

REGISTRATION REPORT

Part A

Risk Management

Product code: 1.31077.00

Product name: TRADIANOL DUO

Chemical active substances:

Glyphosate, 180 g/L

Dicamba, 40 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: TRADI-AGRI

Date: 29/11/2019

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PART A

RISK MANAGEMENT

1 Details of the application

The company TRADI-AGRI has requested a marketing authorisation in France for the product TRADIANOL DUO (formulation code: 1.31077.00), 180 g/L glyphosate¹ and 40g/L dicamba² as a herbicide for professional uses.

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

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

1.1 Application background

The present registration report concerns the evaluation of TRADI-AGRI's application submitted on 14/08/2015 to market TRADIANOL DUO (1.31077.00) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2015-2284 and 2016-3472) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009³, the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")⁴. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of TRADIANOL DUO (1.31077.00) have been made using endpoints agreed in the EU peer reviews of glyphosate and dicamba . It also includes assessment of data and information related to TRADIANOL DUO (1.31077.00) where those data have not been considered in the EU peer review process.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU)

¹ COMMISSION IMPLEMENTING REGULATION (EU) 2017/2324 of 12 December 2017, renewing the approval of the active substance glyphosate in accordance with Regulation (EC) N°1107/2009 of the European Parliament and the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) N°540/2011.

² COMMISSION IMPLEMENTING REGULATION (EU) 1100/2011 of 31 October 2011 amending implementing regulation (EU) N° 540/2011 as regards the conditions of approval of the active substances dicamba, difenoconazole, and imazaquin.

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 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](#)

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No 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of TRADIANOL DUO (1.31077.00).

1.2 Letters of Access

The applicant has provided a letter of access for active substance dicamba. This letters of access is available upon request.

After renewal of the active substance glyphosate, no access has been provided to the active substance glyphosate via letter of access or acceptable data matching table.

1.3 Justification for submission of tests and studies

Justification not submitted by the applicant.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of TRADIANOL DUO (1.31077.00), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	1.31077.00
Product name in MS	TRADIANOL DUO
Authorisation number	N/A : no marketing authorisation granted
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	TRADI-AGRI
Active substance(s) (incl. content)	glyphosate, 180 g/L dicamba, 40 g/L
Formulation type	Soluble concentrate [SL]
Packaging	N/A : not registered in France

⁵ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

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Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for TRADIANOL DUO (1.31077.00) resulted in the decision **to refuse the authorisation**.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

N/A : no marketing authorisation granted

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

N/A : no marketing authorisation granted

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

N/A : no marketing authorisation granted

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017⁶ provides that:

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

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

⁶ 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>

appendix 3 of the above-mentioned French Order.

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

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

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁹ is to supply “minor” crops with registered plant protection products.

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

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

2.5.1 Restrictions linked to the PPP

N/A : no marketing authorisation granted

2.5.2 Specific restrictions linked to the intended uses

N/A : no marketing authorisation granted

⁷ Avis du 8 octobre 2004 à tous les détenteurs d'autorisations de mise sur le marché pour des spécialités commerciales à base de glyphosate, https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT000000445445

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

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

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2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 1, date: 2019/11/29

PPP (product name/code): TRADIANOL DUO/1.31077.00

Formulation type: SL ^(a, b)

Active substance 1: glyphosate

Conc. of a.s. 1: 180 g/L ^(c)

Active substance 2: dicamba

Conc. of a.s. 2: 40 g/L ^(c)

Applicant: TRADI AGRI

Professional use: ☒

Zone(s): Southern Zone ^(d)

Non-professional use: ☐

Verified by MS: Yes

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method/K ind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Amenities (weed control for non crop areas, parks, gardens, pavement, industrial sites)	F	Monocotyle-dons and dicotyledons	Spray	-	2	(1 spring application + 1 autumn application)	10 L/ha	1800 (glyphosate) 400 (dicamba)	100- 500		Not acceptable (genotoxic potential child resident exposure, child bystander exposure, efficacy, groundwater aquatic organisms, (*)

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

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Remarks table heading:	(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d) Select relevant
	(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c) g/kg or g/l	(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	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
	2 Use official codes/nomenclatures of EU Member States	8 The maximum number of application possible under practical conditions of use must be provided.
	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)	9 Minimum interval (in days) between applications of the same product
	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	10 For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	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.	12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		13 PHI - minimum pre-harvest interval
		14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

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

The product TRADIANOL DUO (1.31077.00) does not contain POE-tallowamines (CAS n° 61791-26-2).

TRADIANOL DUO (1.31077.00) is a soluble concentrate formulation (SL). 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 pale yellow limpid liquid, with a characteristic odour. It is not explosive and has no oxidising properties. The product has no flash point up to 110°C. It has a self-ignition temperature higher than 592°C. In 1% aqueous solution, it has a pH value of 4.69 at 21.2°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed.

The active substance glyphosate contains relevant impurities formaldehyde and N-nitrosoglyphosate.

The concentrations of these impurities during storage of the preparation are below the acceptable limit. 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 soluble concentrate formulation.

3.2 Efficacy (Part B, Section 3)

Considering the submitted data :

The efficacy level of TRADIANOL DUO (1.31077.00) is considered as insufficient for all the claimed uses considering the very low number of valid trials and the spectrum of action limited to 3 weeds.

Glyphosate having an herbicidal activity on all types of plants (known as “total weed killer”), the preparation TRADIANOL DUO (1.31077.00) cannot therefore be considered selective. Given the foliar penetration of glyphosate, the preparation should not be directed to the green parts of crops/non target plants.

The risk of negative impact on adjacent crops is considered as acceptable. Nevertheless, specific attention should be paid to susceptible adjacent crops.

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

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

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Analytical methods for the determination of the active substances dicamba and glyphosate and the relevant impurities (formaldehyde and N-nitrosoglyphosate) in the formulation are available and validated.

3.3.2 Analytical methods for residues

Analytical methods for the determination of the residues of dicamba and glyphosate in plants and in food-stuff of animal origin are not necessary.

Considering the intended uses, analytical methods are available in this dossier or in the Renewal Assessment Report (RAR) and validated for the determination of residues of dicamba in soil, water (surface and drinking) and air.

Analytical methods are available in this dossier or in the Renewal Assessment Report (RAR) and validated for the determination of residues of glyphosate in soil, water (surface and drinking) and air.

3.4 Mammalian toxicology (Part B, Section 6)

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		
AAOEL	Not applicable		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 180 g/L	Spray dilution (used in formulation) 3.6 g/L
	Dermal absorption endpoints %	20%	20%
Oral absorption			20%

Active Substance: Dicamba			
ADI	0.3 mg kg bw/d		EU (2009)
ARfD	0.3 mg/kg bw		
AOEL	0.3 mg/kg bw/d		
AAOEL	Not applicable		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate	Spray dilution

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		(used in formula- tion) 40 g/L	(used in formulation) 0.8 g/L
	Dermal absorption endpoints %	75%	75%
Oral absorp- tion			100%

3.4.1 Acute toxicity

TRADIANOL DUO (1.31077.00) containing 180 g/L glyphosate and 40 g/L dicamba has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.4.2 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”.

No test has been provided by the applicant. Consequently, the genotoxic potential of TRADIANOL DUO (1.31077.00) cannot be finalised.

3.4.3 Operator exposure

Summary of critical use patterns (worst cases):

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Crop type	F/G ¹⁰	Equipment <i>Application method</i>	Maximum application rate kg as /ha	Minimum volume wa- ter (L/ha)
Non crops area	F	Manual Hand held <i>Down-ward spraying</i> [MODOP ZNA]	1.8 kg glyphosate / ha 0.4 kg dicamba / ha	100
	F	Manual Knapsack <i>Down-ward spraying</i> [MODOP ZNA]	1.8 kg glyphosate / ha 0.4 kg dicamba / ha	100
	F	Vehicle mounted <i>Down-ward spraying</i> [MODOP ZNA]	1.8 kg glyphosate / ha 0.4 kg dicamba / ha	100

Considering proposed uses, operator systemic exposure was estimated using the French study from UPI 2009-2010¹¹ dedicated to non-agricultural areas:

Crop	Equipment	PPE and/or working coverall	% AOEL Glyphosate	% AOEL Dicamba
Non crops area	Manual Hand held <i>Down-ward spraying</i>	Working coverall and gloves during mix- ing/loading and application	51.49%	13.79%
	Manual Knap- sack <i>Down-ward spraying</i>	Working coverall and gloves during mix- ing/loading and application	3.58%	0.97%
	Vehicle mounted <i>Downward spraying</i>	Working coverall and gloves during mix- ing/loading and application	37.03%	10.2%

According to the model calculations, it can be concluded that the risk for the operator using TRADIANOL DUO (1.31077.00) is acceptable with a working coverall and gloves during mixing/loading and application.

3.4.4 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 AOEM model. Exposure is estimated to 58.28 % of the AOEL of glyphosate with PPE (work wear).

Exposure is estimated to 15.63 % of the AOEL of dicamba with PPE (work wear).

¹⁰ Open field or glasshouse

¹¹ Studies and models that can be used to estimate operator exposure during the use of plant protection products in non- agricultural areas. Report from expert group « produits phytosanitaires : substances et préparations chimiques » Working group "évaluation de l'exposition des utilisateurs de produits phytopharmaceutiques en zones non agricoles" - June 2011

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

3.4.5 Bystander and resident 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 set¹².

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.”*

Recreational exposure was assessed according to EFSA model with mitigation measures such as a buffer zone of 3 meters and drift reduction technology. **Exposure is estimated to 110% and 48.9% of the AOEL of glyphosate for children and adults, respectively and to 31.2% and 13.6 % of the AOEL of dicamba for children and adults, respectively. It is concluded that there is an unacceptable risk anticipated for recreational exposure.**

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

The assessment of “residues and consumer exposure” section is not necessary. Indeed, intended uses are non crop areas.

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

PEC calculations presented for glyphosate and AMPA were not performed considering the appropriate EU agreed endpoints from the EFSA Journal (2015). Additionally, PEC calculations for dicamba and DCSA do not comply with current guidance, especially regarding their mobility in soil.

Hence, the risk assessment on groundwater contamination cannot be finalised for this preparation, and PEC_{sw} cannot be used for the ecotoxicological risk assessment.

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

3.7 Ecotoxicology (Part B, Section 9)

¹² 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)

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The risk assessment presented for glyphosate and its metabolites were not performed considering the appropriate EU agreed endpoints from the EFSA Journal (2015).

Consequently, the risk assessment cannot be finalised for this product.

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. Among the intended uses, this information is not considered necessary for some uses made highly anthropized area (weed control of industrial sites).

3.8 Relevance of metabolites (Part B, Section 10)

Not relevant.

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

N/A : no marketing authorisation granted.

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

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

5.1.1 Post-authorisation monitoring

N/A : no marketing authorisation granted .

5.1.2 Post-authorisation data requirements

N/A : no marketing authorisation granted

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Appendix 1 Copy of the product authorisation



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 réglementaire,

Vu la demande d'autorisation de mise sur le marché et la demande associée du produit phytopharmaceutique
TRADIANOL DUO

de la société

TRADI-AGRI SA

enregistrées sous les

n°2015-2284, 2016-3472

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 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.

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Informations générales sur le produit	
Nom du produit	TRADIANOL DUO
Type de produit	Produit de référence
Titulaire	TRADI-AGRI SA 55, rue Raspail CS 70104 92594 LEVALLOIS-PERRET CEDEX France
Formulation	Concentré soluble (SL)
Contenant	242,9 g/L - glyphosate sel d'isopropylamine (équivalent à 180 g/L de glyphosate) 48,2 g/L - dicamba sel de diméthylamine (équivalent à 40 g/L de dicamba)
Numéro d'intrant	461-2015.01
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)



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)
11015904 Usages non agricoles* Désherb. total	10 L/ha	2/an	Non applicable
Motivation du refus : L'usage revendiqué correspondant aux nouveaux libellés « Usages non agricoles * Désherb.total * Sites Indust. et autres infrastructures » et « Traitements généraux * Désherbage * Zones non cult. » est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également refusé en raison d'un risque d'effet nocif pour les résidents enfants et les personnes présentes enfants. L'usage est également refusé en raison du niveau d'efficacité insuffisant.			
11015903 Usages non agricoles* Désherbage* All. PJT, Cimet., Voies	10 L/ha	2/an	Non applicable
Motivation du refus : L'usage revendiqué correspondant au nouveau libellé « Usages non agricoles * Désherbage * PJT », est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également refusé en raison d'un risque d'effet nocif pour les résidents enfants et les personnes présentes enfants. L'usage est également refusé en raison du niveau d'efficacité insuffisant.			

TRADIANOL DUO
AMM n°.

1.31077.00 / TRADIANOL DUO
Part A - National Assessment
FRANCE

Appendix 2 Copy of the product label

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

TRADIANOL DUO			
NOM COMMERCIAL : TRADIANOL DUO N° D'AMM : ... DETENTEUR DE L'AMM : Tradi-Agri – 47, rue Raspail – 92594 Levallois-Perret cedex TYPE D'ACTION : Herbicide (HRAC G, O) FORMULATION : Concentré soluble (SL) COMPOSITION : 180 g/L (16,38%) glyphosate (sous forme de sel de diisopropylamine 242,90 g/L – 22,10%) 40 g/L (3,64%) dicamba (sous forme de sel de diméthylamine 48,16 g/L – 4,38%)			
Catégories et doses d'emploi			
Usages autorisés	Doses homologuées	Nombre maximum d'application	Zone non traitée (ZNT)
Désherbage allées de parcs, jardins, trottoirs, cimetières, voies	10 L/ha	2	5 mètres
<ul style="list-style-type: none"> L'utilisation de ce produit sur ses usages autorisés n'est recommandée que sur les cultures et cibles indiquées dans le tableau ci-dessus. TRADI-AGRI décline en conséquence toute responsabilité en cas d'utilisation du produit sur des cultures ou pour des cibles non recommandées. Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur. Délai de rentrée : 6 heures. 			
Définition			
TRADIANOL DUO est une spécialité herbicide à base de glyphosate et de dicamba particulièrement conseillé pour la destruction des plantes herbacées ou ligneuses. Le glyphosate est absorbé par les parties vertes de la plante. Le dicamba est absorbé par les feuilles et les racines des végétaux et peut persister dans le sol jusqu'à trois mois en fonction du type de sol.			
Périodes et doses d'emploi			
TRADIANOL DUO est un désherbant à persistance d'action (de 1 à 3 mois selon les conditions climatiques) s'utilisant en pulvérisation en période de végétation active pour le désherbage des zones non cultivées : allées de parcs, jardins, trottoirs, cimetières, voies. Il est recommandé d'utiliser au maximum 300 litres d'eau à l'hectare en pulvérisation à faible pression. <ul style="list-style-type: none"> Sur les mauvaises herbes annuelles : traiter au stade jeune. Sur vivaces : traiter sur adventices bien développées. Plantes herbacées : en début de floraison. Plantes ligneuses : préférer les traitements d'automne. 			
Préparation			
Verser la quantité nécessaire de TRADIANOL DUO dans la cuve du pulvérisateur à demi remplie d'eau, puis compléter le remplissage en agitant.			
Bonnes pratiques phytosanitaires			
<ul style="list-style-type: none"> Traiter en l'absence de vent et de risque de pluie dans un délai de 6 heures. 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. Eviter tout traitement à base de glyphosate sur les fossés en eau ou à proximité. Ne pas utiliser dans les serres ou tunnels plastiques. Ne pas toucher le feuillage ou les parties vertes des plantes cultivées, ne pas appliquer sur gazon. En cas de contact avec le produit, couper les parties touchées. Toujours conserver le produit dans son emballage d'origine. Le stocker dans un local réservé à cet usage, frais, sec, bien ventilé et fermant à clé, à l'abri du gel et de la chaleur. Réservé à un usage professionnel. 			
Elimination du produit et de l'emballage :			
<ul style="list-style-type: none"> Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux. Réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et rincer le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Eliminer les emballages vides via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR. Eliminer les fonds de cuve conformément à la réglementation en vigueur. 			
TRADIANOL DUO Contient : glyphosate et dicamba SC – Sans Classement P260 Ne pas respirer les aérosols. SP1 Ne pas polluer l'eau avec le produit ou son emballage. [Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.] Spe3 Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente. EUH401 Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.		Distribué par : TRADI-AGRI 47, rue Raspail - 92594 Levallois-Perret cedex Tél. : 01 41 06 90 00 – Fax : 01 41 06 90 01 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. Consultez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous les 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. Pour les données issues de cultures protégées avec cette spécialité et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur.	
Premiers soins : <ul style="list-style-type: none"> Enlever immédiatement les vêtements contaminés par le produit. Après inhalation : Donner de l'air frais. Après contact avec la peau : Laver immédiatement et abondamment à l'eau et au savon. Bien rincer. Après contact avec les yeux : Rincer les yeux pendant plusieurs minutes, sous l'eau courante en écartant bien les paupières. Après ingestion : Rincer la bouche à l'eau. Ne pas faire vomir. Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité. 		La fiche de données de sécurité peut être obtenue gratuitement sur Internet à l'adresse www.quickfds.com .	
EMB : 49215 F Date de fabrication : voir sur l'emballage			