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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 24 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ID No. 359-686 (RCB NO. 3260) - Lindane
Registration Standard Followup, Storage
Stability - MRID Nos. 404312-03 and 404312-06

FROM: Nancy Dodd, Chemist
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THRU: Charles L. Trichilo, Ph.D., Chief
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TO: Amy Rispin, Chief
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Hazard Evaluation Division (TS-769C)

and

George T. LaRocca, PM 15
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

and

Toxicology Branch (Attention: Edwin Budd)
Hazard Evaluation Division (TS-769C)

The law firm of McKenna, Conner, and Cuneo on behalf of its client the Centre International d'Etudes du Lindane and the Centre's 3 members holding U.S. Lindane registrations [Rhone-Poulenc, Inc. (representing Rhone-Poulenc Agrochemie), E.M. Industries, Inc., (representing Shell Agrar GmbH & Co., KG), and Inquinosa (Industrias Quimicas del Noroeste, SA)] now submit two storage stability studies in response to the Lindane Registration Standard and the Special Data Call-In Notice of January 23, 1986. The studies are "Insecticide: Lindane: Storage Stability Study on Fortified Spinach Samples," P.J. Godward, Laboratory Project No. 572, May and Baker, Ltd.

(England), September 18, 1987 and "Insecticides: Lindane: Storage Stability Study on Fortified Cucumber Samples," P.J. England, Laboratory Project ID No. 569, May and Baker, Ltd., (England), September 18, 1987.

Pertinent data gaps cited in the Registration Standard will be restated below, followed by CIEL's response and RCB's Comments/Conclusions.

Summary of Conclusions re: Data Gaps Covered in this Review

- Storage stability data for lindane residues on a tree fruit (pome or stone) and storage stability data for at least one animal commodity (tissue or milk) are still needed.

- Tentatively, RCB concludes that the storage stability data for lindane (parent) on cucumbers and spinach are adequate for an 8-month period. Whenever the field trials are carried out, those residue data should reflect the storage conditions and storage periods supported by the submitted storage stability data.

- Storage conditions and storage periods for previously submitted residue data are needed.

- If the requisite plant and animal metabolism studies indicate the occurrence of other residues of toxicological concern (besides lindane per se), storage stability data on these residues will also be needed. Therefore, this could constitute a future data gap.

  Note: An update of the pertinent section of Table A of the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard is attached to this review.

Recommendations

1. RCB recommends that the registrant carry out the requested storage stability study for lindane on a tree fruit and at least one animal commodity (tissue or milk).

2. RCB recommends that if plant and animal metabolism studies indicate the occurrence of other residues of toxicological concern, then storage stability data on those residues should also be considered.

§158.125 Residue Chemistry

171-4: Magnitude of the Residue

Storage Stability

The following additional storage stability data were required by the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard:

1. No storage stability data on lindane residues have been submitted for any crop. In the vast majority of the crops for which residue data exists, neither storage conditions nor storage periods are specified. Unless it can be shown that samples were promptly analyzed, data delineating the stability of lindane residues in/on representative crops from three crop groupings (cucurbits, leafy vegetables, and a tree fruit--pome or stone) would be required. Also, data describing the stability of lindane residues in at least one animal commodity (tissue or milk) would be required. The lack of storage stability data on crops and animal commodities constitutes a data gap.

2. If the requisite plant and animal metabolism studies indicate the occurrence of other residues of toxicological concern (besides lindane per se), storage stability data on these residues will also be needed. Therefore, this could constitute a future data gap.

3. Because of the total lack of storage stability data for lindane residues on crops, the magnitude of the residue reported on crops must be regarded with caution.

CIEL's Response

The petitioner has submitted two storage stability studies, one on cucumbers and one on spinach.

Cucumber

A storage stability study was conducted on cucumbers between November 1985 and August 1987. Cucumbers were fortified with ^{14}C-lindane at a concentration of 1 ppm and stored at -20 °C. Samples were analyzed at 0, 1, and 2 weeks; and at 1, 2, 4, and 8 months after fortification. Analysis methods were liquid scintillation counting (LSC) and gas chromatography (GC) with electron capture detection.

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The petitioner submits the following tabulated recovery data:

Percent Recoveries of Lindane on Stored Fortified Cucumber Samples

Storage Period	Replicate	Percentage Recovery LSC		GC	
			Mean		Mean
0	A	93.6	93.3	87.2	87.7
	B	92.9		88.2	
1 Week	A	91.0	90.5	81.0	81.0
	B	90.0		81.0	
2 Weeks	A	87.8	86.4	79.1	79.1
	B	85.0		79.1	
1 Month	A	94.1	93.3	85.8	84.4
	B	92.4		82.9	
2 Months	A	90.1	90.2	82.5	82.0
	B	90.3		81.5	
4 Months	A	93.4	93.8	86.3	87.5
	B	94.1		88.6	
8 Months	A	86.1	79.8	78.7	72.3
	B	73.5		65.9	

Spinach

A storage stability study on spinach was conducted between December 1986 and August 1987. Spinach was fortified with ^{14}C-lindane at a concentration of 1 ppm and stored at -20 °C. Samples were analyzed at 0, 1, and 2 weeks; and at 1, 2, 4, and 8 months after fortification. Analysis methods were LSC and GC with electron capture detection.

The petitioner submits the tabulated recovery data on the following page.

Percent Recoveries of Lindane on Stored Fortified Spinach Samples

Storage Period	Replicate	Percentage Recovery LSC		GC	
			Mean		Mean
0	A	92.5	93.6	89.2	92.7
	B	94.7		96.2	
1 Week	A	94.4	94.7	85.0	86.0
	B	94.9		86.9	
2 Weeks	A	91.2	92.2	85.4	85.7
	B	93.2		85.9	
1 Month	A	91.6	92.0	83.6	84.3
	B	92.4		85.0	
2 Months	A	88.5	89.1	80.8	82.0
	B	89.7		83.1	
4 Months	A	88.0	88.4	86.4	85.0
	B	88.8		83.6	
8 Months	A	83.7	82.2	77.0	77.0
	B	80.6		77.0	

RCB's Discussion/Conclusion re: Storage Stability

The storage stability study on cucumbers indicates that recoveries on cucumbers declined from 93.3 percent at 0 time to 79.8 percent at 8 months when analyzed by LSC, and from 87.7 percent at 0 time to 72.3 percent at 8 months when analyzed by GC.

The storage stability study on spinach indicates that recoveries declinedfrom 93.6 percent by LSC and 92.7 percent by GC at 0 time to 82.2 percent by LSC and 77.0 percent by GC at 8 months.

Some deficiencies related to storage stability which were listed in the Residue Chemistry Chapter of the September 30, 1985 Lindane Registration Standard still remain outstanding. Storage conditions and storage periods for the previously submitted residue data are still needed. Storage stability data on a tree fruit (pome or stone) and storage stability data for tissues or milk are also needed. RCB will tentatively

conclude that the storage stability for lindane (parent) on cucumbers and spinach are adequate for an 8-month period. RCB will reserve its conclusion as to whether or not storage stability studies are needed on any lindane metabolites until the plant and animal metabolism studies have been completed satisfactorily.

Attachment I: Table A

cc: RF,SF,Circu,Reviewer-N.Dodd,W.Boodee,Lindane Registration Standard File, TOX, PM #15, A. Rispin
RDI:JHOnley:3/11/88:RDSchmitt:3/14/88
TS-769:RCB:CM#2:RM810:X1681:NDodd:Kendrick & Co.:3/16/88

TABLE A

GENERIC DATA REQUIREMENTS FOR LINDANE

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission 2/
§158.125 Residue Chemistry					
171-4 - Nature of Residue					
- Plants	PAIRA	Partially		Yes	24 Months
- Livestock	PAIRA and Plant Metabolites	Partially		Yes	18 Months
171-4 - Residue Analytical Method					
- Plant and Animal Residues	TGAI	Partially		Reserved	
171-4 - Storage Stability Data					
Animal Commodities	PAI	No		Yes	18 Months
Plant Commodities	PAI	Partially	MRID 404312-03 MRID 404312-06	Yes	48 Months
	Metabolites	No		Reserved	
171-4 - Magnitude of the Residue - Residue Studies					
- Crop Group #1 - Root and Tuber Vegetables					
o Crop 1 - Beets					
-- Crop field trials	TEP	No		Yes	48 Months

ATTACHMENT I
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