

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: ASA-01

Product name(s): **VIARES**

Chemical active substance:

Acetamiprid, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: XXXX

Submission date: March 2024

Evaluation date: May 2025

MS Finalisation date: July 2025

Version history

When	What
March 2024	Applicant version
May 2025	zRMS assessment

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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 substance.

Noticed data gaps are:

- none

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: XXXX
Address: XXXX
XXXX
XXXX

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 Acetamiprid

Acetamiprid min. 990 g/kg (acc. to Reg. (EU) 2018/113)

Confidential information on equivalence reports are provided separately (Part C).

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

Trade name: Please refer to application form

Company code number: ASA-01

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 formulation is not the representative formulation.

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

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Acetamiprid	300 g/L	± 5 % of declared content 285 - 315 g/L	CONFIDENTIAL information is provided separately (Part C).	
			303g/L	27.8

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers i.e. 990g/kg (acc. to EFSA Journal 2016;14(11):4610)

** Based on the density of the formulation = 1.0897 g/cm³

Table 1.4-2: Safener and synergists

Safener / synergist	Declared content of the safener / synergist (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
None	-	-	-	-

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
None	-

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

Table 1.4-4: Information on acetamiprid

Type	Name/Code Number
ISO common name	acetamiprid
CAS No.	135410-20-7
EC No.	603-921-1
CIPAC No.	649

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: Suspension concentrate

[Code: SC]

1.6 Function (KCP 1.6)

Insecticide

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 white liquid, with a medium intense, characteristic odour. Flash point was not observed. The product is not flammable. It is not explosive, has no oxidising properties. It has an auto-ignition temperature of 485°C. In aqueous solution, it has a pH value around 5.28 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 and 12 weeks at 35±2°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE bottles. Its technical characteristics are acceptable for a suspension concentrate formulation (SC).

The intended concentration of use is 0.003% to 0.05% (v/v).

The product is not intended to be mixed in the tank together with other formulations.

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

No classification with regard to physio-chemical properties.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

None.

Compliance with FAO specifications:

The product ASA-01 complies with FAO specifications.

Formulation used for tests

The product used in the tests has the same composition as the one cited in 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)	OPPTS 830.6302, 830.6303 and 830.6304	ASA-01 (ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	Colour (Munsell's notation) – N 9/ (white) Physical state – liquid Odour – medium intense, characteristic.	Y	Study code: ICB/45/2021, Knapik I.	Acceptable
Explosive properties (KCP 2.2.1)	A.14	ASA-01 (ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	The product ASA-01 has no explosive properties.	Y	Study code: BW-27/21, Buczkowski D.	Acceptable Explosive properties of the formulation can be excluded based on UN RTDG criteria (screening procedure) and no further test is necessary
Oxidizing properties (KCP 2.2.2)	A.21	ASA-01 (ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	The product ASA-01 has no oxidizing properties.	Y	Study code: BC-35/21, Flasińska P.	Acceptable The formulation is considered to be a non-oxidizing liquid based on the negative results of the test A.21.
Flash point (KCP 2.3.1)	-	-	Not required.	-	-	The test is not required as the individual components of the product are not flammable (ref.: MSDSs of co-formulants)
Flammability (KCP 2.3.2)	-	-	-	-	-	The product ASA-01 is not flammable liquid as the individual components of the product are not flammable (ref.: MSDSs of co-formulants)
Self-heating	A.15	ASA-01	The product ASA-01 has got auto-ignition temperature: 485°C.	Y	Study code:	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.3.3)		(ACETAMIPRID 300 g/L) SC Batch No: 005-20-91			BC-35/21, Flasińska P.	the formulation is not considered as self-heating based on CLP criteria (under section 2.11.4.2 of Guidance on the Application of the CLP Criteria): 'In general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method (UN RTDG test N.4) is not applicable to liquids. Therefore liquids are not classified as self-heating.'
Acidity or alkalinity and pH (KCP 2.4.1)	-	-	Not relevant because pH of product is: 4<pH<10	-	-	-
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	ASA-01 (ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	1% (w/v) suspension - 5.28 Undiluted - 5.08, at temp. 20.0°C	Y	Study code: ICB/45/2021, Knapik I.	Acceptable
Viscosity (KCP 2.5.1)	OECD 114	ASA-01 (ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	Results of dynamic viscosity determination at 20°C temperature: 25 s ⁻¹ – 368 mPa·s 30 s ⁻¹ – 321 mPa·s 40 s ⁻¹ – 260 mPa·s. 50 s ⁻¹ – 220 mPa·s. Results of dynamic viscosity determination at 40°C temperature: 25 s ⁻¹ – 296 mPa·s 30 s ⁻¹ – 257 mPa·s. 40 s ⁻¹ – 209 mPa·s.	Y	Study code: BF-41/21, Arevalo E.	Acceptable. The product is non-Newtonian liquid. The conversion to kinematic viscosity is not required as the product does not contain hydrocarbons ≥10% or co-formulants classified for aspiration hazard (ref.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments								
			50 s ⁻¹ – 174 mPa·s.			MSDSs of co-formulants). The product ASA-01 is not classified as Asp. Tox. 1, H304								
Surface tension (KCP 2.5.2)	EEC A.5	ASA-01 (ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	Undiluted – 34.60 [mN/m] 0.05% (w/v) – 46.64 [mN/m] at temp. 20±1°C	Y	Study code: ICB/45/2021, Knapik I.	Acceptable <60 mN/m, the product is surface active. Note: If the highest in use dilution is < 1 g/L the surface tension should be determined at 1 g/L (0.1%(w/v) as given by the test method.								
Relative density (KCP 2.6.1)	EEC A.3	ASA-01 (ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	$D^{20}_4 = 1.0897 \frac{g}{cm^3}$	Y	Study code: ICB/45/2021, Knapik I.	Acceptable								
Bulk density (KCP 2.6.2)	-	-	Not relevant for liquid formulations	-	-	-								
Storage Stability after 14 days at 54° C (KCP 2.7.1)			Not relevant. Product ASA-01 was stored 12 weeks at 35±2°C.			-								
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	CIPAC MT 46 / GIFAP Monograph 17	ASA-01 (ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	<div><div><u>Test item was stored at 35±2°C for 12 weeks.</u></div><table><tr><th>Study</th><th>Method</th><th>Results initial</th><th>Results after accelerated storage</th></tr><tr><td>Appearance</td><td>OPPTS 830.6302, 830.6303 and 830.6304</td><td>Colour (Munsell’s notation) – 2.5Y 9/2 (white with gray tinge) Physical state –</td><td>Colour (Munsell’s notation) – N 9/ (white) Physical state – liquid</td></tr></table></div>	Study	Method	Results initial	Results after accelerated storage	Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell’s notation) – 2.5Y 9/2 (white with gray tinge) Physical state –	Colour (Munsell’s notation) – N 9/ (white) Physical state – liquid	Y	Study code: ICB/45/2021, Knapik I. Study code: ICB/98/2021, Knapik I.	Acceptable The formulation is considered to be physically and chemically stable for 12 weeks at 35°C in HDPE packaging material.
Study	Method	Results initial	Results after accelerated storage											
Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell’s notation) – 2.5Y 9/2 (white with gray tinge) Physical state –	Colour (Munsell’s notation) – N 9/ (white) Physical state – liquid											

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
					solid Odour – characteristic	Odour – medium intense, characteristic			
			pH	CIPAC MT 75.3	1% (w/v) suspension – 5.28 Undiluted – 5.08	1% (w/v) suspension – 5.59 Undiluted – 5.33			
			Suspensibility	CIPAC MT 184	0.01% (w/v) in Standard Water D (30±2°C): - acetamiprid 100% 0.05% (w/v) in Standard Water D (30±2°C): - acetamiprid 100% 0.2% (w/v) in Standard Water D (30±2°C): - acetamiprid 100%	0.01% (w/v) in Standard Water D (30±2°C): - acetamiprid 99% 0.05% (w/v) in Standard Water D (30±2°C): - acetamiprid 100% 0.2% (w/v) in Standard Water D (30±2°C): - acetamiprid 100%			
			Spontaneity of dispersion	CIPAC MT 160	Standard Water C (30±2°C): - acetamiprid 96% Standard Water D (30±2°C): - acetamiprid 97%	Standard Water C (30±2°C): - acetamiprid 85% Standard Water D (30±2°C): - acetamiprid 85%			
			Wet sieve	CIPAC MT 185	Residue (sieve 75 µm) – 0%	Residue (sieve 75 µm) – 0%			
			Particle size distribution	CIPAC MT 187 and Standard Operational Procedure SPB/32	d10-0.477 [µm] d20-0.900 [µm] d30-1.300 [µm] d40-1.748 [µm] d50-2.317 [µm] d60-3.059 [µm] d70-4.127 [µm]	d10-0.453 [µm] d20-1.152 [µm] d30-1.684 [µm] d40-2.287 [µm] d50-3.025 [µm] d60-3.992 [µm] d70-5.293 [µm]			

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
					d80-5.796 [µm] d90-8.800 [µm] d99-36.499[µm]	d80-7.102 [µm] d90-10.269 [µm] d99-43.669 [µm]			
			Pourability	CIPAC MT 148.1	Residue – 4.44%	Residue – 3.84%			
			Stability of package	SPB/38	-	Commercial packaging (type HDPE), 1 L: Change in packaging weight – 0.28 [%] Change in gross weight – 0.028 [%]			
			a.s. content	HPLC-DAD	Acetamiprid – 302.07 g/L	Acetamiprid – 301.31 g/L			
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Not required, since the preparation is not heat sensitive (see data point KCP 2.7.2)				-	-	Not relevant as no loss of active substance >5% was observed after storage 12 weeks at 35°C.
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 OPPTS 830.6302, 830.6303 and 830.6304 CIPAC MT 184 CIPAC MT 187 and Standard Operational Procedure SPB/32	ASA-01 (ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	Storage test under low temperature conditions (7 days at 0°C).				Y	Study code: ICB/45/2021, Knapik I.	Acceptable The formulation is considered to be stable for 7 days at 0°C.
			Study	Method	Results				
			Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation) – N 9/ (white) Physical state – liquid Odour – medium intense, characteristic				
			Suspensibility	CIPAC MT 184	0.01% (w/v) in Standard Water D (30±2°C): - acetamiprid 100% 0.05% (w/v) in Standard Water D (30±2°C): - acetamiprid 100% 0.2% (w/v) in Standard Water D				

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments																
	CIPAC MT 185		<table><tr><td></td><td></td><td colspan="2">(30±2°C): - acetamiprid 100%</td></tr><tr><td>Particle size distribution</td><td>CIPAC MT 187 and Standard Operational Procedure SPB/32</td><td colspan="2">d10-0.461 [µm] d20-0.790 [µm] d30-1.141 [µm] d40-1.497 [µm] d50-1.936 [µm] d60-2.530 [µm] d70-3.367 [µm] d80-4.704 [µm] d90-7.248 [µm] d99-28.514[µm]</td></tr></table> <p>After low temperature stability 0°C for 7 days – no phase separation, no sediment. After 24 h in room temperature and one invert – no phase separation, no sediment. Residue on the wet sieve – 0%</p>						(30±2°C): - acetamiprid 100%		Particle size distribution	CIPAC MT 187 and Standard Operational Procedure SPB/32	d10-0.461 [µm] d20-0.790 [µm] d30-1.141 [µm] d40-1.497 [µm] d50-1.936 [µm] d60-2.530 [µm] d70-3.367 [µm] d80-4.704 [µm] d90-7.248 [µm] d99-28.514[µm]												
		(30±2°C): - acetamiprid 100%																							
Particle size distribution	CIPAC MT 187 and Standard Operational Procedure SPB/32	d10-0.461 [µm] d20-0.790 [µm] d30-1.141 [µm] d40-1.497 [µm] d50-1.936 [µm] d60-2.530 [µm] d70-3.367 [µm] d80-4.704 [µm] d90-7.248 [µm] d99-28.514[µm]																							
Ambient temperature shelf life (KCP 2.7.5)	own method SPB/40, OPPTS 830.6302, 830.6303 and 830.6304, CIPAC MT 75.3, CIPAC MT 184, CIPAC MT 160, CIPAC MT 185, CIPAC MT 187 and SPB/32,	ASA-01 (ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	<u>Test item was stored at ambient temperature for 24 months.</u> <table><tr><th>Study</th><th>Method</th><th>Results initial</th><th>Results after storage</th></tr><tr><td>Appearance</td><td>OPPTS 830.6302, 830.6303 and 830.6304</td><td>Colour (Munsell’s notation) – 2.5Y 9/2 (white with gray tinge) Physical state – solid Odour – characteristic</td><td>Colour (Munsell’s notation) – N 9/ (white) Physical state – liquid Odour – medium intense, characteristic</td></tr><tr><td>pH</td><td>CIPAC MT 75.3</td><td>1% (w/v) suspension – 5.28 Undiluted – 5.08</td><td>1% (w/v) suspension – 5.21 Undiluted – 4.93</td></tr><tr><td>Suspensibility</td><td>CIPAC MT 184</td><td>0.01% (w/v) in Standard Water D (30±2°C): - acetamiprid</td><td>0.01% (w/v) in Standard Water D (30±2°C): - acetamiprid</td></tr></table>				Study	Method	Results initial	Results after storage	Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell’s notation) – 2.5Y 9/2 (white with gray tinge) Physical state – solid Odour – characteristic	Colour (Munsell’s notation) – N 9/ (white) Physical state – liquid Odour – medium intense, characteristic	pH	CIPAC MT 75.3	1% (w/v) suspension – 5.28 Undiluted – 5.08	1% (w/v) suspension – 5.21 Undiluted – 4.93	Suspensibility	CIPAC MT 184	0.01% (w/v) in Standard Water D (30±2°C): - acetamiprid	0.01% (w/v) in Standard Water D (30±2°C): - acetamiprid	Y	Study code: ICB/48/2021, Knapik I.	Acceptable The formulation is considered to be physically and chemically stable for 2 years at ambient temperature in HDPE packaging material.
Study	Method	Results initial	Results after storage																						
Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell’s notation) – 2.5Y 9/2 (white with gray tinge) Physical state – solid Odour – characteristic	Colour (Munsell’s notation) – N 9/ (white) Physical state – liquid Odour – medium intense, characteristic																						
pH	CIPAC MT 75.3	1% (w/v) suspension – 5.28 Undiluted – 5.08	1% (w/v) suspension – 5.21 Undiluted – 4.93																						
Suspensibility	CIPAC MT 184	0.01% (w/v) in Standard Water D (30±2°C): - acetamiprid	0.01% (w/v) in Standard Water D (30±2°C): - acetamiprid																						

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 148.1, own method SPB/38, validated own method SPB/217				100% 0.05% (w/v) in Standard Water D (30±2°C): - acetamiprid 100% 0.2% (w/v) in Standard Water D (30±2°C): - acetamiprid 100%	100% 0.05% (w/v) in Standard Water D (30±2°C): - acetamiprid 100% 0.2% (w/v) in Standard Water D (30±2°C): - acetamiprid 100%			
			Spontaneity of dispersion	CIPAC MT 160	Standard Water C (30±2°C): - acetamiprid 96% Standard Water D (30±2°C): - acetamiprid 97%	Standard Water C (30±2°C): - acetamiprid 94% Standard Water D (30±2°C): - acetamiprid 93%			
			Wet sieve	CIPAC MT 185	Residue (sieve 75 µm) – 0%	Residue (sieve 75 µm) – 0%			
			Particle size distribution	CIPAC MT 187 and Standard Operational Procedure SPB/32	d10-0.477 [µm] d20-0.900 [µm] d30-1.300 [µm] d40-1.748 [µm] d50-2.317 [µm] d60-3.059 [µm] d70-4.127 [µm] d80-5.796 [µm] d90-8.800 [µm] d99-36.499[µm]	d10-0.463 [µm] d20-0.830 [µm] d30-1.217 [µm] d40-1.654 [µm] d50-2.198 [µm] d60-2.894 [µm] d70-3.851 [µm] d80-5.277 [µm] d90-7.689 [µm] d99-30.147 [µm]			
			Pourability	CIPAC MT 148.1	Residue – 4.44%	Residue – 3.57%			
			Stability of package	SPB/38	-	<u>Commercial packaging (type HDPE), 1 L:</u> Change in packaging weight			

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
						– 0.30 [%] Change in gross weight – 0.04 [%]			
			a.s. content	HPLC-DAD	Acetamiprid – 302.07 g/L	Acetamiprid – 301.02 g/L			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	variable	ASA-01 (ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	Test item was stored at ambient temperature for 12 months.				Y	Study code: ICB/45/2021, Knapik I. Study code: ICB/47/2021, Knapik I.	Acceptable The formulation is considered to be physically and chemically stable for 2 years at ambient temperature (see above).
			Study	Method	Results initial	Results after 12 months at ambient temperature			
			Appearance	OPPTS 830.6302, 830.6303 and 830.6304	Colour (Munsell's notation) – 2.5Y 9/2 (white with gray tinge) Physical state – solid Odour – characteristic	Colour (Munsell's notation) – N 9/ (white) Physical state – liquid Odour – medium intense, characteristic			
			pH	CIPAC MT 75.3	1% (w/v) suspension – 5.28 Undiluted – 5.08	1% (w/v) suspension – 5.14 Undiluted – 5.06			
			Suspensibility	CIPAC MT 184	0.01% (w/v) in Standard Water D (30±2°C): - acetamiprid 100% 0.05% (w/v) in Standard Water D (30±2°C): - acetamiprid 100% 0.2% (w/v) in Standard Water D (30±2°C): - acetamiprid 100%	0.01% (w/v) in Standard Water D (30±2°C): - acetamiprid 101% 0.05% (w/v) in Standard Water D (30±2°C): - acetamiprid 100% 0.2% (w/v) in Standard Water D (30±2°C): - acetamiprid 101%			

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
			Spontaneity of dispersion	CIPAC MT 160	Standard Water C (30±2°C): - acetamiprid 96% Standard Water D (30±2°C): - acetamiprid 97%	Standard Water C (30±2°C): - acetamiprid 96% Standard Water D (30±2°C): - acetamiprid 96%			
			Wet sieve	CIPAC MT 185	Residue (sieve 75 µm) – 0%	Residue (sieve 75 µm) – 0%			
			Particle size distribution	CIPAC MT 187 and Standard Operational Procedure SPB/32	d10-0.477 [µm] d20-0.900 [µm] d30-1.300 [µm] d40-1.748 [µm] d50-2.317 [µm] d60-3.059 [µm] d70-4.127 [µm] d80-5.796 [µm] d90-8.800 [µm] d99-36.499[µm]	d10-0.530 [µm] d20-1.096[µm] d30-1.720 [µm] d40-2.473 [µm] d50-3.363 [µm] d60-4.466 [µm] d70-5.870 [µm] d80-7.836 [µm] d90-11.602 [µm] d99-57.067 [µm]			
			Pourability	CIPAC MT 148.1	Residue – 4.44%	Residue – 3.82%			
			Stability of package	SPB/38	-	<u>Commercial packaging (type HDPE), 1 L:</u> Change in packaging weight – 0.25 [%] Change in gross weight – 0.024 [%]			
			a.s. content	HPLC-DAD	Acetamiprid – 302.07 g/L	Acetamiprid – 301.62 g/L			
Wettability (KCP 2.8.1)	-	-	Not required, since ASA-01 is not a solid product.				-	-	-
Persistence of	CIPAC MT	ASA-01	0.01% (w/v):				Y	Study code:	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
foaming (KCP 2.8.2)	47.3	(ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	- after 1 minute – 0 mL - after 12 minutes – 0 mL 0.02% (w/v): - after 1 minute – 0 mL - after 12 minutes – 0 mL 0.05% (w/v): - after 1 minute – 0 mL - after 12 minutes – 0 mL		ICB/45/2021, Knapik I.	
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	ASA-01 (ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	0.01% (w/v) in Standard Water D (30±2°C): - acetamiprid 100% 0.05% (w/v) in Standard Water D (30±2°C): - acetamiprid 100% 0.2% (w/v) in Standard Water D (30±2°C): - acetamiprid 100%	Y	Study code: ICB/45/2021, Knapik I.	Acceptable The tested concentration of 0.2% is within the scope of the method. Note: Based on requirements of SANCO/10473/2003 – rev.5, 21.10.2021, CIPAC MT 184.1 should be used, however the study was conducted before the current guidance was issued.
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	ASA-01 (ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	12.5 mL in 250 mL Standard Water C (30±2°C): - acetamiprid 96% 12.5 mL in 250 mL Standard Water D (30±2°C): - acetamiprid 97%	Y	Study code: ICB/45/2021, Knapik I.	Acceptable spontaneity of dispersion is within acceptable limits (60 - 105%)
Dispersion stability (KCP 2.8.3.3)	-	-	Not required.	-	-	-
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required.	-	-	-
Particle size	CIPAC MT	ASA-01	d10-0.477 [µm]	Y	Study code:	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
distribution / nominal size range of granules (KCP 2.8.5.1.1)	187 and Standard Operational Procedure SPB/32	(ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	d20-0.900 [µm] d30-1.300 [µm] d40-1.748 [µm] d50-2.317 [µm] d60-3.059 [µm] d70-4.127 [µm] d80-5.796 [µm] d90-8.800 [µm] d99-36.499[µm]		ICB/45/2021, Knapik I.	
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	ASA-01 (ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	Residue (sieve 75 µm) – 0%	Y	Study code: ICB/45/2021, Knapik I.	Acceptable
Dust content (KCP 2.8.5.2.1)	-	-	Not required.	-	-	-
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required.	-	-	-
Attrition (KCP 2.8.5.3)	-	-	Not required.	-	-	-
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required.	-	-	-
Emulsifiability (KCP 2.8.6.1)	-	-	Not required.	-	-	-
Emulsion stability (KCP 2.8.6.2)	-	-	Not required.	-	-	-
Re-emulsifiability	-	-	Not required.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.6.3)						
Flowability (KCP 2.8.7.1)	-	-	Not required.	-	-	-
Pourability (KCP 2.8.7.2)	CIPAC MT 148.1	ASA-01 (ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	Residue – 4.44%	Y	Study code: ICB/45/2021, Knapik I.	Acceptable
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required.	-	-	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not required.	-	-	-
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not required.	-	-	-
Adhesion to seeds (KCP 2.10.1)	-	-	Not required.	-	-	-
Distribution to seed (KCP 2.10.2)	-	-	Not required.	-	-	-
Other/special studies (KCP 2.11)	Efficacy Guideline 305	ASA-01 (ACETAMIPRID 300 g/L) SC Batch No: 005-20-91	<u>Effectiveness of cleaning:</u> Single rinse procedure: 99.91 [%] acetamiprid removed from the bottle Double rinse procedure:	Y	Study code: ICB/45/2021, Knapik I.	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			> 99.93 [%] acetamiprid removed from the bottle Triple rinse procedure: > 99.93 [%] acetamiprid removed from the bottle			

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)

zRMS comment:

A 2-year storage stability study (at 20°C) and accelerated storage stability study (12-week at 35°C) were carried out in commercial containers (1 L HDPE bottles). No changes were observed in the product formulation and no evidence of corrosion of the packaging material was observed during the course of the studies (see KCP 2.7.5/01, KCP 2.7.5/02 and KCP 2.7.2/01) indicating good compatibility of the product with its packaging. The following HDPE containers are suitable for storing the product ASA-01.

Table 4.1-1: Packaging information for 0.1 L bottle

Type	Description
Material:	HDPE
Shape/size:	cylindrical / H=77.5mm, W=55.2mm
Opening:	31.3 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Foil seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information for 0.5 L bottle

Type	Description
Material:	HDPE
Shape/size:	cylindrical / H=135mm, W=88±2.0mm
Opening:	38.8 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Foil seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-3: Packaging information for 1 L bottle

Type	Description
Material:	HDPE
Shape/size:	cylindrical / H=236±2.5mm, W=89±1.0mm
Opening:	42±0.3 mm inner diameter
Closure:	polyethylene screw cap
Seal:	Foil seal
Manner of construction	extruded
UN/ADR	compliant

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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 KCP 2.4.2 KCP 2.5.2 KCP 2.6.1 KCP 2.7.2 KCP 2.7.4 KCP 2.7.6 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11	Knapik I.	2021	FINAL REPORT Determination of physicochemical properties. Test item: ASA-01 (ACETAMIPRID 300 g/L) SC ICB/45/2021 ICB Pharma GLP Unpublished	N	XXXX
KCP 2.7.2	Knapik I.	2022	FINAL REPORT Determination of physicochemical properties after accelerated storage test. Test item: ASA-01 (ACETAMIPRID 300 g/L) SC ICB/98/2021 ICB Pharma GLP Unpublished	N	XXXX
KCP 2.7.6	Knapik I.	2022	FINAL REPORT	N	XXXX

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
			Determination of physicochemical properties after 12 months shelf-life test. Test item: ASA-01 (ACETAMIPRID 300 g/L) SC ICB/47/2021 ICB Pharma GLP Unpublished		
KCP 2.7.5	Knapik I.	2023	FINAL REPORT Determination of physicochemical properties after 24 months shelf-life test. Test item: ASA-01 (ACETAMIPRID 300 g/L) SC ICB/48/2021 ICB Pharma GLP Unpublished	N	XXXX
KCP 2.2.2 KCP 2.3.3	Flasińska P.	2021	REPORT ASA-01 (Acetamiprid 300 g/l) SC Determination of auto-ignition temperature and oxidizing properties BC-35/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Unpublished	N	XXXX
KCP 2.5.1	Arevalo E.	2021	ASA-01 Viscosity determination BF-41/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Unpublished	N	XXXX
KCP 2.2.1	Buczkowski D.	2021	ASA-01 (Acetamiprid 300 g/l) SC Determination of explosive properties BW-27/21 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Unpublished	N	XXXX

* XXXX

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

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

The following tables are to be completed by MS.

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	Verte- brate 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	Verte- brate study Y/N	Owner

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

A 2.1 Acetamiprid

There are no new data on the active substance acetamiprid.