

REGISTRATION REPORT

Part A

Risk Management

Product code: GF-2895

Product names: CLIOPHAR 600 SL

Active Substances:

Clopyralid, 600 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

**Applicant: ARYSTA LIFESCIENCE BENELUX
SPRL**

Date: 29/04/2016

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PART A – Risk Management

The company ARYSTA LIFESCIENCE BENELUX SPRL has requested marketing authorisation in France for the product CLIOPHAR 600 SL (formulation code: GF-2895), containing 600 g/L clopyralid 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 CLIOPHAR 600 SL (GF-2895) where that data have not been considered in the EU review process. Otherwise assessments for the safe use of CLIOPHAR 600 SL (GF-2895) have been made using endpoints agreed in the EU review of clopyralid.

This document describes the specific conditions of use and labelling required for France for the registration of CLIOPHAR 600 SL (GF-2895).

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 ARYSTA LIFESCIENCE BENELUX SPRL.'s application to market CLIOPHAR 600 SL in France as a herbicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Clopyralid

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.

and

Commission Implementing Regulation (EU) No 678/2014 of 19 June 2014 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances clopyralid, cyprodinil, fosetyl, pyrimethanil and trinexapac.

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 clopyralid for uses other than spring applications, 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 clopyralid, and in particular Appendices I and II thereof, as finalised in the

Standing Committee on the Food Chain and Animal Health on 4 April 2006 shall be taken into account.

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

- the protection of non-target plants and groundwater under vulnerable conditions. Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated to verify potential groundwater contamination in vulnerable zones, where appropriate.

The concerned Member States shall request the submission of further studies to confirm the results on animal metabolism. They shall ensure that the notifiers at whose request clopyralid has been included in this Annex provide such studies to the Commission within two years from the approval

EFSA conclusions are available (EFSA Scientific Report 2005 50,1-65 [original] and EFSA (European Food Safety Authority), 2014; Outcome of the consultation with Member States, applicant and EFSA on the pesticide risk assessment of confirmatory data submitted for the active substance clopyralid. EFSA supporting publication 2014: EN-624. 8pp. [confirmatory data]).

A Review Report is available (SANCO/10012/2006 rev. 3, 4 April 2006).

1.3 Regulatory Approach

The present application (2013-0587) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)¹ 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”)² – 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 12 September 2006³ 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 1107/2009⁴, 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 regulatory compliance are based on the criteria indicated in Regulation (EU) No546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁶ provides that:

- an authorisation granted for a “reference” crop applies also for “linked” crops, unless formally stated in the

¹ French Food Safety Agency, Afssa, before 1 July 2010

² 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

³ <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000425570>

⁴ 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

⁵ 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

⁶ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI1407093A/jo>

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 extrapolation⁷ is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and decision may include uses on crops not originally requested by the applicant.

The decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

1.4 Data Protection Claims

Where protection for data is being claimed for information supporting registration of CLIOPHAR 600 SL (GF-2895), 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 letters of access is reproduced in Part A, Appendix 3.

2 DETAILS OF THE AUTHORISATION

2.1 Product Identity

Product name (code)	CLIOPHAR 600 SL (GF-2895)
Authorisation number	2160343
Function	Herbicide
Applicant	ARYSTA LIFESCIENCE BENELUX SPRL
Composition	600 g/L clopyralid
Formulation type (code)	Soluble Concentrate [Code: SL]
Packaging	HDPE (high density polyethylene)/EVOH : 100 mL; 250 mL; 500 mL; 1L PET (polyethylene terephthalate) : 500 mL; 1L; 5L HDPE : 1 L; 5 L

2.2 Classification and Labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

For information: no classification.

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

⁷ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

No classification

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

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres ⁸ to surface water bodies
SPe 3	To protect non-target plants, respect an unsprayed buffer zone of 5 metres to non-agricultural land.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment ⁹ : refer to the Decision in Appendix 1 for the details		
Re-entry period ¹⁰ : 6 hours		
Pre-harvest interval ¹¹ :	Beetroot (red beet)	Growth stage BBCH 39 at the latest
	Sugar and fodder beet	Growth stage BBCH 39 at the latest
	Maize (for grain)	Growth stage BBCH 32 at the latest
	Maize (for forage)	60 days before harvest
	Linseed (flax)	Growth stage BBCH 50 at the latest
	Forestry	-
	Oilseed rape	Growth stage BBCH 51 at the latest
	Sorghum (for grain)	Growth stage BBCH 32 at the latest
	Sorghum (for forage)	42 days before harvest
Other mitigation measures: -		
The label must include the following recommendations: To avoid the build-up of resistance, it is recommended to vary or to mix preparations including an active substance with a different mode of action during the growing season and along the crop rotation. Do not sow or plant crops on which clopyralid is not authorised within 125 days of application on a treated plot. Crops re-sown or re-planted within 125 days of application must not be treated with a clopyralid based product. The label must reflect the conditions of authorisation.		

⁸ The legal basis for this is **Titre III Article 11** of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

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

¹⁰ The legal basis for this is **Titre I Article 3** of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

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

2.3 Product uses

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

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

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

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

GAP rev. 1, date: 2016-04-29

PPP (product name/code) **CLIOPHAR 600 SL (GF-2895)**
active substance 1 **clopyralid**

Formulation type: **SL**
Conc. of as 1: **600 g/L**

Applicant: **ARYSTA LIFESCIENCE BENELUX SPRL**
Zone: **southern EU**

professional use ☒
non-professional use ☐

Verified by MS: Yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg ae/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
6	France	Beet, Red	F	Broad-Leaved weeds	Broadcast- Foliar	BBCH 10 to 39 (Spring/Summer)	a) 1 (NA) b) 1 (NA)	a) 0.20 a) 0.20	a) 0.120 b) 0.120	100/400	42	1 application every 3rd year
8	France	Beet, sugar	F	Broad-Leaved weeds	Broadcast- Foliar	BBCH 10 to 39 (Spring/Summer)	a) 1 (NA) b) 1 (NA)	a) 0.20 a) 0.20	a) 0.120 b) 0.120	100/400	42	1 application every 3rd year
12	France	Corn, Field, Grain, Common millet/proso millet	F	Broad-Leaved weeds	Broadcast- Foliar	BBCH 10 to 32 (Spring)	a) 1 (NA) b) 1 (NA)	a) 0.20 a) 0.20	a) 0.120 b) 0.120	100/400	90	

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg ae/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
13	France	Corn/ Maize, Common millet/proso millet	F	Broad-Leaved weeds	Broadcast- Foliar	BBCH 10 to 32 (Spring)	a) 1 (NA) b) 1 (NA)	a) 0.20 a) 0.20	a) 0.120 b) 0.120	100/400	60	
14	France	Flax	F	Broad-Leaved weeds	Broadcast- Foliar	BBCH 30 to 51 (Spring)	a) 1 (NA) b) 1 (NA)	a) 0.20 a) 0.20	a) 0.120 b) 0.120	100/400	42	1 application every 2 nd year
15	France	Forest, Plantings	F	Broad-Leaved weeds	Broadcast- Foliar	Unspecified (Spring)	a) 1 (NA) b) 1 (NA)	a) 0.20 a) 0.20	a) 0.120 b) 0.120	100/400	-	1 application every 3 rd year
17	France	Oilseed rape, summer, Mustard, Gold of pleasure, Canola, Hemp, Borage, Sesame (summer)	F	Broad-Leaved weeds	Broadcast- Foliar	BBCH 10 to 51 (Spring)	a) 1 (NA) b) 1 (NA)	a) 0.20 a) 0.20	a) 0.120 b) 0.120	100/400	56	1 application every 2 nd year
18	France	Oilseed rape, winter Mustard, Gold of pleasure, Canola, Hemp, Borage, Sesame (summer)	F	Broad-Leaved weeds	Broadcast- Foliar	BBCH 30 to 51 (Spring)	a) 1 (NA) b) 1 (NA)	a) 0.20 a) 0.20	a) 0.120 b) 0.120	100/400	56	1 application every 3 rd year
20	France	Sorghum	F	Broad-Leaved weeds	Broadcast- Foliar	BBCH 14 to 18 (Spring)	a) 1 (NA) b) 1 (NA)	a) 0.20 a) 0.20	a) 0.120 b) 0.120	100/400	70	
21	France	Sorghum Forage (green)	F	Broad-Leaved weeds	Broadcast- Foliar	BBCH 14 to 18 (Spring)	a) 1 (NA) b) 1 (NA)	a) 0.20 a) 0.20	a) 0.120 b) 0.120	100/400	42	

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg ae/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

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 CLIOPHAR 600 SL (GF-2895) is a soluble concentrate (SL). All studies have been performed in accordance with the current requirements. The appearance of the formulation is a yellow liquid, without any odour. It is not explosive and has no oxidising properties. It has a self-ignition temperature of 441 ± 4 °C and has no flash point below 130 °C. In aqueous solution at 1 %, its pH is 3.5 at 20 °C. Stability data indicate a shelf life of at least 2 years at ambient temperature. Its technical characteristics are acceptable for a SL formulation.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of active substance in the formulation are available and validated.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the monograph [draft assessment report] and in this dossier and validated for the determination of residues of clopyralid in plants (cereal and dry matrices, fatty products and matrices with high water content), foodstuffs 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.

Nevertheless, post-authorisation, a validated method and its ILV should be provided for the determination of residues (clopyralid, its salts and conjugates) in plants and in foodstuffs of animal origin.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

CLIOPHAR 600 SL (GF-2895) has a low acute oral, dermal and inhalation toxicity. It is not irritating to the rabbit skin or eye and it is not a skin sensitiser.

3.1.3.2 Operator Exposure

The dermal absorption value of clopyralid used for risk assessment is 0.31% for the undiluted and 7.1% for the diluted, based on an in vitro study on human skin using CLIOPHAR 600 SL (GF-2895).

Endpoint used in assessment for CLIOPHAR 600 SL	
Clopyralid	
Systemic AOEL	1 mg/kg bw/d
Dermal absorption of undiluted and diluted product:	0.31 % and 7.1 % respectively

Operator exposure was modelled using the German BBA and UKPOEM models:

Parameters used in operator exposure assessment				
Crop	Equipment	Application rate L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model used
Open field				
Beet	Tractor-mounted/trailed boom sprayer	0.25 L/ha (Clopyralid: 150 g/ha)	/	BBA
Forest plantings	Hand-held sprayer hydraulic nozzles outdoor low level target	0.20 L/ha (Clopyralid: 120 g/ha)	100-400 L/ha	UKPOEM

These results show that for the use of a tractor-mounted/trailed boom sprayer, exposure to clopyralid is estimated to be 0.1 % of the AOEL with working coverall and without gloves during mixing/loading and application.

These results show that for the use of a hand-held sprayer, exposure to clopyralid is estimated to be 5 % of the AOEL with working coverall and with gloves during mixing/loading and application.

According to the model calculations, it can be concluded that the risk for the operator using CLIOPHAR 600 SL (GF-2895) on beet and in forestry is acceptable with the use of a tractor-mounted/trailed boom sprayer or hand-held sprayer with working coverall and with gloves, during mixing/loading and application.

The following personal protective equipment is recommended by the applicant and confirmed by ANSES (France):

➤ **Application with a tractor-mounted boom sprayer, a tractor-mounted broadcast air-assisted sprayer or an atomiser.**

• **for mixing/loading**

- Nitrile gloves certified EN 374-3;
- Working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment;
- Long-sleeved aprons, Category III Type PB3 worn over the coverall proposed above;

• **For application - Downward spraying**

If application with tractor with cab

- Working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment;
- Disposable nitrile gloves certified EN 374-2 in the case of an intervention on application equipment, but not inside the cab. In the case of an intervention on application equipment, it should be noted that gloves should be worn only outside the tractor cab and stored after use outside the cab.

If application with tractor without cab

- Working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment;
- Disposable nitrile gloves certified EN 374-2 during application and in the case of an intervention on application equipment;

• **for equipment cleaning**

- Nitrile gloves certified EN 374-3;
- Working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment;
- Long-sleeved aprons, Category III Type PB3 worn over the coverall proposed above.

➤ **Application with a hand-held sprayer –outdoor**

• **for mixing/loading**

- Nitrile gloves certified EN 374-3;
- Protective coveralls category III Type 3 or 4 (according to the protection level recommendation during spraying);

OR

- Nitrile gloves certified EN 374-3;
- Working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment;
- Long-sleeved aprons, Category III Type PB3 worn over the coverall proposed above

• **for application: without intense contact with crops**

- Nitrile gloves certified EN 374-3;
- Working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment;
- Rubber boots certified EN 13 832-3;

• **for equipment cleaning**

- Nitrile gloves certified EN 374-3;
- Protective coveralls category III Type 3 or 4 (according to the protection level recommendation during spraying);

OR

- Nitrile gloves certified EN 374-3;
- Working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment;
- Long-sleeved aprons, Category III Type PB3.

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to the EUROPOEM II model for the use of CLIOPHAR 600 SL (GF-2895). It is concluded that there is no undue risk to the bystander after incidental short-term exposure to the product.

3.1.3.4 Worker Exposure

As CLIOPHAR 600 SL (GF-2895) is an herbicide, entry of worker is not necessary. Therefore, no worker exposure assessment has been carried out.

Nonetheless a worker who intervenes in a treated area must wear working coveralls 65 % polyester / 35 % cotton; minimum 230 g/m²; with water-repellent treatment, and, if in contact with treated crops, nitrile gloves certified EN 374-3.

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

Primary crop metabolism of clopyralid was sufficiently investigated to define residue for enforcement and risk assessment purposes in the crops under consideration.

Regarding the magnitude of residues in those crops, a sufficient number of residue trials is available to support the intended GAPs, except for rape seed, for which four additional residues trials in the south zone of Europe are required. Data resulting from this GAP allowed the expected residue concentrations in the relevant plant commodities to be estimated, and to confirm that no MRL exceedence will result from the intended uses.

The effects of processing on the nature of clopyralid residues have been investigated. Clopyralid remains stable under processing conditions. Data on effects of processing on the amount of residue have been submitted, but not considered for risk assessment.

Residues in succeeding crops have been investigated, the following mitigation measures have been proposed (in the form of a label amendment):

Do not sow or plant crops on which clopyralid is not authorised within 125 days of application on a treated plot. Crops re-sown or re-planted within 125 days of application must not be treated with a clopyralid-containing product. 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 are therefore not necessary.

3.1.4.2 Consumer exposure

The toxicological profile of clopyralid was evaluated at EU level, which resulted in the proposal of an ADI that was considered in the context 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 acceptable for all groups of consumers.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have 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 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 of clopyralid 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 review or agreed in the assessment based on new data provided.

PEC soil and PECsw derived for the active substance and its metabolites are used for the ecotoxicological risk assessment.

PECgw for clopyralid do not exceed the trigger of 0.1 µg/L based on both FOCUS and FROGS simulations.

- For a single application every year on maize, PECgw are < 0.1 µg/L for all FOCUS scenarios. The use on sorghum is covered by the PECgw modelling performed for the use on maize.
- For application on sugar beet, PECgw are > 0.1 µg/L for at least one scenario even if clopyralid is applied every third year. However, additional modelling performed using the tool FROGS showed that PECgw are > 0.1 µg/L for a single application every year on sugar beet.
- For application on summer oil seed rape, additional modelling performed using the tool FROGS showed that PECgw are > 0.1 µg/L for a single application every year on this crop and < 0.1 µg/L for single application every second year.
- For application on winter oil seed rape, additional modelling performed using the tool FROGS showed that PECgw are < 0.1 µg/L for a single application every third year on this crop
- For use in forestry, PECgw for clopyralid are above 0.1 µg/L for at least one FOCUS scenario when the formulated product is applied every third year in forestry.

Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses except for the use in forestry before planting, the assessment is not finalized.

Based on vapour pressure, information on volatilisation from plants and soil, and DT50 calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

The risk assessment of the formulation CLIOPHAR 600 SL (GF-2895) was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review for active substance 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 and other soil macro-organisms, micro-organisms and terrestrial plants are acceptable for the intended uses.

For aquatic organisms, the risks are acceptable when a buffer zone of 5 metres is applied for all intended uses.

For terrestrial non-target plants, the risks are acceptable when a buffer zone of 5 metres is applied.

3.1.7 Efficacy

The analysis is based on comparability of efficacy and crop selectivity of the new formulation CLIOPHAR 600 SL (GF-2895) with commercial clopyralid based reference products. CLIOPHAR 600 SL (GF-2895) contains a dimethylamine salt while the reference products contained a monoethylamine salt. The objective of this biological assessment dossier was a “bridging” approach.

For bridging purposes, CLIOPHAR 600 SL (GF-2895) is intended to be applied at the same dose rate (in terms of amount of active substance clopyralid per ha) as the commercial reference products registered in each country where this new product will be submitted for registration.

The applicant noticed that the trials were implemented before the re-registration of the clopyralid-based products. Consequently CLIOPHAR 600 SL (GF-2895) was tested in trials according the previous GAPs, which are not necessarily identical to the new GAPs proposed in the dossier. Nevertheless, CLIOPHAR 600 SL (GF-2895) was always tested according the dose range proposed and within the critical GAPs.

Crops	Harmful organism	Method of application	Maximum rate per treatment	Maximum number of application per use	Maximum number of applications per crop	Conclusion of France for efficacy section	Remarks
Fodder, red and sugar beet	Dicotyledonous weeds	Spraying	0.2 L/ha	1	1	Not finalized	
Maize, forage, grain	Dicotyledonous weeds	Spraying	0.2 L/ha	1	1	Not finalized	
Linseed	Dicotyledonous weeds	Spraying	0.2 L/ha	1	1	Not finalized	
Forestry, Plantings	Dicotyledonous weeds	Spraying	0.2 L/ha	1	1	Not finalized	
rape seed	Dicotyledonous weeds	Spraying	0.2 L/ha	1	1	Not finalized	
Sorghum	Dicotyledonous weeds	Spraying	0.2 L/ha	1	1	Not finalized	

The product complies with the Uniform Principles.

Considering the data submitted:

- ✓ The similarity of CLIOPHAR 600 SL's efficacy with that of other clopyralid standards is not considered to be demonstrated. Few weed species were tested and when several trials were available for one weed, statistical differences were sometimes observed between CLIOPHAR 600 SL (GF-2895) and the clopyralid standard at the same dose, so the bridging cannot be acceptable. Efficacy is then not considered as fully demonstrated (not finalized).
- ✓ The selectivity of CLIOPHAR 600 SL (GF-2895) is considered satisfactory on winter wheat, oilseed rape, sugar beet and maize
- ✓ Concerning the risk of negative impact (yield, quality, transformation processes, propagation, succeeding crops, adjacent crops), it is not possible to exclude a risk, as the similarity of CLIOPHAR 600 SL (GF-2895) with other clopyralid standards was not considered to be sufficiently demonstrated in terms of efficacy and selectivity.
- ✓ The risk of resistance development or appearance is considered to be low.

3.2 Conclusions arising from French assessment

Taking into account the above, the assessment was considered as not finalized because the similarity of behavior in terms of efficacy of preparation CLIOPHAR 600 SL (GF-2895) compared to reference preparations based on clopyralid is not demonstrated. Also, the risk assessment of groundwater contamination for the use in forestry before planting is not finalized.

However, considering that 100 000 ha of forest are planted each year in France in comparison with 400 000 ha of industrial beet and almost 4 million hectares of maize and oilseed the risk of groundwater contamination related to the use in forest before planting is considered as limited.

The interest of CLIOPHAR 600 SL (GF-2895) is to provide a lower dose of a.s. per hectare for all uses in comparison with reference preparations so, post-authorisation data are required concerning the similarity of CLIOPHAR 600 SL's efficacy with that of other clopyralid standards, with additional trials.

Therefore, an authorisation can be granted, but a new efficacy data package should be submitted in post-registration. A copy of the decision is included in Appendix 1.

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 following data are required only when authorisation is granted:

- For the active substance, a validated method and its ILV must be provided for the determination of residues (clopyralid, its salts and conjugates) in plants and foodstuffs of animal origin.
- Four additional residues trials on rape seed are required, reflecting the proposed GAP in the south zone of Europe.
- Efficacy trials to prove the similarity of CLIOPHAR 600's efficacy with that of other clopyralid standards.

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 d'autorisation de mise sur le marché d'un produit phytopharmaceutique

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 la demande d'autorisation de mise sur le marché du produit phytopharmaceutique **CLIOPHAR 600 SL***

de la société ARYSTA LIFESCIENCE BENELUX SPRL

enregistrée sous les n°2013-0587 et 2015-6403

Vu les conclusions de l'évaluation du 3 décembre 2015,

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

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.



Informations générales sur le produit	
Nom du produit	CLIOPHAR 600 SL
Type de produit	Produit de référence
Titulaire	ARYSTA LIFESCIENCE BENELUX SPRL 26/1, rue de Renory, B-4102 Ougrée BELGIQUE
Formulation	Concentré soluble (SL)
Contenant	600 g/L - clopyralid
Numéro d'intrant	969-2013.01
Numéro d'AMM	2160343
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. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 30 avril 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

29 AVR. 2016

Françoise WEBER
Directrice générale adjointe des produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)



ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation ne peut mettre sur le marché le produit que dans les emballages suivants :	
Emballage	Contenance
Bouteilles en polyéthylène haute densité / éthylène vinyl alcool	100 mL ; 250 mL ; 500 mL et 1 L
Bouteilles en polyéthylène téréphtalate	500 mL et 1 L
Bidons en polyéthylène téréphtalate	5 L
Bouteilles en polyéthylène haute densité	1 L
Bidons en polyéthylène haute densité	5 L

Classification du produit
La classification retenue est la suivante :
Sans classement.
Pour les phrases P se référer à la réglementation en vigueur.
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.



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	Délai avant récolte (jours)	Zone Non Traitee arthropodes non cibles (mètres)	Zone Non Traitee plantes non cibles (mètres)	Mention abeilles
15205901 Crucifères oléagineuses*Désherbage	0,2 L/ha	1/an	BBCH 10 - BBCH 51	56	5	5	-
	1 application tous les 2 ans sur crucifères oléagineuses de printemps.						
	0,2 L/ha	1/an	BBCH 30 - BBCH 51	56	5	5	-
15555901 Sorgho*Désherbage	1 application tous les 3 ans sur crucifères oléagineuses d'hiver						
	0,2 L/ha	1/an	BBCH 14 - BBCH 18	42	5	5	-
	Sur sorgho ensilage						
401013 Forêt*Désherbage*Avt Plantation	0,2 L/ha	1/an	BBCH 14 - BBCH 18	70	5	5	-
	Sur sorgho grain						
	0,2 L/ha	1/an	-	Non applicable	5	5	-
15055911 Betterave industrielle et fourragère*Désherbage	1 application tous les 3 ans.						
	0,2 L/ha	1/an	BBCH 10 - BBCH 39	42	5	5	-
	1 application tous les 3 ans.						
16175901 Betterave potagère*Désherbage	0,2 L/ha	1/an	BBCH 10 - BBCH 39	42	5	5	-
	1 application tous les 3 ans.						
	0,2 L/ha	1/an	BBCH 30 - BBCH 51	42	5	5	-
15505902 Lin*Désherbage	1 application tous les 2 ans.						
	0,2 L/ha	1/an	BBCH 10 - BBCH 32	60	5	5	-
	Sur maïs ensilage						
15555901 Maïs*Désherbage	0,2 L/ha	1/an	BBCH 10 - BBCH 32	90	5	5	-
	Sur maïs grain						

CLIOPHAR 600 SL
n°2160343



Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Il convient de rappeler que 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 complémentaires comme les protections individuelles.

En tout état de cause, 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

Pour les pulvérisateurs portés ou traînés 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/m² 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.

- **Pendant l'application - Pulvérisation vers le bas**

Si application avec tracteur avec cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² 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/m² 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/m² 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 une pulvérisation manuelle (forêt) :

- **Pendant le mélange/chargement**
 - Gants en nitrile certifiés EN 374-3 ;
 - Combinaison de protection de catégorie III type 4 ou 3 (selon le niveau de protection recommandé pendant la phase d'application).



OU

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² 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.

• **Pendant l'application**

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Bottes de protection certifiées EN 13 832-3 ;
- Gants en nitrile certifiés EN 374-3.

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

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de protection de catégorie III type 4 ou 3 (selon le niveau de protection recommandé pendant la phase d'application).

OU

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² 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 (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m²) avec traitement déperlant.
- Gants en nitrile certifiés EN 374-3, en cas de contact avec la culture traitée.

Délai de rentrée

6 heures en application de l'arrêté du 12 septembre 2006.

Respect des limites maximales de résidus (LMR)

Les conditions d'utilisation de la préparation, compte tenu des bonnes pratiques agricoles critiques proposées pour chaque usage figurant dans la liste des usages autorisés, permettent de respecter les limites maximales de résidus.

Afin de garantir l'absence de résidu dans les cultures suivantes, il conviendra de ne pas implanter de culture sur lesquelles le clopyralid n'est pas autorisé moins de 125 jours après application sur une parcelle traitée. Les cultures ré-implantées moins de 125 jours après application ne devront pas être traitées avec une préparation contenant du clopyralid.



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.

Protection de la flore

- SPe 3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.

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)
Fournir une méthode d'analyse validée et sa validation inter-laboratoires pour la détermination des résidus de clopyralid (clopyralid, ses sels et ses conjugués) dans les plantes (céréales et produits secs, matrices riches en eau et produits riches en graisse) et dans les denrées d'origine animale (muscle, graisse, foie, rein, œufs, lait).	24	-
Fournir quatre essais résidus supplémentaires sur colza conduits en zone sud de l'Europe conformément aux bonnes pratiques agricoles.	24	-
Fournir des essais d'efficacité complémentaires démontrant la similitude de comportement en termes d'efficacité de la préparation CLIOPHAR 600 SL et des préparations de référence composées de clopyralid.	24	-

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer les informations suivantes sur l'étiquette :

« Afin de limiter le risque de résistance, il est recommandé d'alterner ou d'associer sur une même parcelle des préparations à base de substances actives à modes d'action différents tant au cours d'une saison culturale que dans la rotation ».

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

(Source: Applicant's draft registration report Part A Update 2015,
Document "dRR Part A_Cliophar 600 _updated 2015_Final", 28/01/2015)

Proposed label:

CLIOPHAR 600 SL

SYSTEMIC FOLIAR ACTING HERBICIDE OF PYRIDINE CLASS FOR THE
CONTROL OF A RANGE OF PERENNIAL AND ANNUAL BROAD-LEAVED
WEEDS, IN PARTICULAR THISTLES AND MAYWEES, IN BEET, OILSEED
RAPE, MAIZE, FORESTRY, FLAX AND SORGHUM.

*TO AVOID RISKS TO MAN AND THE ENVIRONMENT,
COMPLY WITH THE INSTRUCTIONS FOR USE
READ ALL PRECAUTIONS BEFORE USE*

REGISTRATION NUMBER : AMM n°.....
ACTIVE SUBSTANCE : Clopyralid
CONCENTRATION : 600 g/l
FORMULATION TYPE : SOLUBLE CONCENTRATE (SL)

CLIOPHAR 600 SL

RISK PHRASES

None

SAFETY PHRASES

S2: Keep out of reach of children
S13: Keep away from food, drink and animal feeding stuffs
S20/21: When using do not eat, drink or smoke
S35: This material and its container must be disposed of in a safe way.
S59: Refer to manufacturer/supplier for information on recovery/recycling.
S60: This material and its container must be disposed of as hazardous waste
S61: Avoid release to the environment. Refer to special instructions/Safety data sheets.
To avoid risks to men and the environment, comply with the instructions for use.

Agriphar S.A

SAFETY PRECAUTIONS

Operator protection:

WASH HANDS AND EXPOSED SKIN before meals and after work.

Environmental protection:

Extreme care must be taken to avoid spray drift onto non-crop plants outside the target area.

KEEP LIVESTOCK OUT of treated areas for at least 7 days and until foliage of any poisonous weeds such as ragwort has died and become unpalatable.

Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from yards and roads.

COMPOSITION: Soluble Concentrate (SL)

Clopyralid (dimethylamine salt) ⁽¹⁾: 600 g acid eq/L

⁽¹⁾: Active substance manufactures and patented by Dow AgroSciences

INSTRUCTIONS FOR USE

It is essential to select a rate appropriate for the weed size. Best results will be obtained when weeds are actively growing at treatment.

USES

Crops/Situation	Maximum Individual Dose L product/ha	Stage of application	Number of application	Pre-harvest interval (days)
Sugar beet, Fodder beet, Red beet	0.2 L	BBCH 10 to 39 (Spring, from 1 st of March)	1 every 3 years	42
Oilseed rape, winter	0.20 L	BBCH 30 to 51 (end of winter from 1 st of February)	1 every 2 years	56
Oilseed rape, Spring	0.20 L	BBCH 10 to 51	1 every 2 years	56
Maize	0.20 L	BBCH 10 to 32	1	60 (silage) 90 (grain)

Sorghum	0.20 L	BBCH 14 to 18	1 every 2 years	42 (forage) 70 (grain)
Forestry (plantings)	0.20 L		1 every 2 years	
Flax	0.20		1 every 2 years	42

Tank-mix with other

Maximum Residue Limits (LMR) are available on
http://ec.europa.eu/sanco_pesticides/public/

Caution before use:

....

PRODUCT DESCRIPTION:

Mode of action:

Clopyralid is an auxin-type growth hormone herbicide that is readily absorbed by foliage and roots, clopyralid is translocated upward and downward. It accumulates in the growing points of shoots where it disrupts normal development, resulting in necrosis and plant death. Perennial weeds are completely killed and no regrowth is observed in subsequent crops.

Mixing

Fill the spray tank half full with water and add the required amount of CLIOPHAR 600 SL mixing well, then complete filling. The spray mix must be agitated continuously until application is complete.

Use a spray volume from 100 to 400 L/ha.

After treatment rinse container thoroughly by using an integrated pressure rinsing device or manually rinsing three times. Add washings to sprayer at time of filling and dispose of safely. Preferably, use a sprayer for only herbicide applications.

EFFICACY:

CLIOPHAR 600 SL is particularly active on annual and perennial weeds of the Compositae family e.g. annual and perennial thistles and mayweeds, leguminous and on few species of the Umbelliferae, Polygonaceae and Solanaceae families.

For best results apply CLIOPHAR 600 SL when the weeds are actively growing. Control of mayweeds may be reduced if they are suffering from drought stress at the time of application.

On annuals, CLIOPHAR 600 SL should be applied on young plants before scape elongation.

On perennials, CLIOPHAR 600 SL should be applied on actively growing plants.

ANNUELLES

Anthémis	<i>Anthemis sp</i>	2 leaf to rosette
Bleuet	<i>Centaurea cyanus</i>	2 leaf to rosette
Chrysanthème	<i>Chrysanthemum</i>	2 leaf to 6 leaf
	<i>Segetum</i>	
Datura stramoine	<i>Datura stramonium</i>	2 leaf to 6 leaf
Erigeron du canada	<i>Conyza canadensis</i>	2 leaf
Galinsoga	<i>Galinsoga sp.</i>	2 leaf to 6 leaf
Helminthe	<i>Picris echinoides</i>	1 leaf to 2 leaf
fausse-vipérine		
Laiteron	<i>Sonchus sp.</i>	2 leaf to 6 leaf
Lampsane	<i>Lampsane communis</i>	before flowering
Matricaire	<i>Matricaria sp.</i>	2 leaf to rosette
Séneçon	<i>Senecio vulgaris</i>	2 leaf to rosette
Tournesol (volunteers)	<i>Helianthus annuus</i>	2 leaf to 6 leaf
Vesce	<i>Vicia sativa</i>	before flowering

Efficacy of CLIOPHAR 600 SL at 0.2 l/ha

Susceptible: good kill		
Perennials		
Common name	Scientific name	Growth stage
Chardons des champs	<i>Cirsium arvense</i>	15 cm and before flower buds
Fausse-épervine	<i>Picris hieracioides</i>	before 6 leaf
Gesse tuébreuse	<i>Lathyrus tuberosus</i>	15 to 20 cm
Laiteron des champs	<i>Sonchus arvensis</i>	5 leaf to 8 leaf
Luzerne (volunteers)	<i>Medicago sativa</i>	until flowering
Trèfle	<i>Trifolium sp.</i>	until flowering

Moderately Susceptible: moderate kill		
Common name	Scientific name	Optimum growth stage
Renouée liseron	<i>Polygonum convolvulus</i>	1 leaf to 2 leaf
Ammi élevée	<i>Ammi majus</i>	1 leaf to 2 leaf
Ethuse	<i>Aethusa cynapium</i>	2 leaf to 6 leaf
Torilis des champs	<i>Torilis arvensis</i>	2 leaf to 6 leaf
Tussilage pas d'âne	<i>Tussilago farfara</i>	soon after emergence

Moderately Resistant: Poor kill but useful suppression	
Common name	Scientific name
Ronces	<i>Rubus sp.</i>
Grande ortie	<i>Urtica dioica</i>
Gaillet	<i>Galium sp.</i>
Stellaire	<i>Stellaria media</i>
Amarantes	<i>Amaranthus sp.</i>
Chénopodes	<i>Chenopodium sp.</i>

Applicant (Arysta LifeScience S.A.)

Evaluator

Crucifères	<i>Brassicaceae</i>
Labiées	<i>Lamiaceae</i>

RECOMMENDATIONS OF USE :

Stage of application per crop:

Beet: CLIOPHAR 600 SL may be used from the fully expanded cotyledon stage of the crop and before crop canopy closure

Autumn sown oilseed rape:

CLIOPHAR 600 SL can be applied from 15 of February to all varieties of autumn sown oilseed rape from the two fully expanded leaf stage but before the flower buds are visible above the crop canopy.

Spring sown oilseed rape:

CLIOPHAR 600 SL can be applied to all varieties of spring sown oilseed rape from BBCH 30 to BBCH 51.

Maize: CLIOPHAR 600 SL can be applied until the crop reach 60 – 70 cm height

Sorghum: CLIOPHAR 600 SL can be applied at 4 leaf to 8 leaf.

Flax: CLIOPHAR 600 SL can be applied at the crop stage from 10 cm height to flower buds

Selectivity forestry species:

CLIOPHAR 600 SL is safe on *Abies nordmannia*, *Abies pectinata*, *Piceas abies*, *Picea omorica*, *Pinus cembra*, *Pinus nigra*, *Pseudotsuga douglasii*, *Taxus baccata*, *Acer pseudoplatanus*, *Aesculus hippocastanum*, *Cornus mas*, *Corylus avellana*, *Crataegus laevigata*, *Euonymus europea*, *Fraxinus excelsior*, *Juglans regia*, *Ligustrum vulgare*, *Prunus spinosa*, *Sorbus aria*, *Syringa vulgaris*.

For all other species, advice is required from professional and/or Agriphar technical service.

SPECIFIC RECOMMENDATIONS:

- Do not use manure from animals fed on crops treated with CLIOPHAR 600 SL on vegetable crops and flowers
- Take all necessary precaution during CLIOPHAR 600 SL treatments to avoid drift of to susceptible adjacent crops (vines, susceptible orchards, sunflower, leguminous, vegetables, ornamentals, tobacco, potato, tomato, ...)
- Do not spray in windy weather
- Before planting susceptible crops such as leguminous and sunflower, respect a minimum deadline of 5 months after CLIOPHAR 600 SL treatment. For crops on which the use of CLIOPHAR 600 SL is not authorized, respect a 125 days deadline between the CLIOPHAR 600 SL application and the crop implementation.

Manufactured by AGRIPHAR S.A., 26/1, rue de Renory, B-4102 Ougrée, Belgium.

Appendix 3 – Letter(s) of Access



Dow AgroSciences S.A.S

6, Rue Jean-Pierre Timbaud – 78067 St Quentin en Yvelines – France – Tél. : 33 (0)1 30 23 13 13 – Fax : 33 (0)1 30 23 13 14

Agence Nationale de sécurité sanitaire de l'alimentation,
de l'environnement et du travail
Direction Produits réglementés
Unité Gestion des AMM
253 av. Du Général Leclerc
94701 Maisons-Alfort Cédex
FRANCE

15/11/2012

ACCESS TO DOW AGROSCIENCES DATA ON THE ACTIVE INGREDIENT CLOPYRALID

Dear Regulatory Authority,

Agriphar SA applies for authorization of Cliophar 600 SL, containing clopyralid (TGAi) which will be sourced from Dow AgroSciences.

In support of Agriphar SA application, Dow AgroSciences SAS authorizes the Regulatory Authority to access the Dow AgroSciences data package on Clopyralid.

This authorization shall not be construed as authorization to use or consider said data, directly or indirectly, in support of any other application submitted by the applicant including, without limitation, applications for new registrations or amended registrations of Cliophar 600 SL. This letter of authorization does not permit release in whole or in part of the data to the applicant.

Sincerely,

Montigny le bretonneux,

Véronique ROY
Responsable Homologation
Dow AgroSciences S.A.S

cc: Agriphar SA (attn Mr Gilles Gauthier)
Rue de Rénory, 26/1, 4102 Ougrée
Belgium
T +32 (0)4 385 97 91

Dow AgroSciences S.A.S. au capital de 21 541 047 Euros – SIREN 590 417 493 – RCS CANNES – Siège Social : 790, Avenue du Docteur Maurice Dorziat – BP 1220 – 06254 Mougins Cedex