REGISTRATION REPORT

Part A

Risk Management

Product code: F8142-6

Product name(s): STALLION SYNC TEC

Chemical active substance(s):

Pendimethalin, 333 g/L
Clomazone, 30 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(authorisation renewal according to Art. 43)

Applicant: FMC FRANCE

Date: 28/03/2025

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PART A

RISK MANAGEMENT

1 Details of the application

The company FMC FRANCE has requested a marketing authorisation in France for the product STALLION SYNC TEC (formulation code: F8142-6), containing 333 g/L pendimethalin[1] and 33 g/L clomazone[2] as a herbicide for professional uses.

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

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

1.1 Application background

The present registration report concerns the evaluation of FMC FRANCE's application submitted on 01/12/2017 to market STALLION SYNC TEC (F8142-6) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the re-registration of authorisation after the renewal of approval of the active substance Pendimethalin of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2017-3325 and 2022-0176) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[3], the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[4]. When risk mitigation measures were necessary, they are adapted to the situation in France.

The updated version concerns the evaluation of new data (propose a validation method and analysis to determine the residual contents of MDI and MDA) submitted by FMC FRANCE on 18/01/2022 (application 2022-0176). The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of STALLION SYNC TEC (F8142-6) has been made using endpoints agreed in the EU peer reviews of Pendimethalin and Clomazone. It also includes assessment of data and information related to STALLION SYNC TEC (F8142-6) where those data have not been considered in the EU peer review process.

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

In order to comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance

[1] Commission Implementing Regulation (EU) 2017/1114 of 22 June 2017 renewing the approval of the active substance pendimethalin, as a candidate for substitution, 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

[2] 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

[3] 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

[4] 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

with the guidance document SANCO/2010/13170, the outcome of the risk assessment for the re-registration of plant protection product only applies to pendimethalin following its renewal of approval. For clomazone, provisions of the initial authorisation remain.

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

This document also describes the specific conditions of use and labelling required for France for the registration of STALLION SYNC TEC (F8142-6).

1.2 Letters of Access

The applicant has provided a letter of access for active substance. This letter of access is available upon request.

1.3 Justification for submission of tests and studies

Justification not submitted by the applicant.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of STALLION SYNC TEC (F8142-6), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	F8142-6
Product name in MS	STALLION SYNC TEC
Authorisation number	2140023
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	FMC FRANCE
Active substance(s) (incl. content)	Pendimethalin, 333 g/ Clomazone, 33 g/L
Formulation type	Capsule Suspension [CS]
Packaging	HDPE[6] (1 L, 5 L and 10 L)

[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] High-density polyethylene

Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for STALLION SYN TEC (F8142-6) resulted in the decision **to grant the authorisation.**

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Reproductive toxicity, category 2 Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	 GHS09
Signal word:	Warning
Hazard statement(s):	H361d: Suspected of damaging the unborn child. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the existing legislation***
Additional labelling phrases:	EUH208: Contains pendimethalin and 1,2-benzisothiazolin-3-one. May produce an allergic reaction.

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

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

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).
	For other restrictions refer to 2.5

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

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017[7] provides that:

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

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

Finally, the French Order of 12 April 2021[8] provides that:

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "related" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those "related" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[9] is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.

[7] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

[8] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

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

Bystander and resident protection	
-	Respect an unsprayed zone of 3 meters from the extremity of the boom and : - areas where bystanders are present during treatment - areas where residents could be present
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 20 meters including a vegetative strip of 20 meters to surface water bodies.
SPe 3	To protect non-target plants respect an unsprayed buffer zone of 20 meters to non-agricultural land.
Other specific restrictions	
Re-entry period	48 hours
Storage	When applying the product, use an approved device to limit spray drift (refer to the list updated by a service note published in the Official Bulletin of the Ministry of Agriculture and Food Sovereignty), in order to limit the spread of pendimethalin in the air.
Risk mitigation measure	In order to limit contamination of the air compartment by pendimethalin, additional mitigation measures should be implemented, such as increased edge-of-field distances, use of spray reducing equipment, or modified application conditions.
	To prevent any risk of phytotoxicity, specify the optimum conditions for application in relation to adjacent crops.
	To prevent any risk of phytotoxicity, specify the optimum conditions for planting replacement crops.
Agricultural recommendations	

The conditions of use of the active substance clomazone specified in the previous evaluations are not changed.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable" or "not finalised", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2025-03-28

PPP (product name/code):	STALLION SYNC TEC / F8142-6	Formulation type:	CS [a, b]
Active substance 1:	Pendimethalin	Conc. of a.s. 1:	333 g/L [c]
Active substance 2:	Clomazone	Conc. of a.s. 2:	33 g/L [c]
Applicant:	FMC FRANCE	Professional use:	☒
Zone(s):	Southern Zone [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)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./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	FR	Spring peas (combining and vining) PIBSX, PIBSA, CNAGL VICFM, LUPAN, CICFX, VIGSI	F	Broad-leaved and grass weeds	Overall spray	Pre-emergence BBCH 00-09	1	N/A	2.4	a) 0.072 / 0.799 b) 0.072 / 0.799	200-500	F (BBCH 09)	**Acceptable** Efficacy demonstrated on dicotyledonous weeds

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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)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
2	FR	Spring field beans PHSVX, PHSLU	F	Broad-leaved and grass weeds	Overall spray	Pre-emergence BBCH 00-09	1	N/A	2.4	a) 0.072 [1]/0.799 [2] b) 0.072 [1]/0.799 [2]	200-500	F (BBCH 09)	**Acceptable** Efficacy demonstrated on dicotyledonous weeds

* As some standards may have undergone changes, it is the responsibility of the applicant to update the references.

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 Background of authorisation decision and risk management

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

STALLION SYNC TEC (F8142-6) is an herbicide (CS). 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 dark yellow suspension, free from foreign matter with a faint nutty odour. It is not explosive and has no oxidising properties. The product is not flammable and has a flash point of >100 °C. It has a self- ignition temperature of 260 °C. In aqueous solution (1%), it has a pH value around 7.8 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 Bottles. Its technical characteristics are acceptable for a CS formulation.
The formulation is not classified for the physico-chemical aspect.

3.2 Efficacy (Part B, Section 3)

The efficacy level of STALLION SYNC TEC (F8142-6) is considered acceptable for the claimed uses.
The selectivity level of STALLION SYNC TEC (F8142-6) is considered acceptable for all the claimed uses.
The risks of negative impact of STALLION SYNC TEC (F8142-6) on yields, quality and propagation are considered negligible.
The risk of negative impact of STALLION SYNC TEC (F8142-6) on replacement and succeeding crops is considered as acceptable. **Nevertheless, specific attention should be paid to the establishment of replacement and succeeding crops.**
The risk of negative impact of STALLION SYNC TEC (F8142-6) on adjacent crops is considered as acceptable. **Nevertheless, specific attention should be paid to the conditions of application of the preparation next to adjacent crops.**
The risk of resistance apparition or development to clomazone or pendimethalin does not require any monitoring for the claimed uses.

3.3 Methods of analysis (Part B, Section 5)

Analytical methods for the determination of the active substances and the relevant impurities in the formulation are available and validated.

Analytical methods are available in the Draft Assessment Report for the determination of residues of clomazone in plants, food of animal origin, soil, water (surface and drinking) and air.

Analytical methods are available in the Renewal Assessment Report/this dossier and validated for the determination of residues of pendimethalin in plants, food of animal origin, soil, water (surface and drinking), air and body fluids.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active Substance: **CLOMAZONE**			
ADI	0.133 mg kg bw/d		EU (2008)
ARfD	Not applicable		
AOEL	0.133 mg/kg bw/d		
AAOEL	Not determined		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa, 2012):		
		Concentrate	Spray dilution
	Dermal absorption endpoints %	**75**	**75**
Oral absorption	87-100% *EFSA Peer review 2007*		
Vapour pressure	**1.92×10^{-2} Pa** (97.5 %, 25 °C) *EFSA Peer review, 2007*		

Active Substance: **PENDIMETHALIN**			
ADI	0.125 mg kg bw/d		EU (2017)
ARfD	0.3 mg/kg bw		
AOEL	0.17 mg/kg bw/d		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate	Spray dilution
	Dermal absorption endpoints %	**25**	**57**
Oral absorption	57% *EFSA Journal 2016;14(3):4420*		
Vapour pressure	**3.34×10^{-3} Pa** at 25°C *EFSA Journal 2016;14(3):4420*		

3.4.1 Acute toxicity

STALLION SYNC TEC (F8142-6) containing 30 g/L clomazone and 333 g/L pendimethalin has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.4.2 Operator exposure

In the application of the guidance on the review of a substance under Article 43 only the SA under review pendimethalin is evaluated. Data and risk assessment provided by the applicant for the other active substance clomazone are not reviewed by zRMS.

Summary of critical use patterns (worst case):

Crop type	F/G[10]	Equipment *Application method*	Maximum application rate kg as /ha	Volume water (L/ha)
Peas *(legume vegetables)*	F	Vehicle mounted *Downward spraying*	2,4 L/ha Pendimethalin: 0,799 kg/ha	200 – 500

Considering proposed uses, operator systemic exposure was estimated using the EFSA model[11]:

Crop	Equipment	PPE and/or working coverall	% AOEL pendimethalin
Peas	Vehicle mounted *Downward spraying*	Working coverall	245
		Working coverall and gloves during mixing/loading and application	10.9

According to the model calculations, it can be concluded that the risk for the operator using STALLION SYNC TEC (F8142-6) is acceptable with a working coverall and gloves during mixing/loading and application.

3.4.3 Worker exposure

In the application of the guidance on the review of a substance under Article 43 only the SA under review pendimethalin is evaluated. Data and risk assessment provided by the applicant for the other active substance clomazone are not reviewed by zRMS.

Workers may have to enter treated areas after treatment for crop reaching, picking. Therefore, estimation of worker exposure was calculated according to AOEM model. Exposure is estimated to 62 % of the AOEL of pendimethalin with PPE.
It is concluded that there is no unacceptable risk anticipated for the worker.

3.4.4 Bystander exposure

In the application of the guidance on the review of a substance under Article 43 only the SA under review pendimethalin is evaluated. Data and risk assessment provided by the applicant for the other active substance clomazone are not reviewed by zRMS.

[10] Open field or glasshouse
[11] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[12].
Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure*."

3.4.5 Resident exposure

In the application of the guidance on the review of a substance under Article 43 only the SA under review pendimethalin is evaluated. Data and risk assessment provided by the applicant for the other active substance clomazone are not reviewed by zRMS.

Residential exposure was assessed according to EFSA model incorporating a distance of 3 metres from the spray boom and a drift reduction technology. An acceptable risk was determined for residents (adult and child) when a buffer zone of 3 meters are taken.

Model (AOEM) - All pathways (mean)	**% AOEL Pendimethalin**
Resident (children)	60
Resident (adults)	26

3.4.6 Combined exposure

In the application of the guidance on the review of a substance under article 43, only the active substance under review pendimethalin is evaluated.
Thus, combined exposure is not taken into consideration by RMS.

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

The product STALLION SYNC TEC (F8142-6) is composed of pendimethaline and clomazone.
However in order to comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, this risk assessment report for the sections "Metabolism and Residue" only applies for the active substance pendimethaline following its renewal of approval.
For clomazone, provisions of the initial authorization remain.

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.05* mg/kg on beans (with or without pods) or peas (with or without pods) and 0.15 mg/kg on pulses (beans and peas) for pendimethalin laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of pendimethalin are unlikely to present a public health concern.

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

As far as consumer health protection is concerned, France as zRMS agrees with the authorization of the intended uses.
According to available data, additional information about possible contamination from mechanical harvesting would have been required.

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

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

In order to comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, this risk assessment report for the sections "Fate and behaviour in the Environment / Ecotoxicology" only applies for the active substance pendimethalin following its renewal of approval. For the other active substance (i.e. clomazone), provisions of the initial authorization remain.

The PEC of pendimethalin and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.
PEC soil and PECsw derived for the active substance and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw for pendimethalin and its metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[13]. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

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

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

[13] 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.

3.8 Relevance of metabolites (Part B, Section 10)

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

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

The product STALLION SYNC TEC (F8142-6) contains pendimethalin which is approved as candidate for substitution because:

- it fulfills two of PBT criteria: Persistant and Toxic.

As a conclusion of the comparative assessment intended uses are not suitable for substitution because:

Step 1 (French guidance document 27 July 2015):

- Taking into account the management of resistance:

In accordance with Article 50(1)(c) of Regulation (EC) No 1107/2009, in the framework of taking the prevention of the appearance of resistance into account, if the candidate a.s. for substitution is an important part of the resistance management strategy and if there are too few modes of action[14] available, substitution will not be considered for the 2 uses.

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

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

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

None.

[14] For information, the guidance document EPPO PP 1/271 (2) [https://pp1.eppo.int/downpdf.php5?id=4ed75af132854159936ccef7924f230ale] recommends at least two modes of action in situations of low resistance risk, at least three in situations of moderate risk, and at least four in situations of high risk.

Appendix 1 Copy of the product authorisation

Docusign Envelope ID: F3BDF1C0-8980-47B8-80AB-4F6B1C74D4E3

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Décision relative à une demande de renouvellement de l'autorisation de mise sur le marché d'un produit phytopharmaceutique et à la demande associée

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

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

Vu les demandes de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active pendiméthaline, et de modification des informations déclarées, du produit phytopharmaceutique ***STALLION SYNC TEC***

de la société	*FMC FRANCE*
enregistrées sous les	*n° 2017-3325 et 2022-0176*

Vu les conclusions de l'évaluation de l'Anses du 24 septembre 2021 et du 13 juin 2022,

Vu la notification de mise à jour de la classification en date du 8 septembre 2023,

Vu le courrier transmis par la direction en charge de l'évaluation des produits règlementés de l'Anses le 17 janvier 2025 confirmant la pertinence de la classification proposée dans la notification,

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

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

Avertissement :

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

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Informations générales sur le produit	
Nom du produit	STALLION SYNC TEC
Type de produit	Produit de référence
Titulaire	FMC FRANCE 11 bis quai Perrache 69002 LYON France
Formulation	Suspension de capsules (CS)
Contenant	30 g/L - clomazone 333 g/L - pendiméthaline
Numéro d'intrant	2140041
Numéro d'AMM	2140023
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 qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 15 juin 2026.

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

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

A Maisons-Alfort, le 28/03/2025

DocuSigned by:
Charlotte Grastilleur
AE281A865A42454...

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 : 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	1 L
Bidons en polyéthylène haute densité	5 L ; 10 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Toxiques pour la reproduction - Catégorie 2	H361d : Susceptible de nuire au fœtus
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
EUH208 : Contient de la pendiméthaline et de la 1,2-benzisothiazol-3(2H)-one. Peut produire une réaction allergique.	
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.	

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Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
16855905 Graines protéagineuses*Désherbage	**2,4 L/ha**	**1/an**	jusqu'au stade BBCH 09	F (BBCH 09)	20 (dont DVP 20)	-	20	Non concerné
	Uniquement sur graines protéagineuses de printemps. Efficacité montrée sur dicotylédones.							
16575901 Haricots et Pois écossés frais*Désherbage	**2,4 L/ha**	**1/an**	jusqu'au stade BBCH 09	F (BBCH 09)	20 (dont DVP 20)	-	20	Non concerné
	Uniquement sur pois écossés frais de printemps. Efficacité montrée sur dicotylédones.							

DVP : Dispositif Végétalisé Permanent.

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Pour l'application du produit, utiliser un dispositif homologué pour limiter la dérive de pulvérisation des produits (se référer à la liste actualisée par note de service publiée au Bulletin officiel du ministère chargé de l'agriculture) afin de limiter la dissémination de la pendiméthaline dans l'air.

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, porter :

• pendant le mélange/chargement

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

ou

- Gants en nitrile certifiés EN ISO 374-1/A1 et EN 16523-1+A1 (type A) ;
- Combinaison de protection chimique de catégorie III type 4 ou 3 certifiée EN 14605+A1:2009.

• pendant l'application

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) 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

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) 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 NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus le vêtement de protection précité.

ou

- Gants en nitrile certifiés EN ISO 374-1/A1 et EN 16523-1+A1 (type A) ;
- Combinaison de protection chimique de catégorie III type 4 ou 3 certifiée EN 14605+A1:2009.

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Pour le travailleur, porter

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1.

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

- 48 heures.

Protection des personnes présentes et des résidents (au sens du règlement (UE) N°284/2013)

Respecter une distance d'au moins 3 mètres entre la rampe de pulvérisation et :

- l'espace fréquenté par les personnes présentes lors du traitement ;
- l'espace susceptible d'être fréquenté par des résidents.

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.

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

Protection de l'eau

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

Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres en bordure des points d'eau.

Protection de la flore

- SPe 3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 20 mètres par rapport à la zone non cultivée adjacente.

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.

Pour la mise sur le marché français, la fabrication du produit s'opère exclusivement selon la composition intégrale figurant en annexe des conclusions de l'évaluation, dans un délai maximum de 12 mois à compter de la présente décision.

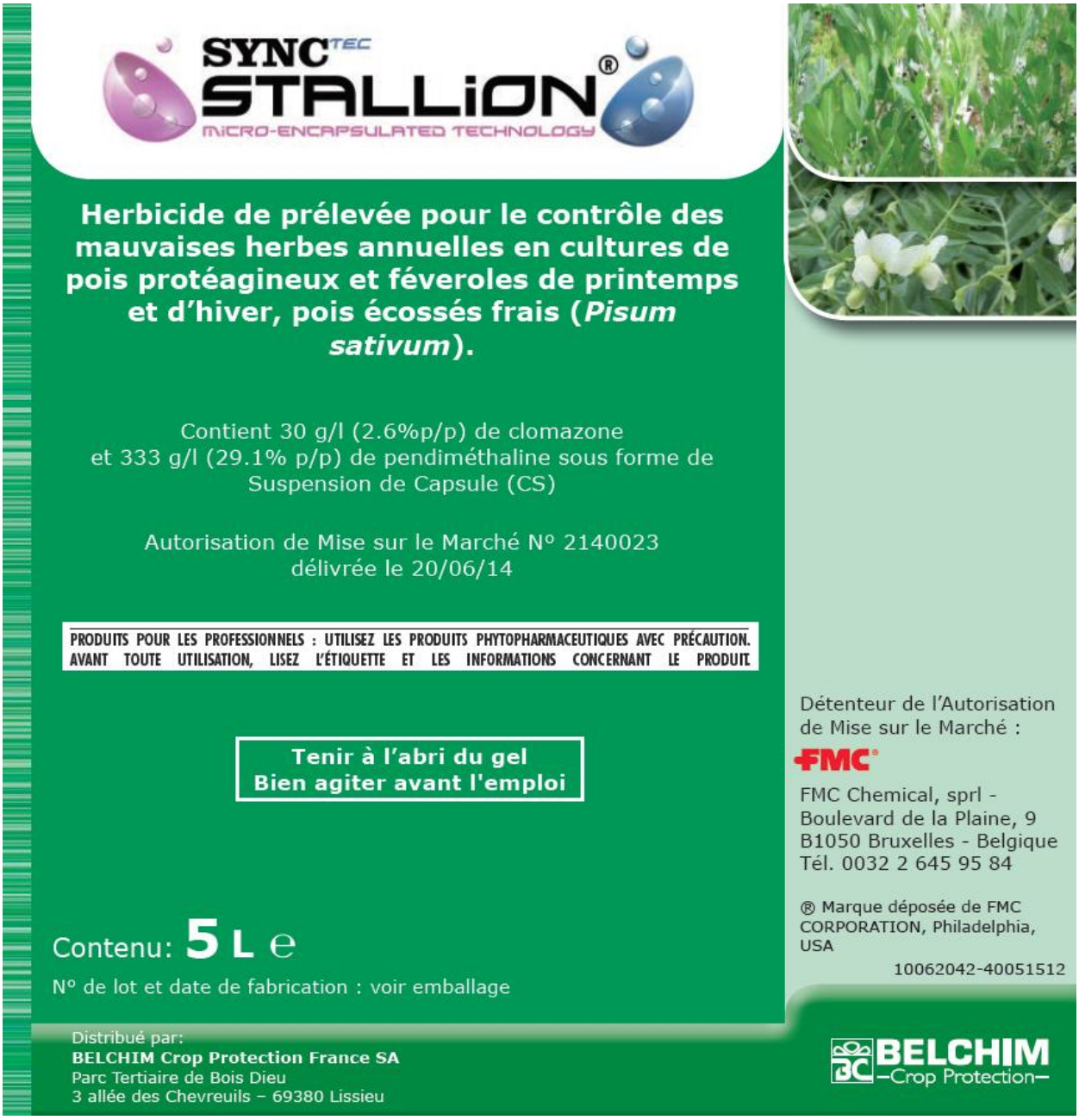
Recommandations relatives à l'étiquette du produit

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

- Pour prévenir tout risque éventuel de phytotoxicité, préciser les conditions optimales d'application par rapport aux cultures adjacentes.
- Pour prévenir tout risque éventuel de phytotoxicité, préciser les conditions optimales d'implantation des cultures suivantes ou de remplacement.

Appendix 2 Copy of the product label

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



SYNC TEC STALLION® MICRO-ENCAPSULATED TECHNOLOGY

STALLION Sync TEC®
Contient : Clomazone 30 g/l (2.6%p/p) + Pendiméthaline 333 g/l (29.1%p/p)
Suspension de capsule (CS)
AMM n°2140023

ATTENTION
H410 **Très toxique pour les organismes aquatiques, entraine des effets néfastes à long terme**
CONSEILS DE PRUDENCE
P102 Tenir hors de portée des enfants.
P270 Ne pas manger, boire ou fumer en manipulant ce produit.
P273 Éviter le rejet dans l'environnement.
P280 Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/ du visage.
P391 Recueillir le produit répandu.
P501 Éliminer le contenu/récipient conformément à la réglementation locale/nationale.
SP1 Ne pas polluer l'eau avec le produit ou son emballage. [Ne pas nettoyer le matériel d'application près des eaux de surface. /Eviter 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 20 mètres comportant un dispositif végétalisé de 20 mètres par rapport aux points d'eau.
SPe3 Pour protéger les plantes non cibles, respecter une zone non traitée de 20 mètres par rapport à la zone non cultivée adjacente.
Délai de rentrée : 6h
EUH208 **Contient de la Pendiméthaline. Peut produire une réaction allergique.**
EUH401 **Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.**

Fiche de données de sécurité disponible sur le site www.quickfds.com

En cas d'urgence: En cas d'intoxication humaine, APPELER LE 15 (depuis un téléphone fixe) OU LE 112 (depuis un téléphone mobile) OU LE CENTRE ANTIPOISON et consulter la Fiche de Données de Sécurité puis signalez vos symptômes au réseau Phyt'attitude (N° Vert 0 800 887 887) (appel gratuit depuis un poste fixe).
Vous pouvez également appeler au 00 32 14 58 45 45 (24h/24 n° d'appel d'urgence).

10062042-40051513

SYNC TEC STALLION® MICRO-ENCAPSULATED TECHNOLOGY

Herbicide de prélevée pour le contrôle des mauvaises herbes annuelles en cultures de pois protéagineux et féveroles de printemps et d'hiver, pois écossés frais (*Pisum sativum*).

Contient 30 g/l (2.6%p/p) de clomazone
et 333 g/l (29.1% p/p) de pendiméthaline sous forme de
Suspension de Capsule (CS)

Autorisation de Mise sur le Marché N° 2140023
délivrée le 20/06/14

PRODUITS POUR LES PROFESSIONNELS : UTILISEZ LES PRODUITS PHYTOPHARMACEUTIQUES AVEC PRÉCAUTION. AVANT TOUTE UTILISATION, LISEZ L'ÉTIQUETTE ET LES INFORMATIONS CONCERNANT LE PRODUIT.

Tenir à l'abri du gel
Bien agiter avant l'emploi

En cas d'urgence: En cas d'intoxication humaine, APPELER LE 15 (depuis un téléphone fixe) OU LE 112 (depuis un téléphone mobile) OU LE CENTRE ANTIPOISON et consulter la Fiche de Données de Sécurité puis signalez vos symptômes au réseau Phyt'attitude (N° Vert 0 800 887 887) (appel gratuit depuis un poste fixe).
Vous pouvez également appeler au 00 32 14 58 45 45 (24h/24 n° d'appel d'urgence).

Contenu: **4 x 5 Le**

N° de lot et date de fabrication : voir emballage

Détenteur de l'Autorisation de Mise sur le Marché :

FMC

FMC Chemical, sprl -
Boulevard de la Plaine, 9
B1050 Bruxelles - Belgique
Tél. 0032 2 645 95 84

® Marque déposée de FMC CORPORATION, Philadelphia, USA

10062042-40051514

Distribué par:
BELCHIM Crop Protection France SA
Parc Tertiaire de Bois Dieu
3 allée des Chevreuils – 69380 Lissieu

BELCHIM Crop Protection