

## **REGISTRATION REPORT**

### **Part A**

### **Risk Management**

**Product code: Prochloraz 450 g/L EC**

**Product name: PROCHLORUS**

**Active substance:**

**Prochloraz, 450 g/L**

**COUNTRY: FRANCE**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**  
**(authorisation renewal and label extension)**

**Applicant: SOCIETE FINANCIERE DE**  
**PONTARLIER**

**Date: 2018/11/29**

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## PART A – Risk Management

The companies SOCIETE FINANCIERE DE PONTARLIER have requested marketing authorisation renewal and label extension in France for the product PROCHLORUS (formulation code: Prochloraz 450 g/L EC)), containing 450 g/L prochloraz, 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 PROCHLORUS (Prochloraz 450 g/L EC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of PROCHLORUS (Prochloraz 450 g/L EC) have been made using endpoints agreed in the EU peer review(s) of prochloraz.

This document describes the specific conditions of use and labelling required for France for the registration of PROCHLORUS (Prochloraz 450 g/L EC).

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 SOCIETE FINANCIERE DE PONTARLIER's application to market PROCHLORUS (Prochloraz 450 g/L EC) 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 substance of this product in France and in other MSs of the Southern zone.

### 1.2 Active substance approval

#### Prochloraz

Commission Implementing Regulation (EU) No 1143/2011 of 10 November 2011 approving the active substance prochloraz, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and Commission Decision 2008/934/EC

Specific provisions of Regulation (EU) No 1143/2011 were as follows:

#### PART A

Only uses as fungicide may be authorised. In the case of outdoor uses, rates shall not exceed 450 g/ha per application.

#### 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 prochloraz, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011, shall be taken into account.

In this overall assessment Member States:

- (a) shall pay particular attention to the protection of operators and workers and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate;
- (b) shall pay particular attention to the risk to aquatic organisms, and shall ensure that conditions of authorisation include risk mitigation measures, where appropriate;

(c) shall pay particular attention to the long-term risk to mammals and shall ensure that conditions of authorisation include risk mitigation measures, where appropriate.

The applicants shall submit confirmatory information as regards:

- (1) comparison and verification of the test material used in the mammalian toxicity and ecotoxicity dossiers against the specification of the technical material;
- (2) the environmental risk assessment for the metal complexes of prochloraz;
- (3) the potential endocrine disrupting properties of prochloraz on birds.

The notifier shall submit to the Commission, the Member States and the Authority the information set out in points 1 and 2 by 31 December 2013 and the information set out in point 3 within 2 years after the adoption of the pertinent OECD test guidelines on endocrine disruption.

An EFSA conclusion is available (EFSA Journal 2011; 9(7):2323).

A Review Report is available (SANCO/11959/2011 final Rev 4, 19 May 2016).

### 1.3 Regulatory approach

The present applications (2014-1553 and 2014-1747) 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 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:

<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>

<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/AGRGI1407093A/jo>

- 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 duplicated 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 PROCHLORUS (Prochloraz 450 g/L EC), 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.

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<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>	PROCHLORUS (Prochloraz 450 g/L EC)
<b>Authorisation number</b>	9200328
<b>Function</b>	Fungicide
<b>Applicants</b>	SOCIETE FINANCIERE DE PONTARLIER
<b>Composition</b>	450 g/L prochloraz
<b>Formulation type (code)</b>	Emulsifiable concentrate (EC)
<b>Packaging</b>	HDPE-f bottles (5 L)

### 2.2 Classification and labelling

#### 2.2.1 Classification and labelling in accordance with Regulation (EC) No1272/2008

<b>Physical hazards</b>	-	
<b>Health hazards</b>	Acute oral toxicity, Category 4; Aspiration Toxicity, Category 1; Acute inhalation toxicity, Category 4; Eye damage, Category 1; Specific Target Organ Toxicity – Single Exposure, Category 3.	
<b>Environmental hazards</b>	Aquatic Acute 1; Aquatic Chronic 1.	
<b>Hazard pictograms</b>		
<b>Signal word</b>	Danger	
<b>Hazard statements</b>	H302	Harmful if swallowed
	H304	May be fatal if swallowed and enters airways
	H318	Causes serious eye damage
	H332	Harmful if inhaled
	H336	May cause drowsiness or dizziness
	H400	Very toxic to aquatic life
	H410	Very 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>	EUH066	Repeated exposure may cause skin dryness or cracking.
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*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 3	To protect aquatic organisms respect an unsprayed buffer zone of 5 meters <sup>8</sup> to surface water bodies for use on spring cereals.
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 5 meters to surface water bodies including a strip of permanent, unsprayed plant cover 5 metres wide near surface water bodies for use on winter cereals.
SPa 1	To avoid the build-up of resistance of prochloraz, the number of applications is limited to one per crop cycle on wheat, spelt and triticale.  In order to control risks of resistance with product PROCHLORUS (Prochloraz 450 g/L EC), it is recommended to follow the restrictions on use per chemical group put forward in the note on resistance management on cereal diseases <sup>9</sup>

## 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> : 24 hours
Pre-harvest interval <sup>12</sup> : 35 days
Other mitigation measures: - The formulation must be protected from frost.
The label may include the following recommendations: - Protect from frost The label must reflect the conditions of authorisation.

<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> Note Commune (2017) INRA, ANSES, ARVALIS-Institut du végétal pour la gestion de la résistance aux fongicides utilisés pour lutter contre les maladies des céréales à paille.

<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 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>12</sup> According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

## 2.3 Product uses

**Please note:** The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.  
When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev., date: 2018-11-29

PPP (product name/code) **PROCHLORUS (Prochloraz 450 g/L EC)**  
active substance 1 **prochloraz**  
Formulation type: **EC**  
Conc. of a.s. 1: **450 g/L**  
Applicants: **SOCIETE FINANCIERE DE PONTARLIER**  
Zone(s): **southern**  
Verified by MS: **yes**  
professional use ☒  
non-professional use ☐

Crop and or situation (a)	country	F or G	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days)	Remarks (m)
				Type	Conc. of a.s.	Method, kind	Growth stage	Number (range)	Minimum interval between applications	g a.s./hL	water L/ha	g a.s./ha		
Wheat (TRZSS), triticale (TTLZO), spelt (TRZSP), Rye (SECCE)	FR	F	<i>Pseudocercospora herpotrichoides</i>	EC	450 g/L	Spraying	Beginning of stem elongation: pseudostem and tillers erect, first internode begins to elongate, top of inflorescence at least 1 cm above tillering node (BBCH 30-32)	1	-	150-642	150-500	450	35	<b>Not acceptable</b> Absence of data from trials to characterise the sensitivity of <i>Oculimacula</i> spp. to prochloraz and taking into account conclusions of the national resistance note which confirms that prochloraz is not efficient anymore against eyespot, the efficacy of PROCHLORUS (Prochloraz 450 g/L EC) is not considered as satisfactory against <i>Oculimacula</i> spp.
Wheat (TRZSS), triticale (TTLZO), spelt (TRZSP)	FR	F	<i>Septoria tritici</i> (SEPTTR)	EC	450 g/L	Spraying	BBCH 30-32	1	-	150-642	150-500	450	35	<b>Acceptable</b>

Applicant:  
SOCIETE FINANCIERE DE PONTARLIER

Evaluator: FRANCE  
Date: 2018/11/29



- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
  - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
  - (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
  - (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
  - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
  - (f) All abbreviations used must be explained
  - (g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
  - (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
  - (i) g/kg or g/l
  - (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
  - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
  - (l) PHI - minimum pre-harvest interval
  - (m) Remarks may include: Extent of use/economic importance/restrictions

### 3 RISK MANAGEMENT

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

##### 3.1.1 Physical and chemical properties

The formulation PROCHLORUS (Prochloraz 450 g/L EC) is an emulsifiable concentrate (EC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of orange limpid liquid. It is not explosive and has no oxidising properties. The product has a flash point of 71 °C. It has a self-ignition temperature of 429°C. In aqueous solution (1 %), it has a pH value of 5.17 at 20.5 °C. There is no effect of low and high temperatures on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. As the stability was performed on HDPE packaging, the HDPE/PA and HDPE-f packaging can both be considered acceptable. Its technical characteristics are acceptable for an emulsifiable concentrate (EC) formulation.

The formulation is classified H304 cat1.

The formulation must be protected from frost.

##### 3.1.2 Methods of analysis

Analytical methodology for the determination of the active substance is available and validated.

Relevant impurities (PCDDs and PCDFs) are by-products of the manufacturing process for prochloraz and cannot be formed by storage of the formulation. However an analytical method for the determination of relevant impurities in the formulation is required post-authorisation.

Analytical methods are available in the monograph/this dossier and validated for the determination of residues of prochloraz in plants (winter wheat, spring wheat, oats, triticale, rye, durum wheat), food of animal origin, soil, water (surface and drinking) and air. .

The active substance is 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

Endpoints used in risk assessment:

Active Substance: <b>prochloraz</b>			
ADI	0.01 mg kg bw/d		EU agreed endpoint 2012
ARfD	0.025 mg/kg bw/d		EU agreed endpoint 2012
AOEL	0.02 mg/kg bw/d		EU agreed endpoint 2012
Dermal absorption	Based on an <i>in vitro</i> rat, <i>in vivo</i> rat and <i>in vitro</i> human studies performed on the formulation (using a triple pack approach):		
		Concentrate (tested) 450 g/L	Diluted formulation (tested) 0.9 g/L
	<i>In vitro</i> (human) %	5 %	29 %
	<i>In vitro</i> (rat) %	8 %	47 %
	<i>In vivo</i> (rat) %	5 %	23 %

		Concentrate (used in formulation) 450 g/L	Spray dilution (used in formulation) 0.9 g/L
	<b>Dermal absorption endpoints %</b>	<b>3 %</b>	<b>14 %</b>

### 3.1.3.1 Acute Toxicity

PROCHLORUS (Prochloraz 450 g/L EC) containing 450g/L prochloraz is toxic to acute oral and inhalation studies and has a low toxicity to dermal toxicity and is not irritating to the rabbit skin but it is irritating to the chicken eye and is not a skin sensitiser.

### 3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G <sup>13</sup>	Equipment	Application rate L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Cereals	F	Tractor-mounted/trailed boom sprayer – hydraulic nozzles	1 L/ha (450)	150-500	BBA

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

Crop	Equipment	PPE and/or working coverall	% AOEL Prochloraz
Cereals	Tractor-mounted/trailed boom sprayer – hydraulic nozzles	Working coverall and gloves during mixing/loading and application	29 %

According to the model calculations, it can be concluded that the risk for the operator using PROCHLORUS (Prochloraz 450 g/L EC) is acceptable with a working coverall (90 % protection factor) 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

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 2.8 % of the AOEL of prochloraz.

It may be concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to PROCHLORUS (Prochloraz 450 g/L EC).

### 3.1.3.4 Resident Exposure

Residential exposure was assessed according to Martin *et al* model. Exposure is estimated to be 3.2 % of the AOEL of prochloraz for adults and 6.6 % of the AOEL of prochloraz for children.

It is concluded that there is no unacceptable risk to the resident exposed to PROCHLORUS (Prochloraz 450 g/L EC).

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

The currently available data (2001-2006) in the report of the ORP (French pesticides residues observatory) show a range of values, reaching the maximum value for prochloraz of 0.1 ng/m<sup>3</sup> (maximum daily measurements only). Based on these data, the respiratory exposure of people living near sprayed areas was estimated to be < 0.1 % of the ADI of the active substance for an adult and for a child.

### 3.1.3.5 Worker Exposure

Workers may have to enter treated areas after treatment for crop inspection activities. Therefore estimation of worker exposure was calculated according to EUROPOEM II. Exposure is estimated to be 15.8 % of the AOEL of prochloraz.

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 crops treated with PROCHLORUS (Prochloraz 450 g/L EC).

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

### 3.1.4 Residues and Consumer Exposure

#### Overall conclusion

The data available are considered sufficient for risk assessment.

Any exceedence of the current MRL on wheat of 0.5 mg/kg for prochloraz as laid down in Reg. (EU) 396/2005 is not expected.

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

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

#### Data gaps

No data gap identified.

#### Data required post-authorisation

- A storage stability study in straw should be provided in post-authorisation for prochloraz. Nevertheless, it should be noted that the applicants provided evidence that a draft report will be available in January 2018).

#### Summary of the evaluation

The preparation PROCHLORUS (Prochloraz 450 g/L EC) is composed of prochloraz.

**Table 3.1-1: Summary for prochloraz**

Use-No.*	Crop	Plant metabolis m covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL complian ce Reg (EU) No 520/2011	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
/	Wheat (TRZSS ), triticale (TTLSO ), spelt (TRZSP)	Yes	Yes (12 NEU and 7 SEU)	Yes	Yes	Yes	No	No	A storage stability study on straw should be provided in post-registration.

Use- No.*	Crop	Plant metabolis m covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL complan ce Reg (EU) No 520/2011	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
	1								Triticale by extrapolatio n from wheat data.

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

The effects of processing on the nature of prochloraz residues have been investigated. Data on effects of processing on the amount of residue have been submitted. These data were considered for risk assessment.

Considering dietary burden and based on the intended uses, significant modification of the intake was calculated for livestock (dairy cattle and beef cattle). Further investigation of residues as well as the modification of MRLs in commodities of animal origin would therefore normally be necessary, but considering that the uses under consideration are already registered in the EU, this will be achieved in the framework of article 12 of Regulation (EC) No 396/2005.

#### Summary for PROCHLORUS (Prochloraz 450 g/L EC)

**Table 3.1-2: Information on PROCHLORUS (Prochloraz 450 g/L EC)**

Crop	PHI for PROCHLORUS (Prochloraz 450 g/L EC)  proposed by applicant	PHI/withholding period* sufficiently supported for	PHI for PROCHLORUS (Prochloraz 450 g/L EC)  proposed by zRMS	zRMS Comments (if different PHI proposed)
		Prochloraz		
Wheat (TRZSS), triticale (TTLSO), spelt (TRZSP)	35 days	Yes	35 days	

NR: not relevant

\* Purpose of withholding period to be specified

#### 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 prochloraz and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS

models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PECsoil and PECsw values derived for prochloraz and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw values for prochloraz and its metabolites do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000<sup>14</sup>. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and 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 conclusions for the active substance and its metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

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

Risk mitigation measures are needed for aquatic organisms:

- To protect aquatic organisms respect an unsprayed buffer zone of 5 meters with an unsprayed vegetated buffer zone of 5 meters to surface water bodies for winter cereals,
- To protect aquatic organisms respect an unsprayed buffer zone of 5 meters to surface water bodies for spring cereals.

### 3.1.7 Efficacy

Considering the data submitted :

- ✓ The efficacy of PROCHLORUS (Prochloraz 450 g/L EC) is considered acceptable against *Septoria tritici*.

However, given the absence of data from trials to characterise the sensitivity of *Oculimacula* spp. to prochloraz and taking into account conclusions of the national resistance note which confirm that prochloraz is not efficient anymore against eyespot<sup>15</sup>, the efficacy of PROCHLORUS (Prochloraz 450 g/L EC) is not considered satisfactory against *Oculimacula* spp.

- ✓ The selectivity of PROCHLORUS (Prochloraz 450 g/L EC) is considered acceptable in the claimed conditions.
- ✓ The risk of negative impact (on yield, quality, transformation processes, propagation, succeeding and adjacent crops) is considered acceptable.
- ✓ The risk of the development of resistance to prochloraz is considered moderate for *Septoria tritici* and high for *Oculimacula* spp. To avoid the development of resistance to prochloraz, the number of applications of the preparation PROCHLORUS (Prochloraz 450 g/L EC) is limited to 1 application maximum per year on wheat due to *Septoria tritici*. The establishment of surveillance is deemed necessary.

<sup>14</sup> Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

<sup>15</sup> Note Commune INRA, ANSES, ARVALIS - Institut du végétal pour la gestion de la résistance aux fongicides utilisés pour lutter contre les maladies des céréales à paille (available at [http://driaaf.ile-de-france.agriculture.gouv.fr/IMG/pdf/note\\_commune\\_maladies\\_cereales\\_cle061b44.pdf](http://driaaf.ile-de-france.agriculture.gouv.fr/IMG/pdf/note_commune_maladies_cereales_cle061b44.pdf)), *op. cit.*

For *Septoria tritici* of wheat, resistance monitoring and efficacy trials in situations of characterised resistance should be established. Any new information which would change the assessment of the risk of resistance should be provided to the competent authorities, for all uses.

### **3.2 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.

### **3.3 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**

A monitoring of resistance and efficacy trials in situation of characterised resistance must be put in place on *Septoria tritici* of wheat. Any new information which would change the assessment of the risk of resistance for *Septoria tritici* of wheat. must be provided to the competent authorities.

#### **3.4.2 Post-authorisation data requirements**

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

- An analytical method for the determination of relevant impurities (the sum of dioxins and furans) in the formulation.
- A residues storage stability study in straw for prochloraz. Nevertheless, it should be noted that the applicants provided evidence that a draft report will be available in January 2018.

#### **3.4.3 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 des demandes associées

*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 de modification des informations déclarées du produit phytopharmaceutique **PROCHLORUS***

*de la société SOCIETE FINANCIERE DE PONTARLIER*

*enregistrées sous les n°2014-1553, 2014-1747, 2016-3795*

*Vu les conclusions de l'évaluation de l'Anses du 11 juin 2018,*

*Vu le courrier d'intention de retrait d'usage de l'Anses en date du 11 octobre 2018,*

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	
Noms du produit	PROCHLORUS PROFI PZ 450 EC
Type de produit	Produit de référence
Titulaire	SOCIETE FINANCIERE DE PONTARLIER 11 boulevard de la Grande Thumine Parc d'Ariane, Bâtiment B 13090 AIX-EN-PROVENCE FRANCE
Formulation	Concentré émulsionnable (EC)
Contenant	450 g/L - prochloraze
Numéro d'intrant	9200328
Numéro d'AMM	9200328
Fonction	Fongicide
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 2022.

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,

29 NOV. 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)

PROCHLORUS  
AMM n°9200328

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## ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Bidons en polyéthylène haute densité fluoré	5 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Toxicité aiguë par voie orale - Catégorie 4	H302 : Nocif en cas d'ingestion
Danger par aspiration - Catégorie 1	H304 : Peut être mortel en cas d'ingestion et de pénétration dans les voies respiratoires
Lésions oculaires graves et irritation oculaire - Catégorie 1	H318 : Provoque des lésions oculaires graves
Toxicité aiguë par inhalation - Catégorie 4	H332 : Nocif par inhalation
Toxicité spécifique pour certains organes cibles à la suite d'une exposition unique - Catégorie 3 : effets narcotique	H336 : Peut provoquer somnolence ou des vertiges
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
EUH066 : L'exposition répétée peut provoquer dessèchement ou gerçures de la peau.	
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 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 arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
15103221 Blé*Trt Pat.Aer.*Septoriose(s)	1 L/ha	1/an	entre les stades BBCH 30 et BBCH 32	35	5	-	-
	Uniquement sur cultures de printemps.						
15103221 Blé*Trt Pat.Aer.*Septoriose(s)	1 L/ha	1/an	entre les stades BBCH 30 et BBCH 32	35	5 (dont DVP 5)	-	-
	Uniquement sur cultures d'hiver.						

DVP : Dispositif Végétalisé Permanent

PROCHLORUS  
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### Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
00125008 Seigle*Trt Part.Aer.*Piétin verse	1 L/ha	1/an	35
<b>Motivation du refus :</b> L'usage est refusé en raison de la situation de résistance du piétin verse vis-à-vis du prochloraze.			

### Liste des usages retirés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	Délai accordé pour la vente et la distribution	Délai accordé pour le stockage et l'utilisation des stocks
15103210 Ble*Trt Part.Aer.*Piétin verse	1 L/ha	1/an	35	6 mois	18 mois
<b>Motivation du retrait :</b> L'usage est retiré en raison de la situation de résistance du piétin verse vis-à-vis du prochloraze.					

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## 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 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 ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3) ;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143) ou A2P3 (EN 14387).

#### **• 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 ;

*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 ;

#### **• 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.

### **Pour le travailleur, porter**

- 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 374-3 en cas de contact avec la culture traitée.

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

- 24 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 5 mètres par rapport aux points d'eau pour les usages sur céréales de printemps.

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau pour les usages sur céréales d'hiver.

**Gestion des résistances**

- Spa 1 : Pour éviter le développement de résistance à la substance prochloraze, le nombre d'applications du produit est limité à une application maximum par campagne sur « blé » du fait de la septoriose du blé.

Afin de gérer au mieux les risques de résistance, il est recommandé de suivre les limitations d'emploi par groupe chimique préconisées par la « Note commune INRA, ANSES, ARVALIS - Institut du Végétal pour la gestion de la résistance aux fongicides utilisés pour lutter contre les maladies des céréales à pailles ».

**Le produit peut être utilisé sur les usages autorisés, conformément aux conditions d'emploi antérieures à la présente décision 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 d'analyse pour la détermination des impuretés pertinentes dans le produit.	24	-
Fournir des données de stabilité au stockage des résidus de prochloraze dans la paille.	24	-
Poursuivre le suivi de la résistance au prochloraze pour la septoriose du blé. Fournir aux autorités compétentes toute nouvelle information susceptible de modifier l'analyse du risque de la résistance.	-	-
Mettre en place des essais d'efficacité en situation de résistance caractérisée au prochloraze pour la septoriose du blé.	-	-



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

S.F.P.

Société Financière de Pontarlier

MASTER LABEL

PROCHLORUS® (Prochloraz 450 g/L, EC)


Date/Revised :  
18/12/2013

Page 1 of 5

*A fungicide for use against Septoria tritici and Pseudocercospora herpotrichoides (eye spot) in winter wheat, spring wheat, oats, durum wheat, rye and triticale*

FOR USE ONLY AS AN AGRICULTURAL FUNGICIDE

Emulsifiable concentrate (EC) containing 450 g/l prochloraz

Net content: ... L 

Production date / Batch number: see packaging



MAPP number: #####



This label is compliant with the CPA Voluntary Initiative Guidance.

Approval holder:

Société Financière de Pontarlier  
Villa Celony  
1175 Montée d'Avignon  
13090 Aix en Provence  
FRANCE

Marketing company

Phytorus SA  
Parc Ariane Bât B  
11, Boulevard de la Grande Thumine  
13100 Aix en Provence  
FRANCE

SFP Europe  
Espace des Remparts 10  
1950 Sion  
SUISSE

S.F.P.

Société Financière de Pontarlier

## MASTER LABEL

**PROCHLORUS®** (Prochloraz 450 g/L, EC)

Date/Revised :  
18/12/2013

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**PROCHLORUS® - Emulsifiable Concentrate (EC) containing 450 g/L prochloraz**

Indication of Danger: Danger



GHS 05



GHS 07



GHS 08



GHS 09

### Hazard statements

- H302 Harmful if swallowed  
H304 May be fatal if swallowed and enters airways  
H318 Causes serious eye damage.  
H332 Harmful by inhalation  
H336 May cause drowsiness or dizziness  
H410 Very toxic to aquatic life with long lasting effects

### Precautionary statements

- P273 Avoid release to the environment.  
P280 Wear protective gloves/protective clothing/eye protection/face protection  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P391 Collect spillage  
P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician  
P501 Dispose of contents/container in accordance with local/national/International regulations  
  
SP1 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  
SPe3 To protect aquatic organisms respect an unsprayed buffer zone of 20 meters to surface water bodies

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

24-hour emergency number: 0032 14 58 45 45



Société Financière de Pontarlier

## MASTER LABEL

**PROCHLORUS®** (Prochloraz 450 g/L, EC)

Date/Revised :  
18/12/2013

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Important Information FOR USE ONLY AS AN AGRICULTURAL FUNGICIDE			
Crops	Maximum individual dose (L product per hectare)	Maximum total dose (L product /ha/crop)	Latest time of application
Winter wheat Spring wheat Oats Durum wheat Rye Triticale	1	2	End of heading: inflorescence fully emerged (BBCH 59)
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 contaminated surfaces.
- However, engineering controls may replace personal, protective equipment if a COSHH assessment shows they provide an equal or higher standard of protection.
- WASH CONCENTRATE from skin or eyes immediately.
- WASH HANDS AND EXPOSED SKIN before meals and after work.
- WHEN USING DO NOT EAT, DRINK OR SMOKE.

#### Environmental protection

- Do not contaminate water with the product or its container. Do not clean application equipment near surface water and avoid contamination via drains from farmyards and roads.
- Extreme care must be taken to avoid spray drift onto non-crop plants outside the target area.

#### Storage and disposal

- KEEP OUT OF REACH OF CHILDREN.
- KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDINGSTUFFS.
- KEEP IN ORIGINAL CONTAINER, tightly closed, in a safe place.

Dispose in safe manner in accordance with local/national regulations. Disposal of product would usually be by incineration in an appropriately licensed commercial incinerator. Small quantities may be accepted in licensed landfill sites. Advice may be obtained from the local waste regulation authority.



*Société Financière de Pontarlier*

## MASTER LABEL

**PROCHLORUS®** (Prochloraz 450 g/L, EC)

Date/Revised :  
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Container disposal: Do not reuse. Do not dispose empty containers as domestic waste. Deliver cleaned containers to assembly points.

### Resistance strategy

**PROCHLORAZ 450g/L EC** contains Prochloraz, a group code 3 fungicide according to the mode of action classification system of the Fungicide Resistance Action Committee guidelines (FRAC). Repeated use of fungicides with the same mode of action can increase the risk of strains of fungus/pathogens developing resistance to these compounds, leading to poor control/suppression. In order to minimise the risk, a strategy for preventing and managing such resistance should be adopted.

The azole based fungicides already have known resistance to some economically important pathogens, in order to extend the product lifespan ensure alternate product selection is used alongside tank mixtures of varying fungicides with different modes of actions belonging to different FRAC fungicide groups integrated with appropriate pathogen risk monitoring, and cultural techniques to include varietal resistance.

Further guidance on fungicide resistance management is available from the Fungicide Resistance Action Committee (FRAC).

### FIRST AID MEASURES

General advice: Remove person from danger zone. Remove contaminated clothing.

Inhalation: Move the patient to fresh air and keep at rest. Call for medical help.

Skin contact: In case of contact with skin wash off immediately with soap and water. Seek medical help.

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water for 15 – 20 minutes with eyelids held open and seek medical help.

Ingestion: Do not induce vomiting. Wash out mouth with water and give nothing by mouth. Keep at rest. Seek medical help immediately. If ingested perform gastric lavage and administer activated charcoal

### Notes to physician:

There is no specific antidote. Treat symptomatically and give supportive therapy.

### FOLLOWING CROPS

There are no restrictions in choice of a following crop.



Société Financière de Pontarlier

## MASTER LABEL

**PROCHLORUS® (Prochloraz 450 g/L, EC)**

Date/Revised :  
18/12/2013

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### DIRECTIONS FOR USE

Prochlorus® is a fungicide which offers a preventive, translaminar and curative effect against *Septoria tritici* and *Pseudocercospora herpotrichoides* (eye spot) on winter wheat, spring wheat, oats, durum wheat and triticale.

It exhibits a translaminar and local systemic action.

#### Winter wheat, spring wheat, oats, durum wheat and triticale

*Septoria tritici*

Timing: Stem elongation (BBCH 30-32) to head emergence (BBCH 59)

Dose: 1 L/ha

Maximum 2 applications per year

Minimum interval between applications: 14 days

*Pseudocercospora herpotrichoides* (eye spot)

Timing: End of tillering (BBCH 30) to second node (BBCH 32)

Dose: 1 L/ha

Maximum 1 application per year

#### Tank mixtures and sequences

Tank mixes and sequences should be done according to legislation. For tank mixture, it is often necessary to test physical and biological compatibility on a small part of the crop.

### PREPARATION OF THE SPRAY SOLUTION

Apply the product in a water volume of 150 to 500 liter water per ha to achieve a homogeneous distribution across the crop. Prochlorus® can be applied with all types of commonly used spray equipment.

**WARRANTY:** The seller makes no warranty, expressed or implied, concerning the use of the product other than indicated on the label. The purchaser and user shall assume all risk associated with the use and/or handling and/or storage of the product if this use and/or handling and/or storage are carried out contrary to label instructions.

**DAMAGES:** Buyer's or user's exclusive remedy for damages for breach of warranty or negligence shall be limited to direct damage not exceeding the purchase price of the product, and shall not include incidental or consequential damages.

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

Not applicable.