Tolerance Reassessment Decision (TRED) for Bromine

September 30, 2005

United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510C)

September 26, 2005

Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Bromine

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) "Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision for Bromine," which was approved on September 26, 2005. This document is also known as a Tolerance Reassessment Decision, or TRED. A Notice of Availability of this tolerance reassessment decision will be published shortly.

Regulatory Determination

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, requires EPA to reassess all the tolerances for registered chemicals in effect on or before the enactment of the FQPA on August 3, 1996. In reassessing these tolerances, the Agency must consider whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. Once a safety finding has been made, the tolerances are considered reassessed. Any existing tolerances associated with bromine must be reassessed in accordance with FFDCA, as amended by FQPA.

Bromine is an active ingredient in four products; two products with multiple active ingredients and two products as the sole active ingredient. The multiple active ingredient products control mold, mildew, fungi, insects, and odors in exposed surfaces of bedding, mattresses, textiles, drapes, upholstered furniture, rugs, carpets, and storage areas. The other two bromine products, formulated as cartridges, are used to disinfect drinking water in nonresidential settings. The ready-to-use liquid products containing bromine as well as other active ingredients are intended for household, farm premises, and animal quarters use. Use of the two drinking water bromine products is for ships and oil rig platforms.

The Agency has issued two reregistration eligibility decision documents for bromine: the Bromine RED (case 4015) and the Inorganic Halides RED (case 4051). A tolerance exemption for use of residual bromine in potable water has been granted. In the 1993 Bromine RED, the Agency indicated the need for confirmatory data (i.e., 171-4(f) magnitude of residue in potable water) to alleviate potential concerns about the conversion of bromine into bromate, which is a known carcinogen. In response to the data call-in, two studies were conducted to determine the magnitude of bromate residues in potable water. At the pH level expected for drinking water disinfection on ships/oil platforms, the bromate levels in these studies were non detect. Hence at this time the Agency does not have concerns for the use of bromine as a drinking water disinfectant (on ships/oil platforms).

The Agency has evaluated all current registered uses of bromine and has determined based on available data, that there is a reasonable certainty that no harm to any population subgroup will result from exposure to bromine. Therefore, no mitigation measures are needed, and the current tolerances established at 40 CFR180.519 for residues of residual bromine in potable water are now considered reassessed under section 408(q) of the FFDCA.

Risk Assessment

The Agency has issued two reregistration eligibility decision documents for bromine. In both of the Agency's RED documents, it was noted that the chemicals of toxicological concern for human health assessments were bromide/sodium bromide. The active moiety, bromide, is a normal constituent of the human diet and the expected exposures from the uses considered at that time were determined to be minimal. The Agency also concluded that there was no need for a quantitative assessment from exposure to bromine containing products.

. This assessment summarizes the available information on the use, physical/chemical properties, toxicological effects and exposure profiles for bromine. The potential human health effects for the tolerance use and residential exposure to bromine are evaluated in this document as required for tolerance reassessment. An aggregate exposure and risk assessment for bromine is not necessary because it was determined that there are no overlapping exposures to bromine. Exposures to the household product uses of bromine are negligible based on the low concentration of bromine in those products (i.e., 0.04 percent). In addition, an aggregate assessment of the breakdown product of bromine (i.e., bromide ion) and the registered uses of sodium bromide are also not necessary because there are no toxicological endpoints of concern for bromide ion. The reader is referred to the sodium bromide sanitizer assessment (EPA DP No. 321794) and the sodium bromide residential use assessment (i.e., swimming pools, spas, sugar beets, and fruit &vegetable wash) (EPA DP No. 321793) for specific details on the risk assessment for bromide ion. Finally, because this document is a TRED, it does not include an occupational risk assessment.

There are a total of four bromine products; all formulated as ready to use (RTU). Two of the products are liquids with a 0.04 percent concentration of bromine and may be applied by hand or power sprayers, wipes or foggers at the current maximum application rate. The other two products, both formulated as 30 percent bromine cartridges, are for treating drinking water on Navy ships and oil rig platforms. These cartridges are ready to use at a maximum application rate of 1 ppm.

The Bromine/Bromide - Report of the Antimicrobials Division Toxicity Endpoint Selection Committee (USEPA, 2005b) indicates that there are no toxicological endpoints of concern specifically for bromine for the dermal and oral exposure routes because exposure of bromine to aqueous media or acidic conditions results in rapid conversion to bromide. The exposure/risks to bromide are being assessed in a separate document. Since no toxicological endpoints of concern were identified for bromine via the dermal and incidental oral routes of exposures, residential exposures for these routes is not assessed in this document. In addition,

because the exposure to bromine products in residential settings is expected to be negligible due to the low percentage of bromine in registered products (i.e., 0.04 percent) no inhalation toxicological data were selected. Therefore, inhalation exposures were not assessed quantitatively in this document.

Acute toxicity specific to bromine are not available. However, bromine readily converts to bromide ion in mammals. Therefore, the acute toxicity values and toxicity categories for bromide are given. Bromide is classified as Toxicity Category III for acute dermal and oral toxicity and Toxicity Category IV for dermal irritation. The data indicates that bromide is of low acute oral and dermal toxicity and causes mild eye and skin irritation.

This document summarizes the Agency's decision on the tolerance reassessment for bromine. Please contact Sharon Carlisle of my staff with any questions regarding this decision. She may be reached by phone at (703) 308-6427 or by e-mail at carlisle.sharon@epa.gov.

Sincerely,

Frank T. Sanders, Director
Antimicrobials Division

Enclosures: *Risk Assessment for Bromine*

Bromine/Bromide - Report of the Antimicrobials Division Toxicology Endpoint Selection

Potassium Bromide and Sodium Bromide Tolerance Reassessment Decision Document (Sanitizer Use)

Dietary Assessment of Sodium Bromide for Bromine and Sodium/Potassium Bromide RED