



HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. **BESLUIT**

Op 8 mei 2014 is van

Dow AgroSciences B.V.
Sneeuwbeslaan 20 bus 10
B-2610 WILRIJK
BELGIE

een aanvraag tot toelating ontvangen als bedoeld in artikel 33 Verordening (EG) 1107/2009 (verder te noemen: de Verordening) voor het gewasbeschermingsmiddel

LONTREL 600

op basis van de werkzame stof clocypralid. Nederland is in deze een betrokken lidstaat, als bedoeld in artikel 36, tweede lid; de beoordelend lidstaat is Verenigd Koninkrijk.

HET COLLEGE BESLUIT tot toelating van bovenstaand middel.

Alle bijlagen, waaronder registratierapport deel A, vormen een onlosmakelijk onderdeel van dit besluit.

1.1 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

1.2 Gebruik

Het middel mag slechts worden gebruikt volgens het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.

1.3 Classificatie en etikettering

Mede gelet op de onder “wettelijke grondslag” vermelde wetsartikelen, dienen alle volgende aanduidingen en vermeldingen conform de geldende regelgeving op of bij de verpakking te worden vermeld:

- De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder “verpakkingsinformatie” in bijlage I.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.
- De classificatie die overeenkomstig het toelatingsbesluit is vastgesteld, moet volgens de voorschriften op de verpakking worden vermeld, zoals beschreven in bijlage II en in paragraaf 2.2 van deel A van het registratierapport.

1.4 Aflever- en opgebruiktermijn (respijperiode)

Niet van toepassing. Het betreft een nieuwe toelating.

2. WETTELIJKE GRONDSLAG

Besluit	artikel 28 en artikel 36, derde lid, Verordening (EG) 1107/2009
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Conform Bgb en Rgb d.d. 16 december 2011 en Evaluation Manual Zonaal 2.0.

3. BEOORDELINGEN**3.1 Fysische en chemische eigenschappen**

De aard en de hoeveelheid van de werkzame stoffen en de in humaan-toxicologisch en ecotoxicologisch opzicht belangrijke onzuiverheden in de werkzame stof en de hulpstoffen zijn bepaald. De identiteit van het middel is vastgesteld. De fysische en chemische eigenschappen van het middel zijn vastgesteld en voor juist gebruik en adequate opslag van het middel aanvaardbaar geacht.

3.2 Analysemethoden

De geleverde analysemethoden voldoen aan de vereisten om de residuen te kunnen bepalen die vanuit humaan-toxicologisch en ecotoxicologisch oogpunt van belang zijn, volgend uit geoorloofd gebruik.

3.3 Risico voor de mens

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor de mens verwacht.

3.4 Risico voor het milieu

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor het milieu verwacht.

3.5 Werkzaamheid

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften verwacht dat het werkzaam is.

Bezwaarmogelijkheid

Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 217, 6700 AE WAGENINGEN. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Wageningen, 3 april 2015

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING**2.1 Aanvraaginformatie**

Aanvraagnummer: 20145250 NLTG
Type aanvraag: Nederland is in deze een betrokken lidstaat, als bedoeld in artikel 36, tweede lid; de beoordelend lidstaat is Verenigd Koninkrijk.
Middelnaam: LONTREL 600
Verzenddatum aanvraag: 30 april 2014
Formele registratiedatum: * 4 juli 2014
 * Datum waarop zowel de aanvraag is ontvangen als de aanvraagkosten zijn voldaan.

2.2 Stofinformatie

Werkzame stof	Gehalte
clopyralid	600G/L

- De stof is per 1 januari geplaatst op Annex I van Richtlijn 91/414/EEG (Dir 2006/64/EC d.d. 18 juli 2006) en vervolgens bij Uitvoeringsverordening (EU) 540/2011 d.d. 25 mei 2011 goedgekeurd. De goedkeuring van deze werkzame stof expireert op 30 april 2018.

2.3 Toelatingsinformatie

Toelatingsnummer: 14800 N
Expiratiedatum: 30 april 2019
Afgeleide parallel of origineel: n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof: Gewasbeschermingsmiddel
Gebruikers: Professioneel

2.4 Verpakkingsinformatie

Aard van het preparaat:
 Met water mengbaar concentraat

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BIJLAGE II Etikettering van het middel LONTREL 600

de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:

Pictogram

Signaalwoord

Gevarenaanduidingen

Vorzorgsmaatregelen SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.

Aanvullende EUH210 Veiligheidsinformatieblad op verzoek verkrijgbaar.

etiketelementen EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.

Kinderveilige sluiting verplicht Nee

Voelbare gevaarsaanduiding verplicht Nee

**REGISTRATION REPORT
Part A**

Risk Management

Product code: Lontrel 600

Active Substance: Clopyralid 600g a.e./L

**Central Zone
Zonal Rapporteur Member State: United Kingdom**

NATIONAL ASSESSMENT: The Netherlands

Applicant: Dow AgroSciences B.V.

Date: March 2015

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PART A – Risk Management

This document describes the acceptable use conditions required for the registration of Lontrel 600 containing clopyralid in The Netherlands. This evaluation is required subsequent to the inclusion of clopyralid on Annex 1.

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 for the addendum for The Netherlands. The information, data and assessments provided in Registration Report, Parts B includes 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 Lontrel 600 where that data has not been considered in the EU review. Otherwise assessments for the safe use of Lontrel 600 have been made using endpoints agreed in the EU review of clopyralid.

This document describes the specific conditions of use and labelling required for The Netherlands for the registration of Lontrel 600.

Appendix 1 of this document provides a copy of the final product authorisation for The Netherlands.

Appendix 2 of this document is a copy of the approved product label for The Netherlands.

Appendix 3 of this document provides a list of data submitted in support of the evaluation.

1 Details of the application

1.1 Application background

This application was submitted by Dow AgroSciences B.V. in March 2013.

The application was for approval of Lontrel 600, a SL (Soluble Concentrate) containing 600 g/l of clopyralid for use as a herbicide covering a variety of crops (cereals, oilseed rape, sugar and fodder beet, onion, etc.)

1.2 Annex I inclusion

Clopyralid was included on Annex I of Directive 91/414/EEC on 01/01/2007 under Inclusion Directive (2006/64/EC).

The Annex I Inclusion Directive for clopyralid (2006/64/EC) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, 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 should/must/may pay particular attention to the:

- 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.

These concerns were all addressed in the submission.

1.3 Regulatory approach

To obtain approval the product Lontrel 600 must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

This application was submitted in order to allow the first approval of this product in The Netherlands in accordance with the above.

1.4 Data protection claims

The studies submitted in support of this evaluation are listed in Appendix 1 part B, section 1-7 and part C of the registration report. A 10 year data protection period (from the approval) is claimed for all studies used in this evaluation that are owned by Agriphar S.A. and Dow AgroSciences and which were not previously submitted to the authority.

1.5 Letters of Access

No letter of access is needed.

2 Details of the authorisation

2.1 Product identity

Product Name	Lontrel 600
Function	Herbicide
Applicant	Dow AgroSciences B.V.
Composition	600 g/L clopyralid
Formulation type	Soluble Concentrate [Code: SL]
Packaging	0.1L (COEX HDPE/EVOH), 0.25L (COEX HDPE/EVOH), 0.5L (COEX HDPE/EVOH, PET), 1 L bottle (COEX HDPE/EVOH, HDPE, PET), 5 L container (HDPE, PET)

2.2 Classification and labelling

Based on the profile of the substance, the provided toxicology of the preparation, the characteristics of the co-formulants, the method of application and the risk assessment for the operator, as mentioned above, the following labeling of the preparation is proposed:

The identity of all substances in the mixture that contribute to the classification of the mixture *:

-

Pictogram:	-	Signal word:	-
H-statements:	-		
P-statements:	-		
Supplemental Hazard information:	EUH210	Safety data sheet available on request	
	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.	
	SP1	Do not contaminate water with the product or its container	

Child-resistant fastening obligatory?

Not applicable

Tactile warning of danger obligatory?

Not applicable

Explanation:

Pictogram:	-
H-statements:	-
P-statements:	-
Other:	EUH210 is assigned according to Regulation 1272/2008/EC, as the formulation contains > 0.1% substance classified as causing serious damage to eyes (H318).

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

Other phrases

A 125 day plant back interval is required for rotational crops.

2.3.1 Product uses – The Netherlands

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation	F G or I	Pests or Group of pests controlled	Application			Application rate per treatment			PHI (days)	Remarks: a) max. no. of applications per crop and season b) Maximum product rate per season c) additional remarks
					Method / Kind	Timing / Growth stage of crop & season	Number / (min. Interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
2.	The Netherlands	Beet (sugar and fodder)	F	Broad Leaved weeds	Broadcast- Foliar	BBCH 10-19 (Spring) Mar-Jun	a) 1 (NA) b) 1 (NA)	a) 0.2 b) 0.2	a) 0.12 b) 0.12	200/400	-	Full rate in one shot of 0.12 kg ai/ha Max per season is 0,25 l/ha product
3.	The Netherlands		F	Annual broad Leaved weeds	Broadcast- Foliar	BBCH 10-19 (Spring) Mar-Jun	a) 3 (7) b) 3 (7)	a) 0.08 b) 0.25	a) 0.05 b) 0.15	200/400	-	Split applications: 3 appl. at 0.05 kg ai/ha Max per season is 0,25 l/ha product
4.	The Netherlands	Cabbage, head or white, Broccoli, Cauliflower	F	Broad Leaved weeds	Broadcast- Foliar	BBCH 12-19 (Spring/Summer) Mar-Jun	a) 1 (NA) b) 1 (NA)	a) 0.17 b) 0.17	a) 0.10 b) 0.10	200/400	-	Full rate in one shot of 0.10 kg ai/ha
5			F	Annual broad Leaved weeds	Broadcast- Foliar	BBCH 12-19 (Spring/Summer) Mar-Jun	a) 2 (10) b) 2 (10)	a) 0.08 b) 0.17	a) 0.05 b) 0.10	200/400	-	Fractional application in 2 steps on small annual weeds, starting from 10 days after planting
6	The Netherlands	Corn/ Maize	F	Broad Leaved weeds	Broadcast- Foliar	BBCH 16-19 (Spring) Mar-Jun	a) 1 (NA) b) 1 (NA)	a) 0.2 b) 0.2	a) 0.12 b) 0.12	200/400	-	

11.	The Netherlands	Flax	F	Broad Leaved weeds	Broadcast-Foliar	BBCH 15-19 (Spring) Mar-Jun	a) 1 (NA) b) 1 (NA)	a) 0.17 b) 0.17	a) 0.10 b) 0.10	200/400	-	Application when flax has reached 12 to 18 cm. Seeds may not be used in fodder.
12.	The Netherlands	Oilseed rape	F	Broad Leaved weeds	Broadcast-Foliar	BBCH 12-59 (Spring) Mar-Jun	a) 1 (NA) b) 1 (NA)	a) 0.2 b) 0.2	a) 0.12 b) 0.12	200/400	-	
Minor uses according to article 51												
13.	The Netherlands	Seed production ornamentals	F	Broad Leaved weeds	Broadcast-Foliar	BBCH 00 or BBCH12-19 Mar-Aug	a) 1 (NA) b) 1 (NA)	0.125/0.2	0.075/0.12	200 /400	-	
14.	The Netherlands		F	Broad Leaved weeds			a) 3 (7) b) 3 (7)	a) 0.08 b) 0.25	a) 0.05 b) 0.15	200 /400	-	
16.	The Netherlands	Madder (meekrap)	F	Broad Leaved weeds	Broadcast-Foliar	BBCH 12-19 April-July	a) 1 (NA) b) 1 (NA)	a) 0.20 b) 0.20	a) 0.12 b) 0.12	200/400	-	
17.	The Netherlands		F	Broad Leaved weeds			Broadcast-Foliar	BBCH 12-39 April-July	a) 3 (7) b) 3 (7)	a) 0.08 b) 0.25	a) 0.05 b) 0.15	200/400
18.	The Netherlands	(Stinging) nettle	F	Broad Leaved weeds	Broadcast-Foliar	BBCH 00-19 Mar-Jun			a) 1 (NA) b) 1 (NA)	0.125/0.2	0.075/0.12	200/800
19.	The Netherlands	Weld (<i>Reseda luteola</i>) (wouw)	F	Broad Leaved weeds	Broadcast-Foliar	BBCH 00-09 Mar-Aug	a) 1 (NA) b) 1 (NA)	0.125/0.2	0.075/0.12	200/400	-	
20.	The Netherlands		F	Broad Leaved weeds			Broadcast-Foliar	BBCH 12-19 Mar-Aug	a) 3 (7) b) 3 (7)	a) 0.08 b) 0.25	a) 0.05 b) 0.15	200/400

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 (Part b, Section 1, Points 2 and 4)

Overall summary: The product Lontrel 600 is a Soluble Concentrate (SL). All studies have been performed in accordance with the current requirements, the critical EU-GAP (EU-GAP covers NL-GAP) and the results are deemed to be acceptable. The appearance of the product is that of daffodil yellow without any characteristic odour. It is not explosive and has no oxidizing properties. It has a mean self-ignition temperature of 441 ± 4 °C. It is acidic (pH 1% dispersion is 3.52). The stability data indicate storage stability after 14 days at 54°C. Its technical characteristics are acceptable for a Soluble Concentrate (SL) formulation.

The core assessment did not include data on the pH of the undiluted product. An additional non-GLP report was provided, showing the pH of the undiluted product is 5, using the appropriate test method (CIPAC MT75.3). Although GLP determinations should normally be conducted to GLP, in this case, it is sufficient that the study confirms the pH of the product is >2. The pH value indicates no concern for the risk assessment nor classification and labelling.

No final shelf-life study was included in the final RR. At national level, the final shelf-life study, performed in PET, HDPE and HDPE COEX was provided and evaluated. A shelf-life of 2 years in PET, HDPE and HDPE/EVOH is supported by the data provided.

Implications for labelling: none

Compliance with FAO specifications: The product Lontrel 600 complies with FAO specifications.

Compatibility of mixtures: Not intended to be used in mixtures.

Nature and characteristics of the packaging: Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leak-proofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment: Information regarding the required protective clothing and equipment for the safe handling of Lontrel 600 has been provided and is considered to be acceptable.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for determination of clopyralid, impurities and relevance of CIPAC methods in Lontrel 600 were not evaluated as part of the EU review of clopyralid. Therefore all relevant data are provided and are considered adequate.

Active substance analysis

Full details are provided in section 2 of the dRR for the determination of clopyralid in Lontrel 600 (Jean-Baptiste, C., 2011). The percentage of clopyralid was determined by HPLC. The method was considered fully validated and is acceptable for the determination of clopyralid in SL formulations.

Impurities analysis

No relevant impurities were detected.

Applicability of existing CIPAC methods

No CIPAC method available for the determination of clopyralid content in technical clopyralid or clopyralid formulation.

3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)

EU Conclusions: Analytical methods for residues of clopyralid in crops

Crop/Matrix	EU agreed methods (EFSA Journal 2005;50:1-65)
Cereals, Sugar beet	GC-MSD, 0.01 mg/kg
Rape Seed	GC/NCI-MS, 0.01 mg/kg (rape seed)

Summary

All analytical methods are active substance data and were provided in the EU review of clopyralid and were considered adequate.

The existing method for the determination of clopyralid residues in surface water has a LOQ of 0.05 µg/L. This satisfies the Dutch national requirements.

3.1.3 Mammalian Toxicology (Part B, Section 3, Point 7)

The Plant Protection Product Lontrel 600 containing 600 g/L of clopyralid is intended to be used on a variety of crops. The formulation is a soluble concentrate commercialized in 0.1, 0.25, 0.5, 1 and 5 L containers. Applications of Lontrel 600 are to be made with a tractor-mounted boom sprayer with hydraulic nozzles. Manual application (handheld sprayer with hydraulic nozzle) cannot be excluded for some of the minor crops. Water will be the diluent/carrier in all situations.

Calculations were performed according to the national requirements for the Netherlands and according to the critical uses for the Netherlands. Critical uses (worst-case scenario) are summarised in table 3.1.3/01 below.

Table 3.1.3/01 Worst case use (risk envelope) for estimation of operator, bystander and worker exposure of Lontrel 600 in the Netherlands

GAP uses	Application equipment	Application rate [g a.i./ha]	Water volume [L/ha]

Field crops	Vehicle, ground boom	120	200
Field crops (some minor crops)	Manual, hydraulic nozzle	120	200

3.1.3.1 Acute Toxicity (Part B, Section 3, Point 7.1)

Acute toxicity studies for Lontrel 600 were not evaluated as part of the EU review of the clopyralid. Therefore, all relevant data were provided and are considered adequate.

Lontrel 600, containing 600 g/L clopyralid, has a low toxicity in respect to acute oral and dermal toxicity and is not irritating to the rabbit eye. It has been found to be not classifiable for irritancy to rabbit skin and is not a skin sensitizer to the guinea pig. Taking into account all submitted data and the labelling of clopyralid, Lontrel 600 does not require classification.

Parameter [Reference]	Species	Result mg/kg or mg/m ³ or effect	Classification
acute LD50 oral [7.1.1: Richeux, F. (2011a)]	rat	>2000 mg/kg	Not required
acute LD50 dermal* [7.1.2 : Dalal, V., 2008, 7856] [7.1.3]	rat NA	>2000 mg/kg (rabbit) NA	Not required Not required
skin irritation [7.1.4: Richeux, F. (2011b)]	rabbit	not irritant to the skin	Not required
eye irritation [7.1.5: Richeux, F. (2011c)]	New Zealand rabbit	not irritant for the eyes	Not required
sensitization of the skin (LLNA) [7.1.6: Richeux, F. (2011d)]	mouse	Non sensitizer	Not required

*results of studies coming from EFSA conclusion

3.1.3.2 Operator Exposure (Part B, Section 3, Point 7.3)

Operator exposure to Lontrel 600 was not evaluated as part of the EU review of clopyralid for this submitted rates and crops. Therefore all relevant data and risk assessments have been provided and are considered to be adequate.

For mixing and loading and application during downward mechanically applications exposure was estimated using the model EUROPOEM I.

For manual downward applications, the EUROPOEM I model need to be used for estimating the dermal exposure due to mixing and loading of a liquid formulation. The NL Model need to be used for estimating the inhalation exposure due to mixing and loading of a liquid formulation due to manual applications. The UK POEM model need to be used for estimation of dermal and inhalation exposure during manual application.

The dermal absorption values were used according to the following data obtained from the study KIIIA1 7.6.2/01: *In vitro percutaneous absorption of clopyralid, formulated as Clopyralid 600 SL* (R.A.F., De Ligt, 2012).

The values of dermal absorption obtained in this study are given in the table 3.1.3.2-01. For reference, also dermal absorption values and AOEL value from EFSA Scientific Report (2005) 50, 1-65 are provided.

Table 3.1.3.2-01 End-Points for Lontrel 600

End-Point	Active Substance EFSA Scientific Report (2005) 50, 1-65	Study KIIIA1 7.6.2/01 In vitro percutaneous absorption of Clopyralid, formulated as Clopyralid 600 SL, through human skin membranes (values used in the calculations)
Dermal penetration	10% as default	Concentrate: 0.31% Spray Dilution: 7.10%
AOEL	1.0 mg/kg bw/day	

End-points for **dermal absorption** from the study KIIIA1 7.6.2/01 have been used for exposure calculations instead of EFSA end-points.

The dermal absorption for concentrate is estimated to be 0.31% and the value for dermal absorption of 100 x diluted spray is 7.1% in the study KIIIA1 7.6.2/01.

Results of the operator exposure calculations are given below.

Table 3.1.3.2-02: Mechanical downward spraying: estimated operator exposure to clopyralid without PPE for clopyralid (max dose: 0.2 L/ha in the lowest volume of 200 L/ha)

	Route	Estimated internal exposure (mg /day)	Systemic AOEL (mg/day)	Risk-index
<i>Mechanical downward spraying on field crops</i>				
Mixing/ Loading	Respiratory	0.0090	70	0.00
	Dermal	0.1116	70	0.00
Application	Respiratory	0.0144	70	0.00
	Dermal	0.3834	70	0.01
	Total	0.5184	70	0.01

Table 3.1.3.2-03: Manual downward spraying: estimated operator exposure to clopyralid without PPE for clopyralid (max dose: 0.2 L/ha in the lowest volume of 200 L/ha)

	Route	Estimated internal exposure (mg /day)	Systemic AOEL (mg/day)	Risk-index
<i>Manual downward spraying on field crops</i>				
Mixing/ Loading	Respiratory	0.001	70	<0.01
	Dermal	1.975	70	0.028
Application	Respiratory	0.072	70	<0.01

Route	Estimated internal exposure (mg /day)	Systemic AOEL (mg/day)	Risk-index
Dermal	5.208	70	0.07
Total	7.256	70	0.10

According to the model calculations, it can be concluded that the risk for the operator using Lontrel 600 either by mechanical applications or manual applications on all requested crops is acceptable without the use of personal protective equipment.

3.1.3.3 Bystander Exposure (Part B, Section 3, Point 7.4)

Bystander exposure to Lontrel 600 was not evaluated as part of the EU review of clopyralid. Therefore, all relevant data and risk assessments have been provided and are considered adequate.

The bystander risk assessment was carried out using the EUROPOEM II model. Bystander exposure is assumed to occur when spray drift reach persons next to fields being sprayed, and the bystander is assumed to be situated adjacent to the treated field at a reasonable distance. The wind direction is assumed to be from the field being sprayed directly toward the bystander.

Bystanders are exposed to spray drift at the time of application. Predicted levels of dermal and inhalation exposure will therefore be highest from exposure to the highest in-use spray concentration. Bystander exposure was estimated for an application rate of 120 g ai/ha in a minimum water volume of 200 l/ha, which was considered to be worst case.

The calculated total systemic bystander exposure for the worst-case scenario uses <0.1% of the AOEL of clopyralid. Thus, an acceptable risk for bystanders is indicated for the envisaged uses of Lontrel 600. A summary of estimated bystander exposure values is given in Table 3.1.3.3 -01.

Table 3.1.3.3-01: Summary of estimated bystander exposure and percentage of AOEL for clopyralid

Inhalation exposure (mg/person/d)	Dermal exposure (mg/person/d)	Dermal absorption [%]	Estimated systemic exposure [mg a.s./d]	AOEL based on 70 kg bw [mg a.s./d]	% of AOEL
0.0225	0.12	7.10	0.031	70	<0.1

It can be concluded that there is no undue risk to any bystander after accidental short-term exposure to Lontrel 600 600 g/l SC. This has no labelling implications.

3.1.3.4 Worker Exposure (Part B, Section 3, Point 7.5)

Worker exposure to Lontrel 600 was not evaluated as part of the EU review of clopyralid. Therefore, all relevant data and risk assessments have been provided and are considered adequate.

Predicted levels of dermal and inhalation exposure will therefore be highest from exposure to the highest in-use spray concentration. Bystander exposure was estimated for an application rate of 120 g a.i./ha in a minimum water volume of 200 l/ha, which was considered to be worst case.

The worker re-entry risk assessment was carried out using the EUROPOEM II model. Activities such as inspection may lead to contact between crop and workers. Dermal exposure is considered to be by far the most important exposure route during re-entry activities.

For re-entry activities in the field, no model is available for estimation of inhalatory exposure. However, since the vapour pressure of clopyralid is only 1.36×10^{-3} Pa at 25 °C inhalatory exposure upon re-entry in a dried crop is considered low compare to dermal exposure and inhalatory exposure is therefore negligible.

The intensities of the workers contact with the treated crop, expressed as TC values, are given in the EUROPOEM II re-entry model and can be extrapolated to other crop groups where the intensity of workers contact with the crop is judged to be similar. The worst case is therefore represented by a combination of the DFR and the TC values. A task duration of 6 hours and a default DFR value of 30 mg a.s./m²/kg a.s./ha were considered.

The following indicative TC values for potential dermal exposure are proposed for harvesting scenarios with bare hands:

- Vegetables (field) 2500 cm²/hour

The exposure to clopyralid for workers uses maximally 1% of the AOEL. The exposure does not exceed the AOEL for clopyralid for the use in field crops. Therefore, the calculated exposure to clopyralid is expected to result in acceptable risk for workers.

In Table 3.1.3.4-01, the estimated worker exposure is presented.

Table 3.1.3.4-01: Summary of estimated worker exposure and percentage of AOEL without PPE for clopyralid

Crop group	TC [m ² /h]	Dermal absorption [%]	Estimated systemic exposure [mg a.s./d]	AOEL based on 70 kg bw [mg a.s./d]	% of AOEL
Vegetable, oilseeds and cereals (field)	0.25	7.10	0.383	70	1

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing (but no PPE), when re-entering crops treated with Lontrel 600.

As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

Implications for labelling resulting from operator, worker, bystander assessments:

According to Directive 1999/45/EC

Hazard Symbol: none

Indication of danger: none

Risk Phrases: none

Safety Phrases: none

According to Regulation 1272/2008/EC

GHS pictogram: none

Signal word: none

Hazard statement: None

Precaution statements: none

Response: none

Storage: none

Disposal: none

3.1.4 Residues and Consumer Exposure (Part B, Section 4, Point 8)

3.1.4.1 Residues (Part B, Section 4, Points 8.3 and 8.7)

All data relied upon for this evaluation are those considered in the EU DAR (See EFSA Scientific Report (2005) 50, 1-65) or data previously considered by UK. The proposed uses for cereals, sugar beet, fodder beet, oilseed rape, flax (linseed) and fodder grassland are covered by residue data considered for Annex I inclusion. The proposed uses for head cabbage, white cabbage, cauliflower and maize are within uses considered in a previous central zone assessment considered by UK.

New residue data were submitted for the proposed uses in broccoli and onion.

An assessment residues and consumer exposure of equivalent uses in cereals, sugar beet and fodder beet, head cabbage, white cabbage, cauliflower, broccoli, corn/maize, flax, oilseed rape, onions and fodder grassland has been presented in Part B. Section 4 and previous registration reports submitted by UK as appendices.

The following residue definitions for food of plant origin have been proposed in Draft Assessment Report, point 2.4:

Definitions for risk assessment: clopyralid (parent compound)

Definitions for monitoring: clopyralid (parent compound)

Rest products of flax (fiber and/or seed) can be used as livestock feed. To exclude residues in commodities of animal origin the applicant suggested a feeding restriction for rest product of flax. This restriction is considered appropriate.

On the basis of rotational crop data it was concluded that all residues in succeeding crops would be expected to be less than 0.02 mg/kg, if a 125 day plant back interval was set. The applicant proposed a 90 day plant back interval prior to planting of oilseed rape, sugar beet and cereals. Use on oilseed rape, sugar beets and cereals is approved with existing EU MRLs for clopyralid at 0.5 mg/kg, 1.0 mg/kg and 2.0 mg/kg, respectively. The magnitude of these MRLs sufficiently covers the potential residue estimated in rotational crops.

The proposed uses (except Brussels sprouts) including rotational crops comply with the current EU MRLs. The MRLs for clopyralid are published in Annexes II and IIIB of Regulation (EC) No 396/2005.

Regarding rotational crops, a plant back interval of 4 months is required.

3.1.4.2 Consumer exposure (Part B, Section 4, Point 8.10)

Sufficient data are available to perform a robust consumer risk assessment. The estimated consumer intake levels do not exceed the EU agreed ADI of 0.15 mg/kg bw/day for clopyralid. It can therefore be concluded that acceptable margins of safety exist for consumers.

TMDI calculations using the EFSA model were performed to take account of all crops to which clopyralid may be applied.

NESTI calculations were not performed, as no ARfD was allocated because the active substance does not exhibit toxicological properties which trigger the setting of an ARfD. In that case, no acute risk assessment was calculated.

Based on the different calculations made to estimate the risk for consumers through diet and other means it can be concluded that the use of product Lontrel 600 does not lead to an unacceptable risk for consumers when applied according to the recommendations.

3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)

Appropriate endpoints from the EU review and endpoints based on data provided in this submission were used to calculate PECs for clopyralid (in soil, groundwater, and surface water) for the intended use patterns. The NL-GAP is covered by the EU-GAP. Therefore, only Dutch specific calculations for predicted environmental concentrations in groundwater and surface water were done for the intended NL-GAP while other calculations were done for the EU-GAP.

3.1.5.1 Predicted Environmental Concentration in Soil (PEC_{soil}) (Part B, Section 5, Points 9.4 and 9.5)

The PEC of clopyralid in soil has been assessed using equations given in the guidance on persistence in soil (PSD calculator-reference: Sanco/7193/VI/99 rev 0), the focus groundwater interception values and the DT₅₀ values established in the DAR.

Based on the recommended uses given in the EU-GAP, the maximum initial predicted environmental concentration in soil (PECs) of clopyralid was calculated for Sugar beet at 300 g a.s./ha using 20% interception that was considered as a worst case which covers the rest of the crops in the EU-GAP and the proposed NL GAP (including the minor uses). Results are given in table 3.1.5.1-1.

Table 3.1.5.1-1 PEC_{soil} values for clopyralid

Crop	Max parent PEC _{soil}
	(mg/kg)
Sugar Beet	0.314

The results for PEC soil for the active substance were used for the eco-toxicological risk assessment.

3.1.5.2 Predicted Environmental Concentration in Ground Water (PEC_{GW}) (Part B, Section 5, Point 9.6)

The PEC of clopyralid in ground water according to the EU-GAP has been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS-PELMO, FOCUS PEARL. Parameters used in the evaluation can be found in the study KIII 9.6. Results of the calculations confirm that there is no excess of the threshold values (0.1µg/l) with neither PELMO nor PEARL for the application of Lontrel 600 on cereals, oilseed rape, sugar beet, grass, maize, onion and cabbage when applied according to the label. A lysimeter study also confirms this trend.

The uses specific to the Netherlands are within the risk envelop assessed in the core dossier. The results obtained for the Kremsmünster scenario with Focus Pearl 4.4.4. that for the uses according to the EU-GAP modeled, the PEC_{gw} was always <0.01, using a geometric mean standardised modeling DT₅₀(field). However, since this value is shorter than 10 days and the average K_{om} is lower than 10 L/kg for clopyralid, the time of application has a great effect on the calculated leaching concentration. This means that in some cases the concentration calculated with GeoPEARL (tier 2) is not lower than the 80 percentile of the concentration calculated with Kremsmünster scenario. Therefore tier 2 modeling, supplemental to the modeling performed for the core dossier, has been conducted for clopyralid according

to the critical gap of Lontrel 600 for the Netherlands. From the discussion under Annex points IIIA 9.1 – IIIA 9.3 of the core dossier, no metabolites are considered to be of relevance for groundwater assessment. Results of the calculations with GeoPEARL confirm that there is no excess of the threshold values (0.01 µg/l) for the application of Lontrel 600 on cereals, oilseed rape, beets, maize, cabbage, onion, grassland, swede, turnip, seed production of ornamental crops, madder, (stinging) nettle and weld when applied according to the Dutch label.

Monitoring data groundwater

In the LoEP reference is made to a survey (K75) on the occurrence of clopyralid in groundwater and surface water in Europe (15 EU Member States, as well as Norway and Switzerland). Clopyralid was found in groundwater in Denmark, Germany and the UK in a small proportion of samples (0.3% of about 2000 samples and almost 700 sites). A concentration of 0.1 µg/L was exceeded in 2 samples in Denmark only.

Two surveys of monitoring data on the occurrence of clopyralid in groundwater have been submitted with previous demands of Lontrel SG (13827 N) based on 720 g/L clopyralid:

Knowles, K., Horth, H. & Blackmore, K (2008). Review of monitoring and occurrence of clopyralid in groundwater and surface water in Europe – update 2008 (DAS Report No.: GHE-P-11880).

Berardozi, M. (2009). Review of clopyralid monitoring data in groundwater in France (DAS Report No.: GHE-P-12059).

Knowles et al. (2008) is an update of the survey mentioned in the LoEP. Clopyralid was found in groundwater in a small proportion of samples (0.7% of about 20000 samples and almost 6000 sites). A concentration of 0.1 µg/L was exceeded in 53 samples, with a maximum concentration up to 10.6 µg/L.

Berardozi (2009) comprised data from France over the period 2002 – 2006 (6703 samples in total). Clopyralid was found in groundwater in only four samples, one of which was an error (in 2004) and the three remaining (in 2006) being representative of atypical uses, linked to exceptional climatic conditions and specific agricultural practice in a minor region of sales.

These data all refer to the European assessment of available data, and it is unclear how these data are relevant for the Netherlands. Therefore, no consequences can be drawn for the current application of Lontrel 600.

3.1.5.3 Predicted Environmental Concentration in Surface Water (PEC_{SW}) (Part B, Section 5, Points 9.7 and 9.8)

Calculations of PEC_{sw} according to the EU-GAP for clopyralid have been performed using Steps 1-2, FOCUS SW group of models.

The highest FOCUS Step 2 PEC_{sw} value for risk assessment is 21.23 µg/l in Sugar beet. The highest Step PEC_{sed} is 0.6214 µg/l in Sugar beet.

The PEC_{SW} calculated for clopyralid of Lontrel 600 during the Steps 1 and 2 led to favorable TER values for aquatic organisms. As a consequence, there was no need to perform Focus step 3.

The PEC_{sw} according to the NL-GAP of clopyralid in surface water has been assessed with the TOXSWA-NL model and Dutch specific drift figures and the DT₅₀ water/sediment values established in the EU review or agreed based on new data provided for this assessment.

The highest TOXSWA-NL PEC_{sw} value for risk assessment is 0.69 $\mu\text{g/l}$.

Table 3.1.5.3-1: PEC_{sw} for Clopyralid – Comparison Focus (Step1-2) and TOXSWA-NL values

Crop EU GAP	PEC_{sw} ($\mu\text{g/L}$)		Crop NL GAP	PEC_{sw} ($\mu\text{g/L}$)
	Focus Step 1	Focus Step 2		TOXSWA-NL
Winter cereals	41	6.3	Barley	0.57
Oilseed Rape/flax	137	16.7	Oilseed rape	0.57
			Flax	0.57
Sugar beet *	137	21.2	Beets	0.69
Corn/maize	51	7.8	Corn/maize	0.57
Cabbage, broccoli, cauliflower	34	2.6	Cabbage, broccoli, cauliflower	0.47
Grass (established)	68	4.7	Grassland	0.57
Onion	51	9.1	Onion	0.57

* Sugar beet at 3 x 50 g ai/ha also covers the minor uses seed production of ornamentals, madder, (stinging) nettle and weld.

Dutch specific PEC_{sed} values have not been determined with TOXSWA-NL since they are not relevant for the risk assessment.

Monitoring data surface water

The Pesticide Atlas on internet (www.pesticidesatlas.nl, www.bestrijdingsmiddelenatlas.nl) is used to evaluate measured concentrations of pesticides in Dutch surface water, and to assess whether the observed concentrations exceed threshold values.

The active substance clopyralid was observed in the surface water (most recent data from 2013). In the Pesticide Atlas, surface water concentrations are compared to the authorisation threshold value of 300 $\mu\text{g/L}$ (consisting of higher tier acute ecotoxicological threshold value, including relevant safety factors, which is used for risk assessment, in this case $0.01 \cdot EC_{50}$ algae and to the indicative Maximum Permissible Concentration (MPC) of 75 $\mu\text{g/L}$ as presented in the Pesticide Atlas.

Currently, this MPC value is not harmonised, which means that not all available ecotoxicological data for this substance are included in the threshold value. In the near future and in the framework of the Water Framework Directive, new quality criteria will be developed which will include both MPC data as well as authorisation data. The currently available MPC value is reported here for information purposes. Pending this policy development, however, no consequences can be drawn for the proposed applications.

In Table 3.1.5.3-2 the number of observations in the surface water are presented:

Table 3.1.5.3-2: Monitoring data in Dutch surface water for substance clopyralid (from www.pesticidesatlas.nl, version 3)

Total no of locations (2013)	<i>n</i> > authorisation threshold	<i>n</i> > EQS		
		MAC-EQS	AA-EQS	MPC (ad-hoc/indicative)
43	0	n.a.	n.a.	0

* the number of observations at each location varies between 4 and 30; total number of measurements is 357 in 2013.

** n.a. not available

As there are no exceedings of thresholds, the monitoring data have no consequences for the proposed uses of the product.

Drinking water criterion

Substances are categorized as new substances on the Dutch market (less than 3 years authorisation) or existing substances on the Dutch market (authorised for more than 3 years).

- For new substances, a pre-registration calculation is performed.
- For existing substances, the assessment is based on monitoring data of VEWIN (drinking water board).
 - o If for an existing substance based on monitoring data no problems are expected by VEWIN, Ctgb follows this VEWIN assessment.
 - o If for an existing substance based on monitoring data a potential problem is identified by VEWIN, Ctgb assesses whether the 90th percentile of the monitoring data meet the drinking water criterion at each individual drinking water abstraction point.

Active substance clopyralid has been on the Dutch market for > 3 years (authorised since 03-02-1995). This period is sufficiently large to consider the market share to be established. From the general scientific knowledge collected by the Ctgb about the product and its active substance, the Ctgb concludes that there are in this case no concrete indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. The Ctgb does under this approach expect no exceeding of the drinking water criterion. The standards for surface water destined for the production of drinking water are met.

3.1.5.4 Predicted Environmental Concentration in Air (PEC_{Air}) (Part B, Section 5, Point 9.9)

Predicted Environmental Concentration in Air (PEC_{Air}) was not assessed.

Implications for labelling resulting from environmental fate assessment:

None

3.1.5 Ecotoxicology (Part B, Section 6, Point 10)

Unless stated otherwise the risk assessments presented below were performed according to the following critical EU-GAP (Table 3.1.6-1). For specific aspects the NL specific GAP (Table 3.1.6-2) was used for risk assessment.

Table 3.1.6-1 Lontrel 600 use patterns used for Risk Envelope assessment – EU

Risk Envelope Description for Birds	Crops covered by Risk Envelope	Max. No of application per season	Minimum Interval (days)	Maximum application rate (kg as/ha)
Grassland	Grass	1	-	0.20
Cereals	Cereals	1	-	0.12
Sugarbeet	Sugar Beet	2	5	0.2
Leafy Crops	Cabbage, Cauliflower, Broccoli, Chives	2	7	0.05
Oilseed Rape	Oilseed Rape Flax	2	60	0.20
Bulbs and onion like crops	Onion	1	-	0.15
	Ornamentals	1	-	0.20
Maize	Maize	1	-	0.15
Ornamentals/ Nursery ¹	Forest/Trees nursery	1	-	0.15

¹ There was no FOCUSsw model to cover ornamentals and forestry so they were not part of the calculation in this section, due to lack of data to insert in EFSA calculator. Data on bulbs and onion like crops can be suggested to cover ornamentals.

Table 3.1.6-2 Lontrel 600 use patterns used for Risk Envelope assessment – NL

Crop	Max. No of application per season	Minimum Interval (days)	Maximum application rate (kg as/ha)
Cereals	1	-	0.12
Beets	1	-	0.12
	3	7	0.05
Cabbage, head or white, Broccoli, cauliflower	2	7	0.05
Corn/ Maize	1	-	0.12
Flax	1	-	0.10
Oilseed rape	1	-	0.12
Grassland	1	-	0.12
Onion	1	-	0.12

3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)

Effects on birds and terrestrial vertebrates other than birds are not a national specific requirement. The NL-GAP (including minor uses) is covered by the critical GAP used in the core assessment. For the national addendum, national specific drift rates are used to calculate exposure to off-field areas (both surface water and land). However, the Dutch PEC_{sw} values determined with TOXSWA-NL are lower than the PEC_{sw} (step 1-2) values from the core assessment. Therefore the risk assessment on Terrestrial Vertebrates has been carried out according to the EU-GAP as stated under point 3.6.1.

Birds

The risk assessment for effects on birds is carried out according to the latest draft of the 'EC Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC' (Anonymous 2002)¹.

A. The acute, short-term and long-term risks of Lontrel 600 to birds from food

The acute, short-term and long-term risks of Lontrel 600 to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with clopyralid, and maximum residues occurring on food items following applications according to the proposed use pattern. Risk of secondary poisoning was not assessed, since clopyralid has low log P_{OW} = -2.63.

The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk, thus indicating no unacceptable risk to birds from the proposed uses.

B. Acute and long-term exposure to birds through contaminated drinking water

Summary of risk assessment performed for non-target organisms is presented below.

A. Acute and long-term exposure to birds through contaminated drinking water

As recommended, in the B&M GD (Anonymous 2009), The DT₅₀ used in the PEC_{SW} and PEC_{GW} should be used, i.e. DT₅₀ = 3.4.

For sugar beet which represents the worst case scenario crop, with n=2 applications, i=5 days, k = 0.204, we obtained an AR_{eff} of 272. The ratio between AR_{eff} and LD₅₀ (1465 mg/ kg bw for birds) is 0.186 which is very far from the threshold of 50.

Therefore, we do consider that no specific calculation of exposure and TER is necessary for the product Lontrel 600 due to the very low risk for birds and mammals through drinking water.

Conclusion on the exposure of birds through drinking water contamination:

We can consider that the application of Lontrel 600 on any crops is not an issue in terms of contamination through drinking water due to the very low acute toxicity of clopyralid to birds.

B. Bioaccumulation

The risk assessment was carried out together for birds and mammals.

¹ EC Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC. SANCO/4145/2000, 25th September 2002.

In accordance with the EC Guidance Document on Risk Assessment for Birds and Mammals² substances with a log P_{ow} greater than 3 have potential for bioaccumulation and should be assessed for the risk of bioaccumulation in terrestrial food chains.

We are not expecting major risk of bioaccumulation for clopyralid since the log P_{ow} is -2.63 according to the method used (EFSA Scientific Report 2005, 50, 1-65).

It can be concluded, that the long-term exposure of birds and mammals to Lontrel 600 through food chain is therefore deemed acceptable.

3.1.6.2 Terrestrial vertebrates (other than birds)

A. Acute toxicity exposure ratio (TER_A) for mammals

Effects on terrestrial vertebrates other than birds for Lontrel 600 were not evaluated as part of the EU review of clopyralid. However further data on Lontrel 600 is not relevant as active substance data on toxicity to terrestrial vertebrates other than birds is used and additional formulation data are not considered essential. Therefore all relevant data were assessed in the EU review. Risk assessments for Lontrel 600 with the proposed use pattern are provided and are considered adequate. The risk assessment is performed with the critical GAPs which were given in table 3.1.6.-1 (the minor uses are covered by the risk envelope from the major uses in the Core assessment – particularly use in grasslands, for the wild mammal risk assessment).

The EU agreed end points used in the calculations are given below.

Study	Test species	EU agreed endpoints used in the assesment (EFSA Scientific report No.50. 1-65 (2005))
Acute toxicity	Rat	Rat: acute LD_{50} > 5000 mg/kg body weight Rat: 13-week subchronic NOAEL 300 mg as/kg bw/day
	Dog	Dog: 12-month subchronic NOAEL 100 mg as/kg bw/day

The screening step and the first tier risk assessment have been performed using the latest calculator tool issued by EFSA (as available on <http://www.efsa.europa.eu/fr/efsajournal/pub/1438.htm>) in accordance with the new guidance document of EFSA.

The TER_A values are greater than the Annex VI trigger of 10, indicating low acute risk to mammals from clopyralid following application of Lontrel 600 at all proposed label rates.

B. Long term toxicity exposure ratio (TER_{LT}) for mammals

The EU agreed end points used in the calculations are given below.

Study	Test species	EU agreed endpoints used in the assessment (EFSA Scientific report No.50. 1-65 (2005))
Reproductive toxicity (long-term)	Rat	2-year chronic NOAEL 50 mg /kg bw/day

² Guidance of EFSA: Risk Assessment for Birds and Mammals, European Food Safety Authority, EFSA Journal 2009;7(12):1438, 2009

The screening step and the first tier risk assessment have been performed using the latest calculator tool issued by EFSA (as available on <http://www.efsa.europa.eu/fr/efsajournal/pub/1438.htm>) in accordance with the new guidance document of EFSA.

The TER_{LT} values for clopyralid are greater than the Annex VI trigger of 5, indicating Lontrel 600 600 SL presents no unacceptable long-term risk to mammals.

3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)

For the national addendum, national specific drift rates are used to calculate exposure to off-field areas (both surface water and land). However, the Dutch PEC_{sw} values determined with TOXSWA-NL are lower than the PEC_{sw} (step 1-2) values from the core assessment. Therefore the risk assessment on aquatic organisms has been carried out according to the EU-GAP as stated under point 3.6.1. This EU GAP is covering all major and minor uses from the GAP of Lontrel 600.

1. Rainbow trout

a/ TER_A for fish (Rainbow trout)

Toxicity end points used in the calculations are given in the table below:

Clopyralid	Rainbow trout	96 h LC ₅₀ >99.9
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The clopyralid acute toxicity endpoints for rainbow trout were used in the assessment. TER_A values were calculated using the FOCUS Step 1. The results are presented below:

Table 3.1.6.2-1 Fish acute TER value following the use of Lontrel 600 using FOCUS Step 1 PEC_{sw} values on Cereals, Oilseed rape, Sugar beet, Grass, Maize, Onion and Cabbage

Test organism	Test substance	96 hr LC ₅₀ (mg a.i./L)	Use pattern	PEC _{sw} (mg a.i./L)		TER _A	Trigger value
Rainbow trout	Lontrel 600	>99.9	Cereals	Step 1	0.041	2415	≥ 100
			Oilseed Rape	Step 1	0.137	723	
			Sugar beet	Step 1	0.137	723	
			Grass	Step 1	0.069	1435	
			Maize	Step 1	0.0514	1926	
			Onion	Step 1	0.0514	1926	
			Cabbage	Step 1	0.0172	5756	

Overall summary

The TER_A values for Lontrel 600 are above the Annex VI trigger value of 100, indicating that clopyralid poses low acute risk to fish following the proposed use of Lontrel 600.

b/ TER_{LT} for fish (Fathead minnow)

The TER_{LT} values for clopyralid for fish were calculated using the chronic NOEC values for Fathead minnow trout (EFSA Review Report 2005, 50, 1-65 Endpoints). The TER_{LT} values calculated using FOCUS Step 1-2 PEC_{SW} worst case values are presented below.

Table 3.1.6.2-2 Fish long-term TER values for clopyralid using FOCUS Step 1 PEC_{SW} values on Cereals, Oilseed rape, Sugar beet, Grass, Maize, Onion and Cabbage

Test organism	Test substance	NOEC (mg a.i./L)	Use pattern	PEC _{SW} (mg a.i./L)		TER _{LT}	Trigger value
Fathead minnow	Lontrel 600	10.8	Cereals	Step 1	0.041	263	≥ 10
			Oilseed Rape	Step 1	0.137	79	
			Sugar beet	Step 1	0.137	79	
			Grass	Step 1	0.069	157	
			Maize	Step 1	0.0514	210	
			Onion	Step 1	0.0514	210	
			Cabbage	Step 1	0.0172	628	

Overall summary

The TER_{LT} values for Lontrel 600 are above the Annex VI trigger value of 10, indicating that clopyralid poses low long-term risk to fish following the proposed use of Lontrel 600.

2. Daphnia magna

a/ TER_A for Daphnia magna

Toxicity end points used in the calculations are given in the table below:

Clopyralid	<i>Daphnia magna</i>	EC ₅₀ >99 mg ai/L
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TER_A values were calculated and are given in the table below.

Table 3.1.6.2-3 Acute TER values for D. magna for clopyralid using FOCUS Step 1 PEC_{SW} values on Cereals, Oilseed rape, Sugar beet, Grass, Maize, Onion and Cabbage

Test organism	Test substance	LC ₅₀ (mg a.i./L)	Use pattern	PEC _{SW} (mg a.i./L)		TER _A	Trigger value
<i>Daphnia magna</i>	Lontrel 600	>99	Cereals	Step 1	0.041	2415	≥ 100
			Oilseed Rape	Step 1	0.137	723	
			Sugar beet	Step 1	0.137	723	
			Grass	Step 1	0.069	1435	
			Maize	Step 1	0.0514	1926	
			Onion	Step 1	0.0514	1926	
			Cabbage	Step 1	0.0172	5756	

Overall summary

The TER_A values are greater than the Annex VI acute trigger value of 100. This indicates that clopyralid poses low acute risk to *D. magna* following application of Lontrel 600 at the proposed label rates.

b/ TER_{LT} for *Daphnia magna*

TER_{LT} values for *Daphnia magna* were calculated for clopyralid and the using FOCUS Step 1 PEC_{SW} values, and are given in Table below.

Table 3.1.6.2-4 Long-term TER values for *D. magna* for clopyralid using FOCUS Step 1 PEC_{SW} values on Cereals, Oilseed rape, Sugar beet, Grass, Maize, Onion and Cabbage

Test organism	Test substance	NOEC (mg a.i./L)	Use pattern	PEC_{SW} (mg a.i./L)		TER_{LT}	Trigger value
<i>Daphnia magna</i>	Lontrel 600	17	Cereals	Step 1	0.041	415	≥ 10
			Oilseed Rape	Step 1	0.137	124	
			Sugar beet	Step 1	0.137	124	
			Grass	Step 1	0.069	246	
			Maize	Step 1	0.0514	331	
			Onion	Step 1	0.0514	331	
			Cabbage	Step 1	0.0172	988	

Overall summary

The TER_{LT} values are greater than the Annex VI acute trigger value of 10. This indicates that clopyralid poses low acute risk to *D. magna* following application of Lontrel 600 at the proposed label rates.

Aquatic insects**a/ TER_A and TER_{LT} for aquatic insect**

Lontrel 600 formulation is not to be issued directly on surface waters and consequently, a risk assessment for acute toxicity to aquatic insects is not required.

Algae**a/ TER_{LT} for algae**

Toxicity end points used in the calculations are given in the table below (KIIIA1 10.8.2.1/01):

Lontrel 600	<i>Desmodesmus subspicatus</i>	E_yC_{50} : 0.41 mg a.s./L
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TER_{LT} values for algae were calculated for clopyralid and the using FOCUS Step 1 PEC_{SW} values, and are given in Table below.

Table 3.1.6.2-5 Algae TER_{LT} value for Lontrel 600 using FOCUS Step 1 PEC_{SW} values of Cereals, Oilseed Rape, Sugar Beet, Grass, Maize, Onion and Cabbage.

Test organism	Test substance	72 hr E _y C ₅₀ (mg a.i./L)	Use pattern	PEC _{SW} (mg a.i./L)		TER _{LT}	Trigger value
<i>Desmodesmus subspicatus</i>	Lontrel 600	49	Cereals	Step 1	0.041	11.95	≥ 10
			Oilseed rape	Step 1	0.137	3.58	
				Step 2	0.011	44.5	
			Sugar beet	Step 1	0.137	3.58	
				Step 2	0.0231	21.2	
			Grass	Step 1	0.069	7.10	
				Step 2	0.0087	56.3	
			Maize	Step 1	0.0514	9.53	
				Step 2	0.0078	62.8	
			Onion	Step 1	0.0514	9.53	
Step 2	0.0091	53.8					
Cabbage	Step 1	0.0172	28.49				

Overall summary

The TER_{LT} values for clopyralid 600 SL are greater than the Annex VI trigger of 10, indicating that application of Lontrel 600 according to the proposed label uses poses low risk to algae.

Aquatic plants

a/ TER for aquatic plants

Toxicity end points used in the calculations are given in the table below:

Clopyralid	Duckweed	96 hr EC ₅₀ :89
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The long-term Toxicity Exposure ratios (TER_{LT}), calculated using EFSA endpoints and FOCUS Step 1 PEC_{SW} values and the results are given below.

Table 3.1.6.2-6 Aquatic macrophytes TER_{LT} values for Lontrel 600 AL using FOCUS Step 1 PEC_{SW} values of Cereals, Oilseed Rape, Sugar Beet, Grass, Maize, Onion and Cabbage.

Test organism	Test substance	96 hr EC ₅₀ (mg a.i./L)	Use pattern	PEC _{SW} (mg a.i./L)		TER _{LT}	Trigger value
<i>Lemna gibba</i> (Duckweed)	Lontrel 600	89	Cereals	Step 1	0.041	2171	≥ 10
			Oilseed rape	Step 1	0.137	650	
			Sugar beet	Step 1	0.137	650	

			Grass	Step 1	0.069	1290	
			Maize	Step 1	0.0514	1732	
			Onion	Step 1	0.0514	1732	
			Cabbage	Step 1	0.0172	5174	

Overall summary

The TER_{LT} values calculated exceed the 91/414/EEC Annex VI trigger values of 10, indicating a low risk to aquatic plants.

3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)

Bees

Effects on bees for Lontrel 600 were not evaluated as part of the EU review of clopyralid. However further data on Lontrel 600 is not relevant as active substance data on toxicity to bees is used and additional formulation data are not considered essential. Therefore all relevant data were assessed in the EU review. Risk assessments for Lontrel 600 with the proposed use pattern were provided and are considered adequate.

Effects on bees are not a national specific requirement. The NL-GAP is covered by the critical GAP used in the core assessment. A national addendum of the risk assessment on bees is therefore not required and the risk assessment on bees has been carried out according to the EU-GAP as stated under point 3.6.1.

For bees, TER values are superseded by the expression of the hazard quotient (Q) which is defined as:

$$Q_{in\ field} = (application\ rate * MAF) / LD_{50}$$

With:

- LD_{50, oral, contact} in µg a.s./bee
- Application rate in g a.s./ha eventually corrected by a
- MAF: multiple application factor

The 48 hour LD₅₀ found in the acute oral and acute contact toxicity tests were used for the assessments, which are presented in the table below.

Species	Test type	EU agreed endpoints (EFSA Scientific Report (2005), 50 1-65)
Honey bee	Oral dosing	LD _{50, oral} >100 µg /bee
	Contact dosing	LD _{50, contact} >98.1 µg /bee

The acute risk to honeybees from use of Lontrel 600 was assessed using the maximum single application rate and the LD₅₀ values to calculate hazard quotients (EPPO 2003)³ as follows:

$$\text{Hazard Quotient} = \frac{\text{Maximum application rate (g formulation/ha)}}{\text{Acute LD}_{50} (\mu\text{g formulation/bee})}$$

All the hazard quotients were found to be considerably less than 50, indicating that the active substance poses a low risk to bees. **Therefore a low risk to bees is expected from the application of Lontrel 600 according to the recommended use pattern.**

Other non-target arthropods

The EU agreed end points used in the calculations are given below.

Species	Test Substance	Endpoint	Value (g clopyralid/ha)	Reference ¹
<i>Aphidius rhopalosiphi</i>	EF-1136 (Lontrel 100)	Tier I LR ₅₀	>200	EFSA, 2005
<i>Typhlo-dromus pyri</i>	EF-1136 (Lontrel 100)	Tier I LR ₅₀	>200	
<i>Chrysoperla carnea</i>	EF-1136 (Lontrel 100)	Tier I LR ₅₀	>200	
<i>Poecilus cupreus</i>	EF-1136 (Lontrel 100)	Tier I LR ₅₀	>200	
<i>Pardosa</i> spp.	EF-1136 (Lontrel 100)	Tier I LR ₅₀	>120	

For the national addendum, national specific drift rates and national specific application rates according to the NL-GAP are used to calculate exposure to off-field areas (both surface water and land). Based on these national specific exposure calculations, national specific risk calculations for non-target arthropods have been performed. Relevant dose rates were used in the calculation: 1x120 g ai/ha and 3x50 g ai/ha, interval 7 days. The TIER I risk Assessment is summarized below:

Sublethal effects in excess of 50% were seen for *A. rhopalosiphi* at 200 g a.s./ha while these effects were less than 50% at 100 g a.s./ha. Therefore a conservative ER₅₀ of 100 g a.s./ha was used for calculation of the HQ for this sensitive species. The resulting Hazard Quotients are presented in the Table below.

³ EPPO/OEPP (2003) Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145.

Table 10.5-2 HQ-values for *A. rhopalosiphi* and *T. pyri*

	Application rate (g a.s./ha)	MAF ¹	Drift factor ² / Vegetation factor ³	PER ⁴ (g a.s./ha)	Safety factor ³	LR ₅₀ /ER ₅₀ (g a.s./ha)	HQ (trigger 2)
<u>In-field</u>							
<i>A. rhopalosiphi</i>	120	-	-	120	10	>100	<1.2
	3x50	2.7	-	135	10	>100	<1.4
<i>T. pyri</i>	120	-	-	120	10	>200	<0.6
	3x50	2.7	-	135	10	>200	<0.7
<u>Off-field</u>							
<i>A. rhopalosiphi</i>	120	-	0.01	1.2	10	>100	<0.12
	3x50	2.7		1.35	10	>100	<0.14
<i>T. pyri</i>	120	-	0.01	1.2	10	>200	<0.06
	3x50	2.7		1.35	10	>200	<0.07

¹: Multiple Application Factor, as the critical use involves only 1 application the MAF can be omitted

²: off-field: drift = 10% for downward spraying, as given in *Evaluation Manual for the Authorisation of Plant protection products and Biocides according to Regulation (EC) No 1107/2009 NL part Plant protection products Chapter 7 Ecotoxicology: terrestrial; non targets version 1.0; January 2013*

³: Vegetation distribution factor = 10, safety factor = 10 (default values)

The HQ values are less than 2 for both sensitive indicator species. Additionally, four additional species were tested (*Chrysoperla carnea*, *Poecilus cupreus*, *Aleochara bilineata*, *Pardosa* spp.). two of them showing no adverse effects greater than 10% at test rates of 120 g a.s./ha and two of them showing no adverse effects greater than 20% at test rates of 200 g a.s./ha. Consequently, the application of clopyralid can be considered as low risk to non-target arthropods.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms (Part B, Section 6, Point 10.6)

The following endpoints were used in the evaluation of the risk for earthworms.

Ecotoxicological endpoints for earthworms

Active substance	EU agreed endpoints (EFSA Scientific Report (2005)50, 1 –65)	Endpoints used in risk assessment ¹
Acute		
Clopyralid technical	LC ₅₀ > 1000 mg a.s./kg	-
Clopyralid or PPP	LC ₅₀ > 97.6 mg a.s./kg	-
Chronic (reproductive toxicity)		
NOEC ≥ 2.0 mg/kg		

Effects on Earthworms and Other Soil Macro-organisms are not a national specific requirement. The NL-GAP, including minor uses, is covered by the critical GAP used in the core assessment. A national addendum of the risk assessment on Earthworms and Other Soil Macro-organisms is therefore not required and the risk assessment has been carried out according to the EU-GAP as stated under point 3.6.1.

Acute risk

The potential acute risk of Lontrel 600 to earthworms was assessed by comparing the maximum instantaneous PEC_S with the 14-day LC₅₀ value to generate acute TER values. The log P_{OW} value of clopyralid is below 2, and hence there was no need to reduce the LC₅₀ by a factor of 2 in order to account for the relatively high organic matter content of the artificial test soil compared to agricultural soils. The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50} \text{ (mg/kg)}}{PEC_S \text{ (mg/kg)}}$$

In this case:

LC₅₀: > 97.6 mg a.s./kg dry soil (EU agreed endpoint for Lontrel 100 SL)

PECs: 0.314 mg a.s./kg (value calculated for Lontrel 600, cf. Section 5 of this Dossier)

The resulting TER_A values are shown below in Table 3.1.6.4-1.

Table 3.1.6.4-1: Acute TER values for earthworms

Parent compound	Test substance	LC ₅₀ (mg a.s./kg dry soil)	Maximum instantaneous PEC _S (mg a.s./kg)	TER _A
Lontrel 600	Formulated product	> 97.6	0.314	> 310.8

The acute TER value is much higher than the Annex VI acute trigger value of 10, indicating that Lontrel 600 poses low acute risk to earthworms when applied according to the proposed use rates.

Long-term risk

The potential long-term risk of Lontrel 600 to earthworms was assessed by calculating long-term TER (TER_{LT}) values by comparing the NOEC values and the maximum instantaneous PEC_S using the following equation:

$$TER_{LT} = \frac{NOEC \text{ (mg/kg)}}{PEC_S \text{ (mg/kg)}}$$

In this case:

NOEC: > 2.0 mg a.s./kg dry soil (EU agreed endpoint for clopyralid)

PECs: 0.314 mg a.s./kg (value calculated for Lontrel 600, cf. Section 5 of this Dossier)

The resulting TER_{LT} values are presented below in Table 3.1.6:

Table 3.1.6.4-2: Long-term TER values for earthworms

Test substance	NOEC (mg a.s./kg dry soil)	Maximum instantaneous PEC _S	TER _{LT}
Lontrel 600	> 2.0	0.314	> 6.37

The long-term TER value exceeds the Annex VI long-term trigger value of 5, indicating that Lontrel 600 poses low long-term risk to earthworms.

3.1.6.5 Effects on organic matter breakdown (Part B, Section 6, Point 10.6)

The DT₉₀ values for clopyralid are <365 days. Consequently, studies to determine effects on organic matter breakdown are not required.

3.1.6.6 Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)

Effects on soil microbial activity of Lontrel 600 were not evaluated as part of the EU review of clopyralid. No study has been performed since the risk to soil non-target microorganisms from the representative uses in EFSA Scientific Report (2005) 50, 1-65 is considered to be low.

EU Endpoint: Effects on Soil Microbial Activity

Active substance	Test design ¹	EU agreed endpoints (EFSA Scientific report No.50 (2005), 1-65 DAR clopyralid)
clopyralid	N	By day 28 the soil nitrate-nitrogen transformation rates at the 1x and 5x field rates of clopyralid differed by +4.6% and +18% from the control mean, respectively. These values are below the 25% criterion of the effect as stated in the guideline OECD 216.
	C	By day 28 the soil respiration rates at the 1x and 5x field rates of clopyralid differed by -2.0% and -7.8% from the control mean, respectively. These values are below the 25% criterion of effect as stated in the guideline OECD 217.

As none of the persistent effects were more than 25% for the whole studies, a low risk to microbial processes is indicated.

Considering studies presented above, no effect on the micro-organisms of the ground is expected after the treatments implementing Lontrel 600 following the GAPs.

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)

Effects on non-target plants of Lontrel 600 were not evaluated as part of the EU review of clopyralid. Therefore all relevant data and assessments are provided here and are considered adequate.

Agreed EU End-points used in the Evaluation (EFSA Scientific Report (2005) 50, 1-65)

Substance	Species	ER ₅₀ (g clopyralid/ha)
Clopyralid	Monocot	
	Onion (<i>Allium cepa</i>)	>120
	Oat (<i>Avena sativa</i>)	>120
	Yellow nutsedge (<i>Cyperus esculentus</i>)	>120
	Dicot	
	Soybean (<i>Glycine max</i>)	25.4
	Oilseed rape (<i>Brassica napus</i>)	>120
	Sugar beet (<i>Beta vulgaris</i>)	>120

Terrestrial plants

The potential effects of Lontrel 600 on seedling emergence and vegetative vigour of six non-target terrestrial plants has not been tested. Seedling emergence and vegetative vigour studies have been conducted with Lontrel 300 (EF-243 a formulation containing 300 g clopyralid/L and an additional co-formulant at 1.5% w/w) for eleven plant species (3 monocot and 8 dicot). These reports were evaluated as part of the Registration report for Lontrel 72 (GF-1966 June 2010 zRMS: UK) and the summaries are given below in Tables 10.8.1-1. We thus refer to the conclusions of Lontrel 72 (GF-1966 June 2010 zRMS: UK) registration report.

Based on these results the critical endpoints that have been used for the terrestrial non-target plant risk assessment are summarized in the following table.

Endpoint	Seedling Emergence and Growth	Vegetative Vigour
Monocot		
most sensitive species	Onion (<i>Allium cepa</i>)	ER ₅₀ exceeded maximum rate for the four species tested.
ER ₅₀ for the most sensitive monocot	266 g clopyralid/ha	>120 g clopyralid/ha
Dicot:		
most sensitive species	Soybean (<i>Glycine max</i>)	Lettuce (<i>Lactuca sativa</i>)
ER ₅₀ for the most sensitive dicot	11.8 g clopyralid/ha	9.1 g clopyralid/ha

For the national addendum, national specific drift rates are used to calculate exposure to off-field areas (both surface water and land). Based on these national specific exposure calculations, national specific risk calculations for non-target terrestrial plants are performed below according to the NL-GAP.

Table 3.1.6.7-01 Overview of exposure concentrations and TERs for non target plants – drift reducing measures

Use	Application rate [g a.s./ha]	MAF ¹	Drift reducing measure ²	Drift% ²	Exposure (g a.s./ha)	EC ₅₀ [g a.s./ha]	TER (trigger 5)
Beets, maize, oilseed rape, maize, cereals, onion, grassland, swede, turnip, seed production of ornamental crops, madder, (stinging) nettle and weld	120	-	Low drift nozzle + end nozzle	1.5	1.80	9.1	5.06
Flax	100	-	Low drift nozzle	1.7	1.70	9.1	5.4
Cabbage	50	1.7	Low drift nozzle	1.7	1.45	9.1	6.3
Beets	50	2.7	75% drift reducing nozzles	1.0	1.35	9.1	6.7

¹: Multiple Application Factor, taken from ESCORT 2 (see IIIA 10.5)

²: off-field: as given in *Evaluation Manual for the Authorisation of Plant protection products and Biocides according to Regulation (EC) No 1107/2009 NL part Plant protection products Chapter 7 Ecotoxicology: terrestrial; non targets version 2.0; January 2014*

The ratio between the lowest EC50 value and the exposure concentration is > 5. Therefore, the risk for non-target plants is considered to be low when Lontrel 600 is applied with **drift reducing measures**.

Note: The measured drift values for 90% drift-reducing nozzles are higher than those for 75% drift-reducing nozzles, which seems contradictory. It may be a result of the fact that fewer measurements were performed for 90% drift-reducing nozzles. However, it may also be a result of the fact that the reduction percentiles are defined based on their reduction of drift into surface water, which is further from the use area (field). Thus, nozzles with a high reduction percentage for water bodies bordering a field may actually have higher drift in the non-crop vicinity closer to the edge of the field. If an end nozzle is used in conjunction with the drift-reducing nozzle, this situation can be improved (as end nozzles ensure that there is less spray drift off the field area).

Since it would be difficult for the end-user and general public to understand why the use of a 75% drift-reducing nozzle is acceptable but a 90% drift-reducing nozzle is not acceptable, the instructions for use will contain only the lowest acceptable drift-reduction percentage and the words "at least", indicating that nozzles with a higher reduction percentage are also acceptable. The use of an end nozzle will be universally prescribed.

Therefore, the following drift-reducing measures are required for safe use:

To protect non-target plants, use in *Maize, Oilseed rape, Seed production of ornamental crops, Madder, (Stinging) Nettle, Weld, Flax and Cabbage* is only allowed when at least 50% drift reducing (low drift) nozzles are used. These nozzles must always be used in combination with an end nozzle.

To protect non-target plants, use in *Beets* is only allowed when at least 75% drift reducing nozzles are used. These nozzles must always be used in combination with an end nozzle.

The following restriction sentences must appear on the Dutch label:

Om niet tot de doelsoorten behorende planten te beschermen is toepassing van het middel in de teelt van **maïs, koolzaad, lijnzaad, vezelvlas, sluitkool, bloemkoolachtigen, bloemenzaadteelt, meekrap, brandnetel en wouw** uitsluitend toegestaan indien gebruik gemaakt wordt van minimaal **50%** driftreducerende doppen. Deze doppen dienen altijd te worden gecombineerd met het gebruik van een kantdop.

Om niet tot de doelsoorten behorende planten te beschermen is toepassing van het middel in de teelt van **bieten** uitsluitend toegestaan indien gebruik gemaakt wordt van minimaal **75%** driftreducerende doppen. Deze doppen dienen altijd te worden gecombineerd met het gebruik van een kantdop.

3.1.7 Efficacy (Part B, Section 7, Point 8)

All the data regarding the efficacy of the product have been submitted. These data demonstrate that Lontrel 600 fulfils all criteria for the authorization of preparations described in Directive 97/57/EC (Uniform Principles, Annex VI to Directive 91/414/EEC).

The ZRMS (UK) concluded in the core evaluation:

The evaluation is based on comparability of efficacy and crop selectivity of the new formulation LONTREL 600 with commercial reference products (clopyralid-based products).

Data to support the proposed label claims for use of Lontrel 600 (active substance clopyralid 600 g/L; SL) for the control of several broadleaved weeds in cereals (wheats and barley), in beets (sugar and fodder beet) and oilseed rape (winter and spring rape) were generated in a total of 27 trials, conducted in the United Kingdom, North of France, Germany, Czech Republic, Poland and Denmark in 2011 and 2012. All studies were carried out in fields (7 trials on wheat, 3 on barley, 10 on beet and 7 on oilseed rape) in areas typical of those where these crops are grown commercially.

The commercial reference products in the relevant countries were:

- United Kingdom: Dow Shield (clopyralid 200 g/l, SL)
- France & Germany: LONTREL 100 (clopyralid 100 g/l, SL)
- Czech Republic and Poland: LONTREL 300 (clopyralid 300 g/l, SL)
- Denmark: MATRIGON (clopyralid 100 g/l, SL)

Efficacy and crop selectivity results generated on cereals, beet crops and oilseed rape showed comparability between Lontrel 600 and existing commercial formulations. The proposed uses specified in the GAP are much more extensive however. The zRMS evaluation has been conducted on the basis of assessing the extent to which the efficacy of 'Lontrel 600' is comparable to the reference products included in the trials. However, the zRMS has not been able to validate the currently authorised uses for the reference products in each cMS.

In The Netherlands Lontrel 100 is authorised. The dossier for the Netherlands is based on bridging approach with this product, therefore label claims have to be in agreement with the label claims of Lontrel 100.

In a total of 10 trials comparability of Lontrel 100 and Lontrel 600 is demonstrated (when applied at the same active ingredient dose): two French trials in winter wheat, three German and two French trials in beets and two German and 1 French trial in oilseed rape. As comparability between the authorised and the proposed clopyralid-based products is demonstrated, extrapolation is possible from the tested uses to the non tested uses on the authorised label of Lontrel 100. Uses or dose rates which are not authorised on the label of Lontrel 100 cannot be claimed on the label of Lontrel 600; therefore the spray interval in heading cabbage and cauliflower family is 10 days.

As the application in cereals, grassland, swede, turnip and onion (claimed in the NL GAP) were not placed on the EU GAP, these applications are not evaluated by the zRMS UK for the use in The Netherlands and therefore cannot be claimed in The Netherlands.

The application in seed production of ornamentals, madder, stinging nettle and weld is applied for as a minor use. Efficacy and crop safety are not evaluated for these uses.

As the following restriction is written on the current label of Lontrel 100, this restriction is also placed on the label of the proposed product Lontrel 600:

Bij het mislukken van de teelt kunnen problemen verwacht worden bij de teelt van de vervanggewassen boon, erwt, aardappel, klaver, sla, schorseneer, witlof, cichorei, wortel, ui, spinazie (deze lijst is niet volledig).

Lontrel 600 is based on the active ingredient clopyralid. Clopyralid belongs to the pyridine carboxylic acids (HRAC group O).

The risk of resistance is considered to be low and no specific resistance management strategy is required.

3.2 Conclusions

An authorisation can be granted for the use in beet (sugar and fodder), cabbage, head or white, Broccoli, Cauliflower, Corn/ Maize, Flax, Oilseed rape, Seed production ornamentals, Madder, (Stinging) nettle and Weld (*Reseda luteola*).

No authorisation could be granted for the use in Cereals, Grassland, Swede, Turnip and Onion as extrapolation for efficacy was not possible using the bridging approach with current authorisations.

3.3 Substances of concern for national monitoring

None.

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

No further information is required.

Appendix 1 – Copy of the product authorisation

Refer to the covering letter.

Appendix 2 – Copy of the product label**Wettelijk Gebruiksvoorschrift**

Toegestaan is uitsluitend het professionele gebruik als onkruidbestrijdingsmiddel in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.0, Ctgb juni 2011) onder de vermelde toepassingsvoorwaarden

Toepassings-gebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus of per 12 maanden	Maximaal aantal liter middel per ha per teeltcyclus of per 12 maanden	Minimum interval tussen toepassingen in dagen
Bieten	na opkomst	breedbladige onkruiden	0,2 l/ha	1 x per teeltcyclus	0,25 l/ha per teeltcyclus	-
		eenjarige breedbladige onkruiden	0,08 l/ha*	3 x per teeltcyclus		7
Mais	na opkomst	breedbladige onkruiden	0,2 l/ha	1 x per teeltcyclus	0,2 l/ha per teeltcyclus	-
Koolzaad	na opkomst	breedbladige onkruiden	0,2 l/ha	1 x per teeltcyclus	0,2 l/ha per teeltcyclus	-
Lijnzaad	na opkomst	breedbladige onkruiden	0,17 l/ha	1 x per teeltcyclus	0,17 l/ha per teeltcyclus	-
Vezelvlas	na opkomst	breedbladige onkruiden	0,17 l/ha	1 x per teeltcyclus	0,17 l/ha per teeltcyclus	-
Sluitkool (onbedekte teelt)	na uitplanten of na opkomst	breedbladige onkruiden	0,17 l/ha	1 x per teeltcyclus	0,17 l/ha per teeltcyclus	-
		eenjarige breedbladige onkruiden	0,08 l/ha*	2 x per teeltcyclus		10
Bloemkoolachtigen (onbedekte teelt)	na uitplanten of na opkomst	breedbladige onkruiden	0,17 l/ha	1 x per teeltcyclus	0,17 l/ha per teeltcyclus	-
		eenjarige breedbladige onkruiden	0,08 l/ha*	2 x per teeltcyclus		10

* LDS-systeem in combinatie met toegelaten middelen

Het gebruik in de onbedekte teelt voor bloemenzaad, de onbedekte teelt van meekrap en onbedekte teelt van brandnetel is beoordeeld conform artikel 51 EG 1107/2009. Er is voor deze toepassingen geen werkzaamheids- en fytotoxiciteitonderzoek uitgevoerd. Er wordt daarom aangeraden een proefbespuiting uit te voeren, voordat het middel gebruikt wordt. Gebruik van dit middel in deze toepassingsgebieden, komt voor risico en verantwoordelijkheid van de gebruiker.

Het gebruik in de onbedekte teelt van wouw is op basis van een “derdenuitbreiding” en beoordeeld conform artikel 51 EG 1107/2009. Deze “derdenuitbreiding” is aangevraagd door Stichting Trustee Bijzondere Toelatingen. Er is voor deze uitbreiding geen werkzaamheids- en fytotoxiciteitonderzoek uitgevoerd. Er wordt daarom aangeraden een proefbespuiting uit te voeren, voordat het middel gebruikt wordt. Gebruik van dit middel in dit toepassingsgebied, komt voor risico en verantwoordelijkheid van de gebruiker.

Toepassings-gebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus	Maximaal aantal liter middel per ha per teeltcyclus	Minimum interval tussen toepassingen in dagen
Bloemenzaadteelt (onbedekte teelt)	voor opkomst of na opkomst	breedbladige onkruiden	0,125-0,2 l/ha	1	0,2 l/ha	-
		eenjarige breedbladige onkruiden	0,08 l/ha*	3	0,25 l/ha	7
Meekrap (onbedekte teelt)	na uitplanten	breedbladige onkruiden	0,2 l/ha	1	0,2 l/ha	-
		eenjarige breedbladige onkruiden	0,08 l/ha*	3	0,25 l/ha	7
Brandnetel (onbedekte teelt)	na opkomst	breedbladige onkruiden	0,125-0,2 l/ha	1	0,2 l/ha	-
Wouw	Voor opkomst	breedbladige onkruiden	0,125-0,2 l/ha	1	0,2 l/ha	-
	Na opkomst		0,08 l/ha*	3	0,25 l/ha	7

* LDS-systeem in combinatie met toegelaten middelen

Toepassingsvoorwaarden

Brandnetel mag niet voor menselijke consumptie worden gebruikt.

Restproducten uit de teelt van vezelvlas en brandnetel mogen niet worden vervoerd en/of in de handel gebracht.

Om niet tot de doelsoorten behorende planten te beschermen is toepassing van het middel in de teelt van **maïs, koolzaad, lijnzaad, vezelvlas, sluitkool, bloemkoolachtigen, bloemenzaadteelt, meekrap, brandnetel en wouw** uitsluitend toegestaan indien gebruik gemaakt wordt van minimaal **50%** driftreducerende doppen. Deze doppen dienen altijd te worden gecombineerd met het gebruik van een kantdop.

Om niet tot de doelsoorten behorende planten te beschermen is toepassing van het middel in de teelt van **bieten** uitsluitend toegestaan indien gebruik gemaakt wordt van minimaal **75%** driftreducerende doppen. Deze doppen dienen altijd te worden gecombineerd met het gebruik van een kantdop.

In verband met residuen in volggewassen mogen in de eerstvolgende 90 dagen na toepassen geen koolzaad, bieten en granen worden geteeld en in de eerstvolgende 125 dagen na toepassen geen andere gewassen voor consumptie of voederdoeleinden worden geteeld.

Bij het mislukken van de teelt kunnen problemen verwacht worden bij de teelt van de vervanggewassen boon, erwt, aardappel, klaver, sla, schorseneer, witlof, cichorei, wortel, ui, spinazie (deze lijst is niet volledig).

Appendix 3 – List of data submitted in support of the evaluation

Identity, physico-chemical properties and analytical methods

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Relied on Y/N	Owner
KIIIA1 2.1/01	2012	Determination of physical and chemical properties of one batch of CLOPYRALID 600 SL, Agriphar S.A., Anadiag study B1279, GLP, unpublished	Y	Y	Y	CAG/DAS
KIIIA 2.4.1/01	2015	Clopyralid 600SL, Agriphar S.A., Not to GLP, unpublished	Y	Y	Y	CAG/DAS
KIIIA 2.7.5/02	2014	Determination of Physical and Chemical properties of one batch of CLOPYRALID 600 SL Agrpihar S.A, ANADIAG Study No. B1280 GLP Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 5.2.1/01	2011	Method validation and determination of Clopyralid content in one batch of CLOPYRALID 600 SL formulation, Agriphar S.A., Anadiag Project # B1278, GLP, unpublished.	Y	Y	Y	CAG/DAS

Human toxicology

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Relied on Y/N	Owner
KIIIA1 7.1.1/01	(2011a)	Clopyralid 600 SL. Evaluation of acute oral toxicity in rats – acute toxic class method. Study number: TAO423-PH-11/0470 Date: 15/11/2011 GLP status: yes	Y	Y	Y	CAG/DAS
KIIIA1 7.1.2/01	(2008)	Acute Dermal Irritation Study of GF-2000 in Rabbits Study number: 7856 Date: 10/10/2008 GLP status: yes	Y	Y	Y	DAS* Evaluated under COP 2009/00695

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Relied on Y/N	Owner
KIIIA1 7.1.4/01	(2011b)	Clopyralid 600 SL. Assessment of acute dermal irritation. Study number: IC-OCDE-PH-11/0470 Date: 03/11/2011 GLP: yes	Y	Y	Y	CAG/DAS
KIIIA1 7.1.5/01	(2011c)	Clopyralid 600 SL. Assessment of acute eye irritation. Study number: IC-OCDE-PH-11/0470 Date: 03/11/2011 GLP: yes	Y	Y	Y	CAG/DAS
KIIIA1 7.1.6/01	(2011d)	Clopyralid 600 SL. Assessment of the skin sensitisation potential in the mouse using the local lymph node assay (LLNA). Study number: LLNA-PH-11/0470 Date: 02/11/2011 GLP: yes	Y	Y	Y	CAG/DAS
KIIIA1 7.6.2/01	(2012)	In vitro percutaneous absorption of Clopyralid, formulated as Clopyralid 600 SL, through human skin membranes. TNO, Utrechtseweg 47, 3704 HE Zeist, Postbus 360, 3700 AJ Zeist, The Netherlands Study number: V9054 Date: 16/02/2012 GLP: yes	Y	Y	Y	CAG/DAS

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Study Relied on Y/N	Data protection granted Y/N
IIIA 8.3	2012	Residues of Clopyralid in bulb onions following two applications of EF-1136 - Northern Europe - 2011 DOW AGROSCIENCES LIMITED Report No : GHE-P-12680 GLP Status : yes Not published	Y	Dow AgroSciences B.V.	Y	Y

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Study Relied on Y/N	Data protection granted Y/N
IIIA 8.3	2009	Residues of Clopyralid in Broccoli at harvest and at intervals following a single or multiple application(s) of EF-1136 Northern/Southern zone – 2008 DOW AGROSCIENCES LIMITED Report No : GHE-P-12057 GLP Status : yes Unpublished	Y	Dow AgroSciences B.V.	Y	Y
IIIA 8.3	2010	Residues of Clopyralid in Broccoli at harvest and at intervals following a single or multiple application(s) of EF-1136 Northern/Southern zone – 2009 DOW AGROSCIENCES LIMITED Report No : GHE-P-12431 GLP Status : yes Unpublished	Y	Dow AgroSciences B.V.	Y	Y
IIA 6.3, IIIA 8.2/08	2005	Residues of Clopyralid In Cabbage At Harvest And At Intervals Following A Single Application Of Lontrel 100 (EF-1136), Southern Europe-2003. CEM Analytical Services Ltd, Glendale Park North Ascot, UK DAS Report No: GHE-P-10808 (Masterfile Number: N212) GLP/GEP (Y/N):Y Published (Y/N): N	Y	Dow AgroSciences B.V.	Y	Previous authorisation LONTREL 100, 11526N
IIA 6.3, IIIA 8.2/09		Residues of Clopyralid in Cabbage at Intervals Following two Applications of Lontrel 100 (EF-1136, Northern Europe-2004. CEM Analytical Services Ltd, Glendale Park North Ascot, UK DAS Report No: GHE-P-11077 (Masterfile Number: N217) GLP/GEP (Y/N):Y Published (Y/N): N	Y	Dow AgroSciences B.V.	Y	Previous authorisation LONTREL 100, 11526N
IIA 6.3, IIIA 8.2/10	2006	Residues of Clopyralid in Cabbage at Intervals Following two Applications of Lontrel 100 (EF-1136), Northern Europe-2005. CEM Analytical Services Ltd, Glendale Park North Ascot, UK DAS Report No: GHE-P-11268 (Masterfile Number: N203) GLP/GEP (Y/N):Y Published (Y/N): N	Y	Dow AgroSciences B.V.	Y	Previous authorisation LONTREL 100, 11526N

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Study Relied on Y/N	Data protection granted Y/N
III 8.2/11	2005	Residues of Clopyralid In Cabbage At Harvest and At Intervals Following Two Applications Of Lontrel 100 (EF-1136), UK-2003. CEM Analytical Services Ltd, Glendale Park North Ascot, UK DAS Report No: GHE-P-10809 (Masterfile Number: N213) GLP/GEP (Y/N):Y Published (Y/N): N	Y	Dow AgroSciences B.V.	Y	Previous authorisation LONTREL 100, 11526N
IIA 6.3, IIIA 8.2/12	2005	Residues of Clopyralid In Cauliflower At Harvest and At Intervals Following Two Applications of Lontrel 100 (EF-1136), UK-2003. CEM Analytical Services Ltd, Glendale Park, North Ascot, UK DAS Report No: GHE-P-10810 (Masterfile Number: N214) GLP/GEP (Y/N):Y Published (Y/N): N	Y	Dow AgroSciences B.V.	Y	Previous authorisation LONTREL 100, 11526N
IIA 6.3, IIIA 8.2/13	2005	Residues of Clopyralid in Cauliflower at Intervals Following two Applications of Lontrel 100 (EF-1136, Northern Europe-2004. CEM Analytical Services Ltd, Glendale Park, North Ascot, UK DAS Report No: GHE-P-11078 (Masterfile Number: N218) GLP/GEP (Y/N):Y Published (Y/N): N	Y	Dow AgroSciences B.V.	Y	Previous authorisation LONTREL 100, 11526N
IIA 6.3, IIIA 8.2/15	2005	Residues of clopyralid in cauliflower at intervals following two applications of Lontrel 100 (EF-1136), Northern Europe-2005. CEM Analytical Services, North Ascot, Berks, UK DAS Report No: GHE-P-11269 GLP/GEP (Y/N):Y Published (Y/N): N	Y	Dow AgroSciences B.V.	Y	Previous authorisation LONTREL 100, 11526N
IIA 6.3, IIIA 8.2/17	2002	Residues of Clopyralid in Maize at Harvest Under Open Field Conditions Following Multiple Application of Lontrel 100 (EF-1136), Germany – 2000. CEM Analytical Services Ltd, Glendale Park North Ascot, UK DAS Report No: GHE-P-9364 (Masterfile Number: N202) GLP/GEP (Y/N):Y Published (Y/N): N	Y	Dow AgroSciences B.V.	Y	Previous authorisation LONTREL 100, 11526N

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Owner	Study Relied on Y/N	Data protection granted Y/N
IIA 6.3, IIIA 8.2/18	2005	Residues of Clopyralid in maize at intervals under open field conditions following a single application of Lontrel (EF-1136), France and Germany 2000. CEM Analytical Services, North Ascot, Berks, UK DAS Report No: GHE-P-9365 (Masterfile Number: N225) GLP/GEP (Y/N):Y Published (Y/N): N	Y	Dow AgroSciences B.V.	Y	Previous authorisation LONTREL 100, 11526N
IIA 6.3, IIIA 8.2/19	2005	Residues of Clopyralid and Picloram in Maize at intervals and at Harvest following a single application of GF-224, Germany, Poland and Hungary – 2004. CEM Analytical Services Ltd, Glendale Park, North Ascot, UK DAS Report No: GHE-P-11075 (Masterfile Number: N215) GLP/GEP (Y/N):Y Published (Y/N): N	Y	Dow AgroSciences B.V.	Y	Previous authorisation LONTREL 100, 11526N
IIA 6.3, IIIA 8.2/20	2006	Residues of Clopyralid and Picloram in maize at intervals and at harvest following a single application of GF-224, Germany, Poland and Hungary – 2006. CEM Analytical Services, North Ascot, Berks, UK DAS Report No: GHE-P-11266 (Masterfile Number: N230) GLP/GEP (Y/N):Y Published (Y/N): N	Y	Dow AgroSciences B.V.	Y	Previous authorisation LONTREL 100, 11526N
IIA 6.3, IIIA 8.2/22		Residues of Clopyralid in Maize at intervals and at harvest following one or two applications of Lontrel 100 (EF-1136), Northern and Southern Europe, 2002. CEM Analytical Services Ltd, Glendale Park North Ascot, UK DAS Report No: GHE-P-10534 (Masterfile Number: N205) GLP/GEP (Y/N):Y Published (Y/N): N	Y	Dow AgroSciences B.V.	Y	Previous authorisation LONTREL 100, 11526N

Fate and behaviour

No reference to studies used in NL Addendum and Core dossier.

Ecotoxicology

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data used (Y/N)	Data protection granted Y/N	Owner
KIIIA 1 10.2.2.3/01	2012	Freshwater algae, Growth inhibition test with Clopyralid 600 g/L (OECD 201, March 2006), Agriphar S.A., PHYTOSAFE s.a.r.l. – France, Report # 11-99-071-ES, GLP, unpublished	Y	Y	Y	CAG/DAS

Efficacy

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Study Relied on Y/N	Data protection granted Y/N	Owner
KIIIA1 6.1.3/01	2011	"Efficacy of different application rates of CLOPYRALID on winter wheat. England 2011" Trial report ADT-11-9758-GB01 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/02	2011	"Efficacy of different application rates of CLOPYRALID on winter wheat. Czech Republic 2011" Trial report ADT-11-9758-CZ04 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/03	2011	"Efficacy of different application rates of CLOPYRALID on winter wheat. France 2011" Trial report ADT-11-9758-FR07 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Study Relied on Y/N	Data protection granted Y/N	Owner
KIIIA1 6.1.3/04	2011	"Efficacy of different application rates of CLOPYRALID on winter wheat. France 2011" Trial report ADT-11-9758-FR08 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/05	2011	"Efficacy of different application rates of CLOPYRALID on winter wheat. England 2011" Trial report ADT-11-9758-GB09 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/06	2011	"Efficacy of different application rates of CLOPYRALID on spring barley. Czech Republic 2011" Trial report ADT-11-9759-CZ04 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/07	2011	"Efficacy evaluation of CLOPYRALID applied on sugar beet post-emergence. United Kingdom 2011" Trial report ADT-11-9762-GB01 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/08	2011	"Efficacy evaluation of CLOPYRALID applied on sugar beet post-emergence. Germany 2011" Trial report ADT-11-9762-DE02 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/09	2011	"Efficacy evaluation of CLOPYRALID applied on sugar beet post-emergence. Germany 2011" Trial report ADT-11-9762-DE03 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Study Relied on Y/N	Data protection granted Y/N	Owner
KIIIA1 6.1.3/10	2011	"Efficacy evaluation of CLOPYRALID applied on sugar beet post-emergence. Czech Republic 2011" Trial report ADT-11-9762-CZ04 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/11	2011	"Efficacy evaluation of CLOPYRALID applied on sugar beet post-emergence. Poland 2011" Trial report ADT-11-9762-PL05 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/12	2011	"Efficacy evaluation of CLOPYRALID applied on sugar beet post-emergence. France 2011" Trial report ADT-11-9762-FR06 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/13	2011	"Efficacy evaluation of CLOPYRALID applied on sugar beet post-emergence. France 2011" Trial report ADT-11-9762-FR07 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/14	2011	"Efficacy evaluation of CLOPYRALID applied on sugar beet post-emergence. Germany 2011" Trial report ADT-11-9762-DE08 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/15	2012	Efficacy evaluation of clopyralid 600 SL applied on winter oilseed rape crop. Germany 2011/12" Trial report FPT-12-9761-DE01 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Study Relied on Y/N	Data protection granted Y/N	Owner
KIIIA1 6.1.3/16	2012	Efficacy evaluation of clopyralid 600 SL applied on winter oilseed rape crop. Germany 2011/12" Trial report FPT-12-9761-DE02 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/17	2012	Efficacy evaluation of clopyralid 600 SL applied on winter oilseed rape crop. France 2011/12" Trial report FPT-12-9761-FR03 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/18	2012	Efficacy evaluation of clopyralid 600 SL applied on winter oilseed rape crop. Poland 2011/12" Trial report FPT-12-9761-PL04 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/19	2012	Efficacy evaluation of clopyralid 600 SL applied on spring oilseed rape crop. Poland 2011/12" Trial report FPT-12-9761-PL05 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/20	2011	"Determination of selectivity of different application rates of CLOPYRALID on winter barley. United Kingdom 2011" Trial report ADT-11-9760-GB01 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/21	2011	"Determination of selectivity of different application rates of CLOPYRALID on winter wheat. France 2011" Trial report ADT-11-9760-FR02 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Study Relied on Y/N	Data protection granted Y/N	Owner
KIIIA1 6.1.3/22	2011	"Determination of selectivity of different application rates of CLOPYRALID on spring barley. United Kingdom 2011" Trial report ADT-11-9760-GB03 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/23	2011	"Selectivity of CLOPYRALID in BEAVA. Germany 2011" Trial report ADT-11-9764-DE01 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/24	2011	"Selectivity of CLOPYRALID in BEAVA. Poland 2011" Trial report ADT-11-9764-PL02 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/25	2012	"Selectivity evaluation of CLOPYRALID 600 SL applied on winter oilseed rape crop. Denmark 2011/2012" Trial report FPT-12-9763-DK01 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/26	2012	"Selectivity evaluation of CLOPYRALID 600 SL applied on winter oilseed rape crop. Poland 2011/2012" Trial report FPT-12-9763-PL02 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS
KIIIA1 6.1.3/27	2011	"Efficacy of different application rates of CLOPYRALID on spring barley. England 2011" Trial report ADT-11-9759-GB01 (GEP) Staphyt Unpublished	Y	Y	Y	CAG/DAS

CAG= Agriphar S.A

DAS = Dow AgroSciences