

## **REGISTRATION REPORT**

### **Part A**

### **Risk Management**

**Product code: FAZ02**

**Product name(s): NAUTILE**

**Active Substance(s):**

**Cymoxanil, 50 g/kg**

**Mancozeb, 680 g/kg**

**COUNTRY: FRANCE**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**  
**(renewal of authorisation and extension of use)**

**Applicant: UPL FRANCE**

**Date: 08/06/2018**

## Table of Contents

<b>1</b>	<b>DETAILS OF THE APPLICATION.....</b>	<b>3</b>
1.1	APPLICATION BACKGROUND.....	3
1.2	ACTIVE SUBSTANCE APPROVAL.....	3
1.3	REGULATORY APPROACH .....	4
1.4	DATA PROTECTION CLAIMS .....	5
1.5	LETTER(S) OF ACCESS .....	5
<b>2</b>	<b>DETAILS OF THE AUTHORISATION .....</b>	<b>6</b>
2.1	PRODUCT IDENTITY .....	6
2.2	CLASSIFICATION AND LABELLING.....	6
2.2.1	<i>Classification and labelling under Directive 99/45/EC .....</i>	<i>6</i>
2.2.2	<i>Classification and labelling in accordance with Regulation (EC) No 1272/2008 .....</i>	<i>6</i>
2.2.3	<i>Other phrases in compliance with Regulation (EU) No 547/2011 .....</i>	<i>7</i>
2.2.4	<i>Other phrases linked to the preparation .....</i>	<i>7</i>
2.3	PRODUCT USES.....	8
<b>3</b>	<b>RISK MANAGEMENT.....</b>	<b>10</b>
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	10
3.1.1	<i>Physical and chemical properties .....</i>	<i>10</i>
3.1.2	<i>Methods of analysis .....</i>	<i>10</i>
3.1.3	<i>Mammalian Toxicology.....</i>	<i>10</i>
3.1.4	<i>Residues and Consumer Exposure .....</i>	<i>12</i>
3.1.5	<i>Environmental fate and behaviour.....</i>	<i>13</i>
3.1.6	<i>Ecotoxicology.....</i>	<i>13</i>
3.1.7	<i>Efficacy .....</i>	<i>15</i>
3.1	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT .....	16
3.2	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING .....	16
3.3	FURTHER INFORMATION TO PERMIT A DECISION TO BE MADE OR TO SUPPORT A REVIEW OF THE CONDITIONS AND RESTRICTIONS ASSOCIATED WITH THE AUTHORISATION .....	16
3.3.1	<i>Post-authorisation monitoring .....</i>	<i>16</i>
3.3.2	<i>Post-authorisation data requirements .....</i>	<i>16</i>
3.3.3	<i>Label amendments .....</i>	<i>16</i>
	<b>APPENDIX 1 – COPY OF THE FRENCH DECISION .....</b>	<b>17</b>
	<b>APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT .....</b>	<b>24</b>
	<b>APPENDIX 3 – LETTER(S) OF ACCESS .....</b>	<b>26</b>

## PART A – Risk Management

The company UPL FRANCE SAS has requested renewal of authorisation and extension of use in France for the product NAUTILE (formulation code: FAZ02), containing 50 g/kg cymoxanil and 680 g/kg mancozeb for use as a fungicide.

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 NAUTILE (FAZ02) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of NAUTILE (FAZ02) have been made using endpoints agreed in the EU peer review of cymoxanil and mancozeb.

This document describes the specific conditions of use and labelling required for France for the registration of NAUTILE (FAZ02).

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 FRANCE SAS's application to market NAUTILE (FAZ02) in France as a fungicide (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 substances cymoxanil and mancozeb of this product in France and in other MSs of the Southern zone.

### 1.2 Active substance approval

#### Cymoxanil

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

Specific provisions of Regulation (EU) No 540/2011 were as follows :

#### PART A

Only uses as fungicide 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 cymoxanil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.

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

- the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment;
- the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;
- the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate.

An EFSA conclusion is available (EFSA Scientific Report (2008) 167, 1-116).  
A Review Report is available (SANCO/179/08 – final rev. 1 – 9 July 2010).

### **Mancozeb**

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

Specific provisions of Regulation (EU) No 540/2011 were as follows :

#### **PART A**

Only uses as fungicide 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 mancozeb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 June 2005 shall be taken into account.

Member States must pay particular attention to the potential for groundwater contamination when the active substance is applied in regions with vulnerable soils and/or extreme climatic conditions.

Member States must pay particular attention to the residues in food and evaluate the dietary exposure of consumers.

Member States must pay particular attention to the protection of birds, mammals, aquatic organisms and non-target arthropods and ensure that the conditions of authorisation include risk mitigation measures.

Member States shall request the submission of further studies to confirm the risk assessment for birds and mammals and for developmental toxicity.

They shall ensure that the notifiers at whose request mancozeb has been included in this Annex provide such studies to the Commission within two years from the approval.

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

A Commission Working Document is available (SANCO/4058/2001 - rev. 4.4 - July 2009).

### **1.3 Regulatory approach**

The present applications (2012-1022 & 2012-1023) were evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)<sup>1</sup> 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>2</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 4th May 2017<sup>3</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

<sup>1</sup> French Food Safety Agency, Afssa, before 1 July 2010

<sup>2</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>3</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 <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte>

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>4</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>5</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014<sup>6</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 “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>7</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 NAUTILE (FAZ02), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

#### **1.5 Letter(s) of Access**

The applicant has provided equivalent studies to the original applicant's Annex II dossier for cymoxanil.

For mancozeb, the applicant has provided sufficient data to show that access is not required.

A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

<sup>4</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>5</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>6</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo>

<sup>7</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>	NAUTILE (FAZ02)
<b>Authorisation number</b>	9700452
<b>Function</b>	fungicide
<b>Applicant</b>	UPL FRANCE SAS
<b>Composition</b>	Cymoxanil, 50 g/kg Mancozeb, 680 g/kg
<b>Formulation type (code)</b>	Water dispersible granule (WG)
<b>Packaging</b>	Paper/PE bags (10 kg)

### 2.2 Classification and labelling

#### 2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

<b>Physical hazards</b>	None	
<b>Health hazards</b>	Skin Sensitization Cat. 1A Reproductive toxicity Cat. 2	
<b>Environmental hazards</b>	Aquatic Acute 1 Aquatic Chronic 1	
<b>Hazard pictograms</b>		
<b>Signal word</b>	Warning	
<b>Hazard statements</b>	H317	May cause an allergic skin reaction
	H361fd	Suspected of damaging fertility (f) and the unborn child (d)
	H400	Very toxic to aquatic life
	H410	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>	-	-

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

### 2.2.3 Other phrases in compliance with Regulation (EU) No 547/2011

The authorisation of the preparation is linked for professional uses only to the following conditions:

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 50 metres <sup>8</sup> to surface water bodies for uses on grapes, potatoes and tomatoes.
Spa 1:	<p>To avoid the development of resistance of cymoxanil for downy mildew, the number of application is limited to 2 applications per crop cycle on grapevine. To manage the risk of resistance with NAUTILE it is recommended to follow the limitations of use by chemical group recommended by the note on resistance management on grapevine diseases.</p> <p>To avoid the development of resistance of cymoxanil for downy mildew, the number of application is limited to 6 applications per crop cycle on potatoes. To manage the risk of resistance with NAUTILE it is recommended to follow the limitations of use by chemical group recommended by the note on resistance management on potatoes diseases.</p>

### 2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment <sup>9</sup> : refer to the Decision in Appendix 1 for the details
Re-entry period <sup>10</sup> : 48 hours
<p>Pre-harvest interval<sup>11</sup>:</p> <p>7 days for potatoes</p> <p>3 days for tomatoes for fresh consumption</p> <p>10 days for tomatoes for industry</p>
Other mitigation measures: -
<p>The label may include the following recommendations: -</p> <p>The label must reflect the conditions of authorisation.</p>

<sup>8</sup> The legal basis for this is **Titre III Article 12** of the French Order of 4th 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]

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

<sup>10</sup> The legal basis for this is **Titre I Article 3** of the French Order of 4th 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]

<sup>11</sup> According to the French Order of 12 September 2006, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

## 2.3 Product uses

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

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

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

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

GAP rev. 1, date: 2018-06-08

PPP (product name/code): **NAUTILE (FAZ02)**  
Active substance 1: **cymoxanil**  
Active substance 2: **mancozeb**  
Applicant: UPL FRANCE SAS  
Zone(s): southern <sup>(d)</sup>  
Verified by MS: yes/no  
Field of use: fungicide

Formulation type: **WG** <sup>(a, b)</sup>  
Conc. of as 1: **50 g/kg** <sup>(c)</sup>  
Conc. of as 2: **680 g/kg** <sup>(c)</sup>  
Professional use: ☒  
Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn 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 <sup>(i)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
1	FR	Grapes (wine and table grapes)	F	Downy mildew ( <i>Plasmopara viticola</i> )	Spraying	BBCH 07-83	4	7-10	2.4	120 (cymoxanil) + 1632 (mancozeb)	200- 1000	28	<b>Not acceptable (risk for workers,)</b>
2	FR	Potatoes	F	Late blight ( <i>Phytophthora infestans</i> )	Spraying	BBCH 21-95	8	7-9	2	100 (cymoxanil) + 1360 (mancozeb)	200- 1000	7	<b>Not acceptable (resistance)</b>
2	FR	Potatoes	F	Late blight ( <i>Phytophthora infestans</i> )	Spraying	BBCH 21-95	<b>6</b>	7	2	100 (cymoxanil) + 1360 (mancozeb)	200- 1000	7	<b>Acceptable</b>



1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn 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 <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
3	FR	Tomatoes	F	Downy mildew ( <i>Phytophthora infestans</i> )	Spraying	BBCH 14-87 for fresh consumption; BBCH 13-85 for industry	5	7	2	100 (cymoxanil) + 1360 (mancozeb)	200- 1000	3 (for fresh consumpt ion)  10 (for industry)	<b>Acceptable</b>

**Remarks  
table  
heading:**

- (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008  
(c) g/kg or g/l

- (d) Select relevant  
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

**Remarks  
columns:**

- 1 Numeration necessary to allow references  
2 Use official codes/nomenclatures of EU Member States  
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)  
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.  
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.  
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application  
8 The maximum number of application possible under practical conditions of use must be provided.  
9 Minimum interval (in days) between applications of the same product  
10 For specific uses other specifications might be possible, e.g.: g/m<sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".  
13 PHI - minimum pre-harvest interval  
14 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

NAUTILE (FAZ02) is water dispersible granules (WG). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is olive brown coloured granules, with a wood-like odour. It is not explosive and has no oxidizing properties. It has a self-ignition temperature of 165°C and is not flammable. In aqueous solution (1% dilution), it has a pH value of 6.1 at ambient temperature. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in paper/PE package. Its technical characteristics are acceptable for a WG formulation.

The formulation is not classified for the physico-chemical aspect.

##### 3.1.2 Methods of analysis

Analytical methods for the determination of active substances and relevant impurities in the formulation are available and validated.

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of mancozeb and cymoxanil in plants, food of animal origin, soil, water (surface and drinking) and air.

The active substances are neither toxic nor very toxic; hence no analytical method is required for the determination of residues in biological fluids and tissues.

##### 3.1.3 Mammalian Toxicology

The endpoints used in risk assessment are reported below.

Active Substance: cymoxanil			
ADI	0.013 mg kg bw/d		EU agreed endpoint
ARfD	0.08 mg/kg bw/d		
AOEL	0.01 mg/kg bw/d		
Dermal absorption	Based on an <i>in vitro/in vivo</i> rat/human study performed on a similar formulation (using a triple pack approach):		
		Concentrate (tested) 45 g/L	Diluted formulation (tested) 0.12 g/L
	In vivo (rat) %	1.09	18.3
	In vitro (rat) %	6.5	49.9
	In vitro (human) %	1.4	48.9
		Concentrate (used in formulation) 50 g/L	Spray dilution (used in formulation) 0.12 g/L
	Dermal absorption endpoints %		0.3 23

Active Substance: mancozeb			
ADI	0.05 mg kg bw/d		EU agreed endpoint
ARfD	0.6 mg/kg bw/d		
AOEL	0.035 mg/kg bw/d		
Dermal absorption	Based on an <i>in vitro/in vivo</i> rat/human study performed on formulation or on a similar formulation (using a triple pack approach; <i>pro rata</i> correction) or default values according to guidance on dermal absorption (EFSA 2012):		
	Concentrate (tested) 1200 g/L	Diluted formulation (tested) 1.4 g/L	

	In vivo (rat) %	0.11	0.24
	In vitro (rat) %	-	-
	In vitro (human) %	-	-
		Concentrate (used in formulation) 800 g/L	Spray dilution (used in formulation) g/L
	<b>Dermal absorption endpoints %</b>	<b>0.5</b>	<b>0.6</b>

### 3.1.3.1 Acute Toxicity

NAUTILE (FAZ02) has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is a skin sensitizer.

### 3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G <sup>12</sup>	Equipment	Application rate kgproduct/ha (g as/ha)	Spray dilution (L/ha)	Model
Potato	F	Tractor-mounted boom sprayer, hydraulic nozzle	2 (100 g Cymoxanil/ha) (1360 g Mancozeb/ha)	200-1000	BBA
Grapes	F	Tractor mounted air assisted sprayer	2.4 (120 g Cymoxanil/ha) (1632 g Mancozeb/ha)	200-1000	BBA
Grapes	F	Hand held sprayer	2.4 (120 g Cymoxanil/ha) (1632 g Mancozeb/ha)	200-1000	BBA
Tomato	F	Tractor-mounted boom sprayer, hydraulic nozzle	2 (100 g Cymoxanil/ha) (1360 g Mancozeb/ha)	200-1000	BBA

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

Crop	Equipment	PPE and/or working coverall	% AOEL Cymoxanil	% AOEL Mancozeb
Potato	Tractor-mounted boom sprayer, hydraulic nozzle	Working coverall and gloves during mixing/loading and application	20	14
Grapes	Tractor mounted air assisted sprayer	Working coverall and gloves during mixing/loading and application	74	21
Grapes	Hand held sprayer	Working coverall and gloves during mixing/loading and application	39	25
Tomato	Tractor-mounted boom sprayer, hydraulic nozzle	Working coverall and gloves during mixing/loading and application	20	12

According to the model calculations, it can be concluded that the risk for the operator using NAUTILE is acceptable during mixing/loading and application.

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

<sup>12</sup> Open field or glasshouse

After refinement according to the AOELs by organ, the cumulative estimate of exposure to active substances cymoxanil and mancozeb linked to use of the product NAUTILE (FAZ02) gives a Risk Index (RI) of less than one for operators.

### 3.1.3.3 Bystander Exposure

For potatoes, bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to 2 % of the AOEL of cymoxanil and 2% of the AOEL of mancozeb. For tomatoes and grapes, exposure is estimated to 17 % of the AOEL of cymoxanil and 4% of the AOEL of mancozeb (worst case scenario)

It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to NAUTILE (FAZ02).

After refinement according to the AOELs by organ, the cumulative estimate of exposure to active substances cymoxanil and mancozeb linked to use of the product NAUTILE (FAZ02) gives a Risk Index (RI) of less than one for bystanders.

### 3.1.3.4 Worker and resident Exposure

Workers may have to enter treated areas after treatment for crop harvesting activities. Therefore, estimation of worker exposure was calculated according to EUROPOEM II.

For potatoes, exposure is estimated to 48 % of the AOEL of cymoxanil and 6% of the AOEL of mancozeb. It is concluded that without taking into account a re-entry period, there is no unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering potatoes crops treated with NAUTILE (FAZ02).

For tomatoes, exposure is estimated to 92% of the AOEL of cymoxanil and 9% of the AOEL of mancozeb. It is concluded that without taking into account a re-entry period, there is no unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering tomatoes crops treated with NAUTILE (FAZ02).

After refinement according to the AOELs by organ, the cumulative estimate of exposure to active substances cymoxanil and mancozeb linked to use of the product NAUTILE (FAZ02) on potatoes and tomatoes gives a Risk Index (RI) of less than one for workers.

**For grapes, exposure is estimated to 166% of the AOEL of cymoxanil and 17% of the AOEL of mancozeb. It is concluded that without taking into account a re-entry period, there is an unacceptable risk anticipated for workers wearing a working coverall, when re-entering grapes crops treated with NAUTILE (FAZ02).**

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

Based on the currently available data in the report of the ORP (French pesticides residues observatory), it is concluded that there is no unacceptable risk to the resident exposed to NAUTILE (FAZ02).

## 3.1.4 Residues and Consumer Exposure

### 3.1.4.1 Residues

Primary crop metabolisms were sufficiently investigated to define residues of cymoxanil and mancozeb for enforcement and risk assessment in crops under consideration.

Regarding the magnitude of residues in grapes and tomatoes, a sufficient number of residue trials are available to support the intended GAPs in France and in Southern zone. These data allowed to estimate the expected residues concentrations in grapes and tomatoes, and to confirm that no MRL exceedance will result from intended uses.

As residues of cymoxanil do not exceed the trigger value of 0.1 mg/kg in potatoes and grapes, there is no need to investigate the effect of industrial and/or household processing.

For mancozeb, studies showed that under pasteurization, sterilization and cooking processes mancozeb is converted into ethylenethiourea (ETU). Magnitude of residue studies showed that wine and tomatoes processing leads to a decrease of mancozeb residues and a production of ETU.

Residues in succeeding crops have been sufficiently investigated; it is very unlikely that residues of cymoxanil and mancozeb will be present in succeeding crops.

As intended crops are not fed to livestock, data on residue levels in animal commodities are not necessary.

### 3.1.4.2 Consumer exposure

The toxicological profile of cymoxanil and mancozeb were evaluated at EU level, which resulted in the proposal of ADIs (0.013 mg/kg for cymoxanil, 0.05 mg/kg for mancozeb and 0.002 mg/kg for ETU) and ARfDs (0.08 mg/kg for cymoxanil, 0.6 mg/kg for mancozeb and 0.05 for ETU) that were considered in the frame of this evaluation.

Chronic consumer exposure resulting from the uses assessed in the framework of this application was calculated for both active substances. Based on EFSA PRIMo (rev2), chronic and acute exposures were considered as acceptable for all groups of consumers.

### 3.1.5 Environmental fate and behaviour

The fate and behavior in the environment of the formulation has been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs for the active substances and their metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PECs of cymoxanil and mancozeb and their metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU review or agreed in the assessment based on new data provided.

The results for PEC soil and PEC surface water for the active substances and their metabolites are used for the ecotoxicological risk assessment. One may note that mitigation measures are proposed in order to protect aquatic organisms.

PEC groundwater for cymoxanil and mancozeb and their metabolites do not exceed the trigger of 0.1 µg/L.

Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapor pressure, information on volatilization 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

#### 3.1.6.1 Effects on Terrestrial Vertebrates

The risk assessment for birds is carried out according to the 'EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)<sup>13</sup> and considering the EU agreed endpoints of cymoxanil and mancozeb. The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and of 5 for long-term risk, indicating that the risk to birds<sup>14</sup> is acceptable following use of NAUTILE (FAZ02) according to the proposed use patterns.

<sup>13</sup> European Food Safety Authority; Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA. EFSA journal 2009; 7(12):1438. [139 pp.]

<sup>14</sup> From direct dietary exposure, drinking water and secondary poisoning.

The risk assessment for mammals (other than birds) is carried out according to the EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009) and considering the EU agreed endpoints of cymoxanil, mancozeb and data on the formulation NAUTILE (FAZ02). The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute and of 5 for long-term risk, thus indicating an acceptable risk to mammals from the proposed use.

#### **3.1.6.2 Effects on Aquatic Species**

The risk assessment for aquatic organisms is carried out according to the Guidance Document on Aquatic Ecotoxicology (Sanco/3268/2001) and considering the EU agreed endpoints of cymoxanil and mancozeb, their metabolites and data on the formulation NAUTILE (FAZ02). The TER values using worst-case PEC<sub>SW</sub> values for cymoxanil and mancozeb, their metabolites exceed the relevant triggers, indicating that the risk to aquatic organisms is acceptable.

#### **3.1.6.3 Effects on Bees and Other Arthropod Species**

The risk assessment for bees is carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the EU agreed endpoints of cymoxanil and mancozeb and data on the formulation FAZ11 used as surrogate for NAUTILE (FAZ02). All the hazard quotients for cymoxanil, mancozeb and NAUTILE are less than 50, indicating that the risk to bees is acceptable following use of NAUTILE (FAZ02) according to the proposed use pattern.

The risk assessment for other non-target arthropods is carried out according to the Guidance Document ESCORT 2 and considering the EU agreed endpoints of the formulation FAZ11 used as surrogate for NAUTILE (FAZ02). The in-field foliar HQ values are below the trigger value indicating that the risk to in-field non-target arthropods is acceptable following use of NAUTILE (FAZ02) according to the proposed use pattern. The off-crop HQ values are below the trigger value indicating that the risk to off-crop non-target arthropods is acceptable following use of NAUTILE (FAZ02) according to the proposed use patterns.

#### **3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms**

The risk assessment for earthworms and other soil macro-organisms is carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the EU agreed endpoints of cymoxanil, mancozeb, their metabolites and the formulation FAZ11 used as surrogate for NAUTILE (FAZ02).

The acute and chronic TER values for NAUTILE (FAZ02), cymoxanil, mancozeb and their metabolites are greater than the triggers of 10 and 5 respectively, indicating that the risk to earthworms is acceptable following use of NAUTILE (FAZ02) according to the proposed use pattern.

Cymoxanil and mancozeb are not expected to pose an unacceptable risk to other soil non-target macro-organisms following the recommended use of NAUTILE (FAZ02), and no soil non-target macro-organisms studies are required.

#### **3.1.6.6 Effects on Soil Non-target Micro-organisms**

The risk of NAUTILE (FAZ02) to soil micro-organisms was evaluated by comparison of no-effect concentrations, derived from laboratory tests, with PECs.

The no effect levels exceed the relevant PECs values, indicating that the risk to soil micro-organisms is acceptable following use of NAUTILE (FAZ02) according to the proposed use pattern.

#### **3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna)**

The risk assessment for non-target plants is carried out according to the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) and considering the EU agreed endpoints of the formulation FAZ11 used as surrogate for NAUTILE (FAZ02). Therefore, the risk to non-target plants is considered acceptable.

### 3.1.7 Efficacy

The product complies with the Uniform Principles.

Considering the data submitted:

#### *- on late blight of potato*

- the efficacy of NAUTILE (FAZ02) at 2 kg/ha is considered as satisfying,
- the phytotoxicity of NAUTILE (FAZ02) is considered as negligible.
- the risk of negative impact (yield, quality, propagation, succeeding crops, adjacent crops) is considered as negligible.
- the risk of resistance development or appearance for cymoxanil and mancozeb does not require a monitoring of resistance on this use. To avoid the development of resistance of late blight of potato to cymoxanil, **the number of application of the product NAUTILE (FAZ02) is limited to 6 applications per crop cycle on potato.**

#### *- on downy mildew of grape*

- the efficacy of NAUTILE (FAZ02) at 1.8 kg/ha is considered as satisfying,
- the phytotoxicity of NAUTILE (FAZ02) is considered as negligible.
- the risk of negative impact (yield, quality, propagation, adjacent crops) is considered as negligible.
- Considering the resistance context to cymoxanil, there is no need to have a monitoring on downy mildew of grapevine. To avoid the development of resistance of downy mildew to cymoxanil, the number of application the product NAUTILE (FAZ02) should be limited to 2 applications per crop cycle on grapevine.

#### *- on late blight of tomato*

- the efficacy of NAUTILE (FAZ02) at 2 kg/ha is considered as satisfying,
- the phytotoxicity of NAUTILE (FAZ02) is considered as negligible.
- the risk of negative impact (yield, quality, propagation, succeeding crops, adjacent crops) is considered as negligible.
- the risk of resistance development or appearance for cymoxanil and mancozeb does not require a monitoring of resistance on this use.
- The ratio and the amount of mancozebe are not justified.

### **3.1 Conclusions arising from French assessment**

Taking into account the above assessment, an authorisation can be granted as proposed in Appendix 1 – Copy of the product Decision.

### **3.2 Substances of concern for national monitoring**

No information stated.

### **3.3 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation**

#### **3.3.1 Post-authorisation monitoring**

#### **3.3.2 Post-authorisation data requirements**

No requirement

#### **3.3.3 Label amendments**

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.



## Appendix 1 – Copy of the French Decision



### Décision relative à une demande de renouvellement de l'autorisation de mise sur le marché d'un produit phytopharmaceutique et à une 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, d'extension d'usage majeur et la demande associée du produit phytopharmaceutique **NAUTILE***

*de la société UPL France SAS*

*enregistrées sous les n°2012-1022 ; n°2012-1023 et n°2012-2132*

*Vu les conclusions de l'évaluation de l'Anses du 26 décembre 2017,*

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **est renouvelée** en France pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

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	NAUTILE
Type de produit	Produit de référence
Titulaire	UPL France SAS Energy Park, bâtiment 4, 5ème étage 132-190 Boulevard de Verdun 92400 Courbevoie France
Formulation	Granulé dispersable (WG)
Contenant	50 g/L - cymoxanil 680 g/L - mancozèbe
Numéro d'intrant	9700452
Numéro d'AMM	9700452
Fonction	Fongicide
Gamme d'usages	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 janvier 2020.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le

08 JUIN 2018

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

NAUTILE  
AMM n°9700452

Page 2 sur 7



## 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
Sacs en papier / polyéthylène basse densité	10 kg

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Sensibilisants cutanés - Catégorie 1A	H317 : Peut provoquer une allergie cutanée
Toxiques pour la reproduction - Catégorie 2	H361fd : Susceptible de nuire à la fertilité. Susceptible de nuire au fœtus
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H400 : Très toxique pour les organismes aquatiques
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
Pour les phrases P se référer à la réglementation en vigueur.	
<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>	

<b>Liste des usages autorisés</b>									
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 Traînée aquatique (mètres)	Zone Non Traînée arthropodes non cibles (mètres)	Zone Non Traînée plantes non cibles (mètres)	Mention abeilles	
<b>15653201</b> Pomme de terre*Trt Part.Aer.*Midiou(s)	2 kg/ha	6/an	entre les stades BBCH 21 et BBCH 95	7	50	-	-	-	
Intervalle minimum entre les applications : 7 jours. Diminution de 8 à 6 du nombre d'application en raison d'un risque de résistance du mildiou de la pomme de terre.									
<b>16953201</b> Tomate*Trt Part.Aer.*Midiou(s)	2 kg/ha	5/an	entre les stades BBCH 14 et BBCH 87	3	50	-	-	-	
Uniquement sur tomate de bouche. Intervalle minimum entre les applications : 7 jours.									
<b>16953201</b> Tomate*Trt Part.Aer.*Midiou(s)	2 kg/ha	5/an	entre les stades BBCH 13 et BBCH 85	10	50	-	-	-	
Uniquement sur tomate industrielle. Intervalle minimum entre les applications : 7 jours.									



Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12703203 Vigne*Trt Part.Aer.*Mildiou(s)	2,4 kg/ha	4/an	28
<b>Motivation du refus :</b> L'usage est refusé en raison d'un risque inacceptable pour les travailleurs.			

NAUTILE  
AMM n°9700452

Page 5 sur 7



## Conditions d'emploi du produit

### **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 pneumatique

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

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
- Masque ou demi-masque de type filtration FFP2 ;

#### **• pendant l'application - Pulvérisation**

*Si application avec tracteur avec cabine*

- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

*Si application avec tracteur sans cabine*

- Combinaison de protection de catégorie III type 4 avec capuche ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;
- Masque ou demi-masque de type filtration FFP2.

#### **• pendant le nettoyage du matériel de pulvérisation**

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
- Masque ou demi-masque de type filtration FFP2.

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

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

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
- Masque ou demi-masque de type filtration FFP2.



• **pendant l'application**

*Si application avec tracteur avec cabine*

- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;
- Masque ou demi-masque de type filtration FFP2.

*Si application avec tracteur sans cabine*

- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;
- Masque ou demi-masque de type filtration FFP2.

• **pendant le nettoyage du matériel de pulvérisation**

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
- Masque ou demi-masque de type filtration FFP2.

**Pour le travailleur, porter**

- Une combinaison de travail (cotte en coton / polyester 35 % / 65 % - grammage d'au moins 230 g/m<sup>2</sup>) avec traitement déperlant et, en cas de contact avec la culture traitée, des gants en nitrile certifiés EN 374-3.

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

- 48 heures.

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

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

**Protection de l'environnement (milieux, faune et flore)**

**Protection de l'eau**

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

**Protection de la faune**

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 50 mètres par rapport aux points d'eau.

**Gestion des résistances**

- Spa 1 : Pour éviter le développement de résistances du mildiou de la pomme de terre à la substance active cymoxanil, le nombre d'applications du produit est limité à 6 applications maximum par campagne sur pomme de terre.

Afin de gérer au mieux les risques de résistance avec le produit, il est recommandé de suivre les limitations d'emploi par groupe chimique préconisées par la Note relative à la gestion des résistances des maladies de la pomme de terre.

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

**NAUTILE<sup>®</sup>**

Face recto

(Photo d'un plant de pomme de terre)

Formulation DG

**POIDS NET**  
**10 KG**

  
**cerexagri**  
 United Phosphorus Ltd

face verso

**NAUTILE<sup>®</sup>**  
*Fongicide Pomme de Terre*

**COMPOSITION :**

5 % cymoxanil  
68 % mancozèbe

**TYPE DE FORMULATION :** Granulés dispersibles (WG)

**HOMOLOGATION :** n° 9700452 du 01/02/2001


**Xn- Nocif**


**N - Dangereux pour l'environnement**

**R43 :** Peut entraîner une sensibilisation par contact avec la peau  
**R50/53 :** Très toxique pour les organismes aquatiques. Peut entraîner des effets néfastes à long terme  
**R63 :** Risque possible pendant la grossesse d'effets néfastes pour l'enfant

Respecter un délai de réentrée de 48 heures après la fin de la pulvérisation

**S2 :** Conserver hors de la portée des enfants.  
**S13 :** Conserver à l'écart des aliments et boissons y compris ceux pour animaux.  
**S20/21 :** Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.  
**S24 :** Eviter le contact avec la peau  
**S29/35 :** Ne pas jeter les résidus à l'égout ; ne se débarrasser de ce produit et de son récipient qu'en prenant toutes les précautions d'usage  
**S36/37 :** Porter un vêtement de protection et des gants appropriés.  
**S46 :** En cas d'ingestion, consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette  
**S49 :** Conserver uniquement dans le récipient d'origine.  
**S60 :** Eliminer le produit et son récipient comme un déchet dangereux  
**S61 :** Eviter le rejet dans l'environnement. Consulter les instructions spéciales / la Fiche de Données de sécurité.

Respecter les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.  
**SP1 –** Ne pas polluer l'eau avec le produit ou son emballage. (Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes).

La Fiche de Données de Sécurité peut être obtenue sur simple demande auprès de Cerexagri à l'adresse suivante :  
[contact.cerexagri@cerexagri.com](mailto:contact.cerexagri@cerexagri.com)

**TABLEAU DES USAGES AUTORISES : Traitements des parties aériennes**

Culture/organisme nuisible	Dose	Délai avant récolte (DAR)	Nombre d'applications	Zone non traitée (ZNT)
Pomme de terre / Mildiou	2.0 kg/ha	7 jours	Max 8	ZNT = 5 m
Vigne / mildiou	3.0 kg/ha	28 jours	Max 4	5 m
Tomate / mildiou	2.0 kg/ha	3 consommation 10 industrie	Max 5	5 m



**MODE D'UTILISATION :**

• **Mise en œuvre**

NAUTILE® s'emploie aussi bien en pulvérisation mécanique qu'en pulvérisation pneumatique.

Verser progressivement NAUTILE® directement dans la cuve de pulvérisation à demi remplie d'eau en agitant le mélange puis compléter au volume d'eau désiré.

• **Recommandations**

NAUTILE® est un fongicide pénétrant qui présente une efficacité préventive et curative précoce (au maximum, jusqu'à 48 h après le début d'une pluie contaminatrice). NAUTILE® doit être appliqué en fonction des recommandations des Avertissements Agricoles concernant les produits à base de cymoxanil. Le traitement doit être renouvelé en fonction de la pression de maladie et de la croissance des végétaux, soit tous les 7 à 8 jours en général.

**EMBALLAGE :**

Réemploi de l'emballage interdit. Bien le vider et l'éliminer via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR.



**IMPORTANT:**

Respectez les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez, sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...  
Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture.

®marque déposée Cerexagri

**Poids Net : 10 kgs**

**Cerexagri SAS**

1, rue des Frères Lumière B.P. 9 - 78373 PLAISIR Cedex  
Tél : 01 30 81 73 00 - Fax : 01 30. 81 72 50 - R.C.S. Versailles 569 804 982

Fabriqué et conditionné par **Cerexagri B.V**

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### **Appendix 3 – Letter(s) of Access**