

**REGISTRATION REPORT**

**Part A**

**Risk Management**

**Product code: GLOB267H**

**Product name(s): TORSO**

**Chemical active substance(s):**

**metazachlor, 214 g/L**

**quinmerac, 71 g/L**

**napropamide, 206 g/L**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(label extension)**

**Applicant: GLOBACHEM NV**

**Date: 10/09/2025**

## Table of Contents

|          |   |           |
|----------|---|-----------|
| <b>1</b> | <b>Details of the application .....</b>   | <b>4</b>  |
| 1.1      | Application background .....  | 4         |
| 1.2      | Letters of Access.....  | 4         |
| 1.3      | Justification for submission of tests and studies .....   | 4         |
| 1.4      | Data protection claims.....   | 4         |
| <b>2</b> | <b>Details of the authorisation decision.....</b>   | <b>4</b>  |
| 2.1      | Product identity.....   | 4         |
| 2.2      | Conclusion DAMM.....  | 5         |
| 2.3      | Substances of concern for national monitoring .....   | 5         |
| 2.4      | Classification and labelling.....   | 5         |
| 2.4.1    | Classification and labelling under Regulation (EC) No 1272/2008 .....   | 5         |
| 2.4.2    | Standard phrases under Regulation (EU) No 547/2011 .....  | 5         |
| 2.4.3    | Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009) .....   | 5         |
| 2.5      | Risk management .....   | 6         |
| 2.5.1    | Restrictions linked to the PPP.....   | 6         |
| 2.5.2    | Specific restrictions linked to the intended uses.....  | 7         |
| 2.6      | Intended uses (only NATIONAL GAP) .....   | 8         |
| <b>3</b> | <b>Background of authorisation decision and risk management .....</b>   | <b>11</b> |
| 3.1      | Physical and chemical properties (Part B, Section 2) .....  | 11        |
| 3.2      | Efficacy (Part B, Section 3) .....  | 11        |
| 3.3      | Methods of analysis (Part B, Section 5).....  | 11        |
| 3.3.1    | Analytical method for the formulation.....  | 11        |
| 3.3.2    | Analytical methods for residues .....   | 12        |
| 3.4      | Mammalian toxicology (Part B, Section 6) .....  | 12        |
| 3.4.1    | Acute toxicity.....   | 12        |
| 3.4.2    | Operator exposure.....  | 12        |
| 3.4.3    | Worker exposure.....  | 13        |
| 3.4.4    | Bystander exposure .....  | 14        |
| 3.4.5    | Resident exposure.....  | 14        |
| 3.4.6    | Combined exposure.....  | 15        |
| 3.5      | Residues and consumer exposure (Part B, Section 7) .....  | 16        |
| 3.6      | Environmental fate and behaviour (Part B, Section 8).....   | 17        |
| 3.7      | Ecotoxicology (Part B, Section 9) .....   | 18        |
| 3.8      | Relevance of metabolites (Part B, Section 10) .....   | 19        |
| <b>4</b> | <b>Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation.....</b> | <b>19</b> |
| 4.1.1    | Post-authorisation monitoring.....  | 19        |
| 4.1.2    | Post-authorisation data requirements .....  | 19        |

GLOB267H / TORSO  
Part A - National Assessment  
FRANCE DEPR version

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**Appendix 1**      **Copy of the product authorisation DAMM.....20**

**Appendix 2**      **Copy of the product label .....21**

# **PART A**

## **RISK MANAGEMENT**

### **1 Details of the application**

The company GLOBACHEM NV has requested a marketing authorisation in France for the product TORSO (formulation code: GLOB267H), containing 214 g/L metazachlor<sup>1</sup>, 71 g/L quinmerac<sup>1</sup> and 206 g/L napropamide<sup>1</sup>, as a herbicide for professional uses.

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

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

#### **1.1 Application background**

The present registration report concerns the evaluation of GLOBACHEM NV's application submitted on 09/11/2022 to market TORSO 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 label extension of this product in France and in other Member States (MSs) of the Southern zone.

#### **1.2 Letters of Access**

Not necessary: actives substances datas 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 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. |
|--------------|-----------|

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<sup>1</sup> 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.

GLOB267H / TORSO  
Part A - National Assessment  
FRANCE DEPR version

|  |  |
|--|--|
| Product name in MS                                     | TORSO.   |
| Authorisation number                                   | 2220272  |
| Kind of use  | Professional use.  |
| Low risk product (article 47)                          | No.  |
| Function   | Herbicide.   |
| Applicant  | GLOBACHEM NV.  |
| Active substance(s)<br>(incl. content)                 | Metazachlor, 214 g/L.<br>Quinmerac, 71 g/L.<br>Napropamide, 206 g/L. |
| Formulation type                                       | Suspension concentrate (SC).   |
| Packaging  | Packaging not changed  |
| Coformulants of concern for<br>national authorisations | -  |
| Restrictions related to identity                       | -  |
| Mandatory tank mixtures                                | None   |
| Recommended tank mixtures                              | None   |

## 2.2 Conclusion DAMM

The evaluation of the application for TORSO resulted in the decision **to grant** the authorisation.

## 2.3 Substances of concern for national monitoring

Refer to 5.1.1.

## 2.4 Classification and labelling

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

Classification not changed.

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

|      |   |
|------|---|
| SP 1 | Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). |
|      | For other restrictions refer to 2.5   |

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

None.

## 2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017<sup>2</sup> provides that:

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

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

Finally, the French Order of 12 April 2021<sup>3</sup> 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<sup>4</sup> is to supply “minor” crops with registered plant protection products.

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

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

### 2.5.1 Restrictions linked to the PPP

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

|                                   |  |
|-----------------------------------|--|
| Operator protection:              |  |
| -                                 | Refer to the Decision in Appendix 1 for the details. |
| Worker protection:                |  |
| -                                 | Refer to the Decision in Appendix 1 for the details. |
| Bystander and resident protection |  |

<sup>2</sup> Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

<sup>3</sup> <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

<sup>4</sup> SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

GLOB267H / TORSO  
Part A - National Assessment  
FRANCE DEPR version

|   |   |
|---|---|
|   | Maintain a distance of at least 3 metres between the spray boom and :<br>- areas frequented by people present at the time of spraying;<br>- areas likely to be frequented by residents.   |
| Integrated pest management (IPM)/sustainable use: |   |
|   | -   |
| Environmental protection                          |   |
| SPe 1   | To protect groundwater, for application on winter oilseed rape, do not apply this or any other product containing quinmerac more than every third year.   |
| SPe 1   | To protect groundwater, do not apply this product or any other product containing metazachlor more than once every 3 years at the rate of 500 g metazachlor/ha or more than once every 4 years at the rate of 750 g metazachlor/ha.   |
| SPe 2   | To protect aquatic organisms; do not apply this product to artificially drained soils having a clay content of 45% or more for the uses on oilseed rape at 2.2 L/ha.  |
| SPe 2   | To protect groundwater, do not apply this product to a plot with a referenced concrete pit.   |
| SPe 3   | To protect aquatic organisms, respect an unsprayed buffer zone of 20 metres with a 20-metre permanent planted buffer strip to surface water bodies for uses on oilseed rape on post-emergence (BBCH 10 to 14).  |
| Other specific restrictions                       |   |
| Re-entry period                                   | 48 hours.   |
| Storage   | -   |
| Risk mitigation measures                          | For each use on the list of authorised uses, the conditions of use of the product ensure compliance with the maximum residue limits.  |
| Risk mitigation measures                          | <ul style="list-style-type: none"> <li>- For root and tuber crops, a waiting period of 180 days after treatment is required before planting or sowing rotational crops;</li> <li>- For leafy crops, a waiting period of 365 days after treatment is required before planting or sowing rotational crops;</li> <li>- For the other crops, a waiting period of 60 days after treatment is required before planting or sowing rotational crops.</li> </ul>   |
| Agricultural recommendations                      | Specify the measures to limit the transfer of metazachlor and its metabolites, in particular: <ul style="list-style-type: none"> <li>- In clay soils with significant shrinkage cracks, shallow tillage is necessary to limit rapid run-off into groundwater.</li> <li>- Its use should be avoided on plots of land with areas of rapid infiltration (other than the beakers listed).</li> <li>- In karstic areas, use must be accompanied by measures to slow transfers to groundwater (such as grassing over sinkholes).</li> </ul> |

### 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.

GLOB267H / TORSO  
 Part A - National Assessment  
 FRANCE DEPR version

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## 2.6 Intended uses (only NATIONAL GAP)

**Please note:** The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

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

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1.0, date: 2025-09-10

PPP (product name/code): TORSO/GLOB267H

Active substance 1: Metazachlor

Active substance 2: Quinmerac

Active substance 3: Napropamide

Safener: /

Synergist: /

Applicant: Globachem NV

Zone(s): Southern

Verified by MS: yes

Field of use: herbicide

Formulation type: SC

Conc. of as 1: 214 g/L

Conc. of as 2: 71 g/L

Conc. of as 3: 206 g/L

Conc. of safener: /

Conc. of synergist: /

Professional use:

Non professional use:



GLOB267H / TORSO  
Part A - National Assessment  
FRANCE DEPR version

| 1                          | 2                  | 3  | 4  | 5   | 6                              | 7  | 8   | 9  | 10   | 11  | 12                                | 13            | 14   |
|----------------------------|--------------------|--|--|---|--------------------------------|--|---|--|--|---|-----------------------------------|---------------|--|
| Use-<br>No. <sup>(e)</sup> | Member<br>state(s) | Crop and/<br>or situation<br><br>(crop destination /<br>purpose of crop) | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<br>or<br>I | Pests or Group of pests<br>controlled<br><br>(additionally: develop-<br>mental stages of the pest<br>or pest group) | Application                    |  |   |  | Application rate   |   |                                   | PHI<br>(days) | Remarks:<br><br>e.g. g safener/synergist<br>per ha<br><sup>(f)</sup> |
|                            |                    |  |  |   | Method /<br>Kind               | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between ap-<br>plications<br>(days) | kg or L product /<br>ha<br>a) max. rate per<br>appl.<br>b) max. total<br>rate per<br>crop/season | g or kg as/ha<br><br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season   | Water<br>L/ha<br><br>min /<br>max |               |  |
| 1                          | FR                 | Winter oilseed rape<br>(BRSNW)   | F  | GERDI, PAPRH, POAAN   | Normal<br>downward<br>spraying | early post-emer-<br>gence (BBCH 10<br>-14)   | a) 1 every 4<br>years<br>b) 1                       | /  | a) 3.5 L/ha<br>b) 3.5 L/ha   | a) 0.749 kg me-<br>tazachlor/ha +<br>0.249 kg quin-<br>merac/ha +<br>0.721 kg napro-<br>pamide/ha<br>b) 0.749 kg me-<br>tazachlor/ha +<br>0.249 kg quin-<br>merac/ha +<br>0.721 kg napro-<br>pamide /ha | 150-<br>400<br>L/ha               | N/A           | <b>Not acceptable</b><br>(groundwater, aquatic<br>organisms)         |
| 2                          | FR                 | Winter oilseed rape<br>(BRSNW)   | F  | GERDI, PAPRH  | Normal<br>downward<br>spraying | early post-emer-<br>gence (BBCH 10<br>-14)   | a) 1 every 3<br>years<br>b) 1                       | /  | a) 2.3 L/ha<br>b) 2.3 L/ha   | a) 0.492 kg meta-<br>zachlor/ha +<br>0.164 kg quin-<br>merac/ha + 0.474<br>kg napropa-<br>mide/ha<br>b) 0.492 kg me-<br>tazachlor/ha +<br>0.164 kg quin-<br>merac/ha + 0.474<br>kg napropa-<br>mide/ha  | 150-<br>400<br>L/ha               | N/A           | <b>Not acceptable</b><br>(groundwater, aquatic<br>organisms)         |
| 3                          | FR                 | Winter oilseed rape<br>(BRSNW)   | F  | GERDI, PAPRH  | Normal<br>downward<br>spraying | early post-emer-<br>gence (BBCH 10<br>-14)   | a) 1 every 3<br>years<br>b) 1                       | /  | a) 2.2 L/ha<br>b) 2.2 L/ha   | a) 0.471 kg meta-<br>zachlor/ha +<br>0.156 kg quin-<br>merac/ha + 0.453<br>kg napropa-<br>mide/ha<br>b) 0.471 kg me-<br>tazachlor/ha +<br>0.156 kg quin-<br>merac/ha + 0.453                            | 150-<br>400<br>L/ha               | N/A           | <b>Acceptable</b>  |

GLOB267H / TORSO  
Part A - National Assessment  
FRANCE DEPR version

| 1                          | 2                  | 3  | 4   | 5   | 6                | 7  | 8   | 9  | 10   | 11  | 12                                | 13            | 14   |
|----------------------------|--------------------|--|---|---|------------------|--|---|--|--|---|-----------------------------------|---------------|--|
| Use-<br>No. <sup>(e)</sup> | Member<br>state(s) | Crop and/<br>or situation<br><br>(crop destination /<br>purpose of crop) | F,<br>Fn,<br>Fpn<br>G,<br>Gn,<br>Gpn<br>or<br>I | Pests or Group of pests<br>controlled<br><br>(additionally: develop-<br>mental stages of the pest<br>or pest group) | Application      |  |   |  | Application rate   |   |                                   | PHI<br>(days) | Remarks:<br><br>e.g. g safener/synergist<br>per ha<br><sup>(f)</sup> |
|                            |                    |  |   |   | Method /<br>Kind | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between ap-<br>plications<br>(days) | kg or L product /<br>ha<br>a) max. rate per<br>appl.<br>b) max. total<br>rate per<br>crop/season | g or kg as/ha<br><br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | Water<br>L/ha<br><br>min /<br>max |               |  |
|                            |                    |  |   |   |                  |  |   |  |  | kg napropa-<br>mide/ha  |                                   |               |  |

**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  
 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/m<sup>3</sup> 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 physico-chemical properties of the formulation have been evaluated taken into account the concentration of uses (concentration from 0.88 % to 2.3 % v/v) and considered acceptable during the registration of this formulation.

The concentrations of uses claimed for this extension of uses (concentration from 0.58 % to 2.3 % v/v) are not covered by this previously assessment. No new data were provided for suspensibility in order to cover lowest use rate (0.58% v/v). However results were provided in previous studies submitted for the first registration and for two different concentrations (3.1%v/v and 0.88% v/v). Suspensibility was acceptable for each active substance at both concentration. Results at 0.58% v/v are not expected to be significantly different. The physico-chemical properties provided in the dossier for the first authorisation are considered acceptable and covered this use extension.

#### **3.2 Efficacy (Part B, Section 3)**

The effectiveness of TORSO applied in early post-emergence at 3.5 L/ha is considered satisfactory for the control of annual broadleaf weeds and grasses on winter oilseed rape.

The effectiveness of TORSO applied in early post-emergence at 2.3 L/ha is considered acceptable for the control of annual broadleaf weeds and grasses on winter oilseed rape.

No data was submitted in order to sustain the use of the rate 2.2 L/ha in early post emergence, however, the efficacy of the product at this rate can be extrapolated from the rate of 2.3 L/ha

The level of selectivity of TORSO is considered acceptable for the use claimed.

The risk of negative impact on yield, quality and multiplication is considered acceptable.

The risk of negative impact on subsequent crops is considered acceptable. Nevertheless, particular attention should be paid to the conditions under which replacement crops are planted.

The risk of negative impact on adjacent crops is considered acceptable.

There is a risk of resistance to quinmerac on poppies, requiring monitoring for the claimed use.

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

##### **3.3.1 Analytical method for the formulation**

Analytical methods for the determination of the active substances and the relevant impurities in the formulation were assessed during the first authorisation and found acceptable.

### 3.3.2 Analytical methods for residues

The analytical methods for the determination of the active substance residues in matrices (high oil content crops and food of animal origin) submitted at European level and in the dossier of the preparation meet the regulatory requirements.

Methods used for pre-registration are validated, except method used in report IF-11/0218218 (Lebrun, F, 2012) due to a lack of validation data.

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

### Endpoints used in risk assessment

| Active substance(s)<br>(incl. content) | <b>Metazachlor</b><br>214 g/L   | <b>Quinmerac</b><br>71 g/L   | <b>Napropamide</b><br>206 g/L   |
|--|---|--|---|
| AOEL systemic                          | 0.2 mg/kg bw/d  | 0.08 mg/kg bw/d  | 0.5 mg/kg bw/d  |
| Inhalation absorption                  | 100 %   | 100 %  | 100 %   |
| Oral absorption                        | 100 %   | 100 %  | 100 %   |
| Dermal absorption                      | Concentrate: 0.35 %<br>Dilution: 10,4%<br>(Dilution rate: 1: 114)<br>Dilution: 15,8%<br>(Dilution rate 1:182)<br>(Based on product<br>(GLOB267H)) | Concentrate: 1 %<br>Dilution: 1,1% (Dilution<br>rate: 1:114)<br>Dilution: 1,1%<br>(Dilution rate: 1:182)<br>(Based on product<br>(GLOB267H)) | Concentrate: 0.4 %<br>Dilution: 4.4%<br>(Dilution rate: 1: 114)<br>Dilution: 6.7%<br>(Dilution rate: 1:182)<br>(Based on product<br>(GLOB267H)) |

### 3.4.1 Acute toxicity

TORSO (GLOB267H) containing 214 g/L metazachlor, 71 g/L quinmerac, 206 g/L napropamide has a low oral, dermal and inhalation toxicity, is not irritating to the skin, causes serious eye irritation and is a skin sensitizer.

### 3.4.2 Operator exposure

|  |    |   |                     |  |                           |  |                           |  |                           |
|--|----|---|---------------------|--|---------------------------|--|---------------------------|--|---------------------------|
| Comments<br>zRMS   | of | zRMS has reassessed the operator exposure for metazachlor, quinmerac and napropamid according to EFSA model (2014): |                     |  |                           |  |                           |  |                           |
|  |    |   |                     | <b>metazachlor</b>                     |                           | <b>quinmerac</b>                       |                           | <b>napropamide</b>                     |                           |
|  |    | <b>Model data</b>   | <b>Level of PPE</b> | <b>Total absorbed dose (mg/kg/day)</b> | <b>% of systemic AOEL</b> | <b>Total absorbed dose (mg/kg/day)</b> | <b>% of systemic AOEL</b> | <b>Total absorbed dose (mg/kg/day)</b> | <b>% of systemic AOEL</b> |
| Critical use: oilseed rape<br>Tractor mounted, downward application, outdoor |    |   |                     |  |                           |  |                           |  |                           |

GLOB267H / TORSO  
Part A - National Assessment  
FRANCE DEPR version

| Application rate (kg a.s./ha):  |   | 0.749 |        | 0.249 |        | 0.721 |       |
|---|---|-------|--------|-------|--------|-------|-------|
| EFSA Model<br>Body weight:<br>60 kg   | Potential exposure                              | 0,03  | 15.43% | 0,01  | 13,63% | 0,02  | 3.63% |
|   | Work wear (arms, body and legs covered) (M/L+A) | 0,02  | 10.14% | 0,007 | 8,63%  | 0,01  | 2.38% |
| M/L = mixing/loading; A = application; PPE = personal protective equipment  |   |       |        |       |        |       |       |
| <b>Conclusion:</b> According to the exposure assessment using EFSA model, operator exposure to TORSO (GLOB267H) is below the AOEL of active substances without PPE. |   |       |        |       |        |       |       |

### 3.4.3 Worker exposure

|                  |   |   |                           |  |                           |  |                           |        |
|------------------|---|---|---------------------------|--|---------------------------|--|---------------------------|--------|
| Comments of zRMS | zRMS has assessed the worker exposure using the following dermal absorption rate for metazachlor, quinmerac and napropamid for the crop type oilseed: |   |                           |  |                           |  |                           |        |
|                  | <b>Table 3.4-1: Estimated worker exposure</b>   |   |                           |  |                           |  |                           |        |
|                  |   | Metazachlor   |                           | quinmerac                              |                           | napropamid                             |                           |        |
|                  | <b>Model data</b>   | <b>Efsa model</b>                                       |                           |  |                           |  |                           |        |
|                  | <b>Level of PPE</b>   | <b>Total absorbed dose (mg/kg/day)</b>                  | <b>% of systemic AOEL</b> | <b>Total absorbed dose (mg/kg/day)</b> | <b>% of systemic AOEL</b> | <b>Total absorbed dose (mg/kg/day)</b> | <b>% of systemic AOEL</b> |        |
|                  | Critical use: oilseed rape<br>Inspection, irrigation<br>Work rate: 2 hours/day<br>DT50: 30 days<br>DFR: 3 µg a.s./ cm2/kg a.s./ha                     |   |                           |  |                           |  |                           |        |
|                  | Number of applications and application rate:  | 1 x 0.749 kg a.s./ha                                    |                           | 1 x 0.249 kg a.s./ha                   |                           | 1 x 0.721 kg a.s./ha                   |                           |        |
|                  | <b>Spray application</b> (AOEM; 95th percentile) Body weight: 60 kg   | Potential exposure TC: 12500 cm2 /hr                    | 0,15                      | 73,96%                                 | 0,003                     | 4,28%                                  | 0,06                      | 12.08% |
|                  | <b>Spray application</b> (AOEM; 95th percentile) Body weight: 60 kg   | Workwear (arms, body and legs covered) TC: 1400 cm2 /hr | 0,02                      | 8.28%                                  | 0,0004                    | 0,48%                                  | 0,007                     | 1.35%  |

GLOB267H / TORSO  
Part A - National Assessment  
FRANCE DEPR version

|  |  |
|--|--|
|  | <p><b>Conclusion:</b><br/>According to the exposure assessment using the EFSA model, the worker exposure to TORSO (GLOB267H) is below the AOEL of active substances without PPE.</p> |
|--|--|

### 3.4.4 Bystander exposure

|                   |  |
|-------------------|--|
| Comments of zRMS: | <p><b><u>Bystander exposure:</u></b></p> <p>In the absence of the AAOEL determined for metazachlor, quinmerac and napropamid, it is considered that the risk assessment for the bystander is covered by the resident risk assessment. Indeed, only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and by-standers in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): <i>“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.”</i></p> |
|-------------------|--|

### 3.4.5 Resident exposure

| Comments of zRMS:   | <p><b><u>Resident exposure :</u></b></p> <p>zRMS has reassessed the resident exposure according to EFSA model (2014) for active substances:</p>  |                                    |                    |                                    |                    |                                    |                    |            |  |            |  |                                    |                    |                                    |                    |                                    |                    |   |  |  |  |  |  |  |  |                         |  |                      |  |                      |  |                      |  |   |                                      |      |        |        |       |       |       |                                 |       |       |       |       |       |       |   |       |       |        |      |       |       |                                   |      |       |        |       |       |       |                   |             |               |              |              |             |              |
|---|--|------------------------------------|--------------------|------------------------------------|--------------------|------------------------------------|--------------------|------------|--|------------|--|------------------------------------|--------------------|------------------------------------|--------------------|------------------------------------|--------------------|---|--|--|--|--|--|--|--|-------------------------|--|----------------------|--|----------------------|--|----------------------|--|---|--------------------------------------|------|--------|--------|-------|-------|-------|---------------------------------|-------|-------|-------|-------|-------|-------|---|-------|-------|--------|------|-------|-------|-----------------------------------|------|-------|--------|-------|-------|-------|-------------------|-------------|---------------|--------------|--------------|-------------|--------------|
|   | <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2"></th> <th colspan="2">metazachlor</th> <th colspan="2">quinmerac</th> <th colspan="2">napropamid</th> </tr> <tr> <th colspan="2">Model data</th> <th>Total absorbed dose (mg/kg bw/day)</th> <th>% of systemic AOEL</th> <th>Total absorbed dose (mg/kg bw/day)</th> <th>% of systemic AOEL</th> <th>Total absorbed dose (mg/kg bw/day)</th> <th>% of systemic AOEL</th> </tr> </thead> <tbody> <tr> <td colspan="8">           Vehicle mounted<br/>           Bufferzone : 2-3m<br/>           Drift reduction technology: no<br/>           Number of application: 1<br/>           DT50: 30 days<br/>           DFR = 3 µg s.a/cm<sup>2</sup>/kg a.s./ha         </td> </tr> <tr> <td colspan="2"><b>Application rate</b></td> <td colspan="2">1 x 0.749 kg a.s./ha</td> <td colspan="2">1 x 0.249 kg a.s./ha</td> <td colspan="2">1 x 0.721 kg a.s./ha</td> </tr> <tr> <td rowspan="5" style="vertical-align: top;">Resident child<br/>Body weight:<br/>10 kg</td> <td>Spray drift (75<sup>th</sup> perc.)</td> <td>0,02</td> <td>10,63%</td> <td>0,0005</td> <td>0,66%</td> <td>0,009</td> <td>1,75%</td> </tr> <tr> <td>Vapour (75<sup>th</sup> perc.)</td> <td>0,001</td> <td>0,54%</td> <td>0,001</td> <td>1,34%</td> <td>0,001</td> <td>0,21%</td> </tr> <tr> <td>Surface deposits (75<sup>th</sup> perc.)</td> <td>0,002</td> <td>1,17%</td> <td>0,0002</td> <td>0,3%</td> <td>0,001</td> <td>0,26%</td> </tr> <tr> <td>Re-entry (75<sup>th</sup> perc.)</td> <td>0,02</td> <td>9,99%</td> <td>0,0004</td> <td>0,58%</td> <td>0,008</td> <td>1,63%</td> </tr> <tr> <td><b>Sum (mean)</b></td> <td><b>0,03</b></td> <td><b>15,21%</b></td> <td><b>0,002</b></td> <td><b>2,39%</b></td> <td><b>0,01</b></td> <td><b>2,67%</b></td> </tr> </tbody> </table> |                                    |                    | metazachlor                        |                    | quinmerac                          |                    | napropamid |  | Model data |  | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL | Vehicle mounted<br>Bufferzone : 2-3m<br>Drift reduction technology: no<br>Number of application: 1<br>DT50: 30 days<br>DFR = 3 µg s.a/cm <sup>2</sup> /kg a.s./ha |  |  |  |  |  |  |  | <b>Application rate</b> |  | 1 x 0.749 kg a.s./ha |  | 1 x 0.249 kg a.s./ha |  | 1 x 0.721 kg a.s./ha |  | Resident child<br>Body weight:<br>10 kg | Spray drift (75 <sup>th</sup> perc.) | 0,02 | 10,63% | 0,0005 | 0,66% | 0,009 | 1,75% | Vapour (75 <sup>th</sup> perc.) | 0,001 | 0,54% | 0,001 | 1,34% | 0,001 | 0,21% | Surface deposits (75 <sup>th</sup> perc.) | 0,002 | 1,17% | 0,0002 | 0,3% | 0,001 | 0,26% | Re-entry (75 <sup>th</sup> perc.) | 0,02 | 9,99% | 0,0004 | 0,58% | 0,008 | 1,63% | <b>Sum (mean)</b> | <b>0,03</b> | <b>15,21%</b> | <b>0,002</b> | <b>2,39%</b> | <b>0,01</b> | <b>2,67%</b> |
|   |  | metazachlor                        |                    | quinmerac                          |                    | napropamid                         |                    |            |  |            |  |                                    |                    |                                    |                    |                                    |                    |   |  |  |  |  |  |  |  |                         |  |                      |  |                      |  |                      |  |   |                                      |      |        |        |       |       |       |                                 |       |       |       |       |       |       |   |       |       |        |      |       |       |                                   |      |       |        |       |       |       |                   |             |               |              |              |             |              |
| Model data  |  | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |            |  |            |  |                                    |                    |                                    |                    |                                    |                    |   |  |  |  |  |  |  |  |                         |  |                      |  |                      |  |                      |  |   |                                      |      |        |        |       |       |       |                                 |       |       |       |       |       |       |   |       |       |        |      |       |       |                                   |      |       |        |       |       |       |                   |             |               |              |              |             |              |
| Vehicle mounted<br>Bufferzone : 2-3m<br>Drift reduction technology: no<br>Number of application: 1<br>DT50: 30 days<br>DFR = 3 µg s.a/cm <sup>2</sup> /kg a.s./ha |  |                                    |                    |                                    |                    |                                    |                    |            |  |            |  |                                    |                    |                                    |                    |                                    |                    |   |  |  |  |  |  |  |  |                         |  |                      |  |                      |  |                      |  |   |                                      |      |        |        |       |       |       |                                 |       |       |       |       |       |       |   |       |       |        |      |       |       |                                   |      |       |        |       |       |       |                   |             |               |              |              |             |              |
| <b>Application rate</b>   |  | 1 x 0.749 kg a.s./ha               |                    | 1 x 0.249 kg a.s./ha               |                    | 1 x 0.721 kg a.s./ha               |                    |            |  |            |  |                                    |                    |                                    |                    |                                    |                    |   |  |  |  |  |  |  |  |                         |  |                      |  |                      |  |                      |  |   |                                      |      |        |        |       |       |       |                                 |       |       |       |       |       |       |   |       |       |        |      |       |       |                                   |      |       |        |       |       |       |                   |             |               |              |              |             |              |
| Resident child<br>Body weight:<br>10 kg   | Spray drift (75 <sup>th</sup> perc.)   | 0,02                               | 10,63%             | 0,0005                             | 0,66%              | 0,009                              | 1,75%              |            |  |            |  |                                    |                    |                                    |                    |                                    |                    |   |  |  |  |  |  |  |  |                         |  |                      |  |                      |  |                      |  |   |                                      |      |        |        |       |       |       |                                 |       |       |       |       |       |       |   |       |       |        |      |       |       |                                   |      |       |        |       |       |       |                   |             |               |              |              |             |              |
|   | Vapour (75 <sup>th</sup> perc.)  | 0,001                              | 0,54%              | 0,001                              | 1,34%              | 0,001                              | 0,21%              |            |  |            |  |                                    |                    |                                    |                    |                                    |                    |   |  |  |  |  |  |  |  |                         |  |                      |  |                      |  |                      |  |   |                                      |      |        |        |       |       |       |                                 |       |       |       |       |       |       |   |       |       |        |      |       |       |                                   |      |       |        |       |       |       |                   |             |               |              |              |             |              |
|   | Surface deposits (75 <sup>th</sup> perc.)  | 0,002                              | 1,17%              | 0,0002                             | 0,3%               | 0,001                              | 0,26%              |            |  |            |  |                                    |                    |                                    |                    |                                    |                    |   |  |  |  |  |  |  |  |                         |  |                      |  |                      |  |                      |  |   |                                      |      |        |        |       |       |       |                                 |       |       |       |       |       |       |   |       |       |        |      |       |       |                                   |      |       |        |       |       |       |                   |             |               |              |              |             |              |
|   | Re-entry (75 <sup>th</sup> perc.)  | 0,02                               | 9,99%              | 0,0004                             | 0,58%              | 0,008                              | 1,63%              |            |  |            |  |                                    |                    |                                    |                    |                                    |                    |   |  |  |  |  |  |  |  |                         |  |                      |  |                      |  |                      |  |   |                                      |      |        |        |       |       |       |                                 |       |       |       |       |       |       |   |       |       |        |      |       |       |                                   |      |       |        |       |       |       |                   |             |               |              |              |             |              |
|   | <b>Sum (mean)</b>  | <b>0,03</b>                        | <b>15,21%</b>      | <b>0,002</b>                       | <b>2,39%</b>       | <b>0,01</b>                        | <b>2,67%</b>       |            |  |            |  |                                    |                    |                                    |                    |                                    |                    |   |  |  |  |  |  |  |  |                         |  |                      |  |                      |  |                      |  |   |                                      |      |        |        |       |       |       |                                 |       |       |       |       |       |       |   |       |       |        |      |       |       |                                   |      |       |        |       |       |       |                   |             |               |              |              |             |              |

GLOB267H / TORSO  
Part A - National Assessment  
FRANCE DEPR version

|   |   |             |              |               |              |              |              |
|---|---|-------------|--------------|---------------|--------------|--------------|--------------|
| Resident adult<br>Body weight:<br>60 kg | Spray drift (75 <sup>th</sup> perc.)      | 0,005       | 2.54%        | 0,0001        | 0,15%        | 0,002        | 0,42%        |
|   | Vapour (75 <sup>th</sup> perc.)           | 0,0002      | 0.12%        | 0,0002        | 0,29%        | 0,0002       | 0,05%        |
|   | Surface deposits (75 <sup>th</sup> perc.) | 0,0008      | 0.40%        | 0,00002       | 0,02%        | 0,0003       | 0,07%        |
|   | Re-entry (75 <sup>th</sup> perc.)         | 0,01        | 5.55%        | 0,0003        | 0,32%        | 0,005        | 0,91%        |
|   | <b>Sum (mean)</b>                         | <b>0,01</b> | <b>6.04%</b> | <b>0,0005</b> | <b>0,63%</b> | <b>0,005</b> | <b>1,01%</b> |

**Conclusion:**

According to the EFSA model calculation results, resident child and adult exposure levels for application of TORSO (GLOB267H) is below the AOEL values of active substances.

### 3.4.6 Combined exposure

|  |  |                                       |                                     |
|--|--|---------------------------------------|-------------------------------------|
| Comment of zRMS  | Currently no EU-harmonised guidance is available on the risk assessment of combined exposure to multiple active substances. Most assessment approaches employed up to now make use of the Hazard Index (HI) concept. It is therefore suggested to use this as a first tier assessment. |                                       |                                     |
|  | A cumulative assessment has been performed. 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 HI (sum of hazard quotients) are:  |                                       |                                     |
|  | <b>Application scenario</b>  | <b>Active Ingredient</b>              | <b>Estimated exposure/AOEL (HQ)</b> |
|  | <b>Cumulative risk exposure for operator</b>   |                                       |                                     |
|  | Operators – vehicule mounted<br>Potential exposure   | metazachlor                           | 0,1543                              |
|  |  | quinmerac                             | 0,1363                              |
|  |  | napropamide                           | 0,0363                              |
|  |  | <b>Cumulative risk Operators (HI)</b> | <b>0,3269</b>                       |
|  | <b>Cumulative risk exposure for worker</b>   |                                       |                                     |
| Workers – inspection, irrigation<br>Potential exposure | metazachlor  | 0,7396                                |                                     |
|  | quinmerac  | 0,0428                                |                                     |
|  | napropamide  | 0,1208                                |                                     |
|  | <b>Cumulative risk Workers (HI)</b>  | <b>0,9032</b>                         |                                     |
| <b>Cumulative risk exposure for Resident</b>           |  |                                       |                                     |
| Resident – <b>Child</b><br>Vehicle mounted             | metazachlor  | 0,1521                                |                                     |
|  | quinmerac  | 0,0239                                |                                     |

GLOB267H / TORSO  
Part A - National Assessment  
FRANCE DEPR version

|  |  |  |               |
|--|--|--|---------------|
|  | Buffer strip: 2-3 m<br>Without drift reduction<br>technology   | napropamide                                  | 0,0267        |
|  |  | <b>Cumulative risk Resident – Child (HI)</b> | <b>0,2027</b> |
|  | Resident – <b>Adult</b><br>Vehicle mounted<br>Buffer strip: 2-3 m<br>Without drift reduction<br>technology | metazachlor                                  | 0,0604        |
|  |  | quinmerac                                    | 0,0063        |
|  |  | napropamide                                  | 0,0101        |
|  | <b>Cumulative risk Resident – Adult (HI)</b>   | <b>0,0768</b>                                |               |
| <u>Conclusion:</u>   |  |  |               |
| The Hazard Index is < 1. Thus, the combined exposure to all active substances in TORSO is not expected to present a risk for operators, workers, bystanders and residents, considering a buffer zone of 2-3 meters. No further refinement of the assessment is required. |  |  |               |

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

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.15 mg/kg for quinmerac, 0.06 mg/kg for metazachlor and 0.02 mg/kg napropamide as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of quinmerac, metazachlor and napropamide residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France, zRMS agrees with the authorization of the intended use.

#### Summary for GLOB267H

Table : information on GLOB267H

| Crop                | PHI for GLOB267H proposed by applicant | PHI/ Withholding period* sufficiently supported for |                |                | PHI for GLOB267H proposed by zRMS | zRMS Comments (if different PHI proposed) |
|---------------------|--|---|----------------|----------------|-----------------------------------|---|
|                     |  | Metazachlor   | Quinmerac      | Napropamide    |                                   |   |
| Winter oilseed rape | NR                                     | F – BBCH10-14                                       | F – BBCH 10-14 | F – BBCH 10-14 | F – BBCH 10-14                    |   |

-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).

Table: Waiting periods before planting succeeding crops

|   |  |
|---|--|
| Waiting period before planting succeeding crops | Overall waiting period proposed by zRMS for GLOB268H |
|---|--|



GLOB267H / TORSO  
Part A - National Assessment  
FRANCE DEPR version

| Crop group     | Led by metazachlor | Led by quinmerac | Led by napropamide |          |
|----------------|--------------------|------------------|--------------------|----------|
| Oilseed        | -                  | -                | 60 days            | 60 days  |
| Leafy          | 365 days           |                  | 60 days            | 365 days |
| Root and tuber | 120 days           | -                | 180 days           | 180 days |
| Cereals        | 60 days            | -                | 60 days            | 60 days  |

### 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.

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.

The PEC<sub>soil</sub> values derived for the three active substances and their metabolites are used for the ecotoxicological risk assessment.

For the intended uses on winter oilseed rape at the application rates of 3.5 L/ha and 2.3 L/ha, the PEC<sub>sw</sub> values derived for napropamide and quinmerac are used for the ecotoxicological risk assessment.

For metazachlor, the ecotoxicological risk assessment based on the PEC<sub>sw</sub> values provided failed to pass even if the maximal mitigation measures are proposed. Refined PEC<sub>sw</sub> are proposed by the notifier refining the application windows considered for PEC<sub>sw</sub> calculations. However, the new application windows are not selected in accordance with FOCUS guidance (FOCUS, 2015)<sup>5</sup> and do not correspond to the intended application periods reported for the uses of the product TORSO. The refined PEC<sub>sw</sub> values cannot be used for the ecotoxicological risk assessment. Consequently, the risk assessment for non-target aquatic organisms cannot be finalized for these uses.

For the intended use on winter oilseed rape at the application rate of 2.2 L/ha, the PEC<sub>sw</sub> values derived for metazachlor are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PEC<sub>gw</sub> for napropamide and its metabolite do not occur at levels exceeding those mentioned in regulation EU No 546/2011 and guidance document SANCO 221/2000<sup>6</sup>. PEC<sub>gw</sub> for quinmerac and its metabolites do not occur at levels exceeding those mentioned in regulation EU No 546/2011 and guidance document SANCO 221/2000 for application every third year.

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

<sup>5</sup> FOCUS (2015) Generic guidance for FOCUS surface water Scenarios, Version: 1.4, Date: May 2015

<sup>6</sup> Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. SANCO/221/2000-rev.11, 21 October 2021

intended uses of the product TORSO.

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 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, mammals, non-target arthropods, earthworms, other soil macro- and micro-organisms and terrestrial plants are acceptable for the intended uses in the conditions of uses described under 2.5.

For aquatic organisms, the risk can be considered acceptable only for an application of 2.2 L/ha on oilseed rapes. For application at 3.5 L/ha and 2.3 L/ha, the risk to aquatic organisms could not be finalised the exposure levels estimated for metazachlor are higher than the toxicity value retained at European level, including consideration of the maximum management measure proposed by the applicant (20 m no spray zone including 20 m unsprayed vegetated buffer strip). The applicant provided refined exposure levels for aquatic organisms by modifying the application windows considered in the calculations. However, these new application windows were not selected according to the recommendations of the guide document in force (FOCUS, 2015)<sup>7</sup> and do not correspond to the application period claimed for the uses of the TORSO

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<sup>7</sup> FOCUS (2015) Generic guidance for FOCUS surface water Scenarios, Version: 1.4, Date: May 2015

preparation. These refined exposure levels could not be used. Consequently based on the guidance documents, the risks aquatic organisms at 2.3 L/ha and 3.5 L/ha cannot be finalized.

For bees, the risk assessment provided by the applicant is based on the EFSA Guidance Document . The risk can be considered acceptable for application at 2.2 or 2.3 L/ha on oilseed rapes. For application at 3.5 L/ha, the risk can not be considered acceptable for chronic adult bees and acute bumblebees. The refinement proposed by the applicant to refine exposure estimate is based on general information on residue levels in plants (leaves) that can not be considered reliable and on proportion of weeds in arable fields. As no dedicated measured data in pollen/nectar of the treated crop and proportion of weeds in the field, as recommended by the EFSA guidance, was available the risk assessment cannot be finalized for an application of 3.5 L product/ha on oilseed rape.

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

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

## **4 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”.

### **4.1.1 Post-authorisation monitoring**

Any appearance or development of resistance should be monitored on the basis of efficacy failure analyses for quinmerac, particularly for poppies (*Papaver rhoeas*). When applying for renewal of the product's authorization, a summary of the results of the monitoring carried out for all products based on this substance should be provided.

Continue to monitor relevant and irrelevant metabolites of metazachlor in groundwater, particularly that intended for human consumption.

If the quality limit for water intended for human consumption is exceeded, inform the competent authorities and rapidly implement additional measures to protect the catchment areas.

### **4.1.2 Post-authorisation data requirements**

None.

GLOB267H / TORSO  
Part A - National Assessment  
FRANCE DEPR version

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## **Appendix 1 Copy of the product authorisation DAMM**



TORSO\_PMAJ\_2022-  
3625\_D.pdf

## 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.

**TORSO®**

**HERBICIDE COLZA**

Contient 214 g/L (18,94% p/p) de **métazachlore**, 206 g/L (18,23% p/p) de **napropamide** et 71 g/L (6,28% p/p) de **quinmerac** sous forme de Suspension concentrée (SC)

Autorisation de Mise sur le Marche n° 2220272

Date de fabrication / Numéro de lot : voir emballage

|        |           |           |
|--------|-----------|-----------|
| GROUPE | <b>15</b> | HERBICIDE |
|        | <b>0</b>  |           |
|        | <b>4</b>  |           |

**RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL**

Contenu : 1 ; 2 ; 3 ; 5 ; 10 ; 20 L e

Distribué par : BELCHIM  
 A compléter

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



|   |  |
|---|--|
| <p><b>TORSO®</b><br/> <b>AMM n° 2220272</b> – Contient 214 g/L (18,94% p/p) de métazachlore, 206 g/L (18,23% p/p) de napropamide et 71 g/L (6,28% p/p) de quinmerac sous forme de Suspension concentrée (SC)<br/>           UFI : 1410-Q0H8-W004-E0DW</p>   |  |
| <br><br><br><br>  | <p><b>H317 : Peut provoquer une allergie cutanée.</b><br/> <b>H319 : Provoque une sévère irritation des yeux.</b><br/> <b>H351 : Susceptible de provoquer le cancer.</b><br/> <b>H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.</b></p> <p>P280 - Porter un équipement de protection des yeux, un équipement de protection du visage, des vêtements de protection, des gants de protection<br/>           P302+P352 - EN CAS DE CONTACT AVEC LA PEAU: laver abondamment à l'eau et au savon<br/>           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<br/>           P333+P313 - En cas d'irritation ou d'éruption cutanée: consulter un médecin<br/>           P337+P313 - Si l'irritation oculaire persiste: consulter un médecin<br/>           P391 - Recueillir le produit répandu.</p> |
| <p><b>ATTENTION</b></p>   |  |
| <p>SP1: 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.<br/>           SPe1: Pour protéger les eaux souterraines, ne pas appliquer ce produit ou tout autre produit contenant du métazachlore plus d'une fois tous les 3 ans à la dose de 500 g métazachlore/ha ou plus d'une fois tous les 4 ans à la dose de 750 g métazachlore/ha.<br/>           SPe1: Pour protéger les eaux souterraines, ne pas appliquer ce produit ou tout autre produit contenant du quinmérac plus d'une fois tous les 4 ans après l'application du TORSO en pré-émergence.<br/>           SPe1: Pour protéger les eaux souterraines, ne pas appliquer ce produit ou tout autre produit contenant du quinmérac plus d'une fois tous les 3 ans après l'application du TORSO en post-émergence.<br/>           SPe2 :Pour protéger les eaux souterraines ne pas appliquer ce produit sur une parcelle comportant une bétail référencée.<br/>           SPe2 : Pour protéger les organismes aquatiques, ne pas appliquer ce produit sur sols artificiellement drainés ayant une teneur en argile supérieure ou égale à 45%.<br/>           SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau.</p> |  |

**Délai de rentrée : 48 Heures**

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

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

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

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

Contient de la 1,2-benzisothiazol-3(2H)-one. Peut produire une réaction allergique.

Conserver à l'abri du gel.

**EN CAS D'URGENCE**

**Composer le 15 ou le 112 ou contacter le centre  
anti poison le plus proche**

puis 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 d'irritation ou éruption cutanée, consulter un spécialiste.

En cas de projection dans les yeux : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Consulter un spécialiste.

En cas d'inhalation : Emmener la victime à l'air frais. En cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre antipoison.

En cas d'ingestion : rincer immédiatement la bouche avec de l'eau. Ne pas faire vomir sans avis médical. Contacter sans délai les secours : le 15, le 112 ou un centre antipoison.

Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité.

En cas d'intoxication animale : contactez votre vétérinaire.

Fiche de données de sécurité disponible sur le site [www.quickfds.com](http://www.quickfds.com)

## DESRIPTIF DU PRODUIT

TORSO® est un herbicide de post-semis prélevée et de post-levée précoce du colza d'hiver. Il se compose de métazachlore, matière active de la famille des chloroacétamides (code HRAC K3), quinmérac, matière active de la famille des acides quinoléine-carboxyliques (code HRAC O) et de napropamide matière active de la famille des acétamides (code HRAC Z). Il présente une efficacité sur dicotylédones et sur graminées.

### Tableau des usages autorisés

| Cultures                  | Cibles  | Dose maximale d'emploi (L/ha) | Nbre maximum d'applications par an | Stade d'application      | Délai avant récolte (DAR) | Zone non traitée (ZNT) aquatique |
|---------------------------|---|-------------------------------|------------------------------------|--------------------------|---------------------------|----------------------------------|
| Cultures d'hiver de colza | Adventices (graminées et dicotylédones annuelles) | 3,5                           | 1                                  | Entre BBCH 01 et BBCH 09 | F (BBCH 14)               | 20 mètres (dont DVP 5 mètres)    |
|                           |   | 2,2-3,5                       | 1                                  | Entre BBCH 10 et BBCH 14 |                           |                                  |

**Globachem NV ne préconise 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>

Afin d'éviter la présence de résidus dans les cultures suivantes, ne pas implanter :

- de céréales, moins de 60 jours après traitement ;
- de cultures de racines ou tubercules moins de 180 jours après traitement ;
- de cultures de légumes feuilles ou tiges moins de 365 jours après traitement.



## Recommandations d'emploi

### Remarque préliminaire

Afin de limiter le transfert du métazachlore et de ses métabolites vers les eaux souterraines, les mesures suivantes devront impérativement être prises en compte :

- dans les sols argileux présentant des fentes de retrait importantes, un travail superficiel du sol est nécessaire afin d'éviter les écoulements rapides vers les eaux souterraines.
- l'utilisation est à éviter dans les parcelles qui présentent des zones d'infiltration rapide (autres que les bétouilles référencées).
- dans les zones karstiques, l'utilisation doit être accompagnée de mesures permettant de freiner les transferts vers les eaux souterraines (comme l'enherbement des dolines par exemple).

### Champ d'activité

TORSO® s'utilise en prélevée post-semis ou en post-levée précoce de la culture de colza d'hiver. Il est particulièrement efficace à la dose de 3,5 L/ha comme le démontre le spectre :

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.

### Conditions d'application

TORSO® s'utilise en un seul passage, dans les 3 jours après le semis ou en post-levée précoce de la culture.

Appliquer TORSO® 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 TORSO® 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.

### Précautions d'emploi

- 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.
- Ne pas respirer les vapeurs, ni le brouillard de pulvérisation.
- Ne pas pulvériser à proximité des points d'eau (mares, cours d'eau, fossés...).
- Attention aux dérives d'embruns de la pulvérisation sur les cultures voisines. Ne pas traiter en présence de vent, même faible (selon la réglementation en vigueur)
- Ne pas conserver la bouillie de pulvérisation dans la cuve plus de 48 heures.

### 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

### **Mélanges extemporanés**

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

### **Préparation de la bouillie**

Avant de débiter 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 au  $\frac{3}{4}$  d'eau la cuve du pulvérisateur. Agiter le bidon de TORSO® et verser dans la cuve la dose de produit nécessaire. Ajouter enfin le reste du volume d'eau requis. Maintenir la bouillie en état d'agitation jusqu'à la fin de la pulvérisation. Ne préparez jamais plus de bouillie qu'il n'en est nécessaire.

### **PREVENTION ET GESTION DE LA 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, l'utilisateur doit raisonner en premier lieu les pratiques agronomiques et respecter les conditions d'emploi du produit. 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 cette préparation liée à ces phénomènes de résistance. De ce fait, GLOBACHEM NV décline toute responsabilité quant à d'éventuelles conséquences qui pourraient être dues à de telles résistances.

Consultez votre préconisateur pour connaître les cas avérés de résistance au niveau de votre région.

### **MISE EN ŒUVRE REGLEMENTAIRE ET BONNES PRATIQUES**

#### **Stockage du produit**

Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur, à l'écart des aliments et boissons y compris ceux pour animaux. Conserver hors de la portée des enfants et des personnes non autorisées. Ne pas stocker le produit à des températures supérieures à 40°C.

#### **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  |   | PROTECTION DE L'UTILISATEUR PENDANT LES PHASES DE : |                         |                         |                   | PROTECTION DU TRAVAILLEUR |
|---|---|---|-------------------------|-------------------------|-------------------|---------------------------|
|   |   | MÉLANGE<br>CHANGEMENT                               | APPLICATION AVEC :      |                         | NETTOYAGE         |                           |
|   |   |   | TRACTEUR<br>AVEC CABINE | TRACTEUR<br>SANS CABINE |                   |                           |
| GANTS EN NITRILE NF EN ISO 374-1/A1 réutilisables (NF EN 16523-1/A1 (type A)) à usage unique (NF EN ISO 374-2 (types A,B ou C)) |    | Réutilisables                                       | À usage unique (*)      | À usage unique          | Réutilisables     |                           |
| EPI VESTIMENTAIRE conforme à la norme NF EN ISO 27065/A1  |    | EPI vestimentaire                                   |                         |                         | EPI vestimentaire |                           |
| EPI PARTIEL blouse ou tablier à manches longues catégorie II type P03 certifié EN14809+A1                                       |   | EPI partiel   |                         |                         | EPI partiel       |                           |
| COMBINAISON DE PROTECTION CHIMIQUE catégorie II type 3 ou 4 certifiée EN 14809+A1:2009  |  | Type 3 ou 4   |                         |                         | Type 3 ou 4       |                           |

\* Dans le cas d'une intervention sur le matériel pendant la pulvérisation, ces gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine

Rapporter les équipements de protection individuelle (EPI) usagés dans un sac translucide, à votre distributeur partenaire ECO 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.

### Nettoyage du pulvérisateur et gestion des fonds de cuve

À la fin de la période d'application du produit, l'intégralité de l'appareil (cuve, rampe, circuit, buses...) doit être nettoyée très soigneusement avec un produit adapté (type Phytnet) puis rincée à l'eau claire. Le rinçage du pulvérisateur, l'épandage ou la vidange du fond de cuve et l'élimination des effluents doivent être réalisés conformément à la réglementation en vigueur.

### 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 (rinçage manuel à 3 reprises en agitant le bidon rempli au 1/3 ou rinçage 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.I.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.I.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.I.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 préconisateur 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.