

# **REGISTRATION REPORT**

## **Part B**

### **Section 1: Identity**

### **Section 2: Physical and chemical properties**

### **Section 4: Further information**

Detailed summary of the risk assessment

Product code: EF-243

Product name(s): Lontrel 300

Chemical active substance:

Clopyralid-olamine, 395 g/l (300 g ae/l)

Central Zone

Zonal Rapporteur Member State: Poland

## **CORE ASSESSMENT**

(Renewal of Authorization under Art.43)

Applicant: Corteva Agriscience

Submission date: 22/12/2021

MS Finalisation date: 05/12/2022

After commenting: 22/02/2023

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## Version history

When	What
December 2021	Article 43 submission for reregistration of EF-243 following Clopyralid Renewal of approval (Commission Implementing Regulation (EU) 2021/1191)
December 2022	First zRMS evaluation
February 2023	After commenting

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State whether or not submitted data are sufficient for evaluation. Data gaps and conditions for registration should be listed, if appropriate.

Sufficient data on identity, physical and chemical properties and other information are **not** available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- **None**

## 1 Section 1: Identity of the plant protection product

### 1.1 Applicant (KCP 1.1)

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Contact	<b>Elzbieta Bodecka</b> <b>(Country Regulatory Manager)</b>

### 1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

#### 1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

#### 1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

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### 1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

#### 1.2.3.1 Clopyralid

End-Point	Clopyralid
Reference	Commission Implementing Regulation (EU) 2021/1191 of 19 July 2021
Purity of active substance	950 g/kg minimum

There are no relevant impurities in EF-243

### 1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Please refer to Registration Report Part A for the relevant country (or)

Trade name: Lontrel 300

Company code number: EF-243

### 1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

#### 1.4.1 Composition of the plant protection product (KCP 1.4.1)

**Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)**

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits <sup>1</sup> (min – max)	Technical content <sup>2</sup> (g/L or g/kg)	Technical content <sup>3</sup> (%w/w)
Clopyralid (Clopyralid-olamine <sup>4</sup> )	300 g/L (395 g/L)	285 – 315 g/L (375 – 415 g/L)	315.8 g/L (416 g/L)	27.7 (36.5)

1. FAO limits for above 250 up to 500 g/L  $\pm$  5%

2. Based on the minimum purity of the active substance (950 g/kg)

3. Based on the nominal density of the formulation = 1.1408 g/mL

4. a.e. factor for clopyralid-olamine = 0.759

#### Table 1.4-2: Safeners and synergists

There are no safeners or synergists in EF-243.

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**Table 1.4-3: Relevant impurities**

There are no relevant impurities in EF-243.

**1.4.2 Information on the active substance(s) (KCP 1.4.2)**

**Table 1.4-4: Information on clopyralid**

Type	Name/Code Number	
ISO common name	Clopyralid	Variant: Clopyralid-olamine
CAS No.	1702-17-6	57754-85-5
EC No.	216-935-4	260-929-4
CIPAC No.	455	455.110

**1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)**

CONFIDENTIAL information is provided separately (Part C).

**1.5 Type and code of the plant protection product (KCP 1.5)**

Type: Soluble concentrate

Code: SL

**1.6 Function (KCP 1.6)**

Herbicide

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## 2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of hazy, pale yellow liquid. It is not explosive, has no oxidising properties. The product has a flash point of  $>100^{\circ}\text{C}$ . It has a self ignition temperature of greater than  $400^{\circ}\text{C}$ . In aqueous solution, it has a pH value around 7.38 at  $21.6^{\circ}\text{C}$ . There is no effect of low and high temperature on the stability of the formulation, since after 7 days at  $0^{\circ}\text{C}$  and 8 weeks at  $40^{\circ}\text{C}$ , neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in PET. Its technical characteristics are acceptable for a SL formulation.

The intended concentration of use is 0.01% v/v to 0.5% v/v.

No application is being made for the authorisation of the combined use of the preparation with any other product. However the product is expected to be compatible (physically/chemically) in mixtures with other commercial products in agitated spray tanks.

### Evaluator comments

The product was stable for 2 years storage at  $20\pm 2^{\circ}\text{C}$ .

The analytical method which was used to determined active ingredient content was validated in GLP laboratory.

No significant change in content of the active substances was observed following 2 years storage at  $20\pm 2^{\circ}\text{C}$ .

The commercial packaging material (PET) showed no visual or physical signs of any corrosion or deterioration after 2 years of storage at  $20\pm 2^{\circ}\text{C}$ . Monitoring of weight of packaging indicated a stable packaging.

No significant changes were observed in any of the parameters tested following 2 years storage at  $20\pm 2^{\circ}\text{C}$ :

- appearance,
- persistence of foaming,
- pH,
- dilution stability.

There is no effect of low and high temperature on the stability of the formulation, since after 7 days at  $0^{\circ}\text{C}$  and 8 weeks at  $40^{\circ}\text{C}$ , neither the active ingredient content nor the technical properties were changed.

Based on the chemical and physical results obtained from the study it can be concluded that test item (product) is chemically and physically compatible in PET for eight weeks storage at  $40^{\circ}\text{C}$  and two years storage at ambient temperature.

### Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Not relevant. No physical chemical hazards identified.

### Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not relevant. No physical chemical hazards identified.

### Compliance with FAO specifications:

The product EF-243 complies with FAO specifications.

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### **Formulation used for tests**

The product used in the testing has the same composition as the one cited in Part C.



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**Table 2-1: Physical, chemical and technical properties of the plant protection product**

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual	EF-243, TSN400033, 395 g/L clopyralid-olamine	Hazy pale yellow liquid	Y	191215, King, T., 2019	<b>Acceptable</b>  The physical state and colour of the test item were evaluated visually. The physical state was observed at ambient temperature (19.7°C).
Explosive properties (KCP 2.2.1)	EEC A14	EF-243, SB08150106, 303 g/L clopyralid	Not explosive	Y	NAFST-04-872, Turner, B., 2005	<b>Acceptable</b>  The sensitivity to heat (flame) and sensitivity to shock were tested according to EEC A14 test method. The product is not explosive.
Oxidizing properties (KCP 2.2.2)	EEC A21	EF-243, TSN400033, 394 g/L clopyralid-olamine	Non-oxidizing	Y	191214, Cowlyn, N., 2019	<b>Acceptable</b>  The mean pressure rise time for the reference mixture (1:1 w/w mixture of 65% w/w aqueous nitric acid and cellulose) was 2.7 seconds, while the mean pressure rise time

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						for the test item mixture (1:1 w/w mixture of test item and cellulose) was 18.1 seconds. As the time taken for the pressure rise is longer for the test item than for the reference mixture, test item is considered non-oxidising.
Flash point (KCP 2.3.1)	EEC A9	EF-243, TSN400033, 395 g/L clopyralid-olamine	>100°C	Y	191215, Croffie, J., 2019	<b>Acceptable</b>  The flash point was not observed and is reported as > 100°C. The test item is not flammable.
Flammability (KCP 2.3.2)			Not applicable to SL formulations.			<b>Acceptable</b>  Not relevant to an SL formulation.
Self-heating (KCP 2.3.3)		EF-243, TSN400033, 394 g/L clopyralid-olamine	None below 400°C	Y	191214, Cowlyn, N., 2019	<b>Acceptable</b>  The auto-ignition temperature of the test item was assessed by the procedure described in EC Method A.15. Test item was found

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						not to have an auto-ignition temperature below 400°C.
Acidity or alkalinity and pH (KCP 2.4.1)			Not applicable; the pH of a 1% dilution was not < 4 or > 10.			<b>Acceptable</b>  Acidity or alkalinity was not determined because the pH value of 1% suspension was between 4 and 10.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3  CIPAC MT 75.3	EF-243, TSN400033, 395 g/L clopyralid-olamine  EF-243, SB08150106, 35.4% w/w clopyralid-olamine	7.38 at 21.6°C  Before storage: 6.94 After 8 weeks of storage at 40°C in PET: 6.98 After 2 years of ambient storage in PET: 6.54	Y  Y	191215, Croffie, J., 2019  FOR-05-003, Stock, M., 2007	<b>Acceptable</b>
Viscosity (KCP 2.5.1)	OECD 114	EF-243, TSN400033, 395 g/L clopyralid-olamine	Newtonian fluid: At 20°C, mean viscosity = 5.42 mPa·s At 40°C, mean viscosity = 6.75 mPa·s  Editorial error: according to the study report viscosity at 40°C, mean viscosity = 3.5 mPa·s	Y	191215, Croffie, J., 2019	<b>Acceptable</b> The viscosity is required for all Newtonian liquids and the results should be reported with full details of the test methodology. The viscosity must be determined at 20 °C

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						and 40 °C. The procedure used in the test was based on the rotational viscometer method. Two readings were taken at each rotational speed. The formulation was Newtonian at both temperatures: 20°C and 40°C.
Surface tension (KCP 2.5.2)	EEC A5	EF-243, SB08150106, 303 g/L clopyralid  EF-243, TSN400033, 394 g/L clopyralid-olamine	0.01% v/v dilution at 20°C: 54.0 mN/m 1% v/v dilution at 20°C: 31.5 mN/m  Neat at 25°C: 30.5 mN/m Neat at 40°C: 29.5 mN/m	Y  Y	NAFST-04-872, Turner, B., 2005  191214, Cowlyn, N., 2019	<b>Acceptable</b>  The surface tension of the neat test item at 25 and 40°C was determined. The method used to determined surface tension was compatible with the EC Method A.5 and OECD Method 115.
Relative density (KCP 2.6.1)	OECD 109	EF-243, TSN400033, 395 g/L clopyralid-olamine	Density = 1.1408 g/mL at 20°C	Y	191215, Croffie, J., 2019	<b>Acceptable</b>
Bulk density (KCP 2.6.2)			Not applicable to SL formulations.			<b>Acceptable</b>  Not relevant to an SL

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						formulation.
Storage Stability after 14 days at 54° C (KCP 2.7.1)			See KCP 2.7.2. The accelerated storage stability study was performed for 8 weeks at 40°C.			The accelerated storage stability study was performed for 8 weeks at 40°C.
Stability after storage for other periods and/or temperatures (KCP 2.7.2)		EF-243, SB08150106, 35.4% w/w clopyralid-olamine	Before storage: 35.4% w/w clopyralid-olamine After 8 weeks at 40°C in PET: 35.6% clopyralid-olamine (101% active ingredient retention)  See individual Annex points for the results of the physical properties testing.	Y	FOR-05-003, Stock, M., 2007	<b>Acceptable</b>  The product was stable after 8 weeks of storage at 40°C in PET.  The analytical method which was used to determined active ingredient (clopyralid-olamine) content was validated in GLP laboratory (analytical method EU-AM-95-01). The content of active ingredient was determined by GC method. The initial concentration of clopyralid-olamine was 35.4 %, the concentration of clopyralid-olamine after 8 weeks of storage at 40°C was 35.6%.

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						It is recognized that a loss of up to 5 % of the active substance is unlikely to adversely affect the safety or efficacy of the preparation.
Minimum content after heat stability testing (KCP 2.7.3)			See KCP 2.7.2			The product was stable after 8 weeks of storage at 40°C in PET.
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	EF-243, VA27150115, 35.0% w/w clopyralid-olamine	The formulation was homogeneous after one week of storage at 0°C.	N	NAFST-10-67, Koors, B., 2010	<b>Acceptable</b>  Test item was stored in glass at 0°C for seven days to assess the stability of the formulation. The stored product showed no significant changes after storage. After one week storage at 0°C, the formulation appeared homogenous. Based on the physical results obtained from the study, it can be concluded that test item is physically stable at 0°C in glass.
Ambient temperature shelf life		EF-243, SB08150106,	Before storage: 35.4% w/w clopyralid-olamine After 2 years of ambient storage in PET: 35.1%	Y	FOR-05-003, Stock, M., 2007	<b>Acceptable</b>

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.7.5)		35.4% w/w clopyralid-olamine	<p>clopyralid-olamine (99% active ingredient retention)</p> <p>See individual Annex points for the results of the physical properties testing.</p>			<p>The product was stable after 2 years of storage at ambient temperature in PET.</p> <p>The analytical method which was used to determined active ingredient (clopyralid-olamine) content was validated in GLP laboratory (analytical method EU-AM-95-01). The content of active ingredient was determined by GC method.</p> <p>The initial concentration of clopyralid-olamine was 35.4 %, the concentration of clopyralid-olamine after 2 years of storage at ambient temperature was 35.1%.</p> <p>It is recognized that a loss of up to 5 % of the active substance is unlikely to adversely affect the safety or efficacy of the</p>

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																				
						preparation.																				
Shelf life in months (if less than 2 years) (KCP 2.7.6)			Not applicable; EF-243 was stable for at least 24 months at ambient temperature in PET			Not applicable test item was stable for at least 24 months at ambient temperature in PET.																				
Wettability (KCP 2.8.1)			Not applicable to SL formulations.			<b>Acceptable</b>  Not relevant to an SL formulation.																				
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2	EF-243, SB08150106, 35.4% w/w clopyralid-olamine	At 0.5% v/v in standard water D: <table><tr><td>Time</td><td>Before storage</td><td>After 8 weeks at 40°C in PET</td><td>After 2 yrs ambient in PET</td></tr><tr><td>10 sec</td><td>6 mL</td><td>5 mL</td><td>12 mL</td></tr><tr><td>1 min</td><td>4 mL</td><td>2 mL</td><td>6 mL</td></tr><tr><td>3 min</td><td>0 mL</td><td>2 mL</td><td>4 mL</td></tr><tr><td>12 min</td><td>0 mL</td><td>0 mL</td><td>4 mL</td></tr></table>	Time	Before storage	After 8 weeks at 40°C in PET	After 2 yrs ambient in PET	10 sec	6 mL	5 mL	12 mL	1 min	4 mL	2 mL	6 mL	3 min	0 mL	2 mL	4 mL	12 min	0 mL	0 mL	4 mL	Y	FOR-05-003, Stock, M., 2007	<b>Acceptable</b>  Persistent foam is determined to measure the amount of foam likely to be present in a spray tank or other application equipment following dilution of the preparation.  Acceptable limits: -Max 60 mL foam after 1 minute.  All foshm measurements were within acceptable limits (≤ 60 mL foam).
Time	Before storage	After 8 weeks at 40°C in PET	After 2 yrs ambient in PET																							
10 sec	6 mL	5 mL	12 mL																							
1 min	4 mL	2 mL	6 mL																							
3 min	0 mL	2 mL	4 mL																							
12 min	0 mL	0 mL	4 mL																							
Suspensibility (KCP 2.8.3.1)			Not applicable to SL formulations.			<b>Acceptable</b>  Not relevant to an SL																				



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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						formulation.
Spontaneity of dispersion (KCP 2.8.3.2)			Not applicable to SL formulations.			<b>Acceptable</b>  Not relevant to an SL formulation.
Dispersion stability (KCP 2.8.3.3)			Not applicable to SL formulations.			<b>Acceptable</b>  Not relevant to an SL formulation.
Degree of dissolution and dilution stability (KCP 2.8.4)	CIPAC MT 41	EF-243, SB08150106, 35.4% w/w clopyralid-olamine	At 0.5% v/v in standard water D: No significant change in dilution stability was observed after storage for 8 weeks at 40°C in PET or 2 years of ambient storage in PET. At each time point, the dilution was homogeneous after 18 hours of storage at room temperature.	Y	FOR-05-003, Stock, M., 2007	<b>Acceptable</b>
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)			Not applicable to SL formulations.			<b>Acceptable</b>  Not relevant to an SL formulation.
Wet sieve test (KCP 2.8.5.1.2)			Not applicable to SL formulations.			<b>Acceptable</b>  Not relevant to an SL formulation.
Dust content (KCP 2.8.5.2.1)			Not applicable to SL formulations.			<b>Acceptable</b>  Not relevant to an SL formulation.
Particle size of dust (KCP 2.8.5.2.2)			Not applicable to SL formulations.			<b>Acceptable</b>

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						Not relevant to an SL formulation.
Attrition (KCP 2.8.5.3)			Not applicable to SL formulations.			<b>Acceptable</b>  Not relevant to an SL formulation.
Hardness and integrity (KCP 2.8.5.4)			Not applicable to SL formulations.			<b>Acceptable</b>  Not relevant to an SL formulation.
Emulsifiability (KCP 2.8.6.1)			Not applicable to SL formulations.			<b>Acceptable</b>  Not relevant to an SL formulation.
Emulsion stability (KCP 2.8.6.2)			Not applicable to SL formulations.			<b>Acceptable</b>  Not relevant to an SL formulation.
Re-emulsifiability (KCP 2.8.6.3)			Not applicable to SL formulations.			<b>Acceptable</b>  Not relevant to an SL formulation.
Flowability (KCP 2.8.7.1)			Not applicable to SL formulations.			<b>Acceptable</b>  Not relevant to an SL formulation.
Pourability (KCP 2.8.7.2)			Not applicable to SL formulations.			<b>Acceptable</b>  Not relevant to an SL

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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						formulation.
Dustability following accelerated storage (KCP 2.8.7.3)			Not applicable to SL formulations.			<b>Acceptable</b> Not relevant to an SL formulation.
Physical compatibility of tank mixes (KCP 2.9.1)			Product is expected to be physically compatible with other commercial products in agitated spray tanks.			There is no information about tank mixes on the label of the product.
Chemical compatibility of tank mixes (KCP 2.9.2)			Product is expected to be chemically compatible with other commercial products in agitated spray tanks.			There is no information about tank mixes on the label of the product.
Adhesion to seeds (KCP 2.10.1)			Not applicable; not a seed treatment			<b>Acceptable</b>
Distribution to seed (KCP 2.10.2)			Not applicable; not a seed treatment			<b>Acceptable</b>
Other/special studies (KCP 2.11)			Not applicable			<b>Acceptable</b>

### 3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

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## 4 Section 4: Further information on the plant protection product

### 4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

**Table 4.1-1: Packaging information for PET bottles**

Type	Description
Material:	PET
Shape/size:	<p>Bottles/Jerrican 0.05, 0.10, 0.15, 0.25, 0.5, 1, 2, 3, 5, 10 L, 15 L and 20 L</p> <p>0.05 litre bottles, may or may not be packed, 30 x 0.05 litre to an outer corrugated fibreboard case.</p> <p>0.10 litre bottles, may or may not be packed 30 x 0.10 litre to an outer corrugated fibreboard case.</p> <p>0.15 litre bottles, may or may not be packed 20 x 0.15 litre to an outer corrugated fibreboard case.</p> <p>0.25 litre bottles, may or may not be packed 12 x 0.25 litre or 24 x 0.25 litre to an outer corrugated fibreboard case.</p> <p>0.5 litre bottles, may or may not be packed 10 x 0.5 litre or 20 x 0.5 litre to an outer corrugated fibreboard case.</p> <p>1 litre bottles, may or may not be packed 10 x 1 litre to an outer corrugated fibreboard case.</p> <p>2 litre bottles, may or may not be packed 8 x 2 litre to an outer corrugated fibreboard case.</p> <p>3 litre bottles, may or may not be packed 6 x 3 litre to an outer corrugated fibreboard case.</p> <p>5 litre bottles, may or may not be packed 2 x 5 litre, 3 x 5 litre or 4 x 5 litre to an outer corrugated fibreboard case</p> <p>10 litre jerrican, may or may not be packed 2 x 10litre to an outer corrugated fibreboard case</p> <p>15 litre jerrican, may or may not be packed 2 x 15litre to an outer corrugated fibreboard case</p> <p>20 litre jerrican may or may not be packed to an outer corrugated fibreboard case.</p>
Wall thickness:	Minimum 0.2 mm
Opening:	<p>28 mm</p> <p>45 mm</p> <p>63 mm</p>
Closure:	<p>Screw cap</p> <p>28 mm – from 0.05 L up to 0.15 L bottles</p> <p>45 mm – from 0.25 L up to 2 L bottles</p> <p>63 mm – for 2L, 3 L, 5 L, 10 L, 15 L and 20 L bottles/jerricans</p>
Seal:	Induction, bore, compression or vented
Manner of construction	Stretch blow moulded
UN/ADR	compliant

### 4.2 Procedures for Cleaning Application Equipment

**Tank Clean (study 191711)**

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Immediately after use, clean the spray equipment thoroughly. Drain the system completely and rinse spray tank, bottom and nozzles two to three times with clean water until the foam and all traces of product have been removed.

Clopyralid is very soluble and exhibits no propensity to adhere to materials used in the construction of spray machinery. In over 40 years of commercial use, no difficulty in cleaning application equipment has been reported. Once diluted in the spray tank, the spray solution created by using GF-1966 is identical to that created by other “straight” clopyralid formulations.

Consider the following calculation:

Worse case EU single application is 200gae/ha in 200l/ha of water.

For example, using a 1000L capacity sprayer. If the sprayer would contain enough spray solution to treat 5 ha and would therefore have been loaded with 1000gae of clopyralid.

After spraying is complete worse case 10% (more likely 1% for a well-designed sprayer) of the spray solution would stay in the tank containing 100gae of clopyralid.

Fill the tank with water and agitate. Spray out, leaving 10% of the spray solution containing 10gae of clopyralid.

Fill the tank with water and agitate (ie fill for the second time). Spray out, leaving 10% of the spray solution containing 1gae of clopyralid.

The next time the sprayer is used it would be filled with 1000L of water and the 1gae of clopyralid would be sprayed across 5ha ie the 0.2gae/ha might be applied as worse case.

The most sensitive species in seedling emergence tests was soybean (*Glycine max*) with an ER<sub>50</sub> value of 11.8 g clopyralid/ha. The most sensitive species in the vegetative vigor test was lettuce (*Lactuca sativa*) with an ER<sub>50</sub> value of 9.1 g clopyralid/ha.

This calculation demonstrates that even using the most pessimistic assumptions, the amount of clopyralid that would remain in the application equipment after cleaning would be much too low to cause damage to even the most sensitive species.

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## Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1 KCP 2.3.1 KCP 2.4.2 KCP 2.5.1 KCP 2.6.1	Croffie, J.	2019	Determination of Color, Odor, Physical State, pH, Density, Flashpoint and Viscosity for EF-243 191215 Dow Agrosiences GLP Unpublished	N	Corteva Agriscience
KCP 2.2.2 KCP 2.3.3 KCP 2.5.2	Cowlyn, N.	2019	Determination of Oxidising Properties, Auto-Ignition Temperature and Surface Tension of EF-243 191214 Covance CRS Limited GLP Unpublished	N	Corteva Agriscience
KCP 2.2.1 KCP 2.5.2	Turner, B.	2005	Determination of Surface Tension and Explosive Properties for EF-243 NAFST-04-872 Huntingdon Life Sciences Ltd. GLP Unpublished	N	Corteva Agriscience
KCP 2.7.4	Koors, B.	2010	One Week Low Temperature Storage of EF-243 NAFST-10-67 Dow Agrosiences	N	Corteva Agriscience

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Not GLP Unpublished		
KCP 2.4.2 KCP 2.7.2 KCP 2.7.5 KCP 2.8.2 KCP 2.8.4	Stock, M.	2007	Storage Stability and Package Corrosion Characteristics of EF-243; Accelerated and Two-Year Ambient Study FOR-05-003 Dow Agrosience GLP Unpublished	N	Corteva Agriscience
KCP 4.2	Huby, JP.	2019	GF-1966 Tank Clean Out Study Following EPPO 1/292 guidance 191711 Corteva Agriscience nonGLP Unpublished	N	Corteva Agriscience

## List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP	Y/N	Owner

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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Published/Unpublished		
				N	DAS

The following tables are to be completed by MS.

**List of data submitted by the applicant and not relied on**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner



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**List of data relied on and not submitted by the applicant but necessary for evaluation**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Verte- brate study Y/N</b>	<b>Owner</b>
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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## **Appendix 2    Additional data on the physical, chemical and technical properties of the active substance**

Not applicable.