REGISTRATION REPORT Part A Risk Management

Product code: Napropamide 450 g/L SC (HAR01)
Product name: COLZAMID

Active substance:

napropamide, 450 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(Authorisation renewal)

Applicant: UPL Europe Ltd.

Date: 2021-04-28

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PART A - Risk Management

The company UPL Europe Ltd. has requested renewal of the marketing authorisation in France for the product COLZAMID (product code: Napropamide 450 g/L SC (HAR01); marketing authorisation n° 8800603), containing 450 g/L napropamide, 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 COLZAMID (Napropamide 450 G/L SC (HAR01)) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of COLZAMID (Napropamide 450 G/L SC (HAR01)) have been made using endpoints agreed in the EU peer review of napropamide.

This document describes the specific conditions of use and labelling required for France for the registration of COLZAMID (Napropamide 450 G/L SC (HAR01)).

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 UPL Europe Ltd.'s application to market COLZAMID (Napropamide 450 G/L SC (HAR01)) 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 renewal of authorisation after approval of the active substance of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Napropamide

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 substances¹.

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 napropamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010, shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

- operator safety: conditions of use shall prescribe the use of adequate personal protective equipment, where necessary,
- protection of aquatic organisms: conditions of authorisation shall include risk mitigation measures, where appropriate, such as adequate buffer zones,

Approval expiration date extended to 31 December 2020 by Commission Implementing Regulation (EU) 2018/670.

 consumer safety as regards the occurrence in groundwater of the metabolite 2-(1-naphthyloxy)propionic acid, hereinafter 'NOPA'.

The Member States concerned shall ensure that the applicant presents to the Commission, by 31 December 2012 at the latest, information confirming the surface water exposure assessment as regards the photolysis metabolites and the metabolite NOPA and information for the risk assessment of aquatic plants.

An EFSA conclusion is available (EFSA Journal 2010; 8(4):1565).

A Review Report is available (SANCO/12647/2010 final rev 31 29 June 2017).

1.3 Regulatory approach

The present application (2014-2912 and 2020-0371) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")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 2017³ provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres:
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight 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

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

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 https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

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/AGRG1407093A/jo

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.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of COLZAMID (Napropamide 450 G/L SC (HAR01)), 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 is the owner of the active substance data.

Applicant: UPL Europe Ltd.

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

2 DETAILS OF THE AUTHORISATION

2.1 **Product identity**

Product name (code)	COLZAMID (Napropamide 450 g/L SC (HAR01)).		
	Second trade name: DEVRINOL 450 SC.		
Authorisation number	8800603.		
Function	Herbicide.		
Applicant	UPL Europe Ltd.		
Composition	450 g/L napropamide.		
Formulation type (code)	Suspension concentrate (SC).		
Packaging	PET bottle containing 1 L product.		
	HDPE containers holding 5 L, 10 L, 15 L or 20 L product.		

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No 1272/2008

Physical hazards	-	
Health hazards	-	
Environmental	Hazardous t	to the aquatic environment, Chronic Hazard, Category 2.
hazards		
Hazard pictograms	*	
Signal word	-	
Hazard statements		
	H411	Toxic to aquatic life with long-lasting effects.
Precautionary statements –	For the P pl	hrases, refer to the extant legislation
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH208	Contains 1,2-benzisothiazol-3(2H)-one). May produce an allergic reaction.

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

2.2.2 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
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	surface water. Avoid contamination via drains from farmyards and roads.
SPe 3	To protect non-target plants, respect an unsprayed buffer zone of 5 metres to non-agricultural land.
SPe 2	To protect aquatic organisms do not apply to artificially drained soils with clay content higher than or equal to 45% for the uses on oilseed rape.
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 5 meters ⁸ to surface water bodies for the uses on winter oilseed rape.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 20 meters ⁹ including a strip of permanent, unsprayed plant cover 5 meters wide near surface water bodies for the uses on lettuce, spring oilseed rape, seed production and medicinal and aromatic herbs, spices and flavourings.

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment ¹⁰ : refer to the Decision in Appendix 1 for the details.							
Re-entry period ¹¹ : six hours.							
Pre-harvest interval ¹² :	Lamb's lettuce and rocket	26 days.					
	Escarole, herbs	F - Application must be made at growth stage BBCH 09 at the latest or before pre-planting.					
	Oilseed brassicas	F - Application must be made at growth stage BBCH 09 at the latest.					

Other mitigation measures:

- Do not store the product in a room where the temperature may exceed 40 $^{\circ}$ C. .
- Shake the product in its packaging before use.
- An interval of 180 days must be observed before sowing/planting a succeeding or replacement crop on cereals, oilseeds and leafy vegetables group. An interval of 60 days must be observed before sowing/planting a succeeding or replacement crop on other types of crops.
- Bi-products of non-food medicinal and aromatic herbs, spices and flavourings and of seed crops must not be used for human food or animal feed.

The label may include the following recommendations:

- EUH208: Contains 1,2-benzisothiazol-3(2H)-one. May cause an allergic reaction.

The label must reflect the conditions of authorisation.

in consistency with French Order of 4 May 2017 (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), modified by the French Order of 27 December 2019.

⁹ in consistency with French Order of 4 May 2017 (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), modified by the French Order of 27 December 2019.

¹⁰ If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

The legal basis for this is **Titre I Article 3** of the French Order of 4 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]

According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

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

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

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

PPP (product name/code) COLZAMID (Napropamide 450 G/L SC

 $(HAR01))/(Napropamide\ 450\ g/L\ SC\ (HAR01))$

active substance 1 napropamide
Applicant: UPL Europe Ltd.

Zone(s): southern Verified by MS: yes GAP rev. , date: 2021-04-28

Formulation type: SC Conc. of a.s. 1: 450 g/L

professional use ⊠ non-professional use □

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-	Member	Crop and/	F	Pests or Group of pests		Application		A	pplication rate		PHI	Remarks:
No.	state(s)	or situation (crop destination / purpose of crop)	G or I	controlled (additionally: developmental stages of the pest or pest group)	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		e.g. g safener/synergist per ha
56	France	Oilseeds (oilseed rape, gold-of- pleasure, white mustard; turning rape, hemp, borage, sesame, flax)	F	Annual grasses & BLW	Spraying on soil / Spraying on soil followed by incorporation	BBCH 00 – BBCH 09	a)1 b)1	a) 2.8 b) 2.8	a) 1260 b) 1260	80-200	F	Acceptable
59	France	Medicinal and aromatic herbs, spices and flavourings: Comestible (basil, borage, tarragon, marjoram, lemon balm, mint, oregano, rosemary, annual savory, sage officinale, thyme) and non-comestible.	F	Annual grasses & BLW	Spraying on soil / Spraying on soil followed by incorporation	BBCH 00 – BBCH 09	a)1 b)1	a) 2.5 b) 2.5	a) 1125 b) 1125	200-400	-	Not acceptable (MLR)

Applicant: UPL Europe Ltd.

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-	Member	Crop and/		Pests or Group of pests	Application		A	Application rate		PHI	Remarks:	
No.	state(s)	or situation (crop destination / purpose of crop)	G or I	controlled (additionally: developmental stages of the pest or pest group)	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	(days)	e.g. g safener/synergist per ha
59	France	Medicinal and aromatic herbs, spices and flavourings: Comestible (basil, borage, tarragon, marjoram, lemon balm, mint, oregano, rosemary, annual savory, sage officinale, thyme)	F	Annual grasses & BLW	Spraying on soil / Spraying on soil followed by incorporation	BBCH 00 – BBCH 09	a)1 b)1	a) 1.8 b) 1.8	a) 1125 b) 1125	200-400	F	Acceptable Not acceptable for glasshouse application (MLR)
60	France	lamb's lettuce (VILLO), endive (CICEN, CICEC), wild lettuce (LACSE), salad rocket (ERUVE)	F	Annual grasses & BLW	Spraying on soil	BBCH 00 – BBCH 09	a)1	a) 1.8	a) 810	200-400	26 (lamb's lettuce) F (other crops)	Acceptable
61	France	Seed production (lamb's lettuce and cabbage)	F	Annual grasses & BLW	Spraying on soil	BBCH 00 – BBCH 09	a)1	a) 2.8	a) 1260	200-400	N/A	Acceptable
62	France	Seed production (radish and turnips)	F	Annual grasses & BLW	Spraying on soil	BBCH 00 – BBCH 09	a)1	a) 2.2	a) 990	200-400	N/A	Acceptable

Remarks:

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.*, furnigation 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
- 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
- (1) 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

Commercial packaging:

Bottle of 1 L made of PET.

Containers of 5-10-15-20L made of HDPE.

COLZAMID (Napropamide 450 G/L SC (HAR01)) is a water-based beige flowable liquid (suspension concentrate), with solvent odour. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. It is not explosive, has no oxidising properties and is not flammable. It has a self-ignition temperature of 400 °C. In aqueous solution (1 %), it has a pH value of 9.7 at ambient temperature. There is no effect of low and high temperatures on the stability of the formulation, since after even days at 0 °C, eight weeks at 40 °C, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in plastic bottles; the material was not described. However, since the product is a water-based formulation, it is compatible with all kinds of plastic packaging; its technical characteristics are acceptable for a suspension concentrate formulation.

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

3.1.2 Methods of analysis

3.1.2.1 **Analytical method for the formulation**

Analytical methods for the determination of the active substance in the formulation are available and validated. A validated method for the determination of toluene [methylbenzene] in the formulation is required (limit of quantification: 0.06 % w/w) post-authorisation, with a time limit of six months.

3.1.2.2 Analytical methods for residues

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

3.1.3 **Mammalian Toxicology**

Endpoints used in risk assessment

Active substance: napropamide							
ADI	0.3 mg kg bw/d						
ARfD	ARfD not applicable						
AOEL	0.5 mg/kg bw/d	EU (2011)					
AAOEL	not applicable						
Dermal	Based on an <i>in vitro</i> human study performed on the formulation (r in the EU review of napropamide).		representative formulation				
absorption		Concentrate (tested)	Diluted formulation (tested)				

Applicant: UPL Europe Ltd. Evaluator: FRANCE Date: 2021-04-28

		450 g/L	22.5 g/L	0.9 g/L
	In vitro (human) %	0.7	6.5	13.4
		Concentrate (used in formulation) 450 g/L	(used in fo	dilution ormulation) 3 g/L
	Dermal absorption endpoints %	0.7	13	3.4
Oral absorption			100) %

3.1.3.1 Acute Toxicity

COLZAMID (Napropamide 450 G/L SC (HAR01)) (initial composition) containing 450 g/L/ napropamide had a low acute oral, inhalational and dermal toxicity, was not irritating to the rabbit skin or eye and not a skin sensitiser.

However the applicant provided a new composition for COLZAMID (Napropamide 450 G/L SC (HAR01)), therefore acute toxicity studies could not be used to determine the classification of preparation. Based on the classification of the formulants the classification of COLZAMID (Napropamide 450 G/L SC (HAR01)) was calculated according to the Commission Regulation (EC) No. 1272/2008. Full details of composition and classification of co-formulants are provided in part C, Toxicological Classification document, of this registration report.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop type	F/G ¹³	Equipment Application method	Maximum application rate L product/ha (g a.s./ha)	Minimum volume water (L/ha)	Model
Oilseed rape	F	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	2.8 L/ha (1260 g napropamide/ha)	80	German model

Considering proposed use, operator systemic exposure was estimated using the German BBA model:

Crop	Equipment	PPE and/or working coverall	% AOEL napropamide
Oilseed rape	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	2.7

According to the model calculations, it may be concluded that the risk for the operator using COLZAMID (Napropamide 450 G/L SC (HAR01)) SC is acceptable with a working coverall and gloves during mixing/loading and application.

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

Open field or glasshouse

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 0.36 % of the AOEL of napropamide.

It may be concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to COLZAMID (Napropamide 450 G/L SC (HAR01)).

3.1.3.4 Worker Exposure

COLZAMID (Napropamide 450 G/L SC (HAR01)) is used as herbicidal treatment on crops where there is no need to re-enter the treated area after application. The estimation of worker exposure is considered to be not relevant.

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

3.1.3.5 Resident Exposure

Residential exposure was assessed according to Martin et al. Exposure is estimated to be 0.07 % of the AOEL of napropamide for adults and 0.13 % of the AOEL of napropamide for children.

It may be concluded that there is no unacceptable risk to the resident exposed to COLZAMID (Napropamide 450 G/L SC (HAR01)).

3.1.3.6 Relevance of metabolites

NOPA: PECgw max = $18.825 \mu g/L$ (apples)

NOPA: PECgw max = $1.963 \mu g/L$ (oilseed rape)

According to Efsa's conclusions on napropamide (Efsa 2010), this metabolite is considered to be not relevant. The sufficient presence of NOPA in rat metabolism would allow the adoption of the reference values (ADI) of the parent substance napropamide by the metabolite NOPA as well.

3.1.4 **Residues and Consumer Exposure**

3.1.4.1 Residues

The preparation COLZAMID (Napropamide 450 G/L SC (HAR01)) contains napropamide.

Summary for napropamide

Use- No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EC) 149/2008	consumers	Acute risk for consumers identified?	Comments
58	Winter & spring oilseed rape	Yes	No (only Northern trials)	Yes	Yes	Yes	No	Not required	Yes – two Southern trials must be provided post- registration

Applicant: UPL Europe Ltd. Date: 2021-04-28

Use- No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EC) 149/2008	Acute risk for consumers identified?	Comments
59	Herbs (F)	Yes	Yes For the proposed GAP: pre- emergence or pre- planting application at 0.810 kg/ha	Yes	Yes	Yes	Not applicable	
59	Herbs (G)	Yes	No	No	-	-	-	-
	Lamb's lettuce, rocket, escarole	Yes	Yes	Yes	Yes	Yes	Not applicable	Fall back GAP is proposed for escarole

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

For oilseed rape, additional SEU data are required in post-registration to confirm that a "no-residue" situation occurs in the worst case application: 1 application of 1.260 kg/ha at growth stage BBCH 09.

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

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. The following mitigation measures have been proposed: a waiting period of 180 days after treatment with napropamide before planting or sowing rotational crops is proposed except for cereals, leafy vegetables and oilseed were a plant back interval of 60 days can be proposed.

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

Summary for COLZAMID (Napropamide 450 G/L SC (HAR01))

Information on COLZAMID (Napropamide 450 G/L SC (HAR01))

Use- No.*	Crop	PHI for HAR01 requested by	PHI/withholding period* sufficiently supported for napropamide	PHI for HAR01 proposed by zRMS	zRMS Comments (if different PHI proposed)
56	Oilseed rape	applicant NR***	Yes	NR***	
59	Herbs	45	No	FBBCH09 or pre- planting	Insufficient residue trials to support the

Use- No.*	Crop	PHI for HAR01 requested by applicant	PHI/withholding period* sufficiently supported for napropamide	PHI for HAR01 proposed by zRMS	zRMS Comments (if different PHI proposed)
				application	intended GAP
	Lamb's lettuce, rocket, escarole	26 days	Yes	Lamb's lettuce, rocket: 26 days Escarole: PHI F, BBCH 09 or pre-planting	Insufficient residue trials to support the intended escarole GAP

NR: not relevant

Waiting periods before planting or sowing succeeding crops

Waiting perio	d before planting succeeding crops	Overall waiting period proposed
Crop group	Led by napropamide	by zRMS for COLZAMID (Napropamide 450 G/L SC (HAR01))
Cereals, leafy vegetables and oilseed	60 days	A waiting period of 180 days after treatment with napropamide before planting or sowing rotational crops is proposed except for cereals, leafy
Other crops	180 days	vegetables and oilseed were a plant back interval of 60 days can be proposed.

NR: not relevant

3.1.4.2 Consumer exposure

The data available are considered sufficient for risk assessment. Any exceedence of the current MRLs for napropamide as laid down in Reg. (EU) 396/2005 is not expected for the intended uses on lamb's lettuce and crucifers oilseed and for the proposed uses on escaroles and herbs..

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

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

According to available data, the following specific mitigation measures are recommended: a waiting period of 180 days after treatment with napropamide before planting or sowing rotational crops is proposed except for cereals, leafy vegetables and oilseed were a plant back interval of 60 days can be proposed

Data gaps:

Data required post-authorisation: Two southern trials on oilseed rape, planned in 2018, must be provided post-registration.

3.1.5 Environmental fate and behaviour

^{*} 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).

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for the active substance and its metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC values of napropamide and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PECsoil and PECsw/PECsed values derived for the active substance and its metabolites were used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw values for napropamide and its metabolite do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

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

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review for active substances and their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, mammals, bees and other non-target arthropods, earthworms and other soil macro-organisms and micro-organisms are acceptable for the intended uses.

For terrestrial non-target plants, the risks are acceptable when a buffer zone of 5 metres is applied for all the requested crops.

3.1.7 Efficacy

Considering the data submitted:

- the efficacy level of COLZAMID (Napropamide 450 G/L SC (HAR01)) applied in pre-sowing/pre-plantation or
 in post-sowing/post-plantation pre-emergence of weeds is considered satisfactory for all the requested uses for
 the control of broad-leaf and grass weeds.
- the selectivity level of COLZAMID (Napropamide 450 G/L SC (HAR01)) is considered satisfactory for all the requested uses.
- the risks of negative impact on yield, quality, transformation processes and propagation are considered negligible.
- the risk of negative impact on succeeding crops is considered acceptable. Nevertheless, specific attention should be paid to susceptible succeeding crops.
- the risk of negative impact on adjacent crops is considered acceptable.
- the risk of resistance developing or appearing to napropamide does not require monitoring for the requested uses.

Napropamide 450 g/L SC (HAR01) (COLZAMID) Page 16 of 29

Part A National Assessment - Country – FRANCE Registration Report – Southern Zone

Restrictions: none.

Resistance monitoring data: none.

Post-authorisation data: none.

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.

Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- A validated method for the determination of toluene [methylbenzene] in the product.
- Provide 2 Southern-zone residue trials on oilseed rape.

3.4.3 Label amendments

The draft label proposed by the applicant in Appendix 2 must 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.

Evaluator: FRANCE Applicant: UPL Europe Ltd. Date: 2021-04-28

Appendix 1 - Copy of the French Decision





Décision relative à une demande de renouvellement de l'autorisation de mise sur le marché d'un produit phytopharmaceutique et à la demande associée

Vu les dispositions du règlement (CE) № 1107/2009 du 21 octobre 2009 et de ses textes d'application,

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

Vu les demandes de renouvellement de l'autorisation de mise sur le marché et de modification de l'autorisation du produit phytopharmaceutique COLZAMID

de la société

UPL EUROPE LTD

enregistrées sous les

n°2014-2912 et n°2020-0371

Vu les conclusions de l'évaluation de l'Anses du 11 septembre 2019 et du 11 janvier 2021,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **est renouvelée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, 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.

COLZAMID AMM n°8800603

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Informations générales s	ur le produit
Noms du produit	COLZAMID DEVRINOL 450 SC
Type de produit	Produit de référence
Titulaire	UPL EUROPE LTD Chadwick house Birchwood park, Warrington WA3 6AE CHESHIRE Royaume-Uni
Formulation	Suspension concentrée (SC)
Contenant	450 g/L - napropamide
Numéro d'intrant	8800603
Numéro d'AMM	8800603
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. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 décembre 2024.

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

28 AVR. 2021



COLZAMID AMM n°8800603

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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 téréphtalate	1 L			
Bidons en polyéthylène haute densité	5 L; 10 L; 15 L; 20 L			

Classification du produit					
La classification retenue est la suivante :					
Catégorie de danger	Mention de danger				
Dangers pour le milieu aquatique - Danger chronique, catégorie 2	H411 : Toxique pour les organismes aquatiques entraîne des effets à long terme				

EUH208 : Contient de la 1,2-benzisothiazol-3(2H)-one. Peut produire une réaction allergique

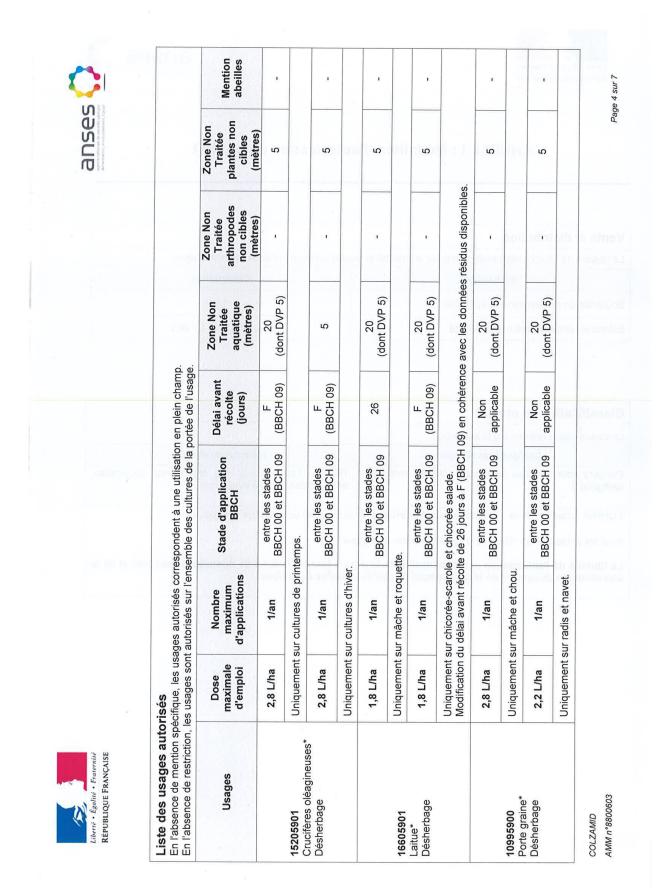
Pour les phrases P se référer à la règlementation en vigueur.

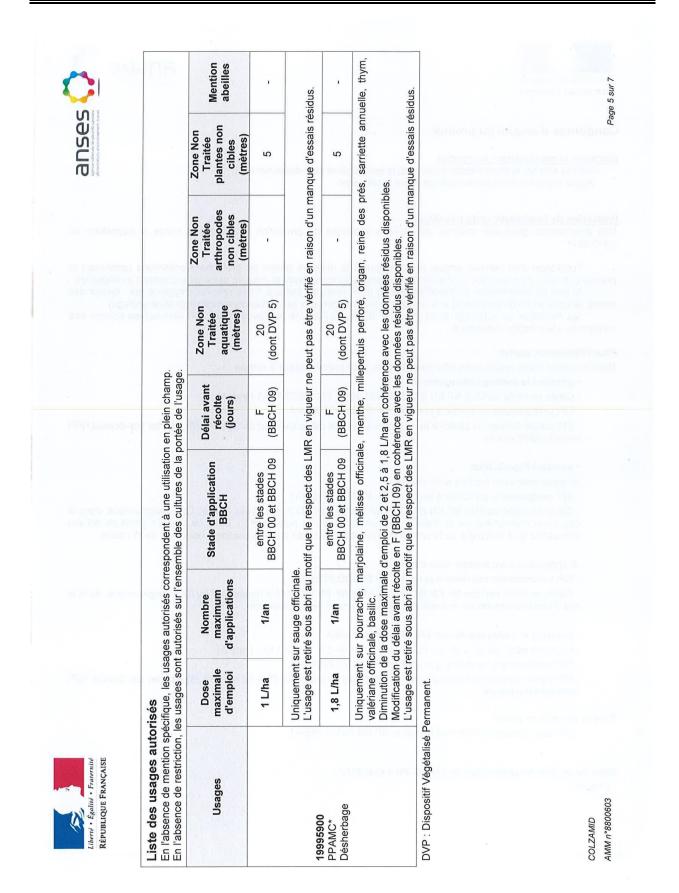
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.

COLZAMID AMM n°8800603

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Applicant: UPL Europe Ltd.









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.
- Agiter le produit dans son emballage avant l'application.

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

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 :

- 6 heures.

COLZAMID AMM n°8800603

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Evaluator: FRANCE Applicant: UPL Europe Ltd.

Date: 2021-04-28





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.

- Respecter un délai de réimplantation de 60 jours entre l'application et l'implantation d'une culture appartenant au groupe des céréales, des oléagineux et des légumes feuilles, et un délai de 180 jours pour les autres types de cultures
- Ne pas utiliser les sous-produits des cultures "porte-graines" et lin textile traitées en alimentation humaine ou animale.

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.

Protection de la faune

- SPe 2 : Pour protéger les organismes aquatiques, ne pas appliquer ce produit sur sol artificiellement drainé ayant une teneur en argile supérieure ou égale à 45 % pour les usages sur "crucifères oléagineuses" d'hiver.
- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau pour les usages sur "crucifères oléagineuses" d'hiver.
- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 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 usages sur "laitue", "porte-graines", "PPAMC" et "crucifères oléagineuses" de printemps.

Protection de la flore

- SPe 3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.

Le produit peut être utilisé sur les usages autorisés, y compris sur les cultures qui seraient exclues de la portée par la présente décision, conformément aux conditions d'emploi antérieures pendant une période de 6 mois.

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)
- Fournir une méthode validée pour la détermination du toluène dans le produit.	24	-
- Fournir deux essais résidus sur colza réalisés dans la zone sud de l'Europe afin de confirmer la situation de non-résidu.	24	

COLZAMID AMM n°8800603

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







HERBICIDE

MAPP 17967

A suspension concentrate (SC) formulation containing 450 g/litre of napropamide (40.9% w/w) for the control of annual grass and broad-leaved weeds in certain brassicas (broccoli, Brussels sprouts, cabbage, calabrese, cauliflower and kale) and winter oilseed rape.



Warning

Very toxic to aquatic life with long-lasting effects

Collect spillage.

Dispose of contents/container to a licensed hazardous-waste contractor or collection site except for clean containers which may be disposed of as non-hazardous waste.

Contains 1,2-benzisothiazolin-3-one.

May produce an allergic reaction.

To avoid risks to human health and the environment, comply with the instructions for use.

COL/GB/5L/F/0617/UPL

A3.0 COLZAMID UK 150517 NOA 0339-17

June 2017

5 Litres 450 g/I NAPROPAMIDE

Applicant: UPL Europe Ltd.

IMPORTANT INFORMATION FOR USE ONLY AS A PROFESSIONAL HERBICIDE							
Crops/situations	Maximum individual dose (I product/ha)	Maximum number of treatments (per crop)	Latest time of application				
Brassicas (broccoli, Brussels sprouts, cabbage, calabrese, cauliflower and kale)	2.8	1	Prior to drilling or transplanting				
Winter oilseed rape	2.5	1	Pre-emergence of the crop				
OTHER SPECIFIC RESTRICTIO Do not apply via hand-held eq	••						

READ THE LABEL BEFORE USE. USING THIS PRODUCT IN A MANNER THAT IS INCONSISTENT WITH THE LABEL MAY BE AN OFFENCE. FOLLOW THE CODE OF PRACTICE FOR USING PLANT PROTECTION PRODUCTS

SAFETY PRECAUTIONS

OPERATOR PROTECTION

Engineering control of operator exposure must be used where reasonably practicable in addition to the following personal protective equipment:
Wear suitable protective gloves when handling the concentrate or handling contaminated surfaces.
However, engineering controls may replace personal protective equipment if a COSHH assessment shows they provide an equal or higher standard of protection. Wash hands and exposed skin before eating and drinking and after work.

When using do not eat, drink or smoke.

ENVIRONMENTAL PROTECTION

To protect aquatic organisms respect an unsprayed buffer zone to surface water bodies in line with LERAP requirements.

DO NOT ALLOW DIRECT SPRAY from horizontal boom sprayers to fall within 5 m of the top of the bank of a static or flowing water body, unless a Local Environment Risk Assessment for Pesticides (LERAP) permits a narrower buffer zone, or within 1 m of the top of a ditch which is dry at the time of application. Aim spray away from water.

This product qualifies for inclusion within the Local Environment Risk Assessment for Pesticides (LERAP) scheme. Before each spraying operation from a horizontal boom sprayer, either a LERAP must be carried out in accordance with CRD's published guidance or the statutory buffer zone must be maintained. The results of the LERAP must be recorded and kept available for three years.

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.

STORAGE AND DISPOSAL

Keep out of reach of children.

Keep away from food, drink and animal feeding stuffs. Do not re-use container for any purpose.

Keep in original container tightly closed in a safe place. Rinse container thoroughly by using an integrated pressure rinsing device or manually rinsing three times. Add washings to sprayer at time of filling and dispose of container safely.

COLZAMID[®] MAPP 17967

DIRECTIONS FOR USE

IMPORTANT: This information is authorised as part of the Product Label. All instructions within this section must be read carefully in order to obtain safe and successful use of this product.

RESTRICTIONS/WARNINGS

- 1. Weed control may be reduced where the spray is mixed too deeply into the soil.
- 2. Do not treat crops adversely affected by poor soil, adverse weather or cultural conditions.
- 3. Avoid spray overlap, particularly on headlands.
- 4. Incorporation under wet conditions is not satisfactory.
- 5. Surface manure, straw, moss or other organic detritus may reduce weed control. Soil cultivations after spraying should be avoided.
- 6. COLZAMID can be used on a wide range of soils but should not be applied to Sands (as defined by the ADAS '85 System) or to soils with more than 10% organic matter.
- 7. It is important to ensure that the seedbed is free from clods and weeds and is in good tilth.

CROP SPECIFIC INFORMATION

BRASSICAS

- COLZAMID may be sprayed prior to transplanting broccoli, Brussels sprouts, cabbage, calabrese, cauliflower, or kale.
- Apply COLZAMID at 2.8 litres/ha as a MEDIUM or COARSE spray in 200-400 litres water/ha.
- To maximise efficacy, COLZAMID should be incorporated to a depth of 50 mm prior to transplanting. Incorporation MUST OCCUR within 30 minutes of application.
- COLZAMID is not recommended for use in plant raising beds.
- Spring Planted Brassicas: Spring tine harrows (triple-K type), tandem disc harrows, power driven reciprocating harrows, the Lely Roterra and rotary cultivator with L-shaped blades are all suitable for incorporation. Make one pass with a rotary cultivator, but two passes, with the second at an angle to the first, are recommended for any other type of harrow. When non-powered harrows are used, a high forward speed of at least 8 kph

- (5 mph) is required to obtain thorough incorporation.
- A slow forward speed of 5 kph (3 mph) is recommended for the Lely Roterra and for rotary cultivators in combination with a high rotor speed.
- Summer Planted Brassicas: i.e. those usually planted during July and August, e.g. winter broccoli: Application should be made during the later stages of seedbed preparation and using a light set of harrows to blend the spray into the top 25 mm of soil. With this implement a high forward speed of at least 8 kph (5 mph) is required and two passes are recommended to obtain thorough mixing, the second pass being at an angle to the first.

Sequential Programme

COLZAMID should be sprayed and incorporated into the soil prior to drilling or transplanting a brassica crop. Incorporation MUST OCCUR on the SAME DAY as application.

A follow up treatment of an approved formulation of an alternative product may be applied after drilling or transplanting according to the manufacturers recommended rate.

> **COLZAMID® MAPP 17967**

2

Date: 2021-04-28

Colzamid Alone, Weeds Controlled

Susceptible (S)	Moderately Susceptible (MS)	Moderately Resistant (MR)	Resistant (R)
Amaranth species Annual meadow grass Common barnyard grass Common chickweed Common purslane Mayweed species	Annual nettle Black bindweed Cleavers Common field speedwell Common groundsel Fat hen Knotgrass Shepherd's-purse	Field pennycress	Corn speedwell Common fumitory Redshank

3

Timing

COLZAMID may be applied pre-drilling and incorporated in a tank mixture with approved formulations or alone as a pre-emergent spray.

WINTER OILSEED RAPE

- Apply COLZAMID at 2.5 litres/ha.
- Use a medium-coarse spray (as defined by BCPC) in 200-550 litres of water/ha at a spray pressure of 2-3 bar.
- COLZAMID may be applied and incorporated into the soil before drilling the crop (incorporation MUST OCCUR within 30 minutes of application) or post-drilling, pre-emergence of the crop.
- Where volunteer cereals are a problem, an additional post-emergence spray of an alternative product may be made according to the manufacturer's recommendations.
- Conventional seedbed preparation: Apply during the later stages of seedbed preparation. Use only a light set of harrows to incorporate the herbicides in the top 25 mm of soil.
- With this implement a high forward speed of at least 8 km/h (5 mph) is required and two passes are recommended, with the second at an angle to the first. Drilling may be carried out immediately or within 14 days of application. Alternatively, a drill fitted with light harrows will provide a second pass during drilling. In this case the direction of sowing should be at an angle to the first pass and should be completed within 48 hours of application.

- Minimum cultivation: May be sprayed directly onto the stubble and incorporated into the top 25 mm of soil as part of the surface cultivations. Tandem discs, spring tine harrows or similar non-powered harrows are suitable implements. Where surface cultivations have been completed before application, use only light tine harrows to incorporate the herbicides.
- In dry conditions better weed control may be achieved where the product is incorporated into the soil. Ideally the soil should be moist at application and there should be rainfall afterwards.

COLZAMID® MAPP 17967

Applicant: UPL Europe Ltd.

Napropamide 450 g/L SC (HAR01) (COLZAMID) Page 29 of 29

 $Appendix \ 3-Letter(s) \ of \ Access$

Not applicable.