

GF-2436 / RUTILANT
Part A - National Assessment
FRANCE DEPR version

REGISTRATION REPORT

Part A

Risk Management

Product code: GF-2436

Product name: RUTILANT

Chemical active substance:

benfluralin, 600 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
(New application)

Applicant: GOWAN France S.A.S.

Date: 2020/08/11

Table of Contents

1	Details of the application	4
1.1	Application background	4
1.2	Letters of Access	5
1.3	Justification for submission of tests and studies	5
1.4	Data protection claims	5
2	Details of the authorisation decision	5
2.1	Product identity	5
2.2	Conclusion DAMM	6
2.3	Substances of concern for national monitoring	6
2.4	Classification and labelling	6
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	6
2.4.2	Standard phrases under Regulation (EU) No 547/2011	6
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	6
2.5	Risk management	6
2.5.1	Restrictions linked to the PPP	7
2.5.2	Specific restrictions linked to the intended uses	7
2.6	Intended uses (only NATIONAL GAP)	8
3	Background of authorisation decision and risk management	10
3.1	Physical and chemical properties (Part B, Section 2)	10
3.2	Efficacy (Part B, Section 3)	10
3.3	Methods of analysis (Part B, Section 5)	10
3.4	Mammalian toxicology (Part B, Section 6)	11
3.4.1	Acute toxicity	11
3.4.2	Operator exposure	11
3.4.3	Worker exposure	12
3.4.4	Bystander exposure	12
3.4.5	Resident exposure	13
3.5	Residues and consumer exposure (Part B, Section 7)	13
	Summary for RUTILANT (GF-2436)	14
3.6	Environmental fate and behaviour (Part B, Section 8)	14
3.7	Ecotoxicology (Part B, Section 9)	15
3.8	Relevance of metabolites (Part B, Section 10)	15
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	15
5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation.....	15
5.1.1	Post-authorisation monitoring	15
5.1.2	Post-authorisation data requirements	15

GF-2436 / RUTILANT
Part A - National Assessment
FRANCE DEPR version

Appendix 1 Copy of the product authorisation 16

Appendix 2 Copy of the product label..... 19

PART A

RISK MANAGEMENT

1 Details of the application

The company GOWAN France SAS has requested a marketing authorisation in France for the product RUTILANT (product code: GF-2436), containing 600 g/kg benfluralin¹, as a herbicide for professional uses.

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

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

1.1 Application background

The present registration report concerns the evaluation of GOWAN France SAS's application submitted on 09/06/2016 to market RUTILANT (GF-2436) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2016-3759) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of RUTILANT (GF-2436) have been made using endpoints agreed in the EU peer review of benfluralin. It also includes assessment of data and information related to RUTILANT (GF-2436) where those data have not been considered in the EU peer review process.

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

¹ 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, as amended by Commission implementing Regulation (EU) 2019/2094 of 29 November 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benfluralin, dimoxystrobin, fluzinam, flutolanil, mancozeb, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin.

² 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

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](#)

GF-2436 / RUTILANT
 Part A - National Assessment
 FRANCE DEPR version

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of RUTILANT (GF-2436).

1.2 Letters of Access

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

1.3 Justification for submission of tests and studies

According to the applicant: “*Studies have been submitted to support the new product authorisation of RUTILANT (GF-2436) in France*”.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of RUTILANT (GF-2436), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	GF-2436.
Product name in MS	RUTILANT.
Authorisation number	N/A : no marketing authorisation granted
Kind of use	Professional use.
Low risk product (article 47)	No.
Function	Herbicide.
Applicant	GOWAN France S.A.S.
Active substance(s) (incl. content)	Benfluralin, 600 g/kg.
Formulation type	Water-dispersible granule [code : WG].
Packaging	N/A : no marketing authorisation granted
Coformulants of concern for national authorisations	-
Restrictions related to identity	The spray mixture should be agitated or stirred during application in accordance with good agricultural practices.
Mandatory tank mixtures	None.
Recommended tank mixtures	None.

⁴ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

GF-2436 / RUTILANT
 Part A - National Assessment
 FRANCE DEPR version

2.2 Conclusion DAMM

The evaluation of the application for RUTILANT (GF-2436) resulted in the decision to **refuse** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Skin sensitisation, category 1B. Carcinogenicity, category 2. Hazardous to the aquatic environment - acute hazard, category 1. Hazardous to the aquatic environment - chronic hazard, category 1.		
Hazard pictograms:	   GHS07 GHS08 GHS09		
Signal word:	Warning.		
Hazard statement(s):	H317: May cause an allergic skin reaction. H351: Suspected of causing cancer. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.		
Precautionary statement(s):	<i>For the P phrases, refer to the extant legislation.</i>		
Additional labelling phrases:	-		

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

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

N/A : no marketing authorisation granted

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

N/A : no marketing authorisation granted

2.5 Risk management

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

The French Order of 4 May 2017⁵ provides that:

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

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

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

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

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

2.5.1 Restrictions linked to the PPP

N/A : no marketing authorisation granted.

2.5.2 Specific restrictions linked to the intended uses

N/A : no marketing authorisation granted.

⁵ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, modifié par l'arrêté du 27 décembre 2019

⁶ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>

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

GF-2436 / RUTILANT
 Part A - National Assessment
 FRANCE DEPR version

2.6 Intended uses (only NATIONAL GAP)

Please note:

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

PPP (product name/code):	RUTILANT / GF-2436											GAP rev. 1, date: 2020-08-11	
Active substance 1:	benfluralin											Formulation type:	WG ^(a, b)
Applicant:	GOWAN France S.A.S.											Conc. of a.s. 1:	600 g/kg ^(c)
Zone(s):	Southern Zone ^(d)											Professional use:	<input checked="" type="checkbox"/>
Verified by MS:	Yes											Non-professional use:	<input type="checkbox"/>
Field of use:	Herbicide											PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)

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/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha	Water L/ha min/ma x			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	FR	Winter oilseed rape	F	Annual grasses and broadleaved weeds	Broadcast spray and incorporati on into soil (hydraulic nozzles)	Pre-sowing 1 st August to end of September	1	-	2.0	1200	200- 400	F – before sowing	Not acceptable (resident child) Not acceptable (soil macro-organisms other than earthworms)	

GF-2436 / RUTILANT

Part A - National Assessment
FRANCE DEPR version

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ 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/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha	Water L/ha min/ma x		
2	FR	Sunflower	F	Annual grasses and broadleaved weeds	Broadcast spray and incorporati on into soil (hydraulic nozzles)	Pre-sowing 15 th March to 15 th May	1	-	2.0	1200	200- 400	F - before sowing	Not acceptable (resident child) Not acceptable (soil macro-organisms other than earthworms)

Remarks table heading:	(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d) Select relevant
	(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c) g/kg or g/l	(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1 Numeration necessary to allow references	7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2 Use official codes/nomenclatures of EU Member States	8 The maximum number of application possible under practical conditions of use must be provided.
	3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9 Minimum interval (in days) between applications of the same product
	4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10 For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/Kind".
		13 PHI - minimum pre-harvest interval
		14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

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

RUTILANT (GF-2436) is a WG formulation. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a dark yellow granular solid, with characteristic odour. It is not explosive and has no oxidising properties. The product is not highly flammable. It has a self-ignition temperature of 255 °C. In aqueous solution (1 %), it has a pH value of 7.2 at 22 °C. There is no effect of low and high temperatures on the stability of the formulation, since after 14 days at 54 °C and eight weeks at 40 °C, neither the active substance 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 a foil-laminated bag (FLB) or a multi-walled paper bag. Its technical characteristics are acceptable for a WG formulation.

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

The spray mixture should be agitated (stirred) during application in accordance with good agricultural practices.

3.2 Efficacy (Part B, Section 3)

The efficacy level of RUTILANT (GF-2436) is considered acceptable on rapeseed (oilseed rape) in a current context where grasses are more difficult to control.

The efficacy level of RUTILANT (GF-2436) is acceptable on sunflower at the requested dose.

Risks of negative impact on yield, quality and multiplication are considered acceptable.

The risk of negative impact on adjacent and succeeding crops is considered acceptable.

The risk of resistance developing or appearing to benfluralin does not require monitoring for the requested uses.

3.3 Methods of analysis (Part B, Section 5)

Analytical methods for the determination of the active substance and the relevant impurity, ethyl-butyl-nitrosamine (EBNA), in the formulation are available and validated.

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of benfluralin in plants (high-oil-content commodities), soil, water (surface and drinking) and air.

An analytical method is available in this dossier and validated for the determination of residues of benfluralin in tissues and body fluids.

GF-2436 / RUTILANT
 Part A - National Assessment
 FRANCE DEPR version

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active substance: benfluralin			
ADI	0.005 mg/kg bw/d	EU (2008)	
ARfD	Not applicable		
AOEL	0.05 mg/kg bw/d		
AAOEL	-		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012)*:		
		Concentrate (used in formulation) 600 g/kg	Spray dilution (used in formulation) 3-6 g/L
	Dermal absorption endpoints %	25	30
Oral absorption	30 %	EFSA (2008)	
Vapour pressure	1.73 x 10 ⁻³ Pa at 20 °C 4.16 x 10 ⁻³ Pa at 25 °C		

*The read-across between EF-1533 and RUTILANT (GF-2436) is not considered acceptable. The dermal absorption study was performed with the emulsionate concentrate formulation EF-1533. RUTILANT (GF-2436) is a wettable granule formulation. According to the EFSA guidance on dermal absorption (EFSA Journal 2012,10(4):2665), the study must be performed on a similar type of formulation

3.4.1 Acute toxicity

RUTILANT (GF-2436), containing 600 g/kg benfluralin, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye but is a skin sensitiser.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

GF-2436 / RUTILANT
Part A - National Assessment
FRANCE DEPR version

Crop type	F/G ⁸	Equipment <i>Application method</i>	Maximum application rate kg product/ha (g a.s./ha)	Minimum volume water (L/ha)
Sunflower, oilseed rape	F	Vehicle-mounted <i>Downward spraying</i>	2 kg RUTILANT (GF-2436) /ha (1200 g benfluralin/ha)	200

Considering the proposed uses, operator systemic exposure was estimated using the EFSA model⁹:

Crop	Equipment	PPE and/or working coverall	% AOEL benfluralin
Oilseed	Vehicle-mounted downward spraying	Working coverall and gloves during mixing/loading and application	23

According to the model calculations, it may be concluded that the risk for the operator using RUTILANT (GF-2436) is acceptable with a working coverall and gloves during mixing/loading and application,

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

3.4.3 Worker exposure

In the EFSA Journal 2019;17(10):5842, it is indicated that “*Workers are not expected to re-enter treated fields*”. Therefore, there is no need to perform the risk assessment for the workers, and worker exposure is thus considered acceptable.

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

3.4.4 Bystander exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOE model where no AAOEL has been set¹⁰.

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): “*No bystander risk assessment is required for PPPs that do not have significant acute*

⁸ Open field or glasshouse

⁹ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

¹⁰ Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure."

3.4.5 Resident exposure

- Residential exposure was assessed according to the EFSA model¹ incorporating a distance of 10 metres from the spray boom and drift reduction technology. **An unacceptable risk was determined for residents (children).**

Model (AOEM) - All pathways (mean)	% AOEL benfluralin
Resident (children)	115
Resident (adults)	57

It has to be noted that the exposure assessment for the resident adult is not necessary, since in the EFSA Journal 2019;17(10):5842 it is indicated that "*Residential exposure during re-entry is not considered relevant for the type of application on bare soils. Accordingly, it is concluded that resident adults' exposure does not exceed the AOEL. Regarding children residents, exceedance is also driven by spray drift exposure. It is noted that mitigation measures may be applied in addition to the ones proposed by the RMS in the revised RAR, such as restricting applications to those using drift reducing technology and requiring minimum spray volume of 400 L/ha (while the GAP refers 200–400 L/ha).*¹⁰ *On that basis, the resident child exposure via all relevant pathways is less than 50% of the AOEL.*" However, the risk assessment has to be performed on resident children since the dermal absorption values used in the EFSA Journal are different. Therefore, an unacceptable risk was determined for residents (children) even when drift reduction technology and mitigation measures such as a buffer zone of 10 metres are taken to reduce the resident exposure.

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

Overall conclusion

The data available are considered sufficient for risk assessment. No exceedence of the current MRL of 0.02* mg/kg for benfluralin as laid down in Reg. (EU) 396/2005 is expected.

The chronic intakes of benfluralin residues are unlikely to present a public health concern. The short-term intake is of no concern since no ARfD is set for benfluralin.

As far as consumer health protection is concerned, France as zRMS agrees with the authorisation of the intended uses.

According to available data, no specific mitigation measures should apply.

Data gaps:

None.

GF-2436 / RUTILANT
Part A - National Assessment
FRANCE DEPR version

Summary for RUTILANT (GF-2436)

Table 1: Information on RUTILANT (GF-2436) (KCA 6.8)

Crop	PHI for RUTILANT (GF-2436) requested by applicant	PHI/withholding period* sufficiently supported for benfluralin	PHI for RUTILANT (GF-2436) proposed by zRMS	zRMS Comments (if different PHI proposed)
Oilseed rape	NR (pre-sowing)	NR	F (application stage pre-sowing)	-
Sun-flowers				

NR: not relevant

Table 2: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for RUTILANT (GF-2436)
Crop group	Led by benfluralin	
All crops	NR	none

NR: not relevant

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

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

The PEC values of benfluralin 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} values for benfluralin do not occur at levels exceeding those mentioned in Regulation (EC) no 1107/2009. 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.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation RUTILANT (GF-2436) was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance and its metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

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

For soil macro-organisms other than earthworms, according to the new requirements of Reg. No. 284/2013, chronic toxicity studies for *Folsomia candida* and *Hypoaspis aculeifer* should have been submitted. Therefore, France as zRMS considers that without these studies, the risk assessment for these specific macro-organisms cannot be finalised.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

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

The active substance benfluralin is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

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

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

5.1.1 Post-authorisation monitoring

. N/A : no marketing authorisation granted

5.1.2 Post-authorisation data requirements

N/A : no marketing authorisation granted

GF-2436 / RUTILANT
Part A - National Assessment
FRANCE DEPR version

Appendix 1 Copy of the product authorisation



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

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

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

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

de la société **GOWAN FRANCE**
enregistrée sous le n°2016-3759

Vu les conclusions de l'évaluation de l'Anses du 15 juin 2020,

Considérant que l'utilisation du produit entraîne un risque d'effet nocif pour les résidents (enfants) et les personnes présentes (enfants) lié au dépassement du niveau acceptable d'exposition à la substance active benfluridine.

Considérant qu'un risque d'effet inacceptable pour les macroorganismes du sol ne peut être exclu.

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

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

GF-2436 / RUTILANT
Part A - National Assessment
FRANCE DEPR version



Informations générales sur le produit	
Nom du produit	RUTILANT
Type de produit	Produit de référence
Titulaire	GOWAN FRANCE 5 Rue du Gué 77139 PUISIEUX France
Formulation	Granulé dispersable (WG)
Contenant	600 g/kg - benfluraline
Numéro d'intrant	9899-2016.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le

11 AOUT 2020

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



ANNEXE I : Conditions de mise sur le marché demandées

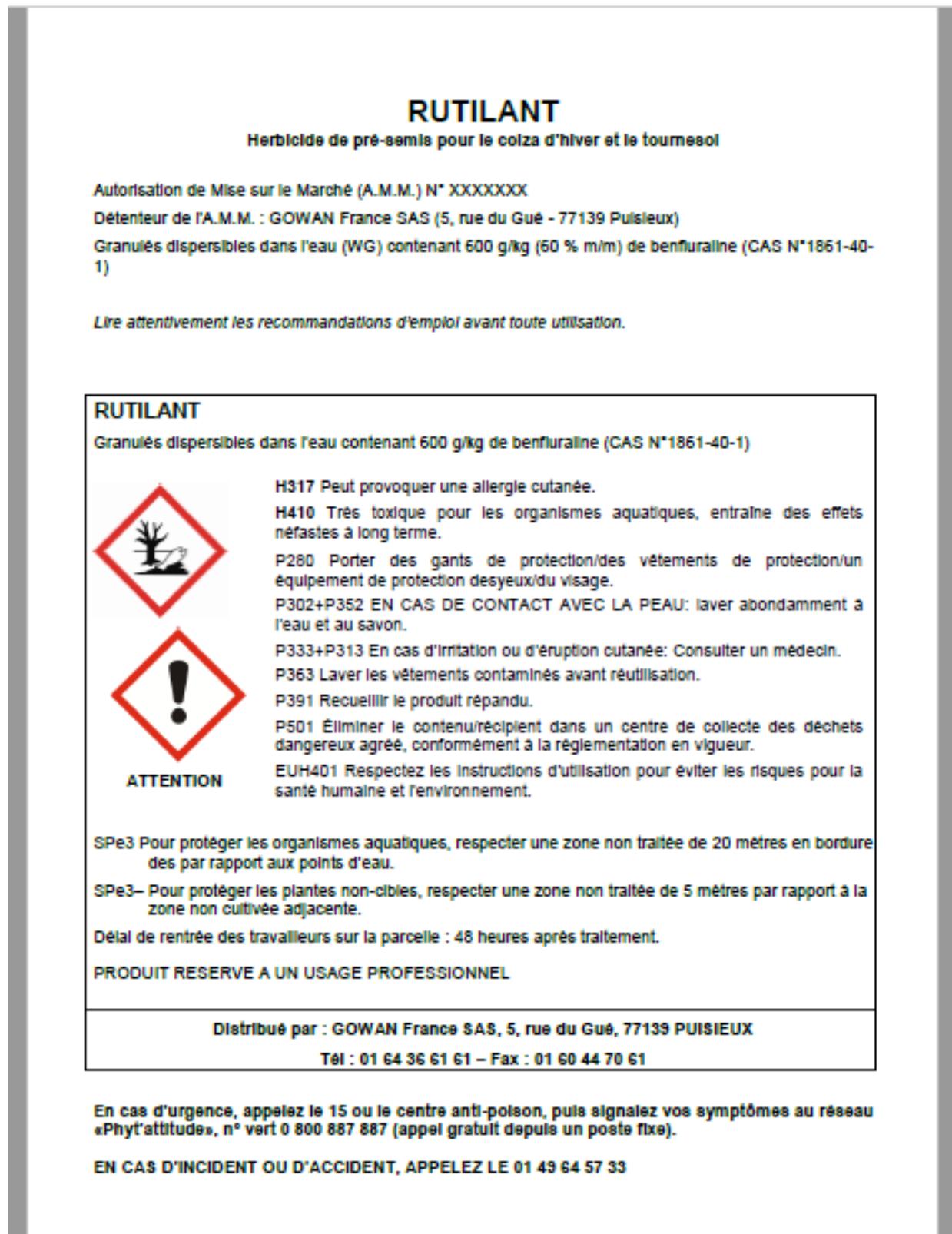
Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15205901 Crucifères oléagineuses*Désherbage	2 kg/ha	1/an	-
Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les résidents (enfants) et les personnes présentes (enfants). L'usage est également refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les macroorganismes du sol.			
15905901 Tournesol*Désherbage	2 kg/ha	1/an	-
Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les résidents (enfants) et les personnes présentes (enfants). L'usage est également refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les macroorganismes du sol.			

GF-2436 / RUTILANT
 Part A - National Assessment
 FRANCE DEPR version

Appendix 2 Copy of the product label

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



GF-2436 / RUTILANT
 Part A - National Assessment
 FRANCE DEPR version

RUTILANT – Herbicide

RUTILANT est un herbicide de pré-semis du colza d'hiver et du tournesol qui doit être incorporé dans le sol. Il agit au niveau des tiges et des radicelles des adventices en cours de germination, en inhibant la formation des micro-tubules (groupe HRAC K1).

RUTILANT peut s'appliquer sur colza sous couvert de légumineuses.

TABLEAU DES USAGES AUTORISÉS :

Culture	Usage	Dose (kg/ha)	Délai Avant Récolte (DAR) jours	Zone Non Traitée (ZNT)
Crucifères oléagineuses (Colza d'hiver)	Désherbage antigraminées et antidicotylédones	2	-	20 m
Tournesol	Désherbage antigraminées et antidicotylédones	2	-	20 m

Les limites maximales de résidus sont disponibles à l'adresse suivante : http://ec.europa.eu/sanco_pesticides/public/

Gowan France S.A.S. ne préconise l'utilisation de RUTILANT que sur les cultures et usages mentionnés dans le tableau des usages autorisés et, à ce titre, décline toute responsabilité concernant l'élargissement de son utilisation à d'autres usages tels que prévus par l'arrêté du 26 mars 2014. Avant toute utilisation de RUTILANT, s'assurer de son adéquation avec votre filière de production et avec les recommandations officielles régionales.

EFFICACITÉ

RUTILANT agit sur les mauvaises herbes annuelles en les détruisant dès leur germination. Il est inefficace sur les adventices déjà établies.

Graminées annuelles sensibles à très sensibles :

Agrostis-jouet du vent, dactyle aggloméré, digitale, folle-avoine, sétaire. Efficace sur les graines non germées se trouvant dans la zone traitée.

Graminées annuelles moyennement sensibles :

Panic, pâturens annuel et commun, ray-grass, vulpin.

Dicotylédones annuelles sensibles à très sensibles :

Amarante, atriplex, chénopode, coquelicot, mouron des champs, mouron des oiseaux, myosotis, pourpier potager, renouée iliseron, renouée des oiseaux, renouée persicale, véronique feuille de ferre.

Dicotylédones annuelles moyennement sensibles :

Fumeterre, gallet-gratéron, lamier, renouée feuille de patience, renoncule des champs, véronique de Perse.

PRÉPARATION DE LA BOUILLIE

REMPLIR le réservoir de l'appareil aux trois-quarts avec de l'eau ; verser la quantité nécessaire de RUTILANT et compléter le remplissage.

Employer un pulvérisateur distribuant de 200 à 400 litres de bouillie à l'hectare et assurant une répartition régulière de l'herbicide sur le sol.

RUTILANT s'utilise en pulvérisation sur sol nu, propre, sans résidus végétaux, hersé, peu motteux, avant la dernière façon culturale précédant le semis.

Il est possible de traiter jusqu'à 2 semaines avant la mise en place de la culture.

CONDITIONS D'UTILISATION

L'incorporation doit se faire le plus rapidement possible après l'application, dans les 4 heures qui suivent le traitement, à une profondeur de 4 à 8 cm.

GF-2436 / RUTILANT
 Part A - National Assessment
 FRANCE DEPR version

RUTILANT peut supporter, après son incorporation, un léger travail du sol (binage, par exemple) réalisé à une profondeur inférieure à la profondeur d'incorporation, sans perdre son efficacité. Dans les sols riches en matière organique (plus de 3%) et dans les sols argileux, l'efficacité de RUTILANT peut être réduite.

RECOMMANDATIONS D'EMPLOI

Utiliser RUTILANT dans le cadre d'un programme de désherbage du colza d'hiver ou du tournesol.

Cultures voisines :

Dans nos essais « évaluation du risque dérive » aucune culture implantée ne s'est montrée sensible à RUTILANT. Il est cependant conseillé de laisser 1 mètre non traité en bordure de votre champ.

Cultures de remplacement :

En cas de retourement accidentel de la culture traitée avec RUTILANT, il est possible d'implanter les cultures suivantes :

- Sans restriction : chanvre, luzerne, haricot, pois, soja, trèfle, chou, colza, chicorée, laitue, tournesol, melon, oignon.
- Après labour : pomme de terre (avec un délai de 2 mois après traitement), lin, carotte, tomate, lentille.

Dernière un colza, ne pas planter : de céréales, de graminées fourragères, de betterave ni de sorgho. Une culture de maïs est possible après un labour.

Dernière un tournesol, ne pas planter : de graminées fourragères, de maïs, de sorgho ni de betterave.

Cultures suivantes :

Après un colza : aucune restriction.

Après un tournesol : il est déconseillé d'implanter une culture d'avoine, d'épinard ou de betterave.

Pour les autres cultures, nous consulter.

L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action peut conduire à l'apparition d'individus résistants. Pour réduire ce risque, et quelle que soit la culture traitée, il est conseillé d'alterner sur une même parcelle, des préparations à base de substances actives de familles différentes ou à modes d'action différents, tant au cours de la saison culturelle que dans la rotation.

COMPATIBILITE DES MELANGES

Les mélanges doivent être mis en oeuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques officiels. Consulter le site : <http://ephy.agriculture.gouv.fr>.

PRÉCAUTIONS D'EMPLOI

Pour la protection de l'opérateur, porter :

- pendant le mélange / chargement et le nettoyage du matériel d'application, porter :
- combinaison de travail en polyester 65% / coton 35% avec un grammage de 230 g/m² ou plus avec traitement déperiant,
- gants en nitrile certifiés pour la protection chimique EN 374-3,
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée,
- Protection respiratoire certifiée : conforme aux normes EN 136 (masque complet) ou EN 140 (demi-masque) et équipé d'un filtre FFP3 au minimum.
- pendant l'application, porter :
- combinaison de travail en polyester 65% / coton 35% avec un grammage de 230 g/m² ou plus avec traitement déperiant.

Si application avec tracteur sans cabine :

GF-2436 / RUTILANT
 Part A - National Assessment
 FRANCE DEPR version

- Gants en nitrile certifiés pour la protection chimique EN 374-2 à usage unique.

Si application avec tracteur avec cabine :

- Gants en nitrile certifiés pour la protection chimique EN 374-2 à usage unique dans le cadre d'une intervention sur le matériel pendant la phase d'application. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine.

Conserver hors de la portée des enfants. Conserver le récipient bien fermé. Conserver à l'écart des aliments et boissons, y compris ceux pour animaux. Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation. Conserver uniquement dans l'emballage d'origine.

Premiers soins :

Retirer immédiatement les vêtements contaminés par le produit.

Après Inhalation : repos, air frais, secours médical.

Après contact avec la peau : se laver immédiatement et longuement à l'eau courante.

Après contact avec les yeux : rincer aussitôt à l'eau courante pendant au moins 15 minutes en maintenant les paupières écartées. Consulter un ophtalmologue.

Après Ingestion : ne pas faire vomir, ne pas faire boire. Consulter immédiatement un médecin.

PREVENTION DE LA RESISTANCE

La résistance des adventices est devenue un problème critique dans de nombreuses cultures.

La Benfluraline, matière active de RUTILANT est utilisée en Europe depuis plus 30 ans sur de nombreuses cultures (la chicorée, la laitue, les pois, les haricots, les salsifis, le tabac, la luzerne, le trèfle, les arachides, l'all, les lentilles) ; à ce jour, aucun cas de résistance des mauvaises herbes ciblées n'a été rapporté.

Cela vient du fait que la Benfluralin est utilisée dans des programmes avec d'autres herbicides ayant d'autres modes d'action, soit pour renforcer le contrôle des mauvaises herbes et/ou pour élargir le spectre d'activité. Comme les cultures sur lesquelles la Benfluraline est utilisée, ne sont pas cultivées en monoculture, le risque de développement peut donc être considéré comme très faible. Cependant, dans la mesure du possible, varier les substances chimiques et alterner avec des produits ayant des modes d'action différents.

ÉLIMINATION DU PRODUIT ET DE SON EMBALLAGE

Lors de l'utilisation du produit, bien vider l'emballage. Rendre inutilisable l'emballage vide. Aussitôt après la fin des traitements, nettoyer et rincer soigneusement le pulvérisateur à l'eau claire. Pour les reliefs de produit, respecter la réglementation en vigueur concernant l'utilisation des produits phytopharmaceutiques. Éliminer les fonds de cuve conformément à la réglementation en vigueur.

Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux. Réemploi de l'emballage Interdit. Éliminer les emballages vides via les collectes organisées par des distributeurs partenaires de la filière ADIVALOR.

IMPORTANT : Respectez les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez sur ces bases la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces, etc... Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture. Compte tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur.