

REGISTRATION REPORT

Part A

Risk Management

Product code: BAS 773 01 H

Product name: ANITOP

Active Substances:

Dimethenamid-P, 100 g/L

Metazachlor, 300 g/L

Quinmerac, 100 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: BASF FRANCE SAS

Date: 04/11/2019

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PART A – Risk Management

The company BASF FRANCE SAS has requested marketing authorisation in France for the product ANITOP (formulation code: BAS 773 01 H), containing 100 g/L dimethenamid-P, 300 g/L metazachlor and 100 g/L quinmerac, for use as an 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 ANITOP (BAS 773 01 H) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of ANITOP (BAS 773 01 H) have been made using endpoints agreed in the EU peer reviews of dimethenamid-P, metazachlor and quinmerac.

This document describes the specific conditions of use and labelling required for France for the registration of ANITOP (BAS 773 01 H).

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 BASF FRANCE SAS's application to market ANITOP (BAS 773 01 H) (second trade names: DECISION, NOVALL STAR) in France as an 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

Dimethenamid-P

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 Regulation (EU) No 823/2012 of 14 September 2012 derogating from Implementing Regulation (EU) No 540/2011 as regards the expiry dates of the approval of the active substances 2,4-DB, benzoic acid, beta-cyfluthrin, carfentrazone ethyl, *Coniothyrium minitans* Strain CON/M/91-08 (DSM 9660), cyazofamid, cyfluthrin, deltamethrin, dimethenamid-P, ethofumesate, ethoxysulfuron, fenamidone, flazasulfuron, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mecoprop, mecoprop-P, mesosulfuron, mesotrione, oxadiargyl, oxasulfuron, pendimethalin, picoxystrobin, propiconazole, propineb, propoxycarbazone, propyzamide, pyraclostrobin, silthiofam, trifloxystrobin, warfarin and zoxamide

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 dimethenamid-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 July 2003 shall be taken into account. In this

overall assessment Member States:

- should pay particular attention to the potential of the metabolites of dimethenamid-P for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climate conditions,
- should pay particular attention to the protection of aquatic ecosystems, especially of aquatic plants.

Risk mitigation measures should be applied where appropriate.

The Member States shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.

Specific provisions of Regulation (EU) No 823/2012 were to extend the expiry date to 31 October 2016.

There is no definitive EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance.

A Review Report is available (SANCO/1402/2001-Final 3 July 2003).

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).

Quinmerac

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 quinmerac, 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:

- the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions;
- the dietary exposure of consumers to residues of quinmerac (and its metabolites) in succeeding rotational crops ;
- the risk to aquatic organisms and the long term risk for earthworms.

Conditions of use shall include risk mitigation measures, where appropriate.

The Member States concerned shall request the submission of information as regards:

- the potential of plant metabolism to result in an opening of the quinoline ring;
- residues in rotational crops and the long term risk for earthworms due to the metabolite BH 518-5.

They shall ensure that the applicant provides such confirmatory data and information to the Commission by 30 April 2013.

An EFSA conclusion is available (EFSA Journal 2010; 8(3): 1523); plus the *Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment of confirmatory data for quinmerac*, Efsa Technical Report, published 04 March 2015.

A Review Report is available (SANCO/12192/2010 final 7 December 2010).

1.3 Regulatory approach

The present applications (2012-0930, 2012-0931 and 2015-1366) 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 4th May 2017³ 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 1107/2009⁴, 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 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁶ 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 extrapolation⁷ 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 Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime

⁴ REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

⁵ 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

⁶ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

⁷ 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 ANITOP (BAS 773 01 H), 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

Not necessary: the applicant has provided sufficient data to show that access is not required.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity


Product name (code)	ANITOP (BAS 773 01 H) ; second trade names: DECISION and NOVALL STAR
Authorisation number	2190639
Function	Herbicide
Applicant	BASF FRANCE SAS
Composition	100 g/L dimethenamid-P 300 g/L metazachlor 100 g/L quinmerac
Formulation type (code)	Suspo-emulsion (SE)
Packaging	High-density polyethylene (HDPE) bottles or containers holding 0.25, 1, 3, 5 or 10 L product. HDPE/polyamide (PA) bottles or containers holding 0.15, 0.25, 0.5, 1, 3, 5 or 10 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	Sensitisation — Skin, Hazard Category 1B 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	H317	May cause an allergic skin reaction
	H351	Suspected of causing cancer
	H400	Very toxic to aquatic life
	H410	Very toxic to aquatic life with long-lasting effects.
Precautionary 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)		“Contains 1,2-benzisothiazol-3(2H)-one and 2-methyl-3(2H)-isothiazolone – may cause 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 dimethenamid-P or quinmerac or metazachlor more than once every three years.
SPe 2	<i>For post-emergence application:</i> To protect aquatic organisms, do not apply to artificially drained soil with clay content greater than or equal to 45 %.
SPe 3	<i>For pre-emergence application:</i> To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres ⁸ to surface water bodies.
SPe 3	<i>For post-emergence application:</i> To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres including a strip of permanent, unsprayed plant cover of 5 metres wide to surface water bodies.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment ⁹ : refer to the Decision in Appendix 1 for the details
Re-entry period ¹⁰ : 48 hours
Pre-harvest interval: F- Application must be made at growth stage BBCH 18 at the latest

⁸ The legal basis for this is **Titre III Article 12** of the French Order of 04 May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

⁹ If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

¹⁰ The legal basis for this is **Titre I Article 3** of the French Order of 04 May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

Other mitigation measures:

- Rinse the empty container at least twice before disposal.
- Do not store the product in a room where the temperature may exceed 40° C.
- 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.

The label must contain the following statement: “Contains 1,2-benzisothiazol-3(2H)-one and 2-methyl-3(2H)-isothiazolone – may cause an allergic reaction”.

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.

PPP (product name/code)	ANITOP (BAS 773 01 H)	Formulation type:	GAP rev. 1, date: 2019-11-3004
active substance 1	dimethenamid-P	Conc. of a.s. 1:	Suspo-emulsion (SE)
active substance 2	metazachlor	Conc. of a.s. 2:	100 g/L
active substance 3	quinmerac	Conc. of a.s. 3:	300 g/L
Applicant:	BASF FRANCE SAS	professional use	<input checked="" type="checkbox"/>
Zone(s):	Southern EU	non-professional use	<input type="checkbox"/>
Verified by MS:	yes		

(a)	Member State	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg a.s./hL min max	water L/ha min max	kg a.s./ha min max		

General remark: max. of 1000 g metazachlor/ha every 3 years (EU restriction)															
Winter oilseed rape	FR	BAS 773 01 H	F	Weeds (general)	SE	300* + 100** + 100***	Spraying	00-18	1 (possibilit y of 2 split applicatio ns)	-	0.19-0.75* 0.063-0.25** 0.063-0.25***	100-400	0.75* 0.25** 0.25***	F	2.5 L product/ha (max.). possibility of split applications (2 applications) Acceptable

* metazachlor; ** dimethenamid-P; *** quinmerac

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
 - (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
 - (f) All abbreviations used must be explained
 - (g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at 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
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) 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

The formulation ANITOP (BAS 773 01 H) is an off-white liquid suspo-emulsion with a moderate fruity odour. 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 of 517 °C and a flash point > 100 °C. In aqueous solution (1 %), its pH is 3.6 at ambient temperature. Stability data indicate a shelf life of at least 2 years at ambient temperature (HDPE). Its technical characteristics are acceptable for a suspo-emulsion. The product is compatible with HDPE and HDPE/polyamide (PA) packaging.

The formulation is not classified for the physico-chemical aspect. The formulation must be stored at a temperature below 40 °C.

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.

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 validated for the determination of residues of metazachlor in plants (high-oil-content commodities), foodstuffs of animal origin, soil, water (surface and drinking) and air.

Analytical methods are available in the DAR and in this dossier and validated for the determination of residues of dimethenamid-P in plants (high-oil-content commodities), soil, water (surface and drinking) and air. Analytical methods for the determination of residues of dimethenamid-P in foodstuffs of animal origin are not necessary. Nevertheless, an ILV of method 474/0 (Benz A., Mackenroth, 2003a) for the determination of dimethenamid-P in high-oil-content commodities must be provided for re-registration of the a.s.

Analytical methods are available in the DARs / a dossier of this applicant and validated for the determination of residues of quinmerac in plants (high-oil-content matrices), foodstuffs of animal origin, soil, water (surface and drinking) and air.

However, some data gaps remain (cf. the dRR Part B):

- a confirmatory method for the determination of metabolites BH 518-2 and BH 518-5 of quinmerac in soil, according to guidance document SANCO/825/00 rev.8.1.

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 ANITOP (BAS 773 01 H) and yielded the following results:

- rat oral LD50 > 2000 mg/kg bw;
- rat dermal LD50 > 5000 mg/kg bw;
- rat inhalation LC50 > 5.1 mg/L/4h;
- no eye irritancy effect in rabbit;
- no skin irritancy effect in rabbit;
- skin sensitising effect in mice (local lymph node assay [LLNA]).

On the basis of these experimental results and the classification of active substance and co-formulants, the classification of ANITOP (BAS 773 01 H) is as shown in Section 2.2.

3.1.3.2 Operator Exposure

Dermal absorption

Dimethenamid-P: For the human risk assessment, the dermal absorption value for dimethenamid-P is 2.2 % for the undiluted product and 25 % for the diluted spray.

Metazachlor: For the human risk assessment, the dermal absorption value for metazachlor is 0.5 % for the undiluted product and 3.5 % for the diluted spray.

Quinmerac: For the human risk assessment, the dermal absorption value for quinmerac is 2 % for the undiluted product and 5 % for the diluted spray.

Exposure assessments

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.

Crop ha/day	Formulation			Application rate per treatment			Equipment type
	Type	Conc. of a.s.	container size & type	dose product (L or g/ha)	water L/ha min max	Maximum application rate (g a.s./ha)	
Oil seed rape 20 ha/day	SE	100 g/L dimethenamid- P 300 g/L metazachlor 100 g/L quinmerac	HDPE 1 L, 5 L, 10 L open diameter 54 mm	2.5 L/ha	100 400	250 g/ha dimethenamid- P 750 g/ha metazachlor 250 g/ha quinmerac	Tractor-mounted/trailed boom sprayer, hydraulic nozzles

The risk is acceptable for metazachlor and quinmerac without personal protective equipment (PPE) (20.6 % AOEL and 13.0 % AOEL respectively) and for dimethenamid-P with gloves during mixing/loading or treatment (91.5 % AOEL). The classification of the formulation justifies wearing gloves and protecting clothing.

An additional evaluation has been performed with the German model with similar entry parameters in the model as presented in the Table of exposure assessment; however taking into account a protection factor of 90 % for the working coverall. With this consideration, the estimation of operator exposure represented 3.7 % of the AOEL of metazachlor, 36.5 % of the AOEL of dimethenamid-P and 7.1 % of the AOEL of quinmerac with working coverall and without PPE.

3.1.3.3 Bystander Exposure

The risk is acceptable for bystanders according EUROPOEM II.

3.1.3.4 Worker Exposure

No exposure is expected, as there is a no re-entry of the treated area. An estimate of exposure for workers is not necessary.

A re-entry period of 48 hours is set, due to the sensitising effect of the formulation (French Order of 4th May 2017)

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 MRL of 0.02* mg/kg for dimethenamid-P, 0.06* mg/kg for metazachlor and 0.1* mg/kg for quinmerac as laid down in Reg. (EU) 396/2005 is not expected.

Summary for dimethenamid-P

Use- No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg (EU) No 149/2008	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	Winter oilseed rape	Yes	Yes (5N, 5S; all results below the LOQ)	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 dimethenamid-P 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 use being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended use, 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 Reg (EU) No 400/2015	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	Winter oilseed rape	Yes	Yes (20N, 14S; all results below the LOQ)	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 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 ANITOP (BAS 773 01 H) on oilseed rape according to the intended GAP.
- Do not grow root and tuber vegetables less than 120 days after the application of ANITOP (BAS 773 01 H) on oilseed rape according to the intended GAP.

Considering dietary burden and based on the intended use, 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 quinmerac

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg (EC) No 149/2008	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	Winter oilseed rape	Yes	Yes (18N, 6S; all results below the LOQ)	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 quinmerac 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 use being considered here. It is very unlikely that residues will be present in wheat grain, carrots and radish roots, cauliflower and broccoli. Foliar crops (lettuce and spinach) present a high probability of residues being

present at measurable level whatever the plant-back interval (PBI). Nevertheless, residue levels measured at all PBIs are always below the extant MRL of 0.1* mg/kg (Reg. (EC) No.149/2008). Hence, no restriction has to be set, but residues levels from rotational crops have still been considered in the dietary burden calculation.

Considering dietary burden and based on the intended uses and residue levels in rotational crops, the trigger for investigation of the nature and magnitude of residues in livestock is exceeded. However, no agreed peer-reviewed livestock residue definition is available. EFSA considers that future assessments would benefit from EU peer-reviewed livestock studies and an agreed livestock residue definition, established in an expert consultation. The non-finalisation of the assessment is however not considered a critical area of concern, since the consumer exposure is expected to still be below the toxicological reference values. Moreover, based on the available metabolism study, residues below LOQ are not expected in animal commodities.

Data gaps for quinmerac:

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

Summary for ANITOP (BAS 773 01 H)

Crop	PHI for ANITOP (BAS 773 01 H) proposed by applicant	PHI / Withholding period* sufficiently supported for			PHI for ANITOP (BAS 773 01 H) proposed by zRMS	zRMS Comments (if different PHI proposed)
		dimethenamid-P	metazachlor	quinmerac		
Winter oilseed rape	F** (BBCH 18)	Yes	Yes	Yes	F** (BBCH 18)	NR

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 dimethenamid-P, metazachlor and quinmerac residues are unlikely to present a public health concern.

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

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 dimethenamid-P, metazachlor, quinmerac and their metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU 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.

Following use of the preparation ANITOP (BAS 773 01 H) as proposed, the PEC_{gw} calculated for dimethenamid-P and its metabolites M23, M27 and M31, quinmerac and its metabolites BH 518-2 and BH 518-5, metazachlor and for one to three of its soil metabolites are below the threshold values defined in the guidance SANCO/221/2000¹¹. 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 ANITOP (BAS 773 01 H).

Additional data were provided with a 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 oilseed rape). 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 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 dimethenamid-P or quinmerac or metazachlor more than once every third year.

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.

3.1.6 Ecotoxicology

3.1.6.1 Effects on Terrestrial Vertebrates

The risk assessments for birds and wild mammals are carried out following the latest guidance document by EFSA¹² hereafter cited as EFSA/2009/1438.

All acute and long-term TER values exceed the triggers set by Commission Regulation (EU) 546/2011 for acceptability of effects.

3.1.6.2 Effects on Aquatic Species

Studies performed with the formulated product ANITOP (BAS 773 01 H) indicate no higher (or unexpected) acute and chronic toxicity to fish, daphnids and algae than predicted based on the results with the active substances. For *Lemna gibba*, however, the toxicity of the formulations is (slightly) higher than expected from the data on the active substances when considering yield data only.

Taking into account all the information and including all new data covering a large number of species for metazachlor and dimethenamid-P, as well as time-to-effect studies for metazachlor, it can be concluded that application of ANITOP (BAS 773 01 H) according to the proposed uses could be considered acceptable, with risk mitigation measures for some uses as detailed in the table below :

Time of application on winter oilseed rape	Risk mitigation proposal
Pre-emergence	5 m unsprayed buffer zone
Post-emergence	Do not apply on artificially drained soils with clay content greater than or equal to 45% and 5 m strip of permanent, unsprayed plant cover

3.1.6.3 Effects on Bees and Other Arthropod Species

ANITOP (BAS 773 01 H) and the active substances dimethenamid-P, quinmerac and metazachlor are considered to be practically non-toxic to bees. All hazard quotients for acute oral and acute contact exposure were below the Commission regulation (EU) 546/2011 trigger of 50, indicating an acceptable risk to honeybees.

The risk to non-target arthropods has been assessed using the approach recommended in the ESCORT 2 document. Based on laboratory and extended laboratory studies on *Aphidius rhopalosiphi* and *Typhlodromus pyri* and laboratory studies with *Chrysoperla carnea* and *Aleochara bilineata*, the off-risk to non-target arthropods can be considered acceptable. However in view of the effects observed on reproduction for *T. pyri*, it appears necessary to demonstrate the acceptability of the in-field risk assessment. Thus, an aged-residue study on *T. pyri* with the formulation ANITOP (BAS 773 01 H) is needed.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

An acute study on earthworms was performed with ANITOP (BAS 773 01 H). In the risk assessment, the TER values exceeded the trigger of 10 for acute and 5 for chronic exposure.

In the risk assessments, all TER values for metazachlor, dimethenamid-P, quinmerac and their major soil metabolites exceeded the trigger value of 10 for acute exposure and 5 for chronic exposure.

It is concluded that the proposed use of ANITOP (BAS 773 01 H) will not pose an unacceptable risk to populations of earthworms or other soil macro-organisms if applied according to the recommended use pattern.

¹² Anonymous 2009: Guidance Document on risk assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7 (12):1438. European Food Safety Authority

3.1.6.5 Effects on organic matter breakdown

See Part B.

3.1.6.6 Effects on Soil Non-target Micro-organisms

ANITOP (BAS 773 01 H) had no significant effect on soil micro-organisms at 12.5 L/ha, i.e. five times the intended dose rate on winter oilseed rape.

The NOEC values of the major soil metabolites of metazachlor (BH 479-4 and BH 479-8), as well as for dimethenamid-P's major soil metabolites M23 and M27 and for quinmerac's major soil metabolites BH 479-5, are higher than the respective worst-case PEC values.

It is concluded that the use of ANITOP (BAS 773 01 H) will not pose an unacceptable risk to non-target soil micro-organisms, if applied according to the proposed good agricultural practice.

3.1.6.7 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 170.9 mL BAS 773 01 H/ha, the TER-value for terrestrial plants is above the trigger value of 1 for one application in winter oilseed rape 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.

For all oilseed brassicas, considering the data submitted:

- The efficacy of ANITOP (BAS 773 01 H) is considered satisfactory.
- The selectivity of ANITOP (BAS 773 01 H) is considered acceptable.
- The risk of negative impact (yield, quality, propagation, succeeding and adjacent crops) is considered acceptable.
- The risk of resistance development or appearance is considered low.

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

No further information is required.

3.4.2 Post-authorisation data requirements

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

- To provide a validated method and its inter-laboratory validation for the determination of metabolites BH 518-2 and BH 518-5 of quinmerac in soil.

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

- To provide storage stability data for quinmerac residues to confirm the validity of the results obtained in the cereal rotation tests.

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

- To provide monitoring of the effects of aged residues for *T. pyri* made with the formulation ANITOP (BAS 773 01 H).

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 et les demandes associées du produit phytopharmaceutique **ANITOP***

de la société BASF FRANCE SAS

enregistrées sous les n°2012-0930, 2012-0931, 2012-1139, 2014-2676, 2014-2810 et 2015-1366

Vu les conclusions de l'évaluation de l'Anses du 2 mai 2016,

Vu les éléments complémentaires transmis par la direction en charge de l'évaluation des produits réglementés de l'Anses le 29 août 2019,

Vu la décision du Directeur général de l'Anses du 30 août 2019,

Vu le recours gracieux formé le 19 septembre 2019 par la société BASF France,

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 ses annexes.

La présente décision abroge et remplace la décision du 30 août 2019 et 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	
Noms du produit	ANITOP DECISION NOVALL STAR
Type de produit	Produit de référence
Titulaire	BASF FRANCE SAS Division Agro 21 chemin de la Sauvegarde 69134 ECULLY CEDEX FRANCE
Formulation	Suspo-émulsion (SE)
Contenant	300 g/L - métazachlore 100 g/L - diméthénamide-P 100 g/L - quinmérac
Numéro d'intrant	955-2012.01
Numéro d'AMM	2190639
Fonction	Herbicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date de ré-approbation de la substance active diméthénamide-P. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 1^{er} septembre 2020.

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,

04 NOV. 2019

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)

ANITOP
AMM n°2190639

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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	250 mL ; 1 L
Bouteilles en polyéthylène haute densité / polyamide	150 mL ; 250 mL ; 500 mL ; 1 L
Bidons en polyéthylène haute densité	3 L ; 5 L ; 10 L
Bidons en polyéthylène haute densité / polyamide	3 L ; 5 L ; 10 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Sensibilisants cutanés - Catégorie 1B	H317 : Peut provoquer une allergie cutanée
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
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

En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

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	entre les stades BBCH 00 et BBCH 18	F (BBCH 18)	5 (dont DVP 5)	-	-	-

Uniquement sur colza d'hiver.

Fractionnement possible en deux applications en prélevée et post-levée.

DVP : Dispositif Végétalisé Permanent.

ANITOP

AMM n°2190639

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Ne pas stocker le produit dans un local où la température peut dépasser 40°C.

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 EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

• pendant l'application - Pulvérisation vers le bas

Si application avec tracteur avec cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 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

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 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 EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.

Pour le travailleur, porter

- une combinaison de travail (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m²) avec traitement déperlant.



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.

Les délais de réimplantation des cultures suivantes devront être respectés :

- un an pour les légumes feuilles,
- 120 jours pour les cultures racines et tubercules.

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 du diméthénamide-P ou du quinnérac ou du métazachlore plus d'une fois tous les trois ans.

Protection de la faune

- SPe 2 : Pour protéger les organismes aquatiques, ne pas appliquer sur sol artificiellement drainé ayant une teneur en argile supérieure ou égale à 45 % pour les applications en post-émergence.

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

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau pour les applications en post-émergence.

Exigences complémentaires post-autorisation

A défaut de transmission de ces données, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Date limite	Réurrence (mois)
Fournir une méthode validée et sa validation inter-laboratoires pour la détermination des métabolites BH 518-2 et BH 518-5 du quinnérac dans le sol.	30/08/2021	-
Fournir les données de stabilité au stockage des résidus de quinnérac afin de confirmer la validité des résultats obtenus dans les essais de rotation.	-	-
Fournir un suivi des effets de résidus vieillis pour <i>Typhlodromus pyri</i> réalisé avec le produit	-	-

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- Contient du 1,2-benzisothiazol-3(2H)-one et 2-méthyl-3(2H)-isothiazolone. Peut produire une réaction allergique.

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

Draft label

BAS 77301 H

**Herbicide anti-dicotylédones
et anti-graminées de pré-levée ou de post-
levée précoce du colza**

Suspo-émulsion (SE) contenant :
300 g/L de métazachlore + 100 g/L de dmta-p + 100 g/L de quinmérac

Autorisation de Vente n°
délivrée le

Usages et doses autorisés, nombre maximum de traitements par an, délai
d'emploi
avant récolte et zone non traitée par rapport aux points d'eau :

Culture	Dose autorisée	Nb trait./an	DAR	ZNT
Colza	2,5 L/ha	1 (pleine dose) 2 (application fractionnée)	-	5 m

Numéro de lot et date de fabrication : voir sur le bidon.

5 litres

BASF Agro S.A.S.
21, chemin de la Sauvegarde
F-69134 ECULLY cedex
Tel : 04 72 32 45 45

® Marque déposée BASF

IMPORTANT :

Pour toutes les spécialités :

Respectez strictement les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...

BASF Agro garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de mise en marché du Ministère de l'Agriculture.

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

Prévention de la résistance :

L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, il est conseillé d'alterner, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation.

En dépit du respect de ces règles, on ne peut pas exclure une altération de l'efficacité de l'herbicide liée à ces phénomènes de résistance. De ce fait, nous déclinons toute responsabilité quant à d'éventuelles conséquences qui pourraient être dues à de telles résistances.

BAS 77301 H est un herbicide de post-semis prélevée ou de post-levée précoce des cultures de colza.

L'association des trois substances actives confère à BAS 77301 H un champ d'activité large à la fois sur graminées et sur dicotylédones.

Usages et doses autorisés, nombre maximum de traitements par an, délai d'emploi avant récolte et zone non traitée par rapport aux points d'eau :

Culture	Dose autorisée	Nb trait./an	DAR	ZNT
Colza	2,5 L/ha	1 (pleine dose) 2 (application fractionnée)	-	5 m

- Limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union Européenne (consultables à l'adresse : http://ec.europa.eu/sanco_pesticides/public/index.cfm)
- Délai de rentrée dans la culture : 48 h après traitement.

CHAMP D'ACTIVITE

Champ d'activité de BAS 77301 H à 2,5 L/ha en prélevée :

Adventices très sensibles (95-100%)	Adventices sensibles (85-94%)	Adventices moyennement sensibles (70-84%)
Anthemis des champs Gaillet gratteron Matricaire sp. Laiteron rude Mouron des oiseaux Veronique de Perse	Coquelicot Repousses de blé Véronique à feuilles de lierre Vulpie queue-de-rat	Vulpin des champs Geranium à feuilles rondes Ray-grass d'Italie Pensée des champs

Champ d'activité de BAS 77301 H à 2,5 L/ha en post-levée précoce :

Adventices très sensibles (95-100%)	Adventices sensibles (85-94%)	Adventices moyennement sensibles (70-84%)
Anthemis des champs Gaillet gratteron Matricaire inodore Coquelicot Laiteron rude Mouron des oiseaux Repousses de blé	Vulpin des champs Capselle bourse à Pasteur Geranium à feuilles disséquées Matricaire camomille	Pensée des champs

* Le pourcentage d'efficacité correspond à une moyenne issue des résultats de nos essais, ce qui n'exclut pas ponctuellement un taux d'efficacité pouvant être inférieur pour l'une ou l'autre des mauvaises herbes.

CONDITIONS D'EMPLOI

Cas général :

UTILISATION EN POST-SEMIS PRELEVEE
Dose : 2,5 L/ha

- Semis effectué à une date normale pour la région, dans des conditions climatiques favorisant la levée (**sol frais**), le peuplement et l'enracinement.
 - Sol bien préparé, finement grumeleux, non motteux.
 - Semis bien recouvert, à une profondeur régulière de 2 à 3 cm.
- Dans ces conditions, BAS 77301 H s'utilise en un seul passage, après le semis.

Utilisation en fractionné :

Dose : 1,5 L/ha en post-semis prélevée
puis 1 L/ha en post-levée précoce

Le fractionnement de l'application de BAS 77301 H :

- régularise l'efficacité du produit en conditions difficiles (temps sec et sol motteux)
- renforce l'efficacité sur certaines adventices (ex : coquelicot)
- renforce la sélectivité en conditions difficiles (sols motteux ou filtrants)

En post-levée précoce, BAS 77301 H s'applique le plus tôt possible c'est-à-dire dès que 70% des pieds de colza sont au stade cotylédons. Cela correspond au stade « colza rayonnant », soit en moyenne 5 à 10 jours après le semis selon les conditions météorologiques.

Attention : Seul le stade des adventices importe pour déterminer l'époque limite de traitement, BAS 77301 H étant efficace avant leur levée ou lorsqu'elles sont les plus jeunes possible. Dans tous les cas, ne pas traiter au-delà du stade 2 feuilles des adventices.

Semis en conditions difficiles :

UTILISATION EN POST-LEVEE PRECOCE
Dose : 2,5 L/ha

- Sol caillouteux ou très motteux ne permettant pas de recouvrir correctement les graines.
- Sol très battant ou très filtrant.
- Sol trop sec rendant la levée aléatoire.
- Semis tardif.

En post-levée précoce, BAS 77301 H s'applique le plus tôt possible c'est-à-dire dès que 70% des pieds de colza sont au stade cotylédons. Cela correspond au stade « colza rayonnant », soit en moyenne 5 à 10 jours après le semis selon les conditions météorologiques.

Attention : Seul le stade des adventices importe pour déterminer l'époque limite de traitement, BAS 77301 H étant efficace avant leur levée ou lorsqu'elles sont les plus jeunes possible. Dans tous les cas, ne pas traiter au-delà du stade 2 feuilles des adventices.

Remarque : Des pertes de pieds ou des tassements de végétation peuvent être observés après application de BAS 77301 H notamment en conditions difficiles (voir ci-dessus) et/ou après des pluies significatives.

CONDITIONS D'APPLICATION

- Appliquer BAS 77301 H de préférence en prélevée sur un sol finement préparé et non motteux. Veiller à ce que le semis soit effectué à une profondeur régulière et suffisante (2 à 3 cm).
- Ne pas rouler la culture après traitement
- Ne pas irriguer dans les trois semaines qui suivent le traitement
- Si un orage ou de fortes pluies sont annoncées dans les heures qui suivent le semis, appliquer BAS 77301 H après la pluie.
- Ne pas traiter en conditions météorologiques défavorables : vent, pluie, fortes températures supérieure à 25°C à l'ombre.
- Traiter par temps calme afin de protéger les cultures voisines.

NB : Nous rappelons que toute utilisation pour un usage non autorisé à la vente est interdite et que tout usage non conforme à nos préconisations est sous l'entière responsabilité de son utilisateur.

CULTURES DE REMPLACEMENT

En cas de retournement du colza dû à une cause accidentelle (gel, limaces...), les cultures suivantes peuvent être ré-ensemencées :

- En hiver, à condition de faire un labour préalable et de semer un peu plus dru : blé tendre et orge
- Au printemps, à condition de faire un bon labour préalable et de semer un peu plus dru : blé tendre et orge
- Sans restriction (quel que soit le travail du sol préalable) : betterave, maïs, pois, sorgho
- L'automne suivant : toutes cultures.

COMPATIBILITE

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques officiels.
Consulter le site <http://e-phy.agriculture.gouv.fr>

PREPARATION DE LA BOUILLIE

Remplir la cuve aux $\frac{3}{4}$ du volume d'eau nécessaire. Mettre l'agitation en marche et verser la quantité nécessaire de BAS 77301 H, puis compléter avec de l'eau jusqu'au volume final. Dans le cadre des bonnes pratiques agricoles, rincer 3 fois les emballages

et verser l'eau de rinçage dans la cuve du pulvérisateur. Laisser l'agitateur en fonctionnement pendant le trajet et jusqu'à la fin de la pulvérisation.

PRÉCAUTIONS D'EMPLOI

Respectez les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.

Pendant le stockage :

- Conserver le produit uniquement dans le récipient d'origine, à l'abri de l'humidité, du gel, dans un endroit frais, aéré et ventilé, à l'écart des aliments et boissons y compris ceux pour les animaux.

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

- Porter un vêtement de protection approprié, des gants et un appareil de protection des yeux et du visage.
- En cas de contact avec la peau et les yeux, laver immédiatement et abondamment avec de l'eau et consulter un spécialiste.
- Ne pas respirer les vapeurs, ni le brouillard de pulvérisation.

Eviter les rejets dans l'environnement :

- Ne pas pulvériser à proximité des points d'eau (mares, cours d'eau, fossés...).
- Ne pas traiter en présence de vent afin de respecter les cultures voisines.
- Eliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur.

Après application :

- Nettoyer très soigneusement et rincer le pulvérisateur aussitôt après le traitement.
- Immédiatement après l'application, changer de vêtements et rincer le visage et les mains à l'eau savonneuse.

ELIMINATION DES EMBALLAGES

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

Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux. Eliminer les emballages vides via une collecte organisée par un service de collecte spécifique. BASF Agro est partenaire de la filière A.D.I.VALOR.

Toute reproduction du présent texte est interdite.

PRECAUTIONS D'EMPLOI



Xi
XI - Irritant



N - Dangereux pour
l'environnement

BAS 77301 H

métezachlore 300 g/L, dmta-p 100 g/L, quinmérac 100 g/L

R43 Peut entraîner une sensibilisation par contact avec la peau.
R50/53 Très toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique.

Délai de rentrée dans la culture : 48 heures

S2 Conserver hors de la portée des enfants.

S13 Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.

S20/21 Ne pas manger, ne pas boire, ne pas fumer pendant l'utilisation.

S24 Éviter le contact avec la peau.

S35 Ne se débarrasser de ce produit et de son récipient qu'en prenant toutes les précautions d'usage.

S36/37 Porter un vêtement de protection et des gants appropriés

S46 En cas d'ingestion, consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette.

S57 Utiliser un récipient approprié pour éviter toute contamination du milieu ambiant.

SPe3 Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

Respectez les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.

SP1 - Ne pas polluer l'eau avec le produit ou son emballage. (Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.)

BASF Agro S.A.S.

21, chemin de la Sauvegarde - F-69134 ECULLY cedex – Tél. 04 72 32 45 45

En cas d'urgence, appeler le 15 ou le centre anti-poison puis signalez vos symptômes au réseau Phyt'attitude, n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

En cas d'incident ou d'accident, appeler le 01 49 64 57 33

Informations techniques sur nos produits : N° Azur - 0 810 023 033

Fiche de Données de Sécurité et Etiquette disponibles sur www.basf-agro.fr

Appendix 3 – Letter(s) of Access

Not applicable.