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Monograph prepared in the context of the inclusion of the following active substance in Annex I of the Council Directive 91/414/EEC

ENDOSULFAN

Volume III.1

Summary, Scientific Evaluation and Assessments

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TABLE OF CONTENTS

ANNEX B

ENDOSULFAN

B - 1 : IDENTITY

B.1 Identity

B.1.1 Identity of the active substance (IIA, 1 and 3.1)

See Monograph Volume 1 Level 1 Section 1.3.

B.1.2 Identity of the plant protection product (IIIA, 1)

See Monograph Volume 1 Level 1 Section 1.4.

B.1.3 References relied on

Annex II or Annex III point(s)	Year	Author(s) Title Company (insert name) Report No. Source (where different)	GLP GEP Y / N	Published Y / N	Owner	Data Protection
IIA, 1.11	1993	Weller, O.; Guebert, M.; Guebert, C. Endosulfan (Hoe 002671) Analysis of seven typical production batches Hoechst C Produktentwicklung Oekologie 1, Germany. Report No.: A51214	No	No	AgrEvo	Yes
IIA, 1.3 / 1.5.1; IIIA, 1.4.2	1977	Heller Active Ingredient and Product Designations Hoechst AG. Report No.: A25302	No	No	AgrEvo	No
IIA, 1.4 / 1.7	1976	Heubach Active Ingredient and Product Designations Hoechst Pfl.Fo.Chem., Germany. Report No.: A25301	No	No	AgrEvo	No
IIA, 1.5.2; IIIA, 1.4.1	1995	Schoeni J.P.; Rexer, K. Endosulfan Emulsifiable concentrate 352 g/l (Code: Hoe 002671 00 EC33 B300) Composition Statement of the End Use Product AgrEvo Forschung Formulierung, Germany. Report No.: A53950	No	No	AgrEvo	Yes
IIA, 1.8	1992	Dehmer; Welter Hoe 002671 Endosulfan technical Description of beginning materials and manufacturing process Hoechst C Produktion Landwirtschaft, Germany. Report No.: A48048	No	No	AgrEvo	Yes
IIA, 1.9	1993a	Kehne Hoe 002671 technical. Purity Hoechst C Forsch.Chemie, Germany. Report A51120	No	No	AgrEvo	Yes
IIA, 1.10.1	1993b	Kehne Subject: Impurities Hoechst C Forsch.Chemie, Germany. Report A51117	No	No	AgrEvo	Yes
IIA, 1.10.2	1979a	Heubach Plant Protection / Designations of Substance and Formulated Product Hoechst Pfl.Fo.Chem., Germany. Report No.: A17530	No	No	AgrEvo	Yes
IIA, 1.10.2	1979b	Heubach	No	No	AgrEvo	Yes

Annex II or Annex III point(s)	Year	Author(s) Title Company (insert name) Report No. Source (where different)	GLP GEP Y / N	Published Y / N	Owner	Data Protection
		Plant Protection / Designations of Substance and Formulated Product Hoechst Pfl.Fo.Chem., Germany. Report No.: A17532				
IIA, 1.10.2	1979c	Heubach Plant Protection / Designations of Substance and Formulated Product Hoechst Pfl.Fo.Chem., Germany. Report No.: A17534	No	No	AgrEvo	Yes
IIA, 1.10.2	1984	Willms Plant Protection / Designations of a Substance Hoechst Pfl.Fo.Chem., Germany. Report No.: A29533	No	No	AgrEvo	Yes
IIA, 1.10.2	1987	Kehne Plant Protection / Substance Identity Hoechst Pfl.Fo.Chem., Germany. Repot No.: A35104	No	No	AgrEvo	Yes
IIA, 1.10.3	1993	Weller, O.; Welter, W. Hoe 002671 (Endosulfan) Discussion of the formation of impurities in the technical grade substance Hoechst C Produktentwicklung Oekologie 1, Germany. Report No.: A51137	No	No	AgrEvo	Yes
IIIA, 1.5	1985p	Roechling Endosulfan Emulsifiable Concentrate 352 g/l Hoechst Pfl.Formul., Germany. Report No.: A30557	No	No	AgrEvo	No
IIIA, 1.9/01	1994	Lesser, J. Technical thionex - analytical method development, validation and analysis for the aactive ingredient (AI) and impurities present in concentrations greater than or equal to 0.1%., MCW; israel Report No.: R-6768			M-Agan	
IIIA, 1.9/02	1991	Lesser, J. Endosulfan determination in technical endosulfan, MCW, Israel Report No.: R-5887			M-Agan	
IIIA, 6/01		Visvanathan, T.	No	Yes	Publ.	No

Annex II or Annex III point(s)	Year	Author(s) Title Company (insert name) Report No. Source (where different)	GLP GEP Y / N	Published Y / N	Owner	Data Protection
		Evaluation of endosulfan (Endocel 35 EC) for the control of major pests of cotton.				
IIIA, 10.1.10.3	1992	Ehmann, J. Hexachlorobenzene and pentachlorobenzene quantitation in technical endosulfan Institute Fresenius. Report No.: R-7028			M-Agan	

TABLE OF CONTENTS

ANNEX B

ENDOSULFAN

B - 9 : ECOTOXICOLOGY

B.9 Ecotoxicology

A large number of studies on the ecotoxicity of endosulfan for different non-target organisms has been submitted by the notifier. As usual for existing pesticides, the information arises form different sources and types of studies, which require a different approach for validation. The rapporteur has tried to assess the validity of all useful information, although it has not been possible to assess all the studies for different reasons.

The validity of the “ad hoc” studies conducted by the industry has been checked, as usual, going back to the original reports and when required, the raw data, while the scientific papers collected in the open literature have been submitted to a peer review in order to assess their validity either as essential source for data or as additional supporting information.

However, it has not been possible to check the validity of some of the reports, due to several reasons. In some cases, the reports submitted by the industry were not in English, in others, only a summary, incomplete documents or a presentation with references to non submitted studies were presented. These studies were considered as non validable and therefore have not been included in this assessment.

Finally, some of the studies submitted were regarded as non relevant for the intended uses included in this assessment, and therefore were not reviewed in depth.

In order to simplify the presentation of the relevant information, the rapporteur has tried to summarise in tables the available information as much as possible. Obviously, some studies require a specific presentation, and therefore the reader will found individual large descriptions for some studies while only a value and a reference included in a table are mentioned in other cases.

The active substance, technical endosulfan is a mixture of two isomers, alfa and beta, which have demonstrated to posses different characteristics in terms of their environmental fate and behaviour. The rapporteur has revised the information to address the possibility of considering these differences in the ecological risk assessment of endosulfan. However, the available information on the relative toxicity of each isomer and the potential to predict synergistic effects at different alpha/beta ratios does not exist or is too scarce for a proper assessment. Therefore, the current assessment compares the predicted environmental concentrations for the active substance as a whole versus the toxicity data reported for technical endosulfan, without considering differences between the environmental fate differences of the isomers. If the notifier presents the required information, a refinement of this assessment to consider these differences could be conducted.

In addition, the route of degradation of endosulfan has not been properly addressed, although the production of endosulfan sulphate, a metabolite considered by the notifier as of equivalent toxicity than the parent compound is evident.

The rapporteur considers that there is not enough validable information to refine the risk by using twa-PECs, particularly when several applications per season are considered. Therefore, only the initial PECs have been used in the assessment, and the risk of metabolites has not been addressed due to lack of information.

B.9.1 Effects on birds (IIA, 8.1; IIIA, 10.1)

The toxicity of the active substance has been addressed for at least two bird species, while no studies on the formulated product have been submitted. The studies submitted regarding acute and reproduction toxicity were specific studies conducted for endosulfan, while the short-term toxicity is only addressed in a general report which included several pesticides. Each study will be individually commented.

B.9.1.1 Acute oral toxicity

- **Active substance**

Roberts and Phillips, 1983
The Acute Oral Toxicity (LD 50) of Endosulfan-technical to the Bobwhite Quail was studied. The test was conducted under EPA guidelines and with GLP. The study is considered valid.

Six groups of five males and five females of Bobwhite Quail were treated with different doses of endosulfan (corn oil was used as vehicle). Bodyweight changes and food consumption were considered within normal limits. Birds on groups 4 and 5 became subdued; unsteadiness signs were found in birds on group 6. No abnormalities were detected in any birds during post mortem examination.

The LD_{50} was calculated to be 42 mg/kg body weight, with 95% confidence limits of 35 mg/kg - 56 mg/kg.

Roberts and Phillips, 1983 b
The Acute Oral Toxicity (LD_{50}) of Endosulfan-technical was investigated to the Mallard Duck. The study was conducted under GLP and performed following the US EPA pesticides guidelines. The study is considered valid.

Six groups of ten animals (males and females), were dosed as followed: 0, 5, 10, 20, 40, and 80 mg/kg. The mortalities occurred within 4 hours of dosing. The LD_{50} was calculated to be 28 mg/kg with 95% confidence limits of 22 mg/kg - 36 mg/kg bodyweight. Shortly after dosing, birds in groups 4, 5 and 6 (Endosulfan at 20, 40 and 80 mg/kg respectively) showed signs of unsteadiness. Surviving birds in groups 4 and 5 remained unsteady for several hours, but recovered by the end of day 1. Bodyweight increases during the 7-day period following dosing (days 0 - 7) and no treatment-related effects were seen. Food consumption and gross post mortem abnormalities were within normal limits.
The acute oral toxicity (LD_{50}) of endosulfan, technical substance to the mallard duck was calculated to be 28 mg/kg (95% confidence limits: 22-36 mg/kg).

- **Plant Protection product**

No studies have been submitted.

B.9.1.2 Dietary short-term toxicity

- **Active substance**

Hill *et al*., 1975

This study correspond to a generic study conducted by the US EPA to assess the short-term risks of several chemicals to birds. The study includes several pesticides and therefore the rapporteur considered that the validation of the study should not be conducted at a substance-by-substance level, but as a generic decision of the ECCO meeting, including comparison between the results presented in this report and those obtained in other recent studies. For the specific case of endosulfan no other studies have been submitted, and therefore the results will be used in the assessment, while the final decision on the need to request an additional specific study will be considered at the ECCO level.

The study shows the results of the endosulfan short-term toxicity in four species. These studies were not conducted under GLP, but along the lines of the experimental design specified in the OECD guideline nº. 205. During the five days exposure period fresh diet was added to all pens daily. Mortality and food consumption was recorded daily. No other symptoms were recorded. The results for the species are:

- Bobwhite quail:	805 (690-939) ppm
- Japanese quail:	≅1250 (not stated) ppm
- Ring-necked pheasant:	1275 (1098-1482) ppm
- Mallard:	1053 (781-1540)ppm.

- **Plant Protection Products**

No information has been submitted.

B.9.1.3 Effects on reproduction

- **Active substance**

Scholz; Weigand , 1973

This study was performed with Thiodan ENDOSULFAN Op 2/387 97.1 % active ingredient. The test was not conducted under GLP. One control group and four groups of Japanese quail were feed with chick diet mixed with different concentrations of Thiodan dissolved in acetone during 30 days. Test concentration and duration was:

- group I: 500 ppm; 14 days
- group II: 50 ppm; 28 days
- group III: 5 ppm; after day 28 these animals were given non-contaminated feed until day 35.
- group IV: control

The behaviour and general physical conditions were checked daily. The body weight was determined twice a week. The egg production was checked daily from the 14th trial day onward. The birds showed a normal behaviour except one male that died without substance-induced signs. The weight increments of the male quails in the test group I (500 ppm) were stagnant or slightly declining as compared to the control birds. The weight increases of the females in group I and the males and females of the remaining test groups were normal and corresponded to that of the controls.

The weight increments of the male quails in the test group I (500 ppm) were stagnant or slightly declining as compared to the control birds. The weight increases of the females in group I and the males and females of the remaining test groups were normal and corresponded to that of the controls.

The histological examination showed no macroscopically or microscopically changes in the organs except in the liver, where the examination in test group III (5 ppm) produced moderate, in test group II and I (50 and 500 ppm) very marked fat retention in the liver of the treated female birds with medium to large fat droplets. The residue analyses for endosulfan revealed in the 500 ppm concentration distinct concentration in the fatty tissue, in the liver, the ovaries and the faeces. Analyses of diets for endosulfan were not conducted.

The endosulfan NOEC for Japanese quail was 50 ppm, equivalent to a mean daily substance intake of approx. 5 mg/kg body weight.

Roberts and Phillips, 1984

The Effects of Dietary Inclusion of Endosulfan - Technical on Reproduction in the Bobwhite Quail were investigated. The study was conducted under EPA guidelines and with GLP. Acetone and corn oil were used to aid dispersion of the test substance in the diet. The test substance was dissolved in the minimum volume of acetone necessary and then mixed with corn oil so that the resulting amount would be equivalent by weight to 2% of the premix.

Test species: Bobwhite quail (*Colinus virginianus*)
Age: Approx. 12 month old at the start of the study
Number of replicates: 20
Birds per replicate: 1 male and 1 female
Birds per treatment: 20 males and 20 females

Treatment groups:

- control
- endosulfan 30 ppm
- endosulfan 60 ppm
- endosulfan 120 ppm

The diets were given over a 24-week period (12 weeks prior to the start of egg production and 12 weeks during egg production). A further 3-week withdrawal period was added to the end of the study. Analyses of diets for endosulfan were conducted and revealed actual diet concentrations within – 7.3/ + 1.7% of the nominal diet concentrations.

The results of this study for Japanese quail showed a NOEL of 60 ppm.

Roberts and Phillips, 1985
The objective of this study was to investigate the Effects of dietary inclusion of Endosulfan - Technical (Code: Hoe 002671 OI ZD97 0003) on Reproduction in the Mallard Duck. The study was conducted under EPA guidelines and with GLP.

Test species: Mallard duck (Anas platyrhynchos)
Age: approx. 33 weeks old at the start
Number of replicates: 6
Birds per replicate: 2 males and 5 females
Birds per treatment: 12 males and 30 females

Treatment groups:

- control
- endosulfan 30 ppm
- endosulfan 60 ppm
- endosulfan 120 ppm

The diets were given over a 22-week period - 10 weeks prior to the start of egg production and 12 weeks during egg production. A further 4-week withdrawal period was added to the end of the study. Analyses of diets for endosulfan revealed actual diet concentrations close to nominal concentrations. Reproductive effects were observed at 120 and 60 ppm. Therefore the NOEL for mallard duck was 30 ppm.

Beavers *et al*., 1987

A One-Generation Reproduction Study with the Mallard (*Anas platyrhynchos*) was performed. The study was conducted in compliance with the EPA guidelines for pesticides assessment and ASTM draft and was performed under GLP.

Endosulfan technical substance (96% purity) was exposed to adult mallard over an 18 week period at 4 concentrations (0, 7.5, 15, 30, and 60 ppm; measured concentrations were 0, 7.8, 15.0, 30.3, and 63.6 ppm). Acetone was used as solvent and corn oil as carrier. Each of the 5 groups (4 treatment groups and 1 control) contained 16 pairs of birds with 1 male and 1 female per pen. Two mortalities occurred in the 15 ppm treatment group (weeks two and nine) and one mortality occurred at 60 ppm treatment group. No apparent overt signs of toxicity were observed at any concentration tested. The lesions that were observed in the surviving animals were not related to the treatment exposure. In the treatment group of 60 ppm there is a statistically significant difference in males body weight related to the control in the week 2. At 60 ppm exposure, there were statistically significant differences from the control in feed consumption. At this concentration there were statistically significant reductions in the number of egg laids, and in the number of hatchlings as a percentage of live 3-week embryos. This was also reflected in the number of 14-day old survivors as a percentage of maximum set.

At 15 ppm, the number of 14-day old survivors as a percentage of hatchlings was significantly different from the control but no dose-response relationship was observed and no differences at the higher concentration detected.

The no-observed-effect concentration for endosulfan technical substance in this study was 30 ppm (equivalent to a daily intake of 4 mg/kg of body weight).

Beavers *et al*, 1987

A One-Generation Reproduction Study with the Bobwhite (*Colinus virginianus*) is presented. The study was conducted under GLP and in compliance with the EPA guidelines for pesticides assessment.

Adults of bobwhite was exposed a 4 concentration of Endosulfan technical substance (96% purity) (nominal 15, 30, 60 and 120 ppm; measured concentrations, 15, 30.6, 63.6 and 134, 1 ppm). Acetone was used as solvent and corn oil as carrier. There were two mortalities in the control group. There were no treatment related effects upon bobwhite exposed to dietary concentrations of 15, 30 or 60 ppm endosulfan, substance technical. At 30, 60 and 120 ppm there were statistically significant differences versus the control for feed consumption. In the 120 ppm group there was a statistically significant increase in the number of cracked eggs as a percentage of eggs laid. At 60 ppm group there was a statistically significant difference in the number of hatchlings as a percentage of live 3-week embryos.

In conclusion, the no-observed-effect concentration for endosulfan technical substance in this study was 60 ppm (equivalent to a daily intake of 6 mg/kg of body weight).

- **Plant Protection Products**

No studies have been submitted.

B. 9. 1.4 Supervised cage or field trials

No information has been submitted.

B. 9.1.5 Acceptance of bait, granules, or treated seed by birds

Taking into consideration that the product is used in the form of a water based spray liquid there is no necessity for special testing of the acceptance of granules or baits.

However, a palatability study for water suspension has been submitted.

Ebert and Leist, 1990

A repellence study was conducted with the spray mix to permit a more accurate assessment of the hazard to wild birds resulting from direct ingestion of spray mix. In this study, two groups of 8 male and 8 female adult Japanese quails under extreme heat stress (30 °C) received either a 0.1% spray mix or tap water as sole source of liquid over a period of 3 days, after which they were kept under observation for another 9 days. Under these test conditions, the quails with spray mix as sole source of drinking water showed considerably reduced intake of liquid as compared with the controls (tap water) and survived until the end of the study without clinical signs.

The notifier suggest that this study indicates that endosulfan will not posses a significant risks for birds due to repellence. However, the study, conducted by mixing endosulfan with water, do not properly address the palatability of the food items selected for the assessment of the risk for birds. Therefore, and also considering that bird mortality has been associated to endosulfan treatments in some field studies, the conclusion of the rapporteur is not accepted and the study is regarded as no relevant for this assessment.

B. 9.1.6 Effects of secondary poisoning

No studies have been submitted.

Summary of toxicity to birds

Table 9.1.6-1: Summarises the toxicity data of endosulfan to birds.

Acute oral toxicity	**Route**	**Exposure**	**Chemical**	**LD_{50} mg/kg**		**Doc. No.**	**Study**	**Authors**	**Remark**
Bobwhite quail	Gavage	Single gavage	Technical grade 97.2%	42 (35-56)		A27035	GLP	Roberts & Phillips, 1983 a	
Mallard Duck	gavage	Single gavage	Technical 97.2%	28 (22-36)		A27036	GLP	Roberts & Phillips, 1983 b	
Short-term toxicity	**Route**	**Exposure**	**Chemical**	**LC_{50}**		**Doc no.**	**Study**	**Authors**	**Remark**
				ppm	**mg/ kg/d**				
Japanese quail	dietary	5 days	Not specified	1250	250	A26820	No GLP or publis hed	Hill et al., 1975	
Bobwhite quail	dietary	5 days		805	161				
Mallard duck	dietary	5 days		1053	211				
Pheasant	dietary	5 days		1275	255				
Effectos on Reproduct	**Route**	**Exposure**	**Chemical**	**NOEC**		**Doc. No**	**Study**	**Authors**	**remark**
				ppm	**mg/ kg/d**				
Japanese quail	dietary	28 days	Active ingredient 97.1%	50	5	A18268	No GLP No publ.	Scholz & Weigand (1973)	
Bobwhite quail	dietary	>20 weeks	Technical 97.2%	60	6	A29572	GLP	Roberts and Phillipls, 1984	
Mallard duck	dietary	>20 weeks	Technical 97.2%	30	4	A 30678	GLP	Roberts and Phillips (1985)	
Mallard duck	dietary	>20 weeks	Technical (96%)	30	4	A 36310	GLP	Beavers et al. (1987)	
Bobwhite quail	dietary	>20 weeks	Technical (96%)	60	6	A 36311	GLP	Beavers et al. (1987b)	

B. 9.1.7 Risk assessment for birds

The risk assessment for endosulfan has been doing using the available information. The results showed that mallard duck was the most sensible specie for acute and reproduction tests, and Bobwhite quail for dietary short-term test.

For the estimations of ETE values, the Hoerger and Kenaga method was used. Considering the intended uses, leaves instead of grass have been considered as the most appropriate food item for herbivorous vertebrates. Acute TERs have been calculated for large and small birds, considering that the daily feed demand is 10% of their body weight for large birds and 30% for small birds. TER estimations have been done for three different crops, representing the worst cases.

Table 9.1.7-1: TER estimations for acute oral toxicity studies of endosulfan in citrus, pome fruit and vineyards crops for large birds.

Feed	Application rate (kg a.s/ha)	Typical maximum residue (mg/kg)	Estimated initial residue (mg/kg)	Maximum daily intake (mg/kg bw)	Acute toxicity (mg/kg)	TERa
Leaves	1.05	31 X R	32.55	3.255	28	8.6
Insects	1.05	29 X R	30.45	3.045	28	9.2
Fruits	1.05	1.3 X R	1.365	0.1365	28	205.1

Table 9.1.7-2: TER estimations for acute oral toxicity studies of endosulfan in citrus, pome fruit and vineyards crops for small birds.

Feed	Application rate (kg a.s/ha)	Typical maximum residue (mg/kg)	Estimated initial residue (mg/kg)	Maximum daily intake (mg/kg bw)	Acute toxicity (mg/kg)	TERa
Leaves	1.05	31 X R	32.55	9.765	28	2.86
Insects	1.05	29 X R	30.45	9.13	28	3.06
Fruits	1.05	1.3 X R	1.365	0.4	28	70

Table 9.1.7-3: TER estimations for acute oral toxicity studies of endosulfan in Tomatoes, potatoes and cucurbits crops for large birds.

Feed	Application rate (kg a.s/ha)	Typical maximum residue (mg/kg)	Estimated initial residue (mg/kg)	Maximum daily intake (mg/kg bw)	Acute toxicity (mg/kg)	TERa
Leaves	0.53	31 XR	16.43	1.643	28	17.04
Insects	0.53	29 XR	15.37	1.537	28	18.21
Fruits	0.53	1.3 XR	0.68	0.068	28	411.7

Table 9.1.7-4: TER estimations for acute oral toxicity studies of endosulfan in Tomatoes, potatoes and cucurbits crops for small birds.

Feed	Application rate (kg a.s/ha)	Typical maximum residue (mg/kg)	Estimated initial residue (mg/kg)	Maximum daily intake (mg/kg bw)	Acute toxicity (mg/kg)	TERa
Leaves	0.53	31 XR	16.43	4.9	28	5.71
Insects	0.53	29 XR	15.37	4.61	28	6.07
Fruits	0.53	1.3 XR	0.68	0.20	28	140

Table 9.1.7-5: TER estimations for acute oral toxicity studies of endosulfan in stone fruits crops for large birds.

Feed	Application rate (kg a.s/ha)	Typical maximum residue (mg/kg)	Estimated initial residue (mg/kg)	Maximum daily intake (mg/kg bw)	Acute toxicity (mg/kg)	TERa
Leaves	0.8	31 XR	24.8	2.48	28	11.3
Insects	0.8	29 XR	23.2	2.32	28	12.06
Fruits	0.8	1.3 XR	1.04	0.104	28	269.2

Table 9.1.7-6: TER estimations for acute oral toxicity studies of endosulfan in stone fruits crops for small birds.

Feed	Application rate (kg a.s/ha)	Typical maximum residue (mg/kg)	Estimated initial residue (mg/kg)	Maximum daily intake (mg/kg bw)	Acute toxicity (mg/kg)	TERa
Leaves	0.8	31 XR	24.8	7.44	28	3.7
Insects	0.8	29 XR	23.2	6.96	28	4.02
Fruits	0.8	1.3 XR	1.04	0.312	28	89.74

These calculations show TERa higher than the trigger values for herbivorous and insectivorous birds in citrus, pome fruits and vineyards crops, in tomatoes, potatoes and stone fruits crops for small birds. Taking into account the expected birds populations for the crops in which endosulfan is intended to be used the rapporteur consider that the real risk for herbivorous birds is small, however potential risk for insectivorous birds has been identified and must be addressed by higher tier studies.

The short-term dietary toxicity is based in a study that must be validated at the ECCO level, therefore the TER values included in the following tables must be considered as provisional values.

Table 9.1.7-7: TER estimations for acute dietary toxicity studies of endosulfan in citrus, pome fruit and vineyards crops.

Feed	Application rate (kg a.s/ha)	Estimated initial residue (mg/kg)	Acute dietary toxicity (ppm)	TERst
Leaves	1.05	32.55	805	24.73
Insects	1.05	30.45	805	26.4
Fruits	1.05	1.365	805	589.7

Table 9.1.7-8: TER estimations for acute dietary toxicity studies of endosulfan in tomatoes, potatoes and cucurbits crops.

Feed	Application rate (kg a.s/ha)	Estimated initial residue (mg/kg)	Acute dietary toxicity (ppm)	TERst
Leaves	0.53	16.43	805	49
Insects	0.53	15.37	805	52.37
Fruits	0.53	0.68	805	1183.8

Table 9.1.7-9: TER estimations for acute dietary toxicity studies of endosulfan in stone fruits crops.

Feed	Application rate (kg a.s/ha)	Estimated initial residue (mg/kg)	Acute dietary toxicity (ppm)	TERst
Leaves	0.8	24.8	805	32.45
Insects	0.8	23.2	805	34.7
Fruits	0.8	1.04	805	774.03

The TERst are in all cases higher than the trigger values and therefore it is provisionally considered that the potential risk is low.

The long-term TER values are included in the following tables. Considering the expected dissipation of endosulfan, these values have been estimated using single applications. However, birds can be exposed to several times to these concentrations (spray intervals as low as 1 week are included for some crops) and therefore the use of time-weighting averages is not considered appropriate.

Table 9.1.7-10: TER estimations for reproduction toxicity studies of endosulfan in Citrus, pome fruits and vineyards.

Feed	Application rate (kg a.s/ha)	Estimated initial residue (mg/kg)	Reproductive toxicity (ppm)	TERlt
Leaves	1.05	32.55	30	0.92
Insects	1.05	30.45	30	0.98
Fruits	1.05	1.365	30	22

Table 9.1.7-11: TER estimations for reproduction toxicity studies of endosulfan in tomatoes, potatoes and cucurbits.

Feed	Application rate (kg a.s/ha)	Estimated initial residue (mg/kg)	Reproductive toxicity (ppm)	TERlt
Leaves	0.53	16.43	30	1.82
Insects	0.53	15.37	30	1.95
Fruits	0.53	0.68	30	44.11

Table 9.1.7-12: TER estimations for reproduction toxicity studies of endosulfan in stone fruits.

Feed	Application rate (kg a.s/ha)	Estimated initial residue (mg/kg)	Reproductive toxicity (ppm)	TERlt
Leaves	0.8	24.8	30	1.2
Insects	0.8	23.2	30	1.3
Fruits	0.8	1.04	30	28.8

The calculations clearly demonstrate that the TERlt values are lower than the trigger for herbivorous and insectivorous birds. The use of initial ETE values for single applications instead of time-weighted averages is justified by the multiple application patterns included in the intended uses. Therefore it is concluded that a potential long-term risk for birds has been identified and must be addressed by higher tier assays.

The bioaccumulation potential of endosulfan has also been identified, and therefore the potential risk for fish eating birds must be estimated. Assuming a BCF of 5000 and the initial PEC values for all crops without using buffer zones, both, acute and chronic risk for fish-eating birds can be identified. Nevertheless these concentrations will also produce significant fish mortalities. Concentrations of endosulfan in water of about 1 µg/l, a concentrations resulting in a large fish kill in the pond study, and expected to be lethal on a significant amount of fish species according to the sensitivity distribution curve, will results in fish concentrations of about 5 ppm. The TER values estimated for this concentration (30% daily food consumption) are:

TERa = 18
TERst = 161
TERlt = 6

Therefore it is concluded that water concentrations of endosulfan large enough to produce acute fish mortalities can also constitute a potential risk for fish-eating birds. However, those concentrations which are not expected to be lethal for fish species do not represent a significant risk for ictivorous birds.

B.9.2 Effects on aquatic organisms (IIA, 8.2; IIIA, 10.2)

The applicant has presented a large number of studies on the toxicity of endosulfan to aquatic organisms. Most of the submitted data correspond to publish studies collected from the open literature. The rapporteur has carefully checked the validity of these studies; obviously, the information on the testing conditions, quality assurance, etc., provided in a scientific paper is lower than that included in the report of a GLP study. Nevertheless the rapporteur, following the principles already accepted for the risk assessment of other existing plant protection products, considers that the information collected in published scientific papers of enough quality is clearly relevant when setting the ecotoxicological profile and potential risk of this active substance.

Considering the large amount of studies submitted, and to facilitate the comprehension of this chapter, the information has been summarised in tables as much as possible.

Nevertheless, whenever required the specific studies have been summarised at the individual level, to explain the rapporteur's assumptions when conducting the risk assessment or to justify discrepancies between the rapporteur opinion and the interpretations presented by the authors or the applicant.

B.9.2.1 Acute toxicity to aquatic organisms

B.9.2.1.1 Acute toxicity to fish

- **Active substance**

The notifier has submitted several studies on the acute toxicity of endosulfan to fish species. Most data come form scientific papers published in the open scientific literature, the specific reports of industry owned studies are mostly non GLP studies.

After the revision of the submitted reports, the rapporteur decided to consider, as a whole, all the available information in order to establish a proper assessment of the potential acute risk of endosulfan to fish.

The available information on the acute toxicity of endosulfan to fish has been summarised in Table 9.2.1.1-1. A total of 41 values for 29 fish species were reported by the notifier and some additional values have been included by the rapporteur.

All studies suggest that endosulfan is highly toxic to fish, with 96 hours LC_{50} values in the range of 0.1 to 160 µg/l. Differences can be observed depending on the type of tests. The range for the flow-through and semistatic tests is 0.1 to 4.8 µg/l, while the static tests shows a very wide range, from 0.3 to 160 µg/l.

In most cases, the acute LC_{50s} obtained for the same species in different studies are in the same range. However, there are two exceptions to this general rule: the common carp (*Cyprinus carpio*) and the harlequin fish (Rasbora sp.). In both cases, two studies showing large differences between the observed values (0.1 and 6.9 µg/l for carp; 0.2 and 160 µg/l for harlequin fish) have been presented. The studies showing the lowest sensitivity were in both cases static tests, while those showing higher sensitivity were semi-static and dynamic assays respectively.

Several factors can be responsible for the large differences observed among the experiments. The larger differences observed for the data obtained from static tests suggest that test conditions could be critical for a proper design of static tests with endosulfan, and therefore data from static tests must be taken with care. The lowest data observed for carp and harlequin fish comes from the same study by Sunderam *et al.*, 1992, which reports values for other species that are in agreement with values reported by other authors although mostly in the lowest end. The additional data reported for harlequin fish can be clearly considered as out-layers, while the additional data reported for carp is within the rage observed for other species.

The rapporteur concludes that the acute toxicity of endosulfan to fish is mostly in the range of 0.1 to 10 µg/l with an average value of about 1 µg/l (geometric mean of 2 µg/l according to the notifier).

Table 9.2.1.1-1: Acute toxicity of endosulfan to fish

Test organisms	Study type	Chemical	Test duration	LC_{50} and 95% CI (µg/l)	Study conditions	Doc, Authors	Remarks
Bluegill fish	Static	Technical (96.6%)	96 h	3.3	Published	Pickering & Henderson, 1966 A14124	Study with hard and soft water
Guppy fish	Static	Technical (96.6%)	96 h	3.7	Published	Pickering & Henderson, 1966 A14124	Study with hard and soft water
Rainbow trout	Static	Thiodan ®	96 h	1. 5	Published	Macek et al, 1969 A 23688	At 12º C
Rainbow trout	Static	Technical (96.4%)	96 h	0.3	Published	Schoettger (1970) A14253	At 10 º C
White sucker	Static	Technical (96.4%)	96 h	3.0	Published	Schoettger (1970) A14253	At 19 ºC
Fathead minnow	Intermitent flow-bioassay	Endosulfan (99%)	7 días	0.86	Published	Macek et al (1976)	
Golden orfe	Static	Active substance	96 h	2	No GLP. No publ.	Knauf (1977) A 167322	
Common carp	Static	Active substance	96 h	6.9	No GLP. No publ.	Knauf (1978) A 31512	
Mosquito fish	Static	Technical grade	96 h	8	Published	Joshi& rege (1980) A 29254	
Indian fish species	Flow through	Active ingredient	96 h	1.2 (1.1-1.3)	Published	Mohanaranga & Murty (1980) A 29255	
Labeo rohita Indian fish species	Flow through	Technical grade (96%)	96 h	1.1	Published	Rao et al (1980) A 22299	
Channa punctatus	Flow through	Technical grade (96%)	96 h	4.8	Published	Devi et al (1981) A 22297	
Walking catfish	Static	Technical grade (90%)	96 h	14 (14.5-13.4)	Published	Gopal et al (1981) A 23187	
Mystus vittatus	Dynamic	Not specified	96 h	1.9 (1.8-2.1)	Published	Rao &Murty 1982 A 26105	
M cavasius	Dynamic	Not specified	96 h	2.2 (2-2.4)	Published	Rao &Murty 1982 A 26105	
Heteropneu	Dynamic	Not	96 h	1.1	Published	Rao	

Test organisms	Study type	Chemical	Test duration	LC_{50} and 95% CI (µg/l)	Study conditions	Doc, Authors	Remarks
stes fossilis		specified		(0.93-1.30)		&Murty 1982 A 26105	
Heteropneu stes fossilis	Static	Not specified	96 h	9.7	Published	Singh & Narein, 1982 A 23196	
Heteropneu stes fossilis	Static	No especifican que endosulfan	96 h	2 (1.8-2)	Published	Singh & Srivastava (1981) A 32901	
Rainbow trout	Static	Active ingredient (95.9%)	96 h	0.93 (0.81-1.08)	No GLP No published	Fischer (1983) A 26006	At 12ºC
Rainbow trout	Static	Technical grade	96 h	1.6	Published	Nebeker et al, 1983 A 27380	
Rainbow trout	Dynamic	Technical grade	96 h	0.3	Published	Nebeker et al, 1983 A 27380	
Fathead minnow	Static	Technical grade	96 h	0.8	Published	Nebeker et al, 1983 A 27380	
Fathead minnow	Dynamic	Technical grade	96 h	1	Published	Nebeker et al, 1983 A 27380	
Punctius ticto	Static	Technical grade (96.6%)	96 h	160	Published	Singh & Sahai (1984) A 36683	
Harlequin fish	Static	Technical grade (96.6%)	96 h	160	Published	Singh & Sahai (1984) A 36683	
Channa punctatus	Semi-static	Technical grade	96 h	5.78 (4.49-7.44)	Published	Haider & Moses (1986) A36292	
Saint Peter fish	Semi-static	Not specified	96 h	2.05-2.79	Published	Herzberg, 1986 A 36295	
Freshwater eel	Static	Endosulfan (96%)	96 h	20 (17-23)	Published	Ferrando & Moliner (1989) A 42966	At 29 ºC
Catla Catla	Dynamic	Technical grade (96%)	96 h	1.84 (1.78-1.91)	Published	Rao (1989) A 43108	
Freshwater eel	static	Technical grade (96%)	96 h	41 (33-50)	Published	Ferrando et al, (1991) A 47633	
Golden perch	Semi-static	Technical grade (96.2%)	96 h	0.3	Published	Sunderam (1992) A 49782	
Bony	Semi-static	Technical	96 h	0.2	Published	Sunderam	

Test organisms	Study type	Chemical	Test duration	LC_{50} and 95% CI (µg/l)	Study conditions	Doc, Authors	Remarks
bream		grade (96.2%)				(1992) A 49782	
Silver perch	Semi-static	Technical grade (96.2%)	96 h	2.3	Published	Sunderam (1992) A 49782	
Common carp	Semi-static	Technical grade (96.2%)	96 h	0.1	Published	Sunderam (1992) A 49782	
Mosquito fish	Static	Technical grade (96.2%)	96 h	2.3	Published	Sunderam (1992) A 49782	
Rainbow trout	Static	Technical grade (96.2%)	96 h	0.7	Published	Sunderam (1992) A 49782	
Melanotaenia duboulayi	Flow-through	Technical grade (96.2%)	96 h	0.5	Published	Sunderam (1992) A 49782	At 25 º C
Harleqquin fish	Flow-through	Technical grade (96.2%)	96 h	0.2	Published	Sunderam (1992) A 49782	At 25 º C
Zebra fish	Semistatic	Technical grade (97%)	24 h	1.6	Published	Jonsson & Toledo (1993) A 51153	
Yellow tetra	Semistatic	Technical grade (97%)	24 h	2.6	Published	Jonsson & Toledo (1993) A 51153	
Lagodon rhomboides (pinfish)	Flow-through	Technical endosulfan	96 h	0.3	Published	Schimmel et al. (1977) A 22871	Filtered marine water at 23ºC
Striped bass	Flow-trhough	Technical grade (96%)	96 h	0.23	Published	Fujimura et al. 1991 A 47515	
Leiostomus xanthurus (spot)	Flow-through	Technical endosulfan	96 h	0.09	Published	Schimmel et al. (1977) A 22871	Filtered marine water at 23ºC
Mugil cephalus	Flow-through	Technical endosulfan	96 h	0.38	Published	Schimmel et al. (1977) A 22871	Filtered marine water at 23ºC

Considering the large amount of information, the notifier suggests the use of sensitivity distribution analysis. A Kolmogorov-Smirnof test showed that the LC_{50} values follow a logistic and a normal distribution (see also figure 9.2.1.1-1). The geometric mean of all LC_{50} values lays at 2.0 µg/l and the median estimate for 95% of all fish species results in a LC_{50} of 0.14 µg/l (logistic distribution) and 0.13 µg/l (normal distribution). The notifier proposes to use the LC_{50} estimate for the protection of 95% of the species, 0.13 µg/l, for the calculation of acute TER values for fish.

Taking into account the existence of acute toxicity data for a large number of species and families the use of sensitivity distributions is considered scientifically sound. The rapporteur has estimated additional sensitivity distribution curves, considering all the data, excluding those obtained in static tests, and excluding those for species showing large differences between studies. Log-normal distributions can be assumed, particularly when the non consistent data for carp and harlequin fish are excluded. Probabilistic curves are included in Fig 9.2.1.1-2 and Fig 9.2.1.1-3. The value proposed by the applicant for the protection of 90-95% of the species has also been confirmed and can be used for a higher tier assessment of the acute risk of endosulfan for fish.

Figure 9.2.1.1-1: Frequency distribution of LC_{50} values for acute toxicity in fish proposed by the notifier

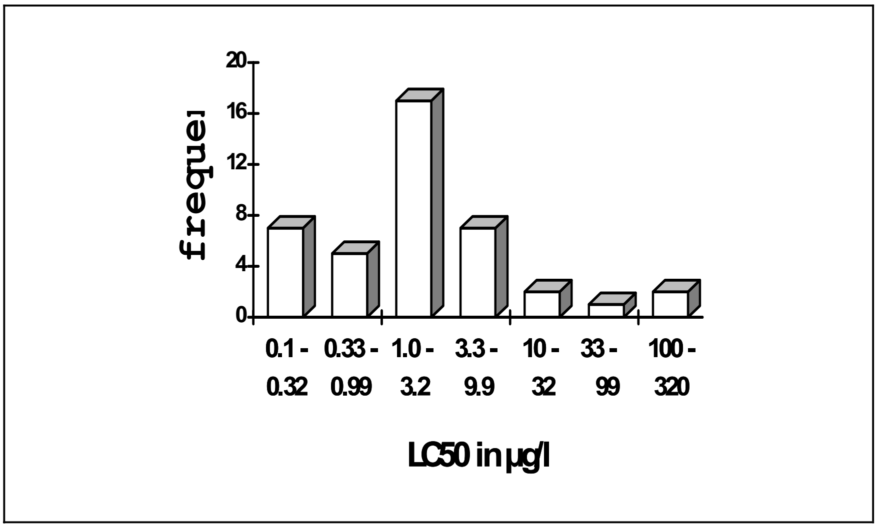


Figure 9.2.1.1-2: Frequency distribution of LC_{50} values for acute toxicity in fish and log-normal distribution estimated by the rapporteur.

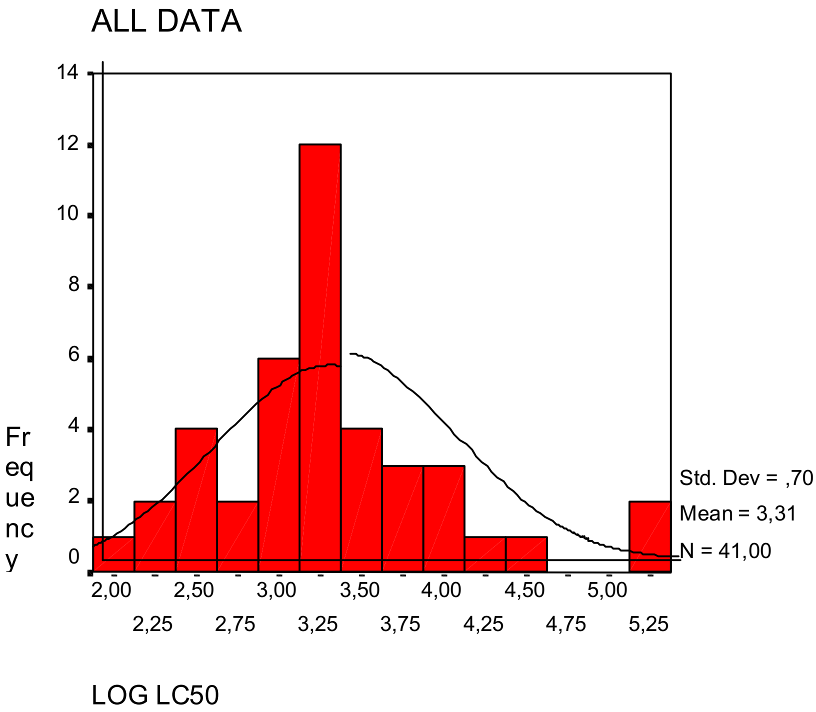
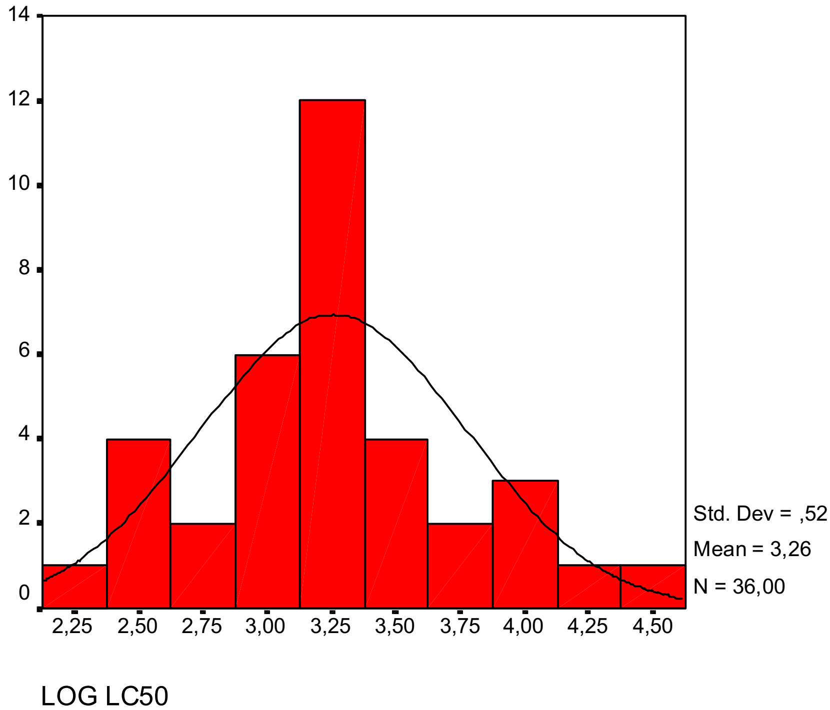


Figure 9.2.1.1-3: Frequency distribution of LC_{50} values for acute toxicity in fish and log-normal distribution estimated by the rapporteur excluding the values for carp and harlequin fish.



- **Specific information on isomers**

Technical endosulfan is a mixture of two isomers, and therefore some authors have tried to clarify the toxicity of each isomer.

Some studies (Rao *et al*., 1980, Doc. No.: A22299; Rao, 1989, Doc. No.: A43108; Devi *et al*., 1981, Doc. No.: A22297) stated that α-endosulfan is more toxic than β-endosulfan, the results are summarised in Table 9.2.1.1-2.

Table 9.2.1.1-2: Acute 96-h toxicity of endosulfan isomers to fish

Test organism	96-h LC_{50} (µg/l)	96-h LC_{50} (µg/l)	96-h LC_{50} (µg/l)	Doc. No.:	Author
	α-Endosulfan	β-Endosulfan	technical. endosulfan		
Channa punctata	0.16	6.6	4.8	A22297	Devi et al. (1981)
Catla catla	0.36	7.67	1.84	A43108	Rao (1989)
Labeo rohita	0.33	7.1	1.1	A22299	Rao et al. (1980)

The toxicity of the two isomers of endosulfan and its degradation products was also studied by Knauf and Schulze (1973, Doc. No.: 05758). The test results suggest that α-endosulfan is more toxic for two of the three studied species while β-endosulfan is the most toxic isomer for the third species. Data are only presented in a graphic form and proper LC_{50}s cannot be obtained.

In summary, the results obtained for the isomers are not always congruent. α-Endosulfan has been reported in some studies to be more toxic than β-Endosulfan, although in the same studies the toxicity of the technical mixture is reported to be lower than that estimated from the toxicity of the α-isomer and its percentage in the technical product. In addition another study suggests species dependence for the relative toxicity of the isomers.

Therefore, and considering that fish populations are expected to be exposed to a mixture of both isomers and the large amount of information available on the toxicity of the technical active substance the rapporteur has considered that the risk assessment should be conducted for the technical product, although differences in the environmental fate and behaviour between both isomers have been demonstrated and possible differences in the toxicity have also been suggested. Taking into account that the possibly more toxic isomer is however the one that shows a faster dissipation in the environment, the use of toxicity and exposure data for the technical product is considered a realistic worst case. If additional information becomes available, the use of independent exposure estimations for each isomer and toxicity data obtained for the expected relative proportion in the mixture during the degradation in the aquatic systems could be considered.

- **Formulated product**

The acute toxicity of the formulated product Thiodan to fish has been summarised in Table 9.2.1.1-3.

These studies include some GLP studies conducted under appropriate guidelines as well as toxicity values reported in the open scientific literature.

Table 9.2.1.1-3: Acute toxicity of Thiodan to fish

Test organisms	Study type	Chemical	Test duration	LC_{50} (µg/l)	Study conditions	Authors, Doc. Nº	Remarks
Puntius sophore	Static	Thiodan 35%	96 h	1.2	Published	Arora et al. 1971 A 25870	
Mystus vittatus	Static	Thiodan 35%	96 h	0.24	Published	Gopalakrishna Reddy & Gomathy (1977) A 259913	
Golden orfe	Static	Thiodan 35%	96 h	7	No GLP or Published	Knauf (1977b) A 16730	
Rainbow trout	Static	Thiodan (not specified)	96 h	4.7	No GLP or published	Knauf (1977 c) A 14970	
Cyprinus carpio	Static	Thiodan 35%	96 h	11	No GLP or published	Knauf (1977d) A 14970	
Channa gachua	Static	Thiodan 35%	96 h	10.6	Published	Dalela et al. (1978) A 25861	
Guppy fish	Static	Thiodan (not specified)	96 h	5.2	No GLP or published	Knauf (1978) A 18466	
Mosquito fish	Static	Thiodan 35%	96 h	3.2	Published	Joshi & Rege (1980) A 29254	Data referred to active ingredient
Labeo rohita	Continuous flow system	Thiodan 35%	96 h	1	Published	Rao et al. (1980) A 22299	Data referred to active ingredient
Channa puctata	Continuous flow	Thiodan 35%	96 h	2.5	Published	Devi et al. (1981) A 22297	Data referred to active ingredient
Mystus vittatus	Static	Thiotox 35%	96 h	0.67	Published	Verma et al. (1981) A29130	Data referred to active ingredient
Ophiocephalus punctatus	Static	Thiotox 35%	96 h	22	Published	Verma et al. (1981) A29130	Data referred to active ingredient
Barbus	Static	Endosulfan	96 h	4.3	Published	Manoharan	

Test organisms	Study type	Chemical	Test duration	LC_{50} (µg/l)	Study conditions	Authors, Doc. Nº	Remarks
stigma		(not specified)				& Subbiah (1982) A 27749	
Saccobranchus Fossilis	Static	Thiotox 35%	96 h	6.6	Published	Verma et al. (1982) A 25048	Data referred to active ingredient
Saccobranchus Fossilis	Static	Thiodan 35%	96 h	10.8	Published	Verma et al. (1982) A 25048	Data referred to active ingredient
Rainbow trout	Static	Endosulfan (352 g/l)	96 h	2.1	GLP	Fisher (1984b) A 30032	
Bluegill sunfish	Static	Endosulfan (352 g/l)	96 h	Between 10 and 5.6	GLP	Fisher (1984c) A 29508	
Lebistes reticulatus	Renewal daily	Endosulfan 35EC	96 h	2.7	Published	Gupta et al. (1984) A 32237	
Channa punctatus	Renewal daily	Thiodan 35%	96 h	3.07	Published	Haider & Inbaraj (1986) A 36292	
Barilius bendelisis	Static	Technical grade Thiodon (35EC)	96 h	13.5 15.6 16.6	Published	Deoray & Wagh (1987) A43067	pH = 6.5 pH = 7.5 pH = 9
Fundulus heteroclitus	Static	Endosulfan (30%)	96 h	1.15	Published	Trim (1987) A 36296	Data referred to active ingredient
Mosquito fish	Static	Thiodan ® (50%)	96 h	1.3	Published	Naqvi & Hawkins (1988) A43065	
Catla catla	Flow trough	Formulation 35% EC	96 h	1.05	Published	Rao (1989) A43108	Data referred to active ingredient
Puntius conchonius	Static	Endosulfan 35% EC	48 h	21.36	Published	Gill et al. (1991) A47588	

NOTE: When no specific information appeared in the report, the values were considered as expressed in µg preparation/l, although this assumption could not be always checked.

Although in some particular studies the toxicity of the formulated product has been identified as higher than that observed for the active substance, the weight of evidence does not seems to support this suggestion.

Both, the toxicity range and the sensitivity distribution seems to be similar, after the correction for the amount of active substance in the formulate, to those reported for technical endosulfan. In addition, the comparisons among those values obtained for the same species under equivalent conditions also suggest that the toxicity of the formulated product is equivalent to that expected according to the proportion of technical endosulfan.

- **Metabolites**

Although the amount of validable information is scarce, the toxicity of endosulfan-sulphate has been reported as similar to that observed for the technical product while other metabolites, which do not content the sulphate group are suggested to be less toxic.

The study of Oeser *et al*., 1971 (Doc. No.: A14255) does not include enough information for the validation of the results, while the study of Knauf and Schulze, 1973 (Doc. No.: A05758) only includes a graphic presentation for the data. Endosulfan sulphate toxicity is in the same range than the isomers. The 48h LC_{50}s for the hydroxyether seems to be lower than 1 ppm, and for the lactone, alcohol and ether, in the range of 1 to 10 ppm. Therefore, these metabolites should be classified as highly toxic or toxic according to the EU regulation and must be included in the risk assessment if relevant.

However, a proper quantitative assessment on the toxicity of the metabolites is not possible, and it must be considered that no enough information on the toxicity of the metabolites, including endosulfan sulfate as well as any other relevant metabolite, has been presented, and therefore the notifier must be requested to present a proper risk assessment for each relevant metabolite.

B.9.2.1.2 Acute toxicity to aquatic invertebrates

- **Active substance**

The acute toxicity of endosulfan to aquatic invertebrates has been extensively studied. Most reports are scientific papers published in the open literature although additional “in-house” reports particularly on *Daphnia magna* have been also submitted. Data are summarised in Table 9.2.1.2-1.

Table 9.2.1.2-1: Acute toxicity to aquatic invertebrates

Test organisms	Study type	Chemical	Test duration	LC_{50} (µg/l)	Study condition	Authors Doc. Nº	Remarks
Daphnia magna	Static	Technical (96.4%)	48 h	62	Published	Schoettger (1970) A14253	
D.magna	Static	Technical grade	48 h	271	Published	Nebeker et al. 1983	
D.magna	Static	Technical grade	48 h	343	Published	Nebeker et al. 1983	
Daphnia magna	Static	Endosulfan (99%)	48 h	166	Published (parece un informe)	Macek et al (1976)	
Daphnia magna	Static	No specified	48 h	158-740	Published	Nebeker 1982 A 25040	

Test organisms	Study type	Chemical	Test duration	LC_{50} (µg/l)	Study condition	Authors Doc. Nº	Remarks
D.magna	Static	Active ingredient	48h	75	No GLP or published	Knauf 1977b A 16733	
D. carinata	Static	Technical grade	48 h	180	Published	Santharam et al. 1976 A25919	
Cyclops sirenus	Static	Formulado (35% emulsionable)	24 h	1000 LC100	Published	Oeser et al. 1971 A 14255	
Brachionus plicatilis	Static	No especifican	24 h	5600 (5800-5400)	Published	Serrano et al. 1986 A 53745	
Brachionus calyciflorus	Static	endosulfan 96%	24 h	5150	Published	Fdez Caslderrey et al. 1992. A 47492	
Enallagma spec.	Static	Technical grade (90%)	96 h	17.5	Published	Gopal et al. 1981 A23187	
Gammarus lacustris	Static	Not specified	96 h	5.8	Published	Sanders (1969) A 26101	
Gammarus faciatus	Static	Not specified	96 h	6 (4-8)	Published	Sanders (1972) A 28837	
Gammmaru s roeselii	Static	Not specified	24 h	5 LC100	Published	Ludemann &Neumann (1960) A 14242	
Caridina weberi	Static	Not specified	96 h	5.1-14.1	Published	Yadav et al. (1991) A47589	
Hydrachna trilobata	Static	Technical grade	48 h	2.8 (2.3-3.4)	Published	Nair (1981) A26111	
Ischnura sp.	Static	Technical grade (96.4%)	96 h	71.8	Published	Schoettger (1970) A 14253	
Moina micrura	Static	Technical grade (90%)	24 h	16.2 (17.1-15.3)	Published	Krishnan& Chockaling am (1989) A 43063	
Oziotelphu sa senex	Static	Technical grade (99%)	96 h	570-1490	Published	Naidu et al. (1987) A 43105	
Oziotelphu sa senex	Static	Technical grade (95%)	96 h	12200-28600	Published	Reddy et al. (1992)	Data at 38º and 12ª respectively
Pteronarcys californica	Static	Not specified	96 h	2.30 (1.6-3.3)	Published	Sanders &Cope (1968) A 25918	

Results suggest that insects and some crustacean groups (shrimps, amphipods) are the most sensitive groups, while other crustaceans (crabs) can be clearly less sensitive.

The most sensitive organism reported is the pink shrimp with an LC_{50} of 0.04 µg/l. This value was obtained by Schimmel *et al* (1977) in a study with several estuarine species and measured concentrations and clearly showed the highest sensitivity of this shrimp. The toxicity for the standard species the cladoceran species *Daphnia sp*. range from 62 to 740 µg/l. However, the cladoceran species *Moina micrura* with a LC_{50} of 16.2 µg/l is more sensitive than the Daphnia species (Krishnan and Chockalingam, 1989).

The rapporteur proposes the use of an LC_{50} of 0.04 µg/l, as the acute toxicity endpoint for the most sensitive aquatic invertebrate; and a 48 h. EC_{50} of 150 µg/l for *Daphnia magna* which corresponds to the 90th percentile for the toxicity data on this species. The use of the pink shrimp data is considered appropriate because of the socio-economic importance of this species in areas near to crops included in the intended uses of endosulfan.

- **Formulated product**

The acute toxicity of the formulated product to aquatic invertebrates has been summarised in Table 9.2.1.2-2.

Table 9.2.1.2-2: Acute toxicity of the preparation on aquatic invertebrates

Test organisms	Study type	Chemical	Test duration	LC_{50} (µg/l)	Study conditions	Authors Docs. Nº	Remarks
Chironomus spec.	Static	Thiodan (not specified)	24 hours	53	Published	Ludermann & Neumann (1960) A18837	
Daphnia magna	Static	Endosulfan (35EC)	48 hours	470	Nor GLP or published	Knauf (1976) A16729	
Aedes Aegypti	Static	Endosulfan (35EC)	96 hours	54	Nor GLP or published	Knauf (1977) A16736	
Daphnia magna	Static	Endosulfan (35EC)	48 hours	4	GLP	Fischer (1984) A29798	
Lamellidens marginalis	Semi-static	Endosulfan (35EC)	96 hours	6	Published	Mane & Muley (1984) A31349	
Lamellidens corrianus	Semi-static	Endosulfan (35EC)	96 hours	17	Published	Mane & Muley (1984) A31349	
Procambarus clarkii	Static	Thiodan ®	96 hours	24	Published	Naqvi et al. (1989) A 43061	Data for juveniles
Procambarus clarkii	Static	Thiodan ®	96 hours	423	Published	Naqvi et al. (1989) A 43061	Data for adults
Penaeus monodon	Renewal daily	Endosulfan (35EC)	48 hours	4.6	Published	Joshi & Mukhopad hyay A 48339	Data for postlarvae
Penaeus monodon	Renewal daily	Endosulfan (35EC)	48 hours	12.2	Published	Joshi & Mukhopad hyay A 48339	Data for juveniles
Diverse microcrustac eans	Static	Thiodan ® (33.7%)	48 hours	0.1-0.9	Published	Naqvi & Hawkins (1989) A43062	

The large differences among studies submitted for different species as well as for the toxicity data reported for *Daphnia magna* are also observed for the formulated product.

The amount of information reported is lower than for the active substance and it is not easily validable. Therefore, the data presented for the active substance will be used in the assessment.

B.9.2.1.3 Acute toxicity to algae

Acute toxicity data of endosulfan have been reported for two green algae. The 72 hours E_bC_{50} *Scenedesmus subspicatus* according to the OECD guideline was greater than 560 µg/l active substance.

Chlamydomonas reinhardtii was even less sensitive with an EC_{50} of 10000 µg/l (Netrawali *et al*., 1986, Doc. No.: A33977).

The results of the acute and chronic toxicity of endosulfan to algae are summarised in Table 9.2.2.1-1.

The aquatic plant *Lemna sp* has been reported to be insensitive to endosulfan, tolerating 50 mg/l over a period of 7 days without any observed effects (Oeser *et al*., 1971, Doc. No.: A14255).

B.9.2.2 Chronic toxicity to aquatic organisms

B.9.2.2.1 Chronic toxicity to fish

The notifier has submitted three studies on the chronic toxicity of endosulfan to three fish species. All studies were conducted using proper guidelines. One study was conducted under GLPs and the others prior the GLP request.

Each study considers the effects on a different fish species and use different endpoints.

The studies are described below:

Hansen and Cripe, 1991; Doc. No.: A47514

These authors report the results of an interlaboratory calibration study for the ASTM early life stage test with the sheepshead minnow (*Cyprinodon variegatus*). Endosulfan was one of the selected chemicals and its toxicity was investigated at five contract and two US-EPA laboratories. Each laboratory conducted two tests. Tests began with newly fertilised to 48-hour-old embryos, continued through embryonic development, hatching, and growth of fish to the juvenile stage, and were terminated after 28 days. Effects on survival of embryos, survival of hatched fish, and weight of surviving fish were quantified. Ten of the 14 tests with endosulfan were judged acceptable by the authors. Survival was most sensitive in 6 of 10 acceptable tests. Chronic values were calculated as the geometric mean of the lowest concentration at which statistically significant effects occur (LOEC) and the highest concentration with no observed effects (NOEC) and averaged 0.6 µg/l.

Using the average ratio between the NOEC and LOEC, the rapporteur has estimated an average NOEC value for the studies considered valid of 0.4 µg/l.

Knacker *et al*., 1991, Doc. No.: A46835

The effects of endosulfan on the growth of *Oncorhynchus mykiss* (rainbow trout) was investigated in a semi-static test system for 21 days according to the OECD guideline 204. The study was conducted according to GLP.

Test organisms were exposed to nominal concentrations of 0.005, 0.016, 0.05, 0.16 and 0.5 µg/l Endosulfan. Endpoints were mortality, increase in body length and weight and clinical symptoms. Since the measured concentrations were higher than 80% of the nominal concentrations, the results of the study were based on nominal concentrations. After 21 days test duration the LC_{50} was 0.283 µg/l, the lowest concentration with observed effects, LOEC, was 0.16 µg/l, and the concentration of no observed effects was 0.05 µg/l,. The most sensitive ecotoxicological endpoint was mortality and intoxication symptoms (increased swimming activity). In weight and length of fish no significant differences could be observed between treatment and control.

Macek *et al*., 1976, Doc. No.: A27951

A life cycle test with fathead minnows (*Pimephales promelas*) was conducted over a time period of about one year. The methodology generally followed the recommended bioassay procedure issued by the US-EPA National Water Quality Laboratory, Duluth, Minnesota (Bioassay Committee, 1971).

The test started with fertilised eggs of F_0 generation and was finished with free swimming larvae of F_1-generation. Test concentrations were 0.04 to 0.4 µg/l. Endpoints that have been analysed were:

F_0-generation:

- after 30 and 60 days: cumulative mortality, total length of live fish
- after 40 weeks: cumulative mortality, length and weight of fish

F_1-generation:

- number of spawns per female
- number of eggs per female
- number of eggs per spawn
- percent hatch
- after another 30/60 days: cumulative mortality, total length of live fish.

Continuous exposure for 60 days to concentrations of endosulfan as high as 0.4 µg/l had no significant effect on the survival and growth of fathead minnows. However, during the period between test days 117 - 145 all fish expired in both duplicate tanks receiving a mean measured concentration of 0.4 µg/l of endosulfan. Analysis of variance of percent survival after 40 weeks for fish in all remaining treatments up to 0.2 µg/l indicated no significant differences due to treatment. Spawning activity (eggs per female) was increased in the concentration of 0.2 µg/l whereas no significant differences were observed in the number of eggs per spawn and in egg hatchability. Three separate groups of eggs from control spawns were incubated in 0.4 µg/l endosulfan and only 1 percent of these eggs hatched successfully.

Analysis of variance of percent survival and mean total lengths of F1 fathead minnows after 30 and 60 days of exposure indicated no significant differences due to exposure to 0.2 µg/l and less. Based on these data derived from continuous exposure of fathead minnows to various concentrations of endosulfan, the chronic NOEC for this species was estimated to be 0.2 µg/l. However, the mortality in the control group was high (20-40%) and the amount of information included in the report do not allow a proper validation, therefore these results must be taken with care.

The results of this study suggest that the effects on reproduction could be considered the most sensitive endpoint regarding the chronic toxicity of endosulfan. The sudden mortality previous to the spawing period at concentrations that do not provoke observable effects during the growth period suggests that reproductive effects could be particularly relevant for this substance. Unfortunately, these effects were not covered by the previous studies on rainbow trout and sheepshead minnow, and therefore the relevant information on the chronic toxicity of endosulfan seems to be limited to a single study on a relatively poorly sensible fish species.

The information available is summarised in Table 9.2.2.1-1.

Table 9.2.2.1-1: Chronic toxicity of endosulfan to fish

Test organism	**Study type**	**Test duration**		**LC_{50} µg/l**	**NOEC µg/l**	**Doc. No.:**	**Author**
Cyprinodon variegatus	early life stage test	28	d	n.r.	0.40	A47514	Hansen & Cripe (1991)
Oncorhynchus mykiss	juvenile growth test	21	d	0.28	0.05	A46835	Knacker et al. (1991)
Pimephales promelas	life cycle test	app. 1	y	0.86	0.2	A27951	Maceck et al. (1976)

n.r.: not reported

The notifier proposes the following conclusion from this study.

"Maceck et al. (1976, Doc. No.: A27951) showed the very steep concentration-effect relationship in Pimephales promelas with an acute LC_{50} over 7 days of 0.86 µg/l and a concentration without any observed effects in the life cycle test of 0.2 µg/l (see also chapter 8.2.3). This was also confirmed by many other authors. This means under conditions of normal practice that concentrations without lethal effects to fish are not to be expected to cause ecologically relevant effects."

However, this suggestion can not be accepted by the rapporteur on the basis of the delayed toxicity observed in the life-cycle test. No standard 96h LC_{50} for *Pimephales promelas* has been presented and this study is the only one which cover effects on the sexual maturity. In addition, other chronic toxicity endpoints such as inhibition of growth rate appear to be less sensitive, and the acute/chronic ratio for rainbow trout falls within the general average of 10 even for non reproductive end-points. Therefore, the rapporteur considers a quite different conclusion, suggesting that although the acute toxicity of endosulfan for fish is well document an opposite situation is observed regarding the chronic toxicity because the use of simplified chronic tests for endosulfan seems to be inappropriate and the effects on reproduction must be addressed in life-cycle studies.

B.9.2.2.2 Chronic toxicity to aquatic invertebrates

- **Active substance**

The reported 21d NOEC for *Daphnia magna* reproduction following OECD guideline and under GLP was 63 µg/l as measured concentration (Heusel, 1991, Doc. No.: A46561).

This value is within the range reported for an intercalibration tests performed to assay the characteristics of the ASTM draft guideline which use endosulfan as a model chemical. Therefore, the value will be used in the risk assessment.

From a non standard test over 64 days (Maceck *et al*., 1976, Doc. No.: A27951) a MATC for mortality and reproduction between 2.7 and 7.0 µg/l was obtained.

- **Formulated product**

The chronic toxicity of the formulated product, EC 352 g/l, to Daphnia magna, according to the OECD guideline and under GLPsd has been studied by Heusel (1991). The reported 21 days NOEC is 210 µg/l, which is in agreement with the value validated for the active substance.

B.9.2.2.3 Chronic toxicity to algae

The effects of endosulfan on algae have been summarised in Table 9.2.2.3-1.

Table 9.2.2.3-1: Effects on algae growth

Test organism	Study type	Chemical	Test duration	LC_{50} (µg/l)	NOEC (µg/l)	Study condition	Doc, authors	Remarks
Scnedesmus subspicatus	Growth inhibition test	Technical endosulfan (95.1%)	72 h	>560	560	GLP	Fisher (1985) A31389	
Chlorella vulgaris	Photosynthetic activity, rate cell division	Endosulfan Beta	120 h	-	2000	Published	Knauf & Schultz (1973) A 5758	
Chlamydomonas reinhardtii	Effects on sexual life cycle	Endosulfan (94% puritu)		10000		Published	Netrawali et al. (1986) A 33977	
Anabaena spec.		Endosulfan (94% pure)	30 days	-	< 1000	Published	Tandon et al. 1988 A 43064	
Aulosira fertilissima		Endosulfan (94% pure)	30 days	-	<1000	Published	Tandon et al. 1988 A 43064	

These results clearly indicates that algae are less sensitive to endosulfan than fish and aquatic invertebrates. The test conditions for the cyanobacteria are not standard and therefore, the 72h NOEC of 560 µg/l obtained for the green alga *Scenedesmus subspicatus* will be used in the assessment.

B 9.2.3 Bioaccumulation in fish

Although the P_{ow} of endosulfan suggests a significant potential for bioaccumulation, a proper study has not been presented by the notifier.

Instead, a list of laboratory studies and estimations from field studies has been presented. Some of these studies are mere measurements of the levels of endosulfan found in fish tissues during toxicity studies, obviously, these studies use toxic concentrations and are not intended to reach steady-state conditions but to estimate toxic or lethal body burdens. These types of studies cannot be accepted for a proper estimation of BCFs.

From the submitted studies, only those reported in Table 9.2.3-1 provide some useful information:

Table 9.2.3-1: Bioaccumulation in fish

Test organism	BCF (C_F/C_W)	Conc. in water (µg/l)	Conc. in fish (mg/kg)	$t_{1/2}$ for elim.	Doc. No.	Authors
Mugil cephalus (striped mullet)	2429 - 2755	0.035	0.085 - 0.097	< 2 days *)	A22871	Schimmel et al. (1977)
Brachydanio rerio (Zebra fish)	2650	0.3 (0.2 - 0.4)	0.81	4.04 days	A50529	Toledo & Jonsson (1992)
Yellow tetra fish	10994	0.2 (alpha)	0.2-1.1	2.01	A49919	Jonsson & Toledo (1993)
Yellow tetra fish	9908	0.1 (beta)	0.13-0.51	1.74	A49919	Jonsson & Toledo (1993)
Yellow tetra fish	11583	0.3 (alpha+beta)		1.8	A49919	Jonsson & Toledo (1993)

conc.: concentration
$t_{1/2}$ for elim.: elimination half live

In addition, an interlaboratory study on chronic toxicity (Hansen and Cripe, 1991) proposed BCF for *Cypronodum variegatus* in the range of 350-3700. However these values correspond to a toxicity test, no to a bioconcentration study.

These results confirm the bioaccumulation potential of endosulfan, with BCF in fish between 2500 and 10000, but also indicate a rapid clearance with half-lives of about 2 days.

Additional studies also suggest the accumulation in other aquatic organisms. A BCF of 600 in mussels for alfa-endosulfan has been reported by Ernst, 1997.

The notifier has also presented some additional estimations on the BCF of endosulfan in fish using data from the pond and field studies which in same cases include the measurement of endosulfan concentrations in fish tissues.

The rapporteur consider that this information is not scientifically valid, due to several reasons and in particular to those presented below:

a) The use of water/fish tissue ratios measured at water concentrations provoking toxicity or even lethality is not acceptable to estimate BCFs.

b) The "crude" estimation of average water concentrations from pond and field studies presenting large variability in the water concentration is not appropriate to estimate BCFs. If valid BCF estimations are required from these kind of studies, a proper toxicokinetic model should be produced and validated versus the raw data comparing the predicted versus the measured concentrations in fish according to the measured changes in the water concentration.

In addition, the field studies are not appropriate because the concentration of endosulfan in the water column were only relatively constant when achieving very low levels, and the detection limit in fish, 10 µg/kg, to high for a proper assessment.

Therefore, the conclusion of the notifier suggesting that the BCFs are expected to be lower, by an order of magnitude, in field versus laboratory studies is not acceptable and the validated laboratory data will be used in the assessment.

B.9.2.4 Toxicity to sediment dwelling organisms

The available information on the toxicity of endosulfan to sediment dwelling species is summarised in Table 9.2.4-1.

Table 9.2.4.1: Sediment species

Test organism	study type	Test duration		LC_{50} µg/kg	NOEC µg/kg	Study	Author
Chironomus plumosus (true midges)	static acute	48	h	25 µg/l	n.r.	Published	Goebel et al. 1982
Chironomus tentans (true midges)	sediment test	96	h	20	<6	GLP	Swigert & Mullen (1988)
Nannopus palustris (benthic copepod)	sediment test	7	d	n.r.	50	Published	Chandler & Scott (1991)
Pseudobradya pulchella (harpacticoid copepod)	sediment test	7	d	n.r.	200	Published	Chandler & Scott (1991)
Streblospio benedicti (polychaete)	sediment test	7	d	n.r.	<50	Published	Chandler & Scott (1991)

n.r. : not reported

The study by Swigert & Mullen (1988) on the Chironomid midge *Chironomus tentans* was conducted with technical endosulfan according to the US EPA guideline and under GLP. The study addressed the toxicity for sediment exposures and the rapporteur considers that this is the most valuable information to estimate the acute toxicity of endosulfan for sediment dwelling organisms and, therefore, the LC_{50} of 20 µg/kg sediment will be used in the assessment. Considering that the study is an acute bioassay using lethality as endpoint the NOEC cannot be validated. The other species, assayed under non standard conditions, showed less sensitivity than the chironomus larvae and therefore cannot be used. The rapporteur concludes that no valid information on the chronic toxicity of endosulfan to sediment dwelling organisms has been submitted.

B 9.2.5 Microcosm or mesocosm studies

Different types of studies have been submitted by the rapporteur as useful information for a higher tier assessment of the potential risk of endosulfan to aquatic organisms.

B 9.2.5.1 Microcosm studies

The first study submitted by the applicant corresponds to a published study (Peterson and Batley, 1993, Doc. No.: A53056) describing environmental fate and biological effects of endosulfan, in a simple static laboratory microcosm.

The microcosms consisted of 25-l-glass tanks filled with natural sediment (2300g wet weight) and natural pond water.

The macrophyte *Vallisneria sp.* was planted into the sediment. Four different total endosulfan concentrations were tested in triplicate: 5, 50, 500, and 5000 µg/l and duplicate control. The experiments were divided into two periods of four weeks each. The first period involved maintaining the tanks at a constant endosulfan concentration and observing changes in physicochemical, chemical and biological parameters within the microcosms with time. During the second period, the tanks were not dosed with any more endosulfan and water and sediment were analysed weekly to measure any changes. Invertebrate organisms were monitored in the microcosm system.

Endosulfan produced no significant changes in organism abundance at treatments of 5 and 50 µg/l. At concentrations of 500 µg/l, or higher, the number of cladocerans were significantly reduced in the water column, and in the sediment the populations of ostracods, nematodes and worms declined. Cladocerans were not significantly affected in the sediment and ostracods were not significantly affected in the water.

There was a measurable increase in chlorophyll a for the 5 µg/l treatment only. The authors suggest a possible nutrient effect of endosulfan at this lower level, where it may act as a carbon source for plankton growth, but this explanation is unlakely. A direct impact of endosulfan on photosynthesis seems highly improbable. Toxicity to phytoplankton could not be detected at higher concentrations by this method.

The results of these study are in good agreement with those expected, suggesting that aquatic invertebrates are more sensitive than algae and aquatic plants. The highest concentration of endosulfan not affecting cladoceran populations was 50 µg/l, in the same range that the NOEC of 63 µg/l reported for *Daphnia magna* reproduction.

B.9.2.5.2 Pond study

The possible effects of endosulfan on structure and function of natural pond ecosystems were investigated in a farm pond study conducted in south-western Georgia (USA) (Cornaby *et al*., 1989, Doc. No.: A41298). The results of this study were reviewed and summarised by Heusel (1992, Doc. No.: A48944).

The study has been already described in the environmental fate and behaviour chapter, therefore only a summary of the most relevant information for the risk assessment will be reported here.

Four ponds were selected for this study and tomatoes were crop in the surrounding area. Two ponds were used as control ponds and the other two as treated ponds. An endosulfan formulation, Thiodan 3EC, was applied to the tomato crops located in the water basin of the treated ponds. Endosulfan was applied as preparation at the highest recommended application rate per year (3 x 1.12 kg active substance/ha) to tomato fields

Both, pond characteristics and crop surface and location relative to the pond edge were not equal for all ponds. The situation is clarified in Figures 9.2.5.2-1 to 9.2.5.2-4.

The reports consider that the study represents worst case conditions for endosulfan application under USA registration. However, the rapporteur considers that the conditions are not necessarily worst-case for the intended uses within the EU, at least assuming the generic scenarios agreed for the estimation of PECs. To clarify this assessment a short description of the treated ponds is included below.

Treatment pond 1 (Pond C-27-1; Figure 9.2.5.2-1). Corresponds to a pond of 1.4 ha surface area and 1.8 m maximum depth. No information on the total water volume or average depth are specifically provided in the report but the rapporteur has estimated an approximated average depth of about 1 m. Therefore the maximum total water volume is about 4.7 times higher than that agreed for the generic scenario (1ha pond 0.3 cm depth) although the total water volume was obviously related to changes in the water level which occurred during the study

The surrounding watershed area was 20.4 ha. The tomato crop area covered 14.2 ha, which were treated 3 times. No efforts to keep a fix buffer zone were made and as can be seen in the figure, the distance between the crop and the pond varied from 5 to more than 50 m.

Figure 9.2.5.2-1: Situation and location of the Pond C-27-1

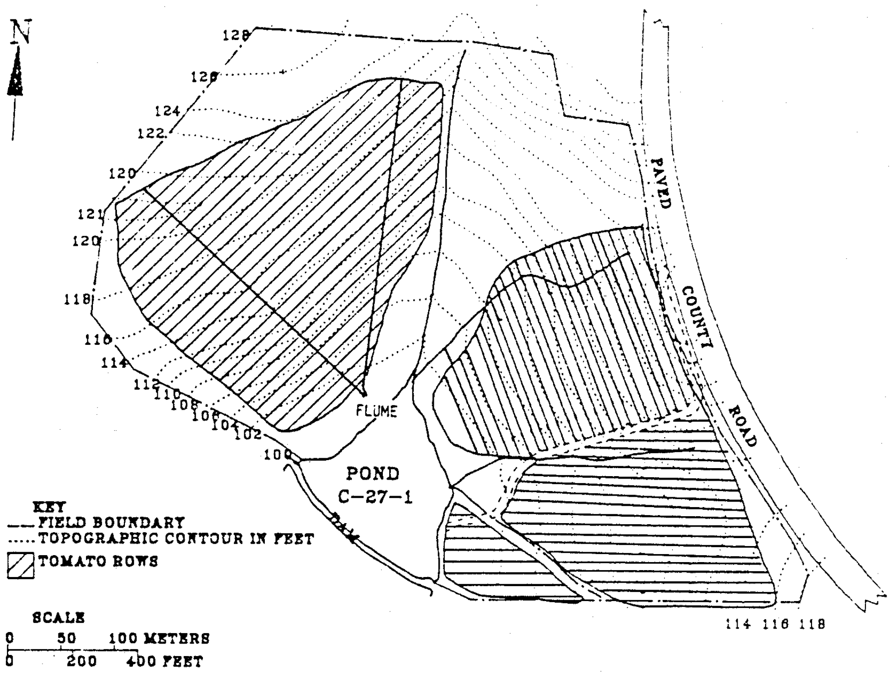


Figure 19. TOMATO ACREAGE AT C-27-1. 14.2 hectares (35 acres) of tomatoes were planted in the two fields. Location of the flume in this drainage area is also shown.

Treatment pond 2 (Pond M-55-8; Figure 9.2.5.2-2). Correspond to a pond of 0.9 ha surface area and 1.5 m maximum depth. The rapporteur has estimated an approximated average depth of about 0.7 m. Therefore the maximum total water volume is about 2.1 times higher than that agreed for the generic scenario (1ha pond 0.3 cm depth) although the total water volume was obviously related to changes in the water level which occurred during the study

The surrounding watershed area was 9.9 ha. The tomato crop area covered 8.5 ha, which were treated 3 times. No efforts to keep a fix buffer zone were made and as can be seen in the figure, the distance between the crop and the pond varied largely, from 15 to more than 50 m in the right and left sides of the pond and the treated area did not covered the bottom part of the pond.

Figure 9.2.5.2-2: Situation and location of the Pond M-55-8

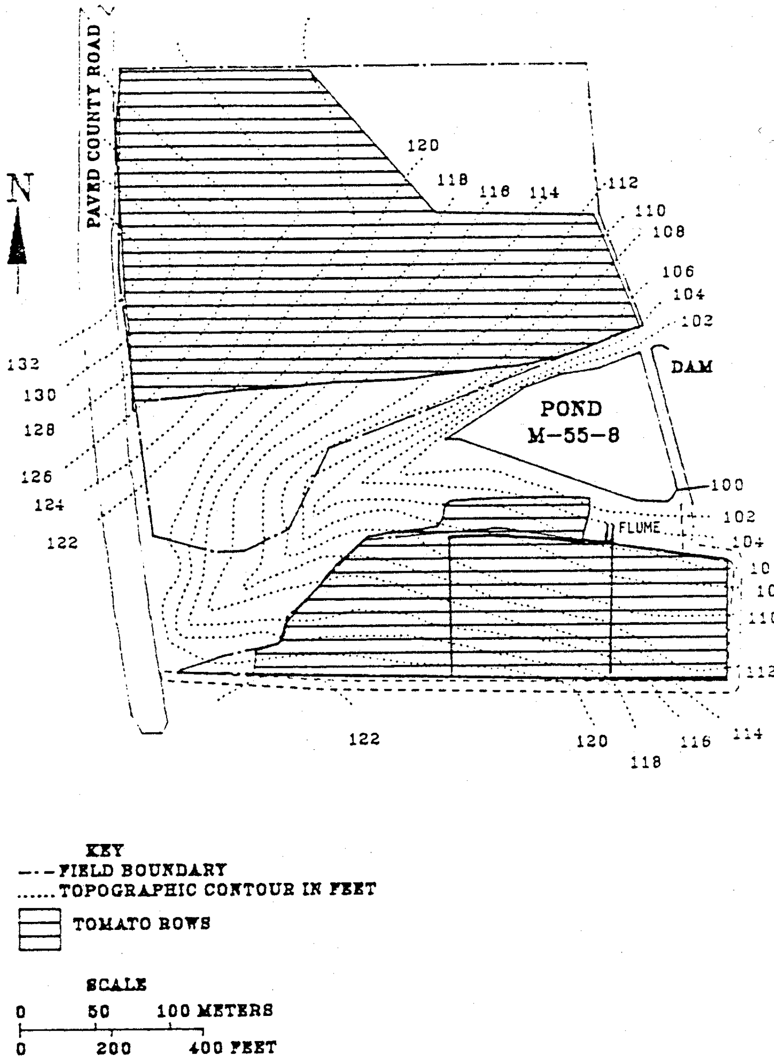


Figure 21. TOMATOES ACREAGE AT M-55-8. 8.5 hectares (21 acres) were planted in the two fields. Location of the flume in this drainage area is also shown.

Control ponds (Figures 9.2.5.2-3 and 9.2.5.2-4): The characteristics of the control ponds were: surface area 0.8 and 1 ha; maximum depth 2.8 and 1.2 m; watershed area 9.6 and 15.1 ha; tomato crop area 8.5 and 10 ha respectively.

The study includes a large amount of information on both fate and behaviour and ecotoxicity. The main results from the environmental fate aspects are summarised in Table 9.2.5.2-1.

Figure 9.2.5.2-3: Situation and location of the Pond M-55-4

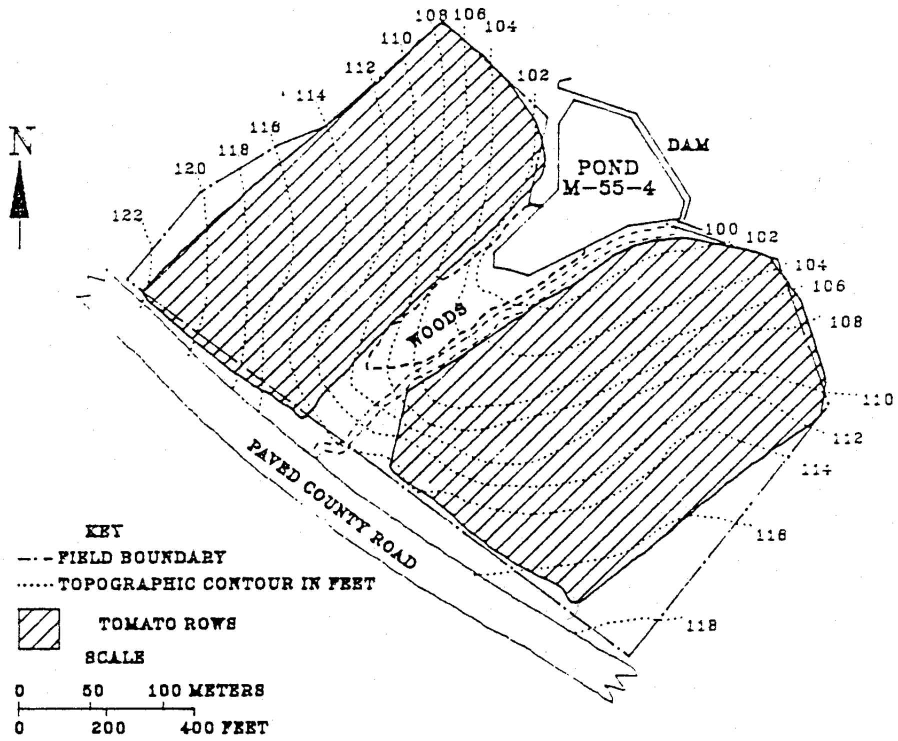


Figure 20. TOMATOES ACREAGE AT M-55-4. 8.5 hectares (21 acres) of tomatoes were planted in the two fields.

Figure 9.2.5.2-4: Situation and location of the Pond T-4-1

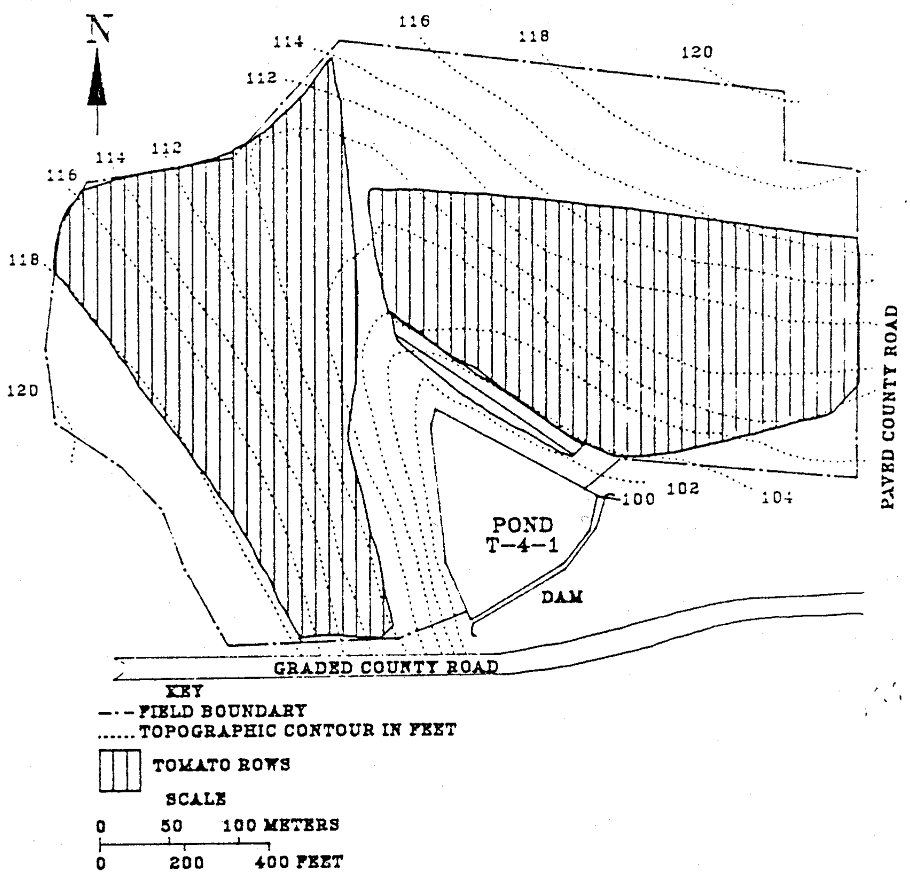


Figure 22. TOMATO ACREAGE AT T-4-1. 10 hectares (25 acres) of tomatoes were planted in the two fields.

Table 9.2.5.2-1: Summary of the main events related environmental fate and behaviour of endosulfan in the first treatment pond.

Day	Parameter/Observation	Result	Comments
0	First application		
0	Spray drift on pond surface during first application	α-E 114±59 µg/m² β-E 52±32 µg/m² E-sulf <0.6 µg/m²	Corresponds to aprox. 0.2% of the amount applied to 1 ha.
1	Soil concentration after first application	α-E 178±235 µg/kg β-E 132±155 µg/kg E-sulf 21±20 µg/kg	mean±sd
1	Water concentration after first application	α-E 42±10 ng/l β-E 38±17 ng/l E-sulf <5±3 ng/l	Corresponds to aprox. 36% (α-E) and 73% (β-E) of the concentration estimated according to spray drift.

Day	Parameter/Observation	Result	Comments
1	Sediment concentration after first application	α-E <5 µg/kg β-E <5 µg/kg E-sulf <5 µg/kg	mean±sd
14	Second application		
14	Spray drift on pond surface during second application	α-E 169±52 µg/m^2 β-E 50±17 µg/m^2 E-sulf <0.6 µg/m^2	Corresponds to aprox. 0.2% of the amount applied to 1 ha.
14	Soil concentration after second application	α-E 405±228 µg/kg β-E 400±195 µg/kg E-sulf 81±25 µg/kg	mean±sd
14	Water concentration after second application	α-E 120±41 ng/l β-E 78±7 ng/l E-sulf 61±3 ng/l	mean±sd
14	Sediment concentration after second application	α-E <5 µg/kg β-E <5 µg/kg E-sulf <5 µg/kg	mean±sd
31	Third application		
31	Spray drift on pond surface during third application	α-E 22±25 µg/m^2 β-E 7±8 µg/m^2 E-sulf <0.6 µg/m^2	Corresponds to aprox. 0.04% of the amount applied to 1 ha.
32	Soil concentration after third application	α-E 870±130 µg/kg β-E 1260±313 µg/kg E-sulf 158±66 µg/kg	mean±sd
32	Run-off (20-30 mm) is induced after third application		
33	Run-off (20-30 mm) is induced Concentrations in run-off	α-E 30000-67000 ng/l β-E 45000-120000 ng/l E-sulf 6700-20000 ng/l	These are the highest concentrations measured in the run-off.
34	Water concentration after third application and run-off	α-E 377±361 ng/l β-E 413±444 ng/l E-sulf 337±326 ng/l	The α-E concentrations correspond to a run-off of about 0.01% of the total applied amount or 0.05% of the amount remaining in the soil top 5 cm.
34	Sediment concentration after third application and run-off	α-E <5 µg/kg β-E 5±9 µg/kg E-sulf <5 µg/kg	mean±sd
36	Water concentration 2 days after run-off	α-E 288±356 ng/l β-E 627±486 ng/l E-sulf 415±482 ng/l	Highest concentrations measured in water
39	Sediment concentration after run-off	α-E 7±8 µg/kg β-E 30±17 µg/kg E-sulf 14±9 µg/kg	Highest concentrations measured in sediment
39	Precipitation (18 mm)		
46	Precipitation (22 mm)		
	Additional run-off events		

Similar patterns were observed for the second treatment pond. The highest concentrations in this pond were 583 ng/l and 99.4 µg/kg (sum of isomers and endosulfan sulphate) in water and sediment respectively, following run-off events after the third application.

No effects associated to the treatment were observed on aquatic plants, algae or water column invertebrates, supporting the values validated in the risk assessment for invertebrates according to the results observed in the laboratory tests.

A significant decrease in the density of chironomids and oligochaetes during and/or after the first run-off were observed. The study authors considered that these effects could not be associated to the treatment, on the basis that were not observed in the second treatment pond where endosulfan concentrations in the sediment were higher than in the first treatment pond. However, the sampling intensity of this study, the high variability within the sampling points (obviously expected in this type of studies and particularly when run-off constitutes the main contamination source), and the lack of information on the relative toxicity of the isomers and the metabolites, creates difficulties in the interpretation of these results. The effects, could be associated to particularly high concentrations of endosulfan (either individual or combined isomers-metabolites) in certain areas of the first pond, which in fact presented water column concentrations much higher than the second treatment pond. Therefore, the rapporteur concludes that the observed effects could on not be associated to the treatment, and therefore no conclusive evidence on the effects on sediment dwelling organisms can be obtained from this study.

The treatments, and in particular the high concentrations produced due to the run-off events observed-induced after the third treatment provoked fish kill events in both treatment ponds.

In the first treatment pond, 447 dead fish were collected after these run-off events. 88% of these fish were observed during the 3 days following the run-off events induced after the third application. Fish mortality affected to 8 species, which represent a 53% or 80% of the fish species in the pond considering species observed at any time in the pond or only during the treatment and post treatment period respectively (5 fish species were sporadically observed during the pre-application observations but not later, no explanations are given in the report but it seems unlikely that this phenomenon could be associated to the treatment).

In the second treatment pond, the number of dead fish was 227, with 73% in the first three days after the run-off event. Fish mortality was observed for 40% of the species present in the pond.

The study also includes population estimations for the most abundant fish species in the ponds. No significant effects on long-term population responses associated to the treatment were observed.

The rapporteur considers that this study confirms the high acute toxicity of endosulfan to fish, which are considered the group supporting the higher short-term risk for this pesticide.

The arguments suggested by the applicant, in the sense that the observed fish kill are not relevant in terms of the percentage and size of the affected individuals and the lack of long-term effects at the population level in the studies species (representing the largest populations) are not considered acceptable by the rapporteur.

In addition to the relevance of mortality among vertebrate species even without population consequences, the study does not demonstrate that all fish populations were not affected. Obviously, large populations are expected to be less affected and/or recover better than small populations and the pond study only included monitoring for the largest populations.

The effects at population level cannot be extrapolated to fish populations belonging to systems with different characteristics and where the pesticide can have different fluxes within the system.

In addition, in the area in which endosulfan should be mainly applied according to the intended uses, several autochthonous fish species of high ecological value can be found, and obviously fish kill in these species can be considered of high ecological relevance.

The comparison of the species sensitivity distribution with the percentage of fish affected at the concentrations detected in the treatment ponds confirms the applicability of this proposal in the risk assessment of endosulfan.

Therefore, it is concluded that concentrations of endosulfan below 1 µg/l can produce acute lethal toxicity on fish. The study also confirms that very large buffer zones are required to avoid this level of contamination due to spray drift when the generic EU scenario is used, and that run-off becomes the most relevant exposure route when these large buffer zones are applied. Therefore, for a higher tier assessment, proper scenarios for the risk assessment of endosulfan in the crops and conditions included in the intended uses should be required.

Finally, the study reports estimations on the concentration of endosulfan in fish, which confirm the bioavailability of the pesticide reaching the pond via run-off. The applicant suggest that these results could be used to estimate a BCF for fish, which should be about one order of magnitude lower than that estimated by the laboratory studies. The rapporteur considers that the study design is not appropriate for an estimation of the BCF, which is defined as the relationship between the concentration of the chemical in the water and in the fish at equilibrium conditions and requires the use of concentrations clearly below the those resulting in toxicity. These essential conditions are not fulfil in the pond study and therefore the proposal of the applicant is not accepted. Nevertheless, the study confirms a relatively rapid clearance of endosulfan in exposed fish as predicted by the laboratory studies.

B. 9.2.5.3 Other field studies

Several field studies can be found in literature. The following have been reported by the notifier and considered by the rapporteur (Table 9.2.5.3-1).

Table 9.2.5.3-1: Other field studies

Region	Chemical	Objectives	Results	Study condition	Authors Doc nº	Remarks
Java	Thiodan ®	Direct application to paddy fields (1.4 l EC formulation/ha	LC100 24 h= 1 ppb	Published	Gorbach et al. (1971) A 18219	
Nigeria	Endosulfan	800 to 1000 g active substance /ha Vector control (Glossina sp) helicopter applications	Birds, snakes, mammals and fish died. Complete elimination of the fish population for more than 1 month.	Published	Koeman et al. (1978) A 25903	
Zambia	Thiodan	2.8 kg/km^2 = 28 g ai/ha Vector control (Glossina morsitans centralis)	No effects on fish or dragonflies	Published	Magadza (1978) A 35665	
Zimbabwe-Rhodesia	Endosulfan 20%	Effects of 14g ai /ha of on fish. Mice, bees, arthropods and frogs Vector control (Glossina)	82.2% death on fish (6 days); 85.5% death on fish (19 days)	Published	Cockbill (1979) A 31704	
Upper Volta	Endosulfan 25% (OMS-570)	Vector control (Glossina tachinoides) 2X100g ai/ha 2X200 g ai/ha	Lethal effects of many fish species and insects. Repopulation of some species after 1 year	Published	Baldry et al. (1981) A21408	
Botswana, Okavango Delta	Endosulfan	Vector control (Glossina morsitans). 9.5 g ai/ha	Up to 25% mortality in fish; effects on reproduction in fish. Effects on chironomus.	Nor GLP or Published	Douthwaite et al. (1981) A 23822	

These studies cannot directly be used for a risk assessment of agricultural uses of endosulfan within the EU as the objectives, application conditions and environmental characteristics of the treated areas are not related to those covered by this risk assessment.

Only those cases in which endosulfan concentrations in the water were measured or can be estimated from the available information, the results of the studies can be considered as additional evidence. In general, the studies confirmed the sensitivity of fish to endosulfan, and fish kill were observed for concentrations in the range of µg/l. Two studies (Gorbach *et al.,* 1971, Doc. No.: A18219; Douthwaite *et al*., 1981, Doc. No.: A23822) suggest that endosulfan, and in particular endosulfan residues remaining several hours after application, could be less toxic to fish than expected from laboratory exposures, at least regarding mortality. However, the differences do not seem to be very large. As an example, the study of Gorbach *et al*. (1971, Doc. No.: A18219) will be commented.

An application rate of 1.4 l Thiodan 35 EC per hectare was directly applied to paddy fields in Java. After treatment, the initial residue levels were between 550 µg/l (field A, standing water) and 68 µg/l (field B, flowing water). As expected, these concentrations had lethal effects on introduced fish (*Puntius javanicus*). Freshly introduced fish survived in field A after 5 days at a measured concentration of 0.87 µg/l, in field B already after 1 day at a measured concentration of 0.9 µg/l. The subsequent 15 days with concentrations of 0.2 to 0.6 µg/l following application were tolerated without noticeable damage. The LC_{100} of this fish species is reported as 1 µg/l, and it was consider that fish can survive for some time periods concentrations near the 24h LC_{100}. However, the measured concentrations are reported as the sum of endosulfan isomers and sulphate, which appeared at different proportions, and therefore are not easily comparable, and no clear evidence of the role of each isomer or even the metabolites are reported.

B.9.2.6 Risk assessment for aquatic organisms

The risk of endosulfan applications for aquatic organisms can be initially addressed comparing laboratory data versus the Predicted Environmental Concentrations.

Considering the large amount of information available on the acute toxicity of endosulfan for fish and aquatic invertebrates covering several species and taxonomic groups specific approaches must be considered.

B.9.2.6.1 Risk assessment for fish

The toxicity to fish species is mostly limited to the range 0.1 to 10 µg/l. The rapporteur has checked that data follows a log-normal distribution and the value of 0.13 µg/l reported as protective for 95% of the species will be used.

The following tables consider the estimated risk of endosulfan for fish assuming worst case conditions.

Table 9.2.6.1-1: Acute TER estimations for fish

Crop	Application rate	Nº	SI Days	Distance m	Drift %	Initial PECsw µg as/L	TER
Citrus	1.05	2	14	3	15.5	54.25	0.002
				10	4.5	15.75	0.008
				50	0.2	0.70	0.18
Vineyards	1.05	2	14	3	7.5	26.25	0.005
				10	1.5	5.25	0.025
				50	0.2	0.70	0.18
Arable crops	0.84	3	14	1	4.0	11.20	0.01
				10	0.4	1.12	0.11
				30	0.1	0.28	0.46
Arable crops	0.53	3	7	1	4.0	7.07	0.018
				10	0.4	0.71	0.18
				30	0.1	0.18	0.72

The results clearly indicate a potential risk for fish even assuming large buffer zones. It is clear that the uncertainty in this assessment is obviously lower than that expected in other cases where the toxicity data are limited to two species with no information on the sensitivity curve distribution.

The trigger value of 100 for the acute TER for fish proposed in the Directive corresponds to a margin of safety (assessment factor) of 100. This value is normally interpreted as a combination of a factor 10, to cover differences within species, and other factor of 10 to extrapolate from acute to chronic value (i.e., see Bro-Rasmussen *et al*., 1994; Tarazona 1998)1. Considering that in this particular case the differences in species sensitivities are already covered by the use of the 95th percentile of a sensitivity distribution curve, the rapporteur considers that in a higher tier assessment, a TER value of 10 on this percentile can be considered as acceptable for the protection of fish species. However, this value is not reached even assuming large buffer zones, and therefore a potential risk for fish is expected.

In addition, the estimations for the risk associated to run-off using a generic scenario also provide TER values lower than 1, and therefore suggest a potential risk.

The long-term chronic TER for the initial assessment are included in Table 9.2.6.1-2. It should be recognised that these values do not represent worst case conditions as the NOEC used correspond to a NOEC for growth when reproductive effects are more relevant for a proper risk assessment of the long-term risk of endosulfan.

Table 9.2.6.1-2: Chronic TER estimations for fish, using the NOEC for rainbow trout

[1] Bro-Rasmussen, F., P. Calow, J.H. Canton, P.L: Chambers, A. Silva Fernandes, L. Hoffmann, J.M. Jouany, W. Klein, G. Persoone, M. Scoullos, J.V. Tarazona and M. Vighi, 1994. EEC water quality objectives for chemicals dangerous to aquatic environment (List 1). Rev. Environ. Contam. Toxicol. 137:83-110.

Crop	Application rate	Nº	SI Days	Distance m	Drift %	Initial PEC_{sw} µg as/L	TER
Citrus	1.05	2	14	3	15.5	54.25	0.001
				10	4.5	15.75	0.003
				50	0.2	0.70	0.07
Vineyards	1.05	2	14	3	7.5	26.25	0.002
				10	1.5	5.25	0.01
				50	0.2	0.70	0.07
Arable crops	0.84	3	14	1	4.0	11.20	0.004
				10	0.4	1.12	0.04
				30	0.1	0.28	0.18
Arable crops	0.53	3	7	1	4.0	7.07	0.007
				10	0.4	0.71	0.07
				30	0.1	0.18	0.28

All TER values are lower than the trigger value even using large buffer-zones. These results suggest a potential long term risk of endosulfan to fish even using an endpoint likely non sensitive.

In addition, the estimations for the risk associated to run-off using a generic scenario also provide TER values lower than 1, and therefore suggest a potential risk.

As mentioned in the introduction, the use of TWA-PEC is not appropriate considering the uncertainty on the environmental fate, the uses requiring several applications and the toxicity of endosulfan sulfate. An therefore, only TER values established on initial PECs are considered reliable by the rapporteur.

From the higher tier studies submitted by the notifier, the pond study including treatment of tomato crops under real situations is considered by the notifier as the most relevant study.

The conclusions presented by Heusel, 1992, in the extended summary suggesting that the highest detected concentration observed in the study, which in fact provoked significant fish mortalities, corresponds in reality to the NOEC for aquatic organisms cannot be supported by the rapporteur.

To provide enough transparency the conclusions of the notifier are reported below:

After the first artificially induced discharge of run-off water supported by natural rainfall following the third application a limited number of fish kills restricted to the littoral zones of both treatment ponds occurred. 91% of the 447 or 227 dead fish were smaller than 6 cm, and 0 and 8 dead adult fish (> 11 cm) were observed, respectively. The concentration of endosulfan in run-off water was 203 µg/l or 80 µg/l respectively, and there was only little dilution in the littoral zones. No signs of intoxication , however, were observed in the surviving fish and no decrease in the number of young of the year. In addition evidence of successful reproduction of sunfish was found during and after the last application. No effects on the condition factor of fish or the structure within and between the fish populations could

Tarazona J.V. (1998) Scientific concepts and uncertainties in the identification of ecotoxicological thresholds of acceptability and danger. The role of biological routes. In D.M. Pugh and J.V. Tarazona (editors) Regulation for Chemical Safety in Europe: Analysis, comment and criticism. Kluwer Academic Publishers. Dordrecht/Boston/London, pp 41-63.

be observed. It can thus be concluded that the observed mortality affected only a negligibly small portion of the total fish population and had no effects on the ecosystem of the ponds as a whole.

It can thus be stated that the maximum endosulfan concentration measured in the pelagic zone constitutes the no observed effect concentration (NOEC) in this pond study and lies at or higher than 1.3 µg/l. The chronic no observed effect concentration (time weighted mean over the observation period of 210 days) lies at or higher than 0.14 µg/l.

The arguments to consider that this conclusion is not acceptable are reported in the description of the pond study. A fish kill under realistic application conditions is considered by the rapporteur as an "Observable Effect", and even more, as an unacceptable effect although the mortality can be associated to "*a negligibly small portion of the total fish population and restricted to the littoral zones*". Even more, the rapporteur considers that the study confirms that run-off and soil erosion can be significant routes of exposure, particularly when buffer zones are applied, and the conditions of the study (an small treated area versus a large and deep pond) does not represent worst case conditions for the intended uses, where small streams and reservoirs can receive the run-off from extended areas of treated crops. The number of fish species affected is also in agreement with the percentage of affected species estimated from the sensitivity distribution curve obtained from laboratory data.

In conclusion, the rapporteur considers that the study confirms a high risk of endosulfan for fish species if the molecule is able to reach aquatic ecosystems even at concentrations lower than 1µg/l. The development of crop-specific scenarios for the refinement of this assessment is considered the best alternative. Taking into account that the isomer alfa seems to be the most toxic but at the same time the most rapidly degraded in both soil and water, an additional level of refinement could be achieved by an independent assessment of the environmental fate and toxicity of each isomer an the metabolites, particularly endosulfan sulphate, which obviously should include the assessment of synergistic effects among the isomers and the metabolite.

B.9.2.6.2 Risk assessment for aquatic invertebrates

Regarding aquatic invertebrates the available information also cover several species bellowing to different taxonomic groups, however, the situation is rather different than that observed for fish. The toxicity range covers several orders of magnitude and large differences are observed even for species belonging to related groups as well as for different developmental stages within the same species. Therefore, the use of sensitivity distribution curves is not considered appropriate in this case. The rapporteur proposes the use of an LC_{50} of 0.04 µg/l, as the acute toxicity endpoint for the most sensitive aquatic invertebrate; and a 48 h. EC_{50} of 150 µg/l for *Daphnia magna* which corresponds to the 90^{th} percentile for the data on this species.

Both values have been used for the TER calculations. The results are summarised in Tables 9.2.6.2-1 and 9.2.6.2-2.

Table 9.2.6.2-1: Acute TER estimations for Daphnids

Crop	Application rate	Nº	SI Days	Distance m	Drift %	Initial PEC_{sw} µg as/L	TER
Citrus	1.05	2	14	3	15.5	54.25	2.7
				10	4.5	15.75	9.5
				50	0.2	0.70	214
Vineyards	1.05	2	14	3	7.5	26.25	5.7
				10	1.5	5.25	28
				50	0.2	0.70	21.4
Arable crops	0.84	3	14	1	4.0	11.20	13
				10	0.4	1.12	134
				30	0.1	0.28	536
Arable crops	0.53	3	7	1	4.0	7.07	21
				10	0.4	0.71	211
				30	0.1	0.18	833

Table 9.2.6.2-2 Acute TER estimations for the most sensitive aquatic invertebrate

Crop	Application rate	Nº	SI Days	Distance m	Drift %	Initial PEC_{sw} µg as/L	TER
Citrus	1.05	2	14	3	15.5	54.25	0.0007
				10	4.5	15.75	0.003
				50	0.2	0.70	0.06
Vineyards	1.05	2	14	3	7.5	26.25	0.002
				10	1.5	5.25	0.008
				50	0.2	0.70	0.06
Arable crops	0.84	3	14	1	4.0	11.20	0.004
				10	0.4	1.12	0.04
				30	0.1	0.28	0.14
Arable crops	0.53	3	7	1	4.0	7.07	0.006
				10	0.4	0.71	0.06
				30	0.1	0.18	0.22

The results obtained for the standard species, *Daphnia magna*, must be interpreted in an standard way, and therefore the use of the trigger value of 100 for this assessment is considered appropriate. The data indicate that using large buffer zones the potential risk of endosulfan for aquatic invertebrates can be managed at least in some crops.

This generic assessment does not cover the most sensitive species. However, it must be recognised that shrimps seems to be particularly sensitive, and according to the rationale discussed for fish, the application of a margin of safety of 100 in this case seems to be not appropriate. The rapporteur considers than from an ecological point of view the risk for this most sensitive aquatic invertebrates should be covered by the risk for fish, and therefore no additional estimations are required. This conclusion is also supported by the information provided by the pond studies, which showed no relevant effects on the invertebrate community at concentrations producing fish kills.

Nevertheless, the situation is different regarding the protection of economical interest associated to the cultivation of some shrimp species. Risks that can be considered of low ecological relevance due to their very localised nature and species redundancy can be however unacceptable for cultivated species that require population-level protection instead of the community-level protection required for the maintenance of the structure and functioning of the ecosystem. Therefore, appropriate risk management measures should be proposed by the applicant and considered by Member States to avoid toxicity problems of cultured shrimps and related species. The rapporteur considered that due to the localised nature of shrimp culture, indications on the label and buffer zones around these cultures should be efficient enough to provide a proper risk management.

The amount on information on the chronic toxicity of endosulfan to aquatic invertebrates is limited and only the risk for Daphnids, are a generic species of this group, can be evaluated. The 21 days NOEC for Daphnia magna is 63 µg/l and this value will be used in the assessment included in Table 9.2.6.2-3.

Table 9.2.6.2-3: Long-term TER estimations for Dapnids

Crop	Application rate	Nº	SI Days	Distance m	Drift %	Initial PEC_{sw} µg as/L	TER
Citrus	1.05	2	14	3	15.5	54.25	1.1
				10	4.5	15.75	4
				50	0.2	0.70	90
Vineyards	1.05	2	14	3	7.5	26.25	2.4
				10	1.5	5.25	12
				50	0.2	0.70	90
Arable crops	0.84	3	14	1	4.0	11.20	5.7
				10	0.4	1.12	56
				30	0.1	0.28	2.25
Arable crops	0.53	3	7	1	4.0	7.07	8.9
				10	0.4	0.71	90
				30	0.1	0.18	350

The results show a potential long-term risk, with TER values below the trigger, when no buffer zones are applied, while the risk can be reduced to acceptable levels for all crops by requiring appropriate buffer zones.

B.9.2.6.3 Risk assessment for algae

The information on algae is limited to a reduced number of species and the most relevant information corresponds to the data on an standard species under standard conditions. Therefore, the 72h NOEC obtained for the green alga *Scenedesmus subspicatus* of 560 µg/l and an LC_{50} reported as higher than this value will be used.

Table 9.2.6.3-1 considers the estimated risk of endosulfan for algae.

Table 9.2.6.3-1: Acute TER estimations for fish

Crop	Application rate	Nº	SI Days	Distance m	Drift %	Initial PEC_{sw} µg as/L	TER
Citrus	1.05	2	14	3	15.5	54.25	10.3

				10	4.5	15.75	36
				50	0.2	0.70	800
Vineyards	1.05	2	14	3	7.5	26.25	22
				10	1.5	5.25	108
				50	0.2	0.70	800
Arable crops	0.84	3	14	1	4.0	11.20	50
				10	0.4	1.12	500
				30	0.1	0.28	2000
Arable crops	0.53	3	7	1	4.0	7.07	79
				10	0.4	0.71	800
				30	0.1	0.18	3111

The TER values are higher than the trigger value of 10 and therefore is concluded that endosulfan does not represent a relevant risk for algae and aquatic plants.

B.9.2.6.4 Final conclusion on the potential risk for aquatic organisms

The weight of evidence clearly show that despite the high sensitivity of some crustaceans at particular development stages, fish can be considered as the aquatic taxonomic group supporting the highest ecologically relevant risk associated to endosulfan applications. Regardless the large amount of studies reviewed by the rapporteur to produce this monograph, it is evident the lack of relevant information, particularly on the relative toxicity and synergistic effects among the endosulfan isomers and the metabolites including endosulfan sulphate. It has been impossible to conduct independent risk assessment for each of these molecules, although the rapporteur consider that large differences in terms of environmental fate and behaviour are evident, and also, likely differences in terms of toxicity to aquatic organisms can be expected. However, the isomers and the metabolites are expected to appear together during enough time periods to require a proper quantitative assessment of potential synergistic effects, and this information cannot be obtained from the studies submitted by the notifier.

The higher tier studies confirm the applicability of the probabilistic approach selected for the protection of fish population. However, the information on potential long-term effects, and particularly those associated to reproductive disorders, is very limited, and the hypothesis of the notifier suggesting a rapid drop of the dose-response curve and therefore, reduced acute-to-chronic factors cannot be validated by the rapporteur on the basis on the sudden mortality observed during fish sexual maturation in the life-cycle study, and the fact that the other chronic studies do not address reproductive effects.

Therefore, the rapporteur considers that a margin of safety of 10 on the lowest end (95 percentile) of the fish acute toxicity sensitivity distribution curve should be applied to guarantee the protection of fish populations, and therefore, endosulfan applications resulting in a significant likelihood of surface water contamination at levels higher than 0.01 µg/l should not be allowed.

The use of the generic EU worst case scenario suggests that concentrations higher than this threshold value can be achieved for the intended application rates even assuming large buffer zones.

However, the rapporteur considers that this generic worst case scenario could be non realistic for most of the crops in which endosulfan is intended to be used, particularly after the notifier decision of limiting the intended used to South Europe. Unfortunately, the notifier has not presented higher tier scenarios for the crops and application conditions included under their intended uses, and therefore, a proper higher tier realistic risk assessment cannot be conducted.

Therefore, the rapporteur concludes than from the available information, a potentially unacceptable risk of endosulfan for aquatic organisms has been identified. The risk, quantified by potentially non realistic worst case scenarios, is so high that cannot be handle by conventional risk management decisions such as buffer zones, and therefore, the notifier should be asked to present realistic worst-case scenarios for each crop and application conditions included in the list of intended uses.

The pond study confirms that when buffer zones are set, run-off and soil-erosion becomes the critical route of exposure, being more relevant than spray drift. In addition, due to the relatively high persistence of endosulfan in the soil, this contamination route can be still relevant several weeks after the application of the pesticide, and therefore this route should be particularly considered when providing scenarios for a high tier risk assessment.

B.9.2.6.5 Risk assessment for sediment dwelling organisms

The acute LC_{50} of 20 µg/kg sediment of endosulfan on the Chironomid midge *Chironomus tentans* has been considered the most valuable information to estimate the acute toxicity of endosulfan for sediment dwelling organisms, while a valid chronic NOEC cannot be estimated from the available laboratory tests.

In addition, no valid chronic toxicity data have been submitted, and no information on the acute and chronic toxicity of the metabolites, and particularly of endosulfan sulphate, has been presented. Therefore a proper risk assessment for sediment dwelling organisms cannot be produced but at least a potential short term risk has been identified.

Proper PEC sediment concentrations cannot be established with the current information, but the pond study can be used as a non-worst case reference.

The pond study includes determinations on both, sediment concentrations and effects on sediment dwelling organisms. The study clearly confirms the potential of endosulfan to achieve higher concentrations in the sediment. Even for this non-worst case scenario, the concentrations in the sediment are up to 2.5 and 5 times higher than the acute toxicity to chironomids estimated from laboratory species.

Regarding the observed effects in the pond study, the results are not conclusive, significant decreases in the density of chironomids and oligochaetes coinciding with the highest concentrations of endosulfan in water and sediment were observed in one of treatment ponds (the pond showing the highest concentration in water) but not in the other (the pond showing the highest concentration in the sediment) and it is impossible from the available data to clarify if this effect was or not associated to the endosulfan application.

Therefore, additional information is required for a proper assessment of the potential risk of endosulfan for sediment dwelling organisms.

B.9.2.6.6 Risk assessment for bioaccumulation/biomagnification through the food chain.

From the available information, a high potential for bioaccumulation in fish tissues but a rapid clearance can be considered. The values suggested by the rapporteur are a BCF in fish of 5000 and a half life of 2 days.

Using this information the relevance of the bioaccumulation and biomagnification has been assessed according to the models developed by the INIA.

The relevance of bioacumulation has been assessed comparing expected concentrations *via* water *versus* food for fish eating fish (Carbonell *et al*., 1998)[2]. The model suggests that for short-term exposures, the concentration of endosulfan in fish food items can be significant in terms of the total exposure.

Regarding biomagnification through the food chain a three levels food chain was modelled [3] assuming, as worst case, an assimilation efficiency for endosulfan in food of 90%, half life for depuration of 2 days, and daily food consumption of 30, 10 and 5% of their body weight for herbivorous, predators and top predators respectively. The model suggests that the risk of biomagnification through the trophic chain is very low for this pesticide.

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[2] Carbonell G, Ramos C, Pablos MªV, Ortíz JA, Tarazona JV (1998). Desarrollo de un modelo para valorar diferentes rutas de exposición en ecosistemas acuáticos. **Cuad Invest. Biol**. 20:131-134.

[3] Spanish Proposal to establish a generic scenario for the estimation of biomagnification potential, presented to the ECB for the discussions on the Technical Guide Document revision.

B.9.3 Effects on other terrestrial vertebrates (IIIA, 10.3)

The toxicity on mammals is included in chapter 6. The studies have been considered in terms of the environmental relevance of the endpoints. The selected data were: acute LD50 of 10 mg/kg bw for female rat; and a NOEC of 1 mg/kg bw/day from the NOAEL obtained in the two generation study on rats, with is also at the same level that the NOEC for relevant effects observed for mice (combined toxicity/carcinogenicity) and rabbit (developmental toxicity). The value is lower than that observed in the subchronic oral studies, and therefore cover all long-term effects.

A daily food intake for small mammals of 25% their body weight have been used and the ETE values were estimated for leaves according to Hoeger and Kenaga. The values for leaves are similar to those expected in small insects, and therefore the assessment covers both herbivorous, insectivorous and omnivorous small mammals.

Table 9.3-1: TER acute estimation for terrestrial mammals

Application rate	Estimation initial residue	Maximum daily intake	TER
1.05 (citrus, pome fruits and vineyards)	32.55	8.1	1.2
0.53 (tomatoes, potatoes and cucrbits)	16.43	4.1	2.4
0.83 (stone fruits)	25.73	6.43	1.5

Table 9.3-2: TER estimation for long-term toxicity of endosulfan for terrestrial mammals.

Application rate	Estimation initial residue	Maximum daily intake	TER
1.05 (citrus, pome fruits and vineyards)	32.55	8.1	0.12
0.53 (tomatoes, potatoes and cucurbits)	16.43	4.1	0.24
0.83 (stone fruits)	25.73	6.43	0.15

The TERa and TERlt are lower than the trigger values and therefore a potential risk for small mammals has been identified.

As already commented for the bird assessment the use of initial ETE values instead of time-weighted average for the long-term assessment is justified by the intended uses covered by the GAPs and the lack of information for a most in depth assessment of expected long-term exposures.

B. 9. 4 Effects on bees (IIA, 8.3.1; IIA, 10.4)

Several studies have been submitted on the toxicity of endosulfan to bees.

B.9.4.1 Acute toxicity

- **Active substance**

No information has been submitted.

- **Plant Protection Product**

Bock, K.-D. 1986

This study shows the laboratory investigations of the effects of Thiodan 35 EC on the honey bee *Apis mellifera*. The study was not conducted under GLP. 1.0, 3.0, 4.0, 5.0, 6.0, 7.0, and 14.0 µg product / bee were dissolved in sugar solution and offered to groups of ten bees; 5 replicates per dose level and 10 bees per replicate were used. The test were repeated in five different laboratories. The ED_{50} value after 48 hours was 5.99 µg formulated product /bee (95% range of confidence: 5.52-6.64), which corresponds to 2 µg a.i./bee.

B.9.4.2 Acute Contact toxicity

- **Active substance**

This study presents the laboratory trials to determine the effect of endosulfan on the Honeybee *Apis mellifera* L The study was not conducted under GLP. The test was developed for the determination of the contact effect of endosulfan (substance, pure; >99%) on bees following topical application. The test substance was dissolved in acetone. The mortality rate was determined after 24 and 48 hours. Test species was *Apis mellifera L.*, worker honey bees that were treated with 6 different dosages: 1.5, 2.0, 2.5, 3.0, 4.0, and 4.5 µg/bee). The average effect dose for mortality, LD_{50}, for endosulfan, active substance, from 11 tests after 24 hours was 2.58 µg/bee (95% confidence range 2.53 - 2.63) and after 48 hours 2.35 µg/bee (95% confidence range 2.30 - 2.41).

- **Plant Protection Product**

Bock, K.-D. 1986

This study shows the laboratory contact toxicity of Thiodan 35 EC to honey bees. The study was not conducted under GLP.1.5, 2.0, 2.5, 3.0, 3.5, 4.0, and 4.5 µg test material were dissolved in 1 µl acetone and applied to the ventral thorax; 5 replicates per dose level and 10 bees per replicate were used. The test was repeated in 8 different laboratories. Mortality was assessed 24 and 48 hours after treatment. Based on 8 separate tests contact LD_{50} values of 2.61 µg formulated product /bee (24 hours) and 2.49 µg formulated product /bee (48 hours) were established. The values corresponds to 0.86 and 0.82 µg a.i./bee respectively, and suggest that the formulated product is more toxic than technical endosulfan in terms of active substance content.

B.9.4.3 Field and semi-field studies

Bock, K.-D. 1996

This study is a summary of different laboratory, semi-field and field tests on honey bees. There is no information about the performance of these studies. Thus we can not validate these data, and they have not to be used on the risk assessment.

B. 9.4.4 Risk assessment for bees

The risk of endosulfan has been calculated using the reliable lower values of the validated reports. These data are 2 µg a.i./bee for the oral toxicity and 0.82 µg a.i./bee for contact toxicity. Results have been summarised in the following table.

Table 9.4.4-1: Hazard quotients for honey bees

Application rate (kg as/ha)	Crop	Route	Hazard quotient
1.05	Citrus, pome fruit and vineyards	Oral	525
1.05	Citrus, pome fruit and vineyards	Contact	1280
0.53	Tomatoes, Potatoes	Oral	265
0.53	Tomatoes, Potatoes	Contact	646
0.8	Stone fruits	Oral	400
0.8	Stone fruits	Contact	975
0.53	Cucurbits	Oral	265
0.53	Cucurbits	Contact	646

All HQ are higher than the trigger value and therefore a potential risk for bees must be considered. Validable higher tier studies are required.

B.9.5 Other non-target arthropods

The notifier has submitted a set of laboratory and field studies which do not corresponds to the currently requested end-points or even to the application rates included in the intended uses. Therefore only a weight of evidence approach is possible.

B. 9. 5.1 Laboratory studies

- **Active substance**

Mead-Briggs, Michael A. 1988

A laboratory and field investigation of the direct toxicity of endosulfan (technical grade and formulated 35 EC) to non-target beneficial arthropods was performed. In the laboratory toxicological study endosulfan, substance technical was used. It was applied topically with a single droplet The maximum concentration was:

- N. biguttatus, adults 200 mg/ml
- T. hypnorum, adults 1.5 mg/ml
- C. septempunctata, adults 200 mg/ml
- M. corollae, larvae 500 mg/ml

Endosulfan was dissolved in butanone and topically applied by means of a micro-applicator. The toxic standard used was dimethoate. In comparison to this standard the LD_{50} value of endosulfan at 72 hours after treatment was found to be two orders of magnitude higher for the carabide *Notiophilus biguttatus* and the lady-bird *Coccinella septempunctata* and one order of magnitude greater for the staphylinide *Tachyporus hypnorum*. For the syrphide *Metasyrphus corollae* only 33% mortality was obtained at 72 hours at the highest dose applied (250 µg). It was therefore not possible to calculate a LD_{50} value for this species.

Table: 9.5.1-1: Toxicity of the active substance to beneficial arthropods

Test organism	Study type	Test duration	LD_{50} Endo-sulfan (µg/organism)	LD_{50} Di-methoate (µg/organism)	Doc. No.:	Author
Metasyrphus corollae (Syrphidae)	contact toxicity	72 hours	>250	0.018	A37899	Mead-Briggs (1988)
Coccinella septem-punctata (Coccinellidae)	contact toxicity	72 hours	5.31	0.064	A37899	Mead-Briggs (1988)
Tachyporus hypnorum (Staphylinidae)	contact toxicity	72 hours	0.20	0.017	A37899	Mead-Briggs (1988)
Notiophilus biguttatus (Carabidae)	contact toxicity	72 hours	6.41	0.072	A37899	Mead-Briggs (1988)

Bock K.D. 1990a

The objective of this study was to detect the laboratory effects of Thiodan 35 liquid on the larvae of Coccinella septempunctata. The study was not conducted under GLP, but it was performed in accordance with the BBA Guideline (23-2.1.5).The test substance was applied in a concentration of 0.4% (1.6l/400l). Ten replicates (one test unit per replicate; five arthropods per test unit) was used. Contact toxicity on glass plate was the criterium of evaluation.

An efficacy of 100% was reached at the test concentration.

Bock KD.1990b

A laboratory study to investigate the effects of Thiodan 35 liquid on larvae of the green lacewing *Chrysopa carnea*. The study was not conducted under GLP but it was in accordance with the IOBC/WPRS guideline. The test substance was applied as a spray solution in a concentration of 0.4% (1.6 1 /400 l). Contact toxicity on glass plate was the criterium of evaluation. Four animals in eight replicates were tested. The efficacy index calculated on the basis of the larval mortality, the rate of pupation, the emergence rate of imagines, the average egg number/female, larval hatching and the number of viable progeny/female was 52.9%.

Bock KD. 1990c

The effects of Thiodan 35 liquid on larvae of the hover-fly *Syrphus corollae* were investigated in a laboratory study. The work was not conducted under GLP but it was in accordance with the BBA guideline (23-2.1.7).The test solution was applied as a spray solution in a concentration of 0.4% (1.6 l/400l). Contact toxicity on glass plate was the criterium of evaluation. Seven animals in seven replicates were tested. The efficacy index calculated on the basis of the larval mortality, the rate of pupation, the hatching rate of imagines, the average egg number/female, larval hatching and the number of viable progeny/female was 66.4%.

B. 9.5.2 Field and semifield studies

- **Plant Protection product**

Mead-Briggs, Michael A. 1988

The objective of this study was to investigate the direct effects of endosulfan on beneficial arthropods in field studies.

In the field trials on winter wheat endosulfan 35 EC was used. The rates were 0.6 (211 g/ha) or 1.2 L formulated product in 600 L water/ha L (422 g/ha).

In the field trials on fallow ground for most of the test species endosulfan 35 EC initially was applied at 10 times the normal dilution rate. If significant mortality was observed at this high concentration a series of other rates was applied to other test samples in order to calculate the concentration needed to kill 50% of a sample at a given time after treatment.

The toxic standard used in the field trials was formulated dimethoate (Rogor), applied at 1L/600L water/ha. Control plots were left untreated.

In the field tests on beneficials confined on fallow ground, endosulfan 35 EC was not found to have significant effects on the survival of *Notiophilus biguttatus, Bembidion lampros, Tachyporus hypnorum* or *Metasyrphus corollae* when applied at a rate of 1.2 L/ha. *Coccinella septempunctata* was affected, however, and a field LC_{50} of 0.5 L/ha (176 g/ha) was obtained for 72 h post-treatment.

The treatment of winter wheat included a lot of trial methods in obtaining the data (field cages, clip cages, inclusion barriers).

At both 0.6 and 1.2 l/ha Thiodan was not found to have a significant effect on the survival of *N. Brevicollis, N. Biguttatus, T. hypnorum or M. corollae*. Nevertheless these doses caused significant mortality of the *Pardosa* spp. At 1.2 l/ha it was proved a moderately toxic effect to *Coccinella septempunctata.* The parasitoid study did not proved a toxic effect at both doses.

Mead-Briggs, 1988b

This study is a report of a field trial about the effects of endosulfan on non-target arthropods in winter oilseed rape. The study was not conducted under GLP or any standardised method.

This trial assessed the effects of a single application of Thiodan 35 EC comparing the effects with a positive control (deltamethrin) and a negative control (area not treated). Three replicates for each treatment were used. Thiodan 35 EC and deltamethrin were applied at a rate of 1.4 l/ha (493 g/ha) in 200 l water and 0.25 l/ha in 200 l of water respectively. The results of this study showed that the application of Thiodan EC 35 to winter oilseed rape at green yellow bud (early May) resulted in reductions in the densities of Staphylinidae (up to 4 weeks after application), adult Carabidae (from 4-12 weeks after application when numbers were at their greatest) and Linyphiidae (throughout the 12 weeks trial period). The application of Decis resulted in reductions in densities of Staphylinidae (at 1 and 4 weeks after application) and, to a lesser extent, Linyphiidae (inconsistent trends were seen over the trial period), but did not lead to reductions in Carabidae. Neither product had a detrimental effect on the density of Braconidae or Ichneumonidae. However, Empididae were reduced in number in Decis plots. The total number of Linyphiidae, Staphylinidae and Carabidae collected in all post-application D-vac and quadrat samples showed a reduction of 60.2%, 51% and 57.5% in the Thiodan treated areas.

Mead-Briggs MA. 1989

This study is a supplementary information of the above report. The study investigated the effects on endosulfan on non-target arthropods winter oilseed rape. Supplementary reports on sampling carried out in the season subsequent to the original application in May 1987. The study was not conducted under GLP or any standardised method.

The aim of this work was to identified any persistent product effects on the non-target fauna. The Thiodan and decis treatments were not repeated during this study. Two methods for sampling invertebrates were employed: suction sampling and pitfall sampling. There was no indication that Decis and Thiodan applied in May 1987 resulted in significant effects on the numbers of arthropods present in the succeeding crop of winter wheat.

Ferch Th. 1991

Effects of Thiodan 35 liquid on predatory mites in vineyards. The study was not conducted under GLP, but is in compliance with the BBA guideline (23-2.3.4). The test substance was applied at concentrations of 0.2%-0.4% with water volumes of 300-1200 l/ha. In any case there the inhibition percentage was higher than 40%. Thiodan 35 EC didn't cause any effects on T. pyri in vineyards.

B.9.5.3 Risk assessment for beneficial arthropods

The submitted studies do not allow a proper assessment but identify a potential high risk for beneficial arthropods.

The laboratory studies showed that endosulfan is highly toxic for some species of beneficial arthropods (*Coccinella septempunctata, Chrysopa carnea* and *Syrphus corollae*). The field and semi-field studies have proved high or moderately toxic effects in many species even at concentrations lower than the proposed application rates. Nevertheless, one study shows a recovery of the effects in two years.

It is concluded that endosulfan has a potential high risk on non target arthropods, which must be addressed by proper semi field or field studies adequately designed according to the intended uses.

B. 9.6 Effects on earthworms (IIA, 8.4; IIA, 10.6.1)

B.9.6.1 Acute toxicity

- **Active substance**

Fischer, R. 1990a

Effect of endosulfan technical grade (97.7% purity) to *Eisenia foetida* (Earthworm) in a 14 day Artificial Soil Test. The method followed was that described in the OECD Guideline 207, "Earthworm, Acute toxicity test". The study is considered valid.

Artificial soil was prepared from 10% dried and sifted spagnum peat, 20% kaolin clay and 69.7% of industrial sand. The data were referred to nominal concentrations. The results of the study were:

LC_{50} = 14 mg/kg (12.5-16)

Hans *et al.*, 1990. Bull. Environ. Contam. Vol. 45. pages 358-364 Toxicology.

Determination of the toxicity of endosulfan to an Indian native species of earthworm *Pheretima posthuma*. The test compound (endosulfan technical) was dissolved in ethanol. The study was not conducted under GLP. The method followed the EEC Directive 79/831.

The acute median LC_{50} values for endosulfan after an exposure period of 24 h were 1.46 ppm (98% confidence limits 1.02-1.98) and 5.01 ppm (98% confidence limits 2.88-8.69) by contact filter method and soil pot method respectively.

- **Plant protection Product**

Haque and Ebing, 1983

This study investigated the acute toxicity of Thiodan 35 to *Lumbricus terrestris*. The study was not conducted in accordance with GLP, but it was performed according to OECD methods (excepting the use of natural soil).The LC50 14 days was 23.9 mg/kg for *L. terrestris*.

Heimbach F. 1985

This study investigated the acute toxicity of Thiodan to *Eisenia foetida*. The study was not conducted with GLP but it was in accordance to the BBA guideline.

An artificial soil consisted of 83.5% fine quartz sand , 5% bentonite, 10% ground dried sphagnum peat, 1% calcium carbonate and 0.5% finely ground dried cattle manure was used. 10 earthworms per container were used. After 14 days the number of living earthworms were determined. The LC50 14 days was 9.4 mg ai/kg weight soil.

Heimbach F. 1984

This study reports the comparison of the effects on earthworm (*Eisenia foetida andrei*) of endosulfan EC (35%) between three different assays methods (contact filter paper test, artificial soil test and artisol test). The study was not performed under GLP, but it was in concordance with EEC guideline, BBA guideline and EEC guideline test respectively.

The test conditions were different in the three assays: the contact filter paper test was performed during two days, a 20º C of temperature and in a constant darkness. The artificial soil test was performed during 28 days at a temperature of 22º C and with a photoperiod of ligth: dark of 12:12h. The artisol test was performed during 14 days, at 20º C of temperature and in a constant darkness. The LC_{50} values was 5.7 μg/cm^2 for the contact filter paper, 6.7 mg/kg for the artificial soil test and 3.0 mg/kg for the artisol test. Data are referred to active ingredient.

Fischer R. 1990b

Effects of Endosulfan 35 EC on *Eisenia foetida* in a 14 day Artificial soil test. This study was conducted in compliance with GLP and it was performed following OECD method. Nine concentration were tested. The LC_{50} value for 14 days was 30.3 mg product/kg (27.5-33.4, 95 percent confidence limits).

B.9.6.2 Field studies

Reddy MV. and Reddy VR. 1992

This study investigated the effects of endosulfan 35% EC on earthworms in a semi-arid tropical grassland. Nine plots were used for the test (3 were treated at normal dose of endosulfan (0.4 l/ha), 3 were used as control and 3 of them were treated with three times the normal dose). The earthworms were sampled prior to the treatment, and after 40,60 and 80 days. The results showed that no earthworms was recorded in plots treated with the high dose of endosulfan until 80 days after treatment, and the earthworms abundance was reduced significantly in the plots treated with the normal dose.

Table 9.6.2: Summary of the results of the effects of endosulfan on earthworms

Test organism	Study type	Substance	Test duration	LC/EC_{50} ppm	NOEC ppm	Author
Eisenia foetida	Artificial soil test (OECD)	Technical grade (97.7%)	14 days	14	0.1	Fischer 1990 A43674
Pheretima posthuma	Soil pot	Technical grade	24 h	5.01	-	Hans et al. 1990. A 53744
Lumbricus terrestris	Natural soil	Thiodan 35	14 days	23.9	-	Haque and Ebing, 1983. A28776
Eisenia foetida	Artificial soil test	Thiodan	14 days	9.4 (a.i)	-	Heimbach 1985. A 32902
Eisenia foetida andrei	Artificial soil test	Endosulfan 35%	28 days	6.7 (a.i.)	-	Heimbach 1984. A 32903
Eisenia foetida andrei	Artisol test	Endosulfan 35%	14 days	3 (a.i)	-	Heimbach 1984. A 32903
Eisenia foetida	Artificial soil	Endosulfan 35 EC	14 days	30.3	0.32	Fischer 1990. A 43675
Natural population	Semi-arid tropical grassland	Endosulfan 35% EC	80 days	No earthworms at high dose tested. Significantly reduced at normal dose	-	Reddy and Reddy. 1992. A 51812

B.9.6.3 Risk assessment for earthworms

Several studies on the toxicity of endosulfan to earthworms have submitted. The standard species *Eisenia foetida* showed to be either more or less sensitive than other species, and will be used in the assessment.

Therefore, the 14 days LC_{50} of endosulfan for earthworms has been estimated using a geometric mean of the validated toxicity data for *Eisenia foetida* obtained under the standard conditions. This value is 11 mg/kg. The acute risk assessment of endosulfan for earthworms has been estimated for all the crops. The results are summarised in the following table.

Table 9.6.3-1: TER short-term estimations for earthworms

Crop	Application rate	PECs several (ppm)	14 d LC_{50} (ppm)	TERst
Citrus, pome fruits vine grapes	1.05	1.33	11	8.3
Cotton		1.52	11	7.2
Tomatoes		0.69	11	16
Potatoes		0.67	11	16.4
Stone fruits		1.44	11	7.6
Cucurbits		1	11	11
Sugar beet		0.63	11	17.4
Hazel nuts		1.01	11	10.9

Several values are above the trigger, and therefore the results indicate that endosulfan have a potential acute risk for earthworms in many crops (citrus, cotton and stone fruits).

No information on the reproduction toxicity of endosulfan on earthworms has been presented, and a NOEC cannot be extracted from the field study because the results showed effects even at the lowest application rate. Therefore, the long term risk can not be estimated due to lack of data. At the same time, there are not available information about metabolites.

The rapporteur concludes that a potential acute risk has been identified in certain cases, which must be addressed at a higher tier level, and that information on the long term effects of both the active substance and the metabolites is required.

B.9.7 Effects on other soil non-target macro-organisms (IIIA, 10.6.2)

Drake *et al*. 1971

This study shows the effects of endosulfan on soil arthropods. The test was not conducted under GLP or standardised methods. Endosulfan was applied at a rate of 4.5 kg/ha. Two years later, the detected residue was 0.03 ppm (as endosulfan-sulphate). The study concludes that there were no significant differences in numbers and kinds of soil invertebrates from control plots and those treated 2 years previously.

Risk assessment

The need of a risk assessment for other soil non-target macro-organisms must be addressed after the final decision on the persistence of endosulfan an its metabolites.

B.9.8 Effects on soil non-target micro-organisms (IIA, 8.5; IIIA, 10.7)

Both, the standard ammonification/nitrification and soil respiration studies as well as studies on other end points or specific groups of micro-organisms have been submitted.

B.9.8.1 Laboratory tests

- **Active substance and plant protection product**

Peeters, J.F 1975. J. Agric. Food Chem. Vol. 23, No. 3. pages 404-406. 1975.
Influence of Pesticides on the Presence and Activity of Nitrogenase in Azotobacter vinelandii. The endosulfan (technical grade) was applied in a saturated solution. The study was not conducted under GLP.

The results showed a stimulation of endosulfan over the growth of Azotobacter v. Experiments of inhibition of specific activity of nitrogenase showed that endosulfan up to 1 mM had no influence on the activity (0% inhibition).

Wainwright, M.; Kowalenko, C.G. 1977. Plant and soil 48: 253-258.
The study investigate the effects of pesticides, lime and other amendments on soil ethylene. The study was not conducted under GLP.

Endosulfan was applied at 100 mg/kg on a soil (pH 6.7, 2.9% of organic C and 22% of total N) and the production of soil ethylene was studied during 14 days. The test concentration of endosulfan had no effect on the concentration of ethylene in the atmosphere above the soil at both sampling times.

Taubel, N. 1985
Investigation into the Effect of Endosulfan Technical Grade a.i. on the Ammonification and Nitrification of Horn Meal Nitrogen.

The test substance (endosulfan technical substance, 94.6% purity) was dissolved in acetone and thoroughly mixed into the test soil. The study was not conducted under GLP and was not published. Endosulfan was applied at different doses (normal dose: 0.5 kg/ha (0.47 ppm a.s.), 5-fold dose: 2.5 kg/ha (2.37 ppm a.s.) and 10-fold dose: 5.0 kg/ha (4.73 ppm a.s.)). A reference compound, N-Serve, 1 ppm (1 ha at 5 cm topsoil depth = 750 000 kg soil) was used as positive control. The test duration was 28 days.

Horn meal (12.0% N) was added as organic N substrate at a rate equivalent to 20 mg N/100 g soil to a fresh soil sample taken from topsoil.

The ammonification rate of all 3 treatment groups was not or not significantly different from the control. The variations between the treated test variants lie within the permissible biological range of variation and unlike the commercial nitrification inhibitor N-Serve used as a control give no indication of a slowdown in nitrification, even at 10 times the normal dose of the test substance.

The results reveal that the effect of endosulfan, substance technical on ammonification and nitrification of horn meal nitrogen in accordance with the classification scheme of Domsch (Domsch *et al*. 1983) can be regarded as negligible.

Stratton G. 1990
Effects of the Insecticide Endosulfan on Nitrification in Low pH Agricultural Soils. The study was not conducted under GLP.

Both, the endosulfan technical grade (95% purity) and commercial endosulfan (Thiodan 4 EC) were used. Stock solutions of endosulfan, technical substance were prepared in acetone, Thiodan 4EC was diluted with glass-distilled water. Three type of soils were used: a sandy loam, a silt loam and a clay loam.

Five concentrations (10, 50, 100, 500 and 1000 ppm) of endosulfan, supplied as technical grade and commercial formulation were used for the soil perfusion technique. Treatments were prepared in replicates of five and each experiment was repeated three times. In the batch incubation three concentrations (10, 100 and 1000 ppm) of both endosulfan (technical grade and commercial formulation) were used.

Nitrification in soil was measured using a soil perfusion technique (after Lees and Quastel, 1946; Parkinson *et al*., 1971) and a batch incubation method.

Testing of effects of endosulfan on nitrification in low pH agricultural soils resulted in a significant inhibition of nitrification at concentrations of 10 ppm, but levels considerably higher than recommended field rates were required for substancial effects. Endosulfan should have no long-term deleterious effects on soil nitrification when used at recommended application rates, given the test conditions employed in the present study.

Muralikrishna & Venkateswarlu 1984
The effect of endosulfan 50% EC on soil algal population was studied in this report. The study was not conducted under GLP.

Red laterite soil was treated with five different concentrations of endosulfan (5,10,25,50,100 µg ai/g soil). After 21 days of incubation, the total algal population was determined by the most probable number method (MPN). Two water regimes (nonflooded and flooded) was used.

Table 9.8.1-1

Endosulfan	Algal population 10^3 /g soil Nonflooded soil	Algal population 10^3 /g soil Flooded soil
0	98.20	47.09
5	118.64	22.5
10	107.13	28.76
25	107.13	38.38
50	86.16	14.92
100	47.09	2.94

The results obtained in this study showed that at recommended levels of field application endosulfan is not harmful to the soil algal population.

Baedelet H. 1989b

This study investigated the effects of Endosulfan (35% EC) on the nitrification of ammonium sulphate in two soils in concentrations equivalent to 1.6 l/ha (normal dose = 563 g/ha), 8 l/ha (five times the normal dose = 2816 g/ha) and 16 l/ha (ten times normal dose = 5632 g/ha). The study used a loamy sand and silty loam during a period of 28 days. The test was not performed under GLP, but it was in accordance with the BBA guideline.

Ammonium sulphate at a rate of 10 mg N/100 g soil was added to a fresh soil sample taken from topsoil. The ammonium nitrogen and nitrate nitrogen determination were carried out on days 0, 7, 14, 21 and 28. The results showed a rapid conversion into nitrate of the ammonium nitrogen added in the loamy sand soil except a dose-dependent minimum delay during the first week. The results on the silty loam didn't show an inhibition of the nitrification process at any concentration.

Baedelt 1991

This study investigated the short-term effect of Thiodan 33 EC on aerobic soil respiration over a period of 28 days after admixture of glucose. It was conducted under GLP and in accordance with BBA guideline. Test substance was applied at a normal dosage (3 l/ha = 1056 g/ha) and 10-fold dosage (30 l/ha = 10560 g/ha) in two different soils (loamy sand and silty loam).

The respiration rates were determined on days 0, 7, 14 and 28 days. The total measurement period was 24 hours.

The results showed a negligible impact on soil respiration even at 10-fold dosage of the highest application rate (corresponding to 14.08 mg active substance /kg soil) for any kind of soil.

Baedelt 1989a

The study showed the short-term effects of Thiodan 35 EC on aerobic soil respiration. The test was not conducted under GLP but it was carried out in accordance with the BBA guideline. The possible effect of the product on aerobic soil respiration was observed in a loamy sand and silty loam over a period of 28 days after admixture of glucose. The application rate was a normal dose (1.6 l/ha = 563 g/ha) and a

5-fold dosage rate (8 l/ha = 2816 g/ha). The effects of the substance on aerobic soil respiration was negligible both at normal and higher dosage.

B.9.8.2 Risk assessment for soil non-target micro-organisms

The results show that there were no effects of endosulfan on nitrogenase activity, ammonification and nitrification processes and on soil respiration even at application rates of 5 to 10 times higher than the maximum intended rate.

It is concluded that the risk of endosulfan for soil micro-organisms is relatively low.

B.9.9 Effects on other non-target organisms (flora and fauna) believed to be at risk.

Information on the toxicity of endosulfan to amphibian species has been reported and is summarised in Table 9.9-1.

Table 9.9-1: Toxicity of endosulfan for amphibian species

Test organism	Study type	Chemical	Test duration	LC_{50} (µg/l)	NOEC (µg/l)	Study condition	Doc, authors	Remarks
Bufo melanostictus	Static renewal	Not specified	96 h	123 (127.8-118.4)	-	Published	Vardia et al. 1984 A 31350	
Rana tigrina	Static acute	Technical grade (90%)	96 h	1.8	0.55	Published	Gopal et al. 1981 A 23187	

These results suggest that amphibians are similar or less sensitive to endosulfan than fish, and therefore the risk is expected to be covered by the risk for fish.

Metabolites

An study of the insecticidal activity of some metabolites has been presented.

Knauf and Waltersdorfer 1989

This study shows the effects of endosulfan and its metabolites on target arthropods.

This study was not conducted under GLP or standardised methods. In all test endosulfan was the compound with the highest insecticidal activity. Endosulfan sulphate has some insecticidal properties, but its activity is only sometimes comparable with endosulfan itself. Neither endosulfan lactone nor endosulfan diole are acting as insecticides. The observed activities in the highest doses tested are less than with endosulfan by some orders of magnitudes.

B.9.10 Effects on biological methods for sewage treatment (IIA, 8.7)

The reports submitted for this point cannot be validated.

B.9.11 References relied on

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
IIA, 8.0/01; 5/02; 7/03	1979	Gupta, P.K.; Gupta, R.C. Pharmacology, toxicology and degradation of endosulfan, a review. Toxicology, 13, 115-130	No	Yes	Publ.	No
IIA, 8.1.1	1983a	Roberts, Nicholas L.; Phillips, Christine N.K. The Acute Oral Toxicity (LD 50) of Endosulfan-technical (Code: Hoe 002671 0I ZD97 0003) to the Bobwhite Quail [redacted] Report No.: A27035	No	Yes	Publ.	No
IIA, 8.1.1	1983b	Roberts, Nicholas L.; Phillips, Christine N.K. The Acute Oral Toxicity (LD 50) of Endosulfan-technical (Code: Hoe 002671 0I ZD97 0003) to the Mallard Duck [redacted] Report No.:	Yes	No	AgrEvo	No
IIA, 8.1.1/01		Acute oral (MLD), Pigeon.	No	No	Excel	No
IIA, 8.1.1/02		Excel Industries Ltd. Protocol for acute oral (MLD), Pigeon and chicken.	No	No	Excel	No
IIA, 8.1.1/02	1972	Hudson, R.H.; Tucker, R.K.; Haegele, M.A. Effect on age on sensivitie: Acute oral toxicity of 14 pesticides to Mallard Ducks of several ages. Toxicol. Appl. Pharmacol., 22: 556-561				
IIA, 8.1.1/03	1972	Schafer, E.W. The acute oral toxicity of 369 pesticidal pharmaceutical and other chemicals to wild birds. Toxicology and applied Pharmacology, 21, 315-330	No	Yes	Publ.	No
IIA, 8.1.2	1975	Hill, Elwood F.; Heath, Robert G.; Spann, James W.; Williams, Joseph D. Lethal dietary toxicities of environmental pollutants to birds [redacted] USA. Report No.: A26820 U.S. Fish and Wildlife Service. Special Scientific Report.. Wildlife No. 191. 1975	No	Yes	Publ.	No
IIA, 8.1.3	1987a	Beavers, Joann B.; Frank, Peter; Jaber, Mark J.	Yes	No	AgrEvo	No

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
		Endosulfan Technical Substance (Code: Hoe 002671 0I ZD95 0005): A One-Generation Reproduction Study with the Mallard (Anas platyrhynchos) [redacted] A36310				
IIA, 8.1.3	1987b	Beavers, Joann B.; Frank, Peter; Jaber, Mark J. Endosulfan Technical Substance (Code: Hoe 002671 0I ZD95 0005): A One-Generation Reproduction Study with the Bobwhite (Colinus virginianus) [redacted] A36311	Yes	No	AgrEvo	No
IIA, 8.1.3	1984	Roberts, Nicholas L.; Phillips, Christine N. K. The Effects of Dietary Inclusion of Endosulfan - Technical (Code: Hoe 002671 0I ZD97 0003) on Reproduction in the Bobwhite Quail [redacted] Report No.: A29752	Yes	No	AgrEvo	No
IIA, 8.1.3	1985	Roberts, N.L.; Anderson, A.; Chanter, D.O. The Effects of Dietary Inclusion of Endosulfan - Technical (Code: Hoe 002671 OI ZD97 0003) on Reproduction in the Mallard Duck [redacted] Report No.: A30678	Yes	No	AgrEvo	No
IIA, 8.1.3; 8.3	1973	Scholz; Weigand Thiodan - ENDOSULFAN Op.2/387 97.1 % active ingredient. 30-Day Feeding Test in the Quail [redacted] Germany. Report No.: A18268	No	No	AgrEvo	No
IIA, 8.1.4	1995	Ebert, E.; Leist, K.-H. Endosulfan - substance technical (Code: Hoe 002671) Compilation of invalid studies and literature on experimental avian toxicity studies AgrEvo, A Company of Hoechst and Schering, Toxicology, Frankfurt, Germany. Report No.:	No	No	AgrEvo	No
IIA, 8.2/01; 8.2.4/01; 8.3/01	1984	Who Environmental Health Criteria 40, endosulfan, Worl Health Organization, Item 7.1-7.4	No	Yes	Publ.	No
IIA, 8.2/02		Excel industries Ltd.	No	No	Excel	No

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
		Protocol for toxicity to fresh water fish				
IIA, 8.2.1 / IIIA, 10.2.1.1	1981	Devi, A.P.; Rato, D.M.R.; Tilak, K.S.; Murty,A.S. Relative Toxicity of the Technical Grade Material, Isomers, and Formulations of Endosulfan to the Fish Channa punctata [redacted] A22297 Bull. Environm. Toxicol. Vol. 27. pages 239-243. 1981	No	Yes	Publ.	No
IIA, 8.2.1	1989	Ferrando,M.D.;and Andreu-Moliner, E. Effects of temperature, exposure time and other waterparameters on the acute toxicity of endosulfan to european eel, Anguilla anguilla [redacted] A42966 J. Environ. Science Health. Vol. B24, No. 3. pages 219-224. 1989	No	Yes	Publ.	No
IIA, 8.2.1	1991	Ferrando, M.D.; Sancho, E.; Andreu-Moliner, E. Comparative Acute Toxicities of Selected Pesticides to Anguilla anguilla [redacted]: A47633 J. Environm. Sci. Health. Vol. B26, No. 5/6. pages 491-498. 1991	No	Yes	Publ.	No
IIA, 8.2.1	1983	Fischer, R. The Effect of Hoe 002671 0I ZD96 0002 (Endosulfan, Active Ingredient 95,5 %) on Salmo gairdneri (Rainbow Trout) in a Static Test [redacted]: A26006	No	No	AgrEvo	No
IIA, 8.2.1	1991	Fujimura, Robert; Finlayson, Brian; Chapman, Gary Evaluation of Acute and Chronic Toxicity Tests with Larval Striped Bass [redacted] A47515 Aquat. Toxicol. and Risk Assessment. 1991. Vol 14. 193-211	No	Yes	Publ.	No
IIA, 8.2.1/4/9	1981	Gopal, K.; Khanna, R.N.; Anand, M.; Gupta, G.S.D. The Acute Toxicity of Endosulfan to Fresh-Water Organisms [redacted] Report No.: A23187 Toxicology Letters. Vol. 7. pages 453 - 456. 1981	No	Yes	Publ.	No
IIA, 8.2.1 / IIIA, 10.2.1.1	1986	Haider, S.; Imbaraj, R. Moses	No	Yes	Publ.	No

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**
		Relative Toxicity of Technical Material and Commercial Formulation of Malathion and Endosulfan to a Freshwater Fish, Channa punctata (Bloch) [redacted]A36292 Ecotoxic. and Environm. Safety. Vol. 11. pages 347-351. 1986				
IIA, 8.2.1	1986	Herzberg, A.M. Accumulation and Toxicity of Endosulfan in the Common Carp (Cyprinus carpio) and Saint Peters Fish (Oreochromis aureus) [redacted] No.: A36295 Bamidgeh. Vol. 38, Part 4. pages 99 - 107. 1986	No	Yes	Publ.	No
IIA, 8.2.1	1993b	Jonsson, Claudio M.; Toledo, Maria Cecilia F. Acute Toxicity of Endosulfan to the Fish Hyphessobrycon bifasciatus and Brachydanio rerio [redacted] A51153 Arch. Environ. Contam. Toxicology. Vol. 24. pages 151-155. 1993	No	Yes	Publ.	No
IIA, 8.2.1 / IIIA, 10.2.1.1	1980	Joshi, A.G.; Rege, M.S. Acute Toxicity of Some Pesticides & a Few Inorganic Salts to the Mosquito Fish Gambusia affinis (Baird & Girard) [redacted]: A29254 Ind. J. Exp. Biol. Vol.1, No. 4. pages 435-437. 1980	No	Yes	Publ.	No
IIA, 8.2.1	1977a	Knauf Effect of Hoe 02671 0 I AT202 (Active Ingredient) on Idus Melanotus (Golden Orfe) [redacted] A16732	No	No	AgrEvo	No
IIA, 8.2.1	1978	Knauf Effect of Hoe 002671 0 I AT 202 (Active Ingredient) on Cyprinus carpio (Carp) [redacted] Germany. Report No.: A31512	No	No	AgrEvo	No

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
IIA, 8.2.1; 8.2.4; 8.2.2.3; 8.2.5	1976	Maceck, Kenneth J.; Lindberg, Mark A.; Sauter, Scott; Buxton, Kenneth S.; Costa, Patricia A. Toxicity of Four Pesticides to Water Fleas and Fathead Minnows. Acute and Chronic Toxicity of Acrolein, Heptachlor, Endosulfan, and Trifluralin to the Water Flea (Daphnia magna) and the Fathead Minnow (Pimephales promelas). Bionomics, USA. Report No.: A27951 National Technical Information Service, Springfield, Virginia 22161, USA	No	Yes	Publ.	No
IIA, 8.2.1	1969	Macek, Kenneth J.; Hutchinson, Curt; Cope, Oliver B. The Effects of Temperature on the Susceptibility of Bluegills and Rainbow Trout to Selected Pesticides [redacted] Report No.: A23688 Bull. Environm. Contam. Toxicol. Vol. 4. pages 174-183. 1969	No	Yes	Publ.	No
IIA, 8.2.1	1980	Mohanaranga Rao, D.; Murty, A.S. Toxicity, Biotransformation & Elimination of Endosulfan in Anabas testudineus (Bloch) Univ.Nagarjuna, India. Report No.: A29255 Indian Journal of Exp. Biol. Vol. 18. pages 664-666. 1980	No	Yes	Publ.	No
IIA, 8.2.1/4	1983	Nebeker, Alan V.; McCrady, K.; Mshar, Roger; McAuliffe, Chris K. Relative Sensitivity of Daphnia magna, Rainbow Trout and Fathead Minnows to Endosulfan. [redacted] A27380 Environm. Toxicology and Chem. Vol. 2. pages 69-72. 1983	No	Yes	Publ.	No
IIA, 8.2.1/3/4/8; 8.3.5	1971	Oeser, H.; Gorbach, S.; Knauf, W. Endosulfane and the Environment Hoechst AG, Germany. Report No.: A14255 Giornate Fitopatologiche. Udine, Italy, 11-14 maggio. 1971	No	Yes	Publ.	No
IIA, 8.2.1	1966	Pickering, Quentin H.; Henderson, Crosswell The Acute Toxicity of Some Pesticides to Fish [redacted] A14124 The Ohio Journal of Science. Vol. 66, No. 5. pages 508-513. 1966	No	Yes	Publ.	No

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
IIA, 8.2.1 / IIIA, 10.2.1.1	1980	Rao, D.M.; Devi, A.P.; Murty, A.S. Relative Toxicity of Endosulfan, its Isomers, and Formulated Products to the Freshwater Fish Labeo rohita [redacted] A22299 J. Toxicol. Environm. Health. Vol. 6. pages 825-834. 1980	No	Yes	Publ.	No
IIA, 8.2.1	1982	Rao, D.M.; Murty, A.S. Toxicity and Metabolism of Endosulfan in Three Freshwater Catfishes [redacted] A26105 Environm.Pollution. 1982. (Series 4). 27. 223-231	No	Yes	Publ.	No
IIA, 8.2.1 / IIIA, 10.2.1.1	1989	Rao, D.M.R. Studies on the relative Toxicity and metabolism of Endosulfan to the Indian Major Carp Catla catla with Special Reference to Some Biochemical Changes Induced by the Pesticide [redacted]: A43108 Pestic. Biochem. Physiol. Vol. 33. pages 220-229. 1989	No	Yes	Publ.	No
IIA, 8.2.1/4	1970	Schoettger, Richard A. Investigations in Fish Control. Toxicology of Thiodan in Several Fish and Aquatic Invertebrates U.S.Dep.Inter., USA. Report No.: A14253	No	No	AgrEvo	No
IIA, 8.2.1	1982	Singh, B.B.; Narein, A.S. Acute Toxicity of Thiodan to Catfish (Heteropneustes fossilis) [redacted] A23196 Bull. Environm. Contam. Toxicol. Vol. 28. pages. 122-127. 1982	No	Yes	Publ.	No
IIA, 8.2.1	1982	Singh, Narendra N.; Srivastava, Anil K. Toxicity of a Mixture of Aldrin and Formothion and Other Organophosphorus, Organochlorine and Carbamate Pesticides to the Indian catfish, Heteropneustes fossilis [redacted]: A32901 Comp. Physiol. Ecol. Vol. 7, No. 2. pages 115 - 118. 1982	No	Yes	Publ.	No
IIA, 8.2.1	1984	Singh, Suneeta; Sahai, S. Toxicity of Some Pesticide to Two Fresh Water Teleosts [redacted] A36683 J. Environm. Biol. Vol. 5, No. 4. pages 255-259. 1984	No	Yes	Publ.	No

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
IIA, 8.2.1	1992	Sunderam, R.I.M.; Cheng, D.M.H.; Thompson, G.B. Toxicity of Endosulfan to Native and Introduced Fish in Australia [redacted] A49782 Environm. Toxiciol. Chem. Vol. 11. pages 1469-1476. 1992	No	Yes	Publ.	No
IIA, 8.2.1/01; IIIA, 10.2.1		Dikshith, T.S.S. Report on TLm values of endosulfan technical (Excel Industries) in fresh water fish Channa punctatus (Girai)	Yes	No	Excel	No
IIA, 8.2.1/02	1984	Ramakrishna, V. Toxicity study of endosulfan (technical) in fresh water fish. Excel industries Ltd. [redacted]	No	No	Excel	No
IIA, 8.2.1/03; 8.2.2/01	1982	Sastry, K.V.; Siddiqui, A.A. Effect of endosulfan and quinalphos on intestinal absorption of glucose in the fresh water murrel, Channa Punctatus. Toxicology Letters 12, 289-293	No	Yes	Publ.	No
IIA, 8.2.1/04	1992	Tripathi, G.; Shukla, S.P. Toxicity of endosulfan and Methyl parathionto to a freshwater catfish. Naturalia, Sao Paulo, 17, 9-15	No	Yes	Publ.	No
IIA, 8.2.2	1981	Joshi, H.C., *et. al*. Chronic toxicity study of some pesticides for estimating matc for two fresh water fishes. J. Envirn. Biol., 2 (1) 43-57	No	Yes	Publ.	No
IIA, 8.2.2/02	1988	Sharma, R.M. Effect of endosulfan on Adenosine Triphosphatase (ATPase) activity in liver, kidney and muscles of *Channa gachua.* Bull. Environm. Contam. Toxicol. Vol. 41: 317-323	No	Yes	Publ.	No
IIA, 8.2.2/03	1990	Sharma, R.M. Effect of endosulfan on acid and alkaline phosphatase activity in liver, kidney and muscles of *Channa gachua* Bull. Environm. Contam. Toxicol. Vol. 44: 443-448	No	Yes	Publ.	No

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
IIA, 8.2.2.1; 8.2.3	1991	Hansen, David J.; Cripe, Geraldine M. Interlaboratory Comparison of the Early Life-Stage Toxicity Test Using Sheepshead Minnows (Cyprinodon variegatus) EPA, USA. Report No.: A47514 Aquatic Toxicol. and Risk Assessment, ASTM, Mayes/Barron. pages 354-375. 1991	No	Yes	Publ.	No
IIA, 8.2.2.2	1991	Knacker, Th.; Zietz, E.; Schallnass, H.; Diehl, Th. A Study of the Prolonged Toxicity to Fish (Oncorhynchus mykiss) of Endosulfan - substance technical (Hoe 002671 00 ZD98 0005) according to the OECD Guidelines for Testing of Chemicals [redacted] A46835	Yes	No	AgrEvo	No
IIA, 8.2.3 / IIIA, 10.2.2.2	1989	Cornaby, B.W.; Maciorowski, A.F.; Griffith, M.G. et al. Assessment of the Fate and Effects of Endosulfan on Aquatic Ecosystems Adjacent to Agricultural Fields Planted with Tomatoes (Pont study) Battelle, Columbus Laboratory, USA; Hickey´s Agri-Services Inc., USA. Repot no.: A41298	Yes	No	AgrEvo	No
IIA, 8.2.3	1977	Ernst, W. Determination of the Bioconcentration Potential of Marine Organisms. A Steady State Approach Institut fuer Meeresforschung, Germany.Report No.: A25849 Chemosphere. No.11. pages 731 - 740. 1977	No	Yes	Publ.	No
IIA, 8.2.3 / IIIA, 10.2.2.2	1992	Heusel, R. Extended summary and evaluation of the farm pond study on endosulfan (Hoe 002671) Hoechst C Produktentwicklung Oekologie 1, Germany. Report No.: A48944	No	No	AgrEvo	No
IIA, 8.2.3	1993a	Jonsson, Claudio M.; Toledo, Maria Cecilia F. Bioaccumulation and Elimination of Endosulfan in the Fish Yellow Tetra (Hyphessobrycon bifasciatus) [redacted] Brazil. Report No.: A49919 Bull.Environ.Toxicol. 1993. 50. 572-577	No	Yes	Publ.	No

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
IIA, 8.2.3	1977	Schimmel, S.C.; Patrick, Jr., J.M.; Wilson, Jr., A.J. Acute Toxicity to and Bioconcentration of endosulfan by Estuarine Animals [redacted] Report No.: A22871 Aquatic Toxicology and Hazard Evaluation. ASTM STP 634. pages 241-252. 1977	No	Yes	Publ.	No
IIA, 8.2.3	1992	Toledo, M. Cecilia; Jonsson, Claudio M. Bioaccumulation and Elimination of Endosulfan in Zebra Fish (Brachydanio rerio) [redacted] A50529 Pestic. Sci. 1992. 36. 207-211	No	Yes	Publ.	No
IIA, 8.2.3/01	1984	Kulshrestha, S.K.; Ahora, N. Impairments induced by sublethal doses of two pesticides in the ovaries of a freshwater teleost *Channa striatus* Bloch. Toxicol. Letters 20: 93-98	No No	Yes Yes	Publ. Publ.	No No
IIA, 8.2.4	1992	Fernandez-Casalderry, A.; Ferrando, M.D.; Andreu-Moliner, E. Acute Toxicity of Several Pesticides to Rotifer (Brachionus calyciflorus) Univ.Valencia, Spain. Report No.: A47492 Bull. Environ. Toxicol. Vol. 48. pages 14-17. 1992	No	Yes	Publ.	No
IIA, 8.2.4	1977b	Knauf Hoe 02671 0 I AT202 (Active Ingredient) Effect on Daphnia Magna (Water Flea) Hoechst Pfl.Fo.Biol., Germany. Report No.:	No	No	AgrEvo	No
IIA, 8.2.4	1989	Krishnan, M.; Chockalingam, S. Toxic and Sublethal Effects of Endosulfan and Carbaryl on Growth and Egg Production of Moina micrura Kurz (Cladocera: Moinidae) Thiagarajar College, India. Reort No.: A43063 Environm. Pollution. Vol. 6. pages 319-326. 1989	No	Yes	Publ.	No
IIA, 8.2.4	1960	Luedemann, Dietrich; Neumann, Horst Versuche ueber die akute toxische Wirkung neuzeitlicher Kontaktinsektizide auf Suesswassertiere (2.Beitrag) BGA, Germany. Report No.: A14242 Publication of the Bundesgesundheits{Abs}amt, Berlin-Dahlem, Germany	No	Yes	Publ.	No

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
IIA, 8.2.4	1987	Naidu, K. Rajendra Prasad; Devi, G. Subhadra; Naidu, B.P. Toxicity evaluation of endosulfan and its impact on the organic composition of different age groups of juvenile crabs S.V.Univ.,Tirupati, Goa. Report No.: A43105 Nat. Acad. Letters. Vol.10, No. 7. pages 251-254. 1987	No	Yes	Publ.	No
IIA, 8.2.4	1981	Nair, G.A. Toxic Effects of Certain Biocides on a Fresh Water Mite, Hydrachna trilobata Viets (Arachnida: Hydrachnoidea: Hydrachnidae) Univ.Kerala, India. Report No.: A26111 J. Environm. Biol. Vol. 2, No. 2. pages 91-96. 1981	No	Yes	Publ.	No
IIA, 8.2.4/5	1982	Nebeker, A.V. Evaluation of a Daphnia magna, Renewal Life-cycle Test Method with Silver and Endosulfan EPA, United States. 4 contract and 2 U.S.EPA laboratories. Report No.: A25040 Water Res. 1982. Vol. 16. pages 739-744	No	Yes	Publ.	No
IIA, 8.2.4	1992	Reddy, D.C.; Kalarani, V.; Davies, Ronald W. Influence of Thermal Prehistory on Endosulfan Susceptibility of Oziotelphusa senex senex, a Freshwater Crab University of Calgary, Canada. Report No.: A47495 Bull. Environ. Contam. Toxicol. Vol. 48. pages 1-6. 1992	No	Yes	Publ.	No
IIA, 8.2.4	1968	Sanders, Herman O.; Cope, Oliver B. The Relative Toxicities of Several Pesticides to Naiads of Three Species of Stoneflies Fish-Pestic.Res.Lab., USA. Report No.: A25918 Limnology and Oceanography. Vol. 13, No. 1. pages 112-117. 1968	No	Yes	Publ.	No
IIA, 8.2.4	1969	Sanders, Herman O. Toxicity of Pesticides to the Crustacean Gammarus lacustris Fish-Pesticide Research Labor., USA. Report No.: A26101 Technical Papers of the Bureau of Sport Fisheries and Wildlife	No	Yes	Publ.	No
IIA, 8.2.4	1972	Sanders, Herman O. Toxicity of Some Insecticide to Four Species of Malacostracan Crustaceans U.S.Dep.Inter, USA. Report No.: A28837 Techn. Paper U.S. Bureau Sport Fish. Wildlife. No. 66. pages 1-19. 1972	No	Yes	Publ.	No

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
IIA, 8.2.4	1976	Santharam, K.P.; Thayumanavan, B.; Krishnaswamy,S. Toxicity of Some Insecticides to Daphnia carinata King, an Important Link in the Food Chain in the Freshwater Ecosystems Univ.Madurai, India. Report No.: A25919 Indian J. Ecol. Vol. 3, No. 1. pages 70-73. 1976	No	Yes	Publ.	No
IIA, 8.2.4	1986	Serrano, L.; Miracle, M. R.; Serra, M. Differential Responses of Brachionus plicatilis (Rotifera) Ecotypes to various Insecticides. University of Valencia, Spain. Report No.: A53745 J. Environm. Biol. Vol. 7, No. 4. pages 259-275. 1986	No	Yes	Publ.	No
IIA, 8.2.4	1987	Tandon, R.S.; Lal, Rup; Narayana Rao, V.V.S. Effects of malathion and endosulfan on the growth of Paramecium aurelia Univ.Kumaun, India. Report No.: A43103 Acta Protozoologica. Vol. 6, No. 4. pages 319-326. 1987	No	Yes	Publ.	No
IIA, 8.2.4	1991	Yadav, B.S.; Sarojini, R.; Nagabhushanam, R. Toxicity of Pesticide Endosulfan on Freshwater Prawn, Caridina WEBERI Marathwada University, India. Report No.: A47589 J. Advanced Zoology. Vol. 12, No. 1. pages 19-22. 1991	No	Yes	Publ.	No
IIA, 8.2.4/01	1991	Rajendran, N.; Venugopalan, V.K. Bioconcentration of endosulfan in different body tissues of stuarine organism under sublethal exposure. Bull. Environ. Contam. Toxicol. Vol. 46: 151-158	No	Yes	Publ.	No
IIA, 8.2.5	1991	Heusel, R. Endosulfan - substance, technical (Hoe 002671 00 ZD98 0005). Effect to Daphnia magna (Waterflea) in a 21-day Reproduction Test (method OECD) Hoechst C Produktentwicklung Oekologie 1, Germany. Report No.: A46561	Yes	No	AgrEvo	No
IIA, 8.2.6	1985	Fischer, R. The Effect of Endosulfan, Substance, Technical Identification Code: Hoe 002671 0I ZD95 0005 to Scenedesmus subspicatus (Green alga) in a Growth Inhibition Test (Method OECD) Hoechst AG, Plant Protection Research, Biology, Germany. Report No.: A31389	Yes	No	AgrEvo	No

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
IIA, 8.2.6; 8.3.5; 8.2.1	1973	Knauf, W.; Schulze, E.-F. New Findings on the Toxicity of Endosulfan and its Metabolites to Aquatic Organisms Hoechst AG, Germany. Report No.: A05758 Mededelingen Fakulteit Landbouwwetenschappen, Gent. No. 38. 1973	No	Yes	Publ.	No
IIA, 8.2.6	1986	Netrawali, M. S.; Gandhi, S. R.; Pednekar, M. D. Effects of Endosulfan, Malathion, and Permethrin on Sexual Life Cycle of Chlamydomonas reinhardtii Bhabha Atomic Research Centre, India. Report No.: A33977 Bull. Environ. Contam. Toxicol. Vol. 36. pages 412-420. 1986	No	Yes	Publ.	No
IIA, 8.2.6	1988	Tandon, R.S.; Rup Lal; and Narayana Rao, V.V.S. Interaction of Endosulfan and Malathion with Blue-Green Algae Anabaena and Aulosira fertilissima Univ.Kumaun, India; Sri Venkateswara.Coll., India. Report No.: A43,64 Environm. Pollution. Vol. 52. pages 1-9. 1988	No	Yes	Publ.	No
IIA, 8.2.7	1991	Chandler, G.T.; Scott, G.I. Effects of sediment-bound Endosulfan on survival, reproduction and larval settlement of meiobenthic polychaetes and copepods University of South Carolina, USA. Report No.: A45651 Environm. Toxicol. Chem. Vol. 10. pages 375-382. 1991	No	Yes	Publ.	No
IIA, 8.2.7; 8.3.5 / IIIA, 10.3.6	1982 1972	Goebel, H.; Gorbach, S.; Knauf, W.; Rimpau, R.H.; Huettenbach, H. Properties, Effects, Residues, and Analytics of the Insecticide Endosulfan Hoechst AG, Germany. Report No.: A30407 Residue Reviews. Vol. 83. pages 1 - 174. 1982	No	Yes	Publ.	No
IIA, 8.2.7	1988	Swigert, James P. Acute Toxicity of Hoe-002671 to Midge Larvae (Chironomus tentans) Analytical Bio-Chem. Laboratories, Inc., USA. Report No.: A38295	Yes	No	AgrEvo	No
IIA, 8.2.9	1983	Vardia, H.K.; Rao, P.S.; Durve, V.S. Sensitivity of Toad Larvae to 2,4-D and Endosulfan Pesticides Univ.Poona and Univ.Udaipur, India. Report No.: A31350 Arch.Hydrobiol. Vol. 100, No. 3. pages 395-400. 1984	No	Yes	Publ.	No

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
IIA, 8.3.1/01	1978	Stevenson, J.H. The acute toxicity of unformulated pesticides to worker honey bees (Apis mellifera L.) Pl. Path 27, 38-40	No	Yes	Publ.	No
IIA, 8.3.1/01; 8.3.2/02	1981	Makar, P.V.; Jadhav, L.D. Toxicity of some insecticides to the aphid predator menochilus sexmaculatus Farbicus. Indian Journal of Entomology, 43, 140-144	No	Yes	Publ.	No
IIA, 8.3.1/02	1974	Singh, B.B., *et. al.* Toxicity of insecticides to honeybee workers, *Apis cerana indica F.* Pesticides	No	Yes	Publ.	No
IIA, 8.3.1/04	1977	Stevenson, J.H., *et. al.* Poisoning in honeybees by pesticides: Investigation of the changing pattern in Britain over 20 years. Pl. Path 27, 38-40	No	Yes	Publ.	No
IIA, 8.3.1.1	1986	Bock, K.-D. Laboratory Trials to Determine the Effect of Endosulfan (Hoe 0026710IZB990002) on the Honeybee Apis mellifera L Hoechst AG, LEA, Germany. Report No.: A37371	No	No	AgrEvo	No
IIA, 8.3.1/03		Needham, P.H.; Steveson, J.H. The toxicity of foraging honeybees *Apis mellifera* of endosulfan, melathion, and azinphos-methyl applied to flowering oil seed rape, *Brassica napus*.	No	No	Excel	No
IIA, 8.3.1/05	1981	Ghatnekar, S.D. Report of Endosulfan (technical) toxicity to honeybees. Personal letter, C.C. Shroff Research Institute	No	No	Excel	No
IIA, 8.3.1/06	1969	Attri, B.S.; Sharma, P.L. Toxicity of some insecticides to Indian honey bee (*Apis indica F.)* Pesticides	No	Yes	Publ.	No
IIA, 8.3.2 / IIIA, 10.3.3.1	1988a	Mead-Briggs, Michael A. Technical grade endosulfan (Hoe 002671 0I ZD96 0002) and formulated thiodan 35 ec (Hoe 002671 0I EC33 B307). A laboratory and field investigation of the direct toxicity to non-target beneficial arthropods University Southampton, Dep. Biol., United Kingdom. Report No.: A37889	No	No	AgrEvo	No
IIA, 8.3.2/01	1982	Sithanantham, S.	No	Yes	Publ.	No

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
		Effects of insecticide application on selected arthroped populations in sugarcane crop. Indian Journal of Plant Protection, 8, 85-88				
IIA, 8.3.2/03	1980	Sharma, H.C.; Sarup, P. Feasibility of integrated control for the stalk borer, *Chilo partellus* (Swinhoe) infecting maize crop. Journal of Entomological Research, 4, 203-214	No	Yes	Publ.	No
IIA, 8.3.2/05	1981	Sharma, H.C.; Adlakha, R.L. Selective toxicity of some insecticide to the adults of laybird beetle, *Coccinella septempunctata L. And cabbage aphid. Brevicoryne brassicae*. Journal of Entomological Research, 43, 92-99	No	Yes	Publ.	No
IIA, 8.3.2/04	1980	Dutt, N.; Somchodhury, A. K. Persistent toxicity of some insecticide to *Trichogramma perkinsi* Girault and *Trichogramma australicum* Girault (Hymenoptera: Trichogrammatidae) Journal of entomological research, 4, 203-214	No	Yes	Publ.	No
IIA, 8.3.2/06	1981	Mansour, F. *et. al.* The effect on commonly esed pesticides on Chiracaanthium mildei and other spieders occuring on apple. Phytoparasitica, 9, 139-144	No	Yes	Publ.	No
IIA, 8.3.2/07/08	1981	Hislop, R.G.; Prokopy, R.J. Integrated management on phytophagous mitesin Massachustts (U.S.A.) Apple Ochards. 2. Influence of pesticides on the predator *Amblyseius fallacis* (Acarina: *Phytoseiidae*) under laboratory and fiels conditions. Protection Ecology, 3, 157-172	No	Yes	Publ.	No
IIA, 8.3.2/09	1982	Brettel, J.H. Green lacewings (Neuroptera: Chrysopidae) of cotton fields in Central Zimbabwe, 2. Biology of Chrysopa congrua Walker and C. Nudica Navas and toxicity of certain insecticides to their larvae. Zzimbabwex Journal of agricultural Research, 20. 77-84	No	Yes	Publ.	No
IIA, 8.3.2/10	1982	Gravena, S.; Batista, G.C. Effect of sucrose, protein hydrolasate and insecticides on the greenbug *Scizaphis gramineum* (Rondai, 1852) (*Homoptera Aphididae*) and its associated natural enemmies on grain *shorgum*. Anais da Sociedade entomologica do Brasil, 8. 345-356	No	Yes	Publ.	No
IIA, 8.3.2/11	1982	Beraldo, M.J.A.H.; Batista, G.C. Toxicity of cyclodiene insecticides and their effect	No	Yes	Publ.	No

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
		on oxygen consumption in *Atta sexdens rubropilosa* Forel, 1908 (*Hymenoptera-Formicidae*) Anais da Sociedade Entomologicca do Brasil, 8. 225-232				
IIA, 8.3.2/12	1981	Hagley, E.A.C., *et. al.* Toxicity of insecticides to parassits of the spotted teentiform leafminer (Lepidoptera: Gracillariidae) Canadian Entomologist, 113 (10) 899-906	No	Yes	Publ.	No
IIA, 8.3.3/01	1981	Srivastava, V.; Misra, P.C. Effect of endosulfan on plasma membrane function on the yeast *Rodotorula Gracili.* Toxicol. Letters 7: 475-480	No	Yes	Publ.	No
IIA, 8.3.3/02	1981	El Beit, I.O.D.; Wheelock, J.V.; Cotton, D.E. Pesticide-mocrobial interaction in the soil. Int. J. Environ. Studies 16: 171-180	No	Yes	No	No
IIA, 8.3.3.1	1990	Fischer, R. Endosulfan - substance, technical (Hoe 002671 00 ZD98 0005). Effect to Eisenia fetida (Earthworm) in a 14 day Artficial Soil Test (method OECD) Hoechst C Produktentwicklung Oekologie 1, Germany. Report No.: A43674	Yes	No	AgrEvo	No
IIA, 8.3.3.1	1990	Hans, R. K.; Gupta, R. C.; Beg, M. U. Toxicity Assessment of Four Insecticides to Earthworm, Pheretima posthuma Industrial Toxicology Research Centre, India. Report No.: A53744 Bull. Environ. Contam. Vol. 45. pages 358-364 Toxicology. 1990	No	Yes	Publ.	No
IIA, 8.3.4	1975	Peeters, J.F.; Van Rossen, A.R. ; Heremans, K.A.; Delcambe, L. Influence of Pesticides on the Presence and Activity of Nitrogenase in Azotobacter vinelandii Univ.Leuven, Belgium. Report No.: A25670 J. Agric. Food Chem. Vol. 23, No. 3. pages 404-406. 1975	No	Yes	Publ.	No
IIA, 8.3.4 / IIIA, 10.3.5.1	1990	Stratton, Glenn W. Effects of the Insecticide Endosulfan on Nitrification in Low pH Agricultural Soils Nova Scotia Agricultural College, Canada. Report No.: A48342 Toxicity Assessment: An International Journal. Vol. 5. pages 319-336. 1990	No	Yes	Publ.	No
IIA, 8.3.4	1985	Taubel, N.; Baedelt, H.; Frings, H.	No	No	AgrEvo	No

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
		Investigation into the Effect of Endosulfan Technical Grade a.i. Identifying Code: Hoe 002671 01 ZD95 0005 on the Ammonification and Nitrification of Horn Meal Nitrogen Hoechst AG, LEA, Germany. Report No.: A32668				
IIA, 8.3.4	1977	Wainwright, M.; Kowalenko, C.G. Effects of Pesticides, Lime and Other Amendments on Soil Ethylene Soil Res.Inst., Canada. Report No.: A32091 Plant and Soil. Vol. 48. pages 253-258. 1977	No	Yes	Publ.	No
IIA, 8.3.5	1970	Gorbach, S.; Knauf, W. ENDOSULFAN und Umwelt. Das Rueckstandsverhalten von ENDOSULFAN in Wasser und seine Wirkung auf Organismen, die im Wasser-leben Hoechst Pharma Fo.To., DEU; Schriftenreihe des Vereins für Wasser-, Boden- und Lufthygiene, 1971. Report No.: A14220 Hoechst Pfl.Fo.Biol., Germany	No	Yes	Publ.	No
IIIA, 10.1	1972	Hoerger, Fred; Kenaga, Eugene Pesticide Residues on Plants: Correlation of Representative Data as a Basis for Estimation of Their Magnitude in the Environment Dow Chem. Corp., USA. Report No.: A32850 Environmental Quality I; Academic Press, New York; 1972; 9 - 28	No	Yes	Publ.	No
IIIA, 10.1	1973	Kenaga, E. E. Factors to be Considered in the Evaluation of the Toxocity of Pesticides to Birds in Their Environment Dow Chem. Company, USA. Report No.: A32849 Environmental Quality and Safety II,{Abs}Academic Press; New York; {Abs}1973; 166 - 181	No	Yes	Publ.	No
IIIA, 10.1	1995	Sochor H. Endosulfan, Estimating mean residues in leafy crops AgrEvo GmbH, Development, Residues and Consumer Safety, Germany. Report No.: A53761	No	No	AgrEvo	No
IIIA, 10.1.1	1990c	Ebert, E.; Leist, K.-H. Endosulfan - emulsifiable concentrate (352 g/l) (Code: Hoe 002671 0I EC33 B313) repellence study with a 0.1 % spray mix offered under heat stress to Japanese quails (Coturnix coturnix japonica) [redacted]: A43995	No	No	AgrEvo	No
IIIA, 10.1.1/01		Dikshith, T.S.S.	Yes	No	Excel	No

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
		Report on acute oral toxicity of Endocel (Excel Industries) EC 35 in Chicken. Excel Industries Ltd. [redacted]				
IIIA, 10.1.1/02		Dikshith, T.S.S. Report on acute oral toxicity of Endocel (Excel Industries) EC 35 in Pigeon. Excel Industries Ltd. [redacted]	Yes	No	Excel	No
IIIA, 10.1.2/01	1980	Douthwaite, R.J. Occurrence of birdss in Acacia Woodland in Northern Botswana related to endosulfan sprayed for Tsetse fly control. Environ. Poll. (Series A) 22: 273-279	No	Yes	Publ.	No
IIIA, 10.2	1995	Ganzelmeier, H.; Rautmann, D. *et al.* Studies on the spray drift of plant protection products - Results of a test programm carried out throughout the Federal Republic of Germany, Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft, Berlin-Dahlem, Heft 305, Backwell Wissenschafts-Verlag GmbH Berlin/Wien Landesanstalt fuer Pflanzenschutz, Stuttgart. Fraunhofer Institut fuer Umweltchemie und Oekotoxikologie, Schmallenberg. Report No.: A56850	No	Yes	Publ.	No
IIIA, 10.2.1/02; 10.2.3/01	1982	Fox, P.J.; Mathiessen, P. Acute toxicity to fish of Low-dose aerosol applications of endosulfan to control tsetse fly in the Okavango Delta, Botswana. Environ. Poll. (series A) 27: 129-142	No	Yes	Publ.	No
IIIA, 10.2.1.1	1971	Arora, H.C.; Shrivastava, S.K.; Seth, A.K. Bioassay Studies of Some Commercial Organic Insecticides. Part I. Studies with an Exotic Carp Puntius Sophore (Ham.) [redacted] Report No.: A25870 Indian J. Environm. Health. Vol. 13, No. 3. pages 226-233. 1971	No	Yes	Publ.	No
IIIA, 10.2.1.1	1978	Dalela, R.C.; Verma, S.R.; Batnagar, M.C. Biocides in Relation to Water Pollution. Part I: Bioassay Studies on the Effects of a Few Biocides on Fresh Water Fish, Channa gachua [redacted] A25861 Acta hydrochim. hydrobiol. Vol. 6, No.1. pages 15-25. 1978	No	Yes	Publ.	No
IIIA, 10.2.1.1	1987	Deoray, B.M.; Wagh, S.B.	No	Yes	Publ.	No

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
		Acute toxicity of Thiodon, Nuvan and Dithane M-45 to the freshwater fish, Barilius bendelisis(Ham.) [redacted]: A43067 Geobios. Vol. 14. pages 151-154. 1987				
IIIA, 10.2.1.1	1984b	Fischer, R. The Effect of Hoe 002671 0I EC33 B305 (Endosulfan, Emulsifiable Concentrate 352 g/l) to Salmo gairdneri (Rainbow Trout) in a Static Test [redacted] A30032	Yes	No	AgrEvo	No
IIIA, 10.2.1.1	1984c	Fischer, R. The Effect of Hoe 002671 0I EC33 B305 (Endosulfan, Emulsifiable Concentrate 352 g/l) to Lepomis macro- chirus (Blugill sunfish) in a Static Test [redacted] A29508	Yes	No	AgrEvo	No
IIIA, 10.2.1.1	1991	Gill, T.S.; Pande, J.; Tewari, H. Individual and combined toxicity of common pesticides to teleost Puntius conchonius Hamilton [redacted] A47588 Indian Journal Experim. Biol. Vol. 29. pages 145-148. 1991	No	Yes	Publ.	No
IIIA, 10.2.1.1	1977	Gopalakrishna Reddy, A.; Gomathy, S. Toxicity and Respiratory Effects of Pesticide, Thiodan on Catfish, Mystus vittatus [redacted] A25913 Indian J. Environ. Health. Vol. 19, No. 4. pages 360-363. 1977	No	Yes	Publ.	No
IIIA, 10.2.1.1	1984	Gupta, P.K.; Mujumdar, V.S.; Rao, P.S. Studies on the Toxicity of Some Insecticides to a Freshwater Teleost Lebistes reticulatus (Peters) [redacted] Report No.: A32237 Acta hydrochim. hydrobiol. Vol. 12. pages 629-636. 1984	No	Yes	Publ.	No
IIIA, 10.2.1.1	1977b	Knauf Effect of Hoe 02671 0 I EG022 (35 Emulsifiable Concentrate) on Idus Melanotus (Golden Orfe) [redacted] A16730	No	No	AgrEvo	No
IIIA, 10.2.1.1	1977d	Knauf	No	No	AgrEvo	No

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
		Effect of Hoe 02671 0 I G022(Emulsifiable Concentrate 35) on Cyprinus Carpio (carp) [redacted] A14970				
IIIA, 10.2.1.1	1978	Knauf Effect of Hoe 02671 0I EG022 (Emulsifiable Concentrate) on Lebistes Reticulatus (Guppy) [redacted] A18466	No	No	AgrEvo	No
IIIA, 10.2.1.1	1977c	Knauf Effect of Hoe 026710 I EG022 (Emulsifiable Concentrate) on Salmo gairdneri (Rainbow Trout) [redacted] A14969	No	No	AgrEvo	No
IIIA, 10.2.1.1	1982	Manoharan, T.; Subbiah, G.N. Toxic and Sublethal Effects of Endosulfan on Barbus stigma (Pisces: Cyprinidae) [redacted]: A27749 Proc. Ind. Acad. Sci. Vol. 91, No. 6. pages 523-532. 1982	No	Yes	Publ.	No
IIIA, 10.2.1.1	1988	Naqvi, Syed M.; Hawkins, Reanold Toxicity of Selected Insecticides (Thiodan(R), Security(R), Spartan(R), and Sevin(R)) to Mosquitofish, Gambusia affinis [redacted]: A43065 Bull. Environ. Contam. Toxicol. Vol. 40, pages 779-784, 1988	No	Yes	Publ.	No
IIIA, 10.2.1.1	1987	Trim, A. H. Acute Toxicity of Emulsifiable Concentrations of Three Insecticides Commonly Found in Nonpoint Source Runoff into Estuarine Waters to the Mummichog, Fundulus heteroclitus South Carolina Dep.Health and Envir. Control, USA. Report No.: A36296 Bull. Environ. Contam. Toxicol. Vol. 38. pages 681-686. 1987	No	Yes	Publ.	No
IIIA, 10.2.1.1	1981	Verma, S.R.; Rani, Sarita; Bansal, S.K.; Dalela, R.C. Evaluation of the Comparative Toxicity of Thiotox, Dichlorvos and Carbofuran to Two Fresh Water Teleosts Ophiocephalus punctatus and Mystus vittatus. [redacted] A29130 Acta hydrochim. hydrobiol. Vol.9, No. 2. pages 119-129. 1981	No	Yes	Publ.	No

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, 10.2.1.1	1982	Verma, S.R.; Bansal, S.K.; Gupta, A.K.; Pal, N.; Tyagi, A.K.; Bhatnagar, M.C.; Kumar, V.; Dalela, R.C. Bioassay Trials with Twenty Three Pesticides to a Fresh Water Teleost, Saccobranchus fossilis [redacted] A25048 Water Res. Vol. 6. pages 525-529. 1982	No	Yes	Publ.	No
IIIA, 10.2.1.2	1984a	Fischer, R. The Effect of Hoe 002671 0I EC33 B305 (Endosulfan, emulsifiable Concentrate 352 g/l) to Daphnia magna (Waterflea) in a Static Test Hoechst Pfl.Fo.Biol., Germany. Report No.: A29798	Yes	No	AgrEvo	No
IIIA, 10.2.1.2	1991	Heusel, R. Endosulfan - emulsifiable concentrate; 352 g/l (Hoe 002671 00 EC33 B319). Effect to Daphnia magna (Waterflea) in a 21-day Reproduction Test (method OECD) Hoechst AG Product Development Ecology I, Germany. Report No.: A46381	Yes	No	AgrEvo	No
IIIA, 10.2.1.2	1988	Joshi, H.C.; Mukhopadhyay, M.K. Toxicity of Quinalphos and Endosulfan to Different Life-stages of Tiger Prawn (Penaeus monodon) Cent.Inland Capture Fish., India. Report No.: A48339 Environmental Conservation. (year of publication estimated, no information available). pages 266-267. 1988	No	Yes	Publ.	No
IIIA, 10.2.1.2	1976	Knauf Effect of Hoe 02671 0I EG022 (Emulsifiable Concentrate 35) on Daphnia Magna (Water Flea) Hoechst Pfl.Fo.Biol., Germany. Report No.: A16729	No	No	AgrEvo	No
IIIA, 10.2.1.2	1977a	Knauf Effect of Hoe 02671 0 I EG022 (Emulsifiable Concentrate 35) on Aedes aegypti (Yellow Fever Mosquito) Hoechst Pfl.Fo.Biol., Germany. Report No.: A16736	No	No	AgrEvo	No
IIIA, 10.2.1.2	1960	Luedemann, D. ; Neumann, H.	No	Yes	Publ.	No

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
		Experiments on the Acute Toxic Effect of Modern Contact Insecticides on Freshwater Organisms. Third Contribution: Chironomidae Larvae BGA, Germany. Report No.: A18837 Zeitschr. f. angew. Zool. Vol.47. pages 493-505. 1960				
IIIA, 10.2.1.2	1984	Mane, U.H.; Muley, D.V. Acute Toxicity of Endosulfan 35 EC to Two Freshwater Bivalve Molluscs from Godavari River at Maharashtra State, INDIA Univ.Marathwada, India. Report No.: A31349 Toxicology Letters. Vol. 23. pages 147-155. 1984	No	Yes	Publ.	No
IIIA, 10.2.1.2	1989	Naqvi, Syed M.; Hawkins, Reanold H. Reponses and LC_{50} Values for Selected Microcrustaceans Exposed to Spartan(R), Malathion, Sonar(R), Weedtrine-D(R) and Oust(R) Pesticides Univ.Louisiana, USA. Report No.: A43062 Bull. Environ. Contam. Toxicol. Vol. 43. pages 386-393. 1989	No	Yes	Publ.	No
IIIA, 10.2.1.2	1987	Naqvi, Syed M.; Hawkins, Reanold; Naqvi, Nusrat H. Mortality Response and LC 50 Values for Juvenile and Adult Crayfish, Procambarus clarkii, Exposed to Thiodan(R) (Insecticide), Treflan(R), MSMA, Oust(R) (Herbicides) and Cutrine-Plus(R) (Algicide) Univ.Louisiana, USA. Report No.: A43061 Environm. Pollution. Vol. 48. pages 275-283. 1987	No	Yes	Publ.	No
IIIA, 10.2.2.1	1993	Peterson, S.M.; Batley, G.E. The fate of endosulfan in aquatic ecosystems CSIRO Inst.Biol.Resour., Australia. Report No.: A53056 Environmental Pollution. Vol. 82. pages 143-152. 1993	No	Yes	Publ.	No
IIIA, 10.2.2.3	1981	Baldry, D.A.T.; Everts, J.; Roman, B.; Boon von Ochssee, G.A.; Laveissiere, C. The Experiment Application of Insecticides from a Helicopter for the Control of Riverine Populations of Glossina tachinoides in West Africa. Part VIII: The Effects of Two Spray Applications of OMS-570 (endosulfan) and of OMS-1998 (decamethrin) on G. tachinoides and Non-Target Organisms in Upper Volta. WHO, Switzerland. Report No.: A21408 Tropic. Pestic Managem.. Vol. 27. pages 83-110. 1981	No	Yes	Publ.	No

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, 10.2.2.3	1981	Douthwaite, R.J.; Fox, P.J.; Matthiessen, P.; Russel-Smith, A. The Environmental Impact of Aerosols of ENDOSULFAN Applied for Tsetse Fly Control in the Okavango Delta, Botswana. Final Report of the ENDOSULFAN Monitoring Project Overseas Development Administration, United Kingdom. Report No.: A23822	No	No	AgrEvo	No
IIIA, 10.2.2.3	1971	Gorbach, S.; Haarring, R.; Knauf, W.; Werner, H.J. Residue Analyses and Biotests in Rice Fields of East Java Treated with Thiodan Hoechst AG, Germany. Report No.: A18219 Bull. Environ. Contam. Toxicol. Vol. 6. pages 193-199. 1971	No	Yes	Publ.	No
IIIA, 10.2.2.3	1978	Koeman, J.H.; Den Boer, W.M.J.; Feith, A.F.; de Jongh, H.H.; Spliethoff, P.C. Three Years´ Observation on Side Effects of Helicopter Applications of Insecticides Used to Exterminate Glossina Species in Nigeria Agric. Univ.Wageningen, Netherlands. Report No.: A25903 Environmental Pollution. Vol. 15. pages 31 - 59. 1978	No	Yes	Publ.	No
IIIA, 10.2.2.3	1978	Magadza, C.H.D. Field Observations on the Environmental Effect of Large-Scale Aerial Applications of Endosulfan in the Eradication of Glossina morsitans centralis Westw. in the Western Province of Zambia in 1968 National Counc.for Scientific Research, Zambia. Report No.: A35665 Rhodesian J. Agric. Res. Vol.16. pages 211-220. 1978	No	Yes	Publ.	No
IIIA, 10.3.1	1989a	Ebert, E.; Leist, K.-H. Endosulfan; emulsifiable concentrate; 352 g/l (Code: Hoe 002671 00 EC33 B317). Testing for acute oral toxicity in the male and female Wistar rat [redacted] A42355	Yes	No	AgrEvo	No
IIIA, 10.3.1	1989b	Ebert, E.; Leist, K.-H. Endosulfan; emulsifiable concentrate; 352 g/l, (Code: Hoe 002671 00 EC33 B317). Testing for acute oral toxicity in the male and female NMRI mice [redacted] A42359	Yes	No	AgrEvo	No

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, 10.3.1	1990a	Ebert, E.; Leist, K.-H. Endosulfan; Emulsifiable Concentrate; 352 g/l (Code: Hoe 002671 00 EC33 B317), testing for acute oral toxicity in the male and female rabbit [redacted] A43165	Yes	No	AgrEvo	No
IIIA, 10.3.1	1984	Edwards, J. A.; Reid, Y. J.; Offer, J. M., Almond, R. H., Gibson, W. A. Effect of Endosulfan-Technical (Code: Hoe 02671 0I AT209) on Reproductive Function of Multiple Generations in the Rat [redacted] No.: A29428	Yes	No	AgrEvo	No
IIIA, 10.3.2.1.1	1986	Bock, K.-D. Laboratory investigations into the effects of Thiodan 35 EC (Code: Hoe 002671 0I EC33 B305) on the honey bee Apis mellifera L. Hoechst LEA, Germany. Report No.: A45397	No	No	AgrEvo	No
IIIA, 10.3.2.1.2; 10.3.2.4; 10.3.2.3	1996	Bock, K.-D. Endosulfan, emulsifiable concentrate 352 g/l (Code: Hoe 002671 00 EC33 B3**) Summary and evaluation of the effects of Thiodan 35EC on honey bees Hoechst Schering AgrEvo GmbH, Germany. Report No.: A57215	No	No	AgrEvo	No
IIIA, 10.3.2.3	1985	Bock, K.-D. Ergebnis der Pruefung auf Bienengefaehrlichkeit (Zusammenfassung) LEA Hoechst AG, Germany. Report No.: A32371	No	No	AgrEvo	No
IIIA, 10.3.3/01	1986	Anderson, J.F.; Wojtas, M.A. Pesticides and polychlorinated biphenyls in honey bees. J. Econ. Entomol. 79: 1200-1205	No	Yes	Publ.	No
IIIA, 10.3.3/02	1988	Douthwaite, R.J.; Mahmoud, D.A., Abdisalam, S.I. Effects on drift sprays of endosulfan. Applied for tsetse fly control, on *honeybees (Apis mellifera* L.) in Somalia J. Apic. Res. 27 (1): 40-48	No	Yes	Publ.	No
IIIA, 10.3.3.1	1990a	Bock, K.-D. Testing the effects of Thiodan 35 liquid on the larvae of Coccinella septempunctata in laboratory tests Hoechst C Produktentwicklung Oekologie 2, Germany. Report No.: A56008	No	No	AgrEvo	No

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, 10.3.3.1	1990b	Bock, K.-D. Testing the effects of (R)Thiodan 35 liquid on the larvae of Chrysopa carnea in laboratory tests Hoechst AG, Produktentwicklung Oekologie II, Germany. Report No.: A56007	No	No	AgrEvo	No
IIIA, 10.3.3.1	1990c	Bock, K.-D. Testing the effects of (R)Thiodan 35 liquid on the larvae of Syrphus corollae in laboratory tests Hoechst AG, Produktentwicklung Oekologie II, Germany. Report No.: A56009	No	No	AgrEvo	No
IIIA, 10.3.3.1	1992a	Kuehner, Ch. Erfassung der Nebenwirkungen von Thiodan 35 fluessig (Hoe 002671 0I EC33 B313) auf die Florfliege, Chrysoperla carnea Steph. im Labor GAB Biotechnologie GmbH, Germany. Report No.: A48847	Yes	No	AgrEvo	No
IIIA, 10.3.3.1	1992b	Kuehner, Ch. Erfassung der Nebenwirkungen von Thiodan 35 fluessig (Hoe 002671 0I EC33 B313) auf den Grossen Siebenpunkt Marienkaefer, Coccinella septempunctata L. (Labor-Pruefung) GAB Biotechnologie GmbH, Germany. Report No.: A48846	Yes	No	AgrEvo	No
IIIA, 10.3.3.2 / 10.3.2.4	1985	Brasse, Dietrich Zur Wirkung von endosulfanhaltigen Insektiziden auf Nuetzlinge und Bienen / Side effects of Endosulfan-containing insecticides to beneficial organisms and honey bees Biolog. Bundesanstalt fuer Land- und Forstwirtsch., Germany. Report No.: A32235 Nachrichtenbl. Deutsch. Pflanzenschutzdienst. Vol. 37, No. 4. pages 54-58.	No	Yes	Publ.	No
IIIA, 10.3.3.2	1991	Ferch, Th. Effects of (R) Thiodan 35 liquid on predatory mites in vineyards Hoechst AG, Produktentwicklung Oekologie II, Germany. Report No.: A56511	No	No	AgrEvo	No
IIIA, 10.3.3.2	1992	Krull, Stefan Die Selektive Wirkung von Thiodan (Endosulfan) auf Nutzarthropoden Univ.Giessen, Germany. Report No.: A47600	No	No	AgrEvo	No

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, 10.3.3.2	1988b	Mead-Briggs, M., A. The Effects of endosulfan on non-target arthropods in winter oilseed rape Univ. Southampton, United Kingdom. Report No.: A43303	No	No	AgrEvo	No
IIIA, 10.3.3.2	1989	Mead-Briggs, M.,A. The effects of endosulfan on non-target arthropods on winter oilseed rape. Supplementary report on sampling carried out in the season subsequent to the original application in May 1987 Univ. Southampton, Dep. Biol., United Kingdom. Report No.: A43302	No	No	AgrEvo	No
IIIA, 10.3.4.1.1	1990	Fischer, R. Endosulfan - emulsifiable concentrate 352 g/l (Hoe 002671 00 EC33 B319). Effect to Eisenia fetida (Earthworm) in a 14 day Artificial Soil Test (method OECD) Hoechst C Produktentwicklung Oekologie 1, Germany. Report No.: A43675	Yes	No	AgrEvo	No
IIIA, 10.3.4.1.1	1983	Haque, Ajazui; Ebing, Winfried Toxicity Determination of Pesticides to Earthworms in the Soil Substrate BBA, Germany. Report No.: A28776 Z. Pflanzenkrankh. Pflanzenschutz. Vol.90, No. 4. pages 395-408. 1983	No	Yes	Publ.	No
IIIA, 10.3.4.1.1	1984	Heimbach, Fred Correlations Between Three Methods for Determining the Toxicity of Chemicals to Earthworms Bayer, Germany. Report No.: A32903 Pestic. Sci. Vol. 15. pages 605-611. 1984	No	Yes	Publ.	No
IIIA, 10.3.4.1.1	1985	Heimbach, Fred Comparison of Laboratory Methods, Using Eisenia foetida and Lumbricus terrestris, for the Assessment of the Hazard of Chemicals to Earthworms Bayer, Germany. Report No.: A32902 Z. Pflanzenkrankh. Pfl.schutz. Vol. 92, No. 2. pages 186-193. 1985	No	Yes	Publ.	No
IIIA, 10.3.4.1.3	1992	Reddy, M. Vikram; Reddy, V. Ravinder Effects of organochlorine, organophosperus and carbamate insecticides on the population structure and biomass of earthworms in a semi-arid tropical grassland Univ.Warangal, India. Report No.: A51812 Soil Biol. Biochem. Vol. 24. No. 12. 1733 - 1738. 1992	No	Yes	Publ.	No

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, 10.3.4.2	1971	Drake, J.L.; Warf, G.W.; Werner , F.G. Insecticidal Effects on Soil Arthropods Univ.Arizona, United States. Report No.: A25658 J. Econ. Entomol. Vol. 64, No. 4. pages 842 - 845. 1971	No	Yes	Publ.	No
IIIA, 10.3.5.1	1989a	Baedelt, H. Thiodan liquid (endosulfan) - emulsifiable concentrate (352 g/l) (Code: Hoe 002671 00 EC33 B313) Investigating the short-term effect on aerobic soil respiration Hoechst AG, Produktentwicklung Oekologie II, Germany. Report No.: A55890	No	No	AgrEvo	No
IIIA, 10.3.5.1	1989b	Baedelt, H. Thiodan liquid (endosulfan) - emulsifiable concentrate (352 g/l) (Code: Hoe 002671 00 EC33 B313) Investigation into the effect on the nitrification of ammonium sulphate Hoechst AG, Produktentwicklung Oekologie II, Germany. Report No.: A42099	No	No	AgrEvo	No
IIIA, 10.3.5.1	1991	Baedelt, H. Code: Hoe 002671 00 EC33 B320 (endosulfan) emulsifiable concentrate (352 g/l) Investigating the short-term effect on aerobic soil respiration (in accordance with BBA, VI, 1-1) Hoechst AG Produktentwicklung Oekologie II, Germany. Report No.: A56010	Yes	No	AgrEvo	No
IIIA, 10.3.5.1	1984	Muralikrishna, P.V.G.; Venkateswarlu, K. Effect of Insecticides on Soil Algal Population Univ. Nagarjuna, India. Report No.: A31347 Bull. Environ. Contam. Toxicol. Vol. 33. pages 241-245. 1984	No	Yes	Publ.	No
IIIA, 10.3.6	1989	Knauf, Werner; Waltersdorfer, Anna The Insecticidal Efficacy of Endosulfandiol (Hoe 051329), Endosulfanlacton (Hoe 051328), Endosulfansulfate (Hoe 051327) in comparison with Endosulfan (Hoe 002671) Hoechst C Produktentwicklung Oekologie 1, Germany. Report No.: A41240	No	No	AgrEvo	No
	1984	World Health Organization IPCS (International Programme on Chemical Safety), environmental Health Criteria, 40, endosulfan World Health Organization, Geneva		Yes	Publl.	No
	1994	British Crop Protection Coooouncil The pesticide Manual, incorporing the agrochemical handbook, 10th edition, page 388-390		Yes	Publ.	No

TABLE OF CONTENTS

APPENDIX 1

STANDARD TERMS AND ABBREVIATIONS

Part 1 Technical Terms

A	Ampere
a	Area
ACCase	Acetyl-CoA-carboxylase
ACh	acetilcholine
AChE	acetilcholinesterase
ADI	Acceptable daily intake
ADP	Adenosine diphosphate
AE	Acid equivalent
AFID	alkali flame-ionization detector or detection
A/G	Albumin/globulin ratio
ai	Active ingredient
ALD_{50}	Approximate median lethal dose, 50%
ALT	Alanine aminotransferase (SGPT)
AMD	Automatic multiple development
ANOVA	Analysis of variance
AOEL	Acceptable operator exposure level
AOLD	Approximate oral lethal dose
AOPP	aryloxyphenoxypropanoates
AP	Alkaline phosphatase
approx.	approximate
appr.	Approximately
AR	Applied radioactivity
AR	Area of cornea involved
ARC	Anticipated residue contribution
ARfD	Acute reference dose
as	Active substance
AST	Aspartate aminotransferase (SGOT)
ASV	Air saturation value
ATP	Adenosine triphosphate
AUC	Area under the curve
AUD	Area under the data
AUD_1	Area under the data at time 1
β	Mean elimination rate constant
BCF	Bioconcentration factor
bfa	Body fluid assay
BOD	Biological oxygen demand
bp	Boiling point
BrdU	Bromocleoxyuridine
BSAF	Biota-sediment accumulation factor
BSE	Bovine spongiform encephalopathie
BSP	bromosulfophthalein
Bt	Bacilus thuringiensis
Bti	Bacilus thuringiensis israelensis
Btt	Bacilus thuringiensis tenebrionis
BUN	Blood urea nitrogen
Bw/bwt	Body weight
c	Centi- (x 10^{-2})
C	Concentrations
C_0	Initial concentration
ºC	Degree celsius (centigrade)
CA	Controlled atmosphere

CAD	Computer aided design
CADDY	Computer aided dossier and data supply (an electronic dossier interchange and archiving format)
CAS name	Chemical abstract name
cd	candela
CDA	Controlled drop(let) application
cDNA	Complemetary DNA
CEC	Cation exchange capacity
cf	Confer, compare to
CFU	Colony forming units
CG	Cytoplasmatic grain
CI	Confidential interval
CL	Confidential limits
cm	Centimetre
CMC	Caarboxymethyl cellulose
C_{max}	Maximum plasma concentrations of total radioactivity
CNS	Central nervous system
COD	Chemical oxygen demand
CPK	Creatinine phosphatase
CPP	Cyclophosphamide
cv	Coefficient of variation
Cv	Ceiling value
CXL	Codex Maximum Resideu Limit (Codex MRL)
d	day
d	Diameter of MN
D	Cell diameter
D	Applied dosage
DAMC	Days after the maximum concentration
DAP	Days after planting
DAT	Day after treatment/application
DCM	dichloromethane
DES	diethylstilboestrol
DFR	Dislogeable foliar residue
DI	deischarge
d.l.	detection limit
DM	Dry matter
DMSO	Dimethylsulfoxide
DNA	Deoxiribonuclei acid
dna	Designated national authority
dns	Unscheduled DNA-synthesis
DO	Dissolved oxygen
DOC	Dissolved organic carbon
dpi	Days pot inoculation
DRES	Dietary risk evaluation system
DT	Disappearance time
DT_{50}	Period required for 50 per cent dissipation (define method of estimation)
$DT_{50, calc}$	Calculated half life
$DT_{50, ref}$	Reference half life
DT_{90}	Period required for 90 per cent dissipation (define method of estimation)
dw	Dry weight
DWQG	Drinking water quality guidelines
ε	Decadic molar extinction coefficient
EC_x	Effective concentration that produces x% of effect
EC_{50}	Median effective concentration
ECD	Electron capture detector
ECU	European currency unit
ED_{50}	Median effective dose
EDI	Estimated daily intake
ELISA	Enzyme linked immunosorbent assay
e-mail	Electronic mail

EMDI	Estimated maximum daily intake
EPMA	Electron probe micro analysis
ETE	Estimated theoretical exposure
Eq	Equivalent
ERC	Environmentally relevant concentration
ERL	Extraneous residue limit
f	female
F	field
ºF	Degree Fahrenheit
F_0	Parental generation
F_1	Filial generation, first
F_2	Filial generation, second
FC	Field capacity
f_{drift}	Drift factor
FIA	Fluorescence immuno assay
FID	Flame ionization detector
FOB	Functional observation battery
fp	Freezing point
FPD	Flame photometric detector
FPLC	Fast protein liquid chromatography
g	Gram
G	Glasshouse
GAP	Good agricultural practice
GC	Gas chromatography
GC-EC	Gas chromatography with electron capture detector
GC-FID	Gas chromatography with flame ionization detector
GC-MS	Gas chromatography-mass spectrometry
GC-MSD	Gas chromatography with mass-selective detection
GEP	Good experimental practice
GFP	Good field practice
GGT	Gamma-glutamyl transferase
G.I.	Gastro intestinal
GIT	Gastro intestinal tract
GLC	Gas liquid chromatography
GLP	Good laboratory practice
GM	Geometric mean
GMM	Genetically modified micro-organism
GMO	Genetically modified organism
GPC	Gel-permeation chromatography
GPPP	Good plant protection practice
GPS	Global positionen system
GR	Growth reduction rate
GS	Growth stage
GSH	glutathion
GST-P	Glutathione-S-Transferase P
GV	granulosevirus
ΔH_{vap}	Molar heat of vaporisation
H	Henry’s Law constant (calculated as a unitless value) (see also K)
h/hr	Hour(s)
ha	Hectare
Hb	Haemoglobin
HCG	Human chorionic gonadotropin
Hct	Haematocrit
HDPE	High density polyethylene
HDT	Highest dose tested
HEED	High energy electron diffraction
HID	Helium ionization detector
hl	Hectolitre
HPAEC	High performance anion exchange chromatography

HPLC	High pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	High pressure liquid chromatography – mass spectrometry
HPPLC	High pressure planar liquid chromatography
HPTLC	High performance thin layer chromatography
HRGC	High resolution gas chromatography
H_S	Shannon-Weaver index
Ht	Hematocrit
I	indoor
I_{50}	Inhibitory dose 50%
IC_{50}	Median immobilisation concentration
ICM	Integrated crop management
ID	Ionization detector
i.d.	Internal diameter
IEDI	International estimated daily intake
IGR	Insect growth regulator
im	Intramuscular
inh	Inhalation
ip	intraperitoneal
i.p.	intraperitoneal
IPM	Integrated pest management
IR	infrared
IS	Loamy sand
ISBN	International standard book number
ISSN	International standard serial number
iv	intravenous
IVF	*In vitro* fertilisation
k	Kilo
K	Kelvin or Henry's Law Constant (in atmospheres per cubic meter per mole)
K_{ads}	Adsorption constant
K_d	Distribution coefficient
K_{des}	Apparent desorption coefficient
K_{oc}	Organic carbon adsorption coefficient
K_{om}	Organic matter adsorption coefficient
K_{ow}	n-octanol water partition coefficient
kg	kilogram
l	litre
L	Loam
LAN	Local area network
LASER	Light amplification by stimulated emission of radiation
LBC	Loosely bound capacity
LC	Lethal concentration
LC	Liquid chromatography
LC_{50}	Lethal concentration, median
LC_{Lo}	Lethal concentration low
LCA	Life cycle analysis
LC-MS	Liquid chromatography – mass spectrometry
LC-MS-MS	Liquid chromatography with tandem mass spectrometry
LD_{50}	Lethal dose, median
LD_{Lo}	Lethal dose low
LDH	Lactate dehydrogenase
LOAEC	Lowest observable adverse affect concentration
LOAEL	Lowest observable adverse effect level
LOD	Limit of determination
LOEC	Lowest observable effect concentration
LOEL	Lowest observable effect level
log	logarithm
LOQ	Limit of quantitation
LPLC	Low pressure liquid chromatography
LSC	Liquid scintillation counting or counter

LSD	Least squared denominator multiple range test
LSS	Liquid scintillation spectrometry
LT	Lethal threshold
m	Metre / male
M	Molar
MAT	Month after treatment
MC	Moisturee content
MCH	Mean corpuscular haemoglobin
MCHC	Mean corpuscular haemoglobin concentration
µCi	micro curios
MCV	Mean corpuscular volume
MDL	Method detection limit
meq	Miliequivalents
MFO	Mixed function oxidase
µg	microgram
mg	milligram
MHC	Moisture
min	minute
µl	microlitre
ml	millilitre
MLD	Method detection limit
MLT	Median lethal time
mm	Millimetre
µm	Micrometer
MMAD	Mass median aerodynamic diametre
MNPCE	Micronucleated polychromatic erythrocytes
mo	Months
mol	Mole(s)
MOS	Margin of safety
m.p.	melting point
MPC	Maximum plasma concentration
MR	Moderately resistant
MRE	Maximum residue expected
MRL	Maximum residue level
mRNA	Messenger ribonucleic acid
MS	Mass spectrometry
MS	Moderately susceptible
MSDS	Material safety data sheet
MTD	Maximum tolerated dose
MWC	Maximum water holding capacity
N	Newton
n	Normal (definiting isomeric configuration) or number of observations
nº	Number
NA	Not applicable
NAEL	No adverse effect level
NCE	Normochromatic erythrocyte
nd	Not determined
n.d.	Not detected
NEDI	National estimated daily intake
NEL	No effect level
NERL	No effect residue level
n.f.	Not found
ng	Nanogram
NNM	N-Nitrosomorpholine
n.m.	Not measurable
nm	Nanometre
NMR	Nuclear magnetic resonance
NG	Nuclear grain
NNG	Net nuclear grains
no/No	Number

NOAEC	No observed adverse effect concentration
NOAEL	No observed adverse effect level
NOEC	No observed effect concentration
NOED	No observed effect dose
NOEL	No observed effect level
NOIS	Notice of intent to suspend
np	not performed
NPD	Nitrogen-phosphorus detector or detection
NPV	Nuclear polyhedrosis virus
NR	Not reported
ns	Not sampled
NTE	Neurotoxic target esterase
OC	Organic carbon content
OCR	Optical character recognition
ODP	Ozone-depleting potential
ODS	Ozone-depleting substances
O.M.	Organic matter content
OP	Opacity
op	Organophosphorous pesticide
p	para (indicating position in a chemical name)
Pa	Pascal
PAD	Pulsed amperometric detection
2-PAM	2-prlidoxime
PB	Phenobarbitone
pc	Paper chromatography
PC	Personal computer
PCE	Polychromatic erythrocyte
PCV	Haematocrit (packed corpuscular volume)
PEC	Predicted environmental concentration
PEC_A	Predicted environmental concentration in air
PEC_{GW}	Predicted environmental concentration in ground water
PEC_i	Initial PEC
PEC_s	Predicted environmental concentration in soil
$PEC_{s, act}$	Actual PEC_s
$PEC_{s, twa}$	Time-weighed average PEC_s
PEC_{SW}	Predicted environmental concentration in surface water
PED	Plasma-emissions-detector
PEG	Polyethylene glycol
pH	pH - value
PHED	Pesticide handler’s exposure data
PHI	Pre-harvest interval
PIC	Prior informed consent
Pic	Phage inhibitory capacity
PIXE	Proton induced X-ray emission
pKa	Negative logarithm (to the base 10) of the dissociation constant
PNEC	Predicted no effect concentration
po	By mouth
P_{ow}	Partition coefficient between n-octanol and water
POP	Persistent organic pollutants
ppb	Parts per billion (10^{-9})
PPE	Personal protective equipment
ppm	Parts per million (10^{-6})
ppp	Plant protection product
ppq	Parts per quadrillion (10^{-24})
ppt	Parts per trillion (10^{-12})
PRL	Practical residue limit
PrT	Prothrombin residue time
PSP	phenosulfophthalein
PT	Prothrombin time
PTDI	Provisional tolerable daily intake

PTT	Partial thromboplastin time
PVDW	Predicted value drinking water
PVOH	plyvinylalcohol
Q_{10}	Factor for increase of degradation rate with an increase of temperature of 10ºC
QA	Quality assurement
QSAR	Quantitative structure-activity relationship
r	correlation coefficient
r^2	Coefficient of determination
R	Ideal gas constant / resistant
RAC	Raw agriculture commodity
RBC	Red blood cell
RED	Redness
Reg.	Registration
REI	Restrictes entry interval
Rf	Retardation factor
RfD	Reference dose
RH	Relative humidity
RL_{50}	Median residual lifetime
RNA	Ribonucleic acid
RP	Reversed phase
rpm	Rotations per minute
rRNA	Ribosomal ribonucleic acid
RRT	Relative retention time
RSD	Relative standard deviation
S	susceptible
s	second
SAC	Strong adsorption capacity
SAP	Serum alkaline phosphatase
SAR	Structure/activity relationship
SBLC	Shallow bed liquid chromatography
sc	subcutaneous
sce	Sister chromatid exchange
SD	Standard deviation
se	standard Error
SEM	Standard error of the mean
SEP	Standard evaluation procedure
SF	Safety factor
SFC	Supercritical fluid chromatography
SFC	Supercritical fluid extraction
SIMS	Secondary ion mass spectroscopy
SL	Sandy loam
SOP	Standard operating procedures
sp	Species (only after a generic name)
SPE	solid phase extraction
SPF	Specific pathogen free
spp	subspecies
sq	square
SSD	Sulphur specific detector
SSMS	Spark source mass spectrometry
STEL	Short term exposure limit
STMR	Supervised trials median residue
SW	Chemosis
t	Tonne (metric tone)
t_1	Time period
T_3	Tri-iodothyroxine
T_4	thyroxine
T	Absolute temperature
T_{ref}	Reference temperature

T_{calc}	Temperature for which DT_{50} was calculated
$t_{1/2}$	Terminal elimination half-life
T_{max}	Maximum time
TADI	Temporary acceptable daily intake
TBC	Tightly bound capacity
TCD	Thermal conductivity datector
TC_{Lo}	Thermionic concentration, low
TC_{max}	Time to maximum plasma concentration of total radioactivity
$TC_{max/2}$	Time to one-half maximum plasma
TD_{Lo}	Toxic dose low
TDR	Time domain reflectrometry
TID	Thermoionic detector, alkali flame detector
TER	Toxicity exposure ration
TER_I	Toxicity exposure ration for initial exposure
TER_{ST}	Toxicity exposure ration following repeated exposure
TER_{LT}	Toxicity exposure ration following chronic exposure
TEP	Typical end-use product
tert	Tertiary (in a chemical name)
TGAI	Technical grade of the active ingredient
TGGE	Temperature gradient gel electrophoresis
TIFF	Tag image file format
TLC	Thin layer chromatography
Tlm	Median tolerance limit
TLV	Threshold limit value
TMDI	Theoretical maximum daily intake
TMRC	Theoretical maximum residue contribution
TMRL	Temporary maximum residue limit
TOC	Total organic carbon
Tremcard	Transport emergency card
tRNA	Transfer ribonucleic acid
TRR	Total radioactive residue
TSH	Thyroid stimulation hormone
TWA	Time weighted average
UDP-GA	Uridine diphosphate glucoronic acid
UDS	Unscheduled DNA synthesis
UF	Uncertainty factor (safety factor)
ULV	Ultra low volume
UV	Ultraviolet
vl.	volume
V	Volume of the water body
VCR	Vincristine
v/v	Volume ratio (volume per volume)
WBC	White blood cell
wk	week
wt	Weight
wt/vol	Weight per volume
w/v	Weight per volume
w/w	Weight per Weight
XRFA	X-ray fluorescence analysis
yr	year
$<$	Less than
$\leq$	Less than or equal to
$>$	Greater than
$\geq$	Greater than or equal to

Part 2 Organisations and Publications

BBA	Federal Biological Research Centre for Agriculture and Forestry
CA	Chemical Abstracts
CAS	Chemical Abstracts Service
CIPAC	Collaborative International Pesticides Analytical Council Ltd.
D/DE	Germany
E	Spain
EC	European Commission
EEC	European Economic Community
ECCO	European Commission Co-ordination
EINECS	European Inventory of Existing Commercial Chemical Substances
EPA	Environmental Protection Agency
EPPO	European and Mediterranean Plant Protection Organisation
ES	Spain
EU	European Union
FAO	Food and Agriculture Organisation of the UN
FR	France
ISO	International Organisation for Standardisation
I	Italy
IUPAC	International Union of Pure and Applied Chemistry
SETAC	Society of Environmental Toxicology and Chemistry
OECD	Organisation for Economic Co-operation and Development
UK	United Kingdom of Great Britain
US	United States
USA	United States of America

APPENDIX 2

PREPARATION (FORMULATION) TYPES AND CODES

EC	Emulsifiable concentrate	A liquid, homogenous preparation to be applied as an emulsion after dilution in water