

# **ENDOSULFAN**

## **List of studies not cited in the monograph**

**B.1 Identity**

<b>Annex IIA, or Annex IIIA, point(s)</b>	<b>Year</b>	<b>Author(s) Title Company (insert name) Report No. Source (where different)</b>	<b>GLP GEP Y / N</b>	<b>Published Y / N</b>	<b>Owner</b>	<b>Data Protection</b>
	1999	S. Benjamin Preliminary analyses of five representative production batches of Endosulphan Technical grade active ingredient (TGAI) to determine % Endosulphan and to quantify its associated impurities JRF Study No.: 2255	Y		Excel	N

**B.2 Physical and chemical properties**

<b>Annex II A, or Annex III A, point(s)</b>	<b>Year</b>	<b>Author(s) Title Company (insert name) Report No. Source (where different)</b>	<b>GLP GEP Y / N</b>	<b>Published Y / N</b>	<b>Owner</b>	<b>Data Protection</b>
	1999	K. Ayyavoo Accelerated storage stability of Endosulfan 35 EC JRF Study No.: 1726	Y	-	Excel	N
	1999	K. Ayyavoo Physical state of Endosulfan 35 EC (colour & appearance) JRF Study No.: 2057	Y	-	Excel	N
	1987	FAO 6, 7, 8, 9, 10, 10-hexachloro-1, 5, 5a, 9, 9a- hexahydro-6, 9-methano-2, 4, 3- benzo[e]dioxathiepin 3-oxide	N	Y	Publ.	N
	2001	K.A. Sayyad Appearance (colour, physical state and odour) on Endosulfan Technical. JRF Study No.: 3149	Y	-	Excel	N

**B.3 Further information and efficacy**

No new studies submitted.

**B.4 Proposal for classification and labelling**

The applicant has not submitted any reference concerning this point.

**B.5 Methods of analysis**

<b>Annex IIA, or Annex IIIA point(s)</b>	<b>Year</b>	<b>Author (s) Title Company (insert name) Report No. Source (where different)</b>	<b>GLP GEP Y / N</b>	<b>Published Y / N</b>	<b>Owner</b>	<b>Data Protection</b>
	1999	Martens, R. Enforcement method and validation for water by GC Deltamethrin Endosulfan (Codes: AE F032640; AE F002671) Hoechst Schering AgrEvo GmbH Study identification: CR 99/023 (C005528)	N	N	AgrEvo	

**B.6 Toxicology**

<b>Annex IIA, or Annex IIIA point(s)</b>	<b>Year</b>	<b>Author (s) Title Company (insert name) Report No. Source (where different)</b>	<b>GLP GEP Y / N</b>	<b>Published Y / N</b>	<b>Owner</b>	<b>Data Protection</b>
	1988	TSS Dikshith PhD, R.B. Raizada PhD, S.N. Kumar PhD, M.K. Srivastava PhD, R.A. Kaushal BSc, R.P. Singh BSc and K.P. Gupata MSc Effect of repeated dermal application of Endosulfan to Rats  [REDACTED]	N	Publ.	AgrEvo	N
	1989	Edward, L. Carmines, Ph. D. Evaluation of the Human Hazards and risks associated with the application of Endosulfan (Hoechst Celanese Corporation A 59892)	N	N	AgrEvo	Y
	1993	Colborn, T.; vom Saal, F.S.; Soto, A.M. Developmental effects of endocrine-disrupting chemicals in wildlife and humans.  Environ Health Perspect 1993 Oct.; 101 (5) : 378-384		Y	Publ.	N
	1994	Soto, A.M.; Chung, K.L.; Sonnenschein, C. The pesticides endosulfan, toxaphene, and dieldrin have estrogenic effects on human estrogen-sensitive cells.  Environ Health Perspect 1994 Apr.; 102 (4) : 380-383		Y	Publ.	N
	1996	Banerjee, B.D.; Koner, B.C.; Ray, A. Immunotoxicity of pesticides: perspectives and trends.  Indian J. Exp. Biol. 1996 Aug.; 34 (8) : 723-733		Y	Publ.	N
	1996	Mich, G. Operator exposure in greenhouse during practical use of Plant Protection Products ECON Forschungs und Bewertungskonzepte für Umwelt und Gesundheitssicherheit GmbH C009112	Y	N	AgrEvo	Y
	1996	Vonier, P.M.; Crain, D.A.; McLachlan, J.A.; Guillette, L.J. Jr.; Arnold, S.F. Interaction of environmental chemicals with the estrogen and progesterone receptors from the oviduct of the American alligator. Environ Health Perspect 1996 Dec; 104 (2) : 1318-1322		Y	Publ.	N
	1997	George M. Singer, Mark G. Bookbinder, David A. Winkler Biomonitoring exposure of workers during mixing/loading and application of THIODAN® 35 EC (Endosulfan). Insecticide for control of coffee berry borers in Colombia. Heinz Sochor, Ph. D. – AgrEvo GmbH EN-CAS Project number 95-028 – A58676	N	N	AgrEvo	Y

Annex IIA, or Annex IIIA point(s)	Year	Author (s) Title Company (insert name) Report No. Source (where different)	GLP GEP Y / N	Published Y / N	Owner	Data Protection
	1997	George M. Singer, Mark G. Bookbinder, David A. Winkler Monitoring exposure of workers during Mixing/Loading and application of THIODAN ® 35 EC (Endosulfan). Insecticide for Control of coffee berry borers in Colombia [REDACTED] EN-CAS Project number 95-044 – A58632	N	N	AgrEvo	Y
	1997	Wade, M.G., Desaulniers, D., Leingartner, K., Foster, W.G. Interactions between endosulfan and dieldrin on estrogen-mediated processes in vitro and in vivo. <i>Reprod Toxicol</i> Nov. 1997; 11(6) : 791-798		Y	Publ.	N
	2000	Chromosome aberration assay in bone marrow cells to the rat with Endosulfan, substance technical (Code AE F002671 00 1D99 0008) [REDACTED] C007976	N	N	AgrEvo	Y
	2000	Wicke, H. Monitoring exposure of workers during mixing/loading and application of brestanid flow (fentin-hydroxide) fungicide for control of potato late blight in the UK (Code AE F029664 00 SC41 A2) Aventis Crop Science GmbH CR 99/009 – C008680	N	N	Aventis	Y
	2001	Wicke, H.; K.H. Leist Update of the EU-summary on Endosulfan comments to toxicological studies, re-evaluation of the operator exposure and risk assessment for Thiodan 35EC (Code: AE F002671 00 EC33 B3) Aventis CropScience GmbH C010955	N	N	Aventis	Y
	2001	Leist, K. H. Comments to toxicological studies update of the EU-summary on Endosulfan; Skin penetration; AOEL calculation (Substance code: AE F002671) Aventis CropScience GmbH C011009	N	N	Aventis	Y
		Endosulfan – Estimation of the maximum amount absorbed by Colombian Farm workers and comparison between exposure and absorption. Hoechst and Shering C008763 – Report No. OE96/095	N	N	AgrEvo	Y
IIIA, 7.1/A39279	1988	Ph. Thévenaz, H. Luetkemeier, H.J. Chevalier, W. Voegel, Ch. Terrier Endosulfan: Emulsifiable concentrate (Code: HOE 002671 OI EC34 A101) – Subchronic (4-week) repeated dose dermal toxicity study in rats. [REDACTED] A39279	Y	N	AgrEvo	Y



Annex IIA, or Annex IIIA point(s)	Year	Author (s) Title Company (insert name) Report No. Source (where different)	GLP GEP Y / N	Published Y / N	Owner	Data Protection
IIIA/7.1/A394 26	1988	Ernet, E.  Endosulfan – water-dispersible powder (50 %) (Code: Hoe 002671 OI WP50 A501). Subchronic dermal toxicity (21 treatments in 30 days) in the Wistar rat. Hoechst Report No. 88.1209 – Study No. 87.0664	Y	N	AgrEvo	Y
<b>Further information, May 2001</b>						
IIA, 5.2.4	1997a	Bremmer Primary Dermal Irritation in the rabbit  Doc. No. A58442	Y	N	AgrEvo	Y
IIA, 5.2.5	1997b	Bremmer Primary Eye Irritation in the rabbit  Doc. No. A58443	Y	N	AgrEvo	Y
IIA, 5.2.6	1996	Arcelin Contact hypersensitivity in albino guinea pigs. Maximization Test.  Doc. No. A58132	Y	N	AgrEvo	Y
IIA, 5.3.2.1/2	1985	Bernard, <i>et al</i>  13 week toxicity study in rats followed by 4-week withdrawal period. Doc. No. A30700	Y	N	AgrEvo	Y
IIA, 5.3.2.3/3	1989	Brunk 1 year feeding study to Beagle dogs  Doc. No. A40441	Y	N	AgrEvo	Y
IIA, 5.3.3.1/1	1985a	Ebert Subchronic dermal toxicity in Wistar rats  Doc. No. A30750	Y	N	AgrEvo	Y
IIA, 5.4	1983	Jung, Weigand and Kramer Mouse micronucleus test following oral administration  Report No. 83.0458	Y	N	AgrEvo	N
IIA, 5.4	1989	Rupa, D.S., Reddy, P.P. and Reddi, O.S. Chromosomal aberrations in peripheral lymphocytes of cotton field workers exposed to pesticides Published in Environmental Research, 49: 1-6		Y	Publ.	N
IIA, 5.4	1990	Fransson, R. Toxicological evaluation of the insecticide endosulfan Report No. A67384	N	N	AgrEvo	Y
IIA, 5.4	1991b	Rupa, D.S., Reddy, P.P. and Reddi, O.S. Clastogenic effect of pesticides in peripheral lymphocytes of cotton-field workers Published in Mutation Research, 261: 177-180		Y	Publ.	N

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IIA, 5.4	1995	Sinha, N., Narayan, R., Shanker, R. and Saxena, D.K. Endosulfan-induced biochemical changes in the testis of rats.  Published in Vet. Human Toxicol., 37: 547-549		Y	Publ.	N
IIA, 5.4	1996	Khan, P.K. and Sinha, S.P. Ameliorating effect of vitamin C on murine sperm toxicity induced by three pesticides (endosulfan, phosphamidon and mancozeb)  Published in Mutagenesis, 11: 33-36		Y	Publ.	N
IIA, 5.4	1997	Sinha, N., Narayan, R. and Saxena, D.K. Effect of endosulfan on the testis of growing rats.  Published in Bull. Environ. Contam. Toxicol., 58: 79-86		Y	Publ.	N
IIA, 5.4	2000	Völkner, W. Chromosome aberration assay in bone marrow cells of the rat with Endosulfan  Report No. 644101	Y	N	AgrEvo	N
IIIA, 7.1/A39426	1988	Ebert, E.  Endosulfan water dispersible powder (50%) subchronic dermal toxicity (21 treatments in 30 days) in the Wistar rat  Report No. 87.0664	Y	N	AgrEvo	Y
IIIA, 7.1/A39279	1988	Thevenaz, Ph., Luetkemeier, H.J., Chevalier, H.J., Vogel, W. & Terrier Ch. Endosulfan emulsifiable concentrate subchronic (4-week) repeated dose dermal toxicity study in rats  Report No. 88.1735	Y	N	AgrEvo	Y
<b>Further information, September 2001</b>						
	1997	Needham D & Gutierrez Giulianotti L Endosulfan – [14C] Code AE F002671: Distribution, metabolism and excretion in the rat following a single oral dose of 1 or 6 mg/kg body weight  Report No. A59694	Y	N	AgrEvo	Y
	1998	Needham D & Creedy CL & Hemming PA Endosulfan – [14C] Code AE F002671 00 1E: Toxicokinetics in the rat following repeated daily oral administration of 1 mg/kg bodyweight for up to 28 days  Report No. A67138	Y	N	AgrEvo	Y

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	2001	Needham D Endosulfan – [ <sup>14</sup> C]: Rat-Analysis of polar metabolites following a single oral dose of 6 mg/kg bodyweight  Study No. C010989	Y	N	Aventis	Y
	2001	Buerkle LW Summary of New ADME Studies with Rats and Comparison of Rat and Plant Metabolism  Study No. C013032	N	N	Aventis	Y

**B.7 Residue data**

<b>Annex IIA, or Annex IIIA point(s)</b>	<b>Year</b>	<b>Author (s) Title Company (insert name) Report No. Source (where different)</b>	<b>GLP GEP Y / N</b>	<b>Published Y / N</b>	<b>Owner</b>	<b>Data Protection</b>
	1996	Berthold Krebs, Helmut Bürstell, Gerald Huth Residue data summary from supervised trials and processing studies in Fruiting Vegetables PSR96/052 - 57133	Y		Agrevo	N
	1997	David A. Winkler Freezer storage stability of Endosulfan ( $\alpha$ , $\beta$ and sulfate) on crop raw agricultural commodities and processed commodities. BJ-95R-11 – A57831	Y		Agrevo	N
	1998	David A. Winkler Freezer storage stability of Endosulfan ( $\alpha$ , $\beta$ and sulfate) on crop raw agricultural commodities and processed commodities. Amendment No. 1 to Final Report BJ-95R-11 – A67528	Y		Agrevo	N
	1999	H. Welcker, R. Martens Decline of residues in protected tomatoes European Union [southern zone] 1998 – Endosulfan, AE F002671 (suspension of microcapsules (CS)) 25.78% w/w (= 330 g/L) ER 98 ECS 753 - C004455	Y		Agrevo	N

**B.8 Environmental fate and behaviour**

No new studies submitted.

**B.9 Ecotoxicology**

No new studies submitted.