

REGISTRATION REPORT

Part A

Risk Management

Product code: F9131

Product name: CIRCUIT SYNC TEC

Active Substances:

clomazone, 40 g/L

metazachlor, 300 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 CIRCUIT SYNC TEC (FORMULATION CODE: F9131) (formulation code: F9131), containing 40 g/L clomazone and 300 g/L metazachlor 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 CIRCUIT SYNC TEC (FORMULATION CODE: F9131) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of CIRCUIT SYNC TEC (FORMULATION CODE: F9131) have been made using endpoints agreed in the EU peer reviews of both clomazone and metazachlor.

This document describes the specific conditions of use and labelling required for France for the registration of CIRCUIT 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 CIRCUIT SYNC TEC (FORMULATION CODE: F9131) 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 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.

Specific provisions of Regulation (EU) No 540/2011 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 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 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.

Commission Implementing Regulation (EU) No 127/2012 of 14 February 2012 amending Implementing Regulation (EU) No 540/2011 as regards an extension of the use of the active substance metazachlor.

Specific provisions of Regulation (EU) No 540/2011 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/140/08 – final rev. 2 24 January 2012).

1.3 Regulatory approach

The present application (2013-1436) was 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 4 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;
- 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 1107/2009³, 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 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁵ 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 extrapolation⁶ 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 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

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/AGRG1407093A/jo>

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of CIRCUIT 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

Product name (code)	CIRCUIT SYNC TEC (FORMULATION CODE: F9131)
Authorisation number	2210139
Function	Herbicide.
Applicant	FMC CHEMICAL SPRL
Composition	40 g/L clomazone 300 g/L metazachlor
Formulation type (code)	Capsule suspension (CS)
Packaging	Fluorinated high-density polyethylene (f-HDPE) bottles or containers holding 1 L, 5 L or 20 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 –	<i>For the P phrases, refer to the extant legislation</i>	
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 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.
SPe2	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 : 6 hours
Pre-harvest interval ¹⁰ : Oilseed rape – F- Application must be made at growth stage BBCH 07 at the latest.

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.

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).

The label must contain the following statement:

“Contains metazachlor and 1,2-benzisothiazol-3(2H)-one – may produce an allergic reaction”.

“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.”

The label must reflect the conditions of authorisation.

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" or "not finalised", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

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

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

PPP (product name/code) (F9131)
active substance 1 clomazone
active substance 2 metazachlor
Applicant: FMC CHEMICAL SPRL
Zone: southern EU
Verified by MS: yes

CIRCUIT SYNC TEC (FORMULATION CODE: F9131)

Formulation type: capsule suspension (CS)
Conc. of a.s. 1: 40 g/L
Conc. of a.s. 2: 300 g/L

GAP rev. 1, date: 15/04/2021

professional use ☒
non-professional use ☐

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	2.5	750 metazachlor + 100 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	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

3 ISK MANAGEMENT

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

3.1.1 Physical and chemical properties

CIRCUIT SYNC TEC (FORMULATION CODE: F9131) 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 > 96 °C. In aqueous solution (1 %), its pH is 8.5 at 21 °C. Stability data indicate a provisional shelf life of at least two years at ambient temperature (HDPE). The preparation 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, the specificity of the method must be demonstrated with the formulation CIRCUIT SYNC TEC (FORMULATION CODE: F9131) in 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 and metazachlor in plants (high-oil-content commodities), foodstuffs of animal origin, soil, water (surface and drinking) and air.

To update the dossier, a confirmatory method for the determination of metazachlor residues in milk, with a LOQ $\leq 0.01\text{mg/kg}$, is required post-authorisation.

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 substance clomazone:

- 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.

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 CIRCUIT SYNC TEC (FORMULATION CODE: F9131) (F9131) formulation and yielded the following results:

- Rat oral LD₅₀ > 2000 mg/kg bw

- Rat dermal LD₅₀ > 2000 mg/kg bw
- Rat inhalation LC₅₀ > 2.356 mg/L air (max. concentration achievable)
- 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 CIRCUIT SYNC TEC (FORMULATION CODE: F9131) 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).

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: 2.5 L/ha, being 100 g clomazone/ha + 750 g metazachlor/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
Oilseed rape	Tractor- mounted/trailed boom sprayer, hydraulic nozzles	With working coverall and no gloves	48.4	6.5
		With working coverall and gloves during mixing/loading	13.6	4.9
		With working coverall and gloves during mixing/loading and application	8.1	2.3

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 0.4 % of the AOEL for clomazone and 0.36 % of the AOEL for metazachlor 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

CIRCUIT SYNC TEC (FORMULATION CODE: F9131) is used as herbicidal treatment on oilseed rape, 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 is 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 oilseed rape of 0.02* mg/kg for clomazone and 0.06* mg/kg for metazachlor as laid down in Reg. (EU) 396/2005 are 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 8 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 the case of “usual” crop rotation, it is very unlikely that any rotational crop will be grown less than 90 days after treatment, and then no residue is expected in this following crop. If this is not the case, the possibility of failure of the treated crop must be considered and hence the following risk mitigation measure:

- In the case of crop failure, do not grow a short-cycle crop in the treated plot less than 90 days after an application of F9131 (CIRCUIT SYNC TEC (FORMULATION CODE: F9131)).

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 metab-olism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance SANCO/105 65/2014	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 (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 F9131
- Do not grow root and tuber vegetables less than 120 days after the application of F9131

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 F9131

Crop	PHI for F9131 proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for F9131 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Clomazone	Napropamide	Metazachlor		
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 the short-term intakes of clomazone and metazachlor 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 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.

PEC_{soil} and PEC_{sw} derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

The PEC_{gw} calculated for clomazone, metazachlor and for one to three of its soil metabolites are below the threshold values defined in the guidance SANCO/221/2000¹¹, after the use of the preparation CIRCUIT SYNC TEC (FORMULATION CODE: F9131). The PEC_{gw} calculated for two to four metazachlor metabolites are above the threshold values defined in SANCO/221/2000, after the use of the preparation CIRCUIT SYNC TEC (FORMULATION CODE: F9131).

Additional data were provided with groundwater monitoring for the five soil metabolites of metazachlor, dedicated to the intended use on oilseed rape. 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 PEC_{gw} calculations and the data from the French monitoring show a 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.

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.

Implications for labelling resulting from environmental fate assessment:

To protect groundwater do not apply this or any other product containing clomazone 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.

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 F9131 revealed that the TER_A and TER_{LT} values are above the triggers of 10 and 5, respectively. 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 and thus, secondary poisoning through F9131 via the food chain can be excluded. The estimation of potential risk for birds and mammals exposed to F9131 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 F9131 indicate no higher toxicity to fish, daphnids, algae and *Lemna* than predicted, based on the results of the two 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 F9131 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 F9131 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 F9131 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 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

F9131 had no significant effect on soil micro-organisms at 18.82 mg product/kg dry weight (dw) soil. This is approximately five times higher than the maximum PECs of 3.77 mg F9131/kg dw soil. This supports the

conclusion that under field conditions, the risk to non-target soil micro-organisms following application of F9131 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 240 mL F9131/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 CIRCUIT SYNC TEC (FORMULATION CODE: F9131) is considered satisfactory.
- The selectivity of CIRCUIT SYNC TEC (FORMULATION CODE: F9131) 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	2.5 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**, due to the risk of groundwater contamination. 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 CIRCUIT SYNC TEC (FORMULATION CODE: F9131).
- To update the dossier, a confirmatory method for the determination of metazachlor residues in milk, with a $LOQ \leq 0.01\text{mg/kg}$.

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



Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et réglementaire,

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique **CIRCUIT SYNC TEC***

*de la société **FMC CHEMICAL SPRL***

*enregistrée sous le **n°2013-1436***

Vu les conclusions de l'évaluation de l'Anses du 2 mai 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.



Informations générales sur le produit	
Nom du produit	CIRCUIT SYNC TEC
Type de produit	Produit de référence
Titulaire	FMC CHEMICAL SPRL Rue Royale 97, 4 floor 1000 Brussels Belgique
Formulation	Suspension de capsules (CS)
Contenant	40 g/L - clomazone 300 g/L - métazachlore
Numéro d'intrant	954-2013.01
Numéro d'AMM	2210139
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)



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	1 L
Bidons en polyéthylène haute densité fluoré	5 L ; 20 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 réglementation 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.	



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	2,5 L/ha	1/an	jusqu'au stade BBCH 07	F (BBCH 07)	5	-	-	-	-
	Uniquement sur colza d'hiver.								

CIRCUIT SYNC TEC
AMM n°2210139

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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.



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 120 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

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 clomazone 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 bétail 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 observé 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 bétails référencés).
 - 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).

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

NOM DU PRODUIT: CIRCUIT SYNCTec®

UTILISATION:

CIRCUIT SYNCTec®

Est un herbicide de post semis pré émergence du colza d'hiver visant le control tant de certaines graminées annuelles que de dicotylés.

COMPOSITION:

Formulation CS contenant 300 g/l de métazachlore et 40 g/l de clomazone

DOSE D'UTILISATION: 2.5L / ha

CONTENU : 1, 5 ou 20 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, cours d'eau, fossés). Respecter une zone non traitée de 5m par rapport aux 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 fonds de cuves et les eaux de rinçage des pulvérisateurs ainsi que les emballages selon la législation en vigueur.

Mode d'emploi

CIRCUIT SYNC^{tec}® est un herbicide de post semis-prélevée herbicide qui peut être utilisé sur toutes les variétés de colza d'hiver

CIRCUIT SYNC^{tec}® est adapté pour une utilisation sur tous les types de sols sauf les sables et/ou les sols contenant plus de 10% de matière organique.

Cet herbicide est une Co formulation de deux matières actives:

Métazachlore (acétamide K3) et Clomazone (isoxazolidinones F4) où les deux actifs sont micro-encapsulés

Ces 2 composants confèrent au **CIRCUIT SYNC^{tec}®** un large spectre de mauvaises herbes pour le contrôle tant de certaines graminées que de dicotylédones annuelles.

1 restrictions d'utilisation

L'activité herbicide de **CIRCUIT SYNC^{tec}®** est dépendante essentiellement de l'absorption racinaire du produit par les adventices. Lors de l'application **CIRCUIT 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 **CIRCUIT SYNC^{tec}®** est utilisé dans un sol léger ou à la suite des pluies excessives. Ces symptômes disparaissent rapidement et n'ont pas d'incidence sur le développement de la culture, ni sur le rendement ou la qualité de la récolte. Si **CIRCUIT 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.

Évitez les recroisements en particulier en fourrière.
Ne pas traiter sur 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 **CIRCUIT SYNC^{tec}®**

CIRCUIT - 2,5 L/ha Application de post semis pré levé			
Excellent contrôle	Bon contrôle	Efficacité limitée	Adventices peu ou pas contrôlées
APESV CAPBP CHEAL DESSO GALAP LAMSS MATSS	VERHE SENVU CENCY	ALOMY PAPRH	GERDI LOLMU VIOAR

MYOSS			
POAAN			
SONOL			
STEME			
THLAR			
VERPE			

Où:

Excellent contrôle à 100 à 85%

Bon contrôle de 84 à 70%

Efficacité limitée de 70 à 50%

Adventices peu ou pas contrôlées <50%

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

CIRCUIT 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 2,5 L de **CIRCUIT SYNC^{tec}®** par hectare. En cas de sol sableux ou léger ne pas dépasser 2 L / ha. Ne pas utiliser sur des sols contenant plus de 10% de matière organique.

3.3 Recommandations d'utilisation

Appliquer **CIRCUIT SYNC^{tec}®** sur un semis finement préparés et un sol non motteux. Prenez soin 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 **CIRCUIT SYNC^{tec}®** sur la couche superficielle du sol et la bonne pénétrations par les racines par les mauvaises herbes. 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 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 annoncées 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 surdosages

3.4 volume d'application

Lors de l'application **CIRCUIT 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 **CIRCUIT SYNC^{tec}®**

- Après labour: blé de printemps, orge de printemps, avoine de printemps, betterave à sucre, luzerne, trèfle, colza d'hiver.
- Sans restriction: colza de printemps, maïs, pois de printemps, pommes de terre

4.2 culture 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 Phytol, dès la fin de l'application de CIRCUIT SYNC^{tec}®.

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

Appendix 3 – Letter(s) of Access



BASF SE, 67114 Limburgerhof, Germany

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

France

July 18, 2013
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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 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:
Egbert 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



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

A handwritten signature in blue ink, appearing to read "MDA".

Martin Dust
Head of Registration Fungicides

A handwritten signature in blue ink, appearing to read "S. Brosius".

Sibylle Brosius
European Registration