

REGISTRATION REPORT

Part A

Risk Management

Product code: GF-4021

Product name: LaDiva

Chemical active substances:

Halauxifen-methyl 10 g a.s./L (9.594 g a.e./L)

Picloram 48 g a.s./L

Aminopyralid 32 g a.s./L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland
(new submission of the product)

Applicant: Corteva AgriScience

Submission date: November/2020

MS Finalisation date: August 2022 (initial National Assessment)

January 2023 (final National Assessment), updated June 2023

Version history

When	What
November 2020	New submission of GF-4021 to the Central Zone.
August 2022	Initial zRMS assessment. In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table and the product label are highlighted in grey, while not agreed use pattern is struck through and shaded .
January 2023	Final report (National Assessment updated following the commenting period). Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded .
June 2023	zRMS autocorrect on PAPRH sensitivity assessment (all changes are highlighted in turquoise).

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by Corteva (Dow AgroSciences) in November 2020.

The application was for approval of GF-4021, an emulsifiable concentrate formulation (EC) formulation containing 10g/L (9.594g ae/L) g/kg of halauxifen-methyl, 48g/kg picloram and 32g/L aminopyralid active substances for use as a herbicide in winter oil seed rape.

zRMS is Poland for this application and cMS are Germany, Czech Republic, Slovakia, Hungary, Romania and Slovenia.

1.2 Letters of Access

Letter of access are not necessary for the application. Dow AgroSciences are the sole producer of halauxifen-methyl, picloram and aminopyralid technical products and this application refers to the same technical source as has been assessed during the EU active approval process.

1.3 Justification for submission of tests and studies

The studies submitted are necessary for first authorisation of the plant protection product in the EU Central Zone and are in accordance with Reg. (EU) No. 284/2013.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4, for all studies used in supporting the registration of GF-4021.

2 Details of the authorization decision

2.1 Product identity

Product code	GF-4021
Product name in MS	LaDiva
Authorization number	Not applicable.
Function	Herbicide.
Applicant	Corteva Agriscience (Dow AgroSciences)
Active substance(s) (incl. content)	Halauxifen-methyl; 10 g a.s. (9.594 g a.e.)/L; Aminopyralid 32 g a.s./L; Picloram 48 g a.s./L.
Formulation type	Emulsifiable Concentrate [Code: EC]
Packaging	<p>Professional Use Only.</p> <p>PET:</p> <p>Bottles/Jerrican 0.05, 0.10, 0.15, 0.25, 0.5, 1, 2, 3, 5, 10L, 15L and 20L</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 2x10litre to an outer corrugated fibreboard case</p> <p>15 litre jerrican, may or may not be packed 2x15litre to an outer corrugated fibreboard case</p> <p>20 litre jerrican may or may not be packed to an outer corrugated fibreboard case.</p> <p>COEX PE/PA:</p> <p>0.1 litre bottles may or may not be packed 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>5.2 litre bottles may or may not be packed to an outer corrugated fibreboard case</p> <p>6.2 litre bottles may or may not be packed to an outer corrugated fibreboard case</p> <p>7 litre bottles may or may not be packed to an outer corrugated fibreboard case.</p> <p>10 litre jerrican, may or may not be, packed 2x10litre to an outer corrugated fibreboard case</p> <p>15 litre jerrican, may or may not be packed 2x15litre to an outer corrugated fibreboard case</p> <p>20 litre jerrican may or may not be packed to an outer corrugated fibreboard case.</p>
Coformulants of concern for national authorizations	Not applicable.
Restrictions related to identity	Not applicable.

Mandatory tank mixtures	Not applicable.
Recommended tank mixtures	Not applicable.

2.2 Conclusion

The evaluation of the application for LaDiva resulted in the decision to grant the authorisation. All uses applied for were authorised. Due to potential leaching of aminopyralid, frequency of application is restricted to one every third year.

2.3 Substances of concern for national monitoring

No national monitoring data are available by the applicant.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:
The following labelling information is derived from the classification and to be mentioned in the safety data sheet.

Hazard symbol(s)



GHS05



GHS07



GHS09

Signal word

Danger

Hazard statement(s)

Skin irritation Cat 2	H315	Causes skin irritation.
Eye irritation Cat 1	H318	Causes serious eye damage
STOT SE Cat 3	H335	May cause respiratory irritation.
Chronic aquatic Cat 1	H410	Very toxic to aquatic life with long lasting effects.

Precautionary statement(s)

P261	Avoid breathing mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302 + P352	IF ON SKIN: Wash with plenty of water.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305 + P351 + P338 + P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
P391	Collect spillage
P501	Dispose of contents/container in accordance with applicable regulations.

EU specific statements

EUH401	To avoid risks to human health and the environment, comply with the instructions for use.
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See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe 1	To <u>protect groundwater</u> do not apply this or any other product containing aminopyralid more than once every third year.
SPe 3	To protect non-target plants respect an unsprayed buffer zone of 5 m to non-agricultural land or reduce the spray drift by 75% using appropriate drift reducing techniques

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None required.

2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
respective code if available	national PPE requirements
Worker protection:	
respective code if available	national PPE requirements
Integrated pest management (IPM)/sustainable use:	
respective code if available	e.g. The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.
Environmental protection	
SPe 1	To <u>protect groundwater</u> do not apply this or any other product containing aminopyralid nicosulfuron more than once every third year.
SPe 3	To protect non-target plants respect an unsprayed buffer zone of 5 m to non-agricultural land or reduce the spray drift by 75% using appropriate drift reducing techniques
Other specific restrictions	
respective code if available	are there any other national requirements

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
respective code if available	e.g. The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorization is applied.

2.5.2 Specific restrictions linked to the intended uses

No specific restrictions are required.

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code):	GF-4021	Formulation type:	EC ^(a, b)
Active substance 1:	Halauxifen methyl	Conc. of as 1:	10 g/L (9.594 g ae/L) ^(c)
Active substance 2:	Picloram	Conc. of as 2:	48 g/L ^(c)
Active substance 3:	Aminopyralid	Conc. of as 3:	32 g/L ^(c)
Safener:	N/a.	Conc. of safener:	N/a ^(c)
Applicant:	Dow AgroSciences.	Professional use:	F
Zones:	Central ^(d)	Non professional use:	n/a
Verified by MS:	No		
Field of use:	Herbicide		

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15							
Use- No. (e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gp n or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syn ergist per ha (f)	Overall conclusions							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applicat ions (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season <i>Arylex</i> ™ (<i>Halauxifen</i> -methyl) + <i>Picloram</i> + <i>Aminopyral</i> <i>id</i>	Wate r L/ha min / max			Phys-chem	Analytical methods	Toxicology	Residues	Groundwater	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																					
1	CZ (Germany; Poland; Czech Republic; Slovakia; Hungary; Romania; Slovenia)	Winter oil seed rape Brassica napus BRSNN MRL code: 041060	F	Broadleaf weeds (post-em): <i>Matricaria species</i> <i>chamomilla</i> (MATSS) (MATCH) <i>Stellaria media</i> (STEME) <i>Papaver rhoeas</i> (PAPRH) <i>Galium aparine</i> (GALAP) <i>Fumaria species officinalis</i> (FUMSS) (FUMOF) <i>Lamium purpureum</i> (LAMPU) and others <i>Capsella bursa-pastoris</i>	Overall, Broadcast foliar spray	BBCH 12-19 autumn use	a) 1 b) 1	N/a	a, b) 0.25	a, b) 2.5 (2.4ae) + 12 + 8	100- 300	N/a	Timing: 90% of crop has to be in BBCH 12.	A	A	A	A	R Triennial application	R NTTP	A	A

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
			13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions
			15	Overall conclusions - explanation for the column 15 is below*

* Explanation for column 15 “Overall conclusions”

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

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 brown liquid at 21.2°C. It is not explosive, has no oxidising properties. The product has a flash point of >100 °C. It has a self-ignition temperature of 239 °C. In aqueous solution, it has a pH value around 3.49 at 18.8 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The two years storage stability study is ongoing. The packaging listed in the point 2.1 (COEX/PA and PET) are acceptable as a storage stability study at elevated temperature for 14 days was carried out in COEX/PA and PET. Its technical characteristics are acceptable for an EC formulation.

The intended concentration of use is 0.083% to 0.25%.

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.

3.2 Efficacy (Part B, Section 3)

3.2.1 Efficacy data

Considering the submitted data the efficacy level of LaDiva (GF-4021) is considered as satisfactory for all claimed uses (CAPBP, CENCY, CHEAL, DESSO, FUMOF, GALAP, GERPU, LAMPU, MATCH, MATIN, MYOAR, PAPRH, STEME, THLAR, VERPE, VIOAR).

Considering the submitted data the selectivity level of LaDiva (GF-4021) EC is considered as satisfactory for all claimed uses.

Considering the submitted data no negative effect on the quality of winter oilseed rape, oil and protein content is expected if LaDiva (GF-4021) is applied at the requested dose of 0.25 L/ha according to the Good Agricultural Practices and label recommendations.

3.2.2 Information on the occurrence or possible occurrence of the development of resistance

The overall risk resistance developing is medium. The unmodified use is unacceptable for *P. rhoeas* population's resistance to ALS and group 4 (legacy HRAC O) herbicides. Hence, the anti-resistance recommendations are necessary to the product label. The Synthetic Auxin Working Group propose to use diversity in weed control practices:

1. *Rotation or mixtures of herbicide mechanisms of action.*
2. *Using at least two herbicides a year from different herbicide mechanisms of action that are still effective on the particular population of the target weed. This may include use of pre-emergence herbicides.*
3. *Using cultural/mechanical weed control methods including shallow tillage in the spring, crop rotation, and cleaning equipment.*
4. *Using full herbicide rates applied at the correct weed size and to carefully monitor results.*
5. *Scouting fields after herbicide application and controlling escapes.*

Moreover, the general anti-resistance recommendation should be included to the product label:

GF-4021 should be applied according to the label directions, including time and number of applications and the recommended dose rate.

Based on the rules of crop rotation, the below statement is proposed to include to the product label:

Repeated applications of auxin herbicides in consecutive years in cereal crops are likely to increase the selection pressure for resistance evolution. To avoid of that, it is recommended to use of chemical groups other than auxin herbicides to control of weeds in cereals growing as succeeding crops after oilseed rape.

Cultural (e.g.: ploughing, late sowing) and mechanical practices are recommended. Ensure that herbicide application is made under favourable environmental conditions, facilitating good and even coverage. To prevent resistance appearance effective tools to be used in conjunction with chemical tools re avoid monocultures situations, ploughing before crop drill, etc Destroy all the seeds produced by no-controlled weeds by the use of mechanical control or effective herbicides with a different mode of action.

3.2.3 Adverse effects on treated crops

Considering the submitted data no negative effect on the quality of winter oilseed rape, oil and protein content is expected if **LaDiva (GF-4021)** is applied at the requested dose of 0.25 L/ha according to the Good Agricultural Practices and label recommendations.

3.2.4 Observations on other undesirable or unintended side-effects

The risk of negative impact on succeeding crops is considered as acceptable. Based on the trial results it can be concluded that sunflower can be sown after application of GF-4021 at 0,25 l/ha.

Considering the result, the risk of negative impact on adjacent crop is considered as acceptable. No negative impact on the adjacent crops is expected during application of product GF-4021, except on alfalfa where should be to keep at least 3 m distance. However, it is recommended to apply treatment as per the good agricultural practices (no wind during spraying, avoid thin droplets formation), especially close to sensitive crops.

From these results it can be concluded that the proposed use pattern of LaDiva (GF-4021) will not pose any significant risk to beneficial organisms.

3.3 Methods of analysis (Part B, Section 5)

An overview on the acceptable methods and possible data gaps for analysis of aminopyralid, picloram and halauxifen-methyl in plant protection product is provided as follows.

3.3.1 Analytical method for the formulation

The method, described in Part B Section 5 (Methods) is applicable for the determination of Halauxifen-methyl, Picloram Aminopyralid at concentrations of 0.69-2.52% Halauxifen-methyl, 1.73-6.93% Aminopyralid and 2.92-11.17 % picloram by weight, in formulation GF-4021. The recovery, linearity, and precision data have shown this method to be acceptable for the assay of Halauxifen-methyl, Aminopyralid and Picloram in the end-use product.

For the further information, please refer to Part B Section 5 (Methods) of the current dRR.

3.3.2 Analytical methods for residues

Halauxifen-methyl

In EFSA Journal 2014;12(12):3913 – “Peer review of the pesticide risk assessment of the active substance halauxifen-methyl” EFSA concluded that *the proposed residue definition monitoring in plants, restricted to cereals, is the sum of halauxifen-methyl and metabolite X11393729 (halauxifen), expressed as halauxifen-methyl. QuEChERS (quick, easy, cheap, effective and safe) method multi-residue method and also single LC-MS/MS (liquid chromatography with tandem mass spectrometry) method exist for monitoring the compounds of the residue definition in food and feed of plant origin with LOQs (limits of quantification) of 0.01 mg/kg in all commodity groups. Residues of halauxifen-methyl and X11393729 (halauxifen), in food of animal origin can be monitored with single LC-MS/MS methods and also with the QuEChERS multi-residue method with LOQs of 0.01 mg/kg in muscle, kidney, liver, fat, milk and eggs. It should be noted, however, that no residue definition has been set for food of animal origin.*

Residues of halauxifen-methyl, metabolite X11393729 (halauxifen) and metabolite X11449757 in soil can be monitored by LC-MS/MS with LOQs of 0.05 µg/kg for each compound. Appropriate LC-MS/MS method with LOQs of 0.05 µg/L exists for monitoring halauxifen-methyl, metabolite X11393729 (halauxifen), and metabolites X11449757 and X11406790 in surface water and drinking water. Residues of halauxifen-methyl and X11393729 (halauxifen) in air can be monitored by LC-MS/MS with LOQs of 0.82 µg/m³. The active substance is not classified as a Health Hazard under CLP and, therefore, a method of analysis is not required for body fluids and tissues.

Considering the results of metabolism study of halauxifen-methyl in the new proposed crop group (oilseed) which are presented in section B7, the same residue definition for halauxifen-methyl for a group of pulses and oilseeds crops can be proposed and adopted as the residue definition for halauxifen-methyl for a group of cereals. Thus, the proposed residue definition for both monitoring and risk assessment for new group of crops is halauxifen-methyl and compound X11393729 (halauxifen) expressed as halauxifen-methyl.

According to the EFSA Journal 2014;12(12):3913:

Methods of Analysis

Analytical methods for residues (Annex IIA, point 4.2)		
Residue definitions for monitoring purposes		
Food of plant origin		The sum of halauxifen-methyl and X11393729 (halauxifen), expressed as halauxifen-methyl (restricted to cereals).
Food of animal origin		Not required.
Soil		halauxifen-methyl
Water	surface	halauxifen-methyl and X11393729 (halauxifen)
	drinking/ground	halauxifen-methyl
Air		halauxifen-methyl

Monitoring/Enforcement methods	
Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	<p>Single method: LC-MS/MS, LOQ = 0.01 mg/kg (turnip root and wheat forage (wet crops), barley (grain, hay and straw) and wheat (grain, hay and straw) (dry crops), canola seed and soybean (oily crops), apple (whole) and orange (whole) (acidic crops), aspirated grain, bran bread, flour, germ, gluten, shorts and starch).</p> <p><i>NB. The method relies on mixed stable isotope labelled internal standards.</i></p> <p>QuEChERS Multi-Residue Method: LC-MS/MS, LOQ = 0.01 mg/kg (kale leaves (wet crops), barley grain (dry crops), oilseed rape seed (oily crops) and lemon (acidic crops)).</p> <p><i>N.B. although mean recoveries in acidic matrices (lemon) and wet matrices (cabbage) were acceptable for the QuEChERS method, it is noted that the individual recoveries were occasionally low.</i></p>
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	<p>Single method: LC-MS/MS, LOQ = 0.01 mg/kg (bovine muscle, liver, kidney, fat, whole milk and cream and poultry muscle, liver, fat and eggs).</p> <p><i>NB. The method relies on mixed stable isotope labelled internal standards.</i></p> <p>QuEChERS Multi-Residue Method: LC-MS/MS, LOQ = 0.01 mg/kg (bovine muscle, kidney, liver, fat and whole milk and poultry muscle and eggs).</p> <p><i>N.B. extraction efficiencies have not been addressed as part of the method validation discussed above; however, residues are not expected to be found in products of animal origin for the proposed use. This will need to be addressed in future however if new uses give rise to positive residues.</i></p>
Soil (analytical technique and LOQ)	<p>LC-MS/MS, LOQ = 0.05 µg/kg (for halauxifen-methyl, X11393729 (halauxifen) and X11449757).</p> <p><i>NB. The method relies on mixed stable isotope labelled internal standards.</i></p>
Water (analytical technique and LOQ)	<p>LC-MS/MS, LOQ = 0.05 µg/L (for halauxifen-methyl, X11393729 (halauxifen), X11449757 and X11406790).</p> <p><i>NB. The method relies on mixed stable isotope labelled internal standards.</i></p>
Air (analytical technique and LOQ)	<p>LC-MS/MS, LOQ = 0.82 µg/m³ (for halauxifen-methyl and X11393729 (halauxifen)).</p>
Body fluids and tissues (analytical technique and LOQ)	<p>Halauxifen-methyl is not classified as toxic or highly toxic; therefore monitoring methods for human tissues and body fluids are not required.</p>

Monitoring methods for the determination of residues in crop commodities and environmental matrices have been evaluated during the EU review of halauxifen-methyl, where they were considered adequate and acceptable.

Furthermore the Applicant submitted two methods for analysis of residues of **halauxifen-methyl, picloram and aminopyralid** for the generation of pre-authorization data. The studies are acceptable. The details of the evaluation of new and additional studies are referred in Appendix 2 of the Part B5.

Picloram

In EFSA Journal 2009; 7(12):1390 – “Peer review of the pesticide risk assessment of the active substance picloram” EFSA concluded that *Only single methods for the determination of residues are available. Residues of picloram in food of plant origin can be monitored by GC-MS with a LOQ of 0.01 mg/kg in oilseed rape. It should be noted however that the experts at the PRAPeR 66 meeting (April 2009) concluded that in the method GRM 00.19 only one fragment ion has been validated and an additional one for identification, and could not agree on the acceptability of the method. It should also be noted, that following the finalization of the residue definition for monitoring, a data gap will have to be set: either to demonstrate that the methods analyse only for picloram or to demonstrate that the extraction procedures cover the picloram conjugates, too.*

Residues in foodstuff of animal origin can be determined by GC-MS with a LOQ of 0.01 mg/kg in all relevant animal products.

Residues of picloram in soil can be monitored by GC-MS with a LOQ of 0.0005 mg/kg.

GC-MS method is available to monitor residues of picloram in surface water and drinking water with LOQs of 0.05 µg/L. It should be noted however, that the experts at the PRAPeR 66 meeting (April 2009) concluded that in the methods GRM 00.18 for soil and GRM 00.17 for water only one fragment ion has been validated and an additional one for identification, and could not agree on the acceptability of the methods. It was however considered not necessary to set a data gap for these methods at EU level.

Residues of picloram in air can be monitored by GC-MS method with a LOQ of 6 µg/m³.

Analytical methods for the determination of residues in body fluids and tissues are not required as picloram is not classified as toxic or highly toxic.

According to the EFSA Journal 2009; 7(12):1390:

Methods of Analysis

Analytical methods for residues (Annex IIA, point 4.2)		
Residue definitions for monitoring purposes		
Food of plant origin		open
Food of animal origin		Picloram
Soil		Picloram
Water	surface	Picloram
	drinking/ground	Picloram
Air		Picloram

Monitoring/Enforcement methods	
Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	GC-MS LOQ 1.0 mg/kg picloram, grass LOQ 0.01 mg/kg picloram, oilseed rape open
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	GC-MS LOQ 0.01 mg/kg for muscle, fat, liver, kidney, milk and eggs
Soil (analytical technique and LOQ)	GC-MS (picloram) – LOQ 0.0005 mg/kg LC-MS/MS (XDE-750) – LOQ 0.0015 mg/kg
Water (analytical technique and LOQ)	GC-MS(picloram) –: LOQ 0.05 µg/L LC-MS/MS(XDE-750) –: LOQ 0.05 µg/L
Air (analytical technique and LOQ)	GC-MS: LOQ 6 µg/m ³
Body fluids and tissues (analytical technique and LOQ)	Not required as picloram is neither toxic nor very toxic

In the EFSA Journal 2013; 11(10):3439 it is stated that *Analytical methods for the determination of picloram residues in plant commodities were assessed in the DAR and during the peer review under Directive 91/414/EEC (United Kingdom, 2007, 2009; EFSA, 2010). The available monitoring method for oilseeds is based on GC-MS with a LOQ of 0.01 mg/kg. The peer review experts could not agree on the acceptability of this method as it was unclear if the method covers conjugated picloram. Therefore a data gap concerning analytical methods for enforcement purpose was defined. Confirmatory data have not been peer reviewed yet but were submitted for the current application and were evaluated by the EMS (United Kingdom, 2013). According to the EMS, the results indicate that the method GRM 00.19 is able to quantify*

picloram, free and conjugated expressed as picloram in high oil content and dry commodities with an LOQ validated at 0.01 mg/kg.

The current enforcement residue definition set in Regulation (EC) No 396/2005 is parent picloram. The applicant did not provide analytical enforcement methods that can be used to monitor parent picloram only. Taking into account that the residue definition should be amended to the sum of picloram and its conjugates, expressed as picloram as proposed in the peer review under Directive 91/414/EEC (see 3.1.1.1) and that the residue trials on which the MRL proposal is based on were also analysed with a method that included the conjugates, the lack of an enforcement method for parent picloram is considered of minor importance.

EFSA concludes that a sufficiently validated analytical method for crops belonging to the group of high oil content is available to control residues of picloram and its conjugates.

Additionally EFSA confirmed in EFSA Supporting publication 2017:EN-1258 – “Outcome of the consultation on confirmatory data used in risk assessment for picloram” *that the analytical method GRM 00.19 is able to quantify picloram residues (free and conjugated) as picloram in oilseed rape seed, forage and straw and that the monitoring analytical method applied in residue trials correctly quantifies the residues of picloram and its conjugates. It should be mentioned that the submitted study can also be considered as an assessment of the extraction efficiency.*

Taking into account the EFSA conclusions that some analytical methods provided by the notifier and validated in the picloram monograph (2007) are not considered highly specific according to SANCO/825/00 rev. 8 and a confirmatory method for the determination of picloram are required, Applicant submitted the new, highly specific analytical methods (LC-MS/MS) and its ILV for post-authorization control and monitoring purposes:

- methods for food and feed of plant origin (Vogl, E., 2012) and its ILV (Austin, R., 2012),
- methods for food and feed of animal origin (Vincent T., 2013) and its ILV (Austin, R., 2013),
- methods for soil (Vincent T., 2013),
- methods for water (Shaffer, S. R., 2012) and its ILV (Austin, R., Turner, R., 2013),
- methods for air (Bacher, R., 2012),
- methods for body fluids and tissues (Sencuic, M., Schmiedt, S., 2016).

The analytical methods are acceptable. The details of the evaluation of new and additional studies are referred in Appendix 2 of Part B5. No other data is required.

Aminopyralid

According to the EFSA Journal 2013;11(9):3352: “A LC-MS/MS method involving hydrolysis and derivatization was validated to monitor aminopyralid and its conjugates determined as aminopyralid in food and feed of plant origin at LOQ of 0.01 mg/kg for all four groups of matrices (high water, high acid and high oil content and dry). Another LC-MS/MS method was validated for the analysis of aminopyralid in food of animal origin at LOQ of 0.01 mg/kg for all matrices (fat, kidney, liver, muscle, milk and eggs). Appropriate HPLC-MS/MS methods exist for monitoring of the residues of aminopyralid in soil, water and in air with LOQs of 0.001 mg/kg, 0.05 µg/L and 7.7 µg/m³ respectively. The active substance is not classified as toxic or very toxic and analytical methods for residues in body fluids and tissues are not required, however a LC-MS/MS method for analysis of aminopyralid in blood (LOQ 0.025 µg/ml) and urine (LOQ 0.01 µg/ml) was provided but without confirmatory method/data.”

Methods of Analysis

Analytical methods for residues (Annex IIA, point 4.2)		
Residue definitions for monitoring purposes		
Food of plant origin		The sum of aminopyralid and its conjugates expressed as aminopyralid.
Food of animal origin		Aminopyralid
Soil		Aminopyralid
Water	surface	Aminopyralid
	drinking/ground	Aminopyralid
Air		Aminopyralid
Monitoring/Enforcement methods		

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	LC/MS/MS, analyte: aminopyralid and its conjugates measured as aminopyralid LOQ = 0.01 mg/kg (water, dry, acid and oil crop groups)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	LC/MS/MS, analyte: aminopyralid LOQ = 0.01 mg/kg (milk, eggs, muscle, fat, kidney, liver)
Soil (analytical technique and LOQ)	LC/MS/MS, analyte: aminopyralid and its conjugates measured as aminopyralid LOQ = 0.001 mg/kg
Water (analytical technique and LOQ)	LC/MS/MS, analyte: aminopyralid LOQ = 0.05 µg/L
Air (analytical technique and LOQ)	LC/MS/MS, analyte: aminopyralid LOQ = 7.7 µg/m ³
Body fluids and tissues (analytical technique and LOQ)	Aminopyralid is not classified as toxic or very toxic.

Additionally in EFSA Journal 2020;18(8):6229 - Review of the existing MRLs for aminopyralid it is stated that *During the peer review, a hyphenated analytical method based on high-performance liquid chromatography (HPLC) coupled to tandem mass spectrometry (MS/MS) detection was validated for the determination of aminopyralid free and conjugated (measured as aminopyralid) in all four crop matrices (high water, high acid, high oil content and dry commodities), with a limit of quantification (LOQ) of 0.01 mg/kg. The method includes hydrolytic conditions that release free aminopyralid from its conjugates. It is supported by an independent laboratory validation (ILV).*

During the completeness check, the EURLs provided a QuEChERS multi-residue analytical method using HPLC–MS/MS with an LOQ of 0.05 mg/kg for the routine analysis of free aminopyralid in high water content, high acid content and dry commodities. During the Member State consultation, the EURLs provided an updated evaluation report and additional validation data for high oil content commodities with the same LOQ of 0.05 mg/kg. However, this method does not cover the default LOQ of 0.01 mg/kg, neither the proposed residue definition for enforcement since aminopyralid conjugates are not analysed. According to the EURLs, aminopyralid is stable under alkaline hydrolysis and as the conjugates residues of aminopyralid are mostly glucosides (easy to breakup), it is confirmed that a modified QuEChERS method including an alkaline hydrolysis step would be suitable for the determination of aminopyralid (free and conjugated) (EURLs, 2019). However, validation data for this method were not provided by the EURLs. No other data is required.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

Table 3.4-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for GF-4021/LaDiva

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)
LD ₅₀ oral, rat (OECD 423)	> 2000 mg/kg bw	Yes	None
LD ₅₀ dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None
LC ₅₀ inhalation, rat (OECD 436)	5.91 mg GF-4021/L air	Yes	Hazard statement (Triggered by concentration limits, not study result): STOT SE Cat 3: H335: May cause respiratory irritation..
Skin irritation, rabbit (OECD 404)	Irritant (moderate to severe dermal reaction fully reversible by day 14).	Yes	Hazard statement: Skin irritation Cat 2. H315: Causes skin irritation.
Eye irritation, in-vitro (OECD TG 437)	Irritant (Predicted to be a severe eye irritant)	Yes	Hazard statement (Triggered by a combination of in-vitro studies): Eye irritation Cat 1; H318: Causes serious eye damage

Eye irritation, in-vitro (OECD TG 492)	Irritant (Considered to have potential for eye irritation or serious eye damage)	Yes	Hazard statement (Triggered by a combination of in-vitro studies): Eye irritation Cat 1; H318: Causes serious eye damage
Skin sensitisation, mouse (OECD 429/LLNA)	Non-sensitising	Yes	None
Supplementary studies for combinations of plant protection products	No data – not required	-	-

Acute Oral Toxicity

No mortality was observed in rat treated with 2000 mg GF-4021/kg body weight. The acute oral LD₅₀ of GF-4021 in female Wistar rats was found to be greater than 2000 mg/kg body weight.

Acute Dermal Toxicity

No mortality, effects on body weight, and macroscopic external or internal abnormality at necropsy was observed in any rat treated with 2000 mg GF-4021/kg body weight.

Based on study results, the acute dermal median lethal dose (LD₅₀ value) of GF-4021 in female Wistar rats was found to be greater than 2000 mg/kg body weight.

Acute Inhalation Toxicity

Two mortalities were observed in rats following 4-hour nose-only inhalation exposure to an aerosol concentration of 5.91 mg GF-4021/L air (TWA). Under the conditions of this study, the 4-hour acute inhalation median lethal concentration (LC₅₀) of GF-4021 in male and female Wistar rats was found to be greater than the time-weighted average (TWA) exposure concentration of 5.91 mg GF-4021/L air.

Acute Dermal Irritation

In conclusion, based on these study results, GF-4021 caused a moderate to severe dermal reaction in all rabbits, fully reversible by day 14. No systemic effects were observed.

Individual rabbit average dermal irritation score observed at 24, 48 and 72 h post patch removal were 2.67, 2.67, 2.67 for erythema and 2.67, 2.67, 2.67 for oedema for Rabbit N° 1, 2 and 3 respectively.

Acute Eye Irritation

In the In-vitro study on the bovine corneal opacity and permeability the In Vitro Score of the test substance was 81.4. According to the prediction model presented in OECD TG 437, the test substance is predicted to be a severe eye irritant (GHS Category 1). The positive control IVIS was 50.4 and was within 2 standard deviation of the historical control mean. According to the EpiOcular™ Eye Irritation Test prediction model, GF-4021 did show the potential for ocular irritation.

Skin Sensitization Study

The SI obtained for GF-4021 at all tested concentrations showed a less than three-fold increase over the control value. Therefore, GF-4021 did not demonstrate dermal sensitisation potential in the local lymph node assay.

3.4.2 Operator exposure

No unacceptable risk for operators from the supported uses of GF-4021 was identified based on exposure estimates from the EFSA Model under conditions of intended use with the operator wearing normal workwear with no additional PPE. However, safety glasses must be worn when handling the concentrated product, and gloves worn during mixing, loading, and application, due to GF-4021 being classified as a risk of causes skin irritation (H315) and serious eye damage (H318). Thus, the predicted operator exposure to GF-4021 based on appropriate workwear and gloves worn for mixing, loading, and application is < 1% of the AOEL for each of the three active substances.

3.4.3 Worker exposure

No unacceptable risk for workers from the supported uses of GF-4021 was identified based on exposure estimates from the EFSA Model. The predicted worker exposure to halauxifen-methyl, picloram, and aminopyralid is < 1% of the AOEL for each of the three active substances, based on normal work wear and no additional PPE.

3.4.4 Bystander and resident exposure

Since the resident and/or bystander exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for halauxifen-methyl, picloram, and aminopyralid will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

3.5 Residues and consumer exposure (Part B, Section 7)

3.5.1 Residues

Halauxifen-methyl

The metabolism of halauxifen-methyl was evaluated during the Annex I inclusion. The residue definitions for plant agreed for monitoring and risk assessment as Sum halauxifen-methyl and X11393729 (halauxifen), expressed as halauxifen-methyl (EFSA Journal 2014;12(12):3913) are restricted to cereals only.

In our opinion the evaluation of metabolism study of halauxifen-methyl in the new crop group (oilseed) and the setting residue definition should be carried out at the EU level and the active substance level, not at the level of plant protection product registration in the Central Zone.

However, it should be noted that several countries in Central Europe have authorized plant protection products containing halauxifen-methyl for use as a herbicide in oilseed rape. It should be noted too that Halauxifen is not on EFSA list for peer review and there is no open question for MRL setting meaning EFSA will not look at this substance soon.

Taking into above account zRMS-PL has evaluated the study. Considering the results of the study, the same residue definition for halauxifen-methyl for a group of pulses and oilseeds crops can be proposed and adopted as the residue definition for halauxifen-methyl for a group of cereals.

The effects of processing on the nature of halauxifen-methyl residues have been investigated. Since all residues in seed of oilseed rape are < 0.02 mg/kg and no residues of halauxifen exceeding 0.1 mg/kg are expected in the treated crops, further considerations about the effects of processing are not required in the framework of this dossier.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

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

The intended use for GF-4021 is oilseed rape. Oilseed rape is the major crop in northern Europe (EU guideline Document [SANCO 7525/VI/95 rev.10.3 of 13 June 2017](#) [SANTE/2019/12752](#)). A minimum of eight trials are required.

Study RDE-15-20345 (evaluated by zRMS, France (RR, GF-3447, 2019)) on the magnitude of residue has been submitted by the applicant in the framework of this application for GF-4021.

Six NEU and ten SEU trials are submitted, in all instances no residues of halauxifen-methyl or halauxifen acid were detected in the seed or straw samples. As a no residue situation is observed, a reduce data package is considered sufficient to support the intended use of halauxifen-methyl on oilseed rape.

According to the available data, the intended use on oilseed rape is considered acceptable. The data submitted show that no exceedance of the MRL will occur. The use is considered acceptable.

Picloram

As residues of picloram do not exceed the trigger values defined in Reg. (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. On the basis of the available data, the following mitigation measure has been proposed: **do not grow leafy vegetables in the treated field less than 120 days after application of GF-4021.**

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

The intended use for GF-4021 is oilseed rape. Oilseed rape is the major crop in northern Europe (EU guideline Document ~~SANCO 7525/VI/95 rev.10.3 of 13 June 2017~~ **SANTE/2019/12752**). A minimum of eight trials are required.

Study RDE-15-20345 (evaluated by zRMS, France (RR, GF-3447, 2019)) on the magnitude of residue has been submitted by the applicant in the framework of this application for GF-4021.

Sixteen residue trials: 6 NEU and 10 SEU were conducted on oilseed rape. Levels of residue are below the LOQ of 0.01 mg/kg for picloram for all the submitted trials.

The GAP proposed for GF-4021 results in an application rate for picloram that is less intensive (1 x 12 g ae/ha) than that which the EU MRL is based (1 x 24 g ae/ha). Consequently, the existing proposed EU MRL of 0.03 mg/kg for picloram and the associated critical GAP upon which it is based fully covers the proposed GAP for GF-4021 in this submission with regard to picloram and will not lead to residues exceeding the proposed EU MRL.

Aminopyralid

The effects of processing on the nature of aminopyralid residues have been investigated. Since no residues of aminopyralid exceeding 0.1 mg/kg are expected in the treated crops and TMDI is below 10% of the ADI, further considerations about the effects of processing are not required in the framework of this dossier.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. A confined rotational crop study (Study title: A confined rotational crop study with ¹⁴C-aminopyralid Authors: Sandra Rotondaro, He Wang, Brittany Kish Date: 16 December 2015 Study ID: 120968) has been evaluated by EMS-United Kingdom, 2017.

EMS-UK conclusions (Evaluation Report: “Modification of MRLs for aminopyralid in barley, rye, oats, wheat, sorghum, millet and maize”, 2017):

Significant residues (>0.01 mg/kg) are expected in leafy/stem vegetable and cereal (forage, hay and straw) crops grown in rotation at a plant back interval of 30 days following application of 10 g aminopyralid/ha. As such, the current MRL of 0.01 mg/kg for leafy crops and stem vegetables may be exceeded when replanting occurs 30 days after application. On this basis the existing 90 day plant back restriction should remain in place.

Taking into account presented above UK conclusions, in our opinion **90 day plant back restriction** should remain in place.

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

The intended use for GF-4021 is oilseed rape. Oilseed rape is the major crop in northern Europe (EU guideline Document ~~SANCO 7525/VI/95 rev.10.3 of 13 June 2017~~ **SANTE/2019/12752**). A minimum of eight trials are required.

No new data are submitted in the framework of this application. A total of 12 residue trials on rape seed (N-EU) were available, all based on a GAP that is more critical (higher rates and later application timings) than the GAP proposed for the product GF-4021. However, these trials support the existing MRL for

aminopyralid and are therefore fully adequate to support the intended use on rape seed.

The residue trials on oilseed rape were previously presented and evaluated in the EFSA 2012.

All the samples were analysed for aminopyralid and its conjugates, determined as aminopyralid. Residues of aminopyralid were from <0.01 to 0.02 mg/kg in oilseed rape. The value of EU MRL for aminopyralid on oilseed rape equals ~~0.03~~ 0.05 mg/kg (Regulation (EU) ~~2019/1015~~ 2021/1841). The residues arising from the proposed use will not exceed the MRL established for oilseeds.

According to the „Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey“ (SANTE/11956/2016 rev. 9; 14 September 2018) residues in honey can occur when a substance with systemic properties is applied prior to the flowering stage (before BBCH 60), of a crop which is foraged by bees.

Halauixifen-methyl, picloram and aminopyralid are the substances with systemic properties. Oilseed rape is a melliferous crop with high melliferous capacity. Residues in honey could be therefore expected.

Applicant provided data showing that for GF-4021 applied according the submitted GAP, the MRL for halauixifen-methyl, picloram and aminopyralid can be expected to below 0.05 mg/kg for honey and bee products.

3.5.2 Consumer exposure

Halauixifen-methyl

The consumer risk assessments were performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMO). The calculation of the TMDI using EFSA model (version 3.1) and MRLs according to Reg. (EU) 2016/67 led to a utilisation of the ADI of 4% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is Milk: Cattle with 2% of the ADI.

The intended uses will not result in a consumer chronic exposure exceeding the ADI.

For the calculation of the acute exposure the MRL has been used only for the use under consideration. The highest International Estimated Short-Term Intake (IESTI) is at 0.1% and 0.05% of the ARfD for the consumption of rapeseeds/canola by children and by adults respectively.

The proposed uses of halauixifen-methyl in the formulation GF-4021 do not represent unacceptable acute and chronic risks for the consumer.

Picloram

The consumer risk assessments were performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMO). The calculation of the TMDI using EFSA model (version 3.1) and MRLs according to Reg. (EU) ~~2016/4~~ 2021/1531 led to a utilisation of the ADI of 2% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is Milk: Cattle with 1% of the ADI.

The intended uses will not result in a consumer chronic exposure exceeding the ADI.

For the calculation of the acute exposure the MRL has been used only for the use under consideration. The highest International Estimated Short-Term Intake (IESTI) is at 0.01% of the ARfD for the consumption of rapeseeds/canola by children and by adults.

The proposed uses of picloram in the formulation GF-4021 do not represent unacceptable acute and chronic risks for the consumer.

Aminopyralid

The consumer risk assessments were performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMO). The calculation of the TMDI using EFSA model (version 3.1) and MRLs according to Reg. (EU) ~~2019/1015~~ 2021/1841 led to a utilisation of the ADI of 1% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is Milk: Cattle with 0.5% of the ADI.

The intended uses will not result in a consumer chronic exposure exceeding the ADI.

For the calculation of the acute exposure the MRL has been used only for the use under consideration. The highest International Estimated Short-Term Intake (IESTI) is at 0.02% and 0.01% of the ARfD for the consumption of rapeseeds/canola by children and by adults respectively.

The proposed uses of aminopyralid in the formulation GF-4021 do not represent unacceptable acute and chronic risks for the consumer.

3.7 Environmental fate and behaviour (Part B, Section 8)

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

Soil exposure for halauxifen-methyl, picloram, aminopyralid and their relevant metabolites was calculated using approach described in respective FOCUS guidance for the intended uses of GF-4021. For all compounds, EU agreed data were taken into account. Soil exposure for the formulated product was also calculated. Obtained PEC_{SOIL} values were used in the risk assessment for soil organisms.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The leaching behaviour of halauxifen-methyl, picloram, aminopyralid and their relevant metabolites was assessed using FOCUS leaching models FOCUS PEARL v. 4.4.4 and FOCUS PELMO v. 5.5.3 on the basis of the EU agreed or modified input parameters and intended use pattern of GF-4021. Endpoints deviating from the EU data were all agreed by the zRMS.

Performed calculations resulted with PEC_{GW} values <0.1 µg/L for halauxifen-methyl, its relevant metabolites and picloram in all relevant Polish scenarios, demonstrating that no unacceptable leaching of these compounds is expected when GF-4021 is used according to recommendations.

Groundwater modelling performed for aminopyralid resulted with PEC_{GW} above the threshold concentration of 0.1 µg/L in some Polish scenarios following annual and biennial application. PEC_{GW} were all <0.1 µg/L when application frequency was restricted to one every third year.

Overall, in order to protect groundwater uses of GF-4021 must be restricted to one application every third year.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The surface water exposure for halauxifen-methyl, picloram, aminopyralid and their relevant metabolites was estimated using the respective FOCUS models. EU agreed or modified endpoints and intended use pattern of GF-4021 were considered. Endpoints deviating from the EU data were all agreed by the zRMS. The surface water exposure to the formulated product was calculated using Spray Drift Calculator. Obtained PEC_{SW} values were used in the risk assessment for aquatic organisms.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The fate and behaviour of halauxifen-methyl, picloram and aminopyralid in air was evaluated during the Annex I renewal. No additional studies are necessary.

As the vapour pressure of all three substances is below the trigger of 10⁻⁵ Pa, no significant volatilisation from soil and plant surfaces is expected. For this reason none of the substances is expected to be subject of the short- and long-range transport, even if the DT₅₀ in the atmosphere is estimated to be >2 days.

Overall, unacceptable contamination of the atmosphere following application of GF-4021 to winter oilseed rape is not expected.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Regulatory testing has been conducted with halauxifen-methyl, picloram and aminopyralid in accordance with EU requirements. The acute risks of GF-4021 to birds and mammals were assessed based on the

predicted toxicity endpoint and maximum predicted exposure based on the sum of the application rates of the active substances. To address the long-term combined risk the TERmix was calculated, as agreed in the Central Zone.

For the active substances and the mixture, the TERs calculated in the screening assessment all exceed the trigger values of 10 and 5 for acute and long-term risk, respectively, indicating acceptable risk to birds and mammals from application of GF-4021 according to the proposed Central Zone use pattern.

For halauxifen-methyl an acceptable risk from secondary poisoning to earthworm and fish-eating birds and mammals was shown. Due to the low potential for bioaccumulation ($\log Pow < 3$) the risk of secondary poisoning from halauxifen-methyl metabolites, picloram and aminopyralid is considered to be low.

Furthermore, the risk assessment for exposure *via* drinking water also showed acceptable risk for the active substances and their pertinent soil metabolites.

3.8.2 Effects on aquatic species

Regulatory testing has been conducted with halauxifen-methyl, picloram, aminopyralid, their respective metabolites and the product in accordance with EU requirements. Based on the active substances and product, the acute and chronic risk assessment for aquatic organisms indicated an acceptable risk to aquatic organisms from the use of GF-4021 in winter oilseed rape without the need for mitigation measures.

3.8.3 Effects on bees

Regulatory testing has been conducted with halauxifen-methyl, picloram and aminopyralid and the product in accordance with EU requirements. An acceptable acute and long-term risk to adult bees and bee larvae is concluded from the proposed use of GF-4021 in winter oilseed rape without the need for risk mitigation measures.

3.8.4 Effects on other arthropod species other than bees

Regulatory testing has been conducted with GF-4021 in accordance with EU requirements. An acceptable in- and off-field risk to non-target arthropods is concluded from the proposed use of GF-4021 in winter oilseed rape without the need for risk mitigation measures.

3.8.5 Effects on soil organisms

Regulatory testing has been conducted with halauxifen-methyl, picloram and aminopyralid and the product in accordance with EU requirements. An acceptable risk to soil macro- meso- and micro-organisms is concluded from the proposed use of GF-4021 in winter oilseed rape.

3.8.6 Effects on non-target terrestrial plants

Regulatory testing has been conducted with the product in accordance with EU requirements. An acceptable risk to terrestrial non-target plants is concluded from the proposed use of GF-4021 in winter oilseed rape with the use of any of the below mitigation measures:

- 1 m buffer zone with 75% drift reducing nozzles or
- 5 m buffer zone with without drift reducing nozzles.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No effects on other terrestrial organisms are anticipated if the previously proposed risk mitigations are implemented during applications of GF-4021 in winter oilseed rape.

3.9 Relevance of metabolites (Part B, Section 10)

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substances halauxifen-methyl, picloram and aminopyralid are not listed as the candidate for

substitution therefore the national comparative assessment is not required.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

None.

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Komentarz oceniających:

Etykieta została sprawdzona w zakresie fizykochemii, metod analitycznych, toksykologii i istotności toksykologicznej metabolitów, pozostałości losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich szarym podświetleniem tekstu (fragmenty dodane) lub ~~przekreśleniem i jasno-szarym cieniem~~ (fragmenty usunięte).

Zakres zmian jest następujący:

Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodne z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008r. nie jest wymagane.
2. Okres ważności: 2 letnie badania stabilności są w toku. Możliwe jest wydanie zgody warunkowo, na podstawie zaakceptowanych wyników 14-dniowego badania przyspieszonego starzenia w temperaturze 54°C środka przechowywanego w opakowaniach wykonanych z PET i COEX/PA (Wozniak, H., 191874, 2020). W związku z powyższym, wszystkie opakowania wymienione, w punktach 2.1 dokumentu A i 4.1 Sekcji 1 można uznać za odpowiednie do celów transportu i magazynowania środka ochrony roślin.
3. Brak uwag do punktów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin i opakowania oraz sporządzania cieczy użytkowej.
4. Brak uwag do zapisów nazw grup chemicznych, do których przyporządkowano substancje czynne. Dodano zawartości substancji czynnych wyrażone w procentach (zawartości substancji czynnych wyrażone w procentach obliczono w oparciu o gęstość środka ochrony roślin 0,946 g/ml zgodnie z danymi zawartymi w punkcie 1.2.1 dokumentu C).
5. Zgodnie z informacjami zawartymi w punktach IIIA 2.9.1 i IIIA 2.9.2 Sekcji 1,2,4 Raportu Rejestracyjnego środek nie jest dedykowany do łącznego stosowania.

Sekcja skuteczność:

1. Na podstawie badań w zakresie skuteczności, przedłożonych przez wnioskodawcę, możliwa jest rejestracja środka LaDiva do zwalczania chwastów dwuliściennych w rzepaku ozimym, w dawce 0,25 l/ha, w aplikacji jesiennej (BBCH 12-19), 1 raz w sezonie wegetacyjnym.
2. Z uwagi na to, że mieszanina zawarta we wnioskowanym środku jest nowa w Polsce, zaakceptowano chwasty występujące w 6 (chwasty o dużej szkodliwości) lub 3 badaniach skuteczności (chwasty mniej istotne). W ustaleniu ważności gatunkowej chwastów posługiwano się Metodą integrowanej ochrony rzepaku ozimego oraz jarego dla doradców (IOR Poznań, 2019).
3. Biorąc pod uwagę powyższe, wymogu tego nie spełniły następujące gatunki chwastów, które nie zostały uwzględnione w projekcie etykiety: bodziszek kosmaty (przedłożono 2 badania w fazie 12-14 i 1 badanie w fazie 14-19), bodziszek porożcinany (przedłożono po 1 badaniu w fazach 12-14 i 14-19), stulicha psia (przedłożono 2 badania w fazie 14-19) oraz przytulia czepna (przedłożono 4 badania w fazie 14-19).
4. Z uwagi na różnice we wrażliwości chwastów w zależności od aplikacji powschodowej wcześniejszej lub późniejszej, w etykiecie doprecyzowano odpowiednie fazy BBCH rzepaku, dla których środek jest najbardziej efektywny.
5. Poprawiono fazę końcową BBCH, w której środek może być stosowany na rzepaku ozimym (w części STOSOWANIE ŚRODKA). Zgodnie z tabelą GAP jest to faza BBCH 19 (9 liści właściwych).
6. Środek może powodować przemijające objawy fitotoksyczności m.in. deformacje lub zahamowanie wzrostu. Uwagę tę umieszczono w projekcie etykiety.
7. W zakresie sekcji skuteczność przedłożono 3 badania dla oceny wpływu środka na uprawy następne. Jedynym gatunkiem, na którym testowano środek był słonecznik. Wyniki badań wskazują, że może być on wysiany po zastosowaniu środka LaDiva, niezależnie od terminu zabiegu. Jakkolwiek ostateczny zapis w tej części etykiety ustalono na podstawie oceny sekcji pozostałości. **Uzupełniono zapis na podstawie wyników badań przedłożonych na etapie komentowania.**
8. Ponadto przedłożono 3 badania dla oceny wpływu na uprawy sąsiednie. Zgodnie z wynikami badań istnieje ryzyko uszkodzenia lucerny, w związku z czym rekomendowane jest zachowanie dystansu w odległości 3m. Zapis wprowadzono do etykiety. **Uzupełniono zapis na podstawie wyników badań przedłożonych na etapie komentowania.**
9. Zgodnie z aktualną klasyfikacją MoA HRAC, substancje czynne haloaktyfen metylu, aminopyralid, oraz pikloram zaliczane są do grupy 4 (dawniej O).

10. Do etykiety wprowadzono dodatkowy zapis w strategii antyodpornościowej wynikający z rotacji uprawianych po sobie gatunków. Celem uniknięcia wykształcenia się genotypów odpornych, zaleca się stosowanie innych niż herbicydy auksynowe grup chemicznych do zwalczania chwastów w zbożach uprawianych po rzepaku.
11. Nie przedłożono dodatkowych badań wpływu opadów deszczu na wykonany zabieg opryskiwania. W związku z brakiem potwierdzenia co do rekomendacji zaproponowanej w etykiecie, usunięto ją z części ŚRODKI OSTROŻNOŚCI.
12. Uzupełniono zapis dotyczący mycia aparatury po zabiegu.
13. W wyniku ponownej analizy wyników badań skuteczności, zmianie uległa klasyfikacja wrażliwości maku polnego. Jest to chwast wrażliwy na działanie środka.

Sekcja metody analityczne:

1. Brak uwag.

Sekcja toksykologia i istotność toksykologiczna metabolitów:

1. W części dotyczącej klasyfikacji zagrożeń zmodyfikowano frazę P280 zgodnie z CLP biorąc pod uwagę wyniki badań toksykologicznych,
2. W części dotyczącej środków ostrożności dla osób stosujących środek zapis zmieniono odpowiednio do szacowania NDE oraz szacowania zagrożeń, zgodnie z wytyczną harmonizacją MRiRW.

Sekcja pozostałości:

1. Dodano zapis dotyczący następstwa roślin. W przypadku wcześniejszej likwidacji plantacji można sadzić lub siać rośliny liściowe co najmniej 120 dni od ostatniego zastosowania środka LaDiva.

Sekcja los i zachowanie w środowisku:

1. Dodano informację o możliwości stosowania środka oraz innych środków zawierających aminopyralid na tym samym polu jeden raz co trzy lata (zwrot SPe 1).

Sekcja ekotoksykologia:

1. Dodano zwrot P391.
2. Poprawiono brzmienie zwrotu P501.
3. Usunięto zarządzenia ryzykiem dla stawonogów lądowych (ocena wykazała dopuszczalne ryzyko dla tej grupy organizmów bez konieczności stosowania narzędzi zarządzania ryzykiem).

Posiadacz zezwolenia:

Corteva Agriscience Polska Sp. z o.o., ul. Józefa Piusa Dziekońskiego 1, 00-728 Warszawa, tel.: +48 22 548 73 00, fax: +48 22 548 73 09, e-mail: biuro@corteva.com, www.corteva.pl


LADIVA

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

halauksyfen metylu – Arylex™ (substancja z grupy związków arylopykolinowych) – 10,6 g/l (1,06%)
pikloram (substancja z grupy pochodnych kwasu pirydynokarboksylowego) – 48 g/l (5,07%)
aminopyralid (substancja z grupy pochodnych kwasu pirydynokarboksylowego) – 32 g/l (3,38%)

Zezwolenie MRiRW nr R

	
Niebezpieczeństwo	
H315	Działa drażniąco na skórę.
H318	Powoduje poważne uszkodzenie oczu.
H335	Może powodować podrażnienie dróg oddechowych.

H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P261 P280 P302 + P352 P304+P340 P305 + P351 + P338 P310 P391 P501	Unikać wdychania rozpylonej cieczy. Stosować rękawice ochronne/ odzież ochronną / ochronę oczu/ ochronę twarzy. W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody. W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH; wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić warunki do odpoczynku w pozycji umożliwiającej swobodne oddychanie. W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ lub lekarzem. Zebrać wyciek Zawartość/pojemnik usuwać do recyklingu bądź składowania na składowiskach odpowiednich dla pestycydów lub spalania w odpowiednich instalacjach Zawartość/pojemnik usuwać do ...

OPIS DZIAŁANIA

HERBICYD selektywny o działaniu układowym, stosowany nalistnie w postaci koncentratu do sporządzania emulsji wodnej (EC).

Zgodnie z klasyfikacją HRAC substancje czynne: haloaksyfen metylu, aminopyralid, oraz pikloram zaliczane są do grupy 4 (dawniej O).

DZIAŁANIE NA CHWASTY

Środek pobierany jest poprzez liścienie i liście chwastów, a następnie szybko przemieszcza się w roślinie. Pierwszym objawem działania herbicydu jest zahamowanie wzrostu, następnie chwasty ulegają deformacji, powstają chlorozy prowadzące do nekroz i zamierania. Objawy wizualne zależą od gatunków chwastów i mogą pojawić się od kilku dni do kilku tygodni po zabiegu.

Środek najskuteczniej niszczy chwasty znajdujące się w fazie 2 – 6 liści.

Dawka 0,25 l/ha

Chwasty wrażliwe:	bodziszek drobny, chaber bławatek, dymnica pospolita, komosa biała (w fazie rzepaku BBCH 12-14), jasnota różowa purpurowa, przytulia czepna (w fazie rzepaku BBCH 12-14), rumianek pospolity, tasznik pospolity, stulicha psia (w fazie rzepaku BBCH 12-14), bodziszek kosmaty , mak polny , maruna bezwonna, bodziszek porożcinany , niezapominajka polna, przetacznik perski (w fazie rzepaku BBCH 12-14)
Chwasty średnio wrażliwe:	tobołki polne (w fazie rzepaku BBCH 12-14), gwiazdnica pospolita, przetacznik perski , fiołek polny, mak polny , komosa biała (w fazie rzepaku BBCH 14-19)
Chwasty odporne:	przetacznik perski (w fazie rzepaku BBCH 14-19), tobołki polne (w fazie rzepaku BBCH 14-19)

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego.

Rzepak ozimy

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,25 l/ha

Termin stosowania: środek stosować jesienią, w fazie 2 - 4 **9** liści właściwych rzepaku (BBCH 12-16-**19**)

UWAGA:

Ze względu na możliwe objawy fitotoksyczności, należy upewnić się, że 100% roślin rzepaku znajduje się w fazie co najmniej 2 liści właściwych.

UWAGA:

Podczas zabiegu należy upewnić się, że chwasty nie są całkowicie zakryte przez roślinę uprawną.

Zalecana ilość wody: 100-300 l/ha.

Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Nie dotyczy

1. Strategia zarządzania odpornością

Środek jest herbicydem zawierającym substancje czynne: haloalksyfen metylu-Arylex, pikloram oraz aminopyralid. Mimo, że ryzyko wystąpienia odporności na substancje z grupy syntetycznych auksyn jest niskie, aby zminimalizować to ryzyko należy postępować zgodnie z Dobrą Praktyką Rolniczą:

- postępować zgodnie z zaleceniami zawartymi w etykiecie środka ochrony roślin – stosować środek w zalecanej dawce oraz w terminie zapewniającym najlepsze zwalczanie chwastów,
- dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
- używać różnych metod kontroli zachwaszczenia, w tym rotację upraw, itp.,
- stosować rotację / mieszanki herbicydów o różnym mechanizmie działania,
- stosować w rotacji i/lub mieszanki herbicydów działające na kilka procesów życiowych chwastów,
- stosować herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
- informować posiadacza zezwolenia o niesatysfakcjonującym poziomie zwalczania chwastów,
- **zaleca się stosowanie innych niż herbicydy auksynowe grup chemicznych do zwalczania chwastów w zbożach uprawianych jako rośliny następcze po rzepaku**
- w celu uzyskania szczegółowych informacji należy skontaktować się z doradcą lub z producentem środka ochrony roślin.

2. Warunki stresowe (długotrwała susza, spadki temperatury poniżej 2°C, przymrozki, uszkodzenia wywołane przez choroby lub szkodniki) w trakcie lub po zastosowaniu środka mają negatywny wpływ na działanie herbicydu, które może skutkować obniżeniem plonowania rzepaku.

3. ~~Środek wnika do rośliny w ciągu 1 godziny od zastosowania. Opady deszczu po tym okresie czasu nie wpływają ujemnie na działanie środka.~~

4. Środka nie stosować:

- **w mieszaninach zbiornikowych z fungicydami zawierającymi metkonazol lub tebukonazol,**
- **w mieszaninach zbiornikowych z graminicydami,**
- **w mieszaninach zbiornikowych z nawozami zawierającymi bor,**
- na rośliny mokre, chore i uszkodzone,
- w temperaturze powietrza poniżej 2°C i powyżej 25°C,
- w czasie nadmiernej suszy,
- po nocnych przymrozkach oraz przed spodziewanymi przymrozkami.

5. Środek może powodować przemijające objawy fitotoksyczności (np. deformacje lub zahamowanie wzrostu).

6. W czasie stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych,
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach

- nie przewiduje się negatywnego wpływu na sąsiednie uprawy podczas stosowania środka, z wyjątkiem lucerny, gdzie należy zachować dystans co najmniej 3 m. zaleca się stosowanie nieopryskiwanej strefy buforowej długości 5 m bez dysz redukujących znoszenie lub 1 m z dyszami redukującymi znoszenie w 75% dla ochrony sąsiednich plantacji. Ponadto, w przypadku lucerny należy zachować dystans co najmniej 3 m. Zabieg powinien być wykonywany zgodnie z zasadami dobrej praktyki rolniczej, jak również zaleca się zachować szczególną ostrożność w pobliżu wrażliwych upraw.

NASTĘPSTWO ROŚLIN

W przypadku wcześniejszego zaorania plantacji potraktowanej środkiem LaDiva (w wyniku uszkodzenia roślin przez przymrozki, mrozy, choroby lub szkodniki) na polu tym można uprawiać - rzepak jary, gorczycę, kapustę z rozsady, **trawę**, zboża lub kukurydzę, jednak nie wcześniej niż po czterech miesiącach od zastosowania środka i po wykonaniu orki na głębokość minimum 15 cm. Taki sam okres karencji dotyczy sadzenia lub siania roślin liściowych (120 dni).

Po zastosowaniu środka, roślinami następczymi mogą być:

- jesienią następnego roku kalendarzowego - zboża, rzepak ozimy, gorczyca, trawy, kukurydza, kapustę z rozsady, **rośliny strączkowe**
 - wiosną kolejnego roku kalendarzowego (po upływie 18 miesięcy od zastosowania środka) - wszystkie rośliny.
- Słoma z roślin opryskanych środkiem LaDiva nie może być użyta do ściółkowania międzyrzędzi w uprawie truskawek oraz do produkcji podłoża dla truskawek, tytoniu, upraw grzybowych (w tym dla pieczarek), ani dla upraw warzyw np. pomidora, papryki, ogórka i innych roślin dyniowatych, sałaty i innych warzyw.
 - Herbicyd LaDiva zawarty w resztkach poźniwnych rzepaku (słoma, ściern) ulega rozkładowi mikrobiologicznemu dopiero po ich wymieszaniu z glebą.
 - Słomę oraz obornik i kompost wytworzone ze słomy potraktowanej środkiem LaDiva należy wykorzystać tylko w obrębie własnego gospodarstwa, w którym użyto ten środek.
 - Słoma z roślin potraktowanych herbicydem LaDiva może być użyta / sprzedana poza gospodarstwo tylko w przypadku przeznaczenia jej na cele energetyczne – spalanie.
 - Słoma z roślin opryskanych środkiem LaDiva nie może być stosowana do produkcji biogazu.
 - Najlepszym sposobem na zagospodarowanie słomy pochodzącej z roślin opryskanych środkiem, jest jej pozostawienie na polu i przyoranie.
 - Słoma oraz inne resztki poźniwne (ściern, łuszczyzny) oraz obornik ze słomy pochodzącej z plantacji, na której stosowano LaDiva, może być zastosowany i wymieszany z glebą tuż przed siewem rzepaku, kukurydzy, zbóż oraz traw bez wsiewki roślin bobowatych.
 - Przed uprawą buraków, ziemniaków, roślin strączkowych, słonecznika, pomidorów, papryki, ogórków i innych roślin dyniowatych, sałaty, marchwi, pietruszki i innych warzyw oraz tytoniu, słoma oraz inne resztki poźniwne (ściern, łuszczyzny) oraz obornik ze słomy pochodzącej z plantacji, na której stosowano LaDiva, muszą być wymieszane z glebą minimum 6 miesięcy przed ich siewem lub sadzeniem.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy, ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć oraz przepłukać ją co najmniej trzykrotnie. Płukanie wykonać przy użyciu czystej wody w zbiorniku wypełnionym do co najmniej 10% jego objętości. Płukanie pośrednie wykonać przy użyciu środka myjącego. Niewystarczające wymycie aparatury po zabiegu i pozostawienie resztek środka w opryskiwaczu może być przyczyną silnych uszkodzeń roślin uprawnych wrażliwych na ten środek.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej, i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

~~Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kałosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.~~

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież roboczą (kombinezon), w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu

Unikać zanieczyszczenia oczu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):
nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

W celu ochrony wód podziemnych nie stosować na tym samym polu tego ani żadnego innego produktu zawierającego aminopyralid częściej niż co trzy lata.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.

W celu ochrony roślin ~~oraz stawonogów~~ niebędących celem działania środka konieczne jest wyznaczenie od terenów nieużytkowanych rolniczo strefy ochronnej o szerokości:

- 5 m lub
- 1 m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0°C - 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku kontaktu ze skórą: Umyć dużą ilością wody.

W przypadku dostania się do dróg oddechowych: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić warunki do odpoczynku w pozycji umożliwiającej swobodne oddychanie

W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

No letters of access is necessary for the current submission, as halauxifen-methyl, picloram and aminopyralid are Corteva Agriscience (Dow AgroSciences) active substances.

Appendix 4 Lists of data considered for national authorization

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 KCP 2.3.1 KCP 2.5.1 KCP 2.6.1	Terrill, M.	2020	Determination of Color, Physical State, Odor, Oxidizing and Reducing Action, Flammability, pH, Viscosity, and Density of GF-4021, an End Use Product Containing Aminopyralid, Halauxifen-methyl, and Picloram. DAS Report No.: 191969. Crop Protection Product Design and Process R&D. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 2.2.1 KCP 2.2.2 KCP 2.3.3 KCP 2.5.2	Comb, T.	2020	Determination of Surface Tension, Explosive Properties, Auto-Ignition Temperature and Oxidising Properties of GF-4021. DAS Report No.: 191970 AgroChemex Environmental LTD GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 2.4.1 KCP 2.4.2/01 KCP 2.7.1 KCP 2.7.4 KCP 2.8.2 KCP 2.8.6.1	Wozniak, H.	2020	GF-4021 Two Week 54°C Accelerated Storage Stability in PET and COEX and One Week 0°C Low Temperature Stability. DAS Report No.: 191874 Crop Protection Product Design and Process R&D. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 2.7.2			Ambient Storage Stability Study of GF-4021 (Study ongoing and will be provided upon completion). DAS Report No.: 191875 GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 2.4.2/02	Wolok, R.	2021	Metal Compatibility for GF-4021. Metal Compatibility Letter, October 5, 2021 GLP (Y/N): N Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1	Cordero Henriquez, L.	2020	Analytical Method and Validation for the Determination of Aminopyralid, Picloram and Halauxifen-Methyl in GF-4021 Formulation. DAS Report No.: AM-191129. Product and Process Technology R&D, Dow AgroSciences LLC. GLP (Y/N): Y. Published (Y/N): N.	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 5.1.1	McNew, B.	2020	Analytical Method and Validation for the Determination of HCB in GF-4021. DAS Report No.: AM-192060. Product and Process Technology R&D, Dow AgroSciences LLC. GLP (Y/N): Y.	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 5.1.2 (for the full summary please see KCP 10.2.1)	Goudie, O., et al.	2020	GF-4021: A 72-Hour Toxicity Test with the Freshwater Alga (<i>Raphidocelis subcapita</i>) DAS Report No.: 190111 Eurofins EAG Agorscience, LLC GLP (Y/N): Y. Published (Y/N): N.	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 5.1.2 (for the full summary please see KCP 10.2.1)	Eser, S.	2020	GF-4021: Growth Inhibition of Myriophyllum spicatum in a Water/Sediment System DAS Report No.: 190151 Eurofins Agrosience Services EcoChem GmbH GLP (Y/N): Y. Published (Y/N): N.	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Vogl, E.	2012	Method Validation Study for the Determination of Residues of Clopyralid and Picloram in Agricultural Commodities by LC-MS/MS DAS Report No.: 120610 ABC Laboratories, Inc. GLP (Y/N): Y. Published (Y/N): N.	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2	Austin, R.	2012	Independent Laboratory Validation of Dow AgroSciences Method 120610, “Method Validation Study for the Determination of Residues of Clopyralid and Picloram in Agricultural Commodities by LC-MS/MS” DAS Report No.: 120614 Battelle UK Ltd. GLP (Y/N): Y. Published (Y/N): N.	N	Y	The study was first submitted in frames of “Belkar” (GF-3447) dossier, and the data protection started on the 23 rd July 2018, upon the registration R-132/2018 entry into force.	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Vincent, T.	2013	Method Validation Study for the Determination of Residues of Picloram in Bovine and Poultry Matrices by Liquid Chromatography with Tandem Mass Spectrometry Detection DAS Report No.: 120622 ABC Laboratories, Inc. GLP (Y/N): Y. Published (Y/N): N.	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Austin, R.	2013	Independent Laboratory Validation of Dow AgroSciences Method 120622, “Method Validation Study for the Determination of Residues of Picloram in Bovine and Poultry Matrices by Liquid Chromatography with Tandem Mass Spectrometry Detection” DAS Report No.: 120607 Battelle UK Ltd. GLP (Y/N): Y. Published (Y/N): N.	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Vincent, T. P.	2013	Method Validation Study for the Determination of Residues of Clopyralid and Picloram in Soil by LC-MS/MS. DAS Report No.: 120612. ABC Laboratories, Inc. GLP (Y/N): Y. Published (Y/N): N.	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Shaffer, S. R.	2012	Method Validation Study for the Determination of Residues of Clopyralid and Picloram in Drinking Water, Ground Water, and Surface Water by LC-MS/MS DAS Report No.: 120611 ABC Laboratories, Inc. GLP (Y/N): Y. Published (Y/N): N.	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2	Austin, R., Turner, R.	2012	Independent Laboratory Validation of Dow AgroSciences Method 120611, “Method Validation Study for the Determination of Residues of Clopyralid and Picloram in Drinking Water, Ground Water, and Surface Water by LC-MS/MS” DAS Report No.: 120613 Battelle UK Ltd. GLP (Y/N): Y. Published (Y/N): N.	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Bacher, R.	2012	The Development and Validation of a Method for the Analysis of Picloram in Air DAS Report No.: 120603 PTRL Europe GMBH. GLP (Y/N): Y. Published (Y/N): N.	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Sencuic, M., Schmiedt, S.	2016	Development and Validation of a Method for the Analysis of Picloram, Aminopyralid and Triclopyr (All Free Acids) in Body Fluids. DAS Report No.: 160866 EAG Laboratories, PTRL Europe. GLP (Y/N): Y. Published (Y/N): N.	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 5.2 (for the full summary please see KCP 8/ KCA 6.6.2)	White, T.	2019	Determination of Residues of Picloram in Rotational Crops (Wheat, Turnip and Kale) After One Application of GF-224 to Bare Soil at Two Sites in Northern Europe and Two Sites Southern Europe 2014 – 2017 DAS Report No.: 140651 Eurofins Agrosience Services Ltd. GLP (Y/N): Y. Published (Y/N): N.	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 5.2 (for the full summary please see KCP 8/ KCA 6.6.2)	White, T.	2019	Determination of Residues of Picloram in Winter and Spring Wheat Grown as Rotational Crops After One Application of GF-224 to Bare Soil at Eight Sites in Northern Europe and Eight Sites in Southern Europe 2014-2016 DAS Report No.: 140652 Eurofins Agrosience Services Ltd. GLP (Y/N): Y. Published (Y/N): N.	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2 (for the full summary please see KCP 8/ KCA 6.6.2)	Delmotte, R.	2016	Magnitude of the Residues of Halauxifen methyl and Picloram in Oilseed rape (RAC Whole plant, Seed, and Straw), following One Application of GF-3447, Northern and Southern Europe – 2015 DAS Report No.: 150006 Staphyt GLP (Y/N): Y. Published (Y/N): N.	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 7.1.1	2020	Acute Oral Toxicity Study of GF-4021 In Rats. DAS Report No.: 190369 GLP (Y/N): Y Published (Y/N): N	Y	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 7.1.2	2020	Acute Dermal Toxicity Study of GF-4021 In Rats. DAS Report No.: 190373. GLP (Y/N): Y Published (Y/N): N	Y	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 7.1.3	2020	Acute Inhalation Toxicity Study of GF-4021 In Rats. DAS Report No.: 190377. GLP (Y/N): Y Published (Y/N): N	Y	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 7.1.4	2020	Acute Dermal Irritation Study of GF-4021 In Rabbits. DAS Report No.: 190381. GLP (Y/N): Y Published (Y/N): N	Y	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 7.1.5/01	2020	GF-4021: Bovine Corneal Opacity And Permeability Assay. DAS Report No.: 200696. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.5/02	2020	GF-4021: EPIOCULAR™ Eye Irritation Test (EIT) For Identifying Chemical Not Requiring Classification And Labelling For Eye Irritation Or Serious Eye Damage. DAS Report No.: 190394. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 7.1.6	2020	Skin Sensitisation Study of GF-4021 By Local Lymph Node Assay In Mice. DAS Report No.: 190544. ... GLP (Y/N): Y Published (Y/N): N	Y	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 8 (KCA 6.1)	Machado, G.	2013	Frozen Storage Stability of Aminopyralid (XDE-750) in Rape Forage, Seed and Oil DAS Report No.: 110634 Dow AgroSciences Ind. Ltda. GLP (Y/N): Y Published (Y/N): N	N	Y	The study was first submitted in frames of “KLIPER™ Herbicide” (GF-2545) dossier, and the data protection started on the 25 th September 2015, upon the registration R-154/2015 and/or R-153/2015 entry into force.	Corteva Agriscience (Dow AgroSciences)
KCP 8 (KCA 6.1)	Lindner, M.	2014	Storage Stability Study for Residues of Aminopyralid in Barley Grain, Malt Sprouts, Spent Grains, Yeast and Beer DAS Report No.: S08-02908 Eurofins Agrosience Services Chem GmbH GLP (Y/N): Y Published (Y/N): N	N	Y	The study was first submitted in frames of “Kantor Forte 195 SE” (GF-1810) dossier, and the data protection started on the 11 th February 2015, upon the registration R-25/2015 entry into force.	Corteva Agriscience (Dow AgroSciences)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 8 (KCA 6.1)	Delmotte, R.	2016	Title: Magnitude of the Residues of Halauxifen-methyl and Picloram in Oilseed rape (RAC Whole Plant, Seed and Straw), following One Application of GF-3447, Northern and Southern Europe – 2015 RDE-15-20345. DAS Report No.: 150006 Source: Dow AgroSciences GLP (Y/N): Y Published (Y/N): N	N	Y	The study was first submitted in frames of “Belkar” (GF-3447) dossier, and the data protection started on the 23 rd July 2018, upon the registration R-132/2018 entry into force.	Corteva Agriscience (Dow AgroSciences)
KCP 8 (KCA 6.2.1)	LaMar, J. E.	2013	The Nature of the Residues of [¹⁴ C] XDE-729 Methyl (2 Radiolabels) in Oilseed Rape DAS Study No. 120997 PTRL West GLP/GEP (Y/N): Yes Published (Y/N): No	N			Corteva Agriscience (Dow AgroSciences)
KCP 6.5.1	Croffie, J. W., Adelfinskaya, Y., Hastings, M.	2016	A Confined Rotational Crop Study with 14C-Picloram. DAS Report No.: 130200 Research For Hire GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 8 (KCA 6.6.2)	White, T.	2017	Determination of residues of picloram in winter and spring wheat grown as rotational crops after one application of GF-224 to bare soil at eight sites in Northern Europe and eight sites in Southern Europe 2014 – 2016 DAS Report No.: 140642 Dow AgroSciences GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 8 (KCA 6.6.2)	White, T.	2019	Determination of Residues of Picloram in Rotational Crops (Wheat, Turnip and Kale) After One Application of GF-224 to Bare Soil at Two Sites in Northern Europe and Two Sites in Southern Europe 2014-2017. DAS Report No.: 140651 Eurofins Agroscience Services Ltd. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 7.3.1	Kennedy, S.	2008	Dissipation of picloram in soil following a single application of GF-224 to bare soil, Northern Europe-2007. DAS Report No.: GHE-P-11837. CEMAS GLP (Y/N): Y Published (Y/N): N	N	Y	The study was first submitted in frames of “Belkar” (GF-3447) dossier, and the data protection started on the 23 rd July 2018, upon the registration R-132/2018 entry into force. It was also relied upon at the Central Zone level for formulation GF-224 SL (Galera) in 2014	Corteva Agriscience (Dow AgroSciences)
KCA 7.3.1	Knowles, S.	2008	Calculation of field kinetics for picloram from two additional field dissipation studies and two accepted studies using FOCUS Kinetics methodology and Q_{10} value = 2.5. DAS Report No.: GHE-P-11865. Dow AgroSciences GLP (Y/N): N Published (Y/N): N	N	N	N Not applicable for calculations	Corteva Agriscience (Dow AgroSciences)
KCA 7.4.1	Simmonds, M.	2010	[¹⁴ C]-Picloram: Adsorption to and desorption from five soils. DAS Report No.: 101391. Battelle UK Ltd. GLP (Y/N): Y Published (Y/N): N	N	Y	The study was first submitted in frames of “Belkar” (GF-3447) dossier, and the data protection started on the 23 rd July 2018, upon the registration R-132/2018 entry into force. It was also relied upon at the Central Zone level for formulation GF-224 SL (Galera) in 2014	Corteva Agriscience (Dow AgroSciences)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.2.4	Reeves, G.	2020	FOCUS groundwater modelling for halauxifen-methyl and its metabolites following early post-emergence use in winter oilseed rape at 2.5 g as/ha. DAS Report No.: 201596. Dow AgroSciences GLP (Y/N): N Published (Y/N): N	N	N Not applicable for calculations ∓	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 9.2.4	Reeves, G.	2020	FOCUS groundwater modelling for picloram following early post-emergence use in winter oilseed rape at 12 g as/ha. DAS Report no.: 201597. Dow AgroSciences GLP (Y/N): N Published (Y/N): N	N	N Not applicable for calculations ∓	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 9.2.4	Reeves, G.	2020	FOCUS groundwater modelling for aminopyralid following early post-emergence use in winter oilseed rape at up to 8 g as/ha. DAS Report No.: 201598. Dow AgroSciences GLP (Y/N): N Published (Y/N): N	N	N Not applicable for calculations ∓	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 9.2.5	Reeves, G.	2020	FOCUS surface water modelling for halauxifen-methyl and its metabolites following early post-emergence use in winter oilseed rape at 2.5 g as/ha. DAS Report No.: 201599. Dow AgroSciences GLP (Y/N): N Published (Y/N): N	N	N Not applicable for calculations ∓	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 9.2.5	Reeves, G.	2020	FOCUS surface water modelling for picloram and its metabolites following early post-emergence use in winter oilseed rape at 12 g as/ha. DAS Report No.: 201600. Dow AgroSciences GLP (Y/N): N Published (Y/N): N	N	N Not applicable for calculations ∓	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.2.5	Reeves, G.	2020	FOCUS surface water modelling for aminopyralid and its metabolites following early post-emergence use in winter oilseed rape at up to 8 g as/ha. DAS Report No.: 201601. Dow AgroSciences GLP (Y/N): N Published (Y/N): N	N	N Not applicable for calculations ≠	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 10.2.1/01	Banman, C.S.; Moore, S.	2015	Picloram: Toxicity to the Aquatic Macrophyte, <i>Myriophyllum spicatum</i> . DAS Report No.: 140737. SynTech Research Laboratory Services LLC. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 10.2.1/02	Gonsior, G.	2015	Picloram metabolite 5,6-dichloropicloram: Growth Inhibition of <i>Myriophyllum spicatum</i> in a Water/Sediment System. DAS Report No.: 150390. Eurofins Agrosience Services EcoChem GmbH. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 10.2.1/03	Eser, S.	2020	GF-4021: Growth Inhibition of <i>Myriophyllum spicatum</i> in a Water/Sediment System. DAS Report No.: 190151. Eurofins Agrosience Services Ecotox GmbH. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 10.2.1/04	Goudie, O.	2020	GF-4021: A 72-Hour Toxicity Test with the Freshwater Alga, <i>Raphidocelis subcapitata</i> . DAS Report No.: 190111. Eurofins EAG Agrosience, LLC. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 10.3.1.1/01 KCP 10.3.1.2/01	Tomé, H.V.V.; Porch, J.R.	2020	GF-4021: An Acute Oral and Contact Toxicity Study with Honey Bee. DAS Report No.: 190458. Eurofins EAG Agrosience LLC GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)

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KCP 10.3.1.2/01	Wendling, K.	2021a	GF-4021: Assessment of the Effects on the Adult Honey Bee, <i>Apis mellifera</i> L., in a 10 day Chronic Feeding Test Under Laboratory Conditions. DAS Report No.: 200622. GLP (Y/N): Y Published (Y/N): N Study ongoing and will be submitted upon completion in February-2021.	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 10.3.1.3/01	Wendling, K.	2021b	GF-4021: – Honey Bee (<i>Apis mellifera</i> L.) 22 Day Larval Toxicity Test (Repeated Exposure). DAS Report No.: 200623. GLP (Y/N): Y Published (Y/N): N Study ongoing and will be submitted upon completion in February-2021.	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 10.3.1.2/02	Oberrauch, S.	2018	XDE 729 Methyl: Assessment of the Effects on the Adult Honey Bee, <i>Apis mellifera</i> L., in a 10 day Chronic Feeding Test Under Laboratory Conditions. DAS Report No.: 170071. Eurofins Agroscience Services EcoChem GmbH/Eurofins Agroscience Services Ecotox GmbH. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 10.3.1.2/03	Lenard, J.; Moore, S.	2017	Pieloram: A laboratory Study to Determine the Chronic Oral Toxicity to the Adult Worker Honey Bee <i>Apis mellifera</i> L. (Hemiptera: Apidae). DAS Report No.: 170090. SynTech Research Laboratory Services LLC. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 10.3.1.2/04	Lenard, J.; Moore, S.	2017	Aminopyralid: A laboratory Study to Determine the Chronic Oral Toxicity to the Adult Worker Honey Bee <i>Apis mellifera</i> L. (Hemiptera: Apidae). DAS Report No.: 170092. SynTech Research Laboratory Services LLC. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)

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KCP 10.3.1.3/02	Oberrauch, S.	2018	XDE 729 Methyl—Honey Bee (<i>Apis mellifera</i> L.) 22 Day Larval Toxicity Test (Repeated Exposure). DAS Report No.: 170073. Eurofins Agrosience Services EcoChem GmbH/Eurofins Agrosience Services Ecotox GmbH. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 10.3.1.3/03	Lenard, J.; Moore, S.	2017	Picloram: A Repeated Exposure Laboratory Toxicity Study in Larvae, Pupae and Emergent Adults of the Honey Bee <i>Apis mellifera</i> Linnaeus. (Hymenoptera: Apidae). DAS Report No.: 170091. SynTech Research Laboratory Services LLC. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 10.3.1.3/04	Lenard, J.; Moore, S.	2017	Aminopyralid: A Repeated Exposure Laboratory Toxicity Study in Larvae, Pupae and Emergent Adults of the Honey Bee <i>Apis mellifera</i> Linnaeus. (Hymenoptera: Apidae). DAS Report No.: 170413. SynTech Research Laboratory Services LLC. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 10.3.2/01	Fallowfield, L.	2020	GF-4021: A Rate-Response Laboratory Study of the Effects of Fresh Residues on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae). DAS Report No.: 190467. Mambo-Tox A Division of Cawood Scientific Ltd. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 10.3.2/02	Stevens, J.	2020	GF-4021: A Rate-Response Laboratory Study of the Effects of Fresh Residues on the Parasitic Wasp <i>Aphidius rhopalosiphii</i> (Hymenoptera, Braconidae). DAS Report No.: 190464. Mambo-Tox A Division of Cawood Scientific Ltd. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)

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KCP 10.4.1.1/01	McCormac, A.	2020	GF-4021: Determination of Chronic Toxicity to the Earthworm <i>Eisenia andrei</i> (Oligochaeta: Lumbricidae) in an artificial soil substrate. DAS Report No.: 190475. Mambo-Tox A Division of Cawood Scientific Ltd. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 10.5/01	Hammesfahr, U.	2020	GF-4021: Effects on the Activity of the Soil Microflora in the Laboratory. DAS Report No.: 190194. Ibacon GmbH GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 10.6.2/01	Bramby-Gunary, J.	2020a	GF-4021 Seedling Emergence and Seedling Growth Terrestrial Non Target Plants. DAS Report No.: 190546. AgroChemex Ltd. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)
KCP 10.6.2/02	Bramby-Gunary, J.	2020b	GF-4021 Vegetative Vigour Terrestrial Non Target Plants. DAS Report No.: 190545. AgroChemex Ltd. GLP (Y/N): Y Published (Y/N): N	N	Y	The study is submitted to Member State Poland for the first time.	Corteva Agriscience (Dow AgroSciences)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2	Olberding, E. L	2011	Determination of Residues of XDE-729 Methyl Ester and XDE-729 Acid in Agricultural Commodities and Wheat Processed Products using Online Solid-Phase Extraction and Liquid Chromatography with Tandem Mass Spectrometry DAS Report No.: 110005 Dow AgroSciences LLC, Indianapolis, Indiana, United States GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Robaugh, D. A.	2012	Independent Laboratory Validation of Method for the Determination of Residues of XDE-729 Methyl Ester and XDE-729 Acid in Agricultural Commodities and Wheat Processed Products using Offline Solid-Phase Extraction and Liquid Chromatography with Tandem Mass Spectrometry DAS Report No.: 110825 Pyxant Labs Inc, Colorado Springs, Colorado, United States GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Ma, M.; Li, Q	2012	Method Validation Study for the Determination of Residues of XDE-729 Methyl Ester and XDE-729 Acid in Bovine and Poultry Tissues using Offline Solid-Phase Extraction and Liquid Chromatography with Tandem Mass Spectrometry Detection DAS Report No.: 110505 Dow AgroSciences LLC, Indianapolis, Indiana, United States GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2	Langridge, G	2012	Independent Laboratory Validation of an Analytical Method for the Determination of XDE-729 Methyl Ester and XDE-729 Acid in Animal Matrices DAS Report No.: 110828 CEM Analytical Services Ltd Glendale Park (CEMAS), North Ascot, Berkshire, United Kingdom GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Blakeslee, B. A.	2012	Method Validation Study for the Determination of Residues of X11393728 (XDE-729 Methyl), X11393729 (XDE-729 Acid) and X11449757 (des-Methyl XDE-729 Acid) in Soil using High Performance Liquid Chromatography with Positive-Ion Electrospray Ionization Mass S DAS Report No.: 110716 Dow AgroSciences LLC, Indianapolis, Indiana, United States GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Rodrigues Jr, A.; Li, Q.	2011	Method Validation Study for the Determination of Residues of XDE-729 and its Metabolites in Surface Water, Ground Water and Drinking Water by Liquid Chromatography with Tandem Mass Spectrometry (Revision) DAS Report No.: 110718S2 Dow AgroSciences Industrial Ltd., Mogi-Mirim, Sao Paulo, Brazil GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Class, T.	2011	The Development and Validation of a Method for the Analysis of XDE-729 Methyl Ester and XDE-729 Acid in Air DAS Report No.: 110028 PTRL Europe, Ulm, Germany GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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KCP 5.2	Senciuc, M.	2011	XDE-729: Development and Validation of an Analytical Method for the Determination of XDE-729 Methyl Ester and Acid in Body Fluid(s) DAS Report No.: 110029 PTRL Europe, Ulm, Germany GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Wendelburg, B. M., Olberding, E. L.	2008	Validation Report for Methods GRM 07.07.R1 – Determination of Residues of Aminopyralid in Agricultural Commodities by Liquid Chromatography with Tandem Mass Spectrometric Detection, GRM 07.08.R1 - Determination of Residues of Aminopyralid in Bovine and Poultry Tissues, Milk, and Eggs by Liquid Chromatography with Tandem Mass Spectrometric Detection, GRM 07.09.R1 - Determination of Residues of Aminopyralid in Soil by Liquid Chromatography with Tandem Mass Spectrometric Detection, and GRM 07.10.R1 - Determination of Residues of Aminopyralid in Drinking Water, Ground Water, and Surface Water by Liquid Chromatography with Tandem Mass Spectrometric Detection DAS Report No.: 071121 Dow AgroSciences LLC GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Beck, I., Class, T.	2008	Independent Laboratory Validation of Dow AgroSciences LLC Method GRM 07.07 – Determination of Residues of Aminopyralid in Agricultural Commodities by Liquid Chromatography with Tandem Mass Spectrometric Detection DAS Report No.: 080117 PTRL Europe GmbH. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)

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KCP 5.2	Beck, I., Class, T.	2008	Independent Laboratory Validation of Dow AgroSciences LLC Method GRM 07.08 – Determination of Residues of Aminopyralid in Bovine and Poultry Tissues, Milk and Eggs by Liquid Chromatography with Tandem Mass Spectrometric Detection DAS Report No.: 080118 PTRL Europe GmbH. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Beck, I., Class, T.	2008	Independent Laboratory Validation of Dow AgroSciences LLC Method GRM 07.10 – Determination of Residues of Aminopyralid in Drinking Water, Ground Water, and Surface Water by Liquid Chromatography with Tandem Mass Spectrometric Detection DAS Report No.: 080116 PTRL Europe GmbH. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Bacher, R.	2009	The Development and Validation of a Method for the Analysis of Aminopyralid in Air. DAS Report No.: 091020. PTRL Europe GmbH. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Mollica, J., West, S.	2003	Method Validation for the Analysis of XDE-750 in Human Blood and Urine. DAS Report No.: 031005. Pyxant Labs Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2	Hastings, M. J.	2003	Determination of Residues of Clopyralid and Picloram in Canola by Gas Chromatography with Negative-Ion Chemical Ionization Spectrometry Method Number: GRM 00.19 DAS Report No.: 021211. Dow AgroSciences LLC GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Balderrama Pinto, O., Pinheiro, A. C., Kalvan, H. C.	2001	Determination of Picloram and 2,4-D in Grass DAS Report No.: 030026. Morse Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Lindsey, A. E., Hastings, M. J.	2003	Method Validation for the Determination of Residues of Picloram in Animal Tissues by Gas Chromatography with Negative-Ion Chemical Ionization Mass Spectrometry Detection Using Dow AgroSciences Method GRM 03.06 DAS Report No.: 031045 Dow AgroSciences LLC. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Reed, D.	2003	Independent Laboratory Validation of Dow AgroSciences LLC Method GRM 03.06 – Determination of Residues of Picloram in Animal Tissues by Gas Chromatography with Negative-Ion Chemical Ionization Mass Spectrometry. DAS Report No.: 030041. Pyxant Labs Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)

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KCP 5.2	Shackelford, D. D., et al.	2003	Conjugate Analyses with [14C]-Picloram Applied to Oilseed Rape DAS Report No.: 110573. Ricerca Biosciences LLC. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Hastings, M. J., Schaeuerman, M.	2001	Determination of Clopyralid and Picloram Residues in Soil by Gas Chromatography with Mass Selective Detection. Method Number: GRM 00.18. DAS Report No.: 001029. Dow AgroSciences Letcombe Laboratory. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Hastings, M. J., Schaeuerman, M.	2001	Determination of Residues of Clopyralid and Picloram in Waters (Drinking Water, Surface Water, and Ground Water) by Gas Chromatography with Mass Selective Detection Method Number: GRM 00.17. DAS Report No.: 001030. Dow AgroSciences Letcombe Laboratory. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 5.2	Atkinson, S.	2003	Determination of Picloram in Air by Capillary Gas Chromatography with Mass Spectrometric Detection Method Number: GRM 02.29 DAS Report No.: GHE-P-10114. CEMAS. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)

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KCP 5.2	Freshour, N.L., Hermann, E.A.	1983	Picloram: Quantitative Determination in Human Blood and Urine DAS Report No.: 833368; K-038323-036. Dow Chemical Company LLC. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCA 5.6.2 (IIA 5.6.2)	2002	XDE-750: Oral Gavage Developmental Toxicity Study in New Zealand White Rabbits. DAS Report No.: 011047. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCA 5.3.2 (IIA 5.3.2)	1988	Picloram: 12-Month Dog Chronic Dietary Toxicity Study. DAS Report No.: K-038323-040. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCA 5.3.2 (IIA 5.3.2)	1992	Picloram Triisopropanolamine Salt: Oral Gavage Teratology Study In New Zealand White Rabbits. DAS Report No.: K-049877-015. ... GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCA 5.6.2 (KIIA 5.6.10)	2012	XDE-729 Methyl: Dietary Development Toxicity Study in Crl: CD(SD) Rats. DAS Report No.: 111137. ... GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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KCP 8 (KCA 6.1)	Devine, H. C.	2013	X11393728 (XDE-729 methyl) and X11393729 (XDE-729): Residue Stability Study in Crops under Frozen Storage Conditions DAS Report No.: 110563 Dow AgroSciences LLC GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 8 (KCA 6.1)	Langridge, G.	2014	Frozen Storage Stability of Residues of XDE-729 Methyl Ester, XDE-729 Acid and X11449757 in Animal Matrices – Twenty Four Months Stability Data for XDE-729 Methyl Ester and XDE-729 Acid and Twenty Four Months Stability Data for the Relevant Metabolite, X11449757 DAS Report No.: 110768 Dow AgroSciences LLC GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 8 (KCA 6.1)	Dolder, S.	2003	Frozen Storage Stability of Picloram in Wheat Green Forage, Wheat Straw, Wheat Grain, Soil, Water, Oilseed Rape Grain and Oilseed Rape Hay DAS Report No.: 980075 Dow AgroSciences LLC GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 8 (KCA 6.1)	Bjerke, E.	1988	Stability Of Picloram In Milk And Egg Whites Stored Frozen DAS Report No.: GH-C 2079 Dow AgroSciences LLC GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)

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KCP 8 (KCA 6.1)	Lindsay, D.	2004	Frozen Storage Stability of XDE-750 in Range Land and Pasture Grass and Hay and Wheat Straw and Wheat Grain Frozen Storage Conditions DAS Report No.: 030004 Dow AgroSciences LLC GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 8 (KCA 6.2.1)	Rotondaro, S. L. and el.	2012	A Nature of the Residue Study with [14C]-XDE-729 Methyl Applied to Turnips. DAS Report No.: 110413 Dow AgroSciences LLC GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 8 (KCA 6.2.1)	Ma, M., Smith, K.P., Jackson, A.U.	2012	A Nature of the Residue Study with [14C]-XR-729 Methyl Applied to Wheat with and without the Safener Cloquintocet Mexyl (Amended Report). DAS Report No.: 101080 (Amended report). Research for Hire GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 8 (KCA 6.2.2)	Rotondaro, S.L.	2011	A Confined Rotational Crop Study with [14C]-XDE-729 Methyl Ester. DAS Report No.: 101635, 026108. Ricerca GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 8 (KCA 6.5.1)	Ma, M., Balcer, J.L.	2011	Processing Study to Determine the Nature of Residues of 14C-XDE-729 Methyl and 14C-X11393729 Following Industrial or Household Preparation. DAS Report No.: 110369. Dow AgroSciences LLC GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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KCP 8 (KCA 6.5.1)	Rotondaro, S.; Adusumilli, H.	2012	Processing Study to Determine the Nature of Residues of 14C-Aminopyralid Following Industrial or Household Preparation. DAS Report No.: 110709. Dow AgroSciences LLC GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 8 (KCA 6.2.3)	Rotondaro, S.L and Adelfinskaya Y. A.	2011	A Nature of the Residue Study in the Ruminant with [14C]-XR-729 Methyl Ester. DAS Report No.: 101389. Southwest Bio-Labs, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 8 (KCA 6.2.2)	Rotondaro, S., Adelfinskaya, Y.A.	2011	A Nature of the Residue Study in the Laying Hen with [14C]-XR-729 Methyl Ester. DAS Report No.: 101390. Southwest Bio-Labs, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 9.2.4 (KCA 7.3.1)	Knowles, S.	2008	Calculation of field kinetics for picloram from two additional field dissipation studies and two accepted studies using FOCUS Kinetics methodology and Q ₁₀ value = 2.5. DAS Report No.: GHE-P-11865. Dow AgroSciences GLP (Y/N): N Published (Y/N): N	N	N	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 9.2.4 (KCA 7.2.1)	Norr, C.	2001	Metabolism of picloram in spring oilseed rape following a foliar application. DAS Report No. 000299; 0C0003 (FBRC); GH-C 5391 Federal Biological Research Centre for Agriculture and Forestry (BBA), Berlin, Germany GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)

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KCP 9.2.4 (KCA 7.2.1)	Stenner, S. S.	1992	[¹⁴ C] picloram: Nature of the residue in wheat - MET92030, RES92105, HWI 6397-111. DAS Report No.: GH-C 2942 Hazleton Wisconsin, Inc, Madison, Wisconsin, United States; Plant Sciences Inc, Watsonville, California, United States GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 9.2.4 (KCA 7.6.1)	Kimmel, E.; Aldcroft, K. S.; Ewing, A.L.	1993	A confined rotational crop study with ¹⁴ C-picloram using turnips, mustard greens, wheat, and corn - MET9106; Ptrl No. 311W. DAS Report No. GH-C 2971R PTRL West Inc, Richmond , California, United States GLP (Y/N): YES Published (Y/N): NO	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 9.2.4 (KCA 7.2.3)	Yackovich, P. R.; Byrne, S. L.	1992	Nature of residues of ¹⁴ C labelled picloram in the lactating goat. DAS Report No.: MET92043 GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 9.2.4 (KCA 7.2.2)	Yackovich, P.R.; Miller, J. H.	1986	The fate of ¹⁴ C labelled picloram fed to laying hens. DAS Report No. GH-C 1827 The Dow Chemical Company GLP/GEP (Y/N): N (prior to GLP) Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 10.1 (KCA 8.1.1.1)	2011	XDE-729 Methyl: An Acute Oral Toxicity Study with the Northern Bobwhite. DAS Report No.: 090026, 379-211 GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.1 (KCA 8.1.1.1)	2011	XDE-729 Methyl: An Acute Oral Toxicity Study with the Zebra Finch (<i>Poephila guttata</i>) DAS Report No.:090027, 379-212 GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.1 (KCA 8.1.1.1)	1986	Picloram Potassium Salt: An Acute Oral Toxicity Study with the Mallard DAS Report No.: ES-DR-0049-3936-5, ES-835 GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 10.1 (KCA 8.1.1.1)	2001	XDE-750: An Acute Oral Toxicity Study with the Northern Bobwhite. DAS Report No.: 011046 GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.1 (KCA 8.1.1.2)	2011	XDE-729 Methyl: A dietary LC50 study with the Mallard. DAS Report No.: 090029, 379-214. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.1 (KCA 8.1.1.2)	2011	XDE-729 Methyl: A dietary LC50 study with the Northern Bobwhite. DAS Report No.: 090028. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.1 (KCA 8.1.1.2)	1986	Picloram Potassium Salt: A Dietary LC50 Study with the Bobwhite DAS Report No.: 103-244 GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 10.1 (KCA 8.1.1.2)	2001	XDE-750: A Dietary LC50 Study with the Northern Bobwhite. DAS Report No.: 011047. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.1 (KCA 8.1.1.3)	2011a	XDE-729 Methyl: A reproduction study with the Northern Bobwhite DAS Report No.: 101137, 379-246 GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.1 (KCA 8.1.1.3)	2011b	XDE-729 Methyl: A reproduction study with the Mallard DAS Report No.: 101139, 379-247. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.1 (KCA 8.1.1.3)	2002	Avian Reproduction Study with Picloram Acid in Northern Bobwhite (Colinus virginianus). DAS Report No.: K-038323-117, 011172, 01014. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.1 (KCA 8.1.1.4)	2003	Avian Reproduction Study with XDE-750 in Northern Bobwhite Quail (Colinus virginianus). DAS Report No.: 011271. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.1.2 (KCA 5.2.1)	2011	XDE-729 Methyl Technical Grade Active Ingredient: Acute Oral Toxicity Up and Down Procedure in Rats. DAS Report No.: 110543. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.1.2 (KCA 5.2.1)	1987	Picloram Acid (Picloram Technical): Acute Oral Toxicity Study in Fischer 344 Rats. DAS: . K-038323-042A. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 10.1.2 (KCA 5.6.11)	2012	XDE-729 Methyl: Developmental toxicity study in New Zealand white rabbits. DAS Report No.: 111137 GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.1.2 (KCA 5.6.2)	1992	Picloram Triisopropanolamine Salt: Oral Gavage Teratology Study in New Zealand White Rabbits. DAS Report No.: K-049877-015. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.1.2 (KCA 5.2.1)	2001	XDE-750: Acute Oral Toxicity Study in Fischer 344 Rats. DAS Report No.: 011115. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.1.2 (KCA 5.10)	2004	Oral Gavage Developmental Toxicity Study in New Zealand White Rabbits. DAS Report No.: 031142. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.2.1.1)	2011a	XDE-729 Methyl: Acute toxicity to the Rainbow Trout, <i>Oncorhynchus mykiss</i> , Determined Under Static-Renewal Test Conditions. DAS Report No.: 090187, 64605. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.2.1)	2001	Picloram Acid: A 96-Hour Static Acute Toxicity Test with the Rainbow Trout (<i>Oncorhynchus mykiss</i>). DAS Report No.: K-038323-122, 379A-103. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.2.1)	2001a	Picloram Acid: A 96-Hour Static Acute Toxicity Test with the Bluegill (<i>Lepomis macrochirus</i>). DAS Report No.: K-038323-123, 011195, 379A-102. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.2 (KCA 8.2.1.2)	2011a	XDE-729 Methyl: Acute Toxicity to the Fathead Minnow, <i>Pimephales promelas</i> , Determined Under Static-Renewal Test Conditions DAS Report No.: 090186, 64604. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.2.1.2)	2011b	XDE-729 Methyl: Acute Toxicity to the Sheepshead Minnow, <i>Cyprinodon variegatus</i> , Determined Under Flow-Through Conditions DAS Report No.: 090188, 64606. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.2.1.3)	2011b	XDE-729 Acid: Acute Toxicity to the Rainbow Trout, <i>Oncorhynchus mykiss</i> , Determined Under Static-Renewal Test Conditions. DAS Report No.: 101152, 65970. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.2.1.3)	2011a	X11449757: Acute Toxicity to the Rainbow Trout, <i>Oncorhynchus mykiss</i> , Determined Under Static-Renewal Test Conditions DAS Report No.: 101166, 66008. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.2.1.3)	2012a	X11406790 (XDE-729 Metabolite): Acute Toxicity to the Rainbow Trout, <i>Oncorhynchus mykiss</i> , Determined Under Static-Renewal Test Conditions DAS Report No.: 120020, 68212. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.2 (KCA 8.2.1)	2001	XDE-750 Herbicide: An Acute Toxicity Study with the Rainbow Trout, <i>Oncorhynchus mykiss</i> Walbaum. DAS Report No.: 011078 GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.2.1)	2002	XDE-750: Acute Toxicity to Bluegill Sunfish, (<i>Lepomis macrochirus</i>) Under Static Conditions. DAS Report No.: 011225. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.16)	2012	XDE-729 Methyl: Fish Short-Term Reproduction Assay with the Fathead Minnow (<i>Pimephales promelas</i>). DAS Report No.: 102125, 379A-153. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.16)	2012	XDE-729 Acid: Fish Short-Term Reproduction Assay with the Fathead Minnow (<i>Pimephales promelas</i>). DAS:120535, 379A-154 GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.2.4)	2012a	XDE-729 Methyl: Early Life-Stage Toxicity Test with the Sheepshead Minnow, <i>Cyprinodon variegatus</i> , Under Flow-Through Conditions DAS Report No.: 120017, 68313. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.2 (KCA 8.2.4)	2011d	XDE-729 Acid: An early Life-stage Toxicity Test with the Fathead minnow, <i>Pimephales promelas</i> , Under Flow Through Conditions. DAS Report No.: 101151, 65971. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.2.4)	2011c	XDE-729 Methyl: Early Life-stage Toxicity Test with the Fathead minnow, <i>Pimephales promelas</i> , Under Flow Through Test Conditions. DAS Report No.:101134, 65896. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.2.4)	2012b	X11449757: Early life stage toxicity test with the Fathead Minnow, <i>Pimephales promelas</i> , under flow through conditions. DAS:101165, 66009. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.2.4)	2011	Aminopyralid: Early Life-Stage Toxicity Test with the Sheepshead Minnow, <i>Cyprinodon variegatus</i> , Under Flow-Through Conditions. DAS Report No.: 101582. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.2.2.2)	1984	The Toxicity of Technical Picloram to the Embryo, Larval, and Juvenile Stages of the Rainbow Trout (<i>Salmo gairdneri</i> Richardson). DAS Report No.: ES-DR-0114-1351-8, ES-703. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.2 (KCA 8.2.2.3)	2002	XDE-750: Toxicity to the Early Life-Stages of the Fathead Minnow, <i>Pimephales promelas</i> Rafinesque. DAS Report No.: 021029. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.2.2.3)	2011	XDE-729 Methyl: Bioconcentration and Metabolism Study with Bluegill, <i>Lepomis macrochirus</i> DAS Report No.: 101135, 66001 GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.3.1.1)	Rebstock, M.	2011c	XDE-729 Methyl: Acute toxicity to the Water Flea, <i>Daphnia magna</i> , Determined Under Static Test Conditions DAS:090185, 64603 ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.3.1.1)	Bergfield, A.	2011b	XDE-729 Acid: Acute toxicity to the Water Flea, <i>Daphnia magna</i> , Determined Under Static-Renewal Test Conditions. DAS:101149, 65969 ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.3.1.1)	Bergfield, A.	2011c	X11449757: Acute toxicity to the Water Flea, <i>Daphnia magna</i> , Determined Under Static-Renewal Test Conditions. DAS:101163, 66007. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2 (KCA 8.3.1.1)	Gaertner, K.	2012b	X11406790 (XDE-729 Metabolite): Acute Toxicity to the Cladoceran, <i>Daphnia magna</i> , Determined Under Static Test Conditions DAS:120019, 68211 ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.2.4)	Drottar, K.R. Kendall, T.Z. Krueger, H.O.	2001	Picloram (Acid): A 48: Hour Static Acute Toxicity Test with the Cladoceran (<i>Daphnia magna</i>). DAS Report No.: K-038323-124, 379A-101B; 011198. Wildlife International, Ltd. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.3.1.1)	Marino, T.S., C.A. Hales, E.L. McClymont and A.M. Yaroch	2001	XDE-750 Herbicide: An Acute Toxicity Study with the Daphnid, <i>Daphnia magna</i> . DAS Report No.: 011079. The Dow Chemical Company. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.3.1.4)	2002	XDE-750 – Acute Toxicity to Eastern Oysters (<i>Crassostrea virginica</i>) under Flow-Through Conditions. DAS Report No.: 011268. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.2.5)	Boeri, R.L., Wyskiel, D.C., Ward, T.J.	2002	Picloram acid: life cycle study in the daphnid, <i>Daphnia magna</i> . DAS Report No.: K-038323-130, 021029, 2391-DO. Wilbury Laboratories Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.2 (KCA 8.3.2.1)	Bergfield, A.	2011e	XDE-729 Methyl: Chronic Toxicity with the Water Flea, <i>Daphnia magna</i> , Exposed Under Static-Renewal Test Conditions DAS Report No.: 101133, 65897 ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.3.2.1)	Bergfield, A.	2011f	XDE-729 Acid: Chronic Toxicity Test with the Water Flea, <i>Daphnia magna</i> , Exposed Under Static-Renewal Test Conditions DAS Report No.: 101150, 65972 ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.3.1.2)	Henry, K.S.; Marino, T.A.; Staley J.L. and McClymont, E.L.	2003	XDE-750: 21-Day Chronic Toxicity with the Daphnid, <i>Daphnia magna</i> Straus. DAS Report No.: 021085. The Dow Chemical Company GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.3.2.2)	Gerke, A.	2011e	XDE-729 Methyl: Chronic Toxicity in Whole Sediment to Freshwater Midge, <i>Chironomus riparius</i> DAS:101130, 65899. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.5.1)	Gerke, A.	2011	XDE-729 Methyl: Whole sediment 10 day Acute Toxicity test with Midge Larvae (<i>Chironomus dilutus</i>). DAS Report No.: 090183, 64607. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.2 (KCA 8.2.7)	Putt, E.A.	2002	Picloram Acid – The Full Life-Cycle Toxicity to Midge (<i>Chironomus riparius</i>) Under Static Conditions. DAS Report No.:K-038323-121, 12550.6157. Springborn Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.5.2)	Putt, A.E.	2002	XDE-750 – Full Life-Cycle Toxicity to Midge (<i>Chironomus riparius</i>) under Static Conditions. DAS Report No.: 011277. Springborn Smithers Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.5.2)	Putt, A.E.	2004	4-amino-5,6-dichloro-2 pyridinecarboxylic acid – Sediment-water chironomid (<i>Chironomus riparius</i>) test using spiked water. DAS Report No.: 040372. Springborn Smithers Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.3.1.3)	Bergfield, A.	2011	XDE-729 Methyl: Acute toxicity Test with the Mysid shrimp, <i>Americamysis bahia</i> , Determined Under Flow-Through Conditions. DAS Report No.: 090184 ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.3.1.4)	Hicks, S.L.	2011	XDE-729 Methyl: Effect on New Shell Growth of the Eastern Oyster (<i>Crassostrea virginica</i>). DAS Report No.: 090120. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.2 (KCA 8.3.2.4)	Hicks, S.L.	2011b	XDE-729 Methyl: Life-Cycle Toxicity Test of the Saltwater Mysid, <i>Americamysis bahia</i> , Conducted Under Flow-Through Test Conditions. DAS Report No.: 101131, 65895. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.16)	Dinehart, S.A.	2012c	XDE-729 Methyl: Acute toxicity to the Tadpole (<i>Xenopus laevis</i>) determined under flow through test conditions DAS:090121, 64610. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.16)	2012	XDE-729 Methyl: Amphibian metamorphosis Assay for the Detection of Thyroid Active Substances. DAS Report No.:102126, 379A-152. GLP (Y/N): Y Published (Y/N): N	Y	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.11.1)	Gerke, A.	2011i	XDE-729 Methyl: Whole sediment acute toxicity to a marine amphipod (<i>Leptocheirus plumulosus</i>). DAS Report No.: 101132, 66366. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.6)	Drottar, K.R. Kendall, T.Z. Krueger, H.O.	2001c	Picloram Acid: A 14-day Toxicity Test with Duckweed (<i>Lemna gibba</i> G3). DAS Report No.: K-038323-126, 379A-104. Wildlife International, Ltd. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.2 (KCA 8.6)	Hoberg, J.R.	2002c	XDE-750 – Toxicity to Duckweed, <i>Lemna gibba</i> . DAS Report No.: 011223. Springborn Smithers Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.6)	Rebstock, M.	2011	XDE-729 Methyl: Growth Inhibition Test with the Freshwater Aquatic Plant, Duckweed, <i>Lemna gibba</i> DAS Report No.: 090182, 64595. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.6)	Rebstock, M.	2011l	XDE-729 Acid: Growth Inhibition Test with the Freshwater Aquatic Plant, Duckweed, <i>Lemna gibba</i> DAS Report No.: 101145, 65968. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.6)	Rebstock, M.	2011m	X11449757: Growth Inhibition Test with the Freshwater Aquatic Plant, Duckweed, <i>Lemna gibba</i> . DAS Report No.: 101159, 66011. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.6)	Rebstock, M.	2012b	X11406790: Growth Inhibition Test with the Freshwater Aquatic Plant, Duckweed, <i>Lemna gibba</i> . DAS Report No.: 120022, 68209. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2 (KCA 8.6)	Gonsior, G.	2012a	XDE-729 Methyl - Growth Inhibition of <i>Myriophyllum spicatum</i> in a Water/Sediment System. DAS Report No.: 102023, S11-02965. Eurofins Agrosience Services EcoChem GmbH. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.6)	Gonsior, G.	2012b	XDE-729 Acid - Growth Inhibition of <i>Myriophyllum spicatum</i> in a Water/Sediment System. DAS Report No.:120533, S12-00215 Eurofins Agrosience Services EcoChem GmbH GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.6)	Gonsior, G.	2012c	X11449757 - Growth Inhibition of <i>Myriophyllum spicatum</i> in a Water/Sediment System. DAS Report No.: 102015, S12-00216. Eurofins Agrosience Services EcoChem GmbH GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.6)	Gonsior, G.	2012	X11406790 - Growth Inhibition of <i>Myriophyllum spicatum</i> in a Water/Sediment System. DAS Report No.: 120534, S12-00217. Eurofins Agrosience Services EcoChem GmbH. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.2.6)	Desjardins, D. Drottar, K.R. Kendall, T.Z. Krueger, H.O.	2001	Picloram Acid: A 96-Hour Toxicity Test with the Freshwater Alga (<i>Selenastrum capricornutum</i>). DAS Report No.: K-038323-125, 379A-105. Wildlife International, Ltd. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.2 (KCA 8.4)	Rebstock, M.	2011d	XDE-729 Methyl: Growth Inhibition Test with the Freshwater Diatom, <i>Navicula pelliculosa</i> DAS Report No.: 090174, 67182. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.4)	Weber, K.	2011a	Testing Effects of XDE-729 Methyl on the Single Cell Green Alga, <i>Pseudokirchneriella subcapitata</i> , in a 96 h Static Test. DAS Report No.: 090173, S09-00613 EurofinsAgroScience Services GmbH GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.4)	Weber, K.	2011b	Testing of Effects of XDE-729 Methyl on the Blue-Green Alga, <i>Anabaena flos-aquae</i> , in a 96 h Static Test. DAS Report No.: 090175, S09-00615. EurofinsAgroScience Services GmbH GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.4)	Rebstock, M.	2011	XDE-729 Methyl: Static Growth Inhibition Test with the Marine Diatom, <i>Skeletonema costatum</i> DAS:090176, 64717 ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.4)	Rebstock, M.	2011	XDE-729 Acid: Growth Inhibition Test with the Unicellular Green Alga, <i>Pseudokirchneriella subcapitata</i> . DAS Report No.: 102027, 66685. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.2 (KCA 8.4)	Rebstock, M.	2011	XDE-729 Acid: Growth Inhibition Test with the Freshwater Diatom, <i>Navicula pelliculosa</i> DAS:102029, 66687. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.4)	Rebstock, M.	2011	XDE-729 Acid: Growth Inhibition Test with the Blue-Green Alga, <i>Anabaena flos-aquae</i> . DAS Report No.: 101144, 65967. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.4)	Rebstock, M.	2011	XDE-729 Acid: Static Growth Inhibition Test with the Marine Diatom, <i>Skeletonema costatum</i> . DAS Report No.: 102028, 66686. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.4)	Rebstock, M.	2011	Growth Inhibition Test with the Unicellular Green Alga, <i>Pseudokirchneriella subcapitata</i> - X11449757. DAS Report No.: 101158, 66006. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.4)	Rebstock, M.	2012	X11406790: Growth Inhibition Test with the Unicellular Green Alga, <i>Pseudokirchneriella subcapitata</i> DAS Report No.: 120021, 68210. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.2 (KCA 8.2.6)	Kirk, H.D. Gilles, M.M. McClymont, E.L. McFadden, L.G.	2001	Picloram (Technical): Growth Inhibition Test with the Bluegreen Alga, <i>Anabaena flos-aquae</i> . DAS Report No.: K-038323-114; 001153. The Dow Chemical Company. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.4)	Hughes, J. S.	2002	The Toxicity of Picloram, Potassium Salt, to <i>Selenastrum capricornutum</i> . DAS Report No.: ES-DR-0049-3936-7, ES-2223 Malcolm Pirnie Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.4)	Hoberg, J.R	2002	XDE-750 – Toxicity to the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i> . DAS Report No.: 011222. Springborn Smithers Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.2 (KCA 8.4)	Hoberg, J.R	2002	XDE-750 – Acute Toxicity to the Freshwater Diatom, <i>Navicula pelliculosa</i> . DAS Report No.: 011278. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.3.1 (KCA 8.7.1)	Schmitzer S.	2011	Effects of XDE-729 Methyl (Acute Contact and Oral) on Honey Bees (<i>Apis mellifera L.</i>) in the Laboratory. DAS Report No.: 101128/ 101129, 49528035 Institut für Biologische Analytik, und Consulting IBACON GmbH GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.3.1 (KCA 8.3.1.1)	Hoberg, J.	2001	Picloram Acid - Acute Contact and Oral Toxicity Tests with Honey Bees (<i>Apis mellifera</i>). DAS Report No.: 011173/ 011174. Springborn Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 10.3.1 (KCA 8.7.1)	Aufderheide, J.	2001	XDE-750: Acute Oral Toxicity Test with the Honeybee (<i>Apis mellifera</i>). DAS Report No.: 011045. ABC Laboratories Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.3.1 (KCA 8.7.2)	Aufderheide, J.	2001	XDE-750: Acute Contact Toxicity Test with the Honeybee, <i>Apis mellifera</i> . DAS Report No.: 011044. ABC Laboratories Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.4 (KCA 8.9.1)	Witte, B.	2011	Acute Toxicity (14 Days) of XDE-729 Methyl to the Earthworm, <i>Eisenia fetida</i> , in Artificial Soil with 5% Peat. DAS Report No.: 090099, 49524021. Institut für Biologische Analytik, und Consulting IBACON GmbH. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.4 (KCA 8.9.1)	Witte, B.	2010b	XDE-729 Acid: Acute Toxicity (14 Days) of XDE-729 Acid to the Earthworm, <i>Eisenia fetida</i> , in Artificial Soil with 5% Peat. DAS Report No.: 101141, 56861021. Institut für Biologische Analytik, und Consulting IBACON GmbH GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.4 (KCA 8.9.1)	Witte, B.	2010c	Acute Toxicity (14 days) of X11449757 (metabolite of XDE-729) to the Earthworm, <i>Eisenia fetida</i> , in Artificial Soil with 5% Peat. DAS Report No.: 101155, 56872021. Institut für Biologische Analytik, und Consulting IBACON GmbH GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.4 (KCA 8.9.1)	Boeri, R.L., Ward, T.J.	2002	Picloram acid: 14-day soil exposure acute toxicity to the earthworm, <i>Eisenia foetida</i> . DAS Report No.: K-038323-120 , 011175, 2290-DO Wilbury Laboratories Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 10.4 (KCA 8.9.1)	Ward, T.J., Boeri, R.L.	2001	XDE-750: 14-Day Soil Exposure Acute Toxicity to the Earthworm, <i>Eisenia foetida</i> . DAS Report No.: 011049. Wilbury Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.4 (KCA 8.9.2)	Witte, B.	2011	Effects of XDE-729 Methyl on Reproduction and Growth of Earthworms, <i>Eisenia fetida</i> , in Artificial Soil with 5% Peat (Revised). DAS Report No.: 090100, 49525022. Institut für Biologische Analytik, und Consulting IBACON GmbH GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.4 (KCA 8.9.2)	Witte, B.	2010	Effects of XDE-729 Acid on Reproduction and Growth of Earthworms, <i>Eisenia fetida</i> , in Artificial Soil with 5% Peat. DAS Report No.: 101142, 56862022. Institut für Biologische Analytik, und Consulting IBACON GmbH GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.4 (KCA 8.9.2)	Witte, B.	2010	Effects of X11449757 (metabolite of XDE-729) on Reproduction and Growth of Earthworms, <i>Eisenia fetida</i> , in Artificial Soil with 5% Peat. DAS Report No.: 101156, 56873022. Institut für Biologische Analytik, und Consulting IBACON GmbH GLP/GEP (Y/N):Y Published (Y/N):N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.4 (KCA 8.9.2)	Mallett, M.J.	2001	The Effects of Picloram on Reproduction and Growth in the Earthworm <i>Eisenia Foetida</i> . DAS Report No: GHE T-1148; CEMS-1639. CEM Analytical Services. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 10.4 (KCA 8.9.2)	McCormac, A.	2012	Determination of the chronic (sub-lethal) toxicity of aged residues of technical-grade XDE-729 Methyl to the earthworm <i>Eisenia fetida</i> in two natural soil substrates. DAS Report No.: 110605, DOW-11-38. Mambo-Tox Ltd. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.4 (KCA 8.9.2)	Davies, N.	2004	XDE-750: Effects on Reproduction and Growth in the Earthworm, <i>Eisenia foetida</i> . DAS Report No.: 040285. CEM Analytical Services Limited, UK. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)
KCP 10.4 (KCA 8.9.2)	Gerke, A.	2011g	XDE-729 Methyl: Inhibition of Reproduction of Collembola, <i>Folsomia candida</i> , in Artificial Soil. DAS Report No.: 090181, 64611. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.4 (KCA 8.9.2)	Witte, B.	2011a	Effects of XDE-729 Acid on Reproduction of the Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil with 5% Peat. DAS Report No.: 102025, DR-0402-7809-066. Institut für Biologische Analytik, und Consulting IBACON GmbH GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.4 (KCA 8.9.2)	Luhrs, U.	2011	Effects of XDE-729 Methyl on Reproduction of the Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil with 5% Peat. DAS Report No.: 110280, 64641089. Institut für Biologische Analytik, und Consulting IBACON GmbH GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.4 (KCA 8.9.2)	Witte, B.	2011b	Effects of XDE-729 Acid on Reproduction of the Collembola <i>Folsomia candida</i> in Artificial Soil with 5% Peat. DAS Report No.: 102024, DR-0402-7809-067 Institut für Biologische Analytik, und Consulting IBACON GmbH. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.4 (KCA 8.9.2)	Witte, B.	2011c	Effects of X11449757 (metabolite of XDE-729) on Reproduction of the Predatory Mite <i>Hypoaspis aculeifer</i> in Artificial Soil with 5% Peat. DAS Report No.: 101154, DR-0417-6492-005. Institut für Biologische Analytik, und Consulting IBACON GmbH GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.4 (KCA 8.9.2)	Gerke, A.	2011h	X11449757: Inhibition of Reproduction of Collembola, <i>Folsomia candida</i> , in Artificial Soil. DAS Report No.: 101153, DR-0417-6492-009. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.5 (KCA 8.10.1)	Feil, N.	2011a	Effects of XR-729 methyl on the activity of the soil microflora in the laboratory. DAS Report No.: 101127, 49527080. Institut für Biologische Analytik, und Consulting IBACON GmbH GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.5 (KCA 8.10.1)	Feil, N.	2010b	Effects of XDE-729 acid on the activity of the soil microflora in the laboratory. DAS Report No.: 101143, 56863080. Institut für Biologische Analytik, und Consulting IBACON GmbH GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.5 (KCA 8.10.1)	Feil, N.	2011	Effects of X11449757 on the Activity of the Soil microflora in the Laboratory. DAS Report No.: 101157, 56874080. Institut für Biologische Analytik, und Consulting IBACON GmbH GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.5 (KCA 8.10.1)	Mallett, M.J.	2001b	The effects of picloram on soil microflora respiration and nitrogen transformations. DAS Report No.: GHE T-1158, CEMS-1630. CEM Analytical Services GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011).	Corteva Agriscience (Dow AgroSciences)
KCP 10.5 (KCA 8.10.1)	McMurray, A.	2002	A Laboratory Assessment of the Effects of XDE-750 on Soil Microflora Respiration and Nitrogen Transformation According to OECD Guidelines. DAS Report No.: GHE-T-1180. Chemex Environmental International Ltd. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 891/2014).	Corteva Agriscience (Dow AgroSciences)

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KCP 10.6 (KCA 8.12)	Rockcliff, C.	2011c	Evaluation of the Phytotoxicity of the XDE-729 acid GLP Seedling Emergence and Seedling Growth Test Terrestrial Non Target Plants (Based on OECD Guideline 208) - Europe 2011. DAS Report No.: 101955, STC/11/E601. Stockbridge Technology Centre Ltd. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.6 (KCA 8.12)	Rockcliff, C.	2011d	Evaluation of the Phytotoxicity of the XDE-729 M-757 metabolite GLP Seedling Emergence and Seedling Growth Test Terrestrial Non Target Plants (Based on OECD Guideline 208) - Europe 2011. DAS Report No.: 101956, STC/11/E602. Stockbridge Technology Centre Ltd. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)
KCP 10.6 (KCA 8.15)	Lee, B.	2010 (Amendment 2011)	XDE-729 Methyl: Activated Sludge, Respiration Inhibition Test. DAS Report No.: 101140, 65898. ABC Laboratories, Inc. GLP (Y/N): Y Published (Y/N): N	N	Y	Active substance data submitted for a new active substance (NAS) initially included on Annex I of Regulation (EU) 1107/2009 (Commission Implementing Regulation (EU) 2015/1165).	Corteva Agriscience (Dow AgroSciences)

List of data submitted by the applicant and not relied on

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

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-	-	-	-	-	-	-	-