

Von: ROTHENBACHER Klaus
An: [RoHS exemptions](#)
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Betreff: RoHS 2 review (Pack 15) - TBBPA
Datum: Montag, 23. April 2018 17:35:52
Anlagen: [image001.jpg](#)
[image003.png](#)
[image002.jpg](#)
[ICL Report on Blooming TBBPA from ABS Prop65 20170727.pdf](#)
[ICL Report Unreacted TBBPA in different stages of PCBs production 20171016.pdf](#)
[Pecquet et al. 2018 Final NSRL TBBPA.pdf](#)
[TBBPA under RoHS 13102015 clean.pdf](#)

Dear Ms Baron, Dear RoHS Team,

BSEF – The International Bromine Council - would like to provide information to support the ongoing evaluation of TBBPA^[1] under the project “Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 - RoHS Pack 15”^[2]

In 2014 BSEF commissioned Fraunhofer ITEM^[3] to carry out an independent evaluation of TBBPA according to the RoHS methodology published in 2014 by the Austrian

Umweltbundesamt^[4]. The study was completed in 2015 and includes a screening assessment (“part II assessment”) as well as a more detailed assessment as described in the RoHS manual (“part III assessment”), and an evaluation of data gaps and uncertainties. It should be noted that the Fraunhofer entity engaged in this study is different from the Fraunhofer entity, which has been engaged to conduct the current study by the Commission (Fraunhofer IZM).

We have asked Fraunhofer ITEM to update the report with current information. In particular, this would be

- An update of the regulatory status
- Inclusion of relevant effect studies that have become available since then
- Some editorial changes
- Updated quantitative usage data

As this update will take some time we are submitting the 2015 version of the report and will submit the updated report as soon as possible. The 2015 version will address many questions raised in the ongoing public consultation. Additional data (e.g., use data) are currently being collected.

We would also like to update you on the most significant regulatory developments regarding TBBPA since 2015:

- The International Agency for Research on Cancer (IARC) issued a preliminary notice in February 2016 that TBBPA was assessed as a “probable carcinogen” (category 2A) in February 2016 ([http://dx.doi.org/10.1016/S1470-2045\(16\)00137-6](http://dx.doi.org/10.1016/S1470-2045(16)00137-6)). No final monograph has been published by IARC yet
- US
 - o The carcinogenicity studies carried out under the National Toxicology Programme (NTP) have been finalised and the results published^[5]

- California's Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) announced its intention to list TBBPA under Proposition 65 list of chemicals known to cause cancer^[6] based on the IARC recommendation.
 - The Toxic Substances Control Act (TSCA) did not add TBBPA to its first batch of priority substances for risk evaluation, published in Dec. 2016^[7]
- EU
 - The Substance Evaluation under REACH is ongoing. A final decision has been agreed in Dec. 2016^[8], which concluded that further studies are necessary. The studies are currently under way. A date for submission of 4th January 2021 was agreed.
- China
 - China's Ministry of Environmental Protection (MEP) has published the first batch of priority control chemicals on 28 December 2017 in conjunction with the Ministry of Industry and Information Technology (MIIT) and the National Health and Family Planning Committee (NHFPCC)^[9]. The list consists of 22 substances. TBBPA had been included in the preliminary list, but after having evaluated all the available scientific data, China MEP decided to remove TBBPA from the final list.

In addition, we would like to provide three new studies that might be relevant for the evaluation:

- Study on emissions of TBBPA from additive use in ABS (blooming)
- Study quantifying the amount of unreacted TBBPA in printed circuit boards
- Recent publication deriving a "no-significant-risk-level" for TBBPA based on the latest mammalian toxicity data^[10]

Please don't hesitate to contact me in case you should have any questions or require additional information.

Could you please briefly confirm receipt by response to this mail?

Thank you, and best regards,

Klaus Rothenbacher

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About BSEF

BSEF, AISBL - the International Bromine Council, is the global representative body of the bromine industry. Our mission is to support the use of bromine for the benefit of society and economy. BSEF supports new and existing bromine applications. Visit our website at: www.bsef.org

- [1] Tetrabromobisphenol A (CAS no. 79-94-7)
- 2 http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/Project_Description_RoHS_15_final.pdf
- 3 Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM), Chemical Risk Assessment, Nikolai-Fuchs-Straße 1, D-30625 Hannover
- 4 Umweltbundesamt Österreich, Manual: Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive, 2014: 1090 Wien/Österreich Available from: http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex1_Manual.pdf
- 5 https://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr587_508.pdf
- 6 <https://prop65news.com/en-us/1/oehha-proposes-listing-of-three-chemicals-via-the-labor-code-listing-method-1>
- 7 <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca#ten>
- 8 <https://echa.europa.eu/documents/10162/84afb981-a86f-b3fe-dab8-df0c8d86fa08>
- 9 http://www.mep.gov.cn/gkml/hbb/bgg/201712/t20171229_428832.htm (in Chinese)
- [1] O Pecquet, Alison M., et al. "Derivation of a no-significant-risk-level for tetrabromobisphenol A based on a threshold non-mutagenic cancer mode of action." Journal of Applied Toxicology

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- [1] Tetrabromobisphenol A (CAS no. 79-94-7)
- [2] http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/Project_Description_RoHS_15_final.pdf
- [3] Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM), Chemical Risk Assessment, Nikolai-Fuchs-Straße 1, D-30625 Hannover
- [4] Umweltbundesamt Österreich, Manual: Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS2 Directive, 2014: 1090 Wien/Österreich Available from: http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex1_Manual.pdf
- [5] https://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr587_508.pdf
- [6] <https://prop65news.com/en-us/1/oehha-proposes-listing-of-three-chemicals-via-the-labor-code-listing-method-1>
- [7] <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca#ten>
- [8] <https://echa.europa.eu/documents/10162/84afb981-a86f-b3fe-dab8-df0c8d86fa08>
- [9] http://www.mep.gov.cn/gkml/hbb/bgg/201712/t20171229_428832.htm (in Chinese)
- [10] Pecquet, Alison M., et al. "Derivation of a no-significant-risk-level for tetrabromobisphenol A based on a threshold non-mutagenic cancer mode of action." Journal of Applied Toxicology