

## **REGISTRATION REPORT**

### **Part A**

### **Risk Management**

**Product name(s): MENHIR FL**

**Active Substance(s):**

**Chloridazon, 300 g/L**

**Metamitron, 280 g/L**

**COUNTRY: FRANCE**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(marketing authorisation)**

**Applicant: PHYTEUROP**

**Date: 2018-07-02**

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## PART A – Risk Management

The company PHYTEUROP has requested renewal authorisation and extension label in France for the product MENHIR FL, containing 300 g/L chloridazon and 280 g/L metamitron for use as a herbicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to MENHIR FL where that data have not been considered in the EU review process. Otherwise assessments for the safe use of MENHIR FL have been made using endpoints agreed in the EU review of both chloridazon and metamitron.

This document describes the specific conditions of use and labelling required for France for the registration of MENHIR FL.

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 PHYTEUROP's application to market MENHIR FL in France as an herbicide (product uses described under point 2.3). France acted as a Zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the renewal of authorisation after approbation of metamitron of this product in France and in other MSs of the Southern zone.

### 1.2 Active substance approval

#### Metamitron

Regulations 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 were as follows :

#### PART A

Only uses as herbicide may be authorised.

#### PART B

In assessing applications to authorise plant protection products containing metamitron for uses other than on root crops, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted.

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 metamitron, 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 safety and ensure that conditions of use prescribe the application of personal protective equipment where appropriate;

—the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;

—the risk to birds and mammals, and non-target terrestrial plants.

Conditions of authorisation shall include risk mitigation measures, where appropriate.

The Member States concerned shall request the submission of further information on the impact of soil metabolite M3 on groundwater, on residues in rotational crops, on the long-term risk to insectivorous birds and the specific risk to birds and mammals that may be contaminated by the intake of water in field. They shall ensure that the notifiers at whose request metamitron has been included in this Annex provide such information to the Commission by 31 August 2011 at the latest.

An EFSA conclusion is available (EFSA Scientific Report (2008) 186, pages 1-43).

A Review Report is available (SANCO/208/08 final, 6 January 2009, 20 March 2015).

### Chloridazon

Regulations 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 were as follows :

#### PART A

Only uses as herbicide in application max. of 2,6 kg/ha only every third year on the same field 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 chloridazon, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 December 2007 shall be taken into account.

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

—the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment,

—the protection of aquatic organisms,

—the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions.

Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated to verify potential groundwater contamination from metabolites B and B1 in vulnerable zones, where appropriate.

An EFSA conclusion is available (EFSA Scientific Report (2008) 186, pages 1-43).

A Review Report is available (SANCO/2822/07 – rev. 2, 25 October 2007).

### 1.3 Regulatory Approach

The present application (2012-0985 and 2012-1006) was 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 in the decision letter.

The French Order of 4<sup>th</sup> May 2017<sup>3</sup> provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 m;
- unless formally stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 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’ assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009<sup>4</sup>, implementing regulations, and French regulation.

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) No546/2011<sup>5</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

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 MENHIR FL, 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 the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

<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

## 2 DETAILS OF THE AUTHORISATION

### 2.1 Product Identity


Product name (code)	MENHIR FL
Authorisation number	9400479
Function	herbicide
Applicant	PHYTEUROP
Composition	300 g/L chloridazon 280 g/L metamitron
Formulation type (code)	Suspension concentrate (SC)
Packaging	High density polyethylene (HDPE) containers holding 5 L product

### 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) No1272/2008

Physical hazards	-	
Health hazards	-	
Environmental hazards	Chronic aquatic toxicity: Category 2	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H411	Toxic to aquatic life with long lasting effects.
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)		“contains 1,2-benzisothiazolin-3-one and chloridazon . may produce an allergic reaction”

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 1	To protect groundwater, do not apply this or any other product containing chloridazon or metamitron (at similar application rates 960 g/ha and 896 g/ha respectively) more than every third year.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres <sup>6</sup> to surface water bodies.

#### 2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment <sup>7</sup> : refer to the Decision in Appendix 1 for the details
Re-entry period <sup>8</sup> : 6 hours
Pre-harvest interval <sup>9</sup> : F – last application at the latest at stage BBCH 18
Other mitigation measures: - Do not to feed animals with the leaves of treated beets, after a cultural failure or a thinning. - Only cereals, root or tuber crops can be grown as succeeding or rotational crops.
The label may include the following recommendations: - The label must reflect the conditions of authorisation.

<sup>6</sup> The legal basis for this is **Titre III Article 11** of the [French Order of 4<sup>th</sup> 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>7</sup> If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

<sup>8</sup> The legal basis for this is **Titre I Article 3** of the [French Order of 4<sup>th</sup> 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> According to the French Order of 4<sup>th</sup> May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.





Seeds production : Sugar & fodder beet, garden beet (BEAVD), chard beet (BEAVV)	FR	13803500	F	Weeds	SC	300 g/L Chloridazon 280 g/L Metamitron	Overall (Hydraulic Sprayer)	Premergence (BBCH 00-09)	1	N/A	-	80 - 150	Chl.: 0.96 Met.: 0.90	F – premergence (BBCH 09)	Acceptable  1 x 3,2L/ha in premergence  Or  up to 4 x0,8 L/ha per application in post-emergence
								BBCH 10-18	4	7	-	80 - 150	Per application Chl.: 0.24 Met.: 0.22	F - later application growth stage BBCH 18	

**Remarks:**

- |   |  |
|---|--|
| <ul style="list-style-type: none"> <li>(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (<i>e.g.</i> fumigation of a structure)</li> <li>(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)</li> <li>(c) <i>e.g.</i> biting and suckling insects, soil born insects, foliar fungi, weeds</li> <li>(d) <i>e.g.</i> wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</li> <li>(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989</li> <li>(f) All abbreviations used must be explained</li> <li>(g) Method, <i>e.g.</i> high volume spraying, low volume spraying, spreading, dusting, drench</li> <li>(h) Kind, <i>e.g.</i> overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated</li> </ul> | <ul style="list-style-type: none"> <li>(i) g/kg or g/l</li> <li>(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</li> <li>(k) The minimum and maximum number of application possible under practical conditions of use must be provided</li> <li>(l) PHI - minimum pre-harvest interval</li> <li>(m) Remarks may include: Extent of use/economic importance/restrictions</li> </ul> |
|---|--|

### 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 MENHIR FL is a suspension concentrate. All studies have been performed in accordance with the current requirements. The appearance of the formulation is homogeneous beige opaque water-based liquid. It is not explosive and has no oxidizing properties. It has a self-ignition temperature of 595°C and a flash point above 190°C. In 1% aqueous solution, its pH is 6.5 at 21°C. Stability data indicate a shelf life of at least 2 years at ambient temperature (PE/PA packaging), nevertheless, seepage data for HPDE packaging must be provided in post authorisation. Its technical characteristics are acceptable for a suspension concentrate formulation.

##### 3.1.2 Methods of analysis

###### 3.1.2.1 Analytical method for the formulation

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

As relevant the impurity 4-amino-5- chloro-isomer is a by-product of the manufacturing process for the active substance, an analytical method for the determination of the relevant impurity in the formulation must be provided or it must be proven it cannot be formed during the storage of the formulation.

###### 3.1.2.2 Analytical methods for residues

Analytical methods are available in the monograph/this dossier and validated for the determination of residues of metamitron in plants, soil, water (surface and drinking) and air. Nevertheless, an analytical method for the determination of residues of metamitron in foodstuff of animal origin is required in post-authorisation.

Analytical methods are available in the monograph/this dossier and validated for the determination of residues of chloridazone in plants, food of animal origin, soil, water (surface and drinking) and air. Nevertheless, confirmatory methods for determination residues of chloridazon in soil and water, and in air if no confirmatory method is available in soil and water must be provided in post-authorisation. A confirmatory method for the determination of residues of chloridazone in foodstuff of animal origin is also required in post-authorisation.

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

###### 3.1.3.1 Acute Toxicity

MENHIR FL 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 not a skin sensitizer.

###### 3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G	Equipment	Application rate L product/ha (g as/ha)	Spray dilution (L/ha)	Model
Sugar & fodder Beet	F	Tractor mounted with boom sprayer	3 L product/ha (chloridazon: 900 g/ha metamitron 840 g/ha)	100-150	German model

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

Crop	Equipment	PPE and/or working coverall	% AOEL Metamitron	% AOEL chloridazon
Sugar & fodder Beet	Tractor mounted with boom sprayer	Working coverall and gloves during mixing/loading and application	59	33

According to the model calculations, it can be concluded that the risk for the operator using MENHIR FL is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.

### 3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to 6.2 % of the AOEL of metamitron and 2.5% of chloridazon.

It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to MENHIR FL.

### 3.1.3.4 Worker Exposure

MENHIR FL is used as herbicidal treatment on several crops where there is no need to re-enter the treated area after application. Worker exposure is considered not relevant.

## 3.1.4 Residues and Consumer Exposure

### 3.1.4.1 Residues

Primary crop metabolisms were sufficiently investigated to define the residue of chloridazon and metamitron for enforcement and risk assessment in crops under consideration.

Regarding the magnitude of residues in sugar beet and fodder beet, a sufficient number of residue trials are available to support the intended GAPs in France. These data allowed to confirm that no MRL exceedance will result from intended uses.

As residues of metamitron do not exceed the trigger value of 0.1 mg/kg in sugar beet, there is no need to investigate the effect of industrial and/or household processing. Magnitude of chloridazon residues in processed commodities was sufficiently documented to support the intended uses of the preparation MENHIR FL.

Residues of metamitron in succeeding crops have been sufficiently investigated. It is very unlikely that residues will be present in succeeding crops.

Concerning chloridazon residues, parent compound and its metabolite B may be present at quantifiable levels in foliar plant parts. Only cereals, root or tuber crops are possible to be grown as succeeding crop (in case of crop failure) or rotational crops. In these conditions, residues levels in the part of succeeding crops used for human consumption will be below the limit of quantification.

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

### 3.1.4.2 Consumer exposure

The toxicological profile of chloridazon was evaluated at EU level, which resulted in the proposal of an ADI that was considered in the frame of this evaluation. An ARfD was not deemed necessary.

Chronic consumer exposure resulting from the uses proposed in the framework of this application was calculated. Based on EFSA PRIMo (rev2), chronic exposure was considered as acceptable for all groups of consumers.

The toxicological profile of metamitron was evaluated at EU level, which resulted in the proposal of an ADI and an ARfD that were considered in the frame of this evaluation.

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

### 3.1.4.3 Mitigation measures (Part B, Section 4, Point 8.11)

According to available data, specific mitigation measures are recommended:

- Tops should not be fed after thinning or crop failure.
- Only cereals, root or tuber crops are possible to be grown as succeeding (in case of crop failure) or rotational crops.

### 3.1.5 Environmental fate and behaviour

The fate and behaviour 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 appropriated (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC of metamidon, chloridazon and their respective metabolites desamino-metamidon, B and B1 in soil and surface water has 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.

PEC soil and PEC<sub>sw</sub> derived for the active substances and their metabolites are used for the eco-toxicological risk assessment, and mitigation measures are proposed.

PEC<sub>gw</sub> for metamidon, chloridazon and the metabolite desamino-metamidon do not exceed the trigger of 0.1 µg/L for applications every third year.

Both metabolites B and B1 of chloridazon are not considered of toxicological relevance according to guidance document SANCO 221/2000. The PEC<sub>gw</sub> calculated for metabolite B1 exceed the trigger of 0.1 µg/L for all scenarios but remain below 10 µg/L (maximum value of 7.8 µg/L). However, the PEC<sub>gw</sub> calculated for the metabolite B are under the regulatory threshold of 10 µg/L only for the following applications:

- 1 application of 3.0 L/ha of preparation on sugar beets every third year at pre-emergence;
- 4 applications of 0.8 L/ha of preparation on sugar beets, every third year at post-emergence.

Therefore, no unacceptable risk of groundwater contamination is expected following the use of MENHIR FL at a maximal application rate of 3.2 L/ha (with a maximum of 3L/ha in pre-emergence).

Based on their vapour pressures, information on volatilisation from plants and soil, and DT50 calculations, no significant contamination of the air compartment is expected for the intended uses for the active substances.

### 3.1.6 Ecotoxicology

#### 3.1.6.1 Effects on Terrestrial Vertebrates

The risk assessment for effects on birds is carried out according to the EFSA guide “Risk Assessment for Birds and Mammals”, EFSA Journal 2009; 7(12):1438.

The acute Tier 1 TERs are above the trigger value indicating an acceptable acute risk for birds. The long-term TER values are below the trigger value. Refined TER for omnivorous birds were below the trigger value. Additional data were required to notifier for granivorous and insectivorous birds but were not submitted. No long-term acceptable risks to birds were concluded for an application of 5 L/ha. For an application of 3.2 L/ha, the long-term risk to birds is acceptable for application on sugar beet at BBCH 10-19.

The risk assessment for effects on terrestrial vertebrates other than birds is carried out according to the EFSA guide “Risk Assessment for Birds and Mammals”, EFSA Journal 2009; 7(12):1438.

The acute Tier 1 TERs are above the trigger value indicating an acceptable acute risk for mammals. The long-term TER values are below the trigger value. Refined TER for herbivorous mammals were calculated based on DT50 of active substances in sugar beet, the TER values are above the trigger value indicating an acceptable risk to mammals.

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

Based on NOAEC of 1.2 mg as/L from mesocosm and PEC Step 3, the risk is acceptable for aquatic organisms with respect of a buffer zone of 5 m.

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

The HQ values are below the trigger value of 50 for active substances and the preparation MENHIR FL indicating acceptable risk to honeybees.

The in-field predicted environmental rates of the preparation MENHIR FL are below the lethal and sublethal toxicity endpoints indicating that the risk to all in-field non-target arthropods is acceptable following use of MENHIR FL according to the proposed use pattern.

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

The acute TER values for active substances, their metabolites and the preparation MENHIR FL are above the trigger values indicating an acute acceptable risk to earthworms. The chronic TER value for metabolite B is above the trigger value indicating an acceptable chronic risk to earthworms.

No complementary study was conducted because as the TER are greatly above the trigger values, it can be considered that there is no potential risk of negative effect on other soil non-target macro-organisms. Moreover DT<sub>90</sub> values of metamitron and chloridazon are less than 365 days.

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

The deviation between treatments and control were below 25 % for nitrogen turnover as well as short-term respiration, so it can be concluded that MENHIR FL has no adverse effect to soil micro-organisms and the risk is acceptable.

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

A vegetative vigour test was conducted with the preparation MENHIR FL. Vegetative vigour TER based on drift at 1 m from the crop edge exceeds the trigger value of 5. Based on active substances EU endpoints, seedling emergence TER exceeds the trigger value. The risk to non-target plants after application of MENHIR FL is considered acceptable following applications in accordance with label recommendations.

### **3.1.7 Efficacy**

The product complies with the Uniform Principles.

Considering the data submitted:

- the efficacy of MENHIR FL is considered as satisfying,
- the selectivity of MENHIR FL is considered as satisfying.
- the risk of negative impact (yield, quality, transformation processes, propagation, succeeding crops, adjacent crops) is considered as negligible.
- the risk of resistance development or appearance is considered as low.

### **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**

No further information is required.

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

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

- As relevant the impurity 4-amino-5- chloro-isomer is by-product of the manufacturing process for active ingredient, an analytical method for the determination of the relevant impurity in the formulation.
- Confirmatory method for the determination of residues of chloridazon in foodstuff of animal origin.
- An analytical method for the determination of residues of metamidron in foodstuff of animal origin.
- Confirmatory methods for determination residues of chloridazon in soil and water, and in air if no confirmatory method is available in soil and water.

#### **3.4.3 Label amendments (see label in Appendix 2):**

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 de la demande associée

*Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,*

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

*Vu les demandes de renouvellement de l'autorisation de mise sur le marché et d'extension d'usage mineur du produit phytopharmaceutique **MENHIR FL***

*de la société PHYTEUROP*

*enregistrées sous les n°2012-0985 et n°2012-1006*

*Vu les conclusions de l'évaluation de l'Anses du 11 janvier 2018 relatives à la demande de renouvellement de l'autorisation,*

*Vu les conclusions de l'évaluation de l'Anses du 11 janvier 2018 relatives à la demande d'extension d'usage mineur,*

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	MENHIR FL SUROIT FL
Type de produit	Produit de référence
Titulaire	PHYTEUROP 55, rue Raspail - CS 80105 92594 Levallois-Perret Cedex FRANCE
Formulation	Suspension concentrée (SC)
Contenant	300 g/L - chloridazone 280 g/L - métamitron
Numéro d'intrant	9400479
Numéro d'AMM	9400479
Fonction	Herbicide
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 décembre 2019.

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

02 JUL. 2018

La directrice générale déléguée  
en charge du pôle des produits réglementés

Françoise WEBER

MENHIR FL  
AMM n°9400479

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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	5 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Dangers pour le milieu aquatique - Danger chronique, catégorie 2	H411 : Toxique pour les organismes aquatiques, entraîne des effets à long terme
Pour les phrases P se référer à la réglementation en vigueur.	
<b>Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.</b>	



### Liste des usages autorisés

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitee aquatique (mètres)	Zone Non Traitee arthropodes non cibles (mètres)	Zone Non Traitee plantes non cibles (mètres)	Mention abeilles
<b>15055911</b> Betterave industrielle et fourragère* Dés herbage	3 L/ha	1/an	jusqu'au stade BBCH 09	F (BBCH 09)	5	-	-	-
	Application de pré levée : ne pas cumuler les applications en pré levée et post levée sur une même culture.							
	0,8 L/ha	4/an	entre les stades BBCH 10 et BBCH 18	F (BBCH 18)	5	-	-	-
<b>10995900</b> Porte graine* Dés herbage	Applications de post levée : ne pas cumuler les applications en pré levée et post levée sur une même culture.							
	3,2 L/ha	1/an	jusqu'au stade BBCH 09	F (BBCH 09)	5	-	-	-
	Uniquement sur betterave potagère, betterave industrielle, betterave fourragère et poirée porte-graines. Diminution de la dose de 5 L/ha à 3,2 L/ha en raison d'un risque pour les eaux souterraines.							
	0,8 L/ha	4/an	entre les stades BBCH 10 et BBCH 18	F (BBCH 18)	5	-	-	-
	Uniquement sur betterave potagère, betterave industrielle, betterave fourragère et poirée porte-graines. Diminution de la dose de 5 L/ha à 3,2 L/ha en raison d'un risque pour les eaux souterraines.							

MENHIR FL  
AMM n°9400479

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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 effectuée 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) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

###### **• pendant l'application**

- Combinaison de travail en polyester 65 % / coton 35 % avec un grammage de 230 g/m<sup>2</sup> ou plus avec traitement déperlant ;
- Bottes de protections certifiées EN 13 832-3

##### **Si application avec tracteur sans cabine**

- Gants en nitrile certifiés EN 374-2 à usage unique ;

##### **Si application avec tracteur avec cabine**

- Gants en nitrile certifiés EN 374-2 à usage unique lors d'interventions sur le matériel de pulvérisation. Les gants doivent être stockés à l'extérieur de la cabine ;

##### **Si application avec un pulvérisateur à dos ou avec lance tenue à la main**

- Gants en nitrile certifiés EN 374-3 réutilisables ;

###### **• 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) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.

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

- Une combinaison de travail polyester 65 % / coton 35 % avec un 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 :**

- 6 heures.





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

Seules des céréales ou des cultures de type tubercules ou racines peuvent être implantées en cas d'échec de la culture ou comme cultures de rotation.

Ne pas utiliser les feuilles de betteraves en alimentation animale après un échec cultural ou un éclaircissage.

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.

- SPe 1 : Pour protéger les eaux souterraines, ne pas appliquer une dose supérieure à 3,2 L/ha de produit (soit 960 g/ha de chloridazone et 896 g/ha de métamitron) ou de tout autre produit contenant de la chloridazone ou de la métamitron (à des doses équivalentes) plus d'une fois tous les 3 ans.

##### **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.

#### **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)	Réurrence (mois)
Déterminer la teneur en impureté pertinente (4-amino-5-chloro-isomère) avant et après un stockage de 2 semaines à 54°C.	24	-
Déterminer la teneur en impureté pertinente (4-amino-5-chloro-isomère) avant et après un stockage de 2 ans à température ambiante.	24	-
Fournir une méthode analytique pour la détermination de l'impureté pertinente de la chloridazone (4-amino-5-chloro-isomère) dans le produit.	24	-
Fournir une méthode de détermination des résidus de métamitron dans les denrées d'origine animale.	24	-
Fournir une méthode de confirmation pour la détermination des résidus de la chloridazone dans le sol, dans l'eau, dans l'air et dans les denrées d'origine animale.	24	-

#### **Recommandations relatives à l'étiquette du produit**

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- Contient du 1,2-benzisothiazolin-3-one et de la chloridazone. Peut produire une réaction allergique.

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

MENHIR® FL				
<b>NOM COMMERCIAL :</b> MENHIR FL <b>N° D'AMM :</b> 9400479 <b>DETENTEUR DE L'AMM :</b> Phyteurop (53 rue Raspail 92594 LEVALLOIS-PERRET CEDEX) <b>TYPE D'ACTION :</b> Herbicide (HRAC : C1) <b>FORMULATION :</b> Suspension concentrée (SC) <b>COMPOSITION :</b> 300 g/l (24,69%) chloridazone 280 g/l (23,05%) métamitron				
<b>Culture / Organisme nuisible</b>	<b>Dose*</b>	<b>ZNT</b>	<b>DAR</b>	
Betteraves industrielles et fourragères / désherbage	5,0 l/ha	5 m	90 jours	
<ul style="list-style-type: none"> <li>Limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse : <a href="http://ec.europa.eu/sanco_pesticides/public/index.cfm">http://ec.europa.eu/sanco_pesticides/public/index.cfm</a>.</li> <li>Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur.</li> <li>Délai de rentrée : 6 heures (non pertinent pour les usages en prélevée).</li> </ul>				
<b>Performances :</b>				
<p><b>MENHIR FL</b> agit préférentiellement par voie racinaire. Les substances actives agissent par systémie ascendante et inhibent la fonction chlorophyllienne.</p> <p><b>MENHIR FL</b> est actif sur de très jeunes plantules avec un spectre essentiellement antiodicotylédones. Les espèces les plus sensibles sont : Amarante, Capselle, Chénopode, Coquelicot, Fumeterre, Lamier amplexicaule, Matricaire, Morelle noire, Mouron rouge, Pensée, , Ravenelle, Réséda, Sanve, Repousses de colza, Renouée des oiseaux, Renouée persicaire, Renouée liseron, Stellaire, Véroniques.</p> <p>Sur ombellifères, mercuriale et gaillet, prévoir un partenaire spécifique complémentaire.</p>				
<b>Périodes et doses d'emploi :</b>				
<p>Post-semis/prélevée : <b>MENHIR FL</b> s'utilise à la dose 3,0 l/ha. Les meilleures performances sont obtenues sur sol frais. Eviter d'intervenir en cas d'épisodes pluvieux significatifs.</p> <p>Post-levée : <b>MENHIR FL</b> peut être utilisé en post-levée en complément des herbicides de base. L'intervention doit toujours être effectuée sur des adventices jeunes et sur une culture en bon état végétatif, le stade de la betterave étant secondaire. La dose pivot recommandée pour <b>MENHIR FL</b> est de 0,8 l/ha. Selon la cadence de traitement, le type de sol, le niveau d'infestation, les herbicides de base mis en œuvre, cette dose peut être ajustée de 0,6 à 1,0 l/ha par passage.</p> <p>*Adaptez votre stratégie de désherbage en tenant compte d'une limitation à 2,6 kg/ha de chloridazone sur une période de trois ans.</p>				
<b>Préparation :</b>				
<p>Verser directement <b>MENHIR FL</b> dans la cuve du pulvérisateur à demi remplie d'eau. <b>MENHIR FL</b> se mélange directement par simple brassage. Il est recommandé d'utiliser la bouillie immédiatement après la préparation et de maintenir une agitation pendant toute la durée du traitement.</p>				
<b>Bonnes Pratiques Phytosanitaires</b>				
<ul style="list-style-type: none"> <li>Toujours conserver le produit dans leur emballage d'origine. Le stocker dans un local réservé à cet usage, frais, sec, bien ventilé et fermant à clé, à l'abri du gel et de la chaleur</li> <li>Réservé à un usage professionnel.</li> </ul>				
<b>Elimination du produit et de l'emballage :</b>				
<ul style="list-style-type: none"> <li>Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.</li> <li>Réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et rincer le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Eliminer les emballages vides via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR.</li> <li>Eliminer les fonds de cuve conformément à la réglementation en vigueur.</li> </ul>				
<b>MENHIR FL</b> contient : chloridazone, peut déclencher une réaction allergique				
 <p><b>R51/53 Toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique.</b></p>				
<p>S61 Eviter le rejet dans l'environnement. Consulter les instructions spéciales / la fiche de données de sécurité.</p>				
<p><b>N – Dangereux pour l'environnement</b></p> <p>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]</p>				
<p>Respectez les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.</p>				
<p>Distribué par :            PHYTEUROP - 53, rue Raspail - 92594 Levallois-Perret Cedex            Tél.: 01 47 59 77 00 - Fax : 01 47 37 54 52 - <a href="http://www.phyteurop.com">www.phyteurop.com</a></p>				
<p><b>Premiers soins</b></p> <ul style="list-style-type: none"> <li>Enlever immédiatement les vêtements contaminés par le produit</li> <li>Après inhalation : Donner de l'air frais</li> <li>Après contact avec la peau : Laver immédiatement et abondamment à l'eau et au savon. Bien rincer.</li> <li>Après contact avec les yeux : Rincer les yeux pendant plusieurs minutes, sous l'eau courante en écartant bien les paupières.</li> <li>Après ingestion : Rincer la bouche à l'eau. Ne pas faire vomir.</li> <li>Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité.</li> </ul>				
<p>La fiche de données de sécurité peut être obtenue gratuitement sur Internet à l'adresse <a href="http://www.quickfds.com">www.quickfds.com</a>.</p>				
<p><b>IMPORTANT :</b>            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 les 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.</p>				
<p><b>EMB : 49215 F</b></p> <p>©Marque déposée par PHYTEUROP SA</p>				
<p>Date de fabrication : Voir sur le bidon</p> <p>Volume net : <b>5 L</b></p>				
<p><b>PHYTEUROP</b>            un éclairage différent</p>				

### Appendix 3 – Letter(s) of Access



**OXON**

**Afssa – DiVE**  
**UGamm**  
**Réexamen post inscription**  
10 rue Pierre Curie  
94704 MAISON ALFORT Cedex  
France

**CC: Ministère de L'agriculture, De L'alimentation,**  
**De La Pêche Et Des Affaires Rurales**  
**Direction générale de l'alimentation**  
**Sous-direction qualité et protection des végétaux**  
**Bureau de la Réglementation et de la Mise sur le Marché**  
**des Intrants**  
251 Rue de Vaugirard  
75732 Paris Cedex 15  
France

Pero, 9<sup>th</sup> December 2008

**Re: MENHIR FL (Reg. No. 9400479): letter of Access to OXON ITALIA SpA annex II data of chloridazon**

Further to the inclusion of chloridazon in Annex I of directive 91/414/EEC, **OXON ITALIA SpA** hereby grant access to chloridazon Annex II data, jointly owned by OXON Italia S.p.A. and BASF, that will be submitted by the 31<sup>st</sup> December 2008, date of the entry into force of Commission Directive 2008/41/EC, to **Afssa – DiVE - UGamm**

**TO**

**PHYTEUROP S.A.** for their product **MENHIR FL (chloridazon 300 g/l, metamithron 280 g/l)** as placed on the market in France under the registration number **9400479**.

This letter is valid exclusively for the product in object containing technical chloridazon from OXON ITALIA SpA and is not a general letter of access.

This letter does not give any right to **PHYTEUROP S.A.** to receive copies of or to have sight of the data.

Access to the data is permitted on the basis of the condition described in this letter only.

This letter of access is not transferable and may not be used in support of any other application for registration or re-registration by companies other than OXON ITALIA SpA.

Yours sincerely,

Nicola Gelmetti

OXON ITALIA SpA

**OXON ITALIA S.p.A.**  
Development & Regulatory Affairs  
Manager  
(Nicola Gelmetti)

OXON ITALIA S.p.A.  
Direzione e Uffici  
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Tel. +39 02 35378-1  
Fax +39 02 3390275  
www.oxon.it

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Registro Imprese di Milano e  
Codice Fiscale n. 00845900158  
R.E.A. Milano n. 804531  
C.F./ P. IVA IT 00845900158





AFSSA - DiVE - UGAmm  
10 rue Pierre Curie  
94704 Maisons – Alfort Cedex  
France

## Letter of Access

With this Letter of Access SD Agchem (Europe) NV authorizes **Phyteurop , 53, rue Raspail, 92594 LEVALLOIS-PERRET Cedex, France** to refer to the 'Step one submission Metamitron', that was carried out by SD Agchem (Europe) NV and AgriChem B.V. in June 2009, to support the following approval in France:

**Menhir FL**  
**AMM N° 9400479**  
**(Metamitron 280 g/l + Chloridazon 300 g/l SC)**

This Letter of Access shall be subjected to the following conditions:

1. This Letter of Access concerns reference right only. It is not allowed to inform **Phyteurop** of the contents of our 'Step one submission Metamitron'. **Phyteurop** does not have the right to inspect the documents included in this 'Step one submission Metamitron' nor to receive copies of it.
2. This reference right is only with respect to our 'Step one submission Metamitron' that was carried out in June 2009 and therefore only concerns data related to 'metamitron' as an active ingredient.
3. This reference right is linked to the continuous supply of metamitron technical of Punjab Chemicals and Crop Protection Limited, the parent company of SD Agchem (Europe) NV and AgriChem B.V., to **Phyteurop** to prepare **Menhir FL (AMM N° 9400479)**.
4. SD Agchem (Europe) NV reserves the right to cancel this reference right in case **Phyteurop** uses metamitron technical from another source than Punjab Chemicals and Crop Protection Limited to prepare **Menhir FL (AMM N° 9400479)**.
5. This reference right is solely granted to **Phyteurop** and is not transferable to any further companies or other legal or natural entities.

---

Uitbreidingstraat 84/3, 2600 Antwerp (Berchem), BELGIUM Tel: 0032-3-8300960 Fax: 0032-3-8303660  
Email: [shail.shroff@pcplsts.com](mailto:shail.shroff@pcplsts.com)/ [fborges@sdagchem.be](mailto:fborges@sdagchem.be) Website: [www.pcplsts.com](http://www.pcplsts.com)

Letter of Access MTM-2009 MENHIR FL PHYTEUROP page 1 of 2





Yours faithfully,

For SD Agchem (Europe) NV

A handwritten signature in blue ink, appearing to read 'Francis Borges', is written over a horizontal line.

Francis Borges  
C.E.O.  
Date: 21 July 2009

Uitbreidingstraat 84/3, 2600 Antwerp (Berchem), BELGIUM Tel: 0032-3-8300960 Fax: 0032-3-8303660  
Email: [shalil.shroff@pcplsts.com](mailto:shalil.shroff@pcplsts.com)/ [fborges@sdagchem.be](mailto:fborges@sdagchem.be) Website: [www.pcplsts.com](http://www.pcplsts.com)

Letter of Access MTM-2009 MENHIR FL PHYTEUROP page 2 of 2





Anses – DPR – UGamm  
253 Avenue du Général Leclerc  
94700 Maisons-Alfort cedex  
FRANCE

## Letter of Access (supplement)

This Letter of Access is a supplement to the letter which was provided by SD Agchem (Europe) NV on the 21<sup>st</sup> of June 2009. With the latter Letter of Access SD Agchem (Europe) NV authorized **Phyteurop, 53, rue Raspail, 92594 LEVALLOIS-PERRET Cedex, France** to refer to the 'Step one submission Metamitron', that was carried out by SD Agchem (Europe) NV and AgriChem B.V. in June 2009, to support the following approval in France:

**Menhir FL**  
**AMM N° 9400479**  
**(Metamitron 280 g/l + Chloridazon 300 g/l SC)**

This supplement gives **Phyteurop** the right to refer to the following statement, addressing further information on the impact of soil metabolite M3 on groundwater, as was requested for Metamitron in Commission Directive 2008/125/2008 of 19 December 2008, in support of the above-mentioned product in France:

Rijswijk, M. van (2012), Statement – Relevance of unidentified metabolite M3 of Metamitron, AgriChem B.V. Report reference C120270A-M00107, 6 February 2012.

This statement is included in the re-registration applications of the metamitron-based products of which AgriChem B.V. is the authorisation holder. The statement can also be provided directly to the authorities on request.

This Letter of Access is only a supplement. Access to the above-mentioned statement is subject to the same conditions as mentioned in the letter of 21 June 2009:

1. This Letter of Access concerns reference right only. It is not allowed to inform **Phyteurop** of the contents of the statement concerned. **Phyteurop** does not have the right to inspect the statement concerned nor to receive copies of it.

Uitbreidingstraat 84/3, 2600 Antwerp (Berchem), BELGIUM Tel: 0032-3-8300960 Fax: 0032-3-8303660  
Email:shalil.shroff@pcplsts.com/ [fborges@sdagchem.be](mailto:fborges@sdagchem.be) Website: [www.pcplsts.com](http://www.pcplsts.com)

Letter of Access (suppl 2012) MENHIR FL PHYTEUROP page 1 of 2



2. This reference right is only with respect to the above-mentioned statement dated 6 February 2012.
3. This reference right is linked to the continuous supply of metamitron technical of Punjab Chemicals and Crop Protection Limited, the parent company of SD Agchem (Europe) NV and AgriChem B.V., to **Phyteurop** to prepare **Menhir FL (AMM N° 9400479)**.
4. SD Agchem (Europe) NV reserves the right to cancel this reference right in case **Phyteurop** uses metamitron technical from another source than Punjab Chemicals and Crop Protection Limited to prepare **Menhir FL (AMM N° 9400479)**.
5. This reference right is solely granted to **Phyteurop** and is not transferable to any further companies or other legal or natural entities.

Yours faithfully,

For SD Agchem (Europe) NV

A handwritten signature in blue ink, appearing to read 'Francis Borges', is written over a faint circular background.

Francis Borges  
Director  
Date: 21 February 2012

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