REGISTRATION REPORT

Part A

Risk Management

Product code: MON 37504

Product name(s): MONITOR

Active Substance: Sulfosulfuron 800 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(authorisation renewal art.43)

Applicant: PHILAGRO France

Date: 2019-03-14

Table of Contents

PART A – Risk Management

The company PHILAGRO France has requested renewal of the marketing authorisation in France for the product MONITOR (formulation code: MON 37504; marketing authorisation n° 9800374), containing 800 g/kg sulfosulfuron 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 MONITOR (MON 37504) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of MONITOR (MON 37504) have been made using endpoints agreed in the EU peer review of sulfosulfuron.

This document describes the specific conditions of use and labelling required for France for the registration of MONITOR (MON 37504).

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 PHILAGRO France's application to market MONITOR (MON 37504) 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 renewal of authorisation after approval of the active substance of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Sulfosulfuron

Commission Implementing Regulation (EU) n°2015/1154 of 14 July 2015 renewing the approval of the active substance sulfosulfuron in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011
Specific provisions of Regulation (EU) n° 2015/1154 were as follows : For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on sulfosulfuron, and in particular Appendices I and II thereof shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; — the risk to soil non-target macro-organisms other than earthworms, non-target terrestrial plants and aquatic organisms.
An EFSA conclusion is available (EFSA Journal 2014;12(7):3764). A Review Report is available (SANCO/12744/2014 Rev 3, 29 May 2015).

1.3 Regulatory approach

The present application (2016-1231, 2016-1512, 2016-4250) 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. 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 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.

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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

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of MONITOR (MON 37504), 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.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	MONITOR (MON 37504)
Authorisation number	9800374
Function	herbicide
Applicant	PHILAGRO France
Composition	800 g/kg sulfosulfuron
Formulation type (code)	Water dispersible granules (WG)
Packaging	HDPE bottle (125 g)

2.2 Classification and labelling

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

Physical hazards	-	
Health hazards	No classification for human health	
Environmental hazards	Hazardous to the aquatic environment — Acute Hazard, Category 1 Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H400 H410	Very toxic to aquatic life 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)	-	-

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

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe 1	To protect ground water do not apply this, or any product containing sulfosulfuron more than every other year to soil with pH<6.6 for a dose less than or equal to 10 g as/ha
SPe 1	To protect ground water do not apply this, or any product containing sulfosulfuron more than every third year to soil with pH>6.6 for a dose less than or equal to 10 g as/ha
SPe 1	To protect ground water do not apply this, or any product containing sulfosulfuron more than every third year to soil with pH<6.6 for a dose higher than 20 g as/ha (or for 2 applications)
SPe 1	To protect ground water do not apply this, or any product containing sulfosulfuron to soil with pH>6.6 for a dose higher than 10 g as/ha (for 1 or 2 applications)
SPe 1	To protect groundwater do not apply this product before stage BBCH 20 on winter cereals.
SPe 1	To protect soil organisms do not apply this product before stage BBCH 20 on winter cereals.
Spe 2	To protect aquatic organisms do not apply to artificially drained soil with clay content higher than or equal to 45%.
Spe 3	To protect aquatic organisms respect an unsprayed buffer zone of 5 meters to surface water bodies for a dose less than or equal to 10 g as/ha for 1 or 2 applications.
Spe3	To protect aquatic organisms respect an unsprayed buffer zone of 5 meters with an unsprayed vegetated buffer zone of 5 meters to surface water bodies for a dose higher than 10 g as/ha (1 application).

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment[8]: refer to the Decision in Appendix 1 for the details
Re-entry period[9]: 6 hours
Pre-harvest interval[10]: 70 days
Other mitigation measures: - The use of ALS inhibitors to control grasses (flupyrsulfuron, iodosulfuron, mesosulfuron, propoxycarbazone, sulfosulfuron, pyroxsulam...) should be limited to one single application per year, except for the control of bromegrass, where 2 applications are possible.
The label must reflect the conditions of authorisation.

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

[9] 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]

[10] 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, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.

GAP rev. , date: 2019-03-14

PPP (product name/code) **MONITOR (MON 37504)** **Formulation type:** **WG**
active substance 1 **sulfosulfuron** **Conc. of as 1:** **800 g/kg**

Applicant: **PHILAGRO France** **professional use** ☒
Zone(s): **southern EU** **non professional use** ☐
Verified by MS: **yes**

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G 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. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	g product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	France	Winter Wheat Triticale	F	*Agropyron repens; Galium aparine; Stellaria media; Matricaria sp.*	Spray	BBCH **20**-32	1	a) 25 b) 25	a) 20 b) 20	100-400	70	Acceptable
				Bromus sp.			2 (Min 14 days between application)	a) 12.5 b) 25	a) 10 b) 20			
				Apera spica-venti			1	a)12.5 b)12.5	a) 10 b) 10			

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 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.
10 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
11 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
12 PHI - minimum pre-harvest interval
13 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

MONITOR (MON 37504) is water dispersible granules (WG). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a cream to ivory colored granular formulation, without characteristic odor. It is not explosive and not flammable. In aqueous solution (1% dilution), it has a pH value of 5.5 at 21°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54 °C; neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE.

Its technical characteristics are acceptable for a WG formulation.

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

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical method for the determination of the active substance in the formulation is available and validated.

To update the dossier, an analytical method for the determination of phenol in the preparation MONITOR (MON 37504) is required.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Renewal Assessment Report/this dossier and validated for the determination of residues of sulfosulfuron in plants (dry commodities), soil, water (surface and drinking) and air.

Analytical methods for the determination of residues of sulfosulfuron in foodstuffs of animal origin are not necessary.

The active substance is 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

<table>
<tr><td colspan="4">Active Substance: Sulfosulfuron</td></tr>
<tr><td>ADI</td><td colspan="2">0.24 mg kg bw/d</td><td rowspan="3">EU (2015)</td></tr>
<tr><td>ARfD</td><td colspan="2">Non pertinent</td></tr>
<tr><td>AOEL</td><td colspan="2">0.4 mg/kg bw/d**</td></tr>
<tr><td rowspan="2">Dermal absorption</td><td colspan="3">Default values according to guidance on dermal absorption (Efsa 2012):</td></tr>
<tr><td></td><td>Concentrate (800g/kg)</td><td>Diluted formulation (0,04g/L à 0,1g/L)</td></tr>
<tr><td></td><td>Valeurs établies au niveau européen (EFSA Journal 2014;12(7):3764)) pour la préparation</td><td>25%</td><td>75%</td></tr>
</table>

		Concentrate (800 g/kg)	Spray dilution (0.025g/L à 0.2g/L)
	Dermal absorption endpoints %	25%	75%

*** AOEL was originally set at 1 mg/kg bw/d, and has been lowered during the European re-assessment of the active substance Sulfosulfuron in 2015.*
http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3764.pdf

3.1.3.1 Acute Toxicity

No toxicological study was provided with MONITOR (MON 37504). The experimental results obtained with formulations MON 37503 (for eye and skin irritation potential) and MON 37588 (for the remaining studies) have been used for extrapolation to MONITOR (MON 37504).
Based on these toxicological data, MONITOR (MON 37504) containing 800 g/kg sulfosulfuron, is considered to have a low toxicity in respect to acute oral, inhalation and dermal toxicity, not to be irritating to the rabbit skin or eye and not to be a skin sensitizer.

3.1.3.2 Operator Exposure

MONITOR (MON 37504) is a WG (water dispersible granules) formulation, containing 800 g/kg sulfosulfuron, intended to be used as an herbicide.

Summary of critical use patterns (worst cases):

Crop	F/G[11]	Equipment	Application rate Kg product/ha	Spray dilution (L/ha)	Model
Wheat, Triticale	F	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	**0.025 kg MONITOR (MON 37504)/Ha ie 0.020 kg a.s./Ha on 1 application/year**** OR 0.0125 kg MONITOR (MON 37504)/Ha ie 0.010 kg a.s./Ha on 2 successive applications/year at a 14 days interval	100-400L/Ha	EFSA model[12]

**worse case exposure

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

Crop	Equipment	PPE and/or working coverall	% AOEL Sulfosulfuron
Wheat, Triticale	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	0.36%

According to the model calculations, it can be concluded that the risk for the operator using MONITOR (MON 37504) 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.

[11] Open field or glasshouse
[12] EFSA 2014. Guidance on the assessment of exposure of operators, worker, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014, 12(10):3874) – version 30 mar 2015.

3.1.3.3 Bystander Exposure

No ARfD nore AAOEL was set for active substance sulfosulfuron. As a consequence, no exposure can be estimated from EFSA model for the Bystander. According to the EFSA guidance[13] bystander risk assessment for plant protection products with no potential acute systemic toxicity is covered by the assessment for residents.
Based on the conclusion made for the Resident exposure, it is concluded that there is no unacceptable risk to the bystander (child and adult) after incidental short-term exposure to MONITOR (MON 37504). Please refer to point 4.4 (Resident Exposure).

3.1.3.4 Resident Exposure

Residential exposure was assessed according to EFSA model. Exposure (all pathways) is estimated to 1.37 % and 0.47% of the AOEL of sulfosulfuron respectively for the child and the adult.
It is concluded that there is no unacceptable risk to the resident exposed to MONITOR (MON 37504).

There is no currently available analytical data (2001-2006) on sulfosulfuron in the report of the ORP (French pesticides residues observatory).

3.1.3.5 Worker Exposure

Worker exposure was assessed according to EFSA model. Exposure is estimated to 0.53% of the AOEL of sulfosulfuron wearing working clothing.
It is concluded that there is no unacceptable risk to the resident exposed to MONITOR (MON 37504).
For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

3.1.4 Residues and Consumer Exposure

Critical GAP(s) and overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.02* mg/kg (wheat) for sulfosulfuron as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of sulfosulfuron residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, France agrees with the authorization of the intended uses.

According to available data, no specific mitigation measures are recommended.

Post-authorisation data:

- Storage stability of sulfosulfuron residues, especially from cereal forage (commodity with high water content).

The preparation MONITOR (MON 37504) is composed of sulfosulfuron.

Summary for sulfosulfuron

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) No 617/2014	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Winter wheat	Yes	Yes (12 NEU and	Yes	Yes[1]	Yes	No	No	/

[13] EFSA 2014 Guidance on the assessment of exposure of operators, worker, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014, 12(10):3874, 55pp., doi:10.2903/j.efsa.2014.3874.
p9 : "…No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure."

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EU) No 617/2014	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
2	Triticale		4 SEU)						

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
[1] EFSA, 2014: sulfosulfuron is stable for up to 533 days at –12 °C. However, further data are required from cereal forage (commodity with high water content).

According to SANCO 7525/VI/95 - rev.10 (December 2015), wheat is considered a major crop in Southern Europe and a total number of 8 trials are required to support this use in this zone. In France, wheat is also considered a major crop. Therefore, at least 8 trials performed in southern- and 8 trials in northern regions are required. However, a reduced data set is sufficient when residues in commodities are all below their respective LOQs (SANCO 7525/VI/95 – rev. 10, December 2015). Indeed, the residues of sulfosulfuron found in winter wheat treated with the product MON 3758 as GW formulation were below the wheat grain EU-MRL set at the level of 0.02* mg/kg. These results can be extrapolated from winter wheat to triticale.

For cereals, additional data are required in post-registration to confirm the stability of residues in forage (commodity with high water content).

Quantifiable residues of sulfosulfuron are not expected in crops and as the chronic exposure does not exceed 10% of the ADI, there was no need to investigate the effect of industrial and/or household processing. Specific processing factors for enforcement of processed commodities are therefore not proposed.

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

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.

Since no ARfD has been set for sulfosulfuron, the calculation of the acute consumer exposure is not required. The use of MONITOR (MON 37504) on wheat and triticale is therefore acceptable.

Information on MONITOR (MON 37504) (KCA 6.8)

Crop	PHI for MONITOR (MON 37504) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for MONITOR (MON 37504) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Sulfosulfuron		
Wheat	70 days	Yes	70 days[1]	/
Triticale				

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).
[1] PHI of 70 days corresponds to a last application at BBCH 32.

Waiting periods before planting succeeding crops

Not required.

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.

The PEC of sulfosulfuron and its metabolites in soil 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. PEC soil derived for the active substances and its metabolites are used for the ecotoxicological risk assessment.

PECgw for sulfosulfuron and its metabolites **do not occur at levels exceeding** those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[14], when the product is applied on winter cereals

- every other year to soil with pH<6.6 at the rate of 10 g as/ha
- every third year to soil with pH>6.6 at the rate of 10 g as/ha
- every third year to soil with pH<6.6 at the rate of 20 g as/ha

Therefore, no unacceptable risk of groundwater contamination is expected in the conditions mentioned above.

PECgw for sulfosulfuron **occurs at levels exceeding** those mentioned in regulation EC 1107/2009 when the product is applied every third year on winter cereals to soil with pH>6.6 at the rate of 20 g ai/ha and no further refinement is proposed. Therefore unacceptable risk of groundwater contamination is expected and restriction applies.

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

Effects on terrestrial vertebrates
The risk assessment for birds and mammals is carried out according to the 'EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)[1] and considering the EU agreed endpoints of sulfosulfuron.
The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk, indicating that the risk to birds and mammals[2] is acceptable following use of MONITOR (MON 37504) according to the proposed use patterns.

Effects on aquatic species
Based on the guidance document, the risks for aquatic organisms is acceptable for the intended uses when mitigation measures are applied.

Effects on bees and other non-target arthropods
Based on the guidance documents, the risks for bees and other non-target arthropods are acceptable for the intended uses.

Effects on earthworms and other soil macro-organisms
The risk assessment for earthworms and other soil macro-organisms is carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the EU agreed endpoints of sulfosulfuron and data on the formulation MONITOR (MON 37504).
The acute and chronic TER values for sulfosulfuron and data on the formulation are greater than the triggers of 10 and 5 respectively, indicating that the risk to earthworms and other soil macro-organisms is acceptable according to the proposed use pattern.

Effects on soil non-target micro-organisms
The risk of MONITOR (MON 37504) to soil micro-organisms was evaluated by comparison of no-effect concentrations, derived from laboratory tests, with PEC_S.
The no effect levels exceed the relevant PEC_S values, indicating that the risk to soil micro-organisms is acceptable following use of MONITOR (MON 37504) according to the proposed use pattern.

[14] 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.

[1] European Food Safety Authority; Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA. EFSA journal 2009; 7(12):1438. [139 pp.]

[2] from direct dietary exposure, drinking water and secondary poisoning.

Effects on non-target plants
The risk assessment for non-target plants is carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the endpoints of the formulation MONITOR (MON 37504).
The application of MONITOR (MON 37504) does not cause unacceptable effects on non-target terrestrial plants.

3.1.7 Efficacy

***split application 2x10 g: second application max 2-3 week after the first**

Country	**Crops**	**Pest**	**Method of application**	**Maximum application rate per cycle**	**Maximum number of application per season (BBCH growth stage)**	**Opinion of France for efficacy section**
FR	Winter wheat and triticale	*Agropyron repens* *Galium aparine* *Stellaria media* *Matricaria sp.* *Apera spica-venti*** Volunteer barley	spraying	25 g/ha	1 (BBCH 13-32)	Acceptable
	Winter wheat and triticale	*Bromus* sp.		25 g/ha (20 g sulfosulfuron/ha)*****	1* (2 if split application) (BBCH 13-32)	Acceptable

****since no case of resistance of *Apera spica-venti* to ALS inhibitors has been reported, the dose rate of the product MONITOR to control *Apera spica-venti* should be as equal as the dose applied against the other weeds except of *Bromus* sp.**

Considering the data submitted:
- The efficacy level of MONITOR (MON 37504) is considered as satisfactory for all the claimed uses.
- The selectivity level of MONITOR (MON 37504) is considered as acceptable for all the claimed uses.
- The risks of negative impact on yield, quality, transformation processes, propagation, succeeding crops and adjacent crops are considered as acceptable.
- There is a risk of resistance development or appearance to ALS inhibitors requiring a monitoring on cereals.

Resistance monitoring data
Monitoring of resistance to ALS inhibitors should be put in place (one monitoring for all products based on *Matricaria* sp. and *Stellaria media* in cereals. Any new information which would change the resistance risk analysis should immediately be provided to Anses. In all cases, the results are expected at the next product authorisation-renewal.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation can 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

Monitoring of resistance to sulfosulfuron should be continued based on efficacy failure analysis, especially on *Matricaria* sp. and *Stellaria media*. Any new information which would change the resistance risk analysis should immediately be provided to Anses.

3.4.2 Post-authorisation data requirements

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

- An analytical method for the determination of phenol in the product.
- Storage stability of sulfosulfuron residues, especially from cereal forage (commodity with high water content).

3.4.3 Label amendments

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision

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Décision relative à une demande de renouvellement de l'autorisation de mise sur le marché d'un produit phytopharmaceutique et aux demandes associées

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 les demandes de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active sulfosulfuron, de changement mineur de composition et de modification des conditions d'autorisation du produit phytopharmaceutique ***MONITOR***

de la société	*PHILAGRO France*
enregistrées sous les	*n°2016-1231, n°2016-1512 et n°2016-4250*

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

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **est renouvelée** en France, en intégrant la nouvelle composition, pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

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

Avertissement :

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

MONITOR
AMM n°9800374

Page 1 sur 6

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Informations générales sur le produit	
Nom du produit	MONITOR
Type de produit	Produit de référence
Titulaire	PHILAGRO France 10A rue de la Voie Lactée Parc d'Affaires de Crécy 69370 SAINT DIDIER AU MONT D'OR France
Formulation	Granulé dispersable (WG)
Contenant	800 g/kg - sulfosulfuron
Numéro d'intrant	9800374
Numéro d'AMM	9800374
Fonction	Herbicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 décembre 2031.

Le dépôt d'une demande de 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, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

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

A Maisons-Alfort le, 14 MARS 2019

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 : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	**Contenance**
Bouteilles en polyéthylène haute densité	125 g

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H400 : Très toxique pour les organismes aquatiques
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
Pour les phrases P se référer à la règlementation en vigueur. **Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.**	

MONITOR
AMM n°9800374

Page 3 sur 6

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Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
15105912 Blé*Désherbage	**25 g/ha**	**1/an**	entre les stades BBCH 20 et BBCH 32	70	5 (dont DVP 5)	-	-	-
	Uniquement sur blé d'hiver et triticale. 1 application à 25 g/ha ou 2 applications à 12,5 g/ha par culture et par parcelle. Modification du stade minimal d'application de BBCH 13 à BBCH 20 en raison d'un risque inacceptable pour les organismes du sol et les eaux souterraines.							
	12,5 g/ha	**2/an**	entre les stades BBCH 20 et BBCH 32	70	5	-	-	-
	Uniquement sur blé d'hiver et triticale. Efficacité montrée sur agrostis jouet du vent pour une application et sur brome pour deux applications. 1 application à 25 g/ha ou 2 applications à 12,5 g/ha par culture et par parcelle. Intervalle minimum entre les applications : 14 jours. Modification du stade minimal d'application de BBCH 13 à BBCH 20 en raison d'un risque inacceptable pour les organismes du sol et les eaux souterraines.							

DVP : Dispositif Végétalisé Permanent.

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

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

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

Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à rampe

• pendant le mélange/chargement

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

• pendant l'application

Si application avec tracteur avec cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. 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 ;

Si application avec tracteur sans cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.

Pour le travailleur, porter

- Une combinaison de travail (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m²) avec traitement déperlant.

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

- 6 heures.

Respect des limites maximales de résidus (LMR)

Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

MONITOR
AMM n°9800374

Page 5 sur 6

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

Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

- SPe 1 : Pour protéger les eaux souterraines, ne pas appliquer ce produit ou tout autre produit contenant du sulfosulfuron plus d'une fois tous les 2 ans sur sol à pH<6,6 à une dose inférieure ou égale à 10 g s.a./ha.

- SPe 1 : Pour protéger les eaux souterraines, ne pas appliquer ce produit ou tout autre produit contenant du sulfosulfuron plus d'une fois tous les 3 ans sur sol à pH>6,6 à une dose inférieure ou égale à 10 g s.a./ha.

- SPe 1 : Pour protéger les eaux souterraines, ne pas appliquer ce produit ou tout autre produit contenant du sulfosulfuron plus d'une fois tous les 3 ans sur sol à pH<6,6 à une dose supérieure à 10 g s.a./ha (pour 1 ou 2 applications).

- SPe 1 : Pour protéger les eaux souterraines, ne pas appliquer ce produit ou tout autre produit contenant du sulfosulfuron sur sol à pH>6,6 à une dose supérieure à 10 g s.a./ha (pour 1 ou 2 applications).

Protection de la faune

- SPe 2 : Pour protéger les organismes aquatiques, ne pas appliquer ce produit sur sol artificiellement drainé ayant une teneur en argile supérieure ou égale à 45 %.

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau, pour 1 ou 2 applications à une dose inférieure ou égale à 10 g s.a./ha.

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau, pour 1 application à une dose supérieure à 10 g s.a./ha.

Gestion des résistances

Dans le cadre de la gestion des adventices des céréales à pailles, l'utilisation des inhibiteurs d'ALS anti graminées doit être limitée à 1 seule application par campagne, exception faite du contrôle des bromes où 2 applications fractionnées peuvent être réalisées.

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

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir une méthode d'analyse validée pour déterminer la teneur en phénol libre dans le produit.	24	-
Fournir des données de stabilité au stockage des résidus de sulfosulfuron sur fourrage et graminées fourragères (matrice riche en eau).	24	-
Poursuivre le suivi de la résistance au sulfosulfuron, en particulier sur *Matricaria sp.* et *Stellaria media*. Fournir aux autorités compétentes, toute nouvelle information susceptible de modifier l'analyse du risque de résistance.	-	-

MONITOR
AMM n°9800374

Page 6 sur 6

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

Appendix 3 – Letter(s) of Access

Not applicable.