

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES



January 14, 2008

MEMORANDUM:

Subject: Dietary and Drinking Water Exposure Chapter for Tributyltin-Containing Compounds for the Reregistration Eligibility Decision (RED) Document (Case 2620)

To: Jill Bloom, Chemical Review Manager
Special Review & Reregistration Division (SRRD)

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DP Barcode: 347646

Chemical Names: Tributyltin oxide (TBTO)
Tributyltin benzoate (TBTB)
Tributyltin maleate (TBTM)

PC Codes: 083001, 083106, 083118

CAS Registry No. TBTO: 56-35-9
TBTB: 4342-36-3
TBTM: 4027-18-3

Attached is a review of the dietary and drinking water exposures for the antimicrobial uses of tributyltin-containing compounds (TBTO, TBTB, and TBTM) to support the Reregistration Eligibility Decision (RED) document.

I. Dietary Exposures to Tributyltin-Containing Compounds

The Antimicrobials Division (AD) assessed the potential dietary exposures for the antimicrobial uses of tributyltin (TBT)-containing compounds, tributyltin oxide (TBTO), tributyltin benzoate (TBTB), and tributyltin maleate (TBTM).

TBT compounds can be used in following use sites where a potential for food contact appears to exist:

- Algicides in water cooling systems for pasteurization/canneries, soft drink and food canning plants
- Algicides in paper mills
- Materials preservative in adhesives

However, all of the TBT labels that have one of these use sites that might pose a potential for contacting food, contain specific “non-food contact” requirements or use directions that minimize the indirect dietary exposure. For example, the label of a product containing directions for use in paper mills (EPA Registration #47371-29) contains the statement, “Do not use in the manufacture of paper which will have direct or indirect contact with food.” At this time, no registrant has indicated that it wishes to support of the use of TBT in pasteurization/canning or paper mills.

The registrants of products bearing labels with directions for use in manufacturing adhesives have indicated that such adhesives are used in applications such as attaching face fibers to carpet backing. It should be noted that TBTO has an FDA clearance under 21 CFR 175.105 as a material preservative in adhesives for use in food packaging, implying that there is a potential for indirect dietary exposure. However, during the SMART meeting, the registrants indicated that they did not intend to support this indirect food use. Therefore, all of the TBTO labels used as a materials preservative for adhesives must state “for non-food contact adhesives.”

It should be further noted that although there are no FDA clearances for any TBT compounds for the pulp and paper uses, the labels all state for non-food contact paper. In order for AD to accept non-food contact language for pulp and paper mill uses, examples of non-food contact paper (i.e., newsprint, Kraft paper, brown paper mills, sheets for corrugated board) must be listed on the labels.

One registrant holds a registration for a product that is used to manufacture household sponges, scouring pads, and sponge mop-heads. This registration (EPA Registration #10466-28) contains the TBTM active ingredient. The use of TBTM will be assessed for incidental exposure for food contact surfaces and floors in the ORE assessment.

In the livestock operation use, hogs, cattle, and poultry are removed prior to the microbiocide treatment and the feeding equipment is rinsed prior to use. The premises must be aired for 24 hours after treatment, and another 24 hours must pass before animals can be returned to the treated areas—a total of 48 hours after application.

AD assumes that removing animals prior to treatment and rinsing feeding equipment after treatment results in negligible residues in the animals living in treated facilities. For this reason, AD does not typically assess livestock premises.

In the case of the TBTO product used in animal housing facilities, the Agency believes there may be a greater potential for animals to be exposed, and thus, a potential for human dietary exposure. This potential is a result of the way in which such treatments are conducted and the particular fate characteristics of TBT. Specifically, 1) the product label does not require rinsing or removal of TBT solution or fogging residue after treatment (except for feed bowls not removed during treatment), 2) animal premises may be treated frequently, and 3) TBT is environmentally persistent and bioaccumulative. The product label should indicate that treated surfaces must be rinsed before animals can be re-housed, although whether this is feasible when applications are made with a fogger rather than by immersion, spraying, mopping, or foaming is not clear. Data are needed to improve our understanding of the scope of actual exposures in animals exposed to TBT via this use. Data on the effectiveness of rinsing in removing TBT residues from the treated premises, and residue data in the associated food commodities will enable the Agency to further refine the assessment of the animal premises use.

AD has, in the past, assumed that incubating eggs do not absorb pesticide chemicals as the result of hatchery treatments, but data are lacking to support the assumption. The hatchery use of TBTO (hatchery rooms, incubators, and hatcher) may pose a greater likelihood of producing residues in eggs. As discussed above, the environmental fate characteristics of TBT may present additional opportunities for dietary exposure. The label of the one TBTO product registered for use in hatcheries provides use directions for fogging equipment, and incubating eggs are not removed from the premises during treatment. The registrant has indicated that eggs removed from the premises for repeated applications of the product will not be viable. In addition, premises may be treated as frequently as once a day. The label does not require that surfaces exposed via fogging be rinsed after treatment, and removing the residues left behind after fogging may not be adequately achieved by rinsing. A chemical like TBT, with its large potential for persistence and bioaccumulation, could pose an increased risk of residues in eggs relative to other pesticides of lesser persistence and bioaccumulative potential. Data appropriate for use in examining the assumption that this pesticide does not penetrate eggshells in incubation would facilitate a quantitative assessment of dietary exposures resulting from the use of TBT in hatcheries.

II. Drinking Water Exposure to Tributyltin-Containing Compounds

AD assessed the potential drinking water exposures for the antimicrobial uses of tributyltin-containing compounds, tributyltin oxide (TBTO), Tributyltin benzoate (TBTB), and Tributyltin maleate (TBTM). Based on the use patterns, the potential for TBT, TBTM, or TBTO to impact drinking water sources is negligible and therefore a quantitative drinking water assessment was not conducted. However, data are lacking to characterize the effectiveness of water used to rinse animal housing facilities after treatment, and conversely, the fate and concentrations of TBT in the rinse water.