

REGISTRATION REPORT

Part A

Risk Management

Product code: COM 503 01 H GR

Product name:

FLORANID GAZON DESHERBANT S 15 5 8 3

Active Substances:

2,4 D, 7 g/kg

dicamba, 1 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: COMPO France SAS

Date: 22/12/2015

Table of Contents

1	DETAILS OF THE APPLICATION.....	3
1.1	APPLICATION BACKGROUND	3
1.2	ACTIVE SUBSTANCE APPROVAL.....	3
1.3	REGULATORY APPROACH.....	4
1.4	DATA PROTECTION CLAIMS.....	5
1.5	LETTERS OF ACCESS.....	5
2	DETAILS OF THE AUTHORISATION	5
2.1	PRODUCT IDENTITY	5
2.2	CLASSIFICATION AND LABELLING	6
2.2.1	<i>Classification and labelling under Directive 99/45/EC</i>	<i>6</i>
2.2.2	<i>Classification and labelling in accordance with Regulation (EC) No1272/2008</i>	<i>6</i>
2.2.3	<i>Other phrases in compliance with Regulation (EU) No 547/2011</i>	<i>6</i>
2.2.4	<i>Other phrases linked to the preparation</i>	<i>7</i>
2.3	PRODUCT USES.....	8
3	RISK MANAGEMENT.....	10
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	10
3.1.1	<i>Physical and chemical properties</i>	<i>10</i>
3.1.2	<i>Methods of analysis</i>	<i>10</i>
3.1.3	<i>Mammalian Toxicology.....</i>	<i>10</i>
3.1.4	<i>Residues and Consumer Exposure</i>	<i>12</i>
3.1.5	<i>Environmental fate and behaviour.....</i>	<i>12</i>
3.1.6	<i>Ecotoxicology.....</i>	<i>13</i>
3.1.7	<i>Efficacy</i>	<i>13</i>
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT	14
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING	14
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	14
3.4.1	<i>Post-authorisation monitoring.....</i>	<i>14</i>
3.4.2	<i>Post-authorisation data requirements</i>	<i>14</i>
3.4.3	<i>Label amendments (see label in Appendix 2):</i>	<i>14</i>
	APPENDIX 1 – COPY OF THE FRENCH DECISION	15
	APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT	20
	APPENDIX 3 – LETTERS OF ACCESS	22

PART A – Risk Management

The company COMPO France SAS has requested marketing authorisation in France for the product FLORANID GAZON DESHERBANT S 15 5 8 3 (formulation code: COM 503 01 H GR), containing 7 g/kg 2,4 D and 1 g/kg dicamba and fertiliser compounds for use as a herbicide and a fertiliser for non-crop lands and for Home and Gardens 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 FLORANID GAZON DESHERBANT S 15 5 8 3 where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of FLORANID GAZON DESHERBANT S 15 5 8 3 have been made using endpoints agreed in the EU peer review 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 S 15 5 8 3.

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 COMPO France SAS's application to market FLORANID GAZON DESHERBANT S 15 5 8 3 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 after approval of dicamba of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

2,4 D

Regulations Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.

Specific provisions of regulation were as follows :

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 2,4-D, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 2 October 2001 shall be taken into account. In this overall assessment Member States:

- must pay particular attention to the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;
- must pay particular attention to the dermal absorption;
- must pay particular attention to the protection of non-target arthropods and must ensure that the conditions

of authorisation include, where appropriate, risk mitigation measures.
There is no definitive EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance. A Review Report is available (2,4-D 7599/VI/97-final 1 October 2001).

dicamba

Regulations Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of regulation 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.
An EFSA conclusion is available (EFSA Journal 2011; 9 (1):1965). A Review Report is available (SANCO/829/08 – rev. 21 07 March 2008).

1.3 Regulatory Approach

The present application (2012-0676) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)¹ 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”)² – 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 12 September 2006³ provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally 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, 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’ assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009⁴, 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

¹ French Food Safety Agency,

² 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

³ <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000425570>

⁴ 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

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 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria. In some cases, the use may be considered “not finalised” based on the data submitted in the dossier, however decision may considers additional criteria.

Finally, the French Order of 26 March 2014⁶ provides that:

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁷ 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 FLORANID GAZON DESHERBANT S 15 5 8 3, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letters 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. A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

2 DETAILS OF THE AUTHORISATION

2.1 Product Identity

Product name (code)	FLORANID GAZON DESHERBANT S 15 5 8 3 (COM 503 01 H GR)
Authorisation number	7700706
Function	Herbicide, fertiliser
Applicant	COMPO France SAS
Composition	2,4 D 7 g/kg + dicamba 1 g/kg
Formulation type (code)	Granule (GR)

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

⁶ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

⁷ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

Packaging	PE/PA/PE (0,5 kg, 1 kg, 1.5 kg, 3 kg, 6 kg, 7.5 kg, 12 kg, 15 kg, 21 kg) PET/OPA/PE-LD (6 kg, 7.5 kg, 12 kg) PET/PET/PE (14 kg, 21 kg) PP (5 kg, 6 kg, 7.5 kg, 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) No1272/2008

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)	-	-

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 non-professional uses only to the following conditions:

Do not discharge into the sink, gutter or any other water hole the non-used container leftovers and the sprayer washing water.
To protect aquatic compartment from eutrophication, do not spread the granules close to a water source (wells, pond, stream, river ...).

2.2.4 Other phrases linked to the preparation

Re-entry period⁸: not applicable (Granule formulation)

Pre-harvest interval⁹: not applicable (Use for managed amenity turf)

The label may include the following recommendations:

- The product should not be directed onto the adjacent ornamental crops.
- Because of the presence of dicamba, it is advisable not to use grass clippings as mulch or compost.

The label must reflect the conditions of authorisation.

The label should indicate that the product is a herbicide and a fertiliser NPK as described by a national or EU regulatory standard.

⁸ The legal basis for this is **Titre I Article 3** of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

⁹ According to the French Order of 12 September 2006, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, evaluated and concluded as safe uses by France as zRMS. When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks. When an use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold. Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2015-12-08

PPP (product name/code): FLORANID GAZON DESHERBANT S 15 5 8 3 / COM 503 01 H GR
active substance 1 2,4 D
active substance 2 dicamba
Applicant: COMPO France SAS
Zone(s): southern ^(d)
Verified by MS: yes

Formulation type: Granule (GR) ^(a, b)
Conc. of as 1: 7 ^(c)
Conc. of as 2: 1 ^(c)
Professional use: ☐
Non-professional use: ☒

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 / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg /ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	IT, PT, FR	Lawn, established (NNNZW)	F	Dicotyledonous weeds (TTTDD)	Strewing	During the growing season (between 1 April to 31 August)	a) max. 1 b) max. 1	Not applicable	300	2,4-D: 2.1 + Dicamba: 0.3	N/A	N/A	Uses on settled grasses only for home gardens and ornamental grasses Application rate: 30 g/m²

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

(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 authorization 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	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	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

The formulation COM 503 01 H GR (FLORANID GAZON DESHERBANT S 15 5 8 3) is a granule. 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 that of pale brown to light green, with a characteristic amine-like odour. It is not explosive and has no oxidizing properties. The product is neither flammable, nor auto-flammable. In aqueous solution (1%), it has a pH value 6.8 at 20°C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C; neither the active ingredients content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in PE bags. Its technical characteristics are acceptable for a granule (GR) formulation.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of active substances in the formulation are available and validated. As the active substances 2,4 D and dicamba do not contain relevant impurity, no analytical method is required.

3.1.2.2 Analytical methods for residues

As the proposed uses are not eaten by humans and animals, no analytical method is required for the determination of both active substances residue in foodstuff of plants and animal origins.

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	0.05 mg kg bw/d	EU agreed endpoint
ARfD	not applicable	EU agreed endpoint
AOEL	0.15 mg/kg bw/d	EU agreed endpoint
Dermal absorption	Based on human data:	
		Concentrate (used in formulation) 7 g/kg
	Dermal absorption endpoints %	2%
Active Substance: Dicamba		
ADI	0.3 mg kg bw/d	EU agreed endpoint
ARfD	0.3 mg/kg bw/d	EU agreed endpoint
AOEL	0.3 mg/kg bw/d	EU agreed endpoint

Dermal absorption	Based on an <i>in vivo</i> rat study and <i>in vitro</i> rat and human study performed on a similar formulation (using a triple pack approach):	
		Concentrate (used in formulation) 1 g/kg
	Dermal absorption endpoints %	0.02%
Active Substance: Sulphate		
ADI	12.5 mg kg bw/d	EU agreed endpoint
ARfD	Not applicable	EU agreed endpoint
AOEL	1.3 mg/kg bw/d	EU agreed endpoint
Dermal absorption	Based on default values:	
		Concentrate (used in formulation) 268 g/kg
	Dermal absorption endpoints %	10%

In the IARC evaluation, published in Lancet Oncology (Volume 16, Issue 8, August 2015, Pages 891–892), a classification of 2,4-D as carcinogen category 2B is proposed.

Pending the availability of the IARC monograph on 2,4-D, the evaluation of FLORANIDE GAZON DESHERBANT S15.5.8.3 is based on the EU evaluation [EFSA Journal 2014;12(9):3812], of 2,4-D approved in Europe by Regulation (EC) N° 1107/2009. Furthermore, the following agencies PMRA (2008) and EPA (2007 et 2012) did not support classification of 2,4-D as a carcinogen.

3.1.3.1 Acute Toxicity

COM 503 01 H GR containing 7 kg/k 2,4-D and 1 g/kg dicamba has a low toxicity in respect to acute oral, inhalation and dermal toxicity, is not irritating to the rabbit skin and eye and is not a skin sensitiser.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G ¹⁰	Equipment	Application rate g/m ²	Spray dilution (L/ha)	Model
lawn	F	Manual spreading	30 g/m ²	Not applicable	French garden studies (UPJ, 2005)

Considering proposed use, operator systemic exposure was estimated using French study 2005 dedicated to amateur use:

Crop	Equipment	PPE and/or working coverall	% AOEL 2,4-D	% AOEL dicamba	% AOEL sulphate
Lawn	Manual spreading	no PPE	1.2%	< 0.01%	25%

¹⁰ Open field or glasshouse

According to the model calculations, it can be concluded that the risk for the operator using COM 503 01 H GR is acceptable without PPE.

3.1.3.3 Bystander Exposure

zRMS considers that resident exposure is not relevant for claimed uses.

Moreover, COM 503 01 H GR is a granular bait formulation; no drift is expected. Therefore, bystander exposure estimation is considered not relevant.

Residential exposure was assessed according to BREAM model. Exposure is estimated to 9.4 %, 0.6% and 25% of the AOEL of 2,4-D, dicamba and sulphate respectively.

A second assessment is to calculate the quantity of granules that a child can ingest per day without unacceptable effects.

For toddlers, the maximum daily intake is about 3 mg dicamba/day assuming a body weight of 10 kg and an ARfD value for dicamba of 0.3 mg/kg bw/day. Considering one granule contains a maximum of 0.00069 mg of dicamba and would be consumed per accidentally ingested granule, a toddler can ingest 4348 granules per day without unacceptable effects.

The maximum daily intake is about 7.5 mg 2,4-D/day assuming a body weight of 10 kg and an ARfD value for 2,4-D of 0.75 mg/kg bw/day. Considering one granule contains a maximum of 0.0051 mg of 2,4-D and would be consumed per accidentally ingested granule, a toddler can ingest 1470 granules per day without unacceptable effects.

In conclusion, there is no unacceptable risk anticipated for toddlers accidentally ingesting a few granules of COM 503 01 H GR.

It is concluded that there is no unacceptable risk of residential exposure or to the bystander after incidental short-term exposure to COM 503 01 H GR.

3.1.3.4 Worker Exposure

COM 503 01 H GR is a granular bait formulation; no work is expected to be practiced after application. Therefore, worker exposure estimation is considered not relevant.

3.1.3.5 Packaging

The composition and the label of the product COM 503 01 H GR are considered acceptable according to French Decree No. 2010-1755 of 30 December 2010 and Orders of 30 December 2010 relating to the use of certain plant protection products by non-professional users.

3.1.4 Residues and Consumer Exposure

The product FLORANID GAZON DESHERBANT S 15 5 8 3 is a herbicide for managed amenity turf, therefore no risk for the consumer is expected.

3.1.5 Environmental fate and behaviour

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

The PEC of dicamba, 2,4-D and their metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU review or agreed in the assessment based on new data provided.

PECsoil and PECsw derived for the active substances and their metabolites are used for the eco-toxicological risk assessment.

For home and garden uses, PECgw for dicamba, 2,4-D and their metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[1]. 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

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. 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, mammals, bees and other non-target arthropods, earthworms and other soil macro-organisms, micro-organisms are acceptable for the intended uses.

FLORANID GAZON DESHERBANT S 15.5.8.3 is used as herbicide and fertiliser. Thus, a risk of eutrophication of aquatic ecosystems due to phosphorous cannot be excluded. Thus, in order to protect aquatic compartment from eutrophication, precaution must be taken to not spread the granules close to a water source (wells, pond, stream, river ...).

For terrestrial non-target plants, precaution must be taken to avoid accidental application outside the treated area.

3.1.7 Efficacy

Considering the data submitted:

- The efficacy of FLORANID GAZON DESHERBANT S15.5.8.3 (COM 503 01 H GR) is considered as satisfactory for the claimed use.
- The selectivity of FLORANID GAZON DESHERBANT S15.5.8.3 (COM 503 01 H GR) is considered as satisfactory on established lawn only.
- The risk of negative impact on adjacent crops and succeeding crops is considered as acceptable. The product should not be directed onto the adjacent ornamental crops. Because of the presence of dicamba, it is advisable not to use grass clippings as mulch or compost.
- The risk of resistance development or appearance is considered as low.

Only weeds found in minimum 3 trials are included in the table.

Efficacy level	Efficacy judgement	Efficacy of COM 503 01 H GR on weeds in lawns	
		Maritime and North-East climate EPPO zones	Mediterranean climate EPPO zone
95 to 100 %	Excellent	-	<i>Hypochoeris radicata</i> <i>Polygonum aviculare</i> <i>Sonchus oleraceus</i>
85 to 94 %	Good	-	<i>Conyza canadensis</i>
70 to 84 %	Medium	<i>Bellis perennis</i> <i>Convolvulus arvensis</i> <i>Plantago lanceolata</i> <i>Ranunculus arvensis</i> <i>Ranunculus repens</i> <i>Rumex acetosa</i> <i>Sonchus arvensis</i> <i>Taraxacum officinale</i> <i>Trifolium repens</i> Weed plants	<i>Taraxacum officinale</i> Weed plants
50 to 69 %	Low	<i>Achillea millefolium</i>	<i>Plantago lanceolata</i>
Below 50 %	Insufficiently	-	-

Crops	Pest	Method of application	Maximum application rate per treatment	Maximum number of application per years	Opinion of France for efficacy section	Remarks
Lawn, established (NNNZW)	Dicotyledonous weeds (TTTDD)	Strewing	300 kg/ha = 30 g/m ² 2,4-D: 2100 g as/ha, Dicamba: 300 g as/ha	1	Acceptable	During the growing season (between 1 April to 31 August)

3.2 Conclusions arising from French assessment

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

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

No further information is required.

3.4.3 Label amendments (see label in Appendix 2):

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



Décision relative à une demande de renouvellement de l'autorisation de mise sur le marché d'un produit mixte

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 changement mineur de composition et de renouvellement de l'autorisation de mise sur le marché du produit mixte **FLORANID GAZON DESHERBANT S 15 5 8 3***

*de la société COMPO FRANCE SAS
enregistrées sous les n°2013-0296 et 2012-0676*

Vu les conclusions de l'évaluation du 14 décembre 2015,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est renouvelée** en France pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

La présente décision s'applique sans préjudice des décisions prises après dépôt de votre demande de réexamen et 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.

La directrice générale adjointe
en charge des produits réglementés

Françoise WEBER

FLORANID GAZON DESHERBANT S 15 5 8 3
AMM n° 7700706

Page 1 sur 6



Informations générales sur le produit	
Nom du produit	FLORANID GAZON DESHERBANT S 15 5 8 3
Type de produit	Produit de référence
Titulaire	COMPO FRANCE SAS Zone Industrielle, 25220 ROCHE LEZ BEAUPRE, FRANCE
Formulation	Granulé (GR)
Contenant	7 g/kg - 2,4-D 1 g/kg - dicamba Eléments fertilisants déclarés conformes à une norme d'application obligatoire
Et	dont la ou les origines et/ou la composition détaillée sont décrites en annexe II, non rendue publique compte tenu de la confidentialité des données.
Numéro d'intrant	7700706
Numéro d'AMM	7700706
Fonctions	Engrais, Herbicide (Produit mixte)
Gamme d'usages	Amateur / emploi autorisé dans les jardins

L'échéance de validité de la présente décision est fixée à trois 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 mars 2016.


A défaut pour le titulaire de demander le renouvellement conformément à l'article 43 du règlement (CE) 1107/2009 dans les trois mois suivant le renouvellement de l'approbation de la substance active, l'autorisation de mise sur le marché est échue de plein droit. Le dépôt d'une demande de renouvellement prolonge de plein droit la durée de validité de l'autorisation de mise sur le marché 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

2 2 DEC. 2015

La directrice générale adjointe
en charge des produits réglementés


Françoise WEBER

FLORANID GAZON DESHERBANT S 15 5 8 3
AMM n° 7700706

Page 2 sur 6



ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation ne peut mettre sur le marché le produit que dans les emballages conditionnés de la façon suivante :	
Emballage	Contenance
Boîte pliante avec sac en polyéthylène basse densité/polyamide/polyéthylène basse densité	1 kg ; 1,5 kg ; 3 kg ; 6 kg
Sac multicouches en polyéthylène basse densité/polyamide/polyéthylène basse densité	0,5 kg
Sac multicouches avec ou sans fermeture de type « zip » en polyéthylène basse densité/polyamide/polyéthylène basse densité, stabilisé UV	7,5 kg ; 12 kg ; 15 kg ; 21 kg
Sac autoportant en polyéthylène téréphtalate/polyamide orienté/polyéthylène basse densité	6 kg ; 7,5 kg ; 12 kg
Sac autoportant en polyéthylène téréphtalate/polyamide orienté/polyéthylène basse densité stratifié	14 kg ; 21 kg
Seau en polypropylène	5 kg ; 6 kg ; 7,5 kg ; 10 kg

Teneurs garanties retenues en éléments fertilisants
Indiquer sur l'étiquette les teneurs (en % MB) 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.
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 avec la classification retenue ci-dessus et de ses éventuelles évolutions.

FLORANID GAZON DESHERBANT S 15 5 8 3
AMM n° 7700706

Page 3 sur 6



Liste des usages autorisés

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application	Délai avant récolte	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
18505901 Gazons de graminées*Désherbage	30 g/m ²	1/an	D'avril à août	Non applicable	-	-	-
Application en jardin d'amateur, sur pelouses ornementales. Application durant la phase de croissance du gazon. Uniquement sur gazons installés							

FLORANID GAZON DESHERBANT S 15 5 8 3
AMM n° 7700706

Page 4 sur 6



Conditions d'emploi du produit

Délai de rentrée :

Non applicable pour ce type d'application (granulés prêts à l'emploi)

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

Protection de l'eau

Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidon non utilisés et les eaux de lavage de l'épandeur.

Protection de la faune

Afin de limiter le risque d'eutrophisation, éviter d'appliquer le produit à proximité d'un point d'eau (puits, bassin, mare, ruisseau, rivière, etc.).

Recommandations relatives à l'étiquette du produit

Il conviendrait de signaler que :

- la préparation ne doit pas être dirigée vers les cultures 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.
- le produit FLORANID GAZON DESHERBANT S 15 5 8 3 est un produit mixte : engrais NPK + Mg + S conforme à une norme d'application obligatoire (à rappeler) et herbicide.

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

ALGOFLASH

**Engrais Gazon
Désherbant**

Nom homologué : FLORANID® Gazon Désherbant S 15.5.8.3
N° d'AMM : 7700706
Défendeur de l'AMM : COMPO France SAS
25220 Roche-Lez-Beaupré

Emploi autorisé dans les jardins
Formulation : Granulés - Engrais avec herbicides
Composition : Engrais NPK contenant de l'isobutylidène diuréé 15.5.8.3 avec herbicides.

15% d'azote (N) total dont :
2.3% d'azote nitrique
8.2% d'azote ammoniacal
4.5% d'azote organique de synthèse de l'isobutylidène diuréé dont
0.3% soluble à 20 °C
4% insoluble à 20 °C mais soluble à 100 °C
0.2% insoluble à 100 °C

5% d'anhydride phosphorique (P₂O₅) soluble dans le citrate d'ammonium neutre et dans l'eau dont 2,5% soluble dans l'eau

8% d'oxyde de potassium (K₂O) soluble dans l'eau

22,5% d'anhydride sulfurique (SO₃) dont 18% soluble dans l'eau

3% d'oxyde de magnésium (MgO) soluble dans l'eau

0.7% de 2,4-D (sel de diméthylamine) (7 g/kg)

0.1% de Dicamba (sel de diméthylamine) (1 g/kg)

Engrais pauvre en chlore
Usage : Gazon de graminées - désherbage
Dose : 30 g/m²
Max. 1 application par an.
Éliminer les emballages, avec ou sans reliquat de produit, dans une déchetterie ou par un organisme agréé.
En cas d'urgence, appeler le 15 ou le centre anti-poison

FLORANID® GAZON DESHERBANT S 15.5.8.3
(contient du 2,4D, 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.
S 37 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. Respecter les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.

COMPO France S.A.S.
Division Grand Public
25220 ROCHE LEZ BEAUPRE
Tél : 03 81 40 25 25

MASSE NETTE :
4 kg e

ENGRAIS GAZON DESHERBANT LONGUE DURÉE

L'engrais Gazon désherbant longue durée Algoflash est un produit spécialement conçu pour détruire efficacement les mauvaises herbes du gazon. Combiné à l'action fertilisante qui agit immédiatement lors de l'application puis pendant 100 jours, il assure croissance, densité et une belle couleur verte à toutes les variétés de gazon : décoratifs, rustiques, de détente et de jeux...

ÉLIMINE LES MAUVAISES HERBES



L'engrais Gazon désherbant longue durée Algoflash contient 2 désherbants sélectifs efficaces contre les feuilles et les racines des mauvaises herbes. Il agit sur les pissenlits, séneçons, trèfles rampants, pâquerettes, renoncules, chardons, etc. et les détruit en 4 à 6 semaines.

ACTION LONGUE DURÉE



L'engrais Gazon désherbant longue durée Algoflash, fournit de façon durable et équilibrée tous les éléments nécessaires à la repousse du gazon. Grâce à la technologie FLORANID®, l'isobutylidène diurée assure une libération progressive (pendant 100 jours) et régulière de l'azote. La perte d'azote par le lessivage (arrosages, eaux de pluie) est limitée et l'engrais mieux absorbé par votre gazon.

FERTILISE



Après l'application de l'engrais Gazon désherbant longue durée Algoflash, votre pelouse va repousser et recouvrir les zones dénudées. L'engrais va permettre une pousse régulière et l'émission de nouveaux brins, plus verts et plus denses. L'application de l'engrais augmente la résistance au piétinement et à la sécheresse.

COMMENT BIEN L'UTILISER ?

A QUELLE PÉRIODE ?

L'engrais Gazon désherbant longue durée Algoflash s'utilise une fois par an, d'avril à août, lorsque les températures nocturnes sont supérieures à 10 °C.

J	F	M	A	M	J	J	A	S	O	N	D

☐ Fertilisation non conseillée
 ☐ Fertilisation possible
 ☐ Fertilisation conseillée

COMMENT L'APPLIQUER ?

Après la dernière tonte, attendre 3 à 4 jours que les mauvaises herbes se soient développées. Appliquer à la main ou avec un épandeur (porter des gants de protection appropriés).

Épandre sur sol humide (le matin, avec la rosée). Pour une efficacité optimale, respecter la dose prescrite : 30 g / m².

1 poignée = environ 50 g.

Attention! Danger pour les cultures voisines.
Respecter strictement le mode d'emploi.

PRECAUTIONS D'EMPLOI

Tenir les animaux domestiques éloignés des surfaces traitées pendant 2 à 3 jours après l'épandage.

Ne pas traiter à proximité des arbres, arbustes et plantes des pelouses.

Eviter toute projection de produit sur les cultures voisines.

Ne pas travailler en présence de vent.

Ne pas appliquer le produit un jour de pluie ou en cas de gel ou de sécheresse.

N'utiliser le produit que sur des gazons de graminées ayant plus d'un an d'implantation.

Si des bulbes sont plantés dans la pelouse, appliquer le produit lorsque les feuilles sont desséchées.

Les déchets de tonte ne doivent pas servir comme nourriture pour animaux pendant un an après l'application.

En cas de contact avec les yeux laver immédiatement et abondamment avec de l'eau et consulter un spécialiste.

QUE FAIRE APRÈS L'APPLICATION ?



Ne pas entrer sur la zone traitée juste après l'application. Laisser le produit agir pendant une demi-journée. Par temps sec, arroser abondamment dans les 24 à 48 heures suivant l'application.

Tondre après 7 à 10 jours suivant l'application. Ne pas composer les 4 premières tontes suivant l'épandage.

DANS LES SEMAINES QUI SUIVENT ...



Après 3 à 4 semaines, ratissez les mauvaises herbes jaunies. Dans le cas d'infestations importantes, nous vous conseillons d'utiliser en complément un mélange de semences de gazon dit de "Regarnissage". Après l'élimination des mauvaises herbes, le semis peut avoir lieu, au plus tôt 1 mois après l'épandage.



CONSERVATION & EMBALLAGE

Conservé à l'abri de l'humidité, du gel et de la chaleur.

Conservé le produit toujours dans l'emballage d'origine.

Bien vider l'emballage lors de la dernière utilisation.

Ne pas réutiliser l'emballage vide.



ALGOFLASH



Engrais Gazon Désherbant

Date et lot de fabrication :
voir sur l'emballage



1. SACHET REFERMABLE ZIP

Emballage carton doublé d'un sachet plastique refermable « ZIP ». Facile à ouvrir et à fermer, le sachet ZIP vous assure une longue conservation du produit à l'abri de l'humidité et un plus grand confort d'utilisation.



2. BOÎTE AVEC POIGNÉE

Pratique, cette boîte est munie d'une poignée pour faciliter le transport. Elle procure un confort d'utilisation optimal.



MASSE NETTE :

4 kg e



EGAD 135



© = Marque déposée

VIDER COMPLÈTEMENT L'EMBALLAGE AVANT DE L'EMMENER À LA COLLECTE DE DÉCHETS.

NOUS GARANTISSONS LA QUALITÉ DE NOS PRODUITS, MAIS NOTRE RESPONSABILITÉ EST EXPRESSEMENT LIMITÉE À LA FOURNITURE DE SPÉCIALITÉS CONTRÔLÉES, LÉGALEMENT AUTORISÉES À LA VENTE ET CONFORMES À LA FORMULE INDICUÉE SUR L'EMBALLAGE.

Appendix 3 – Letters of Access
2.4 D



NUFARM GmbH & Co KG Tel., Fax (0732) 6918-DW
St.-Peter-Straße 25 from abroad +43-732-6918-Ext.
4021 Linz www.nufarm.com
Austria DVR 0813336

ANSES - DPR - Ugamm
253 avenue du Général Leclerc
94701 Maison-Alfort cedex
FRANCE

Linz, December 19th 2011 / NR /caf
Dr. Gibert, ☎ 2313

Letter of access to Data for 2,4-D technical acid – 7700706

Dear Sirs,

Nufarm GmbH & Co KG is a full member company of the 2,4-D Dossier Preparation Working Group which has submitted a complete set of data resulting in the listing of 2,4-D onto Annex I of Directive 91/414/EC. This is recognised in Commission Directive 2001/103/EC of 28 November 2001 and Commission Directive 2010/77/EU of 10 November 2010.

In accordance with National Legislation we hereby grant that we have access to all data submitted to support the inclusion of 2,4-D onto Annex I of Directive 91/414/EC. This permission includes the confidential technical source data submitted by Nufarm GmbH & Co KG or Nufarm UK Ltd. (sections 1.1-1.11 of Annex II Part A of 91/414/EC, Document J) and the protected data mentioned in appendix III A of the review report of 2,4-D, in order to maintain the registration of the following product:

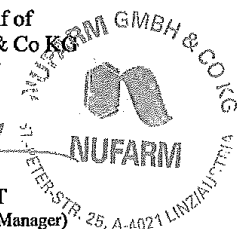
Product	Reg number	Active ingredients	Manufacturer of 2,4-D
Floranid Gazon Désherbant S 15 5 8 3	7700706	Dicamba: 0,1 % 2,4-D: 0,7 %	Nufarm GmbH & Co KG (Nufarm UK Ltd. – alternative source)

This letter of access is supplied for **COMPO France SAS, Zone Industrielle, 25220 Roche Lez Beaupre / France** only for their product **Floranid Gazon Désherbant S 15 5 8 3**, and is supplied on condition that Nufarm GmbH & Co KG or Nufarm UK Ltd. is the sole supplier of 2,4-D in France, for use in the above-mentioned product.

This letter is valid until such time as Nufarm GmbH & Co KG cancels the instruction in writing. This letter does not authorise the applicant sight of data and is not transferable. A new letter of access will be required for all subsequent applications.

For and on behalf of
Nufarm GmbH & Co KG

Dr. Eric GIBERT
(Regulatory Affairs Manager)



Bank details:

Bank Austria
Johann-Konrad-Vogel Straße 7-9, 4020 Linz/Austria
BIC: BKAUAT3333
account no. 09925 163 900
IBAN: AT27 1100 0099 2516 3900
within Austria: BLZ 12000

BAWAG P.S.K.
Untere Donaulände 40, 4010 Linz/Austria
BIC: BAWAAT3333
EUR: account no. 46710-420-220
IBAN: AT85 1400 0467 1042 0220
USD: account no. 46751-002-882
IBAN: AT96 1400 0467 5100 2882
within Austria: BLZ 14000

Registriert beim Landes-
als Handelsgericht Linz
unter FN 134778 d
Gesellschaftssitz: Linz
UID-No. ATU 38748003

Dicamba



The Chemical Company

December 16, 2011

ANSES – DPR - Ugamm
253 avenue du Général Leclerc
94701 Maison-Alfort cedex
France

APD/RHR-RTP
Tel : + 919-547-2860
Fax : + 919-547-2880
E-mail: Susanne.lingard@basf.com

Dear Sir or Madam:

Letter of Access for Dicamba

FRANCE

BASF SE (formerly BASF Aktiengesellschaft), Germany, herewith agree that the files, data, studies, summaries and assessments (hereinafter referred to as the "Dossier") co-owned by **Syngenta Crop Protection AG, Switzerland** and **BASF Aktiengesellschaft, Germany** and submitted by Syngenta Crop Protection or the former Novartis Crop Protection or Sandoz Agro in support of the registration of **Dicamba** as an active ingredient, may be referred to by you in order to grant registration to:

COMPO France SAS
Zone Industrielle
25220 Roche Lez Beaupre
France

For the formulation:

"Floranid Gazon Désherbant S 15 5 8 3"
(7700706)

Dicamba – 0,1%
2,4-D – 0,7%

Formulation Type: granular

BASF Corporation
28 Davis Drive
Research Triangle Park, NC 27709
Tel: (919) 647-2000