FINAL REGISTRATION REPORT
Part A
Risk Management

Product code: CHR/H/CFF 250 EC

Product name(s): Hapi 250 EC/ Turango 250 EC

Chemical active substance(s):

Clopyralid; 120 g/kg

Fluroxypyr-acid, 120 g/L (as fluroxypyr-meptyl, 172.9 g/L)

Florasulam; 10 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT
(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: March 2023

MS Finalisation date: September 2024; November 2024**,** 04.2025, 05.2025,07.2025,07.2025

Version history

When	What
09.2024	ZRMs evaluated dRR submitted by Applicant.
11.2024	The final Registration Report
04.2025	zRMS updated
05.2025	zRMS updated
07.2025	zRMS updated
07.2025	zRMS updated

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PART A
RISK MANAGEMENT

1 Details of the application

This document describes the acceptable use conditions required for zonal registration of CHR/H/CFF 250 EC (Hapi 250 EC/ Turango 250 EC) containing Florasulam, Clopyralid and Fluroxypyr in POLAND (ZRMS).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 0-10 and Part C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required by the EU review. It also includes assessment of data and information relating to CHR/H/CFF 250 EC where that data has not been considered in the EU review. Otherwise assessments for the safe use of CHR/H/CFF 250 EC have been made using endpoints agreed in the EU review of Florasulam, Clopyralid and Fluroxypyr.

This document describes the specific conditions of use and labelling required for the registration of (Hapi 250 EC, Turango 250 EC), product code CHR/H/CFF 250 EC

1.1 Application background

This application was finalized by Innvigo Sp. z o.o. in April 2019. Innvigo Sp. z o.o. is a company located at Aleje Jerozolimskie 178, 02-486, Warsaw, Poland, and registered in the Polish National Court Registry of entrepreneurs (KRS), with the number 0000540684..

The application is for the approval of CHR/H/CFF 250 EC a emulsifiable concentrate type formulation (EC) containing 10 g/L Florasulam, 120 g/L Fluroxypyr, 120 g/L clopyralid for use as a herbicide for controls a broad-spectrum of dicot and monocots weeds in cereals
It is a applied by spray at BBCH 21 to 33 (details GAP table B0 Section)

To obtain authorisation the product CHR/H/CFF 250 EC must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

This application was submitted in order to allow the first authorisation of this product in Poland, in accordance with the above.

1.2 Letters of Access

Letters of Access are being submitted.

1.3 Justification for submission of tests and studies

In accordance with Art. 33 (3), the submitted studies and presented in Appendix 4, are relevant and necessary to obtain the first authorisation the product CHR/H/CFF in Poland.

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.

2 Details of the authorization decision

2.1 Product identity

Product code	CHR/H/CFF 250 EC
Product name in MS	Hapi 250 EC/ Turango 250 EC
Authorization number	N/A
Function	herbicide
Applicant	Innvigo Sp. z o.o.
Active substance(s) (incl. content)	Florasulam 10 g/L Fluroxypyr 120 g/L Clopyralid 120 g/L
Formulation type	Emulsifable conentrate (EC)
Packaging	HDPE/EvOH 250 ml HDPE/EvOH bottles 310 ml HDPE/EvOH bottle 500 ml in HDPE/EvOH bottles 579 ml HDPE/EvOH bottle 1000ml in HDPE/EvOH bottles 1200ml in HDPE/EvOH bottles 5000ml in HDPE/EvOH containers 5650 ml HDPE/EvOH cannister 10000ml in HDPE/EvOH containers 20000ml in HDPE/EvOH containers HDPE/PA: 275 ml HDPE/PA bottles 323 ml HDPE/PA bottles 500 ml HDPE/PA bottles 550 ml HDPE/PA bottles 574 ml HDPE/PA bottles 1000 ml HDPE/PA bottles 1100 ml HDPE/PA bottles 5000 ml HDPE/PA bottles 5000 ml HDPE/PA cannister 5500 ml HDPE/PA bottles 5850 ml HDPE/PA container 10000 ml HDPE/PA container HDPE/F: 312 ml HDPE/F bottles 318 ml HDPE/F bottles 570 ml HDPE/F bottles 575 ml HDPE/F bottles 580 ml HDPE/F bottles 585 ml HDPE/F bottles 1150 ml HDPE/F bottles 1160 ml HDPE/F bottles

	1170 ml HDPE/F bottles 1185 ml HDPE/F bottles 1200 ml HDPE/F bottles 5880 ml HDPE/F cannister 5950 ml HDPE/F bottles 5950 ml HDPE/F cannister 10000 ml HDPE/F cannister
Coformulants of concern for national authorizations	N/A
Restrictions related to identiy	N/A
Mandatory tank mixtures	N/A
Recommended tank mixtures	N/A

2.2 Conclusion

Physical-chemical properties section:
Due to the hydrocarbon content and the results of kinematic viscosity (≤ 20.5 mm2/s, measured at 40°C), the product shall be classified in Category 1, hazard statement H304. The relevant classification should be included on the label.
Due to emulsifiability results, the recommendations for ensuring thorough mixing before and during spraying should be included on the label.
Due to the effectiveness of cleaning study results, the general cleanout with a tank cleaner should be recommended on the label.
In the accelerated storage and shelf-life stability study, the formulation was stored in commercial packaging (the bottles made of HDPE/PA) and the packaging remained stable during the storage, therefore, the proposed commercial packs of HDPE/PA are considered acceptable.
According to the "Polish guideline on the general principles for approval of packaging of plant protection products" (18.10.2021), extrapolation from HDPE/PA to HDPE/F, HDPE/EVOH was possible for EC formulation. However, since the update of 05.09.2023, extrapolation in the above case can only be supported with acceptable seepage data from accelerated storage test (no leakage, no ballooning, no panelling of the packaging etc.). As this application was submitted before 5.09.2023, it is proposed to accept in Poland the extrapolation from HDPE/PA to HDPE/F and HDPE/EVOH. According to SANCO/10473/2003 –rev.5, this extrapolation was not acceptable so the HDPE/F and HDPE/EVOH packaging proposed in Part B4 were not accepted.

Efficacy section:
CHR/H/CFF 250 EC can be granted in Poland in line to accepted GAP table and label project.

Mammalian toxicology:
According to the toxicological properties classification of TURANGO 250 EC is: H302, H304, H315, H318. No risk for health operator, worker and bystander/resident

From a toxicological point of view:
The composition of the assessed product TURANGO 250 EC has been verified in terms of Regulation 2023/574 of March 2023 and does not contain any neutral, prohibited ingredients in plant protection products that have been identified in accordance with Annex III to Regulation (EC) No 1107/2009

Metabolism and residues: uses are accepted
According to the available data following label restriction is proposed: not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown (see EFSA Journal 2021;19(1):6389).
EFSA recommends avoiding rotation with root and tuber crops (in view of the high persistence of the metabolite fluroxypyr methoxypyridine and the absence of toxicological data on this metabolite.

Ecotoxicology section: uses are accepted.
Risk assessment for aquatic plants (*M. spicatum*) has been not performed (insufficient data set - data gap). The new study the product **TURANGO 250 EC** and *Myriophyllum spicatum* should be performed. In order to answer the requirement from the zRMS a study for *Myriophyllum spicatum* has been included. The studies for formulation of Turango 250 EC for earthworms, *Folsomia candida* and *Hypoaspis aculeifer* was accepted by zRMS ***only provisionally***. The toxicity endpoints were based on nominal concentration. At the end on the studies concentration of fluroxypyr-methyl was below 80%. The geometric mean measured concentration should be calculated over the duration of the test and used if the concentration falls under 80% of nominal. The Aplicant should complete the calculations of toxicity endpoints for earthworms and *Folsomia candida* and *Hypoaspis aculeifer* based on geometric mean measured concentration with a risk assessment for eartworms, *Folsomia candida* and *Hypoaspis aculeifer.*

Updated July 2024
To address the current data gap for *Myriophyllum spicatum* conducted by Applicant according to the OECD Guidelines. The new study for Myriophyllum spicatum with formulated product Turango 250 EC has been accepted by zRMS. Toxicity data and risk assessment for *Myriophyllum spicatum* was available for the PPP Turango 250 EC and a low risk was demonstrated for this species. The use Turango 250 EC according to the label will not pose risk to aquatic organisms (ratio PEC/RAC is below 1) with apply 5 meters buffer zone.

The use Turango 250 EC according to the label will not pose risk to aquatic organisms (ratio PEC/RAC is below 1) with apply 5 meters buffer zone.

First tier chronic evaluation of the risk to adult bees exposed to Turango 250 EC resulted with ETR value above the trigger in weeds scenario indicating potentially unacceptable risk (Weeds/ BBCH 10-29 Weeds/ BBCH 30-39). No data enabling refinement of the risk was available. However, Turango 250 EC is herbicide, therefore it can be assumed that no weeds will be in the field after application.
On the basic information from SPe8 phrase in order to improve these risk assessments for cereals the following restrictions are necessary:
• Do not apply when flowering weeds are present/Erase flowering weeds before application
Nevertheless, since the EFSA Bee Guidance Document is yet to be implemented (2013), this result should be treated as indication of area that should be covered in the future, once the guidance document is officially noted and accepted. Further assessments from chronic exposure could be required at national level.

SPe8	SPe 8: Dangerous to bees. To protect bees and other pollinating insects do not apply when flowering weeds are present. Remove weeds before flowering.

Updated April 2024

The Aplicant provided the calculations of toxicity endpoints for earthworms and Folsomia candida and *Hypoaspis aculeifer* based on geometric mean measured concentration with a risk assessment for eartworms, Folsomia candida and *Hypoaspis aculeifer*. The calculations were accepted by RMS. The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate). The TER_{LT} values for active substance and for product are above trigger value of 5, indicating an acceptable risk for earthworm and soil macro-organism for proposed use of the product **Turango 250 EC**.

Identity section:
The evaluators verified whether the co-formulants contained in the plant protection product Turango 250 EC are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023. Based on the currently available MSDSs and other information provided by the applicant or manufacturer of the co-formulant, the product Turango 250 does not contain any unacceptable co-

formulant/ingredient listed in the Commission Regulation (EU) 2021/383 amending Annex III to Regulation (EC) No 1107/2009. According to the current knowledge and available information none of the co-formulants in the plant protection product Turango 250 meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009. Detailed assessment of co-formulants according to Article 3 of Regulation (EU)2023/574 can be found in RR Part C of this submission (section 1.2.2).

2.3 Substances of concern for national monitoring

This point is not relevant for authorisation of CHR/H/CFF 250 EC.

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:

Hazard class(es), categories:	H302, H304, H315, H318, H400,H410 ~~Clopyralid~~ ~~H411 Toxic to aquatic life.~~ ~~Florasulam~~ ~~H400 Very toxic to aquatic life.~~ ~~H410Very toxic to aquatic life with long lasting effects~~ ~~Fluroxypyr~~ ~~H400 Very toxic to aquatic life~~ ~~H410Very toxic to aquatic life with long lasting effects~~ ~~**Turango H410 Very toxic to aquatic life with long lasting effects**~~

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

Hazard pictograms:	
Signal word:	Danger
Hazard statement(s):	Acute Tox.4, H302 – Harmful if swallowed Asp. Tox. 1, H304 – May be fatal if swallowed and enters airways. Skin Irrit. 2, H315 – Causes skin irritation Eye Dam. 1, H318 – Causes serious eye damage. **H410Very toxic to aquatic life with long lasting effects**
Precautionary statement(s):	WARNING SECTION OF THE LABEL (first page) P264 – Wash face, hands and contaminated skin thoroughly after handling. P280 – Wear protective gloves/protective clothing/eye protection/face protection. P301 + P310 - IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. 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 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P301+P310, P331, P330 P332 + P313 P304+P340 P301 + P312 P308 + P313 P391 – Collect spillage For polish version: see the label
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] SPe3 To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies. To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land or apply 1m an unsprayed buffer zone to non-agricultural land with 75% drift reduction nozzles. SPe 8: Dangerous to bees. To protect bees and other pollinating insects do not apply when flowering weeds are present. Remove weeds before flowering.

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	

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).
SPe3	SPe3 To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies. To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land or apply 1m an unsprayed buffer zone to non-agricultural land with 75% drift reduction nozzles.
SPe8	SPe 8: Dangerous to bees. To protect bees and other pollinating insects do not apply when flowering weeds are present. Remove weeds before flowering.

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

	N/A

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:	
N/A	With gloves and work wear during mix/loading and application
Worker protection:	
N/A	With PPE
Integrated pest management (IPM)/sustainable use:	
N/A	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	
N/A	NTP: - 5 m buffer zone - 1 m and use of 75 % drift reducing nozzles Aquatic organisms: - 5 m buffer zone
Other specific restrictions	
N/A	No specific requirements

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

Integrated pest management (IPM)/sustainable use:	
N/A	Before applying should be informed of this fact by all stakeholders, that may be exposed to the spray drift and who have requested such information.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
N/A	The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.	use number from GAP table in 2.6
Environmental protection:		Relevant for use no.
N/A	In order to protect non-target plants and other measure is	use number from GAP

	necessary the appointment of a protection zone with a width of 5 m of land not used for agricultural or 1 m and the use of 75% drift reducing nozzles	table in 2.6

2.6 Intended uses (only NATIONAL GAP)

GAP rev. , date: 2021-01-13

PPP product name:		Formulation type:	EC [a, b]
product code:	CHR/H/CFF		
Active substance 1:	clopyralid	Conc. of as 1:	120 g/l [c]
Active substance 2:	fluroxypyr	Conc. of as 2:	120 g/l [c]
Active substance 3:	florasulam	Conc. of as 3:	10 g/l (c)
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	Innvigo Sp. z o.o.	Professional use:	☒
Zone(s):	Central [d]	Non professional use:	☐
Verified by MS:	YES		

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, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]	ZRMs Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			

Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat (TRZAW), Winter tritica-le (TTLWI)	F	dicotyle-donous weeds	Spray, medium sprayer	spring BBCH 21-32 ~~33~~	a)1 b)1	n/a	a) 0.4 - 0.5 l/ha b) 0.4 - 0.5 l/ha	a) 0.1 - 0.125 kg a.s./ha (0.048 CLO + 0.048 FLUROX + 0.004 FLO) –(0.06 CLO + 0.06 FLUROX + 0.005 FLO) b) 0.1 - 0.125 kg a.s./ha (0.048 CLO + 0.048 FLUROX + 0.004 FLO) –(0.06 CLO + 0.06 FLUROX + 0.005 FLO)	200-300 ~~400~~	n/a		**Eff. section:** accepted BBCH 21-32. and water volume: 200-300 L/ha **Ecotoxicology**: Uses are ~~not~~ accepted.
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
2														
3														
Minor uses according to Article 51 (zonal uses)														
4	PL	Spelt *Triticum spelta* (3SPWC) Emmer wheat *Triticum dicoccum* (TRZDI) Einkorn wheat *Triticum monococcum (TRZMO)* Durum wheat *Triticum durum* (TRZDW) Spring Rye *Secale cere-ale* (SECCS)	F	~~Monocots and dicots~~ Dicoty-ledonous weeds	Spray, medium sprayer	BBCH 21-32 ~~33~~	a)1 b)1	n/a	a) 0.4 - 0.5 l/ha b) 0.4 - 0.5 l/ha	a) 0.1 - 0.125 kg a.s./ha (0.048 CLO + 0.048 FLUROX + 0.004 FLO) –(0.06 CLO + 0.06 FLUROX + 0.005 FLO) b) 0.1 - 0.125 kg a.s./ha (0.048 CLO + 0.048 FLUROX + 0.004 FLO) –(0.06 CLO + 0.06 FLUROX + 0.005 FLO)	200-300 ~~400~~		.	**Eff. section:** accepted BBCH 21-32 and water volume: 200-300 L/ha.. Only use against dicoty-ledonous should be recommended **Ecotoxicology**: Uses are ~~not~~ accepted..
5														

Minor uses according to Article 51 (interzonal uses)														
6														
7														

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 liquid, with a characteristic odour. It is not explosive, has no oxidising properties. The product has a flash point of 98.3 °C. It has a self-ignition temperature of 390 °C. In aqueous solution, it has a pH value around 2-3 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 8 weeks at 40 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE/PA. Its technical characteristics are acceptable for a EC formulation.
The intended concentration of use is 1% to 0.25%.

Study of 2 years stability is ongoing.

3.2 Efficacy (Part B, Section 3)

Preliminary studies:

The active substances of Turango 250 EC / Hapi 250 EC (product code: CHR/H/CFF 250 EC) – fluroxypyr, florasulam and clopyralid are registered and have been commonly used in agricultural practice for many years. So, many efficacy trials are available to evaluate the effectiveness of products containing those active compounds. However, no PPP with those three active substances are registered in Poland yet. So, justification for this mixture is required in the opinion of ZRMs.

In Poland this formulation is not registered yet. Applicant submitted justification to combine all three active ingredients in CHR/H/CFF 250 EC. Applicant did not submit trials for pre-liminary studies. But in the presented efficacy trials, all of these three compounds (florasulam, fluroxypyr and clopyralid) demonstrated the activity against studied weeds in winter cereals. Such comparison and trials should been acceptable in the opinion of ZRMs.

CHR/H/CFF 250 EC demonstrated at least comparable control or even higher to the standard reference products used during trials: Major 300 SL (with 300 g/L of clopyralid, used at dose 0.4 L/ha), Rassel 100 SC (with 100 g of florasulam used at dose 0.05 L/ha) and Starane 333 EC (with 333 g/L of fluroxypyr used at dose 0.54 L/ha). Two standard reference products (Rassel 100 SC and Starane 333 EC) were used in trials carried out on winter wheat and winter triticale. Major 300 SL with 300 g/L of clopyralid was used at dose 0.4 L/ha in trials performed only on winter wheat.

Taking into account the amount of active substance and the applied dose, both in the CHR/H/CFF 250 EC and the reference PPPs, the mixture of the three substances proved to be more effective than the substances used individually. For example, Major 300 SL at 0.4 L/ha – provides 120 g of clopyralid (the same as the CHR/H/CFF evaluated at 0.5 L/ha), Starane 333 EC provides approximately 180 g of fluroxypyr (more than CHR/H/CFF 250 EC at dose 0.5 L/ha) and Rassel 100 SC at 0.05 L/ha – provides 5 g of floraulam/ha (the same content as CHR/H/CFF 250 EC.

Therefore, in the opinion of ZRMs the inclusion of proposed amount of florasulam (10 g/L), fluroxypyr (120 g/L) and clopyralid (120 g/L) in the formulation of CHR/H/CFF 250 EC can be stated as fully justified.

Comparison for the average of efficacy against CHR/H/CFF 250 EC and st. ref. products in winter wheat

Winter wheat				
Weeds	**CHR/H/CFF 250 EC at dose 0.5 L/ha**	**Major 300 SL at dose 0,4 L/ha**	**Rassel 100 SC at dose 0,05 L/ha**	**Starane 333 EC at dose 0,54 L/ha**
ANTAR	89.73%	87.93%	82.03%	68.64%
BRSNW	90.48%	0.00%	88.79%	69.64%
CENCY	85.56%	89.01%	72.66%	72.80%
GALAP	84.86%	13.76%	80.54%	81.11%
PAPRH	85.02%	21.77%	82.03%	39.68%
STEME	87.80%	22.17%	83.94%	82.54%
MATIN	91.43%	90.06%	85.21%	72.18%

S > 85% eff. **MS** 70-85% eff **MT** 60-70% eff. **T** <60% eff.

Classification marked by colour and eff. of weeds sensitivity according to Polish rules

Comparison for the average of efficacy against CHR/H/CFF 250 EC and st. ref. products in winter triticale

Winter triticale				
Weeds	**CHR/H/CFF 250 EC at dose 0.5 L/ha**	**Major 300 SL at dose 0,4 L/ha**	**Rassel 100 S.C. at dose 0,05 L/ha**	**Starane 333 EC at dose 0,54 L/ha**
ANTAR	85.65%	Not studied	82.30%	69.53%
BRSNW	87.23%	Not studied	83.73%	62.53%
CENCY	85.02%	Not studied	78.78%	78.37%
GALAP	78.13%	Not studied	76.57%	83.17%
PAPRH	88.77%	Not studied	82.72%	34.77%
STEME	83.13%	Not studied	75.87%	80.95%
MATIN	85.65%	Not studied	78.97%	69.62%

S > 85% eff. **MS** 70-85% eff **MT** 60-70% eff. **T** <60% eff.

Classification marked by colour and eff. of weeds sensitivity according to Polish rules

Turango 250 EC / Hapi 250 EC (product code: CHR/H/CFF 250 EC) – composition of clopyralid (120 g/L), florasulam (10 g/L) and fluroxypyr (120 g/L) have a very good effectiveness against weeds in winter wheat and winter triticale, as shown in the following section.

MED (minimum effective dose):

To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. However, in the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance with EPPO 1/225 (2).

Turango 250 EC / Hapi 250 EC (product code: CHR/H/CFF 250 EC) containing florasulam (10 g/L), clopyralid (120 g/L) and fluroxypyr (120 g/L) was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with CHR/H/CFF 250 EC applied at different dose rates was evaluated in 18 eff. trials carried out on winter cereals (11 trials-winter wheat, 7 trials – winter triticale). Those trials were conducted in one EPPO zone: N-E EPPO zone in Poland during different growing seasons (2020 and 2021). Following doses were studied during trials: 0,2 L/ha (0.4N full dose), 0,3 L/ha (0.6N full dose), 0,4 L/ha (N dose); 0,5 L/ha (full N dose) and 0.6 L/ha (1.2N full dose).

Below, ZRMs presented results for MED dose against Turango 250 EC / Hapi 250 EC:

- *for winter wheat*

Weed	Number of trials	Mean eff. at 0,2 L/ha	Mean eff. at 0.3 Lha	Mean eff. at 0.4 L/ha	Mean eff at 0.5 L/ha l/ha	Mean eff at 0.6 L/ha l/ha
ANTAR	8	70.08%	83.83%	83.15%	89.73%	90.18%
BRSNW	9	66.52%	89.70%	86.67%	90.48%	94.14%

CENCY	8	70.78%	75.53%	81.39%	85.56%	89.35%
GALAP	8	66.78%	81.48%	81.62%	84.86%	87.32%
PAPRH	9	73.68%	77.33%	80.00%	85.02%	88.69%
STEME	7	67.53%	91.20%	84.81%	87.80%	90.73%
MATIN	9	73.05%	90.77%	86.82%	91.43%	93.44%

S > 85% eff. **MS** 70-85% eff **MT** 60-70% eff. **T** <60% eff.

Classification marked by colour and eff. of weeds sensitivity according to Polish rules

On the basis on obtained results it has been noted that:

- *for dose 0.2 L/ha* – 3 weeds were classified as a moderately tolerant (BRSNW, GALAP, STEME), and 4 weeds as moderately susceptible (ANTAR, CENCY, PAPRH, STEME). Lack of weeds classified as a sensitive.
- *for dose 0.3 L/ha* – 4 weeds were classified as a moderately susceptible (ANTAR, CENCY, GALAP, PAPRH) and 3 weeds as a susceptible (BRSNW, STEME, MATIN).
- *for dose 0.4 L/ha* – 5 weeds were classified as a moderately sensitive weeds (ANTAR, CENCY, GALAP, PAPRH, STEME) and 2 as a senstive weeds (BRSNW, MATIN).
- *for dose 0.5 L/ha* – 1 weed was classified as a moderately sensitive weed (GALAP) and 6 as a senstive weeds (ANTAR, BRSNW, CENCY, PAPRH, STEME, MATIN).
- *for dose 0.6 L/ha* – all weeds were classified as a sensitive weeds (ANTAR, BRSNW, CENCY, GALAP, PAPRH, STEME, MATIN).

- ***for winter triticale:***

Weed	Number of trials	Mean eff. at 0,2 L/ha	Mean eff. at 0.3 Lha	Mean eff. at 0.4 L/ha	Mean eff at 0.5 L/ha l/ha	Mean eff at 0.6 L/ha l/ha
ANTAR	6	60.43%	82.60%	77.52%	85.65%	89.93%
BRSNW	6	51.25%	81.70%	77.52%	87.23%	92.72%
CENCY	6	66.28%	85.65%	89.87%	85.02%	90.38%
GALAP	7	59.40%	84.43%	74.94%	78.13%	84.63%
PAPRH	6	72.10%	82.53%	88.30%	88.77%	93.77%
STEME	6	67.53%	88.80%	78.10%	83.13%	87.32%
MATIN	6	69.87%	88.60%	80.43%	85.65%	89.60%

S > 85% eff. **MS** 70-85% eff **MT** 60-70% eff. **T** <60% eff.

Classification marked by colour and eff. of weeds sensitivity according to Polish rules

On the basis on obtained results it has been noted that:

- *for dose 0.2 L/ha* – 2 weeds were claassified as a tolerant (BRSNW, GALAP), 4 weeds as moderately tolerant (ANTAR, CENCY, STEME, MATIN) and 1 weed as a moderately sensitive (PAPRH). Lack of weeds classified as a sensitive.
- *for dose 0.3 L/ha* – 4 weeds were classified as a moderately susceptible (ANTAR, BRSNW, GALAP, PAPRH) and 3 weeds as a susceptible (CENCY, STEME, MATIN).
- *for dose 0.4 L/ha* – 6 weeds were classified as a moderately sensitive weeds (ANTAR, BRSNW, CENCY, GALAP, STEME, MATIN) and 1 as a senstive weed (PAPRH).
- *for dose 0.5 L/ha* – 2 weeds were classified as a moderately sensitive weed (GALAP, STEME) and 5 as a senstive weeds (ANTAR, BRSNW, CENCY, PAPRH, MATIN).
- *for dose 0.6 L/ha* – 1 weed was classifies as a moderately sensitive weed (GALAP) and 6 weeds as a moderately sensitive (ANTAR, BRSNW, CENCY, STEME, MATIN, PAPRH).

- ***for winter cerals (both wheat and triticale)***

Weed	Number of trials	Mean eff. at 0,2 L/ha	Mean eff. at 0.3 Lha	Mean eff. at 0.4 L/ha	Mean eff at 0.5 L/ha l/ha	Mean eff at 0.6 L/ha l/ha
ANTAR	14	65.23%	83.22%	80.33%	87.69%	90.06%
BRSNW	15	58.89%	85.70%	82.09%	88.86%	93.43%
CENCY	14	68.53%	80.59%	81.13%	85.29%	89.87%
GALAP	15	63.09%	82.96%	78.28%	81.49%	90.98%
PAPRH	15	72.89%	79.93%	81.15%	86.89%	91.23%
STEME	13	67.53%	90.00%	81.46%	85.47%	89.03%
MATIN	15	71.46%	89.69%	83.63%	89.68%	91.52%
S	> 85% eff.	**MS**	70-85% eff	**MT**	60-70%	**T**	<60% eff.

On the basis on obtained results it has been noted that:

- *for dose 0.2 L/ha* – 1 weed was claassified as a tolerant (BRSNW), 4 weeds as moderately tolerant (ANTAR, CENCY, GALAP, STEME) and 2 weeds as a moderately sensitive (PAPRH and STEME). Lack of weeds classified as a sensitive.
- *for dose 0.3 L/ha* – 4 weeds were classified as a moderately susceptible (ANTAR, CENCY, GALAP, PAPRH) and 3 weeds as a susceptible (BRSNW, STEME, MATIN).
- *for dose 0.4 L/ha* – all weeds were classified as a moderately sensitive weeds (ANTAR, BRSNW, CENCY, GALAP, PARH, STEME, MATIN). Lack of weeds classified as a sensitive.
- *for dose 0.5 L/ha* – 1 weed was classified as a moderately sensitive weed (GALAP) and 6 as a sen-stive weeds (ANTAR, BRSNW, CENCY, PAPRH, STEME, MATIN).
- *for dose 0.6 L/ha* – all weeds were classified as a sensitive weeds (ANTAR, BRSNW, CENCY, GALAP, PAPRH, MATIN, STEME).

Trials submitted by Applicant are sufficient for Poland for MED dose. The clear dose responses was observed for the most of studied weed species. The most effective was dose 0.6 L/ha. However, dose 0.5 L/ha was characterized also by a very good effectiveness at should be recommended as a full rate. On the basis on submitted results also dose 0.4 L/ha was characterized by good efficiency and should be recommended for use.

Both doses – 0.4 and 0.5 L/ha showed very good efficacy. Therefore, the highest dose tested (0.6 L/ha) should not be recommended (e.g. for environmental reasons).

Evaluator conclusion: The claimed dose rate is 0.4-0.5 L of product/ha. The minimum effective dose were tested in winter wheat and winter triticale through the NE climatic EPPO zone. The range of 0.4-0.5 L product/ha gives control of many of the main weeds in cereals.
The rate should be adjusted according to the development stage of the weeds and the weed species present in the field. The lower rate should be applied to weeds that are less developed, in the early stages of development and when weed infestation is less severe, while the higher of the recommended rates should be applied when weeds are more advanced in development.

Efficacy:

All details about efficacy methodology used during efficacy trials are presented above by Applicant. Submitted reports from field trials (18 in total) carried out on winter cereals (winter wheat – 11 trials and winter triticale – 7 trials) include a detailed data on soil and field conditions, agro-technological procedures, fore-crop as well as meteorological conditions and technical details of the spraying etc.

Applicant properly presented efficacy results. Applicant wish to register Turango 250 EC / Hapi 250 EC in PL (product code: CHR/H/CFF 250 EC) in Poland (N-E EPPO zone).

Only trials with greater than 4-5 weeds/m^2 or over 2% ground cover should be taken for assessment. According to EPPO PP 1/226 at least 6 fully supportive results for major weeds and 2 trials for minor weeds

should be required. Therefore, based on knowledge of major/minor status of weeds in each country, weeds with insufficient results should be excluded. In Poland, no PPP with florasulam, clopyralid and fluroxypyr is registered in one PPP product. Turango 250 EC / Hapi 250 EC will be the first on the Polish market in this formulation and composition. So, according to Polish rules for major weeds – at least 6 trials are required and for minor weeds – at least 3 weeds.

Submitted efficacy trials are correctly performed according to appropriate EPPO standards. Accepted weed species for Poland (N-E EPPO zone) should be presented to following scale of sensitivity:

- S (susceptible) > 85%;
- MS (moderately susceptible) 70-85%;
- MT (moderately tolerant) 60-70%;
- T (tolerant) < 60%.

Applicant used correct classification of weeds sensitivity in this registration report.

Applicant submitted trials carried out in 2020 and 2021. So, in line to appropriate EPPO standard two growing seasons were studied. Submitted studies were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognized. In the opinion of ZRMs number of trials for winter wheat and winter triticale is accepted for Poland.

Below, ZRMs presented the assessment for studied weed species in winter wheat:

Winter wheat						
Weeds	**Number of trials**	**CHR/H/CFF 250 EC at dose 0.4 L/ha**	**CHR/H/CFF 250 EC at dose 0.5 L/ha**	**Major 300 SL at dose 0,4 L/ha**	**Rassel 100 SC at dose 0,05 L/ha**	**Starane 333 EC at dose 0,54 L/ha**
ANTAR	8	83.15%	89.73%	87.93%	82.03%	68.64%
BRSNW	9	86.67%	90.48%	0.00%	88.79%	69.64%
CENCY	8	81.39%	85.56%	89.01%	72.66%	72.80%
GALAP	8	81.62%	84.86%	13.76%	80.54%	81.11%
PAPRH	9	80.00%	85.02%	21.77%	82.03%	39.68%
STEME	7	84.81%	87.80%	22.17%	83.94%	82.54%
MATIN	9	86.82%	91.43%	90.06%	85.21%	72.18%

Classification marked by colour and eff. of weeds sensitivity according to Polish rules

Number of trials for all mentioned above weed species in table was acceptable. Trials were characterized by sufficient level of infestation.

On the basis on the submitted results it can be stated that for dose 0.4 L/ha of CHR/H/CFF 250 EC – 2 weeds were classified as a susceptible (BRSNW, MATIN) and 5 weeds as moderately susceptible (ANTAR, CENCY, GALAP, PAPRH, STEME).

On the basis on the submitted results it can be stated that against dose 0.5 L/ha of CHR/H/CFF 250 EC – one weed was classified as moderately susceptible (GALAP) and 6 weeds as susceptible (ANTAR, BRSNW, CENCY, PAPRH, STEME, MATIN).

In all trials standard reference products were used. Efficacy of them is presented in the table above, In generally it can be stated that CHR/H/CFF have best efficacy or comparable to st. ref. products.

Below, ZRMs presented the assessment for studied weed species in winter triticale:

Winter triticale						
Weeds	**Number of trials**	**CHR/H/CFF 250 EC at dose 0.4 L/ha**	**CHR/H/CFF 250 EC at dose 0.5 L/ha**	**Major 300 SL at dose 0,4 L/ha**	**Rassel 100 S.C. at dose 0,05 L/ha**	**Starane 333 EC at dose 0,54 L/ha**
ANTAR	6	77.52%	85.65%	-	82.30%	69.53%
BRSNW	6	77.52%	87.23%	-	83.73%	62.53%
CENCY	6	80.87%	85.02%	-	78.78%	78.37%

GALAP	7	74.94%	78.13%	-	76.57%	83.17%
PAPRH	6	82.30%	88.77%	-	82.72%	34.77%
STEME	6	78.10%	83.13%	-	75.87%	80.95%
MATIN	6	80.43%	85.65%	-	78.97%	69.62%

Classification marked by colour and eff. of weeds sensitivity according to Polish rules

Number of trials for all mentioned above weed species in table was acceptable. Trials were characterized by sufficient level of infestation.

On the basis on the submitted results it can be stated that for dose 0.4 L/ha of CHR/H/CFF 250 EC – 7 weeds were classified as a moderately susceptible (BRSNW, MATIN, ANTAR, CENCY, GALAP, PAPRH, STEME).

On the basis on the submitted results it can be stated that against dose 0.5 L/ha of CHR/H/CFF 250 EC – two weeds were classified as moderately susceptible (GALAP, STEME) and 5 weeds as susceptible (ANTAR, BRSNW, CENCY, PAPRH, MATIN).

In all trials standard reference products were used. Efficacy of them is presented in the table above, In generally it can be stated that CHR/H/CFF have best efficacy or comparable to st. ref. products.

Weed species in winter cereals can be assessed together for winter wheat and winter triticale. So, below ZRMS presented results for recommended dose 0.4-0.5 L/ha for labelling purposes:

Winter triticale and winter wheat						
Weeds	**Number of trials**	**CHR/H/CFF 250 EC at dose 0.4 L/ha**	**CHR/H/CFF 250 EC at dose 0.5 L/ha**	**Major 300 SL at dose 0,4 L/ha**	**Rassel 100 S.C. at dose 0,05 L/ha**	**Starane 333 EC at dose 0,54 L/ha**
ANTAR	14	80.33%	87.69%	87.93%	82.16%	69.09%
BRSNW	15	82.09%	88.86%	0.00%	86.26%	66.09%
CENCY	14	81.13%	85.29%	89.01%	75.72%	75.58%
GALAP	15	78.28%	81.49%	13.76%	78.56%	82.14%
PAPRH	15	81.15%	86.89%	21.77%	82.38%	37.22%
STEME	13	81.46%	85.47%	22.17%	79.90%	81.75%
MATIN	15	83.63%	89.68%	90.06%	82.09%	70.90%

Classification marked by colour and eff. of weeds sensitivity according to Polish rules

Number of trials for all mentioned above weed species in table was acceptable. Trials were characterized by sufficient level of infestation.

On the basis on the submitted results it can be stated that for dose 0.4 L/ha of CHR/H/CFF 250 EC – 7 weeds were classified as a moderately susceptible (BRSNW, MATIN, ANTAR, CENCY, GALAP, PAPRH, STEME).

On the basis on the submitted results it can be stated that against dose 0.5 L/ha of CHR/H/CFF 250 EC – one weed is classified as moderately susceptible (GALAP) and 6 weeds as susceptible (ANTAR, BRSNW, CENCY, GALAP, PAPRH, MATIN).

Summary: The most effective for most studied weed species for post-emergence use on winter cereals (wheat, triticale) was dose 0.4 and 0.5 L/ha. The rate should be adjusted according to the development stage of the weeds and the weed species present in the field. The lower rate should be applied to weeds that are less developed, in the early stages of development and when weed infestation is less severe, while the higher of the recommended rates should be applied when weeds are more advanced in development.

Applicant would like to include 7 weed species in the label, for which assessment in this dRR was presented. However, **in the opinion of ZRMs also CAPBP can be included in label as a susceptible weed in line to 4 valid trials** (average eff. for dose 0.4 L/ha – 87,83% and for dose 0.5 L/ha – 97,33%). It is a minor weed in winter wheat and winter triticale according to in accordance wth harmonisation arrangements, so it should be also included in the label project. It level of infestation was acceptable in all 4 trials (3 trials-winter wheat and 1 trial-winter triticale).

VERPE was also represented by sufficient number of trials (4: 3 for winter wheat and 1 for winter triticale). However, it was tolerant against CHR/H/CFF 250 EC in 3 trials and susceptible in one trial. Its average efficacy was 39.10% for dose 0.4 L/ha and 45.03% L/ha. So, it can be concluded that VERPE is tol-

erant against VERPE, so in the opinion of ZRMs it should not been included in the label.

Other weed species were not represented by a sufficient number of field trials: VIOAR (2 trials), VERHE (2 trials), MYOAR (1 trial), THLAR (2 trials), MATCH (2 trials), LITAR (1 trial), LAMPU (1 trials). So, properly they were not assessed by Applicant and not proposed for the Polish label project.

In Polish label following weeds species can be included:

- ***for winter triticale and winter wheat***

- **Dose 0.4 L/ha**: *Susceptible weeds:* CAPBP; *Moderately susceptible weeds*: BRSNW, MATIN, ANTAR, CENCY, GALAP, PAPRH, STEME
- **Dose 0.5 L/ha:** *Susceptible weeds:* ANTAR, BRSNW, CAPBP, CENCY, GALAP, PAPRH, MATIN; *Moderately susceptible weeds:* GALAP.

ZRMs not accepted proposed by Applicant water volume: 200-400 L/ha. During 18 eff. trials Applicant studied 200 L/ha of water in 12 trials; and 300 L/ha in 6 trials. So, recommended water volume should be 200-300 L/ha. 400 L/ha – was not studied and should not been accepted.

ZRMs not accepted application window: BBCH 21-33. During trials following stage of crop development at application was studied: BBCH 21-32. So, Turango 250 EC / Hapi 250 EC should be recommended for use at BBCH 21-32 in the spring according to submitted trials.

This plant protection product 'Turango 250 EC / Hapi 250 EC' can be used in winter wheat and winter triticale against weed species included in the GAP table and label project. The product can be applied post-emergence in spring at BBCH 21-32.

Also, following minor uses can be included in Polish label in line to Article 51 and claimed GAP table: spelt, emmer wheat, *Triticum dicoccum*, Einkorn wheat,
Triticum monococcum, Durum wheat, *Triticum durum*, Spring Rye and Secale cereal. In the opinion of ZRMs the same BBCH 21-32 as for major uses should be recommended on grounds of user convenience. CHR/H/CFF 250 EC can be registered for control dicotyledonous weeds at dose 0.4-0.5 L/ha.

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

„Resistance" is defined as the naturally occurring, inheritable adjustment in the ability of individuals in a population to survive a plant protection product treatment that would normally give effective control. Resistance to crop protection chemicals is a common biological phenomenon that occurs in insects, fungi and weeds. It usually becomes evident after the repeated use of a particular pesticide selected the naturally occurring resistant biotypes allowing them to multiply over several seasons until they become an obvious problem. Although resistance can often be demonstrated in the laboratory this does not necessarily mean that pest control in the field is reduced. "Practical resistance" is the term used for loss of field control due to a shift in sensitivity (OEPP/EPPO, 1988).

The applicant has provided a resistance risk assessment according to the standard: EPPO PP1 PP 1/213 (4) resistance risk analysis.

Weeds are one of the most important reducing factors for crop yield reduction. Yield loss by weeds is reported to be higher than 30% in some cases depending on the different climatic conditions and management practices [Zand et al., 2003]. In particular, potential crop losses due to weeds are estimated to be 32% on average (range 26%–40%), exceeding potential losses due to pests (18%) and pathogens (15%) [Royal Society, 2009].

There are currently 533 unique cases of herbicide resistant weeds globally, with 273 species (156 dicots and 117 monocots). Weeds have evolved resistance to 21 of the 31 known herbicide sites of action and to 168 different herbicides. Herbicide resistant weeds have been reported in 101 crops in 72 countries. The website has 3313 registered users and 711 weed scientists have contributed new cases of herbicide re-

sistant weeds. Resistance events have been reported in Europe for those three active substances and weed species target of Turango 250 EC / Hapi 250 EC (product code: CHR/H/CFF 250 EC).

- **Florasulam**

The applicant has correctly highlighted that florasulam belongs to HRAC group 2 (legacy B) – ALS inhibitors – Inhibition of acetolactate synthase and is part of the triazolopyrimidine chemical family. Inherent resistance risk for the active: high. There are many cases of resistance to ALS inhibitors.

The following table shows the current worldwide resistance cases specifically to the herbicide florasulam:

#	Year	Species	Country	MOAs	Actives	Situations
1	2014	*Papaver rhoeas*	Belgium	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	metsulfuron-methyl, florasulam	Wheat
2	2007	*Polygonum convolvulus (=Fallopia convolvulus)*	Canada (Alberta)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	thifensulfuron-methyl, tribenuron-methyl, florasulam	Wheat, Peas
3	2002	*Amaranthus retroflexus*	Canada (Manitoba)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	florasulam	Wheat
4	2019	*Lithospermum arvense*	China	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	imazethapyr, pyrithiobac-sodium, tribenuron-methyl, florasulam, pyroxsulam	Wheat
5	2021	*Tripleurospermum perforatum (=T. inodorum)*	Czech Republic	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	tribenuron-methyl, florasulam	Wheat
6	1991	*Stellaria media*	Denmark	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	chlorsulfuron, tribenuron-methyl, florasulam, iodosulfuron-methyl-Na	Spring Barley, Wheat
7	2001	*Alopecurus myosuroides*	Denmark	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Acetyl CoA Carboxylase HRAC Group 1 (Legacy A), Inhibition of Microtubule Assembly HRAC Group 3 (Legacy K1)	clodinafop-propargyl, fenoxaprop-ethyl, cycloxydim, flupyrsulfuron-methyl-Na, pendimethalin, florasulam, iodosulfuron-methyl-Na, mesosulfuron-methyl, pyroxsulam	Winter wheat
8	2003	*Papaver rhoeas*	Denmark	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	tribenuron-methyl, florasulam, iodosulfuron-methyl-Na	Wheat
9	2010	*Tripleurospermum perforatum (=T. inodorum)*	Denmark	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	tribenuron-methyl, florasulam, iodosulfuron-methyl-Na	Spring Barley, Winter wheat
10	2010	*Lolium perenne ssp. multiflorum*	Denmark	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Acetyl CoA Carboxylase HRAC Group 1 (Legacy A)	clodinafop-propargyl, florasulam, iodosulfuron-methyl-Na, mesosulfuron-methyl, pyroxsulam	Winter wheat
11	2012	*Capsella bursa-pastoris*	Denmark	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	tribenuron-methyl, florasulam	Spring Barley
12	2016	*Apera spica-venti*	Denmark	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of	fenoxaprop-ethyl, florasulam, iodosulfuron-methyl-Na, mesosulfuron-methyl, pinoxaden	Wheat

#	Year	Species	Country	MOAs	Actives	Situations
				Acetyl CoA Carboxylase HRAC Group 1 (Legacy A)		
13	2009	*Senecio vulgaris*	France	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	tribenuron-methyl, prosulfuron, metsulfuron-methyl, flazasulfuron, imazamox, florasulam, iodosulfuron-methyl-Na, mesosulfuron-methyl, thiencarbazone-methyl	Grapes, Wheat
14	2012	*Stellaria media*	France	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	thifensulfuron-methyl, metsulfuron-methyl, florasulam, iodosulfuron-methyl-Na, mesosulfuron-methyl	Wheat
15	2017	*Rumex obtusifolius*	France	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	thifensulfuron-methyl, metsulfuron-methyl, florasulam	Wheat
16	2005	*Apera spica-venti*	Germany	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	sulfosulfuron, chlorsulfuron, flupyrsulfuron-methyl-Na, sulfometuron-methyl, florasulam, iodosulfuron-methyl-Na, mesosulfuron-methyl, pyroxsulam	Wheat
17	2011	*Stellaria media*	Germany	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	thifensulfuron-methyl, amidosulfuron, triflusulfuron-methyl, tribenuron-methyl, nicosulfuron, imazamox, florasulam, iodosulfuron-methyl-Na, tritosulfuron, mesosulfuron-methyl, pyroxsulam	Spring Barley, Wheat, Rapeseed
18	2012	*Papaver rhoeas*	Germany	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	imazamox, florasulam	Cereals, Rapeseed
19	2017	*Anthriscus caucalis*	Germany	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	thifensulfuron-methyl, tribenuron-methyl, metsulfuron-methyl, florasulam	Winter wheat
20	1998	*Papaver rhoeas*	Greece	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	pyrithiobac-sodium, thifensulfuron-methyl, chlorsulfuron, tribenuron-methyl, triasulfuron, imazamox, florasulam	Winter wheat
21	2021	*Glebionis segetum*	Greece	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	tribenuron-methyl, imazamox, florasulam, pyroxsulam	Wheat, Winter barley
22	2022	*Galium spurium*	Greece	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	bensulfuron-methyl, metsulfuron-methyl, florasulam, pyroxsulam	Wheat
23	2014	*Rumex dentatus*	India	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	florasulam, iodosulfuron-methyl-Na, mesosulfuron-methyl, pyroxsulam	Wheat
24	2010	*Rapistrum rugosum*	Iran	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	bispyribac-sodium, tribenuron-methyl, florasulam, flucarbazone-Na	Winter wheat
25	2007	*Lolium rigidum*	Israel	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Acetyl CoA Carboxylase HRAC Group 1 (Legacy A),	clodinafop-propargyl, imazapyr, chlorsulfuron, tribenuron-methyl, sulfometuron-methyl, flumetsulam, metosulam, glyphosate, florasulam, iodosulfuron-methyl-	Wheat

#	Year	Species	Country	MOAs	Actives	Situations
				Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G)	Na, mesosulfuron-methyl, pinoxaden, propoxycarbazone-Na	
26	2012	*Diplotaxis erucoides*	Israel	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	imazethapyr, tribenuron-methyl, flumetsulam, imazamox, florasulam	Wheat
27	2012	*Erucaria hispanica*	Israel	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	tribenuron-methyl, flumetsulam, florasulam	Wheat
28	1998	*Papaver rhoeas*	Italy	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	tribenuron-methyl, florasulam, iodosulfuron-methyl-Na	Durum wheat
29	2006	*Sinapis arvensis*	Italy	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	tribenuron-methyl, florasulam, iodosulfuron-methyl-Na	Durum wheat
30	2010	*Alopecurus myosuroides*	Netherlands	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	florasulam, iodosulfuron-methyl-Na, mesosulfuron-methyl, pyroxsulam	Winter wheat
31	2006	*Spergula arvensis*	Norway	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	tribenuron-methyl, florasulam	Winter wheat, Winter barley
32	1995	*Stellaria media*	Sweden	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	chlorsulfuron, tribenuron-methyl, florasulam	Spring Barley, Spring wheat, Winter wheat
33	2014	*Matricaria recutita (= M. chamomilla)*	Sweden	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	tribenuron-methyl, florasulam	Wheat
34	2015	*Tripleurospermum perforatum (=T. inodorum)*	Sweden	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	tribenuron-methyl, florasulam	Wheat
35	2020	*Amaranthus retroflexus*	Ukraine	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	imazethapyr, thifensulfuron-methyl, tribenuron-methyl, flumetsulam, imazamox, florasulam, iodosulfuron-methyl-Na, foramsulfuron, thiencarbazone-methyl	Corn (maize), Sunflower
36	2022	*Chenopodium album*	Ukraine	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	thifensulfuron-methyl, tribenuron-methyl, flumetsulam, imazamox, florasulam, iodosulfuron-methyl-Na, thiencarbazone-methyl	Corn (maize), Soybean, Wheat, Sunflower
37	2000	*Stellaria media*	United Kingdom	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	metsulfuron-methyl, florasulam	Cereals

The table above highlights the cross resistance within ALS inhibiting herbicides, as in most cases where there is florasulam resistance there is also resistance to other ALS inhibitors.

Florasulam: high resistance risk. Globally, herbicide resistance to the Group 2 herbicide mode of action has been confirmed and documented in more than 170 grass and broadleaf weed species across more than 40 countries. Resistance to Group 2 is extensive and prolific, with tens of millions of hectares affected, in fact it is the most likely herbicide mode of action to develop resistance.

Research has shown that as few as four applications to the same population of annual ryegrass can result in the selection of resistant individuals and as few as six applications for wild radish. A population can go from an apparently small number of resistant individuals to a whole paddock failure in one season. Group 2 herbicides are presently the only post emergent herbicides that provide effective control of these grass weeds and this poses a severe risk of Group 2 resistance for growers with cereal dominant rotations.

- **Clopyralid**

Clopyralid belongs to the pyridine carboxylic acids group. Applied post-emergence, clopyralid is effective on a broad spectrum of broad-leaved weeds.

Clopyralid is rapidly degraded in soil (DT_{50} = 34 days) thus a prolonged exposure to weed populations does not occur which is a factor which decreases the re-sistance risk.

The probability of development of resistance or cross-resistance of weeds to clopyralis is considered as low. The evaluation of the agronomic risk concludes that clopyralid bears a low risk of resistance.

Plant protection products containing clopyralid are used from many years and no information's concerning weed resistance for this active substance was noted. However, the information on possible development of resistance or cross-resistance is provided by scientific literature from many different countries and describes different weed species. Product should be used in rates neither lower nor higher than recommended in the label due to prevent resistance development.

According to weedscience.org, 4 cases of resistance were reported.

#	Year	Species	Country	MOAs	Actives	Situations
1	2013	*Centaurea stoebe ssp. micranthos*	Canada (British Columbia)	Auxin Mimics HRAC Group 4 (Legacy O)	clopyralid, picloram	Rangeland
2	1999	*Soliva sessilis*	New Zealand	Auxin Mimics HRAC Group 4 (Legacy O)	clopyralid, picloram, triclopyr	Golf courses, Turf
3	2005	*Chenopodium album*	New Zealand	Auxin Mimics HRAC Group 4 (Legacy O)	dicamba, clopyralid, aminopyralid	Corn (maize)
4	2022	*Ambrosia artemisiifolia*	United States (Michigan)	Auxin Mimics HRAC Group 4 (Legacy O)	clopyralid	Christmas Tree

- **Fluroxypyr**

According to the Herbicide Resistance Action Committee (HRAC) fluroxypyr is included in HRAC Group 4 (O) – auxin mimics.

Fluroxypyr is a very effective in controlling a wide range of broadleaf weeds and woody brush making it excellent for controlling weed problems on croplands and pastures as well as rights of way and industrial sights. It is also a selective herbicide meaning it will only harm target weeds and cause little to no effect on non-target desired vegetation.

Fluroxypyr (4-amino-3, 5-dichloro-6-fluoro-2-pyridyloxyacetic acid) is originally applied in cereal, olive tree, and fallow cropland fields, to control annual or perennial weeds (Hellou et al., 2009). These herbicides cause auxin overdose or excessive endogenous auxin concentrations, thereby resulting in an imbalance of auxin homeostasis and interaction with other hormones in tissues, which ultimately cause the succeeding series of biochemical and physiological processes associated with herbicide action (Gross-

mann, 2010). Liu (2014) demonstrated that the label fluroxypyr dose can be used in maize (Zea mays) and winter wheat (Triticum aestivum) fields, and has desirable control effects on broadleaf weeds.

#	Year	Species	Country	MOAs	Actives	Situations
1	1998	*Galeopsis tetrahit*	Canada (Alberta)	Auxin Mimics HRAC Group 4 (Legacy O)	dicamba, MCPA, fluroxypyr	Spring Barley, Cereals, Cropland, Wheat
2	2015	*Kochia scoparia*	Canada (Saskatchewan)	Auxin Mimics HRAC Group 4 (Legacy O), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	thifensulfuron-methyl, tribenuron-methyl, dicamba, fluroxypyr	Spring wheat
3	2010	*Stellaria media*	China	Auxin Mimics HRAC Group 4 (Legacy O)	MCPA, fluroxypyr	Winter wheat
4	2014	*Galium aparine*	China	Auxin Mimics HRAC Group 4 (Legacy O)	fluroxypyr	Wheat
5	2013	*Kochia scoparia*	United States (Kansas)	Auxin Mimics HRAC Group 4 (Legacy O), Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G)	glyphosate, dicamba, fluroxypyr	Corn (maize), Sorghum
6	1994	*Kochia scoparia*	United States (Montana)	Auxin Mimics HRAC Group 4 (Legacy O)	dicamba, fluroxypyr	Cropland, Wheat

The probability of development of resistance or cross-resistance of weeds to fluroxypyr in EU in PL is considered as low. The evaluation of the agronomic risk concludes that fluroxypyr bears a low risk of resistance in the EU.

Herbicide resistance has caused serious problems in weed control programs. Many researchers do not advise continuous applications of one herbicide or even a limited number of herbicides [Beckie et al., 2009]. Therefore, control of weeds should be based on a combination of several agronomic and cultural practices along with chemical solutions. One of the best alternative tactics to inhibit evolution of herbicide-resistant weeds is the rotational application of herbicides with different modes of action and the use of herbicide mixtures [Travlos et al., 2012].

Florasulam inhibits proto-porphyrinogen oxidase (PPO protox) and is used for broadleaf weed control. Florasulam inhibits the production of the ALS enzyme in plants. This enzyme is essential for the production of certain amino acids which are essential for plant growth. **Fluroxypyr** 1-methylheptyl ester will hydrolyse during penetration to form fluroxypyr-acid which acts as an auxin like herbicide causing rapid cell growth within the plant. Once absorbed fluroxypyr acid moves readily through the plant via both the xylem and phloem and is distributed throughout the entire plant to the meristems and other developing parts. In susceptible plant species fluroxypyr induces an epinastic response (ie stimulation of cell elongation and premature senescence, particularly in meristematic tissue) leading to cessation of normal growth and rapid necrosis followed by plant death. **Clopyralid** is an “auxin mimic” or synthetic auxin. This type of herbicide kills the target weed by mimicking the plant growth hormone auxin (indole acetic acid), and when administered at effective doses, cause uncontrolled and disorganized plant growth that leads to plant death. Taking into account that the use of different modes of action may enhance efficacy and increase the weed control spectrum, there is a clear need for evaluation of several new herbicide mixtures against serious weeds. Such a new tank mixture herbicide on the Polish market will be Turango 250 EC / Hapi 250 EC (product code: CHR/H/CFF 250 EC). Use of anti-resistant strategies is one of these principles and certainly, mixtures of herbicides can reduce the costs, lower the selection pressure, and prevent or delay herbicide-resistance issues especially when combined with several agronomic practices.

In the opinion of ZRMs due to the different mode of action of active substances: florasulam, fluroxypyr and clopyralid, the occurrence of resistance to this herbicide is low to medium.

The resistance strategy proposed by the Applicant was accepted by the ZRMs.

Resistance management strategy for Turango 250 EC / Hapi 250 EC:

To minimise the risk of weeds developing resistance to herbicides, follow good agricultural practice:

- follow the instructions on the plant protection product label - apply the product at the recommended rate, at the recommended time to ensure optimum weed control,
- tailor the choice of herbicide and the decision to treat to the prevailing (or potential) weed infestation, taking into account the dominant species and damage thresholds,
- use a rotation of herbicides (active ingredients) with different modes of action,
- use a mixture of herbicides (active substances) with different modes of action,
- use a rotation and/or mixture of herbicides acting on several weed life processes (with different modes of action),
- apply a herbicide with a given mode of action only once per crop growing season,
- adapt tillage to field conditions, especially to the type and severity of weeds,
- use a variety of weed control methods, including crop rotation, etc,
- use certified seeds,
- clean agricultural machinery to prevent the spread of weed propagating material to other sites,
- report unsatisfactory weed control to the licence holder,
- for more information, contact your adviser, the licensee or the licensee's representative.

The abidance of the requirements within the good agricultural practice is necessary. The resistance management is coordinated by HRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restriction should be put on the label.

3.2.2 Adverse effects on treated crops

In the evaluation process the fact that the active ingredients – florasulam, fluroxypyr and clopyralid are used in many plant protection products and has been commonly used in crop protection were taken into consideration by Evaluator. However, in Poland – no PPP with all of those a.s. is already registered. Turango 250 EC / Hapi 250 EC (product code: CHR/H/CFF 250 EC) will be the first on the Polish market with this composition.
The Applicant submitted in total 14 selectivity studies carried out on winter cereals (wheat and triticale). Winter wheat was studied in 8 selectivity trials carried out in two growing seasons 2020 (4 trials) and 2021 (4 trials) in Poland. Winter triticale was studied in 6 selectivity trials carried out in 2020 (3 trials) and 2021 (3 trials) in PL. Trials were conducted in line to appropriate EPPO standards.

Different varietes were studied during selectivity trials: winter wheat (Rotax, Julius, Hondia, Arkadia, Linus, Tonacja, Jantarka, Findus) and winter triticale (Kasyno, Orinoko, Porto, Rotondo, Twingo, Toledo).

Following provinces were studied: kujawsko-pomorskie (7 trials), wielkopolskie (5 trials), mazowieckie (1 trial), warmińsko-mazurskie (1 trial).

Valid plot area was used: 15 – 25 m^2 (25m^2-1 trial; 24m^2-1 trial; 23,75m^2-1 trial; 21,25m^2-1 trial; 21m^2-1 trail; 20 m^2 – 4 trials; 18m^2-2 trial; 17,5m^2-2 trials; 15m^2-1 trial).

Crop stage at application: BBCH 21-32.

Water volume studied: 200-300 L/ha (200 L/ha – 8 trials; 230 L/ha – 3 trials; 300 L/ha -3 trials).

The selectivity evaluation of the herbicide is to be performed according to listed below EPPO guidelines. The evaluation of herbicide selectivity was carried out 4-5 per season. Results were described in percent

of destruction of plant for herbicides treatment compared to plant for untreated, where 0% means no phytotoxicity and 100% - complete destruction.

Phytotoxicity assessment was carried out with the use of different cultivars (commercially grown varieties). N dose (0.5 L/ha) was not studied during selectivity trials. In all trials only 1.2 N dose (0.6 L/ha) and 2.4 N dose (1.2 L/ha) was studied. St. Reference products were used at N dose nad 2 N dose. In the opinion of ZRMs, studied higher than N dose should been accepted.

No phytotoxicity symptom caused by Turango 250 EC / Hapi 250 EC (product code: CHR/H/CFF 250 EC) was observed in most selectivity studies. Only in two trials (A.T/2020/046/PO and SRPL21-417-336HE) carried out on winter wheat some phytotoxicity symptoms on tested product and standard were observed. Phytotoxicity have no impact on yield quality and quantity.

Report A.T/2020/046/PO (Variety: Hondia)

In the trial the tested herbicides were applied in the BBCH 30 phase of winter wheat. During the assessment: A2 (22 DAA A) on some of the tested objects the occurrence of phytotoxicity on wheat plants manifested by delicate leaf brightening (chlorosis) PHYCHL was noted. The highest intensity of the observed damage symptoms was recorded on the objects:

• with the reference preparation Starane 333 EC applied in double dose (1,08 l/ha) - combination No. 7: PHYGEN = 4,8%, PHYCHL = 4,8%

• with the test preparation CHR/H/CFF 250 EC applied in double dose (1,2 l/ha) - combination No. 3: PHYGEN = 3,8%, PHYCHL = 3,8%

• with the reference preparation Starane 333 EC applied in standard dose (0,54 l/ha) - combination No. 6: PHYGEN = 1,5%, PHYCHL = 1,5%

• with the test preparation CHR/H/CFF 250 EC applied in standard dose (0,6 l/ha) - combination No. 2: PHYGEN = 1,3%, PHYCHL = 1,3%

The phytotoxicity symptoms noted on the tested objects, however, were slight and transient. During the assessments A3 (36 DAA A) and A4 (49 DAA A) both the tested preparation CHR/H/CFF 250 EC as well as the reference preparations Major 300 SL, Starane 333 EC and Rassel 100 SC, used in basic and doubled doses, did not show phytotoxic effects on winter wheat.

Report SRPL21-417-336HE (variety: Findus)

During the examination of the CHR / H / CFF 250 EC preparation tested at various doses, symptoms of chlorosis were observed at 14.22 DAA for a dose of 1.2 l / ha - 1-3%, hence it can be concluded that the tested preparation is not fully selective for winter wheat. In the case of reference products, as for the dose of 0.6 l / ha CHR / H / CFF 250 EC, no negative effects on the crop were observed.

Phytotoxicity of recommended doses: 0.4 L/ha and 0.5 L/ha was studied during 18 efficacy trials (11 trials – winter wheat and 7 trials – winter triticale). No negative effect of CHR/H/CFF 250 EC was observed during those trials.

In the opinion of ZRMs it can be concluded that Turango 250 EC/ Hapi 250 EC is safe for use on winter wheat and winter triticale at recommended dose. Hovewer, according to the ZRMs, the following information will be required on the product label: *Transient symptoms of phytotoxicity not affecting yield or quality may occur after application of the product on some winter wheat varieties (e.g. Findus, Hondia).*

Effect on yield:

The effects of Turango 250 EC / Hapi 250 EC (product code: CHR/H/CFF 250 EC) on the yield of winter cereals (winter wheat and winter triticale) were evaluated in 14 selectivity trials (8 winter wheat; 6 winter triticale). In these trials, yield was assessed after application of a single 1.2 N dose (0.6 L/ha) of the above product and a 2.4 N dose (1.2 L/ha). Statistical analysis of yield and its parameters was performed. All results were comparable with standard reference products.

In field trials with winter wheat and winter triticale, Turango 250 EC / Hapi 250 EC applied at single rate of 0.6 L/ha and double rate of 1.2 L/ha had no significant adverse effect on yield. Phytotoxic effects were not observed even on the doubled rate plots (except for two trials on winter wheat): A.T/2020/046/PO and SRPL21-417-336HE. However, this didn't have a negative effect on winter wheat yield.

No statistical differences in yield were observed between the plots treated with CHR/H/CFF 250 EC and the control plots. The absence of a study on the recommended dose should be accepted as doses 1.2 N and 2.4 N have been tested.

Effect on the quality of yield:
The effects of Turango 250 EC / Hapi 250 EC (product code: CHR/H/CFF 250 EC) on yield quality of winter cereals (winter wheat and winter triticale) were evaluated in 14 selectivity trials (8 winter wheat; 6 winter triticale). In these trials, yield quality was assessed after application of a single 1.2 N dose (0.6 L/ha) of the above product and a 2.4 N dose (1.2 L/ha). Statistical analysis of yield quality and its parameters was performed. All results were comparable with standard reference products. The following parameters were studied: HLW, TGW, moisture content (%), protein content (%) and gluten content (only in winter wheat).

In field trials with winter wheat and winter triticale, Turango 250 EC / Hapi 250 EC applied at single rate of 0.6 L/ha and double rate of 1.2 L/ha had no significant adverse effect on yield quality. No phytotoxic effects were observed even on the doubled rate plots (except for two trials on winter wheat): A.T/2020/046/PO and SRPL21-417-336HE. However, this didn't have a negative effect on the yield quality of winter wheat.

No statistical differences in yield quality were observed between the plots treated with CHR/H/CFF 250 EC and the control plots. The lack of a study on the recommended dose should be accepted as the doses 1.2 N and 2.4 N were tested.

3.2.3 Observations on other undesirable or unintended side-effects

Details will be provided in the dRR Part B Section 3 KCP 6.5 point 3.5.

Effects on transformation processes In section B7 the following information is provided for florasulam, clopyralid and fluroxypyr: "*According to the level of residues in plants reported in Section B7 of the core dossier, no significant residues, i.e. >0.1 mg/kg, were found in cereals and therefore no processing studies are required. No further studies were performed. Therefore no effects are predicted for effects on yeasts or lactic bacteria*".

The no data on effects on transformation processes were provided by the ZRMs, taking into account that there are no major transformation processes applicable to cereals and that products containing florasulam, clopyralid or fluroxypyr as the only active substance or together in co-formulations have been registered and extensively used as herbicides on cereals in all EU countries for many years and have been shown to have no adverse effects on all relevant transformation processes. The lack of data is therefore acceptable. For CHR/H/CFF 250 EC, no adverse effects on transformation processes are expected according to the opinion of the ZRMs.

Impact on treated plants or plant products to be used for propagation ZRMS accepted the Applicant's explanation for the lack of propagation trials. Turango 250 EC / Hapi 250 EC (product code: CHR/H/CFF 250 EC) has been shown to be selective to treated crops, similar to the reference products to which it was compared, with negligible phytotoxicity symptoms and no effect on yield at the N dose and higher (even 2.4N). Therefore, the evaluator considers that no further data are needed.

Furthermore, products containing florasulam, clopyralid or fluroxypyr have been used for many years and have been shown to have no negative effect on the viability of the progeny seed. It can therefore be concluded that CHR/H/CFF 250 EC is not expected to have any adverse effects on propagation.

Impact on succeeding crops The EU requirements on plant protection products requires, that sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops if studies and evaluations presented in the other part of the dossier, show that significant residues of the active substance, its metabolites or degradation products, which have or may have biological activity on succeeding crops, remain in soil or in plant materials up to sowing or planting time of possible succeeding crops.

Therefore, the Applicant should present the assessment of the possible effect of CHR/H/CFF 250 EC on crops grown as rotational or replacement crops following crops treated with that product, prepared in accordance to the EPPO Standard Efficacy evaluation of plant protection products.

Effects on succeeding crops (PP 1/207 (2)). This standard is intended as a general standard on the methods used to examine whether the active substance of a plant protection product can cause negative effects on crops grown after a crop treated with that product. These crops can be grown as normal rotational crops as well as replacement crops in case of crop failure.

Components of Turango 250 EC / Hapi 250 EC are old active ingredients (florasulam, fluroxypyr and clopyralid) authorised for cereals production for long time ago. So, restrictions on rotational crops are well-known. According to the scientific data half dissipation time (DT_{50}) of florasulam is 2-18 days, for fluroxypyr - a typical half-life is 36 days and for clopyralid is 40-70 days. So, it can be assumed that the herbicide Turango 250 EC / Hapi 250 EC (product code: CHR/H/CFF 250 EC) is degraded in the soil during the growing season to a level that does not pose a risk to succeeding crops.

ZRMS accepted following entry in the label (proposed by the applicant): „*CHR/H/CFF 250 EC decomposes in the soil (microbial degradation) during the growing season to a level that poses no risk to subsequent crops. If a field treated with the product is ploughed early (as a result of plant damage by frost, disease or pests), all winter and spring cereals and maize can be grown on the field after pre-sowing cultivation. All arable crops can be grown in the same growing season after the crop has been harvested. When using CHR/H/CFF 250 EC in a mixture with other herbicides, follow the crop rotation recommendations for the products in the mixture*."

Impact on other plants including adjacent crops The Turango 250 EC / Hapi 250 EC (product code CHR/H/CFF 250 EC) is effective against some mono- and dicotyledonous weeds. In this situation, this plant protection product may also cause discoloration and damage to non-target foliage plants, including adjacent crops. The information in this registration report and label warns against overlapping and drift of the spray liquid should be presented.

Therefore, warnings to avoid spray drift on adjacent crops should appear on the label. For example: *During spraying, maintain a safety zone of at least 5 m from residential buildings/habitats and members of the public. To protect arthropods, it is necessary to establish a 1 m protection zone from non-agricultural areas and to use techniques that reduce spray drift during treatment by 75%.*

Effects on beneficial and other non-target organisms Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Ecotoxicology section. However, accordingly to documentation submitted by Applicant (efficacy and selectivity trials) – none negative effect was observed on non-target organisms during all trials.

3.3 Methods of analysis (Part B, Section 5)

Analytical methods for determination of Florasulam, Clopyralid, Fluroxypyr impurities and relevance of CIPAC methods in CHR/H/CFF were not evaluated as part of the EU review of florasulam, clopyralid and fluroxypyr. Therefore all relevant data are provided and are considered adequate.

3.3.1 Analytical method for the formulation

The content of active substances clopyralid, florasulam and fluroxypyr in the formulation TURANGO 250 EC was determined by liquid chromatography with diode array detection (HPLC-DAD).
It was confirmed that the method is specific. There were no peaks from placebo interfering with determined compounds. The validation parameters (specificity, linearity, instrument precision, repeatability, accuracy and LOQ) are within the acceptance range and fulfil EU requirements given in SANCO /3030 /99 rev.5.

The content of relevant impurity 2,6-difluoroaniline in the formulation was determined by liquid chromatography with diode array detection (HPLC-DAD).
It was confirmed that the method is specific. There were no peaks from the placebo interfering with determined compounds. The validation parameters (specificity, linearity, repeatability, recovery, and LOQ) are within the acceptance range and fulfil EU requirements given in SANCO/3030/99 rev.5 guidance.

The content of relevant impurity 1-methyl-2-pyrrolidinone in the formulation was determined by gas chromatography with mass detection (GC-MS).
The specificity of the method was evaluated based on the analysis of chromatograms for placebo and samples against chromatograms of standard 1-methyl-2-pyrrolidinone. In placebo, 1-methyl-2-pyrrolidinone was detected. Specificity and selectivity of the validated method for 1-methyl-2-pyrrolidinone determination were assessed at the point of optimizing conditions of analysis, by obtaining parameters for the best impurity separation while maintaining interference impact at its lowest. 1-methyl-2-pyrrolidinone was identified by the presence of specific fragmentation ions and determined by the target ions. The method was set up in a way the percentage ratio between the value of the main ion to identified reference ions doesn't exceed 30% value of the error from the mass spectrum. Ions have been selected by the NIST 11 library. The other validation parameters (linearity, repeatability, recovery, and LOQ) are within the acceptance range and fulfil EU requirements given in SANCO/3030/99 rev.5 guidance.

3.3.2 Analytical methods for residues

Noticed data gaps are:
- Fluroxypyr:
- ILV method for drinking water,
- methods for the analysis of body fluids and tissues.

Noticed data gaps should be addressed at renewal of the CHR/H/CFF 250 EC.

Commodity/crop	Supported/ Not supported
Cereals	Supported

3.4 Mammalian toxicology (Part B, Section 6)

No acute toxicity studies were performed for CHR_H_CFF 250 EC. The classification of CHR_H_CFF 250 EC was based on the composition of the product and was performed by additivity formula according to the Regulation (EC) of the European Parliament and of the Council No. 1272/2008 of December 16th, 2008 on classification, labelling and packaging of substances and mixtures. It was assessed that, regarding toxicology, CHR_H_CFF 250 EC should be classified as:

- Acute Tox. 4, H302 - Harmful if swallowed.
- Eye Dam. 1, H318 - Causes serious eye damage.
- Asp. Tox. 1, H304 – May be fatal if swallowed and enters airways.
- Skin Irrit. 2, H315 – Causes skin irritation

3.4.1 Acute toxicity

3.4.2 Operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

3.4.3 Worker exposure

According to Guidance on Pesticides Exposure Assessment of Operators, Workers, Residents and Bystanders, (EFSA Journal 2014;12(10):3874) to the calculation used the value of 2500 transfer coefficient (TC (cm2/h) arms, body and legs covered - workwear; bare hands) and 8 hours work/day (only crop inspection and irrigation-type). Having regard to the above values, the predicted exposure values for CHR/H/CFF 250 EC without PPP are above 100% of systemic AOEL and therefore exposure of the worker with using PPP is acceptable.

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 florasulam, fluroxypyr and clopyralid 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 there-fore not performed..

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

According to the available data, the intended uses on cereals are considered acceptable, for outdoor use.

All available data presented for this application conclusion is sufficient to support use of CHR/H/CFF 250 EC containing with the application from BBCH 21-33 and highest maximum rate of 0.5L prod/ha.

Pre-harvest intervals for each relevant crop:
The pre-harvest interval is covered by the growing period remaining between the last application and harvest.

The data submitted show that no exceedance of the MRL will occur.

The uses are considered acceptable.

See detailed summary for each active substance below.

3.5.1 Residues

Florasulam

Stability of residues during storage of samples

No new data submitted in the framework of this application.

Storage stability of florasulam was demonstrated in cereal grain, cereal straw and immature cereal plants for a period of 18 to 23 month at temperature ranging from -18°C to -25°C.

Sufficient stability has been demonstrated to support the residue data presented in this document.

No further data are required to support the proposed uses.

Metabolism in plants and animals

The data evaluated during the Annex I inclusion and renewal process of the active substance are sufficient to describe the behaviour of the formulated product, and no further studies are required.

Plant and animal residue definitions for monitoring: Florasulam (Reg. (EU) 2022/1363)

Plant residue definition for risk assessment (EFSA Journal 2015;13(1): 3984): Florasulam and provisionally 4-OH- phenyl-florasulam (data gap)

Animal residue definition for risk assessment (EFSA Journal 2015;13(1): 3984): Florasulam pending assessment with regard to 4-OH-phenyl-florasulam

Conversion factor (monitoring to risk assessment): For milk, liver, kidney and eggs: 1

The data gap concerns the further toxicological evaluation of the plant metabolite 4-OH- phenyl-florasulam.

Magnitude of residues in plants

Winter wheat, spelt, emmer wheat, einkorn wheat, durum wheat, spring rye

Proposed GAP: 1 application, BBCH 21-33 (Spring), 0.004 – 0.005 kg as/ha

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials GAP: 5 g as/ha, BBCH 32, PHI n/a, outdoor

Residues (winter wheat): 4x <0.003 mg/kg (LOD)

According to SANTE/2019/12752 rev.1 extrapolation from wheat to spelt and rye is possible.

Sufficient trials on cereals are available to support the proposed uses.

The residues arising from the proposed uses will not exceed the MRLs established for cereals (0.01 mg/kg; Reg. (EU) 2022/1363)

Magnitude of residues in livestock

According to the new study all residues in cereals (grain, straw and whole plant) are below the LOD (0.003 mg/kg). Therefore, it does not cause any risk for livestock and supplementary livestock feeding studies are not required.

zRMS calculation (input values - proposed uses, see point 7.2.4): trigger values are not exceeded

Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

As quantifiable residues of florasulam are not expected in edible part of crops based on available residue data, there is no need to investigate the effect of industrial and/or household processing.

Magnitude of residues in representative succeeding crops

Considering available data dealing with nature of residues, no study dealing with magnitude of residues in succeeding crops is needed.

EFSA Journal 2015; 13(1):*3984: In the section on residues data gaps were identified with regard to residues in animal commodities and rotational crops. Nonetheless, the margin of safety in the consumer risk assessment is considered big even if the potentially relevant toxicological burden for consumers via their diet might have been underestimated in the current assessment.*

Residues of parent florasulam in succeeding crops are not sufficient to reach measurable levels in monitoring (<0.01 mg/kg) and no specific plant-back restrictions related to florasulam are required.

Other / special studies

Studies are not required. Cereals are not a melliferous crop foraged by bees.

Estimation of exposure through diet and other means

The proposed uses of Florasulam in the formulation CHR/H/CFF 250 EC do not represent unacceptable chronic risks for the consumer.

Clopyralid

Stability of residues during storage of samples

Stability of residues during storage of samples was provided during the EU review of clopyralid.

Residues of clopyralid were found to be stable at ≤ -18°C for up to:

13 months in maize fodder and forage (high water content matrix)

13 months in maize grain (high starch content matrix)

17 months in pasture grass (high water content matrix)

24 months in rape seed (high oil content matrix)

Metabolism in plants and animals

Residue definition for monitoring (Commission Regulation (EU) 2021/1807 of 13 October 2021): clopyralid (plants and animals)

Proposed residue definition for monitoring (EFSA Journal 2021;19(1):6389): clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) (applicable only for cereals/grass).

The proposed change will not have an impact on the existing MRLs, as the analytical methods used to generate data for risk assessment and for enforcement include a hydrolysis step which is capable to cover the common moiety.

Residue definition for risk assessment:

Clopyralid common moiety (sum of clopyralid, its salts and conjugates expressed as clopyralid) – pending the outstanding clarification on the nature of "polar clopyralid" (EFSA Journal 2018;16(7):5389)

During the peer review, the data gap related to the identification of an unknown compound observed in sugar beet and oilseed rape metabolism studies was identified.

The intended uses on cereals are supported by the evaluated plant metabolism studies.

One new hydrolysis study was evaluated as equivalent to protected hydrolysis study and was accepted in data matching (Finland 2022): K. Hamnett; 2019; Study no: FR/001648 which is equivalent to Adusumilli, H. 2014; study no: 140574. The test compound clopyralid was stable under all conditions of high temperature hydrolysis for simulation of food processing.

New metabolism study in rotational crops was evaluated as equivalent to protected study and was accepted in data matching (Finland 2022): Hall, L. R.; 2015; DAS Study No. 130733 to which is equivalent Rooney P., 2021, [14C]-Clopyralid Metabolism in Rotational Crops FR/001647. The requirement for alternative tests has been met.

NOTE: the new alternative studies have not been assessed in this application.

Magnitude of residues in plants

Winter wheat, spelt, emmer wheat, einkorn wheat, durum wheat, spring rye

Proposed uses: 1 application, BBCH 21-33 (Spring), 0.048 – 0.060 kg as/ha, PHI: not required.

Applicant refers to the unprotected EU data. GAP on which EU a.s. assessment is based: 1 x 0.150 kg

as/ha, BBCH 39.

Presented data are still valid and meet criteria of current guidelines.

Additionally, new magnitude of residues in plant studies (bridging studies for studies assessed on EU level) have been submitted by the applicant in the framework of this application.

Trials GAP: 1x 0.060 kg clopyralid/ha, BBCH 33, outdoor

Residues: wheat grain: 0.18, 0.29, 0.37, 0.63 mg/kg

Residues: wheat straw: 0.17, 0.33, 0.52, 1.77 mg/kg

According to SANTE/2019/12752 rev.1 extrapolation from wheat to spelt and rye is possible.

Sufficient trials are available to support the proposed use. The residues arising from the proposed uses will not exceed the MRLs established for wheat (Reg. (EU) 2021/1807).

Livestock feeding studies

New Dietary Burden calculations were performed, taking into account STMR and HR values from residues trials on CHR/H/CFF 250 EC (using Animal model 2017 and EU data). The new animal model calculation (Excel spreadsheet Animal model 2017) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

According to EFSA Journal 2018;16(7):5389 livestock feeding studies are performed during Annex I inclusion and renewal. No new livestock studies feeding studies are necessary.

Magnitude of residues in processed commodities

New, alternative to the protected study was provided by the applicant (White T., 2021, S19-01810; White T., 2021, S20-04397) and was accepted in data matching (Finland 2022). No further data is required.

NOTE: new alternative study has not been assessed in this application.

Processing factors have been established at EU level. Validity is pending the evaluation of the underlying residue field trials.

Rotational study

According to the available data following label restriction is proposed: not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown (see EFSA Journal 2021;19(1):6389).

Other / special studies

Cereals have not melliferous capacity. No further data is required.

Estimation of exposure through diet and other means

The proposed use of clopyralid in the formulation CHR/H/CFF 250 EC do not represent unacceptable acute and chronic risks for the consumer (EFSA PRIMo rev 3.1)

Fluroxypyr

Stability of Residues

Fluroxypyr residues stable in wheat matrices (whole plant, straw and grain) over the period of 24 months, when stored frozen at -18°C. Additional studies are not required.

Metabolism in plants and animals

Residue definition for monitoring (plants and animals): Fluroxypyr (sum of fluroxypyr, its salts, its esters, and its conjugates, expressed as fluroxypyr) (Reg. (EU) 2022/1363)

Residue definition for risk assessment (plants and animals): Fluroxypyr, its esters, salts and its conjugates expressed as fluroxypyr (EFSA Journal 2011;9(3):2091)

The residue definition for risk assessment set for the primary crops may also apply to the rotational crops

on a tentative basis but in view of the high persistence of the metabolite fluroxypyr methoxypyridine and the absence of toxicological data on this metabolite, rotational crops field trials covering the maximum plateau concentration of this metabolite are required. EFSA recommends avoiding rotation with root and tuber crops.

EFSA Journal 2019;17(9):5816 (*Animal residue definition for risk assessment*):

Residue definition for risk assessment (tentatively derived in the MRL review)
Ruminants: sum of fluroxypyr and its salts, expressed as fluroxypyr (tentative) (EFSA, 2013)Poultry: in the context of the MRL review a metabolism study in poultry was submitted but not triggered and therefore no residue definition was proposed for poultry matrices (EFSA, 2013)

Residue definition for risk assessment (evaluation of confirmatory data following the MRL review)
The tentative residue definition for risk assessment (ruminants) could not be confirmed and should be reconsidered, pending on the data gap for toxicological information on the metabolite fluroxypyr pyridinol and its conjugates.

Magnitude of residues in plants

Winter wheat, spelt, emmer wheat, einkorn wheat, durum wheat, spring rye

Proposed uses: 1 application, BBCH 21-33, 0.048 – 0.060 kg as/ha, PHI: not required

New magnitude of residues in plant studies have been submitted by the applicant in the framework of this application.

Trials GAP: 1x 0.060 kg fluroxypyr/ha, BBCH 33, outdoor

Residues: 4 x < 0.01 mg/kg

Sufficient data are available to support the proposed use. The residues arising from the proposed uses will not exceed the MRLs established for cereals (Reg. (EU) 2022/1363)

According to the SANTE/2019/12752 rev.1 extrapolation from wheat to spelt and rye is possible.

Uses are accepted.

Livestock feeding studies

The requested uses do not modify the theoretical maximum daily intake for animals, and there is no risk for animal MRLs to be exceeded.

Magnitude of residues in processed commodities

Residues of Fluroxypyr exceeding 0.1 mg/kg are not expected in the treated crops. Additionally the chronic exposure does not exceed 10 % of the ADI. No further data is required.

Rotational study

Confined studies conducted with 14C-fluroxypyr-MHE at a dose rate of 594 to 676 g a.s./ha (c.a. 3N) indicate that significant residues are not expected to be present in rotational crops.

Nevertheless, EFSA recommends avoiding rotation with root and tuber crops (in view of the high persistence of the metabolite fluroxypyr methoxypyridine and the absence of toxicological data on this metabolite).

Other / special studies

Cereals have not melliferous capacity. No further data is required.

- According to the available data following label restriction is proposed: not to use clopyralid on the same field for 125 days after the initial application regardless of the crop grown (see EFSA Journal 2021;19(1):6389).
- EFSA recommends avoiding rotation with root and tuber crops (in view of the high persis-tence of the metabolite fluroxypyr methoxypyridine and the absence of toxicological data on this metabolite

3.5.2 Consumer exposure

The proposed uses the formulation CHR/H/CFF 250 EC EW do not represent un-acceptable chronic risks for the consumer.

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

No new studies are presented; all data were reviewed in the EU review of florasulam, clopyralid, fluroxypyr. Appropriate endpoints from the EU review were used to calculate PECs for CHR/H/CFF 250 EC, florasulam, clopyralid, fluroxypyr and metabolites of each active substance in soil, surface water, ground water and air for the intended use patterns

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

The PECSOIL of florasulam, diflufenican, flufenacet and metabolites in soil have been assessed with the DT50 values established in the EU review. Based on the recommended use rate of 0.5L [product]/ha (541.3 g prod/ha),

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

According to PECgw modelling with FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5 a ground water contamination of the active substances florasulam, clopyralid, fluroxypyr at a concentration of ≥ 0.1 µg/L is not expected in use on winter/spring cereals. For the metabolites a groundwater concentration of ≥ 0.1 µg/L cannot be excluded .The risk assessment for metabolites was performed in B-10 section and concluded that there is no risk to consumer.

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

The PEC surface water of florasulam, clopyralid, fluroxypyr and metabolites in surface water (PECsw and PECsed) have been assessed with the FOCUS SW and the endpoints values established in the EU review. Based on the maximum recommended use rate PEC values have been calculated according to FOCUS Steps 1-2 for the parents and the metabolites.

The results for PEC surface water for the active substance and its metabolites were used for the ecotoxicological risk assessment.

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

CHR/H/CFF 250 EC pose no unacceptable acute and long term risk to birds and mammals used according to the label.

3.7.2 Effects on aquatic species

The evaluation of the risk for aquatic organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters" (EFSA Journal 2013;11(7):3290). The ratios between predicted environmental concentrations in surface water bodies (PECSW, PECSED) and regulatory acceptable concentrations (RAC) for a.s.- clopyralid, florasulam, fluroxypyr and for product Turango 250 EC based on the worst case for aquatic organisms were <1 indicating acceptable risk to aquatic organism without applying buffer zone. However, as aquatic plants are the most sensitive group of aquatic organisms, further studies should be provided at Member State level. The study with Myriophyllum and product Turango 250 EC should be conducted in accordance with OECD 239 and the root weight and the shoot weight should be measured separately. A final conclusion on the risk to the aquatic environment from the formulation Turango 250 EC can only be drawn after the studies with the formulation and aquatic plants are made available. DATA GAP: In case formulation *Myriophyllum*: 1. Risk assessment for aquatic plants (*M. spicatum*) has been not performed (insufficient data set - data gap). 2. The new study the product Turango 250 EC and *M.spicatum* should be performed.

Updated July 2024
To address the current data gap for *Myriophyllum spicatum* conducted by Applicant according to the OECD Guidelines. The new study for *Myriophyllum spicatum* with formulated product Turango 250 EC has been accepted by zRMS. Toxicity data and risk assessment for *Myriophyllum spicatum* was available for the PPP Turango 250 EC and a low risk was demonstrated for this species. The use Turango 250 EC according to the label will not pose risk to aquatic organisms (ratio PEC/RAC is below 1) with apply 5 meters buffer zone.

The use Turango 250 EC according to the label will not pose risk to aquatic organisms (ratio PEC/RAC is below 1) with apply 5 meters buffer zone.

3.7.3 Effects on bees

The HQ values are lower than the trigger of 50, indicating low risk to bees from following application of **Turango 250 EC**. In addition, the chronic studies for bees were submitted by the applicant. The risk assessment based on these studies should be considered when GD for Bees, 2013 is implemented at EU level.

Updated July 2024
The chronic risk assessment for bees was provided by Applicant. This calculation was accepted by zRMS. First tier chronic evaluation of the risk to adult bees exposed to Turango 250 EC resulted with ETR value above the trigger in weeds scenario indicating potentially unacceptable risk (Weeds/ BBCH 10-29 Weeds/ BBCH 30-39). No data enabling refinement of the risk was available. However, Turango 250 EC is herbicide, therefore it can be assumed that no weeds will be in the field after application.
On the basic information from SPe8 phrase in order to improve these risk assessments for cereals the following restrictions are necessary:

- Do not apply when flowering weeds are present/Erase flowering weeds before application

This approach was accepted by zRMS.

Nevertheless, since the EFSA Bee Guidance Document is yet to be implemented (2013), this result should be treated as indication of area that should be covered in the future, once the guidance document is officially noted and accepted. Further assessments from chronic exposure could be required at national level.

SPe8	SPe 8: Dangerous to bees. To protect bees and other pollinating insects do not apply when flowering weeds are present. Remove weeds before flowering.

3.7.4 Effects on other arthropod species other than bees

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2. The calculations of the risk assessment for $PER_{in\text{-}field}$ for 4 indicator species - *T. pyri*, *A. rhopalosiphi*, *Ch. carnea* and *C. septempunctata* based on extended laboratory studies were accepted by zRMS. The HQ values were below 1 for these species. In addition, based on the results from extended laboratory tests for 4 indicator species - *T. pyri*, *A. rhopalosiphi*, *Ch. carnea* and *C. septempunctata* the $PER_{off\text{-}field}$ of **Turango 250 EC** with the risk off -field for these species were corrected by zRMS (corrected VDF for 2-D studies). PERoff-field was below rate with ≤50 % effect. For LR_{50} > 541.3 g/ha for *Coccinella septempunctata* - this dose the reproduction effect is a little above 50% (54.3%). However, RMS has accepted this endpoint for risk assessment. Justification: It is only slightly above the limit value and for the remaining arthropod species the estimated risk is acceptable.

The effects of freshly-dried and field-aged foliar residues of CHR/H/CFF 250 EC on the predatory mite *Typhlodromus pyri* were evaluated in a series of extended laboratory tests. When applied to sweetcorn plants at a rate equivalent to 0.5 L test item/ha, fresh-dried residues and 14-day field-aged residues resulted in no unacceptable effects on either the survival or the subsequent reproductive capacity of the mites, (i.e. < 50% corrected mortality and < 50% reduction in reproduction, relative to the respective control).

3.7.5 Effects on soil organisms

Soil macroorganisms
The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate). The TER_{LT} values for active substance and for product are above trigger value of 5, indicating an acceptable risk for earthworm and soil macro-organism for proposed use of the product Turango 250 EC. However, the studies for formulation of Turango 250 EC for earthworms, *Folsomia candida* and *Hypoaspis aculeifer* was accepted by zRMS *only provisionally*. The toxicity endpoints were based on nominal concentration. At the end on the studies concentration of fluroxypyr-methyl was below 80%. The geometric mean measured concentration should be calculated over the duration of the test and used if the concentration falls under 80% of nominal. The Applicant should complete the calculations of toxicity endpoints for earthworms and *Folsomia candida* and *Hypoaspis aculeifer* based on geometric mean measured concentration with a risk assessment for eartworms, *Folsomia candida* and *Hypoaspis aculeifer*.

Updated April 2024
The Aplicant provided the calculations of toxicity endpoints for earthworms and *Folsomia candida* and *Hypoaspis aculeifer* based on geometric mean measured concentration with a risk assessment for eartworms, *Folsomia candida* and *Hypoaspis aculeifer*. The calculations were accepted by RMS. The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate). The TER_{LT} values for active substance and for product are above trigger value of 5, indicating an acceptable risk for earthworm and soil macro-organism for proposed use of the product Turango 250 EC.

Soil microorganisms
The risk assessment for soil micro-organism after exposure of Turango 250 EC has been accepted by the zRMS. The effects on the nitrogen transformations are acceptable (<25%) at concentration which is high-

er than the maximum relevant PECs for the maximum application rate of Turango 250 EC. The results indicate no adverse effect on nitrogen transformation even at soil concentrations well higher than the ones expected following application of Turango 250 EC.

3.7.6 Effects on non-target terrestrial plants

Studies on the toxicity to non-target terrestrial plants have been carried out with active substances florasulam, clopyralid, fluroxypyr. Full details of these studies are provided in the respective EU DAR and related documents. Effects on non-target terrestrial plants of CHR/H/CFF 250 EC were not evaluated as part of the EU assessment of florasulam, clopyralid and fluroxypr.

Based on the predicted rates of CHR/H/CFF 250 ECin off-field areas, the TER values describing the risk for non-target plants following exposure to CHR/H/CFF 250 ECaccording to the GAP of the formulation CHR/H/CFF 250 ECachieve the acceptability criteria TER ≥ 1 based on SSD risk refinement, with applying:

- 5m buffer zone
- 1 m and use of 75 % drift reducing nozzles

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant

3.8 Relevance of metabolites (Part B, Section 10)

The metabolites of florasulam, clopyralid and fluroxypyr are predicted to occur in groundwater at concentrations above 0.1 µg/L (see PART B Section 10 of CHR/H/CFF 250 E CdRR). Assessment of the relevance of these metabolites according.

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

None of active substance are candidate of substitution.

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

NA

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

Sekcja fizyko-chemia:

Produkt powinien być sklasyfikowany w kategorii 1, H304 Połknięcie i dostanie się przez drogi oddechowe może grozić śmiercią.

W etykiecie zostały uwzględnione zalecenia dotyczące:

- dokładnego wymieszania środka przed sporządzeniem cieczy użytkowej

- opryskiwania z włączonym mieszadłem

- w przypadku stosowania opryskiwacza niewyposażonego w mieszadło hydrauliczne mechanicznego wymieszania cieczy w zbiorniku przed przystąpieniem do opryskiwania oraz, w przypadku przerw w opryskiwaniu, dokładnego wymieszania cieczy użytkowej w zbiorniku przed ponownym przystąpieniem do pracy.

W etykiecie zostało zalecone czyszczenie aparatury z użyciem środka do czyszczenia.

Skuteczność:

Do listy zaakceptowanych chwastów dodano jeden gatunek sklasyfikowany jako wrażliwy – tasznik pospolity. Rekomendowana faza BBCH do stosowania: 21-32. Akceptowalna ilość wody: 200-300 L/ha. Dodano zapis w uwagach: „*Po zastosowaniu produktu na niektórych odmianach pszenicy ozimej (np. Findus, Hondia) mogą wystąpić przejściowe objawy fitotoksyczności bez wpływu na plon lub jakość.”* Pozostałych zapisów – nie zmieniano.

Pozostałości:

Wprowadzono zmiany w akapicie „następstwo roślin”:

Los i zachowanie w środowisku: brak uwag.

Ekotoksykologia: Wszystkie zastosowania zostały zaakceptowane.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 5 m od zbiorników i cieków wodnych.

W celu ochrony roślin 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%.

Niebezpieczny dla pszczół.

Nie stosować kiedy występują kwitnące chwasty. Usuwać chwasty przed kwitnieniem.

Załącznik do zezwolenia MRiRW nr R / z dnia . . r.

Posiadacz zezwolenia:
Innvigo Sp. z o.o., Al. Jerozolimskie 178, 02-486 Warszawa, tel. +48 22 468 26 70, e-mail: biuro@innvigo.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:
…….

HAPI 250 EC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:
chlopyralid (związek z grupy pochodnych kwasów karboksylowych) – 120 g/l (11.08%)
fluroksypyr (związek z grupy pochodnych kwasów pirydynokarboksylowych) - 120 g/l (11.08%)
florasulam (związek z grupy triazolopirymidyn) – 10 g/l (0.92%)
~~Inne składniki niebezpieczne, niebędące substancją aktywną:~~
~~1-Butylopirolidyn-2-on; kwas benzenosulfonowy, pochodne C10-13-alkilowe, sole wapnia;~~
~~2-metylopropan-1-ol; węglowodory aromatyczne C10-C13.~~

Zezwolenie MRiRW nr R - / z dnia . . r.

Niebezpieczeństwo

H302	Działa szkodliwie po połknięciu.
H304	Połknięcie i dostanie się przez drogi oddechowe może grozić śmiercią.
H315	Działa drażniąco na skórę.
H318	Powoduje poważne uszkodzenie oczu.
~~H400~~	~~Działa bardzo toksycznie na organizmy wodne.~~
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.
P264	Dokładnie umyć twarz, ręce i zanieczyszczoną skórę po użyciu.
P280	Stosować rękawice ochronne/ubranie ochronne/ochronę oczu/ochronę twarzy.
P301 + P310	W PRZYPADKU POŁKNIĘCIA: Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem w przypadku złego samopoczucia.
P302 + P352	W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody.
P304 + P340	W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.
P305 + P351 + P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P391	Zebrać wyciek

OPIS DZIAŁANIA
HERBICYD selektywny o działaniu układowym, stosowany nalistnie, w formie koncentratu do sporządzania emulsji wodnej.
Zgodnie z klasyfikacją HRAC substancje czynne chlopyralid i fluroksypyr zaliczane są do grupy 4 (dawna grupa O), a substancja czynna florasulam zaliczana jest do grupy 2 (dawnej grupy B).
DZIAŁANIE NA CHWASTY
Herbicyd selektywny, o działaniu układowym. Chwasty pobierają go przez liście, z których szybko przemieszcza się po całej roślinie, aż do korzeni, stopniowo powodując deformację i zahamowanie wzrostu, a w efekcie obumieranie chwastu. Herbicyd zawiera substancje czynne fluroksypyr i chlopyralid, zaliczane do grupy inhibitorów wzrostu i rozwoju zwane sztucznymi auksynami lub sztucznymi regulatorami wzrostu. W roślinie powodują one zakłócenia procesu podziału komórek odpowiedzialnych za wzrost roślin.

Środek zakłóca wiele procesów zachodzących w roślinie, w tym procesy podziału komórek, syntezy białek i kwasów nukleinowych i proces oddychania na poziomie komórkowym. Trzecia substancja czynna – florasulam, z grupy triazolopirymidyn należy do inhibitorów syntezy acetylomleczanowej (ALS). W roślinie powoduje zahamowania syntezy aminokwasów odgałęzionych, a tym samym prowadzi do zaburzeń w biosyntezie białek.
Środek stosować podczas dobrej pogody, w okresie intensywnego wzrostu chwastów.

STOSOWANIE ŚRODKA
Środek przeznaczony jest do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.
Dawka 0,4 l/ha

Chwasty wrażliwe	tasznik pospolity
Chwasty średnio wrażliwe	chaber bławatek, gwiazdnica pospolita, mak polny, maruna bezwonna, przytulia czepna, rumian polny, samosiewy rzepaku

Dawka 0,5 l/ha

Chwasty wrażliwe	chaber bławatek, gwiazdnica pospolita, mak polny, maruna bezwonna, rumian polny, samosiewy rzepaku, tasznik pospolity
Chwasty średnio wrażliwe	przytulia czepna

Pszenica ozima, pszenżyto ozime
chwasty dwuliścienne
Zalecana dawka dla jednorazowego zastosowania: 0,4 – 0,5 l/ha.
Maksymalna dawka dla jednorazowego zastosowania: 0,5 l/ha.
Termin stosowania: zabieg wykonywać od początku krzewienia do fazy drugiego ~~trzeciego~~ kolanka (BBCH 21-32 ~~33~~).
Zalecana ilość wody: 200-300 ~~400~~ l/ha.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOOBSZAROWYCH

Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik.

Pszenica orkisz
chwasty dwuliścienne
Zalecana dawka dla jednorazowego zastosowania: 0,4 – 0,5 l/ha.
Maksymalna dawka dla jednorazowego zastosowania: 0,5 l/ha.
Termin stosowania: zabieg wykonywać od początku krzewienia do fazy drugiego ~~trzeciego~~ kolanka (BBCH 21-32 ~~33~~).
Zalecana ilość wody: 200-300 ~~400~~ l/ha.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Pszenica płaskurka
chwasty dwuliścienne
Zalecana dawka dla jednorazowego zastosowania: 0,4 – 0,5 l/ha.
Maksymalna dawka dla jednorazowego zastosowania: 0,5 l/ha.

Termin stosowania: zabieg wykonywać od początku krzewienia do fazy drugiego ~~trzeciego~~ kolanka (BBCH 21-32 ~~33~~).
Zalecana ilość wody: 200-300 ~~400~~ l/ha.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Pszenica samopsza
chwasty dwuliścienne
Zalecana dawka dla jednorazowego zastosowania: 0,4 – 0,5 l/ha.
Maksymalna dawka dla jednorazowego zastosowania: 0,5 l/ha.
Termin stosowania: zabieg wykonywać od początku krzewienia do fazy drugiego ~~trzeciego~~ kolanka (BBCH 21-32 ~~33~~).
Zalecana ilość wody: 200-300 ~~400~~ l/ha.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Pszenica twarda
chwasty dwuliścienne
Zalecana dawka dla jednorazowego zastosowania: 0,4 – 0,5 l/ha.
Maksymalna dawka dla jednorazowego zastosowania: 0,5 l/ha.
Termin stosowania: zabieg wykonywać od początku krzewienia do fazy drugiego ~~trzeciego~~ kolanka (BBCH 21-32 ~~33~~).
Zalecana ilość wody: 200-300 ~~400~~ l/ha.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Żyto jare
chwasty dwuliścienne
Zalecana dawka dla jednorazowego zastosowania: 0,4 – 0,5 l/ha.
Maksymalna dawka dla jednorazowego zastosowania: 0,5 l/ha.
Termin stosowania: zabieg wykonywać od początku krzewienia do fazy drugiego ~~trzeciego~~ kolanka (BBCH 21-32 ~~33~~).
Zalecana ilość wody: 200-300 ~~400~~ 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.

Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia, w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz):
Nie dotyczy.

1. Strategia zarządzania odpornością

W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów na herbicydy należy zgodnie z Dobrą Praktyką Rolniczą:
postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin –stosować środek w zalecanej dawce, w zalecanym terminie zapewniającym optymalne zwalczanie chwastów,
dostosować dobór środka chwastobójczego oraz decyzji o wykonaniu zabiegu do panującego (ewentualnie potencjalnego) zachwaszczenia, z uwzględnieniem gatunków dominujących i progów szkodliwości,
stosować rotację herbicydów (substancji czynnych) o różnym mechanizmie działania,
stosować mieszankę herbicydów (substancji czynnych) o różnym mechanizmie działania,

stosować w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów (o różnym mechanizmie działania),
stosować herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
używać różnych metod kontroli zachwaszczenia, w tym zmianowania upraw itp.,
używać kwalifikowanego materiału siewnego,
czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,
informować posiadacza zezwolenia o niesatysfakcjonującym zwalczaniu chwastów,
w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.

2. Dawkę środka należy dostosować do fazy rozwojowej chwastów i gatunków chwastów występujących na polu. Niższą dawkę stosować na chwasty mniej wyrośnięte, we wczesnych fazach rozwojowych i gdy zachwaszczenie jest mniejsze, natomiast wyższą z zalecanych dawek stosować, gdy chwasty są zaawansowane w rozwoju.
3. Środka nie stosować:
   – na rośliny słabe lub uszkodzone przez przymrozki, choroby czy szkodniki.
   – w temperaturze powyżej 25°C.
4. Podczas stosowania środka nie dopuścić do:

znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

5. Po zastosowaniu produktu na niektórych odmianach pszenicy ozimej (np. Findus, Hondia) mogą wystąpić przejściowe objawy fitotoksyczności bez wpływu na plon lub jakość.

NASTĘPSTWO ROŚLIN

Środek Hapi 250 EC rozkłada się w glebie (degradacja mikrobiologiczna) w ciągu okresu wegetacji do poziomu niestwarzającego zagrożenia dla roślin uprawianych następczo z wyjątkiem roślin korzeniowych i bulwiastych. W przypadku wcześniejszego zaorania plantacji potraktowanej środkiem (w wyniku uszkodzenia roślin przez przymrozki, choroby lub szkodniki), po wykonaniu uprawy przedsiewnej na polu tym można uprawiać wszystkie gatunki zbóż ozimych, jarych oraz kukurydzę. ~~W tym samym sezonie wegetacyjnym po zbiorze rośliny uprawnej można uprawiać wszystkie rośliny uprawne~~. Po zbiorze roślin uprawnych można uprawiać wszystkie rośliny z wyjątkiem roślin korzeniowych i bulwiastych. Podczas stosowania środka Hapi 250 EC w mieszaninie z innymi herbicydami należy przestrzegać zaleceń następstwa roślin dla środków wchodzących w skład mieszaniny.
Nie stosować środków zawierających klopyralid na tym samym polu przez 125 dni po zastosowaniu niezależnie od uprawianej rośliny.

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). Przed otwarciem zawartością opakowania wstrząsnąć Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową. Następnie zbiornik opryskiwacza uzupełnić wodą do potrzebnej ilości.
Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne ciecz w zbiorniku mechanicznie 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 oraz wodę użytą do mycia aparatury 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.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.
Ze względu na dużą wrażliwość niektórych roślin uprawnych nawet na nieznaczne pozostałości środka, bardzo ważne jest dokładne wymycie opryskiwacza po zabiegu, zwłaszcza przed użyciem w innych roślinach uprawnych niż zalecane, zgodnie z podanym poniżej sposobem:

- natychmiast po zabiegu opróżnić zbiornik, usunąć czysta wodą resztki cieczy roboczej pozostałe na częściach zewnętrznych opryskiwacza i następnie napełnić zbiornik opryskiwacza czystą wodą (minimum 1/10 pojemności), wypłukać zbiornik i wszystkie części składowe opryskiwacza i ponownie opróżnić,
- napełnić zbiornik wodą dodając jeden ze środków zalecanych do mycia opryskiwaczy i płukać co najmniej 10 minut z włączonym mieszadłem,
- części składowe rozpylaczy rozmontować, wymyć i wypłukać osobno w roztworze środka do mycia opryskiwaczy,
- ponownie wypłukać zbiornik i wszystkie części składowe opryskiwacza czystą wodą.

Uwaga:
Niezneutralizowane odpowiednio resztki środka pozostawione w opryskiwaczu mogą być powodem uszkodzeń roślin uprawnych wrażliwych na ten środek.

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 lub twarzy oraz odzież roboczą zabezpieczającą przed oddziaływaniem środka ochrony roślin w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.
Stosować rękawice ochronne oraz odzież ochronną podczas wkraczania na obszar po zabiegu.
Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.
~~Nie wprowadzać do oczu, na skórę lub na odzież.~~
Unikać wdychania rozpylonej cieczy.

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.
Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

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

~~W celu ochrony stawonogów 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%.~~

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 5 m od zbiorników i cieków wodnych.

W celu ochrony roślin 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%.

Niebezpieczny dla pszczół.
Nie stosować kiedy występują kwitnące chwasty. Usuwać chwasty przed kwitnieniem.

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 pojemnik lub etykietę.

W PRZYPADKU POŁKNIĘCIA: Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem w przypadku złego samopoczucia. NIE wywoływać wymiotów. Wypłukać usta.

W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.
W przypadku narażenia lub styczności: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata
Data produkcji - .....
Zawartość netto - .....
Nr partii - .....

Sekcja fizyko-chemia:

Produkt powinien być sklasyfikowany w kategorii 1, H304 Połknięcie i dostanie się przez drogi oddechowe może grozić śmiercią.

W etykiecie zostały uwzględnione zalecenia dotyczące:

- dokładnego wymieszania środka przed sporządzeniem cieczy użytkowej

- opryskiwania z włączonym mieszadłem

- w przypadku stosowania opryskiwacza niewyposażonego w mieszadło hydrauliczne mechanicznego wymieszania cieczy w zbiorniku przed przystąpieniem do opryskiwania oraz, w przypadku przerw w opryskiwaniu, dokładnego wymieszania cieczy użytkowej w zbiorniku przed ponownym przystąpieniem do pracy.

W etykiecie zostało zalecone czyszczenie aparatury z użyciem środka do czyszczenia.

Skuteczność:

Do listy zaakceptowanych chwastów dodano jeden gatunek sklasyfikowany jako wrażliwy – tasznik pospolity. Rekomendowana faza BBCH do stosowania: 21-32. Akceptowalna ilość wody: 200-300 L/ha. Dodano zapis w uwagach: „*Po zastosowaniu produktu na niektórych odmianach pszenicy ozimej (np. Findus, Hondia) mogą wystąpić przejściowe objawy fitotoksyczności bez wpływu na plon lub jakość.”* Pozostałych zapisów – nie zmieniano.

Pozostałości:

Wprowadzono zmiany w akapicie „następstwo roślin”:

Los i zachowanie w środowisku: brak uwag.

Ekotoksykologia: Wszystkie zastosowania zostały zaakceptowane.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 5 m od zbiorników i cieków wodnych.

W celu ochrony roślin 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%.

Niebezpieczny dla pszczół.

Nie stosować kiedy występują kwitnące chwasty. Usuwać chwasty przed kwitnieniem.

Załącznik do zezwolenia MRiRW nr R / z dnia . . r.

Posiadacz zezwolenia:
Innvigo Sp. z o.o., Al. Jerozolimskie 178, 02-486 Warszawa, tel. +48 22 468 26 70, e-mail: biuro@innvigo.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:
…….

TURANGO 250 EC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:
chlopyralid (związek z grupy pochodnych kwasów karboksylowych) – 120 g/l (11.08%)
fluroksypyr (związek z grupy pochodnych kwasów pirydynokarboksylowych) - 120 g/l (11.08%)
florasulam (związek z grupy triazolopirymidyn) – 10 g/l (0.92%)
~~Inne składniki niebezpieczne, niebędące substancją aktywną:~~
~~1-Butylopirolidyn-2-on; kwas benzenosulfonowy, pochodne C10-13-alkilowe, sole wapnia;~~
~~2-metylopropan-1-ol; węglowodory aromatyczne C10-C13.~~

Zezwolenie MRiRW nr R - / z dnia . . r.

Niebezpieczeństwo

H302	Działa szkodliwie po połknięciu.
H304	Połknięcie i dostanie się przez drogi oddechowe może grozić śmiercią.
H315	Działa drażniąco na skórę.
H318	Powoduje poważne uszkodzenie oczu.
~~H400~~	~~Działa bardzo toksycznie na organizmy wodne.~~
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.
P264	Dokładnie umyć twarz, ręce i zanieczyszczoną skórę po użyciu.
P280	Stosować rękawice ochronne/ubranie ochronne/ochronę oczu/ochronę twarzy.
P301 + P310	W PRZYPADKU POŁKNIĘCIA: Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem w przypadku złego samopoczucia.
P302 + P352	W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody.
P304 + P340	W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.
P305 + P351 + P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P391	Zebrać wyciek

OPIS DZIAŁANIA
HERBICYD selektywny o działaniu układowym, stosowany nalistnie, w formie koncentratu do sporządzania emulsji wodnej.
Zgodnie z klasyfikacją HRAC substancje czynne chlopyralid i fluroksypyr zaliczane są do grupy 4 (dawna grupa O), a substancja czynna florasulam zaliczana jest do grupy 2 (dawnej grupy B).
DZIAŁANIE NA CHWASTY
Herbicyd selektywny, o działaniu układowym. Chwasty pobierają go przez liście, z których szybko przemieszcza się po całej roślinie, aż do korzeni, stopniowo powodując deformację i zahamowanie wzrostu, a w efekcie obumieranie chwastu. Herbicyd zawiera substancje czynne fluroksypyr i chlopyralid, zaliczane do grupy inhibitorów wzrostu i rozwoju zwane sztucznymi auksynami lub sztucznymi regulatorami wzrostu. W roślinie powodują one zakłócenia procesu podziału komórek odpowiedzialnych za wzrost roślin.

Środek zakłóca wiele procesów zachodzących w roślinie, w tym procesy podziału komórek, syntezy białek i kwasów nukleinowych i proces oddychania na poziomie komórkowym. Trzecia substancja czynna – florasulam, z grupy triazolopirymidyn należy do inhibitorów syntezy acetylomleczanowej (ALS). W roślinie powoduje zahamowania syntezy aminokwasów odgałęzionych, a tym samym prowadzi do zaburzeń w biosyntezie białek.
Środek stosować podczas dobrej pogody, w okresie intensywnego wzrostu chwastów.

STOSOWANIE ŚRODKA
Środek przeznaczony jest do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.
Dawka 0,4 l/ha

Chwasty wrażliwe	tasznik pospolity
Chwasty średnio wrażliwe	chaber bławatek, gwiazdnica pospolita, mak polny, maruna bezwonna, przytulia czepna, rumian polny, samosiewy rzepaku

Dawka 0,5 l/ha

Chwasty wrażliwe	chaber bławatek, gwiazdnica pospolita, mak polny, maruna bezwonna, rumian polny, samosiewy rzepaku, tasznik pospolity
Chwasty średnio wrażliwe	przytulia czepna

Pszenica ozima, pszenżyto ozime
chwasty dwuliścienne
Zalecana dawka dla jednorazowego zastosowania: 0,4 – 0,5 l/ha.
Maksymalna dawka dla jednorazowego zastosowania: 0,5 l/ha.
Termin stosowania: zabieg wykonywać od początku krzewienia do fazy drugiego ~~trzeciego~~ kolanka (BBCH 21-32 ~~33~~).
Zalecana ilość wody: 200-300 ~~400~~ l/ha.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOOBSZAROWYCH

Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik.

Pszenica orkisz
chwasty dwuliścienne
Zalecana dawka dla jednorazowego zastosowania: 0,4 – 0,5 l/ha.
Maksymalna dawka dla jednorazowego zastosowania: 0,5 l/ha.
Termin stosowania: zabieg wykonywać od początku krzewienia do fazy drugiego ~~trzeciego~~ kolanka (BBCH 21-32 ~~33~~).
Zalecana ilość wody: 200-300 ~~400~~ l/ha.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Pszenica płaskurka
chwasty dwuliścienne
Zalecana dawka dla jednorazowego zastosowania: 0,4 – 0,5 l/ha.
Maksymalna dawka dla jednorazowego zastosowania: 0,5 l/ha.

Termin stosowania: zabieg wykonywać od początku krzewienia do fazy drugiego ~~trzeciego~~ kolanka (BBCH 21-32 ~~33~~).
Zalecana ilość wody: 200-300 ~~400~~ l/ha.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Pszenica samopsza
chwasty dwuliścienne
Zalecana dawka dla jednorazowego zastosowania: 0,4 – 0,5 l/ha.
Maksymalna dawka dla jednorazowego zastosowania: 0,5 l/ha.
Termin stosowania: zabieg wykonywać od początku krzewienia do fazy drugiego ~~trzeciego~~ kolanka (BBCH 21-32 ~~33~~).
Zalecana ilość wody: 200-300 ~~400~~ l/ha.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Pszenica twarda
chwasty dwuliścienne
Zalecana dawka dla jednorazowego zastosowania: 0,4 – 0,5 l/ha.
Maksymalna dawka dla jednorazowego zastosowania: 0,5 l/ha.
Termin stosowania: zabieg wykonywać od początku krzewienia do fazy drugiego ~~trzeciego~~ kolanka (BBCH 21-32 ~~33~~).
Zalecana ilość wody: 200-300 ~~400~~ l/ha.
Zalecane opryskiwanie: średniokropliste.
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Żyto jare
chwasty dwuliścienne
Zalecana dawka dla jednorazowego zastosowania: 0,4 – 0,5 l/ha.
Maksymalna dawka dla jednorazowego zastosowania: 0,5 l/ha.
Termin stosowania: zabieg wykonywać od początku krzewienia do fazy drugiego ~~trzeciego~~ kolanka (BBCH 21-32 ~~33~~).
Zalecana ilość wody: 200-300 ~~400~~ 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.

Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia, w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz):
Nie dotyczy.

1. Strategia zarządzania odpornością

W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów na herbicydy należy zgodnie z Dobrą Praktyką Rolniczą:
postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin –stosować środek w zalecanej dawce, w zalecanym terminie zapewniającym optymalne zwalczanie chwastów,
dostosować dobór środka chwastobójczego oraz decyzji o wykonaniu zabiegu do panującego (ewentualnie potencjalnego) zachwaszczenia, z uwzględnieniem gatunków dominujących i progów szkodliwości,
stosować rotację herbicydów (substancji czynnych) o różnym mechanizmie działania,
stosować mieszankę herbicydów (substancji czynnych) o różnym mechanizmie działania,

stosować w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów (o różnym mechanizmie działania),
stosować herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
używać różnych metod kontroli zachwaszczenia, w tym zmianowania upraw itp.,
używać kwalifikowanego materiału siewnego,
czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,
informować posiadacza zezwolenia o niesatysfakcjonującym zwalczaniu chwastów,
w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.

2. Dawkę środka należy dostosować do fazy rozwojowej chwastów i gatunków chwastów występujących na polu. Niższą dawkę stosować na chwasty mniej wyrośnięte, we wczesnych fazach rozwojowych i gdy zachwaszczenie jest mniejsze, natomiast wyższą z zalecanych dawek stosować, gdy chwasty są zaawansowane w rozwoju.
3. Środka nie stosować:
   – na rośliny słabe lub uszkodzone przez przymrozki, choroby czy szkodniki.
   – w temperaturze powyżej 25°C.
4. Podczas stosowania środka nie dopuścić do:

znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

5. Po zastosowaniu produktu na niektórych odmianach pszenicy ozimej (np. Findus, Hondia) mogą wystąpić przejściowe objawy fitotoksyczności bez wpływu na plon lub jakość.

NASTĘPSTWO ROŚLIN

Środek TURANGO 250 EC rozkłada się w glebie (degradacja mikrobiologiczna) w ciągu okresu wegetacji do poziomu niestwarzającego zagrożenia dla roślin uprawianych następczo z wyjątkiem roślin korzeniowych i bulwiastych. W przypadku wcześniejszego zaorania plantacji potraktowanej środkiem (w wyniku uszkodzenia roślin przez przymrozki, choroby lub szkodniki), po wykonaniu uprawy przedsiewnej na polu tym można uprawiać wszystkie gatunki zbóż ozimych, jarych oraz kukurydzę. ~~W tym samym sezonie wegetacyjnym po zbiorze rośliny uprawnej można uprawiać wszystkie rośliny uprawne~~. Po zbiorze roślin uprawnych można uprawiać wszystkie rośliny z wyjątkiem roślin korzeniowych i bulwiastych.
Podczas stosowania środka TURANGO 250 EC w mieszaninie z innymi herbicydami należy przestrzegać zaleceń następstwa roślin dla środków wchodzących w skład mieszaniny.
Nie stosować środków zawierających klopyralid na tym samym polu przez 125 dni po zastosowaniu niezależnie od uprawianej rośliny.

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). Przed otwarciem zawartością opakowania wstrząsnąć Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową. Następnie zbiornik opryskiwacza uzupełnić wodą do potrzebnej ilości.
Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne ciecz w zbiorniku mechanicznie 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 oraz wodę użytą do mycia aparatury 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.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.
Ze względu na dużą wrażliwość niektórych roślin uprawnych nawet na nieznaczne pozostałości środka, bardzo ważne jest dokładne wymycie opryskiwacza po zabiegu, zwłaszcza przed użyciem w innych roślinach uprawnych niż zalecane, zgodnie z podanym poniżej sposobem:

- natychmiast po zabiegu opróżnić zbiornik, usunąć czysta wodą resztki cieczy roboczej pozostałe na częściach zewnętrznych opryskiwacza i następnie napełnić zbiornik opryskiwacza czystą wodą (minimum 1/10 pojemności), wypłukać zbiornik i wszystkie części składowe opryskiwacza i ponownie opróżnić,
- napełnić zbiornik wodą dodając jeden ze środków zalecanych do mycia opryskiwaczy i płukać co najmniej 10 minut z włączonym mieszadłem,
- części składowe rozpylaczy rozmontować, wymyć i wypłukać osobno w roztworze środka do mycia opryskiwaczy,
- ponownie wypłukać zbiornik i wszystkie części składowe opryskiwacza czystą wodą.

Uwaga:
Niezneutralizowane odpowiednio resztki środka pozostawione w opryskiwaczu mogą być powodem uszkodzeń roślin uprawnych wrażliwych na ten środek.

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 lub twarzy oraz odzież roboczą zabezpieczającą przed oddziaływaniem środka ochrony roślin w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.
Stosować rękawice ochronne oraz odzież ochronną podczas wkraczania na obszar po zabiegu.
Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.
~~Nie wprowadzać do oczu, na skórę lub na odzież.~~
Unikać wdychania rozpylonej cieczy.

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.
Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

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

~~W celu ochrony stawonogów 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%.~~

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 5 m od zbiorników i cieków wodnych.

W celu ochrony roślin 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%.

Niebezpieczny dla pszczół.
Nie stosować kiedy występują kwitnące chwasty. Usuwać chwasty przed kwitnieniem.

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 pojemnik lub etykietę.

W PRZYPADKU POŁKNIĘCIA: Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem w przypadku złego samopoczucia. NIE wywoływać wymiotów. Wypłukać usta.

W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.
W przypadku narażenia lub styczności: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata
Data produkcji - .....
Zawartość netto - .....
Nr partii - .....

Appendix 3 Letter of Access

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.5.1	J. Kupiec	2022	CHR/H/CFF 250 EC Viscosity determination Study code: BF-18/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland, GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol Sp. z o.o.
KCP 2.2.2 KCP 2.3.3	P. Flasinska	2022	CHR/H/CFF 250 EC Determination of auto-ignition temperature and oxidizing properties Study code: BC-26/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland, GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol Sp. z o.o
KCP 2.2.1	D. Buczkowski	2022	CHR/H/CFF 250 EC Determination of explosive properties Study code: BW-08/22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland, GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol Sp. z o.o.
KCP 2.1 KCP 2.3.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.2	I. Knapik	2023	Final Report – Part 1 Determination of physicochemical properties of CHR/H/CFF 250 EC before and after accelerated storage test Study code: ICB/46/2022 ICB Pharma, 10 Lema Street, 43-600, Jaworzno, POLAND	N	Y	Data/study report never submitted before	Chemirol Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.6.1 KCP 2.7.2 KCP 2.7.3 KCP 2.7.4 KCP 2.8.2 KCP 2.8.6.2 KCP 2.11			GLP Unpublished				
KCP 2.7.3	I. Knapik	2023	Final Report – Part 2 Determination of physicochemical properties of CHR/H/CFF 250 EC before and after accelerated storage test Study code: ICB/46/2022 ICB Pharma, 10 Lema Street, 43-600, Jaworzno, POLAND GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol Sp. z o.o.
KCP 2.3.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.2 KCP 2.6.1 KCP 2.7.2 KCP 2.7.3 KCP 2.7.4 KCP 2.8.2 KCP 2.8.6.2 KCP 2.11	I. Knapik	2023	Determination of physicochemical properties of CHR/H/CFF 250 EC after 12 months shelf-life test Study code: ICB/47/2022 ICB Pharma, 10 Lema Street, 43-600, Jaworzno, POLAND GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol Sp. z o.o.
KCP 2.11	I. Knapik	2023	Determination of physicochemical property of CHR/H/CFF 250 EC Study code: ICB/47/2022 ICB Pharma, 10 Lema Street, 43-600, Jaworzno, POLAND GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol Sp. z o.o.
KCP 2.11	M. Petryka	2024	CHR/H/CFF 250 EC Test for determining the corrosive	N	Y	Data/study report never submitted	Chemirol Sp.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			properties to metals Study code: BC-24/24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, 6 Annopol St., 03-236 Warsaw, Poland, GLP Unpublished			before	z o.o.
KCP 2.3.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.2 KCP 2.6.1 KCP 2.7.2 KCP 2.7.3 KCP 2.7.4 KCP 2.8.2 KCP 2.8.6.2 KCP 2.11	I. Knapik	2024	Determination of physicochemical properties of CHR/H/CFF 250 EC after 24 months shelf-life test Study code: ICB/48/2022 ICB Pharma, 10 Lema Street, 43-600, Jaworzno, POLAND GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol Sp. z o.o.
KCP 5.1.1/01	I. Knapik	2023	Validation of analytical method for CHR/H/CFF 250 EC for determination of clopyralid, clopyralid and fluroxypyr and impurities 2,6-difluoroaniline and 1-methyl-2-pyrrolidinone – Part 1 Study code: ICB/45/2022 ICB Pharma, 10 Lema Street, 43-600, Jaworzno, POLAND GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol Sp. z o.o.
KCP 5.1.1/02					Y	Data/study report never submitted before	
KCP 5.2	J.Semrau	2016	Final Report Determination of residues of iodosulfuron-methyl, tribenuron-methyl, florasulam and mefenpyr-diethyl after one application of IDS 100 OD or FLOT 150 WG and Adjuwant Super in wheat at 4 sites in Northern Europe 2016 EAS Study Code S16-02449 Eurofins Agroscience Services GmbH, Stade, Germany GLP yes	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 6.2	Joanna Guzińska	2020	Efficacy evaluation of herbicide CHR/H/CFF 250 EC when applied at spring into winter wheat to control of weeds, Poland, 2020 A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2020/037/PO GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.2	Joanna Guzińska	2020	Efficacy evaluation of herbicide CHR/H/CFF 250 EC when applied at spring into winter wheat to control of weeds, Poland, 2020. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2020/038/PO GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.2	Joanna Guzińska	2020	Efficacy evaluation of herbicide CHR/H/CFF 250 EC when applied at spring into winter wheat to control of weeds, Poland, 2020. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2020/039/PO GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.2	Joanna Guzińska	2020	Efficacy evaluation of herbicide CHR/H/CFF 250 EC when applied at spring into winter wheat to control of weeds, Poland, 2020.	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2020/040/PO GEP - yes Unpublished				
KCP 6.2	Joanna Guzińska	2021	Efficacy evaluation of herbicide CHR/H/CFF 250 EC when applied at spring into winter wheat to control of weeds, Poland, 2021. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2021/029/PO GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.2	Joanna Guzińska	2021	Efficacy evaluation of herbicide CHR/H/CFF 250 EC when applied at spring into winter wheat to control of weeds, Poland, 2021. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2021/033/PO GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.2	Robert Idziak	2020	Assessment of efficacy of herbicide CHR/H/CFF applied in winter wheat Poznań University of Life Sciences, Research and Education Center Gorzyń, Agronomy Department; ul. Wojska Polskiego 28, 60-637 Poznań Report no.: AH/20/PO/2/Pr/CFF	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP - yes Unpublished				
KCP 6.2	Łukasz Sobiech	2021	Efficacy and selectivity of the CHR/H/CFF preparation in the control of weeds in the cultivation of winter cereals Poznań University of Life Sciences, Research and Education Center Gorzyń, Agronomy Department; ul. Wojska Polskiego 28, 60-637 Poznań Report no.: AH/21/PO/5/Pr/1 GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.2	Łukasz Sobiech	2021	Efficacy and selectivity of the CHR/H/CFF preparation in the control of weeds in the cultivation of winter cereals Poznań University of Life Sciences, Research and Education Center Gorzyń, Agronomy Department; ul. Wojska Polskiego 28, 60-637 Poznań Report no.: AH/21/PO/5/Ra/2 GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.2	Zdzisław Jaskólski	2021	Efficacy and selectivity of CHR/H/CFF 250 EC (clopyralid 120 g/L, fluroxypyr 120 g/L, florasulam 10 g/L), winter wheat. SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz Poland Report no.: SRPL21-414-336HE GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.2	Zdzisław Jaskólski	2021	Efficacy and selectivity of CHR/H/CFF 250 EC (clopyralid 120 g/L, fluroxypyr 120 g/L, florasulam 10 g/L), winter wheat.	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz Poland Report no.: SRPL21-415-336HE GEP - yes Unpublished				
KCP 6.2	Joanna Guzińska	2020	Efficacy evaluation of herbicide CHR/H/CFF 250 EC when applied at spring into winter triticale to control of weeds, Poland, 2020. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2020/041/PŻO GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemirol Sp. z o.o.
KCP 6.2	Joanna Guzińska	2020	Efficacy evaluation of herbicide CHR/H/CFF 250 EC when applied at spring into winter triticale to control of weeds, Poland, 2020. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2020/042/PŻO GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemirol Sp. z o.o.
KCP 6.2	Joanna Guzińska	2020	Efficacy evaluation of herbicide CHR/H/CFF 250 EC when applied at spring into winter triticale to control of weeds, Poland, 2020 A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno	N	Y	Data/study report never submitted before	PUH Chemirol Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report no.: A.T/2020/043/PŻO GEP - yes Unpublished				
KCP 6.2	Joanna Guzińska	2021	Efficacy evaluation of herbicide CHR/H/CFF 250 EC when applied at spring into winter triticale to control of weeds, Poland, 2021. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2021/030/PŻO GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemirol Sp. z o.o.
KCP 6.2	Łukasz Sobiech	2021	Efficacy and selectivity of the CHR/H/CFF preparation in the control of weeds in the cultivation of winter cereals Poznań University of Life Sciences, Research and Education Center Gorzyń, Agronomy Department; ul. Wojska Polskiego 28, 60-637 Poznań Report no.: AH/21/PszO/5/Bu/2 GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemirol Sp. z o.o.
KCP 6.2	Łukasz Sobiech	2021	Efficacy and selectivity of the CHR/H/CFF preparation in the control of weeds in the cultivation of winter cereals Poznań University of Life Sciences, Research and Education Center Gorzyń, Agronomy Department; ul. Wojska Polskiego 28, 60-637 Poznań Report no.: AH/21/PszO/5/Ra/1 GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemirol Sp. z o.o.
KCP 6.2	Zdzisław Jaskólski	2021	Efficacy and selectivity of CHR/H/CFF 250 EC (clopyralid 120 g/L, fluroxypyr 120 g/L, florasulam 10 g/L), triticale w. SynTech Research Poland Sp. z o.o.	N	Y	Data/study report never submitted before	PUH Chemirol Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			69/1 Jagiellonska 85-027 Bydgoszcz Poland Report no.: SRPL21-413-336HE GEP - yes Unpublished				
KCP 6.3/01	J. Semrau	2016	Final Report Determination of residues of iodosulfuron-methyl, tribenuron-methyl, florasulam and mefenpyr-diethyl after one application of IDS 100 OD or FLOT 150 WG and Adjuwant Super in wheat at 4 sites in Northern Europe 2016 EAS Study Code S16-02449 Eurofins Agroscience Services GmbH, Stade, Germany GLP yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.4	Joanna Guzińska	2020	Selectivity evaluation of herbicide CHR/H/CFF 250 EC when applied at spring into winter wheat, Poland, 2020. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2020/044/PO GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.4	Joanna Guzińska	2020	Selectivity evaluation of herbicide CHR/H/CFF 250 EC when applied at spring into winter wheat, Poland, 2020. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2020/045/PO GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.4	Joanna Guzińska	2020	Selectivity evaluation of herbicide CHR/H/CFF 250 EC when applied at spring into winter wheat, Poland, 2020.	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2020/046/PO GEP - yes Unpublished				
KCP 6.4	Joanna Guzińska	2020	Selectivity evaluation of herbicide CHR/H/CFF 250 EC when applied at spring into winter wheat, Poland, 2020. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2020/047/PO GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.4	Joanna Guzińska	2021	Selectivity evaluation of herbicide CHR/H/CFF 250 EC when applied into winter wheat to control of weeds, Poland, 2021. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2021/031/PO GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.4	Beata Szymańska	2021	Study of herbicide phytotoxicity CHR/H/CFF in cereal winter Poznań University of Life Sciences, Research and Education Center Gorzyń, Wojska Polskiego 28, 60-637 Poznań Report no.: AH/21/PO/5/Br/1 GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.4	Beata Szymańska	2021	Study of herbicide phytotoxicity CHR/H/CFF in cereal winter	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Poznań University of Life Sciences, Research and Education Center Gorzyń, Wojska Polskiego 28, 60-637 Poznań Report no.: AH/21/PO/5/Gr/2 GEP - yes Unpublished				
KCP 6.4	Zdzisław Jaskólski	2021	Selectivity of CHR/H/CFF 250 EC (clopyralid 120 g/L, flurox-ypyr 120 g/L, florasulam 10 g/L), winter wheat. SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz Poland Report no.: SRPL21-417-336HE GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.4	Joanna Guzińska	2020	Selectivity evaluation of herbicide CHR/H/CFF 250 EC when applied at spring into winter triticale, Poland, 2020. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2020/048/PŻO GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.4	Joanna Guzińska	2020	Selectivity evaluation of herbicide CHR/H/CFF 250 EC when applied at spring into winter triticale, Poland, 2020. Report no.: A.T/2020/049/PŻO GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.4	Joanna Guzińska	2020	Selectivity evaluation of herbicide CHR/H/CFF 250 EC when applied at spring into winter triticale, Poland, 2020. A.T Sp. z o.o.	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2020/050/PŻO GEP - yes Unpublished				
KCP 6.4	Joanna Guzińska	2021	Selectivity evaluation of herbicide CHR/H/CFF 250 EC when applied into winter triticale to control of weeds, Poland, 2021. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2021/032/PŻO GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.4	Beata Szymańska	2021	Study of herbicide phytotoxicity CHR/H/CFF in cereal winter Poznań University of Life Sciences, Research and Education Center Gorzyń, Agronomy Department; ul. Wojska Polskiego 28, 60-637 Poznań Report no.: AH/21/PszO/5/Br/1 GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 6.4	Zdzisław Jaskólski	2021	Selectivity of CHR/H/CFF 250 EC (clopyralid 120 g/L, flurox-ypyr 120 g/L, florasulam 10 g/L), triticale w. SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz Poland Report no.: SRPL21-416-336HE GEP - yes Unpublished	N	Y	Data/study report never submitted before	PUH Chemi-rol Sp. z o.o.
KCP 7.1.1 KCP 7.1.7	I. Muchewicz	2023	Toxicological classification of product CHR/H/CFF 250 EC based on calculation method taking into consideration health	N	Y	Data/study report never submitted before	Chemirol Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			hazards of constituent substances; Chemirol Sp. z o.o. Non GLP Unpublished				
KCP 10.2/01	Z. Kacperek-Karetta	2023	CHR/H/CFF 250 EC Daphnia magna, Acute Immobilisation Test W-03-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol
KCP 10.2/02	G. Hodorek	2023	CHR/H/CFF 250 EC Raphidocelis subcapitata SAG 61.81 (formerly Pseudokirchneriella subcapitata), Growth inhibition test W-01-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol
KCP 10.2/03	K. Brzozowska-Wojoczek	2023	CHR/H/CFF 250 EC Anabaena flos-aquae UTEX B 1444 Growth inhibition test W-04-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol
KCP 10.2/04	E. Nierzędska	2021	CHR/H/CFF 250 EC Lemna gibba CPCC 310, Growth inhibition test W-02-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol
KCP	E. Kulec-Płoszczyca	2023	CHR/H/CFF 250 EC Honeybees (Apis mellifera L.), Acute Oral	N	Y	Data/study report never submitted	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
10.3/01			Toxicity Test B-15-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished			before	
KCP 10.3/02	E. Kulec-Płoszczyca	2023	CHR/H/CFF 250 EC Honeybees (Apis mellifera L.), Acute Contact Toxicity Test B-134-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol
KCP 10.3/03	E. Kulec-Płoszczyca	2023	CHR/H/CFF 250 EC Honeybees (Apis mellifera L.), Chronic Oral Toxicity Test B-18-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol
KCP 10.3/04	A. Wozniak	2022	Honey bee larval toxicity test following repeated exposure of the test item CHR/H/CFF 250 EC according to OECD GD 239 ENV/JM/MONO(2016)34 0038/0066/E SORBOLAB Research Laboratory LLC, Zaniemyska Street 11, 61-029 Poznań, Poland GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol
KCP 10.3/05	E. Kulec-Ploszczyca	2023	An extended laboratory test for evaluating the effects of CHR/H/CFF 250 EC on the predatory mite, Typhlodromus pyri (Sch.) B-131-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland	N	Y	Data/study report never submitted before	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 10.3/06	E. Kulec-Ploszczyca	2023	An extended laboratory test for evaluating the effects of CHR/H/CFF 250 EC on the parasitic wasp, Aphidius rhopalosiphi (De Stefani-Perez) B-132-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol
KCP10.3/07	E. Kulec-Ploszczyca	2023	An extended laboratory test for evaluating effects of CHR/H/CFF 250 EC on the green lacewing, Chrysoperla carnea (Steph.) B-11-21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol
KCP 10.3/08	E. Kulec-Ploszczyca	2023	An extended laboratory test for evaluating effects of CHR/H/CFF 250 EC on the ladybird beetle, Coccinella sep-tempunctata (L.) B-133-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol
KCP 10.4/01	P. Pieczka	2023	CHR/H/CFF 250 EC Earthworm reproduction test (Eisenia andrei) G-01-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol
KCP	A. Gierbuszewska	2023	CHR/H/CFF 250 EC Collembolan (Folsomia candida) Repro-	N	Y	Data/study report never submitted	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
10.4/02			duction Test G-02-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished			before	
KCP 10.4/03	P. Pieczka	2021	CHR/H/CFF 250 EC Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil G-02-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol
KCP 10.5/01	A. Gierbuszewska	2023	CHR/H/CFF 250 EC Soil Microorganisms: Nitrogen Transfor-mation Test G-17-22 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol
KCP 10.6/01	A. Wróbel	2023	CHR/H/CFF 250 EC Terrestial Plant Test: Seedling Emergence and Seedling Growth Test G-06-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP Unpublished	N	Y	Data/study report never submitted before	Chemirol
KCP 10.6/02	A. Gierbuszewska	2023	CHR/H/CFF 250 EC Terrestial Plant Test: Vegetative Vigour Test G-05-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Department of Ecotoxicological Studies, Doświadczalna 27, 43-200 Pszczyna, Poland GLP	N	Y	Data/study report never submitted before	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				

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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
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 120610 ABC Laboratories, Inc., Columbia, Missouri, USA GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2013	Validation of a Multi-residue Method Following the QuEChERS Sample Preparatiocn Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin 130729 GLP-yes unpublished	N	N	-	DAS
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 120610 ABC Laboratories, Inc., Columbia, Missouri, USA GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2013	Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin 130729 GLP-yes unpublished	N	N	-	DAS
KCP 5.2	Vogl, E.	2012	Method Validation Study for the Determination of Residues of	N	N	-	DAS

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			Clopyralid and Picloram in Agricultural Commodities by LC-MS/MS 120610 ABC Laboratories, Inc., Columbia, Missouri, USA GLP-yes unpublished				
KCP 5.2		2013	Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin 130729 GLP-yes unpublished	N	N	-	DAS
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 120610 ABC Laboratories, Inc., Columbia, Missouri, USA GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2013	Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin 130729 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2012	Method Validation Study for the Determination of Residues of Clopyralid in Bovine and Poultry Matrices by Liquid Chromatography with Tandem Mass Spectrometry Detection 120483 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2012	Independent Laboratory Validation of an Analytical Method for the Determination of Clopyralid in Animal Matrices 120484 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2013	Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determina-	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			tion of Clopyralid in Matrices of Plant and Animal Origin 130729 GLP-yes unpublished				
KCP 5.2	Shaffer, S.	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 120611 ABC Laboratories, Inc., Columbia, Missouri, USA GLP-yes unpublished	N	N	-	DAS
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 120612 ABC Laboratories, Inc., Columbia, Missouri, USA GLP-yes unpublished	N	N	-	DAS
KCP 5.2	Bacher, R.	2012	The Development and Validation of a Method for the Analysis of Clopyralid in Air 120601 PTRL Europe GmbH, D-89081 Ulm, Germany GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2014	Development and Validation of an Analytical Method for the Determination of Clopyralid in Body Fluid(s) 130727 GLP-yes unpublished	N	N	-	DAS
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 120610 ABC Laboratories, Inc., Columbia, Missouri, USA GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2013	Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			130729 GLP-yes unpublished				
KCP 5.2		2014	Independent Laboratory Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin 130728 GLP-yes unpublished	N	N	-	DAS
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" 120614 Battelle UK Ltd, Ongar, Essex, United Kingdom GLP-yes unpublished	N	N	-	DAS
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 120610 ABC Laboratories, Inc., Columbia, Missouri, USA GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2013	Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin 130729 GLP-yes unpublished	N	N	-	DAS
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" 120614 Battelle UK Ltd, Ongar, Essex, United Kingdom GLP-yes	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			unpublished				
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 120610 ABC Laboratories, Inc., Columbia, Missouri, USA GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2013	Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin 130729 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2014	Independent Laboratory Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin 130728 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2013	Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin 130729 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2014	Independent Laboratory Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin 130728 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2012	Method Validation Study for the Determination of Residues of Clopyralid in Bovine and Poultry Matrices by Liquid Chromatography with Tandem Mass Spectrometry Detection 120483	N	N	-	DAS

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			GLP-yes unpublished				
KCP 5.2		2012	Independent Laboratory Validation of an Analytical Method for the Determination of Clopyralid in Animal Matrices 120484 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2012	Method Validation Study for the Determination of Residues of Clopyralid in Bovine and Poultry Matrices by Liquid Chromatography with Tandem Mass Spectrometry Detection 120483 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2012	Independent Laboratory Validation of an Analytical Method for the Determination of Clopyralid in Animal Matrices 120484 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2013	Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin 130729 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2012	Method Validation Study for the Determination of Residues of Clopyralid in Bovine and Poultry Matrices by Liquid Chromatography with Tandem Mass Spectrometry Detection 120483 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2012	Independent Laboratory Validation of an Analytical Method for the Determination of Clopyralid in Animal Matrices 120484 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2013	Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			130729 GLP-yes unpublished				
KCP 5.2		2014	Independent Laboratory Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin 130728 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2012	Method Validation Study for the Determination of Residues of Clopyralid in Bovine and Poultry Matrices by Liquid Chromatography with Tandem Mass Spectrometry Detection 120483 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2012	Independent Laboratory Validation of an Analytical Method for the Determination of Clopyralid in Animal Matrices 120484 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2013	Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin 130729 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2012	Method Validation Study for the Determination of Residues of Clopyralid in Bovine and Poultry Matrices by Liquid Chromatography with Tandem Mass Spectrometry Detection 120483 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2012	Independent Laboratory Validation of an Analytical Method for the Determination of Clopyralid in Animal Matrices 120484 GLP-yes unpublished	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2		2013	Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin 130729 GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2014	Independent Laboratory Validation of a Multi-residue Method Following the QuEChERS Sample Preparation Technique for the Determination of Clopyralid in Matrices of Plant and Animal Origin 130728 GLP-yes unpublished	N	N	-	DAS
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 120612 ABC Laboratories, Inc., Columbia, Missouri, USA GLP-yes unpublished	N	N	-	DAS
KCP 5.2	Austin, R., Turner, R.	2013	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” 120613 Battelle UK Ltd, Ongar, Essex, United Kingdom GLP-yes unpublished	N	N	-	DAS
KCP 5.2	Shaffer, S.	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 120611 ABC Laboratories, Inc., Columbia, Missouri, USA GLP-yes unpublished	N	N	-	DAS
KCP 5.2	Austin, R., Turner, R.	2013	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”	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			120613 Battelle UK Ltd, Ongar, Essex, United Kingdom GLP-yes unpublished				
KCP 5.2	Bacher, R.	2012	The Development and Validation of a Method for the Analysis of Clopyralid in Air 120601 PTRL Europe GmbH, D-89081 Ulm, Germany GLP-yes unpublished	N	N	-	DAS
KCP 5.2		2014	Development and Validation of an Analytical Method for the Determination of Clopyralid in Body Fluid(s) 130727 GLP-yes unpublished	N	N	-	DAS
KCP 5.2	Rodrigues Junior A.	2011	Residue Metod Validation for the Determination of Florasu-lam in Agricultural Commodities Das Report No. 110535 Mogi Mirim Reg. Lab., Brazil GLP yes Unpublished	N	N	-	DAS
KCP 5.2	Bacher R.	2011	Florasulam: Independet Laboratory Validation of Residue Method for the Determination of Florasulam in Agricultural Commodities. DAS Report No. 110536 PTRL EUROPE Gmbh, Ulm, Germany GLP yes Unpublished	N	N	-	DAS
KCP 5.2	Bacher R.	2011	Method Validation Study for the Determination of Residues of Forasulam in Foodstaff and Animal Origin bt Liquid Chroma-tography with Tandem Mass Spectrometry DAS Report No. 110540 PTRL Europe Gmbh, Ulm, Germany GLP yes Unpublished	N	N	-	DAS
KCP 5.2	Robaugh David A.	2012	Independet Laboratory Validation Study for the determination of Residues of Florasulam in Bolvine and Poultry Tissues by Liquid Chromatography with Tandem Mass Spectrometry	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			DAS Report No. 110541 Pyxant Labs Inc., Colorado Srings, USA GLP yes Unpublished				
KCP 5.2	Lindner M.	2011	Examination of the Applicability of the Modular Analytical Method L 00.00-34 for the Determination of Residues of Florasulam DAS Report No. 110671 Eurofins Agrosciences Services Chem Gmbh, Hamburg, Germany GLP yes Unpublished	N	N	-	DAS
KCP 5.2	Bacher R.	2011	Method Validation Study for the Determination of Residues of Florasulam and its 5-OH Metabolite in Soil by Liquid Chro-matography with Tandem Mass Spectrometry DAS Report No. 110537 PTRL Europe Gmbh, Ulm, Germany GLP yes Unpublished	N	N	-	DAS
KCP 5.2	Class T.	2011	Method Validation Study for the Determination of Residues of Florasulam and its 5-0h Metabolite in Surface Water, Ground Water and Drinking Water by Liquid Chromatography with Tandem Mass Spectrometry DAS Report No. 110538 PTRL Europe Gmbh, Ulm, Germany GLP yes Unpublished	N	N	-	DAS
KCP 5.2	Souza N.	2011	Independet Laboratory Validation of Dow AgroSciences LLC Method – Determination of Residues of Florasulam and its 5-OH Metabolite in Surface Water, Ground Water and Drinking Water ny Liquid Chromatography with Tandem Mass Spec-trometry Detection DAS Report No. 110539 Dow AgroSciences Ind., Mogi Mirim, Brazil GLP yes Unpublished	N	N	-	DAS
KCP 5.2	Class T.	2011	The Development and Validationof a Method for the Analysis of Florasulam in Air	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			DAS Report No. 110282 PTRL Europe Gmbh, Ulm, Germany GLP yes Unpublished				
KCP 5.2	Class T, Göcer M.	2011	Florasulam: Develpoment of an Analytical Method for the Determination of Florasulam in Body Fluid(s) DAS Report No. 110283 PTRL Europe Gmbh, Ulm, Germany GLP yes Unpublished	N	N	-	DAS
	Olberding, E. L., Ng, C.A.	1996	Validation report for the determination of residues of Fluroxypyr and Fluroxypyr-1-methylheptyl ester as the acid equivalent in the grain, forage, straw, and hay of wheat, barley, and oats by capillary gas chromatography with mass selective detection, (GRM 96.02, supplementary) Global Environmental Chemistry Laboratory, Indianapolis, Indiana, USA 1996-06-04 including: Determination of residues of Fluroxypyr 1-methylheptyl ester as the acid equivalent in the grain, forage, straw, and hay of wheat, barley, and oats by capillary gas chromatography with mass selective detection, GRM 96.02 Wildlife International Ltd., Maryland, USA 1996-03-27 GH-C 4049 (RES 95118) GLP: yes not published	N	N	-	DOW
	McKellar, R. L., MacGregor, J.A., Markley, B.J.	1996	Independent laboratory validation of method GRM 96.02 – Determination of Fluroxypyr and Fluroxypyr 1-Methylheptyl ester as the acid equivalent in the grain, forage, straw, and hay of wheat, barley, and oats by capillary gas chromatography with mass selective detection	N	N	-	DOW

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Wildlife International Ltd., Maryland, USA GH-C 4166 (RES96044) 1996-08-02 GLP: yes not published				
	Olberding, E.L., Huskin, M.A.	1996	Determination of Fluroxypyr in ruminant tissues and milk by capillary gas chromatography with mass selective detection Pyxant Labs Inc, Colorado GRM 96.03, Study ID 030053 Annex to report PTR No. 30198040-5008-1, ref. IIA, 4.8 /04 1996-03-27 GLP: no not published	N	N	-	DOW
	Olberding, E.L., Huskin, M.A.	1996	Validation report for the determination of residues of Fluroxypyr in ruminant tissues and milk by capillary gas chromatography with mass selective detection (validation data for analytical method GRM 96.03) Global Environmental Chemistry Laboratory, Indianapolis, Indiana, USA GH-C 4048 1996-06-10 GLP: yes not published	N	N	-	DOW
	Reed, D.E., Bottoms, S.N.	2003	Independent laboratory validation of Dow AgroSciences LLC method GRM 96.03 – Determination of residues of Fluroxypyr in ruminant tissues and milk by gas chromatography with mass selective detection Pyxant Labs Inc., Colorado Springs, USA PTR No. 30198040-5008-1 2003-11-25 GLP: yes not publied	N	N	-	DOW
	Shackelford, D.D.	2009	Determination of Residues of Fluroxypyr in Poultry Tissues and Eggs by Liquid	N	N	-	DOW

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Chromatography with Tandem Mass Spectrometry Dow AgroSciences LLC, Indianapolis, Indiana, Lab. Study I.D. 081043 GLP Unpublished				
	Senciuc, M., Class, T..	2009	Independent Laboratory Validation of Dow AgroSciences LLC Method GRM 08.03 - Determination of Residues of Fluroxypyr in Poultry Tissues and Eggs by High Performance Liquid Chromatography with Tandem Mass Spectrometry Dow AgroSciences Protocol No. 080153, Study No. P 1545G GLP Unpublished	N	N	-	DOW
	Shackelford, D.D.	1999	Method validation report for the determination of Fluroxypyr and its major metabolites in soil by gas chromatography with mass selective detection. GRM 98.04 Global Environmental Chemistry Laboratory, Indianapolis, Indiana, USA GH-C 4908 1999-06-09 GLP: yes not published	N	N	-	DOW
	Shackelford, D.D.	1999	Independent laboratory validation method GRM 98.04 – Determination of residues of Fluroxypyr and its major metabolites in soil by capillary gas chromatography with mass selective detection, GRM 98.04 Enviro-Bio-Tech Ltd., Bernville, USA GH-C 4985 1999-09-21 GLP: yes not published	N	N	-	DOW
	Shackelford, D.D.	2000	Validation report for the determination of residues of Fluroxypyr 1-methylheptyl ester, Fluroxypyr-acid, Fluroxypyr-2-pyridinol, and	N	N	-	DOW

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Fluroxypyr-2-methoxypyridine in surface water by capillary gas chromatography with mass spectrometric detection, GRM 00.21 Global Environmental Chemistry Laboratory, Indianapolis, Indiana, USA GH-C 5157 2000-12-15 GLP: yes not published				
	Bacher, R.	2009	The Development and Validation of a Method for the Analysis of Fluroxypyr-acid and Fluroxypyr-1-methylheptyl ester in Air DOW Study No. 091018, PTRL Report No. B1644 G. GLP Unpublished	N	N	-	DOW
KCA 6.1	Butler, RE, Gambie, A,	1997	The Stability of DE-570 in Wheat Under Frozen Storage Conditions over 18 months (Interim Report) ST96-001 DowElanco Europe, Letcombe Regis, Oxon, UK GLP yes Unpublished	N	N	-	DAS
KCA 6.1/02	Gambie, A, Teasdale R	1999	The Stability of DE-570 in Wheat Under Frozen Storage Conditions over 18 months (Final Report) ST96-001 DowElanco Europe, Letcombe Regis, Oxon, UK GLP yes Unpublished	N	N	-	DAS
KCA 6.2.1	Pillar, F.	1997	The Metabolism of XDE-570 in Winter Wheat - Final Report 5U DowElanco Europe, Letcombe Regis, Oxon, UK GLP yes Unpublished	N	N	-	DAS
KCP 6.2.2	[redacted]	1994	Nature of the Residue of [14C]XDE-570 in Lactating Goats MET94017 [redacted] GLP yes Unpublished	Y	N	-	DAS
KCP 6.2.2	[redacted]	1994	Nature of the Residue of [14C]XDE-570 in Laying Hens	Y	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			MET94018 [redacted] GLP yes Unpublished				
KCP 6.6.1	MacDonald, A.	1997	The Uptake of XDE-570 into Four Succeeding Crops 7U DowElanco Europe, Letcombe Regis, Oxon, UK GLP yes Unpublished	N	N	-	DAS
KCA 6.1	Dial, E., Lindsay, D.	2006	Frozen Storage Stability of Clopyralid in Oilseed Rape DAS Study No. 020122.02 CEM Analytical Services (CEMAS), North Ascot, Berkshire, UK GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCA 6.1	Foster, D.R., Blakeslee, B.A., Rutherford, B.S.	1996	Frozen Storage Stability of Clopyralid, 2,4-D in Corn Grain, Straw and Fodder DAS Study No. RES93050.01 Dow Elanco, Indianapolis, Indiana, US GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCA 6.1	Clements, B, Bolton, A	1996	Determination of the Stability of Clopyralid Residues in Pasture under Frozen Storage Conditions DAS Study No. GHE-P-5350 CEM Analytical Services (CEMAS), North Ascot, Berkshire, UK GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCA 6.1		2004	Frozen Storage Stability of Clopyralid in Beef Muscle, Liver, Kidney, Milk and Chicken Egg Study No. 020120.01 GLP/GEP (Y/N): Yes Published (Y/N): No LoA	N	N	-	DAS
KCA 6.1		2015	Frozen Storage Stability of Clopyralid in Bovine Fat Study No. 120602 GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			LoA				
KCA 6.2.1	Chapleo So. Caley C.Y.	2002	The metabolism of [14C]-Clopyralid in Sugar Beet DAS Study No. GHE-P-9939 Inveresk Research International, Tranent, East Lothian, United Kingdom GLP: Y Unpublished	N	N	-	DAS
KCA 6.2.1	Guo C.	1996	Metabolism of 14C-Clopyralid in Cabbage DAS Study No. GH-C-4289 ABC Laboratories Inc., Columbia, Missouri, USA GLP: Y Unpublished	N	N	-	DAS
KCA 6.2.1	Chapleo So. Caley C.Y.	2002	The metabolism of (14C)-Clopyralid in Oilseed Rape DAS Study No. GHE-P-9938 Inveresk Research International, Tranent, East Lothian, United Kingdom GLP: Y Unpublished	N	N	-	DAS
KCA 6.2.2-6.2.5		2015	A Nature of the Residue Study in the Ruminant with [14C]Clopyralid Study No. 130202 GLP/GEP (Y/N): Yes Published (Y/N): No LoA	N	N	-	DAS
KCA 6.2.2-6.2.5		2014	A Nature of the Residue Study in the Laying Hen with [14C]-Clopyralid Study No. 130906 GLP/GEP (Y/N): Yes Published (Y/N): No Dow AgroSciences LLC, Indianapolis, Indiana, USA LoA	Y	N	-	DAS
KCA 6.4.1-6.4.3		1974	Dowco 290 and 2,4-D Chicken Feeding Study DAS Study No. TA-517 GLP: Y Unpublished	Y	N	-	DAS
KCA 6.4.1-6.4.3		1975	Residues of Dowco 290 (3,6-dichloropicolinic acid) in Tissues of Chicken Fed the Herbicide DAS Study No. GH-C 819	Y	N	-	DAS

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			GLP: N Unpublished				
KCA 6.4.1-6.4.3		2015	Summary of Clopyralid Livestock Feeding Study: Magnitude of Residue in Eggs, Muscle, Liver and Fat of Laying Hens DAS Study No. 150031 Lab Study No. CEMS-6921 GLP: Y Unpublished	Y	N	-	DAS
KCA 6.4.1-6.4.3		1974	Milk Residue Study with Dairy Cows Fed Lontrel Herbicide, Nellite Nematocide and 2,4-D Herbicide: Animal Care, Sampling and Production Records DAS Study No. GH-A 579 GLP: N Unpublished	Y	N	-	DAS
KCA 6.4.1-6.4.3		1974	Residues of Dowco 290 (3,6-dichloropicolini acid) in Milk and Cream from Cows Fed the Herbicide DAS Study No. GH-C 745 GLP: N Unpublished	Y	N	-	DAS
KCA 6.4.1-6.4.3		1975	Residues of Dowco 290 (3,6-dichloropicolini acid) in Bovine Tissues from Calves Fed the Herbicide DAS Study No. GH-C 811 GLP: N Unpublished	Y	N	-	DAS
KCA 6.4.1-6.4.3		2015	Summary of Clopyralid Livestock Feeding Study: Magnitude of Residue in Milk, Muscle, Liver and Fat of Lactating Dairy Cattle DAS Study No. 150030 Lab Study No. CEMS-6968 GLP: Y Unpublished	Y	N	-	DAS
KCA 6.5.1	Adusumili H.	2014	Processing Study to Determine the Nature of Residues of 14C -Clopyralid Following the Industrial or Household Preparation DAS Study No. 140574 Dow AgroSciences LLC, Indianapolis, Indiana, USA GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCA	Devine, H.C.	2006	Residues of clopyralid in wheat and process fractions at har-	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
6.5.1			vest following a single application of EF-1498, Northern France - 2005 DAS Study No. GHE-P-11274 CEM Analytical Services - UK GLP/GEP (Y/N): Yes Published (Y/N): No				
KCA 6.6.1	Hall, L. R.	2015	14C -Clopyralid: Metabolism in Confined Rotational Crops with a 30-Day Plant-back Interval DAS Study No. 130733 ABC Laboratories, Inc., Columbia, Missouri 65202, USA GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCA 6.6.1	Yackovich P.R., Lardie T.S. Brink D.L.	1993	A 10-1/2 Month Rotational Crops Study With 14C-Labeled Clopyralid – MET90080 DAS Study Np. GH-C-2992 Dow AgroSciences LLC, Indianapolis, Indiana, United States GLP: Y Unpublished	N	N	-	DAS
KCA 6.6.1	Yackovich P.R., Lardie T.S. Miller J.H.	1989	A 125-Day Rotational Crops Study With 14C-Labelled Clopyralid DAS Study Np. GH-C-2277 DowElanco, Midland, Michigan, USA GLP: Y Unpublished	N	N	-	DAS
KCA 6.3	Jones, EM Yuill, MM	1976a	Determination of Residues of 3,6-dichloropicolinic Acid (DOWCO 290) in Rape Seed Oil and Cake from 1975 Trials Carried Out by the Boots Company Limited Dow Chemical Company DAS Report No.: GHE-P-325 GLP:N Unpublished	N	N	-	DAS
KCA 6.3	Jones, EM Yuill, MM	1976b	Determination of Residues of 3,6-dichloropicolinic Acid (DOWCO 290) in Rape Seed, Cake, Oil and Straw from a Trial Carried Out in 1975 in Sweden by BT KEMI Dow Chemical Company DAS Report No.: GHE-P-337 GLP:N Unpublished	N	N	-	DAS
KCA 6.3	Rawle N.W.	2002	Residues of Clopyralid in Oilseed Rape at Intervals and at	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
	Khoshab A.		Harvest Following Multiple Applications of Lontrel 100 (EF-1136), EU Northern Zone – 2001. DAS Report No.: GHE-P-9380 GLP: Y Unpublished				
KCA 6.3	Freeman JMH Walker SM	1980	Determination of Residues of 3,6-dichloropicolinic Acid (DOWCO* 290) in Sugar Beet, Roots and Tops, Treated with FORMAT** - UK 1980 Dow Chemical Company DAS Report No.: GHE-P-803 GLP:N Unpublished	N	N	-	DAS
KCA 6.3	Rawle N.W. Khoshab A.	2002	Residues of Clopyralid in Sugarbeet at Intervals Under Open Field Conditions Following Multiple Applications of Lontrel 100 (EF-1136), Northern France and UK – 2000. DAS Report No.: GHE-P-9356 GLP: Y Unpublished	N	N	-	DAS
KCA 6.3	Rawle N.W. Khoshab A.	2002	Residues of Clopyralid in Sugar Beet at Harvest Under Open Field Conditions Following Multiple Applications of Lontrel 100 (EF-1136), Northern France and UK – 2000. DAS Report No.: GHE-P-9357 GLP: Y Unpublished	N	N	-	DAS
KCA 6.3	Rawle N.W. Khoshab A.	2002	Residues of Clopyralid in Sugar Beet at Intervals and at Harvest Following Multiple Applications of Lontrel (EF-1136), Northern Zone – 2001. DAS Report No.: GHE-P-9381 GLP: Y Unpublished	N	N	-	DAS
KCA 6.3	Freeman, JMH at al	1982	Effect of Length of Period Between Application of CY-RONAL* and Harvest on Residues of 3,6-dichoropicolinic Acid (DOWCO 290**) in Winter Wheat, Winter Barley and Maize – Belgium 1981 Dow Chemical Company DAS Report No.: GHE-P-943 GLP:N Unpublished	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3	Freeman, JMH	1984	Clopyralid Residues in Wheat Grain and Straw Treated with Either LONPAR* or LONTREL* 100 from French Trials, 1983 Dow Chemical Company DAS Report No.: GHE-P-1258 GLP:N Unpublished	N	N	-	DAS
KCA 6.3	Rawle N.W. Khoshab A.	2002	Residues of Clopyralid in Wheat at Intervals Under Open Field Conditions Following a Single Application of Lontrel (EF-1136), UK and Germany – 2000. DAS Report No.: GHE-P-9358 GLP:Y Unpublished	N	N	-	DAS
KCA 6.3	Rawle N.W. Khoshab A.	2002	Residues of Clopyralid in Wheat at Intervals Under Open Field Conditions Following a Single Application of Lontrel 100 (EF-1136), EU Northern Zone – 2001. DAS Report No.: GHE-P-9385 GLP:Y Unpublished	N	N	-	DAS
KCA 6.3	Freeman, JMH	1982	Effect of Length of Period Between Application of CY-RONAL* and Harvest on Residues of 3,6-dichoropicolinic Acid (DOWCO 290**) in Winter Wheat, Winter Barley and Maize – Belgium 1981 Dow Chemical Company DAS Report No.: GHE-P-943 GLP:N Unpublished	N	N	-	DAS
KCA 6.3	Rawle N.W. Khoshab A.	2002	Residues of Clopyralid in Barley at Intervals and at Harvest Following a Single Application of Lontrel 100 (EF-1136), EU Northern Zone – 2001. DAS Report No.: GHE-P-9383 GLP:Y Unpublished	N	N	-	DAS
KCA 6.3	Rawle N.W. Khoshab A.	2002	Residues of Clopyralid in Barley at Intervals Under Open Field Conditions Following a Single Application of Lontrel (EF-1136), UK – 2000. DAS Report No.: GHE-P-9360 GLP:Y	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCA 6.3	Rawle N.W. Khoshab A.	2002	Residues of Clopyralid in Barley at Harvest in Open Field Conditions Following a Single Application of Lontrel 100 (EF-1136), UK – 2000. DAS Report No.: GHE-P-9359 GLP:Y Unpublished	N	N	-	DAS
KCA 6.1	Teasdale, R.	1996	Frozen storage stability of Fluroxypyr in winter wheat immature plant, grain and straw Dow Elanco, CEM Analytical Services, Oxon, UK GHE-P-4830 (O32C) 1996-06-19 GLP: yes not published	N	N	-	DOW
KCA 6.1	Woods, J.S.	1990	Determination of residues of Fluroxypyr in eggs, muscle, liver and fat tissues from chickens administered Fluroxypyr herbicide Formulations and Environmental Chemistry Dow Elanco, Michigan, Midland, USA GH-C 2327 (N86) 1990-04-24 GLP: yes not published Also filed under IIA: 6.4.1/01	N	N	-	DOW
KCA 6.2.1	Hawkins D.R., Kirkpatrick, D., Conway, B., Finn, C.M., Powell, G.P.	1981	The metabolism of 14C-DOWCO MHE in spring wheat and soil after field application Dow Chemical, Huntingdon Research Centre, Huntingdon, Cambridgeshire, UK GHE-P-895 (L1) 1982-01-07 GLP: no not published	N	N	-	DOW
KCa 6.2.1	Puvanesarajah V., Stewart, R.C.	1991	Metabolism of 14C-Fluroxypyr in wheat Dow Elanco, ABC Lab., Inc., Columbia, Missouri, USA GHE-C-2650 (L2) 1991-10-25	N	N	-	DOW

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			GLP: yes not published				
KCA 6.2.1	Caley C. Y., O'Boyle, F	1995	Comparative Metabolism of [14C]-Fluroxypyr butoxypropyl ester and [14C]-Fluroxypyr methylheptyl ester in winter wheat DowElanco, Inveresk Research International, Tranent, Scotland GHE-P-4236 1995-04-27 GLP: yes not published	N	N	-	DOW
KCA 6.2.1	Baloch R.I., Brumhard, B., Fuhr, F.	1993	Behaviour of [2,6-14C] Fluroxypyr 1-methylheptyl ester in a sandy Pseudogley Braunerde after post-emerge application to spring barley DowElanco Europe, Institute Radioagronomie, Jülich, Germany GHE-P-2803 (K17B) 1993-05-11 GLP: yes not published	N	N	-	DOW
KCA 6.2.2	[redacted]	1989	The fate of 14C labelled Fluroxypyr fed to laying hens [redacted] GH-C-2148 (N87) 1989-01-20 GLP: yes not published	Y	N	-	DOW
KCa 6.4.1	[redacted].	1985	The excretion and tissue levels of radioactivity in a dairy cow after oral administration of 14C-DOWCO 433 acid [redacted] DET 602 (H3) 1985-06-27 GLP: yes not published	Y	N	-	DOW
KCA 6.2.2	[redacted]	1990	The fate of 14C labelled Fluroxypyr fed to lactating goats	Y	N	-	DOW

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			[redacted] GH-C 2297 1990-02-12 GLP: yes not published				
KCA 6.3	Butler, R.E.	1999	Residues of Fluroxypyr and florasulam in winter wheat at harvest following a single application of Fluroxypyr BPE / Florasulam SE (EF-1466), Northern France - 1998 Dow AgroSciences Europe, Letcombe Lab., Oxon, UK GHE-P-7814 (N100) 1999-05-28 GLP: yes not published	N	N	-	DOW
KCA 6.3	Teasdale, R.	1995	Residues of Fluroxypyr in winter wheat at intervals following a single application of Starane 400 EW (EF-1312), UK - 1994 DowElanco, CEM Analytical Services, Oxon, UK GHE-P-4651 (N27E) 1995-12-18 GLP: yes not published	N	N	-	DOW
KCA 6.3	Teasdale, R.	1995	Residues of Fluroxypyr in winter wheat and soil at harvest following application of novel Starane formulations, UK - 1993 DowElanco, CEM Analytical Services, Oxon, UK GHE-P-4297 (N27) 1995-07-17 GLP: yes not published	N	N	-	DOW
KCA 6.3	Clements, B.	1997	Residues of Fluroxypyr-BPE, Clopyralid and MCPA in cereals at harvest following a single application of Bofix (new) (EF-1403), France (North and South) - 1996 Dow Elanco, Letcombe Lab., Oxon, UK	N	N	-	DOW

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			GHE-P-6502 (N29A) 1997-10-29 GLP: yes not published				
KCA 6.4	Nicholas, L., Cameron, D.M., Macdonald, I.A., Brown, D.	1986	DOWCO 433 (Fluroxypyr) residues in milk and tissue, UK trial Dow Chemical, Huntingdon Research Centre, Huntingdon, Cambridgeshire, UK DWC 422/8693 (N85) 1986-03-27 GLP: yes not published Also filed under IIA 4.8/01	N	N	-	DOW
KCA 6.5.1 KCA 6.6.2	Lickly, L.S., Lardie, T.S., Miller, J.H., Baldwin, W.S.	1990	14C Fluroxypyr-MHE: Confined accumulation study on rotational crops planted at 30, 120 and 366 days after soil treatment Environmental Chemistry Lab. DowElanco, Midland, Michigan, USA GH-C 2410, (N38) 1990-09-17 GLP: yes not published	N	N	-	DOW
KCA 6.5.1 KCA 6.6.2	Yackovich, P. R., McCracken, M., O`Neal, S.	1996	A confined rotational crop study with 14CFluroxypyr Methylheptyl Ester PTRL East, Inc. Richmond, Kentucky and Global Environmental Chemistry Laboratory – Indianapolis Lab, DowElanco, Indianapolis, Indiana GH-C 3988 1996-05-08 GLP: yes not published`	N	N	-	DOW
KCP 7 /01	[redacted]	2008	Salmonella Escherichia coli/ Mammalian-Microsome Reverse Mutation Assay Preincubation Method with a Confirmatory Assay with ASTCA Metabolite of Florasulam [redacted]	Y	N	-	DAS

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			GLP/GEP (Y/N): Y Published: N				
KCP 7/02	[redacted]	2008	Evaluation of Florasulam ASTCA Metabolite in the Chinese Hamster ovary Ell/hypoxanthine-guanine-phosphoribosyl Transferase (cho/hgprt) Forward Mutation Assay Toxicology & Environmental Research and Consulting [redacted] GLP/GEP: Y Published: N	Y	N	-	DAS
KCP 7/03	[redacted]	2008	Evaluation of Florasulam ASTCA Metabolite in an in vitro Chromosomal Aberration Assay Utilizing Rat Lymphocytes Toxicology & Environmental Research and Consulting DAS [redacted] GLP/GEP: Y Published: No	Y	N	-	DAS
KCP 7/04	[redacted]	2011	Bacterial Reverse Mutation Test of TSA Metabolite of Florasulam using Salmonella typhimurium Jai Research Foundation [redacted] GLP: Y Published: N	Y	N	-	DAS
KCP 7/05	[redacted]	2011	In vitro Mammalian Cell Gene Forward Mutation Test at the hgprt Locus of the Chinese Hamster Ovary (CHO)-K1 Cell Line using TSA metabolite of florasulam JAI Research Foundation DAS [redacted] GLP/GEP: Y Published: N	Y	N	-	DAS
KCP 7/06	[redacted]	2011	In vitro Mammalian Chromosome Aberration Test of TSA Metabolite of Florasulam in Human Peri Blood Lymphocytes Jai Research Foundation DAS [redacted] GLP/GEP: Y Published: N	Y	N	-	DAS
KCP 7/07	[redacted]	2011	5-Hydroxy Florasulam: Reverse Mutation Assay "Ames Test" Using Salmonella Typhimurium And Escherichia Coli. [redacted] GLP	N	N	-	DAS

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			Unpublished				
KCP 7/08	[redacted]	2011	Evaluation Of 5-Hydroxy-Florasulam In The Chinese Hamster Ovary Cell/Hypoxanthine-Guanine-Phosphoribosyl Transfer-ase (CHO/HGPRT) Forward Mutation Assay Toxicology & Environmental Research and Consulting The [redacted] GLP Y	N	N	-	DAS
KCP 7/09	[redacted]	2011	Evaluation Of 5-Hydroxy-Florasulam In An In Vitro Chromo-somal Aberration Assay Utilizing Rat Lymphocytes Toxicology & Environmental Research and Consulting [redacted] GLP Y	N	N	-	DAS
KCP 7/10	-	2011	5-Hydroxy-Florasulam: Acute oral toxicity study in Fischer 344 Rats GLP Y	Y	N	-	DAS
KCP 9.1.1	Jackson R., Ghosh D.,	1997	The Aerobic Degradation of XDE-570 in Soil.; Report No. GHE-P-4710; DowElanco Europe, Letcombe Laboratory, Letcombe Regis GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.1.1	Jackson R., Massart J.,	1998	The degradation of DFP-ASTCA and ASTCA (two metabo-lites of DE-570) in Soil. Report No. GHE-P-7522; Dow AgroSciences, Letcombe Laboratory, Letcombe Regis GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.1.1	Cleveland C. B., Sanders L. T., Gilbert J. R.,	1997	Anaerobic Aquatic Metabolism Study of XDE-570. Study report No. ENV95137; North American Environmental Chemistry Laboratory GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.1.1	Krieger M. S., Yoder R. N.,	1996	Photolysis of XDE-570 on Soil Study report No. ENV95083; Global Environmental Chemistry Laboratory – Indianapolis Lab	N	N	-	DowAgroSciences

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			GLP Yes Unpublished				
KCP 9.1.1	Pillar F.,	1997	Effects of temperature on the degradation of DE-570 in soil. Study report No. GHE-P-6749; DowElanco Europe, Letcombe Laboratory, Letcombe Regis GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.1.1	Pillar F.,	1997	Effects of moisture on the degradation of DE-570 in soil Study report No. GHE-P-6750; DowElanco Europe, Letcombe Laboratory, Letcombe Regis GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.1.1	Jackson R.,	2010	Re-evaluation of the Degradation Kinetics of Florasulam and its Major Metabolites in European Soils According to Focus Guidance Report No GHE-P-12511 Dow AgroSciences, European Development Centre GLP No Unpublished	N	N	-	DowAgroSciences
KCP 9.1.1	Simmonds R.,	2012	[14C]-TSA: Rate of Degradation in Four Soils at 20°C Study report No. YR/11/010; Battelle UK Ltd., Battelle House, Fyfield Business and Research Park GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.1.1	Maycock R.	1997	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a single application of EF-1343, Germany, 1995 – 1996. Study report No. GHE-P-6366 Dow Elanco Europe, Letcombe Regis GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.1.1	Maycock R.	1997	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a single application of EF-1343, Northern France - 1995. Study report No. GHE-P-6367 Dow Elanco Europe, Letcombe Regis GLP Yes	N	N	-	DowAgroSciences

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			Unpublished				
KCP 9.1.1	Maycock R.	1997	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a single application of EF-1343, UK – 1996 Study report No. GHE-P-6368 Dow Elanco Europe, Letcombe Regis GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.1.1	Maycock R.	1997	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a single application of EF-1343, Southern France – 1996 Study report No. GHE-P-6369 Dow Elanco Europe, Letcombe Regis GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.1.1	Maycock R.	1997	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a single application of EF-1343, Greece – 1996 Study report No. GHE-P-6370 Dow Elanco Europe, Letcombe Regis GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.1.1	Maycock R.	1997	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a single application of EF-1343, UK – 1995 Study report No. GHE-P-6781 Dow Elanco Europe, Letcombe Regis GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.1.1	Gambie A.,	1997	Residues of DE-570 and its 5-hydroxy metabolite in soil at normal harvest following application of EF-1343 to wheat and barley – Europe: 1995-1996 Study report No. GHE-P-6833 Dow Elanco Europe, Letcombe Regis GLP No Unpublished	N	N	-	DowAgroSciences
KCP 9.1.1	Ostrander J. A.	1996	Mobility Studies of XDE-570 and 5-hydroxy-XDE 570 Study report No. GH-C-3868 (study ID: ENV95020)	N	N	-	DowAgroSciences

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			North American Environmental Chemistry Laboratory GLP Yes Unpublished				
KCP 9.1.2	Simmonds R.	2011	Florasulam: Adsorption and Desorption Properties of [14C]-Florasulam in Eight Soils Study report No. YR/11/005 Battelle UK Ltd., Battelle House, Fyfield Business and Research Park GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.1.2	Simmonds R.	2011	Florasulam: Adsorption Properties of [14C]-5-hydroxyflorasulam in Four Soils Study report No. YR/11/006 Battelle UK Ltd., Battelle House, Fyfield Business and Research Park GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.1.2	Burgess M., Simmonds R.,	2011	Florasulam: Adsorption Properties of [14C]-DFP-ASTCA in Four Soils Study report No. YR/11/009 Battelle UK Ltd., Battelle House, Fyfield Business and Research Park GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.1.2	Burgess M., Simmonds R.,	2011	Florasulam: Adsorption Properties of [14C]-ASTCA in Four Soils Study report No. YR/11/008; Battelle UK Ltd., Battelle House, Fyfield Business and Research Park GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.1.2	Burgess M., Simmonds R.,	2011	Florasulam: Adsorption Properties of [14C]-TSA in Four Soils Study report No. YR/11/007; Battelle UK Ltd., Battelle House, Fyfield Business and Research Park GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.1.2	Pillar F.	1997	The non-aged column leaching of DE-570	N	N	-	DowAgroSciences

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			Study report No. GHE-P-6785 DowElanco Europe, Letcombe Laboratory, Letcombe Regis GLP No Unpublished				
KCP 9.1.2	Jackson R., Paterson G.,	1997	The dissipation of XDE-570 in soil and crops using field lysimeters Study report No. GHE-P-6751 DowElanco Europe, Letcombe Laboratory, Letcombe Regis GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.2	Jackson R., Portwood D.,	1993	The Aqueous Hydrolysis of XR-570 Study report No. GHE-P-3326 DowElanco Limited, Letcombe Laboratory, Letcombe Regis GLP No Unpublished	N	N	-	DowAgroSciences
KCP 9.2	Phillips M.,	1996	The determination of the hydrolytic stability of radiolabelled XDE-570 Study report No. GHE-P-4986 (Inveresk Project No. 386209) Inveresk Research International Ltd. GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.2	Yoder R. N.	1996	Aqueous Photolysis of XDE-570 in Natural Sunlight Study report No. GH-C 3951 (study ID: ENV95023) DowElanco, North American Environmental Chemistry Laboratory GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.2	Yoder R. N., Balcer J. L.	2002	Aqueous Photolysis of Florasulam in pH5 Buffer under Xenon Light Study report No. GH-C 5399; Regulatory Laboratories – Indianapolis Lab, Dow AgroSciences LLC GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.2	Byrne S. L., Crabtree A. B., Balcer J. L., Linder S. J.	2005	Aqueous Photolysis of Florasulam in Natural Water Using a Xenon Lamp Study report No. 050024 Regulatory Laboratories – Indianapolis Lab	N	N	-	DowAgroSciences

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			GLP Yes Unpublished				
KCP 9.2	Gibson R., Portwood D.	1999	Investigation of the degradation of DE-570 in natural water Study report No. GHE-P-7468 Dow AgroSciences, Letcombe Laboratory, Letcombe Regis GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.2	Jenkins W. R.	1994	XDE 570 (PURE): Assessment of Ready Biodegradability. Modified Sturm Test.; Study report No. GHE-P-3736 (Pharmaco study report No.: 94/DES180/0468) Pharmaco LSR Lts GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.2	Jenkins W. R.	1995	XDE 570 5-Hydroxy6 metabolite: Assessment of Ready Bio-degradability. Modified Sturm Test Study report No. GHE-P-4552 (Pharmaco study report No.: 95/DES284/0692) Pharmaco LSR Lts GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.2	Phillips M.	1997	The aerobic degradation of XDE-570 in natural waters and associated sediments Study report No. GHE-P-5039 (Inveresk Project No. 12712) Inveresk Research International Ltd. GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.2	Lewis C., Gilbert J.,	2011	[14C]-Florasulam: Degradation in Water-Sediment Systems under Aerobic Conditions Study report No. 1000576 (Covance Study No. 8235547) Covance Laboratories Ltd GLP Yes Unpublished	N	N	-	DowAgroSciences
KCP 9.3	Knoch E.,	1997	Investigation of the Volatilization of DE-570 formulated as 50 g a. s./L SC from soil and Dwarf Runner Bean Study report No. GHE-P-6747 (Fresenius Institut Study No. IF 97/07970-00) Institut Fresenius, Chemische und Biologische Laboratorien	N	N	-	DowAgroSciences

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			GmbH GLP Yes Unpublished				
KCP 9.3	Mattock S. D.	2011	Florasulam – literature search for toxicology, environmental fate and ecotoxicology in support of Annex I renewal Study report No. GHE-P-12699 (Project number 4-16-6) TGSA Concordia House, St James Business Park GLP No Unpublished	N	N	-	DowAgroSciences
KCP 9.1.1	Baloch, R.;Grant, R.	1991	Degradation and metabolism of Clopyralid in Soil under Aerobic Conditions DAS Report No.GHE-P-2398R Agricultural Research and Development Center, DowElanco Limited, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon, U.K. GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 9.1.1	Skinner, W.; Jao, N.; Smith, J. K.	1995	Aerobic Soil Metabolism of [14C]Clopyralid DAS Report No.GHE-C-3598 PTRL West, Inc. 4123-B Lakeside Drive, Richmond, CA 94806 GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 9.1.1	Wardrope, L.	2009	The Degradation of (14C)-Clopyralid in Soil Under Aerobic Conditions DAS Report No.808711 Charles River Laboratories, Tranent, East Lothian, United Kingdom GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 9.1.1	Allan, J.; Lowrie, C. ; Hall, B. E.	2002	The Degradation of C14 Clopyralid in Soil Under Anaerobic Conditions DAS Report No.GHE-P-9563 Inveresk Research International, Tranent, East Lothian, United Kingdom GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 9.1.1	Schubert, S.	2015	Evaluation of kinetic endpoints for clopyralid from laboratory	N	N	-	DAS

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			soil degradation studies DAS Report No. 151039 Dow AgroSciences, Milton Park, UK GLP/GEP (Y/N): No Published (Y/N): No				
KCP 9.1.2	Rawle, N.; Yon, D.	2002	The dissipation of clopyralid in soil following a single application of LONTREL (EF-1136), Denmark and the UK – 2000 DAS Report No. GHE-P-9370 CEMAS GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 9.1.2	Rawle, N.; Yon, D.	2002	The dissipation of clopyralid in soil following a single application of LONTREL (EF-1136), Germany and Northern France – 2000 DAS Report No. GHE-P-9371 CEMAS GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 9.1.2	Kröger, F.	2015	Soil dissipation study with one spring application of GF-1966 (Clopyralid) at three sites to bare soil in Europe in 2013-2015 Eurofins Agroscience Services, Stade, Germany Eurofins Study S13-00312 DAS Study No. 130673 GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 9.1.2	Robinson, P.	2015	Estimation of kinetic endpoints for clopyralid from soil dissipation studies. Dr Knoell Consult Ltd., Cardiff, UK DAS Study No. 150296 GLP/GEP (Y/N): No Published (Y/N): No	N	N	-	DAS
KCP 9.1.2	Kröger, F.	2016	Soil dissipation study with one spring application of GF-1966 (Clopyralid) at one site to bare soil in South Europe in 2015. Eurofins Agroscience Services, Stade, Germany Eurofins Study S15-02991 DAS Study No. 150672 GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS

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KCP 9.1.2	Kröger, F.	2016	Soil dissipation study with one spring application of GF-1966 (Clopyralid) at one site to bare soil in South Europe in 2015. Eurofins Agroscience Services, Stade, Germany Eurofins Study S15-02992 DAS Study No. 150673 GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 9.1.2	Robinson, P.	2016	Estimation of kinetic endpoints for clopyralid from field soil dissipation studies (Southern Europe). Dr Knoell Consult Ltd., Cardiff, UK DAS Study No. 160486 GLP/GEP (Y/N): No Published (Y/N): No	N	N	-	DAS
KCP 9.1.2	Ahrens, C. & Kröger, F.	2017	Final report – Field soil dissipation study with one spring application of GF-1966 (Clopyralid) at one site in North EU and one site in South EU to bare soil in 2016 - 2017. Eurofins Agroscience Services, Stade, Germany; Eurofins Study S16-01795 DAS Study No. 160394 GLP/GEP (Y/N): No Published (Y/N): No	N	N	-	DAS
KCP 9.1.2	Robinson, P.	2017	Estimation of kinetic endpoints for clopyralid from soil dissipation studies (North and South Europe). Dr Knoell Consult Ltd., Cardiff, UK DAS Study No. 170481 GLP/GEP (Y/N): No Published (Y/N): No	N	N	-	DAS
KCP 9.1.2	Reeves, G. L. & Mittelstaedt, W.	2002	Adsorption/Desorption of Clopyralid in Soil: Corrections to Final Report of Study DW 2/92 from August 1993 DAS Report No.GHE-P-9762 Forschungszentrum Julich GmbH, Julich, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 9.1.2	Buntain, I., Simmonds, M.	2015	[14C]-Clopyralid: Adsorption to and Desorption from Five Soils DAS Report No.130699 Battelle UK Ltd., Chelmsford, Essex, UK GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 9.1.2	Schnöder, F.	2004	[14C] Clopyralid: Leaching in outdoor lysimeters following spring application to oilseed rape – Final report DAS Report No.000136	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Covarance Laboratories, Germany GLP/GEP (Y/N): Yes Published (Y/N): No				
KCP 9.1.2	Dust, M., Führ, F.	1994	Degradation and leaching of clopyralid monoethylamine salt after post emergence application of LONTREL 100 to winter rape in German lysimeters DAS Report No.GHE-P-4037 Forschungszentrum Julich GmbH, Julich, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 9.1.2	Brumhard, B., Führ, F., Baloch, R.	1994	Behaviour of [2,6 14C] Clopyralid (LONTREL*) in a sandy Pseudogley Braunerde after post-emergence application to sugar beet DAS Report No.GHE-P-2908 Forschungszentrum Julich GmbH, Julich, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 9.1.2	Brumhard, B., Baloch, R., Führ, F.	1994	Behaviour of [2,6 14C] clopyralid formulated as LONTREL 100 in Parabraunerde (Orthic Luvisol) after post emergence application to sugar beet lysimeters DAS Report No.GHE-P-2580 Forschungszentrum Julich GmbH, Julich, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 9.1.2	Smith-Drake, J. K.	2000	Hydrolysis of 14C Clopyralid in Natural Water And Buffered Water as a Function of pH DAS Report No.000132 Dow AgroSciences LLC, Indianapolis, Indiana, United States GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 9.1.2	Hall B.E.; Allen, J.; Clements B.	2002	The Aerobic Degradation of [14]-Clopyralid in Natural Waters and their Associated Sediments DAS Report No.GHE-P-9564 Inveresk Research International, Tranet, East Lothian, UK Published (Y/N): No	N	N	-	DAS
KCP 9.1.2	Ponte, M.	2014	Direct Aqueous Photodegradation of [14C]Clopyralid in pH 7 Buffer DAS Report No.140077	N	N	-	DAS

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			PTRL West, Hercules, California, USA GLP/GEP (Y/N): Yes Published (Y/N): No				
KCP 9.2	Jenkins, W. R.	1991	LONTREL T: Assessment of its Biodegradability - Modified Sturm Test Life Science Research, Eye, Suffolk, UK DAS Report No. GHE-P-2522 GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 9.3	Day, S. R.; Rudel, H.	1994	The evaporation of Clopyralid acid from soil and leaf surfaces following application of LONTREL 100 DAS Report No. GHE-P-3507 Fraunhofer Institute, D-57392 Schmallenberg, Graf-schaft/Hochsauerland, Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 9.3	Madsen, S.	2002	Calculation of the Stability in Air of Clopyralid - Photochemi-cal Degradation. DAS Report No. LLC NAFST GLP/GEP (Y/N): No Published (Y/N): No	N	N	-	DAS
KCP 9.1	Lehmann, R. G.	1988	Extraction of Fluroxypyr and its Metabolites from Aged Soil Dow Chemical U.S.A. GH-C 2048 GLP: No not published	N	N	-	DOW
KCP 9.1	Dawson, J	1987	An Extractability Assessment of Fluroxypyr 1- Methylheptyl Ester from Soil and Immature Cereal Plants Dow Chemical Europe, Oxon, UK GHE-P-1706R GLP: no not published	N	N	-	DOW
KCP 9.1	Grant, R. K.	1992	Degradation and Metabolism of Fluroxypyr 1-methylheptyl ester in soil under aerobic conditions DowElanco, Oxon, UK GHE-P-2754	N	N	-	DOW

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP: yes not published				
KCP 9.1	Hawkins, D. R., Kirkpatrick, D., Conway, B., Finn, C.M., Powell, G. P. and Biggs, S.	1982	The Metabolism of 14CDOWCO 433 MHE in Laboratory Soil under Aerobic and Anaerobic Conditions Department of Chemical Metabolism and Radiosynthesis, Huntingdon Research Centre, Huntingdon, Cambridgeshire, PE18 6ES, UK Dow Chemical Europe, Norfolk, UK GHE-P-1018 GLP: yes not published	N	N	-	DOW
KCP 9.1	Lehmann, R. J. and Miller, J. R.	1989	Aerobic Soil Metabolism of Fluroxypyr-MHE Agricultural Chemistry R&D Laboratories, The Dow Chemical Co, USA GH-C 2149R GLP: yes not published	N	N	-	DOW
KCP 9.1	Ballantine, L. G. and Zabik, S. E.	1993	Aerobic Soil Metabolism of 14CFluroxypyr- MHE Hazleton Wisconsin Inc, 3301 Kinsman Boulevard, Madison, Wisconsin 53704, USA Dow Elanco, USA GH-C 3026 GLP: yes not published	N	N	-	DOW
KCP 9.1	Hawkins, D. R., Kirkpatrick, D., Conway, B., Finn, C.M., Powell, G. P. and Biggs, S.	1982	The Metabolism of 14CDOWCO 433 MHE in Laboratory Soil under Aerobic and Anaerobic Conditions Department of Chemical Metabolism and Radiosynthesis, Huntingdon Research Centre, Huntingdon, Cambridgeshire, PE18 6ES, UK Dow Chemical Europe, Norfolk, UK GHE-P-1018	N	N	-	DOW

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			GLP: yes not published				
KCP 9.1	Yon, D.A.	1987	The metabolism of 14CFluroxypyr 1-MHE in laboratory stored soil – Part II. Identification of an anaerobic metabolite Dow Chemical Europe, Oxon, UK GHE-P-1670 GLP: yes not published	N	N	-	DOW
KCP 9.1	Batzer, F. R. and Lubinski, R. N.	1992	Soil Photolysis of Fluroxypyr 1-Methylheptyl Ester in Natural Sunlight Dow Elanco, Midland, USA GH-C 2717 GLP: yes not published	N	N	-	DOW
KCP 9.1	Reeves, G.	2007	Modelling the laboratory soil degradation kinetics of Fluroxypyr meptyl, Fluroxypyr and two metabolites Dow AgroSciences, UK GHE-P-11641 GLP: no not published;	N	N	-	DOW
KCP 9.1	Hawkins, D. R. Kirkpatrick, D. Conway, B. Finn, C. M. and Powell, G. P.	1981	DOWCO 433: 1-Methylheptyl Ester Metabolism in Spring Wheat and Soil After Field Application Department of Chemical Metabolism and Radiosynthesis, Huntingdon Research Centre, Huntingdon, Cambridgeshire, PE18 6ES, UK Dow Chemical Europe, UK GHE-P-895 GLP: yes not published	N	N	-	DOW

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KCP 9.1	Freeman, J. M. H., Houghton, S., McAllister-Hewlings, N. and Smith, D.	1985	Degradation and leaching of fluroxypyr in soil - UK 1984 Dow Chemical Europe, UK GHE-P-1303R GLP: yes not published	N	N	-	DOW
KCP 9.1	Poletika, N. N., Roberts, D. W., Phillips, A. M. and Buttler, I. W.	1994	Terrestrial Field Dissipation of Fluroxypyr in Western Canada A & L Great Lakes Laboratories Inc., 3505 Conestoga Drive, Fort Wayne, Indiana 46808-4413, USA DowElanco, 9330 Zionsville Road, Indianapolis, Indiana 46268-1053, USA DowElanco Canada Inc., 9635-45th Avenue, Edmonton, Alberta, T6E 5Z8, CANADA Enviro-Quest, Box 144, Minto, Manitoba, R0K 1MO, CANADA Normac AES Ltd., Box 880, Swift Current, Saskatchewan, S9H 3W8, CANADA Dow Elanco GH-C 3210 GLP: yes not published	N	N	-	DOW
KCP 9.1	Teasdale, R.	1995	Residues of Fluroxypyr in soft wheat at harvest and residues of Fluroxypyr 1-methylheptyl ester (MHE), Fluroxypyr and two metabolites in soil following a single post-emergence application of Starane (EF 1018), Italy – 1993 Laboratory Phase: DowElanco Europe, UK Field Phase: DowElanco Italia SRL, Via d'Azelgio, 25, 40123 Bologna, ITALY Dow AgroSciences, Oxon, UK GHE-P-3913	N	N	-	DOW

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			GLP: yes not published				
KCP 9.1	Teasdale, R.	1995	Residues of Fluroxypyr in winter barley at harvest and residues of Fluroxypyr 1-methylheptyl ester (MHE), Fluroxypyr and two metabolites in soil following a single postemergence application of Starane (EF 1018), Italy – 1993 Laboratory Phase: DowElanco Europe, UK Field Phase: DowElanco Italia SRL, Via d'Azelgio, 25, 40123 Bologna, ITALY Dow AgroSciences, Oxon, UK GHE-P-3914 GLP: yes not published	N	N	-	DOW
KCP 9.1	Teasdale, R.	1994	Residues of Fluroxypyr in durum wheat at harvest and residues of Fluroxypyr 1-methylheptyl ester (MHE), Fluroxypyr and two metabolites in soil following a single postemergence application of Starane (EF 1018), Italy – 1993 Laboratory Phase: DowElanco Europe, UK Field Phase: DowElanco Italia SRL, Via d'Azelgio, 25, 40123 Bologna, ITALY Dow AgroSciences, Oxon, UK GHE-P-3912 GLP: yes not published	N	N	-	DOW
KCP 9.1	Freeman, J. M. H.	1984	Residues of Fluroxypyr in Soil Following Application of STARANE Herbicides to Summer Wheat, Winter Rye and Winter Barley in Germany 1983 Dow Chemical Europe, UK GHE-P-1244	N	N	-	DOW

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			GLP: no not published				
KCP 9.1	Hale, K. and Gardinal, P.	1995	The adsorption/desorption of [14C]-Fluroxypyr methyl ester, [14C]-Fluroxypyr butoxypropyl ester, [14C]-Fluroxypyr, [14C]- Fluroxypyr pyridinol and [14C]-Fluroxypyr methoxy-pyridine in soil. DowElanco, Oxon, UK GHE-P-4500 R GLP: yes not published	N	N	-	DOW
KCP 9.1	Lehmann, R. G. and Miller, J. R.	1988	An Adsorption/desorption Study of Fluroxypyr The Dow Chemical Company, Midland, MI, USA GH-C 2124 GLP: yes not published	N	N	-	DOW
KCP 9.1	Cleveland, C. B. and Ostrander, J. A.	1996	Adsorption/Desorption Batch Equilibrium Partitioning of Methoxypyridine and Dichloropyridinol Metabolites of Fluroxypyr DowElanco, USA GH-C 3854 GLP: yes not published;	N	N	-	DOW
KCP 9.1	Cleveland, C. B.	1998	Response to the U. S. EPA Data Evaluation Report on: Adsorption/Desorption Batch Equilib-rium Partitioning of Methoxypyridine and Dichloropyridinol Metabolites of Fluroxypyr DowElanco, Indiana, USA GH-C 3854R GLP: yes not published;	N	N	-	DOW
KCP 9.1	Freeman, J. M.	1985	The Leaching Characteristics of Fluroxypyr in Soil Hazleton Laboratories Europe Ltd., Otley Road, Harrogate North Yorkshire, HG3 1PY, UK Dow Chemical Europe, UK GHE-P-1301	N	N	-	DOW

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			GLP: no not published				
KCP 9.1	Freeman, J. M.	1985	The Leaching Characteristics of Starane 180 in Soil According to Merkblatt 37 Guidelines Hazleton Laboratories Europe Ltd., Otley Road, Harrogate, North Yorkshire, HG3 1PY, UK Dow Chemical Europe, UK GHE-P-1355 GLP: no not published	N	N	-	DOW
KCP 9.1	Freeman, J. M. H.	1985	The Leaching Characteristics of Fluroxypyr as Determined in an Aged Leaching Study Hazleton Laboratories Europe Ltd., Otley Road, Harrogate, North Yorkshire, HG3 1PY, UK Dow Chemical Europe, UK GHE-P-1300 GLP: no not published	N	N	-	DOW
KCP 9.1	Baloch, R. I, Brumhard, B. and Fuhr, F.	1992	Behaviour of [2,6-14C] Fluroxypyr 1-Methylheptyl Ester in a Sandy Pseudogley Braunerde After Post- Emergence Application to Spring Barley Institut Für Radioagronomie, Forschungszentrum, Jülich, D-5170 Jülich, GERMANY Dow Elanco, Oxon, UK GHE-P-2803 GLP: yes not published	N	N	-	DOW
KCP 9.1	Reeves, G.	2001	The leaching of Fluroxypyr after autumn application of Starane 200 to pasture grass lysimeters Dow Agrosciences, Oxon, UK GHE-P-8590 GLP: yes not published;	N	N	-	DOW
KCP 9.2	Lehmann, R.	1987	The Hydrolysis of Fluroxypyr MHE in Dilute Aqueous Solu-	N	N	-	DOW

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	G.		tion Dow Chemical U.S.A GH-C 1910 GLP: yes not published				
KCP 9.2	Dawson, J.	1984	The degradation of Fluroxypyr 1-methylheptyl ester and Fluroxypyr in buffered water solutions according to the BBA Protocol Merkblatt 55 Hazelton Laboratories Europe Ltd, Otley Road, Harrogate, North Yorkshire, HG3 1PY, UK Dow Chemical Europe 3995-295/2 GLP: no not published	N	N	-	DOW
KCP 9.2	Meikle, R.W	1979	The hydrolysis rate of DOWCO 433X, 1-methylheptyl ester, in buffered dilute aqueous solution Dow Chemical, Walnut Creek, USA 1979-03-08 GS-1601 GLP: no not published	N	N	-	DOW
KCP 9.2	Cleveland, C. B. and Holbrook, D. L.	1992	The Aqueous Photolysis of Fluroxypyr Methylheptyl Ester and Fluroxypyr (Acid) in Natural Sunlight Dow Elanco, Midland, USA GH-C 2758 GLP: yes not published	N	N	-	DOW
KCP 9.2	Douglas, M. I. and Pell, I. B.	1986	Assessment of the Ready Biodegradability of Fluroxypyr Acid Huntingdon Research Centre Ltd., Huntingdon, Cambridgeshire, PE18 6ES, UK Dow Chemical Europe GHE-P-1582	N	N	-	DOW

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP: yes not published				
KCP 9.2	Knowles, S. J.	1991	Ready Biodegradability of Fluroxypyr-1- methylheptyl ester (Modified Sturm Test) Life Science Research Limited Eye, Suffolk, IP23 7PX, UK DowElanco, UK GHE-P-2439 GLP: yes not published	N	N	-	DOW
KCP 9.2	Yon, D. A.	1988	The Degradation of 14C Fluroxypyr 1-MHE in Ditch Waters and their Associated Sediments, 1987 Main study: Hazleton UK Ltd., Otley Road, Harrogate, North Yorkshire, UK Sediment/Water Characterisation MAFF, ADAS, Lawnswood, Leeds, UK Aerobic Microflora Determination: Grange Laboratories, Wetherby, West Yorkshire, UK Dow Chemical Europe GHE-P-1785 GLP: no not published	N	N	-	DOW
KCP 9.2	Cleveland, C. B. and Miller, J. R.	1993	Aerobic Aquatic Metabolism of Fluroxypyr Methyl Heptyl Ester Dow Elanco, USA GH-C 3008 GLP: yes not published	N	N	-	DOW
KCP 9.1	Lehmann, R. G.	1988	Formation of Fluroxypyr from Fluroxypyr MHE by Soil Catalysis Dow Chemical, USA GH-C 2068	N	N	-	DOW

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			GLP: no not published				
KCP 9.2	Partsch, S.	2008	Modelling the degradation kinetics of Fluroxypyr meptyl, Fluroxypyr and two metabolites from a water/sediment study Dr. Knoell Consult GmbH, Mannheim, Germany Dow AgroChemical, UK GHE-P-11831 GLP: no not published;	N	N	-	DOW
KCP 9.2	Yon, D. A. and Müller, M.	1995	Estimation of the Atmospheric Half-Life of Fluroxypyr-1-methylheptyl ester Fraunhofer Institut für Umweltchemie und Ökotoxikologie, D-57392 Schmallenberg, Germany Dow Elanco Europe GHE-P-4736 GLP: yes not published	N	N	-	DOW
KCP 9.2	Yon, D. A. and Müller, M.	1995	Estimation of the Atmospheric Half-Life of Fluroxypyr Fraunhofer Institut für Umweltchemie und Ökotoxikologie, D-57392 Schmallenberg, Germany Dow Elanco Europe GHE-P-4738 GLP: yes not published	N	N	-	DOW
KCP 9.2	Knowles, S., Wright, K., Blackmore, K., Thorne, J. and Horth, H.	2004	Review of monitoring and occurrence of Fluroxypyr in groundwater and surface water in Europe Water Research Centre (WCR) Blagrove, Swindon, Wiltshire, UK Dow AgroSciences, UK GHE-P-10764	N	N	-	DOW

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			GLP: yes not published;				
KCP 9.2	Gesell J., Balcer J.,	2011	Degradation of Fluroxypyr DMP Metabolite in Four Soils under Aerobic Conditions; Regulatory Sciences & Government Affairs, Dow AgroSciences LLC, Indianapolis, Indiana 46268-1054, USA; Study No. 101798; GLP: Yes; Unpublished study;;	N	N	-	DOW
KCP 9.2	Simmonds M., Burgess M.,	2010	Fluroxypyr: Adsorption and Desorption Properties of [14C]-Pyridinol (DCP) in Five Soils; Battelle UK Ltd., Ongar, Essex, CM5 0GZ, UK for Doow Agro Sciences, Abingdon, Oxon, OX14 4RN, UK; Study No.: Battelle Study Number YR/10/001; GLP: Yes; Unpublished study;	N	N	-	DOW
KCP 10.1	-	1995	XDE-570 Herbicide: A Pilot Reproduction Study with the Mallard [redacted] GLP No Unublished	Y	N	-	DAS
KCP 10.1		1995	XDE-570 Herbicide: A Pilot Reproduction Study with the Northern Bobwhite [redacted] GLP Yes Unublished	N	N	-	DAS
KCP 10.3	Beech, P	1996	A Determination of the Oral LD50s for XDE-570 against the Honey Bee, Apis mellifera Agrochemical Evaluation Unit, Department of Biology, The University, Southampton, UK GHE-P-6705 GLP Yes Unpublished	N	N	-	DAS

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KCP 10.4	Boeri, RL, Magazu, JP, Ward, TJ	1994	XDE-570 Herbicide: Acute Toxicity to the Earthworm, Eisenia foetida TR Wilbury Laboratories Inc, DECO-ES-2798 GLP Yes Unpublished	N	N	-	DAS
KCP 10.1		1994	XDE-570: An Acute Oral Toxicity Study with the Japanese Quail DECO-ES-2799 GLP Yes Unpublished	N	N	-	DAS
KCP 10.5	Ehr, RJ, Alexander, AL	1997	The Activity of DE-570 in Herbicide, Insecticide and Fungicide Screening Tests and the Herbicidal Activity of DE-570 Soil Metabolites DERBI# 60600 DowElanco GLP Yes Unpublished	N	N	-	DAS
KCP 10.2	Ehr, RJ, Schmitzer, PR, Gray, JA	1997	The Activity of DE-570 and Soil Metabolites on Acetolactate Synthase, Lemna minor, and Agrostis palustris DERBI # 60598 DowElanco GLP No Unpublished	N	N	-	DAS
KCP 10.5	Feil, N.	2010	Effects of 5-hydroxy-florasulam on the activity of the soil microflora in the laboratory DAS Report No.: 101342 (Accession Number) 2007411 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	N	-	DAS
KCP 10.5	Feil, N.	2011	Effects of DFP-ASTCA metabolite of florasulam on the activity of the soil microflora in the laboratory. DAS Report No.: 101343 (Accession Number) 2009901	N	N	-	DAS

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			Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished				
KCP 10.5	Feil, N.	2008	Effects of ASTCA metabolite of florasulam on the activity of the soil microflora in the laboratory DAS Report No.: 080039 (Accession Number) 2000205 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	N	-	DAS
KCP 10.5	Feil, N.	2011	Effects of TSA metabolite of florasulam on the activity of the soil microflora in the laboratory DAS Report No.: 110143 (Accession Number) 2010747 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	N	-	DAS
KCP 10.5	Forster, J	1997	A Laboratory Assessment of the Effects of XDE-570 on Soil Microflora Respiration and Nitrogen Turnover According to BBA Guidelmes VI 1-1 (1990) Euro Laboratories Limited GHE-T-713 GLP Yes Unpublished	N	N	-	DAS
KCP 10.1	-	1995	XDE-570: A Reproduction Study with the Northern Bobwhite (Colinus virginianus) DECO-ES-2911 GLP Yes Unpublished	Y	N	-	DAS
KCP 10.1	-	1995	XDE-570: A Reproduction Study with the Mallard (Anas platyrhynchos) DECO-ES-2912 GLP Yes Unpublished	Y	N	-	DAS
KCP 10.1	-	2011	Florasulam technical: an early life-stage toxicity test with the	Y	N	-	DAS

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			fathead minnow (Pimephales promelas) DAS Report No.: 101334 (Accession Number) 2007801 GLP Yes Unpublished				
KCP 10.2	Hancock, G.A. Arnold, B.H., Carr, M.S., Najar, J.R.	2007	5-Hydroxy-florasulam: growth inhibition test with the aquatic plant duckweed, Lemna gibba DAS Report No.: 071032 (Accession Number) 245034 The Dow Chemical Company GLP Yes Unpublished	N	N	-	DAS
KCP 10.2	Hastings, M	1997	Preparation of Soil Extracts for Determination of the Algal Toxicity of XDE-570 Metabolites GHE-P-6616 DowElanco Europe GLP Yes Unpublished	N	N	-	DAS
KCP 10.1	-	1994	XDE-570 Herbicide: 8-day Acute Dietary LC50 Study in Japanese Quail DECO-ES-2797 GLP Yes Unpublished	Y	N	-	DAS
KCP 10.1	-	1994	XDE-570 Herbicide: 8-day Acute Dietary LC50 Study in Mallard Ducklings DECO-ES-2796 GLP Yes Unpublished	Y	N	-	DAS
KCP 10.2	Hughes, JS, Williams, TL, Conder, LA	1995	The Toxicity of XDE-570 to Skeletonema costatum Carolina Ecotox Inc DECO-ES-3021 GLP Yes Unpublished	N	N	-	DAS
KCP 10.2	Jenkins, CA	1997	Two Aqueous Soil Extracts Containing XDE-570 Metabolites: Growth Inhibition of Selenastrum capricornutum (Preliminary Toxicity Screen) Huntingdon Life GHE-T-837	N	N	-	DAS

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			GLP Yes Unpublished				
KCP 10.2	Kelly, CR	1997	To Assess the Toxicity to the Sediment Dwelling Phase of the Midge, Chironomus riparius Huntingdon Life Sciences Ltd, GHE-T-838 GLP Yes Unpublished	N	N	-	DAS
KCP 10.2	-	1996	Evaluation of the Acute Toxicity of 5-hydroxy XDE-570 to the Rainbow Trout, Oncorhynchus mykiss Walbaum DECO-ES-3118 GLP Yes Unpublished	Y	N	-	DAS
KCP 10.2	Kirk, HD, Landre, AM, Hugo, JM	1996	Evaluation of the Acute Toxicity of 5-Hydroxy XDE-570 to the Daphnid, Daphnia magna Straus The Dow Chemical Company DECO-ES-3117 GLP Yes Unpublished	N	N	-	DAS
KCP 10.2	Kirk, HD, Landre, AM, Hugo, JM, Stahl, DC	1996	Evaluation of the Chronic Toxicity of XDE-570 Herbicide to the Daphnid, Daphnia magna Straus The Dow Chemical Company DECO-ES-2944 GLP Yes Unpublished	N	N	-	DAS
KCP 10.2	Kirk, HD, Landre, AM, Massaro, LM, Hugo, JM, Stahl, DC	1995	Evaluation of the Acute Toxicity of XDE-570 Herbicide to the Daphnid, Daphnia magna Straus. The Dow Chemical Compa-ny DECO-ES-2938 GLP Yes Unpublished	N	N	-	DAS
KCP 10.2	-	1995	Evaluation of the Acute Toxicity of XDE-570 Herbicide to the Rainbow Trout, Oncorhynchus mykiss Walbaum DECO-ES-2940 GLP Yes Unpublished	Y	N	-	DAS
KCP 10.2	-	1995	Evaluation of the Acute Toxicity of XDE-570 Herbicide to the Bluegill, Lepomis macrochirus Rafinesque.	Y	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			[redacted] GLP Yes Unpublished				
KCP 10.2	Kirk, H.D. Gilles, M.M., Rick, D.L., McFadden, L.G.	2000	5-(Aminosulfonyl)-1H-1,2,4-triazole-3-carboxylic acid (florasulam M4 metabolite): growth inhibition test with the freshwater green alga, Selenastrum capricornutum DAS Report No.: 001019 Accession Number) 76271 (PRINTZ Toxicology & Environmental Research and Consulting The Dow Chemical Company GLP Yes Unpublished	N	N	-	DAS
KCP 10.2	Kirk, H.D. Gilles, M.M., Rick, D.L., McFadden, L.G.	2000	5-(Aminosulfonyl)-1H-1,2,4-triazole-3-carboxylic acid (florasulam M4 metabolite): growth inhibition test with the freshwater aquatic plant, duckweed, Lemna gibba L. G-3 DAS Report No.: 001021 (Accession Number) 76666 The Dow Chemical Company GLP Yes Unpublished	N	N	-	DAS
KCP 10.2	Kirk, H.D.and Marino, T.A	1998	Toxicity of metabolites of XDE-570 to DaphniaMagna DAS Report No.: 981157 (Accession Number) 66206 The Toxicology Research Laboratory Health and Environmental Research Laboratories GLP Yes Unpublished	N	N	-	DAS
KCP 10.2		1995	Evaluation of the Prolonged (28-day) Toxicity of XDE-570 Herbicide to the Rainbow trout, Oncorhynchus mykiss walbaum [redacted] GLP Yes Unpublished	N	N	-	DAS
KCP 10.4	Lührs, U.	2008	Acute toxicity (14 days) of ASTCA metabolite of florasulam to the earthworm Eisenia fetida in artificial soil DAS Report No.: 080037 (Accession Number) 259941	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP No Unpublished				
KCP 10.4	Lührs, U.	2008	Effects of ASTCA metabolite of florasulam on reproduction and growth of earthworms Eisenia fetida in artificial soil DAS Report No.: 080038 (Accession Number) 2001599 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	N	-	DAS
KCP 10.4.	Lührs, U.	2011	Effects of DFP-ASTCA metabolite of florasulam on reproduction of the Collembola Folsomia candida in artificial soil with 5% peat DAS Report No.: 101345 (Accession Number) 2009902 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	N	-	DAS
KCP 10.4	Lührs, U.	2011	Effects of TSA metabolite of florasulam on reproduction of the Collembola Folsomia candida in artificial soil with 5% peat DAS Report No.: 110133 (Accession Number) 2009861 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP Yes Unpublished	N	N	-	DAS
KCP 10.4	Lührs, U.	2011	Effects of DFP-ASTCA metabolite of florasulam on reproduction of the predatory mite Hypoaspis aculeifer in artificial soil with 5% peat DAS Report No.: 101348 (Accession Number) 2009903 Institut fiir Biologische Analytik und Consulting IBACON GmbH GLP No	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 10.2	Porch, J.R., Kendall, T.Z., Krueger, H.O	2011	TPSA metabolite of florasulam: a 96-hour toxicity test with the freshwater alga (Pseudokirchneriella subcapitata) DAS Report No.: 101350 (Accession Number) 2008420 Wildlife International, Ltd. GLP Yes Unpublished	N	N	-	DAS
KCP 10.2	Porch, J.R., Kendall, T.Z., Krueger, H.O.	2011	Florasulam (TPSA metabolite): a 7-day staticrenewal toxicity test with duckweed (Lemna gibba G3) DAS Report No.: 101351 (Accession Number) 2008814 Wildlife International, Ltd. GLP Yes Unpublished	N	N	-	DAS
KCP 10.2	Rebstock, M	2011	DFP-ASTCA metabolite of florasulam (X12239339): growth inhibition test with the unicellular green alga, Pseudokirch-neriella subcapitata DAS Report No.: 110046 (Accession Number) 2010085 ABC Laboratories, Inc. GLP Yes Unpublished	N	N	-	DAS
KCP 10.2	Rebstock, M.	2011	TSA metabolite of florasulam (X634074): growth inhibition test with the unicellular green alga, Pseudokirchneriella sub-capitata DAS Report No.: 110043 (Accession Number) 2010859 ABC Laboratories, Inc. GLP Yes Unpublished	N	N	-	DAS
KCP 10.2	Rebstock, M.	2011	5-OH-ASTP metabolite of florasulam (X12251401): growth inhibition test with the unicellular green alga, Pseudokirch-neriella subcapitata DAS Report No.: 110044 (Accession Number) 2010120	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			ABC Laboratories, Inc. GLP Yes Unpublished				
KCP 10.2	Rebstock, M	2011	ASTP metabolite of florasulam (X516274): growth inhibition test with the unicellular green alga, Pseudokirchneriella sub-capitata DAS Report No.: 110045 ABC Laboratories, Inc. GLP Yes Unpublished	N	N	-	DAS
KCP 10.2	Rebstock, M.	2011	DFP-ASTCA metabolite of florasulam (X12239339): growth inhibition test with the freshwater aquatic plant, duckweed, Lemna gibba DAS Report No.: 110039 (Accession Number) 2010084 ABC Laboratories, Inc. GLP Yes Unpublished	N	N	-	DAS
KCP 10.2	Rebstock, M.	2011	TSA metabolite of florasulam (X634074): growth inhibition test with the freshwater aquatic plant, duckweed, Lemna gibba DAS Report No.: 110040 (Accession Number) 2010161 ABC Laboratories, Inc. GLP Yes Unpublished	N	N	-	DAS
KCP 10.2	Rebstock, M.	2011	5-OH-ASTP metabolite of florasulam (X12251401): growth inhibition test with the freshwater aquatic plant, duckweed, Lemna gibba DAS Report No.: 110041 (Accession Number) 2010087 ABC Laboratories, Inc. GLP Yes Unpublished	N	N	-	DAS
KCP 10.2	Rebstock, M.	2011	ASTP Metabolite of Florasulam (X516274): Growth Inhibi-tion Test with the Freshwater Aquatic Plant, Duckweed, Lem-na gibba	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			DAS Report No.: 110042 (Accession Number) 2010018 ABC Laboratories, Inc. GLP Yes Unpublished				
KCP 10.2	-	1997	The Bioconcentration of XDE-570 by the Rainbow Trout, Oncorhychus mykiss Walbaum [redacted] GLP Yes Unpublished	Y	N	-	DAS
KCP 10.1		1980	Acute Oral LD50 – Mallard Duck – DOWCO 290 [redacted] GLP/GEP (Y/N): No Published (Y/N): No	Y	N	-	DAS
KCP 10.1		1985	Lontrel Herbicide: A One-Generation Reproduction Study with the Mallard (Anas platyrhynchos) - Final Report. [redacted] GLP/GEP (Y/N): Yes Published (Y/N): No	Y	N	-	DAS
KCP 10.1		1987	Lontrel T Herbicidal Chemical (Penta Process): Acute Oral Toxicity Study in Fischer 344 Rats. [redacted] GLP/GEP (Y/N): Yes Published (Y/N): No	Y	N	-	DAS
KCP 10.1		1987	Lontrel T Herbicidal Chemical (Penta Process): Acute Dermal Toxicity Study in New Zealand White Rabbits. [redacted] GLP/GEP (Y/N): Yes Published (Y/N): No	Y	N	-	DAS
KCP 10.1		1985	Report No A2A-052	Y	N	-	DAS
KCP 10.2		2000	Clopyralid: An Acute Toxicity Study with the Rainbow Trout, Oncorhynchus mykiss Walbaum [redacted] GLP/GEP (Y/N): Yes Published (Y/N): No	Y	N	-	DAS
KCP 10.2		2000	Clopyralid: Toxicity to the Early Life Stages of the Fathead Minnow, Pimephales Promelas Rafinesque. [redacted]	Y	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP/GEP (Y/N): Yes Published (Y/N): No				
KCP 10.2	Marino, T. A., McClymont, E. L. & Staley, J. L.	2000	Clopyralid: An Acute Toxicity Study with the Daphnia, Daphnia magna Straus DAS report no. 001025, Ref. J52 Dow AgroSciences LLC, Midland, Michigan, United States GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 10.2	Douglas, M. T., Bell, G. & Macdonald, I. A.	1992	An Assessment of the Effects of Lontrel T on the Reproduc-tion of Daphnia magna DAS report no. DWC 615/911087, Ref. J35 Huntingdon Research Center Ltd, Huntingdon, Cambridgeshire, United Kingdom GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 10.2	Barrett, K.	2001	Clopyralid Technical Toxicity to the Sediment Dwelling Phase of the Midge Chironomus riparius Huntingdon Life Sciences Ltd, Huntingdon, Cambridgeshire, United Kingdom GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 10.2	Kirk, H. D.; Gilles, M. M.; McClymont, E. L. ; McFadden, L.G.,	2000	Clopyralid: Growth Inhibition Test with the Freshwater Green Alga, Selenastrum capricornutum Printz Dow AgroSciences LLC, Midland, Michigan, United States Raport No: 001040, Ref. J51 GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 10.2	Aufderheide, J.	2014	Clopyralid Technical: Growth Inhibition Test with the Fresh-water Diatom, Navicula pelliculosa DAS Report No. 140515 ABC Laboratories, Inc. 7200 E. ABC Lane Columbia, Mis-souri 65202 USA GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 10.2	Cowgill, U. M. ; Milazzo, D. P. ;	1990	The Fourteen Day Toxicity of Lontrel T to Lemna gibba L G-3 (Duckweed) - ES-DR-0197-3428-4	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
	Potter, R. B.		DAS Report No. ES-2243 Dow AgroSciences LLC, Midland, Michigan, United States GLP/GEP (Y/N): Yes Published (Y/N): No				
KCP 10.2	Banman, C. S., Moore, S.	2015	Clopyralid: Toxicity to the Aquatic Macrophyte, Myriophyllum spicatum DAS Report No. 140735 SynTech Research Laboratory Services LLC 17745 South Metcalf Avenue Stilwell, Kansas 66085-9104 GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 10.2	Banman, C. S. & Moore, S.,	2015	Clopyralid: Toxicity to the Aquatic Macrophyte, Myriophyllum spicatum SynTech Research Laboratory Services LLC 17745 South Metcalf Avenue Stilwell, Kansas 66085-9104 DAS report no. 140735 GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 10.3	Wainwright, M.	2001a	Clopyralid Technical Acute Toxicity To Honey Bees DAS Report No. GHE T-1091 Huntingdon Life Sciences Ltd, Huntingdon, Cambridgeshire, United Kingdom GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 10.3	Wainwright, M.	2001b	Clopyralid Technical Acute Toxicity To Honey Bees DAS Report No. GHE T-1091 Huntingdon Life Sciences Ltd, Huntingdon, Cambridgeshire, United Kingdom GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 10.3	Leonard, J. and Moore, S.	2017a	Clopyralid: A laboratory study to determine the chronic oral toxicity to the adult worker honey bee Apis mellifera L. (Hymenoptera: Apidae) 170098	N	N	-	DAS
KCP 10.3	Leonard, J. and Moore, S.	2017b	Clopyralid: A repeated-exposure laboratory toxicity study in larvae, pupae and emergent adults of the honey bee Apis mellifera Linnaeus. (Hymenoptera: Apidae)	N	N	-	DAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			170099				
KCP 10.4	Hayward, J. C.	2001	The Effects of EF-1136 on Reproduction and Growth in the Earthworm Eisenia fetida DAS Report No.: GHE-T-1135, Ref. J69 CEMAS Study CEMS-1637 GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
KCP 10.5	Schöbinger, U.	2013	Clopyralid: Effects on the Activity of the Soil Microflora under Laboratory Conditions (Nitrogen and Carbon Transformation) DAS Report No. 130283 Eurofins Agroscience Services EcoChem GmbH Eutinger Str. 24 D-75223 Niefern-Öschelbronn Germany GLP/GEP (Y/N): Yes Published (Y/N): No	N	N	-	DAS
All points	European Commission	1999	Review report for the active substance fluroxypyr. Fluroxypyr, 6848/VI/98, 15 December 1999 GLP: no published	N	N	-	DOW
KCP 10.2	Marino, T.A., McClymont, E.L. & Kern, J.M.	2000	4-Amino-3-chloro-6-fluoro-2-pyridinol: An acute toxicity study with the rainbow, Oncorhynchus mykiss Walbaum [redacted] GLP: yes not published	Y	N	-	DOW
KCP 10.2	Rick, D.L., Kirk, H.D., Fontaine, D.D. & Woodburn, K.B.	1996	The Bioconcentration and metabolism of Fluroxypyr 1-methylheptyl ester by the rainbow trout, Oncorhynchus mykiss Walbaum [redacted] GLP: yes not published	Y	N	-	DOW
KCP 10.2	Marino, T.A.,	2000	4-Amino-3-chloro-6-fluoro-2-pyridinol: An acute toxicity studywith the Daphnia, Daphnia magna	N	N	-	DOW

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
	McClymo nt, E.L. & Kern, J.M.		Straus Toxicology & Environmental Research and Consulting, The Dow Chemical Company, Midland, Michigan, USA 001010 (75245) 2000-05-16 GLP: yes not published				
KCP 10.2	Kirk, H.D., Miller, J.A., Hugo, J.M. & Landre, A.M.	1996	Evaluation of the chronic toxicity of Fluroxypyr 1- methylheptyl ester to the daphnid, Daphnia magna Straus The Toxicology Research Laboratory, Health and Environ- mental Sciences, The Dow Chemical Company, Midland, Michigan, USA DECO-ES-3079 1996-06-15 GLP: yes not published	N	N	-	DOW
KCP 10.2	Milazzo, D.P., Hugo, J.M. & Martin, M.D.	1996	Fluroxypyr 1-methylheptylester: The toxicity to the blue-green algae, Anabaena flos-aquae The Toxicology Research Laboratory, Health and Environmental Science, The Dow Chemical Company, Midland, Michigan, USA ES-3073 1996-06-04 GLP: yes not published	N	N	-	DOW
KCP 10.2	Hoberg, J.R.	2002	Fluroxypyr 1-methylheptyl ester technical - Acute toxicity to the freshwater diatom (Navicula pelliculosa) Springborn Smithers Laboratories, Wareham, MA, USA 12550.6203 (Project No.: 021014) 2002-11-15	N	N	-	DOW

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP: yes not published				
KCP 10.2	Alexander , M.M.	1996	Fluroxypyr 1-methylheptyl ester: The toxicity to Skeletonema costatum Carolina Ecotox., Inc., Durham, NC, USA DECO-ES-3131 (10-04-1) 1996-05-31 GLP: yes not published	N	N	-	DOW
KCP 10.2	Hancock, G.A., Hales, C.A., McClymo nt, E.L. & Najar, J.R.	2004	Fluroxypyr: Growth inhibition test with the freshwater diatom, Navicula pelliculosa Toxicology & Environmental Research and Consulting, The Dow Chemical Company, Midland, Michigan, USA 031132 GLP: yes not published	N	N	-	DOW
KCP 10.2	Boeri, R.L., Magazu, J.P. & Ward, T.J.	1999	4-Amino-3,5-dichloro-6-fluoro-2-pyridinol (a metabolite of Fluroxypyr): Toxicity to the freshwater bluegreen algae, Anabaena flos-aquae T. R. Wilbury Laboratories, Inc., Marblehead, Massachusetts, USA 990035 1999-09-10 GLP: yes not published	N	N	-	DOW
KCP 10.2	Ward, T.J., Magazu, J.P. & Boeri, R.L.	1999	4-Amino-3,5-dichloro-6-fluoro-2-pyridinol (a metabolite of Fluroxypyr): Toxicity to the freshwater diatom, Navicula pelliculosa T. R. Wilbury Laboratories, Inc.,	N	N	-	DOW

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Marblehead, Massachusetts, USA 990032 1999-09-01 GLP: yes not published				
KCP 10.2	Ward, T.J., Magazu, J.P. & Boeri, R.L.	1999	4-Amino-3,5-dichloro-6-fluoro-2-pyridinol (a metabolite of Fluroxypyr): Toxicity to the saltwater diatom, Skeletonema costatum T. R. Wilbury Laboratories, Inc., Marblehead, Massachusetts, USA 990036 1999-09-13 GLP: yes not published	N	N	-	DoW
KCP 10.2	Kirk, H.D., Gilles, M.M., McClymont, E.L. & McFadden, L.G.	2000	4-Amino-3-chloro-6-fluoro-2-pyridinol: Growth inhibition test with the freshwater green alga, Selenastrum capricornutum Printz Toxicology & Environmental Research and Consulting, The Dow Chemical Company, Midland, Michigan, USA 001008 2000-04-24 GLP: yes not published	N	N	-	DOW
KCP 10.2	Boeri, R.L., Magazu, J.P. & Ward, T.J.	1999	4-Amino-3,5-dichloro-6-fluoro-2-methoxypyridine (a metabolite of Fluroxypyr): Toxicity to the freshwater blue-green algae, Anabaena flos-aquae T. R. Wilbury Laboratories, Inc., Marblehead, Massachusetts, USA 990039 1999-09-15 GLP: yes	N	N	-	DOW

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			not published				
KCP 10.2	Ward, T.J., Magazu, J.P. & Boeri, R.L.	1999	4-Amino-3,5-dichloro-6-fluoro-2-methoxypyridine (a metabolite of Fluroxypyr): Toxicity to the freshwater diatom, Navicula pelliculosa T. R. Wilbury Laboratories, Inc., Marblehead, Massachusetts, USA 990037 1999-09-20 GLP: yes not published	N	N	-	DOW
KCP 10.2	Boeri, R.L., Magazu, J.P. & Ward, T.J.	1999	4-Amino-3,5-dichloro-6-fluoro-2-methoxypyridine (a metabolite of Fluroxypyr): Toxicity to the saltwater diatom, Skeletonema costatum T. R. Wilbury Laboratories, Inc., Marblehead, Massachusetts, USA 990040 1999-10-19 GLP: yes not published	N	N	-	DOW
KCP 10.2	Putt, A.E.	2002	Fluroxypyr, 1-Methylheptyl ester – the full life-cycle toxicity to midge (Chironomus riparius) under static conditions Springborn Laboratories, Inc., Wareham, MA, USA 011184 2002-02-11 GLP: yes not published	N	N	-	DOW
KCP 10.2	Kirk, H.D., Milazzo, J.M., Hugo,	1996	Fluroxypyr 1-methylhepthylester: The toxicity to the aquatic plant, duckweed Lemna gibba L. G-3 The Toxicology Research Laboratory, Health and	N	N	-	DOW

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
	J.M. & Martin, M.D.		Environmental Sciences, The Dow Chemical Company, Midland, Michigan, USA DECO-ES-3074 1996-06-04 GLP: yes not published				
KCP 10.2	Ward, T.J., Magazu, J.P. & Boeri, R.L.	1999	4-Amino-3,5-dichloro-6-fluoro-2-pyridinol (a metabolite of Fluroxypyr): Toxicity to the duckweed, Lemna gibba T. R. Wilbury Laboratories, Inc., Marblehead, Massachusetts, USA 990033 1999-11-11 (report amendment) GLP: yes not published	N	N	-	DOW
KCP 10.2	Ward, T.J., Magazu, J.P. & Boeri, R.L.	1999	4-Amino-3,5-dichloro-6-fluoro-2-methoxypyridine (a metabolite of Fluroxypyr): Toxicity to the duckweed, Lemna gibba T. R. Wilbury Laboratories, Inc., Marblehead, Massachusetts, USA 990038 1999-03-17 GLP: yes not published	N	N	-	DOW
KCP 10.4	Rodgers, M.H.	2000	Fluroxypyr pyridinol (MII): Acute toxicity (LC50) to the earthworm (Eisenia foetida) Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, UK GHE-T-1088 2000-06-30 GLP: yes not published	N	N	-	DOW
KCP 10.4	Rees, P.B.	1996	Fluroxypyr methoxypyridine: Acute toxicity study in the earthworm	N	N	-	DOW

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			(artificial soil test) Huntingdon Life Sciences Ltd., Eye, Suffolk, UK GHE-T-645 1996-06-25 GLP: yes not published				
KCP 10.4	Carter, J.N.	2000	Fluroxypyr pyridinol (metabolite MII): Effects on soil non-target micro-organisms Huntingdon Life Sciences Ltd., Huntingdon, Cambridgeshire, UK GHE-T-1089 (85899) 2000-09-20 GLP: yes not published	N	N	-	DOW
KCP 10.5	Knowles, S.J.	1994	Ready Biodegradability of Fluroxypyr-1- methylheptyl ester (Modified Sturm Test) Life Science Research Ltd., Suffolk, England, UK GHE-P-2439 1991-05-23 GLP: yes not published	N	N	-	DOW

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title	Y/N	Y/N	Data/study report never submitted	Owner

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished			before to <insert MS> If previously submitted in **this** MS: Data protection started with: <insert authorization number of first authorization>	

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in **this** MS: Data protection started with: <insert authorization number of first authorization>	Owner