxyfluorfen	0.0592

[10] 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)

	Cumulative risk operators (HI)		**0.065**
Bystanders /Residents (with drift reduction technology and buffer zone 2-3 m) (orchards worst case)	Children - All pathways (mean)	**glyphosate**	0.05
		oxyfluorfen	0.86
	Cumulative risk bystanders/residents (child) (HI)		**0.91**
	Adults - All pathways (mean)	**glyphosate**	0.02
		oxyfluorfen	0.40
	Cumulative risk bystanders/residents (adult) (HI)		**0.42**
Worker	Working coverall and gloves	**glyphosate**	0.027
		oxyfluorfen	0.574
	Cumulative risk workers (HI)		**0.60**

The Hazard Index is < 1. Thus combined exposure to all active substances in FLODEN (GLYPHOSATE 20% + OXYFLUORFEN 3% SC) is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

3.1.4 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment. An exceedance of the current MRL for glyphosate and oxyfluorfen as laid down in respectively Reg. (EU) 293/2013 and Reg. (EC) No 149/2008 is not expected on olives, pome fruits, stone fruits and citrus, providing the application of the mitigation measures.
Intended uses are not supported by available data on glyphosate for grapes.

The chronic and the short-term intakes of glyphosate and oxyfluorfen 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 uses olives, pome fruits, stone fruits and citrus.

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

- Use application material or agricultural practices to avoid edible parts contact with active substance or with soil treated with active substance

Summary of the evaluation of glyphosate

Use-No.	**Crop**	**Plant metabolism covered?**	**Sufficient residue trials?**	**PHI sufficiently supported?**	**Sample storage covered by stability data?**	**MRL compliance**	**Chronic risk for consumers identified?**	**Acute risk for consumers identified?**
1	Grapes	Yes	**No**	N/A	N/A	N/A	N/A	N/A
2	Olives	Yes	Yes	Yes	Yes	Yes	No	No
3	Pome fruit	Yes	Yes	Yes	Yes	Yes	No	No

Use-No.	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
4	Stone fruit	Yes	Yes	Yes	Yes	Yes	No	No
5	Citrus	Yes	Yes	Yes	Yes	Yes	No	No

The effects of processing on the nature of glyphosate residues have been investigated. Data on effects of processing on the amount of residue have been submitted. These data were not considered for risk assessment.

Nature of residues in succeeding crops have been sufficiently investigated. Crops under evaluation are not expected to be grown in rotation. Then, residues level in succeeding crops is not of concern.

Considering the intended uses, no residues are expected in animal feedstuff. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Summary of the evaluation of oxyfluorfen

Use-No.	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Grapes	Yes	Yes	Yes	Yes	Yes	No	No
2	Olives	Yes	Yes	Yes	Yes	Yes	No	No
3	Pome fruit	Yes	Yes	Yes	Yes	Yes	No	No
4	Stone fruit	Yes	Yes	Yes	Yes	Yes	No	No
5	Citrus	Yes	Yes	Yes	Yes	Yes	No	No

Considering the intended uses, no residues are expected in crops which are commonly heated. Investigations about the effects of processing on the nature of oxyfluorfen residues are therefore not required. Data on effects of processing on the amount of residue in olive have been submitted. These data were not considered for risk assessment.

Nature of residues in succeeding crops have been sufficiently investigated. Crops under evaluation are not expected to be grown in rotation. Then, residues level in succeeding crops is not of concern.

Considering the intended uses, no residues are expected in animal feedstuff. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Summary of the evaluation of the product FLODEN (GLYPHOSATE 20% + OXYFLUORFEN 3% SC)

Crop	PHI for product code proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for <u>FLODEN (GLYPHOSATE 20% + OXYFLUORFEN 3% SC)</u> proposed by zRMS	zRMS Comments (if different PHI proposed)
		Glyphosate	Oxyfluorfen		
Grapes	180 days	**No**	Yes		
Olives	1 days for tree picked fruits 28 days for ground picked fruits	Yes	Yes	1 days for tree picked fruits 28 days for ground picked fruits	
Pome fruits	180	Yes	Yes	180	
Stone fruits	180	Yes	Yes	180	
Citrus	21	Yes	Yes	21	

3.1.5 Environmental fate and behaviour

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

The PEC of glyphosate, oxyfluorfen 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.

PEC soil and PECsw derived for the glyphosate, oxyfluorfen and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw for glyphosate, oxyfluorfen and their metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[11] when considering the condition of uses mentioned below. 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 DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

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(s) and its/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.

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

Based on the guidance documents, the risks for birds, mammals, other non-target arthropods, micro-organisms and terrestrial plants are acceptable for the intended uses. Risk mitigation measure are required in order to protect non-target plants.

The risks to aquatic organisms from exposure to the active substance oxyfluorfen were not acceptable considering the data available using the peer reviewed ETO-RAC for aquatic organisms and mitigation proposed. Therefore, zRMS concluded that risk for aquatic organisms is not finalised.

The risks to bees is considered non-finalised, as according to new requirements of Reg. No. 284/2013, data on chronic effects on adult bees and on development of bees should have been submitted by notifier as exposure of bees to the formulation containing two active substances cannot be excluded. Therefore, the risk to bees cannot be completely fulfilled.

For the risk assessment to soil macro-organisms, the notifier did not provide a toxicity study of the formulation to the soil invertebrate indicator species *Hypoaspis aculeifer* according to (Reg. (UE) N° 284/2013). Therefore, the risk assessment to soil macro-organisms is not considered finalised.

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

3.1.7 Efficacy

The ratio in active substances in the preparation FLODEN (GLYPHOSATE 20% + OXYFLUORFEN 3% SC) as well as its efficacy level **show a limited agronomic interest when applied at the intended dose of 4 L/ha**.

The selectivity level of the preparations FLODEN (GLYPHOSATE 20% + OXYFLUORFEN 3% SC) is considered acceptable for the claimed uses. Regarding the mode of penetration of glyphosate (foliar penetration), the preparation should not be directed to the green parts of the treated crops.

The risks of negative impact of the preparation FLODEN (GLYPHOSATE 20% + OXYFLUORFEN 3% SC) on yield, quality and transformation processes are considered acceptable. The risk of negative impact on propagation 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.

The risk of resistance apparition or development to the substance oxyfluorfen requires a monitoring for *Lolium rigidum*. The risk of resistance development to glyphosate requires monitoring data for *Lolium sp. (Lolium multiflorum, Lolium perenne, Lolium rigidum), Conyza sp.* and *Ambrosia artemisiifolia*.

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

FLODEN (glyphosate, 200 g/L + oxyfluorfen, 30 g/L – SC) contains oxyfluorfen, which is approved as a candidate for substitution because it fulfills two of PBT criteria (Persistant, Bio-accumulable, Toxic).

Preliminary Step / Request for derogation from comparative assessment **implemented for the candidate for substitution active substance oxyfluorfen**:
The information submitted to comply with Article 50(3) of Regulation (EC) No 1107/2009 is considered as acceptable.
Where it is necessary to acquire experience first through using the product in practice, comparative assessment will not be put in place for any of the requested uses.

The conclusion is reached without taking into account the specific provisions for the active substance glyphosate, implemented in France in accordance with Article 50(2) of Regulation (EC) No 1107/2009.

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

3.5.1 Post-authorisation monitoring

N/A : not registered in France

3.5.2 Post-authorisation data requirements

N/A : not registered in France

3.5.3 Label amendments

N/A : no marketing authorisation granted

Appendix 1 – Copy of the French Decision

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agence nationale de sécurité sanitaire alimentation, environnement, travail

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 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 d'autorisation de mise sur le marché et la demande associée du produit phytopharmaceutique ***FLODEN***

de la société	*LAINCO S.A.*
enregistrées sous les	*n°2018-1030 et 2018-3951*

Vu les conclusions de l'évaluation de l'Anses du 17 octobre 2019,

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 la concentration en impureté pertinente formaldéhyde dans le produit est supérieure à la limite acceptable,

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

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

FLODEN
AMM n°-

Page 1 sur 4

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Informations générales sur le produit	
Nom du produit	FLODEN
Type de produit	Produit de référence
Titulaire	LAINCO S.A. Av. Compositor Bizet 8-12 Pol. Ind. Can Jardi 08191 RUBI Barcelona Espagne
Formulation	Suspension concentrée (SC)
Contenant	269,9 g/L - glyphosate sel d'isopropylamine (équivalent à 200 g/L de glyphosate) 30 g/L - oxyfluorfène
Numéro d'intrant	9992-2018.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 29 NOV. 2019

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

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ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12055911 Agrumes*Désherbage* Cult. Installées	4 L/ha	1/an	21
	Motivation du refus : L'usage revendiqué correspondant au nouveau libellé « Cultures fruitières*Désherbage*Cult. Installées », est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également refusé du fait que la concentration en impureté pertinente formaldéhyde dans le produit est supérieure à la limite acceptable.		
12555902 Fruits à noyau*Désherbage* Cult. Installées	4 L/ha	1/an	180
	Motivation du refus : L'usage revendiqué correspondant au nouveau libellé « Cultures fruitières*Désherbage*Cult. Installées », est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également refusé du fait que la concentration en impureté pertinente formaldéhyde dans le produit est supérieure à la limite acceptable.		
12505901 Olivier*Désherbage* Cult. Installées	4 L/ha	1/an	21
	Motivation du refus : L'usage revendiqué correspondant au nouveau libellé « Cultures fruitières*Désherbage*Cult. Installées », est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également refusé du fait que la concentration en impureté pertinente formaldéhyde dans le produit est supérieure à la limite acceptable. L'usage est également refusé pour un délai avant récolte de 1 jour sur olives de table au même motif.		

FLODEN

AMM n°-

Page 3 sur 4

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12605905 Pommier*Désherbage* Cult. Installées	4 L/ha	1/an	180
	Motivation du refus : L'usage revendiqué correspondant au nouveau libellé « Cultures fruitières*Désherbage*Cult. Installées », est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également refusé du fait que la concentration en impureté pertinente formaldéhyde dans le produit est supérieure à la limite acceptable.		
12705902 Vigne*Désherbage* Cult. Installées	4 L/ha	1/an	180
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également refusé du fait que la concentration en impureté pertinente formaldéhyde dans le produit est supérieure à la limite acceptable. L'usage est également refusé au motif que le respect des limites maximales de résidus n'a pas pu être vérifié en raison d'un manque d'essais résidus.		

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

FLODEN

HERBICIDE

Suspension Concentrée (SC), contenant 200 g/L de glyphosate (sel d'isopropylamine) + 30 g/L d'oxyfluorfène.

AMM nº 00000

Homologué et Distribué par :

LAINCO, S.A.
Pol. Ind. Can Jardí
Avda. Bizet, 8-12
08191 RUBÍ (Barcelona - Espagne)
Telf. +34 935 86 20 15
Téléfax: +34 935 86 20 16
Email: afrasa@afrasa.es

RÉSERVÉE AUX UTILISATEURS PROFESSIONNELS

Numéro du lot et date de fabrication, voir sur le bidon.

1, 5, 10 et 20 Litres

PRESENTATION DU PRODUIT

FLODEN est un désherbant total avec une très grande efficacité contre les mauvaises herbes mono et dicotylédonées. FLODEN combine l'action de deux substances actives, le glyphosate, doté de la systémie et qui agit par contact et l'oxyfluorfène, doté d'une persistante activité résiduelle.

USAGES, DOSES, NOMBRE D'APPLICATIONS MAXIMUM ET DÉLAI AVANT RÉCOLTE (DAR)

Culture	MMHH	Dose l/ha	Applications par culture / saison	DAR (jours)	ZNT
Vigne (raisin de table et à vin) cultures installées	Mono et Dicotylédonées annuelles et vivaces	4.0-	1	180	20 m
Olivier (olive de table et à huile)		4.0	1	28 / 1	20 m
Fruitiers à pépin (pommier, poirier, cognassier, nashi, etc) cultures installées		4.0	1	180	20 m
Fruitiers à noyau (pêcher/nectarine, abricotier, prunier, cerisier, etc) cultures installées		4.0	1	180	20 m
Agrumes (oranges, citrons, mandarines, etc), cultures installées		4.0	1	21	20 m

Vigne (raisin de table et à vin): pulvérisation directe au sol, à basse pression, localisé sous le rang (seule la surface sous le rang, sans traiter les entre rangs), pendant le repos végétatif (BBCH 00), d'automne jusqu'à la sortie d'hiver. Délai avant récolte: 180 jours.

Olivier (olive de table et à huile): pulvérisation directe au sol, à basse pression,localisé sous le rang (seule la surface sous le rang, sans traiter les entre rangs).
Traitement avant et pendant la récolte (automne et hiver, BBCH 80-90): Délai avant récolte: 28 jours pour olive à huile et 1 jour pour olive de table.
Traitement après récolte jusqu'à avant floraison (hiver et printemps, BBCH 00-49): Délai avant récolte: non fixé.

Fruitiers à pépin (pommier, poirier, cognassier, nashi, etc): pulvérisation directe au sol, à basse pression, localisé sous le rang (seule la surface sous le rang, sans traiter les entre rangs), pendant le repos végétatif (BBCH 00), d'automne jusqu'à la sortie d'hiver. Délai avant récolte: 180 jours.

Fruitiers à noyau (pêcher/nectarine, abricotier, prunier, cerisier, etc): pulvérisation directe au sol, à basse pression, localisé sous le rang (seule la surface sous le rang, sans traiter les entre rangs), pendant le repos végétatif (BBCH 00), d'automne jusqu'à la sortie d'hiver. Délai avant récolte: 180 jours.

Agrumes (oranges, citrons, mandarines, etc): pulvérisation directe au sol, à basse pression, localisé sous le rang (seule la surface sous le rang, sans traiter les entre rangs), d'automne jusqu'à la sortie d'hiver. Délai avant récolte: 21 jours.

RECOMMANDATIONS D'EMPLOI

- Soigner la pulvérisation par une application homogène, sur toutes les mauvaises herbes à éliminer.
- Appliquer sur des mauvaises herbes jeunes et de conditions poussantes.
- Appliquer la dose plus haute en présence de mauvaises herbes annuelles bien développes ou en présence de mauvaises herbes vivaces.
- Volume d'eau conseillé:
  - Application avec pulvérisateur suspendu au tracteur: 250-400 l/ha.
  - Application avec pulvérisateur à dos: 500 l/ha.

PRÉPARATION DE LA BOUILLIE

FLODEN s'utilise en pulvérisation après dilution dans l'eau. Remplir la cuve à 1/2 d'eau, mettre sous agitation, agiter le bidon et verser la quantité de FLODEN nécessaire puis compléter le remplissage. Maintenir l'agitation jusqu'à la fin de l'application.

PRECAUTIONS

- 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 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.
  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.
- Stocker 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.

Mélanges

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

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.

FLODEN

BIEN LIRE L'ÉTIQUETTE AVANT TOUTE UTILISATION

En cas d'urgence appeler le n° 15 ou le Centre Anti-poison de Paris 01 40 05 48 48.
Signaler les symptômes au réseau Phyt'attitude, n° 0 800 887 887 (appel gratuit depuis un poste fixe)
Fiche de Données de Sécurité: contacter XXXX - xxx@xxxx.es - Tel.: +34 000 000 000

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

200 g/l de glyphosate (sel d'isopropylamine) + 30 g/l d'oxyfluorfène - Suspension Concentrée (SC)
Autorisation Mise Marché n° 000000

Usages et doses autorisés:
Vigne * Désherbage * Cultures installées, 4.0 l/ha; Olivier * Désherbage, 4.0 l/ha; Pommier * Désherbage * Cultures installées, 4.0 l/ha; Poirier - Cognassier - Nashi * Désherbage * Cultures installées, 4.0 l/ha; Pécher * Désherbage * Cultures installées, 4.0 l/ha; Abricotier * Désherbage * Culture installée, 4.0 l/ha; Cerisier * Désherbage * Cultures installées, 4.0 l/ha; Prunier * Désherbage * Cultures installées, 4.0 l/ha; Agrumes * Désherbage * Cultures installées 4.0 l/ha;


ATTENTION

H351: Susceptible de provoquer le cancer
H411: Toxique pour les organismos aquatiques, entraîne des effets à long
P102: Tenir hors de portée des enfants
P260: Ne pas respirer les brouillards ni les aérosols
P262: Éviter tout contact avec les yeux, la peau ou les vêtements
P280: Porter des gants de protection/des vêtements de protection
P309+P310+P101: EN CAS d'exposition ou d'un malaise: Appeler immédiatement un CENTRE ANTIPOISON ou un médecin. En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette

RESPECTER LES INSTRUCTIONS D'UTILISATION POUR ÉVITER LES RISQUES POUR L'HOMME ET L'ENVIRONNEMENT
Porter un vêtement de protection et des gants, pendant toutes les phases de mélange et de chargement. Consulter les instructions spéciales/la fiche de données de sécurité.
Sp1 Ne pas polluer l'eau avec le produit ou son emballage.
Spe3 Pour protéger les organismes aquatiques, respecter une bande tampon de végétation par rapport aux points d'eau de 20 mètres.
Spe 3 Pour protéger les plantes non ciblées, respecter une zone-tampon non traitée de 5 mètre par rapport aux terres non agricoles.
Délai rentrée: 6 heures.

Contenu: 1, 5, 10, 20 Litres


Appendix 3 – Letter(s) of Access

Letter(s) of access and, if necessary, an argumentation according to art. 62.4 of Reg (UE) No 1107/2009 have been submitted and are available under request