Response to Comments on the Updated Draft Alternatives Assessment for Flame Retardants in Printed Circuit Boards – August 2015

On December 15, 2014, the U.S. Environmental Protection Agency (EPA)'s Design for the Environment (DfE) Alternative Assessment Program released an updated draft of the report *Partnership to Evaluate Flame Retardants in Printed Circuit Boards*. The report assesses the environmental and human health impacts of flame retardants used or that could be used in printed circuit boards for electronic products, such as cell phones and computers. The draft report was first released in 2008 and was released again in 2014 to solicit public comment on information added to describe combustion testing conducted between 2008 and 2012. The updated report includes hazard profiles aligned with the 2011 DfE Hazard Assessment criteria. This alternatives assessment focuses on the use of flame retardants in FR-4 circuit boards. The updated draft was posted on the DfE website for public review and a 60-day comment period.

DfE's Alternatives Assessment Program helps industries choose safer chemicals and provides a basis for informed decision-making by developing a detailed comparison of potential human health and environmental effects of chemical alternatives. The alternatives assessment for flame retardants in printed circuit boards is one project in the broader scope of EPA's work on flame retardant chemicals. DfE has applied its alternatives assessment methodology to other flame retardant chemicals including decabromodiphenyl ether, hexabromocyclododecane in expanded polystyrene and extruded polystyrene foam, and pentabromodiphenyl ether in polyurethane foam in furniture. As part of its chemical safety program, EPA has identified a Work Plan of chemicals for further assessment under the Toxic Substances Control Act. Information regarding work plan chemicals can be found here: http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html.

DfE received comments from two entities on the updated draft report *Partnership to Evaluate Flame Retardants in Printed Circuit Boards* during the comment period, which ran from December 15, 2014 to February 15, 2015. One comment was directed at general report content. The other was directed at the hazard profile of a specific chemical. DfE greatly appreciates the effort of those who submitted comments.

Below, DfE presents and discusses the comments received on the updated draft assessment and indicates planned changes to the text of the *Partnership to Evaluate Flame Retardants in Printed Circuit Boards*. Please note that the comments have at times been paraphrased, summarized and combined, as appropriate, for efficiency and readability; full versions are available in docket number EPA-HQ-OPPT-2014-0893 at www.regulations.gov. The final report is available on the DfE website at http://www2.epa.gov/saferchoice/alternatives-assessment-partnership-evaluate-flame-retardants-printed-circuit-boards.

Comments and Responses

Comment from ICL-IP America, Inc.:
EPA scored the Skin Sensitization endpoint of Magnesium Hydroxide as having Moderate degree of hazardous potential based on a Mouse Local Lymph Node study (see draft assessment report, reference entitled: ECHA, 2013 and cited summary in the adjacent column on the left).

A confidential study found magnesium hydroxide to be negative for causing delayed contact hypersensitivity to guinea pigs. Based on this finding, we request EPA to amend the Skin Sensitization score of Magnesium Hydroxide to LOW hazard.

Response:
The submitted Delayed contact hypersensitivity study in the guinea-pig for the product FR-20 was added to the Magnesium Hydroxide hazard profile referenced as a "Submitted confidential study". Although there was a positive, mouse local lymph node assay, a weight-of-evidence approach was taken that considered the negative results of the submitted study and professional judgment. As a result, the hazard designation for the Sensitization endpoint has been changed from Moderate to Low. The updated hazard profile entry is presented below. In addition to these edits to the hazard profile edits, the Skin Sensitization entries for magnesium hydroxide in Table ES-2 and Table 4-5 were changed from "M" to "L."

PROPERTY/ENDPOINT		DATA	REFERENCE	DATA QUALITY
Skin Sensitization		**LOW: A mouse local lymph node assay (LLNA) reported some sensitization following exposure to $Mg(OH)_2$ (purity not reported), while negative results for sensitization were reported in guinea pigs in a maximization test. Magnesium hydroxide is not expected to cause skin sensitization based on professional judgment. Based on the weight-of-evidence (WOE), a hazard designation of Low is appropriate.**		
	Skin Sensitization	Not sensitizing in a modified Magnusson and Kligman maximization test in Guinea pigs; phase 1 induction: administered intra-dermally at a concentration of 5% v/v in 0.5% methyl cellulose; phase 2 induction: topically administered at a concentration of 25% in petrolatum; challenged: topical application	Submitted confidential study	Test substance identified as $Mg(OH)_2$; purity not reported; negative and positive controls were used.

PROPERTY/ENDPOINT		DATA	REFERENCE	DATA QUALITY
		of 25% in petrolatum; no reaction was observed in any treated animal in the challenge phase.		
		Sensitizing in a mouse local lymph node assay (LLNA); application of 10, 25 or 50% w/w $MgOH_2$ in propylene glycol to the ears. Very slight erythema in all animals treated with 50% $MgOH_2$, staining on the ears at 10, 25 and 50%. SI (stimulation index) at 10, 25 and 50% was 2.0, 3.6 and 5.9, respectively. Dose response and EC3 value >/= 3.	ECHA, 2013	Well documented secondary source; GLP study conducted according to guidelines. $MgOH_2$, purity not stated
		Does not cause skin sensitization. (Estimated)	Professional judgment	Estimated by professional judgment.

Comment from Dennis Fritz, private citizen and expert in printed circuit boards:
In the Agency's announcement of the release of the updated draft report via the Chemicals in Commerce, Information Related to the Toxic Substances Control Act (TSCA) listserv, the following statement was made: "In parallel with this draft assessment, industry trade groups tested alternative non-halogen flame retardants and found that they function equally well as TBBPA circuit boards for certain products."

The commenter cannot find that the industry trade groups have included any testing to the required operating conditions for US Department of Defense products. These trade groups are more representative of the companies who supply individual consumers, telecommunications facilities and educational institutions. Because there is no official regulation of TBBPA in the United States, the commenter cannot determine that any company in the Defense Industry supply chain base has undertaken testing of TBBPA-free laminate. Department of Defense testing of new laminate products will take a 1-2 year qualification testing to change circuit board laminate composition. The commenter states that the same is true of other federal agencies such as NASA and Department of Energy.

The commenter requests that EPA supply any background information the Partnership to Evaluate Flame Retardants in Printed Circuit Boards it may have concerning the performance of non-halogenated laminate in the harsh use environment conditions required for Department of Defense. Recent data from the Association Interconnecting Electronics (IPC) - shows that 28% of the United States production of printed circuits is for the Defense/Aerospace industry. The commenter fears that the equivalency statement used in the listserv announcement will encourage non-qualified materials to be used by suppliers Department of Defense and a waste of taxpayer dollars.

The commenter would like also to point out that there are small changes in electrical properties between halogen containing and halogen-free laminates. All suppliers of high frequency electronics, where these small electrical property differences create performance differences, will have to re-design their new product circuitry. The commenter thinks this should also be pointed out in EPA's communications to industry.

Response:
Clarifying language has been added to the report's Executive Summary.
EPA acknowledges that there may be products or applications where TBBPA and other halogenated chemicals are the best performers. The report explains that performance testing carried out by iNEMI, a not-for-profit, research & development consortium of leading electronics manufacturers, suppliers, associations, government agencies and universities, found that the eight halogen-free flame-retardant laminates tested in the project outperformed the traditional FR-4 laminate control based on the based on electrical and thermo-mechanical properties required of the high-reliability market segment. In addition to including a brief explanation, the EPA report cites the original iNEMI research.