

# 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: **AMINO 30 SL**

Product name(s): **El Camino 30 SL, Ranchero 30 SL**

Chemical active substance:

**Aminopyralid, 30 g/L**

Central Zone

Zonal Rapporteur Member State: PL

**CORE ASSESSMENT**

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: 01/2025

zRMS Assessment: 18/04/2025

Following commenting period/Verification of reference list:  
01/07/2025

## Version history

When	What
April 2025	zRMS assessment
July 2025	Following commenting period Verification of reference list

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State whether or not submitted data are sufficient for evaluation. Data gaps and conditions for registration should be listed, if appropriate.

Sufficient data on identity, physical and chemical properties and other information are not available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- data gap 1: missing storage stability study at ambient temperature - study is ongoing. It is required to set a shelf-life for the PPP from real time storage test at ambient temperature and may be evaluated in post-registration at national level.

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

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

Name: Innvigo Sp. z o.o.  
Address: Aleje Jerozolimskie 178  
02-486 Warsaw, Poland

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

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

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

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

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

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

#### **1.2.3.1 Aminopyralid**

According to the *SANCO/11423/2014 rev 1* :

Aminopyralid min. 920 g/kg

Picloram max. 40 g/kg

### 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 (or)  
 Trade name: El Camino 30 SL  
 Ranchero 30 SL  
 Company code number: AMINO 30 SL

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

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

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

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Aminopyralid	30 g/L	27 - 33	32.61	3.19

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

\*\* Based on the density of the formulation = 1.0217 g/mL (Note: only applies if a liquid formulation – delete this comment if not needed)

**Table 1.4-3: Relevant impurities**

Relevant impurity	Maximum content (g/L or g/kg)
Picloram	1.2

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

**Table 1.4-4: Information on Aminopyralid**

Type	Name/Code Number
ISO common name	Aminopyralid
CAS No.	150114-71-9
EC No.	Not available.
CIPAC No.	771

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

Type: Soluble concentrate

[Code: SL]

**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 homogenous red-orange clear liquid, with a delicate odour. It is not explosive, has no oxidising properties. The product is not flammable. It has not a self ignition temperature. In aqueous solution, it has a pH value around 8.56 at 8.66 °C. 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 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. Its technical characteristics are acceptable for a *SL* formulation.

The intended concentration of use is 0.089% to 0.15%.

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

No classification is necessary.

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

Not required.

According to DAR: The active substance is not classified with regard to flammability, explosivity and oxidising properties.

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

The product AMINO 30 SL complies with FAO specifications.

### **Formulation used for tests**

All batches used for tests have the same composition.

Material: AMINO 30 SL

Active ingredient: Aminopyralid

Producer: PUH CHEMIROL Sp. z o.o., Przemysłowa 3 Str., 88-300 Mogilno

Date of production: 31.07.2024

Expiration date: -

Batch No: 1/24



**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 830.6303, 830.6304 and own method SPB/37	AMINO 30 SL Production date: 31.07.2024 Batch No: 1/24	<u>Initial preparation:</u> Colour (visually): red-orange Physical state: clear liquid Odour: delicate  <u>After accelerated storage test:</u> Colour (visually) – red-orange Physical state – clear liquid Odour – delicate	Y	Górka, I., 2024, <i>Determination of physico-chemical properties of AMINO 30 SL before and after accelerated storage test</i> , ICB/92/2024	<b>Accepted</b>
Explosive properties (KCP 2.2.1)	Procedures SPO/BW/01/b (edition 3), SPO/BW/03/b (edition 3) in accordance with method EC A.14, published in the Council Regulation (EC) No. 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).	AMINO 30 SL Production date: 31.07.2024 Batch No: 1/24	AMINO 30 SL does not have explosive properties according to the criteria of EC A.14 method.	Y	Buczkowski, D., 2024, <i>AMINO 30 SL Determination of explosive properties</i> , BW-22/24	<b>Accepted</b>  Determination of explosive properties of AMINO 30 SL was performed in accordance with EC A.14 method published in Council Regulation (EC) No. 440/2008. During the study determination of impact sensitivity and thermal sensitivity was performed. Based on the results of the study, test item AMINO 30 SL does not have explosive properties.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Oxidizing properties (KCP 2.2.2)	Oxidizing properties was performed according to Standard Operating Procedure No. SPO/BC/05/b (6 edition). This test method corresponds to Test UN O.2 Manual of Tests and Criteria, rev. 8, 2023.	AMINO 30 SL Production date: 31.07.2024 Batch No: 1/24	AMINO 30 SL does not have the oxidizing properties according to Test UN O.2.	Y	Pachnicki, P., 2024, <i>Determination of auto-ignition temperature and oxidizing properties</i> , BC-68/24	<b>Accepted</b>  Oxidising properties was performed according to Test method UN O.2. According to the data obtained during the test, pressure rise did not reach the critical value for mixture of AMINO 30 SL and cellulose. Test item AMINO 30 SL does not have the oxidising properties according to Test UN O.2.
Flash point (KCP 2.3.1)	EEC A.9	AMINO 30 SL Production date: 31.07.2024 Batch No: 1/24	Flash point was not observed.  Flash point was not observed, therefore the preparation is not classified as H226: Flammable liquid 3.	Y	Górka, I., 2024, <i>Determination of physico-chemical properties of AMINO 30 SL before and after accelerated storage test</i> , ICB/92/2024	<b>Accepted</b>  The flash point was conducted according to method EEC A.9. Flash point for the test item was not observed. Test item AMINO 30 SL is not classified as flammable according to CLP Regulation.
Flammability (KCP 2.3.2)	Not required for this preparation.					<b>Accepted</b>
Self-heating (KCP 2.3.3)	Auto-ignition temperature was performed according to	AMINO 30 SL Production	AMINO 30 SL does not have the auto-ignition temperature according to criteria of PN-EN ISO/IEC 80079-20-1:2020.	Y	Pachnicki, P., 2024, <i>Determination of auto-ignition temperature</i>	<b>Accepted</b>  Auto-ignition

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	Standard Operating Procedure No. SPO/BC/06/b (6 edition). This test method corresponds to PN-EN ISO/IEC 80079-20-1:2020 – Explosive atmospheres – Part 20-1: Material characteristics for gas and vapour classification – Test methods and data.	date: 31.07.2024 Batch No: 1/24			and oxidizing properties, BC-68/24	temperature was performed according to PN-EN ISO/IEC 80079-20-1:2020. Negative results were obtained in two tests (no auto-ignition occurs up to 640°C) – the study was finished. AMINO 30 SL does not have the auto-ignition temperature according to criteria of PN-EN ISO/IEC 80079-20-1:2020.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3 method	AMINO 30 SL Production date: 31.07.2024 Batch No: 1/24	<u>Initial preparation</u>  Undiluted test item: -pH after 0 minute (20°C): 8.66 -pH after 1 minute (20°C): 8.65  <u>After accelerated storage test:</u>  Undiluted test item: -pH after 0 minute(20°C): 8.58 -pH after 1 minute(20°C): 8.57	Y	Górka, I., 2024, <i>Determination of physicochemical properties of AMINO 30 SL before and after accelerated storage test</i> , ICB/92/2024	<b>Accepted</b>  The acidity or alkalinity should be tested if the preparation has pH < 4 or pH > 10 (for either 1 % dilution or neat formulation). The test was not required.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3 method	AMINO 30 SL Production date: 31.07.2024 Batch No:	<u>Initial preparation</u>  1% (w/v) solution in deionized water: -pH after 0 minute (20°C): 8.56 -pH after 1 minute (20°C): 8.56	Y	Górka, I., 2024, <i>Determination of physicochemical properties of AMINO 30 SL before and after accelerated storage</i>	<b>Accepted</b>  The acidity or alkalinity should be tested if the preparation has pH < 4 or pH > 10 (for

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																														
		1/24	<u>After accelerated storage test:</u>  1% (w/v) solution in deionized water: -pH after 0 minute (20°C): 8.67 --pH after 1 minute (20°C): 8.67		test, ICB/92/2024	either 1 % dilution or neat formulation). The test was not required.																														
Viscosity (KCP 2.5.1)	The dynamic viscosity was determined by the use of Brookfield Test Method in accordance with SPO/BF/05/b (edition 5), which is in compliance with OECD 114  Kinematic viscosity was obtained by dividing the dynamic viscosity of the test item by its density, obtained at the same temperature. Density was obtained from the Sponsor (certificate of analysis). $v \text{ [mm}^2\text{/s]} = \eta \text{ [mPa}\cdot\text{s]} / \rho \text{ [g/ml]}$ where, $\eta$ - dynamic viscosity [mPa·s] $\rho$ – density [g/ml] of the tested material at 20 or 40 °C.	AMINO 30 SL Production date: 31.07.2024 Batch No: 1/24	Dynamic viscosity: <table><tr><td>shear rate</td><td>at 20°C :</td><td>at 40°C:</td></tr><tr><td>25.0 s<sup>-1</sup></td><td>1.51 mPa·s</td><td>1.12 mPa·s,</td></tr><tr><td>50.0 s<sup>-1</sup></td><td>1.57 mPa·s</td><td>1.13 mPa·s</td></tr><tr><td>100.0 s<sup>-1</sup></td><td>1.54 mPa·s</td><td>1.05 mPa·s</td></tr><tr><td>200.0 s<sup>-1</sup></td><td>1.50 mPa·s</td><td>1.09 mPa·s</td></tr></table> Kinematic viscosity: <table><tr><td>shear rate</td><td>at 20°C :</td><td>at 40°C:</td></tr><tr><td>25.0 s<sup>-1</sup></td><td>1.48 mm<sup>2</sup>/s</td><td>1.10 mm<sup>2</sup>/s,</td></tr><tr><td>50.0 s<sup>-1</sup></td><td>1.54 mm<sup>2</sup>/s</td><td>1.11 mm<sup>2</sup>/s</td></tr><tr><td>100.0 s<sup>-1</sup></td><td>1.51 mm<sup>2</sup>/s</td><td>1.03 mm<sup>2</sup>/s</td></tr><tr><td>200.0 s<sup>-1</sup></td><td>1.47 mm<sup>2</sup>/s</td><td>1.07 mm<sup>2</sup>/s</td></tr></table>	shear rate	at 20°C :	at 40°C:	25.0 s <sup>-1</sup>	1.51 mPa·s	1.12 mPa·s,	50.0 s <sup>-1</sup>	1.57 mPa·s	1.13 mPa·s	100.0 s <sup>-1</sup>	1.54 mPa·s	1.05 mPa·s	200.0 s <sup>-1</sup>	1.50 mPa·s	1.09 mPa·s	shear rate	at 20°C :	at 40°C:	25.0 s <sup>-1</sup>	1.48 mm <sup>2</sup> /s	1.10 mm <sup>2</sup> /s,	50.0 s <sup>-1</sup>	1.54 mm <sup>2</sup> /s	1.11 mm <sup>2</sup> /s	100.0 s <sup>-1</sup>	1.51 mm <sup>2</sup> /s	1.03 mm <sup>2</sup> /s	200.0 s <sup>-1</sup>	1.47 mm <sup>2</sup> /s	1.07 mm <sup>2</sup> /s	Y	Rymarzak, O., 2024, <i>AMINO 30 SL Determination of viscosity</i> , BF-37/24	<b>Accepted</b>  The dynamic viscosity of AMINO 30 SL was determined at different shear rates. The test was conducted at 20°C and 40°C. Kinematic viscosity was obtained by dividing the dynamic viscosity of the test item by its density, obtained at the same temperature.
shear rate	at 20°C :	at 40°C:																																		
25.0 s <sup>-1</sup>	1.51 mPa·s	1.12 mPa·s,																																		
50.0 s <sup>-1</sup>	1.57 mPa·s	1.13 mPa·s																																		
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200.0 s <sup>-1</sup>	1.47 mm <sup>2</sup> /s	1.07 mm <sup>2</sup> /s																																		
Surface tension (KCP 2.5.2)	EEC A.5	AMINO 30 SL	0.15% (v/v) – 68.82 [mN/m]	Y	Górka, I., 2024, <i>Determination of</i>	<b>Accepted</b>																														

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
		Production date: 31.07.2024 Batch No: 1/24					<i>physicochemical properties of AMINO 30 SL before and after accelerated storage test, ICB/92/2024</i>	The determination of the surface tension was conducted according to method EEC A.5 at the highest in use concentrationat at 20°C.
Relative density (KCP 2.6.1)	EEC A.3	AMINO 30 SL Production date: 31.07.2024 Batch No: 1/24	1.0217 at 20°C			Y	Górka, I., 2024, <i>Determination of physicochemical properties of AMINO 30 SL before and after accelerated storage test, ICB/92/2024</i>	<b>Accepted</b>  Determination of the relative density was carried out by determination of the absolute density (at 20°C) of the test item using an oscillating densitometer, and the relative density was calculated as the average value of all absolute density measurements of the test item to the value of absolute density of water at 4°C.
Bulk density (KCP 2.6.2)	Not required for this preparation.							<b>Accepted</b>
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3	AMINO 30 SL Production date: 31.07.2024 Batch No:	Colour and physical state	Method: OPPTS 830.6303, 830.6304 and own method SPB/37	Colour (visually) – red-orange Physical state – clear liquid Odour –	Y	Górka, I., 2024, <i>Determination of physicochemical properties of AMINO 30 SL before and after accelerated storage</i>	<b>Accepted</b>  The content of active substance - aminopyralid - in PPP was determined by

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
		1/24			delicate		test, ICB/92/2024	<p>High Performance Liquid Chromatography with diode array detection (HPLC-DAD). The method was developed and validated in GLP laboratory (validated in ICB/91/2024). The loss of active substance after 2 weeks storage of test item at 54°C was almost negligible. It is recognised that a loss of up to 5 % of the active substance is unlikely to adversely affect the safety or efficacy of the preparation. Active substance content before and after storage meet FAO Limits.</p> <p>The content of picloram as impurity - relevant impurity of aminopyralid - in PPP was determined by High Performance Liquid Chromatography with diode array detection (HPLC-</p>
			Acidity or alkalinity and pH	Method: CIPAC MT 75.3 method	Undiluted test item: -pH after 0 minute(20°C): 8.58 -pH after 1 minute(20°C): 8.57			
			pH of a 1% aqueous dilution, emulsion or dispersion	Method: CIPAC MT 75.3 method	1% (w/v) solution in deionized water: -pH after 0 minute (20°C): 8.67 -pH after 1 minute (20°C): 8.67			
			Degree of dissolution and dilution stability	Method: CIPAC MT 41.1	Concentration 0.089% (v/v) in 30±2°C: Standard Water D -30 minutes: Homogeneous solution -24 h: Homogeneous solution  Concentration			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
					0.15% (v/v) in 30±2°C Standard Water D -30 minutes: Homogeneous solution -24 h: Homogeneous solution			DAD). The method was developed and validated in GLP laboratory (validated in ICB/91/2024). The content of of picloram as impurity - relevant impurity of aminopyralid in pre storage and after 14 days storage at 54°C was below the specification Limit for this impurity in the active substance as manufactured (max. 40 g/kg) and below maximum limit of this impurity in plant protection product (formulation) (maximum content 1.2 g/kg of formulation).
			Content of aminopyralid	Method: Standard Operational Procedure SPB/328	Average content of aminopyralid in test item after accelerated storage test is 30.67 g/L.  Average content of aminopyralid in test item before accelerated storage test is 31.07 g/L.			
			Content of picloram as impurity	Method: Standard Operational Procedure SPB/329	Average content of picloram in test item after accelerated storage test is 0.20052 g/kg.			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
					Average content of picloram in test item before accelerated storage test is 0.21159 g/kg.			
			Stability of packaging (HDPE)	Method: Standard Operational Procedure SPB/38	Packaging 3/6 Change in packaging weight – 1.44 [%] Change in gross weight – 0.07 [%] Packaging without any visible changes.			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	Not required for this preparation.							
Minimum content after heat stability testing (KCP 2.7.3)	Not required for this preparation.							
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	AMINO 30 SL Production date: 31.07.2024 Batch No: 1/24	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.			Y	Górka, I., 2024, <i>Determination of physicochemical properties of AMINO 30 SL before and after accelerated storage test</i> , ICB/92/2024	<b>Accepted</b>  The product is stable at low temperature.



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Ambient temperature shelf life (KCP 2.7.5)	The study is in progress.					<b>Data gap</b> Missing storage stability study at ambient temperature - study is ongoing. It is required to set a shelf-life for the PPP from real time storage test at ambient temperature and may be evaluated in post-registration at national level.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	The study is in progress.					<b>Data gap</b> Missing storage stability study at ambient temperature - study is ongoing. It is required to set a shelf-life for the PPP from real time storage test at ambient temperature and may be evaluated in post-registration at national level.
Wettability (KCP 2.8.1)	Not required for this preparation.					<b>Accepted</b>
Persistence of foaming (KCP 2.8.2)	The study was conducted according to CIPAC MT 47.3 method for two concentrations: 0.089% (w/v) and	AMINO 30 SL Production date: 31.07.2024	Amount of persistent foam obtained for concentration 0.089% (w/v): after 1 min: 0 mL after 12 min: 0 mL	Y	Górka, I., 2024, <i>Determination of physicochemical properties of AMINO 30 SL before and after</i>	<b>Accepted</b>  Persistent foam is determined to measure the amount of foam

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	0.15% (w/v) of the test item.	Batch No: 1/24	Amount of persistent foam obtained for concentration 0.15% (w/v): after 1 min: 0 mL after 12 min: 0 mL		<i>accelerated storage test</i> , ICB/92/2024	likely to be present in a spray tank or other application equipment following dilution of the preparation. Acceptable Limits: Max 60 mL foam after 1 minute. The above mentioned criteria were met for lowest and highest recommended concentration.
Suspensibility (KCP 2.8.3.1)	Not required for this preparation.					Accepted
Spontaneity of dispersion (KCP 2.8.3.2)	Not required for this preparation.					Accepted
Dispersion stability (KCP 2.8.3.3)	Not required for this preparation.					Accepted
Degree of dissolution and dilution stability (KCP 2.8.4)	CIPAC MT 41.1	AMINO 30 SL Production date: 31.07.2024 Batch No: 1/24	<u>Initial preparation</u>  Concentration 0.089% (v/v) in 30±2°C: Standard Water D -30 minutes: Homogeneous solution -24 h: Homogeneous solution  Concentration 0.15% (v/v) in 30±2°C Standard Water D -30 minutes: Homogeneous solution -24 h: Homogeneous solution	Y	Górka, I., 2024, <i>Determination of physicochemical properties of AMINO 30 SL before and after accelerated storage test</i> , ICB/92/2024	Accepted  The dilution stability is determined to ensure that water-soluble preparations dissolve readily and/or, when diluted, produce stable solutions without precipitation, flocculation, etc.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<u>After storage test under low temperature conditions:</u>  Concentration 0.089% (v/v) in 30±2°C: Standard Water D -30 minutes: Homogeneous solution -24 h: Homogeneous solution  Concentration 0.15% (v/v) in 30±2°C Standard Water D -30 minutes: Homogeneous solution -24 h: Homogeneous solution  <u>After accelerated storage test:</u>  Concentration 0.089% (v/v) in 30±2°C: Standard Water D -30 minutes: Homogeneous solution -24 h: Homogeneous solution  Concentration 0.15% (v/v) in 30±2°C Standard Water D -30 minutes: Homogeneous solution -24 h: Homogeneous solution			The study was conducted according to CIPAC MT 41.1 method for two concentrations 0.089% (v/v) and 0.15% (v/v) in Standard Water D at temperature 30°C±2°C. After standing for 30 min and 24 h, the presence of any separated interphase was recorded. Phase separation was not observed.
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	Not required for this preparation.					Accepted
Wet sieve test (KCP 2.8.5.1.2)	Not required for this preparation.					Accepted
Dust content (KCP 2.8.5.2.1)	Not required for this preparation.					Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Particle size of dust (KCP 2.8.5.2.2)	Not required for this preparation.					Accepted
Attrition (KCP 2.8.5.3)	Not required for this preparation.					Accepted
Hardness and integrity (KCP 2.8.5.4)	Not required for this preparation.					Accepted
Emulsifiability (KCP 2.8.6.1)	Not required for this preparation.					Accepted
Emulsion stability (KCP 2.8.6.2)	Not required for this preparation.					Accepted
Re-emulsifiability (KCP 2.8.6.3)	Not required for this preparation.					Accepted
Flowability (KCP 2.8.7.1)	Not required for this preparation.					Accepted
Pourability (KCP 2.8.7.2)	Not required for this preparation.					Accepted
Dustability following accelerated storage (KCP 2.8.7.3)	Not required for this preparation.					Accepted
Physical compatibility of tank mixes	Not required for this preparation.					Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.9.1)						According to the label the product is not used as tank mixes.
Chemical compatibility of tank mixes (KCP 2.9.2)	Not required for this preparation.					<b>Accepted</b>  According to the label the product is not used as tank mixes.
Adhesion to seeds (KCP 2.10.1)	Not required for this preparation.					<b>Accepted</b>
Distribution to seed (KCP 2.10.2)	Not required for this preparation.					<b>Accepted</b>
Stability of packaging (KCP 2.11.1)	Standard Operational Procedure SPB/38	AMINO 30 SL Production date: 31.07.2024 Batch No: 1/24	<u>After accelerated storage test:</u>  Packaging 3/6 Change in packaging weight – 1.44 [%] Change in gross weight – 0.07 [%] Packaging without any visible changes.	Y	Górka, I., 2024 <i>Determination of physicochemical properties of AMINO 30 SL before and after accelerated storage test,</i> ICB/92/2024	<b>Accepted</b>  The test item found to be non-corrosive for HDPE commercial containers as there was no significant change in the weight of commercial containers and the package showed no signs of any visible changes after accelerated storage test (14 days at 54±2°C).
Effectiveness of cleaning (KCP 2.11.2)	Efficacy Guideline 305	AMINO 30 SL Production date: 31.07.2024	Concentration 0.15% (w/v): Single rinse procedure: >99.73 [%] aminopyralid removed from the bottle Double rinse procedure: >99.73 [%] aminopyralid removed from the bottle	Y	Górka, I., 2024 <i>Determination of physicochemical properties of AMINO 30 SL before and after</i>	<b>Accepted</b>  The study was conducted according to Efficacy Guideline 305.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Batch No: 1/24	Triple rinse procedure: >99.73 [%] aminopyralid removed from the bottle		<i>accelerated storage test</i> , ICB/92/2024	The mixture of test item was prepared at a concentration of 0.15% (w/v), then was poured into 3 polyethylene bottles and allowed to stand at temperature (18-28°C) to next day, but not longer than 24h. After that, the bottles was rinsed by the tap water. Then the bottles was rinsed with ACN/H <sub>2</sub> O (1:1) mixture which was analysed for active ingredient content. Three different rinsing procedures were used. Active ingredient content was analyzed by liquid chromatography with diode array detection (HPLC-DAD).

### 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 comments

The HDPE bottle was used in accelerated storage study (14 days at 54°C). The HDPE bottle was stable in accelerated storage study.

**Table 4.1-1: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	64 mm± 2 mm/130 mm ± 3 mm
Opening:	40 mm ± 2 mm
Closure:	screw cap with seal
Capacity	250 ml
Net Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-2: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	72 mm± 2 mm/111,8 mm ± 3 mm
Opening:	38 mm ± 2 mm
Closure:	screw cap with seal
Capacity	250 ml
Net Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-3: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	69 mm± 2 mm/186.5 mm ± 2 mm
Opening:	45.65± 2 mm
Closure:	screw cap with seal
Capacity	564 ml
Net Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-4: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	69 mm± 2 mm/186.5 mm ± 2 mm
Opening:	45.65± 2 mm
Closure:	screw cap with seal
Capacity	564 ml
Net Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-5: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	90,5 mm± 2 mm/151 mm ± 3 mm
Opening:	40,6 mm ± 2 mm
Closure:	screw cap with seal
Capacity	500 ml
Net Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-6: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	77,6 mm± 2 mm/160,6 mm ± 3 mm
Opening:	38 mm ± 2 mm
Closure:	screw cap with seal
Capacity	500 ml
Net Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-7: Packaging information**

Type	JAR
Material:	HDPE
size: approximate diameter/height	79/80 mm / 138 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	510 ml
Net Capacity	500 ml
Seal:	Induction seal



Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-8: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	145.5mm± 2 mm/78mm ± 2 mm
Opening:	56mm ± 2 mm
Closure:	screw cap with seal
Capacity	600 ml
Net Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-9: Packaging information**

Type	JAR
Material:	HDPE
size: approximate diameter/height	79/80 mm / 201 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	800 ml
Net Capacity	800 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-10: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	80 mm± 2 mm/201 mm ± 2 mm
Opening:	64 mm
Closure:	screw cap with seal
Capacity	800 ml
Net Capacity	800 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-11: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	88.5 mm± 2 mm/283.5 mm ± 2 mm
Opening:	45.30 mm ± 2 mm
Closure:	screw cap with seal

Capacity	1000 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-12: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	88.5 mm± 2 mm/283.5 mm ± 2 mm
Opening:	45.30 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-13: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	88 mm± 4 mm/242 mm ± 6 mm
Opening:	39mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-14: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	238 mm± 2 mm/90mm ± 2 mm
Opening:	39 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-15: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	234 mm± 2 mm/88.5mm ± 2 mm

Opening:	42 mm $\pm$ 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-16: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	84 mm $\pm$ 2 mm/248.2 mm $\pm$ 2 mm
Opening:	50 mm $\pm$ 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-17: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	234 mm $\pm$ 2 mm/88.5mm $\pm$ 2 mm
Opening:	42 mm $\pm$ 2 mm
Closure:	cap with seal
Capacity	1200 $\pm$ 50 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-18: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	84 $\pm$ 1.5 mm/230.1 $\pm$ 3 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	1000 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-19: Packaging information**

Type	JAR
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Material:	HDPE
size: approximate diameter/height	108/110mm / 266 mm
Opening:	46 mm minimum
Closure:	screw cap with seal
Capacity	2 000 ml
Net Capacity	2000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-20: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	232 mm± 2 mm/195mm± 2 mm/130mm ± 2 mm
Opening:	50 mm ± 2 mm
Closure:	screw cap with seal
Capacity	3000 ml
Net Capacity	3000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-21: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	94 ± 1 mm/103 ± 1 mm/272.5 ± 3 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	2000 ml
Net Capacity	2000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-22: Packaging information**

Type	CANNISTER
Material:	HDPE
size:	96 ± 3 mm/195 ± 3.5 mm/297.2 ± 4 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	4000 ml
Net Capacity	3000 ml
Seal:	Induction seal
Manner of construction	extruded

UN/ADR	compliant
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**Table 4.1-23: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	224,1 mm± 2 mm/122mm ± 2 mm
Opening:	73 mm ± 2 mm
Closure:	screw cap with seal
Capacity	2000 ml
Net Capacity	2000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-24: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	305mm± 5 mm/193 mm± 5 mm/142 mm ± 5 mm
Opening:	59.20 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	5850 ml±150 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-25: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	305mm± 5 mm/193 mm± 5 mm/142 mm ± 5 mm
Opening:	59.20 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	5850 ml±150 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-26: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	336 mm± 5 mm/195mm± 5 mm/130mm ± 5 mm
Opening:	50 mm ± 5 mm
Closure:	screw cap with seal

Capacity	5000 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-27: Packaging information**

Type	CANNISTER
Material:	HDPE
size:	190 mm± 5 mm /140 mm± 5 mm/ 314 mm ± 5 mm
Opening:	54.5 mm ± 5 mm
Closure:	screw cap with seal
Capacity	5000 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-28: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	310,5 mm± 5 mm/195mm± 5 mm/130mm ± 5 mm
Opening:	63 mm ± 5 mm
Closure:	screw cap with seal
Capacity	5000 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-29: Packaging information**

Type	CANNISTER
Material:	HDPE
size:	127±2 mm/192±2 mm/285±5 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	5000 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-30: Packaging information**

Type	CANNISTER
Material:	HDPE
size:	145±2 mm/190.8±3/294±4 mm
Opening:	38 mm
Closure:	screw cap with seal
Capacity	6000 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-31: Packaging information**

Type	BOTTLE
Material:	HDPE
size:	231,5mm± 5 mm193mm ± 5 mm
Opening:	115 mm ± 5 mm
Closure:	screw cap with seal
Capacity	5000 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-32: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	375mm± 5 mm/240 mm± 5 mm/179 mm ± 5 mm
Opening:	63 mm ± 5 mm
Closure:	screw cap with seal
Capacity	11220±50 ml
Net Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-33: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	375mm± 5 mm/240 mm± 5 mm/179 mm ± 5 mm
Opening:	63 mm ± 5 mm
Closure:	screw cap with seal
Capacity	11220±50 ml
Net Capacity	10000 ml
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-34: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	375mm± 5 mm/240 mm± 5 mm/179 mm ± 5 mm
Opening:	63 mm ± 5 mm
Closure:	screw cap with seal
Capacity	11220±50 ml
Net Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-35: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	375 mm± 5 mm/230± 5 mm/165 mm ± 5 mm
Opening:	54.5 mm ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml
Net Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-36: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	377,7 mm± 5 mm/239,5± 5 mm/178 mm ± 5 mm
Opening:	54 mm ± 5 mm
Closure:	screw cap with seal
Capacity	10000 ml
Net Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-37: Packaging information**

Type	CANNISTER
Material:	HDPE
size:	192±3 mm/228±7/313±7 mm



Opening:	52 mm ± 2 mm
Closure:	screw cap with seal
Capacity	10000 ml
Net Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-38: Packaging information**

Type	CANNISTER
Material:	HDPE
size:	185±2 mm/225±2/312±3 mm
Opening:	40.8 mm ± 0.3 mm
Closure:	screw cap with seal
Capacity	10000 ml
Net Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-39: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	443mm/288mm/230mm
Opening:	44mm (internal) 60mm (external)
Closure:	screw cap with seal
Capacity	22000ml ± 50 ml
Net Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-40: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	443mm/288mm/230mm
Opening:	44mm (internal) 60mm (external)
Closure:	screw cap with seal
Capacity	22000ml ± 50 ml
Net Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-41: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	376.3±3 mm/295±3mm/246±3mm
Opening:	50 mm ± 5 mm
Closure:	screw cap with seal
Capacity	20000 ml
Net Capacity	20000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-42: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	378±5 mm/288±5/258±5 mm
Opening:	53.7±1.5 mm
Closure:	screw cap with seal
Capacity	22000 ml
Net Capacity	20 000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-43: Packaging information**

Type	CONTAINER
Material:	HDPE
size:	376±8 mm/257,5±5/376±8 mm
Opening:	52 mm± 3
Closure:	screw cap with seal
Capacity	20000 ml
Net Capacity	20 000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-44: Packaging information**

Type	CANNISTER
Material:	HDPE
size:	257.5±6 mm/292±8/376±8 mm ± 5 mm
Opening:	52 mm ± 2 mm
Closure:	screw cap with seal
Capacity	20000 ml
Net Capacity	20 000 ml
Seal:	Induction seal
Manner of construction	extruded

UN/ADR	compliant
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The packaging material HDPE was tested during the accelerated storage stability studies. The packaging material was found to be stable. Extrapolation of the data conducted with HDPE packaging material to HDPE/PA, HDPE/F or HDPE/EvOH is possible according to SANCO/10473/2003 –rev.5 21.10.2021 without further data provided.

#### zRMS comments

The HDPE bottle was used in accelerated storage study (14 days at 54°C). The HDPE bottle was stable in accelerated storage study so the storage stability data obtained in this study can be extrapolated for storage in HDPE-EVOH; HDPE-F, HDPE/PA or PET bottles.

(According to SANCO/10473/2003 rev.5 “Guidance Document for the Generation and Evaluation of Data on The Physical, Chemical And Technical Properties of Plant Protection Products Under Regulation (EC) No. 1107/2009” and Technical Monograph N°17 3RD Edition Guidelines for Specifying and Managing Shelf Life and Expiry Date of Crop Protection Products, Crop Life International” the following extrapolations are acceptable: for water-based formulations (e.g. SC, FS, SL) extrapolation between plastic materials is possible and stability data generated for one of the materials can be used in support of any of the others).

**Table 4.1-48: Packaging information**

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

**Table 4.1-49: Packaging information**

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

**Table 4.1-50: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	62.5±1 mm/131.3±1 mm

Opening:	45.65±3 mm
Closure:	screw cap with seal
Capacity	323 ± 5 ml
Net Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-51: Packaging information**

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

**Table 4.1-52: Packaging information**

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

**Table 4.1-53: Packaging information**

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

**Table 4.1-54: Packaging information**

Type	BOTTLE
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Material:	HDPE/PA
size:	88 mm $\pm$ 2 mm/238 mm $\pm$ 2 mm
Opening:	50 mm $\pm$ 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-55: Packaging information**

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

**Table 4.1-56: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	248.5 $\pm$ 3 mm/84 $\pm$ 1.5mm
Opening:	50 mm $\pm$ 5 mm
Closure:	screw cap with seal
Capacity	1000 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-57: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	234 mm $\pm$ 2 mm/88.5mm $\pm$ 2 mm
Opening:	42 mm $\pm$ 2 mm
Closure:	screw cap with seal
Capacity	1000 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-58: Packaging information**

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

**Table 4.1-59: Packaging information**

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

**Table 4.1-60: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	233.5± 1.5 mm/88.5 ± 1 mm/
Opening:	39 mm ± 2 mm
Closure:	screw cap with seal
Capacity	1100 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-61: Packaging information**

Type	BOTTLE
Material:	HDPE/PA
size:	84± 1.5 mm/248.5 ± 3 mm
Opening:	50 mm ± 3mm
Closure:	screw cap with seal
Capacity	1000 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded

UN/ADR	compliant
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**Table 4.1-62: Packaging information**

Type	CONTAINER
Material:	HDPE/PA
size:	305mm± 5 mm/193 mm± 5 mm/142 mm ±5 mm
Opening:	63 mm minimum ± 5 mm
Closure:	screw cap with seal
Capacity	5850 ml±150 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-63: Packaging information**

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

**Table 4.1-64: Packaging information**

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

**Table 4.1-65: Packaging information**

Type	CANNISTER
Material:	HDPE/PA
size:	313± 5mm/190±3/140±5mm
Opening:	50 mm ± 3mm
Closure:	screw cap with seal
Capacity	5000 ml

Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-66: Packaging information**

Type	CONTAINER
Material:	HDPE/PA
size:	305mm/193 mm/142 mm $\pm$ 5 mm
Opening:	63 mm minimum $\pm$ 5 mm
Closure:	screw cap with seal
Capacity	10000 ml $\pm$ 150 ml
Net Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-67: Packaging information**

Type	CONTAINER
Material:	HDPE/PA
size:	377,7mm/178 mm/239,5 mm $\pm$ 5 mm
Opening:	54 mm min $\pm$ 5 mm
Closure:	screw cap with seal
Capacity	10000 ml $\pm$ 150 ml
Net Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-68: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	63.5 $\pm$ 1 mm/126 $\pm$ 1 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	318 $\pm$ 12.5 ml
Net Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-69: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	63.5 $\pm$ 1 mm/126 $\pm$ 1 mm



Opening:	50 mm
Closure:	screw cap with seal
Capacity	312 ± 12.5 ml
Net Capacity	250 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-70: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	570 ± 12.5 ml
Net Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-71: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	575 ± 12.5 ml
Net Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-72: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	580 ± 12.5 ml
Net Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-73: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	69±1 mm/186±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	585 ± 12.5 ml
Net Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-74: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1150 ± 20 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-75: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1160 ± 20 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-76: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1170 ± 20 ml
Net Capacity	1000 ml
Seal:	Induction seal

Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-77: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1185 ± 20 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-78: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	88.5±1 mm/233.2±1.6 mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	1200 ± 20 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-79: Packaging information**

Type	Cannister
Material:	HDPE/F
size:	193±2 mm/142±2mm/305±3mm
Opening:	50 mm
Closure:	screw cap with seal
Capacity	5880 ± 100 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-80: Packaging information**

Type	Cannister
Material:	HDPE/F
size:	193±2 mm/142±2mm/305±3mm
Opening:	63 mm
Closure:	screw cap with seal

Capacity	5880 ± 100 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-81: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	54,2 mm ± 1 mm
Closure:	screw cap with seal
Capacity	5950 ml ± 100 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-82: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	63.4 mm min ± 1 mm
Closure:	screw cap with seal
Capacity	5950 ml ± 100 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-83: Packaging information**

Type	BOTTLE
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm ± 2 mm
Opening:	67,5 mm ± 1 mm
Closure:	screw cap with seal
Capacity	5950 ml ± 100 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-84: Packaging information**

Type	CANNISTER
Material:	HDPE/F

size:	297,3mm/193 mm/142 mm $\pm$ 2 mm
Opening:	54,2 mm min $\pm$ 1 mm
Closure:	screw cap with seal
Capacity	5950 ml $\pm$ 100 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-85: Packaging information**

Type	CANNISTER
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm $\pm$ 2 mm
Opening:	63,4 mm min $\pm$ 1 mm
Closure:	screw cap with seal
Capacity	5950 ml $\pm$ 100 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-86: Packaging information**

Type	CANNISTER
Material:	HDPE/F
size:	297,3mm/193 mm/142 mm $\pm$ 2 mm
Opening:	67,5 mm min $\pm$ 1 mm
Closure:	screw cap with seal
Capacity	5950 ml $\pm$ 100 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-87: Packaging information**

Type	Cannister
Material:	HDPE/F
size:	240 $\pm$ 2 mm/179 $\pm$ 2mm/375 $\pm$ 3mm
Opening:	63 mm
Closure:	screw cap with seal
Capacity	10 000 ml
Net Capacity	10000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-88: Packaging information**

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

**Table 4.1-89: Packaging information**

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

**Table 4.1-90: Packaging information**

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

**Table 4.1-91: Packaging information**

Type	BOTTLE
Material:	HDPE/ EvOH
size:	65 mm/234.8 mm ± 2 mm
Opening:	27.4 mm
Closure:	screw cap with seal
Capacity	500 ml

Net Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-92: Packaging information**

Type	BOTTLE
Material:	HDPE/EvOH
size:	69 mm $\pm$ 1 mm/190 mm $\pm$ 1.5 mm
Opening:	49.5 mm $\pm$ 0.3 mm
Closure:	screw cap with seal
Capacity	579 ml
Net Capacity	500 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-93: Packaging information**

Type	BOTTLE
Material:	HDPE/EvOH
size:	234 $\pm$ 3 mm/88.5 $\pm$ 2mm
Opening:	42 mm $\pm$ 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-94: Packaging information**

Type	BOTTLE
Material:	HDPE/EvOH
size:	234 $\pm$ 3 mm/88.5 $\pm$ 2mm
Opening:	42 mm $\pm$ 2 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-95: Packaging information**

Type	BOTTLE
Material:	HDPE/EvOH

size:	234±3 mm/88.5±2mm
Opening:	50 mm ± 3 mm
Closure:	screw cap with cutter
Capacity	1000 ml
Net Capacity	1000 ml
Seal:	Induction seal
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-96: Packaging information**

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

**Table 4.1-97: Packaging information**

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

**Table 4.1-98: Packaging information**

Type	CANNISTER
Material:	HDPE/EvOH
size:	142 mm ± 1.5 mm/193 mm ± 2 mm/307mm± 3 mm
Opening:	63.3 mm ± 0.3 mm
Closure:	screw cap with cutter
Capacity	5650 ml
Net Capacity	5000 ml
Seal:	Induction seal
Manner of construction	extruded



UN/ADR	compliant
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**Table 4.1-99: Packaging information**

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

**Table 4.1-100: Packaging information**

Type	CONTAINER
Material:	HDPE/EvOH
size:	375 mm $\pm$ 2 mm/290mm $\pm$ 2 mm/245mm $\pm$ 2 mm
Opening:	85mm $\pm$ 2 mm
Closure:	screw cap with cutter
Capacity	20000 ml
Net Capacity	20 000 ml
Seal:	Induction 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 2.3.1, KCP 2.3.2, KCP 2.4.1, KCP 2.4.2, KCP 2.5.2, KCP 2.6.1, KCP 2.7.1 KCP 2.7.2, KCP 2.7.4, KCP 2.8.2, KCP 2.8.4, KCP 2.11.1 KCP 2.11.2	Górka, I.	2024	<i>Determination of physicochemical properties of AMINO 30 SL before and after accelerated storage test</i> ICB/92/2024 ICB Pharma 10 Lema Street 43-600 Jaworzno Poland GLP Not published	N	PUH Chemiroł sp. z o.o.
KCP 2.2.1	Buczkowski, D.	2024	<i>AMINO 30 SL Determination of explosive properties</i> BW-22/24 Łukasiewicz Research Network - Institute of Industrial Organic Chemistry	N	PUH Chemiroł sp. z o.o.

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
			6 Annopol Str. 03-236 Warsaw GLP Not published		
KCP 2.2.2, KCP 2.3.3	Pachnicki, P.	2024	<i>AMINO 30 SL Determination of auto-ignition temperature and oxidizing properties</i> BC-68/24 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry 6 Annopol Str. 03-236 Warsaw Poland GLP Not published	N	PUH Chemirol sp. z o.o.
KCP 2.5.1	Rymarzak, O.	2024	<i>AMINO 30 SL Determination of viscosity</i> BF-37/24 Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Annopol 6 Street 03-236 Warsaw Poland GLP Not published	N	PUH Chemirol sp. z o.o.

The following tables are to be completed by MS.

**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**