

US EPA ARCHIVE DOCUMENT

SUBJECT: Product Chemistry Review of Drexel Lindane Technical

FROM: *ASmith*
Alfred Smith, Chemist
Product Chemistry Review Section
Registration Support Branch
Registration Division (7505W)

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TO: Linda Arrington, PM Team 13
Insecticide-Rodenticide Branch
Registration Division (7505C)

THRU: Harold Podall, Section Head
Product Chemistry Review Section
Registration Support Branch
Registration Division (7505W)

HP 9/1/94

APPLICANT: Drexel Chemical Company

DP BARCODE: D204640
D204641

EPA REG. NO: 19713-61
19713-191

CHEMICAL NAME: Lindane

PRODUCT NAME: Drexel Lindane Technical

USE: insecticide

INTRODUCTION

The Drexel Chemical Company requests that the company Kanoria Chemicals and Industries Limited (New Delhi, India) be accepted as a manufacturer of the source product (active ingredient) lindane. Drexel Chemical Company has submitted product chemistry information in support of the source product. The information is discussed below.

Drexel Chemical Company has provided a "STATEMENT OF NO CONFIDENTIALITY CLAIMS", in which no claim of confidentiality is made for any information contained in the study (MRID 43239301) on the basis of its falling within the scope of FIFRA 10(d)(1)(A), (B), or (C).

SERIES 61: Product Identity and Composition (MRID 43239301)

61-1: Product Identity and Disclosure of Ingredients

Gamma benzene hexachloride is the active ingredient (ai) in the technical grade of the active ingredient (TGAI) produced by Kanoria Chemicals and Industries Limited (India).

Gamma benzene hexachloride is:

1,2,4/3,6-gamma hexachlorocyclohexane

Molecular Formula: $C_6H_6Cl_6$

CAS #: 58-89-9

Pesticide Chemical Code (PCC): 9001

Common Name: Lindane

The composition of the TGAI is provided in a Confidential Statement of Formula (CSF, EPA Form 8570-4, dated 5/9/94). See Confidential Appendix for composition.

The information submitted satisfies the requirements of 40 CFR 158.155. No additional information is needed.

61-2: Beginning Materials and Manufacturing Process

The beginning materials are technical hexachlorocyclohexane (Tech HCH) and ethanol. These materials are adequately described, and their producers are given. The manufacturing process is a batch process which begins with Tech. HCH. No reactions are involved in the manufacturing process.

The manufacturing process entails a purification process in which the gamma isomer is removed from the Tech. HCH through a series of ethanol extractions to yield a high purity of lindane (99.5-99.8%). The product is dried, screened, analyzed for quality control, and packaged in drums containing polythene liners.

The information submitted satisfies the requirements of 40 CFR 158.160-162. No additional information is needed.

61-3: Discussion of the Formation of Impurities

The manufacturing process does not involve intended chemical reactions. Therefore, the only possible source of impurities would be the starting material Tech. HCH. The impurities in this material are the alpha, beta, and delta isomers which have a combined maximum level of 0.1%. However, the manufacturing process effectively reduces these impurities to levels much less than 0.1%, and such levels are not significant.

The information submitted satisfies the requirements of 40 CFR 158.167. No additional information is needed.

SERIES 62: Analysis and Certification of Product Ingredients (MRID 43239301)

62-1: Preliminary Analysis

Drexel Lindane Technical (TGAI) is analyzed through the use of Gas Chromatography (GC) using a flame ionization detector (FID). Five samples from five batches were analyzed for lindane (gamma benzene hexachloride) and its related isomers. The components are quantitated by comparison of peak areas of a standard and the sample. The concentration of the active

ingredient gamma lindane was 100%. No detectable concentration of the isomers was noted.

The results of analyses of the TGAI samples are adequate. The information submitted satisfies the requirements of 40 CFR 158.170. No additional information is needed.

62-2: Certified Limits

A Confidential Statement of Formula (CSF, EPA Form 8570-4, dated May 9, 1994) is submitted, and the CSF contains the composition of the Drexel Lindane Technical. See the Confidential Appendix for details.

The information submitted satisfies the requirements of 40 CFR 158.175. No additional information is needed.

62-3: Enforcement Analytical Method

An analytical method suitable for enforcement purposes is provided for gamma lindane (ai) and its impurities.

The information submitted satisfies the requirements of 40 CFR 158.180. No additional information is needed.

SERIES 63: Physical and Chemical Characteristics (MRID 43239301)

The physicochemical properties for the TGAI are listed

below.

<u>Guidelines</u> <u>Reference</u> <u>Number (GRN)</u>	<u>Property</u>	<u>Description</u>
63-2	Color	White
63-3	Physical State	Colorless monoclinic crystals
63-4	Odor	Odorless
63-5	Melting Point	112 °C
63-6	Boiling Point	Not Applicable (NA)
63-7	Density	1.85g/cc
63-8	Solubility	Water 10mg/L Acetone 43.5g/100g Methanol 7.4g/100g Ethanol 6.4g/100g Benzene 28.9g/100g Xylene 24.9g/100g Ether 20.8g/100g
63-9	Vapor Pressure	9.4 x 10(6)mm Hg, 20 °C
63-10	Dissociation Constant	NA
63-11	Octanol/Water Partition Coefficient	-log P = 3.29 - 3.72
63-12	pH	6.8 - 7.0 at 20 °C
63-13	Stability	Stable to light, heat, air, carbon dioxide, and strong acids. Unstable in the presence of alkali. Decomposes in the presence of cer-powdered metals (e.g., iron, aluminum, zinc).

63-14	Oxidizing or Reducing Action	Stable up to 180 °C where decomposition begins. Incompatible with oxidizing agents; can undergo oxidation when in contact with ozone.
63-15	Flammability	Non-combustible
63-16	Explosibility	Non-Explosive
63-17	Storage Stability	Shelf-life: 2 years (minimum). Stable in fiber/cardboard drum with polythene liner.
63-18	Viscosity	NA
63-19	Miscibility	NA
63-20	Corrosion Characteristics	Non-corrosive when dry. Corrosive to some metals (i.e., iron, aluminum, zinc) in presence of moisture.
63-21	Dielectric Breakdown Voltage	NA

The information submitted satisfies the requirements of 40 CFR 158.190. No additional information is needed.

NOTE TO PM REVIEWER:

Two requests are submitted for Drexel Lindane Technical (EPA Registration Numbers 19713-191, D204641; and, 19713-61, D204640). Both registered products are identical in content (See REFS). The product chemistry studies submitted in support of the new source of the active ingredient appear to be identical. Therefore, the conclusions which have been reached in the review for EPA Reg. No. 19713-61 above also apply to EPA Reg. No. 19713-191 (MRID 43239201). As a result, the product chemistry information submitted also satisfies the requirements of 40 CFR 158.155-158.190 for the registered product #19713-191.

SUMMARY

The information submitted satisfies the product chemistry requirements for 40 CFR 158.155-158.190 for both products.

PCRS/RSB has no objections to the acceptance of Kanoria Chemicals and Industries Limited as a source of the active ingredient lindane.

ATTACHMENT: Confidential Appendix

RIN 1083-95

LINDANE PRODUCT CHEMISTRY REVIEW

Page 5 is not included in this copy.

Pages _____ through _____ are not included.

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 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.

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.
