

Shaughnessy No.: 079401
Date Out of EFGWB: 8/16/90

TO: K. Samek
Product Manager 74
Registration Division (H7505C)

FROM: Henry P. Nelson, Acting Supervisory Chemist *H Nelson*
Environmental Chemistry Review Section #3

THRU: Henry Jacoby, Branch Chief *Henry Jacoby*
Environmental Fate and Ground Water Branch/EFED (H7505C)

Attached, please find the EFGWB review of . . .

Reg./File # : 0709401

Common Name : Endosulfan

Type Product : Insecticide, acaricide

Product Name : Endosulfan

Company Name : Hoechst AG

Purpose : Addendum to an application for full registration

Date Received: 1/9/85 EFGWB # (s): 90-0262

Action Code : 660 Total Review Time (days): 6

Deferrals to: Ecological Effects Branch, EFED
 Science Integration and Policy Staff, EFED
 Non-Dietary Exposure Branch, HED
 Dietary Exposure Branch, HED
 Toxicology Branch I, HED
 Toxicology Branch II, HED

1. CHEMICAL: Common name:

Endosulfan.

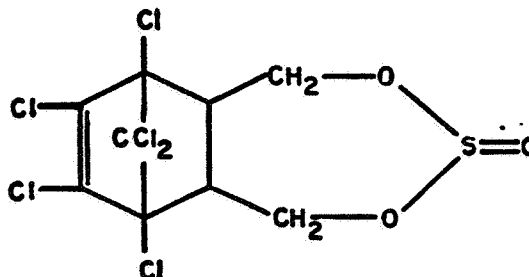
Chemical name:

6,7,8,9,10,10-Hexachloro-1,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzo-dioxathiepin-3-oxide.

Trade name(s):

Thiodan.

Structure:



Formulations:

D (1.5-5%), WP (25, 50%), WP/D (1, 4%), Impr (15%), and EC (2, 3 lb/gal; 9.15-34%).

Physical/Chemical properties:

Molecular formula: C₉H₆Cl₆O₃S.

Molecular weight: 406.9.

Physical state: Brown crystalline solid.

Vapor pressure: 1.2 Pa at 80 C.

Solubility: At 22 C: 0.32 mg/L water; 200 g/L methylene chloride, ethyl acetate, toluene; 65 g/L ethanol; 24 g/L hexane.

2. TEST MATERIAL:

Studies 1-4: Active ingredient.

3. STUDY/ACTION TYPE:

Addendum to an application for full registration.

4. STUDY IDENTIFICATION:

Dorr, Victor A. 1984. Company response to EPA comments (dated 9 January 1984) on hydrolysis and photolysis studies - dated 25 May 1984. Document prepared and submitted by American Hoechst Corporation, Agricultural Division, Somerville, NJ. (Acc. No. 253448)

Dorr, Victor A. 1985. Company response to EPA comments (dated 21 September 1984) on hydrolysis and photolysis studies - dated 9 January

1985. Document prepared and submitted by American Hoechst Corporation, Agricultural Division, Somerville, NJ. (No MRID)

- (1) Gorlitz, G., and C. Klockner. 1982. Hydrolysis of Hoe 02671 (endosulfan). MRID # 00128659. Translation of Document Number A 24433. Unpublished study performed and submitted by Hoechst Ag, Frankfurt, FRG. (Acc. No. 250395)
- (2) Gildemeister, H., and H.J. Jordan. 1983. Photolytic degradation of the insecticide endosulfan on soil covered thin layer plates under simulated sunlight. MRID # 00128660. Laboratory Project ID (B)46/83. Unpublished study performed and submitted by Hoechst Ag, Frankfurt, West Germany.
- (3) Gildemeister, H., and H. J. Jordan. 1984. Aerobic soil metabolism of the insecticide Hoe 002671 (endosulfan). Laboratory Project ID OE-134/04.02. Unpublished study performed and submitted by Hoechst AG, Frankfurt, FRG. (148993?)
- (4) Gildemeister, H. 1985. Anaerobic soil metabolism study with the insecticide endosulfan. Laboratory Project ID OE-134/04.03. Unpublished study performed and submitted by Hoechst AG, Frankfurt, FRG. (146844?)
- (5) Gildemister, H. 1984. Terrestrial Field Dissipation Studies with the Insecticide Endosulfan. Literature studies (4) submitted by Hoechst AG, Frankfurt, FRG. (No MRID #).

5. REVIEWED BY:

B. Kitchens
Chemist
EFGWB/EFED/OPP
Review Section #3

Signature: Bruce F. Kitchens
Date: 8/16/90

6. APPROVED BY:

Henry P. Nelson
Acting Chief
EFGWB/EFED/OPP
Review Section #3

Signature: H Nelson
Date: 8/16/90

7. CONCLUSION:

- (1) EFGWB concludes that study MRID # 00128659 does not meet data requirement for hydrolysis, 161-1, because:
 - (i) the study duration (5 days) and number of sampling intervals (2) were insufficient to establish the decline and half-life of alpha & beta endosulfan at pH 5,
 - (ii) the registrant calculated half-lives for alpha-endosulfan at 22°C of >1 year, 22 days, and 7 hours, respectively for pH 5, 7, and 9 and half-lives for beta-endosulfan of >1 year, 17 days, and 5.1 hours,

respectively for pH 5, 7, and 9. They can only be considered order of magnitude estimates, since only the pH 9 solution was conducted at 22°C. Temperatures for pH 5 hydrolysis were 50 and 70°C, while the temperatures for pH 7 hydrolysis were 40 and 50°C. In addition, the extrapolation method was not provided.

- (iii) no material balance was reported
- (iv) degradation curves and regression analyses were not provided

The explanation of endosulfan's resistance to hydrolysis at neutral and acidic pH's at normal environmental temperatures seems to indicate that conductance of a hydrolysis study at the Agency recommended temperatures would be feasible. Results from this study would probably show that endosulfan is stable to hydrolysis at pH 5 and 7.

If the hydrolysis study is conducted at elevated temperatures, one constant temperature should be used for each individual pH throughout the study.

- (2) EFGWB concludes that study, MRID # 00128660, provides supplemental data, but does not satisfy the data requirement, 161-3, for soil photolysis of endosulfan at this time; however, this study could be made to do so by submitting the following information:

Temperatures at which samples were held (exposed and dark control).

Method used to estimate the soil photolysis half-life of endosulfan.

Endosulfan, a mixture of alpha & beta isomers, degraded with a registrant estimated half-life of > 200 days on a sandy loam soil that was irradiated continuously with a xenon arc lamp for 45 hours (16:1 artificial light:natural sunlight intensity) at an unspecified temperature. Forty-five hours of artificial light is equivalent to thirty days natural sunlight.

¹⁴C-Endosulfan decreased from 90.8% of the applied after 4 hours of irradiation to 84.5% after 45 hours. In, comparison, degradation in the dark control after 45 hours was 88.9% indicating that photolysis was not significant in the degradation of endosulfan.

- (3) This study, no MRID #, is scientifically sound, but does not meet the data requirement for aerobic soil metabolism, 162-1, for the following reasons:

- (i) The study was terminated after 60 days and failed to establish the pattern of decline of the major degradate, endosulfan-sulfate.

- (ii) Four degradates, each comprising up to 0.6 - 4.8% of the applied (0.02- 0.16 ppm), were not identified.

Endosulfan consisting of a mixture of 2 isomers, alpha & beta in a [REDACTED] ratio, degraded with calculated half-lives of 27 days in silt loam soil and 18 days in sandy loam soil. The major degradate was endosulfan-sulfate (6,7,8,9,10,10-hexachloro-1,5,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3,3-dioxide). Other degradates identified were endosulfan-lactone (4,5,6,7,8,8-hexachloro-1,3,3a,4,7,7a-hexahydro-4,7-methano-isobenzofuran-1-one) and endosulfan-ether (4,5,6,7,8,8-hexachloro-1,3,3a,4,7,7a-hexahydro-4,7-methano-isobenzofuran).

(4) This study, no MRID #, does not satisfy the data requirement for anaerobic soil metabolism, 162-2, for the following reasons:

- (i) The material balances were incomplete (up to 44 and 63% of the applied radioactivity was unaccounted for), and
- (ii) the data were too variable to accurately assess the half-life of endosulfan.

8. RECOMMENDATIONS:

(1) Inform the registrant that study, MRID # 00128659, does not meet the data requirement for hydrolysis.

The Agency recommends that a new hydrolysis study be conducted and submitted.

The Agency also recommends that a protocol be submitted prior to conductance of new study. See D.E.R. # 1 for comments.

(2) Inform the registrant that study, MRID # 00128660, provides supplemental data, but does not satisfy the data requirement, 161-3, for soil photolysis; however, the study could be made to do so by submitting the following information:

1. Temperature at which samples were held (exposed and dark control).
2. The method used to estimate the soil photolysis life.
3. The half-lives of the individual isomers, alpha- and beta-endosulfan.

The registrant is advised to use the Subdivision N Guidelines in designing and conducting any future studies submitted to the Agency.

(3) A new aerobic soil metabolism study will have to be submitted to the Agency in order to satisfy the data requirement, 162-1, for aerobic soil metabolism.

Report the half-lives of the individual isomers, alpha- & beta-endosulfan.

The registrant is advised to design a protocol which will meet Subdivision N Guidelines and to submit the protocol prior to initiation of the study.

- (4) Inform registrant that study, no MRID # , does not fulfill the data requirement for anaerobic soil metabolism, 162-2.

Report the half-lives of the individual isomers, alpha- & beta-endosulfan.

Advise registrant that a new anaerobic soil metabolism study will have to be submitted to satisfy the data requirement.

- (5) Advise registrant that the duplicate literature searched Terrestrial Field Dissipation studies were not reviewed since none of the original data was supplied with this study.

9. BACKG ROUND:

A. Introduction

B. Directions for Use

Endosulfan is an insecticide registered for use on a variety of terrestrial food crop, terrestrial nonfood crop, greenhouse food crop, greenhouse nonfood crop, domestic outdoor, and forestry sites. It is a wide range non-systemic contact and stomach insecticide and acaricide effective against numerous insects and certain mites. Endosulfan is a mixture of two stereoisomers in the ratio of [REDACTED] (alpha:beta). Application rates range from 0.375 to 2 lb ai/A/application for row crops and 1.5 to 4 lb ai/A/application for orchard crops; depending on the crop, there can be a maximum of 3 applications/season. The greenhouse fumigation rate is 0.05625 lb ai/10000 ft³. Endosulfan may be formulated with a variety of other pesticides, including amitraz, BPMC, deltamethrin, dimethoate, heptenophos, methomyl, methyl parathion, monocrotophos, pirimicarb, thiometon, and triazophos. Single active ingredient formulations consist of D (1.5-5%), WP (25, 50%), WP/D (1, 4%), Impr (15%), and EC (2, 3 lb/gal; 9.15-34%). Endosulfan may be applied as a preplant dip (entire plant) for nursery stock and row crop transplants, as a spray (delayed dormant, foliar, bark, postharvest bark, postharvest, felled logs), to the soil (prebloom, preplant [band or broadcast], at time of planting, surrounding domestic dwellings), or as a fumigant (greenhouse). Endosulfan is toxic to fish, bees, and birds. Livestock should not be allowed to graze treated areas or be fed treated plant parts. Do not apply within 0 to 40 days of harvest depending on the crop. Do not apply to bearing citrus trees or to citrus trees that will bear fruit within 12 months. Applicators must wear protective clothing with approved masks or respirators; protective clothing is required for workers entering treated fields within 24 hours of application.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

Refer to attached reviews.

11. COMPLETION OF ONE-LINER:

Update through J. Hannan 7/30/90.

12. CBI APPENDIX:

All data reviewed here are considered "company confidential" by the registrant and must be treated as such.

ENDOSULFAN ADDENDUM

TASK 1: REVIEW AND EVALUATION OF INDIVIDUAL STUDIES

July 11, 1990

Initial Draft Report

Contract No. 68D90058

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
11140 Rockville Pike
Rockville, MD 20852

ENDOSULFAN

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4. Anaerobic soil metabolism. (Gildemeister, no Study ID)	4.1
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INTRODUCTION

Endosulfan is an insecticide registered for use on a variety of terrestrial food crop, terrestrial nonfood crop, greenhouse food crop, greenhouse nonfood crop, domestic outdoor, and forestry sites. It is a wide range non-systemic contact and stomach insecticide and acaricide effective against numerous insects and certain mites. Endosulfan is a mixture of two stereoisomers in the ratio of [REDACTED] (alpha:beta). Application rates range from 0.375 to 2 lb ai/A/application for row crops and 1.5 to 4 lb ai/A/application for orchard crops; depending on the crop, there can be a maximum of 3 applications/season. The greenhouse fumigation rate is 0.05625 lb ai/10000 ft³. Endosulfan may be formulated with a variety of other pesticides, including amitraz, BPMC, deltamethrin, dimethoate, heptenophos, methomyl, methyl parathion, monocrotophos, pirimicarb, thiometon, and triazophos. Single active ingredient formulations consist of D (1.5-5%), WP (25, 50%), WP/D (1, 4%), Impr (15%), and EC (2, 3 lb/gal; 9.15-34%). Endosulfan may be applied as a preplant dip (entire plant) for nursery stock and row crop transplants, as a spray (delayed dormant, foliar, bark, postharvest bark, postharvest, felled logs), to the soil (prebloom, preplant [band or broadcast], at time of planting, surrounding domestic dwellings), or as a fumigant (greenhouse). Endosulfan is toxic to fish, bees, and birds. Livestock should not be allowed to graze treated areas or be fed treated plant parts. Do not apply within 0 to 40 days of harvest depending on the crop. Do not apply to bearing citrus trees or to citrus trees that will bear fruit within 12 months. Applicators must wear protective clothing with approved masks or respirators; protective clothing is required for workers entering treated fields within 24 hours of application.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

DATA EVALUATION RECORD

STUDY 1

CHEM 079402

Endosulfan

161-1

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID (Acc. No.) 250395

Gorlitz, G. and C. Klockner. 1982. Hydrolysis of Hoe 02671 (endosulfan). Translation of Document Number A 24433. Unpublished study performed and submitted by Hoechst Ag, Frankfurt, FRG.

STUDY ID (Acc. No.) 253448

Dorr, Victor A. 1984. Company response to EPA comments (dated 9 January 1984) on hydrolysis and photolysis studies - dated 25 May 1984. Document prepared and submitted by American Hoechst Corporation, Agricultural Division, Somerville, NJ.

STUDY ID None

Dorr, Victor A. 1985. Company response to EPA comments (dated 21 September 1984) on hydrolysis and photolysis studies - dated 9 January 1985. Document prepared and submitted by American Hoechst Corporation, Agricultural Division, Somerville, NJ.

DIRECT REVIEW TIME = 9

REVIEWED BY: C. Little

TITLE: Staff Scientist

EDITED BY: S. Syslo
K. Patten

TITLE: Staff Scientist
Task Leader

APPROVED BY: W. Spangler

TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD

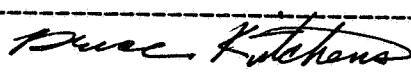
TEL: 468-2500

APPROVED BY: B. Kitchens

TITLE: Chemist

ORG: EFGWB/EFED/OPP

TEL: 557-4355



SIGNATURE:

CONCLUSIONS:

Degradation - Hydrolysis

1. This study, MRID # 00128659, does not fulfill data requirement for hydrolysis, 161-1, because:
 - (i) the study duration (5 days) and number of sampling intervals (2) were insufficient to establish the decline and half-life of alpha & beta endosulfan at pH 5,
 - (ii) the registrant calculated half-lives for alpha-endosulfan at 22°C of >1 year, 22 days, and 7.0 hours, respectively for pH 5, 7, and 9 and half-lives for beta-endosulfan of >1 year, 17 days, and 5.1 hours, respectively for pH 5, 7, and 9. They can only be considered order of magnitude estimates, since only the pH 9 solution was conducted at 22°C. Temperatures for pH 5 hydrolysis was 50 and 70°C, while the temperatures for for pH 7 hydrolysis was 40 and 50°C. In addition, the extrapolation method was not provided.
 - (iii) no material balance was reported
 - (iv) degradation curves and regression analyses were not provides

The explanation of endosulfan's resistance to hydrolysis at neutral and acidic pH's at normal environmental temperatures seems to indicate that conductance of a hydrolysis study at the Agency recommended temperatures would be feasible. Results from this study would probably show that endosulfan is stable to hydrolysis at pH 5 and 7.

If the hydrolysis study is conducted at elevated temperatures, on constant temperature should be employed throughout the study.

METHODOLOGY:

Stereoisomers of endosulfan (alpha-endosulfan purity \geq 99%; purity of beta-endosulfan not specified) were studied separately.

Alpha-endosulfan, dissolved in acetone, was added to flasks containing sterile aqueous 0.1 M buffer solutions adjusted to pH 5 (potassium-biphthalate), 7 (potassium phosphate monobasic), and 9 (boric acid and potassium chloride); the final concentration in solution was 0.155 ug/mL. Beta-endosulfan, dissolved in acetone, was added to buffer solutions as described above; the final concentration in solution was 0.187 ug/mL. The concentration of the co-solvent in all solutions was <1%. All flasks were capped with ground-in stoppers and placed in temperature-controlled water baths at 22, 40, 50, or 70 C. Samples of the alpha- and beta-endosulfan solutions were collected at 0 and 120 hours posttreatment for pH 5 at 50 C; at 0 and 72 hours for pH 5 at 70 C (beta-endosulfan only); at 0, 7, 24,

48, and 96 hours for pH 7 at 40 C; at 0, 2, 5, 7, and 24 hours for pH 7 at 50 C; and at 0, 2, 4, 8, and 15 hours for pH 9 at 22 C.

At each sampling time, solutions were cooled to room temperature and extracted three times with methylene chloride. Extracts were combined and the methylene chloride was evaporated with a stream of nitrogen. Remaining residues were then redissolved in methanol and analyzed using HPLC with a mobile phase of methanol:water (80:20, v:v) and with UV detection (218 nm); peaks were compared with those of known standards of the isomers of endosulfan and of the degradation product endosulfan-alcohol (Hoe 051329).

DATA SUMMARY:

Alpha-endosulfan (purity \geq 99%) at 0.187 ug/ml degraded with registrant calculated half-lives of >1 year, 22 days, and 7.0 hours, respectively, in sterile, aqueous buffer solutions at pH 5, 7, and 9. Beta-endosulfan (purity not specified) at 0.155 ug/ml degraded with registrant-calculated half-lives of >1 year, 17 days, and 5.1 hours in sterile, aqueous buffer solutions at pH 5, 7, and 9, respectively, assuming an incubation temperature of 22°C for both isomers.

In pH 5 solutions, which were analyzed only at 0 and 5 days posttreatment, alpha-endosulfan decreased from 101.7 to 95.0% of the applied at 50 C; beta-endosulfan decreased from 98.8 to 83.4% at 50 C and to 21.2% at 70 C (Tables 5 and 6).

In the pH 7 solutions incubated at 40 C, alpha-endosulfan decreased from 97.7 to 21.0% of the applied during a 4-day experiment; beta-endosulfan decreased from 99.8 to 19.2% during a 3-day experiment (Tables 5 and 6). In the pH 7 solutions incubated at 50 C, alpha-endosulfan decreased from 97.7 to 24.5% of the applied during a 1-day experiment; beta-endosulfan decreased from 99.8 to 23.5% during a 0.67-day experiment.

In the pH 9 solutions incubated at 22 C, alpha-endosulfan decreased from 100.0 to 23.3% of the applied during a 0.625-day experiment; beta-endosulfan decreased from 98.3 to 12.3% during a 0.625-day experiment (Tables 5 and 6).

Endosulfan-alcohol (Hoe 051329; 1,4,5,6,7,7,-hexachloro-bicyclo-/2,2,1/-hept-5-ene-2,3-dimethanol) was the sole degradate in all solutions. During the study, material balances ranged from 95 to 101.9% (Tables 5 and 6).

COMMENTS:

1. The pH 5 and 7 solutions were incubated at 40 to 70 C, rather than the recommended 25 ± 1 C. The study authors extrapolated from the data obtained at high temperatures to estimate hydrolytic half-lives

at 22 C presumably through computation of the Arrhenius frequency factor and the Energy of activation; however, those values were not provided. The study authors explained that endosulfan is relatively resistant to hydrolysis under neutral and acidic conditions and normal environmental temperatures. The extrapolated rates are regarded to be order-of-magnitude estimates only.

2. The test substances were incompletely characterized. In a response to EPA comments, it was stated that the "endosulfan test substance" (code number Hoe 052618 OI AT 302) was provided by Riedel-de Haen with a "purity guarantee equal to or greater than 99% (Pestanal grade)" [Acc. No. 253448]; however, the code number corresponds to the alpha-isomer only (Table 1). The code number for the beta-isomer was Hoe 52619 OI AT 302 (Table 2); no purity information was provided.
3. Endosulfan is a mixture of two stereoisomers, alpha-endosulfan and beta-endosulfan, in the ratio of [REDACTED]. The study authors stated that to accurately measure hydrolytic behavior, separate measurements had to be taken for each isomer. Therefore, individual data were presented in the study for both alpha- and beta-endosulfan. No method provided for the extrapolated half-life calculation.

Endosulfan environmental fate review

Page _____ is not included in this copy.

Pages 15 through 21 are not included in this copy.

The material not included contains the following type of information:

- Identity of product inert ingredients
 - Identity of product impurities
 - Description of the product manufacturing process
 - Description of product quality control procedures
 - Identity of the source of product ingredients
 - Sales or other commercial/financial information
 - A draft product label
 - The product confidential statement of formula
 - Information about a pending registration action
 - FIFRA registration data
 - The document is a duplicate of page(s) _____
 - The document is not responsive to the request
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

DATA EVALUATION RECORD

STUDY 2

CHEM 079402

Endosulfan

161-3

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID: MRID # 0012860

Gildemeister, H., and H.J. Jordan. 1983. Photolytic degradation of the insecticide endosulfan on soil covered thin layer plates under simulated sunlight. Laboratory Project ID (B)46/83. Unpublished study performed and submitted by Hoechst Ag, Frankfurt, West Germany.

STUDY ID (Acc. No.) 253448

Dorr, Victor A. 1984. Company response to EPA comments (dated 9 January 1984) on hydrolysis and photolysis studies - dated 25 May 1984. Document prepared and submitted by American Hoechst Corporation, Agricultural Division, Somerville, NJ.

STUDY ID None

Dorr, Victor A. 1985. Company response to EPA comments (dated 21 September 1984) on hydrolysis and photolysis studies - dated 9 January 1985. Document prepared and submitted by American Hoechst Corporation, Agricultural Division, Somerville, NJ.

DIRECT REVIEW TIME = 11

REVIEWED BY: C. Little

TITLE: Staff Scientist

EDITED BY: T. Colvin-Snyder
K. Patten

TITLE: Staff Scientist
Task Leader

APPROVED BY: W. Spangler

TITLE: Project Manager

ORG: Dynamac Corporation
Rockville, MD

TEL: 468-2500

APPROVED BY: B. Kitchens

TITLE: Chemist

ORG: EFGWB/EFED/OPP

TEL: 557-4355



SIGNATURE:

CONCLUSIONS:

Degradation - Photodegradation on Soil

1. EFGWB concludes that study, MRID # 00128660, provides supplemental data, but does not satisfy the data requirement, 161-3, for soil photolysis of endosulfan at this time; however, this study could be made to do so by submitting the following information:

Temperatures at which the samples were held (exposed and dark control).

Method used to estimate the soil photolysis half-life of endosulfan.

2. Endosulfan, a mixture of alpha & beta isomers, degraded with a registrant estimated half-life of > 200 days on a sandy loam soil that was irradiated continuously with a xenon arc lamp for 45 hours (16:1 artificial light:natural sunlight intensity) at an unspecified temperature. Forty-five hours of artificial light is equivalent to thirty days of natural sunlight.

¹⁴C-Endosulfan decreased from 90.8% of the applied after 4 hours of irradiation to 84.5% after 45 hours. In comparison, degradation in the dark control after 45 hours was 88.9% of the applied indicating that photolysis was not significant factor in the degradation of endosulfan.

METHODOLOGY:

A slurry of sandy loam soil (63.0% sand, 31.6% silt, 5.4% clay, organic carbon 2.7%, pH 4.7, CEC 2.91 meq/100 g) was spread in thin layers (0.5-mm thick) over glass slides. The slides were air-dried and treated at 500 ug/slide with [¹⁴C]endosulfan (uniformly labeled in the hexachloro-cyclo-pentene ring, radiochemical purity >98%, specific activity 12.1 mCi/g, Hoechst Ag), which was dissolved in acetone and applied as spots on the surface of the soil. Following application of the test substance, the slides were "carefully" dried under red light for an unspecified period of time, placed in a quartz glass box, and irradiated continuously with a xenon arc lamp (Figures 1 and 2). The spectral distribution of the light source was similar to sunlight (Figure 3) and the radiation intensity of the photoreactor was 820 w/m² between 300-830 nm; wavelengths <290 nm were filtered out. The ratio of the artificial light source to natural sunlight ("in a field in Central Europe") was reported as 16:1. An additional slide containing treated soil was placed in an aluminum foil-covered quartz glass box to serve as a dark control. The incubation temperatures for the irradiated and dark control samples were not reported. The samples were collected after 4, 8, 16, 32, and 45 hours of irradiation (equivalent to 30 days of natural sunlight); the dark control was collected at 45 hours only. Volatiles were not trapped.

At each sampling interval, the soil was scraped from the glass slides and transferred to a separatory funnel "adding a small amount of water." The slides and the quartz glass incubation boxes were both rinsed repeatedly with acetonitrile; the rinse was transferred to the separatory funnel. Soil samples were extracted three times with acetonitrile:toluene (80:20, v:v). Aliquots of the extract were analyzed for total extractable radioactivity by LSC; additional aliquots were analyzed by one-dimensional TLC using silica gel plates developed in toluene:acetone (85:15, v:v). The plates were divided into zones 5 mm wide, the silica gel in the zones was scraped off the plates, and total radioactivity in each zone was determined by LSC. Unextractable residues in the soil samples were determined by LSC following combustion. Method detection limits were not reported.

DATA SUMMARY:

Hexachloro-cyclo-pentene ring-labeled [¹⁴C]endosulfan (radiochemical purity >98%), applied at 500 ug/soil thin-layer plate, degraded with a registrant-estimated half-life of >200 days on sandy loam soil that was irradiated continuously with a xenon arc lamp for 45 hours (1:16 artificial light:natural sunlight intensity) at an unspecified temperature (Table 1). [¹⁴C]Endosulfan decreased from 90.8% of the applied after 4 hours of irradiation (equivalent to 2.67 days of sunlight) to 84.5% by 45 hours (equivalent to 30 days), compared to 88.9% in the dark control. No degradates were detected in either the irradiated or dark control soil at >10% of the applied, and unextractable radioactivity was <5% at all sampling intervals. During the study, material balances ranged from 93.9 to 97.6% of the applied.

COMMENTS:

1. The artificial light was of much greater intensity than natural sunlight; the study authors estimated that only 45 hours of exposure to the artificial light was necessary to simulate the energy input from 30 days of natural sunlight. This ratio was an estimate based upon information from the manufacturers of the artificial light source (the SUNTEST by Heraeus) that the concentration factor determined experimentally for weathering in the field compared to "filtered illumination behind the window glass in the SUNTEST apparatus for color fastness of various materials" was a ratio of 1:13. The ratio of 1:16 was estimated because an additional UV-filter was placed between the lamp and the test material. The actual intensity of the light reaching the soil surface was never measured.

Also, exposure to the artificial light was continuous; the light:dark cycling that occurs during normal exposure did not occur.

2. The incubation temperatures for the irradiated and the dark control samples were not reported, and it was uncertain if the samples were incubated at the same temperature.
3. The study author failed to confirm the application rate with an immediate posttreatment sampling. The soils were treated and dried under red light (duration of drying not specified), and the first sampling interval was not until after the soils had been irradiated for 4 hours. Using the reported 1:16 ratio for the intensity of the artificial light source to natural sunlight, this would translate to an initial sampling time of 2.67 days post-exposure, at which time 90.8% of the nominal application remained undegraded. The half-life should more accurately have been determined from the rate of degradation between 4 and 45 hours rather than the rate between a theoretical time 0 concentration and 45 hours.
4. The distance between the xenon arc lamp and the soil was not specified. Because xenon arc lamps produce considerable heat, the distance between the lamp and the soil may have had a significant effect on the temperature of the soil surface.
5. The study authors classified the test soil as "loamy sand" (Schwanheimer Sand SS 2.2). Using the USDA Textural Classification System, the correct classification is "sandy loam"; this term was used in the review.
6. Even though the intensity of the artificial light source was greater than that of natural sunlight (16:1), no temperature was reported for the irradiated and dark control samples, the samples were continuously irradiated, and distance between the xenon arc lamp and the soil was not specified endosulfan did not photodegrade appreciable and hence seems to be stable to hydrolysis.

Endosulfan environmental fate review

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and endosulfan-ether (4,5,6,7,8,8-hexachloro-1,3,3a,4,7,7a-hexahydro-4,7-methano-isobenzofuran).

3. This study is scientifically sound, but does not meet Subdivision N guidelines for the following reasons:

the study was terminated after 60 days and failed to establish the pattern of decline of the major degradate, endosulfan-sulfate; and

four degradates, each comprising up to 0.6-4.8% of the applied (0.02-0.16 ppm), were not identified.

4. Degradation curves look to be biphasic; consequently, separate half-lives should be computed for each phase.
5. Because the study was terminated before the pattern of decline of the major degradate was established, the problems with this study cannot be resolved with the submission of additional data. A new study is required.

METHODOLOGY:

Air-dried silt loam (sand 7.2%, silt 70.4%, clay 22.4%, pH 6.4, organic matter 1.6%, CEC 21.3 meq/100 g) and sandy loam (sand 63%, silt 31.6%, 5.4% clay, 2.7% organic matter, pH 4.7, CEC 2.9 meq/100 g) soils were sieved (1-mm), moistened to 40% of water-holding capacity with distilled water, and incubated in the dark for 2 weeks at 22 ± 2 C. The soil (100 g) was then weighed into 500-mL flasks, treated with [^{14}C]endosulfan (radiochemical purity 97%, specific activity 2200 dpm/ug, Hoechst AG) dissolved in methylene chloride, and mixed. Measured application rates of [^{14}C]endosulfan were 3.51 ppm for soils sampled at 1, 2, 4, 8, 16, and 60 days posttreatment, 3.15 ppm for soils sampled at 0 days posttreatment, and 3.26 ppm for soils sampled at 30 days posttreatment. Flasks of each soil (one flask per sampling interval) were sealed with cotton-wool plugs and incubated in the dark at 22 ± 2 C. The soil moisture level was maintained at 40% of water-holding capacity by the addition of distilled water at 2- to 3-day intervals throughout the study period. Soil samples were collected at 0, 1, 2, 4, 8, 16, 30 and 60 days posttreatment.

In order to trap volatile compounds, one flask of each soil was wrapped in aluminum foil and attached to a closed aeration system (Figure 1). Water-saturated air (30 mL/min for 8 hours/day) was passed over the soils and then sequentially through bottles of sulfuric acid, ethylene glycol, and ethanalamine:methanol (3:7) trapping solutions. The trapping solutions were collected at 8, 16, 30 and 60 days posttreatment.

Soil samples were extracted with acetonitrile:toluene (80:20, v:v). Aliquots of the extract were analyzed for total radioactivity using LSC. Soil extracts were then concentrated, and aliquots were analyzed by HPLC using a mobile phase of methanol:water (75:25, v:v) with radioactivity and UV detection. Degradates were identified by comparison of the HPLC plates with an HPLC chromatogram containing known endosulfan degradates. Radioactivity remaining in the soil following extraction was quantified by LSC following combustion. Sulfuric acid, ethylene glycol, and ethanolamine:methanol (3:7) trapping solutions were analyzed for total radioactivity by LSC.

DATA SUMMARY:

[¹⁴C]Endosulfan (radiochemical purity 97%), at 3.15-3.51 ppm, degraded with calculated half-lives of 27 days in silt loam soil and 18 days in sandy loam soil. At 60 days posttreatment, endosulfan (alpha plus beta isomers) comprised 15.8% of the applied in the silt loam soil and 29.3% of the applied in the sandy loam soil (Table 2). The major degradate was

endosulfan-sulfate (6,7,8,9,10,10-hexachloro-1,5,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3,3-dioxide; M1),

which reached maximum concentrations of 18.6% (day 60) and 45.1% (day 30) of the applied in the silt loam and sandy loam soils, respectively. Other degradates identified were

endosulfan-lactone (4,5,6,7,8,8-hexachloro-1,3,3a,4,7,7a-hexahydro-4,7-methano-isobenzofuran-1-one; M2) and

endosulfan-ether (4,5,6,7,8,8-hexachloro-1,3,3a,4,7,7a-hexahydro-4,7-methano-isobenzofuran; M3)

which each comprised $\leq 1.0\%$ of the applied during the study. In addition, five unidentified degradates each comprised up to 0.2-4.8% of the applied. At 60 days posttreatment, volatilized carbon dioxide totaled 1.8-2.8% of the applied, and volatiles other than carbon dioxide totaled 1.2-1.8% of the applied. Material balances during the study, with the exception of day 30 samples, ranged from 84.4 to 103.0% of the applied for the silt loam soil and from 91.1 to 99.7% of the applied for the sandy loam soil; at 30 days posttreatment, material balances were 56.0% for the silt loam soil and 78.1% for the sandy loam soil (Table 1).

COMMENTS:

1. The study was only conducted for 60 days instead of 365 days. Subdivision N guidelines specify that aerobic soil metabolism studies must be conducted either for one year or until the pattern of decline of the test substance and the patterns of formation and decline of

its degradates are established, whichever comes first. The patterns of formation and decline of the degradates have not been established; it cannot be determined from the data in this study if the major degradate, endosulfan-sulfate, would reach higher concentrations with increased incubation time, or if endosulfan-sulfate would later be degraded to other compounds.

2. Four degradates, each comprising up to 0.6-4.8% of the applied (0.02-0.15 ppm), were not identified. In section 5.2 of the original document, "Identification of degradation products," the study authors stated that degradates M4-M8 could not be identified due to the small amounts of each present in the soil extracts. No explanation was provided as to why M4, present at up to 4.8% of the applied, was not identified, yet M3, present at only up to 0.8% of the applied, was identified (Table 2).
3. The test substance consisted of a mixture of the alpha and beta isomers of endosulfan at a ratio of [REDACTED]. The alpha isomer of endosulfan degraded much more quickly than the beta isomer (Table 2).
4. The calculated half-lives (27 days in silt loam soil and 18 days in sandy loam soil) are questionable due to the incomplete material balances obtained for both soils at 30 days posttreatment. Material balances at 30 days posttreatment were 56% for the silt loam soil and 78% for the sandy loam soil. However, the data do indicate that endosulfan degraded with a half-life of 16-60 days.
5. EFGWB prefers that [¹⁴C]residues in samples be separated by chromatographic methods (such as TLC, HPLC, or GC) with at least three solvent systems of different polarities, and that specific compounds isolated by chromatography be identified using a confirmatory method such as MS in addition to comparison to the R_f of the reference standards.

In this study, the sample extracts were analyzed by HPLC using a mobile phase of methanol:water (75:25, v:v) with radioactivity and UV detection. The identities of degradates detected through HPLC analysis were confirmed only by comparison to a chromatograph of known endosulfan degradates.

6. Method detection limits were not reported.
7. Soil II was identified by the study author as "loamy sand" soil; however, based on the USDA soil textural analysis system, this soil should be classified as a "sandy loam" soil and was referred to as such in this review.
8. Calculated half-lives were based on the application rate of 3.51 ppm; data for soils sampled at 0 and 30 days posttreatment (treated at 3.15 and 3.26 ppm) were normalized to an application rate of 3.51 ppm for the half-life calculations.

9. Table 1 lists the total recoveries of radioactive material as the sums of the amounts recovered from the soil extract and the amount recovered from the soil following combustion. The totals given in the table do not reflect the amounts recovered from the volatile traps; however, because the amount of volatilization of radioactivity was small, totaling 3.6-4.0% of the applied at 60 days posttreatment, the contribution of volatilized radioactivity to total material balance is not considered to be significant.
10. The study author stated that the beginning of the decline of the degradate endosulfan-sulfate was observed in the sandy loam soil; however, insufficient data points were available to determine whether or not this was the case. Endosulfan-sulfate was 45.1% of the applied at 30 days posttreatment and was 38.6% at 60 days posttreatment. It is possible that differences in the concentrations of endosulfan-sulfate at these sampling intervals were due to experimental variability rather than an actual decrease in concentration.

Endosulfan environmental fate review

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DATA EVALUATION RECORD

STUDY 4

CHEM 079402

Endosulfan

§162-2

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 146844(?)

Gildemeister, H. 1985. Anaerobic soil metabolism study with the insecticide endosulfan. Laboratory Project ID.OE-134/04.03. Unpublished study performed and submitted by Hoechst AG, Frankfurt, FRG.

DIRECT REVIEW TIME = 23

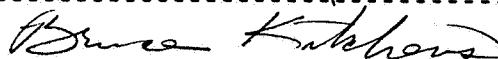
REVIEWED BY: C. Little TITLE: Staff Scientist

EDITED BY: T. Colvin-Snyder TITLE: Staff Scientist
K. Patten Task Leader

APPROVED BY: W. Spangler TITLE: Project Manager

ORG: Dynamac Corporation
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TEL: 468-2500

APPROVED BY: B. Kitchens
TITLE: Chemist
ORG: EFGWB/EFED/OPP
TEL: 557-4355



SIGNATURE:

CONCLUSIONS:

Metabolism - Anaerobic Soil

1. This study cannot be used to fulfill data requirements.
2. These data are considered to be of uncertain value and should not be used to predict the environmental behavior of endosulfan and its degradates.
3. This study is unacceptable for the following reasons:

material balances were incomplete (up to 44 and 63% of the applied radioactivity was unaccounted for), and

the data were too variable to accurately assess the half-lives of endosulfan.

4. Because the material balances were incomplete and the data were too variable to accurately assess the half-lives of endosulfan, the problems with this study cannot be corrected by the submission of additional data. A new study is required.

METHODOLOGY:

Air-dried silt loam (7.2% sand, 70.4% silt, 22.4% clay, 1.6% organic matter, pH 6.4, CEC 21.3 meq/100 g) and loamy sand (77.5% sand, 19.9% silt, 2.6% clay, 1.8% organic matter, pH 4.1, CEC 2.9 meq/100 g) soils were sieved (1 mm), moistened to 40% of their respective moisture-holding capacities with distilled water, and then incubated in the dark for 2 weeks at 22 ± 2 C. Soil (100 g) was then weighed into 500-mL flasks, treated with [14 C]endosulfan (radiochemical purity 97%, specific activity 2200 dpm/ug, Hoechst AG) dissolved in methylene chloride, and mixed. Application rates of [14 C]endosulfan were 3.15 ppm for soils sampled at 0 days posttreatment and 3.26 ppm for soils sampled at other intervals. Flasks of each soil (one per sampling interval) were sealed with cotton-wool plugs and incubated aerobically in the dark at 22 ± 2 C for 30 days. The soil moisture level was maintained at 40% of water-holding capacity by the addition of distilled water at 2- to 3-day intervals throughout the aerobic incubation period. Following the aerobic incubation period, 10 mg of peptone was added to the soil samples, and the samples were flooded with 100 mL of distilled water and purged with nitrogen to establish anaerobic conditions. Flooded samples were sealed and incubated in darkness at 22 ± 2 C. Samples were collected at 0, 30, 45, 60, 74 and 90 days posttreatment (-30, 0, 15, 30, 44, and 60 days after establishing anaerobic conditions).

Soil samples were extracted with acetonitrile:toluene (80:20, v:v). Aliquots of the extract were analyzed for total radioactivity using LSC. Soil extracts were then concentrated, and aliquots were analyzed by HPLC using a mobile phase of methanol:water (75:25, v:v) with radioactivity and UV detection. Degradates were identified by comparison of the HPLC plates with an HPLC chromatogram containing known endosulfan degradates. Radioactivity remaining in the soil following extraction was quantified by LSC following combustion.

DATA SUMMARY:

Concentrations of [14 C]endosulfan (radiochemical purity 97%), applied at 3.15-3.26 ppm, were variable with no discernable pattern in anaerobic silt loam and loamy sand soils incubated for 61 days under anaerobic conditions (flooding plus nitrogen atmosphere) following 30 days of aerobic incubation. Under anaerobic conditions in silt loam soil, endosulfan (alpha plus beta isomers) was 48.2% of the applied at 30 days posttreatment (0 days of anaerobic conditions), 4.5% at 60 days (30 days of anaerobic conditions), 63.3% at 74 days (44 days of

anaerobic conditions), and 43% at 91 days (61 days of anaerobic conditions) (Table 2). Under anaerobic conditions in loamy sand soil, endosulfan was 25.1% of the applied at 30 days posttreatment (0 days of anaerobic conditions), 4.0% at 60 days (30 days of anaerobic conditions), 29.1% at 74 days (44 days of anaerobic conditions), and 17.2% at 91 days (61 days of anaerobic conditions). The major degradate was

endosulfan-sulfate (6,7,8,9,10,10-hexachloro-1,5,5,5a,6,9,9a-hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3,3-dioxide; M5),

which reached maximum concentrations of 67.8% (60 days posttreatment) and 52.7% (74 days posttreatment) of the applied in silt loam and loamy sand soils, respectively. Other degradates identified were

endosulfan-lactone (4,5,6,7,8,8-hexachloro-1,3,3a,4,7,7a-hexahydro-4,7-methano-isobenzofuran-1-one; M4) and

endosulfan-ether (4,5,6,7,8,8-hexachloro-1,3,3a,4,7,7a-hexahydro-4,7-methano-isobenzofuran; M8),

which each comprised up to 8.1% of the applied. In addition, eight unidentified degradates were each present at up to 0.6-3.2% of the applied. Material balances during the study ranged from 56.0 to 92.4% of the applied for the silt loam soil and from 36.9 to 99.7% of the applied for the loamy sand soil (Table 1).

COMMENTS:

1. Material balances were incomplete; up to 44 and 63% of the applied radioactivity was unaccounted for in the silt loam and loamy sand soils, respectively.
2. The variability in the data for both soils was too great to accurately assess the half-lives of endosulfan. In silt loam soil, endosulfan (alpha plus beta isomers) was 48.2% of the applied at 30 days posttreatment (0 days of anaerobic conditions), 4.5% at 60 days, 63.3% at 74 days, and 43% at 91 days (Table 2). In loamy sand soil, endosulfan was 25.1% of the applied at 30 days posttreatment (0 days of anaerobic conditions), 4.0% at 60 days, 29.1% at 74 days, and 17.2% at 91 days. The study author suggested that this variability in the data may be due to differences in the amount of time it took for separate soil samples to be converted from aerobic to anaerobic conditions.
3. Eight degradates each comprising up to 0.6-3.2% of the applied (0.02-0.10 ppm) were not identified. In section 5.2 of the original document, "Identification of degradation products," the study authors stated that degradates M1-M3, M6-M7, and M9-M11 could not be identified due to the small amounts of each present in the soil extracts. No explanation was provided as to why M2, present at up to 3.2% of

the applied, was not identified, yet M4, present at only up to 2.8% of the applied, was identified (Table 2).

4. The test substance consisted of a mixture of the alpha and beta isomers of endosulfan at a ratio of [REDACTED]
5. EFGWB prefers that [¹⁴C]residues in samples be separated by chromatographic methods (such as TLC, HPLC, or GC) with at least three solvent systems of different polarities, and that specific compounds isolated by chromatography be identified using a confirmatory method such as MS in addition to comparison to the R_f of the reference standards.

In this study, the sample extracts were analyzed by HPLC using a mobile phase of methanol:water (75:25, v:v) with radioactivity and UV detection. The identities of degradates detected through HPLC analysis were confirmed only by comparison to a chromatograph of known endosulfan degradates.

6. Soil II was identified by the study author as "silty sand"; however, based on the USDA soil textural analysis system, this soil should be classified as a "loamy sand" soil and was referred to as such in this review.
7. All of the soil samples, with the exception of soils sampled at 0 days posttreatment, were treated with endosulfan at a rate of 3.26 ppm. Soils sampled at 0 days posttreatment were treated at 3.15 ppm.
8. Method detection limits were not reported.

Endosulfan environmental fate review

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REFERENCES

Dorr, Victor A. 1984. Company response to EPA comments (dated 9 January 1984) on hydrolysis and photolysis studies - dated 25 May 1984. Document prepared and submitted by American Hoechst Corporation, Agricultural Division, Somerville, NJ. (Acc. No. 253448)

Dorr, Victor A. 1985. Company response to EPA comments (dated 21 September 1984) on hydrolysis and photolysis studies - dated 9 January 1985. Document prepared and submitted by American Hoechst Corporation, Agricultural Division, Somerville, NJ. (No MRID)

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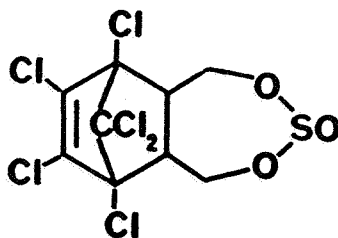
Gildemeister, H., and H. J. Jordan. 1984. Aerobic soil metabolism of the insecticide Hoe 002671 (endosulfan). Laboratory Project ID OE-134/04.02. Unpublished study performed and submitted by Hoechst AG, Frankfurt, FRG. (148993?)

Gorlitz, G., and C. Klockner. 1982. Hydrolysis of Hoe 02671 (endosulfan). Translation of Document Number A 24433. Unpublished study performed and submitted by Hoechst Ag, Frankfurt, FRG. (Acc. No. 250395)

The following document was not reviewed because it contains summary data only. In addition, the description of the methods is inadequate, the data presented are incomplete, the half-lives of endosulfan and possible degradates were not determined, and degradates were not characterized.

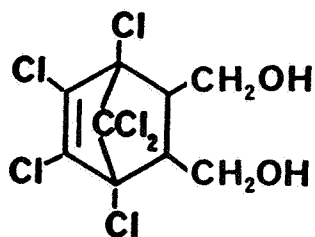
Gildemeister, H. 1983. Terrestrial field dissipation studies with the insecticide endosulfan. Laboratory ID A27207. Unpublished summary report prepared and submitted by Hoechst Laboratories, Frankfurt, FRG. (No study ID)

APPENDIX
ENDOSULFAN AND ITS DEGRADATES



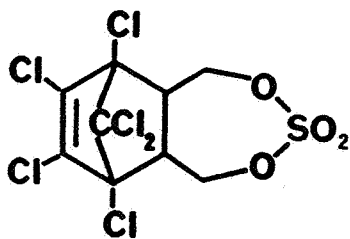
Endosulfan
 Hoe 002671
 Hoe 52618 - Alpha isomer
 Hoe 52619 - Beta isomer

6,7,8,9,10,10-Hexachloro-1,5,5a,6,9,9a-hexahydro-
 6,9-methano-2,4,3-benzo-dioxathiepin-3-oxide



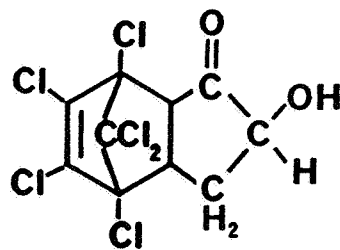
Endosulfan-alcohol
 Hoe 051329

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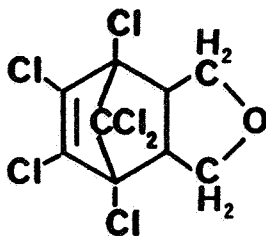
Endosulfan-sulfate

6,7,8,9,10,10-hexachloro-1,5,5,5a,6,9,9a-
 hexahydro-6,9-methano-2,4,3-benzodioxathiepin-3,3-dioxide



Endosulfan-lactone

4,5,6,7,8,8-hexachloro-1,3,3a,4,7,7a-hexahydro-
4,7-methano-isobenzofuran-1-one



Endosulfan-ether

4,5,6,7,8,8-hexachloro-1,3,3a,4,7,7a-
hexahydro-4,7-methano-isobenzofuran