REGISTRATION REPORT

Part A

Risk Management

Product code: GLOB268H

Product name: TRICLO

Chemical active substances:

metazachlor, 333 g/L
quinmerac, 111 g/L
clomazone, 44 g/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 TRICLO (product code: GLOB268H), containing 333 g/L metazachlor, 111 g/L quinmerac and 44 g/L clomazone, as an 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 13/05/2016 to market TRICLO (GLOB268H) 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 MSs of the Southern zone.

The present application (2016-1808) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[1]. 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 TRICLO (GLOB268H) has been made using endpoints agreed in the EU peer reviews of metazachlor, quinmerac and clomazone. It also includes assessment of data and information related to TRICLO (GLOB268H) 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.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[2], 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 TRICLO (GLOB268H).

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

[2] 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

1.2 Letters of Access

The applicant has provided a letter of access for clomazone and clomazone 36CS. This letter of access is available upon request.

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 TRICLO (GLOB268H), 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	GLOB268H.
Product name in MS	TRICLO.
Authorisation number	N/A : no marketing authorisation granted
Low risk (article 47)	No.
Function	Herbicide.
Applicant	Globachem NV.
Active substance(s) (incl. content)	Metazachlor 333 g/L Quinmerac 111 g/L Clomazone 44 g/L
Formulation type	A mixed formulation (ZC) of capsule suspension (CS) and suspension concentrate (SC)
Packaging	0.1-0.15-0.25-0.5-1-2-3-5-10-20 L, HDPE, professional user.
Coformulants of concern for national authorisations	None.
Restrictions related to identity	None.
Mandatory tank mixtures	None.
Recommended tank mixtures	None.

2.2 Conclusion

The evaluation of the application for TRICLO (GLOB268H) resulted in the decision **to not 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

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

Hazard class(es), categories:	Skin sensitisation, Category 1. Respiratory sensitisation, category 1A. Carcinogenicity category 2. Hazardous to the aquatic environment - Acute Hazard, category 1. Hazardous to the aquatic environment - Chronic Hazard, category 1.
Hazard pictograms:	
Signal word:	Warning
Hazard statement(s):	H317 May cause an allergic skin reaction. H351 Suspected of causing cancer. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	***For the P phrases, refer to the existing legislation***
	Contains 1,2-benzisothiazolin-3-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)

N/A : no marketing authorisation granted.

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[3] provides that:

[3] 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

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

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

Finally, the French Order of 26 March 2014[4] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "related" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those "related" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[5] 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

N/A : no marketing authorisation granted.

https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

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

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

2.6 Intended uses (only NATIONAL GAP)

Please note: 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.

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

PPP (product name/code):	TRICLO/GLOB268H	Formulation type:	ZC
Active substance 1:	Metazachlor	Conc. of a.s. 1:	333 g/L
Active substance 2:	Quinmerac	Conc. of a.s. 2:	111 g/L
Active substance 3:	Clomazone	Conc. of a.s. 3:	44 g/L
Applicant:	Globachem NV	Professional use:	☒
Zone(s):	Southern	Non-professional use:	☐
Verified by MS:	yes		
Field of use:	herbicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
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 b) 1 every three years	N/A	a) 2.25 b) 2.25	a) 749 g metazachlor/ha + 250 g quinmerac/ha + 99 g clomazone/ha b) 749 g metazachlor/ha + 250 g quinmerac/ha + 99 g clomazone/ha	150-400	F – BBCH 08	**Not Acceptable** (Risk for ground water)

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/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)

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 a paint odour. It is not explosive, has no oxidising properties and 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 3.94 at 20 °C. There is no effect of low and high temperatures on the stability of the formulation, since after four freeze/thaw cycles and two weeks at 54 °C in HDPE packaging, neither the active substances' content nor the technical properties were changed. A shelf life study is ongoing and the final report is required. The technical characteristics are acceptable for a mixture of a suspension concentrate and capsule suspension formulation.

It should be mentioned on the label to rinse the packaging at least three times before disposal.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The efficacy level of TRICLO (GLOB268H) is considered acceptable for the requested use.
- The selectivity level of TRICLO (GLOB268H) is considered acceptable. Some temporary symptoms of phytotoxicity may appear.
- The risks of negative impact on yield, quality, propagation, succeeding and adjacent crops are considered acceptable. Nevertheless, particular attention should be paid to the conditions of sowing/planting succeeding or replacement crops.
- The risk of resistance developing or appearing to the co-formulation of metazachlor and quinmerac is considered low, and does not require monitoring for the requested use.
- There is risk of resistance developing or appearing to clomazone: this requires resistance monitoring for the requested 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 relevant impurity (toluene [methylbenzene]) in the formulation are available and validated.

3.3.2 Analytical methods for residues

Analytical methods are available in the monograph/this dossier and validated for the determination of residues of quinmerac in plants (high fat content), soil, water (surface and drinking) and air.
To update the dossier, an analytical method for the determination of quinmerac in food of animal origin is required a MRL is fixed at 0.05 mg/kg in animal matrices according to regulation 149/2008.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active substance: **metazachlor**			
ADI	0.08 mg/kg bw/d		EU
ARfD	0.5 mg/kg bw		
AOEL	0.2 mg/kg bw/d		
AAOEL	-		
Dermal absorption	Based on an *in vitro* human study performed on the formulation according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (tested) 333 g/L	Diluted formulation (tested) 18.7 g/L
	In vitro (human) %	8.6	5.1
		Concentrate (used in formulation) 333 g/L	Spray dilution (used in formulation) 1.87 g/L
	Dermal absorption endpoints %	**8.6**	**5.1**

Active substance: **quinmerac**			
ADI	0.08 mg/kg bw/d		EU
ARfD	0.3 mg/kg bw		
AOEL	0.08 mg/kg bw/d		
AAOEL	-		
Dermal absorption	Based on an *in vitro* human study performed on formulation according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (tested) 111 g/L	Diluted formulation (tested) 0.63 g/L
	In vitro (human) %	3.3	1.4
		Concentrate (used in formulation) 111 g/L	Spray dilution (used in formulation) 0.625 g/L
	Dermal absorption endpoints %	**3.3**	**1.4**
Vapour pressure	**< 1 x 10 $^{-10}$ Pa at 20°C**	**Low-volatility substance**	

<table>
<tr><td colspan="4">Active substance: clomazone</td></tr>
<tr><td>ADI</td><td colspan="2">0.133 mg/kg bw/d</td><td rowspan="4">EU</td></tr>
<tr><td>ARfD</td><td colspan="2">-</td></tr>
<tr><td>AOEL</td><td colspan="2">0.133 mg/kg bw/d</td></tr>
<tr><td>AAOEL</td><td colspan="2">-</td></tr>
<tr><td rowspan="3">Dermal absorption</td><td colspan="3">Based on default values according to guidance on dermal absorption (Efsa 2012):</td></tr>
<tr><td></td><td>Concentrate
(used in formulation)
44 g/L</td><td>Spray dilution
(used in formulation)
0.25 g/L</td></tr>
<tr><td>Dermal absorption endpoints %</td><td>75</td><td>75</td></tr>
<tr><td>Vapour pressure</td><td colspan="3">2.7 10^{-2} Pa (20 °C)
5.04 10^{-2} (25 °C)

Moderately volatile substance</td></tr>
</table>

3.4.1 Acute toxicity

TRICLO (GLOB268H), containing 333 g/L metazachlor, 111 g/L quinmerac and 44 g/L clomazone, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye, but is a skin and respiratory sensitiser.

3.4.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop type	F/G[6]	Equipment *Application method*	Maximum application rate g a.s./ha	Maximum volume water (L/ha)
Risk envelope Winter oilseed rape	F	Vehicle-mounted *Downward spraying*	749 g metazachlor/ha 250 g quinmerac/ha 99 g clomazone/ha	400

Considering the proposed use, operator systemic exposure was estimated using the EFSA model[7]:

Crop	Equipment	PPE and/or working coverall	% AOEL		
			Metazachlor	Quinmerac	Clomazone
Oilseed rape	Vehicle-mounted	Working coverall and gloves during mixing/loading and application	2.45	2.67	3.08

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

According to the model calculations, it may be concluded that the risk for the operator using TRICLO (GLOB268H) is acceptable with a working coverall and gloves during mixing/loading and application.

3.4.3 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[8].

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*."

3.4.4 Resident Exposure

Residential exposure was assessed according to the EFSA model. An acceptable risk was determined for residents (adult and/or child) when mitigation measures such as a buffer zone of three metres are taken to reduce the resident exposure[9]:

Model (AOEM) - All pathways (mean)	**% AOEL metazachlor**	**% AOEL quinmerac**	**% AOEL clomazone**
Resident (children)	7.36	3.49	25.7
Resident (adults)	3.08	1.2	8.2

3.4.5 Worker Exposure

Workers may have to enter treated areas after treatment for crop inspection/irrigation or searching, reaching and picking activities. Therefore, estimation of worker exposure was calculated according to the AOE model. Exposure is estimated to be 4.5 % of the AOEL of metazachlor, 1.44 % of the AOEL of quinmerac and 7.82 % of the AOEL of clomazone, with PPE. It may be concluded that there is no unacceptable risk anticipated for the worker.

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

3.4.6 Combined exposure

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.

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8 Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

9 Exposure estimation incorporates a distance of 3 metres from the spray boom (EFSA Journal 2014;12(10):3874).

A cumulative assessment for operators, bystanders/residents and workers was performed. At the first tier, combined exposure was 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:

Population groups and PPE		Active substance	Estimated exposure / AOEL (HQ)
Operators	Working coverall and gloves during mixing/loading and application	**Metazachlor**	0.0245
		Quinmerac	0.0103
		Clomazone	0.0559
	Cumulative risk operators (HI)		**0.09**
Bystanders/Residents	Children - All pathways (mean)	**Metazachlor**	0.0736
		Quinmerac	0.0349
		Clomazone	0.257
	Cumulative risk bystanders/residents (child) (HI)		**0.36**
	Adults - All pathways (mean)	**Metazachlor**	**0.0308**
		Quinmerac	**0.0102**
		Clomazone	**0.0818**
	Cumulative risk bystanders/residents (adult) (HI)		**0.123**
Worker	Working coverall and gloves	**Metazachlor**	0.0451
		Quinmerac	0.0144
		Clomazone	0.0782
	Cumulative risk workers (HI)		**0.1377**

The Hazard Index is < 1. Thus, combined exposure to all active substances in TRICLO (GLOB268H) is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

3.4.7 Relevance of metabolites

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 considers these metabolites relevant according to the SANCO/221/2000 guidance document.

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

Overall conclusion

The data available are considered sufficient for risk assessment. No exceedence of the current MRL of 0.06 mg/kg for metazachlor, 0.02 mg/kg for clomazone and 0.1* mg/kg for quinmerac in rapeseed as laid down in Reg. (EU) 396/2005 is expected.

The chronic and short-term intakes of metazachlor, quinmerac and clomazone residues are unlikely to present a public health concern. As far as consumer health protection is concerned, Anses (France) agrees with the authorisation of the intended use.

According to available data, the following specific mitigation measures should apply:

- **do not grow any crop, except cereals, less than one year after application of TRICLO (GLOB268H) on oilseed rape according to the intended GAP.**

Data gaps

Noticed European data gaps are:

- adequate storage stability data on quinmerac are necessary to demonstrate the validity of the results generated in the rotational crop residue trials with regard to rotational cereals.

Noticed data gaps are:

- adequate storage stability data on metabolites 479M04, 479M08 in rapeseed are necessary.

Summary for TRICLO (GLOB268H)

Information on TRICLO (GLOB268H) (KCA 6.8)

Crop	PHI for TRICLO (GLOB268H) requested by applicant	PHI/withholding period* sufficiently supported for			PHI for TRICLO (GLOB268H) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Metazachlor	Quinmerac	Clomazone		
Rapeseed	N/A (pre-emergence)	Yes	Yes	Yes	F – BBCH 00-10	-

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).

Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops				Overall waiting period proposed by zRMS for TRICLO (GLOB268H)
Crop group	Led by metazachlor	Led by quinmerac	Led by clomazone	
Short-cycle crops	-	-	90 days	One year for all crops except cereals
All crop groups except cereals	365 days	-	-	

NR: not relevant

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 clomazone, 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 clomazone and quinmerac metabolites (for one application of TRICLO (GLOB268H) every third year) are below the threshold values defined in the guidance document SANCO 221/2000.

The PECgw values calculated for quinmerac (for one application of TRICLO (GLOB268H) 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). Thus, the risk of groundwater contamination by quinmerac cannot be finalised by France as zRMS for the use on oilseed rape.

The PECgw values calculated for one 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 calculated for metazachlor metabolites BH 479-9, BH 479-11 and BH 479-12 exceed levels stated 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 France as zRMS.

Despite their very different nature, the data available in national monitoring programmes are consistent with the results from the targeted monitoring from the applicant. Both metabolites BH 479-4 and BH 479-8 are also observed in drinking water in France. Non-compliance 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[10], no concentration measured for BH 479-4 is above the threshold and four analyses for BH 479-8 were 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 in order to identify vulnerable situations

[10] Avis de l'Anses relatif à l'évaluation de la pertinence des métabolites de pesticides dans les eaux destinées à la consommation humaine. Saisine n°2015-SA-0252. 30 Janvier 2019.

that would require the application of specific risk-mitigation measures. Based on all the available information, the zRMS cannot finalise the risk assessment for groundwater contamination by metazachlor and its metabolites on oilseed rape.

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

Based on the guidance documents, the risks for birds, aquatic organisms, mammals and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable. Risk mitigations are required in order to protect aquatic organisms and non-target plants.

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

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

The active substances metazachlor, quinmerac and clomazone 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

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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 ***TRICLO***

de la société	*GLOBACHEM NV*
enregistrée sous le	*n°2016-1808*

Vu les conclusions de l'évaluation de l'Anses du 18 mai 2020,

Considérant qu'un risque inacceptable de contamination des eaux souterraines par la substance active quinmérac et ses métabolites, lié à l'utilisation du produit, ne peut être exclu,

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

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

TRICLO
AMM n°-

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Informations générales sur le produit	
Nom du produit	TRICLO
Type de produit	Produit de référence
Titulaire	GLOBACHEM NV Brustem Industriepark Lichtenberglaan 2019 3800 Sint-Truiden Belgique
Formulation	Formulation mixte de suspension concentrée (SC) et de suspension de capsules (CS) (ZC)
Contenant	44 g/L - clomazone 111 g/L - quinmérac 333 g/L - métazachlore
Numéro d'intrant	526-2016.01
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 Crucifères oléagineuses* Désherbage	2,25 L/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque inacceptable de contamination des eaux souterraines par la substance active quinmérac et ses métabolites.		

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below.

Globachem

Projet d'étiquette **GLOB268H**

GLOB268H

GLOB268H contient 333 g/L (28.7% p/p) de **métazachlore**, 111 g/L (9.6% p/p) de **quinmérac** et 44 g/L (3.79% p/p) de **clomazone** sous forme de ZC, un mélange de deux formulations sous la forme de suspension concentré (SC) et de suspension de capsules (CS)

ATTENTION

H317 - Peut provoquer une allergie cutanée.
H351 - Susceptible de provoquer le cancer.
H410 - Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
P201 – Se procurer les instructions avant utilisation.
P302+P352 - EN CAS DE CONTACT AVEC LA PEAU: laver abondamment à l'eau et au savon
P308+P313 – EN CAS d'exposition prouvée ou suspectée : consulter un médecin.
P333+P313 - En cas d'irritation ou d'éruption cutanée: consulter un médecin
P391 - Recueillir le produit répandu.
P501 – Eliminer le contenu/récipient dans un centre de collecte des déchets dangereux ou spéciaux, conformément à la réglementation locale, régionale, nationale et/ou internationale.

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.
SPe 3 – Pour les plantes non cibles, respecter une zone non-traitée de 5 mètres par rapport à la zone non-cultivée adjacente.
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 (3 L/ha de GLOB268H) 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

Distribué par :

BELCHIM –Crop Protection–

Belchim Crop Protection France SA
Parc Tertiare 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

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

GLOB268H 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 clomazone matière active de la famille des isoxazolidinones (code HRAC F3). 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	2,25 L/ha	-

L'utilisation de GLOB268H 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
Après la récolte normale du colza d'hiver, l'année suivante il est obligatoire d'effectuer un labour de retournement à 15 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 25 cm :
- après 4 mois: pois de conserve, pomme de terre de consommation, haricots.
- après 7 mois: maïs, céréales de printemps, betteraves, oignons, carottes, graines de lin

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 GLOB268H 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

GLOB268H s'utilise en un seul passage, dans les 3 jours après le semis.
Appliquer GLOB268H 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 GLOB268H 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 GLOB268H à 2.25 L/ha :

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

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.