



TEFLUTHRIN

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 3.0

Rapporteur Member State: DE

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Version 3.0 - (28.12.2012)

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	Reports¹ on previous use in granting national authorizations
KIIA 1.10 (OECD)	McIntyre, A.D.	2004	Tefluthrin - Mass spectral library of tefluthrin and related impurities ICI993/0688!TMJ4897B GLP: N, published: N 1864727 /	
KIIA 1.10 (OECD)	Salvesen, T.	2005	Confirmation of identity of components using GC/MS ICI993/1291!05AS054 GLP: N, published: N 1864725 /	
AIIA-1.11	McIntyre, A.D.	2003	Detailed analysis of technical materials representative of established large scale production. ICI993/0651 GLP, unpublished CHE2004-2146	
KIIA 1.11.1	Das, R.	2012	Tefluthrin - Analysis of five representative production batches produced by Huddersfield Manufacturing Centre, Huddersfield, West Yorkshire, HD2 1FF ICI993_10075! 124636 GLP: Y, published: N 2330978	

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KIIA 1.11.1	Das, R.	2012	Tefluthrin - Analysis of five representative production batches produced by Huddersfield Manufacturing Centre, Huddersfield, West Yorkshire, HD2 1FF for hexachlorobenzene ICI993_10076! 124678 GLP: Y, published: N 2330979	
KIIA 1.11.2 (OECD)	Giovannoni, J.	2009	Analysis of a Tox-Reserve (batch P24) ICI993_10008!119871!10388612 GLP: Y, published: N 1864722 /	
KIIA 1.11.2 (OECD)	Giovannoni, J.	2009	Analysis of a Tox-Reserve (batch P25) ICI993_10009!119872!10388895 GLP: Y, published: N 1864723 /	
KIIA 2.2 (OECD)	Weissenfeld, M.	2009	Determination of the relative density (purified A.I.) ICI993_10002!C30863 GLP: Y, published: N 1864724 /	
AIIA-4.1.1	McIntyre, A.D.	2003	The determination of tefluthrin in technical material by capillary gas chromatography. ICI993/0649 not GLP, unpublished CHE2004-2143	
AIIA-4.1.2	McIntyre, A.D.	2003	The determination of tefluthrin associated impurities in technical material by capillary gas chromatography. ICI993/0648 not GLP, unpublished CHE2004-2157	
AIIA-4.1.3	McIntyre, A.D.	2003	Tefluthrin - Validation of analytical methods SA-4/1 and SB-7/1. ICI993/0646 GLP, unpublished CHE2004-2156	
AIIA-4.2.1	Klimmek, S.	2004	Independent Laboratory Validation of the Method -RCC Study No. 850747 (S19) - for the Determination of Residues of tefluthrin in/on Maize Grain and Sugar Beet Roots. ICI993/0810 GLP, unpublished MET2004-896	

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.

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AIIA-4.2.1	Tribolet, R.	2004	Analytical Method Validation (S-19) for tefluthrin in maize grain, maize straw, sugar beet roots, sugar beet leaves with tops, oil seed rape and oranges. ICI993/0676 GLP, unpublished MET2004-892	
KIIA 4.2.3	Kouzoumis, A.; Das, R.	2012	Analytical method SB-55/1: Tefluthrin technical - Determination of the relevant impurity: hexachlorobenzene ICI993_10073! SB-55/1 GLP: N, published: N 2330980	
KIIA 4.2.3	Das, R.	2012	Tefluthrin - Validation of analytical method SB-55/1 ICI993_10074! 124252 GLP: Y, published: N 2330981	
KIIA 4.3 (OECD)	Osborne, V. A.	2004	Residue Study with Tefluthrin (ICI 993) in or on Sugar Beet derived from Treated Seeds in Southern France ICI993/0806 ! 03-5009 GLP: Y, published: N 1864729 /	
KIIA 4.4 (OECD)	Hargreaves, S.	2006	Tefluthrin - Residue Method for the Determination of Tefluthrin in Soil ICI993/1184 ! GRM002.04A GLP: N, published: N 1864731 /	
KIIA 4.4 (OECD)	Nagra, B.S.	2005	PP890: Validation of an Analytical Method for the Determination of Residues of Tefluthrin Metabolite PP890 in Soil PP890/0007 ! RJ3608B!04-S507 GLP: Y, published: N 1864733 /	
KIIA 4.7 (OECD)	Tribolet, R.	2005	Method (RCC 8556939) and validaion of residue analytical method for determination of Tefluthrin in air ICI993/0862 ! 855693 GLP: Y, published: N 1864734 /	

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KIIA 4.5 (OECD)	Robinson N., Gemrot F., Braid S.	2010	Tefluthrin - Analytical Method for the Determination of Residues of Tefluthrin in Water. Final Determination by GC-MS GRM002.07A GLP: Y, published: N BVL-SYNGB187-01.00 IDD0000299687 ASB2010-11059	
KIIA 4.5 (OECD)	Gemrot, F.	2010	Tefluthrin – Validation of Residue method GRM002.07A for the determination of tefluthrin in water TK0025620-REG GLP: Y, published: N BVL-SYNGB187-01.00 IDD0000299688 ASB2010-11060	
KIIA 4.8 (OECD)	Richardson, M.	2007	Tefluthrin (ZA0993) - Residue method for the determination of tefluthrin in whole blood. Final determination by GC-MSD ICI993/1343 ! GRM002.05A GLP: N, published: N 1864735 /	
KIIA 4.8 (OECD)	Jones, S.	2007	To conduct a validation of tefluthrin on whole blood using the sponsor method GRM002.05A ICI993/1342 !AD/12301/SY GLP: Y, published: N 1864736 /	

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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
KIIA 5.4.1 (OECD)	Sokolowski A.	2008	R290193 - Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay - Final Report ICI993/1399 ! 1139502 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864739 /	
KIIA 5.4.1 (OECD)	Sokolowski A.	2008	SYN545561 - Salmonella Typhimurium And Escherichia Coli Reverse Mutation Assay ICI993/1398 ! 1139501 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864740 /	

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
KIIA 6.2.1 (OECD)	Anderson, W., Brown, K.	2006	[Phenyl-U-14C] Tefluthrin and [Cyclopropane-14C] Tefluthrin - Nature of the Residue in Cabbage ICI993/1190 ! T001039-05 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864742 /	
KIIA 6.3 (OECD)	Boxwell, C.	2006	Tefluthrin (ICI993): Residue Study on Sugar Beet in Greece - Seed Treatment ICI993/1155 ! 05-5007 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864743 /	

B.8 Environmental fate and behaviour

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
KIIA 7.2.1 KIIA 7.8.3 (OECD)	Harradine K	2009	Tefluthrin - Evaluation of Kinetic modelling for aerobic soil degradation and water : sediment studies undertaken in the laboratory ICI993_10003 Syngenta - Jealott's Hill, Bracknell, United Kingdom GLP: N, published: N 1864749 / 1864758	
KIIA 7.2.3 (OECD)	Voelkel W.	2005	Tefluthrin: Degradation of PP890, a Metabolite of Tefluthrin and Lambda Cyhalothrin, in Three Soils Incubated under Aerobic Conditions PP890/0009 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864750 /	
KIIA 7.2.3 (OECD)	Mamouni A.	2005	R153946 (Metabolite of Tefluthrin): Degradation in three soils incubated under aerobic conditions R153946/0004 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864751 /	
KIIA 7.3.1 (OECD)	Nagra B.	2006	Dissipation Study with A13226H, Tefluthrin 1.5 G, in or on Cultivated Soil in Germany ICI993/1164 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864752 /	
KIIA 7.3.1 (OECD)	Nagra B.	2006	Dissipation Study with A13226H, Tefluthrin 1.5 G, in or on Cultivated Soil in Italy ICI993/1163 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864753 /	
KIIA 7.3.1 (OECD)	Nagra B.	2006	Dissipation Study with A13226H, Tefluthrin 1.5 G, in or on Cultivated Soil in Spain ICI993/1186 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864754 /	

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KIIA 7.3.1 (OECD)	Balluff M.	2008	Dissipation Study with A13226H, Tefluthrin 1.5 GR, in or on Cultivated Soil in France (North) ICI993/1406 Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom GLP: Y, published: N 1864755 /	
KIIA 7.4.2 (OECD)	Voelkel W.	2005	Tefluthrin: Adsorption/Desorption of [14C]-PP890, a Metabolite of Tefluthrin and Lambda Cyhalothrin, on Three Soils PP890/0010 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864756 /	
KIIA 7.4.2 (OECD)	Oliver R., Edwards P.	2005	Tefluthrin Metabolite R153946: Adsorption/Desorption Properties in Three Soils R153946/0003 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864757 /	

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
KIIA 8.1.2 (OECD)	Gallagher S., Beavers J.	2007	Tefluthrin Technical: Effects of Short Term Dietary Exposure on Individually Caged Adult Northern Bobwhite ICI993/1290 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864759 /	
KIIA 8.1.4 (OECD)	Temple D, Martin K, Beavers J, Jaber M	2009	Tefluthrin - A reproduction study with the northern bobwhite ICI993_10001 Syngenta - Jealott's Hill, Bracknell, United Kingdom GLP: Y, published: N 1864760 /	
KIIA 8.1.4 (OECD)	Prescott C.	2004	The assessment of Wood mouse acceptance /avoidance of different crop seeds when presented in free feeding conditions to individually caged animals in a six hour no- choice situation; and to monitor the incidence of de-husking for each seed type. N/1014 Syngenta Crop Protection AG, Basel, Switzerland GLP: N, published: N 1864778 /	
KIIA 8.1.4 (OECD)	Thompson H.	2007	Tefluthrin - Study to assess avoidance and effects in the wood mouse (<i>Apodemus sylvaticus</i>) ICI993/1317 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864779 /	
KIIA 8.1.4 (OECD)	Watkins R.	2005	Uncoated, film-coated, encrusted and pelleted seeds: Palatability of seed coatings to House sparrows (<i>Passer domesticus</i>) MK936/1494 Syngenta Crop Protection AG, Basel, Switzerland GLP: N, published: N 1864780 /	
KIIA 8.1.4 (OECD)	Watkins R.	2005	Uncoated, film-coated, encrusted and pelleted seeds: Palatability of seed coatings to Grey partridge (<i>Perdix perdix</i>) MK936/1493 Syngenta Crop Protection AG, Basel, Switzerland GLP: N, published: N 1864781 /	

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KIIA 8.1.4 (OECD)	Thompson H	2009	Study to assess the exposure of the woodmouse (Apodemus sylvaticus) consuming treated sugarbeet seed NA_11519 Syngenta - Jealott's Hill, Bracknell, United Kingdom GLP: N, published: N 1864782 /	
KIIA 8.10 (OECD)	Friedrich S.	2006	Tefluthrin (ICI993) CS (200) (A13219F): Effects on the reproduction of the collembolans Folsomia candida ICI993/0986 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864774 /	
KIIA 8.10 (OECD)	Liepold K.	2007	Tefluthrin (A13226H and A13219F) - Effects on the Decomposition of Organic Matter in the Field ICI993/1288 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864775 /	
KIIA 8.15 (OECD)	Seyfried B.	2006	Tefluthrin technical (ICI993) Toxicity to activated sludge in a respiration inhibition test ICI993/1161 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864783 /	
KIIA 8.2.1.3 (OECD)	Hill RW	1986	2,3,5,6-Tetrafluoro-4-methyl benzoic acid: Determination of acute toxicity to bluegill sunfish (Lepomis macrochirus) ICI993/0534 Zeneca Agrochemicals, Jealott's Hill, United Kingdom GLP: Y, published: N 1864761 /	
KIIA 8.2.1.3 (OECD)	Hill RW	1986	2,3,5,6-Tetrafluoro-4-methyl benzoic acid: Determination of acute toxicity to rainbow trout (Salmo gairdneri) ICI993/0532 Zeneca Agrochemicals, Jealott's Hill, United Kingdom GLP: Y, published: N 1864762 /	

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KIIA 8.3.1.1 (OECD)	Farrelly E, Hamer MJ, Hill IR	1986	2,3,5,6-Tetrafluoro-4-methyl benzoic acid: An investigation of the toxicity to First Instar Daphnia magna ICI993/0564 Zeneca Agrochemicals, Jealott's Hill, United Kingdom GLP: Y, published: N 1864765 /	
KIIA 8.5.1 (OECD)	Benyon K., Wyeth K.	2006	Tefluthrin technical: Acute toxicity to Chironomus riparius under static conditions ICI993/0980 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864767 /	
KIIA 8.5.2 (OECD)	Pfeifle V., Wyeth K., Dark R.	2005	Tefluthrin technical: Effects on the development of sediment-dwelling larvae of Chironomus riparius in a water-sediment system ICI993/0868 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864768 /	
KIIA 8.7.1 (OECD)	Kling A	2008	PP890 (R119890) - Acute Oral and Contact Toxicity to the Honeybee Apis mellifera L. In the Laboratory PP890_10757 Syngenta - Jealott's Hill, Bracknell, United Kingdom GLP: Y, published: N 1864769 /	
KIIA 8.7.1 (OECD)	Kling A	2008	R173204 - Acute Oral and Contact Toxicity to the Honeybee Apis mellifera L. In the Laboratory R173204_10852 Syngenta - Jealott's Hill, Bracknell, United Kingdom GLP: Y, published: N 1864770 /	
KIIA 8.8.2 (OECD)	Bruehl C., Halsall N.	2006	ZA0993 (Tefluthrin): Evaluation of Potential Side-effects of a Granular Formulation of Tefluthrin (A13226H) to Ground and Soil Dwelling Non-target Arthropods under Field Conditions in Maize ICI993/1189 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864771 /	

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KIIA 8.9.2 (OECD)	Coulson J., Yearsdon H., Edwards P., et.al.	2006	Tefluthrin: An Investigation of the Effects of Pelleted-Seed Treatments on Earthworms in Sugar Beet. ICI993/0521 Zeneca Agrochemicals, Jealott's Hill, United Kingdom GLP: Y, published: N 1864772 /	
KIIA 8.9.2 (OECD)	Friedrich S.	2006	Tefluthrin (ICI993) CS (200) (A13219F): Sublethal toxicity to the earthworm Eisenia fetida ICI993/0984 Syngenta Crop Protection AG, Basel, Switzerland GLP: Y, published: N 1864773 /	