

REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: ADM.01851.H.1.A

Chemical active substance(s):

ETHOFUMESATE : 500 g/L

CLOPYRALID: 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Country organisation / representative of ADAMA,
as given in Part A

Submission date: August 2024

MS Finalisation date: March 2025 (initial Core Assessment)
June 2025 (final Core Assessment)

Version history

When	What
July 2024	dRR version 1 submitted by applicant
January 2025	Updated points: 3.4.6, 3.4.7
March 2025	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
June 2025	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Comments of zRMS:

Conclusions from the assessment were prepared using grey commenting boxes placed at the end of each chapter. Textual changes were done using grey highlights in the text. The parts of the text amended or added by the zRMS evaluator are highlighted in grey, whereas the parts struck off are ~~visibly marked with the grey font~~.

In order to avoid ambiguity in marking, any grey highlighting used by the applicant in the cells of the tables has been removed by the zRMS.

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract by zRMS

Introduction

ADM.01851.H.1.A is an SC herbicide formulation, containing 500 g/L ethofumesate and 75 g/L clopyralid. As such, in Poland it makes a **new** mixture of known active substances. The present submission is following article 33 of the Regulation (EC) No. 1107/2009, and it is the first time that ADM.01851.H.1.A has been submitted for authorization in Poland. According to the applicant's claim: "The aim of this dossier is to provide data on the efficacy and crop safety in support of the registration of ADM.01851.H.1.A in Poland [...] for use as an herbicide in sugar beet (post-emergence applications)."

The Data Submitted

The data set includes 11 efficacy trials (9 PL, 2 DE, Table 3.2-5) and 10 dedicated selectivity trials (8 PL, 2 DE, on 10 different varieies of BEAVA, Table 3.4-1).

Preliminary trials

Both actives contained in ADM.01851.H.1.A have been known and used in weed control in sugar beet. Therefore the preliminary tests do not include dose rate-finding or ratio-justification trials, but are restricted to **efficacy testing in comparison to already authorized solo products**, containing either ethofumesate or clopyralid ([Table 3.2-7](#)). The number of data points for some weed species is subcritical, but as preliminary data, this summary confirms higher performance of the test item compared to products using both actives as solo ingredients.

Minimum Effective Dose

The dose rate of **3 x 0.66 L/ha** should be considered as the minimum effective dose rate in control of annual broad-leaved weeds in sugar beet crop.

Efficacy tests and weed spectrum

The target weed spectrum of the ADM.01851.H.1.A has been accepted in the shape presented by the applicant in [Table 3.2-16](#). The number of 11 efficacy trials carried out in Poland (9) and in Germany (2) is sufficient to conclude that ADM.01851.H.1.A has been successfully tested in conditions relevant for the prospective (geographical) area of use. The split application of the **3 x 0.66 L/ha** can be accepted as the application pattern appropriate for the control of annual dicotyledonous weeds in sugar beet crop.

Fodder beet

While the efficacy trials on the fodder beet are not required for the efficacy extrapolation from the sugar to fodder crop, the selectivity trials are, in the reduced number of 2-3, since fodder beet is minor crop in Poland. No selectivity trials have been submitted in the fodder beet and consequently, taken that ADM.01851.H.1.A is a new mixture, the use in the fodder crop cannot be authorised under Article 33 of the Regulation 1107/2009, but only following Article 51.

Selectivity and yield data

Phytotoxicity symptoms

Based on the observations of phytotoxicity symptoms in efficacy trials and in dedicated selectivity trials, it has been

concluded that, when applied up to 0.66 L/ha and maximum 3 times per growth season as claimed in the GAP table, the ADM.01851.H.1.A is safe to sugar beet crop. [details](#)

Yield amount

No negative effect of ADM.01851.H.1.A on yield amount of sugar beet has been concluded.

Yield quality

The results of 10 selectivity trials including 8 trials Poland and 2 - from Germany allow to conclude that no unwelcome effects of the ADM.01851.H.1.A applied according to label directions should be expected on parameters affecting root quality and / or the process of sugar extraction from them.

3.4.5 Impact on plant parts used for propagation

As for the new mixture of the known actives, data should be submitted for the 3.4.5 section. In the absence of data the applicant has declared that ADM.01851.H.1.A is not intended for protection of seed plantations in any phase of seed production (neither in autumn nor in spring). The respective statement has been introduced into the product label.

3.4.6 Impact on succeeding crops

ADM.01851.H.1.A is a new mixture of known actives. Based on the submitted data and calculations the appropriate result is TER <1. Consequently, the risk to succeeding crops, and even more to replacement crops, has been concluded as resulting from the application according to the claimed pattern. The issue remains unresolved and should be subject to further elaboration by the applicant. For justification of this standpoint see the [zRMS comments](#) following 3.4.6 .

In the meantime, the label phrase has been proposed by the applicant, meant to prevent cultivation - as replacement crops - of plants other than sugar beet, in case of earlier termination of the treated BEAVA crop.

3.4.7 Impact on other plants including adjacent crops

No risk for adjacent crops **has been concluded**. For further comments see the [zRMS commenting box](#) following 3.4.7 .

Resistance Risk

The issue of risk of resistance development has been addressed adequately by the applicant; the risk level was correctly identified as low. For details see the [zRMS comments](#) to this part.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Mem- ber state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applica- tions (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	Sugar beet BEAVA Fodder-beet BEAVG	F	annual dicot weeds and annual grass-weeds	foliar spray- ing, overall	BBCH 10- 19/ March- June	a) 3 b) 3	a) 5 b) 5	a) 0.66 L/ha b) 1.98 L/ha	a) 330 g ethofumesate/ha 49.5 g clopyralid/ha b) 990 g ethofumesate/ha 148.5 g clopyralid/ha	100-400	n.a.	Total rate per season 2 L/ha Max rate of ethofumesate should not exceed 1.0 kg/ha every 3 years	A N fodder beet possible authorization based on the art. 51 – minor uses
2	PL	Sugar beet BEAVA Fodder-beet BEAVG	F	annual dicot weeds and annual grass-weeds	foliar spray- ing, overall	BBCH 10- 19/ March- June	a) 3 b) 3	a) 5 b) 5	a) 0.66 L/ha b) 1.98 L/ha	a) 330 g ethofumesate/ha 49.5 g clopyralid/ha b) 990 g ethofumesate/ha 148.5 g clopyralid/ha	100-400	n.a.	Band application applied to 50% of the surface, along the plant rows. Total rate / season = 1 L/ha (500+75 g ai/ha) Max rate of ethofumesate should not exceed 1.0 kg/ha every 3 years	A N fodder beet possible authorization based on the art. 51 – minor uses

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

** F: professional field use, Fn: non-professional field use, Fnp: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gnp: professional and non-professional greenhouse use, I: indoor application

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

ADM.01851.H.1.A is an herbicide containing two active ingredients: 500 g/L of ethofumesate and 75 g/L of clopyralid (SC formulation). This application under article 33 of Regulation (EC) No. 1107/2009 submitted by the applicant is for first authorization of the product ADM.01851.H.1.A Poland (Central Regulatory zone).

The aim of this dossier is to provide data on the efficacy and crop safety in support of the registration of ADM.01851.H.1.A in Poland (EU Central Registration zone / North-East EPPO climatic zone) for use as an herbicide in sugar **beet** (post-emergence applications).

Description of active substances

ADM.01851.H.1.A is suspension concentrate (SC) contain two active ingredients: ethofumesate – 500 g/l and clopyralid – 75 g/l.

Table 3.2-1: Details of the active substances

Active substance	Ethofumesate	clopyralid
Concentration (Unit: g/kg or g/L...)	500 g/l	75 g/l
Chemical group	Benzofurans	6-Chloropicolinates
Mode of action	Inhibition of very long-chain fatty acid synthesis (Inhibition of VLCFA)	Auxin Mimics
Biological action	Pre and post emergence herbicide	Post emergence herbicide
HRAC group	HRAC/WSSA Group 15, Legacy HRAC Group K3	HRAC/WSSA Group 4, Legacy HRAC Group O

Mode of action

Ethofumesate

Ethofumesate is a selective and low systemic herbicide. It is absorbed mainly by coleoptile of grasses in the seedling emergence and by the roots for broad-leaved weeds. At stages young seedlings, foliar penetration is also not negligible. It is used in sugar beet and fodder beet in early post-emergence to control annual weeds. Ethofumesate belongs to the chemical class of benzofurane herbicides (HRAC/WSSA Group 15, Legacy HRAC Group K3). It's an inhibitor of elongases, enzymes leading to long chain of fatty acids (over 18 C), precursors of waxy cuticle and suberin. Acts as an inhibitor of cell division and lipid synthesis in the seedling shoot leading to retardation of meristem growth. Selectivity of the beet can be explained by its ability to metabolize this active substance, leading it inactive.

Clopyralid

Clopyralid is an herbicide used for selective control of noxious and nuisance weed. Clopyralid mimics a plant growth hormone and causes uncontrolled and disorganized plant growth that leads to plant death. The exact mode of action of clopyralid has not been fully described but it is believed to acidify the cell wall, which results in cell elongation. Low concentrations of clopyralid can stimulate RNA, DNA, and protein synthesis leading to uncontrolled cell division and disorganized growth, and ultimately, vascular tissue destruction. High concentrations of clopyralid can inhibit cell division and growth.

Clopyralid controls many annual and perennial broadleaf weeds, particularly of the Asteraceae (sunflower family), Fabaceae (legume family), Solanaceae (nightshade family), Polygonaceae (knotweed family), and Violaceae (violet family). The basis of this selectivity is not well understood.

Clopyralid belongs to chemical class of 6-Chloropicolinates HRAC group 4 (Legacy Global HRAC O) it mimics a plant growth hormone and causes uncontrolled and disorganized plant growth that leads to plant death.

Description of the plant protection product

ADM.01851.H.1.A is suspension concentrate (SC) contain two active ingredients: ethofumesate – 500 g/l and clopyralid – 75 g/l.

The product is currently not approved, this application under article 33 of Regulation (EC) No. 1107/2009 submitted by the applicant is for first authorization.

Table 3.2-2: Simplified table of currently registered uses and requested uses for the product code.

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
BEAVA	Annual dicot weeds and annual grass weeds	PL	Max. 0.66 L/ha per application max. 3 applications per season, in full application or in band application	Min. 5 days interval

Further details are in the table “All intended uses” in Part B - Section 0.

Description of the target pests

Table 3.2-3: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name
AMARE	Amaranthus retroflexus
BRSNW	Brassica napus
CHEAL	Chenopodium album
DESSO	Descurainia sophia
ECHCH	Echinochloa crus-galli
GALAP	Galium aparine
GERPU	Geranium pusillum
LAMPU	Lamium purpureum
MATIN	Tripleurospermum inodorum
POLAV	Polygonum aviculare
POLCO	Fallopia convolvulus
POLPE	Polygonum persicaria
RAPRA	Raphanus raphanistrum
SOLNI	Solanum nigrum
STEME	Stellaria media
THLAR	Thlaspi arvense
VERAG	Veronica agrestis
VERPE	Veronica persica
VIOAR	Viola arvensis

On sugar beet plantations, weeds are particularly dangerous when they appear from the moment of sowing until the inter-rows are covered. Later emergence does not constitute significant competition for beets. Weeds, deprived of one of the basic elements needed for life, i.e. light, die before they can develop under the shading, large leaf blades of beets. Weeds interact with crops to compete for resources such as light and nutrients, and in so doing have the potential to affect either the quantity or quality of the yield arising from the crop. When weed control is omitted or control is not sufficient, depending on the weed, harvest can be seriously hampered. Weed control is therefore in most cases economical and necessary.

ADM.01851.H.1.A is an innovative formulation containing two active substances well known for their effectiveness and safety in use: ethofumesate (500 g/L) and clopyralid (75 g/L).

Unclear regulatory situation linked with other well-known active substances widely used in weed control in sugar beets may result that the introduction of a completely new and innovative formulation, i.e. ADM.01851.H.1.A, will have a positive impact on problems related to weed control in sugar beet.

Sugar beet: Sugar beet belongs to the Altissima cultivar group of the common beet. Together with other beet cultivars, such as beetroot and chard, it belongs to the subspecies *Beta vulgaris* subsp. *vulgaris*. The root of sugar beets contains high levels of sucrose. It has a conical, white, fleshy root with a flat crown. The plant consists of the root and a rosette of leaves. Sugar is formed by photosynthesis in the leaves and is then stored in the root.

Sugar beets are the second major source of the world's sugar production. Sugar beets grow exclusively in temperate zones, in contrast to sugarcane, which grows exclusively in tropical and subtropical zones. The soil must contain a large supply of plant food, be rich in humus and must retain a great deal of moisture. Russia is the largest sugar beet producer in the world, followed by France, the US, Germany and Turkey. According to the Polish National Association of Sugar Beet Growers in the 2022/2023 season : sugar beet cultivation took up almost 223,000 hectares in Poland. ha. It is forecast that in 2024 its area will increase to approximately 257 thousand. ha. Thus, the area under sugar beet cultivation will reach its highest level since 2005; sugar beet production amounted to 14 million tons; sugar production reached just over 2 million tons; 27,000 people cultivate sugar beet.

Table 3.2-4: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Sugar beets (BEAVA)	PL	-	Annual dicot weeds and annual grass weeds	PL	

Compliance with the Uniform Principles

All trials presented in this section were implemented in accordance with the GEP principles and according to relevant EPPO guidelines. All the 11 efficacy trials submitted were carried out by GEP certified test facilities.

The assessments and compilation of this dossier were performed in compliance with the uniform principles for evaluation of plant protection products. These include general principles as the evaluation of data in the light of current knowledge, taking account of the particular conditions prevailing in the zone in which the product is to be used and specific principles concerning, among other things, the efficacy and the absence of unacceptable effects on target crops. The overall assessment was performed according to the Uniform Principles

Information on trials submitted (3.1 Efficacy data)

Total of 11 trials were conducted in growing season 2022-2023 in Poland – 9 trials (North East EPPO zone) and in Germany – 2 trials (Maritime EPPO zone).

Trials in this dossier were carried out by contractor companies, all of which following the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

The following EPPO guidelines relate to the conduct of herbicide trials for the control of weed plants in sugar beets, on which data are presented in this dossier.

Guidelines:

- PP 1/135(4)
- PP 1/152(4)
- PP 1/181(4/5)
- PP 1/225(2)

and followed method recommendations published by EPPO. No significant deviation to guidelines was reported. The table below gives an overview of the trials used in section **3.2 Efficacy data** of this dossier.

Table 3.2-5: Presentation of trials (efficacy trials)

Crop	Target	Country	Years	Type of trial*	Number of trials (number of valid trials)		GEP, non-GEP, official**
					Maritime zone	North-East zone	
Sugar beet (BEAVA)	Annual weeds	PL	2022	E + MED		2	GEP
			2023	E + MED		7	GEP
		DE	2023	E + MED	2		GEP
Total Sugar beet					2	9	-
					11		

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-6: Presentation of reference standards used in trials (efficacy trials)

Reference standard	Active substance(s)	Formulation		Countries where the product is registered	Authorization number	Registered application rate (post-emergence)	Application rate per treatment in trials
		Type	Concentration of a.s.				
TORERO 500 SC (FSG 01095 H)	Metamitron + ethofumesate	SC	350 + 150 g/L	Germany Poland	025037-00/00001 R-172/2017	2.0 L/ha per app	3*2.0 L/ha

3.2.1 Preliminary tests (KCP 6.1)

ADM.01851.H.1.A is a new and innovative co-formulation product that combines the complementary and overlapping selective post-emergence herbicidal activities of ethofumesate and clopyralid to provide growers with an effective control of weed plants in sugar beets. Whilst products containing either ethofumesate or clopyralid alone are approved for use in sugar beets, ADM.01851.H.1.A offers the convenience and benefits associated with the use of two complementary and overlapping activities of two active ingredients in a single product. Sales formulations containing ethofumesate and clopyralid as single active substance are well-known and widely used in post-emergence on sugar beets to control weed plants. Since both active substances contained in the product are known and commonly used to protect sugar beet against weeds, no additional targeted preliminary tests were carried out.

The efficacy of ADM.01851.H.1.A was tested in comparison with the sales formulations containing either ethofumesate (TRAMAT F) and/or clopyralid (Lontrel 300 SL).

Table 3.2-7 Efficacy results for justification of the combination of the active ingredients, the assessments on 25-30 DAC (BBCH 19-42)

weed species	Nb of trials	UNCK			TRAMAT F 0,66 l/ha ethofumesate 900 g (3 x 330g)			LONTREL 300 SL 0,1667 l/ha clopyralid 150 g (3 x 50g)			ADM.01851.H.1.A 0,66 l/ha ethofumesate 900 g (3 x 330g) + clopyralid 148,5 (3x49,5 g)		
		mean	min	max	mean	min	max	mean	min	max	mean	min	max
CHEAL	10	30,45	5,80	168,80	54,18	12,50	86,00	37,01	0,00	87,50	71,33	42,50	97,30
LAMPU	3	8,33	5,50	13,50	74,03	55,00	85,80	31,27	0,00	56,30	82,93	62,50	97,50
MATIN	4	5,64	5,00	6,30	86,45	46,30	100,00	94,80	81,00	100,00	92,67	74,80	100,00
POLPE	2	10,15	6,00	14,30	45,00	30,00	60,00	57,90	26,30	89,50	63,15	38,80	87,50
POLCO	7	8,16	5,30	11,50	42,47	0,00	81,00	37,32	0,00	95,00	66,39	31,30	87,50
RAPRA	1	7,50	7,50	7,50	37,50	37,50	37,50	0,00	0,00	0,00	75,00	75,00	75,00
SOLNI	3	24,60	6,00	54,00	62,50	47,50	77,50	76,93	61,30	89,50	83,33	67,50	92,50

The data presented in table 3.2-7 were obtained from 11 trials carried out in Poland (9) and Germany (2) in season 2022-2023. Data presented in the table were obtained at last relevant efficacy assessment when the beet is near row closure which is the assessment performed 25-30 DAC, BBCH 19-42 of the crop plant. In all 11 trials ADM.01851.H.1.A applied at target dose rate 0,66 l/ha was compared to straight products containing ethofumesate (Tramat F) and clopyralid (Lontrel 300 SL).

The amount of active substances: ethofumesate and clopyralid delivered by ADM.01851.H.1.A applied at target dose rate 0,66 l/ha, is matching the amount of respective active substances of compared straight products.

Efficacy of ADM.01851.H.1.A is higher than that of the equivalent rates of ethofumesate and clopyralid products applied alone against some of the main target weed species (LAMPU, CHEAL, POLPE, MATIN, POLCO, SOLNI and RAPRA), which proves the synergistic effect of both substances in the formulation of ADM.01851.H.1.A.

Evidently, the combination of both substances in ADM.01851.H.1.A formulation, resulted in better effectiveness in weed control than the effectiveness observed in the case of straight products as well as a wider range of weed species controlled resulting from the complementary effects of both substances.

Based on presented data, the combination of ethofumesate and clopyralid in ADM.01851.H.1.A is therefore fully justified on the basis of higher efficacy, compared to active substance applied alone, against major target weed species for which label claims are supported for proposed uses in sugar beets.

Comments of zRMS on preliminary data of actives` co-formulation in ADM.01851.H.1.A

Even though the number of data points for some weed species is subcritical, making particular comparisons less reliable than the others (see POLPE, RAPRA and SOLNI), as preliminary data summary the Table 3.2-7 demonstrates higher performance of the test item compared to products using both actives as solo ingredients.

3.2.2 Minimum effective dose tests (KCP 6.2)

All ~~presented in this dossier efficacy trials~~ efficacy trials presented in this dossier included in treatment list dose rates lower than proposed target dose rate. In total 11 efficacy trials were available to evaluate the minimum effective dose of ADM.01851.H.1.A for the control of target uses. Trials were conducted in Poland (North East EPPO zone) – 9 and Germany (Maritime EPPO zone) – 2.

ADM.01851.H.1.A was tested at dose rates:

0,26 l/ha - 40 % of the target dose rate
0,33 l/ha - 50 % of the target dose rate
0,53 l/ha - 80 % of the target dose rate
0,66 l/ha – 100 % of the target dose rate

The rates reflect the proposed label rate and 40%; 50%; 80% of the full recommended rate of ADM.01851.H.1.A in accordance with the EPPO standard PP 1/225 ‘*Minimum effective dose*’. According to GAP, ADM.01851.H.1.A is applied at 3*0,66 l/ha, at BBCH stages:

Application A: BBCH 10

Application B: BBCH 11-14

Application C: BBCH 12-18

A summary of the dose response results is provided in Table 3.2-.

Table 3.2-8: Minimum effective dose. Efficacy of ADM.01851.H.1.A at proposed label rate and 40%; 50%; 80% dose rates, at A4 (25-30 DAC) BBCH 31-42 of the sugar beets in Poland (the set of 9 trials).

weed species	Nb of trials	UNCK		ADM.01851.H.1. A 0,26l/ha (40% of full rate)		ADM.01851.H.1. A 0,33l/ha (50% of full rate)		ADM.01851.H.1. A 0,53l/ha (80% of full rate)		ADM.01851.H.1.A 0,66l/ha (Full rate)	
		mean	min-max	mean	min-max	mean	min-max	mean	min-max	mean	min-max
BRSNW	4	6,28	5,3-7	26,94	5-51,5	32,51	15-55,0	49,35	41,3-67,3	55,90	46,3-70,8
CHEAL	9	32,66	5,8-168	23,48	0-43,75	30,29	0-55,0	54,76	28,8-72,5	55,04	28,8-75,0
GALAP	5	5,73	5,3-7,25	70,71	34,25-94,0	75,37	40-95,3	86,42	63,75-97,8	94,01	85-99,5
LAMPU	2	9,50	5,5-13,0	66,90	51,3-82,5	74,80	63,3-86,3	84,90	82,3-87,5	93,15	88,8-97,5
MATIN	3	5,85	5,25-6,3	59,18	12,5-87,5	78,04	53,3-92,5	85,75	67,8-96,75	90,22	74,8-98,75
POLPE	1	6,00	6,00	57,50	57,5	68,75	68,75	82,50	82,50	87,50	87,50
POLAV	2	7,0	6,0-8,0	36,87	32,5-41,24	48,78	42,5-55,05	63,54	48,8-78,28	85,7	80,0-91,40
POLCO	6	7,85	5,3-11,5	28,13	2,5-5	37,51	5-75	53,24	26,3-91,3	63,08	31,3-87,5
RAPRA	1	7,50	7,50	46,30	46,3	55,0	55,0	71,3	71,3	75,0	75,00
SOLNI	2	9,90	6-13,80	46,25	25-67,5	52,53	28,8-76,25	72,15	58,8-85,50	78,75	67,5-90,0
STEME	4	6,50	5,25-8,25	79,69	23,75-100	85,25	42,5-100	90,63	62,5-100	96,69	86,75-100

Table 3.2-9: Minimum effective dose. Efficacy of ADM.01851.H.1.A at proposed label rate and 40%; 50%; 80% dose rates, at A4 (25-27 DAC) BBCH 19-39 of the sugar beets in Germany (the set of 2 trials).

weed species	Nb. of trials	Infestation of the untreated control (unit)		ADM.01851.H.1.A 0,26l/ha (40% of full rate)		ADM.01851.H.1.A 0,33l/ha (50% of full rate)		ADM.01851.H.1.A 0,53l/ha (80% of full rate)		ADM.01851.H.1.A 0,66l/ha (Full rate)	
		mean	min-max	mean	min-max	mean	min-max	mean	min-max	mean	min-max
CHEAL	1	10,5	10,5	50,0	50,0	92,5	92,50	94,0	94,00	97,3	97,30
LAMPU	1	6,0	6,0	28,8	28,8	23,8	23,80	70,0	70,00	62,5	62,50
POLCO	1	10,0	10,0	31,3	31,3	41,3	41,30	63,8	63,80	86,3	86,30
SOLNI	1	13,8	13,8	25,00	25,0	28,8	28,80	58,8	58,80	67,5	67,50
SOLNI	1	52,0	-	61,3	-	78,8	-	88,8	-	93,8	-
THLAR	1	11,8	11,8	87,5	87,5	95,8	95,80	95,0	95,00	98,5	98,50

Summary and conclusions on the minimum effective dose

The total of 9 trials were conducted in North East EPPO climatic zone (Poland) between 2022-2023. The rates reflect the proposed label rate and 40%; 50%; 80% of the full recommended rate of ADM.01851.H.1.A in accordance with the EPPO standard PP 1/225 'Minimum effective dose'. Dose response is evident for all weed plant species. Data generated in trials carried in the North East EPPO climatic zone clearly show the efficacy of ADM.01851.H.1.A applied at 3*0,66 l/ha against annual broadleaved weed species in sugar beets like *CHEAL*, *LAMPU*, *POLCO*, *MATIN*, *SOLNI*, *STEME*, *POLPE*, *THLAR* to be generally higher and more consistent compared to that of lower rates of product/ha and rate response was evident with all three rates.

Based on the presented data, it is therefore reasonable to conclude that the maximum proposed label rate of 3*0,66 L product/ha is fully justified as the minimum effective dose for the control of annual broadleaved weed species in sugar beets by ADM.01851.H.1.A under conditions in countries in the North-east EPPO climatic zones.

The total of 2 trials were conducted in Maritime EPPO climatic zone (Germany) in 2023. The rates reflect the proposed label rate and 40%; 50%; 80% of the full recommended rate of ADM.01851.H.1.A in accordance with the EPPO standard PP 1/225 'Minimum effective dose'. Dose response is evident for all weed plant species. Data generated in trials carried in the Maritime EPPO climatic zone clearly show the efficacy of ADM.01851.H.1.A applied at 3*0,66 l/ha against annual broadleaved weed species in sugar beets to be generally higher and more consistent compared to that of lower rates of product/ha and rate response was evident with all three rates.

Based on the presented data, it is therefore reasonable to conclude that the maximum proposed label rate of 3*0,66 L product/ha is fully justified as the minimum effective dose for the control of annual broadleaved weed species in sugar beets by ADM.01851.H.1.A.

Comments of zRMS on the MED results:

The conclusion proposed by the applicant is justified in light of the submitted MED dataset. The dose rate of **3 x 0.66 L/ha should be considered as the minimum effective dose** rate in control of annual broadleaved weeds in sugar beet crop.

3.2.3 Efficacy tests (KCP 6.2)

The total of 11 trials were conducted in Poland (North East EPPO zone) – 9 and Germany (Maritime EP-PO zone) – 2 between 2023-2024.

Testing facility or organisation: All trials were carried out by testing facilities officially recognised as competent to carry out efficacy testing in accordance with the requirements of Directive 93/71/EEC, and in accordance with the principles of GEP.

Sites: Trials were located in areas considered to be either representative of the range of agricultural, plant health and environmental conditions (including climatic conditions) likely to be encountered in practice in the area of proposed use, or of a more severe nature of those conditions. The field were selected based on a history of infestation with annual weeds.

Meteorological information: Trials included a range of climatic conditions representative of those where crops are grown commercially. Data describing the climatic conditions at application are presented in individual trial reports. In all cases, conditions were within the normal range for the areas in which the trials were conducted for the duration of the study or were considered to have represented a more severe nature of those conditions.

Experimental details: In all trials, crops were managed according to local agronomical best practices. There were no significant deviations from the specified testing methods in any trial. Trials were conducted in order to investigate the effectiveness of ADM.01851.H.1.A as an herbicide against annual weeds of economical importance in sugar beets, in order to assess its efficacy under the conditions in which it will be applied.

Assessments

Weed control: growth stage and/or density were recorded at each application and each assessment. Weed infestation levels were assessed by counting the number of each species present in 4 x 0.25 m² quadrats in the untreated plots. Weed infestation levels in all trials were sufficient for the evaluation of the effectiveness of the test product and its comparison to the standard product. In the majority of cases, weed densities ranged from moderate to very high, exceeding the economic threshold of 5 plants per m².

For treated plots, a relative percentage of efficacy was estimated. Percentage control, compared to untreated plots, was made visually by estimating the % control and vigour of each weed species (untreated (no control) = 0%, complete control = 100%).

Susceptibility of weeds to ADM.01851.H.1.A is divided as follows*:

Highly susceptible (HS)	95-100 %
Susceptible (S)	85 – 94.9 %
Moderately Susceptible (MS)	70 – 84.9 %
Moderately Tolerant (MT)	50 – 69.9 %
Tolerant (T)	0 – 49.9 %

*amended by zRMS following SANCO/10055/2013 Rev. 4, 3October 2013, Appendix 1, p. 21, while retaining the colour coding used by the applicant.

% of control	Susceptibility of the weed species
>95%	VS: very susceptible
85–94 %	S: susceptible
70–84 %	MS: moderately susceptible
50–69 %	LS: low susceptible
<50%	NS: not susceptible

Evaluation of efficacy focused on the assessment made at A4 (25-30 DAC) BBCH 19-42 of the sugar beets when the sugar beet is near row closure.

Table 3.2-7: Details on trial methodology

Guidelines	General guidelines	PP 1/135(4);PP 1/225(2);PP 1/181(4/5); PP 1/152 (4)
	Specific guidelines	PP 1/52(4)
Experimental	Plot design	RCBD (11),

design	Plot size	12,6-30 ~~24~~ m ²
	Number of replications	~~4~~ (11)
Crop	Trials per crop	Sugar beet (BEAVA) - 11
	Varieties per crop	Sugar beet : Smart Latoria KWS, Graciana KWS, Viola KWS, Mazovia, BTS1985, Jadwiga Rh, BTS SMART 9635, Eliska, Cabriana, Calledia, KWS Smart Janinka
	Sowing period	Sugar beet: 28/03/2022, 27/03/2023; 20/04/2022; 20/04/2023; 21/04/2023 08/04/2023; 02/05/2023; 01/04/2023; 10/04/2023; 12/04/2023; 22/04/2023
Application	Crop stage (BBCH)* at application	Sugar beet: BBCH 10-18 Application A: BBCH 10- ~~11~~ Application B: BBCH ~~11~~ 10-14 Application C: BBCH 12-18
	Timing Pest stage at application (A)	Post-emergence AMARE(BBCH); BRSNW(BBCH10-11), CHEAL (BBCH 10-11), DESSO(BBCH10), ECHCG(BBCH10); GALAP(BBCH10), GERPU(BBCH10); LAMPU(BBCH10), MATIN(BBCH10-12);POLPE(BBCH10); POLAV(BBCH10), POLCO(BBCH 0-10), RAPRA(BBCH10); SOLNI(BBCH10); STEME(BBCH10),THLAR(BBCH10),VERAG(BBCH); VERPE(BBCH),VIOAR(BBCH0-10)
	Pest stage at application (B)	AMARE(BBCH)BRSNW(BBCH10-13),CHEAL (BBCH 10-14), DESSO(BBCH12-16); ECHCG(BBCH12); GALAP(BBCH10-22), GERPU(BBCH11);LAMPU(BBCH12);MATIN(BBCH10-14);POLPE(BBCH13); POLAV(BBCH13), POLCO(BBCH10-12), RAPRA(BBCH10); SOLNI(BBCH10-13)STEME(BBCH12-22),THLAR(BBCH16-19),VERAG(BBCH); VERPE(BBCH10-14),VIOAR(BBCH10-15)
	Pest stage at application (C)	AMARE(BBCH)BRSNW(BBCH12-17), CHEAL (BBCH 11-32), DESSO(BBCH19-31), ECHCG(BBCH13)GALAP(BBCH11-32), GERPU(BBCH14);LAMPU(BBCH12-32); MATIN(BBCH12-19); POLPE(BBCH15); POLAV(BBCH13-15), POLCO(BBCH12-16), RAPRA(BBCH14); SOLNI(BBCH12-17)STEME(BBCH16-34),THLAR(BBCH19-36) ,VERAG(BBCH); VERPE(BBCH12-34)VIOAR(BBCH11-32)
	Number of applications Intervals between applications	3 (11) Min ~~8~~ days (A-B 8-15 days, B-C 8-12 days, A-C 18-26 days)
	Spray volumes	~~10 trials~~ ; 200 - 250 L/ha, 1 trial: 300 L/ha
Assessment	Assessment types	Visual % of efficacy in comparison with the untreated plot Phytotoxicity as % of total leaf area affected by symptom where 0% = no phyto 100% = crop destroyed Crop vigour on a 0-10 (0-100) linear scale, where 0 = no crop 10(100) = the most vigorous plot
	Assessment dates	After each application and 10- 16 days after last application
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	fine loam, sandy loam, loam, silt loam, sandy clay, loamy sand, silty loam loamy silt 6,1; 6,7; 6,4; 6,2; 5,8; 7,2; 7,6
	e.g. Natural / artificial inoculation...	N
	e.g. Field / Greenhouse...	F

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage...

Standard methods

The following EPPO guidelines were followed:

PP 1/135(4)	Phytotoxicity assessment
PP 1/152(4)	Design and analysis of efficacy evaluation trials
PP 1/181(4/5)	Conduct and reporting of efficacy evaluation trials including GEP
PP 1/225(2)	Minimum effective dose
PP 1/52(4)	Weeds in sugar and fodder beet

Table 3.2-11: List of trials testing the efficacy of ADM.01851.H.1.A in sugar beets.

EPPO zone	Country	Year	Trial ID	Testing facility	GEP or not GEP
North-East	Poland	2022	PL22HEBEAVA008C	Fertico Sp z o.o.	GEP
North-East	Poland	2023	PL22HEBEAVA008B	AGRECO Sp. z o.o.	GEP
North-East	Poland	2023	PL23HEBEAVA001A	AGRECO Sp. z o.o.	GEP
North-East	Poland	2023	PL23HEBEAVA001B	AGRECO Sp. z o.o.	GEP
North-East	Poland	2023	PL23HEBEAVA001C	Fertico Sp. z o.o.	GEP
North-East	Poland	2023	PL23HEBEAVA001D	Fertico Sp. z o.o.	GEP
North-East	Poland	2023	PL23HEBEAVA001F	Staphyt Sp z o.o.	GEP
North-East	Poland	2023	PL23HEBEAVA001G	Staphyt Sp z o.o.	GEP
North-East	Poland	2023	PL23HEBEAVA001H	Staphyt Sp z o.o.	GEP
Maritime	Germany	2023	DE23HEBEAVA123C	Field Research Support	GEP
Maritime	Germany	2023	DE23HEBEAVA123D	Agricola	GEP

Treatments

A total of 11 efficacy trials tested the efficacy of ADM.01851.H.1.A applied 3 times at 0.66 L/ha (i.e. the maximal total target dose rate of 1.98 L/ha for Poland and Germany).

In all trials ADM.01851.H.1.A was compared to the zonal standard herbicide FSG 01095 H (metamitron 350 g/L + ethofumesate 150 g/L) applied at registered rate. In the efficacy part, only results of the total intended dose rate (i.e. a total of 1.98 L/ha of formulated product for Poland) are presented. Results of ADM.01851.H.1.A at reduced rates are not presented in this section but in previous section 3.2.2 Minimum effective dose tests.

Table 3.2-12: Treatments used to evaluate the efficacy spectrum of ADM.01851.H.1.A at 3*0.66 L/ha

Treatment	Active substances	Product name	Rate	Timing
North-East EPPO and Maritime EPPO zone				
ADM.01851.H.1.A	Ethofumesate 500 g/L + clopyralid 75 g/L	ADM.01851.H.1.A	0.66 L/ha	ABC
Standard N rate	Metamitron + ethofumesate 350+150 g/L	FSG 01095 H	2.0 L/ha	ABC

North-East EPPO zone 2022-2023

Results from a total of 9 trials carried out in Poland in 2022-2023 are presented in **Table 3.2-13**. The evaluation focused on A4 (25-30 DAC) BBCH 31-42. The efficacy of ADM.01851.H.1.A was compared to the standard product FSG 01095 H = TORERO 500 SC (metamitron 350 g/L + ethofumesate 150 g/L).

Table 3.2-13: Efficacy of ADM.01851.H.1.A at 3*0.66 L/ha against annual weeds - A4 (25-30 DAC) BBCH 31-42 - Summary of Poland (North-East EPPO zone), 2022-2023

weed code	Nb of trials	UNCK		%CONTROL			
		Pest density in the untreated control (p/m²)		ADM.01851.H.1.A (3*0.66 L/ha) 1N		Standard (3*2.0 L/ha) 1N	
		mean	min-max	mean	min-max	mean	min-max
CHEAL	9	32,66 31,77	5,168,8 5,8-160,8	55,04 68,44	28,8-75,00 42,5-86,75	91,16	78,8-100
GALAP	5	5,73	5,3-7,23	94,01	85-99,50	93,36	87,25-99,50
POLCO	6	7,85	5,3-11,50	63,08	31,3-87,50	56,38	0-97,50
VIOAR	7	10,27	5,3-32,80	42,05 50,91	12,5-100 17,5-100	45,42 68,79	0-100 15-100
BRSNW	4	6,28	5,3-7,00	55,90	46,3-70,80	79,70	72,5-88,00

MATIN	3 4	5,85 5,64	5,00-6,30 5,25-6,30	90,22 92,67	74,8-98,75 74,8-100	97,64 98,23	93,3-100
STEME	4	6,50	5,25-8,25	96,69	86,7-100	97,00	88-100
LAMPU	2	9,50	5,5-13,50	93,15	88,8-97,50	98,75	97,5-100
POLAV	2	7,0 8,0	6,0-8,0	91,40 85,7	80,0-91,40	88,52 89,91	88,52-88,52 88,52-91,30
SOLNI	2	9,90	6,00-13,80	78,75	67,50-90,0	82,15	73,8-90,50
VERPE	2	7,30	5,3-9,30	40,75	0,0-81,50	52,25	5-99,50
ECHCG	2	46,65	42,3-51,00	39,40	0-78,80	35,65	0-71,30
POLPE	1	6,00 6,50	6,00 6,50	87,50	87,50	90,50	90,50
RAPRA	1	7,50	7,50	75,00	75,00	95,00	95,00
DESSO	1	5,30	5,30	15,00	15,00	54,00	54,00
GERPU	1	46,50	46,5-46,50	0,00	0,00	77,50	77,50
THLAR	1	5,50	5,50	42,50	42,50	62,80	62,80

Results of 9 trials conducted in Poland in 2022 and 2023 showed that ADM.01851.H.1.A applied as split-up application 3 times at 0.66 L/ha gave a satisfactory level of control against the key weeds *Galium aparine* (GALAP), *Stellaria media* (STEME), *Matricaria inodora* (MATIN), *Lamium purpureum* (LAMPU) which are of economical importance in sugar beet in the Central zone of Europe.

Maritime EPPO zone 2023

Results from a total of 2 trials carried out in Germany in 2023 are presented in **Table 3.2-14**.

The evaluation focused on A4 (25-27 DAC) BBCH 19-39.

The efficacy of ADM.01851.H.1.A was compared to the standard product FSG 01095 H = TORERO 500 SC (metamitron 350 g/L + ethofumesate 150 g/L).

Table 3.2-14: Efficacy of ADM.01851.H.1.A at 3*0.66 L/ha against annual weeds - A4 (25-27 DAC) BBCH 19-39 - Summary of Germany (Maritime EPPO zone), 2023

weed code	nb of trials	UNCK		%CONTROL			
		Pest density in the untreated control (p/m ²)		ADM.01851.H.1.A (3*0.66 L/ha) 1N		Standard (3*2.0 L/ha) 1N	
		mean	min-max	mean	min-max	mean	min-max
AMARE	1	18,5	18,5	58,8	58,8	83,8	83,8
CHEAL	1	10,50	10,50	97,30	97,30	98,80	98,80
GALAP	1	13,00	13,00	99,80	99,80	100,00	100,00
LAMPU	1	6,00	6,00	62,50	62,50	100,00	100,00
POLPE	1	14,30	14,30	38,80	38,80	94,80	94,80
POLAV	1	5,00	5,00	15,00	15,00	45,00	45,00
POLCO	1	10,00	10,00	86,30	86,30	77,00	77,00
SOLNI	1	52,0	52,0	93,8	-	92,5	-
THLAR	1	11,80	11,80	98,50	98,50	94,80	94,80
VERAG	1	10,00	10,00	58,80	58,80	97,50	97,50

Results of 2 trials conducted in Germany in 2023 showed that ADM.01851.H.1.A applied as split-up application 3 times at 0.66 L/ha gave a satisfactory level of control against the key weeds *Chenopodium album* (CHEAL), *Galium aparine* (GALAP), *Polygonum convolvulus* (POLCO), *Solanum nigrum* (SOLNI) which are of economic importance in sugar beet in the Central zone of Europe. For the North-East EPPO zone, in addition to the results from trials carried out in Poland, the German results are used as complementary data.

Due to consistency of level of control on the key weeds in both North-East and Maritime EPPO zones, a global mean is presented for all efficacy trials testing ADM.01851.H.1.A at 3*0.66 L/ha. In addition, the EPPO Maritime zone results are comparable to results in the EPPO North-East zone as in Germany the agronomic conditions and cultural practices in beet crops are very close to what is encountered in Poland, and thus no direct impact on the efficacy of the product is expected. Furthermore, the climatic conditions at application (air temperature and relative moisture) were globally homogeneous from a climatic zone to another.

All trials - Maritime and North-East EPPO zones

Total of 11 efficacy trials were conducted in 2022 – 2023 in Poland and Germany.

The evaluation focused on the key weed species, at A4 (25-30 DAC) BBCH 19-42 when the beet is near row closure. The efficacy of ADM.01851.H.1.A (ethofumesate 500 g/L + clopyralid 75 g/L) was compared to the reference product FSG 01095 H (metamitron 350 g/L + ethofumesate 150 g/L). Results are presented in **Table 3.2-15**.

Table 3.2-15: Efficacy of ADM.01851.H.1.A at 3*0.66 L/ha against key weed species – A4 (25-30 DAC) BBCH 19-42 - Summary of all trials North-East and Maritime EPPO zones, 2022-2023

weed code	nb of trials	UNCK Pest density in the untreated control (p/m ²)		% CONTROL			
				ADM.01851.H.1.A (3*0.66 L/ha) 1N		Standard (3*2.0 L/ha) 1N	
		mean	min-max	mean	min-max	mean	min-max
CHEAL	10	30,45 31,77	5,8-168,80 5,8-160,80	71,33	42,5-97,30	91,92	78,8-100,00
GALAP	6	6,94	5,3-13,00	94,98	85-99,80	94,47	87,25-100,00
POLCO	7	8,16	5,3-11,50	66,39	31,3-87,50	59,33	0-97,50
MATIN	4	5,64	5-6,30	92,67	74,8-100,00	98,23	93,3-100,00
STEME	4	6,50	5,25-8,25	96,69	86,75-100,00	97,00	88-100,00
LAMPU	3	8,33	5,5-13,50	82,93	62,5-97,50	99,17	97,5-100,00
SOLNI	3	24,60 23,93	6-54 6-53	83,33 83,77	67,5-92,50 67,5-93,8	84,77 85,60	73,8-90,50 73,8-92,50
POLAV	3	6,33	5-8,00	62,13	15-91,40	74,94	45-91,30
THLAR	2	8,65	5,5-11,80	70,50	42,5-98,50	78,80	62,8-94,80
POLPE	2	10,15 10,38	6-14,30 6,5-14,3	63,15	38,8-87,50	92,65	90,5-94,80

Results of 11 trials conducted in Germany in 2023 and 9 trials conducted in Poland in 2022-2023 showed that ADM.01851.H.1.A applied as split-up application 3 times at 0.66 L/ha gave a satisfactory level of control against the key weeds *Chenopodium album* (CHEAL), *Galium aparine* (GALAP), *Stellaria media* (STEME), *Lamium purpureum* (LAMPU), *Polygonum convolvulus* (POLCO), *Solanum nigrum* (SOLNI) which are of economic importance in sugar beet in the Central zone of Europe.

Conclusion on the efficacy of ADM.01851.H.1.A at 3*0.66 L/ha against annual weeds in sugar beet:

Data from 11 efficacy trials were used to evaluate the efficacy of ADM.01851.H.1.A applied post-emergence of the crop against annual weeds in sugar beet. ADM.01851.H.1.A was applied 3 times at 0.66 L/ha (i.e. a total of 1.98 L/ha corresponding to the maximum total recommended dose rate for Poland and Germany) and compared to the standard FSG 01095 H (metamitron + ethofumesate, SC, 350 + 150 g/L) applied at registered rate.

Evaluation of efficacy focused at A4 (25-30 DAC) BBCH 19-42 when the sugar beet is near row close. Results of 9 trials conducted in Poland in 2022-2023 showed that ADM.01851.H.1.A applied as split-up application 3 times at 0.66 L/ha, gave a satisfactory level of control against the key weeds *Galium aparine* (GALAP), *Stellaria media* (STEME), *Matricaria inodora* (MATIN), *Lamium purpureum* (LAMPU) which are of economic importance in sugar beet in the Central zone of Europe.

Results of 2 trials conducted in Germany in 2023 showed that ADM.01851.H.1.A applied as split-up application 3 times at 0.66 L/ha controls a number of key weeds of economic importance in sugar beet in the Central zone of Europe, especially against *Chenopodium album* (CHEAL), *Galium aparine* (GALAP), *Polygonum convolvulus* (POLCO), *Solanum nigrum* (SOLNI).

All results support the intended GAP, application in all surface or application applied to 50% of the surface along the plant rows, since weeds receive the same quantity of product.

The weed spectrum of ADM.01851.H.1.A at 3*0.66 L/ha for the North-East and Maritime EPPO zone is presented in the following table. Only weeds with at least 2 results are listed.

Table 3.2-16: Weed spectrum of ADM.01851.H.1.A at 3*0.66 L/ha - A4 (25-30 DAC) BBCH 19-42 - Maritime and North-East EPPO zones 2022-2023, 11 trials (in brackets: no of data points per weed species).

Highly susceptible (HS)	STEME (4)
Susceptible (S)	STEME (4), GALAP(6), MATIN(4)
Moderately Susceptible (MS)	CHEAL (10), SOLNI(3), THLAR(2), LAMPU(3)

Moderately Tolerant (MT)	POLAV(3), POLCO(7), POLPE(2)
Tolerant (T)	No weeds were identified as tolerant
~~S: susceptible (85–94% control)~~	~~STEME (4); GALAP(6); MATIN(4);~~
~~MS: moderately susceptible (70–84 %)~~	~~CHEAL (10); SOLNI(3); THLAR(2); LAMPU(3)~~
~~LS: low susceptible (50–69 %)~~	~~POLAV(3); POLCO(7); POLPE(2)~~
~~Not susceptible (<50% control)~~	

To the [zRMS abstract](#)

Minor use

n.a

Yield (and relevant quality indicators), from efficacy trials (in the presence of challenging pest populations)

~~Any of efficacy trials were harvested.~~ None of the efficacy trials was harvested.

Comments of zRMS on efficacy of the ADM.01851.H.1.A

The target weed spectrum of the ADM.01851.H.1.A has been accepted in the shape presented by the applicant in Table 3.2-16 above.

The number of 9 efficacy trials carried out in Poland together with 2 supporting trials from the neighbouring MS of the Maritime zone, Germany, is sufficient to conclude that the test item has been successfully tested in conditions relevant for the prospective (geographical) area of use, and that the split application of the 3 x 0.66 L/ha can be accepted as the application pattern appropriate for annual weeds` control in sugar beet crop.

Some of the weed species occurred in less than 2 trials (DESSO, GERPU, RAPRA and VERAG) and these have not even been proposed by the applicant in the Table 3.2-16.

[zRMS Abstract](#)

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

The product ADM.01851.H.1.A is suspension concentrate (SC) contain two active ingredients: ethofumesate – 500 g/l and clopyralid – 75 g/l. intended for professional use as herbicide for the control of grassweeds and broadleaved weed species in sugar beets.

“Resistance” is defined as the naturally occurring, inheritable adjustment in the ability of individuals in a population to survive a treatment that would normally give effective control. 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 risk of resistance arising is dependent on the mode of action of the active substance and the inherent ability of the target plant to develop resistance.

Mode of action of the active substances

Ethofumesate belongs to the chemical group of benzofurans. The general mode of action is the inhibition of the fatty acid and lipid biosynthesis. Ethofumesate is a selective systemic herbicide. It is an inhibitor of elongases, enzymes leading to long chain of fatty acids (over 18 C), precursors of waxy cuticle and sobering. It acts as an inhibitor of cell division and lipid synthesis in the seedling shoot leading to retardation of meristem growth. The selectivity of the beet can be explained by its ability to metabolize this active substance, rendering it inactive.

Table 3.3-1: Mode of action of ethofumesate and chemical family

Mode of action according to HRAC	HRAC/WSSA Group 15, Legacy HRAC Group K3 Inhibition of Very Long-Chain Fatty Acid Synthesis
Chemical family	Benzofurans

The following table shows the new classification with active substances belonging to the new group HRAC/WSSA Group 15.

Table 3.3-2: HRAC GROUP 15 - Inhibition of Very Long-Chain Fatty Acid Synthesis

Active substances	classification
cafenstrole, fentrazamide, ipfencarbazone	Azolyl-carboxamides
anilofos, piperophos	α -Thioacetamides
pyroxasulfone, fenoxasulfone	Isoxazolines
indanofan, tridiphane	Oxiranes
acetochlor, alachlor, allidochlor=CDAA, butachlor, butenachlor, delachlor, diethatyl-ethyl, dimethachlor, dimethenamid, metazachlor, metolachlor, pethoxamid, pretilachlor, propachlor, propisochlor, prynachlor, thenylchlor	α -Chloroacetamides
mefenacet, flufenacet	α -Oxyacetamides
butylate*, cycloate, dimepiperate, EPTC, esprocarb, molinate, orbencarb, pebulate*, prosul-focarb, thiobencarb=benthocarb, tiocarbazil*, triallate, vernolate	Thiocarbamates
benfuresate, ethofumesate	Benzofurans

*actives not approved currently (Feb. 2025),

acc. to <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances>

Clopyralid is classified by HRAC within group O (synthetic auxins). It belongs to the chemical group of 6-Chloropicolinates. Other chemical classes classified as group O herbicides are: benzoic acids phenoxy-carboxylic-acids, pyridine carboxylic acids and quinoline carboxylic acids.

Clopyralid is a selective, systemic herbicide used primarily in the control of broadleaf weeds. Clopyralid mode of action is that it operates as a plant growth regulator by imitating natural plant hormones: auxins, altering the plant's metabolism and growth characteristics and often causing a proliferation of abnormal growth that interferes with the transport of nutrients.

Table 3.3-3: Mode of action of clopyralid and chemical family

Mode of action according to HRAC	HRAC GROUP 4 auxin mimics
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Chemical family	6-Chloropicolines
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Table 3.3-4: HRAC GROUP 4 – Auxin mimics

Active substances	New classification
picloram, clopyralid , aminopyralid	6-Chloropicolines
halauxifen, florypyrauxifen	6-Arylpicolines
triclopyr, fluroxypyr	Pyridyloxy-carboxylates
2,4,5-T, 2,4-D, 2,4-DB, clomeprop, dichlorprop, Fenoprop*, mecoprop, MCPA, MCPB	Phenoxy-carboxylates
dicamba, chloramben, TBA*	Benzoates
aminocyclopyrachlor*	Pyrimidine-carboxylates
benazolin-ethyl	Other
chlorfenac=fenac*, chlorfenprop*	Phenyl carboxylates

*actives not approved currently (Feb. 2025),
acc. to <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances>

Mechanism of resistance

Ethofumesate

Whilst the exact target site of HRAC Group 15 herbicides is unknown, it involves inhibition of enzymes involved in the biosynthesis of very long chain fatty acids (VLCFAs) and prevention of cell division. Cases of resistance to HRAC group 15 herbicides are quite rare.

Clopyralid

Clopyralid possess auxin-like qualities. After uptake it is systemically translocated via xylem or phloem to meristems, binds to protein receptor sites that regulate vital processes and disrupt normal metabolic pathways. Clopyralid accumulates in meristems and act on cell division, cell lengthening and growth of cells. Symptoms that may be found are misshaped shoots, stems and leaves, enlarged roots and enhanced growth. Plant growth will stop within 24-48 hours after application.

Evidence of Resistance

HRAC group 15:

HRAC group 15 is the mode of action group for actives substances belonging to the families of azolyl-carboxamides, benzofurans, α -chloroacetamides, isoxazolines, oxiranes, α -thioacetamides and thiocarbamates. Ethofumesate belongs to the family of benzofurans.

Worldwide, resistance to HRAC group 15 is known in 10 different weeds species listed in

Table 3.3-7 (actives substances belonging to the HRAC group 15 are highlighted in yellow). In these weeds, multiple-resistance has also been reported to other groups of herbicides.

In Europe, as shown in **Table 3.3-5** (actives substances belonging to the HRAC group 15 are highlighted in yellow), only 9 cases were reported in Europe against herbicides belonging to HRAC group 15. Three cases out of 4 were related to flufenacet which belongs to the family of α -oxyacetamides. The other one was related to prosulfocarb (thiocarbamates family) in Sweden, none of the weed species with resistance records against the active ingredients is being evaluated in this report.

The table thereafter shows the resistant weeds species to HRAC group 15 in Europe - actives substances belonging to the HRAC group 15 are highlighted in yellow.

Table 3.3-5: Resistant weed species to HRAC group 15 – Situation in Europe in June 2024

Former HRAC group	Species	Country	First Year
K3	<i>Alopecurus myosuroides</i>	2007 - Germany *Multiple - 4 SOAs Crop: Wheat. Multiple resistance has evolved to herbicides in the former Groups A/1, B/2, C2/7, and K3/15: resistance to chlorotoluron, fenoxaprop-P-ethyl, flufenacet, isoproturon, mesosulfuron-methyl, and pinoxaden	2007

Former HRAC group	Species	Country	First Year
N	<i>Alopecurus myosuroides</i>	<u>2011 - Sweden</u> *Multiple - 3 SOAs Crop: Wheat. Multiple resistance has evolved to herbicides in the former Groups A/1, B/2, and K3/15: resistance to fenoxaprop-P-ethyl, flupyr-sulfuron-methyl-sodium, prosul-focarb, and pyroxsulam	
K3	<i>Lolium pe-renne ssp. multiflorum</i>	<u>2018 - France</u> Crop: Wheat. Resistance to flufenacet - Group K3/15. <u>2018 - United Kingdom</u> Crop: Wheat. Resistance to flufenacet - Group K3/15.	2005

Populations of ethofumesate-resistant *Amaranthus palmeri* were found in cotton and soybean fields in Arkansas. These *Amaranthus palmeri* populations evolved multiple resistance to S-metolachlor. So far, no resistance of other dicotyledonous weeds to ethofumesate was reported worldwide.

Table 3.3-6: Resistant broadleaved weed species to ethofumesate – Worldwide situation in June 2024

Weed species	Number of cases (date of reporting) Country	Multiple resistance (HRAC group involved)	actives involved
<i>Amaranthus palmeri</i>	2016 United States (Arkansas)	5 Sites of Action HRAC Group 2 (Legacy B) HRAC Group 14 (Legacy E) HRAC Group 9 (Legacy G) HRAC Group 3 (Legacy K1) HRAC Group 15 (Legacy K3 N)	Ethofumesate, S-metolachlor

Table 3.3-7 Resistant weed species to HRAC group 15 – Situation worldwide (excl. Europe) in June 2024

Former HRAC group	Species	Country	First Year
K3	<i>Amaranthus palmeri</i>	<u>2016 United States</u> *Multiple - 5 SOAs Crops: cotton and soybean. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E), Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G), Inhibition of Microtubule Assembly HRAC Group 3 (Legacy K1), and Very Long-Chain Fatty Acid Synthesis inhibitors HRAC Group 15 (Legacy K3 N). Resistant to acifluorfen, carfentrazone-ethyl, flumetsulam, fluthiacet-methyl, fomesafen, glyphosate, imazethapyr, lactofen, pendimethalin, pyraflufen-ethyl, pyri-thiobac-sodium, S-metolachlor, and tri-floxysulfuron-Na <u>2017 United States</u> Crop: soybean. Resistant to S-metolachlor.	2016

Former HRAC group	Species	Country	First Year
K3/N	<i>Avena fatua</i>	1989 Canada *Multiple - 5 SOAs Crops: cereals, and spring Barley. Multiple resistance has evolved to herbicides in the Groups 15 (Legacy K3 N), and Cell elongation inhibitors HRAC Group 0 (Legacy Z). Resistant to difenzoquat, and tri-allate. 1990 United States *Multiple - 5 SOAs Crop: spring barley. Multiple resistance has evolved to herbicides in the Groups 15 (Legacy K3 N), and Cell elongation inhibitors HRAC Group 0 (Legacy Z). Resistant to difenzoquat, and tri-allate. 1993 United States *Multiple - 2 SOAs Crop: cereals. Multiple resistance has evolved to herbicides in the Groups 15 (Legacy K3 N), and Cell elongation inhibitors HRAC Group 0 (Legacy Z). Resistant to difenzoquat, and tri-allate. 1996 Canada Crop: wheat. Group 15 (Legacy K3 N) herbicides are known as Very Long-Chain Fatty Acid Synthesis inhibitors (Inhibition of Very Long-Chain Fatty Acid Synthesis). Resistant to tri-allate. 1996 Canada *Multiple - 3 SOAs Crops: canola, lentils, spring barley, and wheat. Multiple resistance has evolved to herbicides in the Groups 1 (Legacy A), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), and Very Long-Chain Fatty Acid Synthesis inhibitors HRAC Group 15 (Legacy K3 N). Resistant to fenoxaprop-ethyl, imazamethabenz-methyl, and tri-allate. 1997 Canada Crop: wheat. Resistant to tri-allate. 1997 Canada *Multiple - 4 SOAs Crop: wheat. Multiple resistance has evolved to herbicides in the Groups 1 (Legacy A), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Very Long-Chain Fatty Acid Synthesis inhibitors HRAC Group 15 (Legacy K3 N), and Antimicrotubule mitotic disrupter HRAC Group 0 (Legacy Z). Resistant to fenoxaprop-ethyl, flamprop-methyl, imazamethabenz-methyl, and tri-allate. 1998 Canada *Multiple - 3 SOAs Crop: canola, cereals, peas, and wheat. Multiple resistance has evolved to herbicides in the Groups 1 (Legacy A), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), and Very Long-Chain Fatty Acid Synthesis inhibitors HRAC Group 15 (Legacy K3 N). Resistant to fenoxaprop-ethyl, imazamethabenz-methyl, and tri-allate. 2015 Canada *Multiple - 4 SOAs Crop: spring wheat. Multiple resistance has evolved to herbicides in the Groups 1 (Legacy A), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E), and Very Long-Chain Fatty Acid Synthesis inhibitors HRAC Group 15 (Legacy K3 N). Resistant to fenoxaprop-ethyl, imazamethabenz-methyl, imazapyr, pyroxasulfone, quizalofop-ethyl, sulfentrazone, and tri-allate.	1989
K3	<i>Amaranthus tuberculatus</i> (=A. rudis)	2016 United States Crops: corn and soybean. Resistant to acetochlor, dimethenamid, pyroxasulfone, and S-metolachlor.	2016
K3 K3/N	<i>Echinochloa crus-galli</i> var. <i>crus-galli</i>	1993 China Crop: rice. Resistant to butachlor. 1993 China Crop: rice. Resistant to thiobencarb/benthiocarb. 1998 Thailand *Multiple - 2 SOAs Crop: rice. Multiple resistance has evolved to herbicides in the Groups 5 (Legacy C1 C2), and Very Long-Chain Fatty Acid Synthesis inhibitors HRAC Group 15 (Legacy K3 N). Resistant to butachlor, and propanil. 2000 United States *Multiple - 2 SOAs Crop: rice. Multiple resistance has evolved to herbicides in the Groups 1 (Legacy A), and Very Long-Chain Fatty Acid Synthesis inhibitors HRAC Group 15 (Legacy K3 N). Resistant to cyhalofop-butyl, fenoxaprop-ethyl, molinate, and thiobencarb/benthiocarb. 2000 Philippines *Multiple - 2 SOAs Crop: rice. Multiple resistance has evolved to herbicides in the Groups 5 (Legacy C1 C2), and Very Long-Chain Fatty Acid Synthesis inhibitors HRAC Group 15 (Legacy K3 N). Resistant to butachlor, and propanil.	1993

Former HRAC group	Species	Country	First Year
K3/N	<i>Echinochloa oryzoides</i>	2000 United States Crop: rice. Resistant to molinate , and thiobencarb/benthiocarb .	2000
K3/N	<i>Echinochloa phyllopogon</i> (= <i>E. oryzicola</i>)	1998 United States Crop: rice. Resistant to thiobencarb/benthiocarb . 2000 United States *Multiple - 2 SOAs Crop: rice. Multiple resistance has evolved to herbicides in the Groups 1 (Legacy A), and Very Long-Chain Fatty Acid Synthesis inhibitors HRAC Group 15 (Legacy K3 N). Resistant to cyhalofop-butyl, fenoxaprop-ethyl, molinate , and thiobencarb/benthiocarb .	1998
K3	<i>Lolium perenne</i> ssp. <i>multiflorum</i>	2005 United States *Multiple - 3 SOAs Crops: canola, chickpea, lentils, peas, and wheat. Multiple resistance has evolved to herbicides in the Groups 1 (Legacy A), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), and Very Long-Chain Fatty Acid Synthesis inhibitors HRAC Group 15 (Legacy K3 N). Resistant to clethodim, clodinafop-propargyl, diclofop-methyl, flufenacet , quizalofop-ethyl, and triasulfuron.. 2018 United States Crop: wheat. Resistant to flufenacet . 2018 United States Crop: wheat. Resistant to flufenacet .	2005
K3 K3/N	<i>Lolium rigidum</i>	1982 Australia *Multiple - 6 SOAs Crops: spring barley and wheat. Multiple resistance has evolved to herbicides in the Groups 1 (Legacy A), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Microtubule Assembly HRAC Group 3 (Legacy K1), Inhibition of Microtubule Organization HRAC Group 23 (Legacy K2), Very Long-Chain Fatty Acid Synthesis inhibitors HRAC Group 15 (Legacy K3 N), and Inhibition of Deoxy-D-Xylulose Phosphate Synthase HRAC Group 13 (Legacy F4). Resistant to chlorpropham, chlorsulfuron, clomazone, diclofop-methyl, ethalfluralin, fluazifop-butyl, imazapyr, metolachlor , metsulfuron-methyl, quizalofop-ethyl, sethoxydim, tralkoxydim, tri-allate , triasulfuron, and trifluralin. 1984 Australia Crop: cropland. Resistant to metolachlor . 2015 Australia Crop: wheat. Resistant to tri-allate . 2015 Australia Crop: wheat. Resistant to tri-allate .	1982
	<i>Poa annua</i>	1994 United States Crop: grass seed. Resistant to ethofumesate .	1994

Source: www.weedscience.org consulted on June 2024

In yellow: actives substances belonging to the HRAC group 15 HRAC website, accessed on 1st June 2024

HRAC group 4

HRAC group 4 is the mode of action group for actives substances belonging to the families of 6-Chloropicolines, 6-Arylpicolines, pyridyloxy-carboxylates, phenoxy-carboxylates, benzoates, pyrimidine-carboxylates, other. Clopyralid belongs to 6-Chloropicolines together with picloram and aminopyralid.

Worldwide, resistance to HRAC group 4 is known in 44 different weeds species listed in table

Table 3.3-10 (actives substances belonging to the HRAC group 4 are highlighted in yellow) in some of the species multiple-resistance has also been reported to other groups of herbicides.

In Europe, as shown in **Table 3.3-8** (actives substances belonging to the HRAC group 4 are highlighted in yellow), several cases of resistance to herbicides containing active substances belonging to HRAC 4 have been found, mainly 2,4 D, MCPA, mecoprop belonging to the family of phenoxy-carboxylates, one of dicamba (Poland) from family of benzoates and aminopyralid from family of 6-Chloropicolines. In some of the species multiple-resistance to other groups of herbicides have been reported.

For Europe, a total of 9 cases are reported with resistance to synthetic auxins with only five species being affected and only one species with resistance records against active ingredients of this report (*Stellaria*

media).

Table 3.3-8: Resistant weed species to HRAC group 4 – Situation in Europe in June 2024

Species	Country	First Year
<i>Cirsium arvense</i>	1985 Hungary Pastures. Resistant to 2,4-D , and MCPA .	1979
<i>Cirsium arvense</i>	1979 Sweden Cropland. Resistant to MCPA .	
<i>Centaurea cyanus</i>	2012 Poland Crop: winter wheat. Resistant to dicamba .	2012
<i>Papaver rhoeas</i>	1993 Spain *Multiple - 2 SOAs Crop: wheat. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), and Auxin Mimics HRAC Group 4 (Legacy O). Resistance to 2,4-D , and tribenuron-methyl.	1993
<i>Papaver rhoeas</i>	1998 Italy *Multiple - 2 SOAs Crop : wheat. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), and Auxin Mimics HRAC Group 4 (Legacy O). Resistance to 2,4-D , iodosulfuron-methyl-Na, and tribenuron-methyl.	
<i>Papaver rhoeas</i>	2002 Greece *Multiple - 2 SOAs Crop : wheat. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), and Auxin Mimics HRAC Group 4 (Legacy O). Resistance to 2,4-D , iodosulfuron-methyl-Na, and mesosulfuron-methyl.	
<i>Papaver rhoeas</i>	2015 France Crop : wheat. Resistant to 2,4-D , and aminopyralid .	
<i>Papaver rhoeas</i>	2016 France *Multiple - 2 SOAs Crop : cereals. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), and Auxin Mimics HRAC Group 4 (Legacy O). Resistance to 2,4-D , aminopyralid , iodosulfuron-methyl-Na, MCPA, mesosulfuron-methyl, and metsulfuron-methyl.	
<i>Stellaria media</i>	1985 United Kingdom Crop : wheat. Resistant to mecoprop .	

Populations of clopyralid-resistant broadleaved weed species were found in corn fields (*Chenopodium album*), golf courses and turf (*Soliva sessilis*), rangelands (*Centaurea stoebe ssp. micranthos*) and christmas tree plantation (*Ambrosia artemisiifolia*). So far, no resistance of other dicotyledonous weeds to clopyralid was reported worldwide.

Table 3.3-9: Resistant weed species to clopyralid – Worldwide situation in June 2024

Weed species	Number of cases (date of reporting) Country	Multiple resistance (HRAC group involved)	actives involved
<i>Ambrosia artemisiifolia</i>	1 (2022) United States (Michigan)	0	clopyralid
<i>Centaurea stoebe ssp. micranthos</i>	1 (2013) Canada (British Columbia)	0	Clopyralid , picloram
<i>Chenopodium album</i>	1 (2005) New Zealand	0	clopyralid aminopyralid, clopyralid, dicamba
<i>Soliva sessilis</i>	1 (1999) New Zealand	0	Clopyralid picloram, triclopyr

Table 3.3-10 Resistant weed species to HRAC group 4 – Situation worldwide in June 2024

Species	Country	First Year
<i>Amaranthus hybridus</i> (syn: <i>quiten-sis</i>)	2016 Argentina *Multiple - 2 SOAs Crop: soybean. Multiple resistance has evolved to herbicides in the Groups 9 (Legacy G), and Auxin Mimics HRAC Group 4 (Legacy O). Resistance to 2,4-D , dicamba .	2016
<i>Amaranthus palmeri</i>	2015 United States *Multiple - 5 SOAs Crop: sorghum. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G), and Auxin Mimics HRAC Group 4 (Legacy O). Resistance to 2,4-D , atrazine, chlorsulfuron, glyphosate, and mesotrione. 2020 United States *Multiple - 2 SOAs Crop: cotton and soybean. Multiple resistance has evolved to herbicides in the Groups 9 (Legacy G), and Auxin Mimics HRAC Group 4 (Legacy O). Resistance to dicamba , and glyphosate.	2015
<i>Amaranthus powellii</i>	2019 Canada *Multiple - 2 SOAs Crop: soybean. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), and Auxin Mimics HRAC Group 4 (Legacy O). Resistance to aminocyclopyrachlor , dichlorprop , imazethapyr, MCPA , and mecoprop .	2019
<i>Amaranthus tuberculatus</i> (= <i>A. rudis</i>)	2009 United States *Multiple - 2 SOAs Crop : pastures. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2), and Auxin Mimics HRAC Group 4 (Legacy O). Resistance to 2,4-D , aminopyralid , atrazine, chlorimuron-ethyl, imazethapyr, and picloram . 2016 United States *Multiple - 5 SOAs Crops : corn and soybean. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2), Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), and Auxin Mimics HRAC Group 4 (Legacy O). Resistance to 2,4-D , acifluorfen , atrazine, chlorimuron-ethyl, dicamba , fomesafen, imazethapyr, lactofen, mesotrione, tembotrione, and topramezone. 2021 United States Crop : soybean. Resistant to dicamba	2009
<i>Ambrosia artemisiifolia</i>	2022 United States Crop : Christmas Trees. Resistant to clopyralid and they may be cross-resistant to other Group 4 (Legacy O) herbicides.	2022
<i>Arctotheca calendula</i>	2015 Australia Crop : Fallow. Resistant to 2,4-D	2015
<i>Brassica rapa</i> (= <i>B. campestris</i>)	2015 Argentina Crop : Soybean, Wheat, and Winter barley. Resistant to 2,4-D	2015
<i>Carduus acanthoides</i>	2019 Argentina *Multiple - 2 SOAs Crop : corn and soybean. Multiple resistance has evolved to herbicides in the Groups 9 (Legacy G), and Auxin Mimics HRAC Group 4 (Legacy O). Resistance to 2,4-D , and glyphosate	2019
<i>Carduus nutans</i>	1981 New Zealand Crop : pastures. Resistant to 2,4-D	1981
<i>Carduus pycnocephalus</i>	1997 New Zealand . Crop : pastures. Resistant to 2,4-D , MCPA , and MCPB	1997
<i>Centaurea solstitialis</i>	1988 United States Crop : roadsides. Resistant to picloram	1988

Species	Country	First Year
<i>Centaurea stoebe ssp. micranthos</i>	2013 Canada Crop : rangeland. Resistant to clopyralid, and picloram	2013
<i>Chenopodium album</i>	2005 New Zealand Crop : corn. Resistant to aminopyralid, clopyralid, and dicamba .	2005
<i>Commelina diffusa</i>	1957 United States Crop : sugarcane. Resistant to 2,4-D .	1957
<i>Conyza sumatrensis</i>	2017 Brazil *Multiple - 5 SOAs Crop : soybean. Multiple resistance has evolved to herbicides in the Groups 5 (Legacy C1 C2), PS I Electron Diversion HRAC Group 22 (Legacy D), Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E), Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to 2,4-D , diuron, glyphosate, paraquat, and saflufenacil.	2017
<i>Daucus carota</i>	1957 Canada Crop : roadsides. Resistant to 2,4-D . 1993 United States Crop : cropland and roadsides. Resistant to 2,4-D . 1994 United States Crop : soybean. Resistant to 2,4-D .	1957
<i>Descurainia sophia</i>	2011 China Crop : winter wheat. Resistant to MCPA .	2011
<i>Digitaria ischaemum</i>	2002 United states Crop : rice. Resistant to quinclorac .	2002
<i>Echinochloa colona</i>	2000 Colombia Crop : rice. Resistant to quinclorac .	2000
<i>Echinochloa crus-galli var. crus-galli</i>	1998 United States Crop : rice. Resistant to quinclorac . 1999 Brazil Crop : rice. Resistant to quinclorac . 1999 United States*Multiple - 2 SOAs Multiple resistance has evolved to herbicides in the Groups 5 (Legacy C1 C2), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to propanil, and quinclorac . 2000 China Crop : rice. Resistant to quinclorac . 2009 Brazil*Multiple - 2 SOAs Crop : rice. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to bispyribac-sodium, imazethapyr, penoxsulam, and quinclorac . 2013 Uruguay Crop : rice. Resistant to quinclorac . 2018 Brazil *Multiple - 2 SOAs Crop : rice. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), Inhibition of Cellulose Synthesis HRAC Group 29 (Legacy L), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to florpyrauxifen , penoxsulam, and quinclorac .	1998
<i>Echinochloa crus-galli var. zelayensis</i>	2013 China Crop : rice. Resistant to quinclorac .	2013
<i>Echinochloa crus-pavonis</i>	1999 Brazil Crop : rice. Resistant to quinclorac .	1999

Species	Country	First Year
<i>Fimbristylis miliacea</i>	1989 Malaysia Crop : rice. Resistant to 2,4 D .	1989
<i>Galeopsis tetrahit</i>	1998 Canada Crop : Cereals, Cropland, Spring Barley, and Wheat. Resistant to dicamba , fluroxypyr , and MCPA .	1998
<i>Galium aparine</i>	2014 China Crop : wheat. Resistant to fluroxypyr . 2016 Iran Crop :wheat. Resistant to 2,4-D , and MCPA . 2017 Iran *Multiple - 2 SOAs Crop :wheat. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to 2,4-D , iodosulfuron-methyl-Na, MCPA , mesosulfuron-methyl, sulfosulfuron, and tribenuron-methyl.	2014
<i>Galium spurium</i>	1996 Canada *Multiple - 2 SOAs Crop : canola, cereals and wheat. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to imazethapyr, metsulfuron-methyl, quinclorac , sulfometuron-methyl, thifensulfuron-methyl, triasulfuron, and tribenuron-methyl.	1996
<i>Hirschfeldia incana</i>	2016 Argentina *Multiple - 2 SOAs Crop : wheat. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to 2,4-D , and metsulfuron-methyl.	2016
<i>Kochia scoparia</i>	1994 United States Crop : Cropland, and Wheat. Resistant to dicamba , and fluroxypyr 1995 United States Crop :wheat. Resistant to dicamba . 1997 United States Crop : roadsides. Resistant to dicamba . 1999 United States Crop : corn. Resistant to dicamba . 2009 United States Crop : corn. Resistant to dicamba . 2013 United States *Multiple - 4 SOAs Crop :corn. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2), Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to atrazine, chlorsulfuron, dicamba , and glyphosate. 2013 United States *Multiple - 2 SOAs Crop : corn and sorghum. Multiple resistance has evolved to herbicides in the Groups 9 (Legacy G), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to dicamba , fluroxypyr , and glyphosate. 2015 Canada *Multiple - 2 SOAs Crop :spring wheat. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to dicamba , fluroxypyr , thifensulfuron-methyl, and tribenuron-methyl. 2017 Canada *Multiple - 2 SOAs Crop : Canola, Corn, Fallow, Lentils, Peas, Wheat, and Winter barley. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to dicamba , glyphosate, thifensulfuron-methyl, and tribenuron-methyl.	1994
<i>Lactuca serriola</i>	2007 United States Crop : cereals. Resistant to 2,4-D , dicamba , and MCPA	2007

Species	Country	First Year
<i>Limnocharis flava</i>	1995 Indonesia Crop :rice. Resistant to 2,4-D 1998 Malaysia *Multiple - 2 SOAs Crop : rice. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to 2,4-D , and bensulfuron-methyl.	1995
<i>Limnophila erecta</i>	2002 Malaysia*Multiple - 2 SOAs Crop :rice. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to 2,4-D , bensulfuron-methyl, cinosulfuron, mesosulfuron-methyl, and pyrazosulfuron-ethyl.	2002
<i>Plantago lanceolata</i>	2016 United States Crop : turf. Resistant to 2,4-D .	2016
<i>Ranunculus acris</i>	1998 New Zealand Crop : pastures. Resistant to MCPA . 2010 New Zealand *Multiple - 2 SOAs	1998
<i>Raphanus raphanistrum</i>	1999 Australia Crop : cereals. Resistant to 2,4-D . 2006 Australia *Multiple - 3 SOAs Crop : cereals. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), Phytoene Desaturase inhibitors HRAC Group 12 (Legacy F1), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to 2,4-D , diflufenican, MCPA, and triasulfuron. 2009 Australia *Multiple - 3 SOAs Crop : Spring Barley, and Wheat. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to 2,4-D , chlorsulfuron, and metosulam. 2010 Australia *Multiple - 4 SOAs Crop : Fallow. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), Phytoene Desaturase inhibitors HRAC Group 12 (Legacy F1), Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to 2,4-D , chlorsulfuron, diflufenican, glyphosate, imazethapyr, MCPA , metosulam, and sulfometuron-methyl. 2011 Australia Crop : Spring Barley, and Wheat. Resistant to 2,4-D . 2013 Australia Crop : Oats, Spring Barley, and Wheat. Resistant to 2,4-D . 2015 Australia *Multiple - 5 SOAs Crop : wheat. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2), Phytoene Desaturase inhibitors HRAC Group 12 (Legacy F1), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to 2,4-D , atrazine, chlorsulfuron, diflufenican, fluridone, isoxaflutole, mesotrione, and tembotrione. 2020 Australia *Multiple - 3 SOAs Crop : wheat. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to 2,4-D , dicamba , mesotrione, metsulfuron-methyl, pyrasulfotole, and topramezone.	1999
<i>Sagittaria montevidensis</i>	2023 Brazil Crop : rice. Resistant to florpyrauxifen .	2023
<i>Sinapis arvensis</i>	1990 Canada Crop : Cropland, Spring Barley, and Wheat. Resistant to 2,4-D , dicamba , dichlorprop , MCPA , mecoprop , and picloram . 2008 Turkey*Multiple - 3 SOAs Crop : wheat. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to dicamba , propoxycarbazone-Na, thifensulfuron-methyl, triasulfuron, and tribenuron-methyl.	1999

Species	Country	First Year
<i>Sisymbrium orientale</i>	2005 Australia*Multiple - 2 SOAs Crop :cereals. Multiple resistance has evolved to herbicides in the Groups 2 (Legacy B), and Auxin Mimics HRAC Group 4 (Legacy O). Resistant to 2,4-D , imazethapyr, MCPA , metosulam, and metsulfuron-methyl.	2005
<i>Soliva sessilis</i>	1999 New Zealand Crop : golf courses, and turf. Resistant to clpyralid, picloram, and triclopyr .	1999
<i>Sonchus oleraceus</i>	2015 Australia Crop :wheat. Resistant to 2,4-D .	2015
<i>Sphenoclea zeylanica</i>	1983 Philippines Crop :rice. Resistant to 2,4-D .	1983
<i>Stellaria media</i>	2010 China Crop :winter wheat. Resistant to fluroxypyr, and MCPA .	2010

Cross resistance/Multiple resistance

Cross-resistance is defined as the expression of a genetically endowed mechanism conferring the ability to withstand herbicides from different chemical classes. Cross-resistance may develop when two or several compounds “act on the same target site or are affected by the same resistance mechanism” . It is most often found for compound sharing the same MOA and/or are chemically related. As mechanism of resistance needs to be known before cross-resistance information can be assigned, no cross resistance with ethofumesate was observed as well as cross-resistances within HRAC 4 are so far not well documented. Multiple resistances are considered to be a documented resistance to more than one HRAC group. Papaver rhoeas multiple resistance (HRAC 0/4 and B/2) and Alopecurus myosuroides (HRAC K13/N and B/2, C2/7, A/1) is documented in Europe. None of the described cases concerns the active substances included in the formulation, as well as weeds which in the described cases are not subject to control in the presented dossier.

Sensitivity data

For both active substances Clopyralid and ethofumesate no baseline sensitivity studies are available. The overview of the Herbicide Resistance Action Committee (HRAC) about the evidence of resistance can replace baseline sensitivity studies (Heimbach, U. et al. 2002)¹ . Although baseline sensitivity data become more and more important, requirements for every weed species is not practicable due to the high costs (Moss, S. 2006)² .

Resistance risk analysis

Determination of inherent risk of resistance for target weeds

A lot of plants, especially weeds, have a wide range of genetic variability, which gives them an enormous adaptability and survival capability under various conditions. Resistance occurs generally if existing unsusceptible biotypes will be selected. The further development and spread of the resistance particularly depend on the seed production of the weed species and on the fitness of the resistant biotypes. However, herbicides mostly effect on a specific target site, which is only controlled by one or a few genes, so that one mutation of few genes already can cause a resistance. Use of herbicides with the same mode of action in one population produces a considerable selection pressure, which results in reproduction of the resistant biotypes. These biotypes produce increased population sizes and may infest more arable land without limitation, because the sensitive species and varieties are controlled by the herbicide.

The following factors influence the resistance risk of species:

- Family and life-form
- Genetic variability and mode of heredity

- Density of individuals and seed production
- Paths of propagation
- Dormancy and lifetime of seeds in soil
- Capacity of metabolism
- Resistant biotypes already known
- Fitness of the resistant species

¹ Heimbach, U. et al. (2002): EU - regulatory aspects of resistance risk assessment. Pest. Manag. Sci. 5 8, 935 - 938

² Moss, S. (2006): Vortrag Ak - Herbologie - Tagung in Braunschweig (1./2. February 2006)

Table 3.3-11 displays target weed species of ADM.01851.H.1.A (annual dicot weeds) according to their inherent risk to develop resistance to herbicides across HRAC groups and countries. This classification is based on the frequency of the recorded resistance occurrence to all herbicides. Those data are from <http://www.weedscience.com/>

The inherent risk is classified according to the number of resistant biotypes already recorded in the weedscience data base: HIGH: number >5 / MEDIUM: number between 1 and 4 / LOW: no case.

Table 3.3-11 Inherent risk of weeds to develop resistance to herbicides

EPPO code	Weed species	Number of herbicide resistant biotypes across all HRAC groups			inherent risk to develop resistance to herbicides
		Geographical Euro- pe	Outside Europe	Worldwide	
AMARE	<i>Amaranthus retroflexus</i>	14	37	51	
CHEAL	<i>Chenopodium album</i>	19	31	50	
GALAP	<i>Galium aparine</i>	1	5	6	
RAPRA	<i>Raphanus raphanistrum</i>	0	15	15	
MATIN	<i>Matricaria recutita</i>	8	0	8	
POLPE	<i>Polygonum persicaria</i>	3	2	5	
SOLNI	<i>Solanum nigrum</i>	10	4	14	
STEME	<i>Stellaria media</i>	12	12	24	
POLCO	<i>Fallopia convolvulus</i>	2	2	4	medium
POLAV	<i>Polygonum aviculare</i>	2	0	2	
THLAR	<i>Thlaspi arvense</i>	0	3	3	
GERPU	<i>Geranium pusillum</i>	0	0	0	low
LAMPU	<i>Lamium purpureum</i>	0	0	0	
VERSS	<i>Veronica spp.</i>	0	0	0	
VIOAR	<i>Viola arvensis</i>	0	0	0	

Source: **International herbicide-resistant weed database**, <http://www.weedscience.org/Pages/SpeciesbySOATable.aspx>; accessed on 2nd June 2024

Results reported in the previous table show a major risk in Europe for spring broad-leaved weeds most common in beet crops as *Chenopodium album*, *Amaranthus retroflexus*, *Solanum nigrum* or *Stellaria media*. These weeds present in sugar beets and whose resistance comes mainly from a pressure of atrazine and metamitron, exhibit many characteristics that favour the accumulation of herbicide resistance mechanisms. These characteristics include large populations of widespread distribution in cropping areas (it can be found in autumnal and spring crops), high reproductive capacity and genetic flexibility.

Due to the fact that only few cases of resistance against HRAC group 4 and HRAC group 15 herbicides were reported in Europe until now, a low to medium risk for the development of resistance is determined for Clopyralid and ethofumesate.

Determination of inherent risk of resistance for the active substance

Considering the fact that one case of ethofumesate resistance in dicotyledonous weeds worldwide with no documented cases of resistance in dicotyledonous weeds in Europe and 4 cases of clopyralid-resistant dicotyledonous weeds in Europe, with only one weed being discussed in the presented dossier (*Stellaria media*) we can assume that the inherent risk of resistance to formulation is low.

Determination of inherent agronomic risk for resistance development

The risk results from pressure applied to a population of weeds over several years. The occurrence of resistance may result from the application of one herbicide or several herbicides with a similar mode of action, often associated with monocropping and reduced cultivation practices. These cultivation practices have an effect on weed seedbank.

However, the key strategy to manage the resistance development is the reduction of pressure on populations by using combined techniques (HRAC guideline):

Cultivation

Cultivation does not exert a chemical selection pressure and limit the soil seed bank. One of the most efficient for annual weeds is ploughing or deep tillage prior to control of emerged plants. Ploughing and deep tillage also bury new seeds (15-20 cm for ploughing).

Crop rotation

Crop rotation avoids successive crops in the same field which require herbicides with the same mode of action for control of the same weed species.

Different crops will allow rotation of herbicides having a different site of action and can interrupt the growth season of the weed.

A strongly competitive crop in the rotation can give a better chance to restrict weed seed production.

Including autumn and spring sown crops within a rotation increases the range of weed species and reduces overall numbers. This makes easier the weeding.

Generally, sugar beets are cultivated exclusively in crop rotations with an interval of at least 3 years and it is common practice to apply sugar beet herbicides either as tank mixtures or as sequential applications using different herbicides.

Number of applications

In practice, the registered rate of ADM.01851.H.1.A is split into 3 applications. ADM.01851.H.1.A formulation consist of 2 actives representing different mode of action to broaden the spectrum and control the risk of resistance. This minimizes the selection pressure to the maximum.

Alternating herbicides

Alternating herbicides with different modes of action used in the frame of herbicide programs is an excellent tool to limit the resistance development.

Conclusions for inherent agronomic risk

It can be concluded that the inherent agronomic risk is low.

Determination of the combined risk of resistance with ADM.01851.H.1.A

- Inherent risk of resistance for target weeds: low to medium
- Inherent risk of resistance for the active substance: low
- Inherent agronomic risk for resistance development: low

In conclusion, even if the inherent risk for the target weeds can be high, considering the fact that the inherent risk of resistance for the active substance is very low and that the inherent agronomic risk for resistance development is low, it can be concluded that the risk of resistance with **ADM.01851.H.1.A used according to the GAP is low.**

Comments of zRMS on resistance risk:

The reasoning of the applicant is correct and consistent with the EPPO guideline 1/213(3) Resistance risk analysis.

Consulting the weedscience.org database in Feb. 2025 revealed no new records of weeds in Europe that would show reduced sensitivity to the actives of either HRAC 4 or HRAC 15 group, in the years of 2021-2024.

The two active substances of ADM.01851.H.1.A represent two modes of action unrelated to one another, to none of which any specific cross-resistance is known in weeds potentially resistant to the other active of the pair. Being co-formulated, these actives thereby constitute mutual safety measure against the risk of resistance in target weeds.

Moreover, the appropriate risk-mitigating measures proposed by the applicant and already introduced into the product label, with crop rotation and the resulting rotation of herbicides` MsoA in the first place, when used, are in most cases sufficient to prevent resistance from emerging in weed populations at economically important levels. Other resistance-preventing measures such as mechanical control resulting from non-reduced tillage, field scouting for survivors and vigilance in selecting MoA for consecutive applications, are part of commonly acknowledged set of rules which, when applied, also contribute to sustainable weed control.

All these and more have been placed by the applicant in the product label, to be observed by the end user. In light of all the directions for sustainable crop protection, farmer must be considered an important actor of the resistance-management play, and must have their respective share of responsibility apportioned, much alike all the other stakeholders.

The issue of risk of resistance development has been addressed adequately, with the risk correctly concluded as low.

To the [zRMS abstract](#)

3.4 Adverse effects on treated crops (KCP 6.4)

Information on trials submitted (3.4: Adverse effects on treated crops)

A total of 10 specific selectivity trials in weed free conditions were carried out in sugar beet. Trials were conducted in 2022 and 2023, 8 in the North-East EPPO zone (Poland), and 2 in the Maritime EPPO zone (Germany) in order to assess the adverse effects of ADM.01851.H.1.A on sugar beets.

For the North-East EPPO zone, in addition to the results from trials carried out in Poland, the German results are used as complementary data.

Table 3.4-1: Presentation of trials (selectivity trials, transformation trials...)

Crop	Country	Years	Type of trial*	Number of trials (number of valid trials)		GEP, non-GEP, official**
				North-East zone	Maritime zone	
Sugar beet (BEAVA)	PL	2022	S+Y+Q	2 (2)	-	GEP
		2023	S+Y+Q	6(6)		
	DE	2023	S+Y+Q	-	- 2 (2)	GEP
TOTAL				8 (8)	2 (2)	-
				10 (10)		

* According to the GAP table

** S = selectivity trial, Y = trial with yield assessment, Q = trial with quality assessment, T = trial on the basis of the study of impact on transformation process (TP: Physical transformation, TF: transformation involving microbial fermentation), P = trial with assessment of impact on propagation

*** Official: carried out by a national official organisation

ADM.01851.H.1.A was applied up to twice the maximum requested dose rate in all trials. The effects of ADM.01851.H.1.A were compared to a standard product applied at N and 2N rates.

In addition, the phytotoxicity on crop was assessed in the 11 efficacy trials presented in point 3.2.3 of this dossier. Selectivity results of these efficacy trials are presented in this section 3.4.

Reference products used in the trials are presented in the following table.

Table 3.4-2: Presentation of reference standards used in trials (selectivity trial)

Reference standard	Active substance(s)	Formulation		Countries where the product is registered	Authorization number	Registered application rate (post-emergence)	Application rate per treatment in trials
		Type	Concentration of a.s.				
FSG 01095 H (Torrero)	Metamitron + ethofumesate	SC	350 g/L + 150 g/L	Poland Germany	R-172/2017 025037-00/00001	2.0 L/ha per application 2.0 L/ha per application	3*2.0 & 3*4.0 L/ha 3*2.0 & 3*4.0 L/ha

- (1) only on use(s) applied for (with the test product)
(2) e.g. WP (wetable powder), EC (emulsifiable concentrate), etc.
(3) Dose / dose range authorized in the country
(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application...)

Table 3.4-3: List of the selectivity trials

EPPO zone	Country	Year	Trial ID	Testing facility	GEP or not GEP
North-East	Poland	2022	PL22HSBEAVA010A	Fertico Sp. z o.o.	GEP
North-East	Poland	2022	PL22HSBEAVA010B	Staphyt Sp. z o.o.	GEP
North-East	Poland	2023	PL23HSBEAVA003A	Agreco Sp. z o.o.	GEP
North-East	Poland	2023	PL23HSBEAVA003B	Fertico Sp. z o.o.	GEP
North-East	Poland	2023	PL23HSBEAVA003C	Fertico Sp. z o.o.	GEP
North-East	Poland	2023	PL23HSBEAVA003D	Fertico Sp. z o.o.	GEP
North-East	Poland	2023	PL23HSBEAVA003E	Fertico Sp. z o.o.	GEP
North-East	Poland	2023	PL23HSBEAVA003F	Staphyt Sp. z o.o.	GEP
Maritime	Germany	2023	DE23HSBEAVA125A	BioChem agrar GmbH	GEP
Maritime	Germany	2023	DE23HSBEAVA125B	Biochem Agrar GmbH	GEP

Table 3.4-4: Details on trial methodology - 18 selectivity trials

Guidelines	General guidelines	EPPO PP 1/135(4), 1/152(4), 1/181(4), 1/225(2) (18 trials)
	Specific guidelines	EPPO PP 1/52(3) (16 trials)
Experimental design	Plot design	Randomised complete blocks (10 trials)
	Plot size	21-39 m²
	Number of rep.	3 replications (10 trials)
Crop	Trials per crop	Sugar beet (10 trials)
	Varieties per crop	Eliska KWS, Doppler, Smart Manja KWS, BTS 6000 RHC, Viola KWS, Orlik, Kujavia, BTS1985, BTS3865, KWS Smart Janninka
	Sowing period	From 30/03 to 04/05
Application	Number and interval	3 applications (10 trials - PL and DE) - 7-21 days interval
	Crop stage (BBCH) at application	A: BBCH 10 B: BBCH 11-14 C: BBCH 13-17
	Timing	Post-emergence of the crop
	Equipment	Experimental plot sprayers with a boom and several nozzles
	Spray volumes	200-300 L/ha (10 trials)
	Test product rates	Polish trials: 0.66 and 1.32 L/ha (8 trials) German trials: 0.66 and 1.32 L/ha ; 0,5 L/ha and 1,0 L/ha (2 trials)
Assessment	Assessment types	- Phytotoxicity as % of total leaf area affected by symptom where 0% = no phyto and 100% = crop destroyed - Crop vigour as % in comparison with the untreated, where 100% = the most vigorous plot within the trial area <u>At harvest:</u> - Fresh root weight (kg) - per harvested plot - Yield (t/ha) - per harvested plot

		- Sugar content in roots (%) and sugar yield (T/ha) - per harvested plot - Sodium content in roots (mmol/100g) - Potassium content in roots (mmol/100g) - Nitrogen content in roots (mmol/100g)
	Statistical analysis	Data were then analysed using a two-way ANOVA on untransformed or transformed data. The probability of non-significant differences occurring between treatment means is calculated as the F probability value p(F). Student-Newman-Keuls multiple comparison test was applied to separate any significant treatment differences that may be implied by the ANOVA and these are indicated by a letter: treatment means with at least one letter in common are not significantly different according to the test initiated at the 95% confidence level.
	Assessment dates	0; 15; 30 till 161 days after last application, BBCH 39 and at harvest
Other information	Field / greenhouse	Field (10 trials)
	Weeds	Weed free conditions (10 trials)

The following EPPO guidelines were followed:

PP 1/135(4)	Phytotoxicity assessment
PP 1/152(4)	Design and analysis of efficacy evaluation trials
PP 1/181(4/5)	Conduct and reporting of efficacy evaluation trials including GEP
PP 1/225(2)	Minimum effective dose
PP 1/52(3)	Weeds in sugar and fodder beet and industrial chicory

Treatments

ADM.01851.H.1.A was applied at N rate (i.e. a total dose rate of 1.98 L/ha: 3*0,66 L/ha in Polish trials and German trials) and at 2N rate (i.e. a total dose rate of 3.96 L/ha: 3*1,32 L/ in Polish trials and German trials). The standard FSG 01095 H was also applied at N and 2N rates. Details of the treatments are given in the following table (for more details also see Table 3.4-2).

Assessments

Crop selectivity was visually assessed at various intervals after application, in the form of a percentage relative to untreated plots. It was measured on a scale of phytotoxicity (%), 0 to 100.

Yield assessments were done, alongside with quality measurements such as sugar content (%), sugar yield (T/ha), sodium, potassium and amino-nitrogen contents (mmol/100g or mmol/1000g).

Table 3.4-5: Treatments applied in the selectivity trials

Treatment	Active substances	Product name	Rate	Timing
North-East EPPO and Maritime EPPO zone				
Test product N rate	Ethofumesate 500 g/L + clopyralid 75 g/L	ADM.01851.H.1.A	0.66 L/ha	ABC
Test product 2N rate	Ethofumesate 500 g/L + clopyralid 75 g/L	ADM.01851.H.1.A	1.32 L/ha	ABC
Standard N rate	Metamitron + ethofumesate 350+150 g/L	FSG 01095 H	2.0 L/ha	ABC
Standard 2N rate	Metamitron + ethofumesate 350+150 g/L	FSG 01095 H	4.0 L/ha	ABC

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Results for North-East EPPO zone

- Selectivity trials - 8 Polish trials:

ADM.01851.H.1.A was applied up to 3*1.32 L/ha (2N rate in Poland) in 8 selectivity trials conducted in 2022 -2023 on the following crop varieties:

Eliska KWS, Doppler, Viola KWS, Orlik, Kujavia, BTS1985, BTS3865, KWS Smart Janninka

The results are presented in the following table.

Table 3.4-6: General phytotoxicity of ADM.01851.H.1.A in the selectivity trials - North-East EPPO zone - Summary table

Number of trials with...		ADM.01851.H.1.A		Standard	
		N (3*0.66 L/ha)	2N (3*1.32 L/ha)	N	2N
Maximum of phytotoxicity recorded during the trials	0%	8/8	8/8	8/8	8/8
	> 0% to 5%	0/8	0/8	0/8	0/8
	> 5% to 10%	0/8	0/8	0/8	0/8
	> 10% to 15%	0/8	0/8	0/8	0/8
	> 15%	0/8	0/8	0/8	0/8
Level of symptoms at the last assessments	0%	8/8	8/8	8/8	8/8
	> 0% to 5%	0/8	0/8	0/8	0/8
	> 5% to 10%	0/8	0/8	0/8	0/8
	> 10% to 15%	0/8	0/8	0/8	0/8
	> 15%	0/8	0/8	0/8	0/8

No symptoms of phytotoxicity and no loss of crop vigor were observed in any of the 8 selectivity trials, at any assessment date and for any treatment.

- Efficacy trials - 9 Polish trials:

ADM.01851.H.1.A was applied up to 3*0.66 L/ha (N rate for Poland) in 9 trials efficacy implemented in 2022 and 2023 on the following crop varieties:

Smart Latoria KWS, Graciana KWS, Viola KWS, Mazovia, BTS1985, Jadwiga Rh, BTS SMART 9635 , Eliska, KWS Smart Janinka

The results are presented in the following table.

Table 3.4-7: General phytotoxicity of ADM.01851.H.1.A in the efficacy trials - North-East EPPO zone - Summary table

Number of trials with...		ADM.01851.H.1.A N (3*0.66 L/ha)	Standard N
Maximum of phytotoxicity recorded during the trials	0%	9/9	8/9
	> 0% to 5%	0/9	0/9
	> 5% to 10%	0/9	0/9
	> 10% to 15%	0/9	1/9
	> 15%	0/9	0/9
Level of symptoms at the last assessments	0%	9/9	9/9
	> 0% to 5%	0/9	0/9
	> 5% to 10%	0/9	0/9
	> 10% to 15%	0/9	0/9
	> 15%	0/9	0/9

No phytotoxicity symptoms were observed with ADM.01851.H.1.A applied at 3*0.66 L/ha. Acceptable (<15%) and transient phytotoxicity symptoms were observed in 1 out of 9 trials with the standard FSG 01095 H (TORERO 500 SC) applied at 1N dose rate. Phytotoxicity symptoms observed on treatments had disappeared at the end of the trials.

Results of the Maritime EPPO zone

Selectivity trials - 2 German trials:

ADM.01851.H.1.A was applied up to 3*1.32 L/ha in 2 selectivity trials implemented in 2023 on the following crop varieties: Smart Manja KWS, BTS 6000 RHC
The results are presented in the following table.

Table 3.4-8: General phytotoxicity of ADM.01851.H.1.A in the selectivity trials - Maritime EPPO zone - Summary table

Number of trials with...		ADM.01851.H.1.A		Standard	
		N (3*0.66 L/ha)	2N (3*1.32 L/ha)	N	2N
Maximum of phytotoxicity recorded during the trials	0%	2/2	1/2	1/2	1/2
	> 0% to 5%	0/2	0/2	1/2	0/2
	> 5% to 10%	0/2	1/2	0/2	1/2
	> 10% to 15%	0/2	0/2	0/2	0/2
	> 15%	0/2	0/2	0/2	0/2
Level of symptoms at the last assessments	0%	2/2	2/2	2/2	2/2
	> 0% to 5%	0/2	0/2	0/2	0/2
	> 5% to 10%	0/2	0/2	0/2	0/2
	> 10% to 15%	0/2	0/2	0/2	0/2
	> 15%	0/2	0/2	0/2	0/2

Very slight and transient phytotoxicity symptoms were observed in 1 out of 2 selectivity trials with the 2N (1,32 L/ha; 1,0 L/ha) rate of ADM.01851.H.1.A at 7 DA-A (A1) and 13 DAA/3 DAB (A2); also phytotoxicity symptoms were observed on standard product's treatments for both 1N and 2N. In all trials, these symptoms were equivalent to those of the reference products. The symptoms had disappeared at the end of the trials. A slight loss of crop vigor was observed in trial but was no longer observed when the phytotoxicity symptoms disappeared.

- Efficacy trials –2 German trials:

ADM.01851.H.1.A was applied up to 3*0.66 L/ha (N rate for Germany and Poland) in 2 trials efficacy implemented in 2023 on the following crop varieties: Cabriana, Calledia

The results are presented in the following table.

Table 3.4-9: General phytotoxicity of ADM.01851.H.1.A in the efficacy trials - Maritime EPPO zone - Summary table

Number of trials with...		ADM.01851.H.1.A N (3*0.66 L/ha)	Standard N
Maximum of phytotoxicity recorded during the trials	0%	2/2	2/2
	> 0% to 5%	0/2	0/2
	> 5% to 10%	0/2	0/2
	> 10% to 15%	0/2	0/2
	> 15%	0/2	0/2
Level of symptoms at the last assessments	0%	2/2	2/2
	> 0% to 5%	0/2	0/2
	> 5% to 10%	0/2	0/2
	> 10% to 15%	0/2	0/2
	> 15%	0/2	0/2

No symptoms of phytotoxicity and no loss of crop vigor were observed in any of the 2 efficacy trials, at any assessment date and for any treatment.

Conclusion of selectivity

According to the results of 8 selectivity trials and 9 efficacy trials carried out in the North-East EPPO zone (Poland) in 2022 and 2023, ADM.01851.H.1.A applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (i.e. a total rate of 1.98 L/ha) is safe to sugar beet.

According to the results of 2 selectivity trials and 2 efficacy trials carried out in the Maritime EPPO zone (Germany) in 2023, ADM.01851.H.1.A applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (i.e. a total rate of 1,98 L/ha) is safe to sugar beet.

Regarding beet crops, the agronomic conditions and cultural practices in Germany (Maritime EPPO zone) is very close to what is encountered in Poland (North-East EPPO zone). Moreover, the climatic conditions at application were globally homogeneous from a climatic zone to another. Thus, complementary data from Germany is considered as supportive to evaluate the selectivity of ADM.01851.H.1.A on sugar beet in Poland.

Comments of zRMS on selectivity of ADM.01851.H.1.A:

Indeed, as described by the applicant, the only phytotoxic symptoms caused by the test item occurred in a single selectivity trial (reported in KCP 6.2-02_DE23HSBEAVA125B.pdf) in plots treated with 2N dose rate of ADM.01851.H.1.A.

The symptoms of 10 – 7.3 % intensity (7 DAA – 3 DAB respectively) have been described as “necrosis /burn” and accompanied by some decline in plant vigor (8.8 – 9.0 on a 0-10 scale; 7 DAA – 3 DAB respectively). The symptoms had receded and the plant vigor returned back to normal already on the assessment 4 days later, at 7 DAB, and stayed so until the end of the trial.

Therefore it has been concluded that when applied up to 0.66 L/ha and maximum 3 times per growth season as claimed in the GAP table, the ADM.01851.H.1.A is safe to sugar beet crop.

[#zRMS_Abstract](#)

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

The yield of crop was evaluated in the 11 selectivity trials.

Results for North-East EPPO zone - 8 Polish trials 2022-2023:

ADM.01851.H.1.A was applied up to 3*1.32 L/ha (2N rate in Poland) in 8 selectivity trials implemented in 2022 -2023 on the following crop varieties:

Eliska KWS, Doppler, Viola KWS, Orlik, Kujavia, BTS1985, BTS3865, KWS Smart Janninka

Yield results are presented in the following table.

Table 3.4-10: Yield of sugar beet roots with ADM.01851.H.1.A applied 3 times - North-East EPPO zone - 8 selectivity trials

Treatment	UNCK		ADM.01851.H.1.A				FSG 01095 H			
			0,66 L/ha 1N		1,32 L/ha 2N		2,0 L/ha 1N		4,0 L/ha 2N	
n=8	mean	range	mean	range	mean	range	mean	range	mean	range
YIELD (t/ha)	70,7	57,3-87,6	71,7	59,1-88,3	70,61	58,7-89,0	70,9	58,8-86,6	70,5	57,7-87,0
YIELD (% UNCK)			102,0	95-110,5	100,1	93-104,0	100,6	94-106,0	100,6	94-107,0

ADM.01851.H.1.A at N and 2N rates showed yield results comparable to that of the untreated control and the standard (FSG 01095 H). The differences were not statistically significant in any trial.

Complementary results in Maritime EPPO zone - 2 German trials 2023:

ADM.01851.H.1.A was applied up to 3*1.32 L/ha (2N rate in Poland and Germany) in 2 selectivity trials implemented in 2023. Yield results are presented in the following table.

Table 3.4-11: Yield of sugar beet roots with ADM.01851.H.1.A applied 3 times - Maritime EPPO zone 2023 - 2 selectivity trials

Treatment	UNCK		ADM.01851.H.1.A				FSG 01095 H			
			0,66 L/ha 1N		1,32 L/ha 2N		2,0 L/ha 1N		4,0 L/ha 2N	
n=2	mean	range	mean	range	mean	range	mean	range	mean	range
YIELD (t/ha)	68,9	61,8-76,1	68,7	61,6-75,7	68,4	62,1-74,6	70,3	63,9-76,6	70,2	63,4-77
Yield (% UNCK)			100,4	100,3-100,4	100,05	99,1-101	103,10	101,9-104,3	102,60	102-103,2

ADM.01851.H.1.A at N and 2N rates showed yield results comparable to that of the untreated control and the standard (FSG 01095 H). The differences were not statistically significant in any trial.

Conclusion on the effect on yield:

According to the results of 8 selectivity trials carried out in the North-East EPPO zone (Poland) in 2022-2023, ADM.01851.H.1.A applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (corresponding to a total dose rate of 1.98 L/ha) has no negative impact on the yield of the treated beets.

According to the results of 2 selectivity trials carried out in the Maritime EPPO zone (Germany) in 2023, ADM.01851.H.1.A applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (corresponding to a total dose rate of 1,98 L/ha) has no negative impact on the yield of the treated beets.

Regarding beet crops, the agronomic conditions and cultural practices in Germany (Maritime EPPO zone) is very close to what is encountered in Poland (North-East EPPO zone). Moreover, the climatic conditions at application were globally homogeneous from a climatic zone to another. Thus, complementary data from Germany are considered as supportive to evaluate the impact of ADM.01851.H.1.A on the yield of treated beets in Poland.

Comments of zRMS on yield:

No negative effect of ADM.01851.H.1.A on yield amount of sugar beet has been concluded.

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

The following quality parameters of the treated roots were evaluated in the 10 selectivity trials: sugar content (%), sugar yield (T/ha), sodium content, potassium content and amino-nitrogen content.

Results for North-East EPPO zone - 8 Polish trials, 2022-2023:

ADM.01851.H.1.A was applied up to 3*1.32 L/ha (2N rate in Poland) in 8 selectivity trials implemented in 2022-2023. Quality results are presented in the following table.

Table 3.4-12: Quality parameters of treated roots - North-East EPPO zone - 8 selectivity trials

Treatment	UNCK		ADM.01851.H.1.A				FSG 01095 H			
			0,66 L/ha 1N		1,32 L/ha 2N		2,0 L/ha 1N		4,0 L/ha 2N	
	mean	range	mean	range	mean	range	mean	range	mean	range
sugar content										
n= 8	16,33	14,89-18,20	16,38	14,58-18,41	16,43	14,9-18,29	16,43	14,95-18,23	16,51	14,91-18,64
sugar yield per ha										
n= 7	11,97	9,74-15,84	12,04	9,44-16,26	12,00	9,46-16,20	12,01	9,83-15,80	12,05	9,93-15,76
Potassium content (mmol per 1000g)										
n= 7	46,96	39,05-59,00	49,33	41,6-64,25	48,72	41,45-62-38	46,24	37,78-58,68	46,26	39,45-57,83
Amino-nitrogen content (mmol per 1000g)										
n= 7	20,40	13,03-29,70	22,26	11,68-33,20	22,33	12,45-31,86	21,30	11,7-31,70	21,37	12,6-29,90
Sodium content (mmol per 1000g)										
n=7	6,86	3,75-9,20	7,64	3,8-11,50	7,39	3,9-11,30	6,92	4,4-8,85	6,39	3,9-9,13

ADM.01851.H.1.A at N and 2N showed quality parameters of roots comparable to that of the untreated control and the zonal standard product. The differences were not statistically significant in any trial.

Complementary results in Maritime EPPO zone - 2 German trials, 2023:

ADM.01851.H.1.A was applied up to 3*1.32 L/ha (2N rate in Germany and Poland) in 2 selectivity trials implemented in 2023.

Quality results are presented in the following table.

Table 3.4-13: Quality parameters of treated roots - Maritime EPPO zone - 2 selectivity trials

treatment	UNCK		ADM.01851.H.1.A				FSG 01095 H			
			0,66 L/ha 1N		1,32 L/ha 2N		2,0 L/ha 1N		4,0 L/ha 2N	
	mean	range	mean	range	mean	range	mean	range	mean	range
sugar content										
n= 2	16,05	15,4-16,70	16,20	15,4-17,00	16,60	15,2-18,00	15,00	14,6-15,40	15,10	14,7-15,50
sugar yield per ha										
n= 1	10,31	10,31	10,50	10,50	11,14	11,14	9,32	9,32	9,28	9,28
Potassium content (mmol per 1000g)										
n= 2	43,25	41,8-44,7	45,05	44,90-45,2	44,3	42,40-46,2	43,25	42,90-43,6	43,15	42,20-44,1
Amino-nitrogen content (mmol per 1000g)										
n= 2	20,9	13,3-28,50	20,8	12,6-29,00	21,95	14,8-29,10	20,55	13,7-27,40	21,3	13-29,60
Sodium content (mmol per 1000g)										
n= 2	5,5	4,1-6,90	5,5	4,4-6,60	5,4	4,4-6,40	4,95	3,9-6,00	5,05	4-6,10

ADM.01851.H.1.A at N and 2N showed quality parameters of roots comparable to that of the untreated control and the zonal standard product. The differences were not statistically significant in any trial.

Conclusion on the effect on quality :

According to the results of 8 selectivity trials carried out in the North-East EPPO zone (Poland) in 2022-2023, ADM.01851.H.1.A applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (corresponding to a total dose rate of 1.98 L/ha) has no negative impact on the quality of the treated roots.

According to the results of 2 selectivity trials carried out in the Maritime EPPO zone (Germany) in 2023, ADM.01851.H.1.A applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (corresponding to a total dose rate of 1,98 L/ha) has no negative impact on the quality of the treated roots.

Regarding beet crops, the agronomic conditions and cultural practices in Germany (Maritime EPPO zone) are very close to what is encountered in Poland (North-East EPPO zone). Moreover, the climatic conditions at application were globally homogeneous from a climatic zone to another. Thus, complementary data from Germany are considered as supportive to evaluate the impact of ADM.01851.H.1.A on the quality of the treated roots in Poland.

Comments of zRMS on yield QUALITY:

The results of 10 selectivity trials including 8 trials Poland and 2 - from Germany allow to conclude that no unwelcome effects of the ADM.01851.H.1.A applied according to label directions should be expected on parameters affecting root quality and / or the process of sugar extraction from them.

3.4.4 Effects on transformation processes (KCP 6.4.4)

Not relevant for sugar beets.

~~The effect of ADM.01851.H.1.A on sugar content was addressed in point 3.4.3 Effects on the quality of plants or plant products.~~

Comments of zRMS:

Accepted: sugar extraction from beet roots is not transformation process as defined in EPPO guideline PP 1/243 (2).

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Results from 11 efficacy trials and 10 selectivity trials on sugar beet showed that ADM.01851.H.1.A applied according to the recommendations up to a total of 1.98 L/ha (3*0.66 L/ha) is safe to sugar beets therefore no adverse effects on treated plants or plant products to be used for propagation are expected.

Yield results from 10 selectivity trials carried out in 2022-2023 showed that ADM.01851.H.1.A applied up to a total of 1.98 L/ha (3*0.66 L/ha) has no negative impact on the yield of the treated beets.

Results from 10 selectivity trials carried out in 2022 and 2023 showed that ADM.01851.H.1.A applied up to a total of 1.98 L/ha (3*0.66 L/ha) has no negative impact on the sugar content, sugar yield, sodium content, potassium content and amino-nitrogen contents of the treated roots.

No impact on treated plants or plant products used for propagation is expected.

Comments of zRMS:

The absence of effect on root yield amount and yield parameters, as described by the applicant, does not mean by default that no effect on seed viability can be anticipated, should the product be used in the seed-producing plantations. Since TAXATUM is a new mixture of known actives, the effects on plant parts used for propagation should be documented with new data. EPPO guideline PP 1/135 (4) Phytotoxicity assessment defines situations in which data on effects on propagating material are required. According to the Table 2 in that guideline, possible approval of the product in the seedling protection in autumn, or in the seed plantations in spring, would require data confirming that there is no effect on the vigor and growth of mother plants and pollinator plants (Table 2, *Bulbs and corms, herbicides, Post-emergence of the crop: Yes*).

When inquired about the relevant data to address the 3.4.5, the applicant declared that the test item ADM.01851.H.1.A is not intended for the protection of seed plantations in any phase of seed production (neither in autumn nor in spring). The respective statement has been also introduced, by the applicant, to the product label.

Summary and conclusion

Results from 11 efficacy trials and 10 selectivity trials on sugar beet showed that ADM.01851.H.1.A applied according to the recommendations up to a total of 1.98 L/ha (3*0.66 L/ha) is safe to sugar beets*.

~~Observations on other undesirable or unintended side effects (KCP 6.5)~~

*Comments of zRMS:

*Only on condition that ADM.01851.H.1.A is not used to control weeds in seed-producing plantations of the crop, since the effect on growth and seed-setting process had not been investigated for the present dossier. As the result of the communication between the evaluator and the applicant this restriction has now been placed in the product's national label.

3.4.6 Impact on succeeding crops (KCP 6.5.1)

This section has been prepared in accordance with the EPPO guideline PP 1/207 (2) "Effects on succeeding crops". The study on the toxicity to non-target terrestrial plants has been carried out with ADM.01851.H.1.A. For further details please refer to Terrestrial Plant Test according to ~~OECD 227~~ **OECD 208** presented in details in the Section 9 of the dRR (chapter 9.10).

For ER50 values of the tested species please refer to table below.

Table 3.5 1: ER50 values of different test plants

Succeeding crop	Exposure system	ER50 L product/ha	Reference
<i>Avena sativa</i> m ¹⁾ <i>Triticum aestivum</i> m ²⁾ <i>Glycine max</i> d ³⁾ <i>Vicia faba</i> d ⁴⁾ <i>Lactuca sativa</i> d ⁵⁾	21 d Seedling emergence	2, 3, 4, 5) ER ₅₀ emergence > 0.413 L prod./ha 2, 3, 4, 5) ER ₅₀ survival > 0.413 L prod./ha 3, 4) NOER phytotoxicity = 0.0176 L prod./ha 2) ER ₅₀ plant height = 0.329 L prod./ha 1) ER ₅₀ shoot dry weight = 0.239 L prod./ha	Friedemann A./ 2024a / 23 46 PSE 0012

m: monocotyledonous; d: dicotyledonous

In the study ER₅₀ values were indicated as L prod./ha therefore, ER₅₀ were recalculated to ER₅₀ expressed as mg product/kg soil, taking into consideration: bulk density of soil = 1.5 g/cm³ and soil depth 5 cm. ER₅₀ shoot dry weight for *A. sativa* was taking into consideration. PEC_s value was calculated for the initial PECsoil value for the formulation ADM.01851.H.1.A using the single application rate of 0.66 L/ha as a worst case and the formulation density of 1.1622 g/mL. The crop interception of 20% was assumed.

Table 3.5 2: TER calculation of ADM.01851.H.1.A based on ER50-values

Succeeding crop	ER50 ₀ (mg product/kg soil)	PEC _s (mg product/kg soil), 5 cm	TER (ER ₅₀ /PEC _s) criterion: TER >1
<i>Avena sativa</i> (worst case)	3.693	0.818	4.515

Conclusions:

The respective TER values are >1, as requested in EPPO guideline PP 1/207, therefore no further testing is required.

Comments of zRMS on 3.4.6 Impact on succeeding crops:

Data to address the 3.4.6 has been selected from the test report by A. Friedemann (Friedemann A./ 2024a / 23 46 PSE 0012).

The application rate 0.66 L/ha product has been converted correctly into initial PEC_{soil} = of 0.818 mg product per kg soil, according to the EPPO guideline PP 1/207 *Effects on succeeding crops*. The ER₅₀ = 0.239 L/ha, assumed as the worst case for dry shoot weight of *Avena sativa*, represents single application of 0.66 L / ha formulated product. It has been converted into ER₅₀ of **3.693** mg / kg soil (actually the EC: effective concentration). The value of TER calculated subsequently is 4.515 >1 which, according to EPPO PP 1/207, **seems to allow** for “no risk” conclusion. While the method of conversion has not been explained by the applicant, using formula proposed in the EPPO 1/207 (with interception factor = 0) converts ER₅₀ of 0.239 L/ha into **0.370**, instead of 3.693 mg / kg soil, with the resulting TER=**0.453** < 1. Moreover, the applicant is using the endpoint of ER₅₀ - as if following OECD 208 method - instead of ER₁₀ - as stipulated by EPPO PP 1/207 guideline. Using ER₁₀ = 0.0863 L / ha, that is also available in the report by Friedmann (2024a), and converting it into soil concentration by the same formula (EPPO 1/207) (0.134 mg /kg soil), results in the TER=**0.164** <1.

Consequently, the risk to succeeding crops, and even more to replacement crops, has been concluded as resulting from the application of ADM.01851.H.1.A according to the claimed pattern. The issue remains unresolved and should be subject to further elaboration by the applicant.

In the meantime, the label phrase has been proposed, meant to prevent cultivation - as replacement crops - of plants other than sugar beet in case of earlier termination of the treated BEAVA crop.

To the [zRMS abstract](#)

3.4.7 Impact on other plants including adjacent crops (KCP 6.5.2)

This section has been prepared in accordance with the EPPO guideline PP 1/256 (2) “Effects on adjacent crops”.

The study on the toxicity to non-target terrestrial plants has been carried out with ADM.01851.H.1.A. For further details please refer to Terrestrial Plant Test according to OECD 227 (presented in details in the Section 9 of the dRR (chapter 9.10)).

Table 3.5 2: ER50- values of different test plants

Species	Substance	Exposure System	Results	Reference
<i>Lepidium sativum</i> ^{d 1)} <i>Glycine max</i> ^{d 2)} <i>Lycopersicon esculentum</i> ^{d 3)} <i>Vicia faba</i> ^{d 4)} <i>Lactuca sativa</i> ^{d 5)} <i>Fagopyrum esculentum</i> ^{d 6)}	ADM.01851.H.1.A	21 d Vegetative vigour	1,2,3,4,5,6) ER ₅₀ survival > 0.188 L prod./ha 2) NOER phytotoxicity = 0.00802 L prod./ha 2) ER ₅₀ plant height = 0.0712 L prod./ha 4) ER₅₀ shoot dry weight = 0.0537 L prod./ha	Friedemann A./ 2024b / 23 46 PVV 0011

For three applications in beet root, 2.77 % of application rate was assumed to reach areas at 1 m from the edge of the crop (worst case scenario). The application rate 3 x 0.66 L product/ha, giving a maximum off-field predicted environmental rate PER_{off-field} (MAF for 3 applications=2.7) of 0.049 L product /ha.

Table 3.5 2: PER_{off field} (L product/ha) values for triple application (drift) in sugar beet with maximum use rate 3 x 0.66 L product/ha, according Rautmann (2001)

Single application rate (L/ha)	% drift	MAF	PER _{off-field} (L product/ha)
0.66	2.77	2.7	0.049

MAF: Multiple application factor; PER: Predicted environmental rate;

Table 3.5 3: TER for ADM.01851.H.1.A on vegetative vigour

Test product	ER ₅₀ * (L product/ha)	PER _{off-field} (L product/ha)	TER (ER ₅₀ / PER _{off-field}) criterion: TER >1
ADM.01851.H.1.A	0.0537	0.049	1.096

*Based on shoot dry weight, PER: Predicted environmental rate; TER: toxicity to exposure ratio;

Conclusions:

An acceptable risk is indicated for terrestrial non-target plants, at minimum distance. The respective TER values are >1, as requested in EPPO guideline PP 1/256. No further testing is required.

Comments of zRMS on 3.4.7 Impact on other plants including adjacent crops:

The ER₅₀ and PER_{off-field}, **obtained from Ecotox and Fate sections** respectively, have been used in accordance with the EPPO guidance PP 1/256, to calculate TER value and to estimate risk to adjacent crops. **TER > 1 enables to conclude no risk for adjacent crops**, with no further testing necessary.

However, relying on the trials not specifically designed for Efficacy section is inappropriate, the more that, the same as 3.4.6, the 3.4.7 has its own respective EPPO guideline, following which should make it possible to address the issue adequately.

To the [zRMS abstract](#)

3.4.8 Effects on beneficial and other non-target organisms (KCP 6.5.3)

No adverse effect of ADM.01851.H.1.A on beneficial and other non-target organisms was reported in the efficacy and selectivity trials presented in this dossier.

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

3.5 Other/special studies

No other/special studies are presented in the dossier.

3.6 List of test facilities including the corresponding certificates

Table 3.6-1: List of test facilities

Test facility	Address	Certificate (Yes or No)
Fertico Sp z o.o.	Goliany 43, 05-620 Błędów, Poland	Y
Agreco Sp z o.o.	al. Lipowa 21, lok. 1, 53-124 Wrocław, Oddział: Gać 64A, 55-200 Oława, Poland	Y
Staphyt Sp z o.o.	ul, Poznanska 62/53; 60-853 Poznań, Poland	Y
Field Research Support	Field Research Support Max-Planck-Straße 5 D- 31515 Wunstorf, Germany	Y
Agricola	Tannenstraße 2; D-94339 Leiblfing, Germany	Y
BioChem agrar GmbH	Kupferstraße 6, 04827 Machern, Germany	Y

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1-01	Dagmar von Hörsten	2023	Efficacy of ADM.01851.H.1.A with 3 applications against broadleaves weeds on sugar beets, in Gemrnay Trial ID: DE23HEBEAVA123C Company Report No FRS016/23 GEP Unpublished	Y	ADAMA
KCP 6.1.02	PD Dr. agr. habil. Peter Wolf	2023	Efficacy of ADM.01851.H.1.A with 3 applications against broadleaves weeds on sugar beet, in Germany in 2023 Trial ID: DE23HEBEAVA123D GEP Unpublished	Y	ADAMA
KCP 6.2-01	Udo Zickart	2023	Selectivity of ADM.01851.H.1.A on sugar beet, in Germany in 2023 Trial ID: DE23HSBEAVA125A GEP Unpublished	Y	ADAMA
KCP 6.2-02	Karl-Wilhelm Maßmann	2023	Selectivity of ADM.01851.H.1.A on sugar beet, in Germany in 2023 Trial ID: DE23HSBEAVA125B GEP Unpublished	Y	ADAMA
KCP 6.1-03	dr inż. Justyna Trajdos, PhD	2022	Ocena skuteczności preparatu ADM.01851.H.1.A w zwalczaniu chwastów dwuliściennych w uprawie buraka cukrowego Efficacy of ADM.01851.H.1.A with 3 applications against broadleaves weeds on sugar beet, in Poland in 2022 Trial ID: PL22HEBEAVA008B Report nr: 22ADA01065-2 GEP Unpublished	Y	ADAMA
KCP 6.1-04	Mgr Krzysztof Rusek	2022	Skuteczność preparatu ADM.01851.H.1.A in control of chwastów w uprawie buraka cukrowego, Polska 2022 Efficacy of ADM.01851.H.1.A in weed control in sugar beet, Poland 2022 Report number: 48_01_F22_103 Trial ID: PL22HEBEAVA008C GEP Unpublished	Y	ADAMA

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2-03	Mgr Krzysztof Rusek	2022	Selektywność preparatu ADM.01851.H.1.A stosowanego w zwalczaniu chwastów w uprawie buraka cukrowego.Polska 2022 Selectivity of ADM.01851.H.1.A in weed control in sugar beet, Poland 2022 Report number: 49_02_F22_105 Trial ID: PL22HSBEAVA010A GEP Unpublished	Y	ADAMA
KCP 6.2-04	Mateusz Pszczółkowski	2022	Selectivity of ADM.01851.H.1.A on sugar beet, in Poland in 2022 Trial ID: PL22HSBEAVA010B Report nr: MP2-22-101837-01-PL01 GEP Unpublished	Y	ADAMA
KCP 6.1-05	dr inż. Justyna Trajdos, PhD	2023	Ocena skuteczności preparatu ADM.01851.H.1.A w zwalczaniu chwastów dwuliściennych w uprawie buraka cukrowego ,Polska 2023 Efficacy of ADM.01851.H.1.A with 3 applications against broadleaves weeds on sugar beets, Poland 2023 Trial ID: PLHEBEAVA001A Report nr: 23ADA01249-1 GEP Unpublished	Y	ADAMA
KCP 6.1-06	dr inż. Justyna Trajdos, PhD	2023	Ocena skuteczności preparatu ADM.01851.H.1.A w zwalczaniu chwastów dwuliściennych w uprawie buraka cukrowego ,Polska 2023 Efficacy of ADM.01851.H.1.A with 3 applications against broadleaves weeds on sugar beets, Poland 2023 Trial ID: PLHEBEAVA001B Report nr: 23ADA01249-2 GEP Unpublished	Y	ADAMA
KCP 6.1-07	Adam Szemendera	2023	Skuteczność preparatu ADM.01851.H.1.A in control of chwastów w uprawie buraka cukrowego, Polska 2023 Efficacy of ADM.01851.H.1.A in weed control in sugar beet, Poland 2023 Report nr: 09_01_F23_012 Trial ID: PLHEBEAVA001C GEP Unpublished	Y	ADAMA
KCP 6.1-08	Adam Szemendera	2023	Skuteczność preparatu ADM.01851.H.1.A in control of chwastów w uprawie buraka cukrowego, Polska 2023 Efficacy of ADM.01851.H.1.A in weed control in sugar beet, Poland 2023	Y	ADAMA

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Report nr: 09_02_F23_013 Trial ID: PLHEBEAVA001D GEP Unpublished		
KCP 6.1-09	Mateusz Pszczółkowski	2023	Efficacy of ADM.01851.H.1.A with 3 applications against broadleaves weeds on sugar beet, in Poland in 2023 Report nr: MP2-23-105198-01-PL02 Trial ID: PL23HEBEAVA001F GEP Unpublished	Y	ADAMA
KCP 6.1-10	Mateusz Pszczółkowski	2023	Efficacy of ADM.01851.H.1.A with 3 applications against broadleaves weeds on sugar beet, in Poland in 2023. Report nr: MP2-23-105198-01-PL03 Trial ID: PL23HEBEAVA001G GEP Unpublished	Y	ADAMA
KCP 6.1-11	Mateusz Pszczółkowski	2023	Efficacy of ADM.01851.H.1.A with 3 applications against broadleaves weeds on sugar beet, in Poland in 2023. Report nr: MP2-23-105198-01-PL04 Trial ID: PL23HEBEAVA001H GEP Unpublished	Y	ADAMA
KCP 6.2-05	dr inż. Justyna Trajdos, PhD	2023	Ocena selektywności preparatu ADM.01851.H.1.A w uprawie buraka cukrowego Trial ID: PLHEBEAVA003A Report nr: 23ADA1251-1 GEP Unpublished	Y	ADAMA
KCP 6.2-06	Adam Szemendera	2023	Selektywność preparatu ADM.01851.H.1.A w uprawie buraka cukrowego, Polska 2023 Selectivity of ADM.01851.H.1.A on sugar beet, in Poland, in 2023. Trial ID: PLHEBEAVA003B Report number: 11_01_F23_016 GEP Unpublished	Y	ADAMA
KCP 6.2-07	Adam Szemendera	2023	Selektywność preparatu ADM.01851.H.1.A w uprawie buraka cukrowego, Polska 2023	Y	ADAMA

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Selectivity of ADM.01851.H.1.A on sugar beet, in Poland, in 2023. Trial ID: PLHEBEAVA003C Report number: 11_01_F23_017 GEP Unpublished		
KCP 6.2-08	Adam Szemendera	2023	Selektywność preparatu ADM.01851.H.1.A w uprawie buraka cukrowego, Polska 2023 Selectivity of ADM.01851.H.1.A on sugar beet, in Poland, in 2023. Trial ID: PLHEBEAVA003D Report number: 11_01_F23_018 GEP Unpublished	Y	ADAMA
KCP 6.2-09	Adam Szemendera	2023	Selektywność preparatu ADM.01851.H.1.A w uprawie buraka cukrowego, Polska 2023 Selectivity of ADM.01851.H.1.A on sugar beet, in Poland, in 2023. Trial ID: PLHEBEAVA003E Report number: 11_01_F23_019 GEP Unpublished	Y	ADAMA
KCP 6.2-10	Mateusz Pszczółkowski	2023	Selectivity of ADM,01851,H,1,A on sugar beet, in Poland, in 2023 Trial ID: PL23HSBEAVA003F GEP Unpublished	Y	ADAMA

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