

REGISTRATION REPORT

Part A

Risk Management

Product code: F8716-2

Product name(s): FURY GEO

Active Substance(s):

Zeta-cypermethrin, 8 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing extension of use)

Applicant: FMC Chemical s.p.r.l.

Date: 23/08/2016

Table of Contents

1	DETAILS OF THE APPLICATION.....	3
1.1	APPLICATION BACKGROUND.....	3
1.2	ACTIVE SUBSTANCE APPROVAL.....	3
1.3	REGULATORY APPROACH	4
1.4	DATA PROTECTION CLAIMS	5
1.5	LETTER(S) OF ACCESS	5
2	DETAILS OF THE AUTHORISATION	5
2.1	PRODUCT IDENTITY	5
2.2	CLASSIFICATION AND LABELLING.....	6
2.2.1	<i>Classification and labelling under Directive 99/45/EC</i>	<i>6</i>
2.2.2	<i>Classification and labelling in accordance with Regulation (EC) No1272/2008</i>	<i>6</i>
2.2.3	<i>Other phrases in compliance with Regulation (EU) No 547/2011</i>	<i>6</i>
2.2.4	<i>Other phrases linked to the preparation</i>	<i>7</i>
2.3	PRODUCT USES.....	8
3	RISK MANAGEMENT.....	10
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	10
3.1.1	<i>Physical and chemical properties</i>	<i>10</i>
3.1.2	<i>Methods of analysis</i>	<i>10</i>
3.1.3	<i>Mammalian Toxicology.....</i>	<i>10</i>
3.1.4	<i>Residues and Consumer Exposure</i>	<i>11</i>
3.1.5	<i>Environmental fate and behaviour.....</i>	<i>12</i>
3.1.6	<i>Ecotoxicology.....</i>	<i>12</i>
3.1.7	<i>Efficacy</i>	<i>12</i>
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT	13
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING	13
3.4	FURTHER INFORMATION TO PERMIT A DECISION TO BE MADE OR TO SUPPORT A REVIEW OF THE CONDITIONS AND RESTRICTIONS ASSOCIATED WITH THE AUTHORISATION	13
3.4.1	<i>Post-authorisation monitoring.....</i>	<i>13</i>
3.4.2	<i>Post-authorisation data requirements</i>	<i>13</i>
3.4.3	<i>Label amendments (see label in Appendix 2):</i>	<i>13</i>
	APPENDIX 1 – COPY OF THE FRENCH DECISION	14
	APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT	17
	APPENDIX 3 – LETTER(S) OF ACCESS	21

PART A – Risk Management

The company FMC Chemical s.p.r.l. has requested marketing authorisation in France for the product FURY GEO (F8716-2), containing 8 g/kg zeta-cypermethrin for use as an insecticide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to FURY GEO (F8716-2) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of FURY GEO (F8716-2) have been made using endpoints agreed in the EU peer review of zeta-cypermethrin.

This document describes the specific conditions of use and labelling required for France for the registration of FURY GEO (F8716-2).

Appendix 1 of this document provides a copy of the French Decision.

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

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

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of FMC Chemical s.p.r.l.'s application to market FURY GEO (F8716-2) in France as an insecticide (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 label extension of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval.

Zeta-cypermethrin

Regulations Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances..

Specific provisions of regulation were as follows :

PART A

Only uses as insecticide may be authorised.

PART B

In assessing applications to authorise plant protection products containing zeta-cypermethrin for uses other than in cereals, notably as regards the exposure of consumers to mPBAldehyde, a degradation product that may be formed during processing, Member States shall pay particular attention to the criteria in Article 4(1)(b), and shall ensure that any necessary data and information is provided before such an authorisation is granted.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on zeta-cypermethrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

— the operator safety and ensure that conditions of use prescribe the application of adequate personal protective

equipment, where appropriate,

— the protection of birds, aquatic organisms, bees, non-target arthropods and non-target soil macro-organisms.

Conditions of authorisation shall include risk mitigation measures, where appropriate.

The Member States concerned shall request the submission of further information on the fate and behaviour (aerobic degradation in soil), the long-term risk to birds, aquatic organisms and non-target arthropods. They shall ensure that the notifier at whose request zeta-cypermethrin has been included in this Annex provide such information to the Commission by 30 November 2011 at the latest.

An EFSA conclusion is available (EFSA Scientific Report (2008) 196, 1-119).

A Review Report is available (SANCO/142/08 final rev 1, 20 November 2012).

1.3 Regulatory approach

The present application (2014-0048) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)¹ in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses (“risk envelope approach”)² – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 12 September 2006³ 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.

The current document (RR) based on Anses’s assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009⁴, implementing regulations, and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁶ 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

¹ French Food Safety Agency, Afssa, before 1 July 2010

² SANCO document “risk envelope approach”, European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the “risk envelope approach”; SANCO/11244/2011 rev. 5

³ <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000425570>

⁴ REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

⁵ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

⁶ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

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 extrapolation⁷ is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant. The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

1.4 Data protection claims

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

1.5 Letter(s) of Access

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

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	FURY GEO (F8716-2)
Authorisation number	2130261
Function	Insecticide
Applicant	FMC Chemical s.p.r.l.
Composition	8 g/kg zeta-cypermethrin
Formulation type (code)	Microgranule (MG)
Packaging	PET/Al/PE (1 kg, 10 kg)

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


2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

For information, a change of chemical composition was considered acceptable and the classification of the preparation was updated (application n°2014-1522).

Physical hazards	-	
Health hazards	Sensitisation — Skin, Hazard Category 1 Serious eye damage/eye irritation, Hazard Category 1	
Environmental hazards	Hazardous to the aquatic environment — Acute Hazard, Category 1 Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Hazard pictograms		
Signal word	Danger	
Hazard statements	H317	May cause an allergic skin reaction.
	H318	Causes serious eye damage.
	H400	Very toxic to aquatic life.
	H410	Very toxic to aquatic life with long lasting effects.
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	-

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

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
------	---

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment ⁸ : refer to the Decision in Appendix 1 for the details
Re-entry period ⁹ : not applicable ¹⁰
Pre-harvest interval ¹¹ : F- Application must be made at growth stage BBCH 00 at the latest.
Other mitigation measures: according to available data, no specific mitigation measures should apply.
<p>The label may include the following recommendations:</p> <p>The label should include the following sentences:</p> <ul style="list-style-type: none">- “The preparation FURY GEO (F8716-2) containing zeta-cypermethrin, it may cause paresthesia. According to the “<i>arrêté du 9 novembre 2004</i>”, it should be mentioned on the label to avoid contact with skin.”- “Contains 2-ethylhexyl-S-lactate” <p>The label must reflect the conditions of authorisation.</p>

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

⁹ The legal basis for this is **Titre I Article 3** of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

¹⁰ The legal basis for this is Article 3 II of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

¹¹ According to the French Order of 12 September 2006, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

Please note:

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

PPP (product name/code): **FURY GEO (F8716-2)** Formulation type: **MG** ^(a, b)
 Active substance 1: **Zeta-cypermethrin** Conc. of as 1: **8 g/kg** ^(c)
 Applicant: **FMC Chemical s.p.r.l.** Professional use: ☒
 Zone(s): Southern Non professional use: ☐
 Verified by MS: yes
 Field of use: Insecticide

GAP rev. 1, date: 2016-08-23

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Sunflower	F	Wireworms	T-Band applicatio n	At plant BBCH 00	1	-	15 kg/ha	120 g a.s./ha	-	-	Not acceptable (risk to aquatic organisms)

Use on *Sorghum spp* is already granted in France according to French Order of 26 March 2014 (sub category of corn)

- 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 authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

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

3 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

The preparation FURY GEO (F8716-2) is formed by free flowing beige granules containing 8 g/kg of zeta cypermethrin. This formulation does not present explosive and oxidising properties. It is not highly flammable, and is not auto-flammable up to 400°C. Its bulk density is 0.9924 g/mL and 1.0338 g/mL when taped. It has an alkalinity of 0.003% (as NaOH). There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C and after 2 years at ambient temperature, neither the active ingredient content nor the technical properties were changed.

Under recommended use, no particular problems should be expected due to technical characteristics or physico-chemical properties.

3.1.2 Methods of analysis

Analytical methods are available in the monograph and in this dossier and validated for the determination of residues of zeta-cypermethrin in plants (cereal and dry products and fatty products), food of animal origin, soil, water (surface and drinking) and air.

The active substance is toxic (T), therefore an analytical method is available in the monograph and validated for the determination of residues of cypermethrin (as sum of isomers) in tissues and body fluids.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

FURY GEO (F8716-2) containing 8 g/kg of zeta-cypermethrin has a low toxicity in respect to oral, dermal and inhalational toxicity and is slightly irritating to rabbit skin. It has been found to be classifiable for irritancy to rabbit eyes. The sensitization study is not considered acceptable.

FURY GEO (F8716-2) contains 8% of 2-ethylhexyl-S-lactate, classified as a skin sensitizer, Xi, R43. According to the European Directive 99/45/EC and according to CLP (Regulation EC No 1272/2008), FURY GEO (F8716-2) is classified as a skin sensitizer by calculation method.

3.1.3.2 Operator Exposure

Operator exposure was assessed against the AOEL agreed in the EU review of zeta-cypermethrin. Data on dermal absorption of FURY GEO (F8716-2) was provided and considered acceptable.

Endpoint used in assessment for FURY GEO	
Zeta-cypermethrin	
Systemic AOEL :	0.02 mg/kg bw/d
Dermal absorption:	10%

The risks related to the new uses (sorghum and sunflower) for the preparation FURY GEO (F8716-2) are covered by the risk assessment performed by Anses for the already permitted use (maize). Accordingly, the risk for operator is considered acceptable.

The following personal protective equipment is recommended by applicant:

Loading of the hopper

- Nitrile gloves certified EN 374-3;

- Working coveralls 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment (coverall or long sleeved work jacket and long trousers);
- Long-sleeved aprons, Category III Type PB3, worn over the coverall proposed above ;
- Googles or face shield certified according to EN 166 standard with frame marking 3.

Spreading

- Disposable nitrile gloves certified EN 374-2 in the case of an intervention on application equipment;
- Working coveralls 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment (coverall or long sleeved work jacket and long trousers).

Cleaning

- Nitrile gloves certified EN 374-3;
- Working coveralls 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment (coverall or long sleeved work jacket and long trousers);
- Long-sleeved aprons, Category III Type PB3, worn over the coverall proposed above ;
- Googles or face shield certified according to EN 166 standard with frame marking 3.

3.1.3.3 Bystander Exposure

FURY GEO (F8716-2) is a granular formulation buried with the seed at application. Furthermore, the formulation does not generate any dust drift.

The estimation of bystander exposure is not relevant.

3.1.3.4 Worker Exposure

FURY GEO (F8716-2) is a granular formulation buried with the seed at application. No worker's intervention is expected after treatment.

The estimation of worker exposure is considered to be irrelevant.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues (Part B, Section 4, Points 8.1 to 8.9)

Primary crop metabolisms were sufficiently investigated to define residue of zeta-cypermethrin for enforcement and risk assessment in crops under consideration.

Regarding the magnitude of residues in sorghum and sunflower, a sufficient number of residue trials are available to support the intended GAPs in France. These data allowed to consider that no quantifiable residues of cypermethrin will be present in grains, and to confirm that no MRL exceedance will result from intended uses.

As residues of cypermethrin do not exceed the trigger value of 0.1 mg/kg, there is no need to investigate the effect of industrial and/or household processing.

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

The residue data do not modify the dietary burden for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

3.1.4.2 Consumer exposure (Part B, Section 4, Point 8.10)

The toxicological profile of zeta-cypermethrin was evaluated at EU level, which resulted in the proposal of an ADI (0.04 mg/kg) and an ARfD (0.125 mg/kg) that were considered in the frame of this evaluation.

Based on EFSA PRIMo (rev2), chronic and acute exposures were considered as acceptable for all groups of consumers.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs 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 zeta-cypermethrin 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 review or agreed in the assessment based on new data provided.

PEC soil and PEC_{sw} derived for the active substance and its metabolites are used for the eco-toxicological risk assessment, and mitigation measures are proposed.

PEC_{gw} for zeta-cypermethrin and its metabolites do not exceed the trigger of 0.1 µg/L. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT50 calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation FURY GEO (F8716-2) was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review for active substances and 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, mammals, bees, earthworms and other soil macro-organisms, micro-organisms are acceptable for the intended uses.

For non-target arthropods (NTA), the % effect expected in field for exposure to maximum residues on soil for the representative species *Poecilus cupreus* is below the trigger of 50% indicating an acceptable in field risk. The submitted study on the *Aleochara bilineata* was not considered reliable. However, zRMS considers sufficient the results of study for *Poecilus cupreus* to conclude for an acceptable risk of FURY GEO (F8716-2) for NTA according to the intended uses.

The EU agreed endpoints for effects of zeta-cypermethrin to aquatic life are available. TER values were determined on the basis of endpoints for the active substance and PEC values derived from FOCUS at Step 4. Risk assessment could not be finalised for all focus scenarios.

3.1.7 Efficacy

The aim of this dossier is to apply for an insecticide use against *Agriotes sp.* and *Diabrotica virgifera* in maize and sweet maize, for the preparation FURY GEO (F8716-2). A label extension on sorghum and sunflower was submitted 2 years later, for a use also against *Agriotes sp.*

Based on the trials provided, the efficacy of the product on targeted pests was judged acceptable on maize and sunflower crops. By extrapolation, the efficacy is also judged acceptable on sweet maize and sorghum against the same pests.

No phytotoxicity has been observed in efficacy and selectivity trials. Unacceptable adverse effects are not expected.

The risk of resistance is considered low on wireworms. However, against *Diabrotica virgifera*, the risk is considered medium. If *Diabrotica virgifera* will establish massively in France, the applicant must establish an inventory of the sensibility to zeta-cypermethrin on different populations.

3.2 Conclusions arising from French assessment

The risk to aquatic organisms is considered unacceptable on sunflower.

Considering that the PPP is already registered on Corn (*Zea mäs*), and according to French Order of 26 march 2014, an authorisation is also given on *Sorghum spp.*

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

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

No further information is required.

3.4.3 Label amendments (see label in Appendix 2):

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

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

Appendix 1 – Copy of the French Decision



Décision relative à une demande d'extension d'usage d'un produit phytopharmaceutique

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

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

*Vu la demande d'extension d'usage majeur du produit phytopharmaceutique **FURY GEO***

de la société FMC CHEMICAL SPRL

enregistrée sous le n°2014-0048

Vu les conclusions de l'évaluation du 15 mars 2016,

Considérant les risques pour les organismes aquatiques,

*Considérant que l'usage revendiqué « 15562105 - Sorgho*Trt Sol*Ravageurs du sol » est inclus dans la portée de l'usage « 15552102 - Maïs*Trt Sol*Ravageurs du sol » par arrêté du 26 mars 2014 et de ses notices et annexes, pour lequel le produit FURY GEO bénéficie déjà d'une autorisation de mise sur le marché,*

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

L'autorisation de mise sur le marché du produit référencé ci-après **n'est pas étendue** aux usages décrits dans la présente décision

FURY GEO

AMM n°2130261

Page 1 sur 3



Information générales sur le produit	
Noms du produit	FURY GEO GEMINI GEO MINUET GEO
Type de produit	Produit de référence
Titulaire	FMC CHEMICAL SPRL Boulevard de la plaine 9/3 1050 Bruxelles BELGIQUE
Formulation	Microgranulé (MG)
Contenant	8 g/kg - zêta-cyperméthrine
Numéro d'intrant	2110065
Numéro d'AMM	2130261
Fonction	Insecticide
Gamme d'usages	Professionnel

A Maisons-Alfort, le 23 AOÛT 2016

Françoise WEBER
Directrice générale adjointe des produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

FURY GEO

AMM n°2130261

Page 2 sur 3



ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15902102 Tournesol*Trt Sol*Ravageurs du sol	15 kg/ha	1/an	F (BBCH 00)
Motivation du refus : Les risques pour les organismes aquatiques ne sont pas considérés comme acceptables.			

FURY GEO
AMM n°2130261

Page 3 sur 3

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

Fury® Geo

Insecticide du maïs, du maïs doux, du tournesol et du sorgho

Contient 0.8% de zétacyperméthrine sous forme MG (Microgranulé)

Autorisation de Mise sur le Marché n° ...

Contenu: 1 ou 10 kg **e**

Numéro de lot et date de fabrication: voir emballage

UN 3077

Bien lire l'étiquette avant utilisation et respecter les précautions d'emploi afin d'assurer la sécurité personnelle des manipulateurs et utilisateurs.

Distribué par :



Belchim Crop Protection France S.A.

Parc Tertiaire de Bois Dieu

3 allée des Chevreuils – 69380 LISSIEU

Tél. 04 78 83 40 66 – Fax 04 78 83 49 23

www.belchim.com

Détenteur de l'homologation: FMC Chemical, srl

Bvd de la Plaine 9/3

B-1050 Bruxelles (Belgique)

Tél. 0032 2 645 95 84

® marque déposée de FMC CORPORATION, Philadelphia, USA

Fury® Geo : contient 0.8% de zétacyperméthrine



GHS06



GHS09

DANGER

H318 : Provoque des lésions oculaires graves.

H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.

P102 : Tenir hors de portée des enfants.

P270 : Ne pas manger, boire ou fumer en manipulant ce produit.

P280 : Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage.

P305+P351+P338 : EN CAS DE CONTACT AVEC LES YEUX: rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer.

P501 : Eliminer le contenu/récipient conformément à la réglementation locale/nationale

EUH208 : Contient de la Zeta-cypermethrin (52315-07-8). Peut produire une réaction allergique.

EUH401 : Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.

Respecter les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.

Distribué par : Belchim Crop Protection France SA

Parc Tertiaire de Bois Dieu - 3 allée des Chevreuils

69380 LISSIEU

Tél.: 04 78 83 40 66 - Fax: 04 78 83 49 23

Fiche de données de sécurité disponible au: 04 78 83 40 66 ou sur le site www.quickfds.com

24h/24 Numéro d'appel d'urgence: 0032 14 58 45 45

GENERALITES

Fury® Geo est un insecticide du sol à base de zétacyperméthrine (famille des pyréthrinoïdes), qui agit par contact et ingestion.

Fury® Geo est constitué de microgranulés prêts à l'emploi sans préparation ni dilution préalable. Il doit être positionné dans la raie de semis à l'aide d'un microgranulateur fixé sur le semoir.

USAGES ET DOSES D'EMPLOI

Culture	Cible	Dose	Délai avant récolte (DAR)
Maïs Maïs doux	Taupin (en localisation)	15 kg/ha	Non requis
	chrysomèle des racines du maïs (en localisation)	15 kg/ha	Non requis
Toumesol	Taupin (en localisation)	15 kg/ha	Non requis
Sorgho	Taupin (en localisation)	15 kg/ha	Non requis

Les limites maximales de résidus sont consultables à l'adresse suivante :
http://ec.europa.eu/food/plant/protection/pesticides/index_fr.htm

RECOMMANDATIONS D'EMPLOI

L'application de Fury® Geo se fait par un microgranulateur présent sur le semoir, impérativement équipé d'un diffuseur recommandé par Belchim Crop Protection France.

De ce fait, les granulés de Fury® Geo sont répartis directement dans l'intégralité de la raie de semis et entourent la semence, permettant un contrôle complet des ravageurs pendant la période de sensibilité de la culture.

Tableau de réglage de microgranulateurs :

Type de microgranulateur	Réglage	Dose obtenue (kg/ha)	Mécanismes permettant les réglages
--------------------------	---------	----------------------	------------------------------------

Préparation du traitement

Ne pas exposer les granulés à l'humidité avant l'application. S'assurer que l'appareil soit propre et en parfait état de fonctionnement avant de commencer à traiter. Vider complètement l'appareil après chaque usage.

Réalisation du traitement :

Veiller à une bonne répartition des granulés sur la profondeur du sillon et à leur absence à la surface du sol. Bien veiller au bon réglage du microgranulateur avant l'utilisation.

Après application :

Vider le réservoir du microgranulateur et remettre son contenu dans l'emballage d'origine tout en s'assurant qu'aucun granulé ne se retrouve sur le sol.

GESTION DU RISQUE DE RÉSISTANCE

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

PRÉCAUTIONS D'EMPLOI

Pendant le stockage :

Conserver Fury® Geo dans son emballage d'origine, hermétiquement fermé, à l'abri de la lumière, à température ambiante, dans un endroit sec, aéré et fermant à clef.

Pendant toute la durée de manipulation du produit et l'application, veiller à porter des gants et une tenue de protection adaptée.

Après l'application, nettoyer les appareils de traitement sur le lieu même du travail selon la réglementation en vigueur. Changer de vêtements et rincer le visage et les mains à l'eau savonneuse.

ELIMINATION DU PRODUIT ET DES EMBALLAGES :

Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

Réutilisation de l'emballage interdite. Eliminer les emballages vides via une collecte organisée par un service de collecte spécifique.



IMPORTANT :

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé.

Conduisez, sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...

Compte tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur.

GARANTIE :

Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture. FMC ne donne aucune garantie, explicite ou implicite, relative à l'utilisation du produit d'une autre manière que celle indiquée sur l'étiquette. L'acheteur et l'utilisateur seront responsables des risques liés à l'utilisation et/ou la manipulation et/ou l'entreposage de ce produit en cas de non respect des recommandations de l'étiquette.

RESPONSABILITES - En cas de non respect de la garantie ou de négligence, le recours de l'acheteur/utilisateur sera limité au remboursement de dommages et intérêts, à concurrence du prix d'achat, à l'exclusion de tout autre dommage.

Appendix 3 – Letter(s) of Access

Not applicable.