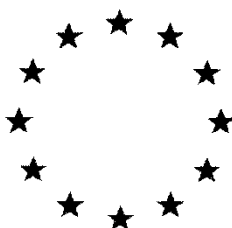


European Commission



**Draft Renewal Assessment Report prepared according to the Commission
Regulation (EU) N° 1107/2009**

Ethofumesate

Volume 3 – B.3 (AS)

Rapporteur Member State: Austria
Co-Rapporteur Member State: Denmark

Version History

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1998	Initial DAR
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B.3. DATA ON APPLICATION

B.3.1. USE OF THE ACTIVE SUBSTANCE

Ethofumesate is used as pre- and post-emergence herbicide in sugar-, fodder- and red beet. It is a well-known standard herbicide, widely used for many years in nearly all sugar beet areas of the world.

Ethofumesate should be used in post-emergence 1 – 3 times in a sequential spray programme. Application can be made from the time the smallest beets are at the cotyledon stage or when the weeds are at the cotyledon stage. A second treatment of Ethofumesate could be applied 5 - 14 days later when the next flush of weeds has reached the cotyledon stage. If further weed control is required, a third application can be made. The last application has to be made at the latest at a BBCH (crop growth stage) of 18.

B.3.2. FUNCTION

Ethofumesate is a broad spectrum herbicide which controls a wide range of annual grasses and broad leaved weeds in beet crops (sugar-, fodder-, red beet).

B.3.3. EFFECTS ON HARMFUL ORGANISMS

Study on biological activity of ethofumesate and its metabolite NC 20645 was provided from the **Task Force Ethofumesate**. However, since the study is not conducted according to GLP or GEP, no data protection can be granted.

No studies were provided from UPL. Since for the study provided by the Task Force Ethofumesate no data protection can be granted (no GEP or GLP studies), this study apply also for the UPL. Additionally, since metabolite NC 20645 is not predicted in groundwater > 0.1 µg/l, no studies on biological activity of the metabolite are considered necessary.

Report:	KCA 3.3 /01;Noeding, S.;2012;M-436350-01
Title:	Evaluation of the pre-emergence biological activity of ethofumesate and its metabolite NC 20645
Report No:	FFS125016
Document No:	M-436350-01-1
Guidelines:	not applicable
GLP/GEP:	no

Objective:

This pre-emergence test was conducted to determine differences in the biological activity of ethofumesate and its metabolite NC 20645. The study was conducted under standardized glasshouse conditions using WP20 formulations of both ethofumesate and its metabolite NC 20645.

Material and methods:

<u>Test Materials</u>	<u>Dose rates (g a.s./ha)</u>
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NC 20645 (= BCS-CU 88901) WP20	250 – 125 – 62.5 – 31.25
Ethofumesate formulated as a WP20	250 – 125 – 62.5 – 31.25
Blind formulation of WP20	1000

Pots were filled to within 2 cm of the top with a silt-loam soil (20% sand, 57% silt, 23% clay, pH 6.8 and 1.4% organic matter). Seeds of four different weed species (see table below) were sown into these pots and covered with 0.5 to 1 cm of the same soil mixed 1 to 1 with sharp sand. The sowing density was selected based on prior experience to provide approximately 60-70% soil cover by the plants at application timing. After sowing the pots were watered slightly.

All compounds used in the test were dissolved in deionized water and diluted to obtain the required dose rates. The pre-emergence application (11 APR 2012) was made using a track-sprayer with a spray volume of 300 L/ha via a flat fan nozzle.

After application, the pots were placed into a glasshouse set $21 \pm 2^\circ\text{C}$ day and $12 \pm 2^\circ\text{C}$ night and watered according to need. High pressure sodium lamps were used to augment daylight during cloudy conditions and to extend the day length to 14 hours.

Two weeks and four weeks after application, the treated plants were visually assessed for injury compared with the untreated control plants.

The assessments were on a percentage basis (0 = no effects, 100 = complete kill).

Table 3.3-1: Plant species tested

Plant species (EPPPO Code)
<i>Avena fatua</i> (AVEFA)
<i>Setaria viridis</i> (SETVI)
<i>Amaranthus retroflexus</i> (AMARE)
<i>Stellaria media</i> (STEME)

Results:

The results of the visual assessments are presented as means from the 2 replicates (first assessment, (14 DAT) and second assessment (28 DAT)).

Table 3.3-2: Results from First assessment (14 DAT):

	g a.s./ha	Monocots		Mean Monocots	Dicots		Mean Dicots
		AVEFA	SETVI		AMARE	STEME	
BCS-CU 88901	250	0	0	0	0	40	20
NC 20645, Ethofumesate metabolite WP20	125	0	0	0	0	35	18
	62.5	0	0	0	0	20	10
	31.25	0	0	0	0	0	0
AE B049913	250	93	45	69	92	80	86
Ethofumesate WP20	125	60	35	48	89	75	82
	62.5	40	25	33	60	65	63

	31.25	0	0	0	50	45	48
WP Blindformulation	1000	0	0	0	0	0	0

Table 3.3-3: Results from Second assessment (28 DAT):

		Monocots AVEF A	SETVI	Mean Monocots	Dicots AMARE	STEME	Mean Dicots
	g a.s./ha						
BCS-CU 88901	250	0	0	0	0	35	18
NC 20645, Ethofumesate metabolite WP20	125	0	0	0	0	25	13
	62.5	0	0	0	0	20	10
	31.25	0	0	0	0	0	0
AE B049913 WP20	250	78	85	81	100	94	97
Ethofumesate WP20	125	45	73	59	95	95	95
	62.5	35	40	38	73	78	75
	31.25	0	25	13	50	60	55
WP Blindformulation	1000	0	0	0	0	0	0

Conclusion:

In a direct comparison study under highly sensitive glasshouse screening conditions, the ethofumesate metabolite NC 20645 showed very low and insignificant biological activity on one weed, *Stellaria media* (STEME). Even 28 DAT a low efficacy against STEME was visible. But compared to the assessed values which were obtained for Ethofumesate it is acceptable.

Therefore it can be concluded that the metabolite NC 20645 (Ethofumesate –carboxylic acid) is not herbicidally active.

Two studies on biological activity of isomers were provided from the **Task Force Ethofumesate**. However, since these studies are not conducted according to GLP or GEP, no data protection can be granted.

No studies were provided from UPL. Since for the studies provided by the Task Force Ethofumesate no data protection can be granted (no GEP or GLP studies), these studies apply also for the UPL.

Report:	KCA 3.3 /02;Noeding, S.;2010;M-401886-01
Title:	Evaluation of the pre-emergence biological activity of ethofumesate and its two enantiomers (enantiomer 1, enantiomer 2)
Report No:	FFS105044
Document No:	M-401886-01-1
Guidelines:	not specified
GLP/GEP:	no

Objective:

The study was conducted under standardized glasshouse conditions using a WP20 formulation of each enantiomer compared to an Ethofumesate SC 500 formulation.

Material and methods:

Test Materials	Dose rates (g a.s./ha)
AE B049913 00 SC45 A2 (Ethofumesate SC500)	2000 – 1000 – 500 – 250 - 125
Enantiomer 1 formulated as a WP20	2000 – 1000 – 500 – 250 - 125
Enantiomer 2 formulated as a WP20	2000 – 1000 – 500 – 250 - 125
Ethofumesate racemate formulated as a WP20	2000 – 1000 – 500 – 250 - 125
Blind formulation of WP20	2000

Jiffy pots (7 cm diameter) were filled to within 2 cm of the top with a silt-loam soil (20% sand, 57% silt, 23% clay, pH 6.8 and 1.4 % organic matter). Seeds of the weed species listed in Table 1 were sown into these pots and covered with 0.5 to 1 cm of the same soil mixed 1 to 1 with sharp sand. After sowing the pots were watered slightly.

All compounds used in the test were dissolved in deionized water and diluted to obtain the required dose rates. The pre-emergence applications (01.07.2010) were made using the Herbicide Research track-sprayer with a spray volume of 300 l/ha via a flat fan nozzle (TeeJet 8001).

After application, the pots were placed into a glasshouse set 16°C+/-2°C day and 12°C+/-2°C night and watered according to need. High pressure sodium lamps (400W) were used to augment daylight during cloudy conditions and to extend the day length to 14 hours.

Two weeks (15.07.2010) and four weeks (29.07.2010) after application the treated plants were visually assessed for injury compared with the untreated control plants. The assessments were on a percentage basis (0 = no effects, 100 = complete kill).

Table 3.3-4: Plant species tested

Plant species
<i>Beta vulgaris vulg. altissima</i> (BEAVA)
<i>Triticum aestivum</i> (TRZAS)
<i>Hordeum vulgare</i> (HORVS)
<i>Avena fatua</i> (AVEFA)
<i>Setaria viridis</i> (SETVI)
<i>Poa annua</i> (POAAN)
<i>Apera spica venti</i> (APESV)
<i>Solanum nigrum</i> (SOLNI)
<i>Stellaria media</i> (STEME)
<i>Amaranthus retroflexus</i> (AMARE)
<i>Veronica persica</i> (VERPE)
<i>Capsella bursa pastoris</i> (CAPBP)
<i>Galium aparine</i> (GALAP)

Results:

The results of the visual assessment is presented as means in Table 3.3-5 (28 DAT).

Table 3.3-5: Results from assessment 28 DAT

	Herbicide g a.i./ha	Crops BEAVA Aries	TRZAS Trio	HORVS Adonis	Mean Crops	AVEFA	Monocots SETVI	POAAN	APESV	Mean Monocots	SOLNI	STEME	Dicots AMARE	VERPE	CAPBP	Mean Dicots
Ethofumesate SC500	2000	0	100	100	67	100	100	100	100	100	88	100	100	90	83	92
	1000	0	100	100	67	100	100	100	100	100	78	100	93	75	50	79
	500	0	100	100	67	88	100	100	100	97	55	98	73	45	20	58
	250	0	90	50	47	87	88	99	78	88	30	96	40	20	0	37
	125	0	45	10	18	30	55	83	65	58	20	78	0	0	0	20
Enantiomer 1	2000	10	100	100	70	100	100	100	100	100	97	100	100	96	75	94
	1000	10	100	100	70	99	100	100	100	100	78	100	100	85	50	82
	500	0	100	100	67	85	100	100	100	96	40	100	88	50	20	59
	250	0	80	30	37	78	95	98	100	93	25	93	20	50	5	39
	125	0	20	0	7	30	0	50	60	35	0	78	0	0	0	16
Enantiomer 2	2000	5	100	100	68	100	100	100	100	100	89	100	100	70	73	86
	1000	0	100	100	67	100	100	100	100	100	75	100	91	68	60	79
	500	0	100	99	66	78	100	100	98	94	35	98	70	45	35	57
	250	0	80	60	47	75	97	100	95	92	25	94	20	0	20	32
	125	0	50	30	27	55	65	100	78	74	10	84	0	0	0	19
Racemate	2000	0	100	100	67	99	100	100	100	100	95	100	100	88	75	91
	1000	0	100	100	67	83	100	100	100	96	80	100	83	55	50	74
	500	0	99	100	66	80	100	100	99	95	73	99	78	30	30	62
	250	0	70	55	42	50	85	100	75	78	35	90	10	0	0	27
	125	0	35	0	12	55	50	85	50	60	25	60	0	0	0	17
Blind formulation WP	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(selectivity/ efficacy)	excellent +++ (0-5/95-100)	good ++ (6-10/90-94)	sufficient + (11-15/80-89)	side effects +- (16-20/60-79)	not sufficient/gaps - (>20/<60)
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Conclusion:

In a direct comparison study, no differences in both selectivity and efficacy could be observed between Ethofumesate SC, enantiomer 1, enantiomer 2, and the racemate.

Report:	KCA 3.3 /03;Noeding, S.;2010;M-401889-01
Title:	Evaluation of the Post-emergence biological activity of ethofumesate and its two enantiomers (enantiomer 1, enantiomer 2)
Report No:	FFS105043
Document No:	M-401889-01-1
Guidelines:	not specified
GLP/GEP:	no

Objective:

The study was conducted under standardized glasshouse conditions using a WP20 formulation of each enantiomer compared to an Ethofumesate SC 500 formulation.

Material and methods:

Test Materials

Dose rates (g a.s./ha)

AE B049913 00 SC45 A2 (Ethofumesate SC 500)	2000 – 1000 – 500 – 250 – 125
Enantiomer 1 formulated as a WP20	2000 – 1000 – 500 – 250 – 125
Enantiomer 2 formulated as a WP20	2000 – 1000 – 500 – 250 – 125
Ethofumesate racemate formulated as a WP20	2000 – 1000 – 500 – 250 – 125
Blind formulation of WP20	2000

Jiffy pots (7 cm diameter) were filled to within 2 cm of the top with a silt-loam soil (20% sand, 57% silt, 23% clay, pH 6.8 and 1.4 % organic matter). Seeds of the weed species listed in Table 3.3-7 were sown into these pots and covered with 0.5 to 1 cm of the same soil mixed 1 to 1 with sharp sand. The sowing density was selected based on prior experience to provide approximately 60-70% soil cover by the plants at application timing. After sowing the pots were placed into a glasshouse set 16°C+/-2°C day and 12°C+/-2°C night and watered according to need. High pressure sodium lamps (400W) were used to augment daylight during cloudy conditions and to extend the day length to 14 hours.

All compounds used in the test were dissolved in deionized water and diluted to obtain the required dose rates. The post-emergence applications (01.07.2010) were made using the Herbicide Research track-sprayer with a spray volume of 300 l/ha via a flat fan nozzle (TeeJet 8001).

One week (08.07.2010) and three weeks (22.07.2010) after application the treated plants were visually assessed for injury compared with the untreated control plants. The assessments were on a percentage basis (0 = no effects, 100 = complete kill).

Table 3.3-6: Plant species tested

Plant species
Beta vulgaris vulg. altissima (BEAVA)
Triticum aestivum (TRZAS)
Hordeum vulgare (HORVS)
Avena fatua (AVEFA)
Setaria viridis (SETVI)
Poa annua (POAAN)
Apera spica venti (APESV)
Solanum nigrum (SOLNI)
Stellaria media (STEME)
Amaranthus retroflexus (AMARE)
Veronica persica (VERPE)
Capsella bursa pastoris (CAPBP)
Galium aparine (GALAP)

Results:

The results of the visual assessment are presented as means in Table 3.3-7 (assessment, 21 DAT).

Table 3.3-7: Results from assessment 21 DAT

	Herbicide g/ha	BEAVA Aries	Crops TRZAS Trio	HORVS Adonis	Mean Crops	AVEFA	Monocots SE TVI	POAAN	APESV	Mean Monocots	SOLNI	STEME	Dicots AMARE	VERPE	CAPBP	GALAP	Mean Dicots
Ethofumesate SC500	2000	0	65	75	47	94	65	92	98	80	86	90	75	60	80	88	79
	1000	0	60	55	38	83	70	89	97	75	83	85	65	35	78	83	69
	500	0	50	40	30	55	45	30	85	65	56	83	50	20	50	73	55
	250	0	30	10	13	40	30	0	40	50	32	75	35	0	40	70	44
	125	0	20	0	7	20	0	0	0	43	13	65	30	0	20	35	30
Enantiomer 1	2000	0	75	78	51	78	70	99	100	85	86	90	83	60	80	88	80
	1000	0	73	55	43	70	50	85	99	78	76	88	73	40	73	80	71
	500	0	60	30	30	50	30	30	85	70	53	83	45	25	55	70	56
	250	0	40	20	20	30	0	0	10	50	18	79	25	0	25	60	38
	125	0	25	0	8	0	0	0	0	40	8	70	0	0	0	35	21
Enantiomer 2	2000	0	75	78	51	93	75	97	97	85	89	90	88	45	83	90	79
	1000	0	75	43	39	70	30	83	90	70	69	88	68	45	73	80	71
	500	0	35	20	18	30	0	30	78	60	40	85	45	35	60	70	59
	250	0	30	0	10	30	0	0	15	40	17	85	30	0	30	68	43
	125	0	30	0	10	10	0	0	0	30	8	75	0	0	0	50	25
Racemate	2000	0	78	78	52	94	85	95	99	80	91	90	83	65	78	88	81
	1000	20	70	40	43	45	50	88	98	75	71	85	60	30	73	80	66
	500	5	40	25	23	35	10	60	77	60	48	83	50	25	45	70	55
	250	5	25	0	10	10	0	30	40	50	26	80	40	0	35	50	41
	125	0	20	0	7	10	0	0	0	30	8	65	0	0	0	45	22
Blind formulation VVP	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(selectivity/ efficacy)	excellent +++ (0-5/95-100)	good ++ (6-10/90-94)	sufficient + (11-15/80-89)	side effects +- (16-20/60-79)	not sufficient/gaps - (>20/<60)
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Conclusion:

In a direct comparison study, no differences in both selectivity and efficacy could be observed between Ethofumesate SC 500, enantiomer 1, enantiomer 2, and the racemate.

B.3.4. FIELD OF USE ENVISAGED

Weed control in agricultural field crops (arable and vegetable crops).

B.3.5. HARMFUL ORGANISMS CONTROLLED AND CROPS OR PRODUCTS PROTECTED OR TREATED

Ethofumesate is used primarily post-emergence to control a wide range of annual grasses including *Alopecurus myosuroides*, *Poa annua*, *Avena fatua*, *Digitaria spp.* and *Setaria spp.* and broad-leaved weeds including *Amaranthus spp.*, *Galium aparine*, *Portulaca oleracea*, *Stellaria media* and *Spergula arvensis*. It is often used in tank-mixtures with other herbicides to provide broad-spectrum weed control.

The treated crops are sugar-, fodder- and red beets.

B.3.6. MODE OF ACTION

Ethofumesate belongs to the benzofurane group of pesticides and is a potent inhibitor of lipid synthesis and cell division in susceptible weeds by a reduction of photosynthesis and respiration. It is absorbed by both shoots and roots. As ethofumesate is non-volatile, uptake always occurs from the aqueous solution. In post-emergence use ethofumesate will be active via the soil as well as by foliar uptake. Post-emergence treatments generally cause severe growth inhibition (particularly in the apical region) often resulting in a dark green coloration and leaf deformity in broad-leaved species.

B.3.7. INFORMATION ON THE OCCURRENCE OR POSSIBLE OF THE DEVELOPMENT OF RESISTANCE AND APPROPRIATE MANAGEMENT STRATEGIES

There is no evidence of the development of resistance to ethofumesate by grass weeds or broad-leaved weeds in over 30 years of use.

To avoid the development of resistance, repeated use of high rates is not recommended and the implementation of low-dose sequential applications, usually in co-formulations or tank-mixtures with other herbicides, has allowed the rates of use to be reduced progressively over the years. Since the active substance is generally used in mixtures and/or sequences with other herbicides in any one season, and due to crop rotational practices, it would not usually be re-applied on an annual basis to the same field.

B.3.8. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 3.3	Noeding, S.	2012	Evaluation of the pre-emergence biological activity of ethofumesate and its metabolite NC 20645 Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: FFS125016, Edition Number: M-436350-01-1 Date: 2012-05-09 GLP/GEP: no, unpublished	N	N Study not GEP/GLP – no data protection granted according to Article 59 of Regulation (EC) 1107/2009	Assumed by the notifier to be triggered by groundwater guidance document (SANCO/221/2000)	Bayer CropScience	Submitted for the purpose of renewal (2014), not considered necessary
KCA 3.3	Noeding, S.	2010	Evaluation of the pre-emergence biological activity of ethofumesate and its two enantiomers (enantiomer 1, enantiomer 2) Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: FFS105044, Edition Number: M-401886-01-1 Date: 2010-07-29 GLP/GEP: no, unpublished ...also filed: KCA 1.9 /01	N	N Study not GEP/GLP – no data protection granted according to Article 59 of Regulation (EC) 1107/2009	New regulatory requirement	Task Force Ethofumesate	Submitted for the purpose of renewal (2014)
KCA 3.3	Noeding, S.	2010	Evaluation of the Post-emergence biological activity of ethofumesate and its two enantiomers (enantiomer 1, enantiomer 2) Bayer CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: FFS105043, Edition Number: M-401889-01-1	N	N Study not GEP/GLP – no data protection granted according to Article 59 of Regulation (EC) 1107/2009	New regulatory requirement	Task Force Ethofumesate	Submitted for the purpose of renewal (2014)

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
			Date: 2010-07-29 GLP/GEP: no, unpublished ...also filed: KCA 1.9 /02					