REGISTRATION REPORT

Part A

Risk Management

Product code: F9135

Product name: COLZOR SYNC TEC

Active Substances:

clomazone, 24 g/L

metazachlor, 150 g/L

napropamide, 150 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: FMC CHEMICAL SPRL

Date: 15/04/2021

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PART A – Risk Management

The company FMC CHEMICAL SPRL has requested marketing authorisation in France for the product COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), containing 24 g/L clomazone, 150 g/L metazachlor and 150 g/L napropamide for use as a herbicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), have been made using endpoints agreed in the EU peer reviews of the active substances.

This document describes the specific conditions of use and labelling required for France for the registration of COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), .

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

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

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

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of FMC CHEMICAL SPRL's application to market COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), in France as a herbicide (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.

1.2 Active substance approval

Clomazone

Commission Implementing Regulation (EU) No 524/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of regulation were as follows : PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on clomazone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 9 October 2007 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective

equipment, — the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones
An EFSA conclusion is available (EFSA Scientific Report (2007) 109, 1-7). A Review Report is available (SANCO/2823/07 rev 2, 10 September 2007).

Metazachlor

Commission Implementing Regulation (EU) No 524/2011 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. Commission Implementing Regulation (EU) No 127/2012 of 14 February 2012 amending Implementing Regulation (EU) No 524/2011 as regards an extension of the use of the active substance metazachlor.
Specific provisions of Regulation (EU) No 524/2011 were as follows : PART A Only uses as herbicide may be authorised; application max. of 1.0 kg/ha only every third year on the same field. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on metazachlor, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 September 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment, — the protection of aquatic organisms, — the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential groundwater contamination from the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 in vulnerable zones, where appropriate. If metazachlor is classified under Regulation (EC) No 1272/2008 as ‘suspected of causing cancer’, the Member States concerned shall request the submission of further information on the relevance of the metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 with respect to cancer. They shall ensure that the notifiers provide that information to the Commission within six months from the notification of such a classification decision. Specific provisions of Regulation (EU) No 127/2012 were to amend Part A above as follows: PART A Only uses as herbicide may be authorised. Applications shall be limited to a total dose of not more than 1.0 kg metazachlor/ha in a three-year period on the same field.
An EFSA conclusion is available (EFSA Scientific Report (2008) 145, 1-132 Conclusion on the peer review of

metazachlor).

A Review Report is available (SANCO/124/08 – final rev. 2 24 January 2012).

Napropamide

Commission Implementing Regulation (EU) No 524/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of Regulation (EU) No 524/2011 were as follows : PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on napropamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — operator safety: conditions of use shall prescribe the use of adequate personal protective equipment, where necessary, — protection of aquatic organisms: conditions of authorisation shall include risk mitigation measures, where appropriate, such as adequate buffer zones, — consumer safety as regards the occurrence in groundwater of the metabolite 2-(1-naphthyloxy)propionic acid, hereinafter 'NOPA'. The Member States concerned shall ensure that the applicant presents to the Commission, by 31 December 2012 at the latest, information confirming the surface water exposure assessment as regards the photolysis metabolites and the metabolite NOPA and information for the risk assessment of aquatic plants.
An EFSA conclusion is available: (EFSA Scientific Report (2008) 140, 1-74, supplemented by the Conclusion on the peer review of napropamide; EFSA Journal 2010; 8(4):1565 and EFSA Technical Report, 9 March 2016). A Review Report is available (SANCO/12647/2010 final 28 October 2010).

1.3 Regulatory approach

The present applications (2013-1438 for COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), 2013-1439 for TRIBECA SYNC TEC) were evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the Southern zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.
The French Order of 04 may 2017 provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;

[1] French Food Safety Agency, Afssa, before 1 July 2010
[2] SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

- unless formally stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

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

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[3], implementing regulations, and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[5] provides that:

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] is to supply "minor" crops with registered plant protection products.

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

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

The applicant has provided the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

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

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

[5] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1247093A/jo

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

Product name (code)	COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), (formulation code F9135) Second trade name TRIBECA SYNC TEC
Authorisation number	2210140
Function	Herbicide.
Applicant	FMC CHEMICAL SPRL
Composition	24 g/L clomazone 150 g/L metazachlor 150 g/L napropamide
Formulation type (code)	Capsule suspension (CS)
Packaging	Fluorinated high-density polyethylene (f-HDPE) bottles or containers holding 1, 5, 10, 20 or 120 L product.

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

Physical hazards	-	
Health hazards	Carcinogenicity, Hazard Category 2	
Environmental hazards	Hazardous to the aquatic environment — Acute Hazard, Category 1 Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H351	Suspected of causing cancer
	H400	Very toxic to aquatic life
	H410	Very toxic to aquatic life with long-lasting effects.
Precautionary statements –	***For the P phrases, refer to the extant legislation***	

Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH208	Contains metazachlor and 1,2-benzisothiazol-3(2H)-one and metazachlor – may produce an allergic reaction.

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

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe 1	To protect groundwater, do not apply this or any other product containing clomazone or napropamide more than once every third year.
SPe 1	To protect groundwater, do not apply this or any other product containing metazachlor more than once every 3 years at the application rate of 500 g / ha or more than once every 4 years at the dose of 750 g / ha.
SPe 2	To protect groundwater, do not apply this product on a field with referenced naturel well or gulf
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres[7] to surface water bodies.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment[8]: refer to the Decision in Appendix 1 for the details
Re-entry period[9]: 48 hours
Pre-harvest interval[10]: Oilseed rape – F- Application must be made at growth stage BBCH 07 at the latest.
Other mitigation measures: - The product must be shaken well prior to use. - For succeeding crops, respect the following plant back interval: • a waiting period of 365 days for leafy crops, • a waiting period of 120 days for root and tuber crops, • a waiting period of 90 days for crops having a short growth cycle (around 30 days between sowing/plantation and harvest), • a waiting period of 60 days for the other crops.

[7] The legal basis for this is **Titre III Article 11** of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

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

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

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

The label must contain the following statement:

"Contains metazachlor and 11,2-benzisothiazol-3(2H)-one and metazachlor – may produce an allergic reaction".

The label must reflect the conditions of authorisation.

Specify the measures limiting the transfer, in particular:

• In clayey soils with large shrinkage cracks, surface cultivation is necessary in order to limit rapid flow to groundwater.

• Use should be avoided in plots with areas of rapid infiltration (other than the referenced naturel well or gulf).

• In areas with karstic subsoils, the use of the active substance must be accompanied by measures to slow down its transfer to groundwater, such as grassing of sinkholes."

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
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, date: 2016-04-12

PPP (product name/code)	**COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), (F9135)**	**Formulation type:**	**capsule suspension (CS)**
active substance 1	**clomazone**	**Conc. of a.s. 1:**	**24 g/L**
active substance 2	**metazachlor**	**Conc. of a.s. 2:**	**150 g/L**
active substance 3	**napropamide**	**Conc. of a.s. 3:**	**150 g/L**
Applicant:	**FMC CHEMICAL SPRL**	**professional use**	☒
Zone:	**southern EU**	**non-professional use**	☐
Verified by MS:	**yes**		

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G 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. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	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		
General remark: max. of 1000 g metazachlor./ha every 3 years (EU restriction)												
1	France	Winter Oilseed Rape (*Brassica napus*)	F	Annual broadleaf weeds and grass weeds	Overall spraying	BBCH 00-07	1	5	1620 (750 metazachlor + 750 napropamide + 120 clomazone)	200 - 400	F	**Acceptable**

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 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), is a light brown homogeneous liquid formulation (aqueous capsule suspension). All studies have been performed in accordance with the current requirements. It is not explosive and has no oxidising properties. It has a self-ignition temperature > 400 °C and a flash point > 100 °C. In aqueous solution (1 %), its pH is 8.8 at 22 °C. Stability data indicate a provisional shelf life of at least two years at ambient temperature (HDPE). The product is compatible with HDPE-f (extrapolation). Its technical characteristics are acceptable for an aqueous capsule suspension.

The product must be shaken before use.

A two- year storage stability study in the commercial packaging is required post-authorisation.

The formulation is not classified for the physico-chemical aspect.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of the active substances in the formulation are available and validated. Nevertheless, specificity of the method must be demonstrated with the formulation COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), post-authorisation.

As the relevant impurity (toluene) is a by-product of the manufacturing process for metazachlor and as such cannot be formed by storage of the formulation, an analytical method for its determination in the formulation is not necessary.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Reports (DARs) and in this dossier and validated for the determination of residues of clomazone, napropamide and metazachlor in plants (high-oil-content commodities), foodstuffs of animal origin, soil, water (surface and drinking) and air.

To update the dossier, the following methods are required post-authorisation:
- A confirmatory method for the determination of metazachlor residues in milk, with a LOQ ≤ 0.01 mg/kg.
- An analytical method with ILV for the determination of napropamide residues in foodstuffs of animal origin.

To update the dossier and to be in accordance with SANCO 825/00/rev8.1, the following analytical methods are required for the re-registration of the active substances, post-authorisation:

- A fully validated method with ILV for the determination of clomazone residue in liver/kidney and fat.
- A confirmatory method and an ILV of method Bacher (2002) for the determination of clomazone residue in muscle, eggs and milk.
- A confirmatory method for the determination of clomazone residue in surface and drinking water.
- A confirmatory method for the determination of napropamide residue in soil, water and air.

The active substances are neither toxic nor very toxic, hence no analytical method is required for the determination of residues in biological fluids and tissues.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

Acute toxicity studies were performed on COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), (F9135) formulation and yielded the following results:

- Rat oral LD_{50} > 2000 mg/kg bw
- Rat dermal LD_{50} > 2000 mg/kg bw
- Rat inhalation LC_{50} > 1.992 mg/L air (maximum achievable concentration)
- No skin irritancy effect with the rabbit
- No eye irritancy effect with the rabbit
- No skin sensitisation in the mouse (LLNA test)

On the basis of these experimental results and the classification of active substance and co-formulants, the classification of COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), is as shown in Section 2.2.

3.1.3.2 Operator Exposure

The applicant made an estimate of operator exposure and recommendations for the prevention of risks to operators.

- **during mixing/loading**
  - Gloves (nitrile, EN 374-3)
  - Working coveralls 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment
  - Partial PPE (long-sleeved aprons or overall) of Category III and Type PB (3), to wear over the coverall mentioned above;
- **during application**

  If application with tractor with a cab
  - Working coveralls 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment
  - Disposable nitrile gloves certified EN 374-2, in the case of an intervention on application equipment during spraying is necessary. However, gloves should be worn only outside the tractor cab and stored after use outside the cab.

  If application with tractor without cab
  - Working coveralls 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment
  - Disposable nitrile gloves certified EN 374-2, in the case of an intervention on application equipment during spraying is necessary.
- **During cleaning of spraying equipment**
  - Nitrile gloves certified EN 374-3 ;
  - Working coveralls 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment
  - Partial PPE (long-sleeved aprons or overall) of Category III and Type PB (3), to wear over the coverall mentioned above.

Dermal absorption

For clomazone, the risks to operators, bystanders and workers have been estimated on the basis of default dermal absorption values of 75 % for the non-diluted and 75 % for the diluted formulation (Guidance on Dermal Absorption; EFSA, 2012).

For metazachlor, the risks to operators, bystanders and workers have been estimated on the basis of dermal absorption values of 0.7 % for the non-diluted and 7 % for the diluted formulation (determined from an *in vitro* human skin study with a similar formulation).

For napropamide, the risks to operators, bystanders and workers have been estimated on the basis of default dermal absorption values of 25 % for the non-diluted and 75 % for the diluted formulation (Guidance on Dermal Absorption; EFSA, 2012).

Exposure assessment

Considering the proposed uses, operator systemic exposure was estimated using the BBA (German) Operator Exposure Model, with the following parameters:

- Tractor-mounted/trailed boom sprayer, hydraulic nozzles
- Application rate: 5 L/ha, being 120 g clomazone/ha, 750 g metazachlor/ha, 750 g napropamide/ha
- Average area treated per day: 20 ha
- Duration of spraying: 6 hours

Estimated exposure according to the German model:

Crops	Equipment	Personal protection	% AOEL clomazone 0.133 mg/kg bw/d	% AOEL metazachlor 0.2 mg/kg bw/d	% AOEL metazachlor 0.5 mg/kg bw/d
Oilseed rape	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	With working coverall and no gloves	58	7	45
		With working coverall and gloves during mixing/loading	16	5	22
		With working coverall and gloves during mixing/loading and application	10	2	11

These results show that with working coverall and gloves during mixing/loading and application, calculated operator exposure is less than 100 % of the AOEL of the active substances. The health risk to operators is considered acceptable with a working coverall and gloves during mixing/loading and application.

3.1.3.3 Bystander Exposure

The exposure of bystanders present at the time of spraying was calculated using data presented in the report of EURO-POEM II. Exposure is calculated as 0.5 % of the AOEL for clomazone, 0.3 % of the AOEL for metazachlor and 0.8 % of the AOEL for napropamide for a 60 kg person situated 7 metres away from the spraying operation and exposed for 5 minutes.

The health risk to bystanders is therefore considered acceptable.

3.1.3.4 Worker Exposure

COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), is used as herbicidal treatment on oilseed brassicas, where there is no need to re-enter the treated area after application. Worker exposure is considered to be negligible and is thus not calculated.

A re-entry period of 6 hours in the field should be recommended.

If the worker would have performed different tasks on the treated crops:

- Working coverall 65% polyester / 35% cotton; minimum 230 g/m²; with water repellent treatment.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

The data available are considered sufficient for risk assessment. An exceedence of the current MRLs on rapeseed of 0.02* mg/kg for clomazone, 0.06* mg/kg for metazachlor and 0.1 mg/kg for napropamide as laid down in Reg. (EU) 396/2005 is not expected.

Summary for clomazone

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EC) No 777/2013	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Oilseed rape Possible extrapolation to other oilseed brassicas (mustard, gold-of-pleasure…)	Yes	Yes (17 NEU and 11 SEU)	Yes	Yes	Yes	No	No	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

As residues of clomazone do not exceed the trigger values defined in Reg. (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. Considering the intended GAPs, in case of "usual" crop rotation, it is very unlikely that any rotational crop will be grown less than 90 days after treatment, and thus no residue is expected in this following crop. It is not the case, considering the possibility of treated crop failure. The following risk mitigation measure is therefore proposed:

- In case of crop failure, do not grow a short-cycle crop in the treated plot less than 90 days after an application of F9135 (COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC)).

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigations of residues, as well as the modification of MRLs in commodities of animal origin, are therefore not necessary.

Summary for metazachlor

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance SANCO/10565/2014	Chronic risk for consumers identified?	Acute risk for consumers identified?	Com-ments
1	Oilseed rape Possible extrapolation to other oilseed brassicas (mustard, gold-of-pleasure…)	Yes	Yes (12N + 7 S)	Yes	Yes	Yes	No	No	No-residue situation

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

As residues of metazachlor do not exceed the trigger values defined in Reg. (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. The following mitigation measures are proposed:

- Do not grow leafy vegetables less than one year after the application of F9135.
- Do not grow root and tuber vegetables less than 120 days after the application of F9135.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigations of residues, as well as the modification of MRLs in commodities of animal origin, are therefore not necessary.

Summary for napropamide

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance SANCO/10565/2014	Chronic risk for consumers identified?	Acute risk for consumers identified?	Com-ments
1	Oilseed rape Possible extrapolation to other oilseed brassicas (mustard, gold-of-pleasure…)	Yes	Yes (10 N + 3 S)	Yes	Yes	Yes	No	No	No-residue situation

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

As residues of napropamide do not exceed the trigger values defined in Reg. (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. There is a potential for low but measurable residues of napropamide to be taken up into rotational crops, particularly root crops.

The following mitigation measures are proposed:
- For root crops, an interval of 180 days after treatment with napropamide before planting or sowing is required.
- For other crops, an interval of 60 days after treatment with napropamide before planting or sowing is required.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigations of residues, as well as the modification of MRLs in commodities of animal origin, are therefore not necessary.

Summary for F9135

Crop	PHI for F9135 proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for F9135 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Clomazone	Metazachlor	Napropamide		
Oilseed rape Possible extrapolation to other oilseed brassicas (mustard, gold-of-pleasure…)	F** BBCH 07	Yes	Yes	Yes	F** BBCH 07	GS at application seems more accurate than a PHI in days

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

3.1.4.2 Consumer exposure

The chronic and short-term intakes of clomazone, metazachlor and napropamide residues are unlikely to present a public health concern. As far as consumer health protection is concerned, the zRMS agrees with authorisation for the intended uses.

3.1.5 Environmental fate and behaviour

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

PECsoil and PECsw derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

The PECgw calculated for clomazone, metazachlor and for one to three of its soil metabolites, napropamide and its metabolite NOPA are below the threshold values defined in the guidance SANCO/221/2000[11], after the use of the preparation COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), . The PECgw calculated for two to four metazachlor metabolites are above the threshold values defined in SANCO/221/2000, after the use of the preparation COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), .

Additional data were provided with groundwater monitoring for the five soil metabolites of metazachlor, dedicated to the intended use on rapeseed. The design of the monitoring study has been considered appropriate in terms of well selection (vulnerability and representativeness of the use of metazachlor on rapeseed). The data show a groundwater contamination throughout the year for at least half of the selected wells for two non-relevant metabolites BH 479-8 (for which around 30 % of the analyses are above the threshold value of 0.1 µg/L) and BH 479-4 (for which 14 % of the analyses are above the threshold value of 0.1 µg/L).

The results from the PECgw calculations and the data from the French monitoring show groundwater contamination by metazachlor metabolites. Moreover, there are some uncertainties due to the limited number of analyses. Therefore, a significant groundwater contamination by the non-relevant metazachlor metabolites and a punctual exceedence of the regulatory threshold of 0.1 µg/L for the relevant metabolite BH 479-9 cannot be excluded.

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

Implications for labelling resulting from environmental fate assessment:

To protect groundwater do not apply this or any other product containing clomazone or napropamide more than once every third year.

To protect groundwater, do not apply this or any other product containing metazachlor more than once every 3 years at the application rate of 500 g / ha or more than once every 4 years at the dose of 750 g / ha.

[11] Guidance document on the assessment of the relevance of metabolites in groundwater of substance regulated under Council Directive 94/414/EEC. SANCO/2000-rev10-final, 25 February 2003.

To protect groundwater, do not apply this product on a field with referenced naturel well or gulf.

3.1.6 Ecotoxicology

3.1.6.1 Effects on Terrestrial Vertebrates

The acute screening assessment and long-term Tier1 assessment for birds exposed to F9135 revealed that the TER_A and TER_{LT} values are above the triggers of 10 and 5, respectively. Therefore the acute and long-term risks for birds and mammals are considered acceptable.

Due to the low log Pow (not greater than 3) bio-accumulation of clomazone and metazachlor is not expected. For napropamide, the log Pow is greater than 3 and a risk assessment for secondary poisoning has been conducted. A risk for earthworm- and fish-eating birds and mammals through F9135 via the food chain can be excluded. The estimation of potential risk for birds and mammals exposed to F9135 through consumption of contaminated water from puddles on soil shows no unacceptable risk.

3.1.6.2 Effects on Aquatic Species

Studies performed with the formulated product F9135 indicate no higher toxicity to fish, daphnids, algae *Lemna* and *Myriophyllum* sp. than predicted based on the results of the three active substances.

Taking into account all the information and including all new data covering a large number of species and time-to-effect studies for metazachlor, it can be concluded that application of F9135 as proposed can be considered acceptable.

3.1.6.3 Effects on Bees and Other Arthropod Species

All hazard quotients for oral (HQ_O) and contact exposure (HQ_C) are below the trigger of 50, indicating that the risk to bees following application of F9135 is considered acceptable.

All hazard quotients (HQs) for *Typhlodromus pyri* and *Aphidius rhopalosiphi* are below the trigger of 2, indicating that the risk to non-target arthropods other than bees following application of F9135 is considered acceptable.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

The acute and long-term TER values for earthworms are higher than the respective acute trigger values of 10 or 5 and the acute and long-term risks to earthworms are considered acceptable.

The long-term TER values for the two soil metabolites metazachlor-oxalic acid and metazachlor-sulphonic acid for the soil-dwelling collembolan species *Folsomia candida* are above the trigger of 5. The risk to soil non-target macro-organisms is considered acceptable.

3.1.6.5 Effects on organic matter breakdown

See Part B.

3.1.6.5 Effects on Soil Non-target Micro-organisms

F9135 had no significant effect on soil micro-organisms at 36.5 mg product/kg dry weight (dw) soil. This is approximately five times higher than the maximum PECs of 7.25 mg F9135/kg dw soil. This supports the conclusion that under field conditions, the risk to non-target soil micro-organisms following application of F9135 is acceptable.

3.1.6.6 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna)

Considering a hazardous concentration for five percent of the species (HC5) of 380 mL F9135/ha, the TER value for terrestrial plants is above the trigger value of 1 for one application in winter rapeseed at 1 m distance, if applied as recommended in the use pattern. Thus, the risk to non-target plants is considered acceptable for the proposed use.

3.1.7 Efficacy

The product complies with the Uniform Principles.

Considering the data submitted :

- ✓ The efficacy of COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), is considered satisfactory.
- ✓ The selectivity of COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), is considered satisfactory.
- ✓ The risk of negative impact (yield, quality, propagation, succeeding and adjacent crops) is considered acceptable.
- ✓ The risk of resistance developing or appearing is considered to be low.

Crop	Harmful organism	Application				zRMS conclusion
		Method	Rate per treatment	Growth stage & season	Number	
Oilseed rape	Annual broadleaf weeds and grasses	Foliar application	5 L/ha	Pre-emergence	1	France agrees.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation **can be granted**,. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

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

3.4.2 If the water quality limit for human consumption is observed, notify the competent authorities and quickly put in place additional measures to protect the supply areas of the catchment areas.Post-authorisation data requirements

For physical-chemical properties, the following confirmatory data would have been necessary or requested post-authorisation:

- A two- year storage stability study in the commercial packaging.

For analytical method, the following confirmatory data would have been necessary or requested post-authorisation:

- The specificity of the analytical methods for the determination of the active substances in the formulation must be demonstrated using the formulation COLZOR SYNC TEC (FORMULATION CODE: F9135; SECOND TRADE NAME TRIBECA SYNC TEC), .

- To update the dossier, a confirmatory method for the determination of metazachlor residues in milk, with a LOQ $\leq$ 0.01mg/kg.
- An analytical method with ILV for the determination of napropamide residues in foodstuffs of animal origin.

3.4.3 Label amendments (see label in Appendix 2):

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

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

Appendix 1 – Copy of the French Decision

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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 et la demande associée du produit phytopharmaceutique ***COLZOR SYNC TEC***

de la société	*FMC CHEMICAL*
enregistrées sous les	*n°2013-1438 et 2013-1439*

Vu les conclusions de l'évaluation de l'Anses du 2 août 2016 et du 11 mars 2020,

Vu le procès-verbal de la réunion du comité de suivi des AMM en date du 24 septembre 2020,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, pour les usages et dans les conditions précisés dans la présente décision et son annexe.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

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Informations générales sur le produit	
Noms du produit	COLZOR SYNC TEC TRIBECA SYNC TEC
Type de produit	Produit de référence
Titulaire	FMC CHEMICAL 4 Floor, 97 rue Royale 1000 Brussels Belgique
Formulation	Suspension de capsules (CS)
Contenant	24 g/L - clomazone 150 g/L - métazachlore 150 g/L - napropamide
Numéro d'intrant	953-2013.01
Numéro d'AMM	2210140
Fonction	Herbicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 juillet 2022.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

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 : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	**Contenance**
Bouteilles en polyéthylène haute densité fluoré	1L
Bidons en polyéthylène haute densité fluoré	5 L ; 10 L ; 20 L
Fûts en polyéthylène haute densité fluoré	120 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Cancérogénicité - Catégorie 2	H351 : Susceptible de provoquer le cancer
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H400 : Très toxique pour les organismes aquatiques
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
EUH208 : Contient de la 1,2-benzisothiazolin-3(2H)-one et du métazachlore. Peut produire une réaction allergique.	
Pour les phrases P se référer à la règlementation en vigueur.	
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.	

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Liste des usages autorisés

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
15205901 Crucifères oléagineuses* Désherbage	**5 L/ha**	**1/an**	jusqu'au stade BBCH 07	F (BBCH 07)	5	-	-	-
	Uniquement sur colza d'hiver.							

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Conditions d'emploi du produit

Stockage et manipulation du produit

Agiter le produit dans son emballage avant utilisation.

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- 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 individuelles.
- 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.

Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à rampe

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;

• pendant l'application - Pulvérisation vers le bas

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité.

Pour le travailleur, porter

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1.

Délai de rentrée en application de l'arrêté du 4 mai 2017 :

- 48 heures.

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Respect des limites maximales de résidus (LMR)

- Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

- Afin d'éviter la présence de résidus dans les cultures suivantes, ne pas implanter :
  - De cultures de légumes feuilles ou tiges moins de 365 jours après traitement,
  - De cultures de racines ou de tubercules moins de 180 jours après traitement,
  - De cultures à cycle court (environ 30 jours entre le semis/la plantation et la récolte) moins de 90 jours après traitement.
  - D'autres cultures moins de 60 jours après traitement.

Protection de l'environnement (milieux, faune et flore)

Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.
- SPe 1 : Pour protéger les eaux souterraines, ne pas appliquer ce produit ou tout autre produit contenant de la clomazone ou du napropamide plus d'une fois tous les 3 ans.
- SPe 1 : 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.
- SPe 2 : Pour protéger les eaux souterraines, ne pas appliquer ce produit sur une parcelle comportant une bétoire référencée.

Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Mettre en place un monitoring des métabolites pertinents et non pertinents du métazachlore dans les eaux souterraines notamment celles destinées à la consommation humaine. En cas de dépassement observés des limites de qualité de l'eau destinée à la consommation humaine, prévenir les autorités compétentes et mettre en place rapidement des mesures complémentaires de nature à protéger les aires d'alimentation de captage.	-	-

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer les informations suivantes sur l'étiquette :
- Préciser les mesures limitant le transfert du métazachlore et de ses métabolites, comme notamment :

- Dans les sols argileux présentant des fentes de retrait importantes, un travail superficiel du sol est nécessaire afin de limiter 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 bétoires 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).

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

NOM DU PRODUIT: **COLZOR SYNC^{tec} ®**

UTILISATION:
COLZOR SYNC^{tec} ®

Est un herbicide de post semis pré levée du colza d'hiver visant le contrôle de certaines graminées et dicotylédones annuelle

COMPOSITION:

Formulation CS contenant 150 g/l de Metazachlore, 150 g/ l de Napropamide and 24 g/l Clomazone

DOSE D'UTILISATION: 5L / ha

CONTENU : 1, 5, 20 ou 120 L

Détenteur de l'AMM : FMC Chemicals Sprl – Byd de la plaine 9/3 – 1050 Bruxelles - Belgique

DISTRIBUTEUR :

CLASSEMENT :

GHS08 GHS09

Mention d'avertissement: Attention
Mentions de danger:
H351 - Susceptible de provoquer le cancer
H410 - Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
Conseils de prudence:
P281 - Utiliser l'équipement de protection individuel requis
P308+P313 - EN CAS d'exposition prouvée ou suspectée: consulter un médecin
P501 : Eliminer le contenu/récipient conformément à la réglementation locale/nationale
EUH401 - Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement

La dose maximale de métazachlore appliquée sur une parcelle est de 1000 gr par période de 3 ans
Les limites maximales de résidus sont consultables à l'adresse suivante :
http://ec.europa.eu/sanco_pesticides/ public/index.cfm

Mesures de sécurité :

Protection de l'opérateur :
Porter un vêtement de travail et de protection approprié, et un appareil de protection des yeux et du visage. Porter des gants pendant la phase de mélange/chargement.

Lors d'un contact avec la peau et les yeux, rincer abondamment à l'eau claire et consulter un spécialiste

Ne pas respirer les vapeurs ni le brouillard de pulvérisation

Protection de l'environnement :
Ne pas pulvériser à proximité des points d'eaux (mares, cous d'eau, fossés). Respecter une zone non traité de 10m par rapport au points d'eau. Toutes les précautions usuelles doivent être prises pour éviter la dérive sur les cultures voisines.

Stockage et élimination

- Conserver dans le contenant d'origine hermétiquement fermé, dans un endroit sûr.
- Eloigner de la nourriture, des boissons et des aliments pour animaux.
- GARDER HORS DE PORTÉE DES ENFANTS.
- rincer soigneusement les bidons, vider les eaux de rinçage dans le réservoir de pulvérisation et éliminer les fond de cuves et les eaux de rinçage du pulvérisateurs ainsi que les emballages selon la législation en vigueur.

Mode d'emploi

COLZOR SYNC^{tec} ® est un herbicide de post semis-prélevée qui peut être utilisé sur toutes les variétés de colza d'hiver
COLZOR SYNC^{tec} ® est adapté pour une utilisation sur tous les types de sols mis a part les sols léger ou très sableux et/ou les sols contenant plus de 10% de matière organique.
Cet herbicide est une Co formulation de trois matières actives:
Métazachlore (acétamide K3), napropamide (chloroacetamides K3) et Clomazone (isoxazolidinones F4) où les 3 actifs sont micro-encapsulés
ces 3 composants confèrent au **COLZOR SYNC^{tec} ®** un large spectre adventice pour le

contrôle tant de certaines graminées que de dicotylédones annuelles.

1 restrictions d'utilisation

L'activité herbicide de **COLZOR SYNC^{tec} ®** est dépendante essentiellement de l'absorption racinaire du produit par les adventices
Lors de l'application de **COLZOR SYNC^{tec} ®** il est important pour la sélectivité des cultures d'assurer une séparation physique entre l'herbicide et les semences de colza. Ceci est réalisé en veillant à ce que ces dernières soient bien couvertes avec de la terre (semis régulier)
Un blanchiment des premières feuilles de la culture peut se produire en particulier lorsque **COLZOR SYNC^{tec} ®** est utilisé dans un sol léger ou à la suite des pluies excessives. Ces symptômes disparaissent rapidement et n'ont pas d'incidences ni sur le développement de la culture, ni sur le rendement ou la qualité de la récolte.
Si **COLZOR SYNC^{tec} ®** est appliquée sur sol sec, il ne deviendra actif qu'après une pluie. Le désherbage est dépendant d'une humidité du sol adéquate

Evitez les recroisements en particulier en fourrière.
Ne pas traiter sur un semis de mauvaise qualité.
Éviter la dérive de pulvérisation sur les cultures voisines

Laver soigneusement les équipements de pulvérisation immédiatement après usage. Des traces du produit peuvent causer des dommages aux cultures sensibles traitées ultérieurement

2 Champ d'activité

2.1 sensibilité des adventices à **COLZOR SYNC^{tec} ®**

COLZOT SYNC^{TEC} 5 L/ha Post semis – pré lévée			
Excellent contrôle (>95%)	**Bonne efficacité (85-95%)**	**Efficacité limitée (70-84%)**	**Adventices peu ou non contrôlées (50-69%)**
CAPBP	CENCY	ALOMY	VIOAR
CHEAL	DESSO	GERSS	Repousses de céréales
GALAP	VERHE	MYOAR	
LAMSP			
MATSP			

PAPRH			
SONSP			
STEME			
THLSP			
VERPE			
LOLMU			
POAAN			

Ces pourcentage d'efficacité correspondent à la moyenne des données générées dans nos essais, ce qui n'exclut pas des résultats inférieurs locaux pour une ou plusieurs espèces d'adventice
Le contrôle de fortes infestations de graminées peu nécessiter l'utilisation de produits spécifiques appliqués en post-levée.

2.2 Mise en garde contre les phénomènes de résistance:

l'utilisation répétée, sur une même parcelle, de substances actives de la même famille chimique ou ayant le même mode d'action peut conduire à l'apparition de plantes résistantes. Pour réduire ce risque, il est conseillé d'alterner, dans la rotation, sur une même parcelle, des herbicides à base de substances actives de familles chimiques différentes ou de modes d'action différents.

3 cultures

3.1 stade d'application d'application

COLZOR SYNC^{tec} ® doit être utilisé en post semis pré-levée, le plus tôt possible après le semis et dans tous les cas avant la levée de la culture

3.2 dose d'utilisation
Appliquer 5 L de **COLZOR SYNC^{tec} ®** par hectare. En cas de sol sableux ou léger ne pas dépasser4.4 L / ha. Ne pas utiliser sur des sols contenant plus de 10% de matière organique.

3.3 Recommandations d'utilisation

Appliquer **COLZOR SYNC^{tec} ®** sur un lit de semis finement préparés et un sol non motteux
Prenez soin du fait que le semis soit réalisé à une profondeur suffisante et régulière (1,5 cm)
Le maximum d'efficacité sera atteint si le produit est appliqué sur un sol humide permettant une bonne répartition du **COLZOR SYNC^{tec} ®** sur la couche superficielle du sol ainsi bonne pénétrations racinaire
Suite à certaines conditions spécifiques et en particulier lorsque l'application est suivie par une période de sécheresse, puis par une forte pluviométrie, des symptômes de blanchiment transitoires de la culture peuvent apparaître
Des températures basses suivant l'application peuvent t également augmenter la sensibilité de la culture
Ne pas rouler la culture après traitement
Ne pas irriguer dans les 3 semaines suivant le traitement
Si de fortes pluies sont annoncé pour les prochaines heures, retarder / reporter le traitement après la pluie
Eviter toute dérive du produit sur les cultures adjacentes, appliquer par temps calme, sans vent
Eviter tous surdosage

3.4 volume d'application
Lors de l'application **COLZOR SYNC^{tec} ®** utiliser un volume d'eau dans la plage de 200 à 400 litres par hectare

4 cultures Rotationnelles

4.1 cultures de remplacement

Plusieurs cultures peuvent être implantées en cas de destruction accidentelle d'un colza d'hiver traité avec **COLZOR SYNC^{tec} ®**

Sans restriction: colza, mais, pois de printemps, pomme de terre, tournesol

Après labour: haricots

Non recommandés: betteraves, céréales a paille-

4.2 cultures suivante

Aucune restriction

5 Compatibilité

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

7 Après utilisation

Nettoyage du pulvérisateur

Afin d'éviter tout dommage aux cultures traitées ultérieurement avec le même matériel, il est nécessaire de nettoyer soigneusement le pulvérisateur avec un produit type Phytnet, dès la fin de l'application de **COLZOR SYNC^{tec} ®**

Rincer soigneusement le visage et les mains avec de l'eau et du savon, changer de vêtements

Appendix 3 – Letter(s) of Access

BASF
The Chemical Company

BASF SE, 67114 Limburgerhof, Germany

ANSES – DPR
UGAmm
253 , avenue du Général Leclerc
94701 MAISONS-ALFORT Cedex

France

July 18, 2013
Dr. Sibylle Brosius
APD/RE - Li 556
Tel.: ++49/(0)621/60-27447
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e-mail: sibylle.brosius@basf.com

Letter of Access for Metazachlor

Dear Madam or Sir,

BASF SE, Ludwigshafen, Germany (hereafter referred to as „**BASF**") hereby agrees that all files, data, studies, summaries and assessments (hereafter referred to as the „**Dossier**") owned and submitted by BASF or its affiliates in support of:

- the inclusion of Metazachlor as an active as active substance into Annex I to Council Directive 91/414/EEC by Commission Directive 2008/116/EC and amended by Commission Implementing Regulation (EU) No 540/2011 and 127/2012 and/or
- BASF metazachlor-containing formulation Butisan S (registration number: 8100291).

may be referred to by you in order to grant registration to the products, developed by FMC, containing Metazachlor and at least one other product, under the codes

F9131 and F9135

(hereafter referred to as „**Product**") for application on oil seed rape in France.

For purpose of clarity, the right of referral includes all files, data, studies, summaries and assessments related to Metazachlor and its metabolites, filed after Annex 1 inclusion to support the re-registration of BASF Metazachlor containing formulations. However, the right of referral does not include any files, data and studies generated to obtain the forthcoming renewal of Metazachlor approval under the regulation (EC) 1107/2009, the subsequent re-registration of any formulations containing Metazachlor.

The applicant is FMC Chemical, sprl, Agricultural Products Group, Boulevard de la Plaine 9/3, B-1050 Brussels, Belgium (hereinafter referred to as FMC).

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Chairman of the Supervisory Board:
Eggert Voscherau

Board of Executive Directors:
Kurt Bock, Chairman;
Martin Brudermueller, Vice Chairman;
Hans-Ulrich Engel, Michael Heinz,
Andreas Kreimeyer, Harald Schwager,
Wayne T. Smith, Margret Suckale

BASF
The Chemical Company

The underlying non-exclusive Supply and License Agreement for Metazachlor of June 26, 2013 (the "Supply Agreement") has been agreed by BASF and FMC.

The right to refer to the Dossier is subject to the following restrictions;

1. The right of referral only gives access to the Dossier
2. The right of referral only gives access for the registration of Product in France. Any future application for registration of Product will require a new letter of access.
3. The right of referral only gives access for the registration of Product for uses on oil seed rape.
4. The right of referral is solely granted to FMC and its above mentioned affiliate and is not transferable nor sub-licensable to any further companies or other legal or natural entities.
5. The Dossier contains valuable information proprietary to BASF. The Dossier shall remain strictly confidential and must not be viewed or copied either in writing or by electronic means or otherwise disclosed to any third party including the FMC. This Letter of Access does not authorize FMC and its employees or any person other than the competent authority personnel to have access to the Dossier, to receive any copies of the Dossier nor to inspect or view the Dossier or any specific document in whole or in part. Therefore, neither any registration authority nor FMC and its Affiliates shall be entitled to disclose the Dossier to any third party nor to allow its use by any third party, unless BASF has given its prior written approval to such disclosure or use.
6. This Letter of Access shall in no event be construed as granting FMC or any of its Affiliates any property rights whatsoever to the Dossier.
7. For the purpose of this Letter of Access the term "**Affiliate**" means any entity which, directly or indirectly, controls, is controlled by, or is under common control with BASF or FMC, respectively. An entity shall be deemed to "control" another entity if it beneficially owns, directly or indirectly, more than 50% of the voting stock or any other comparable equity or ownership interest with respect to an entity.

BASF SE
Crop Protection

Martin Dust
Head of Registration Fungicides

Sibylle Brosius
European Registration

United Phosphorus Limited

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ANSES
Direction des Produits Réglementés
Unité de Coordination de l'évaluation et des affaires européennes
253 avenue du Général Leclerc
94701 Maison Alfort cedex - FRANCE

Date: 17/06/2013

Dear Sir/Madam,

Re: Letter of Access – Regulation (EC) No. 1107/2009 – NAPROPAMIDE AND METABOLITES

United Phosphorus Limited is aware of the fact that **FMC Corporation**, including its Affiliates and Distributors as designated by the Data Access Purchaser (hereafter, 'the Data Access Purchaser') wishes to support, maintain, obtain, amend or renew a new or existing authorisation of certain plant protection product(s), formulated with the active substance napropamide, CAS No. 15299-99-7 EC 239-333-3, whether alone or in combination with other active substances, in the territory of the European Union (hereafter, 'the Product' or 'Products').

This letter of access authorises the relevant competent national authority for granting plant protection product ('PPP') authorisations to refer to and use the studies listed below in Table 1, which are the property of **United Phosphorus Limited** and which were previously submitted by **United Phosphorus Limited** in support of napropamide's inclusion in Annex I to Directive 91/414/EEC and resulted in the adoption of Directive 2010/83/EU, for the sole benefit of the Data Access Purchaser.

In particular the studies may be referred to and used by the relevant competent national authority for granting a PPP authorisation for the sole and exclusive purpose of enabling the Data Access Purchaser to demonstrate to the relevant competent national authority for granting a PPP authorisation that they have access to a dossier for napropamide satisfying the requirements of Regulation (EC) No. 1107/2009 (the 'right of referral'). The Data Access Purchaser may further use these access rights to the studies in order to support, maintain, obtain, amend or renew existing or new plant protection product registrations and applications for registrations in the EU.

The Data Access purchaser are not granted the right to inspect the studies or rely upon the studies for any purpose other than those described in this letter of access. The confidentiality of the studies included in this letter of access is not waived by **United Phosphorus Limited** and must be respected at all times. All property rights in the studies remain exclusively with **United Phosphorus Limited.**

For the avoidance of doubt, the studies are the Data Owners confidential commercial or industrial information and intellectual property, the disclosure of which would adversely affect its legitimate economic interests. The Data Owner asserts that the studies do not relate to information on emissions into the environment (as defined under Aarhus Convention and its implementing measures in EU and national law). It reserves the right to be consulted in the event that a request to receive copies of all or part of the studies or underlying material or supporting data is made by any third party including but not limited to the Data Access Purchaser.

Modification of this letter of access may only be affected in writing signed by **United Phosphorus Limited** (following agreement by the parties).

In the event of any questions regarding the scope and the effect of this letter of access, **United Phosphorus Limited** will be able to provide a prompt clarificatory response, copying the Data Access Purchaser where matters of confidential commercial interest are not addressed.

This letter of access is granted for an unlimited duration and until the data protection for the studies concerned expires in every EU Member State.

For and on behalf of United Phosphorus Ltd.

Robin Ingham
Regulatory Affairs Director

Jean-Philippe Pollet
Marketing Director

cc: [FMC]

Registered in England No. 2844616

Table 1	
ANNEX II DATA POINT	VETERBRATE ANIMAL DATA FOR WHICH THIS LETTER OF ACCESS APPLIES FOR THE BENEFIT OF THE DATA REFERRAL PURCHASER
5.2.3	4-hour acute inhalation toxicity study in the rat Hext, P.M. 1989 Napropamide: 4-hour acute inhalation toxicity study in the rat ICI Central Toxicology Laboratory Company Report No.: CTL/P/2418 GLP: Yes
5.2.5	Eye irritation rabbit Morgan R.L. 1987 Acute toxicity tests: oral and dermal toxicity, skin and ocular irritation for Devrinol technical Stauffer Chemical Company Company Report No.: T-13121 GLP: Yes
5.3	52 week toxicity study in the beagle Smith T.G. 1995 Napropamide: toxicity to dogs by repeated oral administration for 52 weeks. Company Report No.: CT/C/2860 GLP: Yes
5.4.4	NOPA – Mouse micronucleus study Durward, R. 2008 NOPA: Micronucleus test in the mouse Company Report No.: 0237/0227 GLP: Yes
8.1.4	Reproduction study in the Northern Bobwhite quail J.B. Beavers, J. Foster, S.P. Lynn, M. Jaber 1991a Napropamide: a one-generation reproduction study with the bobwhite (*Colinus virginianus*) Wildlife International Ltd Company Report No.: 123-159 GLP: Yes
8.2.1.2	Acute tox blue gill sunfish

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	J.F. Tapp, S.A. Sankey, J.E. Caunter, K.W.J. Long, A.J. Penwell 1990a Napropamide: determination of acute toxicity to bluegill sunfish (*Lepomis macrochirus*) ICI PLC, Brixham Laboratory Company Report No.: BL3804/B GLP: Yes
8.2.3	28 day LC50 rainbow trout J.F. Tapp, S.A. Sankey, J.E. Caunter, H.M. Miller 1989 Napropamide: determination of the 28 day LC_{50} to rainbow trout (*Salmo gairdneri*) ICI PLC, Brixham Laboratory Company Report No.: BL/B3624 GLP: Yes

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