REGISTRATION REPORT
Part A
Risk Management

Product code: SHA 3800 A
Product name: FREQUENT
Chemical active substance:
fluazifop-P-butyl, 125 g/L

Southern Zone
Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
(new application)

Applicant: Sharda Cropchem España S.L.
Date: 2019/03/22

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PART A
RISK MANAGEMENT

1 Details of the application

The company Sharda Cropchem España S.L. has requested marketing authorisation in France for the product FREQUENT (formulation code: SHA 3800 A), containing 125 g/L fluazifop-P butyl for use as a herbicide for professional uses.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 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 FREQUENT (SHA 3800 A) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of FREQUENT (SHA 3800 A) have been made using endpoints agreed in the EU peer review of fluazifop-P.

This document describes the specific conditions of use and labelling required for France for the registration of FREQUENT (SHA 3800 A).

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

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

Appendix 3 of this document is a copy of the letter(s) of Access.

Appendix 4 of this document is the list of data considered for national authorisation.

1.1 Application background

The present registration report concerns the evaluation of Sharda Cropchem España S.L.'s application to market FREQUENT (SHA 3800 A) in France as a 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.

The present application (2016-2022) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) 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")[1] – the highest application rates over the Southern zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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[2], 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)

[1] 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

[2] REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

No 546/2011[3], and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

1.2 Letters of Access

Not necessary: the applicant is the owner of the active substance and/or PPP data.

1.3 Justification for submission of tests and studies

According to the applicant: “*This dossier relies on test and studies providing data and information specific to the formulation FREQUENT (SHA 3800 A) as required by the EU regulations*”.

1.4 Data protection claims

2 **Where protection for data is being claimed for information supporting registration of FREQUENT (SHA 3800 A), it is indicated in the reference lists in Appendix 1 of the** Registration Report, Part B Sections 1-7.**Details of the authorisation decision**

2.1 Product identity

Product code	SHA 3800 A
Product name in MS	FREQUENT
Authorisation number	2190019
Low risk (article 47)	No
Function	Herbicide
Applicant	Sharda Cropchem España S.L.
Active substance(incl. content)	Fluazifop-P, 125 g/L
Formulation type	Emulsifiable concentrate (EC)
Packaging	PA/HDPE bottles containing 0.25 L, 0.5 L or 1 L product. PA/HDPE containers holding 5 L or 10 L product. Fluorinated HDPE containers holding 20 L product.
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 FREQUENT (SHA 3800 A) resulted in the decision to grant the authorisation for weed control in sunflower, sugar and fodder beet, soya and eggplant at modified

[3] 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

application rates from those originally requested by the applicant.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Skin Sensitisation, category 1B Reproductive toxicty, category 2 Aspiration toxicity, category 1 Hazardous to the aquatic environment, chronic, category 1
Hazard pictograms:	 GHS07 GHS08 GHS09
Signal word:	Danger
Hazard statement(s):	H304 : May be fatal if swallowed and enters airways H317 : May cause an allergic skin reaction. H361d : Suspected of damaging the unborn child. H410 : Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the extant legislation***
Additional labelling phrases:	Repeated exposure may cause skin dryness or cracking [EUH066]

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 [4] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

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

Finally, the French Order of 26 March 2014[5] 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[6] 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
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 2	To protect groundwater do not apply to more than 30 % of the area for orchard uses (pome fruit trees).
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres to surface water bodies

[4] 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
[5] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo
[6] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

SPe 3	To protect non-target plants, respect an unsprayed buffer zone of 5 metres to non-agricultural land
Other specific restrictions	
Re-entry period	48 hours
Risk mitigation measure	Do not harvest fruit that have been in direct contact with the ground.

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 26 March 2014 (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", 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.

GAP rev. 1, date: 2019-03-22

PPP (product name/code):	FREQUENT (SHA 3800 A)	Formulation type:	EC [a, b]
Fluazifop-P:	fluazifop-P	Conc. of a.s. 1:	125 g/L [c]
Applicant:	Sharda Cropchem España S.L.	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 applica-tions (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Wa-ter L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	SEU (France)	ORCHARDS: Pome fruit trees	F	Annual weeds (*Agrostis* spp., *Phalaris brachystachys*, *Lolium* spp., *Avena* spp., *Bromus* spp., *P. minor*, *Digitaria sanguinalis*, *Echinochloa* spp., *Setaria* spp., *Alopecurus* spp.)	Spray	1-3 leaves	1		a) 2.0 b) 2.0	a) 250 b) 250	200 / 600	**28**	**Acceptable** Residue trials only support a pre-harvest interval of **28** days

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	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
2	SEU (France)	ORCHARDS: Pome fruit trees (apple, pear)	F	Perennial weeds (*Panicum repens, Cynodon dactylon, Agropyron repens, Papalum paspalodes, Sorghum halepense)*	Spray	when perennials are actively growing (10-50 cm high) (*)	1		a) 3.0 b) 3.0	a) 375 b) 375	200 / 600	**28**	(*) *Sorghum halepense*: not higher than 25 cm Unacceptable (worker exposure, efficacy) Residues data only support a pre-harvest interval of **28** days Efficacy data only support an application rate of **2 L/ha**
3	SEU (France)	Sunflower	F	Annual weeds (*Agrostis* spp., *P. brachystachys, Lolium* spp., *Avena* spp., *Bromus* spp., *P. minor, D. sanguinalis, Echinochloa* spp., *Setaria* spp., *Alopecurus* spp.)	Spray	1-3 leaves	1		a) 2.0 b) 2.0	a) 250 b) 250	200 / 600	90	Unacceptable (efficacy)
3	SEU (France)	Sunflower	F	Annual weeds (*Agrostis* spp., *P. brachystachys, Lolium* spp., *Avena* spp., *Bromus* spp., *P. minor, D. sanguinalis, Echinochloa* spp., *Setaria* spp., *Alopecurus* spp.)	Spray	1-3 leaves	1		a) **1.5** b) **1.5**	a) **188** b) **188**	200 / 600	90	Acceptable
4	SEU (France)	Sunflower	F	Perennial weeds (*Panicum repens, Cynodon dactylon, Agropyron repens, Papalum paspalodes, Sorghum halepense)*	Spray	when perennials are actively growing (10-50 cm high) (*)	1		a) 3.0 b) 3.0	a) 375 b) 375	200 / 600	90	(*) *S. halepense*: not higher than 25 cm Acceptable
5	SEU (France)	Sugar and fodder beet	F	Annual weeds (*Agrostis* spp., *P. brachystachys, Lolium* spp., *Avena* spp., *Bromus* spp., *P. minor, D. sanguinalis, Echinochloa* spp., *Setaria* spp., *Alopecurus* spp.)	Spray	1-3 leaves	1		a) 2.0 b) 2.0	a) 250 b) 250	200 / 600	56	Unacceptable (efficacy)

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	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
5	SEU (France)	Sugar and fodder beet	F	Annual weeds (*Agrostis* spp., *P. brachystachys*, *Lolium* spp., *Avena* spp., *Bromus* spp., *P. minor*, *D. sanguinalis*, *Echinochloa* spp., *Setaria* spp., *Alopecurus* spp.)	Spray	1-3 leaves	1		a) **1.5** b) **1.5**	a) **188** b) **188**	200 / 600	56	Acceptable
6	SEU (France)	Sugar and fodder beet	F	Perennial weeds (*P. repens*, *C. dactylon*, *A. repens*, *P. paspalodes*, *S. halepense)*	Spray	when perennials are actively growing (10-50 cm high) (*)	1		a) 3.0 b) 3.0	a) 375 b) 375	200 / 600	56	(*) *S. halepense*: not higher than 25 cm Acceptable
7	SEU (France)	Soya bean	F	Annual weeds (*Agrostis* spp., *Phalaris brachystachys*, *Lolium* spp., *Avena* spp., *Bromus* spp., *P. minor*, *D. sanguinalis*, *Echinochloa* spp., *Setaria* spp., *Alopecurus* spp.)	Spray	1-3 leaves	1		a) 2.0 b) 2.0	a) 250 b) 250	200 / 600	90	Unacceptable (efficacy)
7	SEU (France)	Soya bean	F	Annual weeds (*Agrostis* spp., *Phalaris brachystachys*, *Lolium* spp., *Avena* spp., *Bromus* spp., *P. minor*, *D. sanguinalis*, *Echinochloa* spp., *Setaria* spp., *Alopecurus* spp.)	Spray	1-3 leaves	1		a) **1.5** b) **1.5**	a) **188** b) **188**	200 / 600	90	Acceptable
8	SEU (France)	Soya bean	F	Perennial weeds (*P. repens*, *C. dactylon*, *A. repens*, *P. paspalodes*, *S. halepense)*	Spray	when perennials are actively growing (10-50 cm high) (*)	1		a) 3.0 b) 3.0	a) 375 b) 375	200 / 600	90	(*) *S. halepense*: not higher than 25cm Unacceptable (MRL) Not finalised (efficacy and selectivity)
8	SEU (France)	Soya bean	F	Perennial weeds (*P. repens*, *C. dactylon*, *A. repens*, *P. paspalodes*, *S. halepense)*	Spray	when perennials are actively growing (10-50 cm high) (*)	1		a) **2.5** b) **2.5**	a) **313** b) **313**	200 / 600	90	(*) *S. halepense*: not higher than 25cm Not finalised (efficacy)

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	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
9	SEU (France)	Olive tree	F	Annual weeds (*Agrostis* spp., *P. brachystachys*, *Lolium* spp., *Avena* spp., *Bromus* spp., *P. minor*, *D. sanguinalis*, *Echinochloa* spp., *Setaria* spp., *Alopecurus* spp.)	Spray	1-3 leaves	1		a) 2.0 b) 2.0	a) 250 b) 250	200 / 600	**28**	Acceptable Residues data only support a pre-harvest interval of **28** days
10	SEU (France)	Olive tree	F	Perennial weeds (*P. repens*, *C. dactylon*, *A. repens*, *P. paspalodes*, *S. halepense)*	Spray	when perennials are actively growing (10-50 cm high) (*)	1		a) 3.0 b) 3.0	a) 375 b) 375	200 / 600	**28**	(*) *S. halepense*: not higher than 25 cm Unacceptable (worker exposure, efficacy) Residues data only support a pre-harvest interval of **28** days. Efficacy data only support an application rate of **2 L/ha.**
11	SEU (France)	Tomato, aubergine	F	Annual weeds (*Agrostis* spp., *P. brachystachys*, *Lolium* spp., *Avena* spp., *Bromus* spp., *P. minor*, *D. sanguinalis*, *Echinochloa* spp., *Setaria* spp., *Alopecurus* spp.)	Spray	1-3 leaves	1		a) 2.0 b) 2.0	a) 250 b) 250	200 / 600	35	Tomato: Unacceptable (MRL, efficacy) Aubergine: Unacceptable (efficacy)
11	SEU (France)	~~Tomato,~~ aubergine	F	Annual weeds (*Agrostis* spp., *P. brachystachys*, *Lolium* spp., *Avena* spp., *Bromus* spp., *P. minor*, *D. sanguinalis*, *Echinochloa* spp., *Setaria* spp., *Alopecurus* spp.)	Spray	1-3 leaves	1		a) **1.5** b) **1.5**	a) **188** b) **188**	200 / 600	35	: Unacceptable on Tomato (MRL) Aubergine: **Acceptable**

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	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
12	SEU (France)	~~Tomato,~~ aubergine	F	Perennial weeds (P. repens, C. dactylon, A. repens, P. paspalodes, S. halepense)	Spray	when perennials are actively growing (10-50 cm high) (*)	1		a) 3.0 b) 3.0	a) 375 b) 375	200 / 600	35	(*) S. halepense: not higher than 25 cm Unacceptable on Tomato (MRL)) Aubergine: Acceptable

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)

FREQUENT (SHA 3800 A) is an emulsifiable concentrate (EC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a semi-transparent dark brown liquid with a paraffin-like odour. It is not explosive and has no oxidising properties. The product is not flammable and has a self-ignition temperature above 400 °C. In aqueous solution (1 % dilution), it has a pH value of 6.12 at 20 °C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and 14 days at 54 °C, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in HDPE/PA. As the stability was performed on HDPE/PA packaging, the fluorinated HDPE packaging can be considered acceptable. The technical characteristics are acceptable for an EC formulation.

The formulation is classified H304 Cat.1.

The relevant impurity 2-chloro-5-(trifluoromethyl)-pyridine is below the threshold in the formulation FREQUENT (SHA 3800 A) in the accelerated storage stability.
However**, the content of the relevant impurity 2-chloro-5-(trifluoromethyl)-pyridine in the formulation FREQUENT (SHA 3800 A) must be determined after two years' storage and the information provided post-authorisation**.

3.2 Efficacy (Part B, Section 3)

3.3 Efficacy data

FREQUENT (SHA 3800 A) is a new herbicide product based on 125 g/L of fluazifop-P butyl(EC). Products with the same concentration of active substance are already authorised in France for the same uses as those requested here: weed control in arboriculture, sunflower, soya bean, sugar beet and tomato (FUSILADE MAX, marketing authorisation No. 2000044). The dossier is built on the basis of a bridging between FUSILADE MAX and FREQUENT (SHA 3800 A). The applicant has provided data on a large number of crops, most of which are not requested in this dossier but which justify bridging. However, the rates requested in this dossier are not all in accordance with those already authorised for FUSILADE MAX.

The 2 L/ha rate requested for control of annual weeds of sunflower, beet, soya bean and tomato has not been demonstrated. Taking into account the bridging, the doses of FREQUENT (SHA 3800 A) cannot be different from those of FUSILADE MAX: 1.5 L/ha.

The rate of 3 L/ha requested for the control of perennial weeds in arboriculture, olive groves and soya bean has also not been demonstrated. These uses are not authorised for FUSILADE MAX; this rate cannot therefore be authorised on these uses for FREQUENT (SHA 3800 A).

The application of FREQUENT (SHA 3800 A) at doses N and 2N sometimes led to decreased yields in

arboriculture. These decreases were not significantly different from the reference and the untreated control. A warning statement must appear on the label.

Considering the data submitted:

The efficacy level of FREQUENT (SHA 3800 A) applied post-emergence is considered satisfactory for weed control of annual grasses at 1.5 L/ha and perennial grasses at 3 L/ha for annual crops (sunflower, sugar beet and tomato) with the exception of soya bean. Indeed, the requested dose of 2 L/ha against annual grasses is not justified and similar products are currently authorised at the rate of 1.5 L/ha.

Given the lack of efficacy and selectivity data for weed control of perennial grasses in soya bean at the 3 L/ha requested rate, the assessment for this use cannot be finalised.

The efficacy level of FREQUENT (SHA 3800 A) is considered satisfactory for the weed control of annual and perennial grasses at the rate of 2 L/ha for perennial crops (apple and olive trees). **Indeed, the rate of 3 L/ha on perennial grasses is not justified and no similar product is currently authorised for this use.**

The selectivity level FREQUENT (SHA 3800 A) is considered satisfactory for all the requested uses.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

There is a risk of development or development of resistance to fluazifop-P, requiring monitoring, for *Alopecurus myosuroides*, *Lolium* sp., *Avena* sp. and *Apera spica-venti*.

Resistance monitoring data: Any occurrence or development of resistance to fluazifop-P (a single follow-up for all products) should be monitored on the basis of efficacy failure analysis, in particular on *Alopecurus myosuroides*, *Lolium* sp. *Avena* sp. and *Apera spica-venti*. **Any new information that may modify the risk analysis of resistance for these weeds must be provided to the authorities** immediately. In any case, a report of the results of the monitoring put in place must be provided when the product's authorisation is renewed.

3.3.2 Adverse effects on treated crops

The risks of negative impact on yield and quality are considered acceptable.

The risk of negative impact on succeeding crops is considered negligible.

The risk of negative impact on adjacent crops is considered acceptable. Nevertheless, particular attention should be paid to the conditions of application of the product close to adjacent crops.

3.3.3 Observations on other undesirable or unintended side-effects

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Analytical methods for the determination of the active substance and its relevant impurity 2-chloro-5-(trifluoromethyl)-pyridine in the formulation are available and validated.

3.4.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR) and this dossier and validated for the determination of residues of fluazifop-P in plants (high water-, high oil- and dry-matter content commodities), foodstuffs of animal origin, soil, water (surface and drinking) and air.

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.

3.5 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

<table>
<tr><td colspan="4">Active substance: fluazifop-P</td></tr>
<tr><td>ADI</td><td colspan="2">0.01 mg kg bw/d</td><td rowspan="3">EU (2011)</td></tr>
<tr><td>ARfD</td><td colspan="2">0.017 mg/kg bw</td></tr>
<tr><td>AOEL</td><td colspan="2">0.02 mg/kg bw/d</td></tr>
<tr><td rowspan="5">Dermal absorption</td><td colspan="3">Based on an in vitro/vivo rat/human study performed on the formulation or on a similar formulation (using a triple-pack approach; pro rata correction) or default values according to guidance on dermal absorption (Efsa 2012):</td></tr>
<tr><td></td><td>Concentrate (tested)
125 g/L</td><td>Diluted formulation (tested)
0.417 g/L</td></tr>
<tr><td>In vitro (human) %</td><td></td><td></td></tr>
<tr><td></td><td>Concentrate (used in formulation)
125 g/L</td><td>Spray dilution (used in formulation)
0.625 g/L</td></tr>
<tr><td>Dermal absorption endpoints %</td><td>0.30</td><td>19</td></tr>
</table>

3.5.1 Acute toxicity

FREQUENT (SHA 3800 A), containing 125 g/L fluazifop-P, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye but is a skin sensitiser.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.4.1.

3.5.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G[7]	Equipment *Application method*	Application rate kg/L product/ha (g as/ha)	Spray dilution (L/ha)	Model
Risk envelop high crops (pome fruit and olive trees)	F	Vehicle mounted *downward spraying*	3 L PPP/ha (0.375 kg a.s/ha)	200	EFSA
Risk envelop low crops (sugarbeet, sun-flower, soybean, tomato)		Vehicle mounted *Downward spraying*			
Risk envelop high crops (pome fruit and olive trees)	F	Vehicle mounted *downward spraying*	2 L PPP/ha (0.250 kg a.s/ha)	200	EFSA
Risk envelop low crops (sugarbeet, sun-flower, soybean, tomato)	F	Vehicle mounted *downward spraying*	1.5 L PPP/ha (0.1875 kg a.s/ha)	200	EFSA

Considering the proposed uses, operator systemic exposure was estimated using the EFSA model[8]:

Crop	Equipment	PPE and/or working coverall	% AOEL Fluazifop-p-butyl
3L PPP/ha (0.375 kg a.s/ha)			
Risk envelop high crops (pome fruit and olive trees)	Vehicle mounted	Working coverall and gloves during mix-ing/loading and application	4.55
Risk envelop low crops (sugarbeet, sunflower, soybean, tomato)	Vehicle mounted	Working coverall and gloves during mix-ing/loading and application	6.63
2L PPP/ha (0.250 kg a.s/ha)			
Risk envelop high crops (pome fruit and olive trees) (2L PPP/ha)	Vehicle mounted	Working coverall and gloves during mix-ing/loading and application	3.36
1.5 L PPP/ha (0.1875 kg a.s/ha)			

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

As per the efficacy data (cf the abstract of this document), for the use of SHA 3800 A/FREQUENT on soybean, tomato, sunflower and sugar beet with an application rate of 1.5L PPP/ha the assessment is presented below:			
Risk envelop low crops (sugarbeet, sunflower, soybean, tomato)	Vehicle mounted	Working coverall and gloves during mixing/loading and application	5.25

According to the model calculations, it may be concluded that the risk for the operator using FREQUENT (SHA 3800 A) is acceptable with a working coverall and gloves during mixing/loading and application for an application of 2 L product/ha or 3 L product/ha.

The use of FREQUENT (SHA 3800 A) on low crops (soybean, sugar beet, sunflower and tomato) with vehicle mounted is acceptable without the use of PPE for an application rate of 1.5 L/ha taking into account new dermal absorption value for the diluted dose, considering a pro rata correction for this dose rate according to the EFSA guidance on dermal absorption (2012).

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

3.5.3 Worker exposure

Workers may have to enter treated areas after treatment for crop inspection/irrigation or searching, reaching and picking activities. Therefore, estimation of worker exposure was calculated according to the AOEM model.

For low crops (sunflowers, sugar beet and soya bean), exposure is estimated to be 50 % of the AOEL of fluazifop-P with PPE (work wear) considering an application rate of 3 L PPP/ha.

FREQUENT (SHA 3800 A) is used as herbicide in orchards.
For these uses, the AOEM model does not take into account worker tasks such as inspection and irrigation. In accordance with the TCs proposed in the EFSA Guidance and the default value of 2 hours for inspection activities, the following formula is applied:

Systemic exposure [mg a.s/kg bw/day] = (DFR [µg/cm²] × TC [cm²/h] × T [h/day]) × MAF / 1 000 × DA [%] / BW

Where:
Dislodgeable foliar residue (DFR): 3 µg/cm² of foliage/kg a.s. applied/ha × application rate [kg a.s/ha]
Transfert coefficient (TC): 12500 cm²/h (total potential exposure) and 1400 cm²/h (arms, body and legs covered)
Work rate (T): 2 hours
Multiple appication factor (MAF): x
Dermal absorpiton (DA): 19 % for an application rate of 2 and 3 L PPP/ha
Body weight (BW): 60 kg

Therefore, for high crops (pome fruit and olive trees), considering that only inspection/irrigation activities is required for an herbicide (work rate of 2 hours), exposure is estimated to 146 % of the AOEL of

fluazifop-p-butyl with PPE (workwear, arms body and legs covered)) for an application of 3L FREQUENT (SHA 3800 A)/ha.
For an application rate of 2L FREQUENT (SHA 3800 A)/ha, worker exposure is estimated to 97% of the AOEL of fluazifop-p-butyl with PPE (workwear).

As per the efficacy data (cf the abstract of the dRR Part B section 6), for the use of SHA 3800 A/ FREQUENT (SHA 3800 A) on soybean, tomato, sunflower and sugar beet with an application rate of 1.5L PPP/ha the assessment is presented below :
For an application on low crops (sunflowers, sugar beet and soybean) and tomatoes, exposure is estimated to 33% of the AOEL of fluazifop-p-butyl with PPE (workwear).

It may be concluded that there is unacceptable risk anticipated for the worker on high crops for an application rate of 3L PPP/ha.

At the dose rate of 2L PPP/ha, there is an acceptable risk anticipated for the worker with PPE (workwear) when FREQUENT (SHA 3800 A) is applied on high crops (olives trees and pome fruits). For an application on low crops (soybean, sunflower, sugar beet) and tomatoes, there are acceptable risks anticipated for the worker with PPE.

3.5.4 Bystander and resident exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set [9].

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.*"

Residential exposure was assessed according to the EFSA model. An acceptable risk was determined for residents (adult and/or child) when FREQUENT (SHA 3800 A) is applied on the low- and high-level crops requested.

For low crops (sugar beet, sunflower, tomato and soya bean):

Model (AOEM) - All pathways (mean)	**% AOEL fluazifop-P**
Resident (children)	84.65
Resident (adults)	35.00

	Fluazifop-P	
	Total absorbed dose (mg/kg bw/day)	**% of systemic AOEL**
DT_{50} (days)	30	
DFR (µg/cm²/kg a.s./ha)	3	

[9] 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)

Buffer zone	2-3 m		
Drift reduction technology	no		
Application rate (g a.s./ha)	375		
Resident child Body weight: 10 kg	Drift (75th perc.):	0.0095937	47.97
	Vapour (75th perc.):	0.0010700	5.35
	Deposits (75th perc.):	0.0013419	6.71
	Re-entry (75th perc.)	0.0120234	60.12
	Sum (mean):	**0.0169293**	**84.85**
Resident adult Body weight: 60 kg	Drift (75th perc.):	0.0022914	11.46
	Vapour (75th perc.):	0.0002300	1.15
	Deposits (75th perc.):	0.0004855	2.43
	Re-entry (75th perc.):	0.0066797	33.40
	Sum (mean):	**0.0070008**	**35.00**

For high crops (pome fruit and olive trees) with an application rate of 3 L product/ha:

Model (AOEM) - All pathways (mean)	**% AOEL fluazifop-P**
Resident (children)	84.95
Resident (adults)	35.85

		Fluazifop-P	
		Total absorbed dose (mg/kg bw/day)	**% of systemic AOEL**
DT_{50} (days)	30		
DFR (µg/cm²/kg a.s./ha)	3		
Buffer zone	5 m		
Drift reduction technology	no		
Application rate (g a.s./ha)	375		
Resident child Body weight: 10 kg	Drift (75th perc.):	0.0248240	31.93
	Vapour (75th perc.):	0.0010700	5.35
	Deposits (75th perc.):	0.0010735	18.92
	Re-entry (75th perc.)	0.0120234	60.12
	Sum (mean):	**0.0277216**	**84.95**
Resident adult Body weight: 60 kg	Drift (75th perc.):	0.0137383	5.81
	Vapour (75th perc.):	0.0002300	1.15
	Deposits (75th perc.):	0.0003884	6.84
	Re-entry (75th perc.):	0.0066797	33.40
	Sum (mean):	**0.0148041**	**35.85**

For high crops (pome fruit and olive trees) with an application rate of 2 L product/ha:

Model (AOEM) - All pathways (mean)	**% AOEL fluazifop-P**
Resident (children)	70.08
Resident (adults)	28.01

		Fluazifop-P	
		Total absorbed dose (mg/kg bw/day)	**% of systemic AOEL**
DT_{50} (days)	30		
DFR (µg/cm²/kg a.s./ha)	3		
Buffer zone	2-3 m		
Drift reduction technology	no		
Application rate (kg	0.250		

a.s./ha)			
Resident child Body weight: 10 kg	Drift (75th perc.):	0.0165494	31.98
	Vapour (75th perc.):	0.0010700	5.35
	Deposits (75th perc.):	0.0012612	19.14
	Re-entry (75th perc.)	0.0080156	40.08
	Sum (mean):	**0.0192866**	**70.08**
Resident adult Body weight: 60 kg	Drift (75th perc.):	0.0091589	7.64
	Vapour (75th perc.):	0.0002300	1.15
	Deposits (75th perc.):	0.0004563	6.92
	Re-entry (75th perc.):	0.0044531	22.27
	Sum (mean):	**0.0101085**	**28.01**

For low crops (sugar beet, sunflower, tomato and soybean) at the application rate of 1.5L/ha (0.1875 kg a.s/ha):

Model (AOEM) - All pathways (mean)	**% AOEL Fluazifop-p-butyl**
Resident (children)	57.32
Resident (adults)	23.42

		Fluazifop-p-butyl	
		Total absorbed dose (mg/kg bw/day)	**% of systemic AOEL**
DT_{50} (days)	30		
DFR (µg/cm²/kg a.s./ha)	3		
Buffer zone	2-3 m		
Drift reduction technology	no		
Application rate (kg a.s./ha)	0.1875		
Resident child Body weight: 10 kg	Drift (75th perc.):	0.0063052	31.53
	Vapour (75th perc.):	0.0010700	5.35
	Deposits (75th perc.):	0.0008348	4.17
	Re-entry (75th perc.)	0.0079102	39.55
	Sum (mean):	0.0114635	57.32
Resident adult Body weight: 60 kg	Drift (75th perc.):	0.0015070	7.54
	Vapour (75th perc.):	0.0002300	1.15
	Deposits (75th perc.):	0.0003194	1.60
	Re-entry (75th perc.):	0.0043945	21.97
	Sum (mean):	0.0046840	23.42

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

3.6.1 Residues

The data available are considered sufficient for risk assessment. An exceedence of the current MRL of 0.01* mg/kg for fluazifop-P on tomato as laid down in Reg. (EU) 396/2005 is expected.

The chronic and short-term intakes of fluazifop-P residues are unlikely to present a public health concern. As far as consumer health protection is concerned, France agrees with the authorisation of the intended or proposed uses, except on tomato.

According to available data, the following specific mitigation measures are recommended:

- Orchard (pome fruits) and olive trees: prevent fruits from contacting the active substance or with soil treated with the active substance.

Data gaps

Noticed data gaps are:

1 SEU and 1 NEU additional residue trials on sunflower.

3.6.2 Consumer exposure

FREQUENT (SHA 3800 A) contains fluazifop-P. Toxicological reference values for the dietary risk assessment are given in Section 3.5.

Summary for fluazifop-P

Table 2: Summary for fluazifop-P

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Pome fruit (apple, pear)	Yes	Yes	Yes	Yes	Yes	No	No
2	Sunflower	Yes	Yes (7 NEU and 7 SEU)	Yes	Yes	Yes		No
3	Sugar beet	Yes	Yes	Yes	Yes	Yes		No
4	Soya bean	Yes	Yes	Yes	Yes	Yes		No
5	Olive	Yes	Yes	Yes	Yes	Yes		No
6	Tomato	Yes	Yes	Yes	Yes	No		Yes

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

For sunflower, two additional residue trials (1 NEU, 1 SEU) are required post-authorisation to complete the data set. For tomato, according to the available data, an MRL exceedence is expected.

Nature of residues in processed commodities was not investigated. However, analytical methods reported for enforcement of residues include severe hydrolytic conditions. It was therefore concluded that the metabolic pattern in processed commodities will not differ significantly from the metabolic pattern observed in raw commodities (EFSA, 2012). Data on effects of processing on the amount of residue have been submitted, but not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated; it is very unlikely that residues will be present in succeeding crops.

The requested uses do not modify the theoretical maximum daily intake for animals estimated by EFSA in the framework of the MRLs review (Art 12 Reg. 396/2005). As a consequence, the intended uses evaluated in this dossier are not expected to result in an exceedence of the current MRLs (except for tomato).

Chronic consumer exposure resulting from the uses proposed in the framework of this application was calculated. Based on EFSA PRIMo (rev2), chronic and acute exposures were considered acceptable for all groups of consumers (except for tomato).

Summary for FREQUENT (SHA 3800 A)

Table 3: Information on FREQUENT (SHA 3800 A)

Crop	PHI for FREQUENT (SHA 3800 A) requested by applicant	PHI/withholding period* sufficiently supported for	PHI for FREQUENT (SHA 3800 A) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Fluazifop-P		
Pome fruit (apple, pear)	21	No	28	In accordance with available residue trials
Sunflower	90	Yes		
Sugar beet	56	Yes		
Soya bean	90	Yes		
Olive	21	No	28	In accordance with available residue trials
Tomato	35	Yes		For Aubergine

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).

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

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

The PEC of fluazifop-P 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.

PECsoil and PECsw values derived for the active substance and its metabolites are used for the ecotoxicological risk assessment.

PECgw values for fluazifop-P and its metabolites do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000 on the relevance of metabolites in groundwater (for use on orchards, only when the product is applied on 30 % of the area). Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.8 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation A12791B was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review for the active substance and their metabolites were used for the intended use patterns.
Based on the guidance documents, the risks for birds, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms are acceptable for the intended uses.
For aquatic organisms, the risks are acceptable when a buffer zone of 5 metres is applied for all uses.
For terrestrial non-target plants, the risks are acceptable when a buffer zone of 5 metres is applied for all uses.

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

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

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

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

5.1.1 Post-authorisation monitoring

Any occurrence or development of resistance to fluazifop-P (a single follow-up for all products) should be monitored on the basis of efficacy failure analysis, in particular on *Alopecurus myosuroides*, *Lolium* sp. *Avena* sp. and *Apera spica-venti*. Any new information that may modify the risk analysis of resistance for these weeds must be provided to the authorities immediately. In any case, a report of the results of the monitoring put in place must be provided when the product’s authorisation is renewed.

5.1.2 Post-authorisation data requirements

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

- the content of the relevant impurity 2-chloro-5-(trifluoromethyl)-pyridine in the formulation FREQUENT (SHA 3800 A) after two years’ storage, the relevant impurity 2-chloro-5-(trifluoromethyl)-pyridine being below the threshold in the formulation FREQUENT (SHA 3800 A) in the accelerated storage stability, must be determined .
- 1 SEU and 1 NEU additional residue trials on sunflower.

Appendix 1 Copy of the product authorisation

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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 ***FREQUENT***

de la société	*SHARDA CROPCHEM ESPAÑA S.L.*
enregistrée sous le	*n°2016-2022*

Vu les conclusions de l'évaluation de l'Anses du 14 janvier 2019,

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

La présente décision s'applique sans préjudice des 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	FREQUENT
Type de produit	Produit de référence
Titulaire	SHARDA CROPCHEM ESPAÑA S.L. Carril Condomina n°3 30006 Murcia Espagne
Formulation	Concentré émulsionnable (EC)
Contenant	125 g/L - fluazifop-P-butyl
Numéro d'intrant	576-2016.01
Numéro d'AMM	2190019
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 2024.

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, 22 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 / polyamide	250 mL ; 500 mL ; 1 L
Bidons en polyéthylène haute densité / polyamide	5 L ; 10 L
Bidons en polyéthylène haute densité fluoré	20 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Danger par aspiration - Catégorie 1	H304 : Peut être mortel en cas d'ingestion et de pénétration dans les voies respiratoires
Sensibilisants cutanés - Catégorie 1 sous-catégorie B	H317 : Peut provoquer une allergie cutanée
Toxiques pour la reproduction - Catégorie 2	H361d : Susceptible de nuire au fœtus
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
EUH066 : L'exposition répétée peut provoquer dessèchement ou gerçures de la peau 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)	Mention abeilles
15055911 Betterave industrielle et fourragère*Désherbage	**3 L/ha**	**1/an**	-	56	5	-	5	-
	Efficacité montrée sur adventices pérennes. Efficacité montrée à 1,5 L/ha sur adventices annuelles.							
12505901 Olivier*Désherbage*Cult. Installées	**2 L/ha**	**1/an**	-	28	5	-	5	-
	Efficacité montrée sur adventices annuelles. Augmentation du délai avant récolte de 21 jours à 28 jours en raison d'un risque de dépassement des limites maximales de résidus. L'usage à la dose de 3 L/ha, revendiquée sur adventices pérennes, est refusé en raison d'un risque d'effet nocif pour les travailleurs et d'une efficacité non justifiée à cette dose.							
12605905 Pommier*Désherbage*Cult. Installées	**2 L/ha**	**1/an**	-	28	5	-	5	-
	Efficacité montrée sur adventices annuelles. Application sous le rang : ne pas appliquer sur plus de 30 % de la surface de la parcelle. Augmentation du délai avant récolte de 21 jours à 28 jours en raison d'un risque de dépassement des limites maximales de résidus. L'usage à la dose de 3 L/ha, revendiquée sur adventices pérennes, est refusé en raison d'un risque d'effet nocif pour les travailleurs et d'une efficacité non justifié à cette dose.							
15805901 Soja*Désherbage	**1,5 L/ha**	**1/an**	-	90	5	-	5	-
	Uniquement sur soja. Efficacité montrée sur adventices annuelles. Diminution de 2 L/ha à 1,5 L/ha de la dose sur adventices annuelles en raison d'une efficacité non justifiée à la dose revendiquée. L'usage à la dose de 3 L/ha, revendiquée sur adventices pérennes, est refusé en raison d'un risque de dépassement des limites maximales de résidus, d'une efficacité non démontrée à cette dose et d'un manque de données de sélectivité.							

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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
16955901 Tomate*Désherbage	**3 L/ha**	**1/an**	-	35	5	-	5	-
	Uniquement sur aubergine. Efficacité montrée sur adventices pérennes. Efficacité montrée à la dose de 1,5 L/ha sur adventices annuelles. L'usage sur tomate est refusé en raison d'un risque de dépassement des limites maximales de résidus							
15905901 Tournesol*Désherbage	**3 L/ha**	**1/an**	-	90	5	-	5	-
	Efficacité montrée sur adventices pérennes. Efficacité montrée à 1,5 L/ha sur adventices annuelles.							

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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 effectuer 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 ;
- Demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143) ou A2P3 (EN 14387) ;
- Lunettes certifiées norme EN 166 (CE, sigle 3)

• 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 ;
- En cas d'exposition aux gouttelettes pulvérisées, porter un demi-masque filtrant à particules (EN 149) ou un demi-masque (EN 140) équipé d'un filtre à particules P3 (EN 143).
- Lunettes certifiées norme EN 166 (CE, sigle 3)

• 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.
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

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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 :

- 48 heures.

Respect des limites maximales de résidus (LMR)

- Ne pas récolter les fruits en contact direct avec le sol.

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.

- SPe 2 : Pour protéger les eaux souterraines, ne pas appliquer ce produit sur plus de 30 % de la surface pour les usages "pommiers".

Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

Protection de la flore

- SPe 3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.

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 la teneur en impureté pertinente : 2-chloro-5-(trifluoromethyl) pyridine dans le produit avant et après stockage 2 ans à température ambiante.	24	-
Fournir 1 essai résidus conduit dans la zone Nord et 1 essai résidus conduit dans la zone Sud de l'Europe pour compléter le jeu de données sur tournesol.	24	-
Poursuivre le suivi de l'apparition ou du développement de résistance à la substance fluazifop-P (un seul suivi tous produits confondus), en particulier sur *Alopecurus myosuroides*, *Lolium sp.*, *Avena sp.* et *Agrostis spica-venti*. Fournir aux autorités compétentes toute nouvelle information susceptible de modifier l'analyse de risque de résistance pour ces adventices.	-	-

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.

NOTICE D'EMPLOI

IMPORTANT: Ces informations font parties de l'étiquette du produit FREQUENT. Toutes les instructions de cette étiquette doivent être lues attentivement avant l'emploi.

PRECAUTIONS:

Pour l'utilisateur: Eviter le contact du produit avec les yeux, la peau et les voies respiratoires. En cas d'incident en cours d'application, arrêter le pulvérisateur en zone non contaminée autant que possible, ne pas porter les mains ou les gants souillés à la bouche, ne pas déboucher une buse en soufflant. Après l'application, rincer les équipements de protection, se laver les gants puis les mains, prendre une douche. Ne pas réutiliser l'emballage du produit.

Stockage: Conserver le produit dans son emballage d'origine fermé de manière étanche, dans un endroit bien ventilé et sous clef, hors de portée des enfants. Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.

Après utilisation: Eliminer les emballages *via* les collectes organisées par les distributeurs partenaires de la filière ADIVALOR (08 10 12 18 85, numéro Azur prix d'un appel local), en accord avec la réglementation en vigueur.

PREPARATION DE LA BOUILLIE:

Bien agiter l'emballage avant utilisation. Remplir la cuve à moitié d'eau. Mettre l'agitateur en marche. Ajouter FREQUENT, compléter en eau pour remplir la cuve. Maintenir l'agitation.

MELANGE:

Respecter la réglementation en vigueur et les recommandations des guides de bonnes pratiques officiels disponibles sur le site : http://e-phy.agriculture.gouv.fr

NOTES GENERALES:

Consulter les procédures de nettoyage des appareils sur les étiquettes de tous produits associés et être sûr d'utiliser le procédé le plus rigoureux et recommandé. Respecter les bonnes pratiques agricoles.

CONDITIONS DE VENTE:

Tous nos produits sont de haute qualité et sont appropriés aux usages recommandés. Toutefois nous ne pouvons contrôler les conditions dans lesquels ils seront stockés, manipulés, mélangés ou utilisés ni contrôler les conditions climatiques dans lesquels ils seront employés. Ces différents paramètres précités peuvent affecter la performance du produit. C'est pourquoi, notre société et nos revendeurs déclineront toute responsabilité quant à la qualité des produits qui serait altérée par de mauvaises conditions de stockage, de manipulation ou d'application par l'utilisateur.

USAGES ET DOSES AUTORISES:

FREQUENT est un fongicide pouvant être utilisé sur les cultures et aux doses d'application suivantes:

Culture	Cibles	dose d'emploi	Nombre maximum d'application	Volume de dilution	Délai avant récolte	Stade d'application
Pommier	Adventices annuelles[1]	2 l / ha	1	200 -600 l	21	1-3 feuilles
Pommier	Adventices pérennes[2]	3 l / ha	1	200 -600 l	21	Lors de la pousse des adventices (10-50cm)[3]
Olivier	Adventices annuelles[1]	2 l / ha	1	200 -600 l	21	1-3 feuilles
Olivier	Adventices pérennes[2]	3 l / ha	1	200 -600 l	21	Lors de la pousse des adventices (10-50cm)[3]
Tournesol	Adventices annuelles[1]	2 l / ha	1	200 -600 l	90	1-3 feuilles
Tournesol	Adventices pérennes[2]	3 l / ha	1	200 -600 l	90	Lors de la pousse des adventices (10-50cm)[3]
Soja	Adventices annuelles[1]	2 l / ha	1	200 -600 l	90	1-3 feuilles
Soja	Adventices pérennes[2]	3 l / ha	1	200 -600 l	90	Lors de la pousse des adventices (10-50cm)[3]
Tomate	Adventices annuelles[1]	2 l / ha	1	200 -600 l	35	1-3 feuilles
Tomate	Adventices pérennes[2]	3 l / ha	1	200 -600 l	35	Lors de la pousse des adventices (10-50cm)[3]
Betterave sucrière	Adventices annuelles[1]	2 l / ha	1	200 -600 l	56	1-3 feuilles
Betterave sucrière	Adventices pérennes[2]	3 l / ha	1	200 -600 l	56	Lors de la pousse des adventices (10-50cm)[3]

[1] **Adventices annuelles** : *Agrostis spp., Phalaroïdes-chystachys, Lolium spp., Avena spp., Bromus spp., Phalaris minor, Digitariasanguinalis, Echinochloa spp., Setaria spp., Alopecurus spp.*
[2] **Adventices pérennes** : *Panicum repens, Cynodon dactylon, Agropyron repens., Papalum paspaloides., Sorghum halepense*
[3] *Sorghum halepense : pas plus de 25cm de haut.*

FREQUENT

Concentré Emmulsionnable (EC) contenant 125 g/l de fluazifop-P-butyl

AMM n° XXXXXXXXX délivrée le XX/XX/XXXX par le Ministère de l'agriculture, de l'agro-alimentaire et de la forêt

HERBICIDE / Pommier, Olivier, Tomate, Betterave, Soja, Tournesol

FREQUENT est un herbicide à usage agricole et professionnel uniquement, pouvant être utilisé sur les céréales et les pêchers

FREQUENT se présente sous d'un Concentré Emmulsionnable (EC) contenant 125 g/l de fluazifop-P-butyl.

Poids net: XXXXX

Lot N°: XXXXX

Date de fabrication : XX/XX/XXXX
Date d'expiration: XX/XX/XXXX

Détenteur d'homologation:
Sharda Cropchem Limited
Dornic Holm, Road 29th, Bandra (West),
Mumbai 400010,
India

Distribué par:
XXXXX
XXXXX

En cas d'urgence, appeler le 15 ou le centre antipoison puis signalez vos symptômes au réseau "Phyt'attitude" n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

SGH07 SGH08 SGH09

Mentions de danger:

H304 : Peut être mortel en cas d'ingestion et de pénétration dans les voies respiratoires
H317 : Peut provoquer une allergie cutanée
H361d : Susceptible de nuire au fœtus
H410 : Très toxique pour les organismes aquatiques, entraîne des effets à long terme

EUH066 : L'exposition répétée peut provoquer dessèchement ou gerçures de la peau.
EUH401: Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.

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.).
Spe 3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente et utiliser des buses anti dérives (50%).

Conseils de prudence :

P201 : Se procurer les instructions avant utilisation.
P202 : Ne pas manipuler avant d'avoir lu et compris toutes les précautions de sécurité.
P261 : Éviter de respirer les poussières / fumées / gaz / brouillards / vapeurs / aérosols.
P272 : Les vêtements de travail contaminés ne devraient pas sortir du lieu de travail.
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.
P281 : Utiliser l'équipement de protection individuel requis.
P301+P310 : EN CAS D'INGESTION: appeler immédiatement un CENTRE ANTIPOISON/un médecin/...
P302+P352 : EN CAS DE CONTACT AVEC LA PEAU: laver abondamment à l'eau/...
P333+P313 : En cas d'irritation ou d'éruption cutanée: consulter un médecin.
P308+P313 : EN CAS d'exposition prouvée ou suspectée: consulter un médecin.
P321 : Traitement spécifique (voir ... sur cette étiquette).
P331 : NE PAS faire vomir.
P333+P313 : Si l'irritation oculaire persiste: consulter un médecin.
P363 : Laver les vêtements contaminés avant réutilisation.
P391 : Recueillir le produit répandu.
P405 : Garder sous clef.
P501 : Éliminer le contenu / récipient en accord avec la règlementation applicable.

ÉQUIPEMENT DE PROTECTION:

1. Mélange/chargement:
Les caractéristiques du vêtement de travail et de l'EPI pour la phase de mélange/chargement du produit FREQUENT, sont les suivantes :
Combinaison de travail tissée en coton/polyester (35%/65%) avec un grammage d'au moins 230 g/m² avec traitement déperlant
Gants en nitrile certifiés EN 374-3
Protection respiratoire : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143)
Lunettes norme EN 166 (CE, sigle 3)

2-Application du produit:
Les caractéristiques du vêtement de travail et de l'EPI, pour la phase d'application du produit FREQUENT, sont les suivantes :
Combinaison de travail tissée en coton/polyester (35%/65%) avec un grammage d'au moins 230 g/m² avec traitement déperlant

Si application avec tracteur sans cabine:
Gants en nitrile certifiés EN 374-3
Protection respiratoire : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143)
Lunettes norme EN 166 (CE, sigle 3)

Si application avec tracteur avec cabine
Gants en nitrile certifiés EN 374-3 à usage unique lors d'interventions sur le matériel de pulvérisation. Dans ce cas les gants doivent être stockés à l'extérieur de la cabine
En cas de risque d'exposition à des particules pulvérisées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143) et lunettes norme EN 166 (CE, sigle 3). Le masque doit être stocké à l'extérieur de la cabine.

3-Nettoyage du matériel de pulvérisation:
Les caractéristiques du vêtement de travail et de l'EPI, pour la phase de nettoyage du matériel de pulvérisation utilisé pour l'application du produit FREQUENT, sont les suivantes:
Combinaison de travail tissée en coton/polyester (35%/65%) avec un grammage d'au moins 230 g/m² avec traitement déperlant
Gants en nitrile certifiés EN 374-3
Protection respiratoire : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143)
Lunettes norme EN 166 (CE, sigle 3)

Appendix 3 Letter of Access

Not applicable.