COMMENTS ON POPS LINDANE RISK PROFILE

Submitted by CropLife International on behalf of Chemtura Corporation

Contacts:

Mark Trewhitt
BASF Aktiengesellschaft
APD/RRI-LI556
D-67117
Limburgerhof
Germany
Mark.trewhitt@basf.com

Edwin Johnson
Technology Sciences Group Inc.
1150 18th Street NW Suite 1000
Washington DC
20036
United States
ejohnson@tsgusa.com

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CLI and Chemtura appreciate the opportunity to comment on the Lindane Risk Profile prepared for consideration by the POPs working group. We apologize that our comments did not arrive by your deadline, but we were engaged with the EPA risk assessment for lindane and other isomers. Our comments to EPA can be found on the EPA website.

Before getting into specific comments we emphasize the following points:

1. The Risk Profile cites a litany of potential effects based primarily on animal testing studies of lindane and other isomers. But it does not put these into the context of exposure. Risk is a function of hazard and exposure. The Risk Profile needs to take a hard look at exposure to place the risks in context. Especially in light of the limited seed treatment uses remaining for lindane.

2. Production of lindane under modern conditions prevailing in Romania and India does not contribute to waste isomers into the environment. Since the other "waste "isomers are transformed into TCB and HCL for sale as industrial chemicals. Thus placing lindane on the POPs list will not yield any environmental improvement from production nor will it affect residues already in the environment from past uses of HCH.

Comments on LINDANE Risk Profile

Executive Summary (p. 1)

At the beginning of the third paragraph, the Risk Profile states “For each ton of lindane produced, 8-12 tons of other isomers are also obtained.”

In fact, the other isomers are currently used as feedstock to prepare chlorinated benzenes and hydrochloric acid, which are sold. That is, the other isomers are generated, but immediately used to prepare different chemical species, which are salable. As it stands, the statement implies that the other isomers remain within the environment. This is not correct, and is misleading.

In paragraph four, the Risk Profile states the following for lindane … “reported half lives in air, water and soil are: 2.3 days, 3-300 days and up to 2 to 3 years, respectively.”

There is considerable controversy regarding these parameters. First, a half-life for lindane in air has never been measured. Second, official estimates of half-lives in water and soil, respectively, are 30 days and 30 to 45 days (Environmental Health Criteria 124 - Lindane, UNEP, ILO & WHO, 1991).

In paragraph six, the Risk Profile states “HCH isomers, including lindane, are the most abundant and persistent organochlorine contaminants in the Arctic where they have not been used, …”

This statement is not correct. In the Arctic, levels of PCBs (polychlorinated biphenyls) are about the same as, and often exceed, levels of HCH isomers. Further, levels of HCH isomers in the Arctic have steadily decreased over the past decades.

2.1 Sources (p. 7)

In paragraph one of this section, the Risk Profile states "The production of lindane is therefore inefficient as for each ton of lindane (gamma isomer) obtained, 8-12 tons of other isomers are also obtained (IHPA, 2006). According to IHPA (report and Annexes), there have been variations in the production methods for HCH and lindane, as well as for HCH isomers destruction or re-use. However, most of the methods to process or re-use the inactive HCH isomers have been given up over the years and consequently, most of the waste products have been dumped over the last 50 years (IHPA, 2006). The lindane industry claims that modern production technology processes the waste isomers into TCB (trichlorobenzene) and HCl (hydrochloric acid) thereby reducing or eliminating environmental contamination from these byproducts (Crop Life, 2006)."

Parts of this statement are not factual. It is true that at one time waste isomers were disposed of in permitted landfills. Today, however, manufacturers of lindane convert the waste isomers into trichlorobenzenes (TCB) and hydrochloric acid, for which active markets exist. A March, 2006 audit at one producer (in Romania) showed that TCB and hydrochloric acid are in fact manufactured there in concert with production of lindane. A second producer (in India) recently affirmed (May, 2006) the presence and operation of a similar conversion process. Present manufacture of lindane differs from past practice, in that the waste isomers are not simply discarded, but instead are converted to different chemical species (which are sold).

2.1 Sources (p. 7)

In paragraph four of this section, the Risk Profile states the following: "It appears that in the last years the production of lindane has rapidly decreased leaving only a small number of producing countries. Romania, India, China and possibly Russia are the only countries in the world still currently producing Lindane (IHPA, 2006 and USEPA, 2006)."

Lindane is currently produced only in Romania and in India.

2.2.1 Persistence (p. 9)

In paragraph one of this section, the Risk Profile states "Lindane has half lives of 3-30 days in rivers and 30 to 300 days in lakes. Other studies report calculated or experimental hydrolysis half lives ranging from 92 to 3090 hours depending on the study; a persistence of about 2 to 3 years in soil is also reported …"

As noted above, there is considerable controversy regarding these parameters. First, a half-life for lindane in air has never been measured. Second, official estimates of half-lives in water and soil, respectively, are 30 days and 30 to 45 days (Environmental Health Criteria 124 - Lindane, WHO, 1991).

2.2.3 Potential for long-range environmental transport (p. 10)

In paragraph one of this section, the Risk Profile states "HCH isomers are the most abundant and persistent organochlorine insecticide contaminants in the Arctic ,,,"

As noted above, this statement is not accurate. In the Arctic, levels of PCBs (polychlorinated biphenyls) are about the same as, and often exceed, levels of HCH isomers. Further, levels of HCH isomers in the Arctic have steadily decreased over the past several decades.

2.2.3 Environmental monitoring data (p. 12)

In paragraph two of this section, the Risk Profile states "A total of 186 bottom sediment specimens were also surveyed in 2003 and Lindane was detected in all the specimens, with a concentration of Lindane of 4,000 pg/g dry."

This sentence is unclear. Were 186 specimens composited, and the composite contained 4,000 pg/g? Or was each analyzed separately, and each contained 4,000 pg/g?

2.3 Exposure (p. 13)

In paragraph one of this section, the Risk Profile states "More than 90% of human exposure to all HCH isomers, including lindane, originates from food sources, particularly those that are animal-based (WHO, 1991). Other sources of direct exposure include facilities at which lindane is still being produced, abandoned pesticide plants, and hazardous waste sites…"

First, HCH isomers other than lindane are not currently used on any food crop, or on any animal used for food. Second, during production there is only a potential for exposure to HCH. The Romanian production works (audited in March, 2006) takes great care in producing HCH, lindane, TCB, and hydrochloric acid, and controls exposure to its workers stringently, through engineering means. The Risk Profile also fails to acknowledge that the use of lindane in agriculture has been greatly restricted in the years since the WHO statement and that dietary exposure to Lindane is now negligible (see US EPA RED of 2002). Currently, the primary route of human exposure to lindane is from pharmaceutical uses.

The conclusion in Section 2.3 that indigenous people are more likely to be exposed to HCH isomers is not consistent with the extensive evaluation of maternal blood levels of beta isomer that was recently published by Van Oostdam et al., (2004). In this study, Inuit populations of in Greenland, Canada and the North Slope of Alaska were found to have similar blood levels of this isomer as the general populations in Norway, Sweden and Finland and lower levels than the general population in Iceland.

2.4 Hazard assessment for endpoints of concern (p.14)

The second paragraph of Section 2.4 states that “some evidence is available for immunotoxic effects…” The paragraph fails to note that this evidence came from non-GLP studies with lindane of uncertain quality. The recent Lindane Review Board in Canada, after carefully considering the evidence, concluded “In the Boards opinion, the evidence for Lindane-related immunotoxicity is not compelling.”

The third paragraph of Section 2.4 states that lindane causes hepatocarcinogenicity in mice and thyroid tumors in rats. Studies showing no carcinogenicity are dismissed due to “poor survival rates”. These conclusions are not consistent with those of the US EPA in the RED or with those of the 2002 JMPR. The US EPA has acknowledged that lindane causes an increase in tumors in mice only at levels that approach or exceed the Maximum Tolerated Dose. The JMPR concluded that “In the absence of genotoxicity and on the basis of the weight of the evidence from the studies of carcinogenicity, the Meeting concluded that lindane is not likely to pose a carcinogenic risk.” The Risk Profile should be amended to reflect these recent evaluations of carcinogenicity by these authoritative bodies. The summary of carcinogenicity data that is currently in the Risk Profile is neither accurate nor up-to-date.

The discussion of reproductive toxicity fails to acknowledge the high quality, state-of-the-art studies that were submitted to and reviewed by the US EPA. The Risk Profile cites only a single published study that is also discussed in the US EPA evaluation of the three isomers. This large body of information concerning reproductive toxicity allows the establishment of No Observed Adverse Effect Levels that can be used in risk assessment. The risks of reproductive toxicity from the use of lindane are negligible. Acceptable risks for reproduction and other all endpoints of toxicity were determined by the US EPA for occupational and dietary exposures to lindane.

The Risk Profile fails to distinguish between signs of poisoning seen in cases of misuse or suicide attempts and the history of safe use that is evident when lindane label directions are followed. No support is provided in the Risk Profile for the statement that lindane is associated with respiratory, cardiovascular, hematological, hepatic and endocrine effects in humans. As discussed in the US EPA RED, very few adverse effects have been associated with the use of lindane in the US in recent years.

3. Synthesis of Information (p. 16)

In paragraph four of this section, the Risk Profile states “Although current production of lindane seems to be declining with only a few producing countries remaining, the inefficient production process used to manufacture this insecticide over the years has been a world wide contamination problem which has left, and might still be leaving behind, an enormous legacy of contaminating waste products …”

At one time unused isomers of HCH were sent to permitted landfills. Today, however, the waste isomers are converted to different chemical species, which are sold. The production process does not “still” leave behind waste products leading to any form of environmental contamination.

Conclusions

In summary, the hazard and exposure information in this Risk Profile is misleading and outdated. Although the document is entitled “Risk Profile” there is no discussion in the document of the risks associated with the very limited uses of lindane in agriculture and medicine. These risks are clearly negligible.