Triclosan Facts

Current as of March 2010

Triclosan (2,4,4' –trichloro-2'-hydroxydiphenyl ether) is a chlorinated aromatic compound. Its functional groups include both phenols and ethers. It is used as a synthetic broad-spectrum antimicrobial agent. Triclosan was first registered as a pesticide in 1969.

EPA completed its reregistration eligibility decision (RED) for the pesticide uses of triclosan in 2008. The RED is available on EPA's Web site. In addition, the RED, revised risk assessments and Response to Comments document are available in the federal docket at: http://www.regulations.gov in docket number EPA-HQ-OPP-2007-0513.

Uses of Triclosan

Triclosan is an antimicrobial active ingredient contained in a variety of products where it acts to slow or stop the growth of bacteria, fungi, and mildew. There are currently 20 antimicrobial registrations, which EPA regulates under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

There are also consumer uses of triclosan, such as its use in over-the-counter drugs (e.g., antimicrobial hand soaps and some toothpaste). These drugs are regulated by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act (FFDCA). Although the FDA uses are not regulated under pesticide law, EPA considered these exposures in the aggregate risk assessment. EPA used population-based biological monitoring data to assess the co-occurrence of uses to develop an aggregate exposure assessment.

Triclosan uses include:

- commercial, institutional, and industrial premises and equipment;
- residential and public access premises; and
- as a materials preservative.

Triclosan is used as a registered pesticide only in a small portion of its overall uses. In commercial, institutional, and industrial equipment uses, triclosan is incorporated in conveyor belts, fire hoses, dye bath vats, or ice-making equipment as an antimicrobial pesticide. Triclosan can be directly applied to commercial HVAC coils, where it prevents microbial growth.

As a material preservative, triclosan is used in many products including adhesives, fabrics, vinyl, plastics (toys, toothbrushes), polyethylene, polyurethane, polypropylene, floor wax emulsions, textiles (footwear, clothing), caulking compounds, sealants, rubber, carpeting, and a wide variety of other products. It has been used in latex paints; however registrants who use it in paint have recently requested a voluntary cancellation.

Summary of the findings of the risk assessments

Human Health

EPA conducted a human health risk assessment for triclosan to support the reregistration eligibility decision. EPA evaluated toxicology, product and residue chemistry, and occupational/residential exposure studies as well as available open literature and determined that the data are adequate to support the reregistration decision. EPA conducted these assessments using available animal studies.

In its reregistration review, EPA considered all available data on triclosan, including data on

- endocrine effects,
- developmental and reproductive toxicity,
- chronic toxicity, and
- carcinogenicity.

The 2008 EPA assessment relied in part on the 2003-2004 data available from the National Health and Nutrition Examination Survey (NHANES) measurements of urinary concentrations of triclosan in the U.S. population. Therefore, the 2008 EPA assessment is inclusive of all triclosan-related exposures (i.e., EPA and FDA regulated uses).

Aggregate Assessment and Regulatory Determination

EPA conducted an aggregate assessment using the NHANES data to evaluate the potential for co-occurrence of uses, including the uses that are regulated by the FDA (e.g. antimicrobial hand soaps, toothpaste, deodorants, cosmetics, and medical devices).

The Agency determined that, with the exception of preservative use of triclosan in paints and stains, pesticides containing triclosan met the statutory safety standard in FIFRA, provided that risk mitigation measures as outlined in the RED were implemented, confirmatory data gaps were addressed, and label amendments were incorporated as presented in the RED document. Subsequent to the issuance of the RED, the registrant of triclosan products for use in paints and stains voluntarily requested cancellation of the registration of products for these uses.

Assessment being updated with recent data

EPA is updating its 2008 assessment of triclosan exposure using the newly released 2005-2006 NHANES urinary monitoring results. Once completed, EPA will post its revised assessment in the public docket, and revisit its regulatory decision, if the science supports a change.

Since the 2008 assessment, additional data on effects of triclosan on thyroid hormones and estrogen-related effects have also been made available from EPA's Office of Research and Development (ORD). ORD studies on the thyroid and estrogen effects led EPA to determine that more research on the potential health consequences of endocrine effects of triclosan is warranted. This research is underway and will help characterize the human relevance and potential risk of these effects observed in initial laboratory animal studies.

The Agency has previously indicated that because of the amount of research being planned and currently in progress, it will undertake another comprehensive review of triclosan beginning in 2013. The Agency will pay close attention to the ongoing endocrine research and will amend the regulatory decision if the science supports such a change.

Environmental Fate and Ecological Risks

Based on available data, triclosan is expected to be immobile in soil and is not expected to volatilize from soil (moist or dry) or water surfaces. In aquatic environments, triclosan is expected to attach to the surface of suspended solids and sediments and may bioaccumulate, potentially posing a concern for aquatic organisms.

There is also a low-to-moderate potential for bioconcentration in aquatic organisms. The majority of published studies on the occurrence of triclosan in waste water treatment plants, treatment plant efficiency, and open water measurements of triclosan suggest that aerobic biodegradation is one of the major and most efficient biodegradation pathways.

Based on monitoring data, triclosan was found in approximately 36 U.S. streams where effluent from activated sludge waste water treatment plants, trickle-down filtration, and sewage overflow appear to contribute to the occurrence of triclosan in open water.

EPA performed a qualitative environmental risk assessment using levels of triclosan found through monitoring data in waterways and toxicity values to develop risk quotients (RQs) and compare them to levels of concern (LOCs) for triclosan. LOCs were not exceeded for fish but were exceeded for aquatic plants.

In addition, the Agency performed consumer environmental modeling for triclosan, which demonstrated that estimated concentrations of triclosan in surface water do not exceed concentrations of concern for acute risk for aquatic organisms and plants.

Considering the low probability of triclosan being released into household wastewater and surface waters from EPA-regulated antimicrobial uses, the Agency also concluded that chronic aquatic risks are unlikely originating from consumer uses of triclosan-treated plastic and textile items. Therefore, the Agency can reasonably conclude that the antimicrobial uses of triclosan (e.g., triclosan-treated plastic and textile items in households) are unlikely to contribute significant quantities of triclosan into household wastewater and eventually in surface water.

Additional requirements for technical registrants

Because it is unknown how much triclosan is released from industrial sites (where triclosan is incorporated into plastic and textile items) into the environment the Agency is requiring the technical registrants to perform environmental modeling and surface water monitoring. In addition, EPA is requiring pesticide registrants to add labeling statements indicating that triclosan is toxic to fish and other aquatic animals, and that any discharges into waterways need to conform to the requirements of the National Pollutant Discharge Elimination System (NPDES).

Depending upon the results of this modeling and monitoring effort, additional ecological effects data may be required. Four studies to address bioaccumulation potential will also be required, as well as one environmental fate study.

Next Steps

- Given the rapidly developing scientific database for triclosan, the Agency intends to accelerate the schedule for the registration review process for this chemical. Currently, the Agency intends to begin that process in 2013, ten years earlier than originally planned.
- EPA and FDA are collaborating on research projects that will help both agencies to better characterize the endocrine-related effects of triclosan, including toxicological effects, human relevance, and the doses at which they occur to determine if levels of human exposure are safe or not. The Agency will pay close attention to this ongoing research and will amend the regulatory decision if the science supports such a change.
- The Agency is also updating its 2008 assessment of triclosan exposure using the newly released 2005-2006 NHANES urinary monitoring results and will incorporate those results into the revised risk assessment.
- The Agency will continue to participate in the Interagency Task Force on Antimicrobial Resistance and evaluate information that results from that activity, and will continue its cooperative efforts with the FDA to share information on triclosan and discuss future research efforts and needs that will best meet the needs of the two agencies.

Related Information

The RED, revised risk assessments and Response to Comments document are available at EPA's public docket: www.regulations.gov EPA-HQ-OPP-2007-0513