

## **REGISTRATION REPORT**

### **Part A**

### **Risk Management**

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

**Product name: DEVRI~~N~~OL F**

**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: 2021/08/31 (Decision)**

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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 DEVIRINOL F (product code: Napropamide 450 g/L SC (HAR01); marketing authorisation n° 2070133), containing 450 g/L napropamide, for use as a herbicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to DEVIRINOL F (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 DEVIRINOL F (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 DEVIRINOL F (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 DEVIRINOL F (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 substances<sup>1</sup>.

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,

<sup>1</sup> 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-naphthoxy)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 3 29 June 2017).

### 1.3 Regulatory approach

The present application (2014-2917 and 2020-0370)<sup>2</sup> 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”)<sup>3</sup> – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4 May 2017<sup>4</sup> 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 1107/2009<sup>5</sup>, implementing regulations, and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011<sup>6</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 12 April 2021<sup>7</sup> 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

<sup>2</sup> A request for a minor formulation change (2018-2917) was also evaluated.

<sup>3</sup> 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

<sup>4</sup> 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, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

<sup>5</sup> 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

<sup>6</sup> 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

<sup>7</sup> <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

“reference” crops to “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation<sup>8</sup> 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 DEVRI<sup>N</sup>OL F (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.

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<sup>8</sup> 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

<b>Product name (code)</b>	DEVIRINOL F (Napropamide 450 g/L SC (HAR01)).
<b>Authorisation number</b>	2070133.
<b>Function</b>	Herbicide.
<b>Applicant</b>	UPL Europe Ltd.
<b>Composition</b>	450 g/L napropamide.
<b>Formulation type (code)</b>	Suspension concentrate (SC)
<b>Packaging</b>	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

<b>Physical hazards</b>	-	
<b>Health hazards</b>	-	
<b>Environmental hazards</b>	Hazardous to the aquatic environment, Chronic Hazard, Category 2.	
<b>Hazard pictograms</b>		
<b>Signal word</b>	-	
	H411	Toxic to aquatic life with long-lasting effects.
<b>Precautionary statements –</b>	<i>For the P phrases, refer to the extant legislation</i>	
<b>Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)</b>	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 surface water/Avoid contamination via drains from farmyards and roads.
SPe 2	To protect groundwater, this product should not be applied around stone fruit and pome fruits between June and December.

SPe 2	To protect groundwater, this product must only be applied around grape vines between February and May.
SPe 3	To protect non-target plants, respect an unsprayed buffer zone of 5 metres to non-agricultural land.
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 20 m meters <sup>9</sup> with an unsprayed vegetated buffer zone of 20 meters to surface water bodies for uses on stone fruit trees, pome fruit trees and grape vines (application not localised on the row).
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 20 m meters with an unsprayed vegetated buffer zone of 5 meters to surface water bodies for uses on medicinal and aromatic herbs, spices and flavourings plants.
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 5 m meters to surface water bodies for uses grape vines (application on the row)
SPe 2	To protect aquatic organisms do not apply to artificially drained soils for uses on stone fruit trees pome fruit trees and grape vines.
SPe 2	To protect aquatic organisms do not discharge waste water from soil-less greenhouses directly into surface water for uses on non-edible medicinal and flavourings plants..
Spe 2	To protect aquatic organisms, the product must not be applied on more than 50 % of the soil surface for uses on grape vine (application on the row).

### 2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment <sup>10</sup> : refer to the Decision in Appendix 1 for the details
Re-entry period <sup>11</sup> : six hours
Pre-harvest interval <sup>12</sup> Stone fruit trees, apple trees (not medlar and cherry) : F - Application must be made at growth stage BBCH 59 at the latest. Herbs : F- Application must be made at growth stage BBCH 09 at the latest or before transplanting Table grapes : F- Application must be made at growth stage BBCH 09
Other mitigation measures: - Do not store the product at temperatures above 40 °C. - Shake well before use. - An interval of 60 days must be observed before sowing/planting as succeeding or replacement crop : cereals, oilseeds and leafy vegetables group. An interval of 180 days must be observed before sowing/planting as succeeding or replacement crop : other types of crops. - By-products of non-edible medicinal flavourings plants 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.

<sup>9</sup> 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.

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

<sup>11</sup> 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], modified by the French Order of 27 December 2019

<sup>12</sup> According to the French Order of 4 May 2017 modified by the French Order of 27 December 2019, 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” or “not finalised”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

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

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

GAP rev. , date: 2021/08/31

PPP (product name/code) **DEVIRINOL F/(Napropamide 450 g/L SC (HAR01))**  
active substance I **napropamide**  
Applicant: **UPL Europe Ltd.**  
Zone(s): **southern**  
Verified by MS: **yes**

Formulation type: **SC**  
Conc. of a.s. I: **450 g/L**  
professional use   
non-professional use

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha
					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		
9	France	Pome and stone fruit trees (apple, pear, quince, japanese peer, peach, apricot, plum, jujube, nectarine)	F	Annual grasses & broad- leaved weeds (BLW)	Spraying on soil / Spraying on soil followed by incorporation	Jan- May Before BBCH 59	a)1 b)1	a) 9.0 a) 9.0	a) 4050 b) 4050	150- 300	F	<b>Acceptable</b>
16	France	Grape vines (young plants)	F	Annual grasses & BLW	Spraying on soil / Spraying on soil followed by incorporation	Feb - May Before BBCH 59	a)1 b)1	a) 9.0 b) 9.0	a) 4050 b) 4050	200- 300	Not applicable	<b>Acceptable</b>
16	France	Grape vines (installed crops)	F	Annual grasses & BLW	Spraying on soil / Spraying on soil followed by incorporation	Feb - May BBCH 00-09	a)1 b)1	a) 9.0 b) 9.0	a) 4050 b) 4050	200- 300	Not applicable on rootstock mother vine  F on table grape	<b>Acceptable only on rootstock mother vine (application not localised on the row)) and table grape (application on the row)</b>  <b>Not acceptable on wine grape (MLR)</b>



1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha
					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		
59	France	Non edible Medicinal and and flavourings plants	F	Annual grasses & BLW	Spraying on soil / Spraying on soil followed by incorporation	Between BBCH 00 and BBCH 09	a)1 b)1	a) 2.5 b) 2.5	a) 1125 b) 1125	200- 400	Not applicable	<b>Acceptable (non edible)</b>
59	France	Medicinal and aromatic herbs, spices and flavourings	F	Annual grasses & BLW	Spraying on soil / Spraying on soil followed by incorporation	Between BBCH 00 and BBCH 09	a)1 b)1	<del>a) 2.5</del> <del>b) 2.5</del>  <b>a) 1,8</b> <b>b) 1,8</b>	<del>a) 1125</del> <del>b) 1125</del>  <b>a) 810</b> <b>b) 810</b>	200- 400	F	<b>Acceptable (edible)</b>

**Remarks:**

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

- (i) g/kg or g/l
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (k) The minimum and maximum number of application possible under practical conditions of use must be provided
- (l) PHI - minimum pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/restrictions

### 3 RISK MANAGEMENT

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

##### 3.1.1 Physical and chemical properties

Commercial packaging:

Bottle of 1 L made of PET.

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

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

		450 g/L	22.5 g/L	0.9 g/L
	<i>In vitro</i> (human) %	0.7	6.5	13.4
		Concentrate (used in formulation) 450 g/L	Spray dilution (used in formulation) 1.373 g/L	
	<b>Dermal absorption endpoints %</b>	<b>0.7</b>	<b>13.4</b>	
Oral absorption			<b>100 %</b>	

### 3.1.3.1 Acute Toxicity

DEVIRINOL F (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 DEVIRINOL F (NAPROPAMIDE 450 G/L SC (HAR01)), therefore acute toxicity studies could not be used to determine the classification of the product. Based on the classification of the co-formulants the classification of DEVIRINOL F (NAPROPAMIDE 450 G/L SC (HAR01)) was calculated according to 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 <sup>13</sup>	Equipment <i>Application method</i>	Maximum application rate L product/ha (g a.s./ha)	Minimum volume water (L/ha)	Model
Fruit trees	F	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	9 L/ha (4050 g napropamide/ha)	150	German model

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

Crop	Equipment	PPE and/or working coverall	% AOEL napropamide
Fruit trees	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	8.8

According to the model calculations, it may be concluded that the risk for the operator using DEVIRINOL F (NAPROPAMIDE 450 G/L SC (HAR01)) 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.

### 3.1.3.3 Bystander Exposure

<sup>13</sup> Open field or glasshouse

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 1.19 % of the AOEL of napropamide.

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

### 3.1.3.4 Worker Exposure

DEVIRINOL F (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 0.09 % of the AOEL of napropamide for adults and 0.19 % of the AOEL of napropamide for children.

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

### 3.1.3.6 Relevance of metabolites

NOPA: PEC<sub>gw</sub> max = 18.825 µg/L (apples)

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

#### Summary of the evaluation

The preparation DEVIRINOL F (NAPROPAMIDE 450 G/L SC (HAR01)) is composed of 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	MRL Compliance Reg 2020/770	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
9	Fruit trees (pome fruits, stone fruits)	Yes	Yes	Yes	Yes	Yes	Yes		Not applicable	
16	Vines and vine nurseries	Yes	Yes	Yes	Yes	Yes	Not applicable		Not applicable	
16a	Vines	Yes	Yes	Yes	Yes	Yes	No for wine grapes Yes for table grapes		Not applicable	
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	Fall back GAP is proposed
59	Herbs (G)	Yes	No	No	-	-	-	-	-	-

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 where 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 is therefore not necessary.

### Summary for DEVRIOL F (NAPROPAMIDE 450 G/L SC (HAR01))

**Table 0-1: Information on DEVRIOL F (NAPROPAMIDE 450 G/L SC (HAR01)) (KCA 6.8)**

Use- No.*	Crop	PHI for HAR01/HAR15 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for HAR01 proposed by zRMS	zRMS Comments (if different PHI proposed)
			napropamide		
9	Fruit trees (pome fruits, stone fruits)	F, BBCH 59	Yes	F, BBCH 59	
16a	Vines	F, BBCH 09	Yes for table grapes only	F, BBCH 09	Available residue for NEU lead to an MRL exceedance
59	Herbs (F)	F, BBCH 09	Yes	F, BBCH 09 or pre-planting application	

#### 3.1.4.2 Consumer exposure

The data available are considered sufficient for risk assessment.

An exceedance of the current MRL for napropamide as laid down in Reg. (EU) 396/2005 is not expected for the intended uses on pome fruits, stone fruits, table grapes, and for the proposed uses on herbs.

Lower LMR on grapes is proposed in Reg. EU 2020/770 and according to the available residue data, compliance can no longer be guaranteed for the FR intended use on wine grapes.

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

As far as consumer health protection is concerned, authority, France agrees with the authorization:

- of the intended uses on pome fruits and stone fruits
- of the proposed uses on herbs.

Furthermore France, disagrees with the intended uses on wine grapes.

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 where a plant back interval of 60 days can be proposed

#### 3.1.5 Environmental fate and behaviour

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.

PEC<sub>soil</sub> and PEC<sub>sw</sub>/PEC<sub>sed</sub> values derived for the active substance and its metabolites were used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PEC<sub>gw</sub> values for napropamide do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009. PEC<sub>gw</sub> values for metabolite NOPA do not occur at levels exceeding those mentioned in guidance document SANCO 221/2000, when used between January and May on fruit trees and between February and May on grape vines.

Based on vapour pressure, information on volatilisation from plants and soil, and DT<sub>50</sub> 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, aquatic organism, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and non-target plants are acceptable for the intended uses.

### 3.1.7 Efficacy

Considering the data submitted:

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

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.

#### **3.4.2 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.

#### **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.

## 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) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,*

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

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

*de la société UPL EUROPE LTD  
enregistrées sous les n°2014-2917 et n°2020-0370*

*Vu les conclusions de l'évaluation de l'Anses du 11 septembre 2019 et du 28 juin 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.





Informations générales sur le produit	
Nom du produit	DEVIRINOL F
Type de produit	Produit de référence
Titulaire	UPL EUROPE LTD The Centre, 1st Floor Birchwood Park WARRINGTON, CHESHIRE WA3 6YN Royaume-Uni
Formulation	Suspension concentrée (SC)
Contenant	450 g/L - napropamide
Numéro d'intrant	2070466
Numéro d'AMM	2070133
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

**31 AOUT 2021**

**Charlotte GRASTILLEUR**  
Directrice générale déléguée  
en charge du pôle produits réglementés  
Agence nationale de sécurité sanitaire de  
l'alimentation, de l'environnement et du travail (ANSES)



## ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Bouteilles en polyéthylène 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 réglementation en vigueur.	
<b>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.</b>	



**Liste des usages autorisés**

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.  
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
<b>12555902</b> Fruits à noyau*Désherbage* Cult. Installées	9 L/ha	1/an	jusqu'au stade BBCH 59	F (BBCH 59)	20 (dont DVP 20)	-	5	-
Uniquement sur abricotier, pêcher, prunier et nectarinier.								
<b>12555904</b> Fruits à noyau*Désherbage* Pépi. Jeunes plantat.	9 L/ha	1/an	jusqu'au stade BBCH 59	Non applicable	20 (dont DVP 20)	-	5	-
Uniquement sur abricotier, pêcher, prunier et nectarinier.								
<b>12605905</b> Fruits à pépins*Désherbage* Cult. Installées	9 L/ha	1/an	jusqu'au stade BBCH 59	F (BBCH 59)	20 (dont DVP 20)	-	5	-
Uniquement sur pommier, poirier, cognassier et nashi.								
<b>12605904</b> Fruits à pépins*Désherbage* Pépi. Jeunes plantat.	9 L/ha	1/an	jusqu'au stade BBCH 59	Non applicable	20 (dont DVP 20)	-	5	-
Uniquement sur pommier, poirier, cognassier et nashi.								
<b>19335901</b> PPAM – non alimentaire* Désherbage	2,5 L/ha	1/an	entre les stades BBCH 00 et BBCH 09	Non applicable	20 (dont DVP 5)	-	5	-
Également autorisé sous abri.								
<b>19995900</b> PPAMC*Désherbage	1,8 L/ha	1/an	entre les stades BBCH 00 et BBCH 09	F (BBCH 09)	20 (dont DVP 5)	-	5	-
Uniquement sur PPAMC alimentaires. Diminution de la dose maximale d'emploi de 2,5 à 1,8 L/ha en cohérence avec les données résidus disponibles. L'usage est retiré sous abri car le nombre d'essais résidus disponibles est insuffisant pour vérifier le respect des LMR et effectuer une évaluation du risque pour le consommateur.								

DEVIRINOL F  
AMM n°2070133



**Liste des usages autorisés**

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.  
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
12705902 Vigne*Désherbage* Cult. Installées	9 L/ha	1/an	entre les stades BBCH 00 et BBCH 09	Non applicable	20 (dont DVP 20)	-	5	-
	Uniquement sur vignes-mères.							
12705901 Vigne*Désherbage* Pépi. Jeunes plantat.	9 L/ha	1/an	entre les stades BBCH 00 et BBCH 09	F (BBCH 09)	5	-	5	-
	Uniquement sur raisin de table. Application sur le rang uniquement. L'usage est retiré sur raisin de cuve en raison d'un risque de dépassement des limites maximales de résidus de la substance active napropamide.							
12705901 Vigne*Désherbage* Pépi. Jeunes plantat.	9 L/ha	1/an	jusqu'au stade BBCH 59	Non applicable	5	-	5	-
	Application sur le rang uniquement. 1 application maximum par an et par parcelle.							
1 application maximum par an et par parcelle.								

DVP : Dispositif Végétalisé Permanent.

DEVIRINOL F  
AMM n°2070133





## Conditions d'emploi du produit

### Stockage et manipulation du produit

- Stocker le produit à une température inférieure à 40°C.
- Agiter le produit dans son emballage avant utilisation.

### Protection de l'opérateur et du travailleur

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

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage).
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

#### ***Pour l'opérateur, porter***

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

###### **• pendant le mélange/chargement**

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

###### **• pendant l'application**

###### *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.

#### ***Délaï de rentrée en application de l'arrêté du 4 mai 2017 :***

- 6 heures.



### **Respect des limites maximales de résidus (LMR)**

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

- 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 "PPAM" 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.
- SPe 2 : Pour protéger les eaux souterraines, ne pas appliquer ce produit entre juin et décembre pour les usages sur "fruits à noyaux" et "fruits à pépins".
- SPe 2 : Pour protéger les eaux souterraines, ne pas appliquer ce produit entre juin et janvier pour les usages sur "vigne".

#### ***Protection de la faune***

- SPe 2 : Pour protéger les organismes aquatiques, ne pas appliquer ce produit sur sol artificiellement drainé pour les usages sur "fruits à noyaux", "fruits à pépins" et "vigne" (application en plein).
- SPe 2 : Pour protéger les organismes aquatiques, ne pas rejeter les eaux usées des serres hors sol directement dans les eaux de surface pour les usages sur "PPAM".
- SPe 2 : Pour protéger les organismes aquatiques, ne pas appliquer ce produit sur plus de 50 % de la surface de la parcelle pour les usages sur "vigne" (application sur le rang).
- 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 20 mètres en bordure des points d'eau pour les usages sur "fruits à noyaux", "pommier" et "vigne" (application en plein).
- 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 "PPAMC" et "PPAM".
- 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 "vigne" (application sur le rang).

#### ***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	-

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



# Devrinol®

MAPP 09374

A suspension concentrate (SC) formulation 450 g/litre of napropamide (40.9% w/w) for the control of annual grass and broad-leaved weeds in; strawberries, blackcurrants, gooseberries, raspberries, certain brassicas (broccoli, Brussels sprouts, cabbage, calabrese, cauliflower and kale), field and container-grown trees and shrubs, and winter oilseed rape.

The (COSHH) Control of Substances Hazardous to Health Regulations may apply to the use of this product at work.

**IMPORTANT INFORMATION**  
FOR USE ONLY AS A PROFESSIONAL HERBICIDE

Crops/situations	Maximum individual dose (litres product/ha)	Maximum number of treatments	Latest time of application
Oilseed rape (winter)	2.8	One per crop	Before emergence
Strawberry, blackcurrant, gooseberry, raspberry	7	One per annum	Before end of February (see other specific restrictions)
Ornamental plant production, forest nursery	9	One per annum	Before end of April (see other specific restrictions)
Broccoli/calabrese, Brussels sprout, cabbage, cauliflower, kale	2.8	One per crop	Before transplanting

**Other Specific Restrictions:**

- Application to strawberries, established blackcurrants, gooseberries and raspberries must be made after 1st November and before the end of February.
- Application to strawberries must only be made to plants where the mature foliage has previously been removed (topped).
- Application to plants grown for ornamental production (trees & shrubs) and forest nurseries must be made after 1st November and before the end of April.
- When applying by knapsack sprayer the minimum water volume must not be less than 1000 litres water per hectare.

**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 contaminated surfaces.**
- Wear suitable protective gloves when applying by knapsack sprayer or pedestrian.**
- However, engineering controls may replace personal protective equipment if a COSHH assessment shows they provide an equal or higher standard of protection.
- Wash any contamination from skin and eyes immediately.**
- Wash hands and exposed skin** before eating and drinking and after work.
- When using do not eat, drink or smoke.**
- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.**

**Environmental protection**

- 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 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.

**PROTECT FROM FROST**

For Batch Number and Manufacturing Date see bottle

Net Contents  
**5 Litres**



**TOXIC TO AQUATIC LIFE WITH LONG-LASTING EFFECTS.**

Keep out of reach of children.  
Avoid release to the environment.  
Collect spillage. Hazardous to the aquatic environment.  
Dispose of contents/container to a licensed hazardous waste disposal contractor or collection site except for empty clean containers which may be disposed of as non-hazardous waste.

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

A2.2 DEVIRINOL UK 090415 NDA 0290-05



**UPL Europe Ltd**  
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Telephone: 01925 819999 Fax: 01925 817425  
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DEV/GB/5L/F/0415/UPL

April 2015





## **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. All Crops**

- 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.
- Surface manure, straw, moss or other organic detritus may reduce weed control. Soil cultivations after spraying should be avoided.
- DEVIRINOL 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.

#### **2. Maiden Strawberry Crops**

- Runners should be planted carefully so that no roots are left exposed.
- Soil should be firmed around the roots before application.
- Do NOT treat runners of poor vigour or with shallow roots.
- Do NOT apply DEVIRINOL to runner beds.
- DEVIRINOL has been used successfully on a wide-range of strawberry varieties. However, owing to the introduction of a plethora of new varieties and changes in the methods of crop husbandry, only a small area of new varieties should be treated in their first season.

#### **3. All Fruit Crops**

- DEVIRINOL must not be used on protected crops.
- PROCESSED CROPS: Tests have proved that DEVIRINOL does not taint strawberries, blackcurrants, or gooseberries; nevertheless, growers should consult the processor before use.
- RASPBERRY, BLACKCURRANT and GOOSEBERRY crops should be established for at least 10 months before treatment.
- Soft fruit grown in Very Light Soils (as defined by the ADAS '85 System) should not be treated.

#### **4. Ornamental Plant Production**

- Nursery stock should be planted carefully so that no roots are left exposed.
- Soil or compost should be firmed around the roots before application.
- Do NOT treat nursery stock of poor vigour or with shallow roots.
- Do NOT treat liners or containers less than 1 litre in size.
- DEVIRINOL has been used on a wide range of newly-planted and established trees and shrubs, both field and container grown and, with the exception of yellow and golden varieties of conifers and container grown alpine species, no phytotoxicity has occurred. However owing to the large number of varieties in cultivation, and to the different husbandry methods employed, treat only a small number of plants of any one variety in their first season.
- Trees and shrubs grown in containers with peat or peat/soil composts may be treated. Ensure compost has a fine tilth free of lumps before application. Weed control may be less persistent in organic composts.

## Treatment of Crops

### 1. Fruit Crops

Crop	Rate of Use	Timing
Established* strawberry crops	Apply DEVRINOL at 7 litres/ha as a MEDIUM or COARSE spray in 200-400 litres water/ha.	Apply during November to the end of February after existing weeds have been removed.
Maiden strawberry crops	On light soils, apply DEVRINOL at 5 litres/ha. On medium and heavy soils, apply DEVRINOL at 7 litres/ha.	Apply during November to the end of February after planting but before weeds emerge. Any existing weeds should be removed before application.
Blackcurrants† Gooseberries† Rasp- berries†	Apply DEVRINOL at 7 litres/ha water/ha.	Apply during November to the end of February after existing weeds have been removed.

\* Established crops are those that have made at least one season's growth.

† Crops should be established for at least ten months before treatment.

### 2. Forest Tree Nurseries & Ornamental Plant Production (Trees & Shrubs) – including transplant and 2nd year undercuts.

- Apply DEVRINOL at 9 litres/ha.
- DEVRINOL should be applied evenly as a MEDIUM or COARSE spray, (as defined by BCPC) in 200-1000 litres of water per hectare by conventional sprayer.
- In containerised stock the plant leaf canopy can shadow the compost surface. To ensure adequate dampening of the compost, the spray volume may be increased to a maximum of 2000 litres/ha, depending on the amount of foliage present.
- Apply during November to the end of February. DEVRINOL may also be applied during March and April provided 25mm of irrigation is applied within 24 hours of spraying.
- Newly planted or containerised stock should be treated after planting but before weeds emerge. All existing weeds should be removed before application.
- Apply overhead irrigation for a short while after application if available.

### Weeds Controlled

By Devrinol alone (5-9 litres/ha)

Susceptible (S)	Moderately Susceptible (MS)	Tolerant (T)
Annual meadow-grass Black-grass Common chickweed Common field-speedwell Common poppy Corn spurrey Fat-hen Field forget-me-not Groundsel Knotgrass Mayweeds Willowherbs	Cleavers Clover <sup>(1)</sup> Field pansy Liverworts <sup>(1)</sup> Pale persicaria Redshank Sheep's sorrel <sup>(2)</sup> Shepherd's-purse Small nettle <sup>(3)</sup> Sow thistles Volunteer cereals	Black nightshade Charlock Corn marigold Field pennycress Hairy bittercress <sup>(4)</sup> Parsley-piert Moss <sup>(4)</sup>

#### Notes:

(1) Variable control - for best results apply 9 litres/ha only.

(2) Susceptible only at 9 litres/ha.

(3) For the control of small nettle, a rate of 5 litres/ha rate is not recommended.

(4) Susceptible at 9 litres/ha.

### 3. Brassicas

- DEVIRINOL may be sprayed prior to transplanting broccoli, Brussels sprouts, cabbage, calabrese, cauliflower, or kale.
- Apply DEVIRINOL at 2.8 litres/ha as a MEDIUM or COARSE spray in 200-500 litres water/ha.
- To maximise efficacy, DEVIRINOL should be incorporated to a depth of 50 mm prior to transplanting. Incorporation MUST OCCUR within 30 minutes of application.
- DEVIRINOL 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 8kph (5mph) 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:

- DEVIRINOL 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.

#### Timing

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

### 4. Winter Oilseed Rape

- Apply DEVIRINOL at 2.8 litres/ha as a MEDIUM or COARSE spray.
- DEVIRINOL may be applied 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 (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.

#### Devirinol Alone, Weeds Controlled (2.8 litres/ha)

Susceptible (S)	Moderately Susceptible (MS)	Resistant (R)
Annual meadow grass Knotgrass Mayweeds Chickweed	Small nettle Groundsel Fat Hen Black-grass*	Black nightshade Field pansy Fumitory Redshank

\* Moderately Susceptible to OSR crop

#### **Succeeding Crops**

- Before planting any following crop, the soil should be mould-board ploughed to a depth of 20 cm.
- Do not use DEVRINOL in the same season as replanting/drilling is planned.
- No crop, other than supported uses including brassica crops (leaf, flower), root crops, fodder crops and oilseed rape, can be drilled within 7 months following application of DEVRINOL.
- Maize may be grown providing a period of 9 months has elapsed since DEVRINOL was applied. Autumn sown wheat and grass or any other crop may be planted/drilled providing a period of 12 months has elapsed since DEVRINOL was applied.

#### **Mixing**

- Half fill the tank with water and begin agitation. Add the required quantity of DEVRINOL 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 DEVRINOL to the tank first. Continue agitation during spraying.
- Wash out sprayer thoroughly after use.

#### **Compatibility**

- To control weeds not fully susceptible to DEVRINOL, in established fruit crops, trees and shrubs, a tank-mixture or a sequential programme of DEVRINOL at the recommended rate with an approved formulation is recommended.
- Alternatively, in established strawberry crops, DEVRINOL may be followed by an approved formulation of phenmedipham.
- Follow the manufacturer's recommendations for the application of phenmedipham.
- Please refer to the UPL Europe Limited website for further information, ([www.upleurope.com](http://www.upleurope.com)).

#### **Conditions of Supply**

All goods supplied by UPL Europe Limited are of high grade and we believe them to be suitable but, as we cannot exercise control over their storage, handling, mixing or use or weather conditions before, during and after application which may affect the performance of the goods, all conditions and warranties statutory or otherwise, as to the quality or fitness for any purpose of our goods are excluded, and no responsibility will be accepted by us or re-sellers for any failure in performance, damage or injury whatsoever arising from their storage, handling, application or use. Our staff or agents cannot vary these conditions whether or not they supervise or assist in the use of such goods.

**Appendix 3 – Letter(s) of Access**

Not applicable.