

# 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: HBZ10

Product name: Wizard

Chemical active substances:

Ethofumesate, 125 g/L

Phenmedipham, 125 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

(Authorisation - Art. 33 application)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: October 2021

MS Finalisation date: June 2022 (initial Core Assessment)

September 2023 (final Core Assessment)

### Version history

When	What
October 2021	Applicant submission
June 2022	<p>Initial assessment by the zRMS</p> <p>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 <del>struck through</del> and shaded for transparency.</p>
September 2023	<p>Final report (Core Assessment updated following the commenting period)</p> <p>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 <del>is struck through</del> and shaded.</p>

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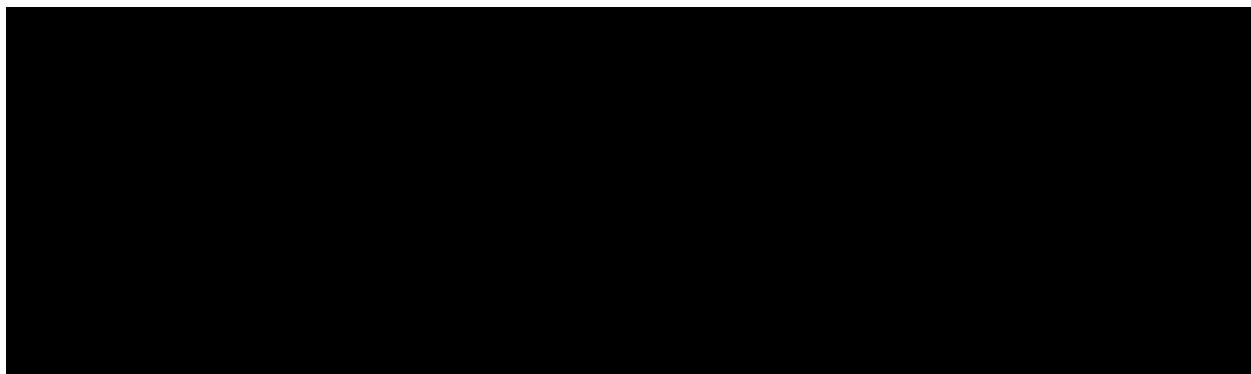
Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substances.

Noticed data gaps are:

- Ambient temperature study is currently ongoing, and should be provided upon completion.

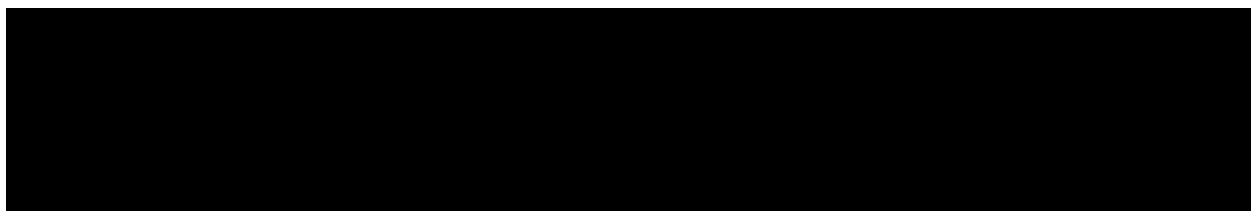
## **1 Section 1: Identity of the plant protection product**

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

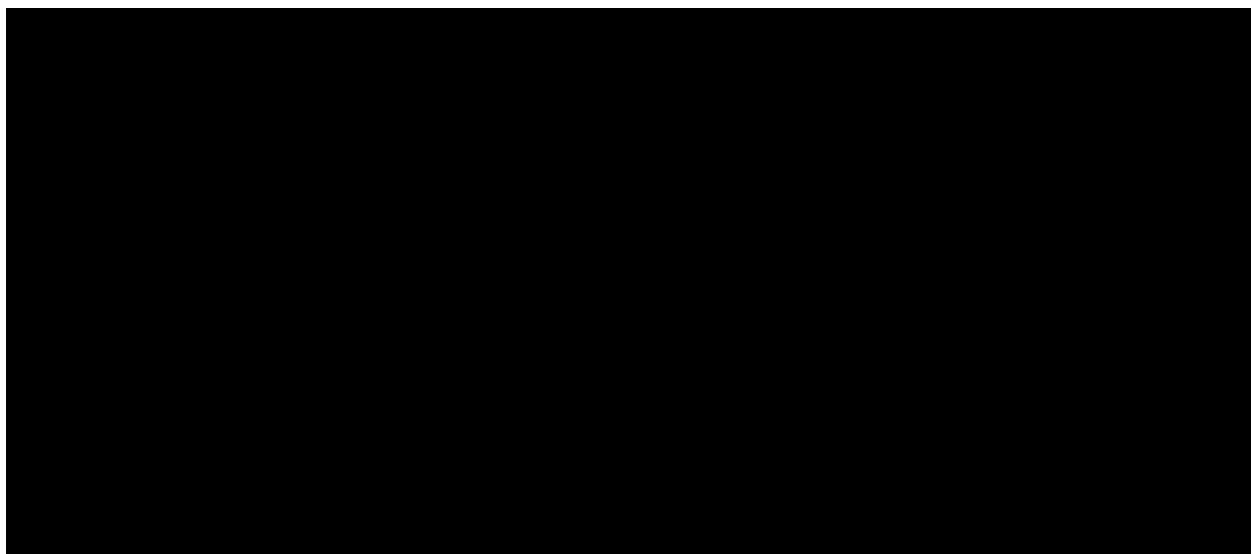


### **1.2 Producer of the plant protection product and of the active substances (KCP 1.2)**

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



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



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

#### 1.2.3.1 Ethofumesate

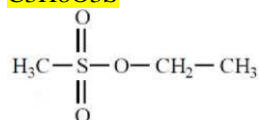
Ethofumesate min. 970 g/kg (Commission Implementing Regulation (EU) 2016/1426)

An assessment of equivalence is not required since sources for the active substance have been previously approved at EU level (Please refer to Part C).

Information relating to the impurities EMS and iBMS is provided below. For further information and therefore please refer to Part C.

##### Ethyl methane sulfonate (EMS)

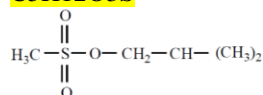
Chemical name (IUPAC): Ethyl methanesulfonate  
Chemical name (CA): Methanesulfonic acid ethyl ester  
Common name (ISO): not allocated  
CAS No.: 62-50-0  
EU Index No.: not allocated  
EINECS No.: 200-536-7  
CIPAC No.: not allocated  
Molecular formula: C<sub>3</sub>H<sub>8</sub>O<sub>3</sub>S  
Structural formula:



Molecular mass: 124.16 g/mol

##### Methanesulfonic acid, 2-methylpropyl ester (iBMS)

Chemical name (IUPAC): 2-Methylpropyl methanesulfonate  
Chemical name (CA): Methanesulfonic acid isobutyl ester  
Common name (ISO): not allocated  
Trivial name: Isobutyl methanesulfonate  
CAS No.: 16156-53-9  
EINECS/ CIPAC No.: not allocated  
Molecular formula: C<sub>5</sub>H<sub>12</sub>O<sub>3</sub>S  
Structural formula:



Molecular mass: 152.21 g/mol

#### 1.2.3.2 Phenmedipham

Phenmedipham min. 970 g/kg (Commission Implementing Regulation (EU) No 540/2011)

An assessment of equivalence is not required since sources for the active substance have been previously approved at EU level (Please refer to Part C).

Information relating to the impurities is confidential information and therefore please refer to Part C.

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

Trade name: Please refer to Registration Report Part A for the relevant country

Company code number: HBZ10

## 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)

The product HBZ10 was not evaluated previously as a representative formulation during the EU reviews of the active substances Ethofumesate and Phenmedipham. The contents of Ethofumesate and Phenmedipham in HBZ10 are given in the table below. Information on the actives is addressed under point 1.4.2.

Information on the formulants including safeners and synergists is confidential and is included in Part C (Confidential information).

**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	125	117.5 g/L – 132.5 g/L	128.9	13.2
Phenmedipham	125	118.75 g/L – 131.25 g/L	128.9	13.2

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

\*\* Based on the density of the formulation = 0.977 g/mL

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

**Table 1.4-2: Information on Ethofumesate**

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

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

Type	Name/Code Number
ISO common name	Phenmedipham
CAS No.	13684-63-4
EC No.	237-199-0
CIPAC No.	77

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

CONFIDENTIAL information is provided separately (Part C).

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

Type: Emulsion Concentrate

[Code: EC]

## 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 uniform brown liquid, with an organic solvent type odour. It is not explosive, has no oxidising properties. The product is not flammable and has a flash point of 128°C. It has a self-ignition temperature above 400°C. In aqueous solution, it has a pH value around 4.0 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C ± 2°C and 14 days at 54 °C ± 2°C, neither the active ingredient content nor the technical properties were changed. A 2-years shelf-life study at ambient temperature when stored in HDPE/EVOH, HDPE/PA and HDPE-F commercial packaging is on-going and study plan is provided until final report will be available. Its technical characteristics are acceptable for a Emulsifiable Concentrate formulation.

The intended concentration of use is 0.3% to 3.0%.

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

According to Regulation (EC) No. 1272/2008 no specific labelling or classification is proposed based on the measured physico-chemical properties of HBZ10.

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

According to Regulation (EC) No. 1272/2008 no specific labelling or classification is proposed based on the measured physico-chemical properties of HBZ10.

### **Compliance with FAO specifications:**

The product HBZ10 complies with FAO specifications.

### **Formulation used for tests**

Studies were performed on formulation HBZ10. Thus, no bridging to other formulations is required.

**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 assessment	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	Physical state: Homogeneous liquid Colour: Brown Odour: Organic solvent type odour	Y	Norris, D., report No. DNA6253	Accepted.
Explosive properties (KCP 2.2.1)	EC A.14	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	The formulation is not considered to have explosive properties.	Y	Buchholz, V., report No. 21-921003-001	Accepted.  The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Oxidizing properties (KCP 2.2.2)	EC A.21	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	The formulation is not considered to have oxidising properties.	Y	Buchholz, V., report No. 21-921003-001	Accepted.  The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Flash point (KCP 2.3.1)	EEC A9	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	The formulation flashed at 128.0°C at 1020-1021 mbar		Norris, D., report No. DNA6253	Accepted.  The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Flammability (KCP 2.3.2)	Not relevant since the formulation is not a solid or a gas preparation.					-
Self-heating (KCP 2.3.3)	EEC A15	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	The formulation did not auto-ignite below 400°C and is therefore not considered as highly flammable	Y	Norris, D., report No. DNA6253	Accepted.  The formulation does not need to be classified according to Reg. (EC)



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	Acidity [% w/w H <sub>2</sub> SO <sub>4</sub> ]: 0.4870% pH : 5.74 at 20.0°C	Y	Norris, D., report No. DNA6253	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	pH of a 1% dilution: 4.0 at 20.0°C	Y	Norris, D., report No. DNA6253	Accepted.
Viscosity (KCP 2.5.1)	OECD 114	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	Dynamic Viscosity: 43.40 mPa.s at 20°C Dynamic Viscosity: 31.90 mPa.s at 40°C Kinematic Viscosity: 0.4440 cm <sup>2</sup> /s at 20°C Kinematic Viscosity: 0.3306 cm <sup>2</sup> /s at 40°C  According to regulation 1272/2008, “A mixture is classified as Category 1 when the sum of the concentrations of Category 1 ingredients is ≥ 10 % and the mixture has a kinematic viscosity ≤ 20,5 mm <sup>2</sup> /s, measured at 40 °C”. Kinematic viscosity is of 0.3306 cm <sup>2</sup> /s at 40°C according to report DNA6253, which is equivalent to 3.306 mm <sup>2</sup> /s at 40°C and thus below the kinematic viscosity threshold. However, none of the coformulants contained in the HBZ10 formulations are classified as H304 (see Part C), therefore, an aspiration hazard classification is not triggered.	Y	Norris, D., report No. DNA6253	Accepted.
Surface tension (KCP 2.5.2)	EEC A5	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	27.75 mN/m ± 0.0225 at 20°C ± 0.1°C 27.67 mN/m ± 0.0410 at 25°C ± 0.1°C	Y	Norris, D., report No. DNA6253	Accepted. Based on the surface tension results the formulation can be considered surface active.
Relative density (KCP 2.6.1)	EEC A3	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	0.9776 g/mL at 20°C 0.9650 g/mL at 40°C	Y	Norris, D., report No. DNA6253	Accepted.
Bulk density (KCP 2.6.2)	Not relevant since the formulation is not a powder or a granular preparation.					-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	<p><b>Sample appearance in HDPE EVOH packaging:</b> The sample appearance remained unchanged.</p> <p><b>Sample appearance in HDPE-PA packaging:</b> The sample appearance remained unchanged.</p> <p><b>Sample appearance in HDPE-F packaging:</b> The sample appearance remained unchanged.</p> <p><b>Stability of packaging HDPE EVOH:</b> The sample packaging remained unchanged.</p> <p><b>Stability of packaging HDPE-PA:</b> The sample packaging remained unchanged.</p> <p><b>Stability of packaging HDPE-F:</b> The sample packaging remained unchanged.</p> <p><b>Acidity or alkalinity and pH:</b> Pre storage same: Acidity [% w/w H<sub>2</sub>SO<sub>4</sub>]: 0.4870% pH : 5.74 at 20.0°C Post Accelerated: Acidity [% w/w H<sub>2</sub>SO<sub>4</sub>]: 0.5061% pH : 5.05 at 20.0°C</p> <p><b>pH of a 1% aqueous dilution:</b> Pre storage same: 4.00 at 20.0°C Post Accelerated: 3.88 at 20.0°C</p> <p><b>Persistence of foaming:</b> Pre storage same: Low Application Rate of 1.2L of formulation in 400L water: 4.0 mL after 1 minute 1.0 mL after 12 minutes High Application Rate of 2.4L of formulation in 80L water: 0.0 mL after 1 minute 0.0 mL after 12 minutes</p> <p>Post Accelerated: Low Application Rate of 1.2L of formulation in 400L water: 6.0 mL after 1 minute</p>	Y	Norris, D., report No. DNA6253	<p>The product showed no significant physical changes after accelerated storage.</p> <p>No significant changes were observed in the HDPE/EVOH, HDPE/PA and HDPE/F packaging and therefore it can be concluded that the test item was not corrosive to the container material.</p> <p>No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage.</p> <p>The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE/EVOH, HDPE/PA, HDPE/F.</p>

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments
			4.0 mL after 12 minutes High Application Rate of 2.4L of formulation in 80L water: 0.0 mL after 1 minute 0.0 mL after 12 minutes  <b>Emulsifiability:</b> The formulation remained a complete white emulsion with no signs of separation into oil, cream, sediment or claying at both the lowest and the highest dose in all two CIPAC waters (A and D).				
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	Not relevant since the stability was tested after storage for 14 days at 54°C ± 2°C and for 7 days at 0°C ± 2°C.						-
Minimum content after heat stability testing (KCP 2.7.3)	In-house validated method (please refer to section B5)	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	<b>Ethofumesate</b> <u>Before storage:</u> 120.6 g/L (96.44% of declared content)  <u>After storage at 54°C ± 2°C for 2 weeks:</u> 121.2 g/L (96.96% of the declared content)	<b>Phenmedipham</b> <u>Before storage:</u> 127.7 g/L (102.2% of declared content)  <u>After storage at 54°C ± 2°C for 2 weeks:</u> 127.7 g/L (102.1% of declared content)	Y	Norris, D., report No. DNA6253	Accepted.
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	<b>Emulsifiability:</b> The formulation remained a complete white emulsion with no signs of separation into oil, cream, sediment or claying at both the lowest and the highest dose in all two CIPAC waters (A and D).  <b>Sample appearance in HDPE EVOH packaging:</b> The sample appearance remained unchanged.  <b>Sample appearance following addition of Ethofumesate crystal after 24 hours:</b> The sample appearance remained unchanged post low temperature storage with the addition of an Ethofumesate crystal.  <b>Sample appearance following addition of Phenmedipham crystal after 24 hours:</b>		Y	Norris, D., report No. DNA6253	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			The sample appearance remained unchanged post low temperature storage with the addition of an Phanmedipham crystal.			
Ambient temperature shelf life (KCP 2.7.5)	Study on-going	Study on-going	Study on-going	Y	Norris, D., report No. DNA6254 (only study plan is available at submission time)	The final Ambient temperature study is currently ongoing, and should be provided upon completion.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Not relevant as the expected shelf life is 2 years.					Ambient temperature study is currently ongoing, and should be provided upon completion.
Wettability (KCP 2.8.1)	Not relevant since the formulation is not a solid preparation.					-
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	<b>Low Application Rate of 1.2L of formulation in 400L water:</b> 4.0 mL after 1 minute 1.0 mL after 12 minutes  <b>High Application Rate of 2.4L of formulation in 80L water:</b> 0.0 mL after 1 minute 0.0 mL after 12 minutes	Y	Norris, D., report No. DNA6253	Accepted.
Suspensibility (KCP 2.8.3.1)	Not relevant since the formulation is not a water dispersible preparation.					-
Spontaneity of dispersion (KCP 2.8.3.2)	Not relevant since the formulation is not a water dispersible preparation.					-
Dispersion stability (KCP 2.8.3.3)	Not relevant since the formulation is not a water soluble preparation.					-
Degree of dissolution and dilution stability (KCP 2.8.4)	Not relevant since the formulation is not a water soluble preparation.					-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	Not relevant since the formulation is not a powder.					-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Wet sieve test (KCP 2.8.5.1.2)	Not relevant since the formulation is not a water dispersible preparation.					-
Dust content (KCP 2.8.5.2.1)	Not relevant since the formulation is not a granular preparation.					-
Particle size of dust (KCP 2.8.5.2.2)	Not relevant since the formulation is not a granular preparation.					-
Attrition (KCP 2.8.5.3)	Not relevant since the formulation is not a granular preparation.					-
Hardness and integrity (KCP 2.8.5.4)	Not relevant since the formulation is not a granular preparation.					-
Emulsifiability (KCP 2.8.6.1)	CIPAC MT 36.3	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	After 30 seconds, the formulation formed a complete white emulsion with no signs of separation into oil, cream, sediment, or claying, at both the lowest and the highest dose (corresponding to 0.3% and 3% v/v, equivalent to range from 1.2L in 400L to 2.4L in 80L) in all two CIPAC waters (A and D).	Y	Norris, D., report No. DNA6253	Accepted.
Emulsion stability (KCP 2.8.6.2)	CIPAC MT 36.3	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	After 30 minutes, the formulation formed a complete white emulsion with no signs of separation into oil, cream, sediment, or claying, at both the lowest and the highest dose (corresponding to 0.3% and 3% v/v, equivalent to range from 1.2L in 400L to 2.4L in 80L) in all two CIPAC waters (A and D).  After 2 hours, the formulation formed a complete white emulsion with no signs of separation into oil, cream, sediment, or claying, at both the lowest and the highest dose (corresponding to 0.3% and 3% v/v, equivalent to range from 1.2L in 400L to 2.4L in 80L) in all two CIPAC waters (A and D).  After 24 hours (without inverting), the formulation formed a complete white emulsion with no signs of separation into oil, cream, sediment, or claying, at both the lowest and the highest dose in all two CIPAC waters (A and D).	Y	Norris, D., report No. DNA6253	Accepted.
Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT 36.3	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	After 24 hours and 30 Seconds (with inverting), the formulation formed a complete white emulsion with no signs of separation into oil, cream, sediment, or claying, at both the lowest and the highest dose (corresponding to 0.3% and 3% v/v, equivalent to range from 1.2L in 400L to 2.4L in 80L) in all two CIPAC waters (A and D).	Y	Norris, D., report No. DNA6253	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			After 24 hours and 30 minutes, the formulation formed a complete white emulsion with no signs of separation into oil, cream, sediment, or claying, at both the lowest and the highest dose (corresponding to 0.3% and 3% v/v, equivalent to range from 1.2L in 400L to 2.4L in 80L) in all two CIPAC waters (A and D).			
Flowability (KCP 2.8.7.1)	Not relevant since the formulation is not a granular preparation.					-
Pourability (KCP 2.8.7.2)	In-house method	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	<del>Effectiveness of cleaning: Ethofumesate</del> 0.0114% residue remaining in tank  <del>Effectiveness of cleaning: Phenmedipham</del> 0.00741% residue remaining in tank  Not relevant since the formulation is neither a suspension concentrate, capsule suspension, oil in water emulsion, oil dispersion, nor suspo-emulsion.	Y	Norris, D., report No. DNA6253	Accepted. Double rinse
Dustability following accelerated storage (KCP 2.8.7.3)	Not relevant since the formulation is not a dustable powder.					-
Physical compatibility of tank mixes (KCP 2.9.1)	Not relevant.					-
Chemical compatibility of tank mixes (KCP 2.9.2)	Not relevant.					-
Adhesion to seeds (KCP 2.10.1)	Not relevant since the formulation is not a preparation for seed treatment.					-
Distribution to seed (KCP 2.10.2)	Not relevant since the formulation is not a preparation for seed treatment.					-
Other/special studies: Tank cleaning (KCP 2.11)	In-house method	HBZ10 (Batch No. FL20-024-7G) 120.6 g/L Etho. 127.7 g/L Phen.	<b>Effectiveness of cleaning: Ethofumesate</b> 0.0114% residue remaining in tank  <b>Effectiveness of cleaning: Phenmedipham</b> 0.00741% residue remaining in tank	Y	Norris, D., report No. DNA6253	Accepted. Double rinse is recommended.

### **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)

Comments of zRMS:	Ambient temperature study is currently ongoing, will be provided upon completion. The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE/PA, HDPE/EVOH and HDPE/F.
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**Table 4.1-1: Packaging information for 1 litre bottle**

Type	Description
Material:	Coex HDPE/EVOH
Shape/size:	Cylindrical bottle / approximately 89 mm diameter x 235 mm height
Opening:	50 mm
Closure:	Screw Cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

**Table 4.1-2: Packaging information for 5 litres jerry can**

Type	Description
Material:	HDPE Fluorinated
Shape/size:	Rectangular Jerry Can Width – approximately 140 mm Length – approximately 193 mm Height – approximately 305 mm
Opening:	63 mm
Closure:	Screw Cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

**Table 4.1-3: Packaging information for 5 litres jerry can**

Type	Description
Material:	Coex HDPE/PA
Shape/size:	Rectangular Jerry Can Width – approximately 140 mm Length – approximately 193 mm Height – approximately 305 mm
Opening:	63 mm
Closure:	Screw Cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

**Table 4.1-4: Packaging information for 10 litres jerry can**

Type	Description
Material:	Coex HDPE/PA
Shape/size:	Rectangular Jerry Can Width – approximately 179 mm Length – approximately 240 mm Height – approximately 375 mm



Type	Description
Opening:	63 mm
Closure:	Screw Cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

**Table 4.1-5: Packaging information for 10 litres jerry can**

Type	Description
Material:	HDPE Fluorinated
Shape/size:	Rectangular Jerry Can Width – approximately 179 mm Length – approximately 240 mm Height – approximately 375 mm
Opening:	63 mm
Closure:	Screw Cap
Seal:	Induction heat seal
Manner of construction	Extruded
UN/ADR	Compliant

**Table 4.1-6: Packaging information for 20 litres pail**

Type	Description
Material:	HDPE Fluorinated
Shape/size:	Rectangular Pail Width – approximately 245 mm Length – approximately 294 mm Height – approximately 400 mm
Opening:	63 mm
Closure:	Screw Cap
Seal:	Induction heat 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 2.3.1 2.3.3 2.4.1 2.4.2 2.5.1 2.5.2 2.6.1 2.7.1 2.7.3 2.7.4 2.8.2 2.8.6.1 2.8.6.2 2.8.6.3 2.8.7.2	Norris, D.	2021	Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing Ethofumesate and Phenmedipham, stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice Report No DNA6253 and its appendix David Norris Analytical Laboratories Ltd. GLP Unpublished	N	UPL
KCP 2.2.1 2.2.2	Buchholz, V.	2021	Physico-chemical tests on HBZ10 (Ethofumesate 125 + Phenmedipham 125 EC) Report No 21-921003-001 Defitraces GLP Unpublished	N	UPL
KCP 2.7.5	Norris, D.	2021	Determination of Storage Stability and Shelf Life Specification Data for an Emulsifiable Concentrate Formulation containing Ethofumesate and Phenmedipham, stored at ambient temperature for 2 years, in Compliance with Good Laboratory Practice Report No DNA6254 (only study plan is available at submission time) David Norris Analytical Laboratories Ltd. GLP Unpublished	N	UPL
KCP 4.4/01	-	2017	Specification sheet for 1L Coex EVOH packaging UPL Not GLP Unpublished	N	UPL

KCP 4.4/02	-	2017	Specification sheet for 5L HDPE-F packaging UPL Not GLP Unpublished	N	UPL
KCP 4.4/03	-	2017	Specification sheet for 5L Coex PA packaging UPL Not GLP Unpublished	N	UPL
KCP 4.4/04	-	2017	Specification sheet for 10L Coex PA packaging UPL Not GLP Unpublished	N	UPL
KCP 4.4/05	-	2017	Specification sheet for 10L HDPE-F packaging UPL Not GLP Unpublished	N	UPL
KCP 4.4/06	-	2017	Specification sheet for 20L HDPE-F packaging UPL Not GLP Unpublished	N	UPL

**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**

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
-	-	-	-	-	-