REGISTRATION REPORT

Part A

Risk Management

Product code: SAP1020DFFL

Product name: DESTINY

Active Substance(s):

Flufenacet , 400 g/L

Diflufenican, 200 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: **SAPEC AGRO France**

Date: **15/10/2018**

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PART A – Risk Management

The company Sapec Agro S.A. has requested a marketing authorisation in France for the product DESTINY (product code: SAP1020DFFL), containing 400g/L flufenacet and 200 g/L diflufenican for use as an herbicide.

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 DESTINY (SAP1020DFFL) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of DESTINY (SAP1020DFFL) have been made using endpoints agreed in the EU peer review(s) of both flufenacet and diflufenican.

This document describes the specific conditions of use and labelling required for France for the registration of DESTINY (SAP1020DFFL).

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 SAPEC AGRO France's application to market DESTINY (SAP1020DFFL) in France as an herbicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Flufenacet

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 (EU) No 540/2011 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 flufenacet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of algae and aquatic plants, — should pay particular attention to the protection of operators. Risk mitigation measures should be applied where appropriate.
There is no EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance. A Review Report is available (7469/VI/98-Final, 3 July 2003).

Diflufinican

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 (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 diflufenican, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate, — the protection of non-target plants. Risk mitigation measures such as an in-field no spray buffer zones shall be applied, where appropriate.
There is no EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance. A Review Report is available (SANCO/3782/08 – rev.1, 14 March 2008)

1.3 Regulatory approach

The present application (2014-2853) 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 4th May 2017[3] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

The current document (RR) based on Anses's assessment of the application submitted for this product is in

[1] French Food Safety Agency, Afssa, before 1 July 2010
[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] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

compliance with Regulation (EC) no 1107/2009[4], implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[6] 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 extrapolation[7] 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 DESTINY (SAP1020DFFL), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

Not necessary: the applicant has provided sufficient data to show that access is not required.

[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

[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/AGRG1407093A/jo

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

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	DESTINY (SAP1020DFFL)
Authorisation number	N/A : no marketing authorisation granted
Function	herbicide
Applicant	SAPEC AGRO France
Composition	400 g/L or g/kg flufenacet 200 g/L or g/kg diflufenican
Formulation type (code)	suspension concentrate (SC)
Packaging	N/A : no marketing authorisation granted

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No1272/2008

Physical hazards	-	
Health hazards	Acute Toxicity (oral), Hazard Category 4 Skin sensitisation, Hazard Category 1 Specific target organ toxicity after repeated exposure, Hazard Category 2	
Environmental hazards	Hazardous to the Aquatic environment, Chronic, Hazard Category 1 Hazardous to the Aquatic environment, Acute, Hazard Category 1	
Hazard pictograms		
Signal word	warning	
Hazard statements	H302	Harmful if swallowed
	H317	May cause an allergic skin reaction
	H373	May cause damage to organ
	H400	Very toxic to aquatic life
	H410	Very toxic to aquatic life with long lasting effects.
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)		Contains 1,2-benzisothiazol-3(2H)-one (CAS No. 2633-34-5).

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

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

N/A : no marketing authorisation granted

2.2.3 Other phrases linked to the preparation

N/A : no marketing authorisation granted

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant,
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev., date: 2018-10-15

PPP (product name/code):	DESTINY (SAP1020DFFL)	Formulation type:	**<SC>** [a, b]
Active substance 1:	Flufenacet	Conc. of as 1:	**400g/L/g** [c]
Active substance 2:	Diflufenican	Conc. of as 2:	**200 g/L/** [c]
Safener:	n.a	Conc. of safener:	n.a
Synergist:	n.a	Conc. of synergist	n.a [c]
Applicant:	SAPEC AGRO France	Professional use:	☒
Zone(s):	southern [d]	Non professional use:	☐
Verified by MS:	yes		
Field of use:	herbicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PT, FR, IT, BG, GR, SP	Winter Wheat (durum and soft)	F	Grasses and Broadleaved weeds	Broadcast Pulverization	BBCH 11-13	1	-	a) 0.6 b) 0.6	a)120+240 b)120+240	200-400 400	F	**Not acceptable** (Risk of MRL exceedance)
2	PT, FR, IT, BG, GR, SP	Winter Barley	F	Grasses and Broadleaved weeds	Broadcast Pulverization	BBCH 11-13	1	-	a) 0.6 b) 0.6	a)120+240 b)120+240	200-400 400	F	**Not acceptable** (Risk of MRL exceedance)

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 or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													

Remarks table heading:

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

Remarks columns:

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

3 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

The formulation DESTINY (SAP1020DFFL) is a suspension concentrate. 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 a white to beige liquid, with low characteristic odour. It is not explosive and has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 398°C. In aqueous solution (1%), it has a pH value of 6.4 at 24.7 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed (except a slightly change of viscosity). A provisional shelf life of at 2 years at ambient temperature when stored in HDPE is granted, as study is ongoing. However the study needs to be provided in post-authorization. Its technical characteristics are acceptable for a suspension concentrate formulation.

The formulation is not classified for the physical-chemical part.

3.1.2 Methods of analysis

Analytical methods for the determination of active substances in the formulation are available and validated. As active substances flufenacet or diflufenican do not contain relevant impurity, no analytical method is required.

Analytical methods are available in the monograph/this dossier and validated for the determination of residues of diflufenican and flufenacet in plants (dry matrix), food of animal origin, soil, water (surface and drinking) and air.

The active substance(s) are/is neither toxic nor very toxic hence no analytical method is required for the determination of residues in biological fluids and tissues.

According to EFSA conclusions, a data gap was identified by the expert meeting for a new technical specification.

3.1.3 Mammalian Toxicology

<table>
<tr><td colspan="4">Active Substance: diflufenican</td></tr>
<tr><td>ADI</td><td colspan="2">0.2 mg kg bw/d</td><td rowspan="3">EU (2009)</td></tr>
<tr><td>ARfD</td><td colspan="2">not applicable</td></tr>
<tr><td>AOEL</td><td colspan="2">0.11 mg/kg bw/d</td></tr>
<tr><td rowspan="3">Dermal absorption</td><td colspan="3">Based on default values according to guidance on dermal absorption (Efsa 2012):</td></tr>
<tr><td></td><td>Concentrate
(used in formulation)
200 g/L</td><td>Spray dilution
(used in formulation)
0.3-0.6 g/L</td></tr>
<tr><td>Dermal absorption endpoints %</td><td>25%</td><td>75%</td></tr>
<tr><td colspan="4">Active Substance: flufenacet</td></tr>
<tr><td>ADI</td><td colspan="2">0.005 mg kg bw/d</td><td rowspan="2">EU (2004)</td></tr>
<tr><td>ARfD</td><td colspan="2">0.017 mg/kg bw/d</td></tr>
</table>

AOEL	0.017 mg/kg bw/d		
Dermal absorption	Based on an *in vitro* human study performed on formulation (using *pro rata* correction):		
		Concentrate (tested) 400 g/L	Diluted formulation (tested) 0.8 g/L
	In vitro (human) %	2%	27%
		Concentrate (used in formulation) 400 g/L	Spray dilution (used in formulation) 0.6-1.2 g/L
	Dermal absorption endpoints %	**2%**	**36%**

3.1.3.1 Acute Toxicity

DESTINY (SAP1020DFFL) containing 200 g/L of diflufenican and 400 g/L of flufenacet is harmful if swallowed, has a low toxicity in respect to acute inhalation and dermal toxicity, is not irritating to the rabbit skin or eye and is a skin sensitiser.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G[8]	Equipment	Application rate kg/L product/ha (g as/ha)	Spray dilution (L/ha)	Model
Cereals	F	Tractor mounted boom sprayer	0.6 L/ha (flufenacet: 250.02 g.as/ha diflufenican: 121.83 g.as/ha)	200-400	BBA

Considering proposed uses, operator systemic exposure was estimated using the German BBA model:

Crop	Equipment	PPE and/or working coverall	% AOEL flufenacet (0.017 mg/kg bw/d)	% AOEL diflufenican (0.11 mg/kg bw/d)
Cereals	Tractor mounted boom sprayer	Working coverall and gloves during mixing/loading and application	42%	8.1%

According to the model calculations, it can be concluded that the risk for the operator using DESTINY (SAP1020DFFL) is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.
For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to 3.9 % and 0.6% of the AOEL of flufenacet and diflufenican respectively.
It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to DESTINY (SAP1020DFFL).

[8] Open field or glasshouse

3.1.3.4 Worker Exposure

DESTINY (SAP1020DFFL) is used as herbicidal treatment on several crops where there is no need to re-enter the treated area after application. Worker exposure is considered not relevant.

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

3.1.3.5 Resident Exposure

Residential exposure was assessed according to Martin et al approach. Exposure is estimated to 1.9% and 3.6% of the AOEL of flufenacet for adult and child respectively and to 0.3% and 0.5% of the AOEL of diflufenican for adult and child respectively.
It is concluded that there is no unacceptable risk to the resident exposed to DESTINY (SAP1020DFFL).

The currently available data (2001-2006) in the report of the ORP (French pesticides residues observatory) show a range of values, reaching the maximum value for diflufenican of 0.1 ng/m³ (maximum daily measurements). Based on these data, the respiratory exposure of people living near sprayed areas was estimated to be 0.00002% of the ADI of the active substance for an adult and 0.00003% for a child, as well as 0.00004% of the AOEL of the active substance for an adult and 0.00005% for a child.
No values of air concentration data were available for flufenacet from French organizations approved for air quality monitoring.

3.1.3.6 Relevance of metabolites

The expected estimated concentrations in groundwater exceed the threshold of 0.1 µg/L for metabolites FOE oxalate and FOE sulfonic acid (maximum values of 0.6 µg/L and 3.8 µg/L respectively). As no information was provided by the applicant, it is impossible to finalize the assessment of the toxicological non-relevance of metabolites.
Residues of metabolites flufenacet oxalate, flufenacet sulfonic acid, flufenacet thioglycolate sulfoxide, flufenacet sulfinyl lactic acid N-glucoside conjugate of thiaodone and N-malonylalanine conjugate of thiadone are found in some crops. As no information was provided by the applicant, it is impossible to finalize the assessment of the toxicological properties of metabolites compared to flufenacet.

3.1.4 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment. An exceedance of the current MRL wheat and barley of 0.02 mg/kg for diflufenican as laid down in Reg. (EU) 396/2005 is not expected. According to these data, no MRL exceedance will result from these intended uses for diflufenican.
For flufenacet, distribution from southern data set residue trials, demonstrated that residue level could exceed the current MRL of 0.1 mg/kg.

3.1.4.1 Residues

Summary for diflufenican

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg 2017/623	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	wheat	Yes	Yes	Yes	Yes	Yes	No	No	

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg 2017/623	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	barley	Yes	Yes	Yes	Yes	Yes		No	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

The toxicological profile of diflufenican was evaluated at EU level, which resulted in the proposal of an ADI and an ARfD was not deemed necessary.

Diflufenican was approved on 01 January 2009 (Directive 2008/66/EC of 30 June 2008). Most of the metabolism and residue data needed to support the use of DESTINY (SAP1020DFFL) were evaluated during the EU review of diflufenican and are summarised in the EFSA Scientific Report (2007) 122.

The cereal metabolism studies evaluated during the EU review support adequately the use of DESTINY (SAP1020DFFL). Based on these data, the relevant residue of diflufenican in plants was defined as parent diflufenican (for both monitoring and risk assessment).

The cereal residue trials already evaluated during the EU review of diflufenican. For grain, 26 trials from the southern part of Europe and 35 trials from the northern part of Europe in which diflufenican was applied from BBCH 15 to BBCH 37 and at the rate of 150 to 220 g as/ha, with a PHI up to 229 days, were used to support the intended GAP on cereals. For straw, 11 trials from the southern part of Europe and 22 trials from the northern part of Europe in which diflufenican was applied from BBCH 24 to BBCH 30 and at the rate of 150 g as/ha with a PHI up to 229 days, were used. These trials adequately support the intended use of DESTINY (SAP1020DFFL) in France for weed control in barley and wheat. Based on these trials the intended use of DESTINY (SAP1020DFFL) is not expected to result in residues in cereal grain higher than the EU MRL of 0.02 mg/kg.

In the monograph, no data were submitted or required, due to total [14C] residues in rotational crops at harvest being less than 0.06 mg/kg in the rotational crop metabolism study, with the exception of wheat straw which gave residues of 0.08-0.17 mg/kg, for crops planted 12 weeks after application. So considering that diflufenican is only used on cereal crops and perennial crops, any residues resulting from a previous year application are not expected.

The maximum dietary burden was re-calculated taking into account all crops on which diflufenican could potentially be applied. The potential levels of diflufenican residues in the total diet of poultry and pigs were below 0.1 mg/kg whereas they reached a level of 2.16 mg/kg in the total diet for beef cattle. By extrapolation from the dose level of 1.1 mg/kg of the cow metabolism study, it was concluded that the anticipated residue levels of diflufenican in cattle milk and tissues are below LOQ.

Based on the EFSA PRIMo model and the current EU MRLs the TMDI of European consumers to residues of diflufenican is estimated to less than 1% of ADI. Furthermore, diflufenican is of low acute toxicity. Therefore, the herein supported use of DESTINY (SAP1020DFFL) in wheat and barley does not cause unacceptable chronic or acute risk to consumers.

Summary for flufenacet

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. 1127/2014	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	wheat	Yes	Yes	Yes	Yes	No	No	No	Possibility of MRL exceedance
/	barley	Yes	Yes	Yes	Yes	No		No	Possibility of MRL exceedance

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

Flufenacet was approved (Directive 2003/84/EC of 25 September 2003). Most of the metabolism and residue data needed to support the use of DESTINY (SAP1020DFFL) were evaluated during the EU review of flufenacet and are summarised in the monograph.

The cereal metabolism studies evaluated during the EU review are considered to adequately support the use of DESTINY (SAP1020DFFL) up to the growth stage BBCH 13. Based on these data the relevant residue of flufenacet in plants was defined as sum of all compounds containing the N-fluorophenyl-N-isopropyl moiety expressed as flufenacet equivalent (for both monitoring and risk assessment).

The cereal residue trials were already evaluated during the EU review of flufenacet. For grain and straw, 17 trials from the northern part of Europe in which flufenacet was applied early post emergence at the rate of 240 g as/ha, were used to support the intended GAP on cereals. Additional trials, 8 SEU, were submitted, they are conducted according to the intended GAPc. The highest residue level in cereals grain is 0.098 mg/kg below the current MRL of 0.1 mg/kg for wheat and barley. However distribution from southern data set residue trials conducted at the intended GAP demonstrates that residue level could exceed the current MRL of 0.1 mg/kg. As a consequence, the intended GAP cannot be recommended.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Based on the EFSA PRIMo model and the current EU MRLs, the TMDI of European consumers to residues of flufenacet ranges from 12.3 to 59.5% of the ADI and the IESTI reaches 7.3% ARfD from milk products. Therefore, the herein supported uses of DESTINY (SAP1020DFFL) do not cause unacceptable chronic or acute risk to consumers.

Summary for DESTINY (SAP1020DFFL)

Crop	PHI for DESTINY (SAP1020DFFL) proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for DESTINY (SAP1020DFFL) proposed by zRMS	zRMS Comments (if different PHI proposed)
		diflufenican	flufenacet		
wheat	F** (until BBCH 13)	Yes	No		Possible MRL exceedance

Crop	PHI for DESTINY (SAP1020DFFL) proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for DESTINY (SAP1020DFFL) proposed by zRMS	zRMS Comments (if different PHI proposed)
		diflufenican	flufenacet		
barley	F** (until BBCH 13)	Yes	No		Possible MRL exceedance

Waiting periods before planting succeeding crops: not relevant

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values 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 diflufenican, flufenacet 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 conclusions or agreed in the assessment based on new data provided.
PEC soil and PECsw derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.
PECgw for diflufenican and its metabolites and for flufenacet do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[9]. However PECgw for flufenacet metabolites FOE oxalate and FOE sulfonic acid exceed 0.1 µg/L. Based on French agro-pedo-climatic scenarios considering crop rotations, PECgw for FOE oxalate do not exceed 0.1 µg/L but PECgw for FOE sulfonic acid are still above 0.1 µg/L. There is no sufficient information to assess the non-relevance of metabolite FOE sulfonic acid. Therefore the risk assessment of groundwater contamination cannot be finalised.
Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

3.1.6.1 Effects on Terrestrial Vertebrates (Birds)

For diflufenican, the TER values calculated for recommended scenarios, exceed the trigger values of 10 for acute risk and 5 for long-term risk at screening step indicating acceptable risk following the use of diflufenican.
For flufenacet, the acute TER value is above the trigger of 10 at screening step. However, at tier 1, the long-term TER value for large herbivorous birds is below the trigger of 5. Since the TER is close to the trigger (4.8) without any refinements of PT or PD, the long-term risks can be considered acceptable based on a weight of evidence approach.
For diflufenican and flufenacet (log Pow > 3), a risk assessment for fish-eating and earthworm-eating birds was conducted and long-term TER values are above the trigger of 5. The risks due to bioaccumulation of diflufenican and flufenacet via the food chain for birds are then acceptable.

[9] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

The risks for the puddle scenario of the drinking water were considered acceptable.
Therefore, treatment with DESTINY (SAP1020DFFL) in accordance with the proposed use patterns in cereals poses an acceptable risk to birds.

3.1.6.2 Effects on aquatic Species

Toxicity studies were conducted with the formulation and indicate that the formulation is not more toxic than predicted from data available on the active substances.
For diflufenican, the most sensitive organism is algae. Based on the EU refinement approach, the risk to aquatic non-target organisms is acceptable when a non-sprayed vegetated buffer zone of 20 m is applied. A restriction for not using on artificial drained soil may be required at member states level (only the scenario D2 is concerned).
For flufenacet, the most sensitive organisms are algae and aquatic plants. Based on a microcosm available in European level (macrophyte, duckweed and periphyton), the NOEC of 12 µg/L was used in the refined risk assessment with a safety factor of 5 (RAC = 0.024 mg as/L) (already used in previous RR). The risk is then acceptable when a non-sprayed vegetated buffer zone of 20 m is applied. A restriction for not using on artificial drained soil may be required at member states level (D1, D2 and D6 scenarios are concerned).

Overall, the risk to aquatic non-target organisms following treatment with DESTINY (SAP1020DFFL) is acceptable when a non-sprayed vegetated buffer zone of 20 m is applied. A restriction for not using on artificial drained soil may be required at member states level (D1, D2 and D6 scenarios are concerned).

3.1.6.3 Effects on mammals

The TER values calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk for the active substances, indicating that the risk to mammals is acceptable following the use of diflufenican and flufenacet according to the proposed use pattern.
For diflufenican and flufenacet (log Pow > 3), a risk assessment for fish-eating and earthworm-eating mammals was conducted and long-term TER values are above the trigger of 5. The risks due to bioaccumulation of diflufenican and flufenacet via the food chain for mammals are then acceptable.
The risks for the puddle scenario of the drinking water were considered acceptable.
Therefore, treatment with DESTINY (SAP1020DFFL) in accordance with the proposed use patterns in cereals poses an acceptable risk to mammals.

3.1.6.4 Effects on honeybees

Overall, the calculated HQ values for the active substances and the product are less than 50. The risk for honeybees is then considered acceptable when DESTINY (SAP1020DFFL) is applied according to the intended application rate.

3.1.6.5 Effects on non-target arthropods

The in-field HQ value calculated for *A. rhopalosiphi* is below the trigger value of 1 indicating acceptable in-field risk for this species.
For *T. pyri*, only toxicity endpoint measured on aged residue are available. However, since lethal and sublethal effects are below 10% at 1 DAA at the required application rate of 0.6 L/ha, the in-field risk is considered acceptable. Based on the LR_{50} determined at 1 DAA, the off-field HQ is below the trigger of 1. The safety margin is considered sufficient to conclude to an acceptable off-field for *Typhlodromus pyri* without mitigation measure.
It is therefore concluded that there will be acceptable risks to non-target arthropods following the recommended uses of DESTINY (SAP1020DFFL).

3.1.6.6 Effects on earthworms and other macro-organisms

No unacceptable acute or reproductive risk to earthworms and other soil macro-organisms is indicated using active substances, formulation and metabolites data. It is therefore concluded that use of DESTINY (SAP1020DFFL) according to GAP is not expected to result in an unacceptable acute or long-term risk to earthworms and other soil macro-organisms.
Based on a field litter-bag study, diflufenican, applied at the recommended application rates, would not adversely affect the processes affecting decomposition of indigenous organic material under field conditions.

3.1.6.7 Effects on soil micro-organisms

The risk of DESTINY (SAP1020DFFL) to soil micro-organisms was evaluated by comparison of no-effect concentrations derived from laboratory tests with the active substances and metabolites with PEC_{soil}. All no effect levels exceed the relevant PEC_{soil} values by a factor of at least 3, indicating that DESTINY (SAP1020DFFL) does not pose an unacceptable risk to soil micro-organisms.

3.1.6.8 Effects on non-target plants

Based on a probabilistic risk assessment taking into account the most sensitive endpoints from 10 species tested in vegetative vigour and seedling emergence studies, the risk for non-target terrestrial plants is considered acceptable without mitigation measures.

3.1.7 Efficacy

This conclusion concerned the preparation DESTINY (SAP1020DFFL), composed of 200g/L of diflufenican and 400g/l of flufenacet. These active substances are already registered in Europe and used in France as herbicide for cereal crops. France is zRMS on this dossier. CMS are Bulgary, Greece, Italy, Portugal and Spain.

Considering the data submitted:

- The efficacy of DESTINY (SAP1020DFFL) is considering as satisfactory for the claimed uses
- The selectivity of DESTINY (SAP1020DFFL) is considered as satisfactory for the claimed uses
- The risks of negative impact on yield, quality, transformation processes, propagation, succeeding crops and adjacent crops are considered as negligible

Risk of resistance is considered low for flufenacet and moderate for diflufenican. Mix of both substances can reduce risk, which can be considered as acceptable.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation cannot be granted**. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 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

N/A : no marketing autorisation granted

3.4.2 Post-authorisation data requirements

N/A : no marketing autorisation granted

3.4.3 Label amendments

N/A : no marketing autorisation granted

Appendix 1 – Copy of the French Decision

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anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

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

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

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

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

de la société *SAPEC AGRO France*

enregistrée sous le *n°2014-2853*

Vu les conclusions de l'évaluation de l'Anses du 7 juin 2018,

Considérant le risque de dépassement de la limite maximale de résidus en vigueur du flufénacet,

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.

DESTINY
AMM n°-

Page 1 sur 3

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Informations générales sur le produit	
Nom du produit	DESTINY
Type de produit	Produit de référence
Titulaire	SAPEC AGRO France 2/12 Chemin des Femmes Immeuble l'Odyssée -A-3° 91300 MASSY, France
Formulation	Suspension concentrée (SC)
Contenant	200 g/L - diflufénicanil 400 g/L - flufénacet
Numéro d'intrant	9648-2014.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 15 OCT. 2018

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

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ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15105912 Blé*Désherbage	0,6 L/ha	1/an	-
	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus du flufénacet.		
15105913 Orge*Désherbage	0,6 L/ha	1/an	-
	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus du flufénacet.		

DESTINY
AMM n°-

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

HERBICIDE

DESTINY®

Suspension concentrée (SC)

contenant 200 g/L de diflufénicanil et 400 g/L de flufénacet

Herbicide anti dicotylédones et anti graminées du blé et de l'orge

Autorisation de Mise sur le Marché n° XXXXXX

« RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL »

Homologué par:

SAPEC AGRO S.A.

Avenida do Rio Tejo - Herdade das Praias

2910-440 SETÚBAL - PORTUGAL

Tel: +351 265710100

Lot N°.....

Date de fabrication :

Prepared by Sapec Agro SA

DESTINY®
Suspension concentrée contenant 200 g/L de difluénicanil et 400 g/L de flufénacet.

AMM n° XXXXXX

ATTENTION

H302	**Nocif en cas d'ingestion.**
H317	**Peut provoquer une allergie cutanée.**
H373	**Risque présumé d'effets graves pour les organes à la suite d'expositions répétées ou d'une exposition prolongée.**
H400	**Très toxique pour les organismes aquatiques.**
H410	**Très toxique pour les organismes aquatiques, entraîne des effets à long terme.**

P102	Tenir hors de la portée des enfants.
P260	Ne pas respirer brouillards/aérosols.
P270	Ne pas manger, boire ou fumer en manipulant le produit.
P301+P312	EN CAS D'INGESTION: appeler un CENTRE ANTIPOISON ou un médecin en cas de malaise.
P333+P313	En cas d'irritation ou d'éruption cutanée: consulter un médecin.
P273	Éviter le rejet dans l'environnement.
P391	Recueillir le produit répandu.
P501	Éliminer le contenu/récipient conformément à la réglementation nationale.

Conditions d'emploi
Respectez les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.
- Délai de rentrée des travailleurs sur la parcelle: 48 heures après traitement
- SP1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.
- SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 10 mètres comportant un dispositif végétalisé permanent d'une largeur de 10 mètres par rapport aux points d'eau.

Distributeur :

La fiche de données de sécurité est disponible sur demande chez votre fournisseur de produits phytopharmaceutiques et elle est également téléchargeable et imprimable à partir des sites www.sapecagro.fr et www.quickfds.com.

En cas d'urgence **appelez le n° 15 ou le Centre Anti-poison** (Paris : 01 40 05 48 48)

puis signalez vos symptômes au réseau Phyt'attitude, n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Fabriqué au PORTUGAL **Contenu : XX L**

DESTINY® - Marque déposée par SAPEC AGRO
SAPEC AGRO, S.A. Avenida do Rio Tejo - Herdade das Praias, 2910-440 Setúbal – Portugal

DESTINY®
200 g/L de diflufénicanil et 400 g/L de flufénacet

PRESENTATION ET MODE D'ACTION

DESTINY® est un herbicide contenant du diflufénicanil et du flufénacet actif sur de nombreuses graminées et dicotylédones du blé et de l'orge.

DESTINY® est doté d'une excellente efficacité d'action, permettant de maîtriser les graminées et dicotylédones en traitement précoce, dès l'automne et en une application unique.

Le **diflufénicanil** est un herbicide anti-dicotylédones annuel de contact appartenant à la famille chimique des pyridine-carboxamides. En prélevée, il est fortement absorbé par les 2 premiers centimètres du sol et pénètre dans l'adventice par la tigelle. En post-levée son action de contact est meilleure sur les tissus jeunes jusqu'à 4 feuilles. Il agit en inhibant l'enzyme PDS (phytoène désaturase) nécessaire à la biosynthèse des caroténoïdes. Il est fortement absorbé par la tigelle des adventices en pré ou post-levée bloquant ainsi les phytoprotecteurs de la chlorophylle, entrainant un blanchiment de la plante puis sa mort.

Le **flufénacet** est un herbicide de la famille chimique des oxyacétamine, rapidement absorbé par les racines et par l'hypoctyle. Dans le cas d'application en post-levée, il est également faiblement absorbé par les feuilles. Il bloque la division et l'élongation cellulaire au niveau des méristèmes des racines et des jeunes pousses, stoppant ainsi la croissance et le développement des tissus.

De par la combinaison des différents modes d'action de ses deux substances actives **DESTINY®** permet le désherbage complet des graminées et dicotylédones du blé et de l'orge, comme les gaillets gratterons, pâturin annuel, renoncules.

La mise en place de toute autre culture ne figurant pas ci-dessus reste sous l'entière responsabilité de l'agriculteur.

Cultures de remplacement

En cas d'accident nécessitant le remplacement de la culture traitée avec DESTINY, il est possible de réimplanter les cultures ci-dessous:

- Avec ou sans labour et avec un délai de 3 mois entre traitement et semis : blé tendre de printemps, orge de printemps.
- Avec ou sans labour et avec un délai de 4 mois entre traitement et semis : lin textile de printemps.
- Avec ou sans labour et avec un délai de 4,5 mois entre traitement et semis : tournesol.
- Avec ou sans labour et avec un délai de 5 mois entre traitement et semis : maïs, sorgho.- Avec labour obligatoire et un délai de 3 mois entre traitement et semis : blé dur de printemps.
- Avec labour obligatoire et un délai de 4 mois entre traitement et semis : pois protéagineux de printemps.
- Avec labour obligatoire et un délai de 4,5 mois entre traitement et semis : pomme de terre.

Cultures non possibles : avoine de printemps, soja, colza de printemps, betterave, ray-grass, luzerne.

La mise en place de toute autre culture ne figurant pas ci-dessus reste sous l'entière responsabilité de l'agriculteur.

Important
Respecter les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage. Elles ont été déterminées 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...

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.

Appendix 3 – Letter(s) of Access

Not applicable.