REGISTRATION REPORT

Part A

Risk Management

Product code: HAG 500 04 H

Product name: ALEKTO

Active substance:

glyphosate, 360 g/L (acid equivalent)

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: **HELM AG**

Date: **September 2020**

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PART A – Risk Management

The company HELM AG has requested marketing authorisation in France for the product ALEKTO (product code: HAG 500 04 H), containing 360 g/L glyphosate (acid equivalent), for use 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 ALEKTO (HAG 500 04 H) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of ALEKTO (HAG 500 04 H) have been made using endpoints agreed in the EU peer review of glyphosate.

This document describes the specific conditions of use and labelling required for France for the registration of ALEKTO (HAG 500 04 H).

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

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

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

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of HELM AG's application to market ALEKTO (HAG 500 04 H) 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

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-tallow amine (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 (2015-1208) 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.

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

The French Order of 4 May 2017[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 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.

Finally, the French Order of 26 March 2014[5] 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

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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

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 modifié par l'arrêté du 27 décembre 2019 https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

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

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[6] 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 ALEKTO (HAG 500 04 H), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

Not necessary: the applicant is the owner of data which support the renewal of approval of the active substance

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

2 .DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	ALEKTO (HAG 500 04 H).
Authorisation number	N/A : no marketing authorisation granted
Function	Herbicide.
Applicant	HELM AG.
Composition	360 g/L glyphosate (acid equivalent).
Formulation type (code)	Soluble concentrate (SL).
Packaging	N/A : no marketing authorisation granted

The product does not contain tallow amine (n° CAS 61791-26-2).

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No 1272/2008

Physical hazards	-	
Health hazards	-	
Environmental hazards	Hazardous to the aquatic environment, Chronic Hazard, Category 2.	
Hazard pictograms	 GHS09	
Signal word	-.	
Hazard statements	H411	Toxic to aquatic life with long-lasting effects.
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	-

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

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

The authorisation of the product is linked for professional uses only to the following conditions:

N/A : no marketing authorisation granted

2.2.3 Other phrases linked to the preparation

N/A : no marketing authorisation granted

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

GAP date: 30/09/2020

PPP (product name/code)	ALEKTO/(HAG 500 04 H)	Formulation type:	soluble concentrate (SL) (a,b)
active substance 1	glyphosate	Conc. of a.s. 1:	360 g/L (c)
Applicant:	HELM AG	professional use	☒
Zone(s):	southern EU (d)	non-professional use	☐
Verified by MS:	yes		
Field of use:	herbicide		

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	FR	Stubble before spring crop All crops Inter-crops (before sowing and planting) including crop destruction (all crops except forest) (all seeded and transplanted crops)	F	Annual grasses	Tractor-mounted sprayer, broadcast, ground-directed spraying	Before sowing / Pre-planting	1	3	1080	100	**F**	**Not acceptable** (relevant impurity)
2	FR	Stubble before spring crop All crops Inter-crops (before sowing and planting) including crop destruction (all crops except forest) (all seeded and transplanted crops)	F	Annual and biennial broadleaved weeds	Tractor-mounted sprayer, broadcast, ground-directed spraying	Before sowing / Pre-planting	a) 1 b) 1	a) 5 – 6 b) 6	a) 1800 - 2160 b) 2160	a) 100 b) 200	**F**	**Not acceptable** (relevant impurity)
3	FR	Stubble before spring crop All crops Inter-crops (before sowing and planting) including crop destruction (all crops except forest) (all seeded and transplanted crops)	F	Perennial weeds	Tractor-mounted sprayer, broadcast, ground-directed spraying	Before sowing / Pre-planting	a) 1 b) 1	a) 5 – 6 b) 6	a) 1800 - 2160 b) 2160	a) 100 b) 200	**F**	**Not acceptable** (relevant impurity)
4b	FR	Stubble before winter crop All crops Inter-crops (before sowing and planting) including crop destruction (all crops except forest) (all seeded and transplanted crops)	F	Annual grasses	Tractor-mounted sprayer, broadcast, ground-directed spraying	Before sowing / Pre-planting	1	3	1080	100	**F**	**Not acceptable** (relevant impurity)

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
5	FR	Stubble before winter crop All crops Inter-crops (before sowing and planting) including crop destruction (all crops except forest) (all seeded and transplanted crops)	F	Annual and biennial broadleaved weeds	Tractor-mounted sprayer, broadcast, ground-directed spraying	Before sowing / Pre-planting	a) 1 b) 1	a) 5 – 6 b) 6	a) 1800 - 2160 b) 2160	a) 100 b) 200	**F**	**Not acceptable** (relevant impurity)
6	FR	Stubble before winter crop All crops Inter-crops (before sowing and planting) including crop destruction (all crops except forest) (all seeded and transplanted crops)	F	Perennial weeds	Tractor-mounted sprayer, broadcast, ground-directed spraying	Before sowing / Pre-planting	a) 1 b) 1	a) 5 – 7 b) 7	a) 1800 - 2520 b) 2520	a) 100 b) 200	**F**	**Not acceptable** (MRL, relevant impurity)
8b	FR	Weed control in orchards (pome fruit, stone fruit, citrus, tree nuts) including young orchards and olive trees	F	Annual grasses	Tractor-mounted sprayer, ground-directed spraying	Citrus, stone fruit, tree nuts: Application before end of flowering	1	4	1440	100	Olives: 21 Pome fruit: 28 Citrus, stone fruit, tree nuts: **F**	**Not acceptable** (relevant impurity)
9	FR	Weed control in orchards (pome fruit, stone fruit, citrus, tree nuts) including young orchards and olive trees	F	Annual and biennial broadleaved weeds	Tractor-mounted sprayer, ground-directed spraying	Citrus, stone fruit, tree nuts: Application before end of flowering	1	a) 3 – 6 b) 6	a) 1080 - 2160 b) 2160	a) 100 b) 400	Olives: 21 Pome fruit: 28 Citrus, stone fruit, tree nuts: **F**	**Not acceptable** (relevant impurity)
10	FR	Weed control in orchards (pome fruit, stone fruit, citrus, tree nuts) including young orchards and olive trees	F	Perennial weeds	Tractor-mounted sprayer, ground-directed spraying - spot application	Citrus, stone fruit, tree nuts: Application before end of flowering	1	a) 6 – 8 b) 8	a) 2160 – 2880 b) 2880	a) 100 b) 400	Olives: 21 Pome fruit: 28 Citrus, stone fruit, tree nuts: **F**	**Not acceptable** (relevant impurity, (child resident and child bystander)

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
11b	FR	Weed control in grapevine	F	Annual grasses	Tractor-mounted sprayer, ground-directed spraying	Application before end of flowering	1	4	1440	100	Application before end of flowering **F**	**Not acceptable** (relevant impurity, (operators)
12	FR	Weed control in grapevine	F	Annual and biennial broadleaved weeds	Tractor-mounted sprayer, ground-directed spraying	Application before end of flowering	1	3 – 6b) ~~6~~ see column 10	1080 - 2160	100	Application before end of flowering **F**	**Not acceptable** (relevant impurity, (operators)
13	FR	Weed control in grapevine	F	Perennial weeds	Tractor-mounted sprayer, ground-directed spraying - spot application	Application before end of flowering	1	6 – 8	2160 – 2880	100	Application before end of flowering **F**	**Not acceptable** (relevant impurity, (operators, child resident and child bystander)

PHI **F** PHI is defined by the application stage at final treatment (time elapsing between final treatment and harvest of the crop).

Remarks table heading:

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

Remarks columns:

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

3 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

ALEKTO (HAG 500 04 H) is a soluble concentrate (SL). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a yellowish homogeneous liquid, with a characteristic odour. It is not explosive and has no oxidising properties. The product presents no flash point. It has a self-ignition of 475 °C. In aqueous solution (1 %), it has a pH value of 5.0 at 20 °C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and 14 days at 54 °C, neither the active substance content nor the technical properties were changed.

The active substance glyphosate contains two relevant impurities, formaldehyde and N-nitrosoglyphosate. The former is considered to be a by-product of the manufacturing process for glyphosate and as such cannot be formed by storage of the formulation. Monitoring of this impurity in the storage studies is not necessary. However, N-nitrosoglyphosate is unlikely to form during the formulation and storage of the product and no monitoring of its concentration during storage of the product was provided.

The product ALEKTO (HAG 500 04 H) does not contain polyethoxylated (POE)-tallow amine (CAS n° 61791-26-2).

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methodology for the determination of active substance in the formulation is available and validated. Analytical methods for relevant impurities (N-nitrosoglyphosate and formaldehyde) in the formulation are available and validated.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the draft assessment report (DAR)/this dossier and validated for the determination of residues of glyphosate in plants, foodstuffs of animal origin, soil, water (surface and drinking) and air.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

<table>
<tr><td colspan="4">Active substance: glyphosate</td></tr>
<tr><td>ADI</td><td colspan="2">0.5 mg/kg bw/d</td><td rowspan="3">EU (2017)</td></tr>
<tr><td>ARfD</td><td colspan="2">0.5 mg/kg bw</td></tr>
<tr><td>AOEL</td><td colspan="2">0.1 mg/kg bw/d</td></tr>
<tr><td rowspan="3">Dermal absorption</td><td colspan="3">Based on default values according to guidance on dermal absorption (Efsa 2012):</td></tr>
<tr><td></td><td>Concentrate
(used in formulation)
360 g/L</td><td>Spray dilution
(used in formulation)
2.7 g/L</td></tr>
<tr><td>Dermal absorption endpoints %</td><td>20</td><td>20</td></tr>
<tr><td>Oral absorption (%)</td><td colspan="2">20</td><td>EU 2017</td></tr>
</table>

The dermal absorption values are corrected by oral absorption value according to EFSA Guidance on dermal absorption (2012).

3.1.3.1 Acute Toxicity

ALEKTO (HAG 500 04 H), containing 360 g/L glyphosate, has a low toxicity acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

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*".

Two *in vitro* genotoxicity tests performed on ALEKTO (HAG 500 04 H) were submitted by the applicant:

- A bacterial reverse mutation test (OECD TG 471) and
- An *in vitro* mammalian cell micronucleus test (OECD TG 487).

All assays were considered by the zRMS to be adequately conducted and clearly negative. Thus it may be concluded with reasonable certainty that ALEKTO (HAG 500 04 H) has no genotoxic potential.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G[7]	Equipment	Application rate L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Weed control in orchards	F	Tractor-mounted boom sprayer	4-8 L/ha (1440 – 2880 g a.s./ha)	100-400	EFSA AOEM
Weed control in stubbles	F	Tractor-mounted boom sprayer	3-7 L/ha (1080 – 2520 g a.s./ha)	100-200	EFSA AOEM
Weed control in grapevine	F	Hand-held sprayer	4-8 L/ha (1440 – 2880 g a.s./ha)	100-400	EFSA AOEM

[7] Open field or glasshouse

Considering the proposed uses, operator systemic exposure was estimated using the EFSA AOEM.

Crop	Equipment	PPE and/or working coverall	% AOEL glyphosate (0.2 mg/kg bw/d)	% AOEL glyphosate (0.1 mg/kg bw/d)
Weed control in orchards (8 L/ha)	Tractor-mounted boom sprayer	Working coverall and gloves during mixing/loading and application	6.3	13
Weed control in stubbles (7 L/ha)	Tractor-mounted boom sprayer	Working coverall and gloves during mixing/loading and application	18	35
Weed control in grapevine (4 L/ha)	Hand-held sprayer	Working coverall and gloves during mixing/loading and application	59	118

According to the model calculations, it can be concluded that the risk for the operator using HAG 500 04 H on stubbles and orchards is acceptable with the use of personal protective equipment during mixing/loading and application (work wear and gloves) when spraying with tractor mounted equipment for both AOELs.

It also can be concluded that the risk for the operator using HAG 500 04 H on grapevines with a hand-held sprayer is not acceptable at the lowest dose of 4 L of product per ha (1.44 kg of active substance/ha), even with the use of personal protective equipment with the AOEL of 0.1 mg/kg bw/d.
Concerning grapes treatment, operator exposure is below the AOEL (with the use of work wear and gloves during mixing/loading and application) of Glyphosate for application rates less than 3.3 L of product/ha.

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

3.1.3.3 Bystander Exposure

Consideration of acute exposure should only be made where an acute AOEL (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 AOE model where no AAOEL has been set[8].

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."*

3.1.3.4 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 the AOE model. Exposure is estimated to be 81 % of the AOEL of glyphosate for orchards and grapes and 71 % of the AOEL of glyphosate for stubbles with working clothing.

It may be 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.

3.1.3.5 Resident Exposure

Orchards:

[8] 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)

Residential exposure was assessed according to the EFSA model.
Taking into consideration an AOEL of 0.1 mg/kg bw/d, the exposure of a resident to HAG 500 04 H is 200% and 74% of the AOEL of Glyphosate for child and adult respectively when treating orchards at the maximum dose of 8L/ha.
The risk is still unacceptable using drift reduction nozzles and a buffer strip of 10 meters.
The risk is acceptable for residents at the dose of 6 L/ha with a 10 meters buffer strip and use of drift reduction nozzles.
The risk is acceptable for residents at the dose of 4 L/ha with a 3 meters buffer strip and use of drift reduction nozzles.
The risk is acceptable for residents with a maximum application rate of 7.2 L of product / ha (2.6 kg a.s/ha), a 10 meters buffer strip and the use of drift reduction nozzles.

Stubbles:
Residential exposure was assessed according to the EFSA model.
When treating stubbles before winter crops, the resident exposure is estimated to be 151% and 46% of the AOEL (0.1 mg/kg bw/d) of glyphosate for child and adult respectively with a buffer strip of 3 meters.
The risk is acceptable for residents at the dose of 3 L/ha with a 3 meters buffer strip.
The risk is acceptable for residents at the dose of 5 L/ha with a 3 meters buffer strip and use of drift reduction nozzles.
The risk is acceptable for residents at the dose of 7 L/ha with a 5 meters buffer strip and use of drift reduction nozzles.

Grapes:
Residential exposure was assessed according to the EFSA model.
When treating grapes with manual hand-held sprayer, the resident exposure is estimated to be 174% and 65% of the AOEL (0.1 mg/kg bw/d) of glyphosate for child and adult respectively at the maximum dose of 8 L/ha. A 10 meters buffer strip does not change the conclusions of the evaluation.
The risk is acceptable for residents at the dose of 4 L/ha with a 3 meters buffer strip.
The risk is acceptable for residents at the dose of 6 L/ha with a 10 meters buffer strip.
The risk is acceptable for residents with a maximum application rate of 6.1 L of product / ha (2.2 kg a.s/ha), a 10 meters buffer strip.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

The data available are considered sufficient for risk assessment. No exceedence of the current MRL (Reg. (EU) no 293/2013) for glyphosate as laid down in Reg. (EC) no 396/2005 is expected, providing the application of the mitigation measures are observed, except for use when olives come into contact with soil.

Compliance with current MRLs cannot be performed for livestock commodities (linked to the uses on cereals). The intended uses are not supported by sufficient data and compliance with current MRLs cannot be assessed for ground-picked olives (insufficient residue trials for olives destined for oil production; possible MRL exceedence for table olives and olives destined for oil production).

In accordance with the available residue data, a maximum application dose of 2160 g a.s./ha is retained for the inter-crop uses.

3.1.4.2 Consumer exposure

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

As far as consumer health protection is concerned, France as zRMS agrees with the authorisation of the intended uses in inter-cropping, in orchards and for tree-picked olives only.

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

For uses in orchards: “Use application equipment or agricultural practices to avoid edible fruit coming into contact with active substance or with soil treated with the active substance.”

Information on ALEKTO (HAG 500 04 H) (KCA 6.8)

Crop	**PHI for** ALEKTO (HAG 500 04 H) **requested by applicant**	**PHI/withholding period* sufficiently supported for glyphosate**	**PHI for ALEKTO proposed by zRMS**	**zRMS Comments (if different PHI proposed)**
Inter-crops: Pre-planting/pre-sowing or Post-planting/post-sowing at pre-emergence (including stubble)	F**	Yes	F**	
Citrus	Until end of flowering (BBCH 69)	Yes	F** Until end of flowering (BBCH 69)	
Pome fruits	28 days	Yes	28 days	
Stone fruits	Until end of flowering (BBCH 69)	Yes	F** Until end of flowering (BBCH 69)	
Tree nuts	Until end of flowering (BBCH 69)	Yes	F** Until end of flowering (BBCH 69)	
Olives	21 days	Yes	21 days	
Vineyard with soil application: Grapes	Until end of flowering (BBCH 69)	Yes	F** Until end of flowering (BBCH 69)	

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

The results of the rotational crop study demonstrated that neither glyphosate nor its metabolite AMPA[9] show a potential uptake into following crops. No specific waiting period is thus required.

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 predicted environmental concentration (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 values of glyphosate and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PECsoil and PECsw values derived for glyphosate and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw values for glyphosate and AMPA do not occur at levels exceeding those mentioned in Regulation (EC) no 1107/2009 and guidance document SANCO 221/2000. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

[9] 1-aminomethylphosphonic acid

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 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.

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

Risk mitigation measure are required to protect aquatic organisms and non-target plants, (see section 1.1.2).

The risk for non-target arthropods for intended uses at 2880 g a.s./ha (i.e. 8 L/ha) is acceptable with mitigation measures (see section 1.1.2).

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).

3.1.7 Efficacy

The efficacy level of ALEKTO (HAG 500 04 H) is considered satisfactory for all the requested uses.

As glyphosate has a herbicidal activity on all types of plants (“total weed killer”), the product ALEKTO (HAG 500 04 H) cannot therefore be considered selective. Given the foliar penetration of glyphosate, the product should not be directed on to the green parts of crops.

The risks of negative impact on yield, quality and propagation are considered negligible.

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

The risk of negative impact on adjacent crops is considered acceptable, so long as the product 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 developing or appearing to glyphosate for ryegrass (*Lolium multiflorum, L. perenne* and *L. rigidum*), fleabanes (*Conyza* sp.) and common ragweed (*Ambrosia artemisiifolia*). This requires resistance monitoring.

3.2 Conclusion of the national comparative assessment (Art 50 of regulation (EC) No 1007/2009)

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.

For the non-agricultural uses, 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 use on devitalization are considered as widely used and without practical or economical disadvantage, so **substitution will be considered for this use**.
For the uses on clearance (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:

- weed control in forest nursery and seed orchards in forest production because as there is no non-chemical alternative.
- weed control before planting (or forest regeneration) 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.

3.3 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.

3.4 Substances of concern for national monitoring

No information stated.

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 : no marketing authorisation granted

3.5.2 Post-authorisation data requirements

- N/A : no marketing authorisation granted

3.5.3 Label amendments

The draft label proposed by the applicant in Appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision

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

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

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

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

de la société	*HELM AG*
enregistrée sous le	*n°2015-1208*

Vu les conclusions de l'évaluation de l'Anses du 22 septembre 2020,

Considérant que les données fournies ne permettent pas d'exclure la formation de l'impureté pertinente N-nitrosoglyphosate au cours du stockage du produit,

Considérant qu'en conséquence un risque d'effet nocif pour la santé humaine ne peut pas être exclu,

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

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

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Informations générales sur le produit	
Nom du produit	ALEKTO
Type de produit	Produit de référence
Titulaire	HELM AG Nordkanalstrasse 28 20097 Hamburg Allemagne
Formulation	Concentré soluble (SL)
Contenant	360 g/L - glyphosate
Numéro d'intrant	007-2015.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 30 SEP. 2020

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)**
00201024 Cultures fruitières* Désherbage* Cult. Installées	4 L/ha	1/an	F
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure la formation de l'impureté pertinente N-nitrosoglyphosate au cours du stockage du produit. L'usage est également refusé aux doses de 6 et 8 L/ha au même motif, et au motif qu'un risque d'effet nocif pour les résidents enfants ainsi que pour les personnes présentes enfants ne peut être exclu, sur "agrumes", "fruits à noyaux" et "fruits à coque" et, pour un délai avant récolte de 21 jours sur "olivier" et 28 jours sur "pommier".		
11015921 Traitements généraux* Désherbage* Zones Cult. Avt Plantat.	3 L/ha	1/an	F
	Motivation du refus : L'usage revendiqué, correspondant au nouvel usage 11015935 Traitements généraux*Désherbage*Interculture, jachères et destruction de culture, est refusé au motif que les données fournies ne permettent pas d'exclure la formation de l'impureté pertinente N-nitrosoglyphosate au cours du stockage du produit. L'usage est refusé aux doses de 5, 6 et 7 L/ha au même motif, et est également refusé aux doses supérieures à 6 L/ha au motif que les données fournies ne permettent pas d'exclure un risque de dépassement des limites maximales de résidus.		
12705902 Vigne* Désherbage* Cult. Installées	4 L/ha	1/an	F
	Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'exclure la formation de l'impureté pertinente N-nitrosoglyphosate au cours du stockage du produit. L'usage est également refusé au même motif aux doses de 4 et 6 L/ha et en raison d'un risque d'effet nocif pour les opérateurs, et, à la dose de 8 L/ha, en raison d'un risque d'effet nocif pour les opérateurs, les résidents enfants ainsi que pour les personnes présentes enfants.		

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

ALEKTO®

Herbicide foliaire systémique de post-levée

Contient 360 g/L (327,6% P/P) de glyphosate acide sous forme de concentré soluble

Autorisation de Mise sur le Marché n°xxxxxxx

PRODUITS POUR LES PROFESSIONNELS : UTILISEZ LES PRODUITS PHYTOPHARMACEUTIQUES AVEC PRÉCAUTION. AVANT TOUTE UTILISATION, LISEZ L'ETIQUETTE ET LES INFORMATIONS CONCERNANT LE PRODUIT.

N° de lot et date de fabrication : voir emballage

ALEKTO®
Contient 360 g/L de glyphosate acide sous forme de concentré soluble
Contenu : XX L

H411: Toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
EUH401 : Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.
P273: Éviter le rejet dans l'environnement.
P391: Recueillir le produit répandu.
P501: Eliminer le contenu/récipient conformément à la règlementation nationale
SP1 Ne pas polluer l'eau avec le produit ou son emballage.
[Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.]
SPe3 Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres en bordure des points d'eau.
SPe3 Pour protéger les arthropodes non-cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente pour une dose d'utilisation de 2880 g sa/ha.
SPe3 Pour protéger les plantes non cibles, respecter, par rapport à la zone non cultivée adjacente, une zone non traitée de :
o 20 mètres pour une dose d'utilisation de 2160 g sa/ha et 2880 g sa/ha ;
o 5 mètres pour une dose d'utilisation de 1080 g sa/ha et 1440 g sa/ha.
Délai de rentrée : 6 heures
Détenteur de l'homologation:
HELM AG, Nordkanalstrasse 28, D-20097 Hambourg, Allemagne
Tel. +49 (0) 40 / 2375-0, Fax +49 (0) 40 / 2375-1845

Fiche de données de sécurité disponible sur le site www.quickfds.com.

MODE D'ACTION

ALEKTO® est un herbicide de post-levée contenant du glyphosate, unique représentant de la famille des glycines (groupe HRAC G). Il est efficace sur la plupart des adventices graminées annuelles et vivaces ainsi que sur les dicotylédones annuelles, bisannuelles et vivaces. ALEKTO® est absorbé par les feuilles et est transporté par systémie dans tous les organes de la plante, s'accumulant principalement dans les racines et les organes souterrains pour les plantes vivaces. Les symptômes (arrêt du développement, chlorose et nécrose) commencent à apparaître généralement 1 à 2 semaines après l'application et la destruction de l'adventice est complète après environ 4 semaines (8 semaines pour certaines adventices).

USAGES ET DOSES D'EMPLOI

Usages / Cultures	Application					Délai avant récolte (DAR) en jours
	Dose par traitement			Nombre d'application	Stade de développement (culture et/ou adventices)	
	Produit formulé (L/ha)	Substance active (g/ha)	Volume de dilution			
Traitements généraux Désherbage Arboriculture fruitière						
Graminées annuelles	4,0 L/ha	1440	100 – 400	1	Jusqu'au stade BBCH 65 – 69 des adventices	Olive : 21 Fruits à pépins: 28 Agrumes, fruits à coque, fruits à noyau: application avant fin floraison
Dicotylédones annuelles et biannuelles	6,0 L/ha	2160				
Vivaces	8,0 L/ha	2880				
Désherbage Cultures installées Vigne						
Graminées annuelles	4,0 L/ha	1440	100 – 400	1	Jusqu'au stade BBCH 65 – 69 des adventices	Application avant fin floraison
Dicotylédones annuelles et biannuelles	6,0 L/ha	2160				
Vivaces	8,0 L/ha	2880				
Traitements généraux Désherbage en zones cultivées avant mise en culture						
Herbes annuelles	3,0 L/ha	1080	100 – 200	1		F*
Traitements généraux Désherbage avant mise en culture en zones cultivées						
Herbes vivaces	5,0 - 6,0 L/ha (culture de printemps)	1800 - 2160	100 – 200	1	Jusqu'au stade BBCH 65 – 69 des adventices	F*
	5,0 - 7,0 L/ha (culture d'hiver)	1800 - 2520				
Traitements généraux Désherbage avant mise en culture en zones cultivées						
Herbes biannuelles	5,0 - 6,0 L/ha (culture de printemps et d'hiver)	1800 - 2160	100 – 200	1	Après la récolte jusqu'au semis	F*

*F : Le DAR pour les usages considérés est couvert par les conditions d'application et/ou le cycle de croissance de la culture. Par conséquent, il n'est pas nécessaire de proposer un DAR en jours

(1) selon les intitulés des usages correspondants au nouveau catalogue ou à l'avis du JO du 8 octobre 2004
Limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union européenne.

PREPARATION DE LA BOUILLIE

Avant de débuter le remplissage de la cuve du pulvérisateur pour préparer la bouillie de pulvérisation, s'assurer que celle-ci ne contient aucun résidu liquide ou solide d'un traitement précédent.

Remplir à 50% du volume requis le réservoir du pulvérisateur avec de l'eau propre. Mettre en marche le système d'agitation ou d'incorporation puis ajouter progressivement le produit. Ajouter enfin le reste du volume d'eau requis. Maintenir la bouillie en état d'agitation jusqu'à la fin de la pulvérisation. Ne préparez jamais plus de bouillie qu'il n'en est nécessaire.

CONDITIONS D'EMPLOI

Pour une meilleure efficacité, utiliser un volume de bouillie compris entre 100 et 400 litres d'eau par hectare, en fonction de la culture, du stade de développement de l'adventice et de l'équipement disponible. Utiliser le produit sur des adventices en phase de croissance active.

ALEKTO® peut être utilisé sur tout type de sol. Eviter de traiter lors de fortes chaleurs.

ALEKTO® peut être utilisé comme désherbant avant l'implantation de culture de printemps ou d'hiver, en arboriculture fruitière (y compris sur jeunes vergers et oliveraies) et sur vigne. Aucune restriction variétale n'est imposée ; toutefois, en cas de doute, il est fortement conseillé de mettre en place un essai préliminaire.

Ne pas traiter les parties vertes des cultures ou les arbres très jeunes qui ne sont pas bien lignifiés. Utiliser des buses anti-dérives pour les jeunes plantes et les cultures les plus sensibles.

ALEKTO® doit être appliqué sur des adventices émergentes, généralement jusqu'au stade de développement BBCH 65 à BBCH 69 (pleine floraison jusqu'à fin floraison) et même jusqu'au stade BBCH 89 (maturité) pour le Chiendent pied-de-poule (*Cynodon dactylon*) et le Chiendent rampant (*Elytrigia repens*)

Dans le cadre des bonnes pratiques d'utilisation, l'usage de buses à dérive limitée et/ou d'adjuvants appropriés possédant la mention "limitation de la dérive" est recommandé.

MELANGES

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

Nous attirons votre attention sur la nécessité de faire un test de compatibilité physique et biologique en procédant à une pulvérisation sur une surface significative de la culture.

GESTION DU RISQUE DE RÉSISTANCE

L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants.

Pour réduire ce risque, il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation.

Consultez votre distributeur pour connaître les cas avérés de résistance au niveau de votre région.

PRÉCAUTIONS D'EMPLOI

Avant l'application :

• Conserver le produit uniquement dans l'emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur et fermé à clé, à l'abri de l'humidité, du gel, dans un endroit frais, aéré et ventilé, à l'écart des aliments et boissons y compris ceux pour animaux.
• Conserver hors de la portée des enfants.

Pendant la préparation de la bouillie et en cours d'application :

• Ne pas manger, boire, fumer.
• Porter un vêtement de protection approprié, des gants et un appareil de protection des yeux et du visage. (voir paragraphe « PROTECTION DE L'OPERATEUR ET DU TRAVAILLEUR»).
• Vérifier régulièrement et maintenir le bon état et le réglage du matériel d'application, en conformité avec la législation.
• Surveiller le remplissage de la cuve du pulvérisateur et ajuster le volume de bouillie (clapet anti-retour, dispositif de surverse).
• Ne pas souffler dans les buses pour tenter de les déboucher.
• En cas de contact avec la peau et les yeux, laver immédiatement et abondamment avec de l'eau et consulter un spécialiste.
• En cas d'ingestion consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette.
• Ne pas respirer les vapeurs, ni le brouillard de pulvérisation.
• Ne pas pulvériser à proximité des points d'eau (mares, cours d'eau, fossés...).
• Ne pas traiter en présence de vent (selon la réglementation en vigueur).

Après application :

• Eliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur.
• Ne pas conserver la bouillie de pulvérisation dans la cuve plus de 48 heures.
• Nettoyer très soigneusement avec un produit adapté (type Phytnet) et rincer le pulvérisateur aussitôt après le traitement conformément à la réglementation en vigueur.
• Immédiatement après l'application, nettoyer les équipements de protection, se laver les mains à l'eau savonneuse, prendre une douche et changer de vêtements.

ELIMINATION DU PRODUIT ET DES EMBALLAGES

Lors de l'utilisation du produit, rincer le bidon 3 fois en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur.
Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

Réutilisation de l'emballage interdite. Eliminer les emballages vides via une collecte organisée par un service de collecte spécifique.

PROTECTION DE L'OPERATEUR ET DU TRAVAILLEUR

Pour l'opérateur, porter:

❖ **Pendant le mélange et ou chargement**

- Gants en nitrile certifies EN 374-3 ;
- Combinaison de travail cotte en polyester 65 %/coton 35 % avec un grammage de 230 g/m^2 ou plus avec traitement déperlant ;
- EPI partiel (blouse) de categorie III et de type PB (3) à porter par- dessus la combinaison précitée ;
- Bottes de protection conforme à la réglementation et selon la norme EN 13 832-3 ;
- Lunettes de sécurité conforme à la réglementation et selon la norme EN 166.

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❖ **Pendant l'application**

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Bottes de protection conforme à la réglementation et selon la norme EN 13 832-3 ;

Si application avec tracteur sans cabine :

- Gants en nitrile certifies EN 374-2 à usage unique pendant l'application et dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

Si application avec tracteur avec cabine

- Gants en nitrile certifies EN 374-2 à usage unique n'est nécessaire que lors d'interventions sur le matériel de pulvérisation. Dans ce cas, les gants ne doivent être partes qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec pulvérisateur à dos ou avec lance tenue à la main

-Gants en nitrile certifiés EN 374-3 réutilisables ;
- Vêtement imperméable, blouse à manches longues conforme à la réglementation certifiée de catégorie III et de type PB 3 à porter par-dessus la combinaison.

❖ **Pendant le nettoyage du matériel de pulvérisation**

- Gants en nitrile certifies EN 374-3 ;
- Combinaison de travail cotte en polyester 65 %/coton 35 % avec un grammage d'au moins 230 g/m² avec traitement déperlant ;
- EPI partie/ (blouse) de categorie III et de type PB (3) à porter par -dessus la combinaison précitée.
- Bottes de protection conforme à la réglementation et selon la norme EN 13 832-3 ;
- Lunettes de sécurité conforme à la réglementation et selon la norme EN 166.

- Pour protéger le travailleur, s'il doit intervenir sur une parcelle traitée porter une combinaison de travail tissée en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant.

MANIPULATION ET STOCKAGE

- Manipulation

Conseils pour une manipulation sans danger: Pas de mesures spéciales nécessaires si le stockage et la manipulation sont appropriés. Eviter la formation et le dépôt de poussières. Assurer une bonne ventilation de la zone de travail (ventilation locale par aspiration, si nécessaire).

Mesures pour la protection contre l'incendie et l'explosion : La poussière peut former un mélange explosif avec l'air. Prendre des mesures contre les charges électrostatiques. Conserver à l'écart de toute source de feu et de chaleur.

IMPORTANT

• Respectez les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé.
Conduisez, sur ces bases, la culture et les traitements selon la bonne pratique agricole et les recommandations de votre distributeur 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.

GARANTIE - Le fabricant ne donne aucune garantie, explicite ou implicite, relative à l'utilisation du produit d'une autre manière que celle indiquée sur l'étiquette. L'utilisateur sera responsable des risques liés à l'utilisation et/ou la manipulation et/ou l'entreposage de ce produit en cas de non-respect des recommandations de l'étiquette.

RESPONSABILITES - En cas de non-respect de la garantie ou de négligence, le recours de l'utilisateur sera limité au remboursement de dommages et intérêts, à concurrence du prix d'achat, à l'exclusion de tout autre dommage.