

# 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: AG-E1-500 SC1

Product name: Ethosat 500 SC

Chemical active substances:

Ethofumesate, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

(authorization)

Sponsor: ADAMA Agan Ltd.

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

Submission date: March 2021

MS Finalisation date: January 2022 (initial core Assessment),  
updated May 2022

June 2022 (final Core Assessment)

### Version history

When	What
March 2021	Applicant initial dRR.
January 2022	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.
May 2022	dRR Applicant up-date 1 to include the final report of the 2 years shelf-life study - the introduced text highlighted in yellow.
June 2022	Final report (Core Assessment updated following the commenting period).  Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded.

## **DATA PROTECTION CLAIM**

Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for these studies. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A

## **STATEMENT FOR OWNERSHIP**

The summaries and evaluations contained in this document may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either –

- from the owner of the data, or
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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product AG-E1-500 SC1 and the contained technical active substance.

Noticed data gaps are: **none**

- ~~• The 2 years storage stability is still ongoing upon submission of the dossier, which is a formal data GAP. Sufficient data however is available from the accelerated storage testing. Additionally, interim results of the ongoing study after one year storage of AG-E1-500 SC1 formulation is included in this submission.~~

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

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

Country organisation/representative as specified in Part A.

Name	Country organisation/representative of ADAMA Agan Ltd. as given in Part A
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#### **On behalf of:**

Address:	ADAMA Agan Ltd. PO Box 262 Ashdod, 7710201 Israel
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Contact:	XXXXXXXXXXXXXXXXXX
Telephone No.:	XXXXXXXXXXXXXXXXXX
Fax:	-
E-mail:	XXXXXXXXXXXXXXXXXXXX

Please refer to Registration Report Part A for national applicant contact details.

### **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**

Ethofumesate	min. 975 g/kg
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According to Commission Implementing Regulation (EU) 2016/1426 of 25 August 2016 the following impurities of toxicological concern have been identified for ethofumesate:

EMS (ethyl methane sulfonate):	max. 0.1 mg/kg
iBMS (iso-butyl methane sulfonate):	max. 0.1 mg/kg

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

Trade name: Ethosat 500 SC; please refer to Registration Report Part A for the relevant country information

Company code number: AG-E1-500 SC1 and ADM.02650.H.1.A (the ADM code will replace in the future the AG code, both refer to the same product)

### 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)

AG-E1-500 SC1 is a new product. It was not the representative formulation during evaluation of ethofumesate on EU level.

**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)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
Ethofumesate	500	500 g/L ± 25 g/L (475 – 525 g/L)	512.8 g/L ± 25 g/L (487.8 – 537.8)	45.78

\* Based on the minimum purity of the active substance;  
Minimum purity of 97.5 % (w/w)

\*\* Based on the density of the formulation = 1.12 g/mL

**Table 1.4-2: Relevant impurities**

Relevant impurity	Maximum content (g/kg)
EMS (ethyl methane sulfonate): iBMS (iso-butyl methane sulfonate):	0.1 mg/kg related to active substance content 0.1 mg/kg related to active substance content

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

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

Type	Name/Code Number	
ISO common name	ethofumesate	no variant
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)

Safeners or synergists are not present in the formulation.

With regard to co-formulants, this is CONFIDENTIAL information and is 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.

## 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 a homogeneous white liquid. It is not explosive, has no oxidising properties. The product has a flash point of >90 °C. It has a self-ignition temperature of 480°C. The pH value of the neat formulation is 7.7 at ambient temperature. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the content of the active ingredient nor the technical properties were changed. ~~The 2 years shelf life study is on going at the time of submission of this dossier. Interim~~ The results after ~~one year~~ two years of storage are provided. Based on these results and on the accelerated storage stability study, the data confirms the high quality of the formulation and the shelf life ~~expected to be~~ at least 2 years when stored at ambient temperature in HDPE commercial containers. Its technical characteristics are acceptable for a SC formulation.

The intended concentration of use is 0.15% to 1% v/v.

The product can be used in tank mixtures.

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

Experimental results on the product AG-E1-500 SC1 with regard to product classification and labelling:

Studies	Method	Findings	Classification acc. to Regulation (EC) No. 1272/2008
Explosive properties	Expert statement	Not explosive	None
Oxidising properties	Expert statement	Not oxidizing	None
Flammability	--	Not applicable for SC-formulation	--
Flash point	EEC A.9	> 90°C	None
Auto-flammability	EEC A.15	Self-ignition temperature = 480°C	None
pH	CIPAC MT 75.3	7.7	None
Viscosity	CIPAC MT 192, OECD	Dynamic viscosity at 20°C 213.1 mPa*s at 18 s <sup>-1</sup> and 85.5 mPa*s at 105 s <sup>-1</sup> Dynamic viscosity at 40°C 190.0 mPa*s at 18 s <sup>-1</sup> 76.3 mPa*s at 105 s <sup>-1</sup> Kinematic Viscosity at 20°C 170.5 mm <sup>2</sup> /s at 18 s <sup>-1</sup> 62.5 mm <sup>2</sup> /s at 105 s <sup>-1</sup>	None
Surface tension	EEC A.5	41.6 mN/m for 1% (v/v) solution of the test item in water at 21.7°C	None
Relative density	EEC A.3	1.12 g/mL	None

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

No precautionary statements according to Regulation (EC) No. 1272/2008 are needed with regard to the physical/chemical data of the product.

### Compliance with FAO specifications:

The product AG-E1-500 SC1 complies with FAO specifications.

### Formulation used for tests

The test item used in the studies with one exception has the same composition as the one cited in Part C. Only the study for the determination of self-ignition properties has been conducted with a former formulation. The result of this study can be taken into account for AG-E1-500 SC1 as the difference between the compositions can be regarded as non-significant. For details, please refer to Part C.

**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 examination	AG-E1-500 SC1 Content of a.s. (analysed): 517.5 g/L Batch No.: F4905	<u>Before and after storage of 14 days at 54 °C:</u> Homogeneous white liquid <u>After storage:</u> No sedimentation, phase separation or colour change was detected  <u>Before and after storage of 7 days at 0 °C:</u> Homogeneous white liquid. No sedimentation, phase separation or colour change was detected.	Y	KCP 2.1/01 Tsesin, N. (2020a) Study no.: 000104496.057FL	Accepted.
Explosive properties (KCP 2.2.1)	Expert statement (according to EEC A.14)	AG-E1-500 SC1 Content of a.s. 512.8 g/L	No explosive properties.	N	KCP 2.2.1 /01 Köttig, M. (2020) Doc. No.: 000105946  Filed in Part C confidential section	Accepted.
Oxidizing properties (KCP 2.2.2)	Expert statement (according to EEC A.21)	AG-E1-500 SC1 Content of a.s. 512.8 g/L	No oxidising properties.	N	KCP 2.2.1 /01 Köttig, M. (2020) Doc. No.: 000105946  Filed in Part C confidential section	Accepted.
Flash point (KCP 2.3.1)	ASTM D 93 Closed cup non-equilibrium method EEC Method A.9	AG-E1-500 SC1 Content of a.s. (analysed): 517.5 g/L Batch No.: F4905	No flash point until 90 °C, therefore the test item is considered to be not flammable.	Y	KCP 2.1/01 Tsesin, N. (2020a) Study no.: 000104496.057FL	Accepted.
Flammability (KCP 2.3.2)	-	-	Not required for SC preparation.	-	-	-
Self-heating (KCP 2.3.3)	EEC A.15	Ethosat 500 Content of a.s. (analysed): 505 g Batch No.: CVS99008	Self-ignition temperature = 480°C.	Y	KCP 2.3.3/01 Warneke, U. (1999) Study no.: U99PCH07	Accepted.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3	AG-E1-500 SC1 Content of a.s. (analysed):	Pure, undiluted product measured at ambient temperature: <u>Before storage (at 17°C):</u> pH = 7.7 <u>After storage for 14 days at 54°C (at 17°C):</u> pH = 7.7	Y	KCP 2.1/01 Tsesin, N. (2020a) Study no.:	Accepted.



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																					
		517.5 g/L Batch No.: F4905	Acidity or alkalinity not required because pH >4 and <10		000104496.057FL																						
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	AG-E1-500 SC1 Content of a.s. (analysed): 517.5 g/L Batch No.: F4905	1% w/w in deionized water measured at ambient temperature: <u>Before storage (at 18°C)</u> : pH = 7.7 <u>After storage</u> for 14 days at 54°C(at 18°C): pH = 7.6	Y	KCP 2.1/01 Tsesin, N. (2020a) Study no.: 000104496.057FL	Accepted.																					
Viscosity (KCP 2.5.1)	OECD 114, ISO 2431:1993(E) using a spindle	AG-E1-500 SC1 Content of a.s. (analysed): 517.5 g/L Batch No.: F4905	<table border="1"><thead><tr><th>Shear rate (s<sup>-1</sup>)</th><th>Mean viscosity at 20°C</th><th>Mean viscosity at 40°C</th></tr></thead><tbody><tr><td colspan="3">Dynamic viscosity (cP = mPa*s)</td></tr><tr><td>18</td><td>213.1</td><td>170.5</td></tr><tr><td>105</td><td>85.5</td><td>62.5</td></tr><tr><td colspan="3">Kinematic viscosity (cSt = mm<sup>2</sup>/s)</td></tr><tr><td>18</td><td>190.0</td><td>-</td></tr><tr><td>105</td><td>76.3</td><td>-</td></tr></tbody></table> Mean of 2 measurements Kinematic viscosity = dynamic viscosity / density (1.12)	Shear rate (s <sup>-1</sup> )	Mean viscosity at 20°C	Mean viscosity at 40°C	Dynamic viscosity (cP = mPa*s)			18	213.1	170.5	105	85.5	62.5	Kinematic viscosity (cSt = mm <sup>2</sup> /s)			18	190.0	-	105	76.3	-	Y	KCP 2.1/01 Tsesin, N. (2020a) Study no.: 000104496.057FL	Accepted.
Shear rate (s <sup>-1</sup> )	Mean viscosity at 20°C	Mean viscosity at 40°C																									
Dynamic viscosity (cP = mPa*s)																											
18	213.1	170.5																									
105	85.5	62.5																									
Kinematic viscosity (cSt = mm <sup>2</sup> /s)																											
18	190.0	-																									
105	76.3	-																									
Surface tension (KCP 2.5.2)	EEC A.5 Ring Tensiometer	AG-E1-500 SC1 Content of a.s. (analysed): 517.5 g/L Batch No.: F4905	1.0% v/v of product (highest in-use spray concentration) in deionized water at 21.7 °C  41.6 mN/m  Surface active formulation	Y	KCP 2.1/01 Tsesin, N. (2020a) Study no.: 000104496.057FL	Accepted. Product is considered as surface active.																					
Relative density (KCP 2.6.1)	EEC A.3 using an oscillating Density Meter	AG-E1-500 SC1 Content of a.s. (analysed): 517.5 g/L Batch No.: F4905	Density at 20°C: 1.12 g/mL  Relative density 1.12	Y	KCP 2.1/01 Tsesin, N. (2020a) Study no.: 000104496.057FL	Accepted.																					
Bulk density (KCP 2.6.2)	-	-	Not required for SC preparation.	-	-	-																					
Storage Stability after 14 days at 54°C (KCP 2.7.1)	CIPAC MT 46.3  The content of ethofumesate was analysis using validated HPLC-	AG-E1-500 SC1 Content of a.s. (analysed): 517.5 g/L Batch No.: F4905	Results of the analysis before and after storage indicated that AG-E1-500 SC1 is physically and chemically stable when stored for 14 days at 54 °C.  Please refer to Table 2.2 for more details <b>Note:</b> With respect to the relevant impurities, storage data are strictly	Y	KCP 2.1/01 Tsesin, N. (2020a) Study no.: 000104496.057FL	The product showed no significant physical changes after accelerated storage. No significant changes were observed in the																					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	UV method (see KCP 5.1.1/01)		only required where the relevant impurities may form upon storage of the product or during manufacture of the formulation (guidance document for the generation of data on physical, chemical and technical properties of plant protection product under regulation (EC) no. 1107/2009). As the relevant impurities of ethofumesate origin from the manufacturing process of the active substance, their investigation during storage of the formulation are not considered to be required.			<p>packaging and therefore it can be concluded that the test item was not corrosive to the container material and that HDPE was satisfactory for the storage of AG-E1-500 SC1.</p> <p>No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage, evaluation of this parameter after storage is not necessary.</p> <p>The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE.</p>
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required as AG-E1-500 SC1 was shown to be stable for 14 days at 54 °C.	-	-	-
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Not required as AG-E1-500 SC1 was shown to be stable for 14 days at 54 °C.	-	-	-
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3  The content of ethofumesate was analysed using validated HPLC-	AG-E1-500 SC1 Content of a.s. (analysed): 517.5 g/L Batch No.: F4905	Results of the analysis before and after storage indicated that AG-E1-500 SC1 is physically and chemically stable when stored at 0°C for 7 Days.  Please refer to Table 2.3 for more details.	Y	KCP 2.1/01 Tsesin, N. (2020a) Study no.: 000104496.057FL	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	UV method (see KCP 5.1.1/01)					
Ambient temperature shelf life (KCP 2.7.5)	<p>CIPAC MT 75.3 MT 148 MT 184 MT 185 MT 160 MT 187 MT 47.3</p> <p>The content of ethofumesate was analysis using validated HPLC-UV method (see KCP 5.1.1/01).</p>	AG-E1-500 SC1	<p>One batch of Ethosat 500 SC (AG-E1-500 SC1) packed in HDPE commercial containers were stored at ambient temperature for two years. The one-year interim results are presented in Table 2-4. The 2 years shelf life results are presented in Table 2-5, as the study is ongoing.</p> <p>None of the properties under evaluation showed any relevant deviation from specified limits when the results after one year and 2 years of storage were compared to the results before storage.</p> <p>Based on the results of this interim data, the product is expected to be stable when stored in original HDPE commercial containers.</p> <p>Please see Table 2-4 and Table 2-5 below for detailed results of the report.</p> <p><b>Note:</b> With respect to the relevant impurities, storage data are strictly only required where the relevant impurities may form upon storage of the product or during manufacture of the formulation (guidance document for the generation of data on physical, chemical and technical properties of plant protection product under regulation (EC) no. 1107/200). As the relevant impurities of ethofumesate origin from the manufacturing process of the active substance, their investigations during storage of the formulation are not considered to be required.</p>	Y	<p>KCP 2.7.5/01 Tsesin, N. (2022) Study no.: 000104497 KCP 2.7.5/01 Tsesin, N. (2020b) Study no.: 000104497 Interim result</p>	<p>The ambient temperature study is currently ongoing, and should be provided upon completion.</p> <p>The product showed no significant physical changes after 1 year and 2 years of storage. No significant changes were observed in the packaging and therefore it can be concluded that the test item was not corrosive to the container material and that HDPE was satisfactory for the storage of AG-E1-500 SC1.</p> <p>No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage, evaluation of this parameter after storage is not necessary.</p>
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not required formulation is expected to be stable for at least 2 years at shelf life conditions	-	-	<p>The ambient temperature study is currently ongoing, and should be provided upon completion.</p> <p>Not required. Shelf life at least 2 years when stored at ambient tem-</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments															
						perature in HDPE commercial containers.															
Wettability (KCP 2.8.1)	-	-	Not required for SC preparation	-	-	-															
Persistence of foam-ing (KCP 2.8.2)	CIPAC MT 47.3	AG-E1-500 SC1 Content of a.s. (analysed): 517.5 g/L Batch No.: F4905	Persistent foaming (ml) at room temperature (18 °C) in standard water D <table><tr><td>Time</td><td>0.038% v/v product</td><td>0.1% v/v product</td></tr><tr><td>0 s</td><td>11 mL</td><td>31 mL</td></tr><tr><td>After 1 min</td><td>9 mL</td><td>27 mL</td></tr><tr><td>After 12 min</td><td>7 mL</td><td>21 mL</td></tr></table>	Time	0.038% v/v product	0.1% v/v product	0 s	11 mL	31 mL	After 1 min	9 mL	27 mL	After 12 min	7 mL	21 mL	Y	KCP 2.1/01 Tsesin, N. (2020a) Study no.: 000104496.057FL	Accepted.			
Time	0.038% v/v product	0.1% v/v product																			
0 s	11 mL	31 mL																			
After 1 min	9 mL	27 mL																			
After 12 min	7 mL	21 mL																			
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184  The content of ethofumesate was analysis using validated HPLC-UV method (see KCP 5.1.1/01).	AG-E1-500 SC1 Content of a.s. (analysed): 517.5 g/L Batch No.: F4905	Test with standard water D at 30°C <table><tr><td>Test</td><td>0.2% v/v product</td><td>1% v/v product</td></tr><tr><td colspan="3">Suspensibility (%)</td></tr><tr><td>Initial results</td><td>99</td><td>99</td></tr><tr><td>Results after storage 14 days at 54°C</td><td>96</td><td>96</td></tr><tr><td>Results after storage 7 days at 0°C</td><td>99</td><td>99</td></tr></table>	Test	0.2% v/v product	1% v/v product	Suspensibility (%)			Initial results	99	99	Results after storage 14 days at 54°C	96	96	Results after storage 7 days at 0°C	99	99	Y	KCP 2.1/01 Tsesin, N. (2020a) Study no.: 000104496.057FL	Accepted.
Test	0.2% v/v product	1% v/v product																			
Suspensibility (%)																					
Initial results	99	99																			
Results after storage 14 days at 54°C	96	96																			
Results after storage 7 days at 0°C	99	99																			
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160 Analysis using validated in-house method (see KCP 5.1.1/01).  The content of ethofumesate was analysis using validated HPLC-UV method (see KCP 5.1.1/01).	AG-E1-500 SC1 Content of a.s. (analysed): 517.5 g/L Batch No.: F4905	Spontaneity of dispersion 5% v/v measurement of ethofumesate in standard water D. <table><tr><td></td><td>Mean dispersibility*</td></tr><tr><td>Before storage</td><td>95 %</td></tr><tr><td>After storage</td><td>91 %</td></tr></table> * — Mean of two samples		Mean dispersibility*	Before storage	95 %	After storage	91 %	Y	KCP 2.1/01 Tsesin, N. (2020a) Study no.: 000104496.057FL	Accepted.									
	Mean dispersibility*																				
Before storage	95 %																				
After storage	91 %																				
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for SC preparation	-	-	-															
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required for SC preparation	-	-	-															
Particle size distribution / nominal size	CIPAC MT 187 Malvern Master-	AG-E1-500 SC1 Content of a.s.		Y	KCP 2.1/01 Tsesin, N. (2020a)	Accepted.															

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																				
range of granules (KCP 2.8.5.1.1)	size 3000	(analysed): 517.5 g/L Batch No.: F4905	<table><tr><td>Test</td><td>Initial results</td><td colspan="2">Results after storage 14 days at 54 °C</td></tr><tr><td colspan="4">Particle size distribution (µm)</td></tr><tr><td>D(0.9)</td><td>9.9</td><td colspan="2">12.3</td></tr><tr><td>D(0.5)</td><td>4.3</td><td colspan="2">5.3</td></tr><tr><td>D(0.1)</td><td>2.0</td><td colspan="2">2.4</td></tr></table>	Test	Initial results	Results after storage 14 days at 54 °C		Particle size distribution (µm)				D(0.9)	9.9	12.3		D(0.5)	4.3	5.3		D(0.1)	2.0	2.4			Study no.: 000104496.057FL	
Test	Initial results	Results after storage 14 days at 54 °C																								
Particle size distribution (µm)																										
D(0.9)	9.9	12.3																								
D(0.5)	4.3	5.3																								
D(0.1)	2.0	2.4																								
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	AG-E1-500 SC1 Content of a.s. (analysed): 517.5 g/L Batch No.: F4905	<table><tr><td colspan="4">Residue on 75µm sieve</td></tr><tr><td>Test</td><td>Initial results</td><td>After storage 14 days at 54°C</td><td>After storage 7 days at 0°C</td></tr><tr><td>Wet sieve test (%)</td><td>0</td><td>0</td><td>0</td></tr></table>	Residue on 75µm sieve				Test	Initial results	After storage 14 days at 54°C	After storage 7 days at 0°C	Wet sieve test (%)	0	0	0	Y	KCP 2.1/01 Tsesin, N. (2020a) Study no.: 000104496.057FL	Accepted.								
Residue on 75µm sieve																										
Test	Initial results	After storage 14 days at 54°C	After storage 7 days at 0°C																							
Wet sieve test (%)	0	0	0																							
Dust content (KCP 2.8.5.2.1)	-	-	Not required for SC preparation	-	-	-																				
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required for SC preparation	-	-	-																				
Attrition (KCP 2.8.5.3)	-	-	Not required for SC preparation	-	-	-																				
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required for SC preparation	-	-	-																				
Emulsifiability (KCP 2.8.6.1)	-	-	Not required for SC preparation	-	-	-																				
Emulsion stability (KCP 2.8.6.2)	-	-	Not required for SC preparation	-	-	-																				
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not required for SC preparation	-	-	-																				
Flowability (KCP 2.8.7.1)	-	-	Not required for SC preparation	-	-	-																				
Pourability (KCP 2.8.7.2)	CIPAC MT 148	AG-E1-500 SC1 Content of a.s. (analysed): 517.5 g/L Batch No.: F4905	<table><tr><td>Test</td><td>Initial results</td><td colspan="2">Results after storage 14 days at 54°C</td></tr><tr><td>Pourability (%)</td><td></td><td colspan="2"></td></tr><tr><td>Residue R (%)</td><td>2.0</td><td colspan="2">2.1</td></tr><tr><td>Rinsed residue R' (%)</td><td>0.23</td><td colspan="2">0.23</td></tr></table>	Test	Initial results	Results after storage 14 days at 54°C		Pourability (%)				Residue R (%)	2.0	2.1		Rinsed residue R' (%)	0.23	0.23		Y	KCP 2.1/01 Tsesin, N. (2020a) Study no.: 000104496.057FL	Accepted.				
Test	Initial results	Results after storage 14 days at 54°C																								
Pourability (%)																										
Residue R (%)	2.0	2.1																								
Rinsed residue R' (%)	0.23	0.23																								
Dustability following accelerated storage	-	-	Not required for SC preparation	-	-	-																				

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.7.3)						
Physical compatibility of tank mixes (KCP 2.9.1)	ASTM E1518-05	AG-E1-500 SC1 Batch No.: 8194	<p>The mixtures shown in Table 2-6 and 2-7 as “compatible” are physically and chemically compatible under dynamic conditions in the laboratory according to this study.</p> <p>All mixtures reported as “compatible” gave well-dispersed mixtures in water. No separation, flocculation, coagulation, gel or curd were noticed. There were no residues on the wall of the flasks and no residues remaining on a sieve.</p> <p>Most of the mixtures reported as incompatible showed only few small, soft residues on the sieve (pictures are provided in the report). Depending on the spraying equipment it might be nonetheless possible to use them, as it is expected that due to the pressure in the spraying equipment the soft residues will be pushed through. In any case the spraying mixtures should be used shortly after preparation.</p>	Y	KCP 2.9.1/01 Thomas H., (2021) Study no.: 21 35 CRX 0003	Accepted. Compatibility has been confirmed.
Chemical compatibility of tank mixes (KCP 2.9.2)	ASTM E1518-05	AG-E1-500 SC1 Batch No.: 8194	<p>No chemical reactions were observed in the tested mixtures. From the chemical data of the active substances the following conclusions can be drawn:</p> <ul style="list-style-type: none"> <li>• AG-E1-500 SC1 has near neutral pH in the application dilution (1 L in 100 L water, measured pH 6.8)</li> <li>• Ethofumesate, the active substance of AG-E1-500 SC1, is stable from pH 5 to pH 9. Even though some of the mixtures investigated showed pH values below 5 (mixtures with Goltix Queen, Kontakt, Goltix Gold + Kontakt, Tanaris), sufficient stability of Ethofumesate can be assumed.</li> <li>• AG-E1-500 SC1 does not influence the pH of the mixing partners significantly, so the stability of their active substances should not be affected by the mixture.</li> </ul> <p>Ethofumesate is non-ionic, and has no acidic or basic characteristics. Therefore, there is no influence on acidic, basic or ionic mixing partners.</p>	Y	KCP 2.9.1/01 Thomas H., (2021) Study no.: 21 35 CRX 0003	Please refer to the point 2.9.1.
Adhesion to seeds (KCP 2.10.1)	-	-	Not required	-	-	-
Distribution to seed (KCP 2.10.2)	-	-	Not required	-	-	-
Other/special studies (KCP 2.11)	-	-	None	-	-	-

**Table 2-2: Test Results before and after 14 days storage stability at 54°C**

Test Results before and after 14 days storage stability at 54 °C									
Test Method	Results before storage				Results after storage for 14 days at 54°C				
Appearance (physical state and colour)	AG-E1-500 SC1 was a homogeneous white liquid				AG-E1-500 SC1 was a homogeneous white liquid No sedimentation, phase separation or colour change was detected				
Stability of the original test item container (visual)	Before storage the HDPE container (1 L HDPE commercial container). No damage to the container shape or size was observed.				After storage of the container (1 L HDPE commercial container) no visible interaction of the formulation with the packaging was observed.				
Weight change of test item container	-				A minor change in weight was found after storage (0.03 %).				
Content of ethofumesate	509.6 g/L = 45.46% (w/w)				509.2 g/L = 45.42% (w/w)				
pH value of undiluted product (CIPAC MT 75.3)	7.7				7.7				
pH value of 1% (w/w) solution (CIPAC MT 75.3)	7.7				7.6				
Acidity/ Alkalinity (CIPAC MT 191)	Not determined because the pH of the product was >4 and <10				Not determined because the pH of the product was >4 and<10.				
Persistent Foam (CIPAC MT 47.3) Standard water D	C = 0.038% (v/v)		C = 1.00% (v/v)		C = 0.038% (v/v)		C = 1.00% (v/v)		
	After 0 sec	11 mL	After 0 sec	31 mL	After 0 sec	13 mL	After 0 sec	33 mL	
	after 1 min	9 mL	after 1 min	27 mL	after 1 min	9 mL	after 1 min	25 mL	
	after 12 min	7 mL	after 12 min	21 mL	after 12 min	7 mL	after 12 min	19 mL	
Suspensibility* of ethofumesate (CIPAC MT 184)	C = 0.2% (v/v)		C = 1.0% (v/v)		C = 0.2% (v/v)		C = 1.0% (v/v)		
	99		99		96		96		
Spontaneity of dispersion 5% v/v * by ethofumesate (CIPAC MT 160)	95% of ethofumesate				91% of ethofumesate				
Wet Sieving (CIPAC MT 185)	residue on 75 µm sieve: 0.0%				residue on 75 µm sieve: 0.0%				
Particle Size Distribution by Malvern Mastersizer 3000 (CIPAC MT 187)	D (0.9): 9.9 µm D (0.5): 4.3 µm D (0.1): 2.0 µm				D (0.9): 12.3 µm D (0.5): 5.3 µm D (0.1): 2.4 µm				
Pourability (CIPAC MT 148)	Residue R (%)		Rinsed residue R' (%)		Residue R		Rinsed residue R'		
	2.0		0.23		2.1		0.23		

\*The tests suspensibility, persistent foaming and spontaneity of dispersion were performed using CIPAC standard water D.

**Table 2-3: Test Results before and after 7 days storage stability at 0°C**

Test Method	Results before storage		Results after storage at 0 °C for 7 days	
Appearance (physical state and colour)	AG-E1-500 SC1 was a homogeneous white liquid		AG-E1-500 SC1 was a homogeneous white liquid No colour change was detected. No sedimentation, phase separation or	
Wet Sieving (CIPAC MT 185)	residue on 75 µm sieve: 0 %		residue on 75 µm sieve: 0 %	
Suspensibility* by ethofumesate (CIPAC MT 184)	C = 0.2% (v/v)	C = 1.00% (v/v)	C = 0.2% (v/v)	C = 1.00% (v/v)
	99	99	99	99

\*The test suspensibility was performed with CIPAC standard water D.



**Table 2-4: Storage stability at ambient temperature for 2 years for a Product Packed in HDPE commercial containers (1 year interim results)**

Storage stability at ambient temperature for 2 years for a 1 Product Packed in HDPE commercial containers (1 year interim results)								
Test Method	Results before storage				Results after storage for 1 year at ambient temperature			
Appearance (physical state and colour)	AG-E1-500 SC1 was a white slightly viscous liquid				AG-E1-500 SC1 was a white slightly viscous liquid. After storage about 5% bleeding, homogenous after three inverts. no claying or sedimentation was detected.			
Stability of the original test item container (visual)	HDPE container				After storage of the container (HDPE commercial container). No change in packaging. No visible interaction of the formulation with its packaging.			
Weight change of test item container	-				No significant change in weight			
Content of ethofumesate	510 g/L = 45.5 % (w/w)				507.8 g/L = 45.30 % (w/w)			
pH value of undiluted product (CIPAC MT 75.3)	7.7				7.8			
pH value of 1% (w/w) solution (CIPAC MT 75.3)	7.7				7.8			
Persistent Foam (CIPAC MT 47.3) Standard water D	C = 0.038% (v/v)		C = 1.00% (v/v)		C = 0.038% (v/v)		C = 1.00% (v/v)	
	After 0 sec	11 mL	After 0 sec	31 mL	After 0 sec	20 mL	After 0 sec	37 mL
	after 1 min	9 mL	after 1 min	27 mL	after 1 min	14 mL	after 1 min	26 mL
Suspensibility* of ethofumesate (CIPAC MT 184)	C = 0.2% (v/v)		C = 1.0% (v/v)		C = 0.2% (v/v)		C = 1.0% (v/v)	
	99		99		98		98	
Spontaneity of dispersion 5% v/v * by ethofumesate (CIPAC MT 160)	95% of ethofumesate				94% of ethofumesate			
Wet Sieving (CIPAC MT 185)	residue on 75 µm sieve: 0.0%				residue on 75 µm sieve: 0.0%			
Particle Size Distribution by Malvern Mastersizer 3000 (CIPAC MT 187)	D (0.9): 9.9 µm D (0.5): 4.3 µm D (0.1): 2.0 µm				D (0.9): 9.5 µm D (0.5): 4.3 µm D (0.1): 2.1 µm			
Pourability (CIPAC MT 148)	Residue R (%)		Rinsed residue R' (%)		Residue R		Rinsed residue R'	
	2.0		0.23		2.2		0.15	

\*The tests suspensibility, persistent foaming and spontaneity of dispersion were performed using CIPAC standard water D.

**Table 2-5: Storage stability at ambient temperature for 2 years for a Product Packed in HDPE commercial containers (2 years results)**

Test Method	Results before storage	Results after storage for 2 years at ambient temperature
Appearance (physical state and colour) (visual)	AG-E1-500 SC1 was a homogenous white slightly viscous liquid	AG-E1-500 SC1 was a white slightly viscous liquid. After storage about 5% bleeding, homogenous after three inverts. No claying or sedimentation was detected.
Stability of the original test item container (visual)	HDPE container	After storage of the container (HDPE commercial container). No change in packaging. No visible interaction of the formulation with its packaging.
Weight change of test item container	-	No significant change in weight (<2%)
Content of ethofumesate The active ingredient (AI) was assayed using High Performance Liquid Chromatography (HPLC) coupled to Diode Array Detector (DAD). Used test systems and analytical methods ensure obtaining reliable results in the study. A validation (specificity, confirmation of analyte identification, linearity, repeatability, system repeatability, peak purity, intermediate precision, accuracy and identification by HPLC coupled to Mass Spectrometric (MS) detector) of the HPLC analytical method employed for the determination of the Ethofumesate in Ethosat 500 SC formulation was fulfilled as part of study 000104496.057FL titled "Determination of Storage Stability and Physical-Chemical Properties of Ethosat 500 SC (AG-E1-500 SC1) Stored at 54°C for 14 Days and at 0°C for 7 Days".	510 g/L = 45.5 % (w/w)	524.7 g/L = 46.8 (w/w) (0.9% increase after 2 years)
pH value of undiluted product (CIPAC MT 75.3)	7.7	7.6
pH value of 1% (w/w) solution (CIPAC MT 75.3)	7.7	7.5

Test Method	Results before storage				Results after storage for 2 years at ambient temperature			
Persistent Foam (CIPAC MT 47.3) Standard water D	C = 0.038% (v/v)		C = 1.00% (v/v)		C = 0.038% (v/v)		C = 1.00% (v/v)	
	After 0 sec	11 ml	After 0 sec	31 ml	After 0 sec	20 ml	After 0 sec	36 ml
	after 1 min	9 ml	after 1 min	27 ml	after 1 min	15 ml	after 1 min	27 ml
Suspensibility* of ethofumesate (CIPAC MT 184)	C = 0.2% (v/v)		C = 1.0% (v/v)		C = 0.2% (v/v)		C = 1.0% (v/v)	
	99		99		99		97	
Spontaneity of dispersion 5% v/v * by ethofumesate (CIPAC MT 160)	95% of ethofumesate				93% of ethofumesate			
Wet Sieving (CIPAC MT 185)	residue on 75 µm sieve: 0.0%				residue on 75 µm sieve: 0.0%			
Particle Size Distribution by Malvern Mastersizer 3000 (CIPAC MT 187)	D (0.9): 9.9 µm D (0.5): 4.3 µm D (0.1): 2.0 µm				D (0.9): 9.5 µm D (0.5): 4.3 µm D (0.1): 2.1 µm			
Pourability (CIPAC MT 148)	Residue R (%)		Rinsed residue R' (%)		Residue R		Rinsed residue R'	
	2.0		0.23		1.5		0.14	

\*The tests suspensibility, persistent foaming and spontaneity of dispersion were performed using CIPAC standard water D.

**Table 2-65: Product AG-E1 500 SC1, Physical compatibility results**

No.	Product	Application rate	Water	Test application per 100 mL water	Dispersion stability	Nonrinsable residue on flask walls	Residue on sieve / size	Result: compatible?	pH	Temperature (°C)
I1	AG-E1-500 SC1	1.00 mL	100 L/ha	1.00 mL	stable	no	no / 75 µm	yes	6.8	20

**Table 2-76: Tank mixtures, Physical compatibility results**

No.	Product	Application rate	Water	Test application per 100 mL water	Dispersion stability	Nonrinsable residue on flask walls	Residue on sieve / size	Result: compatible?	pH	Temperature (°C)
M1	AG-E1-500 SC1 Goltix 700 SC	1.00 mL 1.50 mL	100 L/ha	1.00 mL 1.50 mL	yes	no	no / 300 µm	yes	6.4	20
M2	AG-E1-500 SC1 Goltix Queen	1.00 mL 1.50 mL	100 L/ha	1.00 mL 1.50 mL	yes	no	no / 300 µm	yes	3.9	20
M3	AG-E1-500 SC1 Kalif 360 CS	1.00 mL 0.2 mL	100 L/ha	1.00 mL 0.2 mL	yes	no	no / 300 µm	yes	7.1	21
M4	AG-E1-500 SC1 Agil 100 EC	1.00 mL 1.50 mL	100 L/ha	1.00 mL 1.50 mL	yes	no	no / 75 µm	yes	6.1	20
M5	AG-E1-500 SC1	1.00 mL	100 L/ha	1.00 mL	yes	no	no / 300 µm	yes	6.7	21

No.	Product	Application rate	Water	Test application per 100 mL water	Dispersion stability	Nonrinsable residue on flask walls	Residue on sieve / size	Result: compatible?	pH	Temperature (°C)
	Leopard	2.50 mL		2.50 mL						
M6	AG-E1-500 SC1 MCW-2222	1.00 mL 0.25 mL	100 L/ha	1.00 mL 0.25 mL	yes	no	no / 300 µm	yes	6.8	20
M7	AG-E1-500 SC1 Mavrik / MCW-5023	1.00 mL 0.20 mL	100 L/ha	1.00 mL 0.20 mL	yes	no	yes / 300 µm	no	5.9	21
M8	AG-E1-500 SC1 Lamdex / Karate	0.6 mL 0.30 g	100 L/ha	0.6 mL 0.30 g	yes	no	yes / 300 µm	no	7.1	22
M9	AG-E1-500 SC1 Mavrik Jet	0.6 mL 3.00 mL	100 L/ha	0.6 mL 3.00 mL	yes	yes	yes / 300 µm	no	6.3	20
M10	AG-E1-500 SC1 Betasana 160	1.00 L/ha 2.00 L/ha	100 L/ha	1.00 mL 2.00 mL	yes	no	no / 300 µm	yes	6.7	21
M11	AG-E1-500 SC1 Safari	1.00 L/ha 0.03 kg/ha	100 L/ha	1.00 mL 0.03 g	yes	no	no / 75 µm	yes	6.7	22
M12	AG-E1-500 SC1 Centium	0.6 L/ha 0.20 L/ha	100 L/ha	0.6 mL 0.20 mL	yes	no	no / 300 µm	yes	7.6	21
M13	AG-E1-500 SC1 Tramat SC 500	0.6 L/ha 0.45 L/ha	100 L/ha	0.6 mL 0.45 mL	yes	no	no / 300 µm	yes	6.7	21
M14	AG-E1-500 SC1 Lontrel 72 SG	1.00 L/ha 0.165 kg/ha	100 L/ha	1.00 mL 0.165 g	yes	no	no / 300 µm	yes	6.0	22
M15	AG-E1-500 SC1 Renol (oil)	1.00 L/ha 0.50 L/ha	100 L/ha	1.00 mL 0.50 mL	yes	yes	no / 300 µm	no	6.0	21
M16	AG-E1-500 SC1 Betanal SE Centium Goltix Gold (new) Renol (oil) Safari	1.00 L/ha 2.00 L/ha 0.20 L/ha 1.00 L/ha 0.50 L/ha 0.020 kg/ha	100 L/ha	1.00 mL 2.00 mL 0.20 mL 1.00 mL 0.50 mL 0.02 g	yes	yes	yes / 300 µm	no	6.2	22
M17	AG-E1-500 SC1 Centium Goltix Queen Kontakt Renol (oil) Safari Tramat SC 500	1.00 L/ha 0.20 L/ha 1.50 L/ha 1.00 L/ha 0.50 L/ha 0.020 kg/ha 0.45 L/ha	100 L/ha	1.00 mL 0.20 mL 1.50 mL 1.00 mL 0.50 mL 0.02 g 0.45 mL	yes	no	yes / 300 µm	no	6.0	22
M18	AG-E1-500 SC1 Foliarel QS	1.00 L/ha 2.500 kg/ha	100 L/ha	1.00 mL 2.50 g	yes	no	yes / 300 µm	no	8.3	22
M19	AG-E1-500 SC1 Manganese sulphate	1.00 L/ha 2.000 kg/ha	100 L/ha	1.00 mL 2.00 g	yes	no	no / 300 µm	yes	6.8	22
M20	AG-E1-500 SC1 Goltix Gold (new)	1.00 L/ha 2.00 L/ha	100 L/ha	1.00 mL 2.00 mL	yes	no	no / 75 µm	yes	6.1	22
M21	AG-E1-500 SC1	1.00 L/ha 3.00	200 L/ha	0.50 mL	yes	no	no / 75 µm	yes	4.4	20

No.	Product	Application rate	Water	Test application per 100 mL water	Dispersion stability	Nonrinsable residue on flask walls	Residue on sieve / size	Result: compatible?	pH	Temperature (°C)
	Kontakt	L/ha		1.50 mL						
M22	AG-E1-500 SC1 Goltix Gold (new) Kontakt	1.00 L/ha 2.00 L/ha 3.00 L/ha	200 L/ha	0.50 mL 1.00 mL 1.50 mL	yes	no	no / 75 µm	yes	4.5	22
M23	AG-E1-500 SC1 Atpolan Bio Goltix Queen	0.6 L/ha 1.00 L/ha 1.50 L/ha	100 L/ha	0.60 mL 1.00 mL 1.50 mL	yes	yes	yes / 300 µm	no	4.1	20
M24	AG-E1-500 SC1 Goltix Super	0.66 L/ha 2.00 L/ha	200 L/ha	0.33 mL 1.00 mL	yes	no	no / 75 µm	yes	6.7	20
M25	AG-E1-500 SC1 Powertwin	0.66 L/ha 1.00 L/ha	200 L/ha	0.33 mL 0.50 mL	yes	no	no / 75 µm	yes	5.1	20
M26	AG-E1-500 SC1 Betanal Tandem	0.66 L/ha 1.00 L/ha	200 L/ha	0.33 mL 0.50 mL	yes	no	no / 75 µm	yes	6.6	21
M27	AG-E1-500 SC1 Safari Duo Active	0.66 L/ha 0.210 kg/ha	100 L/ha	0.66 mL 0.21 g	yes	no	no / 75 µm	yes	7.1	22
M28	AG-E1-500 SC1 Centium	0.66 L/ha 0.05 L/ha	200 L/ha	0.33 mL 0.025 mL	yes	no	no / 75 µm	yes	6.8	21
M29	AG-E1-500 SC1 Dual Gold	0.66 L/ha 0.50 L/ha	200 L/ha	0.33 mL 0.25 mL	yes	no	no / 75 µm	yes	6.4	20
M30	AG-E1-500 SC1 Lontrel 100	0.66 L/ha 0.50 L/ha	200 L/ha	0.33 mL 0.25 mL	yes	no	no / 75 µm	yes	6.7	21
M31	AG-E1-500 SC1 Frontier Optima	0.66 L/ha 0.50 L/ha	200 L/ha	0.33 mL 0.25 mL	yes	no	no / 75 µm	yes	5.6	20
M32	AG-E1-500 SC1 Tanaris	0.66 L/ha 0.60 L/ha	200 L/ha	0.33 mL 0.30 mL	yes	no	no / 75 µm	yes	3.6	21
M33	AG-E1-500 SC1 Fusilade Max	0.66 L/ha 2.00 L/ha	200 L/ha	0.33 mL 1.00 mL	yes	no	no / 75 µm	yes	6.5	20
M34	AG-E1-500 SC1 Pirimor	0.66 L/ha 0.400 kg/ha	200 L/ha	0.33 mL 0.20 g	yes	no	no / 75 µm	yes	7.2	22
M35	AG-E1-500 SC1 Teppeki	0.66 L/ha 0.140 kg/ha	200 L/ha	0.33 mL 0.07 g	yes	no	no / 75 µm	yes	6.9	22
M36	AG-E1-500 SC1 Batavia	0.66 L/ha 0.75 L/ha	200 L/ha	0.33 mL 0.375 mL	yes	no	no / 75 µm	yes	6.0	20
M37	AG-E1-500 SC1 Betanal	1.00 L/ha 4.00 L/ha	200 L/ha	0.50 mL 2.00 mL	yes	no	no / 300 µm	yes	6.6	21
M38	AG-E1-500 SC1 Goltix / AG-M4-700 WG	1.00 L/ha 1.000 kg/ha	200 L/ha	0.50 mL 0.50 g	yes	no	no / 300 µm	yes	6.8	22
M39	AG-E1-500 SC1 Venzar	1.00 L/ha 0.600 kg/ha	200 L/ha	0.50 mL 0.30 g	yes	no	no / 300 µm	yes	6.8	22

### **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

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

The packaging has been designed in accordance with the criteria and guidelines specified in the FAO “Guideline for the Packaging of Pesticides” and has been approved according to criteria of ADR, IATA, IMDG (IMO) regulations.

The formulated product (SC formulation) is intended for containment in 1, 5, 10 and 20 L high density polyethylene (HDPE) bottles/cans and will be distributed in cartons (outer packaging).

Tightness of the intended packaging and compatibility of the packaging material with the preparation have been demonstrated in storage stability tests under accelerated and ambient conditions. For results, please refer to point 2.7.1, 2.7.4 and 2.7.5 above.

Detailed information on the packaging material is summarised below and in ref. KCP 4.4/01-12.

Comments of zRMS:	<del>Ambient temperature study is currently ongoing, and will be provided upon completion.</del> The accelerated stability data and <del>1-year interim</del> <b>2-years</b> shelf life storage data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE.
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Report:	KCP 4.4/01, Anonymous, 2015
Previous evaluation:	No, not previously submitted
Title:	HDPE - 1 L packaging information (Mobilak)
Document No:	Report no. -
Guideline followed in study:	None
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/02, Anonymous, 2019
Previous evaluation:	No, not previously submitted
Title:	HDPE (Reyde) 1 L - Packaging information
Document No:	Report no. -
Guideline followed in study:	ADR 6.1.5.3 (drop test), ADR 6.1.5.4 (leakproofness test), ADR 6.1.5.5 (internal pressure hydraulic test), ADR 6.1.5.6 (stacking test);  IATA clause 6.3.3 (drop test), IATA clause 6.3.4 (leakproofness test), IATA clause 6.3.5 (pressure test), IATA clause 6.3.6 (stacking test)
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/03, Anonymous, 2013
Previous evaluation:	No, not previously submitted
Title:	HDPE (Pachmas) - 1 L packaging information
Document No:	Report no. -
Guideline followed in study:	None
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/04, Anonymous, 2020
Previous evaluation:	No, not previously submitted
Title:	HDPE (Reyde) 1 L - Packaging information
Document No:	Report no. -
Guideline followed in study:	ADR 6.1.5.3 (drop test), ADR 6.1.5.4 (leakproofness test), ADR 6.1.5.5 (internal pressure hydraulic test), ADR 6.1.5.6 (stacking test);  IATA clause 6.3.3 (drop test), IATA clause 6.3.4 (leakproofness test), IATA clause 6.3.5 (pressure test), IATA clause 6.3.6 (stacking test)
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/05, Anonymous, 2018
Previous evaluation:	No, not previously submitted
Title:	HDPE (Mobilak) 5 L - Packaging information
Document No:	Report no. -
Guideline followed in study:	ADR IMDG CODE
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/06, Anonymous, 2017
Previous evaluation:	No, not previously submitted
Title:	HDPE (Pachmas) 5 L - Packaging information
Document No:	Report no. -
Guideline followed in study:	ADR-RID IMO IMDG CODE
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/07, Anonymous, 2019
Previous evaluation:	No, not previously submitted
Title:	HDPE (Reyde) 5 L - Packaging information
Document No:	Report no. -
Guideline followed in study:	ADR-RID IMO IMDG CODE
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/08, Anonymous, 2020
Previous evaluation:	No, not previously submitted
Title:	HDPE (Pachmas) - 10 L packaging information
Document No:	Report no. -
Guideline followed in study:	IMDG code
Current guideline	See above
Deviations from current guideline:	None
GLP:	No



Report:	KCP 4.4/09, Anonymous, 2020
Previous evaluation:	No, not previously submitted
Title:	HDPE (Mobilak) 10 L - Packaging information
Document No:	Report no. -
Guideline followed in study:	None
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/10, Anonymous, 2019
Previous evaluation:	No, not previously submitted
Title:	HDPE (Reyde) 10 L - Packaging information
Document No:	Report no. -
Guideline followed in study:	None
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/11, Anonymous, 2003
Previous evaluation:	No, not previously submitted
Title:	HDPE - 20 L packaging information
Document No:	Report no. -
Guideline followed in study:	IMDG code (packaging group II): IMDG 8.4.4 (drop test), IMDG 8.5 (leakproofness test), IMDG 8.6 (internal pressure hydraulic test), IMDG 8.7 (stacking test)
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

Report:	KCP 4.4/12, Anonymous, 2013
Previous evaluation:	No, not previously submitted
Title:	HDPE - 12x1 L HDPE bottles Outer packaging (carton) information
Document No:	Report no. -
Guideline followed in study:	ADR (packaging group II): ADR 6.1.5.3 (drop test), ADR 6.1.5.6 (stacking test);  IATA: IATA clause 6.3.3 (drop test), IATA clause 6.3.6 (stacking test)
Current guideline	See above
Deviations from current guideline:	None
GLP:	No

**Table 4.1-1: Packaging for AG-E1-500 SC1**

<b>1 litre bottle (Mobilak)</b>	Material	HDPE
	shape/size	Conical / 240 × 90 mm
	Opening	48.4 mm
	outer package	carton, corrugated single wall cardboard (12 × 1 L)
<b>1 litre bottle (Pachmas)</b>	Material	HDPE
	shape/size	Conical / 239.4 +/- 2mm × 90 mm +/- 1 mm
	Opening	50 mm +/- 0.3 mm
	outer package	carton, corrugated single wall cardboard (12 × 1 L)
<b>1 litre bottle (Reyde)</b>	Material	HDPE
	shape/size	Conical / 240 × 88.5 mm
	Opening	50 mm (thread crest)
	outer package	5 Layers with 176 ((11x8) x2) containers per layer. 5x176= 880 Cont/Pallet 7 Planks. On pallets of 1,2 x 1 x 0,125 m. With film wrapped and rainproof coverage.
<b>1 litre bottle (Reyde)</b>	Material	HDPE
	shape/size	Rectangular / 207.5 x 77.3 x 77.3 mm
	Opening	63 mm (thread crest)
	outer package	5 Layers with 176 ((11x8) x2) containers per layer. 5x176= 880 Cont/Pallet 5 Planks. On pallets of 1,2 x 1 x 0,125 m. With film wrapped and rainproof coverage.
<b>5 litre bottle (Mobilak)</b>	Material	HDPE
	shape/size	Square / 190 +/- 3 mm × 140 +/- 3 mm × 307 +/- 3 mm
	Opening	63 mm
	Closure	Screw plastic cap
	outer package	carton, corrugated board (4 × 5 L)
<b>5 litre container (Pachmas)</b>	Material	HDPE
	shape/size	Square / 190 × 140 × 305 mm
	Opening	63 mm
	Closure	Screw plastic cap
	outer package	carton, corrugated board (4 × 5 L)
<b>5 litre container (Reyde)</b>	Material	HDPE
	shape/size	Square / 190 × 148 × 307 mm
	Opening	52.5 mm (inner diameter)
	outer package	4 Layers with 42 (6x7) containers per layer. 4x42= 168 Cont./Pallet CP-1 Heat Treat. With a board in every layer. Film wrapped.
<b>10 litre container (Pachmas)</b>	Material	HDPE
	shape/size	Square / 227× 157 × 401 mm
	Opening	63 mm
<b>10 litre container (Mobilak)</b>	Material	HDPE
	shape/size	Square / 227× 157 × 402 mm
	Opening	63 mm
<b>10 litre container (Reyde)</b>	Material	HDPE
	shape/size	Square / 227 × 157 × 400 mm
	Opening	63.3 mm
	outer package	3 Layers with 30 (6x5) containers per layer. 3x30 = 90 Cont./Pallet CP-1 Heat Treat. With a board in every layer. Film wrapped.

<b>20 litre jerry can</b>	Material	HDHMPWE (High Density High Molecular Weight Poly-Ethylene)
	shape/size	Square / 297 × 246 × 393 mm
	Opening	48 mm
	Closure	K60 + Gasket+ security ring
	outer package	carton, corrugated board

## 4.2 Recommended methods and precautions (KCP 4.2)

### 4.2.1 Procedures for cleaning application equipment and protective clothing (KCP 4.2.1)

Wash all application equipment with water (for cleaning efficiency see chapter 4.2.2 below). Suitable cleaners (commercial detergents) can be used in addition.

Wash protective clothing with washing agents in commercial quality.

### 4.2.2 Effectiveness of the cleaning procedures (KCP 4.2.2)

Comments of zRMS:	Accepted. Triple rinsing with tap water is recommended.
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At the time of compilation of this dossier, no specific study had been conducted for the product AG-E1-500 SC1 to investigate the effectiveness of the cleaning procedure described above. Instead, such investigations were replaced by an assessment on a theoretical basis involving a calculation of the predicted residues remaining in the spray tank after cleaning, and subsequently addressing the risk to other crops from these residues applied to the field during another spraying operation.

The efficacy of cleaning the application equipment with regard to impacts on non-target crops was estimated according to the recommendations of the PSD Efficacy Guideline 302 (December, 2001). For the assessment of residues remaining in the spraying equipment after cleaning, a standard sprayer of 2000 litres was considered. Cleaning is performed by a small volume rinse of 200 L of water in the first cleaning step, followed by another two rinses, each with volumes of 400 L corresponding to 20% of the tank volume. A maximum volume of 20 L spray solution was considered to remain in the spray lines and pump after each rinse. Furthermore, the maximum concentration of AG-E1-500 SC1 in the initial spray solution was used as a conservative starting point. In summary, the following prerequisites were considered for a worst-case assessment:

Maximum rate per application:	<b>1 L AG-E1-500 SC1/ha</b> , corresponding to 500 g ethofumesate/ha
Spray volumes:	100 – 400 L/ha
Spray volume used for the assessment of effectiveness:	<b>100 L/ha</b> (lowest spray volume corresponding to the maximum concentration of AG-E1-500 SC1 in diluted spray)
Tank volume:	2000 L
Volume remaining in spray lines and pump after spraying:	20 L

Based on these prerequisites and in consideration of 3 rinses each with 200-400 L of water based on good agricultural cleaning procedures described above, residues remaining in the tank after spraying will be diluted to the following levels:

Cleaning step	Water volume [L]	Concentration of residues	
		Product [mL PPP/ L of water]	Active substance [g a.s./L]
			ethofumesate

Tank filling: Residues after spraying:	2000 20	10	5
1st step: 1/10 dilution of residual spray volume: Residues after spraying:	200 20	1	0.5
2nd step: 20% of tank volume added: Residues after spraying:	400 20	0.05	0.025
3rd step: 20% of tank volume added: Residues after spraying:	400 20	0.0025	0.00125
Addition of fresh spray solution: Residues in the tank filling:	2000	0.000025	0.0000125

PPP = AG-E1-500 SC1

Based on the calculation above, residues remaining in the spraying equipment after the last of three cleaning steps were estimated at 20 L at a concentration of about 2.5 µL AG-E1-500 SC1 per L of water, corresponding to a total of about 50 µL AG-E1-500 SC1 in the tank. Considering these residues to be completely dissolved in the next tank filling, residues of 0.025 µL AG-E1-500 SC1 per litre of water can be expected after refilling the tank with 2000 L of water for another spraying operation. Assuming a range of spray volumes of 200-600 L/ha to be applied to other crops, **residues of 5 – 15 µL/ha will be applied to a non-target crop by re-use of the application equipment.**

Data on the biological activity of AG-E1-500 SC1 are available from the two standard test models "seedling emergence" (KCP 10.6.2/01) and "vegetative vigour" (KCP 10.6.2/02), which are considered to be most relevant for the assessment of effects on non-target plants (including non-target crops) after broadcast spraying of AG-E1-500 SC1 and tank residues, respectively. The tests were performed according to OECD 208 (2006) and OECD 227 (2006), respectively, and the test substance AG-E1-500 SC1 was sprayed to the test plants or to the soil after sowing of plants. Each test was performed in 10 representative plant species.

The acceptability of the predicted residue level of AG-E1-500 SC1 was assessed by a comparison of the exposure concentration predicted for the re-use of the application equipment with the effect rates (NOER, ER<sub>50</sub>) in the most sensitive plant species of the "vegetative vigour" and "seedling emergence" test. Effects on shoot height and plant weight were considered as reliable endpoints for toxic effects and the most sensitive of these toxicity figures was used for the following risk assessment:

Maximum predicted exposure of non-target crops with spray residues:

PER = 0.015 mL AG-E1-500 SC1/ha; i.e. 0.000015 L prod./ha

Risk from spray residues for seedling emergence of non-target plants:

Toxicity endpoints obtained from reference:

KCP 10.6.2/01: Duffner, A., (2020a): AG-E1-500 SC1: Effects on the Seedling Emergence and Seedling Growth of Non-Target Terrestrial Plant Species under Greenhouse Conditions

Lowest ER<sub>50</sub> < 0.48 L prod./ha (*Medicago sativa*)

Lowest NOER < 0.48 L prod./ha (no NOER defined with effects observed on shoot height and survival in *Fagopyrum esculentum*, *Glycine max*, *Linum usitatissimum*, *Medicago sativa*, *Solanum lycopersicum* at 480 mL prod./ha)

TER (ER<sub>50</sub>/PER) < 32000

NOER/PER < 32000

Risk from spray residues for vegetative vigour of non-target plants:

Toxicity endpoints obtained from reference:

## KCP 10.6.2/02: Duffner, A., (2020b): AG-E1-500 SC1: Effects on the Vegetative Vigour of Non-Target Terrestrial Plant Species under Greenhouse Conditions

Lowest ER <sub>50</sub>	0.37 L prod./ha ( <i>Medicago sativa</i> )
Lowest NOER	< 0.027 L prod./ha (no NOER defined with effects observed on shoot dry weight in <i>Lepidum sativum</i> , <i>Medicago sativa</i> at 27 mL prod./ha)
TER (ER <sub>50</sub> /PER)	24666
NOER/PER	< 1800

According to the PSD efficacy guideline 302, a cleaning method can be considered to be acceptable, if the predicted exposure rate of the plant protection product (when the application equipment is re-used after cleaning) is at least an order of magnitude less than the no observable effect level or ED<sub>10</sub> value for the most sensitive crop species.

Since no NOER values are available from seedling emergence and a vegetative testing by Duffner, A. (2020a, b), the assessment is based on worst-case median effective rates and Toxicity/Exposure Ratios are compared to the standard trigger of 5 for acceptability of risk for terrestrial non-target plants as in accordance with the guidance document SANCO/10329/2002 rev.2 final (October 17, 2002)<sup>1</sup>. The ER<sub>50</sub> based TER values for the most sensitive plant species of the vegetative vigour test are greater than 5<sup>2</sup> by more than 2 orders of magnitude. Therefore, the potential risk for non-target terrestrial plants from product residues remaining in tanks following cleaning is considered to be acceptable.

**Conclusion:** The effectiveness of standard cleaning procedures according to Good Agriculture Practice was assessed for the product AG-E1-500 SC1 on a theoretical basis. Residues of the plant protection product remaining in the tank after 3 rinses with water and the predicted exposure of non-target crops after re-use of the application equipment were calculated for worst case conditions. Compared to the effect levels for non-target plants, which are most likely to be affected by herbicide residues, residue levels are far below concentrations that might pose a risk for the terrestrial flora including non-target crops. Thus, any detrimental effect on plants from tank residues can widely be excluded. The cleaning method is therefore considered to be acceptable, and the performance of any small-scale or a large-scale tests is not considered to be required.

### 4.3 Safety intervals and other precautions to protect humans, animals and the environment (KCP 4.1)

For the safety intervals and other precautions to protect humans, animals and the environment please refer to the national labels provided in Part A. Further information can be found in the dRR Sections 6, 7, 8, 9, respectively.

### 4.4 Emergency measures in the case of an accident (KCP 4.3)

Please refer to the MSDS of the product AG-E1-500 SC1 (alternative code: ADM.02650.H.1.A) filed under KCP 4.3/01.

### 4.5 Procedures for destruction or decontamination of the plant protection product and its packaging (KCP 4.5)

The product and its container must be disposed of in a safe way.

Small amounts of the product and unclean empty packaging should be packaged and sealed, labelled and transferred to a suitable incinerator in accordance with the local regulations.

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<sup>1</sup> Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC

<sup>2</sup> A trigger of 5 can be applied, if at least 6 plant species have been tested

Disposal by incineration in an authorised special waste incineration plant and in compliance with the local legislation. For larger quantities contact the manufacturer of the product.

EU waste keys for the packaging with product: 02 01 08 (Agrochemical waste containing dangerous substances), 20 01 19 (Pesticides).

Where local recycling schemes exist, these should be considered. Empty packaging rinsed with water should be disposed off.

For further information please refer to the MSDS of the product AG-E1-500 SC1 filed under KCP 4.3/01.

## 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	Tsesin, N.	2020a	Determination of Storage Stability and Physical-Chemical Properties of Ethosat 500 SC (AG-E1-500 SC1) Stored at 54°C for 14 Days and at 0°C for 7 Days Report No. 000104496.057 ADAMA Makhteshim Ltd., Israel GLP, unpublished	N	ADM
KCP 2.2.1/01	Köttig, M.	2020	Please refer to KCP 2.2.1/01 filed in Part C - Confidential Section	N	ADM
KCP 2.2.2/01	Köttig, M.	2020	Please refer to KCP 2.2.1/01 filed in Part C - Confidential Section	N	ADM
KCP 2.3.1	Tsesin, N.	2020	Please refer to KCP 2.1/01	N	ADM
KCP 2.3.3/01	Warneke, U.	1999	Determination of the auto-ignition temperature of the test substance Ethosat 500 Report No. U99PCH07 URANIA Agrochem GmbH, Versuchsstation Christinenthal, Germany GLP Unpublished	N	ADM
KCP 2.4.1/01	Tsesin, N.	2020	Please refer to KCP 2.1/01	N	ADM
KCP 2.4.1/02	Tsesin, N.	2020	Please refer to KCP 2.1/01	N	ADM
KCP 2.5.1/01	Tsesin, N.	2020	Please refer to KCP 2.1/01	N	ADM
KCP 2.5.2/01	Tsesin, N.	2020	Please refer to KCP 2.1/01	N	ADM
KCP 2.6.1/01	Tsesin, N.	2020	Please refer to KCP 2.1/01	N	ADM
KCP 2.7.1/01	Tsesin, N.	2020	Please refer to KCP 2.1/01	N	ADM
KCP	Tsesin, N.	2020	Please refer to KCP 2.1/01	N	ADM

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*
2.7.4/01					
KCP 2.7.5/01	Tsesin, N.	2022	Determination of Storage Stability and Physical-Chemical Properties of Ethosat 500 SC (AG-E1-500 SCI) Stored at Ambient Temperature for Two Years Report No. 0001 04497.058FL ADAMA reference No.: 000104497 ADAMA Makhteshim Ltd., Israel GLP, unpublished	N	ADM
KCP 2.7.5/01	Tsesin, N.	2020b	AG-E1-500 SC1 – One year interim results of the ongoing 2 year shelf life study Report No. 000104497 ADAMA Makhteshim Ltd., Israel GLP, unpublished	N	ADM
KCP 2.8.2/01	Tsesin, N.	2020	Please refer to KCP 2.1/01	N	ADM
KCP 2.8.3.1/01	Tsesin, N.	2020	Please refer to KCP 2.1/01	N	ADM
KCP 2.8.3.2/01	Tsesin, N.	2020	Please refer to KCP 2.1/01	N	ADM
KCP 2.8.5.1.1/01	Tsesin, N.	2020	Please refer to KCP 2.1/01	N	ADM
KCP 2.8.5.1.2/01	Tsesin, N.	2020	Please refer to KCP 2.1/01	N	ADM
KCP 2.8.7.2/01	Tsesin, N.	2020	Please refer to KCP 2.1/01	N	ADM
KCP 2.9.1/01	Thomas H.	2021	Evaluation of the Physical and Chemical Compatibility of Tank Mixtures of AG-E1-500 SC1 Report No.: 21 35 CRX 0003 ADAMA reference No.: 000107348 BioChem agrar, Germany GLP, unpublished	N	ADM
KCP 2.9.2/02	Thomas H.	2021	Please refer to KCP 2.9.1/01	N	ADM
KCP 4.3/01	Anonymous	2020	Safety Data Sheet – ADM.02650.H.1.A	N	ADM



<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner*</b>
			ADAMA Agan Ltd., Ashdod., Israel Report no.: not available No GLP Unpublished		
KCP 4.4/01	Anonymous	2015	HDPE - 1 L packaging information (Mobilak) Mobilak Report no.: not available No GLP, unpublished	N	Mobilak
KCP 4.4/02	Anonymous	2019	HDPE (Reyde) - 1 L - Packaging information Reyde, Spain Report no.: not available No GLP, unpublished	N	Reyde
KCP 4.4/03	Anonymous	2013	HDPE - 1 L packaging information Pachmas Packaging Ltd Report no.: not available No GLP, unpublished	N	Pachmas
KCP 4.4/04	Anonymous	2020	HDPE (Reyde) 1 L rectangular bottle - Packaging information Reyde, Spain Report no.: not available No GLP Unpublished	N	Reyde
KCP 4.4/05	Anonymous	2018	HDPE (Mobilak) 5 L - Packaging information Mobilak Report no.: not available No GLP, unpublished	N	Mobilak
KCP 4.4/06	Anonymous	2017	HDPE (Pachmas) 5 L - Packaging information Pachmas Packaging Ltd Report no.: not available No GLP, unpublished	N	Pachmas
KCP 4.4/07	Anonymous	2019	HDPE (Reyde) 5 L - Packaging information Reyde, Spain Report no.: not available No GLP Unpublished	N	Reyde

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner*</b>
KCP 4.4/08	Anonymous	2020	HDPE (Pachmas) - 10 L packaging information PACHMAS Packaging Ltd., Israel Report no.: not available No GLP, unpublished	N	Pachmas
KCP 4.4/09	Anonymous	2020	HDPE (Mobilak) 10 L - Packaging information Mobilak Report no.: not available No GLP, unpublished	N	Mobilak
KCP 4.4/10	Anonymous	2019	HDPE (Reyde) 10 L - Packaging information Reyde, Spain Report no.: not available No GLP, unpublished	N	Reyde
KCP 4.4/11	Anonymous	2003	HDPE - 20 L packaging information Not reported Report no.: not available No GLP, unpublished	N	not reported
KCP 4.4/12	Anonymous	2013	HDPE - 12x1 L HDPE bottles Outer packaging (carton) information Report no.: not available No GLP Unpublished	N	not reported

\*The sponsor company ADAMA Agan Ltd. (ADM) is a member of ADAMA Agricultural Solutions.

Under Article 59, Regulation 1107/2009/EC, the sponsor company claims data protection for these studies. For details on country specific data protection, refer to Part A

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

None.

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

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

**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 Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
-	-	-	-	-	-

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

### **A 2.1              Ethofumesate**

No additional studies.