

RIMSULFURON

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

Rapporteur Member State: Germany

November 2005

Document number

RIMSULFURON

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 - (29 November 2005)

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) Company, Report No. GLP or GEP status (where relevant) Published or not	Reports ¹ on previous use in granting national authorizations
AIIA-1.8	Rajendran, G.	2001	Technical Grade DPX-E9636 (Rimsulfuron) Manufacturing, Description and Formation of Impurities DuPont-6727. GLP, unpublished CHE2002-321	
AIIA-1.10; AIIA-1.11	Rajendran, G. and O'Neal, F.O.l	2002	Justification of the Proposed Increase in the Level of Phenol in Rimsulfuron Technical from 0.3 % max to 0.5 % max DuPont-11086. GLP, unpublished CHE2002-620	
AIIA-1.11; AIIA-4.1	Edwards, D.N.	2001	Technical Grade (Rimsulfuron) Analysis and Certification of Product Ingredients DuPont-3934. GLP, unpublished CHE2002-324	
AIIA-1.11	Jin, L. and Davis, R.	2004	Justification of the Proposed Modifications in Rimsulfuron Confidential Statement of Formula (CSF). DuPont-14821 not GLP, unpublished CHE2004-588	
AIIA-4.1.2	Blank, D.	2004	Rimsulfuron (DPX-E9636): Confirmation of Impurity Analyte Identification in the Active Ingredient. DuPont-14820 GLP: Not relevant Published: no CHE2004-589	

¹ Entries are based on information received from the main data submitter and in certain cases Member States. Neither the Commission nor the Member States are responsible for the completeness or validity of this information received.

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	Reports ¹ on previous use in granting national authorizations
AIIA-2.4	Moore, L.A.	2001	Appearance (Physical State, Color, Odor) of Rimsulfuron (DPX-E9636) Technical and Pure Active Ingredient DuPont-6005. not GLP, unpublished CHE2002-326	
AIIA-2.5	Jeffery, D.J.	2000	Rimsulfuron (DPX-E9636): Mass Spectrum (MS) DuPont-4485. not GLP, unpublished CHE2002-328	
AIIA-2.5	Jeffery, D.J.	2000	Rimsulfuron (DPX-E9636): 1H-NMR Spectrum DuPont-4486. not GLP, unpublished CHE2002-329	
AIIA-2.5	Jeffery, D.J.	2000	Rimsulfuron (DPX-E9636): IR Spectrum DuPont-3922. not GLP, unpublished CHE2002-327	
AIIA-2.5	Moore, L.A.	2001	Rimsulfuron (DPX-E9636) Technical and IN-70942: Determination of the UV/Visible Absorption and Molar Absorptivity DuPont-5017. GLP, unpublished CHE2002-330	
AIIA-2.6	Moore, L.A.	2000	Solubility of Rimsulfuron (DPX-E9636) in Water DuPont-4710. GLP, unpublished CHE2002-331	
AIIA-2.9.3; AIIA- 7.2.1.2	Trabue, S.L. and Schmuckler, M.E.	2001	Calculation of the quantum yield of Rimsulfuron (DPX-E9636) and IN-70942 in water. DuPont-5719 not GLP, unpublished LUF2001-246	
AIIA-2.10; AIIA-7.2.2	Moore, L.A.	2001	The stability in air of Rimsulfuron (DPX-E9636): Atkinson calculation. DuPont-3921 GLP, unpublished WAS2001-304	
AIIA-1.11; AIIA-4.1	Edwards, D.N.	2001	Technical Grade (Rimsulfuron) Analysis and Certification of Product Ingredients DuPont-3934 GLP, unpublished CHE2002-324	

B.6 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	Reports on previous use in granting national authorizations
AIIA-5.2.1	Kurita, T.	1993	Rimsulfuron technical: Acute oral toxicity study in mice. IET 93-0095 GLP, unpublished TOX2001-1414	
AIIA-5.3.2	O`Neal, F.O.	2004	Rimsulfuron dog feeding studies: historical control data for testicular histopathology. DuPont-14854 not GLP, unpublished TOX2004-831	
AIIA-5.8.1	Forichon, A.	1992	Test to evaluate the induction of chromosome aberrations in human lymphocytes. 202380 GLP, unpublished TOX2001-1442	
AIIA- 5.8.1/13	Gudi, R. and Rao, M.	2003	IN-70941: In Vitro Mammalian Chromosome Aberration Study in Human Peripheral Blood Lymphocytes. BioReliance AA78YL.341.BTL GLP: Yes Published: no	
AIIA-5.8.1	Lheritier, M.	1991	Test to evaluate the acute toxicity following a single oral administration (Limit Test) in the rat. 110304 GLP, unpublished TOX2001-1444	
AIIA-5.8.1	Lheritier, M.	1991	Test to evaluate the acute toxicity following a single cutaneous application (Limit Test) in the rat. 110303 GLP, unpublished TOX2001-1443	
AIIA-5.8.1	Mercier, O.	1992	Test to evaluate sensitising potential in the guinea-pig maximisation test. 202355 GLP, unpublished TOX2001-1447	
AIIA-5.8.1	Mercier, O.	1992	Test to evaluate the acute primary cutaneous irritation and corrosivity in the rabbit. 201335 GLP, unpublished TOX2001-1446	

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	Reports on previous use in granting national authorizations
AIIA-5.8.1	Mercier, O.	1992	Test to evaluate acute ocular irritation and reversibility in the rabbit. 201336 GLP, unpublished TOX2001-1445	
AIIA-5.8.1	O'Neal, F.O.	2003	Safety assessment of rimsulfuron metabolites: IN-70941 and IN-E9260. DuPont-13290. Rev.1 not GLP, unpublished TOX2003-2093	
AIIA-5.8.1	Regnier, B.	1992	DPX-E9260 - 4 week oral (gavage) toxicity study in the rat. 35291 GLP, unpublished TOX2001-1452	
AIIA- 5.8.1/12	San, R.H.C. and Clarke, J.J.	2003	IN-70941: In Vitro Mammalian Cell Gene Mutation Test (CHO/HGPRT Test) BioReliance AA78YL.782.BTL GLP: Yes Published: no	
AIIA-5.9.1	Tilbury, L.F.	2001	Medical examination summaries of employees manufacturing DuPont rimsulfuron herbicide loon plage, France facility. DuPont-6730 not GLP, unpublished TOX2001-1455	

B.7 Residue data

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	Reports on previous use in granting national authorizations
AIIA-6.0	Amoo, J.S.	1996	Storage Stability of DPX-E9636 in Frozen Analytical Samples of Tomato Fruit. AMR 3443-95 GLP, unpublished RIP2002-367	
AIIA-6.1	Zhang, M., Fox, G.C. and Naidu, M.V.	1996	Metabolism of 14C-DPX-E9636 Herbicide in Tomatoes. AMR 3520-95 GLP, unpublished RIP2002-382	

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	Reports on previous use in granting national authorizations
AIIA-6.3	Cicotti, M.	1991	Determination of Residues of DPX-E9636 in Tomatoes by HPLC-CS/UV Following Treatment with DPX-E9636 25DF (Season 1990-Italy). BE_A-11-91-07A-BG GLP, unpublished RIP2002-386	Comment of Notifier: Submitted in IT, ES
AIIA-6.3	Dubey, L.	1993	Determination of Residues of Rimsulfuron (DPX-E9636) in Tomatoes by HPLC-UV/CS Following Treatment with Titus 25 % WG (France-Season 1991 and 1992). A-11-93-01 GLP, unpublished RIP2002-435	Comment of Notifier: Submitted in ES
AIIA-6.3	Dubey, L.	1993	Determination of Residues of Rimsulfuron (DPX-E9636) in Tomato Fruit and Juice by HPLC-UV/CS Following Treatment with Titus 25 % WG (Spain-Season 1992). A-11-93-05 GLP, unpublished RIP2002-437	Comment of Notifier: Submitted in ES, EL
AIIA-6.3	Dubey, L.	1994	Determination of Residues of Rimsulfuron (DPX-E9636) in Potatoes and Tomatoes by HPLC-CS/UV Following Treatment with Pilar (JU298-5) (Italy-Season 1993). A-11-94-09 GLP, unpublished RIP2002-443	Comment of Notifier: Submitted in IT, EL
AIIA-6.3	Dubey, L.	1992	Determination of Residues of DPX-E9636 in Corn by HPLC-CS/UV Following Treatment with DPX-E9636 25 DF (Season 1991- Germany). BE-A-11-91-26-BG GLP, unpublished RIP2002-442	Comment of Notifier: Submitted in SE, FI
AIIA-6.3	Dubey, L.	1992	Determination of Residues of DPX-E9636 in Corn by HPLC-CS/UV Following Treatment with DPX-E9636 25 DF + Wetting Agent (Season 1991 - Germany). BE-A-11-91-25-BG GLP, unpublished RIP2002-431	Comment of Notifier: Submitted in SE, FI

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	Reports on previous use in granting national authorizations
AIIA-6.3	Dubey, L., Beuret, V. and Argyri, I.	1999	Magnitude of Residues of Rimsulfuron in Tomatoes Following Applications of DPX- E9636-128 25 WG Greece, Season 1998 (Analysis of Rimsulfuron by HPLC/CS/UV). AMR 5114-98 GLP, unpublished RIP2002-445	
AIIA-6.3	Garcia, J.J.	1994	Determination of Residues of Rimsulfuron (DPX-E9636) in Corn by HPLC-CS/UV Following Treatment with Titus 25DF (Spain-Season 1992). A-11-93-21 GLP, unpublished RIP2002-438	

B.8 Environmental fate and behaviour

	nmental fate and l	1	1	n .
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	Reports on previous use in granting national authorizations
AIIA- 7.1.1.2.1; AIIIA-9.1.3	McClanahan, R.H. and Shah, J.F.	2000	Rate of degradation study of [¹⁴ C]IN-70942 (a metabolite of rimsulfuron) in three soils. DuPont-3505 GLP, unpublished BOD2001-692	
AIIA-7.1.1.2.1; AIIIA-9.1.3	McClanahan, R.H. and Shah, J.F.	2000	Rate of degradation study of [¹⁴ C]IN-70941 (a metabolite of rimsulfuron) in three soils. DuPont-3504 GLP, unpublished BOD2001-691	
AIIA- 7.1.1.2.1; AIIIA-9.1.3	McClanahan, R.H. and Shah, J.F.	2000	Rate of degradation study of [¹⁴ C]IN-E9260 (a metabolite of rimsulfuron) in three soils. DuPont-3503 GLP, unpublished BOD2001-690	
AIIA- 7.1.1.2.2	LeNoir, J.S. et al.	2002	Field soil dissipation of rimsulfuron herbicide applied as Rimsulfuron 25 WG to bare soil in Northern Europe. DuPont-3885 GLP, unpublished BOD2002-657	
AIIA- 7.1.1.2.2	LeNoir, J.S. et al.	2002	Field soil dissipation of rimsulfuron herbicide applied as Rimsulfuron 25 WG to bare soil in Central Europe. DuPont-3802 GLP, unpublished BOD2002-656	
AIIA- 7.1.1.2.2	LeNoir, J.S. et al.	2002	Field soil dissipation of Rimsulfuron herbicide applied as Rimsulfuron 25 WG to bare soil in Southern Europe. DuPont-3884 GLP, unpublished BOD2002-655	
AIIA- 7.1.1.2.2	Taylor, K.A. et al.	2001	Field soil dissipation of rimsulfuron herbicide applied as Rimsulfuron 25WG to bare soil in Northern Europe -Interim report DuPont-3885 GLP, unpublished BOD2001-695	
AIIA- 7.1.1.2.2	Taylor, K.A. et al.	2001	Field soil dissipation of rimsulfuron herbicide applied as Rimsulfuron 25WG to bare soil in Central Europe -Interim report DuPont-3802 GLP, unpublished BOD2001-694	

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	Reports on previous use in granting national authorizations
AIIA- 7.1.1.2.2	Taylor, K.A. et al.	2001	Field soil dissipation of rimsulfuron herbicide applied as Rimsulfuron 25WG to bare soil in Southern Europe -Interim report DuPont-3884 GLP, unpublished BOD2001-693	
AIIA-7.1.2	Hatzenbeler, C.J. and Landphair, C.R.	2000	Adsorption/desorption of [14C]IN-E9260 (a metabolite of rimsulfuron) in four soils. DuPont-3506 GLP, unpublished BOD2001-698	
AIIA-7.1.2	Hatzenbeler, C.J. and Landphair, C.R.	2000	Batch equilibrium (adsorption/desorption) of [14C]IN-70942 (a metabolite of rimsulfuron) in four soils. DuPont-3508 GLP, unpublished BOD2001-697	
AIIA-7.1.2	Hatzenbeler, C.J. and Landphair, C.R.	2000	Batch equilibrium (adsorption/desorption) of [14C]IN-70941 (a metabolite of rimsulfuron) in four soils. DuPont-3507 GLP, unpublished BOD2001-696	
AIIA- 7.2.1.1; AIIA- 7.2.1.3.2	Trabue, S.L. and Lydick, T.M.	2001	Degradation of rimsulfuron in two water sediment systems. DuPont-3980 GLP, unpublished WAS2001-303	
AIIA-2.9.3; AIIA- 7.2.1.2	Trabue, S.L. and Schmuckler, M.E.	2001	Calculation of the quantum yield of rimsulfuron (DPX-E9636) and IN-70942 in water. DuPont-5719 not GLP, unpublished LUF2001-246	
AIIA-2.10; AIIA-7.2.2	Moore, L.A.	2001	The stability in air of rimsulfuron (DPX-E9636): Atkinson calculation. DuPont-3921 GLP, unpublished WAS2001-304	

B.9 Ecotoxicology

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	Reports on previous use in granting national authorizations
AIIA-8.1.3	Beavers, J.B., Foster, J.W., Mitchell, L.R. and Jaber, M.	1994	H-17,463 (Rimsulfuron): A one-generation reproduction study with the northern bobwhite (<i>Colinus virginianus</i>). 112-337/HLO #257-94 GLP, unpublished AVS98-00148	Comment of Notifier: Submitted in BE
AIIA-8.1.3	Frey, L.T., Foster, J.W., Beavers, J.B. and Jaber, M.	1996	DPX-E9636-22 (Rimsulfuron): A reproduction study with the mallard (<i>Anas platyrhynchos</i>). 112-423/AMR-3553-95 GLP, unpublished AVS2000-34	Comment of Notifier: Submitted in DE
AIIA-8.2.1	Grube, P.W.	1998	IN-70941: Static-Renewal, Acute, 96-Hour Limit Test to Rainbow trout, <i>Oncorhynchus mykiss</i> . 1997-00909 GLP, unpublished WAT2001-673	Comment of Notifier: Submitted in NL
AIIA-8.2.1	Pottinger, T.G.	1992	A study of the acute toxicity to fish (rainbow trout) of DPX-E9260. FT-16 GLP, unpublished WAT2001-691	
AIIA-8.2.5; AIIIA- 10.2.1	Baer, K.N.	1991	Chronic Toxicity of IN E9636-37 to <i>Daphnia magna</i> . HLR 134-91 GLP, unpublished WAT2000-94	Comment of Notifier: Submitted in DE, IT, NL, UK
AIIA-8.2.6	Sloman, T.L.	2000	Rimsulfuron technical: Influence on Growth and Growth rate of the Blue-Green Alga <i>Anabaena flos-aquae</i> . DuPont-3777 GLP, unpublished WAT2001-684	
AIIA-8.2.6	Sloman, T.L.	2000	IN-E9260: Influence on Growth and Growth rate of the Green Alga <i>Selenastrum</i> capricornutum. DuPont-3761 GLP, unpublished WAT2001-685	
AIIA-8.2.6	Sloman, T.L.	2000	IN 70942: Influence on Growth and Growth Rate of the Green Alga <i>Selenastrum</i> capricornutum. DuPont-3743 GLP, unpublished WAT2001-683	

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	Reports on previous use in granting national authorizations
AIIA-8.3	Wainwright, M.	2001	Rimsulfuron 25 WG (DPX-E9693): Acute oral toxicity to the honey bee, <i>Apis mellifera</i> L. (Hymenoptera, Apidae) and Rimsulfuron 25 WG (DPX E9636) plus IN-KG691 surfactant: Acute oral and contact toxicity to the honey bee, <i>Apis mellifera</i> L. (Hymenoptera, Apidae). DuPont-5654 GLP, unpublished BIE2002-9	
AIIA-8.3.2; AIIIA- 10.5.1	Bruhnke, C.	2001	Rimsulfuron 25WG (DPX-E9636): Laboratory Study to Evaluate the Effects on the Ground Active Predator <i>Aleochara bilineata</i> (Coleoptera, Staphylinidae). DuPont-4010! Proj.Nr.000301DL GLP, unpublished ANA2002-51	
AIIA-8.4.2	Lührs, U.	2001	IN-70942: Effects on reproduction and growth of the earthworm, <i>Eisenia fetida</i> (Savigny 1826), in artificial soil. DuPont-4156 GLP, unpublished ARW2002-41	
AIIA-8.4.2	Lührs, U.	2001	IN-E9260: Effects on reproduction and growth of the earthworm, <i>Eisenia fetida</i> (Savigny 1826), in artificial soil. DuPont-4157 GLP, unpublished ARW2002-42	
AIIA-8.4.2	Lührs, U.	2001	IN-70941: Effects on reproduction and growth of the earthworm, <i>Eisenia fetida</i> (Savigny 1826), in artificial soil. DuPont-4155 GLP, unpublished ARW2002-40	
AIIA-8.5	Reis, KH.	2001	IN-E9260: Effects on soil non-target microorganisms. DuPont-6345 GLP, unpublished BMF2002-17	
AIIA-8.5	Wachter, S.	2001	IN-70941: Assessment of the effects on soil microflora. DuPont-4116 GLP, unpublished BMF2002-18	

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	Reports on previous use in granting national authorizations
AIIA-8.6; AIIIA-10.8	Leva, S.E. and Rardon, P.	2001	Summary of Herbicide screening data for major metabolites of Rimsulfuron. DuPont-6787 not GLP, unpublished PFL2002-23	
AIIA-8.7	Hertl, J.	2001	Rimsulfuron (DPX-E9636) Technical: Activated sludge, Respiration Inhibition Test. DuPont-4481 GLP, unpublished WAT2001-688	