# REGISTRATION REPORT

# Part A

# Risk Management

## Product code: GLOB267H

## Product name: TORSO

**Chemical active substances:**

**metazachlor, 214g/L**
**quinmerac, 71g/L**
**napropamide, 206g/L**

## Southern Zone

## Zonal Rapporteur Member State: France

## NATIONAL ASSESSMENT FRANCE

## (New application)

## Applicant: GLOBACHEM NV

## Date: 15/04/2021

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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 TORSO (product code: GLOB267H), containing 214g/L metazachlor[1], 71g/L quinmerac[2] and 206g/L napropamide[3], as a herbicide for professional uses.

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

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

Appendix 3 of this document is the list of data considered for national authorisation.

### 1.1 Application background

The present registration report concerns the evaluation of GLOBACHEM NV's application submitted to market TORSO (GLOB267H) 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 (2016-1567) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[4], 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")[5]. 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 TORSO (GLOB267H) has been made using endpoints agreed in the EU peer reviews of the active substances. It also includes assessment of data and information related to TORSO (GLOB267H) 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.

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1 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, as amended by Commission Implementing Regulation (EU) 2017/195 of 3 February 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of several active substances listed in Part B of the Annex to Implementing Regulation (EU) No 686/2012 (AIR IV renewal programme).

2 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011, as amended by Commission Implementing Regulation (EU) 2018/1260 of 20 September 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances pyridaben, quinmerac and zinc phosphide.

3 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011, as amended by Commission Implementing Regulation (EU) 2018/670 of 30 April 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances bromuconazole, buprofezin, haloxyfop-P and napropamide.

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 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 546/2011[6], 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 TORSO (GLOB267H).

### 1.2 Letters of Access

Not necessary: the applicant is the owner of data which support the (renewal of) approval of the active substances.

### 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* [sic] *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 TORSO (GLOB267H), 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 | GLOB267H. |
| Product name in MS | TORSO. |
| Authorisation number | N/A : no marketing authorisation granted |
| Kind of use | Professional use. |
| Low risk product (article 47) | No. |
| Function | Herbicide. |
| Applicant | GLOBACHEM NV. |
| Active substance(s) (incl. content) | Metazachlor, 214 g/L.<br>Quinmerac, 71 g/L.<br>Napropamide, 206 g/L. |
| Formulation type | Suspension concnetrate (SC). |
| Packaging | N/A : no marketing authorisation granted |
| Coformulants of concern for national authorisations | - |

[6] 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

| | |
|---|---|
| Restrictions related to identity | - |
| Mandatory tank mixtures | None. |
| Recommended tank mixtures | None. |

## 2.2 Conclusion DAMM

The evaluation of the application for TORSO (GLOB267H) resulted in the Decision **to refuse** the authorisation. This is due to concerns about, and as the risk evaluation for groundwater, bees and aquatic organisms could not be finalised.

## 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.<br>Eye irritation, category 2.<br>Carcinogenicity, category 2.<br><br>Hazardous to the aquatic environment - Acute Hazard, category 1.<br>Hazardous to the aquatic environment - Chronic Hazard, category 1. |
| Hazard pictograms: |  <br>GHS07 GHS08 GHS09 |
| Signal word: | Warning. |
| Hazard statement(s): | H317: May cause an allergic skin reaction.<br>H319: Causes serious eye irritation.<br>H351: Suspected of causing cancer.<br>H400: Very toxic to aquatic life.<br>H410: Very toxic to aquatic life with long-lasting effects. |
| Precautionary statement(s): | ***For the P phrases, refer to the existing legislation*** |
| Additional labelling phrases: | Contains 1,2-benisothiazol-3(2H)-one. May produce an allergic reaction. |

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

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

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 2017[7] provides that:

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

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

Finally, the French Order of 26 March 2014[8] provides that:

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

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

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

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

### 2.5.1 Restrictions linked to the PPP

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):

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

8 http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

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

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.

GAP rev. 1.0, date: 2021-04-15

| | | | |
|---|---|---|---|
| PPP (product name/code): | TORSO / GLOB267H | Formulation type: | SC [a, b] |
| Active substance 1: | metazachlor | Conc. of a.s. 1: | 214 g/L [c] |
| Active substance 2: | quinmerac | Conc. of a.s. 2: | 71 g/L [c] |
| Active substance 3: | napropamide | Conc. of a.s. 3: | 206 g/L [c] |
| Applicant: | GLOBACHEM NV | Professional use: | ☒ |
| Zone(s): | Southern Zone [d] | Non-professional use: | ☐ |
| Verified by MS: | Yes | | |
| Field of use: | Herbicide | | |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Use-No. [e]** | **Member state(s)** | **Crop and/ or situation**<br><br>**(crop destination / purpose of crop)** | **F, Fn, Fpn G, Gn, Gpn or I** | **Pests or Group of pests controlled**<br><br>(additionally: develop-mental stages of the pest or pest group) | **Application** | | | | **Application rate** | | | **PHI** (days) | **Remarks:**<br><br>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 ap-plications (days) | L product / ha a) max. rate per appl. b) max. total rate per crop/season | g a.s./ha<br><br>a) max. rate per appl. b) max. total rate per crop/season | Water L/ha<br><br>min / max | | |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | | |
| 1 | FR | Winter oilseed rape | F | Weeds | Normal downward spraying | Pre-emergence | a) 1 every three years<br>b) 1 every three years | N/A | a) 3.5<br>b) 3.5 | a) 749 g metaza-chlor/ha + 249 gquin-merac/ha + 721 g napropamide/ha<br>b) 749 gmetaza-chlor/ha + 249 gquin-merac/ha + 721 gnapropa-mide/ha | 150-400 | N/A | **Not acceptable** groundwater, bees and aquatic organisms |

**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)

The formulation TORSO (GLOB267H) is a suspension concentrate (SC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of a uniform white-coloured liquid, with an emulsion paint odour. It is not explosive and has no oxidising properties. The product has a flash point above 100 °C. It has a self-ignition temperature above 400 °C. In aqueous solution, it has a pH value around 4.21 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 eight weeks at 40 °C, neither the active substances' content nor the technical properties were changed. The shelf life stability performed in commercial packaging must be provided. The technical characteristics are acceptable for a suspension concentrate formulation.

The preparation does not contain more than 10 % of hydrocarbon compounds or compounds classified H304.

The maximum content of the relevant impurity, toluene (methylbenzene), in the preparation is 0.32 g/L. Toluene cannot be formed by storage of the formulation; information on the stability of this relevant impurity after storage is therefore not required.

The formulation must be stored at a temperature below 40 °C.

## 3.2 Efficacy (Part B, Section 3)

The level of efficacy of TORSO (GLOB267H) is considered satisfactory for the use as a herbicide on winter oilseed rape, against annual dicotyledons and grassy weeds, pre-emergence.

The selectivity level of the product is considered satisfactory for the requested use.

The risks of negative impact on yield, quality, transformation processes and multiplication are considered negligible.

The risk of negative impact on succeeding crops is considered acceptable. However, particular attention should be paid to the conditions of sowing or planting following or replacement crops.

The risk of negative impact on adjacent crops may be considered negligible.

The risk of the appearance and development of resistance towards metazachlor and napropamide does not require monitoring.

However, there is a risk of resistance to quinmerac from *Papaver rhoeas*: this requires monitoring.

Restrictions: none.

## 3.3 Methods of analysis (Part B, Section 5)

### 3.3.1 Analytical method for the formulation

Analytical methods for the determination of active substances and relevant impurity (toluene) in the formulation are available and validated.

### 3.3.2 Analytical methods for residues

Analytical methods are available in the draft assessment reports (DARs)/this dossier and validated for the determination of residues of quinmerac, metazachlor and napropamide in plants (high-oil-content crops), foodstuffs of animal origin, soil, water (surface and drinking) and air.

To update the dossier, an analytical method with ILV for the determination of quinmerac and napropamide in foodstuffs of animal origin must be provided post-authorisation.

## 3.4 Mammalian toxicology (Part B, Section 6)

**Endpoints used in risk assessment**

| Active substance: **quinmerac** | | | |
|---|---|---|---|
| ADI | 0.08 mg/kg bw/d | | EU (2017) |
| ARfD | 0.3 mg/kg bw | | |
| AOEL | 0.08 mg/kg bw/d | | |
| AAOEL | Not determined | | |
| Dermal absorption | Based on an *in vitro* human study performed on the formulation: | | |
| | | Concentrate (tested) 71 g/L | Diluted formulation (tested) 0.62 g/L |
| | *In vitro* (human) % | 1 | 0.7 |
| | | Concentrate (used in formulation) 71 g/L | Spray dilution (used in formulation) 0.62 g/L |
| | **Dermal absorption endpoints %** | 1 | 0.7 |
| Oral absorption | **> 80-90 %** | | |

| Active substance: **metazachlor** | | |
|---|---|---|
| ADI | 0.08 mg/kg bw/d | EU (2019) |
| ARfD | 0.5 mg/kg bw | |
| AOEL | 0.2 mg/kg bw/d | |
| AAOEL | Not determined | |
| | Based on an *in vitro* human study performed on the formulation: | |

| | | | |
|---|---|---|---|
| Dermal absorption | | Concentrate (tested) 214 g/L | Diluted formulation (tested) 1.87 g/L |
| | *In vitro* (human) % | 0.2 | 11 |
| | | Concentrate (used in formulation) 214 g/L | Spray dilution (used in formulation) 1.87 g/L |
| | **Dermal absorption endpoints %** | **0.2** | **11** |
| Oral absorption | **> 85-95 %** | | |

| | | | |
|---|---|---|---|
| Active substance: napropamide | | | |
| ADI | 0.3 mg/kg bw/d | | EU (2010) |
| ARfD | Not applicable | | |
| AOEL | 0.5 mg/kg bw/d | | |
| AAOEL | Not determined | | |
| Dermal absorption | Based on an *in vitro* human study performed on the formulation: | | |
| | | Concentrate (tested) 206 g/L | Diluted formulation (tested) 1.80 g/L |
| | *In vitro* (human) % | 0.4 | 6 |
| | | Concentrate (used in formulation) 206 g/L | Spray dilution (used in formulation) 1.80 g/L |
| | **Dermal absorption endpoints %** | 0.4 | 6 |
| Oral absorption | **70 %** | | |

**Remark**: According to the conclusions in EFSA Journal 2018;16(11):5465, new toxicological reference values were proposed for napropamide:

- ADI: 0.3 mg/kg bw/d
- ARfD: 1.1 mg/kg bw
- AOEL: 0.35 mg/kg bw/d
- AAOEL: 0.8 mg/kg bw/d

### 3.4.1 Acute toxicity

TORSO (GLOB267H), containing 214 g/L metazachlor, 71 g/L quinmerac and 206 g/L napropamide, has a low acute oral, inhalational and dermal toxicity and is not irritating to the rabbit skin. It is an eye irritant (Cat.2), a skin sensitiser (Cat. 1B) and a carcinogen (Cat.2).

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

### 3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

| Crop | F/G[10] | Equipment | Application rate L product/ha (g a.s./ha) | Spray dilution (L/ha) | Model |
|---|---|---|---|---|---|
| Oilseeds | F | Vehicle-mounted Downward spraying | 3.5 L product/ha<br>()<br>()<br>() | 100 | EFSA |

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

| Crop | Equipment | PPE and/or working coverall | % AOEL metazachlor | % AOEL quinmerac | % AOEL napropamide |
|---|---|---|---|---|---|
| Oilseed | Vehicle-mounted | Working coverall and gloves during mixing/loading and application | 0.68 | 0.49 | 0.20 |

According to the model calculations, it may be concluded that the risk for the operator using TORSO (GLOB267H) is acceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application.

### 3.4.3 Worker exposure

Workers may have to enter treated areas after treatment for crop inspection/irrigation activities. Therefore, estimation of worker exposure was calculated according to the EFSA model.

| Crop | Equipment | PPE and/or working coverall | % AOEL metazachlor | % AOEL quinmerac | % AOEL napropamide |
|---|---|---|---|---|---|
| Oilseed | Vehicle-mounted | Working coverall during mixing/loading and application | 5.71 | 0.44 | 1.21 |

It may be concluded that without taking into account a re-entry period, there is no unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering crops treated with TORSO (GLOB267H).

[10] Open field or glasshouse.

### 3.4.4 Bystander 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 AOE model where no AAOEL has been set (on the basis of the original figures for napropamide).

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.*"

### 3.4.5 Resident exposure

Residential exposure was assessed according to the EFSA model[11] incorporating a distance of 3 metres from the spray boom. An acceptable risk was determined for residents (adult and/or child) :

| **Model (AOEM) - All pathways (mean)** | % AOEL metazachlor | % AOEL quinmerac | % AOEL napropamide |
|---|---|---|---|
| Resident (children) | 10 | 2 | 2 |
| Resident (adults) | 4 | 0.6 | 0.9 |

It may be concluded that there is no unacceptable risk to the resident exposed to TORSO (GLOB267H).

### 3.4.6 Combined exposure

A cumulative assessment for operators, workers, residents (adult/child) was performed. At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.

Hazard quotients (HQ) for each active substance and the hazard index (HI: sum of hazard quotients) are:

| **Population groups and PPE** | | **Active substance** | **Estimated exposure / AOEL (HQ)** |
|---|---|---|---|
| Operators | Working coverall and gloves during mixing/loading and application | Metazachlor | 0.007 |
| | | Quinmerac | 0.005 |
| | | Napropamide | 0.002 |
| | **Cumulative risk operators (HI)** | | **0.014** |
| Residents | | Metazachlor | 0.10 |

[11] *EFSA Journal 2014;12(10):3874*

| | | | |
|---|---|---|---|
| | Children - All pathways (mean) | Quinmerac | 0.02 |
| | | Napropamide | 0.02 |
| | **Cumulative risk residents (child) (HI)** | | **0.14** |
| | Adults - All pathways (mean) | Metazachlor | 0.04 |
| | | Quinmerac | 0.006 |
| | | Napropamide | 0.009 |
| | **Cumulative risk residents (adult) (HI)** | | **0.055** |
| Worker | Working coverall and gloves | Metazachlor | 0.06 |
| | | Quinmerac | 0.004 |
| | | Napropamide | 0.01 |
| | **Cumulative risk workers (HI)** | | **0.074** |

The Hazard Index is < 1. Thus combined exposure to all active substances in TORSO (GLOB267H) is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

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

### 3.5.1 Residues

The data available are considered sufficient for risk assessment. An exceedence of the current MRL of 0.06 mg/kg for metazachlor and 0.1 mg/kg for napropamide as laid down in Reg. (EU) 396/2005 is not expected.

### 3.5.2 Consumer exposure

The chronic and short-term intakes of metazachlor and napropamide residues are unlikely to present a public health concern. For quinmerac, risks for the consumer cannot be evaluated due to the lack of residue data.

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

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for the active substances and their 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 values of napropamide, metazachlor, quinmerac and their 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 substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

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.

The PECgw values calculated for napropamide and its metabolite and for quinmerac metabolites (for an application every third year for quinmerac metabolites) are below the threshold values defined in the guidance SANCO 221/2000, after the use of TORSO (GLOB267H).

The PECgw values calculated for quinmerac (for an application every third year) are above the threshold value of 0.1 µg/L for one FOCUS scenario (maximum PECgw value of 0.309 µg/L), after the use of TORSO (GLOB267H). **Thus, the risk of groundwater contamination by quinmerac cannot be finalised by the zRMS for the use of TORSO (GLOB267H) on oilseed rape**.

The PECgw values calculated for an application every third year for metazachlor and its metabolites BH 479-4 and BH 479-8 do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000. The PECgw values calculated for metazachlor metabolites BH 479-9, BH 479-11 and BH 479-12 exceeded levels mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000. **The risk assessment for groundwater contamination by metazachlor metabolites cannot be finalised for oilseeds and crops for seed production**.

The applicant provided additional data from a targeted groundwater monitoring for metazachlor and its five soil metabolites in France for the use on oilseed rape. In addition, national public data on the monitoring of groundwater and drinking water were analysed.

The targeted monitoring programme provided by the applicant for metazachlor and its metabolites showed a potential groundwater contamination by metabolites BH 479-8 and BH 479-4 in half of the wells considered and in some cases throughout the year. However, based on available data, in zones where metazachlor is used, it is possible to identify situations for which the occurrences observed for the active substance and its metabolites are limited or non-existent. However, no mitigation measure for groundwater contamination risk was proposed by the applicant nor could be identified by the zRMS.

Despite their very different nature, the data available in national monitoring programmes are consistent with the results from the targeted monitoring settled by the applicant. Both metabolites BH 479-4 and BH 479-8 are also observed in drinking water in France. Non-compliances of drinking water can be identified due to both metabolites' concentrations. Considering the threshold value of 0.9 µg/L for non-relevant metabolites in drinking water recently proposed by the zRMS, no measured concentration for BH 479-4 is above the threshold and four analyses for BH 479-8 are above 0.9 µg/L.

In conclusion, to limit groundwater contamination, risk mitigation measures should be applied. They could be based on an analysis of the agro-pedo-climatic context, to identify vulnerable situations that would

require the application of specific risk mitigation measures. **Based on all available information, the risk assessment for groundwater contamination by metazachlor and its metabolites on oilseed rape cannot be finalised.**

### 3.7 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(s) and its/their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

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

For aquatic organisms, the risk to aquatic plants exposed to napropamid can not be considered acceptable based on FOCUS step 3 PECsw. **As no PECsw values with FOCUS step 4 including risk mitigation measures are available, the risk for aquatic orgnanisms can not be finalised.**

**According to new requirements of Reg. No. 284/2013, information on chronic effects on adult bees and on development of bees should have been submitted as exposure of bees to the formulation cannot be excluded. In absence of these data, the risk for bees can not be finalized.**

### 3.8 Relevance of metabolites (Part B, Section 10)

Estimated predicted concentrations in groundwater exceed the threshold of 0.1 µg/L for metabolites BH 479-9 and BH 479-11 of metazachlor. Given the available toxicological information, ANSES (France) considers these metabolites to be relevant according to the SANCO/221/2000 guidance document.

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

The active substances are not approved as candidates 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 marketing authorisation granted.

### 5.1.2 Post-authorisation data requirements

N/A : no marketing authorisation granted.

# Appendix 1 Copy of the product authorisation DAMM

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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 **TORSO***

*de la société* *GLOBACHEM NV*

*enregistrée sous le* *n°2016-1567*

*Vu les conclusions de l'évaluation de l'Anses du 15 février 2021,*

*Considérant qu'un risque inacceptable de contamination des eaux souterraines par la substance active quinmérac et ses métabolites et un risque d'effet inacceptable pour les organismes aquatiques, lié à l'utilisation du produit, ne peuvent être exclus,*

*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.

*TORSO*
*AMM n°-*

*Page 1 sur 3*

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| Informations générales sur le produit | |
|---|---|
| **Nom du produit** | TORSO |
| **Type de produit** | Produit de référence |
| **Titulaire** | GLOBACHEM NV<br>Brustem Industriepark<br>Lichtenberglaan 2019<br>3800 Sint-Truiden<br>Belgique |
| **Formulation** | Suspension concentrée (SC) |
| Contenant | 71 g/L - quinmérac<br>206 g/L - napropamide<br>214 g/L - métazachlore |
| **Numéro d'intrant** | 496-2016.01 |
| **Numéro d'AMM** | - |
| **Fonction** | Herbicide |
| **Gamme d'usage** | Professionnel |

A Maisons-Alfort, le 15 AVR. 2021

**Caroline SEMAILLE**
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 : Conditions de mise sur le marché demandées

| Liste des usages refusés | | | |
|---|---|---|---|
| **Usages** | **Dose d'emploi** | **Nombre maximum d'applications** | **Délai avant récolte (jours)** |
| **15205901**<br>Crucifères oléagineuses*<br>Désherbage | 3,5 L/ha | 1/an | - |
| | **Motivation du refus :**<br>L'usage est refusé car les données disponibles ne permettent ni d'exclure un risque inacceptable de contamination des eaux souterraines par la substance active quinmérac et ses métabolites, ni un risque d'effet inacceptable pour les organismes aquatiques. | | |

# 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 must reflect the detailed conditions stipulated in the Decision.

Globachem

Projet d'étiquette

GLOB267H

## GLOB267H

**GLOB267H** contient 214 g/L (18.94% p/p) de **métazachlore**, 71 g/L (6.28% p/p) de **quinmérac** et 206 g/L (18.23% p/p) de **napropamide** sous forme de Suspension concentrée (SC)

**ATTENTION**

**H317 - Peut provoquer une allergie cutanée.**
**H319 - Provoque une sévère irritation des yeux**
**H351 - Susceptible de provoquer le cancer.**
**H410 - Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.**
P280 - Porter un équipement de protection des yeux, un équipement de protection du visage, des vêtements de protection, des gants de protection
P302+P352 - EN CAS DE CONTACT AVEC LA PEAU: laver abondamment à l'eau et au savon
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
P333+P313 - En cas d'irritation ou d'éruption cutanée: consulter un médecin
P337+P313 - Si l'irritation oculaire persiste: consulter un médecin
P391 - Recueillir le produit répandu.

SP1 - Ne pas polluer l'eau avec le produit ou son emballage.
SPe 2 - Pour protéger les organismes aquatiques, ne pas appliquer ce produit sur sols artificiellement drainés ayant une teneur en argile supérieure ou égale à 45%
SPe 3 - Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres avec dispositif végétalisé par rapport aux points d'eau.
EUH401 - Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.

**Délai de rentrée des travailleurs sur la parcelle : 48 heures.**
**Ne pas dépasser 1000 g/ha de métazachlore (4,7 L/ha de GLOB267H) sur une période de 3 ans en une ou plusieurs applications.**

En cas d'urgence appelez le 15 ou le centre antipoison puis signalez vos symptômes au réseau Phyt'attitude, numéro vert 0800 887 887 (appel gratuit depuis un poste fixe).

**CONSERVER A L'ABRI DU GEL** **BIEN AGITER AVANT L'EMPLOI**

Contenu: 5 lit. e

Numéro du lot: voir emballage

Etiquette GLOB267H Avril 2016 Page 1

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

Détenteur d'homologation:

Globachem NV
Brustem Industriepark • Lichtenberglaan 2019
3800 Sint-Truiden • Belgique
Tel +32 (0)11 78 57 17 • Fax +32 (0)11 68 15 65
Email: globachem@globachem.com
Web : www.globachem.com

Fiche de données de sécurité disponible sur simple appel 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

GLOB267H est un herbicide de post-semis prélevée du colza. Il se compose de quinmérac, matière active de la famille des acides quinoléine-carboxyliques (code HRAC O), de métazachlore, matière active de la famille des chloroacétamides (code HRAC K3) et de napropamide matière active de la famille des cacétamides (code HRAC K3). Il présente une efficacité sur dicotylédones et sur graminées.

## USAGES ET DOSES D'EMPLOI

| Usages autorisé | Cultures cibles recommandées | Dose autorisé | Délai avant récolte (DAR) |
|---|---|---|---|
| Crucifères Oléagineuses - désherbage | colza | 3,5 L/ha | - |

L'utilisation de GLOB267H sur ses usages autorisés n'est recommandée que sur les cultures mentionnées dans le tableau ci-dessus. Belchim Crop Protection décline en conséquence toute responsabilité en cas d'utilisation du produit sur des cultures ou pour des cibles non recommandées.
Les limites maximales de résidus sont consultables à l'adresse suivante :
http://ec.europa.eu/sanco_pesticides/public/index.cfm

## CULTURES DE REMPLACEMENT

**Cultures suivantes dans la rotation**
Dans le cas où une céréale succéderait au colza d'hiver l'année suivante, il est obligatoire d'effectuer un labour de retournement à 20 cm précédant le semis.

**Cultures de remplacement**
Si le colza d'hiver doit être retourné, il est possible d'implanter au printemps après un labour à 20 cm :
- directement : choux, pomme de terre de consommation, colza de printemps.
- après 9 mois: maïs
- 12 mois: céréales, graminées et toute autre culture

## PREPARATION DE LA BOUILLIE

Avant de débuter le remplissage de la cuve du pulvérisateur pour préparer la bouillie de pulvérisation, s'assurer que celle-ci ne contient aucun résidu liquide ou solide d'un traitement précédent. Remplir la cuve aux 3/4 du volume d'eau nécessaire. Mettre l'agitation en marche et bien agiter le bidon de GLOB267H avant de verser la quantité nécessaire, puis compléter avec de l'eau jusqu'au volume final. Dans le cadre des bonnes pratiques agricoles, rincer 3 fois les emballages et verser l'eau de rinçage dans la cuve du pulvérisateur. Laisser l'agitateur en fonctionnement pendant le trajet et jusqu'à la fin de la pulvérisation. Ne préparez jamais plus de bouillie qu'il n'en est nécessaire.

## CULTURES ET CONDITIONS D'APPLICATION

### COLZA D'HIVER : CONDITIONS D'APPLICATION

GLOB267H s'utilise en un seul passage, dans les 3 jours après le semis.
Appliquer GLOB267H sur un sol finement préparé et non motteux. Veiller à ce que le semis soit effectué à une profondeur régulière et suffisante (2 à 3 cm). Ne pas rouler la culture après traitement. Ne pas traiter en conditions météorologiques défavorables: vent, pluie, forte chaleur supérieure à 25 °C à l'ombre. Traiter par temps calme afin de protéger les cultures voisines. Afin d'éviter tout risque de manque de sélectivité pouvant entraîner des retards de croissance, toute irrigation dans les 3 semaines qui suivent l'application de GLOB267H est à proscrire; de plus, ne pas effectuer de traitement si des précipitations importantes (20 mm ou plus) sont à craindre dans les jours qui suivent l'application.

### CHAMP D'ACTIVITE DE GLOB267H à 3.5 L/ha :

Très sensible : Vulpin des champs, Myosotis des champs, mouron des oiseaux, Véronique de Perse
Moyennement sensible : Capselle bourse à pasteur, Séneçon, Gaillet grateron, Lamier pourpre, Matricaire camomille, Coquelicot, Pâturin, Pensée des champs

## COMPATIBILITE

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques des mélanges de produits phytopharmaceutiques.

## GESTION DU RISQUE DE RESISTANCE

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.
En dépit du respect de ces règles, on ne peut pas exclure une altération de l'efficacité de l'herbicide liée à ces phénomènes de résistance. De ce fait, nous déclinons toute responsabilité quant à d'éventuelles conséquences qui pourraient être dues à de telles résistances.
Consultez votre distributeur pour connaître les cas avérés de résistance au niveau de votre région.

## PRECAUTIONS D'EMPLOI

**Avant l'application :**

• Conserver le produit uniquement dans le récipient d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur et fermé à clé, à l'abri de l'humidité, du gel, dans un endroit frais, aéré et ventilé, à l'écart des aliments et boissons y compris ceux pour animaux.
• Conserver hors de la portée des enfants.

**Pendant la préparation de la bouillie et en cours d'application :**

• Ne pas manger, boire, fumer.
• Porter un vêtement de protection approprié, des gants et un appareil de protection des yeux et du visage, selon la réglementation en vigueur.
• Vérifier régulièrement et maintenir le bon état et le réglage du matériel d'application, en conformité avec la législation.
• Surveiller le remplissage de la cuve du pulvérisateur et ajuster le volume de bouillie (clapet anti-retour, dispositif de surverse).
• Ne pas souffler dans les buses pour tenter de les déboucher.
• En cas de contact avec la peau et les yeux, laver immédiatement et abondamment avec de l'eau et consulter un spécialiste.
• En cas d'ingestion consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette.
• Ne pas respirer les vapeurs, ni le brouillard de pulvérisation.
• Ne pas pulvériser à proximité des points d'eau (mares, cours d'eau, fossés...).
• Ne pas traiter en présence de vent (selon la réglementation en vigueur).

**Après application :**

• Eliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur.
• Ne pas conserver la bouillie de pulvérisation dans la cuve plus de 48 heures.
• Nettoyer très soigneusement avec un produit adapté (type Phytnet) et rincer le pulvérisateur aussitôt après le traitement conformément à la réglementation en vigueur.
• Immédiatement après l'application, nettoyer les équipements de protection, se laver les mains à l'eau savonneuse, prendre une douche et changer de vêtements.

## PROTECTION DE L'OPERATEUR ET DU TRAVAILLEUR (EPI)

*A ajouter sur base de la décision*

## ELIMINATION DU PRODUIT ET DES EMBALLAGES

Lors de l'utilisation du produit, rincer le bidon 3 fois en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. 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

• Respectez les usages, doses, conditions et précautions d'emploi mentionnées 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, la pression parasitaire,…

• Le fabricant garantit la qualité du produit vendu dans son emballage d'origine, ainsi que sa conformité à l'autorisation du Ministère de l'Agriculture.

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

• Globachem NV ne saurait être tenu en aucun cas responsable des conséquences inhérentes à toute copie de cette étiquette et la diffusion ou à l'utilisation non autorisée de cette dernière.

## 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.

## RESPONSABILITES

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