



Response to U.S. Department of Defense TBBPA Risk Alert

I. Introduction

Tetrabromobisphenol-a (TBBPA) is a chemical intermediate that provides flame protection of virtually all types of electronics used by the DoD. Recent comprehensive assessments of TBBPA in both Canada and the European Union have found that consumer exposures to TBBPA are not likely to cause adverse health effects in humans or the environment. While alternative flame retardants currently exist, they have not yet been qualified for the DOD supply chain, will be more expensive on a per unit basis and will not provide an improvement to the risk profile of printed circuit boards.

II. Uses of TBBPA

Tetrabromobisphenol-a (TBBPA) and its derivatives are the most commonly used brominated flame retardants by manufacturing volume in the U.S. TBBPA is incorporated into products in two-ways (1) reactively – where it is molecularly bonded into the matrix of the treated polymer, and (2) additively – where it is physically combined with the material being treated, rather than chemically bonded.

The main application (approximately 90 percent) of TBBPA is as a chemical intermediate in the production of epoxy resin for laminates used for printed circuit boards (PCBs). TBBPA in printed circuit boards serve a vital role of improving the fire safety of virtually all types of electronics, and civilian and defense communication equipment requiring FR-4 protection meeting V0 requirements of the UL-94 Standard. Its role in printed circuits has become increasingly important as the miniaturization of electronics in which the use of loaded and condensed laminates produce more heat within smaller devices.

Printed circuit board technologies are critical components of nearly every DoD weapon system including bomb guidance, missile guidance, radar systems, land vehicles, submarine systems, battleship systems, etc. Combined DoD electronics, information technology, and electro-optics are estimated to account for roughly 15% of the total DoD budget. Fundamental to military operations, high-density ruggedized and reliable printed circuit boards are incorporated into all navigation, guidance, surveillance, and communication systems, including severe-service items used in extreme conditions (temperatures, high impact/vibrations, or submerged).

TBBPA may also be used as an additive flame retardant in acrylonitrile-butadiene-styrene (ABS) plastics and less commonly, in high-impact polystyrene (HIPS) and phenolic resins. ABS resins containing TBBPA are used in automotive parts, pipes and fittings, refrigerators, prototypes, structural components, support blocks, housings and covers.



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III. Hazard vs. Risk

Consideration of both hazard and actual exposure to understand risk is a fundamental tenant of effective chemical management. Risk to humans and/or the environment is a function of toxicity, a property inherent to the chemical, and of extent to which a human, or plant or animal species is exposed to the chemical. We are exposed to many chemicals, both natural and synthetic, every day that have inherent toxicity, but because of the level of exposure and/or our body's ability to detoxify many of these chemicals, risk is low or nonexistent.

The mere presence of a chemical needs to be considered in relation to actual levels that might cause adverse effects to human health or the environment.

The primary value of a risk assessment is to aid in the establishment of priorities for further review and/or action. Some exposures to certain populations may warrant potential management such as regulation, labeling or restrictions, whereas others may not require any action.

IV. TBBPA: Recent Science

TBBPA is used mainly as a reactive flame retardant in the base material for PCBs. The manufacture of PCBs is a multi-step process during which TBBPA is reacted into the epoxy resins that form the base material for the PCB. During this process, essentially all the TBBPA is reacted into the epoxy resin laminate that forms the base material for printed circuit.¹ Used in this way, the potential for exposure to TBBPA is extremely low.

Most of the remaining TBBPA is used as an intermediate for production of other polymeric FRs which are also reacted and as an additive in acrylonitrile butadiene styrene (ABS) plastic, where it is encapsulated in the polymer matrix.

When used as an additive to ABS, the TBBPA is encapsulated in the polymer matrix.. TBBPA is used with ABS specifically because it melts at a temperature that allows it to "flow" with the ABS in the molding process. Because TBBPA is embedded within the plastic matrix, the potential for exposure when it is encapsulated in plastic is very low.²

Although relatively low, TBBPA emissions have been observed as a result of its use as an additive flame retardant in the plastic housing of computers and equipment, current estimates suggest that as little as 10 percent of the global production of TBBPA may be used in such additive applications.³ The low potential for exposure to TBBPA is evidenced by the available data from dust and biomonitoring analysis.^{4,5}



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A recent comprehensive assessment of exposure to TBBPA showed that human exposure to this chemical is seven million times below the level associated with potential health effects.⁶ This is consistent with multiple assessments, including those by the European Union, Health Canada and Environment Canada, which have demonstrated that consumer exposures to TBBPA are not likely to cause adverse health effects in humans or the environment.^{7 8}

The North American Flame Retardant Association (NAFRA) has been working to support the development of additional information on TBBPA. NAFRA is aware of a number of publications that have become available recently, or that will become available in next several months, that address the potential environmental and human health impacts of TBBPA that are relevant for the DoD's consideration. These studies are summarized in Section XI.

V. Regulatory Status

TBBPA, like all chemicals, is subject to review by the U.S. Environmental Protection Agency (EPA) and other national regulatory agencies around the world. Some recent government regulatory reviews of TBBPA include the European Union and Canada.

European Union

TBBPA went through an 8-year EU Risk Assessment, which concluded that TBBPA is safe for use in all its applications. In June 2008 the European Commission published a Decision with the conclusions of the Risk Assessment, which cleared TBBPA for use in the EU for all its applications. The data produced in the context of the EU Risk Assessment, along with additional data, have been used to prepare the REACH registration dossier which was submitted in October 2010.

A study was published by the European Food Safety Authority (EFSA) in December 2011 on the exposure of TBBPA and its derivatives in food. The study looked at 344 food samples and concluded that "current dietary exposure to TBBPA in the European Union does not raise a health concern". EFSA also determined that "additional exposure, particularly of young children, to TBBPA from house dust is unlikely to raise a health concern".



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Canada

A Canadian screening assessment report on TBBPA was published in November 2013 under the Canada Chemical Management Plan. The assessment concluded that TBBPA is safe for human health. The report also stated that current levels of TBBPA do not have an immediate or long-term harmful effect on the environment, constitute a danger to the environment, nor do they constitute a danger to human life or health.

United States

There are currently no restrictions on its use in the U.S, and TBBPA is not a priority for assessment under the U.S. EPA TSCA Work Plan for Chemical Assessments. It is highly unlikely that any future U.S. assessment, which begins with a risk assessment, will lead to increased regulation or production bans. As noted above, TBBPA has undergone comprehensive risk assessments in both Canada and the EU which confirmed that additional regulatory controls were unwarranted. In the absence of additional contradictory data, which is not known to exist, any U.S. assessment can be expected to reach the same conclusion.

VI. Production of TBBPA

TBBPA is one of the largest volume brominated flame retardants globally. It is produced in Israel, the United States, Jordan, Japan and China. The use of TBBPA is permitted worldwide. Economic data, forecasts and other publicly available information demonstrate that there is continued strong demand and supply for TBBPA.

The major manufacturers of TBBPA have invested and continue to invest in assuring the continued safe use of TBBPA. Over the past two years they have sponsored a significant number of papers for peer reviewed publication to educate stakeholders on the science regarding the safety of TBBPA.

VII. TBBPA Performance Characteristics

TBBPA is used as flame retardant where high reliability and uptime is a requirement for a long service life. When used as an intermediate which is reacted to make an epoxy, TBBPA is converted into a brominated epoxy. The brominated epoxy is a high molecular weight thermoset plastic that prevents chemical migrations and drastically reduces risk, making TBBPA inherently non-bio-available.



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VIII. Alternatives to Use in Electronic PCBs

While alternatives flame retardants currently exist, they have not yet been qualified for the DOD supply chain, will be more expensive on a per unit basis and will not provide an improvement to the risk profile of printed circuit boards.

Halogen-free (HF) base materials resins are used in some commercial applications, but no HF testing requests for defense applications have been made. No drop-in HF resin system is known. DoD printed circuit boards are required to perform at a high reliability level. Any substitute must meet this characteristic. Replacing printed circuit board resin systems will require re-qualification of each alternative, and replacement resins will most likely require years and hundreds of thousand dollars to qualify each resin for each application.

Additionally, there are halogenated non-TBBPA based resin systems available. In these resin systems the flame retardants are typically added to the polymer. The hazard characteristics and risk profiles of these alternatives are at best comparable to TBBPA or in some cases may be worse than that of TBBPA epoxy resin systems. Furthermore, each of these alternatives may represent an additional cost on a per unit basis and require substantially more quantity of alternative flame retardant to achieve the equivalent fire protection as the existing TBBPA based products.

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- 1 Sellstrom and Jansson measured the TBBPA polymerization reaction to be 99.9999.6% complete. (i.e. residual unreacted TBBPA was only 0.4 ppm). Analysis of Tetrabromobisphenol A in Product and Environmental Samples. *Chemosphere*, Vol. 31, No. 4, pp.3085-3092. 1995.
 - 2 Investigation into the emissions of Tetrabromobisphenol A from computer monitors, ERGO Forschungsgesellschaft mbH, 2002.
 - 3 U.K. Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT). 2004. Tetrabromobisphenol A – Review of the toxicological data.
 - 4 Colnot T, Kacew S, Dekant W. Mammalian toxicology and human exposures to the flame retardant 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (TBBPA): implications for risk assessment. *Arch Toxicol* 88(3):553-573 (2014).
 - 5 Haws LC et al. Development of non-cancer based toxicity factors and daily dose estimates for TBBPA. Poster presents at Society of Toxicology meeting (2014).



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- 6 Wikoff et al., 2015. Development of toxicity values and exposure estimates for tetrabromobisphenol A (TBBPA): application in a margin of exposure assessment. *Journal of Applied Toxicology*. Accepted for publication.
 - 7 European Union (EU). 2006. Risk Assessment Report: 2,2',6,6'-TETRABROMO-4,4'-ISOPROPYLIDENEDIPHENOL (TETRABROMOBISPHENOL-A or TBBP-A), Part II – Human Health. Volume 63.
 - 8 Health Canada/ Environment Canada. 2013. Screening Assessment Report: Phenol, 4,4'-(1-methylethylidene) bis[2,6-dibromo- (Chemical Abstracts Service Registry Number 79-94-7), Ethanol, 2,2'-[(1-methylethylidene)bis[(2,6-dibromo-4,1-phenylene)oxy]]bis (Chemical Abstracts Service Registry Number 4162-45-2), Benzene, 1,1'-(1-methylethylidene)bis[3,5-dibromo-4-(2-propenyloxy)- (Chemical Abstracts Service Registry Number 25327-89-3).
 - 8 Bromine Science and Education Forum, 2012. TBBPA Fact Sheet. http://www.bsef.com/uploads/Factsheet_TBBPA_25-10-2012.pdf