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WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Data for Registration Standard - Lindane

FROM: Hudson Boyd
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TO: George LaRocca
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THRU: John H. Jordan
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THRU: David J. Severn, Chief
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Attached please find final copies of Tasks 1 & 2 plus Table A,
generic data requirements, for lindane.

cc: Amy Rispin
Ann Stavolla
John Dougherty

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TABLE A
GENERIC DATA REQUIREMENTS FOR CHEMICAL

LINDANE

ORIGINAL SIGNED BY
HUDSON L. BOYD

Data Requirement	Composition	1/ Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>5158.130 Environmental Fate</u>					
<u>DEGRADATION STUDIES-LAB:</u>					
161-1 - Hydrolysis	TGAI or PAIRA	ABEFGAKL	No	-	Yes
Photodegradation					
161-2 - In water	TGAI or PAIRA	ABG	No		Yes
161-3 - On soil	TGAI or PAIRA	AG	No		Yes
161-4 - In Air	TGAI or PAIRA	A	No		4/
<u>METABOLISM STUDIES-LAB:</u>					
162-1 - Aerobic Soil	TGAI or PAIRA	ABEGK	No		Yes
162-2 - Anaerobic Soil	TGAI or PAIRA	A	NO		Yes
162-3 - Anaerobic Aquatic	TGAI or PAIRA	-	-		No 5/
162-4 - Aerobic Aquatic	TGAI or PAIRA	-	-		No 5/
<u>MOBILITY STUDIES:</u>					
163-1 - Leaching and Adsorption/Absorption	TGAI or PAIRA	ABEFGHKL	No		Yes
163-2 - Volatility (Lab)	TEP	A E F J K	No		Yes
163-3 - Volatility (Field)	TEP	6/	No		6/

1/ Composition: TGAI - Technical grade of the active ingredient; PAIRA - Pure active ingredient, radiolabelled;
TEP - Typical end-use product.
2/ The use patterns are coded as follows: A-Terrestrial, Food Crop; B-Terrestrial, Non-Food; C-Aquatic, Food Crop; D-Aquatic, Non-Food; E-Greenhouse, Non-Food; F-Greenhouse, Non-Food; G-Forestry; H-Domestic Outdoor; I-Indoor, comm'l indoor, J, animals/premises K, Lumber, L, J, animals/premises K, Lumber, L, J,

A/ Deferred, pending receipt and evaluation of data on photodegradation in water, on soil, and data on aerobic soil metabolism.
5/ No registered aquatic/aquatic impact uses.
6/ Deferred, pending receipt and evaluation of laboratory volatility data

LINDANE

GENERIC DATA REQUIREMENTS FOR CHEMICAL

TABLE A

Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?

Date Requirement	Composition	Use 2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation
<u>§158.130 Environmental Fate (continued)</u>				
<u>DISSIPATION STUDIES-FIELD:</u>				
164-1 - Soil	TEP	A B H	No	Yes
164-2 - Aquatic (Sediment)	TEP	4/	—	No
164-3 - Forestry	TEP	G L	No	Yes 5/
164-4 - Combination and Tank Mixes	—			
164-5 - Soil, Long-term	TEP	A	NU	6/
<u>ACCUMULATION STUDIES:</u>				
165-1 - Rotational Crops (Confined)	PAIRA	A	NU	Yes
165-2 - Rotational Crops (Field)	TEP	2/	NU	2/
165-3 - Irrigated Crops	TEP	5/	NU	5/
165-4 - In Fish	TGAI OF PAIRA A B G L		NU	1/yes
165-5 - In Aquatic Non-Target Organisms	TEP	G L	NO	8/

Not required because use pattern does not indicate a potential for exposure for field workers.

1/ Composition: TGAI - Technical grade of the active ingredient; PAIRA - Pure active ingredient, radiolabeled; TEP - Typical end-use product.

2/ The use patterns are coded as follows: A-Terrestrial, Food Crop; B-Terrestrial, Non-Food; C-Aquatic, Food Crop; D-Aquatic, Non-Food; E-Greenhouse, Food Crop; F-Greenhouse, Non-Food; G-Forestry; H-Domestic Outdoor; I-Indoor;

3/ Data must be submitted no later than _____
Comm'l Indoor, J;
Animals/Premises, K;
Lumber, L.

4/ No registered uses
5/ May be combined with tests for field accumulation, aquatic non-target organisms, per 165-5.

6/ Required only if residues found, per 164-1, exceed 50% of applied at time of subsequent appln.

2/ Deferred pending receipt and evaluation of studies from confined rotational crop study.

8/ Required only if laboratory fish accumulation study show a potential for residue accumulation.

4/8

ORIGINAL SIGNATURE
HUDSON L. BOYD

EEB

LINDANE

Final Report

**Task 2: Environmental Fate and
Exposure Assessment**

Contract No. 68-01-6679

MAY 29, 1985

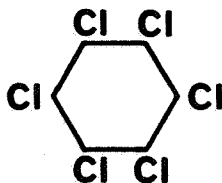
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Environmental Fate and Exposure Assessment

Lindane

EXAGAMA, FORLIN, GALLOGAMA, GAMAPHEX, GAMMEX,
INEXIT, ISOTOX, LINDAFOR, LINDAGRAIN, LINDALO,
LINDAGRANOX, LINDAMUL, LINDAPOUDRE, LINDATERRA,
NOVIGAM, SILVANOL



Gamma isomer of benzene hexachloride

Lindane is an insecticide/acaricide registered for use on a variety of terrestrial food crop (field and vegetable crops including seed treatment) and nonfood crop (ornamentals and tobacco), greenhouse food crop (vegetables) and nonfood crop (ornamentals), forestry including Christmas tree plantations, domestic outdoor and indoor (pets and household), commercial indoor (food/feed storage areas and containers, and animal premises including manure), and wood or wooden structure sites. Of the total amount of lindane applied in the United States in 1982, ~48, 20, and 19% was used for seed treatment, livestock, and hardwood lumber, respectively. Application rates ranged from 0.25 to 2.25 oz/100 lb of seed for seed treatment; ~0.1 to 2.06 lb/A for foliar and soil treatment; 0.8 to 1.5 oz/50,000 ft³ of greenhouse; 0.006 to 0.11 lb/gal for bark; 0.023 to 3% sprays, dips, and dusts for indoor and animal treatment; <0.01 lb/1,000 ft² for animal premises; and <4 lb/1000 ft² (14.64% solutions) for wood and wooden structures. Lindane may be formulated with captan, methoxychlor, sulfur, maneb, zineb, carbaryl, Terraclor, orthodichlorobenzene, kerosene, heavy aromatic naphtha, toxaphene, DDVP, malathion, pine oil, piperonyl butoxide, pyrethrins, naled, dicofol, tetrachlorophenols, methylated naphthalenes, dinocap, benzyl benzoate, rotenone, diazinon, basic copper sulfate, and mancozeb. Single active ingredient formulations consist of 0.75 and 1% D, 6-75% WP, 1-75% WP/D, 0.27-11.2% Impr, 0.35-1.75 lb/gal

and 0.4540% EC, 1.65 lb/gal and 20% SC/L, 2.67 and 4 lb/gal and 0.097-25% RTU-L, 0.75 and 3% PrL, and 1-40% FlC. Lindane is generally surface applied using ground equipment but may be incorporated. Applicators must be certified or under the direct supervision of applicators certified to apply lindane products registered for the following uses: commercial ornamentals, pecans, livestock, forestry, Christmas trees, structural treatment, dog shampoos, and dog dusts.

Available data are insufficient to fully assess the environmental fate of lindane and the exposure of humans and nontarget organisms to lindane. The data in the following summaries do not meet regulatory (guideline) requirements, and therefore, are considered to be preliminary (incomplete) information.

Lindane (analytical grade, purity unspecified) was detected in the leachate from silt loam soil columns (height unspecified) eluted with >7 inches of water based on mosquito larvae bioassay and TLC tests (Lichtenstein et al., 00103661).

Lindane (test substance uncharacterized) was adsorbed to loamy sand, loam, sandy loam, and muck soils with K_d values of 17.3, 20.4, 22.7, and 368, respectively (Kay and Elrick, 00095246).

Lindane (test substance uncharacterized) volatilized (rate not determined) from lindane-treated paper at 24 C (Espoy, 00117390).

In a monitoring study, lindane was detected (average monthly concentrations from May 1964 to February 1965 at 10 sites in Mississippi and Arkansas) in soil at ≤ 0.23 ppm ($\sim 6\%$ of 974 samples) and in sediment at ≤ 0.04 ppm ($\sim 4\%$ of 417 samples) (U.S. Agricultural Research Service, 00025702). Respective values for surface water (ponds and streams), runoff, and well water were ≤ 0.56 ppb ($\sim 37\%$ of 67 samples), ≤ 0.08 ppb ($\sim 29\%$ of 17 samples), and ≤ 0.23 ppb ($\leq 5\%$ of 205 wells). Lindane was detected both at sites with and without known histories of lindane application.

Dermal, ocular, and inhalation exposures to workers may occur during application. The primary potential for exposure from the EC, SC/L, FlC, WP, and RTU-L formulations is during mixing and/or loading operations where both dermal and ocular exposure can occur via splashing when closed transfer systems are not utilized. Exposure during handling and loading operations involving

the D, WP, WP/D, and Impr formulations is expected to be mainly dermal although ocular and ingestion exposure may occur. Dermal, ocular, and inhalation exposure can result with use of the PrL formulation. Indoor use (including greenhouse) increases the potential for inhalation exposure. Human exposure to lindane during handling, mixing, and application operations can be minimized by the use of approved respirators, protective clothing, and goggles. However, data are not available to assess such exposures. Currently, no federal reentry intervals have been established.

Preliminary adsorption data indicate that lindane has a low mobility in mineral soils and is relatively immobile in muck soils; however, the potential for lindane contamination of surface and ground water exists based on the results of a monitoring study conducted in Mississippi and Arkansas.

The following data are required (EPA Data Requirements for Registering Pesticides) to fully assess the environmental fate and transport of, and potential exposure to lindane: hydrolysis studies, photodegradation studies in water and on soil; aerobic and anaerobic soil metabolism studies; anaerobic aquatic metabolism studies; leaching and adsorption/desorption studies; laboratory volatility studies; terrestrial and forestry field dissipation studies; and accumulation studies on rotational crops, fish, and nontarget aquatic organisms.

Hydrolysis studies: No data were submitted; however, all data are required.

Photodegradation studies in water: No data were submitted; however, all data are required.

Photodegradation studies on soil: No data were submitted; however, all data are required.

Photodegradation studies in air: No data were submitted; however, the requirement for data is deferred pending receipt of data on photodegradation in water and on soil, and data on aerobic soil metabolism.

Aerobic soil metabolism studies: No data were submitted; however, all data are required.

Anaerobic soil metabolism studies: No data were submitted; however, all data are required.

Anaerobic aquatic metabolism studies: No data were submitted; however, no data required because there are no aquatic uses.

Aerobic aquatic metabolism studies: One study (Lichtenstein et al., 00103661) was reviewed and considered to be scientifically invalid because the sampling schedule was inadequate to accurately assess the degradation of lindane. In addition, this study would not fulfill data requirements because the study was conducted in water only (Experiment 1), not water plus sediment as recommended; the formation and decline of degradation products was not addressed; a material balance was not determined; and the lake water, lake mud, soil, and test substance were not completely characterized. No data are required because lindane has no registered aquatic or aquatic impact use.

Leaching and adsorption/desorption studies: Five studies were reviewed. The runoff portion of the first study (Lichtenstein, 00103597) is scientifically invalid because nontreated areas downslope of lindane-treated areas were not sampled, the application rate and uniformity of the application technique were not confirmed by immediate posttreatment sampling, and the analytical method was referenced but not described. The portion of this study pertaining to leaching of lindane under field conditions could not be validated because rainfall data were not reported, the data were reported as percent of recovered not as percent of applied, and the analytical method was referenced but not described. The soil column leaching portion of this study could not be validated because the experimental design was inadequately described to permit evaluation of lindane mobility in soil. In addition, some samples were contaminated with lindane residues. These studies would not satisfy data requirements because: runoff and leaching in the field studies - field test data and complete soil characteristics were not provided, a nonspecific method was used, the test substance was not technical grade or purer, and the mobility of lindane was not determined under laboratory conditions using one of the

three recommended methods (e.g., soil TLC, soil column, or adsorption/desorption). In the soil column study, complete soil characteristics were not reported, the test substance was not technical grade or purer, and a nonspecific method was used. The second study (Foschi et al., 00096968) could not be validated because the experimental procedures and protocols were inadequately described (e.g., method of treatment and treatment level were not reported). In addition, this study would not fulfill data requirements because the test substance used was not technical grade or purer and the soil extraction procedure, recovery values, and limit of detection were not reported. The third study (Johnston et al., 00101692) could not be validated because the description of the analytical methodologies and the data presented were inadequate to evaluate the leaching of lindane into drainage tiles. In addition, this study would not fulfill data requirements because the test substance was not characterized, more than one pesticide was applied to the test plot, the test method used was not one of the three recommended (soil column, soil TLC, or batch equilibrium), and soil characteristics were not provided. The fourth study (Lichtenstein et al., 00103661) is valid but does not fulfill data requirements because the concentration of lindane in leachate samples was not quantified, the leached soil column was not segmented and analyzed for lindane, complete soil characteristics were not specified, and the height of the soil column was not reported. The fifth study (Kay and Elrick, 00095246) is valid but does not fulfill data requirements because the test substance was not characterized, the soils were incompletely characterized, and the study was conducted in water rather than a calcium ion solution. All data are required.

Laboratory volatility studies: Two studies were reviewed. The first study (Lichtenstein and Schulz, 00090826) is scientifically invalid because the sampling protocol was inadequate to accurately assess the volatility of lindane and insufficient raw data were reported to support the conclusions. In addition, this study would not fulfill data requirements because the test substance was not a typical end-use product, the soil was not characterized, volatility and air concentrations were not reported, the concentration in air was not monitored continuously, and a nonspecific bioassay was used. The second study (Espoy, 00117390) is valid but does not fulfill data requirements because the test substance was uncharacterized, the application rate was

unspecified, and the experimental design was inappropriate for establishing the rate of volatilization of lindane from treated surfaces. All data are required.

Field volatility studies: No data were submitted; however, the requirement for data is deferred pending the receipt of laboratory volatility data.

Terrestrial field dissipation studies: Three studies were reviewed. The first study (Velsicol Chemical Corp., 00066550) is scientifically invalid because the sampling schedule was inadequate to accurately assess lindane dissipation from soil and the analytical methodology was insufficiently described. In addition, this study would not fulfill data requirements because the test substance was uncharacterized, field test data were incompletely reported, a nonspecific method was used, the patterns of formation and decline of degradates were not determined, immediate posttreatment soil samples were not analyzed to confirm lindane application rates, the soils were not characterized, and lindane was not applied at the highest registered rate. The second study (Bess and Hylin, 00070305) is scientifically invalid because the test site was contaminated with lindane and six other pesticides at the end of the experiment. In addition, this study would not satisfy data requirements because the test substance was uncharacterized, field test data were not reported, complete soil characteristics were not provided, the sampling protocol and analytical methods were incompletely described, and the pattern of formation and decline of degradates was not determined. The third study (U.S. Agricultural Research Service, 00025702) is a scientifically valid monitoring study but does not fulfill data requirements because the test substance was uncharacterized, the soils were incompletely characterized, application rates were not confirmed, the sampling protocol was inadequate to establish a decline curve for lindane, the pattern of formation and decline of degradates was not determined, and more than one pesticide was applied. All data are required.

Aquatic field dissipation studies: No data were submitted; however, no data are required because lindane has no registered aquatic or aquatic impact use.

Forestry dissipation studies: One study (Brady et al., 00064463) was reviewed that cannot be validated because the sampling protocols, analytical methods, and experimental sites were inadequately described and the data were inconsistently reported. In addition, this study would not fulfill data requirements because characteristics of the soil, litter, water, and test substance were incomplete; the pattern of formation and decline of degradates was not determined; field test data were not reported; and application rates could not be confirmed as highest registered rate. All data are required.

Dissipation studies for combination products and tank mix uses: No data were submitted; however, data requirements for combination products and tank mix uses are currently not being imposed for this Standard.

Long-term field dissipation studies: No data were submitted; however, all data may be required based on the results from aerobic soil metabolism/terrestrial field dissipation studies.

Confined accumulation studies on rotational crops: No data were submitted; however, all data are required.

Field accumulation studies on rotational crops: No data were submitted; however, the requirement for data is deferred pending receipt of data for confined accumulation studies on rotational crops.

Accumulation studies on irrigated crops: No data were submitted; however, no data are required because lindane has no registered aquatic food crop or aquatic noncrop use, is not used in or around holding ponds used for irrigation purposes, and has no use involving effluents or discharge to water used for crop irrigation.

Laboratory studies on pesticide accumulation in fish: One study (Sanborn, 00098842) was reviewed that is scientifically invalid because the procedures were inadequate to estimate the potential of lindane to accumulate in aquatic organisms; i.e., the concentration of water was not compared with the concentration in aquatic organisms over sufficient time to generate accumulation data. This study would not fulfill data requirements because aquatic or-

ganisms were not exposed to a constant concentration of lindane, samples were not fractionated into edible and visceral tissues, the test substance was not characterized, incubation conditions were incompletely characterized, and an adjuvant was applied with lindane. All data are required.

Field accumulation studies on aquatic nontarget organisms: No data were submitted; however, no data will be required unless data in the laboratory fish accumulation study demonstrate accumulation of lindane by fish.

Reentry studies: No data were submitted; however, no data are required because the use pattern is unlikely to result in exposure to agricultural workers.

Label Restrictions

Pending the submission of crop rotation data, it is suggested that crops other than those with registered lindane uses be restricted from being planted in lindane-treated soils.

Soil application: Do not make soil application to root crops which might absorb a musty flavor. Do not apply in soil which will be planted to root crops (except potatoes) within 1 year. Do not use in soil which will be planted to potatoes within 2 years.

Aerial application of lindane is prohibited.

Applicators must wear the following protective clothing during the application process: a lightweight protective suit or coveralls; water-resistant hat; unlined, waterproof gloves; and unlined, lightweight boots. Mixers and loaders must also wear goggles or a face shield, waterproof gloves and waterproof apron. In addition to the above protective clothing requirements, some specific uses require explicit warning:

- a) For dog dust use, lindane should be applied in a well-ventilated area.
- b) For structural treatment, applicators working in enclosed areas such as crawl spaces, must wear a respirator approved by Occupational Safety and Health Administration (29 CFR 1910.134).

c) For dog shampoos, applicators must wear the following protective clothing during the application process: waterproof, elbow-length gloves; a waterproof apron; and unlined, waterproof boots.

For homeowner ornamentals, applicators must wear: long-sleeved shirt, long pants, water proof gloves, full foot covering, and a head covering.

For hardwood logs and lumber, applicators must wear: lightweight protective suit or coveralls; unlined, waterproof gloves; and unlined, lightweight boots.

For dog dips, applicators must wear: elbow-length, waterproof gloves; a waterproof apron; and unlined, waterproof boots.

For moth sprays, applicators must wear MSHA/OSHA-approved cartridge respirators.

For seed treatment, applicators who apply this product manually or without the use of a closed-system treatment procedure must wear: long-sleeved shirt; long pants; gloves; and a disposable, paper dust mask which covers at least one-third of the face. The product must be applied in a well-ventilated area.

For other household uses (shelf paper and household sprays), do not allow children to handle or apply this product. Children and pets should not be allowed in treated areas until sprayed surfaces are dry.

References

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