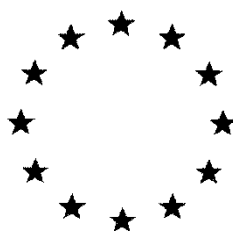


European Commission

**Second Programme for the Renewal of the Inclusion of Active Substances
in Annex I of Council Directive 91/414/EEC**



**Draft Renewal Assessment Report prepared according to the Commission
Regulation (EU) No 1141/2010**

AMITROLE

Volume 3 – Annex B.2

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Table of contents

B.2. PHYSICAL AND CHEMICAL PROPERTIES	3
B.2.1. PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE	3
B.2.1.1. Spectra (UV/VIS, IR, NMR, MS), molecular extinction at relevant wavelengths	3
B.2.2. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT (WEEDAZOL TL, 229 g/L AMITROLE, SL)	6
B.2.2.1. Appearance of the preparation.....	6
B.2.2.2. Explosive and oxidizing properties of the preparation	6
B.2.2.3. Flash point, flammability and auto-flammability of the preparation	7
B.2.2.4. Acidity/alkalinity and pH	7
B.2.2.5. Viscosity and surface tension of the preparation	8
B.2.2.6. Density of the preparation	9
B.2.2.7. Stability	9
B.2.2.8. Technical characteristics of the plant protection product	10
B.2.2.9. Physical and chemical compatibility with other products	13
B.2.2.10. Distribution and adhesion of seed treatment preparations	13
B.2.3. SUMMARY AND ASSESSMENT OF PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES.....	17
B.2.3.1. Active substance.....	17
B.2.3.2. Plant protection product	17
B.2.4. REFERENCES RELIED ON.....	18
B.2.4.1. Active substance.....	18
B.2.4.2. Plant protection product	18

B.2. PHYSICAL AND CHEMICAL PROPERTIES**B.2.1. PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE**

Only data submitted for the reexamination of Amitrole have been evaluated and given below.

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1.1. Spectra (UV/VIS, IR, NMR, MS), molecular extinction at relevant wavelengths						
UV spectrum B.2.1.5.1a (IIA, 2.5.1)	OECD 101	Batch 31090804 Purity: 92.2%	At acid pH : max. absorption at 202.4 nm with $\epsilon = 878 \text{ L.mol}^{-1}.\text{cm}^{-1}$ At neutral pH : max. absorption at 198 nm with $\epsilon = 628 \text{ L.mol}^{-1}.\text{cm}^{-1}$ At basic pH : max. absorption at 217.8 nm with $\epsilon = 224 \text{ L.mol}^{-1}.\text{cm}^{-1}$ No absorption was observed after 290 nm.	Not acceptable, test must be performed on the pure active substance.	Y	Da Conceicao, L., 2002
	OECD 101	Batch RD-794-185 Purity: 99.9%	At acid pH : max. absorption at 202 nm with $\epsilon = 7731.4/7680.4 \text{ L.mol}^{-1}.\text{cm}^{-1}$ At neutral pH : max. absorption at 198 nm with $\epsilon = 5420.4/5545.1 \text{ L.mol}^{-1}.\text{cm}^{-1}$ At basic pH : max. absorption at 217.8 nm with $\epsilon = 1881.6/1858.9 \text{ L.mol}^{-1}.\text{cm}^{-1}$ No absorption was observed after 290 nm. The UV-Vis spectra of the test item are consistent with the chemical structure of Amitrole.	Acceptable	Y	Da Conceicao, L., 2012a
IR spectrum, H NMR spectrum, C NMR spectrum, Mass spectrum B.2.1.5.2 (IIA, 2.5.1)	Explanation	Batch 31090804 Purity: 92.2%	IR: The frequency of the most important absorption bands are: 3414, 3332, 3215, 3059, 2991, 2930, 2844, 2775 and 2727 cm^{-1} (NH_2 , NH) 1642, 1594, 1537, 1428 and 829 cm^{-1} (NH_2 , NH, C=N and triazinic cycle) The IR spectrum of the test item is consistent with the chemical structure of Amitrole.	Not acceptable, test must be performed on the pure active substance.	Y	Da Conceicao, L., 2002

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1.1. Spectra (UV/VIS, IR, NMR, MS), molecular extinction at relevant wavelengths						
			<u>NMR:</u> ¹H: 5.79 ppm (broad singlet, NH₂) 7.47 ppm (singlet, 1H, H1) The NH (triazinic cycle) signal does not appear in the spectrum. ¹³C: 148.0 ppm: C5 158.3 ppm: C3 Both ¹H and ¹³C NMR spectra of the test item are consistent with the chemical structure of Amitrole. <u>MS:</u> Molecular ion: 84 Fragments: 57 (loss of HCN), 42: CN, H₂⁺ The MS spectrum of the test item is consistent with the chemical structure of Amitrole.			
		Batch RD-655-140-7 Purity: 99.6%	<u>IR:</u> The frequencies of the most important absorption bands are: 3413, 3333, 3216, 3057, 2992, 2929, 2842, 2773 and 2725 cm⁻¹: NH₂ and NH 1644, 1594, 1538, 1427 and 830 cm⁻¹: NH₂, NH, C=N and triazinic cycle The IR spectrum is consistent with the chemical structure of Amitrole. <u>NMR:</u> ¹H: 12.06 ppm (broad singlet, 1H, NH) 7.42 ppm (singlet, 1H, H1) 5.87 ppm (broad singlet, 2H, NH₂) Presence of residual signals of water at 3.45 ppm and protonated dimethylsulfoxide at 2.52 ppm. ¹³C: 161.3 ppm (1C, C3) 149.9 ppm (1C, C5) Both ¹H and ¹³C NMR spectra are consistent with the	Acceptable	Y	Da Conceicao, L., 2012b

Test or Study Annex Point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference												
B.2.1.1. Spectra (UV/VIS, IR, NMR, MS), molecular extinction at relevant wavelengths																		
		Batch RD-794-185 Purity: 99.9%	chemical structure of Amitrole. MS:<table><thead><tr><th>Ion peak (m/z)</th><th>Relative abundance (%)</th><th>Structure</th></tr></thead><tbody><tr><td>84</td><td>100</td><td>Molecular ion M⁺</td></tr><tr><td>57</td><td>42</td><td>M-HCN</td></tr><tr><td>42</td><td>19</td><td>CH₂H₂⁺</td></tr></tbody></table>The MS data of the test item is consistent with the chemical structure of Amitrole.	Ion peak (m/z)	Relative abundance (%)	Structure	84	100	Molecular ion M ⁺	57	42	M-HCN	42	19	CH ₂ H ₂ ⁺	Acceptable	Y	Da Conceicao, L 2012c
Ion peak (m/z)	Relative abundance (%)	Structure																
84	100	Molecular ion M ⁺																
57	42	M-HCN																
42	19	CH ₂ H ₂ ⁺																

B.2.2. PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT (WEEDAZOL TL, 229 g/L Amitrole, SL)

Minimum rate of application: 0.8% v/v

Maximum rate of application: 4.4% v/v

The formulation does not contain hydrocarbons $\geq 10\%$.

Commercial packagings: HDPE (High Density PolyEthylene) and PET (PolyEthylene Terephthalate)

The representative formulation for the first annex I inclusion was a soluble concentrate (CA0123) containing 229 g/L of Amitrole and 215 g/L of ammonium thiocyanate (specific synergist). Further to publication of Directive 2003/53/EC dealing with the restrictions on the marketing and use of nonylphenol and nonylphenol ethoxylate, a SL formulation without NPE was developed (CA2210). For this current annex I renewal process the representative formulation is still a soluble concentrate containing 229 g/L of Amitrole and 215 g/L of ammonium thiocyanate (CA2735). Compared with the WEEDAZOL TL (CA 2210), minor changes were made in formulation CA2735 (see confidential part - Vol 4 – Annex C for the detailed composition).

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.2.1. Appearance of the preparation						
B.2.2.1.1. Physical state and odour						
Physical state, colour and odour of the preparation B.2.2.1.1 (IIIA, 2.1)	Visual and olfactory	CA2735 batch no. 310123555	Physical state: fluid liquid Colour: dark brown Odour: odourless	Acceptable	Y	Adam, C., 2011
	Visual and olfactory	CA2210 batch no. RD-816-166B	Dark brown liquid with shades of light brown and greenish, medium odour.	Acceptable	Y	Mourgues, L., Ricau, H., 2006
B.2.2.2. Explosive and oxidizing properties of the preparation						
B.2.2.2.1. Explosive properties						
Explosive properties of the preparation B.2.2.1.1 (IIIA, 2.2.1)	EEC A.14 and OECD n° 113	CA2735 batch n° 310123555	No explosive property. According to the structure of a.s. and co-formulants, exothermic reactions are not probable	Acceptable, formulation is not explosive.	Y	Le Pollès A., 2012
	Assessment	CA2210	No explosive property. According to the structure of a.s. and co-formulants, exothermic reactions are not probable.	Acceptable, formulation is not explosive.	N	-

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.2.2.2. Oxidizing properties						
Oxidizing properties of the preparation B.2.2.2.2 (IIIA, 2.2.2)	EEC A.21 and OECD n° 113	CA2735 batch n° 310123555	CA2735 is an aqueous formulation. The a.s. and co-formulants are not oxidizing.	Acceptable, formulation is not oxidising.	Y	Le Pollès A., 2012
	Assessment	-	CA2210 is an aqueous formulation. The a.s. and co-formulants are not oxidizing.	Acceptable, formulation is not oxidising.	N	-
B.2.2.3. Flash point, flammability and auto-flammability of the preparation						
B.2.2.3.1. Flash point						
Flash point of the preparation B.2.2.3.1 (IIIA, 2.3)	EEC A.9	CA2735 batch n° 310123555	No flash point was observed up to 108°C.	Acceptable	Y	Le Pollès A., 2012
	EEC A.9	CA2210 batch no. RD-816-166B	No flash point was observed up to 126.5°C.	Acceptable	Y	Mourgues, L., Ricau, H., 2006
B.2.2.3.2. Flammability						
Flammability of the preparation, evolution on contact with water B.2.2.3.2 (IIIA, 2.3)				Not required. Such a test is only requested for solid preparations and gases.		
B.2.2.3.3. Auto-flammability						
Auto-flammability of the preparation B.2.2.3.3 (IIIA, 2.3)	EEC A.15	CA2735 batch no. 310123555	No self-ignition of the test item was observed up to a temperature of 652 °C.	Acceptable	Y	Krack, M., 2012
	EEC A.15	CA2210 batch no. RD-816-166B	505 ± 7 °C	Acceptable	Y	Mourgues, L., Ricau, H., 2006
B.2.2.4. Acidity/alkalinity and pH						
B.2.2.4.1. Acidity/alkalinity and pH value of the preparation						
Acidity / alkalinity and pH of the preparation				Acidity or alkalinity was not determined because pH was > 4 and < 10.		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference		
B.2.2.4.1 (IIIA, 2.4.1)								
B.2.2.4.2. pH value of a 1% aqueous dilution, emulsion or dispersion								
pH of a 1% aqueous dilution B.2.2.4.2 (IIIA, 2.4.2)	CIPAC MT 75.3	CA2735 batch no. 310123555	At room temperature: pH: 6.68 (neat product) pH: 6.17 (1% aqueous dilution)	Acceptable	Y	Adam, C., 2011		
	CIPAC MT 75.3	CA2210 batch no. RD-816-166B	pH: 6.81 (neat product) pH: 6.19 (1% aqueous dilution)	Acceptable	Y	Mourgues, L., Ricau, H., 2006		
B.2.2.5. Viscosity and surface tension of the preparation								
B.2.2.5.1. Kinematic viscosity								
Kinematic viscosity of the preparation B.2.2.5.1 (IIIA, 2.5.1)				Not required, because CA2735 is not used for ultra low volume (ULV) sprays.				
B.2.2.5.2. Viscosity								
Viscosity of the preparation and details of the test conditions B.2.2.5.2 (IIIA, 2.5.2)	CIPAC MT 192	CA2735 batch no. 310123555	T°	20°C		Acceptable	Y	Adam, C., 2012
			Commercial packagings	HDPE	PET			
			Dynamic viscosity (mPa*s)	1.75	1.74			
	OECD 114 and ISO standard 3219 (1993)	CA2210 batch no. RD-816-166B	at 20.0 ± 0.2 °C: less than 10 mPa.s (3.3 ± 0.2 mPa.s at 200 rpm). at 40.0 ± 0.2 °C: less than 10 mPa.s (1.8 ± 0.2 mPa.s at 200 rpm).			Acceptable	Y	Mourgues, L., Ricau, H., 2006
B.2.2.5.3. Surface tension								
Surface tension of the preparation B.2.2.5.3 (IIIA, 2.5.3)	EEC A.5	CA2735 batch no. 310123555	T°	20°C		Acceptable, formulation is not surface active.	Y	Adam, C., 2012
			Commercial packagings	HDPE	PET			
			Surface tension (at 1 g/L of CA2735) mN/m	71.1	70.8			
	EEC A.5	CA2210	at 0.2% v/v: 34.8 ± 0.2 mN/m			Acceptable, formulation is surface active.	Y	Mourgues, L.,

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
		batch no. RD-816-166B	at 15.0% v/v: 22.7 ± 0.4 mN/m			Ricau, H., 2006
B.2.2.6. Density of the preparation						
B.2.2.6.1. Relative density						
Relative density of the preparation B.2.2.6.1 (IIIA, 2.6.1)	OCDE 109	CA2735 batch no. 310123555	1.1171 at 20 °C	Acceptable	Y	Adam, C., 2011
	EEC A.3	CA2210 batch no. RD-816-166B	1.116 at 20 °C	Acceptable	Y	Mourgues, L., Ricau, H., 2006
B.2.2.6.2. Bulk (tap) density						
Bulk (tap) density B.2.2.6.2 (IIIA, 2.6.2)				Not required, because CA2735 is neither a powder nor a granule formulation.		
B.2.2.7. Stability						
B.2.2.7.1. Accelerated storage stability						
Stability after accelerated storage (54°C during 14 days) B.2.2.7.1 (IIIA, 2.7.1)	CIPAC MT 46	CA2735 batch no. 310123555	CA2735 is stable during 14 days at 54°C in HDPE and PET packagings (see tables IIIA 2.7.1-1 and IIIA 2.7.1-2, respectively).	Acceptable	Y	Adam, C., 2011
	CIPAC MT 46	CA2210 batch no. RD-816-166B	CA2210 is stable during 14 days at 54°C (see table IIIA 2.7.1-3)	Acceptable	Y	Mourgues, L., Ricau, H., 2006
B.2.2.7.2. Low temperature stability						
Effect of low temperature on stability B.2.2.7.2 (IIIA, 2.7.2)	Visual CIPAC MT 39.3	CA2735 batch no. 310123555	Homogeneous liquid	Acceptable	Y	Adam, C., 2011
	CIPAC MT 39.1	CA2210 batch no. RD-816-166B	Start of the test: The test item was a brown / greenish liquid. After 7 days of cooling at 0 ± 2 °C: A cloudy phase was observed at the bottom of the tube (between approx. 1.6 to 2.8 mL) with cloudy suspended particles (for one cone). The	Acceptable It should be recommended to not store the formulation CA2210 at low temperature.	Y	Mourgues, L., Ricau, H., 2006

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			remaining was brown / yellowish. After standing at room temperature: No change. After one inversion: A part of the cloudy particles was re-suspended. After centrifugation: A dark brown residue (approx. 0.45 mL) was observed. The remaining was brown / yellowish.			
B.2.2.7.3. Shelf life						
Shelf life following storage at ambient temperature B.2.2.7.3 (IIIA, 2.7.3)		CA2735		Study is ongoing and study report will be available in July 2013.		
	GIFAP monograph No. 17	CA2210 batch no. RD-816-166B	CA2210 is stable when stored at ambient temperature for 2 years (see table IIIA 2.7.3.4)	Acceptable	Y	Mourgues, L., Ricau, H., 2006
B.2.2.8. Technical characteristics of the plant protection product						
B.2.2.8.1. Wettability						
Wettability B.2.2.8.1 (IIIA, 2.8.1)				Not required, because CA2735 is not a solid preparation.		
B.2.2.8.2. Persistent foaming						
Persistent foaming B.2.2.8.2 (IIIA, 2.8.2)	CIPAC MT 47.2	CA2735 batch no. 310123555	In standard water D at 0.8% v/v and 4.37% v/v: after 10 seconds 0 mL after 1 minute 0 mL after 3 minutes 0 mL after 12 minutes 0 mL	Acceptable	Y	Adam, C., 2011
	CIPAC MT 47.2	CA2210 batch no. RD-816-166B	At 15% v/v: No foam was observed after 10 s (the foam created after the cylinder inversion disappeared in few seconds). No further observation was performed.	Acceptable	Y	Mourgues, L., Ricau, H., 2006
B.2.2.8.3. Suspensibility and spontaneity of dispersion						
Suspensibility B.2.2.8.3/01 (IIIA, 2.8.3)				Not required, because CA2735 is a soluble concentrate.		
Spontaneity of dispersion B.2.2.8.3/02				Not required, because CA2735 is a soluble concentrate.		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
(IIIA, 2.8.3)						
B.2.2.8.4. Dilution stability						
Dilution stability B.2.2.8.4 (IIIA, 2.8.4)	CIPAC MT 41.1	CA2735 batch no. 310123555	0.8% v:v after 0.5 hour after 24 hours homogeneous phase homogeneous phase, no sediment 4.37% v:v after 0.5 hour after 24 hours homogeneous phase homogeneous phase, no sediment	Acceptable	Y	Adam, C., 2011
	CIPAC MT 41.1	CA2210 batch no. RD-816-166B	No change was observed in the test item solution after standing for 18 h at 20 ± 2°C. It was a yellowish / greyish homogeneous solution.	Acceptable	Y	Mourgues, L., Ricau, H., 2006
B.2.2.8.5. Particle size						
B.2.2.8.5.1. Dry sieve test						
Dry sieve test B.2.2.8.5.1 (IIIA, 2.8.5)				Not required, because CA2735 is not a dustable powder.		
B.2.2.8.5.2. Wet sieve test						
Wet sieve test B.2.2.8.5.2 (IIIA, 2.8.5)				Not required, because CA2735 is a soluble concentrate.		
B.2.2.8.6. Particle size distribution						
B.2.2.8.6.1. Size distribution						
Size distribution of particles / Nominal size range of granules B.2.2.8.6.1 (IIIA, 2.8.6.1)				Not required, because CA2735 is a soluble concentrate.		
B.2.2.8.6.2. Dust content and particle size of dust						
Dust content / Particle size of dust				Not required, because CA2735 is not a granular preparation		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.2.8.6.2. (IIIA, 2.8.6.2)						
B.2.2.8.6.3. Friability and attrition characteristics of granules						
Friability and attrition characteristics of granules B.2.2.8.6.3 (IIIA, 2.8.6.3)				Not required, because CA2735 is not a granular preparation		
B.2.2.8.7. Emulsion characteristics						
B.2.2.8.7.1. Emulsifiability, re-emulsifiability and emulsion stability						
Emulsifiability / Emulsion stability / Re-emulsifiability B.2.2.8.7.1 (IIIA, 2.8.7.1)				Only required for preparations that form emulsions.		
B.2.2.8.7.2. Stability of dilute emulsions						
Stability of dilute emulsions B.2.2.8.7.2 (IIIA, 2.8.7.2)				Only required for preparations that form emulsions.		
B.2.2.8.8. Flowability, pourability and dustability						
B.2.2.8.8.1. Flowability						
Flowability B.2.2.8.8.1 (IIIA, 2.8.8.1)				Not required, because CA2735 is not a granular preparation		
B.2.2.8.8.2. Pourability (including rinsed residue)						
Pourability (including rinsed residue) B.2.2.8.8.2 (IIIA, 2.8.8.2)				Not required, because CA2735 is a soluble concentrate.		
B.2.2.8.8.3. Dustability following accelerated storage						
Dustability following				Only required for dustable powders.		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
accelerated storage B.2.2.8.8.3 (IIIA, 2.8.8.3)						
B.2.2.9. Physical and chemical compatibility with other products						
<i>B.2.2.9.1. Physical compatibility of tank mixes</i>						
Physical compatibility of tank mixtures B.2.2.9.1 (IIIA, 2.9.1)				Not intended to be used in tank mix with other phytopharmaceutical products.		
<i>B.2.2.9.2. Chemical compatibility of tank mixes</i>						
Chemical compatibility of tank mixtures B.2.2.9.2 (IIIA, 2.9.1)				Not intended to be used in tank mix with other phytopharmaceutical products.		
B.2.2.10. Distribution and adhesion of seed treatment preparations						
Distribution B.2.2.10/01 (IIIA, 2.10)				Not intended for use on seeds		
Adhesion B.2.2.10/02 (IIIA, 2.10)				Not intended for use on seeds		

Table IIIA 2.7.1-1: results of the accelerated storage stability study (54°C for 14 days), CA2735 in HDPE packaging

Method	Before storage at 54°C, 14 days	After storage at 54°C, 14 days Appearance and stability of packaging: No weight change or distortion of the bottle, no bleeding, claying or sedimentation.
Visual	Appearance: homogeneous dark-brown liquid, odourless	Appearance: homogeneous pale green-brown liquid, odourless
CIPAC 90/TC/M/- C-Organique-00585- TA, version 1	Content Amitrole: 233.9 g/L (20.94%) Ammonium thiocyanate: 219.8 g/L (19.67%)	Content Amitrole: 235.6 g/L (21.09%) Ammonium thiocyanate: 219.1 g/L (19.62%)
CIPAC MT 75.3	pH neat formulation: 6.68 pH 1% in deionised water: 6.17	pH neat formulation: 6.56 pH 1% in deionised water: 6.04
OECD 109	Relative density: 1.1171 at 20 °C	Relative density: 1.1167 at 20 °C
CIPAC MT 47.2	Persistent foaming: 0.8% v/v and 4.37% v/v after 10 seconds 0 mL after 1 minute 0 mL after 3minutes 0 mL after 12 minutes 0 mL	Persistent foaming: 0.8% v/v and 4.37% v/v after 10 seconds 0 mL after 1 minute 0 mL after 3minutes 0 mL after 12 minutes 0 mL
CIPAC MT 41.1	Dilution stability 0.8% v/v after 0.5 hour homogeneous phase after 24 hours homogeneous phase, no sediment 4.37% v:v after 0.5 hour homogeneous phase after 24 hours homogeneous phase, no sediment	Dilution stability 0.8% v/v after 0.5 hour homogeneous phase after 24 hours homogeneous phase, no sediment 4.37% v:v after 0.5 hour homogeneous phase after 24 hours homogeneous phase, no sediment

Table IIIA 2.7.1-2: results of the accelerated storage stability study (54°C for 14 days), CA2735 in PET packaging

Method	Before storage at 54°C, 14 days	After storage at 54°C, 14 days Appearance and stability of packaging: No weight change or distortion of the bottle, no bleeding, claying or sedimentation.
Visual	Appearance: homogeneous dark-brown liquid, odourless	Appearance: homogeneous pale green-brown liquid, odourless
CIPAC 90/TC/M/- C-Organique-00585- TA, version 1	Content Amitrole: 234.8 g/L (21.03%) Ammonium thiocyanate: 219 g/L (19.61%)	Content Amitrole: 236.9 g/L (21.19%) Ammonium thiocyanate: 220.8 g/L (19.77%)
CIPAC MT 75.3	pH neat formulation: 6.68 pH 1% in deionised water: 6.17	pH neat formulation: 6.55 pH 1% in deionised water: 6.05
OECD 109	Relative density: 1.1166 at 20 °C	Relative density: 1.117 at 20 °C
CIPAC MT 47.2	Persistent foaming: 0.8% v/v and 4.37% v/v after 10 seconds 0 mL after 1 minute 0 mL after 3 minutes 0 mL after 12 minutes 0 mL	Persistent foaming: 0.8% v/v and 4.37% v/v after 10 seconds 0 mL after 1 minute 0 mL after 3 minutes 0 mL after 12 minutes 0 mL
CIPAC MT 41.1	Dilution stability 0.8% v/v after 0.5 hour homogeneous phase after 24 hours homogeneous phase, no sediment 4.37% v:v after 0.5 hour homogeneous phase after 24 hours homogeneous phase, no sediment	Dilution stability 0.8% v/v after 0.5 hour homogeneous phase after 24 hours homogeneous phase, no sediment 4.37% v:v after 0.5 hour homogeneous phase after 24 hours homogeneous phase, no sediment

Table IIIA 2.7.1-3: results of the accelerated storage stability study (54°C for 14 days), CA2210 in commercial packaging (plastic flasks)

Method	Before storage at 54°C, 14 days	After storage at 54°C, 14 days
CIPAC MT 46	Appearance: Dark brown liquid with shades of light brown and greenish, medium odour	Appearance and stability of packaging: No change or distortion of the bottle. Appearance: Dark brown liquid with shades of light brown and greenish, medium odour
C-Organique-00383-E-TA	Amitrole content: 229 g/L (22.9%)	Amitrole content: 230 g/L (23%)
CIPAC MT 75	pH neat formulation: 6.81 pH 1% in deionised water: 6.19	pH neat formulation: 6.53 pH 1% in deionised water: 5.94
CIPAC MT 41	Dilution stability No change was observed in the test item solution after standing for 18 h at 20 ± 2°C. It was a yellowish / greyish homogeneous solution.	Dilution stability No change was observed in the test item solution after standing for 18 h at 20 ± 2°C. It was a yellowish / greyish homogeneous solution.

Table IIIA 2.7.3-1: results of the shelf life study (2 years at ambient temperature), CA2210 in commercial packaging (plastic flasks)

Method	Before storage	After storage at ambient temperature for 2 years.
	Appearance: Dark brown liquid with shades of light brown and greenish, medium odour	Appearance and stability of packaging: No change or distortion of the bottle. Appearance: Dark brown liquid with shades of light brown and greenish, medium odour
C-Organique-00383-E-TA	Amitrole content: 22.9%	Amitrole content: T+12: 24% T+18: 23.3% T+24: 23.2%
CIPAC MT 75.1 and 75.2	pH neat formulation: 6.81 pH 1% in deionised water: 6.19	pH neat formulation: 6.52 pH 1% in deionised water: 6.02
CIPAC MT 47.2	Persistent foaming: No foam was observed after 10 s (the foam created after the cylinder inversion disappeared in few seconds). No further observation was performed.	Persistent foaming: No foam was observed after 10 s (the foam created after the cylinder inversion disappeared in few seconds).
CIPAC MT 41	Dilution stability No change was observed in the test item solution after standing for 18 h at 20 ± 2°C. It was a yellowish / greyish homogeneous solution.	Dilution stability No change was observed in the test item solution after standing for 18 h at 20 ± 2°C. It was a yellowish / greyish homogeneous solution.

B.2.3. SUMMARY AND ASSESSMENT OF PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES**B.2.3.1. Active substance**

Pure Amitrole is a colourless and odourless crystal. It has a melting point of 157 - 159 °C. It has no thermal decomposition. It has a relative density of 1.138 at 20°C. Its vapour pressure ($3.3 \cdot 10^{-5}$ Pa at 20 °C) indicates that it has a very low possibility to volatilize from soil to air. Its volatility ($1.76 \cdot 10^{-8}$ Pa.m³.mol⁻¹) indicates that it has a very low possibility to volatilize from water to air. It is highly soluble in water and from low to moderately soluble in solvents (from < 0.01 g/L in n-hexane to 27 g/L in isopropanol). It has a Log P_{ow} of -0.969 in neutral conditions indicating that it should not be expected to bioaccumulate in the environment. It is stable to hydrolysis at pH 5, 7 and 9 and water photolysis. Degradation in the atmosphere has been evaluated with a DT₅₀ of 4.8 hours. Its dissociation constant is pKa1 = 4.14 and pKa2 = 10.69 at 20°C. Amitrole was not found to have flammable, explosive or oxidizing properties.

B.2.3.2. Plant protection product

The formulation WEEDAZOL TL is a dark brown fluid liquid, odourless soluble concentrate, containing 229 g/L of Amitrole and 215 g/L of ammonium thiocyanate. This formulation does not present explosive and oxidising properties. It is not highly flammable (no flash point was observed up to 108°C), and not auto-flammable (no self ignition observed up to 652 °C) at ambient temperature. The pH of a 1% solution at 20 °C is 6.17. The dynamic viscosity is < 10 mPa.s at 20°C. The surface tension is > 60 mN/m indicating that formulation is not surface active. Its relative density is 1.1171 at 20 °C. There is no effect of high and low temperature on the stability of the formulation, after 14 days at 54 °C and 7 days at 0 °C, neither the active ingredient content nor the technical properties were changed. The content of active substance is unchanged after 2 years of storage at ambient temperature in the previous formulation CA2210 demonstrating an acceptable 2 years shelf life for the product in commercial packaging (plastic flask). The 2-year stability study in CA2735 formulation is on-going. After 1 minute, 0 mL of persistent foam remained, indicating that the formulation is not a foaming product. The dilution stability is acceptable.

Under recommended use, no particular problems should be expected due to technical characteristics or physico-chemical properties.

B.2.4. REFERENCES RELIED ON**B.2.4.1. Active substance**

Annex Point/ Reference Number	Author(s)	Year	Title Source (where different from the Company), Company, Report Number, GLP or GEP status (where relevant), Published or not	Data Protection claimed (Y/N)	Owner
IIA, 2.5.1/01	Da Conceicao, L.	2012a	Amitrole: Determination of UV-VIS spectral data Study reference: 01581 GLP Not published	Y	NUFARM
IIA, 2.5.1/02	Da Conceicao, L.	2012b	Amitrole: Determination of IR and NMR spectral data Study reference: 09/C/1529 GLP Not published	Y	NUFARM
IIA, 2.5.1/03	Da Conceicao, L.	2012c	Amitrole: Determination of mass spectrometry (MS) data Study reference: 09/C/4424 GLP Not published	Y	NUFARM

B.2.4.2. Plant protection product

Annex Point/ Reference Number	Author(s)	Year	Title Source (where different from the Company), Company, Report Number, GLP or GEP status (where relevant), Published or not	Data Protection claimed (Y/N)	Owner
IIIA, 2.1/01 IIIA, 2.4.2/01 IIIA, 2.6.1/01 IIIA, 2.7.1/01 IIIA, 2.7.4/01 IIIA, 2.8.2/01 IIIA, 2.8.4/01	Adam, C.	2011	CA2735 stability of formulation: 1) after a 14 days period of storage at high temperature 2) after a 7 days period of storage at low temperature Nufarm SAS Report n° 01317 GLP Not published	Y	NUFARM
IIIA, 2.1/02 IIIA, 2.7.5/02 IIIA, 2.3.1/02 IIIA, 2.3.3/02 IIIA, 2.4.2/02 IIIA, 2.5.2/02 IIIA, 2.5.3/02 IIIA, 2.6.1/02 IIIA, 2.7.1/02 IIIA, 2.7.4/02 IIIA, 2.7.5/02 IIIA, 2.8.2/02	Mourgues L. & Ricaud H.	2006.	Physico-chemical tests on CA2210 before and after an accelerated storage procedure for 14 days at 54°C and a storage procedure for 2 years at 20+/-2°C in commercial packaging. Defitraces, France Nufarm SAS report n° 03-903025-008 GLP Not published	Y	NUFARM
IIIA, 2.2.1 IIIA, 2.2.2 IIIA, 2.3.1/01	Le Pollès, A.	2012	CA2735: determination of flash point, explosive properties and oxidizing properties. Nufarm Study report n° 01484 GLP Not published	Y	NUFARM
IIIA, 2.3.3/01	Krack, M.	2012	CA2735: determination of the temperature of auto-ignition Report n° 20120025-01 GLP Not published	Y	NUFARM
IIIA, 2.5.2/01 IIIA, 2.5.3/01	Adam, C.	2012	CA2735: determination of surface tension and dynamic viscosity Nufarm report n° 01483 GLP Not published	Y	NUFARM