

REGISTRATION REPORT

Part A

Risk Management

Product code: COM 503 01 H GR

**Product name: FLORANID GAZON DESHERBANT
PRO**

Active substances:

2,4-D 7 g/kg

dicamba 1 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(Authorisation renewal according to Art. 43)

Applicant: COMPO France S.A.S.

Date: 2023/01/09

Table of Contents

1	DETAILS OF THE APPLICATION.....	4
1.1	APPLICATION BACKGROUND.....	4
1.2	ACTIVE SUBSTANCE APPROVAL.....	4
1.3	REGULATORY APPROACH.....	6
1.4	DATA PROTECTION CLAIMS.....	7
1.5	LETTER(S) OF ACCESS.....	7
2	DETAILS OF THE AUTHORISATION.....	8
2.1	PRODUCT IDENTITY.....	8
2.2	CLASSIFICATION AND LABELLING.....	8
2.2.1	<i>Classification and labelling under Directive 99/45/EC.....</i>	<i>8</i>
2.2.2	<i>Classification and labelling in accordance with Regulation (EC) No 1272/2008.....</i>	<i>8</i>
2.2.3	<i>Other phrases in compliance with Regulation (EU) No 547/2011.....</i>	<i>9</i>
2.2.4	<i>Other phrases linked to the preparation.....</i>	<i>9</i>
2.3	PRODUCT USES.....	10
3	RISK MANAGEMENT.....	11
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	11
3.1.1	<i>Physical and chemical properties.....</i>	<i>11</i>
3.1.2	<i>Methods of analysis.....</i>	<i>11</i>
3.1.3	<i>Mammalian Toxicology.....</i>	<i>11</i>
3.1.4	<i>Consumer exposure.....</i>	<i>14</i>
	<i>Given the proposed use, no exposure of consumers is anticipated.</i>	<i>14</i>
3.1.5	<i>Environmental fate and behaviour.....</i>	<i>14</i>
3.1.6	<i>Ecotoxicology.....</i>	<i>15</i>
3.1.7	<i>Efficacy.....</i>	<i>15</i>
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT.....	17
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING.....	17
3.4	FURTHER INFORMATION TO PERMIT A DECISION TO BE MADE OR TO SUPPORT A REVIEW OF THE CONDITIONS AND RESTRICTIONS ASSOCIATED WITH THE AUTHORISATION.....	17
3.4.1	<i>Post-authorisation monitoring.....</i>	<i>17</i>
3.4.2	<i>Post-authorisation data requirements.....</i>	<i>17</i>
3.4.3	<i>Label amendments.....</i>	<i>17</i>
	APPENDIX 1 – COPY OF THE FRENCH DECISION.....	18
	APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT.....	24
	APPENDIX 3 – LETTER(S) OF ACCESS.....	26

zRMS NOTE

In order to comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, the risk assessment conclusions only applies for the active substance 2,4-D following its renewal of approval.

PART A – Risk Management

The company COMPO France S.A.S. has requested renewal of marketing authorisation in France for the product FLORANID GAZON DESHERBANT PRO ¹ (marketing authorisation n°2150968; product code: COM 503 01 H GR), containing 7 g/kg 2,4-D and 1 g/kg dicamba for use as a herbicide and a fertiliser.

The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to FLORANID GAZON DESHERBANT PRO where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of FLORANID GAZON DESHERBANT PRO have been made using endpoints agreed in the EU peer reviews of both 2,4-D and dicamba.

This document describes the specific conditions of use and labelling required for France for the registration of FLORANID GAZON DESHERBANT PRO (COM 503 01 H GR).

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

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

Appendix 3 of this document contains 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 COMPO France S.A.S.'s application to continue to market FLORANID GAZON DESHERBANT PRO (COM 503 01 H GR) in France as a herbicide and a fertiliser (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 renewal of authorisation of this product in France and in other MSs of the Southern zone after re-approval of the active substance 2,4-D.

1.2 Active substance approval

2,4-D

Commission Implementing Regulation (EU) 2015/2033 of 13 November 2015 renewing the approval of the active substance 2,4-D 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.

Specific provisions of Regulation (EU) No 2015/2033 were as follows:

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 2,4-D, 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 risk to aquatic organisms, terrestrial organisms and consumers in cases of uses above 750 g/ha.

Conditions of use shall include risk mitigation measures, where appropriate.

The notifier shall submit to the Commission, the Member States and the Authority:

- (1) confirmatory information in the form of the submission of the complete study results from the existing extended one-generation study;

¹ An identical formulation, for non-professional use, is FLORANID GAZON DÉSHERBANT S 15 5 8 3 (marketing authorisation n° 7700706)

(2) confirmatory information in the form of the submission of the Amphibian Metamorphosis Assay (AMA) (OECD (2009) Test No 231) as to verify the potential endocrine properties of the substance.

The information set out in point (1) shall be submitted by 4 June 2016 and the information set out in point (2) by 4 December 2017.

An EFSA conclusion is available (EFSA Journal 2014; 12(9):3812).

A review report is available in the form of a Revised Renewal report (SANCO/11961/2014 Rev 4 final 6 October 2017).

Dicamba

Commission Implementing Regulation (EU) No 1100/2011 of 31 October 2011 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances dicamba, difenoconazole, and imazaquine.

Specific provisions of Regulation (EU) No 540/2011 were as follows:

PART A

Only uses as herbicide may be authorised.

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dicamba, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.

Specific provisions of Regulation (EU) No 1100/2011 were to amend Part B as follows:

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dicamba, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011 shall be taken into account.

In this overall assessment Member States shall pay particular attention to the protection of non-target plants.

Conditions of use shall include adequate risk mitigation measures, where appropriate.

The notifier shall submit confirmatory information as regards:

- (a) the identification and quantification of a group of soil transformation products formed in a soil incubation study;
- (b) the potential for long range transport through the atmosphere.

The notifier shall submit this information to the Member States, the Commission and the Authority by 30 November 2013.

An EFSA conclusion is available (EFSA Journal 2011; 9(1): 1965) plus the outcome of the consultation on confirmatory data used in the risk assessment (Efsa technical report, 1 April 2016).

A review report is available (SANCO/829/08 – final rev. 2 12 July 2016).

1.3 Regulatory approach

The present application (2016-1252 and 2021-4742) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)² 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”)³ – the highest application rates applied for in 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 2017⁴ provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless otherwise 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, non-spraying 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 1107/2009⁵, 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 on the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011⁶, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁷ 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 “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 extrapolation⁸ 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.

² French Food Safety Agency, Afssa, before 1 July 2010

³ 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

⁴ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

⁵ 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

⁶ 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

⁷ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

⁸ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

Finally, the French Order of 20 November 2021⁹ on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive culture¹⁰ when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

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 FLORANID GAZON DESHERBANT PRO (COM 503 01 H GR), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

The applicant has provided the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. The applicant has provided Letters of Access for both active substances.

⁹ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

¹⁰ List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	FLORANID GAZON DESHERBANT PRO (COM 503 01 H GR)
Authorisation number	2150968
Function	Herbicide, fertiliser
Applicant	COMPO France S.A.S.
Composition	7 g/kg 2,4-D 1 g/kg dicamba
Formulation type (code)	Granule [GR]
Packaging	<ul style="list-style-type: none"> - folding box with plastic bag in PE (polyethylene)/PA(polyamide)/PE, containing 1.0 kg, 1.5 kg, 3.0 kg or 6.0 kg. - multi-layer film bag in PE/PA/PE, containing 0.5 kg. - multi-layer film bag with and without zip-closure and handheld in laminate PE/PA/PE (40/30/40), UV-stabilised, containing 7.5 kg, 12 kg, 15 kg or 21 kg. - free-standing bags in laminate PET/PET/PE containing 14 kg or 21 kg, or in laminate PET (polyethylene terephthalate)/OPA (oriented polyamide)/LDPE (low-density polyethylene), containing 6 kg, 7.5 kg or 12 kg. - buckets (round or rectangular, with lid and plastic handle) in polypropylene (PP), containing 5.0 kg, 6.0 kg, 7.5 kg or 10 kg.

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

Physical hazards	-	
Health hazards	-	
Environmental hazards	-	
Hazard pictograms	-	
Signal word	-	
Hazard statements	-	-
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH208	Contains 2,4-D. May produce an allergic reaction

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

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe 6	To protect birds and wild mammals, remove spillages.
SPe 3	To protect aquatic organisms, respect a vegetated buffer zone of 5 metres to surface water bodies ¹¹ .

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment ¹² : refer to the Decision in Appendix 1 for the details.
The applicant is required to comply with the current applicable standard for clothing-type PPE (ISO EN 27065) ¹³ .
Re-entry period ¹⁴ : Not applicable (spreading of granules).
Pre-harvest interval ¹⁵ : Not applicable.
- Other mitigation measures:
The label may include the following recommendations: The phrase “EUH208 Contains 2,4-D. May produce an allergic reaction” may appear. The label must reflect the conditions of authorisation.

¹¹ to limit the risk of eutrophication

¹² If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

¹³ Protective clothing – Performance requirements for protective clothing worn by operators applying pesticides and for re-entry workers. EN ISO 27065:2017

¹⁴ The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

¹⁵ According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

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

date: 2023-01-09

PPP (product name/code) **FLORANID GAZON DESHERBANT**
active substance 1 **2,4-D**
active substance 2 **dicamba**

Formulation type: **GR**
Conc. of a.s. 1: **7 g/kg**
Conc. of a.s. 2: **1 g/kg**

Applicant: **COMPO France S.A.S.**
Zone(s): **Southern EU**
Verified by MS: **yes**

professional use ☒
non-professional use ☐

1	2	3	4	5	6	7	8	10	11	12	13	14	15
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I (a)	Pests or Group of pests controlled (b) (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days) (g)	Remarks: e.g. g safener/synergist per ha (h)	zRMS Conclusion
					Method / Kind (c-e)	Timing / Growth stage of crop & season (f)	Max. number (min. interval between applications) a) per use b) per crop/ season	kg 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	France	Lawn, established (NNNZW)	F	Dicotyledonous weeds (TTTDD)	Spreading	During the growing season (between 1 May and 31 July)	a) 1 b) 1	a) 300 b) 300	a) 2,4-D: 2100 dicamba: 300 b) 2,4-D: 2100 dicamba: 300	N/A	N/A	Professional uses. (non-agricultural zones: parks and municipal gardens, sports grounds, golf courses, cemeteries) Because of the presence of dicamba, it is advisable not to use grass cuttings as mulch or compost.	Acceptable

Remarks: (a) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(b) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(c) All abbreviations used must be explained
(d) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(e) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

(f) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(g) PHI - minimum pre-harvest interval
(h) Remarks may include: Extent of use/economic importance/restrictions
N/A: not applicable.

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

FLORANID GAZON DESHERBANT PRO (COM 503 01 H GR) is a granule formulation (GR). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is light beige granules, with an amine-like odour. It is not explosive, has no oxidising properties and is not flammable. It has a self-ignition temperature above 400 °C. In 1 % aqueous solution, it has a pH value of 6.8 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 substances' content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in PE-laminated paper bags. As the formulation is GR, all packaging may be considered acceptable. The technical characteristics are acceptable for a GR formulation.

The formulation is not classified for the physico-chemical aspect.

3.1.2 Methods of analysis

Analytical methods for the determination of the active substances in the formulation are available and validated. As the active substance dicamba does not contain any relevant impurity, no pertinent analytical method is required.

Nevertheless the relevant impurities of the active substance 2,4-D (dioxins and furans expressed as TCDD equivalent toxic < 10 ppb) cannot be formed during the production and storage of the product. The contents of its relevant impurities are below the specifications in the active substance. The analytical methods for the determination of these impurities in the technical active substance are validated. However, no analytical method for the determination of these relevant impurities has been submitted for the product and confirmation of the applicability of the method for the technical a.s. to the product is therefore required post-authorisation.

Analytical methods are available in the Renewal Assessment Report (RAR) and validated for the determination of residues of dicamba and 2,4-D in soil, water (surface and drinking) and air.

Analytical methods for the determination of residues of dicamba and 2,4-D in foodstuffs of plant and animal origin are not necessary.

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

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active substance: 2,4-D		
ADI	0.02 mg/kg bw/d	EU (2017 ¹⁶)

¹⁶ Revised Renewal report for the active substance 2,4-D; SANCO/11961/2014 Rev 5, 6 October 2017: "On 6 October 2017, the Standing Committee on Plant, Animals, Food and Feed took note of the revision of this review report after the amendment by EFSA of the human reference toxicological endpoints.

That amendment has been considered appropriate in the light of the further consideration by the peer review experts of studies common to the evaluation of the active substances 2,4-D and 2,4-DB (of which 2,4-D on its turn is a major metabolite). The current revision of the renewal report has been carried out in line with the Guidance document on the evaluation of new active substance data post approval.

The following reference values have been finalised as part of this evaluation:

ADI: 0.02 mg/kg bw per day,

ARfD: 0.3 mg/kg bw,

AOEL: 0.02 mg/kg bw per day.

ARfD	0.3 mg/kg bw/d		
AOEL	0.02 mg/kg bw/d <i>No correction for oral absorption needed.</i>		
AAOEL	- (not set)		
Dermal absorption	Based on an <i>in vitro</i> human study performed on a similar formulation:		
		Concentrate (tested) 2.2 g/kg	Diluted formulation (tested)
	<i>In vitro</i> (human) %	0.5	N/A (ready-to-use product)
		Concentrate (used in formulation) 7 g/kg	Spray dilution (used in formulation)
	Dermal absorption endpoints %	0.5	N/A (ready-to-use solid formulation)
Oral absorption	> 90 %		

Log Pow at 25 °C (2,4-D) = -1.01 (pH 9) at 2.70 (pH 1) (< 4)

MW (2,4-D) = 221 (< 500)

Vapour pressure (Vp): 2.3 x 10⁻⁵ Pa at 25 °C

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 <i>No correction for oral absorption</i>		
AAOEL	- (not set)		
Dermal absorption	Based on an <i>in vitro</i> human study performed on a similar formulation:		
		Concentrate (tested) 1 g/kg	Diluted formulation (tested)
	<i>In vitro</i> (human) %	9	N/A (ready-to-use solid formulation)
		Concentrate (used in formulation) 1 g/kg	Spray dilution (used in formulation)
	Dermal absorption endpoints %	9	N/A (ready-to-use preparation)
Oral absorption	> 86 %		

Log Pow (dicamba) = -1.9 (pH 8.9) at -0.55 (pH 5) (< 4)

MW (dicamba) = 221 (< 500)

Vp: 1.67 x 10⁻³ Pa (extrapolated) at 25 °C

3.1.3.1 Acute Toxicity

At the time of adoption of revision 4 of this document, some Member States had already renewed authorisations according to Article 43 of Regulation (EC) No 1107/2009 or granted new authorisations based on endpoints which are no longer valid. With a view to harmonise the implementation of the new endpoints, due to this exceptional circumstance, Member States should review the authorisations referred to above according to the new endpoints by 22 March 2019. Article 44 should apply and applicants may be asked to update their dossiers, as appropriate. Member States can take advantage of the standard zonal procedure for the evaluation of plant protection products."

FLORANID GAZON DESHERBANT PRO (COM 503 01 H GR), containing 7 g/kg 2,4-D and 1 g/kg dicamba, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin and eye and is not a skin sensitiser.

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	-
Hazard pictograms:	-
Signal word:	-
Hazard statement(s):	Not classified.
Precautionary statement(s):	<i>For the P phrases, refer to the extant legislation.</i>
Additional labelling phrases:	“Contains 2,4-D. May produce an allergic reaction [EUH208]”.

Special rule for labelling of plant protection product (PPP):	
<u>Nature of protective clothing and PPE for the operator:</u> <ul style="list-style-type: none"> • Mixing/loading <ul style="list-style-type: none"> - Nitrile gloves certified EN 374-3; - Working coverall 65 % polyester / 35 % cotton; minimum 230 g/m²; - Long-sleeved apron, Category III Type PB3 worn over the coverall proposed above; • Application <ul style="list-style-type: none"> - Disposable nitrile gloves certified EN 374-2 in the case of an intervention on application equipment; - Working coverall 65 % polyester / 35 % cotton; minimum 230 g/m²; • Cleaning <ul style="list-style-type: none"> - Nitrile gloves certified EN 374-3; - Working coverall 65 % polyester / 35 % cotton; minimum 230 g/m²; - Long-sleeved apron, Category III Type PB3 worn over the coverall proposed above. 	
<u>Nature of protective clothing and PPE for the worker:</u> N/A (spreading of granules).	
Re-entry period: Not applicable (spreading of granules).	
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH208	Contains 2,4-D. May produce an allergic reaction.

3.1.3.2 Operator Exposure

Only 2,4-D is subject to the renewal according to Art. 43, and as such has been assessed.

Summary of critical use patterns (worst cases):

Crop type	F/G ¹⁷	Equipment <i>Application method</i>	Maximum application rate kg a.s./ha	Minimum volume water (L/ha)
Lawn, established	F	Spreader <i>Downward application</i>	300 kg/ha (30 g/m ²) <i>2100 g 2,4-D/ha</i> <i>300 g dicamba/ha</i>	N/A (ready-to-use product)

¹⁷ Open field or glasshouse

Considering the proposed use, operator systemic exposure was estimated using the EFSA model¹⁸:

Crop	Equipment	PPE and/or working coverall	% AOEL 2,4-D
Lawn, established	Manual – Manual application of granules	no PPE	8605
		Gloves and body PPE for mixing and loading, and application	167
	Vehicle-mounted equipment (granules)	no PPE	292
		Gloves and body PPE for mixing and loading, and application	193

Based on the estimation of the exposure done with the EFSA model, the risk for operator is unacceptable when application of FLORANID GAZON DESHERBANT PRO (COM 503 01 H GR) is performed with vehicle-mounted equipment as well as by manual application, without gloves and body PPE during mixing, loading and application operations. The risk for operator is acceptable with gloves and body PPE during mixing, loading and application operations.

3.1.3.3 Bystander Exposure

Due to the application technique for FLORANID GAZON DESHERBANT PRO (COM 503 01 H GR), where the granular formulation is applied directly on to the soil, no drift is expected. In addition, 2,4-D is not volatile in this formulation type and the formulation is a solid non-dusty granule. Consequently, it is considered that it is unnecessary to assess the risk of bystander exposure.

3.1.3.4 Resident Exposure

For the same reasons as for bystanders, it is considered unnecessary to assess the risk of resident exposure.

3.1.3.5 Worker Exposure

FLORANID GAZON DESHERBANT PRO (COM 503 01 H GR) is a solid non-dusty granule applied directly to the soil.

Worker exposure following spray application is usually through contact with dislodgeable foliar or plant residues; this scenario is not relevant to the use of this product, where pellets are applied directly to the soil.

Professional users re-entering the field after application are considered not to be exposed by oral, dermal or inhalational routes. Therefore, it can be concluded that there is no unacceptable risk anticipated for the worker when re-entering the area treated with FLORANID GAZON DESHERBANT PRO (COM 503 01 H GR).

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

3.1.4 Consumer exposure

Given the proposed use, no exposure of consumers is anticipated.

3.1.5 Environmental fate and behaviour

¹⁸ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

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.

To comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, this risk assessment report for the sections “Fate and behaviour in the Environment/Ecotoxicology” only applies for the active substance 2,4-D following its renewal of approval. For the other active substance, provisions of the initial authorisation remain.

The PEC values of 2,4-D 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.

PEC_{soil} and PEC_{sw} values derived for the active substance and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PEC_{gw} for 2,4-D and its metabolites 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.

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

3.1.6 Ecotoxicology

To comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, this risk assessment report for the section “Ecotoxicology” only applies for the active substance 2,4-D following its renewal of approval. For other active substance (dicamba), provisions of the initial authorisation remain.

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review for active substances and their metabolites were used for the intended use patterns.

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

FLORANID GAZON DESHERBANT PRO (COM 503 01 H GR) is used as herbicide and fertiliser. Thus, a risk of eutrophication of aquatic ecosystems due to phosphorous cannot be excluded. In view of their national requirements, Member States may recommend a vegetated buffer zone of 5 metres to protect the aquatic ecosystems from eutrophication following use of FLORANID GAZON DESHERBANT PRO.

3.1.7 Efficacy

Considering the data submitted:

- ✓ The efficacy of FLORANID GAZON DESHERBANT PRO (COM 503 01 H GR) is considered satisfactory for the requested use.
- ✓ The selectivity of FLORANID GAZON DESHERBANT PRO (COM 503 01 H GR) is considered satisfactory for the requested use, on established lawns only. Due to the presence of dicamba, it is advisable not to use grass cuttings as mulch or compost.

-
- ✓ The risk of negative impact on propagation is considered acceptable.
 - ✓ The risk of negative impact on succeeding and adjacent crops is considered acceptable. Nevertheless, specific attention should be paid to susceptible adjacent crops and to the sowing/planting of succeeding and replacement crops.
 - ✓ The risk of resistance developing or appearing to 2,4-D and dicamba is considered low and does not require monitoring for the requested use.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **authorisation can be granted**, as proposed in Appendix 1 – Copy of the product Decision.

Based on the available information submitted by the applicant, the risk assessment for operators cannot be finalised.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- Confirmation of the applicability to the product of the analytical method for the determination of the relevant impurities in the technical active substance 2,4-D (dioxins and furans) expressed as TCDD equivalent toxic < 10 µg/kg).

3.4.3 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 de renouvellement de l'autorisation de mise sur le marché d'un produit mixte et à la demande associée

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

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

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

*Vu les demandes de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active 2,4-D, et de modification de l'autorisation du produit mixte **FLORANID GAZON DESHERBANT PRO***

de la société COMPO EXPERT France

enregistrées sous les n° 2016-1252 et 2021-4742

Vu les conclusions de l'évaluation de l'Anses du 19 octobre 2020 et du 25 octobre 2022, relatives à la demande de modification de l'autorisation de mise sur le marché du produit mixte,

La mise sur le marché du produit mixte désigné ci-après **est renouvelée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et son annexe.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

FLORANID GAZON DESHERBANT PRO
AMM n° 2150008

Page 1 sur 6

DocuSign Envelope ID: 74026928-2940-4BB8-AEEE-EC25774264F7



Informations générales sur le produit	
Nom du produit	FLORANID GAZON DESHERBANT PRO
Type de produit	Produit de référence (initialement seconde gamme avant le renouvellement)
Titulaire	COMPO EXPERT France 49 Avenue George Pompidou 92593 LEVALLOIS-PERRET France
Formulation	Granulé (GR)
Contenant	7 g/kg - 2,4-D 1 g/kg - dicamba Éléments fertilisants (NPK, MgO, SO ₃) déclarés conformes à une norme d'application obligatoire
Numéro d'intrant	973-2012.01
Numéro d'AMM	2150968
Fonction	Engrais et herbicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 décembre 2024.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) n° 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le 09/01/2023

DocuSigned by:

AE281A855A42454...
Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

FLORANID GAZON DESHERBANT PRO
AMM n° 2150968

Page 2 sur 6

DocuSign Envelope ID: 74026928-2940-4BB8-AEEE-EC25774264F7



ANNEXE : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Sacs multicouches en polyéthylène / polyamide / polyéthylène	500 g ; 1 kg ; 1,5 kg ; 3 kg ; 6 kg ; 7,5 kg ; 12 kg ; 15 kg ; 21 kg
Sacs multicouches en polyéthylène téréphtalate / polyamide orienté / polyéthylène basse densité	6 kg ; 7,5 kg ; 12 kg
Sacs multicouches en polyéthylène téréphtalate / polyéthylène téréphtalate / polyéthylène	14 kg ; 21 kg
Seaux en polypropylène	5 kg ; 6 kg ; 7,5 kg ; 10 kg

Teneurs garanties retenues en éléments fertilisants
Indiquer sur l'étiquette les teneurs (en % sur matière brute) des éléments fertilisants revendiqués : N (et ses différentes formes), P ₂ O ₅ (et ses différentes formes), et K ₂ O soluble dans l'eau, MgO soluble dans l'eau, SO ₃ (et ses différentes formes) conformément à la norme d'application obligatoire qui encadre le produit.
Il est de la responsabilité du détenteur de s'assurer de la conformité à la norme à laquelle il se réfère.

Classification du produit
La classification retenue est la suivante :
Sans classement.
EUH208 : Contient du 2,4-D. Peut produire une réaction allergique.
Pour les phrases P se référer à la réglementation en vigueur.
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.

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Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
18505901 Gazons de graminées* Désherbage	300 kg/ha	1/an	-	Non applicable	DVP 5	-	-	Non concerné
Uniquement sur gazons installés. Application de mai à juillet.								

DVP : Dispositif Végétalisé Permanent.

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles ;
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage) ;
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'un épandage manuel

• pendant l'épandage

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Protections respiratoires : demi-masque équipé d'un filtre P2 ou FP2.

Dans le cadre d'une application effectuée à l'aide d'un tracteur équipé d'un microgranulateur :

• pendant le chargement du matériel d'épandage

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;
- Protections respiratoires : demi-masque équipé d'un filtre P2 ou FP2.

• pendant l'épandage

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique en cas d'intervention sur semoir, épandeur à engrais ou microgranulateur ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Protections respiratoires : demi-masque équipé d'un filtre P2 ou FP2.

• pendant le nettoyage du matériel d'épandage

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité.

Délai de rentrée en application de l'arrêté du 4 mai 2017 :

- 6 heures.

FLORANID GAZON DESHERBANT PRO
AMM n° 2150968

Page 5 sur 6

DocuSign Envelope ID: 74026928-2940-4BB8-AEEE-EC25774264F7



Protection de l'environnement (milieux, faune et flore)

Protection de l'eau

- SP 1 : 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.

Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau.

- SPe 6 : Pour protéger les oiseaux et les mammifères sauvages, récupérer tout produit accidentellement répandu.

Le produit peut être utilisé sur les usages autorisés, conformément aux conditions d'emploi antérieures à la présente décision pendant une période de 6 mois.

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- Pour prévenir tout risque éventuel de phytotoxicité, préciser les conditions optimales d'implantation des cultures suivantes ou de remplacement.
- Pour prévenir tout risque éventuel de phytotoxicité, préciser les conditions optimales d'application par rapport aux cultures adjacentes.
- Ce produit est un produit mixte : engrais (NPK, MgO, SO₃) conforme à une norme d'application obligatoire (à rappeler) et herbicide.
- Le produit ne doit pas être dirigé vers les cultures ornementales adjacentes au gazon.
- En raison de la présence de dicamba, il est conseillé de ne pas utiliser les déchets de tonte comme mulch ou compost.

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

	<p>20 kg</p>
<p>Floranid® Gazon Désherbant Pro Engrais gazon à longue durée d'action avec désherbant sélectif gazon de graminées incorporé.</p> <p>Propriétés :</p> <ul style="list-style-type: none"> • Qualité et performance • L'Isodur® contenu dans Floranid® Gazon Désherbant Pro assure une nutrition progressive et régulière du gazon pendant 3 à 4 mois. C'est la seule forme d'azote à libération lente totalement disponible pour la pelouse. • Grâce à la complémentarité de ses deux substances actives, qui agissent à la fois par les feuilles et par les racines, les mauvaises herbes sont détruites 4 à 6 semaines après application. <p>Environnement</p> <ul style="list-style-type: none"> • Fertilise et désherbe le gazon en une seule opération. • Formulation sèche en granulés à épandre avec un épandeur ou à la main (port de gants conseillé). • Contenant de l'Isodur®, Floranid® Gazon Désherbant Pro réduit les pertes par lessivage de l'azote (moins de 0,5 %). Il augmente la capacité du gazon à capter le CO₂ de l'air. • Floranid® Gazon Désherbant Pro bénéficie d'un contrôle strict des matières premières entrant dans sa fabrication. <p>Domaines d'application :</p> <ul style="list-style-type: none"> • Terrains de sport • Parcs et jardins • Départes de golf • Hippodromes <p>Epoque d'utilisation : d'avril à août, par temps « poussant » (température entre 10 °C et 25 °C)</p> <p>Doses d'emploi : 30 g/m² (300 kg/ha) soit 1 sac pour 670 m² - 1 application maximum par an</p> <p>Conseil d'application</p> <ul style="list-style-type: none"> • Appliquer 3 à 4 jours après une tonte. • Par temps sec, arroser la zone traitée dans les 24 à 48 heures. <p>Précautions d'emploi</p> <ul style="list-style-type: none"> • Respecter la dose homologuée. • N'utiliser que sur gazons établis (de plus d'un an). • Eviter d'atteindre les feuilles des plantes (fleurs, arbres et arbustes...) voisines ainsi que de traiter trop près de leurs racines. • Ne pas appliquer en cas de vent, en période de gel ou de sécheresse. • Ne pas confectionner de terreau ou compost avec les déchets de tonte. • Ne pas utiliser les déchets de tonte comme nourriture pour animaux dans l'année suivant l'application. • Sur gazons plantés de bulbes attendre que leur floraison soit finie et leurs feuilles fanées. <p>Nom homologué : Floranid® Gazon Désherbant Pro AMM n°00000000 détenue par COMPO France Granulés (GR) - Engrais avec herbicides. Usage et dose autorisée : gazons de graminées - désherbage : 30 g/m² Maximum 1 application par an</p> <p>Stockage : Conserver uniquement dans l'emballage d'origine, dans endroit frais, sec et à l'abri du gel. Respecter la réglementation en vigueur.</p> <p>ELIMINATION DES EMBALLAGES : Réutilisation interdite. Eliminer les emballages vides via une collecte organisée par un service de collecte spécifique. COMPO France est partenaire de la filière A.D.I.VA.LOR.</p> <p>Composition : 0,1 % (1 g/kg) dicamba (sel de diméthylamine) 0,7 % (7 g/kg) 2,4-D (sel de diméthylamine) Engrais NPK contenant de l'isobutyliène d'urée (Isodur) 15.5.8 (3)</p> <p>15 % d'azote (N) dont : 2,3 nitrrique 8,2 ammoniacal 4,5 de synthèse organique de l'isobutyliène d'urée dont : 0,3 soluble à 20 °C 4,0 insoluble à 20 °C mais soluble à 100 °C 0,2 insoluble à 100 °C</p> <p>5 % d'anhydride phosphorique (P₂O₅) soluble dans le citrate d'ammonium dont 2,5 soluble dans l'eau 8 % d'oxyde de potassium (K₂O) soluble dans l'eau 3 % d'oxyde de magnésium (MgO) soluble dans l'eau 22,5 % d'anhydride sulfurique (S₂O₃) dont 18 soluble dans l'eau</p> <p>Engrais pauvre en chlore</p> <p>Floranid Gazon Désherbant Pro Contient du 2,4-D – Peut déclencher une réaction allergique S2 : Conserver hors de la portée des enfants S13 : Conserver à l'écart des aliments et boissons y compris ceux pour animaux S20/21 : Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation S37 : Porter des gants appropriés S46 : En cas d'ingestion, consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette. SP1 : Ne pas polluer l'eau avec le produit ou son emballage Respectez les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.</p> <p>COMPO France S.A.S. Division COMPO Expert Zone Industrielle 25220 ROCHE LEZ BEAUPRE Tél : 03 81 40 25 25</p> <p>En cas d'urgence, appeler le 15 ou le centre anti-poison puis signalez vos symptômes au niveau Pyl/altitude, n°vert 0 800 887 887 (appel gratuit depuis un poste fixe). Fiche de données de sécurité disponible sur demande ou sur www.quickfms.com</p> <p>IMPORTANT : Respecter 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. 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 Français de l'Agriculture. COMPO France ne saurait être en aucun cas tenu pour responsable des conséquences inhérentes à toute copie de cette étiquette, totale ou partielle, et la diffusion ou l'utilisation non autorisée de cette dernière. NB : nous rappelons que toute utilisation pour un usage non autorisé à la vente et non conforme à nos préconisations est interdite.</p> <p>www.compo-expert.fr Date de fabrication / N° de lot : voir sur emballage</p> <p>20 kg net</p> <p>  </p>	<p></p> <p>Floranid® Gazon Désherbant Pro</p> <p>15.5.8 (+3)</p>



Appendix 3 – Letter(s) of Access

Provided upon request.