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**Final**

**Antimony Trioxide Is Safe for Use  
as a Catalyst in Polyethylene Terephthalate (PET)**

Antimony trioxide (ATO) has been widely used as a catalyst in the production of polyethylene terephthalate (PET) plastic for nearly thirty years. Consumers can be assured that ATO used in food and beverage containers made from PET is well tested and regulated for safety and does not pose a risk to human health.

A wide variety of consumer packaging fabricated from PET uses ATO, not just bottled water containers. Levels reportedly detected in some bottled water samples are simply trace elements or "background noise" and are far, far below health standards and guideline set by national and international regulatory and official health organizations.

ATO also is widely used in the production of PET plastic because of its high quality and performance characteristics.

**Federal Regulations and International Guidelines**

**In the United States**, the U.S. Food and Drug Administration (FDA) comprehensively regulates safety of food, including bottled water, by carefully reviewing food and beverage packaging materials, such as PET made with an ATO catalyst, before allowing them on the market.

As part of its review, FDA assesses the migration potential of plastics and the substances with which they are made. Tests under laboratory conditions have found that migration from PET, including migration data for ATO, is well below levels considered to be safe. FDA, and the Environmental Protection Agency (EPA), which regulates tap water, both have an antimony standard of 6 ppb.

FDA allows food-contact plastics for their intended use based on migration and safety data. The clearance process includes stringent requirements for estimating the levels at which such materials may transfer to the diet. FDA's safety criteria require extensive toxicity testing for any substance that may be ingested at more than negligible levels. This means FDA has affirmatively determined that, when plastics are used as intended in food-contact applications, the nature and amount of substances that may migrate, if any, are safe.

**In the international marketplace**, the World Health Organization (WHO) and European Food Safety Authority (EFSA) have established guideline values, or limits, which they have determined to be safe for ingestion of ATO in food and drinking water. These guidelines are set according to very conservative criteria designed to protect public health and are applicable to food and beverage containers.

## Demonstrating Compliance with Safety Guidelines

Based on a significant body of available safety data, WHO has set a guideline value for antimony in drinking water of 18 parts per billion (ppb), noting in its evaluation that this value “could be highly conservative.” A level of 18 ppb in drinking water represents only 10 percent of the total acceptable daily intake level that WHO has established for antimony. In addition, the European Food Safety Authority (EFSA) has set a migration limit for antimony in food at 40 ppb.

The migration of antimony from PET bottles into beverages has been demonstrated repeatedly to be less than 6 ppb – well below WHO’s and EFSA’s guideline values. In most cases, antimony is not detected in migration tests using protocols that represent common use conditions.

## Scientific Testing and Evaluation

The toxicological properties of PET and compounds that migrate under test conditions have been well studied. In its report on PET in food packaging applications, the International Life Sciences Institute (ILSI) summarizes the large body of test data that demonstrates the safety of PET resins and compounds from food and beverage containers.

*“PET itself is biologically inert if ingested, is dermally safe during handling and is not a hazard if inhaled. No evidence of toxicity has been detected in feeding studies using animals. Negative results from Ames tests and studies into unscheduled DNA synthesis indicate that PET is not genotoxic. Similar studies conducted with monomers and typical PET intermediates also indicate that these materials are essentially nontoxic and pose no threats to human health.”<sup>1</sup>*

ILSI’s findings also support the safe use of ATO catalysts, noting that “a new and very comprehensive animal feeding study concludes that there is no risk arising from the use of antimony trioxide in PET products,” and “in all cases no adverse effects have been observed at exposures expected to occur from the use of PET packaging systems.”

Questions about the safety of ATO were raised by the International Agency for Research on Cancer’s (IARC) classification of ATO as a possible human carcinogen. IARC’s classification was based on inhalation studies in which laboratory animals were exposed to large daily doses of antimony trioxide dust over an extended period of time. Because the ATO catalyst is bound to the PET polymer and not available for inhalation, these concerns are not applicable to ATO’s use as a catalyst in the production of PET.

The latest findings continue to confirm that ATO catalysts used in the production of PET food and beverage containers do not pose a risk to human health.

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<sup>1</sup> Packaging Materials: 1. Polyethylene Terephthalate (PET) for Food Packaging Applications. International Life Sciences Institute; 2000, Washington, DC, p. 11-12.