

# FINAL REGISTRATION REPORT

## Part B

### Section 1: Identity

### Section 2: Physical and chemical properties

### Section 4: Further information

Detailed summary of the risk assessment

Product code: **CHR/H/ETO 500 SC**

Product name(s):

**BITT 500 SC, BETRON 500 SC, ETONAL 500 SC**

Chemical active substance:

**Ethofumesate, 500 g/L**

Central zone

Zonal Rapporteur Member State: Poland

Core assessment

Applicant: Innvigo sp. z o.o.

Submission date: June 2021

MS Finalisation date: 10.2021; 01/2022

## Version history

When	What
October 2021	zRMS evaluation
January 2022	Final version prepared by zRMS after Commenting period

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**zRMS comment:**

Submitted data are sufficient for evaluation

Data gap: The 2 years shelf-life study is on-going, study report shall be submitted when finished (approx. August 2022). Based on the results of the storage studies submitted, one-year conditional registration of the product is proposed.

Packaging: Based on the storage studies, proposed packaging types are acceptable.

## **1 Section 1: Identity of the plant protection product**

In the following document, data for active substance ethofumesate was described during its renewal process in 2016. Were reference to active substance data in the current risk assessment has been made, it was based on the data presented by Bayer.

In June 14<sup>th</sup>, 2018r Kemiron Koncentrat 500SC product has been renewed in Poland thus according to the art. 59 reg. 1107/2009, data protection for mentioned data expired 30 months from date of first renewal of authorisation of product containing that active substance (in this case December, 14<sup>th</sup> 2020).

Considering analogous arguments (art. 59 reg 1107/2009) – data protection of studies presented by UPL for renewal of product Bettix Combi 500 SC (renewal of authorisation granted in Poland 14.02.2019 r.) expires August 14<sup>th</sup>, 2021.

Taking into account that some data was presented by others Notyfiers, Applicant would like to emphasise that unprotected Bayer's endpoints and input parameters accepted during renewal of active substance, should be treated as an equivalent matching data in cases where any of endpoints might be protected.

### **1.1 Applicant (KCP 1.1)**

Name: Innvigo sp. z o.o.

Address: Innvigo sp. z o.o.  
Al. Jerozolimskie 178  
02-486 Warszawa  
Poland

### **1.2 Producer of the plant protection product and of the active substances (KCP 1.2)**

#### **1.2.1 Producer(s) of the preparation**

Confidential information or data are provided separately (Part C).

#### **1.2.2 Producer(s) of the active substance(s)**

Confidential information or data are provided separately (Part C).

### 1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

#### 1.2.3.1 Ethofumesate

According to Commission Implementing Regulation (Eu) 2016/1426:

Ethofumesate min. 960 970 g/kg (EFSA Journal 2016;14(1):4374, SANTE/10119/2016 Rev. 3, Regulation (EU) 2016/1426)

### 1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: BITT 500 SC, BETRON 500 SC, ETONAL 500 SC  
Company code number: CHR/H/ETO 500 SC

### 1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

#### 1.4.1 Composition of the plant protection product (KCP 1.4.1)

**Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)**

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content ** (%w/w)
Ethofumesate	500.0 g/L	475 – 525	515.05 g/L	45.5%w/w

\* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

\*\* Based on the density of the formulation = 1.132 g/ml

**Table 1.4-2: Relevant impurities**

According to Commission Implementing Regulation (EU) 2016/1426:

Relevant impurity	Maximum content
EMS (ethyl methane sulfonate)	max of 0.1 mg/kg max. 0.05 mg/L*
iBMS (iso-butyl methane sulfonate)	max of 0.1 mg/kg max. 0.05 mg/L*

\* In the formulation

#### **1.4.2 Information on the active substance(s) (KCP 1.4.2)**

**Table 1.4-3: Information on Ethofumesate**

Type	Ethofumesate
ISO common name	Ethofumesate
CAS No.	26225-79-6
EC No.	247-525-3
CIPAC No.	233

#### **1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)**

Confidential information - data are provided separately (Part C).

#### **1.5 Type and code of the plant protection product (KCP 1.5)**

Type: Suspension concentrate

[Code: SC]

#### **1.6 Function (KCP 1.6)**

Herbicide in the form of suspension concentrate

## 2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of suspension liquid, white in colour, with a characteristic odour. It is not explosive, has no oxidising properties. It has a self-ignition temperature of 530°C. The product is not flammable and has no flash point. In aqueous solution, it has a pH value around 7.05 at 20 °C. There is no effect of low or high temperature on the stability of the formulation both immediately and after storage at 0 °C, at room temperature and after 24 hours at room temperature, since after 7 days at °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed.

Results of the technical tests (spontaneity of dispersion, suspensibility, wet sieve test, pourability and persistent foaming) showed that Ethofumesate 500 SC is a preparation of a high technical quality which is compatible with several other products commonly used in plant protection.

The stability data indicate a shelf life of at least 1 year at ambient temperature when stored in HDPE/PA. Its technical characteristics are acceptable for a SC formulation.

The intended concentration of use is 0.2% to 0.5 %.

No specific tank mix is recommended.

### Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

No classification

### Notifier Proposals for Risk and Safety Phrases (KCP 12)

P280: Wear protective gloves/protective clothing/eye protection/face protection.

### Compliance with FAO specifications:

The product CHR/H/ETO 500 SC complies with FAO specifications for ethofumesate suspension concentrate:

Lp.	Test type	Method	Requirement
1.	Physical state	Visual inspection	Homogenous white liquid
2.	Ethofumesate content, g/l	HPLC	500 ± 25
3.	Density at 20°C, g/ml	CIPAC MT 3.2	1,13 ± 0,05
4.	pH 1% (m/v) suspension in distilled water, 20°C	CIPAC MT 75.3	6,5 – 8,5
5.	Suspension stability (w/v) in water CIPAC D 30°C after 30 min., chemical method, min. % (initial, at 0°C and after accelerated storage)	0.2%	90
		0.5%	90
6.	Particle size Dv(50), max., µm	CIPAC MT 187	4
7.	Wet sieve test 75 µm, max., % (initial, at 0°C and after accelerated storage)	CIPAC MT 185	2
8.	Foaming (w/v) suspension in water CIPAC D after 1 min., max., ml	0.2%	60
		0.5%	60

Lp.	Test type		Method	Requirement Requirement
	Spontaneity of dispersion, min. % (initial and after accelerated storage)	0.5%	CIPAC MT 160	90
	Pourability, max residue % (initial and after accelerated storage)		CIPAC MT 148	5

#### Formulation used for tests

Material: CHR/H/ETO 500 SC

Active Substances: Ethofumesate, 500 g/L

Producer: PUH „Chemirol” Sp. z o.o.

Batch number: PFORM03

Production date: 04.2020



**Table 2-1: Physical, chemical and technical properties of the plant protection product**

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual inspection nasal inhalation	CHR/H/ETO 500 SC Active Substances: Ethofumesate 500 g/L  Production date: 04.2020 Batch number: PFORM03	<b>Initial preparation:</b> Colour -white homogenous according to visual inspection Physical state – liquid, Odour – characteristic  <b>After accelerated storage:</b> Colour – white homogenous according to visual inspection Physical state – liquid, Odour –characteristic  <b>One year after 8 months:</b> Homogenous white liquid of characteristic odour	Y	<b>KCP 2.1/01</b> Arévalo E., 2020, <del>CHR/H/ETO 500 SC,</del> <i>Ethofumesate 500SC(CHR/H/ETO 500SC) Part I:</i> <i>Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i>  <b>KCP 2.1/02</b> Arévalo E., 2021 <del>CHR/H/ETO 500 SC,</del> <i>Ethofumesate 500SC(CHR/H/ETO 500SC) Part II:</i> <i>Determination of physicochemical properties of the preparation.</i>	Accepted
Explosive properties (KCP 2.2.1)	<del>N/A</del>  Theoretical assessment	N/A	No danger of explosion (active substance do not contain any groups associated with explosive properties in its structure)	N/A	N/A	Accepted  The formulation is not expected to have an explosive behaviour
Oxidizing properties (KCP 2.2.2)	A.21	CHR/H/ETO 500 SC Active Substances:	No oxidising properties	Y	<b>KCP 2.2.2</b> Flasińska P., 2020, <i>Ethofumestae 500SC</i> <i>Determination of flash</i>	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Ethofumesate 240 g/L  Production date: 04.2020 Batch number: PFORM03			<i>point, auto-ignition temperature and oxidizing properties</i>	
Flash point (KCP 2.3.1)	A.9	CHR/H/ETO 500 SC Active Substances: Ethofumesate 500 g/L  Production date: 04.2020 Batch number: PFORM03	Flash point: 32°C Not relevant as the preparation is an aqueous suspension concentrate.	Y	<b>KCP 2.3.1</b> Flasińska P., 2020, <i>Ethofumestae 500SC</i> <i>Determination of flash point, auto-ignition temperature and oxidizing properties</i>	Not relevant. The formulation does not contain flammable solvents
Flammability (KCP 2.3.2)	N/A	N/A	Not relevant for liquid preparations		N/A	Not required
Self-heating (KCP 2.3.3)	<del>N/A</del>  A.15	<del>N/A</del>  CHR/H/ETO 500 SC Active Substances: Ethofumesate 500 g/L  Production date: 04.2020 Batch number: PFORM03	<del>N/A</del>  No ignition until 530 °C.	Y	<del>N/A</del>  <b>KCP 2.3.3</b> Flasińska P., 2020, <i>Ethofumestae 500SC</i> <i>Determination of flash point, auto-ignition temperature and oxidizing properties</i>	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments									
Acidity or alkalinity and pH (KCP 2.4.1)	N/A	N/A	Not relevant because the pH value is between 4 and 10.  <b>Initial preparation:</b> pH=7.05 <b>After accelerated storage:</b> pH=7.30	N/A	N/A	Not required									
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	MT 75.3	CHR/H/ETO 500 SC Active Substances: Ethofumesate 500 g/L  Production date: 04.2020 Batch numer: PFORM03	<b>Initial preparation (at 20 °C):</b> 1% (w/v) aqueous dilution – 7.46 Neat – 7.05  <b>After accelerated storage:</b> 1% (w/v) ) aqueous dilution – 7.67  <b>One year after 8 months:</b> Undiluted- 7.32 1% (w/v) ) aqueous dilution - 7.51	Y	<b>KCP 2.4.2/01</b> Arévalo E., 2020, CHR/H/ETO 500 SC, Ethofumesate 500SC(CHR/H/ETO 500SC) Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C  <b>KCP 2.4.2/02</b> Arévalo E., 2021 CHR/H/ETO 500 SC, Ethofumesate 500SC(CHR/H/ETO 500SC) Part II: Determination of physicochemical properties of the preparation.	Accepted									
Viscosity (KCP 2.5.1)	OECD 114	CHR/H/ETO 500 SC Active Substances: Ethofumesate 500 g/L	Results of dynamic viscosity determination at 20°C and at 40°C <table><tr><td>shear rate</td><td>at 20°C :</td><td>at 40°C:</td></tr><tr><td>2.5 s-1</td><td>1330mPa·s</td><td>970 mPa·s</td></tr><tr><td>5.0 s-1</td><td>869 mPa·s</td><td>638 mPa·s</td></tr></table>	shear rate	at 20°C :	at 40°C:	2.5 s-1	1330mPa·s	970 mPa·s	5.0 s-1	869 mPa·s	638 mPa·s	Y	<b>KCP 2.5.1</b> Arévalo E., 2020, CHR/H/ETO 500 SC, Ethofumesate 500SC(CHR/H/ETO 500SC) Part I: Determination of	Accepted
shear rate	at 20°C :	at 40°C:													
2.5 s-1	1330mPa·s	970 mPa·s													
5.0 s-1	869 mPa·s	638 mPa·s													

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments						
		Production date: 04.2020  Batch numer: PFORM03	<table><tr><td>10.0 s-1</td><td>571 mPa·s</td><td>421 mPa·s</td></tr><tr><td>25.0 s-1</td><td>337mPa·s</td><td>250 mPa·s</td></tr></table>			10.0 s-1	571 mPa·s	421 mPa·s	25.0 s-1	337mPa·s	250 mPa·s		<i>physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i>	
10.0 s-1	571 mPa·s	421 mPa·s												
25.0 s-1	337mPa·s	250 mPa·s												
Surface tension (KCP 2.5.2)	A.5	CHR/H/ETO 500 SC Active Substances: Ethofumesate 500 g/L  Production date: 04.2020  Batch numer: PFORM03	The determined value of surface tension of solution of Ethofumesate 500 SC (0.5% w/w) at 20.0°C is 45.49 mN/m.			Y	<b>KCP 2.5.2</b> Arévalo E., 2020, <del>CHR/H/ETO 500 SC,</del> <i>Ethofumesate 500SC (CHR/H/ETO 500SC) Part I:</i> <i>Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i>	<b>Accepted</b>  Surface active						
Relative density (KCP 2.6.1)	A.3	CHR/H/ETO 500 SC Active Substances: Ethofumesate 500 g/L  Production date: 04.2020  Batch numer: PFORM03	D <sub>4</sub> <sup>20</sup> =1.132			Y	<b>KCP 2.6.1/01</b> Arévalo E., 2020, <del>CHR/H/ETO 500 SC,</del> <i>Ethofumesate 500SC (CHR/H/ETO 500SC) Part I:</i> <i>Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i>	<b>Accepted</b>						
Bulk density	N/A	N/A	N/A			N/A	N/A	Not required						

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																		
(KCP 2.6.2)																								
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46	CHR/H/ETO 500 SC Active Substances: Ethofumesate 500 g/L  Production date: 04.2020  Batch numer: PFORM03	<div>The determined physicochemical properties of the tested material after accelerated storage test are comparable to the results of the initial material tests</div> <table><tr><th>Test type</th><th>Results</th></tr><tr><td>Physical state colour and odour</td><td>Homogenous white liquid of characteristic odour</td></tr><tr><td>pH</td><td>1% dilution- 7.67 undiluted- 7.30</td></tr><tr><td>Dispersion spontaneity</td><td>85.49%</td></tr><tr><td>Suspension stability</td><td>0.2% : 94.58% 0.5% : 93.04%</td></tr><tr><td>Wet sieve test</td><td>0.00 %</td></tr><tr><td>Pourability</td><td>R=4.04% R'=0.28%</td></tr><tr><td>Package stability</td><td>Stable, 1 litre PE/PA</td></tr><tr><td>Active ingredient content</td><td>45.32 ± 0.97%, (513.02 g/l)</td></tr></table>	Test type	Results	Physical state colour and odour	Homogenous white liquid of characteristic odour	pH	1% dilution- 7.67 undiluted- 7.30	Dispersion spontaneity	85.49%	Suspension stability	0.2% : 94.58% 0.5% : 93.04%	Wet sieve test	0.00 %	Pourability	R=4.04% R'=0.28%	Package stability	Stable, 1 litre PE/PA	Active ingredient content	45.32 ± 0.97%, (513.02 g/l)	Y	<b>KCP 2.7.1</b> Arévalo E., 2020, <del>CHR/H/ETO 500 SC,</del> <i>Ethofumesate 500SC (CHR/H/ETO 500SC) Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i>	No significant change of physical chemical properties after storage. A.s. decrease within the limit. Dispersion spontaneity result is under the FAO limit. Information on the necessity of well agitation before use is repeated in the lebel and the result after 12 months is above the FAO limit.  <b>Accepted</b>
Test type	Results																							
Physical state colour and odour	Homogenous white liquid of characteristic odour																							
pH	1% dilution- 7.67 undiluted- 7.30																							
Dispersion spontaneity	85.49%																							
Suspension stability	0.2% : 94.58% 0.5% : 93.04%																							
Wet sieve test	0.00 %																							
Pourability	R=4.04% R'=0.28%																							
Package stability	Stable, 1 litre PE/PA																							
Active ingredient content	45.32 ± 0.97%, (513.02 g/l)																							
Storage Stability after 12 weeks at 35 °C other periods and/or temperatures (KCP 2.7.2)	N/A	N/A	N/A	N/A	N/A	Not required																		
Minimum content after heat stability testing (KCP 2.7.3)	SBP/95  SBP/96	CHR/H/ETO 500 SC Active Substances: Ethofumesate 500 g/L  Production date:	<b>Initial preparation:</b> 46.32 ± 0.68 %, (524.39 g/l) <b>After accelerated storage:</b> 45.32 ± 0.97%, (513.02 g/l)	Y	<b>KCP 2.7.3</b> Arévalo E., 2020, <del>CHR/H/ETO 500 SC,</del> <i>Ethofumesate 500SC (CHR/H/ETO 500SC) Part I: Determination of physicochemical properties</i>	<b>Accepted</b>																		

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
		04.2020  Batch numer: PFORM03					<i>of the initial preparation, after accelerated storage and after storage at 0°C</i>	
Effect of low temperatures on stability (KCP 2.7.4)	MT 39.3 Visual inspection MT 160 MT 184 MT 185	CHR/H/ETO 500 SC Active Substances: Ethofumesate 500 g/L  Production date: 04.2020 Batch number: PFORM03	Test type	Results		Y	<del>KCP 2.7.4/01</del> Arévalo E., 2020, <del>CHR/H/ETO 500 SC, Ethofumesate 500SC(CHR/H/ETO 500SC) Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</del>  <del>KCP 2.7.4/02</del> Arévalo E., 2021 <del>CHR/H/ETO 500 SC, Ethofumesate 500SC(CHR/H/ETO 500SC) Part II: Determination of physicochemical properties of the preparation.</del>	Accepted  The formulation was not affected by low temperature
			Physical state colour and odour	Homogenous liquid				
			Dispersion spontaneity	94.40 %				
			Suspension stability	0.2%	97.65%			
				0.5%	96.78%			
			Wet sieve test	0.00 %				
			<del>One year after: homogenous liquid</del>					
Ambient temperature shelf life (KCP 2.7.5)	GIFAP No 17 Visual inspection, nasal inhalation MT 75.3 MT 160 MT 148.1 MT 184	CHR/H/ETO 500 SC Active Substances: Ethofumesate 500 g/L  Production date: 04.2020	Test type	Results		Y	<del>KCP 2.7.5/01</del> Arévalo E., 2020, <del>CHR/H/ETO 500 SC, Ethofumesate 500SC(CHR/H/ETO 500SC) Part I: Determination of physicochemical properties of the initial preparation,</del>	Accepted  No significant change of physicochemical properties after storage. A.s. decrease within the limit.  <u>Relevant</u>
		Initial preparation	<del>One year after 8 months:</del>					
Physical state colour and odour	Homogenous white liquid of characteristic odour	Homogenous white liquid of characteristic odour						
pH	1% - 7.46	1% - 7.51						

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments		
	MT 185 HPLC/DAD	Batch number: PFORM03		undiluted- 7.05	undiluted-7.32		after accelerated storage and after storage at 0°C  <b>KCP 2.7.5/02</b> Arévalo E., 2021 <del>CHR/H/ETO 500 SC,</del> <i>Ethofumesate 500SC(CHR/H/ETO 500SC) Part II: Determination of physicochemical properties of the preparation.</i>	<u>impurities:</u> According to the equivalence assessment, relevant impurity EMS was not detected and iBMS were not detected or below LOQ in the Ethofumesate technical material (LOQ for EMS was 0.05 mg/kg, LOQ for iBMS was 0.06 mg/kg). Monitoring of the presence of EMS and iBMS was deemed unnecessary in this case.		
			Dispersion spontaneity	94.40 %	83.93%					
			Pourability	R = 4.40%, R' = 0.33%	R = 3.97%, R' = 0.34%					
			Suspension stability	0.2% 97.65%	0.2% 92.61%					
				0.5% 96.78%	0.5% 93.33%					
			Wet sieve test	0.00	0.00					
			Active ingredient content	46.32 %, (524.39 g/l)	46.31%, (524.20 g/l)					
			<b>After 12 months:</b>						Y	<b>KCP 2.7.5/03</b> Arévalo E., 2021 <i>Ethofumesate 500SC(CHR/H/ETO 500SC) Part III: Determination of physicochemical properties of the preparation after the first year of storage</i>
			Physical state colour and odour	Homogenous white liquid of characteristic odour						
			pH	1% - 7.54 undiluted - 7.40						
			Dispersion spontaneity	90.43%						
			Pourability	R = 4.43% R' = 0.52%						
			Suspension stability	0.2%    96.58%						
				0.5%    96.66%						
	Wet sieve test	0.00								
	Active ingredient content	46.23% (523.29 g/l)								
	Packaging (PE/PA bottle)	Negligible changes								
	2 years shelf life study – on-going (the study will end in August 2022)									

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Shelf life in months (if less than 2 years) (KCP 2.7.6)	N/A	N/A	N/A	N/A	N/A	See point KCP 2.7.5
Wettability (KCP 2.8.1)	N/A	N/A	N/A	N/A	N/A	Not required
Persistence of foaming (KCP 2.8.2)	MT 47.3	CHR/H/ETO 500 SC Active Substances: Ethofumesate 500 g/L  Production date: 04.2020  Batch number: PFORM03	0.2% (w/v): - after 1 minute – 16mL - after 12 minutes – 12 mL 0.5% (w/v): - after 1 minute – 25 mL - after 12 minutes – 16 mL	Y	<b>KCP 2.8.2</b> Arévalo E., 2020, <del>CHR/H/ETO 500 SC,</del> <i>Ethofumesate 500SC (CHR/H/ETO 500SC) Part I:</i> <i>Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i>	Accepted
Suspensibility (KCP 2.8.3.1)	MT 184	CHR/H/ETO 500 SC Active Substances: Ethofumesate 500 g/L  Production date 04.2020:  Batch number: PFORM03	<div><div><div><div><div>Test No.</div><div>Mass of tested sample</div><div>Content of a.i.</div><div>Mass of a.i.</div><div>Remaining mass</div><div>Content of a.i. in the remaining d</div><div>Mass of a.i. in remaining</div><div>Suspension stability</div></div><div><div>m</div><div>c</div><div>a</div><div></div><div></div><div></div><div>b</div><div>Xa</div></div><div><div>[g]</div><div>(%)</div><div>[g]</div><div>(%)</div><div>[g]</div><div>(%)</div><div>(%)</div><div>(%)</div></div></div></div><div><div>Initial preparation, 0.2%</div><div><div>1</div><div>0.4859</div><div rowspan="2">46.40</div><div>0.2255</div><div>24.1294</div><div>0.09</div><div>0.0217</div><div>100.32</div></div><div><div>5</div><div>0.5134</div><div></div><div>0.2382</div><div>24.2408</div><div>0.12</div><div>0.0291</div><div>97.44</div></div><div>Average: 98.88 %</div></div><div><div>Initial preparation, 0.5 %</div><div><div>6</div><div>1.2598</div><div rowspan="2">46.40</div><div>0.5845</div><div>24.5412</div><div>0.31</div><div>0.0761</div><div>96.55</div></div><div><div>2</div><div>1.2483</div><div></div><div>0.5792</div><div>24.6143</div><div>0.31</div><div>0.0763</div><div>96.38</div></div><div>Average: 96.46 %</div></div></div> <div>After accelerated storage:</div>	Y	<b>KCP 2.8.3.1/01</b> Arévalo E., 2020, <del>CHR/H/ETO 500 SC,</del> <i>Ethofumesate 500SC (CHR/H/ETO 500SC) Part I:</i> <i>Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i>  <b>KCP 2.8.3.1/02</b> Arévalo E., 2021 <del>CHR/H/ETO 500 SC,</del> <i>Ethofumesate</i>	Accepted



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																																																																																																																																								
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Spontaneity of dispersion (KCP 2.8.3.2)	MT 160	CHR/H/ETO 500 SC Active Substances: Ethofumesate 500 g/L  Production date: 04.2020  Batch number: PFORM03	Initial: 98.64%  After accelerated storage: 85.49%  <b>One year after 8 months:</b> 83.93%	Y	<b>KCP 2.8.3.2/01</b> Arévalo E., 2020, CHR/H/ETO 500 SC, Ethofumesate 500SC(CHR/H/ETO 500SC) Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C  <b>KCP 2.8.3.2/02</b> Arévalo E., 2021 CHR/H/ETO 500 SC, Ethofumesate 500SC(CHR/H/ETO	Results after accelerated storage is under the FAO limit. Information on the necessity of well agitation before use is repeated in the label.  The result after 12 months (90.43%) is above the FAO limit  <b>Accepted</b>																																																																																																																																																								

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					<i>500SC) Part II: Determination of physicochemical properties of the preparation.</i>	
Dispersion stability (KCP 2.8.3.3)	N/A	N/A	N/A	N/A	N/A	Not required
Degree of dissolution and dilution stability (KCP 2.8.4)	N/A	N/A	N/A	N/A	N/A	Not required
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	N/A	N/A	N/A	N/A	N/A	Not required
Wet sieve test (KCP 2.8.5.1.2)	MT 185	CHR/H/ETO 500 SC Active Substances: Ethofumesate 500 g/L  Production date: 04.2020  Batch number: PFORM03	Initial: 0.00%  After accelerated storage: 0.00%  <del>One year</del> after 8 months: 0.00%	Y	<b>KCP 2.8.5.1.2/01</b> Arévalo E., 2020, <del>CHR/H/ETO 500 SC,</del> <i>Ethofumesate 500SC(CHR/H/ETO 500SC) Part I:</i> <i>Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i>  <b>KCP 2.8.5.1.2/02</b> Arévalo E., 2021 <del>CHR/H/ETO 500 SC,</del> <i>Ethofumesate 500SC(CHR/H/ETO 500SC) Part II: Determina-</i>	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					<i>tion of physicochemical properties of the preparation.</i>	
Dust content (KCP 2.8.5.2.1)	N/A	N/A	N/A	N/A	N/A	Not required
Particle size of dust (KCP 2.8.5.2.2)	N/A	N/A	N/A	N/A	N/A	Not required
Attrition (KCP 2.8.5.3)	N/A	N/A	N/A	N/A	N/A	Not required
Hardness and integrity (KCP 2.8.5.4)	N/A	N/A	N/A	N/A	N/A	Not required
Emulsifiability (KCP 2.8.6.1)	N/A	N/A	N/A	N/A	N/A	Not required
Emulsion stability (KCP 2.8.6.2)	N/A	N/A	N/A	N/A	N/A	Not required
Re-emulsifiability (KCP 2.8.6.3)	N/A	N/A	N/A	N/A	N/A	Not required
Flowability (KCP 2.8.7.1)	N/A	N/A	N/A	N/A	N/A	Not required
Pourability (KCP 2.8.7.2)	MT 148.1	CHR/H/ETO 500 SC Active Substances: Ethofumesate 500 g/L  Production date: 04.2020	<b>Initial preparation:</b> R - 4.40 % R' - 0.33%  <b>After accelerated storage:</b> R – 4.04% R ' - 0.28%  <b>One year after 8 months:</b>	Y	<b>KCP 2.8.7.2/01</b> Arévalo E., 2020, <b>CHR/H/ETO 500 SC,</b> <b>Ethofumesate</b> <b>500SC(CHR/H/ETO</b> <b>500SC) Part I:</b> <i>Determination of physicochemical properties of the initial preparation,</i>	<b>Accepted</b>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Batch number: PFORM03	R=3.97% R'=0.34%		after accelerated storage and after storage at 0°C  <b>KCP 2.8.7.2/02</b> Arévalo E., 2021 <del>CHR/H/ETO 500 SC,</del> Ethofumesate 500SC(CHR/H/ETO 500SC) Part II: Determination of physicochemical properties of the preparation.	
Dustability following accelerated storage (KCP 2.8.7.3)	N/A	N/A	N/A	N/A	N/A	Not required
Physical compatibility of tank mixes (KCP 2.9.1)	N/A	N/A	N/A	N/A	N/A	Not required
Chemical compatibility of tank mixes (KCP 2.9.2)	N/A	N/A	N/A	N/A	N/A	Not required
Adhesion to seeds (KCP 2.10.1)	N/A	N/A	N/A	N/A	N/A	Not required
Distribution to seed (KCP 2.10.2)	N/A	N/A	N/A	N/A	N/A	Not required
<del>Stability of packaging</del> Other/special stud-	SPO/BF/21/b (ed.4) and the CropLife International	CHR/H/ETO 500 SC Active Substances:	<del>Stability of packaging:</del>  After accelerated storage: 1 L white PE/PA bottles with no visible structural deformations	Y	<b>KCP 2.11/01</b> Arévalo E., 2020, <del>CHR/H/ETO 500 SC,</del> Ethofumesate	<b>Accepted</b>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
ies (KCP 2.11)	Technical Monograph No. 17	Ethofumesate 500 g/L  Production date: 04.2020  Batch number: PFORM03	<del>One year</del> after 8 months: Stable, 1 litre PE/PA		500SC(CHR/H/ETO 500SC) Part I: <i>Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i>  <b>KCP 2.11/02</b> Arévalo E., 2021 CHR/H/ETO 500 SC, Ethofumesate 500SC(CHR/H/ETO 500SC) Part II: <i>Determination of physicochemical properties of the preparation.</i>	
Effectiveness of cleaning (KCP 2.12)	Efficacy Guideline 305	CHR/H/ETO 500 SC Active Substances: Ethofumesate 500 g/L  Production date: 04.2020 Batch number: PFORM03	Effectiveness of cleaning:  <b>Single rinse procedure:</b> - 91.02 [%] ethofumesate removed - the bottle <b>Double rinse procedure:</b> - 99.53 [%] ethofumesate removed - the bottle <b>Triple rinse procedure:</b> - 99.83 [%] ethofumesate removed - the bottle	Y	<b>KCP 2.12</b> Arévalo E., 2020, CHR/H/ETO 500 SC, Ethofumesate 500SC(CHR/H/ETO 500SC) Part I: <i>Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i>	Accepted

### 3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

### 4 Section 4: Further information on the plant protection product

**zRMS comment:** all changes in this section have been made based on the Applicant’s amendments

#### 4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

**Table 4.1-1: Packaging information for HDPE/PA 0.12 liter bottle**

Packaging information for 120 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA COEX
size:	50 ± 1 mm/93 ± 1 mm
Opening:	28,4 ± 0,3 mm
Closure:	screw cap with seal
Capacity	120 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Packaging information for 120 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA COEX
size:	50 ± 1 mm/93 ± 1 mm
Opening:	28,4 ± 0,3 mm
Closure:	screw cap with seal
Capacity	120 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-2: Packaging information for HDPE/PA 0.25 l bottle**

Packaging information for 250 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA COEX

size:	62.5±1 mm/131.3±1 mm
Opening:	45.65±3 mm
Closure:	screw cap with seal
Capacity	323 ± 5 ml
Seal:	Induction seal
Manner of construction	coextruded
UN/ADR	compliant

**Table 4.1-3: Packaging information**

Packaging information for 250 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA
size:	59 ± 1 mm/143 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	275 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-4: Packaging information for HDPE/PA 0.5 l bottle**

Packaging information for 500 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA
size:	69 mm ± 2 mm/186.5 mm ± 2 mm
Opening:	45.65±3 mm
Closure:	screw cap with seal
Capacity	574 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-5: Packaging information**

Packaging information for 500 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA COEX
size:	74± 1 mm/177 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	550 ml
Seal:	Induction seal

Manner of construction	coextruded
UN/ADR	compliant

Packaging information for 500 ml BOTTLE	-
Type	BOTTLE
Material:	HDPE/PA COEX
size:	74± 1 mm/177 ± 1 mm/
Opening:	41.7±0.7 mm
Closure:	screw cap with seal
Capacity	550 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-6: Packaging information for HDPE/PA 1 l bottle**

Packaging information for 1000 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA COEX
size:	88 mm ± 2 mm/238 mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	coextruded
UN/ADR	compliant

**Table 4.1-7: Packaging information**

Packaging information for 1000 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA
size:	248.5±3 mm/84±1.5mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant



Packaging information for 1000-ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA
size:	248.5±3 mm/84±1.5mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-8: Packaging information**

Packaging information for 1000-ml BOTTLE	
Type	BOTTLE
Material:	PE-PA HDPE/PA
size:	234 mm± 2 mm/88.5mm ± 2 mm
Opening:	42 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-9: Packaging information**

Packaging information for 1000-ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA COEX
size:	238± 1 mm/88 ± 1 mm/
Opening:	41.7±0,7 mm
Closure:	screw cap with seal
Capacity	1100 ml
Seal:	Induction seal
Manner of construction	coextruded
UN/ADR	compliant

**Table 4.1-10: Packaging information**

Packaging information for 1000-ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA COEX
size:	84± 1.5 mm/248.5 ± 3 mm

Opening:	50 mm $\pm$ 3mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	coextruded
UN/ADR	compliant

**Table 4.1-11: Packaging information**

Packaging information for 1000 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA COEX
size:	233.5 $\pm$ 1.5 mm/88.5 $\pm$ 1 mm/
Opening:	39 mm $\pm$ 2 mm
Closure:	screw cap with seal
Capacity	1100 ml
Seal:	Induction seal
Manner of construction	coextruded
UN/ADR	compliant

Packaging information for 1000 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA COEX
size:	84 $\pm$ 1.5 mm/248.5 $\pm$ 3 mm
Opening:	50 mm $\pm$ 3mm
Closure:	screw cap with seal
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-512: Packaging information for HDPE/PA 5 l bottle**

Packaging information for 5000 ml CONTAINER	
Type	CONTAINER
Material:	HDPE/PA COEX
size:	305mm $\pm$ 5 mm/193 mm $\pm$ 5 mm/142 mm $\pm$ 5 mm
Opening:	63 mm minimum $\pm$ 5 mm
Closure:	screw cap with seal
Capacity	5850 ml $\pm$ 150 ml

Seal:	Induction seal
Manner of construction	coextruded
UN/ADR	compliant

**Table 4.1-13: Packaging information**

Packaging information for 5000 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA COEX
size:	193 ± 3/ 142 ± 5 mm/320 mm± 5 mm
Opening:	63,3 ± 3mm
Closure:	screw cap with seal
Capacity	5500 ml
Seal:	Induction seal
Manner of construction	coextruded
UN/ADR	compliant

**Table 4.1-14: Packaging information**

Packaging information for 5000 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/PA COEX
size:	195 ± 3/ 130 ± 5 mm/310,5 mm± 5 mm
Opening:	63,3 ± 3mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	coextruded
UN/ADR	compliant

**Table 4.1-15: Packaging information**

Packaging information for 5000 ml CANNISTER	
Type	CANNISTER
Material:	HDPE/PA COEX
size:	313± 5mm/190±3/140±5mm
Opening:	50 mm ± 3mm
Closure:	screw cap with seal
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	coextruded

UN/ADR	compliant
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**Table 4.1-16: Packaging information for HDPE/PA 10 l bottle**

Packaging information for 10000 ml CONTAINER	
Type	CONTAINER
Material:	HDPE/PA COEX
size:	305mm/193 mm/142 mm ± 5 mm
Opening:	63 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml±150 ml
Seal:	Induction seal
Manner of construction	coextruded
UN/ADR	compliant

**Table 4.1-17: Packaging information**

Packaging information for 10000 ml CONTAINER	
Type	CONTAINER
Material:	HDPE/PA COEX
size:	377,7mm/178 mm/239,5 mm ± 5 mm
Opening:	54 mm min ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml±150 ml
Seal:	Induction seal
Manner of construction	coextruded
UN/ADR	compliant

**Table 4.1-718: Packaging information for HDPE/F 0.1 l bottle**

Type	BOTTLE
Material:	HDPE/F
size:	50 ± 1 mm/93 ± 1 mm
Opening:	28,4 ± 0,3 mm
Closure:	screw cap with seal
Capacity	120 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-819: Packaging information for HDPE/F 0.25 l bottle**

Type	BOTTLE
Material:	HDPE/F
size:	63.5±1 mm/126±1 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	318 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-20: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	63.5±1 mm/126±1 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	312 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-921: Packaging information for HDPE/F 0.5 l bottle**

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	585 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-22 Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	580 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-23 Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	575 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-24 Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	570 ± 12.5 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-1025: Packaging information for HDPE/F 1 l bottle**

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1150 ± 20 ml

Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-26 Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1160 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-27 Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1185 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-28 Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1200 ± 20 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-1129: Packaging information for HDPE/F 5 l bottle**

Type	Cannister
Material:	HDPE/F

size:	193±2 mm/142±2mm/305±3mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	5880 ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-30 Packaging information**

Type	Cannister
Material:	HDPE/F
size:	193±2 mm/142±2mm/305±3mm
Opening:	63 mm
Closure:	screw cap with seal
Capacity	5880 ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-31 Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	54,2 mm ± 1 mm
Closure:	screw cap with seal
Capacity	5950 ml ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-32 Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	63.4 mm min ± 1 mm
Closure:	screw cap with seal
Capacity	5950 ml ± 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant



**Table 4.1-33 Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm $\pm$ 2 mm
Opening:	67,5 mm $\pm$ 1 mm
Closure:	screw cap with seal
Capacity	5950 ml $\pm$ 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-34 Packaging information**

Type	CANNISTER
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm $\pm$ 2 mm
Opening:	54,2 mm min $\pm$ 1 mm
Closure:	screw cap with seal
Capacity	5950 ml $\pm$ 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-35 Packaging information**

Type	CANNISTER
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm $\pm$ 2 mm
Opening:	63,4 mm min $\pm$ 1 mm
Closure:	screw cap with seal
Capacity	5950 ml $\pm$ 100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-36 Packaging information**

Type	CANNISTER
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm $\pm$ 2 mm
Opening:	67,5 mm min $\pm$ 1 mm
Closure:	screw cap with seal
Capacity	5950 ml $\pm$ 100 ml
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-1237: Packaging information for HDPE/F 10 l bottle**

Type	Cannister
Material:	HDPE/F
size:	240±2 mm/179±2mm/375±3mm
Opening:	63 mm
Closure:	screw cap with seal
Capacity	10 000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-138: Packaging information for HDPE/EvOH 0.1 l bottle**

Packaging information for 100ml BOTTLE	
Type	BOTTLE
Material:	COEX HDPE / EVOH
Body diameter / total height:	48,50 +- 1,00 / 95,50 +- 1,00
External thread diameter:	27,3 +- 0,15
Closure:	screw cap with seal
Capacity	100 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	N/A

**Table 4.1- 1439: Packaging information for HDPE/EvOH 0.25 l bottle**

Packaging information for 250ml BOTTLE	
Type	BOTTLE
Material:	COEX HDPE / EVOH
Body diameter / total height:	62,50 +- 0,50 / 126,50 +- 1,50
External thread diameter:	49,65 +- 0,35
Closure:	screw cap with seal
Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	N/A

**Table 4.1-40 Packaging information**

Packaging information for 250ml BOTTLE	
Type	BOTTLE
Material:	COEX HDPE / EVOH
Body diameter / total height:	59 +- 1 mm / 143 +- 1 mm
External thread diameter:	41.7 +- 0,4 mm
Closure:	screw cap with seal
Capacity	310 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	N/A

**Table 4.1-1541: Packaging information for HDPE/EvOH 0.5 l bottle**

Packaging information for 500 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/EvOH
size:	69 mm± 2 mm/186.5 mm ± 2 mm
Opening:	42±3 mm
Closure:	screw cap with cutter
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-42 Packaging information**

Packaging information for 500 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/EvOH
size:	65 mm/234.8 mm ± 2 mm
Opening:	27.4 mm
Closure:	screw cap with seal
Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-43 Packaging information**

Packaging information for 500 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/EvOH
size:	69 mm ±1 mm/190 mm ±1.5 mm
Opening:	49.5 mm ±0.3 mm

Closure:	screw cap with seal
Capacity	579 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-1644: Packaging information for HDPE/EvOH 1 l bottle**

Packaging information for 1000 ml BOTTLE	-
Type	BOTTLE
Material:	HDPE/EvOH
size:	234±3 mm/88.5±2mm
Opening:	42 mm ± 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Packaging information for 1000 ml BOTTLE	-
Type	BOTTLE
Material:	HDPE/EvOH
size:	234±3 mm/88.5±2mm
Opening:	42 mm ± 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

Packaging information for 1000 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/EvOH
size:	234±3 mm/88.5±2mm
Opening:	50 mm ± 3 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-45 Packaging information**

Packaging information for 1000 ml BOTTLE	
Type	BOTTLE
Material:	HDPE/EvOH
size:	242±1.5 mm/88.5±1mm
Opening:	49.5 mm ± 0.3 mm
Closure:	screw cap with cutter
Capacity	1200± 50 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-146: Packaging information for HDPE/EvOH 5 l bottle**

Packaging information for 5000 ml CONTAINER	
Type	CONTAINER
Material:	HDPE/EvOH
size:	165 mm ± 2 mm/195 mm ± 2 mm/228mm± 2 mm
Opening:	48 mm ± 2 mm
Closure:	screw cap with cutter
Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-47 Packaging information**

Packaging information for 1000 ml BOTTLE	
Type	CANNISTER
Material:	HDPE/EvOH
size:	142 mm ± 1.5 mm/193 mm ± 2 mm/307mm± 3 mm
Opening:	63.3 mm ± 0.3 mm
Closure:	screw cap with cutter
Capacity	5650 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-1648: Packaging information for HDPE/EvOH 10 l bottle**

Packaging information for 10000 ml CONTAINER	
Type	CONTAINER
Material:	HDPE/EvOH
size:	195 mm $\pm$ 2 mm/225mm $\pm$ 2 mm/306mm $\pm$ 2 mm
Opening:	48 mm $\pm$ 2 mm
Closure:	screw cap with cutter
Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-1649: Packaging information for HDPE/EvOH 20 l bottle**

Packaging information for 20000 ml CONTAINER	
Type	CONTAINER
Material:	HDPE/EvOH
size:	375 mm $\pm$ 2 mm/290mm $\pm$ 2 mm/245mm $\pm$ 2 mm
Opening:	85mm $\pm$ 2 mm
Closure:	screw cap with cutter
Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

## 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 2.1/01 2.4.2/01 2.5.1 2.5.2 2.6.1 2.7.1 2.7.3 2.7.4 2.7.5/01 2.8.2 2.8.3.1/01 2.8.3.2/01 2.8.5.1.2/01 2.8.7.2/01 2.11/01 2.12	Arévalo E.	2019 2020	<i>Ethofumesate 500SC(CHR/H/ETO 500SC) Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i> BF- 33/20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry 6 Annopol St., 03-236 Warsaw, Poland GLP- Yes Unpublished	N	Chemrol
KCP 2.1/02 2.4.2/02 2.7.5/02 2.8.3.1/02 2.8.3.2/02 2.8.5.1.2/02 2.8.7.2/02 2.11/02	Arévalo E.	2021	<del>CHR/H/ETO 500 SC,</del> <i>Ethofumesate 500SC(CHR/H/ETO 500SC) Part II: Determination of physicochemical properties of the preparation.</i> BF- 33/20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry 6 Annopol St., 03-236 Warsaw, Poland GLP- Yes Unpublished	N	Chemrol
KCP 2.2.2 2.3.1 2.3.3	Flasińska, P.	2020	<i>Ethofumestae 500SC</i> <i>Determination of flash point, auto-ignition temperature and oxidizing properties</i> BC-20/20 Institute of Industrial Organic Chemistry The Department of Physicochemical Properties and Environmental Protection 6 Annopol Str., PL, 03-236, Warsaw GLP- Yes Unpublished	N	Chemrol
KCP 2.7.5/03	Arévalo E.	2021	<i>Ethofumesate 500SC(CHR/H/ETO 500SC) Part III: Determination of physicochemical properties of the preparation after the first year of storage</i> BF- 33/20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry 6 Annopol St., 03-236 Warsaw, Poland GLP- Yes Unpublished	N	Chemrol

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 2.3.1	Flasińska, P.	2020	<i>Ethofumesate 500SC</i> <i>Determination of flash point, auto-ignition temperature and oxidizing properties</i> BC 20/20 Institute of Industrial Organic Chemistry The Department of Physicochemical Properties and Environmental Protection 6 Annopol Str., PL, 03 236, Warsaw GLP Yes Unpublished	N	Chemiroł
KCP 2.4.2/01	Arévalo E.	2019	<i>Ethofumesate 500SC, Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i> BF 33/20 Lukasiewicz Research Network— Institute of Industrial Organic Chemistry 6 Annopol St., 03 236 Warsaw, Poland GLP Yes Unpublished	N	Chemiroł
KCP 2.4.2/01	Arévalo E.	2021	<i>CHR/H/ETO 500 SC,</i> <i>Ethofumesate 500SC(CHR/H/ETO 500SC) Part II:</i> <i>Determination of physicochemical properties of the preparation.</i> BF 33/20 Lukasiewicz Research Network— Institute of Industrial Organic Chemistry 6 Annopol St., 03 236 Warsaw, Poland GLP Yes Unpublished		Chemiroł
KCP 2.5.1	Arévalo E.	2019	<i>Ethofumesate 500SC, Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i> BF 33/20 Lukasiewicz Research Network— Institute of Industrial Organic Chemistry 6 Annopol St., 03 236 Warsaw, Poland GLP Yes Unpublished	N	Chemiroł
KCP 2.5.2	Arévalo E.	2019	<i>Ethofumesate 500SC, Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i> BF 33/20 Lukasiewicz Research Network— Institute of Industrial Organic Chemistry 6 Annopol St., 03 236 Warsaw, Poland GLP Yes Unpublished	N	Chemiroł
KCP 2.6.1	Arévalo E.	2019	<i>Ethofumesate 500SC, Determination of physicochemical properties of the initial preparation, after accelerated</i>	N	Chemiroł



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
			<i>storage and after storage at 0°C</i> <i>BF 33/20</i> <i>Lukasiewicz Research Network –</i> <i>Institute of Industrial Organic Chemistry</i> <i>6 Annopol St., 03-236 Warsaw, Poland</i> <i>GLP – Yes</i> <i>Unpublished</i>		
KCP 2.7.1	Arévalo, E.	2019	<i>Ethofumesate 500SC, Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i> <i>BF 33/20</i> <i>Lukasiewicz Research Network –</i> <i>Institute of Industrial Organic Chemistry</i> <i>6 Annopol St., 03-236 Warsaw, Poland</i> <i>GLP – Yes</i> <i>Unpublished</i>	N	Chemiroł
KCP 2.7.4/01	Arévalo, E.	2019	<i>Ethofumesate 500SC, Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i> <i>BF 33/20</i> <i>Lukasiewicz Research Network –</i> <i>Institute of Industrial Organic Chemistry</i> <i>6 Annopol St., 03-236 Warsaw, Poland</i> <i>GLP – Yes</i> <i>Unpublished</i>	N	Chemiroł
KCP 2.7.4/02	Arévalo, E.	2021	<i>CHR/H/ETO 500 SC,</i> <i>Ethofumesate 500SC(CHR/H/ETO 500SC) Part II:</i> <i>Determination of physicochemical properties of the preparation.</i> <i>BF 33/20</i> <i>Lukasiewicz Research Network –</i> <i>Institute of Industrial Organic Chemistry</i> <i>6 Annopol St., 03-236 Warsaw, Poland</i> <i>GLP – Yes</i> <i>Unpublished</i>	N	Chemiroł
KCP 2.7.5	Arévalo, E.	2021	<i>CHR/H/ETO 500 SC,</i> <i>Ethofumesate 500SC(CHR/H/ETO 500SC) Part II:</i> <i>Determination of physicochemical properties of the preparation.</i> <i>BF 33/20</i> <i>Lukasiewicz Research Network –</i> <i>Institute of Industrial Organic Chemistry</i> <i>6 Annopol St., 03-236 Warsaw, Poland</i> <i>GLP – Yes</i> <i>Unpublished</i>	N	Chemiroł
			<i>CHR/H/ETO 500 SC,</i> <i>Ethofumesate 500SC(CHR/H/ETO 500SC) Part III:</i> <i>Determination of physicochemical properties of the preparation after the first year of storage</i> <i>BF 33/20</i>	N	Chemiroł

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
			<del>Lukasiewicz Research Network – Institute of Industrial Organic Chemistry 6 Annopol St., 03-236 Warsaw, Poland GLP – Yes Unpublished</del>		
KCP 2.8.2	Arévalo, E.	2019	<del>Ethofumesate 500SC, Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C BF 33/20 Lukasiewicz Research Network – Institute of Industrial Organic Chemistry 6 Annopol St., 03-236 Warsaw, Poland GLP – Yes Unpublished</del>	N	Chemiroł
KCP 2.8.3.1/01	Arévalo, E.	2019	<del>Ethofumesate 500SC, Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C BF 33/20 Lukasiewicz Research Network – Institute of Industrial Organic Chemistry 6 Annopol St., 03-236 Warsaw, Poland GLP – Yes Unpublished</del>	N	Chemiroł
KCP 2.8.3.1/02	Arévalo, E.	2021	<del>CHR/H/ETO-500-SC, Ethofumesate 500SC(CHR/H/ETO-500SC) Part II: Determination of physicochemical properties of the preparation. BF 33/20 Lukasiewicz Research Network – Institute of Industrial Organic Chemistry 6 Annopol St., 03-236 Warsaw, Poland GLP – Yes Unpublished</del>	N	Chemiroł
KCP 2.8.3.2/01	Arévalo, E.	2019	<del>Ethofumesate 500SC, Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C BF 33/20 Lukasiewicz Research Network – Institute of Industrial Organic Chemistry 6 Annopol St., 03-236 Warsaw, Poland GLP – Yes Unpublished</del>	N	Chemiroł
KCP 2.8.3.2/01	Arévalo, E.	2021	<del>CHR/H/ETO-500-SC, Ethofumesate 500SC(CHR/H/ETO-500SC) Part II: Determination of physicochemical properties of the preparation. BF 33/20 Lukasiewicz Research Network – Institute of Industrial Organic Chemistry 6 Annopol St., 03-236 Warsaw, Poland</del>	N	Chemiroł

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
			<del>GLP – Yes</del> <del>Unpublished</del>		
KCP 2.8.5.1.2/01	Arévalo, E.	2019	<i>Ethofumesate 500SC, Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i> BF–33/20 Lukasiewicz Research Network – Institute of Industrial Organic Chemistry 6 Annopol St., 03-236 Warsaw, Poland <del>GLP – Yes</del> <del>Unpublished</del>	N	Chemirol
KCP 2.8.5.1.2/02	Arévalo E.	2021	<i>CHR/H/ETO-500-SC, Ethofumesate 500SC(CHR/H/ETO-500SC) Part II: Determination of physicochemical properties of the preparation.</i> BF–33/20 Lukasiewicz Research Network – Institute of Industrial Organic Chemistry 6 Annopol St., 03-236 Warsaw, Poland <del>GLP – Yes</del> <del>Unpublished</del>	N	Chemirol
KCP 2.8.7.2/01	Arévalo, E.	2019	<i>Ethofumesate 500SC, Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i> BF–33/20 Lukasiewicz Research Network – Institute of Industrial Organic Chemistry 6 Annopol St., 03-236 Warsaw, Poland <del>GLP – Yes</del> <del>Unpublished</del>	N	Chemirol
KCP 2.8.7.2/02	Arévalo E.	2021	<i>CHR/H/ETO-500-SC, Ethofumesate 500SC(CHR/H/ETO-500SC) Part II: Determination of physicochemical properties of the preparation.</i> BF–33/20 Lukasiewicz Research Network – Institute of Industrial Organic Chemistry 6 Annopol St., 03-236 Warsaw, Poland <del>GLP – Yes</del> <del>Unpublished</del>	N	Chemirol
KCP 2.11/01	Arévalo, E.	2019	<i>Ethofumesate 500SC, Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C</i> BF–33/20 Lukasiewicz Research Network – Institute of Industrial Organic Chemistry 6 Annopol St., 03-236 Warsaw, Poland <del>GLP – Yes</del> <del>Unpublished</del>	N	Chemirol

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 2.11/02	Arévalo, E.	2021	CHR/H/ETO-500-SC, Ethofumesate 500SC(CHR/H/ETO-500SC) Part II: Determination of physicochemical properties of the preparation. BF-33/20 Lukasiewicz Research Network – Institute of Industrial Organic Chemistry 6 Annopol St., 03-236 Warsaw, Poland GLP- Yes Unpublished	N	Chemiroł
KCP 2.12	Arévalo, E.	2019	Ethofumesate 500SC, Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0°C BF-33/20 Lukasiewicz Research Network – Institute of Industrial Organic Chemistry 6 Annopol St., 03-236 Warsaw, Poland GLP- Yes Unpublished	N	Chemiroł

**List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

**List of data submitted by the applicant and not relied on**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study</b> <b>Y/N</b>	<b>Owner</b>

## **Appendix 2    Additional data on the physical, chemical and technical properties of the active substance**