



AZADIRACHTIN

List of Annex II studies which were considered
as relied upon for the evaluation with a view to
Annex I inclusion
and for which the main submitter has claimed
data protection

Version 1.0

Rapporteur Member State: DE

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Version 1.0 - (22.06.2011)

B.1 Identity, B.2 Physical and chemical properties, B.3 Data on application and further information, B.4 Proposals for classification and labelling, B.5 Methods of analysis

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Reports on previous use in granting national authorizations	Owner
KIIA 1.8.1 (OECD)	Ellenberger, W.	1991	Manufacturing process Azatin technical TM GLP: N, published: N 1279203 / CHE2005-1762		MTA
KIIA 1.8.2, KIIA 1.9.1 (OECD)	Kumar, A.D.	2005	Fortune Aza technical - Manufacturing process, details about the origin of Neem seed used for the preparation of the technical matter GLP: N, published: N 1279206 / CHE2005-1765		SCM
KIIA 1.8.1, KIIA 1.8.2, KIIA 1.11.1 (OECD)	Kunte, A.	2005	Comparative study of Azadirachtin technical manufactured by WR Grace, Agridyne and Fortune Biotech techniques GLP: N, published: N 1279223 / CHE2005-1768		SCM
KIIA 1.8.1 (OECD)	Kunte, A.	2005	Comparative study of Azadirachtin technical manufactured by WR Grace, Agridyne and Fortune Biotech techniques KIIA 1.8.1/03_M GLP: N, published: N 1863403 /		MTA
KIIA 1.8.1, KIIA 1.8.2 (OECD)	Simpson, A.	2000	Azatin 15 % technical (Azadirachtin) GLP: N, published: N 1279200 / CHE2005-1775		MTA
KIIA 1.8.1 KIIA 1.8.2 (OECD)	Simpson, A.	2009	Manufacturing process - Azatin 15% technical KIIA 1.8.1/04_M GLP: Y, published: N 1863404 / 1863405		MTA

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KIIA 1.9.1 (OECD)	Anonymous	2006	Certis USA answers to the BVL questions regarding evaluation for the inclusion of Azadirachtin in Annex I, specifically to the questions regarding to Annex II Points 1.2, 1.8 and 1.11 GLP: N, published: N 1279210 / CHE2006-1427		MTA
KIIA 1.9.1, KIIA 1.11.1 (OECD)	Pacini, A.	2006	Subject: EU-Evaluation for inclusion of a.i. Azadirachtin in Annex I of Council Dir. 91/414/EEC GLP: N, published: N 1279217 / CHE2006-1428		SCM
KIIA 1.9.1.2 (OECD)	Ruch, B.	2006	Quality control: Determination of Azadirachtin A, other limonoids and Aflatoxins in NeemAzal technical between 1997 to 2006 GLP: N, published: N 1279582 / CHE2006-1426		TRF
KIIA 1.10 (OECD)	Kleeberg, H.	2005	NeemAzal technical: Identity and structural formula of single compounds GLP: N, published: N 1279583 / CHE2005-1693		TRF
KIIA 1.11.1 (OECD)	Anonymous	2006	Summary of batches used in ecotoxicological studies with the active substance NeemAzal GLP: N, published: N 1279589 / CHE2006-1794		TRF
KIIA 1.11.1 (OECD)	Anonymous	2006	Summary of batches used in ecotoxicological studies with the preparation GLP: N, published: N 1279214 / CHE2007-201		SCM
KIIA 1.11.1 (OECD)	Anonymous	2006	Summary of batches used in ecotoxicological studies with the active substance Azadirachtin JIIA 1.11.1/08 GLP: N, published: N 1279215 / CHE2007-200		SCM
KIIA 1.11.1 (OECD)	Anonymous	2006	Summary of batches used in ecotoxicological studies with the active substance Azadirachtin JIIA 1.11.1/06 GLP: N, published: N 1279216 / CHE2007-199		MTA
KIIA 1.11.1 (OECD)	Jurek, M.	1992	Determination of total aflatoxin and azadirachtin in technical grade azadirachtin GLP: Y, published: N 1279218 / CHE2005-1777		MTA

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KIIA 1.11.1 (OECD)	Ellenberger, S.	1991	Absolute quantitation of the impurities present in NPI-720 technical using analytical HPLC GLP: Y, published: N 1279219 / CHE2005-1776		MTA
KIIA 1.11.1 (OECD)	Freschi, G.	2004	Detection of aflatoxins in five batches of Fortune Aza technical material GLP: N, published: N 1279220 / CHE2005-1774		SCM
KIIA 1.11.1 (OECD)	Lucini, L.	2005	Azadirachtin technical materials - Analytical profile 025/2005 GLP: N, published: N 1279221 / CHE2005-1772		IAZ
KIIA 1.11 (OECD)	Brogli, E.	2005	Lipids, proteins, sugars and aflatoxins in azadirachtin technical 01/2005 GLP: N, published: N 1279213 / CHE2006-246		IAZ
KIIA 1.11.1 (OECD)	Anonymous	2009	Information on the batches used in toxicological and ecotoxicological studies: Reports owned by Trifolio-M GmbH (Annex II) KIIA 1.11.1/08_T GLP: N, published: N 1863406 /		TRF
KIIA 1.11.1 (OECD)	Anonymous	2009	Information on the batches used in toxicological and ecotoxicological studies: Reports owned by Sipcam S.p.A. (Annex II) KIIA 1.11.1/11_S GLP: N, published: N 1863407 /		SCM
KIIA 1.11.1 (OECD)	Anonymous	2009	Information on the batches used in toxicological and ecotoxicological studies: Reports owned by Mitsui AgriScience International (Annex II) KIIA 1.11.1/13_M GLP: N, published: N 1863409 /		MTA
KIIA 1.11.1 (OECD)	Dively, C.A.	2009	Test substance confirmation KIIA 1.11.1/12_M - GLP: N, published: N 1863408 /		MTA

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KIIA 2.1.1 (OECD)	Ellenberger, S.R.	1990	Report for melting point range determination - revised GLP: N, published: N 1279226 / CHE2005-1728		MTA
KIIA 2.1.3 (OECD)	Smeykal, H.	2006	AZATIN 15% TECHNICAL, BATCH NO. AZ/01/04-05: THERMAL STABILITY (OECD 113) 20060686.01 GLP: Y, published: N 1279227 / CHE2006-1699		IAZ
KIIA 2.2 (OECD)	Smeykal, H.	2006	AZATIN 15% TECHNICAL, BATCH NO. AZ/01/04-05: RELATIVE DENSITY A.3. (OECD 109) 20060686.02 GLP: Y, published: N 1279229 / CHE2006-1700		IAZ
KIIA 2.2 (OECD)	Ellenberger, S.R.	1990	Determination of density of NPI-720 and NPI-720F - revised GLP: N, published: N 1279230 / CHE2005-1731		MTA
KIIA 2.3.1 (OECD)	Heintze, A	2005	Azadirachtin Vapour Pressure Determination GLP: N, published: N 1279231 / CHE2005-1732		IAZ
KIIA 2.3.1, KIIA 2.3.2 (OECD)	Anonymous	1990	Estimation of vapor pressure GLP: N, published: N 1279602 / CHE2005-1707		TRF
KIIA 2.3.1, KIIA 2.3.2 (OECD)	Kleeberg, H.	2005	Vapour pressure of NeemAzal technical GLP: N, published: N 1279603 / CHE2005-1706		TRF
KIIA 2.3.2 (OECD)	Heintze, A.	2005	Azadirachtin Henry's Law Constant GLP: N, published: N 1279233 / CHE2005-1733		IAZ
KIIA 2.4.1, KIIA 2.4.2 (OECD)	Kleeberg, H.	1994	Physico-chemical properties of NeemAzal technical Appearance, Colour and Odour LP 94.03 GLP: N, published: N 1279606 / CHE2005-1709		TRF
KIIA 2.4.1, KIIA 2.4.2 (OECD)	Kleeberg, H.	1994	Physico-chemical properties of Azadirachtin A Appearance, Colour and Odour LP 94.02 GLP: N, published: N 1279607 / CHE2005-1708		TRF

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KIIA 2.4.1 (OECD)	Ellenberger, S.R.	1990	Determination of physical state of NPI-720 and NPI-720F - revised GLP: N, published: N 1279234 / CHE2005-1735		MTA
KIIA 2.4.1 (OECD)	Ellenberger, S.R.	1990	Color determination of NPI-720 and NPI-720F - revised GLP: N, published: N 1279235 / CHE2005-1734		MTA
KIIA 2.4.2 (OECD)	Ellenberger, S.R.	1990	Odor determination of NPI-720 and NPI-720F GLP: N, published: N 1279237 / CHE2005-1736		MTA
KIIA 2.5.1.1, KIIA 2.5.1.2, KIIA 2.5.1.5 (OECD)	Kleeberg, H.	2006	Point 2.5.1: Spectra, A table of signal characteristics and molecular extinction at relevant wavelength for purified active substance GLP: N, published: N 1279610 / CHE2006-1678		TRF
KIIA 2.5.1.1 (OECD)	Walter, D.	2006	UV/VIS Absorption spectrum of Azadirachtin A 20061347/01-PCSD GLP: Y, published: N 1279611 / CHE2006-1677		TAF
KIIA 2.5.1.1, KIIA 2.5.1.2, KIIA 2.5.1.3, KIIA 2.5.1.4, KIIA 2.5.1.5 (OECD)	Kleeberg, H.	2005	Point 2.5.1: NeemAzal technical - spectra of the ingredients of the active substance GLP: N, published: N 1279612 / CHE2005-1710		TRF
KIIA 2.5.1.2 (OECD)	Bär, C.	2005	Infrared Spectrum of Neem Seed Extract GLP: Y, published: N 1279240 / CHE2005-1737		MTA
KIIA 2.5.1.3 (OECD)	Khan, M.R.	1992	Purification and identification of impurities present in NPI-720 technical using HPLC, NMR, and mass spectroscopy (part II) GLP: N, published: N 1279241 / CHE2006-1703		MTA
KIIA 2.5.1.3 (OECD)	Ellenberger, S.R.	1991	Purification and identification of impurities present in NPI-720 technical using HPLC, NMR and mass spectroscopy GLP: N, published: N 1279242 / CHE2006-1702		MTA
KIIA 2.5.1.4 (OECD)	Heintze, A.	2006	AZADIRACHTIN: ANNEX II POINT 2.5.1.4 MASS SPECTRA GLP: N, published: N 1279245 / CHE2006-1704		IAZ

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KIIA 2.6 (OECD)	Heintze, A.	2006	AZADIRACHTIN SOLUBILITY IN WATER 161266-A2-0206-02 GLP: N, published: N 1279249 / CHE2006-1705		IAZ
KIIA 2.6 (OECD)	Heintze, A.	2005	Azadirachtin Solubility in Water GLP: N, published: N 1279250 / CHE2005-1741		IAZ
KIIA 2.6 (OECD)	Ruch, B.	2006	Addendum to report: solubility properties of Neemazal in water LP 95.9 GLP: N, published: N 1279619 / CHE2006-1679		TRF
KIIA 2.7 (OECD)	Ruch, B.	2009	Solubility of NeemAzal technical in organic solvents KIIA 2.7/05 ! TM 0309.01 - GLP: Y, published: N 1863416 /		TRF
KIIA 2.7 (OECD)	Ruch, B.	2009	Solubility of NeemAzal technical in n-hexane and m-xylene KIIA 2.7/06 ! TM 0509.02 - GLP: Y, published: N 1863417 /		TRF
KIIA 2.8.1 (OECD)	Ruch, B.	2006	Addendum to report: partition coefficients of various constituents of various constituents of NeemAzal in n-octanol/water TM 1195.13 GLP: N, published: N 1279623 / CHE2006-1681		TRF
KIIA 2.8.1 (OECD)	Brown, M.J.	1992	Determination of the partition coefficient of NPI-100 GLP: Y, published: N 1279256 / CHE2005-1744		MTA
KIIA 2.9.1 (OECD)	Ruch, B.	2006	Addendum to report: Hydrolytic stability of NeemAzal TM 1195.15 GLP: N, published: N 1279626 / CHE2006-1682		TRF
KIIA 2.9.2 (OECD)	Heintze, A.	2006	Direct phototransformation of purified active substance in water using artificial light (simulating sunlight and excluding wavelengths <290 nm) under sterile conditions - expert statement 234379-A2-020902-01 GLP: N, published: N 1279259 / 1279629 / CHE2006-1683		TAF

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KIIA 2.9.2 KIIA 2.9.3 (OECD)	Hennecke, D.	2008	Aquatic photodegradation and quantum yield of Azadirachtin A KIIA 2.9.2/03 ! GAB-017/7-05 GLP: Y, published: N 1863418 / 1863419		TAF
KIIA 2.9.4 (OECD)	Werle, H.	1999	Estimation of the Environmental Half Life Time of NeemAzal in the Surface Layer of Aqueous Systems 99 50 40 819 GLP: Y, published: N 1279632 / CHE2005-1719		TRF
KIIA 2.10 (OECD)	Müller, M.	1999	Estimation of the Atmospheric Half-Life of Azadirachtin A GLP: N, published: N 1279633 / CHE2005-1722		TRF
KIIA 2.10 (OECD)	Tiemann, J.	2005	Azadirachtin A - Annex II, Point 2.10 Estimation of the photochemical oxidative degradation GLP: N, published: N 1279262 / CHE2005-1746		IAZ
KIIA 2.11.1 (OECD)	Franke, J.	2005	Neem Seed Extract Batch No.: AZ/01/04-05 Flammability (solids) A.10. GLP: Y, published: N 1279263 / CHE2005-1748		MTA
KIIA 2.11.1 (OECD)	Franke, J.	2005	Azadirachtin (A+B) tec. Batch No.: E279 Flammability (solids) A.10 GLP: Y, published: N 1279264 / CHE2005-1747		SCM
KIIA 2.11.1 (OECD)	Franke, J.	2005	Flammability (solids) 20050679.02 GLP: Y, published: N 1279634 / CHE2005-1723		TRF
KIIA 2.11.2 (OECD)	Franke, J.	2005	Neem Seed Extract Batch No.: AZ/01/04-05 Auto-Flammability (Solids - Determination of Relative Self-Ignition Temperature) A.16 GLP: Y, published: N 1279265 / CHE2005-1750		MTA
KIIA 2.11.2 (OECD)	Franke, J.	2005	Azadirachtin (A+B) Batch No.: E279 Auto-Flammability (Solids- Determination of Relative Self-Ignition Temperature) A.16 GLP: Y, published: N 1279266 / CHE2005-1749		SCM

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KIIA 2.11.2 (OECD)	Franke, J.	2005	Auto-flammability (solids-determination of relative self-ignition temperature) A.16 20050679.03 GLP: Y, published: N 1279635 / CHE2005-1724		TRF
KIIA 2.12 (OECD)	Ellenberger, S.R.	1990	Flash point determination of NPI-720 and NPI-720F GLP: N, published: N 1279267 / CHE2005-1751		MTA
KIIA 2.13 (OECD)	Franke, J.	2005	Neem Seed Extract Batch No.: AZ/01/04-05 Explosive Properties A.14 GLP: Y, published: N 1279268 / CHE2005-1753		MTA
KIIA 2.13 (OECD)	Franke, J.	2005	Azadirachtin Batch No.: E279 Explosive Properties A.14 GLP: Y, published: N 1279269 / CHE2005-1752		SCM
KIIA 2.13 (OECD)	Smeykal, H.	2002	NeemAzal 0003-47 Explosive Properties 20020457.01 GLP: Y, published: N 1279636 / CHE2005-1725		TRF
KIIA 2.14 (OECD)	Messerschmidt, S.	2005	Surface tension of Neem Seed Extract GLP: Y, published: N 1279271 / CHE2005-1754		MTA
KIIA 2.14 (OECD)	Franke, J.	2005	Surface tension 20050679.01 GLP: Y, published: N 1279637 / CHE2005-1726		TRF
KIIA 2.14, KIIA 2.7 (OECD)	Lucini, L.	2005	Azadirachtin technical - solubility in organic solvents, pH and surface tension GLP: Y, published: N 1279272 / CHE2005-1743		SCM
KIIA 2.15 (OECD)	Franke, J.	2005	Neem Seed Extract Batch No.: AZ/01/04-05 Oxidising Properties A.17 GLP: Y, published: N 1279273 / CHE2005-1756		MTA
KIIA 2.15 (OECD)	Franke, J.	2005	Azadirachtin (A+B) tec. Batch No.: E279 Oxidising Properties GLP: Y, published: N 1279274 / CHE2005-1755		SCM
KIIA 2.15 (OECD)	Franke, J.	2005	Oxidizing properties 20050679.04 GLP: Y, published: N 1279638 / CHE2005-1727		TRF

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KIIA 3.5.1 (OECD)	Kleeberg, H.	2005	Mode of Action GLP: N, published: N 1279495 / BIO2005-6018		TRF
KIIA 3.6 (OECD)	Kleeberg, H.	2005	Information on the possible occurrence of the development of resistance or cross-resistance GLP: N, published: N 1279505 / BIO2005-6019		TRF
KIIA 4.2.1, KIIA 4.2.3 (OECD)	Brogli, E.	2005	Lipids, proteins, sugars and aflatoxins in azadirachtin technical 01/2005 GLP: N, published: N 1278959 / CHE2006-246		IAZ
KIIA 4.2.1 (OECD)	Lucini, L.	2005	Azadirachtin technical materials - Analytical profile 025/2005 GLP: N, published: N 1278960 / CHE2005-1772		IAZ
KIIA 4.2.3 (OECD)	Freschi, G.	2004	Detection of aflatoxins in five batches of Fortune Aza technical material GLP: N, published: N 1278965 / CHE2005-1774		SCM
KIIA 4.2.3 (OECD)	Schiebel, M.	2004	Determination of residues of aflatoxin B1, B2, G1, and G2 in/on NeemAzal and NeemAzal-T/S GLP: N, published: N 1279353 / CHE2005-1704		TRF
KIIA 4.2.3 (OECD)	Biselli, S.	2004	Report of two validation studies for Aflatoxin analysis in NeemAzal-T/S and the starting material NeemAzal (technical) GLP: N, published: N 1279354 / CHE2005-1703		TRF
KIIA 4.3 (OECD)	Lucini, L.	2005	Validation of the analytical method for determination of residues of Azadirachtin (Azadirachtin A + Azadirachtin B) in apple KIIA 4.3/01 GLP: Y, published: N 1278968 / MET2005-795		SCM
KIIA 4.3 (OECD)	Class, T.	2005	Independent laboratory validation of an analytical method for the determination of Azadirachtin A in/on plant origin by HPLC-MS/MS KIIA 4.3/08 GLP: Y, published: N 1279357 / MET2005-790		TRF

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KIIA 4.3 (OECD)	Mende, P.	2003	Validation of a multiresidue method for the determination of Azadirachtin A in plant matrices 20031142/01-RVP GLP: Y, published: N 1279364 / MET2005-783		TRF
KIIA 4.3 (OECD)	Ruch, B.	2007	Addendum: Method validation: Method: RAn-01.1 "Determination of azadirachtin a-residues in/on apple V-RAn-01.1 GLP: N, published: N ASB2007-4683; 1665639		TRF
KIIA 4.3 (OECD)	Ruch, B.	2002	Method validation; method Ran-06, Determination of azadirachtin A (AzA)-residues in/on spinach V-Ran-06; 11 GLP: N; published: N MET2005-787		TRF
KIIA 4.3 (OECD)	Ruch, B.	2000	Method validation; method RAn-05, Determination of azadirachtin A residues in tomatoes V-RAn-05/A GLP: Y, published: N MET2005-785		TRF
KIIA 4.3 (OECD)	Ruch, B.	2007	Addendum: Method validation: Method: RAn-05 "Determination of azadirachtin a-residues in/on tomatoes V-RAn-05/A GLP: N, published: N ASB2007-4684; 1665647		TRF
KIIA 4.3 (OECD)	Ruch, B.	2007	Addendum: Method validation: Method: RAn-06 "Determination of azadirachtin a-residues in/on spinach V-RAn-06 GLP: N, published: N ASB2007-4685; 1665650		TRF

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KIIA 4.4 (OECD)	Witte, A.	2008	Validation of an Analytical Method for the Determination of Azadirachtin A in Soil KIIA 4.4/03 ! 20081004/01-RVS GLP: Y, published: N 1863420 /		TRF
KIIA 4.4/02	Lucini, L.	2007	Specificity of the analytical method RAn-04.1 "Determination of Azadirachtin A residues in the soil" from Trifolio-M GmbH report no. SIP1569 GLP: Y, published: N ASB2007-4688		TAF
KIIA 4.5 (OECD)	Ruch, B.	2003	Method Validation Method: Ran-03.OW - Determination of Azadirachtin A-Residues in Surface Water KIIA 4.5/02 GLP: Y, published: N 1279366 / MET2005-793		TRF
KIIA 4.5/03 (OECD)	Class, T.	2007	Development and validation of an analytical method for the determination of Azadirachtin A in water, using LC/MS/MS P/B 1305 G GLP: Y, published: N ASB2007-4689		TAF
KIIA 4.7/01 (OECD)	Class, T.	2007	Development and validation of an analytical method for the determination of Azadirachtin A in air P/B 1306 G GLP: Y, published: N ASB2007-4690		TAF

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B.6 Toxicology and metabolism

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Reports on previous use in granting national authorizations	Owner
KIIA 5.1 (OECD)	Pfau, W.	2005	Metabolism and kinetics in mammals 161266-A2-050501-01 GLP: N, published: N 1278972 / TOX2005-2346		IAZ
KIIA 5.1.1 (OECD)	Anonymous	2002	NeemAzal technical metabolism and kinetics in mammals GLP: N, published: N 1279512 / TOX2005-2334		TRF
KIIA 5.1.1 (OECD)	Strang, R.H.C.	2009	Opinion on the feasibility of sufficient isotopically-labelled Azadirachtin A GLP: N, published: N 1863421 /		TRF
KIIA 5.2.1 (OECD)	Mega, W.M.	1992	Oral toxicity assay of NPI 720, Azatin technical grade, batches in female rats L 08367; Study No 3 GLP: Y, published: N 1278976 / TOX2005-2361		MTA
KIIA 5.2.1 (OECD)	Furedi-Machacek, E.M.	1990	Acute oral toxicity study of NPI 720 in rats (Limit-test) L 08270 GLP: Y, published: N 1278977 / TOX2005-2357		MTA
KIIA 5.2.2 (OECD)	Furedi-Machacek, E. M.	1990	Acute dermal toxicity study of NPI 720 in rabbits (Limit-test) L 08270 Study No 3 GLP: Y, published: N 1278979 / TOX2005-2364		MTA
KIIA 5.2.4 (OECD)	Furedi-Machacek, E. M.	1990	Primary dermal irritation testing of NPI 720 in rabbits L 08270 Study No 5 GLP: Y, published: N 1278983 / TOX2005-2375		MTA
KIIA 5.2.5 (OECD)	Furedi-Machacek, E. M.	1990	Primary eye irritation testing of NPI 720 in rabbits L 08270 Study No 6 GLP: Y, published: N 1278984 / TOX2005-2379		MTA
KIIA 5.3.1 (OECD)	Anonymous	2002	NeemAzal. NeemAzal T/S - Statement on: Subchronic toxicity study in a second mammal GLP: N, published: N 1279382 / TOX2005-2335		TRF

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Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Reports on previous use in granting national authorizations	Owner
KIIA 5.3.2 (OECD)	Pfau, W.	2005	Statement on subchronic toxicity study in a second mammal with Azadirachtin 161266-A2-050303-1 GLP: N, published: N 1279152 / TOX2005-2389		IAZ
KIIA 5.4.1 KIIA 5.4.2 (OECD)	Stien, J.	2006	<i>In vitro</i> assesment of the clastogenic activity of Azadirachtin (A+B) in cultured human peripheral lymphocytes 19026/3/05 GLP: Y, published: N 1279155 / TOX2006-464		TAF
KIIA 5.4.1 KIIA 5.4.2 (OECD)	Stien, J.	2006	<i>In vitro</i> assessment of the clastogenic activity of Neem Seed extract in cultured human peripheral lymphocytes 19026/2/05 GLP: Y, published: N 1279156 / TOX2006-463		TAF
KIIA 5.4.2 (OECD)	Stien, J.	2006	<i>In vitro</i> assessment of the clastogenic activity of NeemAzal in cultured human peripheral lymphocytes 19026/1/05 GLP: Y, published: N 1279385 / TOX2006-739		TAF
KIIA 5.4.3 (OECD)	Cifone, M.A.	1993	The L5178Y TK+/- mouse lymphoma forward mutation assay with Neem concentrate TGAI 15032-1-431R - GLP: Y, published: N 1863423 /		MTA
KIIA 5.4.4 (OECD)	Murli, H.	1992	Dose rangefinding and mutagenicity test on Neem concentrate TGAI in an in vivo mammalian mutagenicity assay 15032-0-455 ! 15032-0-459PO - GLP: Y, published: N 1863424 /		MTA
KIIA 5.5.2 (OECD)	Kumar, T.	2000	Long term carcinogenicity study of NeemAzal technical in Wistar rats. 7291 GLP: Y, published: N 1279388 / TOX2001-170		TRF
KIIA 5.5 (OECD)	Murthy, P.B	2001	Teratogenicity and Carcinogenicity studies - OECD FIPPAT/PBK/PARRY/2001 GLP: N, published: N TOX2005-2336		TRF

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KIIA 5.5.2 (OECD)	Pfau, W.	2007	Different sensitivities of rats in subchronic, chronic and two-generation studies with Azadirachtin (variant NeemAzal) KIIA 5.5.2 GLP: N, published: N 1645779 /		TRF
KIIA 5.5.3 (OECD)	Pfau, W.	2007	Verification of the mean heart weight of intermediate group females - Annex IIA, point 5.5.3: mouse carcinogenicity study (Moorthy, 1996) KIIA 5.5.3 GLP: N, published: N 1645781		TRF
KIIA 5.6 (OECD)	Pfau, W.	2009	Evaluation of the reproductive toxicity of Azadirachtin 379234-A2-050601-01 - GLP: N, published: N 1863427 /		TAF
KIIA 5.6.1 (OECD)	Ramamoorthy, S.	2000	Evaluation of toxicity of NeemAzal technical to reproductive process in Wistar rats - segment IV - toxicity to two generation reproductive process. 4826 GLP: N, published: N 1279400 / TOX2001-173		TRF
KIIA 5.6.3 (OECD)	Ramamoorthy, S.	2000	Evaluation of toxicity of Neemazal technical to general reproductive process and fertility in Wistar rats - Segment I 4823 ! Project No. : 05-512-97 - GLP: N, published: N 1863425 /		TRF
KIIA 5.9.1 (OECD)	Mahesh, A.	2005	To whomsoever it may concern GLP: N, published: N 1279024 / TOX2005-2404		SCM
KIIA 5.9.1 (OECD)	Kumar, A. D.	2005	Statement GLP: N, published: N 1279025 / TOX2005-2403		SCM
KIIA 5.9.1 (OECD)	Venkataram, T.V.	2004	Employees health record 2003 GLP: N, published: N 1279414 / TOX2005-2339		TRF
KIIA 5.9.1 (OECD)	Venkataram, T.V.	2003	Employees health record 2002 GLP: N, published: N 1279415 / TOX2005-2338		TRF

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KIIA 5.9.1 (OECD)	Venkataram, T.V.	2002	Employees health record 2001 GLP: N, published: N 1279416 / TOX2005-2337		TRF
KIIA 5.11 (OECD)	Pfau, W.	2005	Summary of the toxicological and metabolism study on the active substance GLP: Y, published: N 1279027 / TOX2005-2405		IAZ
KIIA 5.11 (OECD)	Pfau, W.	2005	Summary of mammalian toxicity and overall evaluation GLP: N, published: N 1279419 / TOX2005-2343		TRF
KIIA 5.11 (OECD)	Pfau, W.	2009	Point 5.11 Summary of the toxicological and metabolism studies on the active substance GLP: N, published: N 1863428 /		TAF

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B.7 Residues

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Reports on previous use in granting national authori- zations	Owner
KIIA 6.1.1 (OECD)	Ruch, B.	2003	HPLC Analytical Determination of the Azadirachtin A Content of Spiked Spinach Samples after Storage at T < -15°C TM 0502.03 GLP: Y, published: N 1279420 / RIP2006-526		TRF
KIIA 6.1.1 (OECD)	Ruch, B.	2003	HPLC Analytical Determination of the Azadirachtin A Content of Spiked Tomato Samples after Storage at T < -15°C TM 1000.03 GLP: Y, published: N 1279421 / RIP2006-525		TRF
KIIA 6.1.1 (OECD)	Ruch, B.	1999	HPLC-analytische Bestimmung des Azadirachtin A Gehaltes in Kartoffelmus nach 21-monatiger Lagerung bei T < -15°C, Berichts-Nr. LP 99.11 BR. LP 99.11 BR GLP: N, published: N 1279422 / RIP2000-207		TRF
KIIA 6.1.1 (OECD)	Ruch, B.	1999	HPLC-analytische Bestimmung des Azadirachtin A Gehaltes in Äpfeln nach 36-monatiger Lagerung bei T < -15°C, Berichts-Nr. LP 99.12 BR. LP 99.12 BR GLP: N, published: N 1279423 / RIP2000-204		TRF
KIIA 6.1.1 (OECD)	Lucini, L.	2006	Freezer storage stability of azadirachtin A and azadirachtin B in apple SIP1497 GLP: Y, published: N 1279028 / RIP2006-2592		IAZ
KIIA 6.1.1 (OECD)	Lucini, L.	2006	Freezer storage stability of Azadirachtin A and Azadirachtin B in apple, (9 months checkpoint) SIP1497 GLP: Y, published: N 1279029 / RIP2006-357		IAZ
KIIA 6.1.2 (OECD)	Lucini, L.	2005	Validation of the analytical method for determination of residues of Azadirachtin (Azadirachtin A + Azadirachtin B) in apple SIP1453 GLP: Y, published: N 1279032 / RIP2006-603		SCM

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KIIA 6.1.2, KIIA 6.2.1, KIIA 6.3.1 (OECD)	Ruch, B.	2005	Residue Study on/in Apple RS-Apple / 2 GLP: Y, published: N 1279424 / RIP2006-528		TRF
KIIA 6.2.1 (OECD)	Daly, G., Ruch, B., Tross, R., Flowers, H., Cole, M., McCracken, D., Kleeberg, H., Strang, R.	2005	The behaviour of azadirachtin A and [22,23-3H2]dihydroazadirachtin A in soil and nasturtium plants (<i>Tropaeolum majus</i>) GLP: N, published: N 1279427 / RIP2006-535		TRF
KIIA 6.2.1 (OECD)	Ruch, B.	2005	Determination of the degradation behaviour of Azadirachtin B residues on/in spinach after treatment with NeemAzal-T/S TM 1003.03 GLP: Y, published: N 1279431 / RIP2006-531		TRF
KIIA 6.2.1 (OECD)	Ruch, B.	2005	Determination of Azadirachtin B, Nimbin and Salannin residues on/in tomatoes after treatment with a BSN formulation TM 1202.05 GLP: Y, published: N 1279432 / RIP2006-530		TRF
KIIA 6.2.1, KIIA 6.3.2 (OECD)	Ruch, B.	2005	Residue Study on/in Tomato RS-Tomato / 1 GLP: Y, published: N 1279433 / RIP2006-529		TRF
KIIA 6.2.1 (OECD)	Strang, R.H.C.	2009	Opinion on the feasibility of sufficient isotopically-labelled Azadirachtin A GLP: N, published: N 1863429 /		TRF
KIIA 6.3.1 (OECD)	Miserocchi, G.	2001	Final Report of Field Phase: Determination of residues of Azadirachtin after Application of Azatin EC (Azadirachtin) in apple at one site in Italy, 2000 20005076/I1-FPAP GLP: Y, published: N 1279435 / RIP2006-542		MTA
KIIA 6.3.1 (OECD)	Gatti, G.C.	2001	Residue determinations of Azadirachtin in apples according to the OECD principles of GLP LN81-00 GLP: Y, published: N 1279436 / RIP2006-541		MTA

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Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Reports on previous use in granting national authorizations	Owner
KIIA 6.3.2 (OECD)	Gatti, G.C.	2001	Determination of residues of Azadirachtin after application of AZATIN EC (Azadirachtin) in tomatoes in green house at one site in Italy, 2000 00NA18R GLP: Y, published: N 1279443 / RIP2006-549		MTA
KIIA 6.3.2 (OECD)	Miserocchi, G.	2001	Final report of field phase. Determination of residues of Azadirachtin after application of AZATIN EC (Azadirachtin) in tomato at one site in Italy, 2000 20005076/I1-FPTO GLP: Y, published: N 1279444 / RIP2006-548		MTA
KIIA 6.3.2 (OECD)	Gatti, G.C.	2001	Residue determinations of Azadirachtin in tomatoes according to the OECD principles of GLP LN83-00 GLP: Y, published: N 1279445 / RIP2006-547		MTA
KIIA 6.3.2 (OECD)	Ruch, B.	2005	Residue Study on/in Tomato RS-Tomato / 3 GLP: Y, published: N 1279448 / RIP2006-544		TRF
KIIA 6.3.2 (OECD)	Ruch, B.	2005	Residue Study on/in Tomato RS-Tomato / 2 GLP: Y, published: N 1279449 / RIP2006-543		TRF
KIIA 6.3.2 (OECD)	Soler Gil-Mascarell, J.-R.	2005	Determination of the magnitude of residues of Azadirachtin A and Azadirachtin B in outdoor Tomato specimens after three applications of OIKOS (Azadirachtin A+B 32 g/l, EC)Spain 2005. AZ2/TO GLP: Y, published: N 1279451 / RIP2006-359		SCM
KIIA 6.3.2 (OECD)	Soler Gil-Mascarell, J.-R.	2005	Determination of the magnitude of residues of Azadirachtin A and Azadirachtin B in outdoor Tomato specimens after three applications of AZATIN XL (Azadirachtin A+B 4.5%, EC) AZ1/TO GLP: Y, published: N 1279452 / RIP2006-358		IAZ

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KIIA 6.3.4 (OECD)	Ruch, B.	2005	Residue Study on/in Spinach RS-Spinach / 4 GLP: Y, published: N 1279458 / RIP2006-558		TRF
KIIA 6.3.4 (OECD)	Ruch, B.	2005	Residue Study on/in Spinach RS-Spinach / 3 GLP: Y, published: N 1279459 / RIP2006-557		TRF
KIIA 6.3.4 (OECD)	Pollmann, B.	2005	Residue behaviour of spinach after application of NeemAzal-T/S - 3 sites in northern Europe 2005 20054058/EI-FPSP GLP: Y, published: N 1279462 / RIP2006-569		TRF
KIIA 6.3.4 (OECD)	Ruch, B.	2007	Azadirachtin (variant NeemAzal) Insecticide and Acaricide: Statement on Storage Periods in Residue trials with NeemAzal-T/S in Spinach KIIA 6.3.4 GLP: N, published: N 1645787 /		TRF

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B.8 Environmental fate and behaviour

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Reports on previous use in granting national authorizations	Owner
KIIA 7.1 (OECD)	Otto, S., Häusler, A.	2009	Statement on the relevance of degradation products of Azadirachtin in soil 234379-A3-0701-01 - GLP: N, published: N 1863431 /		TAF
KIIA 7.1 KIIA 7.8 (OECD)	Strang, R.H.C.	2009	Opinion on the feasibility of sufficient isotopically-labelled Azadirachtin A GLP: N, published: N 1863432 / 1863435		TRF
KIIA 7.2.1 (OECD)	Häusler, A.	2007	Azadirachtin: Aerobic degradation in soil-recalculation of DT ₅₀ values 234379-A3-090101-01 GLP: N, published: N 1662525		TAF
KIIA 7.7 (OECD)	Dengler, D.	2005	Assessment of the ready biodegradability of Neem Seed Extract with the closed bottle test Rep.No. 20051277/01-AACB GLP: Y, published: N 1279467 / WAS2005-346		IAZ
KIIA 7.8	Otto, S., Häusler, A.	2009	Statement on the relevance of degradation products of azadirachtin in aquatic systems Report-no. 234379-A3-0708-01 GLP/GEP: N, Published: N 1863434		TAF

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B.9 Ecotoxicology

Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Reports on previous use in granting national authorizations	Owner
KIIA 8.2.1.1 (OECD)	Teigeler, M.	2008	Rainbow trout (<i>Oncorhynchus mykiss</i>), Acute toxicity test, Flow-through conditions TRF-001/4-13 - GLP: Y, published: N 1863437 /		TRF
KIIA 8.5.2 (OECD)	Gonsior, G.	2008	Assessment of Side Effects of NeemAzal on the Larvae of the Midge, <i>Chironomus riparius</i> with the Laboratory Test Method 2007/1356/01-ASCr GLP: Y, published: N 1863438 /		TRF
KIIA 8.5.2 (OECD)	Gonsior, G.	2008	Assessment of side effects of Azatin Technical-grade Active Ingredient on the larvae of the midge, <i>Chironomus riparius</i> with the laboratory method 2007/1358/01-ASCr GLP: Y, published: N 1863439 /		MTA
KIIA 8.5.2 (OECD)	Gonsior, G.	2008	Assessment of side effects of Fortune on the larvae of the midge, <i>Chironomus riparius</i> with the laboratory test method 2007/1357/01-ASCr GLP: Y, published: N 1863440 /		SCM
KIIA 8.8.2.4 (OECD)	Fifi, A.P.	2008	Effect toxicity evaluation of NEEMAZAL (34% Azadirachtin A Technical) product on the <i>Coccinella septempunctata</i> L. (Coleoptera, Coccinellidae) under extended laboratory conditions BT025/07 GLP: Y, published: N 1863444 /		TRF
KIIA 8.8.2.4 (OECD)	Fifi, A.P.	2008	Effect toxicity evaluation of AZATIN 15% TECHNICAL product on the <i>Coccinella septempunctata</i> L. (Coleoptera, Coccinellidae) under extended laboratory conditions KIIA 8.8.2.4/05 GLP: Y, published: N 1863445 /		MTA

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KIIA 8.8.2.4 (OECD)	Fifi, A.P.	2008	Effect toxicity evaluation of FORTUNE AZA TECHNICAL POWDER product on the <i>Coccinella septempunctata</i> L. (Coleoptera, Coccinellidae) under extended laboratory conditions BT026/07 GLP: N, published: N 1863446 /		SCM
KIIA 8.8.2.4 (OECD)	Klug, T.	2008	NeemAzal: Toxicity to the Green Lacewing, <i>Chrysoperla carnea</i> Steph. (Neuroptera, Chrysopidae) under Extended Laboratory Conditions - Dose Response Test - 20071356/01-NECc GLP: Y, published: N 1863441 /		TRF
KIIA 8.8.2.4 (OECD)	Klug, T.	2008	Azatin Technical-grade Active Ingredient: Toxicity to the Green Lacewing, <i>Chrysoperla carnea</i> Steph. (Neuroptera, Chrysopidae) under Extended Laboratory Conditions - Dose Response Test - 20071358/01-NECc GLP: Y, published: N 1863442 /		MTA
KIIA 8.8.2.4 (OECD)	Klug, T.	2008	Fortune: Toxicity to the Green Lacewing, <i>Chrysoperla carnea</i> Steph. (Neuroptera, Chrysopidae) under Extended Laboratory Conditions - Dose Response Test - 20071357/01-NECc - GLP: Y, published: N 1863443 /		SCM
KIIA 8.16.1 (OECD)	Adelberger I.	2009	Acute and Sublethal Toxicity on the Predatory Mite <i>Hypoaspis (Geolaelaps) aculeifer</i> Canestrini (Acari: Laelapidae) using Standard Soil (LUFA 2.2) with Freshly Applied and Aged Soil Residues S09-00977 GLP: Y, published: N 1863450 /		TAF
KIIA 8.16.1 (OECD)	Geschke S.	2009	Determination of Azadirachtin A and B in Water Samples containing freshly applied or aged residues of NeemAzal S09-01884 - GLP: Y, published: N 1863449 /		TAF

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KIIA 8.16.1 (OECD)	Simon M.	2009	Daphnia magna, Acute Immobilisation Tests with freshly applied and aged water residues of NeemAzal GAB-028/4-20 GLP: Y, published: N 1863448 /		TAF
KIIA 8.16.1 (OECD)	Teigeler M.	2009	Rainbow trout (Oncorhynchus mykiss), Acute Toxicity Tests with freshly applied and aged water residues of NeemAzal GAB-027/4-11 GLP: N, published: N 1863447 /		TAF

Codes of owner

TRF Trifolio-M
 SCM Sipcam
 MTA Mitsui
 IAZ Sipcam, Mitsui
 TAF Trifolio-M, Sipcam, Mitsui

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