

REGISTRATION REPORT

Part A

Risk Management

Product code: TEFLUTHRIN 1.5 GR

Product name: TOFINO

Chemical active substance:

tefluthrin, 15 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: GLOBACHEM NV

Date: 05/05/2022

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PART A

RISK MANAGEMENT

1 Details of the application

The company GLOBACHEM NV has requested a marketing authorisation in France for the product TOFINO (TEFLUTHRIN 1.5 GR), containing 15 g/kg tefluthrin¹, as an insecticide for professional uses.

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

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

1.1 Application background

The present registration report concerns the evaluation of GLOBACHEM NV's application submitted on 02/11/2018 to market TOFINO (TEFLUTHRIN 1.5 GR) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2018-3499) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of TOFINO (TEFLUTHRIN 1.5 GR) has been made using endpoints agreed in the EU peer review of tefluthrin. It also includes assessment of data and information related to TOFINO (TEFLUTHRIN 1.5 GR) where those data have not been considered in the EU peer review process.

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

¹ Commission Implementing Regulation (EU) No 800/2011 of 9 August 2011 approving the active substance tefluthrin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and amending Commission Decision 2008/934/EC, as amended by Commission Implementing Regulation (EU) 2019/291 of 19 February 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-naphthylacetamide, 1-naphthylacetic acid, acrinathrin, azoxystrobin, fluazifop P, fluroxypyr, imazalil, kresoxim-methyl, oxyfluorfen, prochloraz, prohexadione, spiromamine, tefluthrin and terbutylazine.

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

³ 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](#)

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of TOFINO (TEFLUTHRIN 1.5 GR).

1.2 Letters of Access

Not necessary: active substance data are not protected any more.

1.3 Justification for submission of tests and studies

According to the applicant: *“The application is for a new product that has never been authorized in the EU. It follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.”.*

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of TOFINO (TEFLUTHRIN 1.5 GR), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7

2 Details of the authorisation decision

2.1 Product identity

Product code	TEFLUTHRIN 1.5 GR
Product name in MS	TOFINO
Authorisation number	N/A : no marketing authorisation granted
Low risk (article 47)	No.
Function	Insecticide..
Applicant	Globachem NV.
Active substance (incl. content)	Tefluthrin, 15 g/kg.
Formulation type	Granules [Code : GR].
Packaging	N/A : no marketing authorisation granted
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None.

⁴ 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

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Recommended tank mixtures	None.
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2.2 Conclusion

The evaluation of the application for TOFINO (TEFLUTHRIN 1.5 GR) resulted in the decision to refuse the authorisation.



2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Acute toxicity (oral), category 4 Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	  GHS07 GHS09
Signal word:	Warning
Hazard statement(s):	H302: Harmful if swallowed. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation.</i>
Additional labelling phrases:	The label must include the following recommendations: The product TOFINO (TEFLUTHRIN 1.5 GR), containing tefluthrin, may cause paresthesia. According to the “arrêté du 9 novembre 2004”, it should be mentioned on the label to avoid contact with skin.

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

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

N/A : no marketing authorisation granted

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 2017⁵ provides that:

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

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

Finally, the French Order of 12 April 2021⁶ 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 “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data 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.

2.5.1 Restrictions linked to the PPP

N/A : no marketing authorisation granted

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.

⁵ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

⁶ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

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

2.6 Intended uses (only NATIONAL GAP)

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):	TOFINO/TEFLUTHRIN 1.5 GR	Formulation type:	GAP rev.1, c GR ^(a, b)
Active substance 1:	Tefluthrin	Conc. of a.s. 1:	15 g/kg(c)
Applicant:	Globachem N.V.	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Southern ^(d)	Non-professional use:	<input type="checkbox"/>
Verified by MS:	yes		

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Mem- ber 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: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha (i)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	kg 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		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Maize ; (ZEAMX), (PANMI), (SETIM), (MISSI), (SORVU),	F	Agriotes sp. [AGRISP], Western corn rootworm (Diabrotica virgifera vir- gifera; [DIABVI]), centi- pedes [SCUTIM], milli- pedes [BLANGU]	Soil in- corpora- tion	At sowing	a) 1 b) 1	NA	a) 7 b) 7	a) 105 b) 105	NA	F – ap- plication must be made at growth stage BBCH 00 at the lat- est.	Not acceptable (groundwater, non- target arthropods, earthworms, soil mites).
2	FR	Maize ; (ZEAMX), (PANMI), (SETIM), (MISSI), (SORVU),	F	Agriotes sp. [AGRISP] and western corn root- worm (Diabrotica vir- gifera virgifera; [DI- ABVI]) , centipedes [SCUTIM], millipedes [BLANGU]	Soil in- corpora- tion	At sowing	a) 1 every 2 years b) 1	NA	a) 12 b) 12	a) 180 b) 180	NA	F – appli- cation must be made at growth stage BBCH 00 at the lat- est.	Not acceptable (groundwater, non- target arthropods, earthworms, soil mites).
3	FR	Sweet corn : (ZEAMS)	F	Agriotes sp. [AGRISP] and western corn root- worm (Diabrotica vir- gifera virgifera; [DI- ABVI]) , centipedes [SCUTIM], millipedes [BLANGU]	Soil in- corpora- tion	At sowing	a) 1 b) 1	NA	a) 7 b) 7	a) 105 b) 105	NA	NA	Not acceptable (MRL and ground- water, non-target arthropods, earth- worms, soil mites).

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4	FR	Sweet corn: (ZEAMS)	F	<i>Agriotes</i> sp. [AGRISP] and western corn root-worm (<i>Diabrotica virgifera virgifera</i> ; [DI-ABVI]), centipedes [SCUTIM], millipedes [BLANGU]	Soil incorporation	At sowing	a) 1 every 2 years b) 1	NA	a) 12 b) 12	a) 180 b) 180	NA	NA	Not acceptable (MRL and groundwater, non-target arthropods, earthworms, soil mites).
5	FR	Sunflower : (HELAN)	F	<i>Agriotes</i> sp. [AGRISP], centipedes [SCUTIM], millipedes [BLANGU], moths [EUXONI] [AGROY] [AGROSE]	Soil incorporation	At sowing	a) 1 b) 1	NA	a) 7 b) 7	a) 105 b) 105	NA	F – application must be made at growth stage BBCH 00 at the latest.	Not acceptable (groundwater, non-target arthropods, earthworms, soil mites).
6	FR	Sunflower : (HELAN)	F	<i>Agriotes</i> sp. [AGRISP], centipedes [SCUTIM], millipedes [BLANGU], moths [EUXONI] [AGROY] [AGROSE]	Soil incorporation	At sowing	a) 1 every 2 years b) 1	NA	a) 10 b) 10	a) 150 b) 150	NA	F – application must be made at growth stage BBCH 00 at the latest.	Not acceptable (groundwater, non-target arthropods, earthworms, soil mites).

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)

The appearance of the product is that of a solid with various colours (beige, white, black and brown), with an odour resembling modelling clay. It is not explosive, has no oxidising properties and is not flammable. It has a self-ignition temperature higher than 400 °C. In aqueous solution (1 %), it has a pH value around 7 at 20.1 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active substance content nor the technical properties were changed. The technical characteristics are acceptable for a granule formulation.

3.2 Efficacy (Part B, Section 3)

3.3 Efficacy data

Considering the data submitted:

The efficacy level of TOFINO (TEFLUTHRIN 1.5 GR) is considered satisfactory for the requested uses for the rates of 12 kg/ha and 10 kg/ha on maize and sunflower respectively. TOFINO (TEFLUTHRIN 1.5 GR) is still useful at 7 kg/ha for low infestation levels, though with variable results.

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

The risk of development or appearance of resistance to tefluthrin does not require any monitoring for the requested uses.

3.3.2 Adverse effects on treated crops

The phytotoxicity level of TOFINO (TEFLUTHRIN 1.5 GR) is considered negligible for the requested uses.

3.3.3 Observations on other undesirable or unintended side-effects

The risks of negative impact on yield, quality, transformation processes and propagation are considered negligible. The risk of negative impact on succeeding crops is likewise negligible.

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 the relevant impurity

hexachlorobenzene 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 validated for the determination of residues of tefluthrin in plants (high-water-content, oily and dry crops), foodstuffs of animal origin, soil, water (surface and drinking) and air.

An analytical method is available in the DAR and validated for the determination of residues of tefluthrin in tissues and body fluids.

3.5 Mammalian toxicology (Part B, Section 6)

Information on the active substance

Active substance(s) (incl. content)	Tefluthrin 15 g/kg
AOEL systemic	0.0015 mg/kg bw/d
AAOEL	None
Inhalation absorption	100 %
Oral absorption	30 %
Vapour pressure	8.4×10^{-3} Pa at 20 °C
Dermal absorption	0.067 % (Based on product (Tefluthrin 1.5 GR))

3.5.1 Acute toxicity

TOFINO (TEFLUTHRIN 1.5 GR), containing 15 g/kg tefluthrin, has a low acute inhalational and dermal toxicity but is harmful if swallowed. It is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.5.2 Operator exposure

Considering the proposed uses, operator systemic exposure was estimated using the EFSA model⁸:

Model data		Tefluthrin
	Level of PPE	% AOEL
Application : In-furrow application of granules; vehicle-mounted Outdoor Cereals		
Application rate: 12 kg Tefluthrin 1.5 GR /ha		180 g tefluthrin/ha

⁸ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

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Spray ap-plica- tion (AOEM; 75th percentile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application + Respiratory protective equipment FP1, P1 and similar during mix/loading	0.00096	64 %
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According to the model calculations, it may be concluded that the risk for the operator using TOFINO (TEFLUTHRIN 1.5 GR) is acceptable with a working coverall and gloves during mixing/loading and application, and a respiratory protective equipment FP1, P1 and similar, during mixing/loading.

3.5.3 Worker exposure

In-furrow application of granules is intended for TOFINO (TEFLUTHRIN 1.5 GR); no work is expected to be practised after application. Therefore, calculation of worker exposure estimation is considered to be unnecessary.

3.5.4 Bystander exposure

EFSA model (w/o AAOEL): 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 set⁹.

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.”

TOFINO (TEFLUTHRIN 1.5 GR) is applied in the sowing furrow; no drift is expected. Calculation of bystander exposure is considered to be unnecessary.

3.5.5 Resident exposure

In-furrow application of granules is intended for TOFINO (TEFLUTHRIN 1.5 GR). Calculation of resident exposure is considered to be unnecessary.

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

The data available are considered sufficient for risk assessment, **except for sweet corn, due to a lack of**

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)

residues trials.

No exceedence of the current MRL as laid down in Reg. (EU) 396/2005 is expected for the other crops.

The chronic and short-term intakes of tefluthrin residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France as zRMS agrees with the authorisation of the intended uses, except for sweet corn.

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

Information on Tefluthrin 1.5 GR (KCA 6.8)

Crop	PHI for Tefluthrin 1.5 GR requested by applicant	PHI/withholding period* sufficiently supported for	PHI for Tefluthrin 1.5 GR proposed by zRMS	zRMS Comments (if different PHI proposed)
Maize	F**	Yes	F – BBCH 00	Soil incorporation, at sowing
Sweet corn	F**	No	None	No data available on sweet corn (or maize at milky stage)
Sunflower	F**	Yes	F – BBCH 00	Soil incorporation, at sowing

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 metabolite 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 values of tefluthrin and its metabolite 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.

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

PEC_{soil} values derived for the active substance and its metabolite are used for the ecotoxicological risk assessment.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

PEC_{gw} values for tefluthrin 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. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

The PEC_{gw} calculations proposed by the applicant for the metabolite Compound Ia¹⁰ cannot be validated by the zRMS. The degradation pathway of the active substance was not considered, the geometric mean K_{foc} value should have been used according to EFSA Guidance on DegT₅₀ (2014) and the application dates were not appropriately selected for the intended period. **Therefore, the groundwater risk assessment cannot be finalised for the metabolite Compound Ia.**

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

PEC_{sw} values derived for the active substance are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

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.

3.8 Ecotoxicology (Part B, Section 9)

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

Based on the guidance documents, the risks for birds, aquatic organisms, mammals, bees, micro-organisms and terrestrial plants are acceptable for the intended uses.

Further data are required for other non-target arthropods, earthworms and other soil macro-organisms (soil mites). The risk assessment for these organisms is not finalised.

Risk mitigations are required for aquatic organisms, birds and mammals.

3.9 Relevance of metabolites (Part B, Section 10)

No reliable PEC_{gw} calculations are available for intended uses for metabolite Compound Ia of tefluthrin, therefore its relevance could not be assessed.

¹⁰ (1R,3R:1S,3S)-3-S)-3-((Z)-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylic acid.

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

The active substance 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

N/A no registration granted.

5.1.2 Post-authorisation data requirements

- N/A no registration granted

Appendix 1 Copy of the product authorisation

DocuSign Envelope ID: B992D050-2009-47C7-837B-B44728960237



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 réglementaire,

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

de la société GLOBACHEM NV

enregistrée sous le n° 2018-3499

Vu les conclusions de l'évaluation de l'Anses du 14 février 2022,

Considérant qu'un risque inacceptable de contamination des eaux souterraines, lié à l'utilisation du produit, ne peut être exclu,

Considérant également qu'un risque d'effet inacceptable pour les arthropodes non-cibles, les vers de terre et les acariens du sol, lié à l'utilisation du produit, ne peut être exclu,

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

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

TEFLUTHRIN 1.5 GR /TOFINO
Part A - National Assessment
FRANCE

DocuSign Envelope ID: B992D050-2009-47C7-837B-B44728960237



Informations générales sur le produit	
Nom du produit	TOFINO
Type de produit	Produit de référence
Titulaire	GLOBACHEM NV Brustem Industriepark Lichtenberglaan 2019 3800 SINT-TRUIDEN Belgique
Formulation	Granulé (GR)
Contenant	15 g/kg - téfluthrine
Numéro d'intrant	779-2018.01
Numéro d'AMM	-
Fonction	Insecticide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 05/05/2022

DocuSigned by:

 AE281A955A42454...
 Directrice générale déléguée
 en charge du pôle produits réglementés
 Agence nationale de sécurité sanitaire de
 l'alimentation, de l'environnement et du travail (ANSES)

TOFINO
AMM n°-

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TEFLUTHRIN 1.5 GR /TOFINO
Part A - National Assessment
FRANCE

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ANNEXE : Conditions de mise sur le marché demandées

Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
16662105 Maïs doux*Trt Sol* Ravageurs du sol	7 kg/ha	1/an	-
	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus et car les données disponibles ne permettent pas d'exclure un risque inacceptable de contamination des eaux souterraines, ni un risque d'effet inacceptable pour les arthropodes non-cibles, les vers de terre et les acariens du sol.		
15552102 Maïs*Trt Sol* Ravageurs du sol	7 kg/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque inacceptable de contamination des eaux souterraines, ni un risque d'effet inacceptable pour les arthropodes non-cibles, les vers de terre et les acariens du sol.		
15902102 Tournesol*Trt Sol* Ravageurs du sol	7 kg/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque inacceptable de contamination des eaux souterraines, ni un risque d'effet inacceptable pour les arthropodes non-cibles, les vers de terre et les acariens du sol.		

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.

TOFINO

INSECTICIDE

Contient 15 g/kg (1.5% p/p) de téfluthrine sous forme de granulés

Autorisation de Mise sur le Marche n° xxx

Date de fabrication / Numéro de lot : voir emballage

RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL


Contenu : 1-24 kg e

Distribué par :
A compléter

Détenteur d'AMM:
GLOBACHEM NV
Brustem Industriepark – Lichtenberglaan 2019
3800 Sint-Truiden
Belgique
Tel. +32 11 78 57 17
Fax. +32 11 68 15 65



|

<p>TOFINO AMM n° xxx – Contient 15 g/kg (1.5% p/p) de téfluthrine sous forme de granulés (GR)</p>

<p>Attention</p> <p>H302 : Nocif en cas d'ingestion. H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.</p> <p>Conseils de prudence</p> <p>P264 : Se laver les mains, les avant-bras et le visage soigneusement après manipulation. 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 respiratoire. P301+P312 : EN CAS D'INGESTION : Appeler un CENTRE ANTIPOISON/un médecin en cas de malaise. P330 : Rincer la bouche. P391 : Recueillir le produit répandu. P501 : Éliminer le contenu/réceptier dans un centre de collecte de déchets dangereux ou spéciaux, ou autre lieu à la réglementation locale, régionale, nationale et/ou internationale.</p> <p>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. SPe1 : Pour protéger les organismes du sol, ne pas appliquer ce produit plus d'une fois tous les 2 ans pour l'usage de 12 kg/ha sur maïs et maïs doux et de 10 kg/ha sur fourrages. SPe2 : Pour protéger les organismes aquatiques, le produit doit être incorporé dans le sol à une profondeur minimum de 4 cm. SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 10 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 10 mètres en bordure des points d'eau. SPe5 : Pour protéger les oiseaux et les mammifères sauvages, le produit doit être entièrement incorporé dans le sol; s'assurer que le produit est également incorporé en bout de sillons. SPe6 : Pour protéger les oiseaux et les mammifères sauvages, récupérer tout produit accidentellement répandu. SPe8 : Dangereux pour les abeilles. Éviter toute émission des poussières lors de l'application si des plantes-en fleurs sont en bordure de champ.</p> <p>Ne pas planter/implanter de culture suivante ou de remplacement moins de 120 jours après traitement.</p> <p>EUH401 : Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement</p>
<p>Distribué par : À compléter</p>

EN CAS D'URGENCE
Composer le 15 ou le 112 ou contacter le centre
anti poison le plus proche

~~vous~~ signalez vos symptômes au réseau Phyt'Attitude, N° vert : 0-800 887 887 (Appel gratuit depuis un poste fixe).

PREMIERS SOINS

S'éloigner de la zone dangereuse.

En cas de contact cutané : Enlever tout vêtement souillé, rincer immédiatement et abondamment la peau sous l'eau du robinet.

En cas de projection dans les yeux : Rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau tiède, paupières ouvertes et consulter un spécialiste.

En cas d'inhalation : Amener la personne à l'air libre.

En cas d'ingestion : Appeler immédiatement un centre antipoison ou un médecin, et lui montrer l'emballage ou l'étiquette. Ne pas faire vomir.

En cas d'intoxication animale : contactez votre vétérinaire.

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

DESCRIPTIF DU PRODUIT

TOFINO est un insecticide granulé du sol à base de téfluthrine homologué sur maïs et maïs doux contre les taupins, la chrysomèle (*Diabrotica virgifera*) et la coulitétrille et sur tournesol contre les taupins, la coulitétrille et les noctuelles.

Tableau des usages autorisés

Cultures	Cibles	Doses (kg/ha)	Nombre d'applications	DAR (jours)	ZNT aquatique (m)
Maïs	Chrysomèle, Taupins, Coulitétrille	7	1/an	-	10
		12	1/2ans	-	10
Maïs doux	Chrysomèle, Taupins, Coulitétrille	7	1/an	-	10
		12	1/2ans	-	10
Tournesol	Taupins, Noctuelles, Coulitétrille	7	1/an	-	10
		10	1/2ans	-	10

Globechem NV ne préconisent l'utilisation de ce produit que sur les cultures et cibles mentionnées ci-dessus et, à ce titre, déclinent toute responsabilité concernant son utilisation aux autres usages prévus par le catalogue des usages en vigueur.

Limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse : <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database>

RECOMMANDATION 8 D'EMPLOI

Doses préconisées

Les doses préconisées sont celles homologuées (se reporter au tableau des usages).

Conditions d'application

Maïs et maïs doux

Respecter une profondeur minimum d'enfouissement des granulés dans le sol de 4 cm.

Dose : 12 kg/ha (1 application tous les 2 ans) ou 7 kg/ha (1 application par an)

Période d'utilisation : Mars, Avril, Mai, Juin

Stade d'application : Au semis

Tournesol

Respecter une profondeur minimum d'enfouissement des granulés dans le sol de 4 cm.

Dose : 10 kg/ha (1 application tous les 2 ans) ou 7 kg/ha (1 application par an)

Période d'utilisation : Avril, Mai, Juin

Stade d'application : Au semis

Mélanges extemporanés

Les mélanges extemporanés doivent être mis en œuvre conformément à la réglementation en vigueur.

MISE EN ŒUVRE RÉGLEMENTAIRE ET BONNE 8 PRATIQUE 8

Stockage du produit

Conserver le produit uniquement dans son emballage d'origine, dans des locaux fermés à clé, à l'écart des aliments et boissons y compris ceux pour les animaux. Conserver hors de la portée des enfants. Les locaux doivent être frais et ventilés.

Protection de l'opérateur et du travailleur

Se laver les mains après toute manipulation/utilisation/intervention dans une parcelle préalablement traitée.

Ne pas manger, boire, téléphoner ou fumer lors de l'utilisation du produit.

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 complémentaires comme les protections individuelles.

En tout état de cause, 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.

Porter un vêtement de travail et les Équipements de Protection Individuelle (EPI) suivants :

Caractéristiques des EPI		Niveau de protection requis en fonction du risque		
		Risque de contact avec la peau	Risque de contact avec les vêtements	Risque de contact avec les yeux
Combinaison de travail	✓	✓	✓	✓
Gants	✓	✓	✓	✓
Chaussures	✓	✓	✓	✓
Protection des yeux	✓	✓	✓	✓
Protection des voies respiratoires	✓	✓	✓	✓

Tous les EPI doivent être en bon état et conformes aux normes en vigueur.

Rapporter les équipements de protection individuelle (EPI) usagés dans un sac transluide, à votre distributeur partenaire ECD EPI ou faire appel à une entreprise habilitée pour la collecte et l'élimination de produits dangereux.

Immédiatement après l'application, nettoyer les équipements de protection, se laver les mains à l'eau savonneuse, prendre une douche et changer de vêtements.

Élimination du produit, de l'emballage



Réemploi de l'emballage interdit

Lors de l'utilisation du produit, bien vider et rincer le bidon à l'eau claire (rincage manuel à 3 reprises en agitant le bidon rempli au 1/3 ou rincage mécanique d'une durée minimale de 30 secondes) en veillant à verser l'eau de rinçage dans la cuve de l'appareil. Apporter les emballages ouverts, rincés et égouttés à votre distributeur partenaire d'A.D. VALOR ou à un autre service de collecte spécifique.

Pour les fûts, apporter les emballages vidés et fermés à votre distributeur partenaire d'A.D. VALOR ou à un autre service de collecte spécifique.

Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine. Interroger votre distributeur partenaire d'A.D. VALOR ou faites appel à une entreprise habilitée pour la collecte et l'élimination des déchets dangereux.

En cas de déversement accidentel

Se protéger (EPI) et sécuriser la zone. Prévenir les pompiers (18 ou 112) en cas de danger immédiat pour l'environnement que vous ne pouvez gérer avec vos propres moyens. Collecter tout ce qui a pu être en contact avec le produit, terre souillée incluse. Nettoyer le site et le

matériel utilisé, en prenant soin de confiner les effluents générés par l'opération de nettoyage. Les éliminer selon la réglementation en vigueur.



AVERTISSEMENT

Toute reproduction totale ou partielle de cette étiquette est interdite.

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Ils ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases, la culture et les traitements selon la bonne pratique agricole et les recommandations de votre distributeur en tenant compte, sous la responsabilité de l'utilisateur, de tous les facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...

Le fabricant garantit la qualité du produit vendu dans son emballage d'origine et stocké selon les conditions préconisées, ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par les Autorités Compétentes françaises. Pour les denrées issues de cultures protégées avec cette spécialité et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur.

GARANTIE

Le fabricant ne donne aucune garantie, explicite ou implicite, relative à l'utilisation du produit d'une autre manière que celle indiquée sur l'étiquette. L'utilisateur sera responsable 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.