



OCT 17 2002

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CERTIFIED MAIL

Mr. Al Gwilliam
Consultant to Inquinoso Chemicals/JLM Industries
4 Tar Rock Road
Westport, CT 06880

**Subject: Lindane; Product Chemistry Data Evaluation Report
MRIDs 454266-01 through 454266-11**

Dear Mr. Gwilliam:

The Environmental Protection Agency (EPA or the Agency) has completed the review of several product chemistry submissions pertaining to the reregistration of lindane. These submissions were assigned EPA Management Record Identification (MRID) numbers 454266-01 through 454266-11. Taking into account these submissions and the information in the June 7, 2001 Confidential Statement of Formula (CSF), all but two (OPPTS 830.6314 & 830.6317) of the product chemistry requirements for lindane have been satisfied. EPA's Data Evaluation Report of the product chemistry information is enclosed.

Based on the Agency's review of the above referenced data, the following product chemistry guidelines for lindane are satisfied:

Guideline Number	Required Study	MRID number(s)
830.1550	Product Identity and Composition	From CSF
830.1600	Start. Mat. & Mnfg. Process	45426601
830.1620	Description of Production Process	45426601
830.1670	Formation of Impurities	45426601
830.1700	Preliminary Analysis	45426602, 45426603, 45426604, 45426605,
830.1750	Certification of Limits	From CSF
830.1800	Analytical Method	45426606,
830.7050	UV/Visible Absorption	45426611
830.6316	Explosibility	45426608
830.6320	Corrosion Characteristics	45426610

incorporated into the lindane reregistration eligibility decision (RED) document. Product chemistry data for guidelines OPPTS 830.1550, 830.1620, 830.6316, 830.6320, and 830.7050, which are listed as additional generic data requirements in the RED, are no longer required and will not be listed on the generic data call-in (DCI) to be issued for the lindane RED.

However, as referenced above, the following product chemistry guideline requirements remain outstanding, due to deficiencies in the submitted studies and will be listed on the generic DCI:

Guideline Number	Required Study	MRID number
830.6314	Oxidization/Reduction: Chemical Incompatibility	45426607
830.6317	Storage Stability	45426609

The study submitted to satisfy OPPTS Guideline 830.6314, Oxidation/Reduction: Chemical Incompatibility, is deficient because information was not provided on the reducing properties of lindane. The study submitted to satisfy OPPTS Guideline 830.6317, Storage Stability, is deficient because storage stability data for periods greater than 14 days was not determined. Information must be provided to upgrade these two studies and to satisfy the guidelines.

Within 30 days of receiving this letter, please provide the Agency with either the information needed to fulfill guidelines OPPTS 830.6314 and 830.6317, or a schedule of when the information will be available. Note that these two guideline requirements, along with other data requirements stipulated in the lindane RED document will be included in the generic DCI, which will be issued at a later date. If you have any questions or comments, please contact me directly at (703) 308-8172.

Sincerely,



Mark Howard
Chemical Review Manager, RB3
Special Review and Reregistration Division

Enclosure



July 18, 2002

MEMORANDUM:

SUBJECT: Lindane (009001): Reregistration Case 0315. Product Chemistry Guidelines 830.1550, 1600, 1620, 1700, 1750, 1800, 6314, 6316, 6317, 6320, and 7050. DP Barcode: D276032. MRID Nos. 45426601, 45426602, 45426603, 45426604, 45426605, 45426606, 45426607, 45426608, 45426609, 45426610, and 45426611.

FROM: Thurston G. Morton, Chemist
Reregistration Branch 4
Health Effects Division (7509C)

Thurston G. Morton
7/18/02

THROUGH: Susan V. Hummel, Branch Senior Scientist
Reregistration Branch 4
Health Effects Division (7509C)

Susan V. Hummel

TO: [REDACTED] / Betty Shackleford
Reregistration Branch 3,
Special Review & Reregistration Division (7508C)

EXECUTIVE SUMMARY:

- Data on Preliminary Analysis, Certification of Limits, Enforcement Analytical Method, Oxidation/Reduction, Explodability, Corrosion Characteristics, and UV-Visible Absorption are adequate. GLN 830.1550, 830.1600, 830.1620, 830.1700, 830.1750, 830.1800, 830.6316, 830.6320, and 830.7050 are satisfied.
- Data on Oxidation/Reduction and Storage Stability are not adequate. Additional data are required for GLN 830.6314 and 830.6317.

Inquinoso Internacional, S.A. has submitted Product Chemistry data to support the registration of Lindane Technical EPA Reg. No. 40083-1.

A summary review follows in tabular format.

Attachments: Prod. Chem. Summary Table
Confidential Appendix A

cc w/ attachments: Chem F, Chas F. Morton

RDI Team: 7/19/01; SVR7/18/02

TM, Thurston Morton, Rm. 8160 CM2, 305-4691, mail code 7509C

Chemical Name (IUPAC, ANSI, etc.)	Lindane gamma hexachlorocyclohexane
Chemical Number (CAS; PC Code)	CAS No. 58-89-9 Shaughnessy No. 009001
Registration No.	EPA Reg. No. 40083-1
Type of Product (T, FI, MP, EP)	99.5% T
DP Barcodes	D276032

Inquinosa Internacional, S. A. has submitted product chemistry data for the 99.5% T in response to an Agency review (D274754, 6/7/01, T. Morton).

GLN	MRID	Status ¹	Details and/or Deficiency ²
830.1550: Product Identity & Disclosure of Ingredients	CSF dated 6/7/01	A	See Confidential Appendix A.
830.1600: Starting Materials & Manufacturing Process	45426601	A	See Confidential Appendix A.
830.1620: Description of the Product Process	45426601	A	See Confidential Appendix A.
830.1670: Discussion of Formation of Impurities	45426601	A	See Confidential Appendix A.
830.1700: Preliminary Analysis	45426602, 45426603, 45426604, 45426605	A	See Confidential Appendix A.
830.1750: Certification of Limits	CSF dated 6/7/01	A	See Confidential Appendix A.
830.1800: Analytical Methods	45426606	A	See Confidential Appendix A.

¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable.
² Refer to CBI Appendix A for details.

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GLN			
830.6302:Color	00072468	A	White
830.6303:Physical State	00118743	A	Crystalline
830.6304:Odor	00102995	A	Odorless
830.6313:Stability	00072468	A	Stable to light, heat, air, and strong acids. Decomposes to trichlorobenzenes and HCl in alkali.
830.6314:Oxidizing or Reducing Action	45426607	N	The European Commission test method for oxidizing properties, A.17, was used. Lindane was test for oxidizing action by mixing 2 parts lindane with 1 part wood meal into a small pile. The pile was then ignited. The flame was extinguished as soon as the lighter was quenched. No information was provided concerning the reducing properties of lindane.
830.6315:Flammability		N/A	
830.6316:Explosibility	45436608	A	Lindane was tested for thermal and mechanical sensitivity and did not show any explosive properties. The European Commission test method for explosive properties, A.14, was used.
830.6317:Storage Stability	45426609	N	Technical lindane was tested for stability after accelerated storage at 54° C for 14 days. Data showed that lindane is stable in these conditions. However, storage stability data for periods greater than 14 days was not determined.
830.6319:Miscibility		N/A	
830.6320:Corrosion Characteristics	45426610	A	Lindane is packed in polyethylene bags which has not shown any evidence of damage. Lindane is nearly inert except in the presence of strong oxidizing or reducing agents which will not be present in the packing material.
830.7000:pH		N/A	
830.7050:UV/Visible Absorption	45426611	A	No absorption maximum was observed. No significant modification observed (within the range of 200-800 nm) between the spectrum obtained in neutral medium and those obtained in acid and basic medium. No absorption occurred above 290 nm in neutral medium.
830.7100:Viscosity		N/A	
830.7200:Melting Point	00118743	A	112° C
830.7220:Boiling Point		N/A	
830.7300:Density, Bulk Density, or Specific Gravity	00072468	A	1.85
830.7370:Dissociation Constant		N/A	
830.7550:Octanol/Water Partition Coefficient (Shake Flask Method)	00160130	A	3135

GLN			
830.7560:Octanol/Water Partition Coefficient (Generator Column Method)		N/A	
830.7570:Octanol/Water Partition Coefficient (Estimation by Liquid Chromatography Method)		N/A	
830.7840:Solubility (Shake Flask Method)	00118712	A	At 20° C in gm/100 gm Acetone: 43.5 Methanol: 7.4 Pentane: 2.2 Petroleum ether (60-80): 2.7 Petroleum ether (100-120): 3.5
830.7950:Vapor Pressure	00118743	A	9.4 x 10 ⁻⁶ mm Hg 20° C
¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable. ² For example, "brown" for 830.6302; "155° C" for 830.7220.			

Attachments: Confidential Appendix A

Not attached for this letter