OxyChem®

Responsible Care® A Public Commitment

201-15635

Stephen B. Kemp
Vice President
Health, Environment & Safety

September 24, 2004

The Honorable Michael Leavitt, Administrator
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116

ATTN: Chemical Right-to-Know Program
Dechlorane Plus® (CAS# 13560-89-9)

Dear Administrator Leavitt:

Occidental Chemical Corporation ("OxyChem") is pleased to submit the attached test plan and robust summary for Dechlorane Plus (CAS# 13560-89-9) flame retardant. We understand there will be a 120-day review period for the test plan and that all comments received by the EPA will be forwarded to my attention for consideration. This submission includes one electronic copy in .pdf format.

As you will note in the attached test plan and robust summary, OxyChem has completed a number of studies focused on delineating the potential hazards of Dechlorane Plus flame retardant. However, OxyChem believes that minimal, if any, human or environmental exposures exist with respect to the remaining endpoints that are identified in the test plan; therefore, it has not conducted toxicity tests for acute aquatic toxicity, toxicity to aquatic plants, and reproductive and developmental toxicity

Dechlorane Plus flame retardant is manufactured by OxyChem for use solely by industrial customers. In the primary industrial applications of Dechlorane Plus flame retardant, the material is incorporated into a polymer matrix where it is entrapped and immobilized thereby minimizing exposure potential as well as availability for release to the environment. These industrial polymers are then used as coatings for commercial electrical wires and cables, in connectors used in computers, and in plastic roofing material used for commercial building. The addition of Dechlorane Plus flame retardant gives the polymers enhanced flame retardant properties that increase the safety of the products in which it is incorporated. In addition, the polymer is applied in products (e.g. wire coating and cable) that are not routinely handled by susceptible populations such as children.

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OSHA STAR WORKSITE

OxyChem®

The aquatic toxicity tests have not been completed because Dechlorane Plus flame retardant is a water insoluble solid, and in the event of an accidental release, solids are more easily contained than liquids and thereby prevented from entering waterways.

OxyChem is committed to the Responsible Care® program and to product stewardship. OxyChem is also committed to fulfilling its obligation under the High Production Volume (HPV) Challenge Program. However, OxyChem also believes that testing should be performed only when the testing is justified. OxyChem believes that Dechlorane Plus flame retardant is used in a controlled manner and that exposure scenarios that would justify additional testing do not exist. Therefore, OxyChem respectfully considers the commitment for Dechlorane Plus flame retardant under the HPV Challenge Program to be fulfilled with this submittal.

Please contact Debbie Schober by phone at (972) 404-4969 if you have any questions regarding this matter.

Sincerely,

Stephen B. Kemp
Vice President
Health, Environment & Safety

Attachments

201-15635

DECHLORANE PLUS

CAS NO. 13560-89-9

HIGH PRODUCTION VOLUME (HPV)
CHEMICAL CHALLENGE PROGRAM

TEST PLAN

Prepared for:

Occidental Chemical Company

Prepared by:

The ENVIRON Health Sciences Institute (EHSI)
4350 North Fairfax Drive, Suite 300
Arlington VA 22203

August 2004

EXECUTIVE SUMMARY

Occidental Chemical Company voluntarily submits for review and public comment the test plan for the chemical, Dechlorane Plus (1,2,3,4,7,8,9,10,13,13,14,14-dodecachloro-1,4,4a,5,6,6a,7,10,10a, 11,12,12a-dodecahydro-1,4:7,10-dimethanodibenzo[a,e]cyclooctene; CAS No. 13560-89-9), for review under the Environmental Protection Agency's High Production Volume (HPV) Chemicals Challenge Program. Available data and Endpoint data gaps are summarized in Table 1.

Table 1. Data Assessment Matrix

Endpoint	Number of Studies Available	Best Reliability	Data Gap
Physico-Chemical Properties			
Melting Point	1	2	N
Density	2	2	N
Vapor Pressure	1	2	N
Partition Coefficient	1	2	N
Water Solubility	2	2	N
Solubility in various organic solvents	1	2	N
Volatility	1	2	N
pH	1	2	N
Environmental Fate			
Photodegradation	1	2	N
Stability in Water	1	3	Y
Transport between Environmental Compartments (water - soil adsorption)	1	2	N
Biodegradation			
Aerobic	3	2	N
Anaerobic	1	3	Y
Bioaccumulation	4	2	N
Ecotoxicity			
Acute Toxicity to Fish	2	3	N
Acute Toxicity to Aquatic Invertebrates	N		Y
Toxicity to Aquatic Plants	N		Y
Mammalian Toxicity			
Acute Toxicity	7	2	N
Repeated Dose Toxicity	3	2	N
Genetic Toxicity *in Vitro*	4	2	N
Genetic Toxicity *in Vivo* / *in Vitro*	N		Y
Toxicity to Reproduction	N		Y
Developmental Toxicity	N		Y

CONTENTS

I. INTRODUCTION

Occidental Chemical Company (OxyChem) has committed voluntarily to develop screening level physicochemical properties, environmental effects and fate, and human health effects data for Dechlorane Plus, 1,2,3,4,7,8,9,10,13,13,14,14-dodecachloro-1,4,4a,5,6,6a,7,10,10a,11,12,12a-dodecahydro-1,4:7,10-dimethanodibenzo[a,e]cyclooctene under the Environmental Protection Agency's (EPA's) High Production Volume (HPV) Challenge Program ("Program").

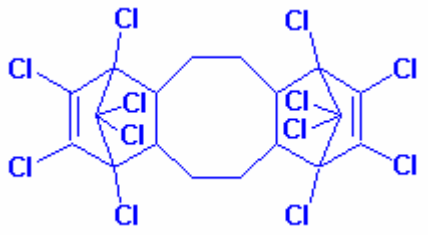
This plan identifies the chemical, its CAS number, existing data of adequate quality, and outlines testing planned to develop screening level data for the chemical under the Program. The objective of this effort is to identify and develop sufficient test data and/or other information to adequately characterize the environmental fate and human health effects for the chemical in compliance with the EPA HPV Program.

II. DESCRIPTION OF THE HPV CHEMICAL

A. STRUCTURE AND NOMENCLATURE

The following is a structural characterization of Dechlorane Plus and associated nomenclature.

- 1,2,3,4,7,8,9,10,13,13,14,14-dodecachloro-1,4,4a,5,6,6a,7,10,10a,11,12,12a-dodecahydro-1,4:7,10-dimethanodibenzo[a,e]cyclooctene
- Empirical formula: $C_{18}H_{12}Cl_{12}$
- CAS No. 13560-89-9
- Structural formula:



- Synonyms:

  Dodecachlorododecahydrodimethanodibenzocyclooctene
  Dechlorane Plus
  Dechlorane Plus 25
  Dechlorane Plus 35
  Dechlorane Plus 515

III. TEST PLAN RATIONALE AND ADEQUACY OF DATA

The information obtained and included to support this Test Plan has come from either internal studies conducted by/or for OxyChem (or its predecessor, Hooker Chemical Corporation), peer-reviewed scientific literature, or predictive environmental models. This initial assessment includes information on physicochemical properties, environmental fate, and possible human health effects associated with Dechlorane Plus. The data used to support this Test Plan include those Endpoints identified by the EPA (1998). Studies have been identified for each data Endpoint and summarized in the Screening Information Data Set (SIDS), which is located in Appendix 1. Additional information has been identified and included in the SIDS, although this information does not fulfill any Endpoint data gaps. This information is relevant to the Test Plan and is discussed in Section V.

All studies were reviewed and assessed for reliability according to standards specified by Klimisch *et al*. (1997), as recommended by the EPA (1999). Those studies receiving a rating of 1 or 2 are considered adequate by themselves to support data assessment needs. A study receiving a rating of 3 is considered inadequate by itself to support data assessment needs. However, some different studies rated 3 may corroborate a specific conclusion and together these studies are considered to fulfill a particular data assessment need.

IV. RELEVANT AVAILABLE INFORMATION

All available studies were reviewed, assessed for adequacy, and included in the SIDS document in Appendix 1. Those fulfilling specific Endpoints are described briefly in this section. Additional information, which does not fulfill Endpoints, is included in a discussion of the Test Plan (Section V).

A. PHYSICOCHEMICAL PROPERTIES

Dechlorane Plus is a white, crystalline, odorless, powder, with a molecular weight of 654 daltons. All major physicochemical parameters (See Table 2) relevant to environmental fate and human health effects received a reliability rating of 2.

Table 2. Physicochemical Parameters

Property	Value
Melting Point	350 deg C with decomposition
Density	1.8 g/cc
Vapor Pressure	0.006 mm Hg @200 deg C
Partition Coefficient (log Pow)	9.3
Water Solubility	44 ng/L - 249 ug/L (insoluble)
pH (methanol-water extract)	6.0 – 8.0
Volatility (4 hours at 100 deg C at 5 mm Hg)	0.12% maximum

Conclusion - No additional testing is recommended.

B. ENVIRONMENTAL FATE

These data are summarized in Table 3 below and the studies are briefly reviewed beginning on the next page.

Table 3. Environmental Fate Parameters

Endpoint	Value
Photodegradation	>24 years
Stability in Water	Stable (qualitative)
Transport between Environmental Compartments (water - soil sorption partition coefficient)	4.5×10^6
Biodegradation	Minimal or no aerobic degradation
Bioaccumulation	Yes in fish

1. Photodegradation

Photodegradation in water was determined in a study utilizing a light source that provided several lines of high photon fluxes in the solar spectral region above 290 nm. Dechlorane Plus was tested in the study for 168 hours, after which the photolysis half-life was calculated from the analytical results. The photolytic half-life in water was estimated to be >24 years.

2. Stability in Water

Based on first-order rate constants for cyclohexanes, which are structurally similar to Dechlorane Plus, the investigators decided it was unnecessary to quantitatively determine the half-life of Dechlorane Plus. Peroxyl radical oxidation of Dechlorane Plus was determined not to be an important transformation process.

3. Transport between Environmental Compartments (Water - Soil Adsorption)

Lake sediment was used in a 6-week study to determine the extent of partitioning of Dechlorane Plus from water into soil. The calculated sorption partition coefficient (Kp) was 4.5×10^6 (+/- 1.9×10^6). Dechlorane Plus preferentially adsorbed to the sediment.

4. Biodegradation

In three aerobic and one anaerobic biodegradation studies, Dechlorane Plus was tested for degradation in mineralized distilled water or BOD dilution water incubated with appropriate sewage sludge organisms for up to 6 weeks. Either Dechlorane Plus was not biodegradable or minimally biodegradable (with CO2 as a possible metabolite), or its extremely low water solubility prevented the bacteria in the domestic sewage from contacting and degrading the test substance.

5. Bioaccumulation

In four subchronic bioaccumulation studies, fish were dosed with Dechlorane Plus for up to 30 days, with the test substance either suspended in water or mixed in food. In these studies, any toxicity observed was not considered treatment related but rather a result of the use of a solvent because Dechlorane Plus is practically insoluble in water.

In one study, equilibrium of tissue accumulation was reached after 7 days of exposure with accumulated concentration in tissues of up to 8.8 ppm. Because of limited water solubility, BCFs were estimated from the octanol-water partition coefficient, water solubility, and the sediment-water partition coefficient, instead of study data. The BCFs were in poor agreement: 7.02 at 48 hours and 1.97 at 96 hours. Dechlorane Plus was found to bioaccumulate in fish after subacute or subchronic administration.

Conclusion - Stability in water and anaerobic biodegradation are recommended for testing to fulfill HPV data requirements. For other Endpoints, testing is not recommended.

C. ECOTOXICOLOGY

1. Acute Toxicity to Fish

Dechlorane Plus was tested for toxicity to freshwater fish in two studies, one static and one flow through for a period of 4 days. Because of the low water solubility, Dechlorane Plus remained suspended as particulates, sank to the bottom of the test vessels, or floated on the surface. There was no mortality or other adverse effects observed during either test. For both studies, the median tolerance limit (TL50) was >100 ppm, the highest concentration tested.

Conclusion - Toxicity to aquatic invertebrates and plants are recommended for testing to fulfill HPV data requirements. For other Endpoints, testing is not recommended.

D. HUMAN HEALTH

These data are summarized in Table 4 below and the studies are briefly reviewed beginning on the next page.

Table 4. Mammalian and Genetic Toxicity

Endpoint	Value
Acute Toxicity	
Oral (LD50)	>25,000 mg/kg bw
Inhalation (LC50)	> 300 mg/l
Dermal (LD50)	>8000 mg/kg bw
Dermal Irritation	Not or mild irritant
Eye Irritation	Not an irritant
Sensitization	Not a sensitizer
Repeated Dose Toxicity	
Inhalation (LOAEL)	0.640 mg/L
Oral feed (NOAEL)	100,000 ppm
Dermal (NOAEL)	2000 mg/kg bw/day
Genetic Toxicity *in Vitro*	
Ames	Negative
Mouse Lymphoma	Negative

1. Acute Toxicity

For the two acute oral toxicity studies, the two inhalation studies, and the one dermal toxicity study, the Median Lethal Dose or Concentration (LD50 or LC50) was greater than the highest dose tested for each study. No adverse effects were observed for any animal in any of the studies.

One eye irritation study and one dermal sensitization study were performed with Dechlorane Plus. The test substance was not an eye irritant and was not a sensitizer. No dermal irritation studies were available, but after repeated dermal exposures in rabbits and guinea pigs, at most mild irritation was observed.

2. Repeated Dose Toxicity

Three subchronic toxicity studies were performed with Dechlorane Plus, one 28-day dermal, one 28-day inhalation, and one 90-day oral dietary study. In the 28-day dermal toxicity study, treated female rabbits had statistically-significant dose-related decreases in absolute and relative liver and ovary weights. There were no corresponding histopathological effects observed. The systemic NOAEL was 2000 mg/kg bw/day, the highest dose tested.

In the 28-day inhalation study, treated male and female rats had significantly increased absolute liver weights and low-dose females and high-dose males and females had significantly increased absolute lung weights. Associated treatment-related histopathological lesions consisted of increased numbers of macrophages in the alveoli and hepatocytomegaly of centrilobular hepatocytes in all treated male rats and in 2 of 5 high-dose females. There was no NOAEL for this study; the LOAEL was 0.640 mg/L. In the 90-day dietary toxicity study there were no statistically-significant adverse effects observed in any parameters examined. The NOAEL was 100,000 ppm, the highest dose tested.

3. Genetic Toxicity '*In Vitro*'

In two bacterial reverse mutation assays, Dechlorane Plus or the urine from rats administered Dechlorane Plus was tested for mutagenicity utilizing *Salmonella typhimurium* strains with and without metabolic activation. No toxicity or dose-related increases in the number of histidine revertants over background was observed in any of the three tests.

In one mouse lymphoma L5178Y TK+/- assay, Dechlorane Plus was tested for mutagenicity in mammalian cell cultures with and without metabolic activation. Dechlorane Plus was not cytotoxic and did not significantly increase the mutation frequencies above the spontaneous control frequency.

Conclusion – A tiered approach is recommended to determine the extent of testing to fulfill HPV data requirements. Relevant *in vitro* or *in vivo* genetic toxicity studies for chromosomal aberrations are recommended for testing. The results when reviewed with the data from repeated dose toxicity studies and from an available toxicokinetic study (See SIDS in Appendix 1) would then determine whether reproductive/developmental testing is necessary.

E. DATA EVALUATION

Adequate studies with Dechlorane Plus have been conducted for the endpoints listed in Table 5 below. These studies are considered adequate to support data assessment needs, either because at least one of the studies for that Endpoint has received a reliability score of 2 or because the results from studies for that Endpoint, even if inadequate, are corroborated by the results from other studies. For example, the two acute fish toxicity studies are inadequate by themselves to fulfill that Endpoint; however, there were three bioaccumulation studies, which lasted up to 30 days with the same species of fish and which resulted in no mortality to those fish. Consequently, the Acute Toxicity to Fish Endpoint is considered fulfilled by the corroborative data.

Table 5. Studies Fulfilling Endpoints

Physico-Chemical Properties
Environmental Fate
Photodegradation
Transport between Environmental Compartments (water - soil adsorption)
Biodegradation, aerobic
Bioaccumulation
Ecotoxicity
Acute Toxicity to Fish
Mammalian Toxicity
Acute Toxicity
Repeated Dose Toxicity
Genetic Toxicity *in Vitro*

V. TEST PLAN SUMMARY

A tiered approach is recommended to determine the extent of testing to fulfill HPV data requirements. This tiered approach prioritizes the data gaps based on related relevant data and the potential hazards from exposure. The following studies are recommended:

Tier 1:

- Conduct relevant *in vitro* or *in vivo* genetic toxicity studies. The results when reviewed with the data from repeated dose toxicity studies and from an available toxicokinetic study (See SIDS in Appendix 1) would then determine whether reproductive/developmental testing is necessary.
- Conduct the following ecotoxicity studies: Acute Toxicity to Aquatic Invertebrates and Toxicity to Aquatic Plants. Because Dechlorane Plus appears to have ecotoxicological effects in fish and it appears to selectively adsorb to soil from water, organisms that associate with the sediment of waterways may be adversely affected by Dechlorane Plus.

Tier 2:

- Conduct a reproductive/developmental screening study. In the 28-day dermal study in rabbits, there were significant, dose-related decreases in absolute and relative ovary weights but there were no corresponding histopathological effects observed. In a toxicokinetics study performed with Dechlorane Plus in rats, ovaries and liver had the greatest concentrations of Dechlorane Plus (See SIDS in Appendix 1).

Tier 3:

Environmental fate data are extensive and indicate that Dechlorane Plus is minimally water soluble and likely will not biodegrade. Conducting the following studies would fulfill data gaps but they are unlikely to result in any additional information. Thus, these two studies are not recommended for immediate testing.

- Conduct a Water Stability study. Considering that Dechlorane Plus appears to have ecological effects on fish (and possibly on other aquatic organisms), this property should be better defined.
- Conduct an Anaerobic Biodegradation study. Although the aerobic biodegradation study results indicate that Dechlorane Plus does not biodegrade, the anaerobic study methodology and conditions do not allow us to conclude that Dechlorane Plus behaves comparably under anaerobic conditions.

Summaries of results will be produced when data and analyses are available. This test plan is expected to provide adequate data to characterize the human health effects and environmental fate and effects endpoints under the Program. OxyChem does not believe additional information is needed to fulfill Endpoint data gaps other than those described in the paragraphs above.

VI. REFERENCES

Klimisch, H.-J., Andreae, M. and U. Tillman. 1997. A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. *Regul. Toxicol. Pharmacol*. 25:1-5.

United States Environmental Protection Agency (EPA). 1998. Guidance for meeting the SIDS requirements (The SIDS Guide). Guidance for the HPV Challenge Program (11/31/98).

United States Environmental Protection Agency (EPA). 1999. Determining the adequacy of existing data. Guidance for the HPV Challenge Program (2/10/99).

APPENDIX 1

SIDS ROBUST SUMMARIES
(in IUCLID format)

RECEIVED
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IUCLID
Data Set

New Chemical	Substance ID: 13560-89-9
CAS No.	13560-89-9
Generic name	Dechlorane Plus
EINECS Name	1,4:7,10-Dimethanodibenzo[a,e]cyclooctene,1,2,3,4,7,8,9,10,13,13,14,14-dodecachloro-1,4,4a,5,6,6a,7,10,10a,11,12,12a-dodecahydro-

Producer Related Part

Company:	ENVIRON Corporation On behalf of Occidental Chemical Corporation
Creation date:	01-DEC-2003

Substance Related Part

Company:	Occidental Chemical Corporation
Creation date:	01-DEC-2003

Printing date:	02-AUG-2004
Revision date:	02-AUG-2004
Date of last Update:	02-AUG-2004

Chapter (profile):	Chapter: 1, 2, 3, 4, 5, 7
Reliability (profile):	Reliability: without reliability, 1, 2, 3, 4
Flags (profile):	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC

1.0.1 OECD and Company Information

Type: Cooperating Company
Name: Occidental Chemical Corporation
02-DEC-2003

1.2 Synonyms

Dodecachlorododecahydrodimethanodibenzocyclooctene
02-DEC-2003

Dechlorane Plus
02-DEC-2003

Dechlorane Plus 25
09-DEC-2003

Dechlorane Plus 35
09-DEC-2003

Dechlorane Plus 515
02-DEC-2003

2.1 Melting Point

Value: = 350 degree C
Decomposition: yes
Method: other: no data
Year: 1977
GLP: no data
Reliability: (2) valid with restrictions
12-DEC-2003 (1)

2.2 Boiling Point

2.3 Density

Type: density
Value: = 1.8 g/cm3
Method: other: no data
Year: 1977
GLP: no data
Reliability: (2) valid with restrictions
12-DEC-2003 (1)

Type: bulk density
Method: other: no data
Year: 1977
GLP: no data
Result: Dechlorane Plus 25, Dechlorane Plus 515: 38-42 lb/cu ft
Dechlorane Plus 35: 25-30 lb/cu ft
Reliability: (2) valid with restrictions
12-DEC-2003 (1)

2.3.1 Granulometry

Type of distribution: average particle diameter
Method: other: no data
Year: 1977
GLP: no data
Test substance: as prescribed by 1.1 - 1.4
Result: Dechlorane Plus 515 10 microns (average); Dechlorane Plus 25
4.5 microns (average); Dechlorane Plus 35 2 microns (average)
Reliability: (3) invalid
12-DEC-2003 (1) (16)

2.4 Vapour Pressure

Value: ca. 0.008 hPa at 200 degree C
Method: other (measured)
Year: 1977
GLP: no data
Result: 0.006 mm Hg at 200 deg C.
Reliability: (2) valid with restrictions
12-DEC-2003 (1)

2.5 Partition Coefficient

log Pow: ca. 9.3
Method: other (calculated)
Year: 1979
GLP: no data
Result: The octanol-water partition coefficient (P) was 1.99E9. This was calculated from a computerized program developed at SRI for chemical structure-activity research. Log(P) was estimated to be 9.3.
Reliability: (2) valid with restrictions
16-DEC-2003 (7)

2.6.1 Water Solubility

Value: ca. 249 ppb at 25 degree C
Qualitative: not soluble
Method: other: no data
Year: 1978
GLP: no data
Result: n-Octanol/water solubility data were used. Duplicate samples of the water and n-octanol fractions after partitioning were analyzed for the test substance. The results were: water - 197 ppb, 301 ppb (average 249 ppb); n-octanol - 346 ppb, 264 ppb (average 305 ppb).
Reliability: (2) valid with restrictions
11-DEC-2003 (21)

Value: ca. 0.00004 mg/l
Qualitative: not soluble
Method: other: no data
Year: 1979

GLP: no data
Result: Approximately 0.75 mg of Dechlorane Plus was dissolved in hexane and then was coated onto the inside of a 5-gallon glass carboy. The carboy was filled with purified water and closed. The contents were allowed to equilibrate for 6 weeks while being slowly stirred. The temperature was maintained at 22 deg C (+/- 2.5 deg C). A sample of approximately 150 ml was collected and then centrifuged and the upper 2/3 of the water solution was extracted with methylene chloride in hexane. Residual water was removed from the extracts. The extracts were analyzed for Dechlorane Plus utilizing a gas chromatograph with an OV-101 glass column and an electron capture detector.

Dechlorane Plus was a mixture of 2 isomers. The aqueous solubility was 207 ng/l for one isomer and 572 ng/l for the second isomer. Indirect results from the sediment-water partitioning experiment suggested that the solubility was about 44 ng/l (total for both isomers). This lower value was considered the best estimate of water solubility.
Reliability: (2) valid with restrictions
11-DEC-2003 (7)

2.6.2 Surface Tension
-

2.7 Flash Point
-

2.8 Auto Flammability
-

2.9 Flammability
-

2.10 Explosive Properties
-

2.11 Oxidizing Properties
-

2.12 Additional Remarks

Memo: Appearance
Result: White, crystalline powder

Reliability: (2) valid with restrictions
03-DEC-2003 (1)

Memo: Empirical Formula
Result: $C_{18}H_{12}Cl_{12}$
Reliability: (2) valid with restrictions
03-DEC-2003 (1)

Memo: Molecular Weight
Result: 654 daltons
Reliability: (2) valid with restrictions
12-DEC-2003 (1)

Memo: Odor
Result: Odorless
Reliability: (2) valid with restrictions
12-DEC-2003 (1)

Memo: Solubility
Result: The solubility of Dechlorane Plus was determined at 25 deg C in the following solvents:

Benzene	2.0 g/100 g
Xylene	1.0 g/100 g
Styrene	1.8 g/100 g
Trichloroethylene	1.4 g/100 g
Methylethylketone	0.7 g/100 g
n-Butyl acetate	0.7 g/100 g
Hexane	0.1 g/100 g
Methyl alcohol	0.1 g/100 g

Reliability: (2) valid with restrictions
12-DEC-2003 (1)

Memo: Volatility
Result: 0.12% maximum at 100 deg C and 5 mm Hg after 4 hours.
Reliability: (2) valid with restrictions
12-DEC-2003 (1)

Memo: pH
Result: 6.0 - 8.0 (methanol-water extract at room temperature)
Reliability: (2) valid with restrictions
12-DEC-2003 (1)

3.1.1 Photodegradation

Type: water
Light source: mercury lamp with a borosilicate immersion well.
Concentration
of substance: 1 mg/l
Direct Photolysis
Halflife t1/2: > 24 years
Degradation: < 10% after 168 hour(s)
Method: other (measured)
Year: 1979 GLP: no data
Test substance: as prescribed by 1.1 - 1.4
Result: Two aqueous solutions of Dechlorane Plus were prepared: one solution with distilled water and the second solution with natural water from an eutrophic lake. Acetonitrile was added to completely solubilize the test substance. Samples of the solutions were irradiated for 168 hours; controls were samples of the same solutions that were not irradiated. Because of the borosilicate immersion well, only wavelengths above 290 nm reached the solutions. This irradiation system did not duplicate natural sunlight, but it did provide several lines of high photon fluxes in the solar spectral region. Utilizing this light source increased the rate of phototransformation over that of natural sunlight.

After 168 hours, the aqueous solutions were extracted with methylene chloride in hexane and concentrated. These concentrates were then analyzed for Dechlorane Plus utilizing a gas chromatograph with an electron capture detector. The photolysis half-life was calculated from the analytical results. The photolytic half-life in water was estimated to be >24 years.
Reliability: (2) valid with restrictions
16-DEC-2003 (7)

3.1.2 Stability in Water

Type: abiotic
Method: other: no data
Year: 1979 GLP: no data
Test substance: as prescribed by 1.1 - 1.4
Result: Prior to performing an experiment to determine the rate of oxidation in water, a first-order rate constant (in air?) was estimated to be 10E-11 sec-1, equivalent to an oxidation half-life of 2100 years.

Based on first-order rate constants of 10E-3 to 10E-4 for cyclohexanes, which are structurally similar to Dechlorane Plus, the investigators decided it was unnecessary to quantitatively determine the half-life of Dechlorane Plus. Peroxyl radical oxidation of Dechlorane Plus was determined not to be an important transformation process.

Reliability: (3) invalid
16-DEC-2003 (7)

3.1.3 Stability in Soil
-

3.2 Monitoring Data (Environment)
-

3.3.1 Transport between Environmental Compartments

Type: adsorption
Media: water - soil
Method: other
Year: 1979
Result: Approximately 0.75 mg of Dechlorane Plus was dissolved in hexane and then coated onto the inside of a 5-gallon glass carboy. The carboy was filled with purified water and capped. The contents were allowed to equilibrate for 6 weeks while being slowly stirred. The temperature was maintained at 22 deg C (+/- 2.5 deg C). After 6 weeks, a sample was collected and then centrifuged, and the supernatant was collected.

Sediment that had a high organic content and a sulfurous odor was collected for the experiment from White Lake, Michigan. The sediment was sieved, suspended in water, and allowed to settle. Suspended material was removed and background concentration of Dechlorane Plus was measured in the sediment. Three test mixtures were prepared: one was a blank containing the Dechlorane Plus/water supernatant; the other two were duplicates containing the supernatant and sediment. The mixtures were shaken overnight, centrifuged, and the supernatants extracted with methylene chloride in hexane. The extracts were filtered and concentrated. The extracts were then analyzed for Dechlorane Plus utilizing a gas chromatograph with an OV-101 glass column and an electron capture detector.

The calculated sorption partition coefficient (Kp) was 4.5E6 (+/- 1.9E6). Dechlorane Plus preferentially adsorbed

to the sediment.
Reliability: (2) valid with restrictions
16-DEC-2003 (7)

3.3.2 Distribution
-

3.4 Mode of Degradation in Actual Use
-

3.5 Biodegradation

Type: aerobic
Inoculum: sewage-sludge microorganisms
Concentration: 0.001 mg/l related to test substance
100 mg/l related to test substance
Contact time: 21 days
Degradation: = 0% after 21 days
Result: under test conditions no biodegradation observed
Method: other: Standard Methods for the Examination of Water and Wastewater. Thirteenth Edition. 1971. Pages 489-491.
Year: 1973 GLP: no
Test substance: as prescribed by 1.1 - 1.4
Result: Stock solutions of Dechlorane Plus were prepared in acetone that, when diluted to 1500 ml, resulted in nominal concentrations of 0.01, 1, 10, and 100 ppm in the test vessels. BOD dilution water was mixed thoroughly and 2 ml of settled sewage, obtained from a water treatment plant, was used to inoculate each liter of this water. The inoculated BOD dilution water and 5.0 ml aliquot of one of the Dechlorane Plus stock solutions were added to each of twelve 2-quart glass Mason jars. An additional 3 jars that just contained the inoculated BOD dilution water and acetone served as controls. Yeast extract (5.09 mg) was added to each of the 15 jars to allow the bacteria to acclimate to the acetone and test material. Immediately following yeast addition, baseline samples were collected. The jars were then maintained at room temperature without shaking for 21 days. Samples were collected every 7 days and extracted using cyclohexane. These extracts were concentrated and then analyzed by gas chromatography.

Results indicated that the bacteria were viable throughout the 21-day exposure period. Recoveries were less than 100% because of solubility problems; the nominal concentrations were 0.01, 1.0, 10, and 100 ppm and the concentrations

determined quantitatively were 0.003-0.004, 0.58 - 0.70, 6.0 - 6.6, and 83-85 ppm, respectively. Because concentrations were constant throughout the test period, the authors concluded that Dechlorane Plus was not biodegradable under the conditions of the test.

Reliability: (2) valid with restrictions
16-DEC-2003 (4)

Type: aerobic
Inoculum: sewage-sludge microorganisms
Concentration: 218 µg/l related to test substance
872 µg/l related to test substance
Contact time: 42 days
Result: no biodegradation after 2 weeks; some biodegradation after 6 weeks.
Method: other: no data
Year: 1979 GLP: no data
Test substance: as prescribed by 1.1 - 1.4
Result: The magnitude of degradation of Dechlorane Plus was determined using aerobic sewage sludge organisms, which were obtained from a sewage treatment plant. The effluent had a pH of 7.1 and a total suspended matter concentration of 185 mg/l. Radiolabeled Dechlorane Plus was injected into each of several 250-ml Erlenmeyer flasks containing 100 ml of effluent; controls only contained the sterilized effluent. Much of the Dechlorane Plus in the test vessels was suspended, not dissolved. Flasks were plugged with cotton and incubated with shaking at 25 deg C. At either 2 or 6 weeks, samples from duplicate flasks were removed and extracted. Three types of extractants (hexane-isopropanol fraction, ethylacetate fraction, and aqueous fraction) were analyzed for radioactivity and by thin-layer chromatography (TLC) for the presence of metabolites.

Although the presence of radioactivity in the ethylacetate and aqueous fractions indicated that Dechlorane Plus was metabolized, no labeled metabolites were present on the TLC plates. Because there was no indication of biodegradation, the differences between the total radioactivity recovery values in the viable and sterile (control) flasks were calculated as a second indication of biodegradation.

The experimenters determined that little or no degradation occurred at 2 weeks but a high percentage (amount not specified) was degraded by 6 weeks. Metabolites were not identified. The experimenters attached CO2 traps to some of the 6-week flasks and determined that only about 1% of total

added radiolabel was trapped. They concluded that CO2 was a metabolic product of Dechlorane Plus.
Reliability: (3) invalid
16-DEC-2003 (7)

Type: aerobic
Inoculum: other: sewage-sludge microorganisms
Concentration: 4 mg/l related to test substance
Contact time: 21 days
Degradation: = 0% after 21 days
Result: under test conditions no biodegradation observed
Method: other: no data
Year: 1971 GLP: no
Test substance: as prescribed by 1.1 - 1.4
Result: This study employed a bottle-dilution technique for estimating the oxygen consumption of Dechlorane Plus under aerobic conditions. Preliminary tests indicated that the test substance was virtually insoluble in water. Consequently, stock solutions were prepared in benzene and each test substance solution was dispersed in water and the benzene stripped out of the solution by aeration. The stripped samples were then siphoned into BOD bottles to which was added settled domestic sewage. The final concentration of the test substance was 4 mg/l in the test vessels. The bottles were capped and incubated (the temperature was not stated). From 2-30 days, samples were collected periodically, and dissolved oxygen concentration in each was compared with a blank containing mineralized distilled water and settled domestic sewage.
There was no significant oxygen utilization in any of the test vessels. Either Dechlorane Plus was not biodegradable or extremely low water solubility of Dechlorane Plus prevented the bacteria in the domestic sewage from contacting and degrading the test substance.
Reliability: (3) invalid
16-DEC-2003 (2)

Type: anaerobic
Inoculum: sewage-sludge microorganisms
Concentration: 218 µg/l related to test substance
872 µg/l related to test substance
Contact time: 42 days
Result: no biodegradation after 2 or 6 weeks.
Method: other: no data
Year: 1979 GLP: no data
Test substance: as prescribed by 1.1 - 1.4

Result: The magnitude of degradation of Dechlorane Plus was determined using anaerobic sewage sludge organisms, which were obtained from a sewage treatment plant. The effluent had a pH of 6.9 and a total suspended matter concentration of 3910 mg/l. Radiolabeled Dechlorane Plus was injected into each of several 125-ml Erlenmeyer flasks containing 100 ml of effluent; controls only contained the sterilized effluent. Much of the Dechlorane Plus was suspended, not dissolved. Flasks were flushed with nitrogen and sealed with rubber stoppers. A glass outlet allowed 14C-CO2 gas to be collected. The flasks were incubated without shaking at 35 deg C. At either 2 or 6 weeks, samples from duplicate flasks were removed and extracted. Three types of extractants (benzene fraction, ethylacetate fraction and aqueous fraction) were analyzed for radioactivity and by thin-layer chromatography (TLC) for the presence of metabolites.

Although the presence of radioactivity in the ethylacetate and aqueous fractions indicated that Dechlorane Plus was metabolized, no labeled metabolites were present on the TLC plates and no radioactivity was found in the CO2 traps. Because there was no indication of biodegradation, the differences between the total radioactivity recovery values in the viable and sterile (control) flasks were calculated as a second indication of biodegradation. Little or no degradation occurred at either 2 or 6 weeks.

Reliability: (3) invalid
16-DEC-2003 (7)

3.6 BOD5, COD or BOD5/COD Ratio

-

3.7 Bioaccumulation

Species: Lepomis macrochirus (Fish, fresh water)
Exposure period: 30 days at 21 degree C
Concentration: 1 mg/l
BCF: no data
Elimination: no data
Method: other: no data
Year: 1973 GLP: no
Test substance: as prescribed by 1.1 - 1.4
Result: A preliminary toxicity test was performed and a target concentration of 1 ppm was selected for use in the 30-day study. A calculated amount of the test substance, as a 1% suspension in acetone, was dispersed into the bioassay vessels while the water was stirred vigorously. Twenty fish were then

introduced into the vessels. The fish were observed daily for adverse effects until the end of the 30-day exposure period. During this time the water was aerated but not stirred. Samples of water and fish were collected just prior to introduction of the fish to the bioassay vessels and on days 7, 14, 21, and 30 of the exposure period.

After rinsing in deionized water and acetone, the fish carcasses were homogenized with anhydrous sodium sulfate and cyclohexane. The tissues were extracted twice more with cyclohexane. Water samples were extracted with cyclohexane. All extracts were further purified and concentrated before analysis by gas chromatography utilizing a electron capture detector. Analytical concentrations in water were less than target because of the low water solubility and/or adsorption to organic matter in the bioassay vessels (there was an algae bloom during part of the exposure period).

There were no adverse effects during the 30-day study. The recovery of Dechlorane Plus from fortified fish samples was 96%. Results indicated that rapid accumulation of Dechlorane Plus occurred and equilibrium was reached after 7 days of exposure. The accumulated concentration in tissues was 6 - 8.8 ppm from days 7 through 30.

Reliability: (3) invalid
16-DEC-2003 (5)

Species: Lepomis macrochirus (Fish, fresh water)
Exposure period: 30 days at 21 degree C
Concentration: 0.1 mg/l
BCF: no data
Elimination: no data
Method: other: no data
Year: 1975 GLP: no
Test substance: as prescribed by 1.1 - 1.4
Result: A preliminary toxicity test was performed and a target concentration of 0.1 ppm was selected for use in the 30-day study. The flow-through test system delivered 300 ml water every 90 seconds into the glass bioassay vessel, which had a capacity of 150 liters. Overflow pipes released water at the same rate, resulting in a turnover time of 12.5 hours. At 90-second intervals, a calculated amount of the test substance, as a 0.001% solution in acetone, was injected directly into the bioassay vessel. Because of the low water solubility of Dechlorane Plus, the test material could not be premixed with delivery water.

All fish were acclimated to the presence of acetone in the

water for 28 days in a similar flow-through vessel. Thirty-six of these acclimated fish were introduced into the bioassay vessel and were observed daily for adverse effects until the end of the 30-day exposure period. During the exposure period, pH, dissolved oxygen concentration, and water temperature were recorded daily. Samples of water and fish were collected on Day 0 (at 6 hours) and on Days 6, 18, 24, and 30; fish samples were also collected on Day 12 of the exposure period. After rinsing in deionized water and acetone, the fish carcasses were frozen until analysis. Analysis preparation was probably comparable to that described for the static test; however, details were not described in this report, only "using the procedure submitted in the October 25, 1973 report under IBT Nos. 665-03736 and 631-02353" [static test].

None of the fish died during the study. Adverse effects observed were quiescence, dark discoloration of the skin, rapid respiration, and passive feeding. The authors attributed these effects to the high concentration of acetone in the water because these effects had first been observed during the 28-day acclimation period when the concentration of acetone was increased gradually from 0.1 to 1%.

Results indicated that the fish began accumulating Dechlorane Plus immediately upon exposure, with tissue concentrations increasing slowly but steadily until the end of the exposure period. Concentrations of Dechlorane Plus in the bioassay water were relatively constant, with starting concentration of 0.104 ppm on Day 0 to 0.069 ppm on Day 30. The recovery of Dechlorane Plus from fortified fish and water samples was 80-83% and 101-109%, respectively. Magnification factors were calculated by dividing the concentration found in fish samples by the concentration in the corresponding water sample. The magnification factor was 1.09 at 6 hours after initiation of exposure and 5.58 at the end of the exposure period. These data indicated that Dechlorane Plus accumulated in fish.

Reliability: (2) valid with restrictions
16-DEC-2003 (8)

Species: Lepomis macrochirus (Fish, fresh water)
Exposure period: 96 hour(s)
Concentration: See Results below
BCF: = 1.97 - 7.02
Elimination: no data
Method: other: no data
Year: 1979 GLP: no data
Test substance: as prescribed by 1.1 - 1.4

Result: Twelve fish were exposed to 283 dpm/ml of 14C-Dechlorane Plus in 30 liters of dechlorinated tap water for 96 hours. Two water samples and 3 fish were analyzed for radioactivity at 48 and 96 hours during this exposure period. The remaining fish were transferred to a clean aquarium and maintained in clean flowing water for 96hours. During this time period, 3 fish were analyzed for radioactivity at 48 and 96 hours.

The results were equivocal because of the "extreme variability in the measured levels of radioactivity in replicate water and fish samples and the absence of a logical pattern in uptake and depuration." The authors believed the results were because Dechlorane Plus was only a suspension in the water and the particulates were distributed nonhomogenously in the aquarium water. This resulted in nonreproducible counts for the water concentrations and likely the fish ingested varying amounts of the particulates. Consequently, the authors estimated steady-state (maximum) BCFs based on the octanol-water partition coefficient, water solubility, and the sediment-water partition coefficient.

The BCFs were in poor agreement: 7.02 at 48 hours and 1.97 at 96 hours. The authors concluded that all data indicated that Dechlorane Plus concentrated significantly in fish.

Reliability: (3) invalid

16-DEC-2003 (7)

Species: Salmo salar (Fish, fresh water, marine)
Exposure period: 96 hour(s) at 10 degree C
Concentration: 6.06 µg/l
BCF: no data
Elimination: yes
Method: other: no data
Year: 1980 GLP: no data
Test substance: as prescribed by 1.1 - 1.4

Result: In one test of two tests, a mixture of 5 dechloranes in hexane and toluene was applied to the bottoms of 4-liter flasks and the solvent evaporated. The nominal concentration of Dechlorane Plus was 76.15 ug/l. Three liters of water and 3 fish were added to each flask. Fish remained in the flasks for up to 96 hours, and water and fish samples were collected periodically during this exposure period. Water temperature was maintained at 10 deg C. After the exposure period, the remaining fish were transferred to clean running water and monitored for an additional 192 hours. Water and fish were sample periodically throughout the exposure and recovery periods.

In the second test, a mixture of 5 dechloranes in hexane and toluene was applied to a suspension of fish food, which was fed to the fish kept in running water for 42 days. Water temperature was maintained at 10 deg C. After the exposure period, the fish were transferred to clean running water and monitored for an additional 71 days. Water and fish were sampled periodically throughout the exposure and recovery periods.

Water samples were extracted with hexane and the extracts were concentrated. Fish and food samples were ground with anhydrous sodium sulfate and then extracted with hexane. Fish and food extracts were purified using column chromatography. All extracts were analyzed by gas chromatography with an electron capture detector. Representative water and fish samples were also analyzed by mass spectrometer.

The concentration of the test substance increased in water over time (dissolution from the residue on the flask bottom). The average concentration of Dechlorane Plus was 6.06 ug/l. Levels of Dechlorane Plus were not detectable in fish after exposure from water (but levels of two other dechloranes were detected).

The nominal concentration of Dechlorane Plus in the fish food was 9.12 ug/g; the actual concentration was 8.88 ug/g. Dechlorane Plus accumulated in the fish from the food over time. Uptake was highest on Day 15 (176 ng/g wet weight) and decreased to 44.2 ng/g wet weight on Day 42. The accumulation factor calculated from water and tissue concentrations at Day 28 was 0.00696, the lowest of the five dechloranes. Dechlorane Plus was eliminated gradually over time after exposure: by Day 71, tissue concentrations were only 18.7 ng/g wet weight. The excretion rate constant (*1000, per day) was 12.0, the highest of the 5 dechloranes. Dechlorane Plus had the lowest tissue accumulation and the greatest excretory rate from food of the five dechloranes tested. The authors concluded that Dechlorane Plus did not accumulate from water into fish tissues but did accumulate from food into tissues.

Reliability: (3) invalid
16-DEC-2003 (24)

3.8 Additional Remarks
-

AQUATIC ORGANISMS

4.1 Acute/Prolonged Toxicity to Fish

Type: flow through
Species: Lepomis macrochirus (Fish, fresh water)
Exposure period: 4 days
Analytical monitoring: yes
TL50 : > 100 mg/l
Method: other: no data
Year: 1973 GLP: no
Test substance: as prescribed by 1.1 - 1.4
Result: A preliminary toxicity test was performed to determine the general level of toxicity. Target concentrations of 6.25, 12.5,25.0, 50.0, and 100 ppm were selected for use in the study.

The flow-through test system delivered 200 ml water every 90 seconds into the glass bioassay vessel, which had a capacity of 30 liters; overflow pipes released water at the same rate. AT 90-second intervals, a calculated amount of the test substance, as a suspension in acetone, was injected directly into each bioassay vessel. Because of the low water solubility of Dechlorane Plus, the test material could not be premixed with delivery water.

Fish from stock tanks were placed into the bioassay vessels and then the test substance was introduced (there was apparently no acclimation period to the presence of acetone in the water). Ten fish were tested at each concentration and 10 were used as untreated controls. Fish were then observed daily for adverse effects until the end of the 96-hour exposure period. During the exposure period, pH, dissolved oxygen concentration, and water hardness, conductivity, and alkalinity were monitored. Stock tanks were maintained at 18 deg C, but maintenance of temperature of the flow-through vessels was not documented in the report.

The experimenters noted that Dechlorane Plus was not water soluble and most of the test material sank to the bottom while some remained suspended. None of the test material floated on the surface. None of the fish died during the study and no other adverse effects were noted. The median tolerance limit (TL50) was >100 ppm, the highest concentration tested.
Reliability: (3) invalid
16-DEC-2003 (19)

Type: static
Species: Lepomis macrochirus (Fish, fresh water)
Exposure period: 4 days
Analytical monitoring: no data
TL50 : > 100 mg/l
Method: other: no data
Year: GLP: no data
Test substance: as prescribed by 1.1 - 1.4
Result: A preliminary toxicity test was performed to determine the general level of toxicity. Target concentrations of 0.1, 1.0, 10, and 100 ppm were selected for use in the study.

Bioassay vessels, lined with polyethylene bags, were filled with 10 liters of well-aerated, reconstituted water and maintained at a temperature of 24 deg C. Two groups of 5 bluegills each were tested at each target concentration, five fish per vessel. After a 24-hour acclimation period, calculated amounts of the test substance was dispersed into the bioassay vessels. Because of the low water solubility of Dechlorane Plus, the test material was likely dissolved in acetone prior to dispersal. The report did not describe this process; however, in the 4-day dynamic fish toxicity test, Dechlorane Plus was dissolved in acetone prior to dispersal.

At the two highest doses, the experimenters noted that the water was clouded with white film on the surface [indicative of suspended particulates in the water]. None of the fish died during the study and no other adverse effects were noted. The median tolerance limit (TL50) was >100 ppm, the highest concentration tested.

Reliability: (3) invalid
16-DEC-2003 (18)

4.2 Acute Toxicity to Aquatic Invertebrates
-

4.3 Toxicity to Aquatic Plants e.g. Algae
-

4.4 Toxicity to Microorganisms e.g. Bacteria
-

4.5 Chronic Toxicity to Aquatic Organisms

4.5.1 Chronic Toxicity to Fish
-

4.5.2 Chronic Toxicity to Aquatic Invertebrates
-

TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Soil Dwelling Organisms
-

4.6.2 Toxicity to Terrestrial Plants
-

4.6.3 Toxicity to other Non-Mammalian Terrestrial Species
-

4.7 Biological Effects Monitoring
-

4.8 Biotransformation and Kinetics
-

4.9 Additional Remarks
-

5.1 Acute Toxicity

5.1.1 Acute Oral Toxicity

Type: LD50
Species: rat
Sex: male/female
Number of Animals: 5/dose
Vehicle: no data
Value: > 25,000 mg/kg bw
Method: other: no data
Year: 1971 GLP: no
Test substance: as prescribed by 1.1 - 1.4
Result: Five groups of Sherman-Wistar rats, each consisting of 3 males and 2 females, were fasted for 24 hours and then administered doses of 1500, 3000, 6000, 12,500, or 25,000 mg/kg bw by gavage. Body weights were taken just prior to dosing. Animals were then observed for mortality for 14 days.
There were no mortalities or adverse effects on body weights. The oral LD50 was >25,000 mg/kg bw.
Reliability: (2) valid with restrictions
16-DEC-2003 (11)

Type: LD50
Species: rat
Sex: male
Number of Animals: 2/dose
Vehicle: no data
Value: > 3160 mg/kg bw
Method: other: no data
Year: 1964 GLP: no
Test substance: as prescribed by 1.1 - 1.4
Result: Twelve adult male Sprague-Dawley rats were fasted for 4 hours and then groups of 2 each were administered doses of 10, 31.6, 100, 316, 1000, or 3160 mg/kg bw by gavage. The animals were observed for mortality and other adverse effects periodically up to 48 hours after administration. At this time, all animals were weighed and then subjected to gross necropsies.
There were no mortalities or other adverse effects observed. Necropsies were unremarkable. The oral LD50 was

>3160 mg/kg bw.
Reliability: (2) valid with restrictions
16-DEC-2003 (17)

5.1.2 Acute Inhalation Toxicity

Type: LC50
Species: rat
Sex: male/female
Number of Animals: 10/dose
Vehicle: air
Exposure time: 1 hour(s)
Value: > 300 mg/l
Method: other: no data
Year: 1971 GLP: no
Test substance: as prescribed by 1.1 - 1.4
Result: Two groups of rats (5/sex/dose; strain unspecified) were exposed to 105 or 300 mg dust/l air for 1 hour (whether whole body or head only was not stated). Animals were then observed for mortality for 14 days. Body weights were also recorded during this time period.
There were no mortalities or adverse effects on body weights. The inhalation LC50 was >300 mg/l air.
Reliability: (3) invalid
16-DEC-2003 (22)

Type: LC50
Species: rat
Sex: male/female
Number of Animals: 10/dose
Vehicle: air
Exposure time: 4 hour(s)
Value: > 2.25 mg/l
Method: other: no data
Year: 1975 GLP: no
Test substance: as prescribed by 1.1 - 1.4
Result: Five female and five male Charles River rats were exposed to 2.25 mg dust/l air for 4 hours (whether whole body or head only was not stated). The chamber size was 80 liters with an atmospheric pressure of 30.08 mm Hg, a temperature of 27 deg C and an air flow of 20 l/min. The particle size distribution data were: 67% of particles were at or below 10 microns in diameter; and 18.2% of the particles were

>25 microns in diameter. Animals were observed for mortality for 14 days. Body weights were also recorded during this time period.

There were no mortalities or adverse effects on body weights. Necropsies were unremarkable. The inhalation LC50 was >2.25 mg/l air.

Reliability: (2) valid with restrictions
16-DEC-2003 (10)

5.1.3 Acute Dermal Toxicity

Type: LD50
Species: rabbit
Sex: no data
Number of Animals: 4/dose
Vehicle: no data
Value: > 8000 mg/kg bw
Method: Section 191.10 of the Final Order, Enforcement Regulations. Federal Register. Vol. 26, No. 155, P. 7336. 12 Aug 1961.
Year: 1971 GLP: no
Test substance: as prescribed by 1.1 - 1.4
Result: Groups of albino rabbits (strain unspecified) were administered doses of 500, 1000, 2000, 4000, or 8000 mg/kg bw to their shaved skin; half of each group also had their skin abraded.

There was no mortality. The dermal LD50 was >8000 mg/kg bw.

Reliability: (2) valid with restrictions
16-DEC-2003 (12)

5.1.4 Acute Toxicity, other Routes
-

5.2 Corrosiveness and Irritation

5.2.1 Skin Irritation
-

5.2.2 Eye Irritation
Species: rabbit
Concentration: undiluted
Dose: 0.1 ml

Exposure Time: rinsed after 2 or 4 seconds, or not rinsed; 3 groups.
Number of Animals: 3/dose
Classification: not irritating
Method: Draize Test
Year: 1971 GLP: no
Test substance: as prescribed by 1.1 - 1.4
Result: Nine rabbits were administered 0.1 ml of the test substance into the right conjunctival sac. The left eyes served as controls. Group 1 animals did not have their eyes washed; Group 2 animals had their eyes washed 4 seconds after administration; Group 3 animals had their eyes washed 2 seconds after administration.

The test substance produced no corneal, iridal, or conjunctival effects in any of the animals up to 3 days after administration.
Reliability: (2) valid with restrictions
16-DEC-2003 (13)

5.3 Sensitization

Type: Buehler Test
Species: guinea pig
Concentration: Induction: 10% active occlusive epicutaneous substance
Challenge: 10% active occlusive epicutaneous substance
Number of Animals: 10/dose
Vehicle: propylene glycol
Classification: not sensitizing
Method: other: modified Buehler
Year: 1975 GLP: no
Test substance: as prescribed by 1.1 - 1.4
Result: Prior to the sensitization study, a test to determine the "irritation threshold" was performed. Concentrations of 0.1, 1.0, or 10% were applied to the backs of guinea pigs under occlusive patches for 5 hours; the sites were then scored 24 and 48 hours after exposure. There was no irritation at any dose site. The highest dose (10%) was used for the sensitization study.

Ten guinea pigs were dosed with 0.5 ml of the 10% solution beneath an occlusive Webril patch on their shaved backs near the midline and their torsos wrapped with Elastoplast. The animals were then placed in restrainers for 5 hours. Whether the doses were wiped or rinsed off was not stated in the report. The animals were dosed once per week for 9 consecutive

weeks. After the first induction period, the animals were scored for erythema 24 and 48 hours after administration. Thereafter, the induction sites were scored only 24 hours after administration.

Two weeks after the last induction exposure, the test animals and 5 control animals were challenged with duplicate patches, one on the induction site and the second one at a "virgin" site. The challenge exposure period was 5 hours. The animals were scored for erythema 24 and 48 hours after exposure.

Any reaction that was greater than that noted after induction dosing or greater than that noted for controls was considered evidence of sensitization. No animals had any erythema after induction or challenge dosing.

Reliability: (3) invalid
16-DEC-2003 (6)

5.4 Repeated Dose Toxicity

Species:	rat	Sex:	male/female
Strain:	other: Charles River strain COBS		
Route of admin.:	inhalation		
Exposure period:	5 days/week for up to 28 days		
Frequency of treatment:	6 hr/day		
Post. obs. period:	none		
Doses:	0.64, 1.524 mg/l (measured)		
Control Group:	yes, concurrent vehicle		
LOAEL:	= 0.64 mg/l		
Method:	other: no data		
Year:	1975	GLP:	no
Test substance:	as prescribed by 1.1 - 1.4		

Result: Groups of young adult rats (5/sex/dose) were exposed to the test substance for 6 hours/day, 5 days/week for a period of 28 days. Air flow rates, chamber temperatures and pressures, particle size distribution, and test substance concentrations were measured. Mortality and other adverse effects were recorded daily and body weights were recorded just prior to initiation of the study and weekly thereafter. Blood and urine samples were collected prior to initiation of dosing and at the end of the dosing period. Necropsies were performed on all animals and the brain, gonads, heart, kidneys, liver, lungs, and spleen of each animal were weighed. At least 12 tissues and organs were collected for histopathological examination. All quantitative data were statistically analyzed.

There were no treatment-related effects on body weights, signs of toxicity, urinalysis, hematology and clinical chemistry parameters, or gross pathology. Male and female rats of both treatment groups had significantly increased absolute liver weights compared to controls, with corresponding hepatocytomegaly of centrilobular hepatocytes in males of both dose groups and in 2 of 5 high-dose females. Low-dose females and high-dose males and females had significantly increased absolute lung weights compared to controls. Slightly increased numbers of macrophages in the alveoli were observed in all treated male and female rats. There were no other treatment-related effects observed. There was no NOAEL for this study.

Reliability: (2) valid with restrictions
16-DEC-2003 (3)

Species: rat Sex: male/female
Strain: other: Charles River
Route of admin.: oral feed
Exposure period: 13 weeks
Frequency of treatment: ad libitum
Post. obs. period: none
Doses: 10,000, 30,000, 100,000 ppm
Control Group: yes, concurrent vehicle
NOAEL: = 100,000 ppm
Method: other: no data
Year: 1975 GLP: no
Test substance: as prescribed by 1.1 - 1.4

Result: Groups of young rats were fed the test substance in their diet for 90 days (15/sex/dose). Mortality and adverse effects were recorded daily and body weights and food consumption were recorded weekly. Blood and urine samples were collected at approximately 45 and 84 days after treatment initiation for blood chemistry and hematology parameters and urinalyses. Necropsies were performed on all rats and the brain, gonads, heart, kidneys, liver and spleen of each animal were weighed. Thirty tissues and organs were collected for histopathological examination. All quantitative data were analyzed statistically.

There were no statistically-significant treatment-related effects on body or organ weights, urinalysis, clinical chemistry, or hematology. There were no treatment-related clinical signs or gross pathological or histopathological effects. Food consumption was slightly higher in high-dose

females, but this parameter was not analyzed statistically. Absolute and relative liver weights were increased in high-dose males. Although these increases were outside the normal range for the laboratory, they were not statistically significant nor were there any associated histopathological lesions. The NOAEL was 100,000 ppm, the highest dose tested.

Reliability: (2) valid with restrictions
16-DEC-2003 (15)

Species: rabbit Sex: male/female
Strain: New Zealand white
Route of admin.: dermal
Exposure period: 4 weeks
Frequency of treatment: 5 days per week
Post. obs. period: none
Doses: 500, 2000 mg/kg bw
Control Group: yes, concurrent no treatment
NOAEL: = 2000 mg/kg bw
Method: other: no data
Year: 1975 GLP: no
Test substance: as prescribed by 1.1 - 1.4
Result: Groups of rabbits (5/sex/dose) were exposed dermally to the test substance suspended in 3% aqueous methylcellulose, 5 days/week for 4 weeks. The test substance was distributed over approximately 20% of the total body surface area and was not rinsed or wiped off between applications. The application sites were not occluded, instead, the animals wore Elizabethan collars throughout the study. The skin was shaved once per week and the skin surface was abraded just prior to initial administration and then twice weekly thereafter. Controls were handled as were the treated animals; however, they did not receive dermal applications of any kind, such as the vehicle.

Body weights were taken weekly for 3 weeks prior to initiation of dosing and then on Day 0 and weekly thereafter. Food consumption was not determined during the study. Animals were observed daily for mortality and adverse effects. Blood chemistry and hematology parameters were measured and urinalyses were performed on samples collected on Day -6 and Day 23 from 2 males and 2 females from each group. Necropsies were performed on all rabbits and the brain, gonads, heart, kidneys, liver, thyroids, adrenals, and spleen of each animal were weighed. Approximately 30 tissues and organs were collected for histopathological examination. All quantitative data were statistically analyzed.

The only treatment-related clinical sign observed was minimal erythema at the dose site after 18-20 applications. There were no treatment-related effects on body weights, urinalysis, hematology and clinical chemistry parameters, gross pathology, or histopathology. Females had statistically-significant decreases in liver and ovary weights. Dose-related decreases were noted in absolute organ weights and in organ/body weight and organ/brain weight ratios for both liver and ovaries; however, there were no corresponding histopathological effects observed. The systemic NOAEL was 2000 mg/kg bw/day, the highest dose tested.

Reliability: (2) valid with restrictions
16-DEC-2003 (23)

5.5 Genetic Toxicity 'in Vitro'

Type: Ames test
System of testing: Salmonella typhimurium, strains TA98, TA100, TA1535, TA1537, TA1538
Concentration: 50-10,000 ug/plate
Metabolic activation: with and without
Result: negative
Method: other: no data
Year: 1980 GLP: no data
Test substance: as prescribed by 1.1 - 1.4
Result: Two sets of tests were performed. The culture interval was 72 hours. The dose levels were 0, 50, 100, 500, 1000, 5000, and 10,000 ug/plate. Each dose was tested in duplicate. Aroclor 1254 induced rat liver fraction activation system was utilized. Positive controls were sodium azide, 9-aminoacridine, 2-nitrofluorene, and 2-anthramine. The negative control was DMSO, the vehicle.
No toxicity or dose-related increases in the number of histidine revertants over the background count were observed. The test substance was non-mutagenic when tested in the presence or absence of S9.
Reliability: (2) valid with restrictions
16-DEC-2003 (14)

Type: Ames test
System of testing: Salmonella typhimurium, strains TA98, TA100, TA1535, TA1537, TA1538.
Concentration: 50-10,000 ug/plate
Metabolic activation: with and without
Result: negative
Method: other: no data
Year: 1980 GLP: no data
Test substance: as prescribed by 1.1 - 1.4
Result: Four groups of male rats were administered either the vehicle (DMSO), the test substance (either 0.5 or 1.0 g/animal) or the positive control (2-acetylaminofluorene). The test substance and vehicle control were administered by gavage and the positive control administered by intraperitoneal injection. Urine was collected from the rats over a 24-hour

period and then tested in the Ames assay.
The culture interval was 72 hours. Dose levels were 0, 0.10, and 0.25 ul urine/plate. Each dose was tested in duplicate. Aroclor 1254 induced rat liver fraction activation system was utilized. B-glucuronidase was incorporated into the agar of half of the plates. Positive controls were sodium azide, 9-aminoacridine, 2-nitrofluorene, and 2-anthramine. The negative control was DMSO, the vehicle.
The urine from treated rats, with and without addition of B-glucuronidase, did not increase the number of histidine revertants above that of controls. The test substance was non-mutagenic when tested in the presence or absence of S9.

Reliability: (2) valid with restrictions
16-DEC-2003 (14)

Type: DNA damage and repair assay
System of testing: Salmonella typhimurium, strains TA1538, TA1978, SL4525 (rfa), SL4700 (rfa).
Concentration: 50-10,000 ug/plate
Metabolic activation: with and without
Result: ambiguous
Method: other: filter disc
Year: 1980 GLP: no data
Test substance: as prescribed by 1.1 - 1.4
Result: The test substance was applied at amounts of 0.5 or 1.0 mg to each filter disc, which was then incubated on agar at 37 deg C for 16-17 hrs. Each dose was tested in duplicate. Aroclor 1254 induced rat liver fraction activation system was utilized. B-glucuronidase was incorporated into the agar of half of the plates. The positive control was methylmethane sulfonate. The negative control was kanamycin. The positive criteria were based on the diameter of the zone of growth inhibition in test cultures compared to controls.
No zone of growth inhibition was observed under the conditions of the test. The experimenters concluded that the results were equivocal.

Reliability: (3) invalid
16-DEC-2003 (14)

Type: Mouse lymphoma assay
System of testing: L5178Y TK+/-

Concentration: 0.5, 1, 5, 10, 20, 40, 80, 100, 130, 150 ug/ml
Metabolic activation: with and without
Result: negative
Method: other: Clive and associates (1972 - 1979)
Year: 1980 GLP: no data
Test substance: as prescribed by 1.1 - 1.4
Result: An initial solubility test was performed. Test samples were run in duplicate for the initial and the definitive assays (i.e., 2 samples per concentration with activation and 2 samples per concentration without activation).

In the initial assay, there were persistent precipitates present after washing the cells at concentrations above 20 ug/ml and consequently these test samples were discarded. The results of this initial assay were used to select a concentration range for the second definitive assay.

Positive controls were ethyl methanesulfonate and 3-methylcholanthrene. The negative control was DMSO. That the assay was acceptable was based on the following criteria: the relative plating efficiency of the solvent control was 70-115%; the mutation frequency of the solvent control was no higher than 120e-6; and the mutation frequency of the positive control was at least twice that of the solvent control. The positive criteria were the mutation frequency of at least one concentration of the test substance had to be at least twice that of the solvent control and the presence of a concentration-related increase in mutation frequency over that of the solvent control.

Dechlorane Plus was not cytotoxic and did not significantly increase the mutation frequencies above the spontaneous control frequencies. The presence of metabolic activation did not affect the mutagenic response.
Reliability: (2) valid with restrictions
16-DEC-2003 (9)

5.6 Genetic Toxicity 'in Vivo'
-

5.7 Carcinogenicity
-

5.8 Toxicity to Reproduction
-

5.9 Developmental Toxicity/Teratogenicity

5.10 Other Relevant Information

Type: Toxicokinetics
Test substance: Dechlorane Plus but with CAS No. 3533-34-1.
Result: Two male and seven female young adult Sprague-Dawley rats were administered a single oral dose of either 1 or 113 mg radiolabeled Dechlorane Plus/kg bw by gavage. Two of the female rats had previously received 1% unlabeled Dechlorane Plus in their diet for 14 days. Urine and feces were collected from 8 animals; one animal was monitored for expired 14C volatiles. One female receiving 1 mg/kg bw was used for the blood plasma study. This female was periodically bled from the orbital sinus throughout the first 48 hours after dosing. Animals were sacrificed and selected tissues collected for determination of radioactivity. Feces and selected tissues were extracted in methanol prior to analysis by LC or were combusted directly to quantify any 14C residues. Plasma and urine samples were quantified by LSC and/or LC.

Animals administered single doses of 1 or 113 mg/kg bw or given 1% in the diet for 14 days preradiolabel had 93-98% of the applied dose excreted in feces unchanged. Less than 0.1% of the radiolabel was excreted in urine and only 0.004% was excreted in expired air. Radiolabel plasma levels peaked at 10 hours after dose administration and the radiolabel was at least 65% Dechlorane Plus. Tissue residues did not increase proportionally with dose; a 113-fold increase in dose resulted in a 8-fold decrease in the percentage of applied dose excreted in urine and remaining in the carcass. Within 4 days of dosing, only 26% of the radiolabel remaining in the carcass was Dechlorane Plus, the remaining radiolabel was more polar but not identifiable by LC. Ovaries and liver contained the highest levels of Dechlorane Plus.
Reliability: (2) valid with restrictions
16-DEC-2003 (20)

5.11 Experience with Human Exposure
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