PMSD/ISB

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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ID No. 52904-C. Lindane Registration Standard Followup. Storage Stability Data. MRID No. 406605-02. RCB No. 4035

FROM: Stephanie H. Willett, Chemist
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THRU: Charles L. Trichilo, Ph.D., Chief
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The law firm of McKenna, Conner, and Cuneo has submitted a partial response to Residue Chemistry data gaps cited in the Lindane Registration Standard (9/30/85) on behalf of its client, CIEL, the Centre International d'Etudes du Lindane. The submission consists of a study entitled "Freezer Storage Stability of Lindane in Animal Tissues, Eggs and Milk".

Summary of Conclusions (resulting from the review of the present submission)

1a. The storage stability study submitted is adequate to support the stability of lindane (parent compound) in animal tissues, eggs and milk at -18 ^{o}C for 9 months.

1b. Additional storage stability data may be necessary for

2. Concentration of samples by using a rotary evaporator provided acceptable recoveries for the parent compound lindane. However, an investigation of this mode of concentration (rotary evaporation) would be needed for handling lindane metabolites if they are of toxicological concern.

3. Storage stability data for lindane, and possibly some metabolites, on a tree fruit (pome or stone) are still needed.

Recommendations

1. DEB recommends that the Registrant proceed with his storage stability study on a tree fruit (pome or stone).

2. DEB recommends that the Registrant proceed with resolving plant and animal metabolism issues cited in the DEB (RCB) review of March 24, 1988, after which a decision can be made as to whether or not additional storage stability data for any of the lindane metabolites are needed.

Detailed Considerations

Pertinent data gaps cited in the Registration Standard will be restated below, followed by CIEL's response and DEB's comments/conclusions.

Data Gap (see footnotes 6 and 7, Guidance for Reregistration of Products Containing Lindane, September 1985)

Data delineating the stability of lindane residues in/on representing crops from 3 groupings (cucurbits, leafy vegetables, and a tree fruit - stone or pome) are required. Also, data describing the stability of lindane in at least one animal commodity (tissue or milk) are required. If the required plant and animal metabolism studies indicate the occurrence of residues of toxicological concern (in addition to the parent lindane itself), storage stability on these residues will also be required.

Petitioner's Response

A storage stability study was conducted by Rhone-Poulenc Ag Company for CIEL in order to determine the effects on storage on Lindane in/on animal commodities.

Chicken, beef, egg and milk samples were fortified with Lindane

Chicken, beef, egg and milk samples were fortified with Lindane at 0.5 ppm and stored at -18 ^{o}C. Samples were analyzed after 2, 4, 5, 6, 9 and 12 months of storage. Samples were extracted as described in the AOAC (Official Methods of Analysis, Association of Official Analytical Chemists). Tissue and egg extracts were purified using gel permeation chromatography. Extracts were concentrated using a rotary evaporator and reconstituted with appropriate volumes of hexane for quantitation by EC-GLC. The limit of detection is 0.01 ppm for beef and chicken tissues, 0.05 ppm in eggs, and 0.001 ppm in milk. Recoveries from the various commodities typically average from 80% in milk to 99% in beef muscle and fat, and chicken gizzard. A summary of the storage stability data submitted follows in Table I.

Table I. Recoveries of Lindane from Animal Commodities Fortified at 0.5 ppm, Stored in a Freezer and Analyzed after 2, 3, 4, 5, 6, 9 and 12 Months

Commodity	Lindane Found (ppm) Months->	Percent Recovered
chicken muscle	.49, .43, .45, .32, .33, .42, .34	98, 86, 90, 64, 66, 84, 68
chicken liver	.43, .49, .39, .45, .42, .59, .47	86, 98, 78, 90, 84, 118, 94
chicken heart	.51, .50, .45, .47, .33, .42, .48	102, 100, 90, 94, 66, 84, 96
chicken gizzard	.44, .51, .22, .41, .33, .46, .38	88, 102, 44, 82, 66, 92, 76
beef muscle	.46, .44, .23, ,40, .24, .49, .41	92, 88, 46, 80, 48, 98, 82
beef fat*	.46, .39, .42, .16, .42, .28, .49, .42	92, 78, 84, 32, 84, 56, 98, 84
beef liver	.43, .48, .39, .38, .36, .44, .42	86, 96, 78, 76, 72, 88, 84
beef kidney	.51, .50, .43, .23, .36, .42, .50	102, 100, 86, 46, 72, 84, 100

Commodity	Found (ppm) Months->	Percent Recovered
milk*	.41, .39, .48, .43, .40, .10, .51, .54	82, 78, 96, 86, 80, 20, 102, 108
eggs*	.46, .38, .43, 1.71, .40, .41, .40, .53	92, 76, 86, - , 80, 82, 80, 106

* - Samples analyzed at 1 ,2 , 3, 4, 5, 6, 9 and 12 months of storage

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The registrant concluded that lindane is stable in animal tissues, eggs and milk at -18 °C for at least 9 months. After that time significant residue degradation occurred, particularly in chicken muscle. Over a 12 month period, there was an approximate loss of 32% in chicken muscle. All other substrates showed smaller losses, ≤ 24%. The occasional low recoveries were attributed to the methodology.

Storage stability data on spinach and cucumbers were previously submitted and reviewed by RCB. In that review, DEB (RCB) concluded that storage stability data were adequate for the parent compound for an 8 month period (see memo of N. Dodd, dated 3/24/88).

DEB's Comments/Conclusions

DEB concludes that the storage stability study submitted is adequate to support the stability of lindane parent compound in animal tissues, eggs and milk for 9 months. Additional storage stability data may be necessary for metabolites found to be of toxicological concern.

Storage stability data for lindane, and possibly some metabolites, on a tree fruit (pome or stone) are still needed (see footnotes 6 and 7, Guidance for Reregistration of Products Containing Lindane, September 1985).

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