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Napropamide-M

Volume 3 – B.3 (PPP) – D-Devrinol

Rapporteur Member State: United Kingdom

Version History

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B.3. DATA ON APPLICATION AND EFFICACY

Volume 3 – B.3 (PPP) – D-Devrinol has been included by the Rapporteur Member State based on the information submitted by the applicant at Document M-CP, Section 6 and proposed label for all zones for 'HBW03'.

HBW03/D-Devrinol containing 450g/l Napropamide-M was used in a series of both crop safety and efficacy preliminary trials on the representative crop winter oilseed rape (2008-2010). The dose rate used in these early trials was 1.6L/ha (0.72kg/ha) and is 6% below the intended use rate of 1.7L/ha (0.765kg/ha).

More recent trials (2013-2016) have been conducted using the representative formulation HBW03 (a suspension concentrate formulation containing 450g/l Napropamide-M). A Biological Assessment Dossier supporting all the intended uses of HBW03 will be submitted in due course to allow a detailed zonal assessment of the efficacy package in compliance with the plant protection product data requirements of Commission Regulation (EU) 545/2011 and according to the Uniform Principles (Commission Regulation (EU) 546/2011).

B.3.1. FIELD OF USE ENVISAGED

The representative field of use for Napropamide-M is as a pre-planting/pre-sowing (with or without incorporation) or post-sowing, crop pre-emergence (without incorporation) herbicide in winter oilseed rape and vegetable brassicas.

B.3.2. EFFECTS ON HARMFUL ORGANISMS

B 3.2.1 Napropamide-M acts as a pre-planting/pre-sowing (with or without incorporation) or post-sowing, crop pre-emergence (without incorporation) agricultural/horticultural herbicide. It has activity on both monocotyledonous and dicotyledonous weeds in a range of broad-leaved crops and works by root uptake with acropetal translocation and selective, systemic activity. Napropamide-M is efficacious when incorporated into the soil pre-weed emergence. It is taken up by the root and translocated in the apoplast where it inhibits root growth and development by inhibiting cell division. It additionally interferes with germination processes, therefore killing seedlings

B 3.2.2 Mode of action

Napropamide-M is an acetamide which interferes with nucleic acid synthesis and thereby affects protein synthesis.

B.3.3. DETAILS OF INTENDED USE

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Winter oilseed rape	All zones	HBW03	F	Annual grasses and broad-leaved weeds	SC	450 g/L	Broadcast soil spray and incorporation	Pre-sowing, summer-autumn	1	na	0.255-0.3825	200-300	0.765	na	
Winter oilseed rape	All zones	HBW03	F	Annual grasses and broad-leaved weeds	SC	450 g/L	Broadcast soil spray only, no incorporation	Pre-sowing, summer-autumn	1	na	0.255-0.3825	200-300	0.765	na	
Brassica vegetable crops	All zones	HBW03	F	Annual grasses and broad-leaved weeds	SC	450 g/L	Broadcast soil spray and incorporation	Pre-planting / pre-sowing, spring-summer	1	na	0.1275-0.3825	200-600	0.765	na	Treatment is made to soil prior to sowing or transplanting of crops
Brassica vegetable crops	All zones	HBW03	F	Annual grasses and broad-leaved weeds	SC	450 g/L	Broadcast soil spray only, no incorporation	Pre-planting / pre-sowing, spring-summer	1	na	0.1275-0.3825	200-600	0.765	na	Treatment is made to soil prior to sowing or transplanting of crops
Winter oilseed rape	All zones	HBW03	F	Annual grasses and broad-leaved weeds	SC	450 g/L	Broadcast soil spray only, no incorporation	Post-sowing, pre-emergence / BBCH 00-08, summer-autumn	1	na	0.255-0.3825	200-300	0.765	na	
Brassica vegetable crops	All zones	HBW03	F	Annual grasses and broad-leaved weeds	SC	450 g/L	Broadcast soil spray only, no incorporation	Post-sowing, pre-emergence / BBCH 00-08, spring-summer	1	na	0.1275-0.3825	200-600	0.765	na	Treatment is made to soil post-sowing but not post-transplanting of crops

<p>(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>	<p>(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).</p> <p>(j) Growth stage range from first to 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</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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Note: Brassica vegetable crops covered by the GAP include (According to Commission Regulation (EU) No 212/2013 of 11 March 2013 replacing Annex I to Regulation (EC) No 396/2005): Broccoli (calabrese, Broccoli raab, Chinese broccoli), cauliflower, brussels sprout, Head cabbage (pointed head cabbage, red cabbage, savoy cabbage, white cabbage) Chinese cabbage (Indian or Chinese) mustard, pak choi, Chinese flat cabbage/ai goo choi), choy sum, Peking cabbage/pe-tsa) kale (Borecole/curly kale, collards, Portuguese Kale, Portuguese cabbage, cow cabbage) and kohlrabi. ***Note the kale, chinese cabbage and kohlrabi uses are not currently supported by residue data.**

B.3.4. APPLICATION RATE AND CONCENTRATION OF THE ACTIVE SUBSTANCE

Winter oilseed rape: a maximum of one application (either pre- or post-sowing, pre-emergence/BBCH 00-08) at 0.765 kg Napropamide-M per hectare, equivalent to one application of 1.7 Litres D-Devrinol per hectare. The concentration range of the active substance in the applied spray is 2.6 – 3.8 g/L Napropamide-M (see CP 3.3).

Brassica vegetable crops: a maximum of one application (either pre-planting/sowing or Post-sowing, pre-emergence/BBCH 00-08) at 0.765 kg Napropamide-M per hectare, equivalent to one application of 1.7 Litres D-Devrinol per hectare. The concentration range of the active substance in the applied spray is 1.3 – 3.8 g/L Napropamide-M (see CP 3.3).

B.3.5. METHOD OF APPLICATION

The product is applied as a broadcast soil spray using tractor mounted boom sprayer with or without incorporation. The label submitted indicates a water volume of 200-600 litres water/ha with applications made as a MEDIUM or COARSE spray. This covers the range of water volumes in the GAP table.

B.3.6. NUMBER AND TIMING OF APPLICATIONS AND DURATION OF PROTECTION**Maximum number of applications and their timings:**Winter oilseed rape

One application of D-Devrinol can be made to the soil, with or without incorporation during summer and autumn. No pre-harvest interval is necessary.

Brassica vegetable crops

One application of D-Devrinol can be made to the soil, with or without incorporation during spring and summer. No pre-harvest interval is necessary.

Growth stages of crops or plants to be protected:Winter oilseed rape

Applications of D-Devrinol can be made to the soil either pre- or post-sowing and pre-emergence of the crop (BBCH 00-08).

Brassica vegetable crops

Applications of D-Devrinol can be made to the soil either pre-planting/sowing or post-sowing and pre-emergence of the crop (BBCH 00-08).

Development stages of the harmful organism concerned:

Napropamide-M is a herbicide used to prevent the germination and establishment of a range of mono- and dicotyledonous weeds in cultivated ground and must therefore be applied pre-emergence of weeds. The active substance and method of application is not effective against weeds that are already established.

Duration of protection afforded by the maximum number of applications:

Weed suppression is achieved during the establishment of the crop. Only one application is permitted.

B.3.7. NECESSARY WAITING PERIODS OR OTHER PRECAUTIONS TO AVOID PHYTOTOXIC EFFECTS ON SUCCEEDING CROPS

See B.3.12

B.3.8. PROPOSED INSTRUCTIONS FOR USE

Instructions for use are provided on the product label.

Proposed instructions for use will be present on National labels. Text of the label submitted by the applicant for the product 'HBW03' is as follows [Note it does include some UK label phrases which may need to be adapted at product authorisation stage]. :

DIRECTIONS FOR USE

HBW03 is a pre-emergence herbicide for the control of annual grass and broad-leaved weeds in brassica vegetable and winter oilseed rape crops.

Resistance

Strains of some annual grasses, e.g. black-grass, wild-oats, and Italian rye-grass, have developed resistance to herbicides, which may lead to poor control. A strategy for preventing and managing such resistance should be adopted. Guidelines have been produced by the Weed Resistance Action Group and copies are available from your distributor, crop adviser or product manufacturer.

Restrictions

All Crops:

- If incorporated, weed control may be reduced where the spray is mixed too deeply into the soil.*
- Do not treat crops adversely affected by poor soil, adverse weather or cultural conditions. AVOID SPRAY OVERLAP, PARTICULARLY ON HEADLANDS.*
- Incorporation under wet conditions is not satisfactory. (not clear. Do we mean 'Avoid incorporation when soils conditions are wet'?)*
- Surface manure, straw, moss or other significant organic matter may reduce weed control.*
- Soil cultivations and disturbance should be avoided after spraying.*
- HBW03 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.*

Treatment of crops

Brassica vegetable crops

Application to soil prior to transplanting:

- Apply HBW03 at 1.7 litres/ha as a MEDIUM or COARSE spray in 200-600 litres water/ha.*
- Where incorporation is planned and to maximise efficacy, HBW03 should be incorporated to a depth of 50 mm prior to transplanting. Incorporation should occur within 24 hours of application.*
- HBW03 is not recommended for use in plant raising beds.*
- Spring Planted Brassicas: Spring tine harrows, tandem disc harrows, power driven reciprocating harrows and rotary cultivator with L-shaped blades are all suitable for incorporation. Consult manufacturers guidelines for use to ensure thorough incorporation.*
- Summer Planted Brassicas: i.e. those usually planted during July and August: 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.*

Application to soil prior to sowing or early post-sowing (pre-emergence):

- Apply HBW03 at 1.7 litres/ha as a MEDIUM or COARSE spray in 200-600 litres water/ha.*
- HBW03 may be applied onto the soil before or after drilling the crop, with or without incorporation or post-drilling, pre-emergence of the crop, without incorporation.*
- Where no incorporation is planned, or before or after drilling of the seed, apply directly to the soil surface using a conventional broadcast sprayer. Seeds should be drilled to a minimum 50 mm depth and seedbeds must have a fine, firm tilth. Unconsolidated clods (especially if larger than 75 mm diameter) may reduce the level of control and cause seed to be inadequately covered, which could result in crop damage.*
- Where incorporation is planned, incorporation should occur within 24 hours of application. Either conventional or minimum cultivation methods of cultivation may be used as follows.*
- 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 (if burnt, allow 24 hours before spraying) 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.*

Winter oilseed rape crops

Application to soil prior to sowing or early post-sowing (pre-emergence) of crops:

- *Apply HBW03 at 1.7 litres/ha as a MEDIUM or COARSE spray in 200-300 litres water/ha.*
- *HBW03 may be applied onto the soil before or after drilling the crop, with or without incorporation or post-drilling, pre-emergence of the crop, without incorporation.*
- *Where no incorporation is planned, or before or after drilling of the seed, apply directly to the soil surface using a conventional broadcast sprayer. Seeds should be drilled to a minimum 10 mm depth and seedbeds must have a fine, firm tilth. Unconsolidated clods (especially if larger than 75 mm diameter) may reduce the level of control and cause seed to be inadequately covered, which could result in crop damage.*
- *Where incorporation is planned, incorporation should occur within 24 hours of application.. Either conventional or minimum cultivation methods of cultivation may be used as follows.*
- *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 (if burnt, allow 24 hours before spraying) 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.*

Weeds controlled

A range of annual grass and broad-leaved weeds.

Following crops

Only supported uses, including brassica vegetable crops and winter oilseed rape, may be drilled/transplanted as following crops. Crops may be drilled only in the following planting season of the next calendar year.

MIXING AND APPLICATION

- *Half fill the tank with water and begin agitation. Add the required quantity of HBW03 to the sprayer using a filling device (e.g. induction bowl, probe etc) or otherwise by direct addition to the spray tank. Wash out container thoroughly, adding washings to the sprayer, preferably using an integrated pressure-rinsing device where available, otherwise manually rinse at least three times.*
- *For all tank mixes, follow the procedure above except add HBW03 to the tank first. Continue agitation during spraying.*
- *Wash out sprayer thoroughly after use.*

COMPATIBILITY

Please refer to the UPL Europe Limited website for further information, (www.upleurope.com).

B.3.9. EFFECTIVENESS

The proposed label does not include individual weed species but rather a general statement regarding the control of annual grass and broadleaved weeds. In document M-CP, Section 6 the weeds controlled are stated as Cleavers (GALAP), Common poppy (PAPRH), Fat hen (CHEAL), Mayweeds (MATSS), Speedwells (VERSS), Blackgrass (ALOMY) and Loose silky bent (APESV).

Effectiveness was assessed in 46 trials conducted in winter oilseed from 2008 to 2010. The trials were undertaken by Officially Recognised Organisations, all of which follow EPPO guidelines and full details can be found in Table 7 of Document M-CP Section 6 along with details of the trial locations (Member State, EPPO Climatic zone and EU Regulatory zone) and the standard reference products used (Table 8). Trials were conducted in Germany (2), Northern France (5), Southern France (4), UK (2), Poland (10), Spain (12), Italy (10) and Greece (1). Therefore trials were conducted in the Maritime, North East and Mediterranean EPPO zones.

No effectiveness data are available from use in vegetable brassicas. However the uses are identical in terms of dose rate and method of application and therefore within the risk envelope. Further consideration of the scope to extrapolate from oilseed rape to vegetable brassicas will need to be considered by MS at product authorisation. For example it may be possible to cite the guidance provided by EPPO on extrapolations at https://www.eppo.int/PPPRODUCTS/minor_uses/minor_uses.htm.

The overall results from these effectiveness trials on winter oilseed rape are presented in Table 9 of Document M-CP Section 6 and are reproduced below;

Summary data showing effectiveness of napropamide-M applied as a pre-drilling incorporated and pre-emergence herbicide on winter oilseed rape using the formulation d-Devrinol, split by EU Regulatory zone: Field trials 2008, 2009 and 2010

Crop	Target	Application method	Applications	Species (EPPO Code)	EU Regulatory zone	No. trials (No. years)	Untreated	Control (%)		
								0.36 kg/ha 0.8L/ha (0.47N)	0.54-0.63kg/ha 1.2-1.4L/ha (0.71-0.82N)	0.72kg/ha 1.6L/ha (0.94N)
Winter oilseed rape	Annual grasses and broad-leaved weeds	Broadcast soil spray and incorporation	1	CHEAL	CEU	3 (2) 2 (1)	2.1% GC 2% GC	- 87	59.7 (88.4)	79.8 (93)
					SEU	1	4% GC	-	-	63.8
				GALAP	CEU	4 (2) 3 (1)	2.5% GC 2.5% GC	- 63.6	71 (66.1)	78.3 (71)
					SEU	9 (2) 2 (1)	39.1/m ² * 18.8/m ²	- 36.6	- 45.6	76.6 (58.6)
				MATSS	CEU	2 (1)	27.3% GC	-	57.1	87.4
					SEU	2 (2) 1	16% GC 30% GC	-	- 65.9	75.7 (71.3)
				PAPRH	CEU	1	2.5% GC	-	100	100
					SEU	14 (3) 2 (1)	37.7/m ² * 7.4/m ²	- 91.5	- 96.5	90.6 (97.9)
				VERSS	CEU	2 (1)	14.1% GC	-	85.5	93.7
					SEU	13 (2) 4 (1)	10.5% GC 11.3% GC	- 58.7	- 76	85.1 (85.2)
				ALOMY	SEU	6 (2) 2 (1)	123.2/m ² * 25.3/m ²	- 57	- 72	91.2 (81.2)
				APESV	CEU	3 (2) 1	6.9% GC 2% GC	- 67.6	78.9 (67.6)	85.3 (76.6)

Crop	Target	Application method	Applications	Species (EPPO Code)	EU Regulatory zone	No. trials (No. years)	Untreated	Control (%)		
								0.36 kg/ha 0.8L/ha (0.47N)	0.54-0.63kg/ha 1.2-1.4L/ha (0.71-0.82N)	0.72kg/ha 1.6L/ha (0.94N)
Winter oilseed rape	Annual grasses and broad-leaved weeds	Broadcast soil spray only, no incorporation	1	CHEAL	CEU	3 (2) 2 (1)	2.1% GC 2% GC	- 86.2	- 90.7	60.4 (90.6)
					SEU	1	4% GC	-	-	91.3
				GALAP	CEU	4 (2) 3 (1)	2.5% GC 2.5% GC	- 67.4	- 68.1	79.2 (72.5)
					SEU	8 (2) 2 (1)	39.9/m ² * 18.8m ²	- 30.2	- 38.4	64.5 (56.9)
				MATSS	CEU	2 (1)	27.3% GC	-	-	91.7
					SEU	2 (2)	16% GC	-	-	67.4
				PAPRH	CEU	1	2.5% GC	-	-	90
					SEU	13 (3) 2 (1)	38.5/m ² * 7.4/m ²	- 90.1	- 91.5	92.2 (97.2)
				VERSS	CEU	2 (1)	14.1% GC	-	-	84
					SEU	13 (2) 4 (1)	10.5% GC 11.3% GC	- 56.8	- 67.5	76.3 (78.3)
				ALOMY	SEU	6 (2) 2 (1)	123.2/m ² * 25.3/m ²	- 57.9	- 77.3	85.3 (80.8)
				APESV	CEU	3 (2) 1	6.9% GC 2% GC	- 70.3	- 74.8	92.4 (80.2)

* Includes 4 trials where weeds were sown (artificial populations). Upper figures are for all trials, lower figures in italics show dose response across the same trials where all 3 doses were included.

% control taken from last assessment point in the trials (49-252 days after application) where weeds number were >2% ground cover (GC) or >5 plants/m²

The results shown are based on good populations (> 2% ground cover or >5 plants/m² at assessment) of five common annual broad-leaved weeds; *Chenopodium album* (CHEAL), *Galium aparine* (GALAP), *Matricaria species* (MATSS), *Papaver rhoeas* (PAPRH) and *Veronica species* (VERSS) plus two annual grass weeds; *Alopecurus myosuroides* (ALOMY) and *Apera spica-venti* (APESV), which are found widely across Europe.

The dose used in these trials was 1.6L/ha (0.72kg a.s./ha) and is 6% below the intended use rate of 1.7L/ha (0.765kg a.s./ha). This difference is not considered significant in relation to demonstrating the effectiveness of the proposed dose.

A number of trials included results at lower doses of 0.8L/ha (0.36kg a.s./ha) and 1.2-1.4 L/ha (0.54-0.63 kg a.s./ha) and the data (results in italics) show a clear dose response with the highest dose (0.72 kg a.s./ha) consistently giving the highest levels of control for all weed species. The results show that generally ALOMY, APESV and PAPRH are susceptible, whilst CHEAL, MATSS, GALAP and VERSS were susceptible/moderately susceptible, with some variations between the zones and application timings. Note, however that no trials on ALOMY were conducted in the Central zone and control may vary from that in the Southern zone. In addition for product authorisation additional results will be required in line with EPPO PP1/226 'Number of efficacy trials' depending on whether species are major or minor.

When the product was applied without incorporation was a slight drop in effectiveness notably on GALAP and VERSS, but no drop in performance on ALOMY, APESV, PAPRH or MATSS. A number of trials used artificial populations of weeds; effectiveness against field populations will, therefore, be required at product authorisation stage.

Data from 2008-2010 used HBW01, whereas trials conducted since 2013 have used HBW03. Results on effectiveness presented here were generated using HBW01. HBW03 is to be the representative formulation for Napropamide-M. The only difference between the two formulations is a change in anti-foam. NOTE:

SANCO/12638/2011 (20 November 2012 rev. 2) 'Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 of the EU Parliament and Council on placing of plant protection products on the market and repealing

Council Directives 79/117/EEC and 91/414/EEC', states; "If a change in a formulation only consists of exchanging co-formulants for the same amount of chemically equivalent co-formulants, a notification is sufficient". Therefore, this is considered to be a 'minor change' in the formulation.

In addition the product will be soil applied herbicide (with soil activity) and such a change is unlikely to impact on effectiveness or crop safety.

B.3.10. INFORMATION ON THE DEVELOPMENT OF RESISTANCE

Napropamide-M belongs to the chemical family of acetamides which are mitosis inhibitors. The Herbicide Resistance Action Committee (HRAC) classifies the active substance in mode of action group K3 – inhibition of cell division via inhibition of very long chain fatty acid (VLCFA) synthesis. It is the resolved single isomer version of racemic Napropamide which has been established on the market in plant protection products for a number of years.

According to the International Survey of Herbicide Resistant Weeds (<http://weedsociety.org/>) the following cases have been reported to group K3 herbicides;

Weeds Resistant to Long chain fatty acid inhibitors (K3/15) by species and country

#	Species	Country	First Year
1	<i>Alopecurus myosuroides</i> Blackgrass	2007 - Germany *Multiple - 4 SOA's	2007
2	<i>Avena fatua</i> Wild Oat	2015 - Canada (Manitoba) *Multiple - 5 SOA's	2015
3	<i>Echinochloa crus-galli</i> var. <i>crus-galli</i> Barnyardgrass	1993 - China 1998 - Thailand *Multiple - 2 SOA's 2005 - Philippines *Multiple - 2 SOA's	1993
4	<i>Lolium perenne</i> ssp. <i>multiflorum</i> Italian Ryegrass	2005 - United States (Idaho) *Multiple - 3 SOA's	2005
5	<i>Lolium rigidum</i> Rigid Ryegrass	1982 - Australia (South Australia) *Multiple - 7 SOA's 1984 - Australia (South Australia)	1982

Resistance to Group K3 herbicides globally has been reported in 5 weed species. One case has been reported in Europe in ALOMY although this was not resistance specifically to napropamide. This does highlight the importance of submission of effectiveness data on ALOMY in the Maritime zone at product authorisation stage.

Resistance management strategies will be considered at product evaluation stage, and adapted as required by each Member State.

B.3.11. ADVERSE EFFECTS ON TREATED CROPS

The proposed crops are stated as winter oilseed rape (BRSNW), Cabbage (BRSOL), Cauliflower (BRSOB), Brussel sprouts (BRFOF) and Calabrese/Broccoli (BRSOK).

Crop safety was assessed in the 46 effectiveness trials and in 14 specific crop safety trials in winter oilseed rape. Trials were conducted in Germany (2), northern France (1), Southern France (1), UK (2), Poland (4), Spain (2) and Italy (2). Trials included doses up to 2.16 kg/ha (2.8N). Phytotoxicity was recorded in 2 effectiveness trials. In both these trials (S08-02687-04 and OGL-11-8341-FR02), the phytotoxicity reported did not exceed 5%. In the other 58 trials (including all selectivity trials), no phytotoxicity was reported.

No data have been submitted to support use on brassica vegetable crops. However the uses are identical in terms of dose rate and method of application. Further consideration of the scope to extrapolate from oilseed rape to vegetable brassicas will need to be considered by MS at product authorisation. For example it may be possible to cite the guidance provided by EPPO on extrapolations at https://www.eppo.int/PPPRODUCTS/minor_uses/minor_uses.htm.

The overall results from these effectiveness trials on winter oilseed rape are presented in Table 10 of Document M-CP Section 6 and are reproduced below;

Summary data showing the crop safety of napropamide-M applied as a pre-drilling incorporate and pre-emergence herbicide using the formulation d-Devrinol, split by EU Regulatory zone: Field trials over the years 2008, 2009 and 2010

Crop	Target	Application method	Applications	EU Regulatory zone	No. trials	Phytotoxicity observed (%) and Yield (% of untreated)	
						At 0.94N rate (0.72kg/ha)	At higher rate >0.765 kg/ha (multiple of N)
Winter oilseed rape	Annual grasses and broad-leaved weeds	Broadcast soil spray and incorporation	1	CEU	14 (2) efficacy	1 DE efficacy trial (S08-02687-04): 2.5%.	1 DE efficacy trial (S08-02687-04) at 0.90kg/ha: 5.0%
				SEU	30 (3) efficacy	1 nFR efficacy trial (OGL-11-8341-FR02): 3.3% (volume reduction).	None
				CEU	8 (2) selectivity	No phytotoxicity. 98% yield (4 trials)	No phytotoxicity. 102.5% yield at 1.08 kg/ha (4 trials), 106.2% yield at 1.44 kg/ha (4 trials), 107.7% yield at 2.16 kg/ha (4 trials)
				SEU	6 (2) selectivity	No phytotoxicity. 103.3% yield (2 trials)	No phytotoxicity. 103.7% yield at 1.08 kg/ha (3 trials), 103% yield at 1.44 kg/ha (2 trials), 99.2% yield at 2.16 kg/ha (3 trials)
Winter oilseed rape	Annual grasses and broad-leaved weeds	Broadcast soil spray only, no incorporation.	1	CEU	14 (2) efficacy	1 DE efficacy trial (S08-02687-04): 1.25%.	None
				SEU	32 (3) efficacy	1 nFR efficacy trial (OGL-11-8341-FR02): 1.7% (volume reduction).	None
				CEU	8 (2) selectivity	No phytotoxicity. 109.2% yield (4 trials)	No phytotoxicity. 106% yield at 1.08 kg/ha (4 trials), 108% yield at 1.44 kg/ha (4 trials), 110.7% yield at 2.16 kg/ha (4 trials)
				SEU	6 (2) selectivity	No phytotoxicity. 102.4% yield (2 trials)	No phytotoxicity. 108.1% yield at 1.08 kg/ha (3 trials), 96.8% yield at 1.44 kg/ha (2 trials), 107.6% yield at 2.16 kg/ha (3 trials)

The submitted data support crop safety in winter oilseed rape. Further information to support the use of 'HBW03' in terms of crop safety and selectivity will be required and considered at product authorisation.

B.3.12. OBSERVATIONS ON OTHER UNDESIRABLE OR UNINTENDED SIDE-EFFECTS

Succeeding crops:

The following assessment is provided in Document M-CP Section 6 and is reproduced below;

The ecotoxicology section of the Annex II submission (Document M-CP section 10) contains the results from a non-target plant studies: ACE-13-164: D-Devrinol 450 SC- Evaluation of the phytotoxicity to non-target terrestrial plants – seedling emergence test (OECD 208 study). The ER50 (50% Effect Rate) and NOER (No Observed Effect Rate) results for seedling emergence from this study are detailed in Table CP 10.6-1 in section 10 and duplicated below:

Table 1
Summary of effect (reduction in biomass) of d-Devrinol SC on seedling emergence

Test species	Seedling emergence	
	ER ₅₀ g a.s./ha	NOER g a.s./ha
Onion (<i>Allium cepa</i>)	244	90
Oats (<i>Avena sativa</i>)	368	90
Ryegrass (<i>Lolium perenne</i>)	76.6	30
Maize (<i>Zea mays</i>)	321	270
Carrot (<i>Daucus carota</i>)	1776	270
Radish (<i>Raphanus sativus</i>)	>2430	2430
Sugar beet (<i>Beta vulgaris</i>)	>2430	810
Cucumber (<i>Cucumis sativus</i>)	>2430	270
Soybean (<i>Glycine max</i>)	1506	270
Tomato (<i>Lycopersicon esculentum</i>)	>2430	2430

The table above details the ER50 and NOER for each species tested. Table 2 below shows the PEC_{soil} calculated for various periods after application for the proposed uses (1 application of 765 g a.s./ha applied pre-emergence to winter oilseed rape or vegetable brassicas) from Document N (Endpoints).

Table 2
PEC_{soil} (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Days after application	PEC _{soil} (mg/kg)- Actual
Initial	1.02
24 hours	0.9832
2	0.9478
4	0.8807
7	0.7888
28	0.5931
50	0.5674
100	0.5131
180	0.4368
240	0.3871
270	0.3644
365	0.3010
550	0.2074

Note: The information in Document N specified the PECs from Initial to 100 days. For this assessment the PEC values have been further calculated to 550 days.

To consider the risk to succeeding crops both in normal rotation and as replacement for a failed crop, TERs have been calculated in line with EPPO PP1/207 'Effects on succeeding crops' and detailed in Tables 3 and 4. EPPO PP1/207 is based on use of an EC10 and TERs >1 is considered to show that no further testing is required. In the absence of an EC10, the NOER has been used as it is considered to be a more critical endpoint.

For each PEC used (50, 180 and 365 days), 2 sets of TER results are shown; the first represents minimum cultivation using the PECs as detailed in Table 2, as these are calculated based on a soil depth of 5 cm which is in line with minimum cultivation. The second column is the TER after ploughing to 20 cm. The PEC is 25% of the original figure to represent dilution of Napropamide-M residues in 20 cm of soil from ploughing to that depth.

The PEC for 50 days has been used as this is considered to be the minimum time between application and succeeding crops grown in rotation with a vegetable brassica or after a failed oilseed rape crop. The quickest vegetable brassica from planting to harvest would be calabrese/broccoli in around 6 weeks (42 days) in summer and allowing time for soil preparation this would equate to a minimum of 50 days between the application of Napropamide-M and drilling of the succeeding crop. It is considered that around 50 days would also be the minimum period before a decision was taken to replace a failed winter oilseed rape crop with another crop. Replacement with winter oilseed rape crop would not be considered an option, as a delay of 50 days after application to the failed crop (i.e. August) would be outside the window for successful establishment of a winter oilseed rape crop. 180 days represents the minimum period between application to late summer/early autumn treated vegetable brassica crop and a succeeding crop in the following spring. The PEC for 365 days has been used as this is considered to be the earliest another crop would be established following successful harvest of a treated winter oilseed rape crop.

In order to calculate the TER values the NOER values have been converted from 'g a.s./ha' to 'mg a.s./kg of soil' using the following equation (the assumptions made in this conversion are that there is an even distribution of chemical in the top 5cm of soil and an average soil bulk density of 1.5 g/cm, which is in line with the assumptions used to calculate the PECs in Document N):

$$\frac{x \text{ g a.s./ha}}{100 \times 5 \text{ (soil distribution)} \times 1.5 \text{ (bulk density)}} = \text{mg a.s./kg of soil}$$

Table 3
Toxicity/Exposure Ratios (TERs) for Napropamide-M for terrestrial plants at 50 and 180 days after application

Species	NOER (g a.s./ha)	NOER (mg/kg of soil)	PECs 50 days (mg/kg of soil)	TER	Ploughed PECs 50 days (mg/kg of soil)#	TER	PECs 180 days (mg/kg of soil)	TER	Ploughed PECs 180 days (mg/kg of soil)#	TER
Onion (<i>Allium cepa</i>)	90	0.120	0.5674	0.211	0.189	0.846	0.4368	0.275	0.109	1.099
Oats (<i>Avena sativa</i>)	90	0.120		0.211		0.846		0.275		1.099
Ryegrass (<i>Lolium perenne</i>)	30	0.040		0.070		0.282		0.092		0.366
Maize (<i>Zea mays</i>)	270	0.360		0.634		2.538		0.824		3.297
Carrot (<i>Daucus carota</i>)	270	0.360		0.634		2.538		0.824		3.297
Radish (<i>Raphanus sativus</i>)	2430	3.240		5.710		22.841		7.418		29.670
Sugar beet (<i>Beta vulgaris</i>)	810	1.080		1.903		7.614		2.473		9.890
Cucumber (<i>Cucumis sativus</i>)	270	0.360		0.634		2.538		0.824		3.297
Soybean (<i>Glycine max</i>)	270	0.360		0.634		2.538		0.824		3.297

Species	NOER (g a.s./ha)	NOER (mg/kg of soil)	PECs 50 days (mg/kg of soil)	TER	Ploughed PECs 50 days (mg/kg of soil)#	TER	PECs 180 days (mg/kg of soil)	TER	Ploughed PECs 180 days (mg/kg of soil)#	TER
Tomato (<i>Lycopersicon esculentum</i>)	2430	3.240		5.710		22.841		7.418		29.670

Ploughed to 20cm (recommended depth for rotational crops) so PECsoil is reduced to 25% of original in top 20cm.

The results in Table 3 show that 50 days after application, TERs of <1 are found for most species except radish, sugar beet and tomatoes. However, after ploughing to 20 cm only ryegrass, oats and onions have a TER <1. After 180 days and ploughing to 20 cm only ryegrass has a TER of <1. Table 4 showed that even up to 550 days after application, the TER for ryegrass is still <1.

Table 4
Toxicity/Exposure Ratios (TERs) for Napropamide-M for ryegrass at 365 and 550 days after application

Species	NOER (g a.s./ha)	NOER (mg/kg of soil)	PECs 365 days (mg/kg of soil)	TER	Ploughed PECs 365 days (mg/kg of soil)#	TER	PECs 550 days (mg/kg of soil)	TER	Ploughed PECs 550 days (mg/kg of soil)#	TER
Ryegrass (<i>Lolium perenne</i>)	30	0.040	0.301	0.133	0.075	0.532	0.274	0.193	0.052	0.771

*Ploughed to 20cm (recommended depth for rotational crops) so PEC_{soil} is reduced to 25% of original in top 20cm.

Based on these figures and the guidance in EPPO PP1/207, it is considered that further field data will be required to determine the exact restrictions for ryegrass and when it can be sown after application of Napropamide-M to winter oilseed rape or vegetable brassicas (this is currently being generated for submission to support future product authorisation). However, to complete the assessment, it is possible to extrapolate the current data out to 2 years (730 days) after application (and following ploughing), which gives a PECs at 730 days (after ploughing to 20cm) of 0.033 mg/kg soil Napropamide-M. This then provides a TER >1 (i.e. 1.2). Therefore, ryegrass would be safe to plant two years after application of Napropamide-M to either winter oilseed rape or vegetable brassicas.

For other crops it is recommended that the soil should be mould-board ploughed to a depth of 20 cm before planting/sowing of a succeeding or replacement crop. Any crop except onions and cereals can be planted provided a period of 50 days has elapsed since the application. Onions and cereals can be planted after 6 months has elapsed since the application.

The label submitted contains the following wording:

Only supported uses, including brassica vegetable crops and winter oilseed rape, may be drilled/transplanted as following crops. Crops may be drilled only in the following planting season of the next calendar year.

The RMS has concluded that this is supported by the data presented. The details of succeeding crops which may be planted following crop failure and subsequent to a normal harvest will be considered at product evaluation stage.

Adjacent crops

The following assessment is provided in Document M-CP Section 6 and is reproduced below;

The ecotoxicology section of the Annex II submission (Document M-CP section 10) contains the results from 2 non-target plant studies: ACE-13-164: D-Devrinol 450 SC- Evaluation of the phytotoxicity to non-target terrestrial plants – seedling emergence test (OECD 208 study) and ACE-13-165: D-Devrinol 450 SC- Evaluation of the phytotoxicity to non-target terrestrial plants – vegetative vigour test (OECD 227 study). The ER50 (50% Effect Rate) and NOER (No Observed Effect Rate) results for seedling emergence and vegetative vigour from these studies are detailed in Table CP 10.6-1 in section 10 and duplicated in Table below:

Table 5
Summary of effect (reduction in biomass) of d-Devrinol SC on seedling emergence and vegetative vigour

Test species	Seedling emergence		Vegetative vigour	
	ER ₅₀ g a.s./ha	NOER g a.s./ha	ER ₅₀ g a.s./ha	NOER g a.s./ha
Onion (<i>Allium cepa</i>)	244	90	1631	270
Oats (<i>Avena sativa</i>)	368	90	521	90
Ryegrass (<i>Lolium perenne</i>)	76.6	30	1159	270
Maize (<i>Zea mays</i>)	321	270	1408	270
Carrot (<i>Daucus carota</i>)	1776	270	>2430	2430
Radish (<i>Raphanus sativus</i>)	>2430	2430	>2430	2430
Sugar beet (<i>Beta vulgaris</i>)	>2430	810	>2430	2430
Cucumber (<i>Cucumis sativus</i>)	>2430	270	>2430	810
Soybean (<i>Glycine max</i>)	1506	270	>2430	90
Tomato (<i>Lycopersicon esculentum</i>)	>2430	2430	>2430	810

From Table 5 it can be seen that Ryegrass (*Lolium perenne*) is the most sensitive species for seedling emergence (ER₅₀ of 76.6 g a.s./ha) and that Oats (*Avena sativa*) is the most sensitive species for post-emergence applications (ER₅₀ of 521 g a.s./ha).

The proposed uses are on winter oilseed rape and brassica vegetable crops for a maximum of one application (pre-sowing/planting/emergence/BBCH 00-08) at 765 g Napropamide-M/ha (1.7 Litres D-Devrinol per hectare) applied using a tractor mounted boom sprayer.

Using spray drift figures from Rautmann et al (2001)¹ [as provided in the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002)] of 2.77% for 1m and 0.57% for 5m for arable crops such as winter oilseed rape and vegetable crops <50 cm height (such as vegetable brassicas- pre-sowing/planting/emergence), it can be considered that the amount of active substance expected to reach adjacent crops is 21.19 g a.s./ha (2.77% of the 765 g a.s./ha dose applied to the target crop) for those 1 m away and 4.36 g a.s./ha for those 5 m away (0.57% of the 765 g a.s./ha dose applied to the target crop).

Based on the figures for spray drift to adjacent crops at 1m being the worst case scenario and using the ER₅₀ for the most sensitive species of oats from the vegetative vigour and ryegrass for pre-emergence studies, the following TERs for adjacent crops can be calculated:

Table 6
TER values for effects of napropamide-M on adjacent crops

Effect	Application rate (g a.s./ha)	Distance (m)	Toxicity endpoint ER ₅₀ (g a.s./ha)	Exposure at 1m (g a.s./ha)	TER	Trigger TER
Seedling emergence (Ryegrass)	765	1	76.6	21.19	3.6	>1
Vegetative vigour (Oats)			521	21.19	24.6	

In EPPO PP1/256 'Effects on adjacent crops', the threshold TER is >1 to negate the requirement for further testing or label restrictions, based on use of an ED₅₀, which can be considered equivalent to an ER₅₀. The above results show that the proposed dose rate of 765 g Napropamide-M will be within acceptable parameters for all adjacent crops. It is therefore considered that Napropamide-M can be authorised for use on the proposed crops without any restrictions relating to adjacent crops.

The RMS has concluded that the risk to adjacent crops is addressed by the data presented.

B.3.13. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
CP 3.0	Anonymous	2015	Document M-CP Section 6	N	Y		UPL	None

Summary

This application for this new active has been assessed in line with SANCO/10054/2013 (11.7.13). At least one representative formulation is proposed and a GAP with the maximum field rate and a summary of effectiveness and crop safety was provided. Data were provided to the appropriate EPPO standards, and GEP certificates are available and will be further examined at the product authorisation stage. It is considered that the data provided here are sufficient to establish that the active substance is sufficiently effective and has no unacceptable effects on the plants or their yield. In line with SANCO/10054/2013, there is no requirement for a biological assessment dossier (BAD) or individual trials reports to be provided at this stage, since a full data package for efficacy will be provided at product authorisation. Here sufficient information has been provided summarising the data available to establish that the proposed GAP is realistic and fulfils the need of a risk envelope and establishes that the proposed formulation is sufficiently effective (subject to detailed evaluation at the product stage).

On the basis of the information provided it is concluded that Napropamide-M (formulated as 'HBW03') complies with the efficacy requirements for a new active laid out in SANCO/10054/2013. No further information is required at this stage.