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

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 5-Chloro-2-(2,4-dichlorophenoxy)phenol (Triclosan): Review of data on the safety of the active ingredient.

EPA Identification Numbers:

P.C. Code: 054901

DP Barcode: D248056

MRID's: 44604001 through 44604007

Submission: S546510

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Action Requested: Review of data submitted in support of the safety of Triclosan.

Background

Seven volumes of data were submitted by Microban Products Company regarding the safety of Triclosan (Irgasan). Two of these volumes (MRID's 44604003 and 44604007) presented Toxicology data, while the remaining five volumes presented data on the chemistry, impurities, and exposure to Irgasan contained within toothpaste handles and bristles. Only the Toxicology aspects are examined in this memorandum.

Detailed Considerations

In MRID # 44606007, a re-print of an article published in the American Journal of Dentistry was submitted. This article, entitled "Triclosan: A Safety Profile," was published in 1989 and contained data submitted to the FDA's OTC Review Panel by Ciba-Geigy in support of the use of Triclosan in toothbrushes. This paper summarizes the Toxicity data available at that time for Triclosan, and includes data on the acute, subchronic, chronic, carcinogenicity, mutagenicity, reproduction and teratology, and metabolism of Triclosan. Part of this database has already been reviewed by the EPA and is being used in support of the risk assessment for this chemical. Certain data have also been conducted for both FDA and EPA since publication of this paper and represent more current toxicity data than that referenced in this publication. However, it is noted that an 8-week inhalation toxicity study, in which rats were exposed to concentrations of Triclosan of 50, 115, and 301 mg/m³ for 2 hours per day, 5 days per week, has not been previously submitted to or reviewed by the EPA. As mortality was reported at the high dose after only a 2 hour exposure per day (normal exposure time is 4 hours or longer), these data are of interest to EPA.

In MRID # 44604003, a summary of the Toxicity data for Triclosan is also presented, this summary having been prepared by Microban Products Company. Some of the data presented is the same as that summarized in MRID # 44604007, while some data represent more recent Toxicology studies conducted by Ciba. There is no additional information in this summary to aid in the current safety determination of Triclosan.

Conclusions

RASSB has reviewed the Toxicology summary data submitted in the present package of materials, and concludes that most of the data do not add any significant new findings on the toxicity of Triclosan. An inhalation study referenced in DeSalva et al.'s publication Triclosan: A

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safety profile (American Journal of Dentistry, Vol.2, Special Issue, September 1989), conducted for 8 weeks, does appear to add new information on the safety of Triclosan, and it would be beneficial for EPA to obtain this study if possible.

Note to PM: According to PRAT, this data package was routed for toxicology review only. The other volumes of this data package need to be examined by scientists in the appropriate disciplines, i.e. human exposure and chemistry.