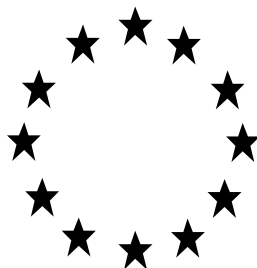


Draft Renewal Assessment Report  
under Regulation (EC) 1107/2009



**CLOPYRALID**

**Volume 3 – B.1 (PPP) – GF-1374**

RMS: Finland  
Co-RMS: Poland

May 2017

## **Volume 1**

**Level 1: Statement of subject matter and purpose for which this report has been prepared and background information on the application**

**Level 2: Summary of active substance hazard and of product risk assessment**

**Level 3: Proposed decision with respect to the application**

Appendix 1: Guidance documents used in this assessment

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## **Volume 2**

**Annex A: List of the tests, studies and information submitted**

## **Volume 3**

**Annex B (Active Substance): Summary, evaluation and assessment of the data and information**

Annex B.1 (AS): Identity

Annex B.2 (AS): Physical and chemical properties of the active substance

Annex B.3 (AS): Data on application

Annex B.4 (AS): Further information

Annex B.5 (AS): Methods of analysis

Annex B.6 (AS): Toxicology and metabolism data

Annex B.7 (AS): Residue data

Annex B.8 (AS): Environmental fate and behaviour

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## **Volume 3**

**Annex B (Plant Protection Product): Summary, evaluation and assessment of the data and information**

**Annex B.1 (PPP): Identity**

Annex B.2 (PPP): Physical and chemical properties of the plant protection product

Annex B.3 (PPP): Data on application and efficacy

Annex B.4 (PPP): Further information

Annex B.5 (PPP): Methods of analysis

Annex B.6 (PPP): Toxicology and metabolism data and assessment of risks to humans

Annex B.7 (PPP): Residue data

Annex B.8 (PPP): Environmental fate and behaviour and environmental exposure assessment

Annex B.9 (PPP): Ecotoxicology data and assessment of risks for non-target species

## **Volume 4**

**Annex C: Confidential information and, where relevant, details of any task force formed for the purpose of generating tests and studies submitted**

## **List of Endpoints**

### Version History

<b>When</b>	<b>What</b>
2017/May	DRAR- First version submitted to EFSA

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**B.1. IDENTITY****B.1.1. IDENTITY OF THE PLANT PROTECTION PRODUCT**

<b>B.1.1.1. Applicant</b>	<table border="1"> <tr> <td data-bbox="641 347 868 510"><b>Central Address</b></td><td data-bbox="868 347 1366 510">Dow AgroSciences Ltd. 3B Park Square, 2nd Floor, Milton Park Abingdon, Oxon. OX14 4RN, UK</td></tr> <tr> <td data-bbox="641 510 868 555">Telephone</td><td data-bbox="868 510 1366 555">[REDACTED]</td></tr> <tr> <td data-bbox="641 555 868 734">Contact</td><td data-bbox="868 555 1366 734">[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]</td></tr> <tr> <td data-bbox="641 734 868 779">E-mail</td><td data-bbox="868 734 1366 779">[REDACTED]</td></tr> </table> <table border="1"> <tr> <td data-bbox="641 806 868 907"><b>Member State Address</b></td><td data-bbox="868 806 1366 907">[REDACTED] [REDACTED] [REDACTED]</td></tr> <tr> <td data-bbox="641 907 868 952">Telephone</td><td data-bbox="868 907 1366 952">[REDACTED]</td></tr> <tr> <td data-bbox="641 952 868 1041">Contact</td><td data-bbox="868 952 1366 1041">[REDACTED] [REDACTED]</td></tr> <tr> <td data-bbox="641 1041 868 1086">E-mail</td><td data-bbox="868 1041 1366 1086">[REDACTED]</td></tr> </table>	<b>Central Address</b>	Dow AgroSciences Ltd. 3B Park Square, 2nd Floor, Milton Park Abingdon, Oxon. OX14 4RN, UK	Telephone	[REDACTED]	Contact	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	E-mail	[REDACTED]	<b>Member State Address</b>	[REDACTED] [REDACTED] [REDACTED]	Telephone	[REDACTED]	Contact	[REDACTED] [REDACTED]	E-mail	[REDACTED]
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<b>B.1.1.2. Producer of the plant protection product</b>	<table border="1"> <tr> <td data-bbox="641 1120 868 1243">Address</td><td data-bbox="868 1120 1366 1243">[REDACTED] [REDACTED] [REDACTED]</td></tr> <tr> <td data-bbox="641 1243 868 1288">Telephone</td><td data-bbox="868 1243 1366 1288">[REDACTED]</td></tr> <tr> <td data-bbox="641 1288 868 1332">Facsimile</td><td data-bbox="868 1288 1366 1332">[REDACTED]</td></tr> <tr> <td data-bbox="641 1332 868 1411">Contact</td><td data-bbox="868 1332 1366 1411">[REDACTED] [REDACTED]</td></tr> <tr> <td data-bbox="641 1411 868 1456">Email</td><td data-bbox="868 1411 1366 1456">[REDACTED]</td></tr> </table> <table border="1"> <tr> <td data-bbox="641 1500 868 1624">Address</td><td data-bbox="868 1500 1366 1624">[REDACTED] [REDACTED] [REDACTED]</td></tr> <tr> <td data-bbox="641 1624 868 1668">Telephone</td><td data-bbox="868 1624 1366 1668">[REDACTED]</td></tr> <tr> <td data-bbox="641 1668 868 1713">Contact</td><td data-bbox="868 1668 1366 1713">[REDACTED]</td></tr> </table>	Address	[REDACTED] [REDACTED] [REDACTED]	Telephone	[REDACTED]	Facsimile	[REDACTED]	Contact	[REDACTED] [REDACTED]	Email	[REDACTED]	Address	[REDACTED] [REDACTED] [REDACTED]	Telephone	[REDACTED]	Contact	[REDACTED]
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Address	[REDACTED] [REDACTED] [REDACTED]																
Telephone	[REDACTED]																
Contact	[REDACTED]																
<b>B.1.1.3. Trade name or proposed trade name and producer's development code number of the plant protection product</b>	<table border="1"> <tr> <td data-bbox="641 1736 836 1859">Trade name(s)</td><td data-bbox="836 1736 1334 1859">Trevistar, Aka, Kaon, Sekens, Ariane C, Colombus, Galaxy, Praxys, Tapir, Dakota, Bofix FFC</td></tr> <tr> <td data-bbox="641 1859 836 1904">Code number</td><td data-bbox="836 1859 1334 1904">GF-1374</td></tr> </table>	Trade name(s)	Trevistar, Aka, Kaon, Sekens, Ariane C, Colombus, Galaxy, Praxys, Tapir, Dakota, Bofix FFC	Code number	GF-1374												
Trade name(s)	Trevistar, Aka, Kaon, Sekens, Ariane C, Colombus, Galaxy, Praxys, Tapir, Dakota, Bofix FFC																
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**B.1.1.4.** Detailed quantitative and qualitative information on the composition of the plant protection product**B.1.1.4.1. Composition of the plant protection product****Active ingredient: Clopyralid**

Pure			Technical (at the minimum purity of 950 g/kg)		
g/L	g/L	g/L	g/L	g/L	g/L
Nominal	Lower limit*	Upper limit*	Nominal	Lower limit*	Upper Limit*
80.0	72.0	88.0	84.2	75.8	92.6

\* FAO tolerance limits for nominal declared content of above 25 up to 100g/L is  $\pm 10\%$

**Active ingredient: Florasulam**

Pure			Technical (at the minimum purity of 970 g/kg)		
g/L	g/L	g/L	g/L	g/L	g/L
Nominal	Lower limit*	Upper limit*	Nominal	Lower limit*	Upper Limit*
2.50	2.13	2.88	2.58	2.20	2.97

\* FAO tolerance limits for nominal declared content of up to 25g/L is  $\pm 15\%$

**Active ingredient: Fluroxypyr (as fluroxypyr-meptyl )**

Pure			Technical (at the minimum purity of 950 g/kg Fluroxypyr-meptyl)		
g/L	g/L	g/L	g/L	g/L	g/L
Nominal	Lower limit*	Upper limit*	Nominal	Lower limit*	Upper Limit*
100.0 (144.1)	90.0 (129.7)	110.0 (158.5)	105.3 (151.7)	94.7 (136.5)	115.8 (166.8)

\* FAO tolerance limits for nominal declared content of 25 up to 100 g/L is  $\pm 10\%$

Full details of the composition of GF-1374 is CONFIDENTIAL information - data provided separately (Volume 4).

<b>B.1.1.4.2. Information on the active substances</b>	<table><tr><td rowspan="6">Clopyralid</td><td>ISO common name</td><td>Clopyralid</td></tr><tr><td>CAS No.</td><td>1702-17-6</td></tr><tr><td>EINECS No.</td><td>216-935-4</td></tr><tr><td>CIPAC No.</td><td>455</td></tr><tr><td>ELINCS</td><td>216-935-4</td></tr><tr><td>Salt, ester anion or cation present</td><td>The monoethanolamine base combines with the clopyralid acid to form the clopyralid olamine salt.</td></tr><tr><td rowspan="6">Florasulam</td><td>ISO common name</td><td>Florasulam</td></tr><tr><td>CAS No.</td><td>145701-23-1</td></tr><tr><td>EINECS No.</td><td>Not available</td></tr><tr><td>CIPAC No.</td><td>616</td></tr><tr><td>ELINCS</td><td>Not available</td></tr><tr><td>Salt, ester anion or cation present</td><td>Not applicable</td></tr><tr><td rowspan="6">Fluroxypyr-meptyl</td><td>ISO common name</td><td>Fluroxypyr-meptyl</td></tr><tr><td>CAS No.</td><td>81406-37-3</td></tr><tr><td>EINECS No.</td><td>279-752-9</td></tr><tr><td>CIPAC No.</td><td>431.214</td></tr><tr><td>ELINCS</td><td>279-752-9</td></tr><tr><td>Salt, ester anion or cation present</td><td>Ester</td></tr></table>	Clopyralid	ISO common name	Clopyralid	CAS No.	1702-17-6	EINECS No.	216-935-4	CIPAC No.	455	ELINCS	216-935-4	Salt, ester anion or cation present	The monoethanolamine base combines with the clopyralid acid to form the clopyralid olamine salt.	Florasulam	ISO common name	Florasulam	CAS No.	145701-23-1	EINECS No.	Not available	CIPAC No.	616	ELINCS	Not available	Salt, ester anion or cation present	Not applicable	Fluroxypyr-meptyl	ISO common name	Fluroxypyr-meptyl	CAS No.	81406-37-3	EINECS No.	279-752-9	CIPAC No.	431.214	ELINCS	279-752-9	Salt, ester anion or cation present	Ester
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	Salt, ester anion or cation present	Ester																																						
<b>B.1.1.4.3. Information on safeners, synergists and co-formulants</b>	CONFIDENTIAL information - data provided separately (Volume 4)																																							
<b>B.1.1.5.</b> Type and code of the plant protection product	emulsifiable concentrate (EC)																																							
<b>B.1.1.6.</b> Function	herbicide																																							
<b>B.1.1.7.</b> Field of use envisaged	in cereals and grassland for the control of a range of broad leaf weeds																																							
<b>B.1.1.8.</b> Effects on harmful	<b>Clopyralid</b> will mainly be absorbed through green																																							

organisms	<p>leaves, uptake through roots is of much less importance. Acropetal translocation of clopyralid in xylem into young meristem and youngest leaves as well as basipetal transport in phloem into roots is possible. The MoA is similar to fluroxypyr and not yet completely understood. But it has been shown that clopyralid is being accumulated in merestemic tissue and influencing cell division, cell elongation and cell extension as well as RNA synthesis. Consequently, merestemic tissue dies off. Typical symptoms of susceptible plants are deformation and curling of young leaves and stem followed by growth stop and necrosis.</p> <p><b>Florasulam</b> belongs to a class of herbicides known to inhibit the plant enzyme acetolactate synthase (ALS), also called acetohydroxyacid synthase (AHAS), a key enzyme in the biosynthesis of the branched chained amino acids isoleucine, leucine and valine.</p> <p><b>Fluroxypyr 1-methylheptyl ester</b> will hydrolyse during penetration to form fluroxypyr-acid which acts as an auxin like herbicide causing rapid cell growth within the plant. Once absorbed fluroxypyr acid moves readily through the plant via both the xylem and phloem and is distributed throughout the entire plant to the meristems and other developing parts. In susceptible plant species fluroxypyr induces an epinastic response (ie stimulation of cell elongation and premature senescence, particularly in meristematic tissue) leading to cessation of normal growth and rapid necrosis followed by plant death.</p>
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**B.1.2. REFERENCES RELIED ON**

<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>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previous evaluation</b>