

Country Status Report: US Lindane Use

Mark T Howard
Office of Pesticide Programs
US Environmental Protection Agency

Presentation Outline:

- Current US Use Patterns
- Quantities
- Production
- Import
- Export
- Regulatory History and Status
- Pharmaceutical Use

Current US Use Patterns

Agriculture – US EPA regulated

- Registered for pre-plant seed treatment for barley, corn, oats, rye, sorghum, and wheat.
- Most other uses (veterinarian, general insecticide, etc.) cancelled in 1998 & 1999.

Pharmaceutical – US FDA regulated

- Human lice and scabies treatment.

Current US Use Patterns - Agriculture

- 99% for Corn and wheat seed treatment use.
- Treatment occurs in seed treating facilities or on individual farms.
- Often co-formulated with other fungicides (e.g., maneb, captan, thiobendazol) and occasionally with the insecticide diazinon.

Quantities – US

- Up to 106 Metric tons (233,000 lbs) of lindane active ingredient (ai) are used annually in the US for seed treatment.
- Average year 64.5 M tons (142,000 lbs) used - 60% of maximum.

Production - US

- 5 registered technical products (99.5% pure lindane) for making end use products imported into US.
- 26 registered end use pesticide products registered for US use. Not all products made every year.
- End use products contain between 6% and 40% of lindane ai.

US Imports

- All lindane technical product used in the US since late 1970s is imported.
- Romania is only source for technical lindane used in US agricultural uses since Dec 2000.
- Worldwide only 3 companies currently manufacture lindane technical product. Romania and 2 in India.

US Exports

US International Trade Commission Data:

● Mexico

- Since 2000, 750 M Tons (1,650,000 lbs) to Mexico.

● Canada

- No export to Canada since 2001
- Approximately 1 M Ton to Canada since 1997.

● South Korea

- 85 M tons (187,000 lbs) over the last two years.

● No other country recently receiving significant quantities from the US.

Regulatory History and Status

- First US registration in 1947 for ear ticks in horses.
- Lindane registrations over time:
 - 286 Companies
 - 949 products
 - 263 use sites
 - 200+ pest species

Regulatory History and Status

Registered Use Sites Have Included:

Fruit crops

Vegetable crops

(including seed treatment)

Landscape ornamentals

Tobacco

Greenhouses,

Forestry

Christmas tree plantations

Hardwood log dips

Livestock dips

Farm animal premises sprays

Domestic outdoor and indoor use by homeowners (including dog dips, household sprays and shelf paper)

Commercial food or feed storage areas and containers

Wood or wooden structure sites

Human skin/clothing/bedding (military use only)

Regulatory History and Status

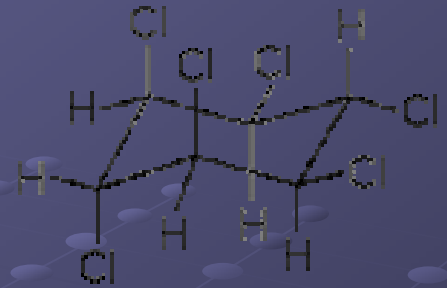
1970s

- Lindane in Special Review. Special Review resulted in some product cancellations and elimination of aerial applications.
- Lindane converted from mixed isomers of HCH to gamma isomer in 1977.

Regulatory History and Status

● Chemistry aside

- Lindane is the gamma isomer of hexachlorocyclohexane (HCH).
- The gamma isomer is the only insecticidally active isomer of hexachlorocyclohexane.
- Gamma isomer is only 12 – 18% of mixture. Alpha is 65%. Beta 11%. Delta 9%.
- Isomers - different chlorine atom ring position.
- Mixed isomers often called BHC.



Regulatory History and Status

- In 1985 Lindane Reregistration Standard issued.

'Reg' Standard

- Set out state of the science at that time.
- Formal document of test data needed.

Regulatory History and Status

- 1998/99 Lindane Reregistration Risk Assessment process begun in earnest. Voluntary cancellations result in removal of all livestock, pet care, turf, general building sprays, foliar crop, timber, lumber, military from the lindane product labels.
- In 2001/02 13 additional (vegetable) seed treatment uses cancelled. 6 seed treatment uses remain.
- 2002 Reregistration Eligibility Decision (RED) issued.

EPA's Lindane RED

- Cancels all 44 *existing* tolerances (obsolete uses).
- Reduces some seed treating rates.
- Reduce worker risk by:
 - Requiring additional protective equipment or engineering controls.
 - Limiting types of formulations used on-farm.
- Requires plant metabolism study for current crops.
- Eligible for reregistration if registrants:
 - Make the label changes required by the RED document,
 - Provide the required product test data, and
 - EPA is able to establish all required tolerances for residues of lindane in food.

Pharmaceutical Use

- FDA Approved for treatment of human ectoparasites (lice and scabies).
- 2 Companies make lice treatment and scabies treatment. 4 products total.
- Less than 1 ton (2,200 lbs) use per year.
I.E., less than 1% of total lindane ai used in US agriculture.
- Lotion and shampoos treatments contain 1% lindane ai.
- FDA recently completed review of lindane labeling.

Pharmaceutical Use

FDA Actions for Addressing Risks:

- Issued Public Health Advisory (March 2003)
- Stronger “boxed” warnings for lindane pharmaceutical products
 - Emphasize lindane is a 2nd line treatment
 - Emphasize caution for children under 50 kgs. Not recommended for infants.
- Increased warnings for immuno-compromised and patients using anti-depressants.

Pharmaceutical Use

- **Maximum product size/dose now 15/30 mL.**
- **Pharmacists will now provide 'plain English' Medication Guide with instructions for use and potential adverse reactions information.**

Further information on US FDA actions visit their lindane web page:

<http://www.fda.gov/cder/drug/infopage/lindane/default.htm> :