

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) N° 1141/2010**

Amitrole

Volume 2 – Annex A

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Co-Rapporteur Member State: Hungary

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A. LIST OF TEST AND STUDIES FOR THE ACTIVE SUBSTANCE

References relied on, by section and annex points

A.1. IDENTITY, PHYSICAL/CHEMICAL, PROPERTIES, FURTHER INFORMATION ON THE ACTIVE SUBSTANCE

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA 1.8.1	Gasse, J.J.	2012	Updated version of the manufacturing process of Amitrole. In Document JII_2012_versus_2002 CONFIDENTIAL	Y	NUFARM
IIA 1.10/02	Saliou, C.	2001	Isolation and structural determination of unknown F. CFPI study n° 09/C/3275 Not published CONFIDENTIAL	Y	NUFARM
IIA 1.10/01	Saliou, C.	2001	Isolation and structural determination of unknown D. CFPI study n° 09/C/3276 Not published CONFIDENTIAL	Y	NUFARM
IIA 1.11	Da Conceicao, L.	2012	Updated five batch-analysis of Amitrole Report n° 01463 CONFIDENTIAL	Y	NUFARM
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
IIA 4.2.2/01	Adam, C.	2012	Validation of analytical method used for one impurity of amitrole determination: C-organique-00383-C-TA Study reference n° 01585 GLP Not published CONFIDENTIAL	Y	NUFARM
IIA 4.2.2/02	DaConceicao, L.	2012	Validation of analytical method used for one impurity of amitrole determination Study reference 01598 GLP Not published CONFIDENTIAL	Y	NUFARM

A.2. ANALYTICAL METHODS ON THE ACTIVE SUBSTANCE

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA 4.3/01	Todd M. A.	2002	Development and validation of analytical methods for the determination of residues of the herbicide amitrole in grapes, juice, must, wine and deposit cards HLS, UK Nufarm SAS Report N°: CPF/026 GLP: yes Unpublished	Y	NUFARM
IIA 4.3/02	Gemrot F.	2011a	Validation of analytical method for amitrole, triazolylalanine and aminotriazolylalanine in grapes eurofins, France Nufarm SAS Report N°: S10-03263 GLP: yes Unpublished	Y	NUFARM
IIA 4.3/07	Gemrot F.	2011 b	Validation of analytical method for amitrole, triazolylalanine and aminotriazolylalanine in olives eurofins, France Nufarm SAS Report N°: S10-03184 GLP: yes Unpublished	Y	NUFARM
IIA 4.3/07bis	Gemrot F.	2012	Validation of analytical method for amitrole, triazolylalanine and aminotriazolylalanine in olives-amendment- eurofins, France Nufarm SAS Report N°: S10-03184 GLP: yes Unpublished	Y	NUFARM
IIA 4.3/08	Amic, S.	2012	Validation of analytical method for amitrole, triazolylalanine and aminotriazolylalanine in apples eurofins, France Nufarm SAS Report N°: S11-03999 GLP: yes Unpublished	Y	NUFARM

Active substance references list
Analytical methods on the active substance

IIA 4.3/03	Ivanov, E	2012	AMITROLE- Independent Laboratory Validation of Analytical Method for Determination of Amitrole, Triazolylalanine and Aminotriazolylalanine Residues in Crops Report N°: S12-00221 GLP: yes Not published	Y	NUFARM
IIA 4.3/04	Monnerie P.	2007	Analysis of aminotriazole residues in wine - Performance assessment CGI laboratory, France Nufarm SAS Report N°: 60211BPL14 GLP: yes Unpublished	Y	NUFARM
IIA 4.3/05	Royer A.	2008	Independent Laboratory Validation of analytical method for the Determination of Amitrole in red wine and white wine by HPLC mass spectrometry detection eurofins, France Nufarm SAS Report N°: NUF/AMI/07001 GLP: yes Unpublished	Y	NUFARM
IIA 4.4/01	Amic, S.	2012	Validation of analytical method for determining amitrole in soils and waters eurofins, France Nufarm SAS Report N°: S11-04001 GLP: yes Unpublished	Y	NUFARM
IIA 4.5/02	Todd M. A.	2004	Development and validation of an analytical method for the determination of residues of the herbicide amitrole in water HLS, UK Nufarm SAS Report N°: CPF/021 GLP: yes Unpublished	Y	NUFARM
IIA 4.5/01	Colin R.	2000	Validation of an analytical method for the determination of the herbicide amitrole in water CGI laboratory, France Nufarm SAS Report N°: 9CFP01 02BPL 1 GLP: yes Unpublished	Y	NUFARM
IIA4.8/01	Gemrot, F.	2011c	Validation of an analytical method for the determination of amitrole on typical protective clothing and in associated samples generated (including urine) from operator exposure study ChR-11-8256. ADME Eurofins Nufarm SAS Report n° S10-03673 GLP: yes Unpublished	Y	NUFARM

A.3. TOXICOLOGY AND METABOLISM

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIA 5.2.4	[REDACTED]	2001	Acute dermal irritation in rabbits. [REDACTED] GLP Not published	Y	NUFARM
IIA 5.2.5	[REDACTED]	2002	Acute eye irritation study with rinse in the rabbit. [REDACTED] GLP Not published	Y	NUFARM
IIA 5.4.1	Wallner, B.	2009	Reverse mutation assay using bacteria (Salmonelle typhimurium and Escherichia coli) with amitrole technical. BSL study n° 092153 GLP Not published	Y	NUFARM
IIA 5.4.2	Oppong-Nketiah, M.	2009	In vitro mammalian chromosome aberration test in human lymphocytes with amitrole technical. BSL Bioservice study n° 092154 GLP Not published	Y	NUFARM
KIIA 5.6.11	[REDACTED]	2000	Amitrole. Study of maternotoxicity in the pregnant female rabbit following oral administration (gavage). [REDACTED] GLP Not published	Y	NUFARM
IIA 5.11	Anonymous	2012	Amitrole: why it should not be considered as an endocrine disruptor in Human? Nufarm's Position Paper Not GLP not relevant Not published	Y	NUFARM

A.4. RESIDUES

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
KIIA 6.1.1/01	Clemson, A.D.	1997	Amitrole: determination of freezer storage stability of amitrole residues in grapes Generated by: Huntington LifeSciences Document No: 95/CPF018/1407 GLP / GEP : Yes un-published	Y	NUFARM
KIIA 6.1.1/02	Biever, R.C.	2000	Amitrole – Stability in Apples Stored Under Frozen Conditions Generated by: Springborn Laboratories, Inc. Wareham, Massachussets. Document No: 12983.0896.6128.395 95-08-6065, GLP / GEP : Yes un-published	Y	NUFARM
KIIA 6.1.1/03	Amic, S.	2011	Determination of Storage Stability of Amitrole in Grapes and Olives under Freezer Storage Conditions Generated by: EUROFINS ADME BIOANALYSIS Document No: S10-03264 GLP / GEP : Yes un-published	Y	NUFARM
KIIA 6.3.1/01	Wilson A.J.	1999	Generation of grape, must, wine and juice samples for determination of the magnitude of the residues of amitrole. Generated by : Viti R&D for the processing phase and Huntignton Lifesciences for the analytical phase Document No: CPF024/982343 GLP/GEP : yes un-published	Y	NUFARM
KIIA 6.3.1/02	Amic, S.	2012	Amitrole: residue study on grapes in France in 2011. Generated by: Eurofins ADME BIOANALYSE Document No: S11-01150 GLP / GEP : yes un-published	Y	NUFARM
KIIA 6.3.1/03	Provot, G.	1997	Determination de residus d'aminotriazole et de terbutylazine dans les echantillons de raisin traités avec le produit expérimental CA1397. Generated by: Centre International de Toxicologie (C.I.T) Document No: 11205 ADR – CFP404 GLP / GEP Yes un-published	Y	NUFARM

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
KIIA 6.3.2/01	Biever, R.C	1996	Amitrole: the accumulation and degradation of amitrole in apples. Generated by: Springborn Laboratories Inc. Document No: 95-08-6065/12983-0594-6107-395 GLP / GEP : Yes un-published	Y	NUFARM
KIIA 6.3.3/01	Amic, S.	2011	Amitrole – Residue Study on Olives in Spain in 2010 Generated by: Eurofins Document No: S10-03088 GLP / GEP : yes un-published	Y	NUFARM
KIIA 6.3.3/02	Amic, S.	2011	Amitrole – residue exploratory trial on processing olives in Spain in 2010. Generated by: Eurofins Document No: S10-035411 GLP / GEP : Yes un-published	Y	NUFARM
KIIA 6.3.3/03	Anonymous.	2000a	Analisis de residuos de 3-amino-1,2,4-triazole en aceitunas tratadas con ETIZOL TL por HPLC-fluorescencia. Generated by: Laboratory Agro-alimentari, Cabrils (E) Document No: report n° 401991S/1N-401992S/1N- 401993S/1N- 401995S/2N-401001B/N- 401001C/N-401001S/1N GLP/GEP : No un-published	Y	NUFARM
KIIA 6.3.3/04	Anonymous	2000b	Analisis de residuos de 3-amino-1,2,4-triazole en aceitunas tratadas con MAXATA TL por HPLC-fluorescencia. Generated by: Laboratory Agro-alimentari, Cabrils (E) Document No: report n° 401991S/2N- 401992S/2N-401993S/2N- 401995S/3N- 401002B/N-401002C/N-401002U/ GLP/GEP : No un-published	Y	NUFARM
KIIA 6.3.3/05	Schanne C.	1998	[¹⁴ C]-Amitrole : Isolation and characterisation of an Unknown Major Radioactive Fraction in Olives Generated by: Springborn Laboratories (Europe) AG, Health and Environmental Sciences, Seestrasse 21, CH-9326 Horn, Switzerland Document No: Springborn Rport # 97-044-1002 – Sprinborn Study # 1002.015.756 Source : CFPI AGRO GLP / GEP : Yes un-published	Y	NUFARM

A.5. FATE AND BEHAVIOUR IN THE ENVIRONMENT

OECD Annex point/ reference number	Author(s)	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protection claimed yes/no	Owner
KIIA 7.1.1/01	Hall, B.E.	1994	The aerobic degradation of radiolabelled amitrole in soil. Report No: 10526. GLP	Y	NUFARM
KIIA 7.1.1/02	Dakhel, N	2001	Effects of pedoclimatic conditions on the mechanisms responsible for amitrole dissipation in soils: adsorption, degradation and stabilisation of residues Thesis Not GLP Not published	N	n.a.
KIIA 7.1.1/03	N. Dakhel, E. Barriuso, M.-P. Charnay, C. Touratier and D. Ambrosi	2001	Amitrole degradation in vineyard soils in relation to pedoclimatic conditions. 2001. Biol Fertil Soils, 33, 490-494. Not GLP Published	N	n.a.
KIIA 7.2.1/01 KIIA 7.3.1/02 KIIA 7.8.3/03	Comoretto, L.	2012a	Amitrole – Estimating persistence and degradation kinetics from environmental fate studies on Amitrole. Study No.: NOFkinetic31082012 Not GLP.	Y	NUFARM
KIIA 7.3.1/01	Biever, R.C.	1995	Amizol: A field dissipation study for terrestrial uses. SLI Report #93-10-4999 GLP	Y	NUFARM
IIA 7.4.1/01	Menerling, M.	2012	Adsorption/desorption study Ibacon report n°70821195 GLP Not published	Y	NUFARM
IIA 7.7/01	Feil-Klein, N	2012	Ready Biodegradability of amitrole (XT91) in a manometric test Ibacon project n°70822163 GLP Not published	Y	NUFARM
KIIA 7.8.3/01	McCowan C., Mackie K. A. and Hall B. E.	1995	The anaerobic degradation of radiolabelled amitrole in a natural water and its associated sediment. Inveresk Research International report n° 382817 GLP Not published	Y	NUFARM
KIIA 7.8.3/02	Williams S. G. P. and McGuire G. M.	1997	The identification of a major unknown radioactive component in a surface water sample treated with ¹⁴ C-amitrole. Inveresk Research International report n° Laboratory report no.: 13541 – report amendment 1 to 382817 GLP Not published	Y	NUFARM
KIIA 7.12/01	Querou, C., Touratier, C. And Ambrosi, D.	1998	Amitrole: ground water survey. 1996-1997 Nufarm (formerly CFPI) dossier reference 145 Not GLP Not published	Y	NUFARM

KIIA 7.12/02	Touratier, C.	1999	Amitrole: ground water survey. 1998. Ground water and treated surface water Nufarm (formerly CFPI) dossier reference 169 Not GLP Not published	Y	NUFARM
KIIA 7.12/03	Dano, A.S., Touratier, C	2000	Amitrole: Water monitoring 1999 ground water and treated surface water. CPFI Agro report n° CT/ASD00318. Not published	Y	NUFARM
KIIA 7.12/04	Dano, A.S.	2004	Amitrole Ground Water_ Survey 1996-2004 Nufarm report n° ASD/04-094 Not published	N	NUFARM

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A.6. ECOTOXICOLOGY

Annex point	Author (s)	Year	Title Source (were different from company) Company, report No GLP status Published or not	Data protection claimed Y/N	Owner
IIA 8.2.1.3/01	[REDACTED]	1985	Acute toxicity of aminotriazole to bluegill sunfish (<i>Lepomis macrochirus</i>) [REDACTED] GLP :N		NUFARM
IIA 8.2.1.3/02	[REDACTED]	1993	Amitrole technical: acute toxicity to sheepshead minnow (<i>Cyprinodon variegatus</i>) under static renewal conditions. [REDACTED] 1 not published GLP :Y	Y	NUFARM
IIA 8.3.1.3/01	Collins, K.	1993	Amitrole technical: acute toxicity to mysids under static conditions. SLI report n° 93-4-4736 Not published GLP :Y	Y	NUFARM
IIA 8.3.1.4/01	Dionne, E.	1993	Amitrole technical: acute toxicity to Estaren Oyster (<i>Crassostrea virginica</i>) under flow through conditions. SLI report n° 93-6-4816 Not published GLP :Y	Y	NUFARM
IIA 8.4/01	Palmer, J.S. and Krueger, H.O.	1998	Amitrole: a 5-d toxicity test with the freshwater alga (<i>Selenastrum capricornatum</i>). Wildlife International Ltd (USA) report n° 461A-101 Not published GLP :Y	Y	NUFARM
IIA 8-4/02	Cross, J.	1993	Non target phytotoxicity of amitrole in terrestrial use. Growth & reproduction of <i>Selenastrum capricornatum</i> . EPL BAS report n° 198S01 part A. GLP :Y	Y	NUFARM
IIA 8.4/03	Palmer, J.S. and Krueger, H.O.	1998	Amitrole: a 5-d toxicity test with the freshwater diatom (<i>Navicula pelliculosa</i>). Wildlife International Ltd (USA) report n° 461A-103 Not published GLP :Y	Y	NUFARM
IIA 8.4/04	Palmer, J.S. and Krueger, H.O.	1998	Amitrole: a 5-d toxicity test with the marine diatom (<i>Skeletonema costatum</i>). Wildlife International Ltd (USA) report n° 461A-102 Not published GLP :Y	Y	NUFARM
IIA 8.8.2./01	Candolfi, M.P.	1996	Extended laboratory test to evaluate the side effects of Weedazol TL applied to plants on adult, <i>Aphidius rhopalosiphii</i> (Hymenoptera: Braconidae) based on Meadbriggs (1994). Springborn Lab. Europe (CH) report n° 95-034-1002 Not published GLP :Y	Y	NUFARM
IIA 8.8.2/02	Moll, M.	2006	Effects of CA2210 on the Parasitoid, <i>Aphidius rhopalosiphii</i> (Hymenoptera, Aphidiidae)-Extended Lab study. Dose response test. Ibacon	Y	NUFARM

Annex point	Author (s)	Year	Title Source (were different from company) Company, report No GLP status Published or not	Data protection claimed Y/N	Owner
			(D) report n° 24842002. Not published GLP :Y		
IIA 8.8.2/03	Rosenkranz, B.	2006	Effects of CA2210 on the Predatory mite, Typhlodromus pyri-Extended Lab study. Dose response test. Ibacon (D) report n° 24843062 Not published. GLP :Y	Y	NUFARM
IIA 8.8.2./04	Schmitzer, S.	2006	Effect of CA 2210 on the wolf spider, pardosa spec. In the laboratory-Extended Laboratory Study. Ibacon report n° 24841066 Not published GLP :Y	Y	NUFARM
IIA 8.8.2./05	Candolfi, M.P.	1996	. Extended laboratory test to evaluate the side effects of Weedazol TL applied to plants on the predator, Orius insidiosus (Heteroptera: Anthocoridae). Springborn Lab. Europe (CH) report n° 95-036-1002 Not published GLP :Y	Y	NUFARM
IIA 8.8.2./06	Rosenkranz, B.	2006	Effects of CA2210 on the Lacewing Chrysoperla carnea-Extended Lab study. Dose response test. Ibacon (D) report n° 24844047 Not published GLP :Y	Y	NUFARM
IIA 8.16/01	Cross, J.	1993	Non target phytotoxicity of amitrole in terrestrial use. Seed germination and vegetative vigor. EPIS BAS report n° 198S01 part B. GLP :Y	Y	NUFARM
IIA 8.16/02	Porch, J & al.	1998	Amitrole: a toxicity test to determine the effects of the test substance on seedling emergence of ten species of plants. WIL report n° 461109 GLP :Y	Y	NUFARM
IIA 8.16/03		2012	CA 2735: A two generations reproduction study with the mallard using pulsed exposure. not published GLP :Y	Y	NUFARM
IIA 8.16/04		2012	Fish two generations life cycle test with the Medaka (Oryzias latipes) GLP : Y Not published	Y	NUFARM

References list for the plant protection product

Identity, physical/chemical, properties, further information on the active substance

B. LIST OF TESTS AND STUDIES FOR THE PLANT PROTECTION PRODUCT

References relied on, by section and annex points

B.1. IDENTITY, PHYSICAL/CHEMICAL, PROPERTIES, FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No 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. Defitrac, 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

B.2. ANALYTICAL METHODS ON THE PLANT PROTECTION PRODUCT

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIIA 5.2.1/01	Amic, S	2012	Validation of an analytical method to analyze amitrole in CA 2735 Eurofins report n°S11-04000 GLP Not published	Y	NUFARM
IIIA 5.2.5	Adam, C.	2011	Validation of analytical method used for ammonium thiocyanate content determination in CA2735. Nufarm report n° 01316 Not published	Y	NUFARM

B.3. TOXICOLOGY AND METABOLISM

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
IIIA 7.1.1	[REDACTED]	2004a	CA2210 - Acute oral toxicity study in the rat: Acute toxic class method. [REDACTED] GLP Not published	N	NUFARM
IIIA 7.1.5	[REDACTED]	2004b	CA2210 - Acute eye irritation study in the rabbit. [REDACTED] GLP Not published	N	NUFARM
IIIA 7.1.6	[REDACTED]	2004b	CA2210 - Skin sensitization study in the guinea pigs (Magnusson and Kligman maximization test method). [REDACTED] GLP Not published	N	NUFARM
IIIA 7.3.2	Redondi, S.	2010	Justification of biomonitoring to measure the operator exposure to aminotriazole. Not GLP Not published.	N	NUFARM
IIIA 7.3.3/01	Wilson, A.J.	1999	Amitrole - ammonium thiocyanate. Pesticide exposure study to mixers/loaders and applicators during typical applications of Weedazol TL in France in 1999. Vol 1&2. Report n° CPF/054 GLP Not published	N but Still protected in FR	NUFARM
IIIA 7.3.3 /02	Thouvenin, I.	2011	Determination of external and systemic exposure (using biomonitoring in urine) of operators to amitrole during downward application. Cehtra/Eurofins ADME Report n° ChR-11-8256 GLP Not published	Y	NUFARM
IIIA 7.6.2/01	Gelis, C	2007	Comparison of the <i>in vitro</i> percutaneous absorption of Weedazol TL old (CA0123) versus new (CA2210) generation. ADME report n° NUF/WEE/06003R GLP Not published	Y	NUFARM
IIIA 7.6.2/02	Gelis, C	2010	In vitro skin penetration of amitrole ADME report n° NUF/AMI/10001R Not GLP Not published	Y	NUFARM

B.4. RESIDUES

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
KIIA 6.1.1/01	Clemson, A.D.	1997	Amitrole: determination of freezer storage stability of amitrole residues in grapes Generated by: Huntington LifeSciences Document No: 95/CPF018/1407 GLP / GEP : Yes un-published	Y	NUFARM
KIIA 6.1.1/02	Biever, R.C.	2000	Amitrole – Stability in Apples Stored Under Frozen Conditions Generated by: Springborn Laboratories, Inc. Wareham, Massachussets. Document No: 12983.0896.6128.395 95-08-6065, GLP / GEP : Yes un-published	Y	NUFARM
KIIA 6.1.1/03	Amic, S.	2011	Determination of Storage Stability of Amitrole in Grapes and Olives under Freezer Storage Conditions Generated by: EUROFINS ADME BIOANALYSIS Document No: S10-03264 GLP / GEP : Yes un-published	Y	NUFARM
KIIA 6.3.1/01	Wilson A.J.	1999	Generation of grape, must, wine and juice samples for determination of the magnitude of the residues of amitrole. Generated by : Viti R&D for the processing phase and Huntignton Lifesciences for the analytical phase Document No: CPF024/982343 GLP/GEP : yes un-published	Y	NUFARM
KIIA 6.3.1/02	Amic, S.	2012	Amitrole: residue study on grapes in France in 2011. Generated by: Eurofins ADME BIOANALYSE Document No: S11-01150 GLP / GEP : yes un-published	Y	NUFARM
KIIA 6.3.1/03	Provot, G.	1997	Determination de residus d'aminotriazole et de terbutylazine dans les echantillons de raisin traités avec le produit expérimental CA1397. Generated by: Centre International de Toxicologie (C.I.T) Document No: 11205 ADR – CFP404 GLP / GEP Yes un-published	Y	NUFARM

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
KIIA 6.3.2/01	Biever, R.C	1996	Amitrole: the accumulation and degradation of amitrole in apples. Generated by: Springborn Laboratories Inc. Document No: 95-08-6065/12983-0594-6107-395 GLP / GEP : Yes un-published	Y	NUFARM
KIIA 6.3.3/01	Amic, S.	2011	Amitrole – Residue Study on Olives in Spain in 2010 Generated by: Eurofins Document No: S10-03088 GLP / GEP : yes un-published	Y	NUFARM
KIIA 6.3.3/02	Amic, S.	2011	Amitrole – residue exploratory trial on processing olives in Spain in 2010. Generated by: Eurofins Document No: S10-035411 GLP / GEP : Yes un-published	Y	NUFARM
KIIA 6.3.3/03	Anonymous.	2000a	Analisis de residuos de 3-amino-1,2,4-triazole en aceitunas tratadas con ETIZOL TL por HPLC-fluorescencia. Generated by: Laboratory Agro-alimentari, Cabrils (E) Document No: report n° 401991S/1N-401992S/1N- 401993S/1N- 401995S/2N-401001B/N- 401001C/N-401001S/1N GLP/GEP : No un-published	Y	NUFARM
KIIA 6.3.3/04	Anonymous	2000b	Analisis de residuos de 3-amino-1,2,4-triazole en aceitunas tratadas con MAXATA TL por HPLC-fluorescencia. Generated by: Laboratory Agro-alimentari, Cabrils (E) Document No: report n° 401991S/2N- 401992S/2N-401993S/2N- 401995S/3N- 401002B/N-401002C/N-401002U/ GLP/GEP : No un-published	Y	NUFARM
KIIA 6.3.3/05	Schanne C.	1998	[¹⁴ C]-Amitrole : Isolation and characterisation of an Unknown Major Radioactive Fraction in Olives Generated by: Springborn Laboratories (Europe) AG, Health and Environmental Sciences, Seestrasse 21, CH-9326 Horn, Switzerland Document No: Springborn Rport # 97-044-1002 – Sprinborn Study # 1002.015.756 Source : CFPI AGRO GLP / GEP : Yes un-published	Y	NUFARM

B.5. FATE AND BEHAVIOUR IN THE ENVIRONMENT

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

OECD Annex point/ reference number	Author(s)	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protectio n claimed yes/no	OWNER
KIIIA 9.6.1/01	Bertrand M.	2011a	Predicted environmental concentration (PEC _{gw}) of Amitrole and 1,2,4-triazole in groundwater following application on orchards and olives using PELMO 3.3.2. Nufarm Report: NUFGW26102011 GLP: n.a. Unpublished	Y	NUFARM
KIIIA 9.6.1/02	Bertrand M.	2011b	Predicted environmental concentration (PEC _{gw}) of Amitrole and 1,2,4-triazole in groundwater following application on vines using PELMO 3.3.2. Nufarm Report: NUFGW02112011 GLP: n.a. Unpublished	Y	NUFARM
KIIIA 9.6.1/03	Comoretto, L.	2012b	Predicted environmental concentration (PEC _{gw}) of Amitrole and 1,2,4-triazole in groundwater following application on vines, orchards, citrus and olives using PELMO 4.4.3. Nufarm Report: NUFGW19072012 GLP: n.a. Unpublished	Y	NUFARM
KIIIA 9.6.1/04	Comoretto, L.	2012c	Statement on the percentage of formation of 1,2,4-triazole used for the modeling GW. Study No: NUFamitrole31082012. GLP: n.a.	Y	NUFARM
KIIIA 9.6.1/05	Comoretto, L.	2012d	Predicted environmental concentration (PEC _{gw}) of Amitrole and 1,2,4-triazole in groundwater following spring application on vines, orchards, citrus and olives using PELMO 4.4.3. Nufarm Report: NUFGW31082012 GLP: n.a. Unpublished	Y	NUFARM
KIIIA 9.6.1/06 KIIIA 9.7.1/07 KIIIA 9.8/06	Bertrand M.	2011c	Predicted environmental concentration of Amitrole and 1,2,4-triazole in groundwater (PEC _{gw}), surface water (PEC _{sw}) and sediment (PEC _{sed}) following application on non crop using HardSPEC 1.2. Nufarm Report: NUFGW03112011 GLP Unpublished	Y	NUFARM
KIIIA 9.6.1/07 KIIIA 9.7.1/08	Comoretto, L.	2012e	Predicted environmental concentration of Amitrole in groundwater (PEC _{gw}), surface water (PEC _{sw}) and sediment (PEC _{sed}) following application on non crop using HardSPEC 1.4.2. Nufarm Report: NUFHS22072012A GLP Unpublished	Y	NUFARM

KIIIA 9.6.1/08 KIIIA 9.8/07	Comoretto, L.	2012f	Predicted environmental concentration of 1,2,4-triazole in groundwater(PEC _{gw}), surface water(PEC _{sw}) and sediment(PEC _{sed}) following application on non crop using HardSPEC 1.4.2. Nufarm Report: NUFHS22072012B GLP Unpublished	Y	NUFARM
KIIIA 9.7.1/01	Bertrand M.	2011d	Predicted environmental concentrations (PEC) of Amitrole in surface water and sediment (PEC _{sw} and PEC _{sed}) according to FOCUS surface water scenarios after applications on pome and stone fruits Nufarm Report: NUFSW301108 GLP: n.a. Unpublished	Y	NUFARM
KIIIA 9.7.1/02	Bertrand M.	2011e	Predicted environmental concentrations (PEC) of Amitrole in surface water and sediment (PEC _{sw} and PEC _{sed}) according to FOCUS surface water scenarios after applications on vines Nufarm Report: NUFSW301108 GLP: n.a. Unpublished	Y	NUFARM
KIIIA 9.7.1/03	Comoretto,L	2012g	Predicted environmental concentrations (PEC) of Amitrole in surface water and sediment (PEC _{sw} and PEC _{sed}) according to FOCUS surface water scenarios after applications on citrus Nufarm Report: NUFSW22072012A GLP: n.a. Unpublished	Y	NUFARM
KIIIA 9.7.1/04	Comoretto,L	2012h	Predicted environmental concentrations (PEC) of Amitrole in surface water and sediment (PEC _{sw} and PEC _{sed}) according to FOCUS surface water scenarios after applications on olives Nufarm Report: NUFSW22072012B GLP: n.a. Unpublished	Y	NUFARM
KIIIA 9.7.1/05	Comoretto,L	2012i	Predicted environmental concentrations (PEC) of Amitrole in surface water and sediment (PEC _{sw} and PEC _{sed}) according to FOCUS surface water scenarios after applications on grapes Nufarm Report: NUFSW22072012C GLP: n.a. Unpublished	Y	NUFARM
KIIIA 9.7.1/06	Comoretto,L	2012j	Predicted environmental concentrations (PEC) of Amitrole in surface water and sediment (PEC _{sw} and PEC _{sed}) according to FOCUS surface water scenarios after applications on pome and stone fruits Nufarm Report: NUFSW22072012D GLP: n.a. Unpublished	Y	NUFARM

KIIIA 9.8/01	Comoretto, L.	2012k	Predicted environmental concentrations (PEC) of the metabolite 1,2,4-triazole in surface water and sediment (PEC _{sw} and PEC _{sed}) according to FOCUS surface water scenarios after applications on citrus Nufarm report n°NUFSW19072012A GLP Unpublished	Y	NUFARM
KIIIA 9.8/02	Comoretto, L.	2012l	Predicted environmental concentrations (PEC) of the metabolite 1,2,4-triazole in surface water and sediment (PEC _{sw} and PEC _{sed}) according to FOCUS surface water scenarios after applications on olives Nufarm report n°NUFSW19072012B GLP Unpublished	Y	NUFARM
KIIIA 9.8/03	Comoretto, L.	2012m	Predicted environmental concentrations (PEC) of the metabolite 1,2,4-triazole in surface water and sediment (PEC _{sw} and PEC _{sed}) according to FOCUS surface water scenarios after applications on vines Nufarm report n°NUFSW19072012C GLP Unpublished	Y	NUFARM
KIIIA 9.8/04	Comoretto, L.	2012n	Predicted environmental concentrations (PEC) of the metabolite 1,2,4-triazole in surface water and sediment (PEC _{sw} and PEC _{sed}) according to FOCUS surface water scenarios after applications on orchards Nufarm report n°NUFSW19072012D GLP Unpublished	Y	NUFARM
KIIIA 9.8/05	Bertrand M.	2011f	Predicted environmental concentrations (PEC) of the metabolite 1,2,4-triazole in surface water and sediment (PEC _{sw} and PEC _{sed}) according to FOCUS surface water scenarios after applications on olive trees, pome and stone fruits and vines Nufarm Report: NUFSW071111 GLP Unpublished	Y	NUFARM

B.6. ECOTOXICOLOGY

Annex point	Author (s)	Year	Title Source (were different from company) Company, report No GLP status Published or not	Data protection claimed Y/N	Owner
IIIA 10.1.2.1/01	[REDACTED]	2006	Bird species in vineyards in France and Italy: Field data for the determination of focal species [REDACTED] Unpublished GLP : Y	Y	Birds and mammals TF
IIIA 10.1.2.1/02	[REDACTED]	2007	Generic field monitoring of birds in vineyards in France [REDACTED] Unpublished GLP : Y	Y	Birds and mammals TF
IIIA 10.1.2.1/03	Knäbe, S.	2009	Residues of Amitrole in Arthropods as Food Sources for Wild Birds and Mammals after Application of Weedazol (Northern Germany 2008) GAB eurofins, Germany Nufram SAS Report N°: S08-00383 Unpublished GLP : Y	Y	NUFARM
IIIA 10.1.2.1/04	Mende, P.	2009	Analytical Phase Report. Residues of Amitrole in Arthropods as Food Sources for Wild Birds and Mammals after Application of Weedazol (Northern Germany 2008) GAB eurofins, Germany Nufram SAS Report N°: S08-00383 Unpublished GLP : Y	Y	NUFARM
IIIA 10.1.2.2/01,	[REDACTED]	2006	Bird species in pome fruit orchards in Poland and Italy: Field data for the determination of focal species [REDACTED] Unpublished GLP : Y	Y	Birds and mammals TF
IIIA 10.1.2.2/02	[REDACTED]	2007	Generic field monitoring of selected bird species in orchards in southern Germany [REDACTED] Unpublished GLP : Y	Y	Birds and mammals TF
IIIA	[REDACTED]	2007	Generic field monitoring of mammals in	Y	Birds and

Annex point	Author (s)	Year	Title Source (were different from company) Company, report No GLP status Published or not	Data protection claimed Y/N	Owner
10.3.1.4/01			vineyards in France [REDACTED] Unpublished GLP : Y		mammals TF
IIIA 10.3.1.5/01	[REDACTED]	2006	Small mammal monitoring in modern pome orchards of Baden-Württemberg and Thuringia [REDACTED] Unpublished GLP : Y	Y	Birds and mammals TF
IIIA 10.5	Pollini.	2010	Position paper NTA: amitrole: study on possible adverse effects versus pollinisateur and other beneficial insects. Not published GLP : N	Y	NUFARM
IIIA 10.5.2.1/01	Candolfi M. P.	1996	Extended laboratory test to evaluate the side effects of weedazol TL applied to plants on adult <i>Aphidius Rhopalosiphii</i> (Hymenoptera: braconidae) based on mead-briggs (1994) Springborn Laboratories, USA Nufarm Report: 95-034-1002 Unpublished GLP : Y ⇒ please refer to KIIA 8.8.2/01	Y	NUFARM
IIIA 10.5.2.1/02	Moll M.	2006	Effect of CA2210 on the parasitoid <i>Aphidius rhopalosiphii</i> , extended laboratory study – dose-response test Ibacon, Germany Nufarm Report: 24842002 Unpublished GLP : Y ⇒ please refer to KIIA 8.8.2/02	Y	NUFARM
IIIA 10.5.2.2/01	Rosenkranz B.	2006	Effects of CA2210 on the predatory mite <i>Typhlodromus pyri</i> , extended laboratory study, dose-response test Ibacon, Germany Nufarm Report: 24843062 Unpublished GLP : Y ⇒ please refer to KIIA 8.8.2/03	Y	NUFARM
IIIA 10.5.2.3/01	Schmitzer S.	2006	Effect of CA2210 on the wolf spider <i>Pardosa sp.</i> In the laboratory, extended laboratory study Ibacon, Germany Nufarm	Y	NUFARM

Annex point	Author (s)	Year	Title Source (were different from company) Company, report No GLP status Published or not	Data protection claimed Y/N	Owner
			Report: 24841066 Unpublished GLP : Y ⇒ please refer to KIIA 8.8.2/04		
IIIA 10.5.2.4/01	Candolfi M. P.	1996	Extended laboratory test to evaluate the side effects of weedazol TL applied to plants on the predator <i>Orius insidiosus</i> (Heteroptera: Anthocoridae) Springborn Laboratories, USA Nufarm Report: 95-036-1002 Unpublished GLP : Y ⇒ please refer to KIIA 8.8.2/05	Y	NUFARM
IIIA 10.5.2.4/02	Rosenkranz B.	2006	Effect of CA2210 on the lacewing <i>Chrysoperla carnea</i> , extended laboratory study – dose-response test Ibacon, Germany Nufarm Report: 24844047 Unpublished GLP : Y ⇒ please refer to KIIA 8.8.2/06	Y	NUFARM