PREVENT CANCER NOW

CSM
Chemical Sensitivities Manitoba

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Transmission by email: eccc.substances.eccc@canada.ca

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Comments Regarding: Canada Gazette Notice Vol. 151, No. 48 — December 2, 2017
Screening assessment of three substances in the Trimellitates Group – 1,2,4-benzenetricarboxylic acid, tris(2-ethylhexyl) ester (TEHT), CAS RN 3319-31-1; 1,2,4-benzenetricarboxylic acid, mixed branched tridecyl and isodecyl esters (BTIT), CAS RN 70225-05-7; and 1,2,4-benzenetricarboxylic acid, tritridecyl ester (TTDT), CAS RN 94109-09-8

and

Draft Screening Assessment. Trimellitates Group. Chemical Abstract Service Registry Numbers 3319-31-1, 70225-05-7 and 94109-09-8. January 2018[1]

We offer the following observations regarding the three trimellitates examined in the current consultation, as well as the narrowly scoped assessment process. Considerations are necessary of environmental fate, and substitutions of a vast number of similar chemicals used for similar purposes.

In particular, for long-term population and environmental health, we recommend that:

1. Assessments of groups of chemicals include considerations of the context of the uses and expected trends of uses (e.g. substitution of chemicals under review, and substitution for other chemicals of concern). TEHT is currently high-volume and trimellitates are increasing in use, for example to make “phthalate-free” products. It must be confirmed that over the long term this will not result in more toxic and endocrine-disrupting chemicals in the environment. Narrowly scoped reviews have previously resulted in sequential regrettable substitutions, such as was seen for flame retardants; [2,3]
2. Environmental fate be identified, and toxicity not only of the parent compound but of environmental breakdown products be considered in hazard (and risk) assessments. In particular:
    a. Scientific evidence is required regarding the environmental fate of the thousands of tonnes (and increasing quantities) of trimellitates introduced in Canada annually. This includes identification of metabolites, that could pose greater hazards than the chemicals under review.

[1] Government of Canada. Draft Screening Assessment. Trimellitates Group. https://www.canada.ca/content/dam/eccc/documents/pdf/pded/trimellitates/English%20draft%20screening%20assessment%20trimellitates%20group1.pdf
[2] Government of Canada. Certain Organic Flame Retardants Substance Grouping. 2016. https://www.canada.ca/en/health-canada/services/chemical-substances/substance-groupings-initiative/certain-organic-flame-retardants-substance-grouping.html
[3] Prevent Cancer Now (PCN). 2016. Response to Government of Canada’s consultation: Certain Organic Flame Retardants Substance Grouping. http://www.preventcancernow.ca/wp-content/uploads/2016/12/PCN+CSM-Submission-OrganicFlameRetardants-2016-Dec7.pdf

b. Trimellitates are the same density as water, so could remain suspended in the water column and act as ultra-small microbeads (that are now banned in Canada[4]). Microbeads are known for concentrating toxicants, and "kickstarting" magnification up the food chain. This possibility merits investigation, as trimellitates may be used in skin care products, including sunscreens.

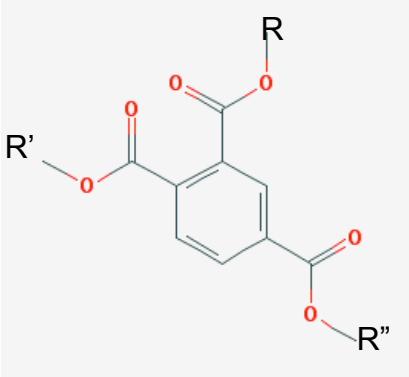
In support of these recommendations, we make the following observations regarding trimellitates, and compounds that are related both chemically and in commerce.

UBIQUITOUS USES: The consultation document indicates that TEHT is used as a plasticizer in floor coverings, building and construction materials, plastic and rubber materials, and medical devices. It is also used as a fuel additive, in adhesives and sealants used in the transportation sector, as a lubricant and lubricant additive, and in cosmetics. BTIT and TTDT are used primarily used in cosmetics, with TTDT also present as a non-medicinal ingredient in drugs, including natural health products. In addition to the uses listed above, TEHT and BTIT have been identified as ingredients of some incidental additives for use in food processing establishments. We believe that with a move towards eliminating phthalates, trimellitates will be used as substitutes, given their current use patterns. Their ubiquitous uses, and potential for vastly expanded applications, mean that careful scrutiny is essential to avoid regrettable substitutions.

CHEMICAL INFORMATION: Trimellitates are chemicals built on a benzene ring with three acid groups, to which three long-chain alcohols are added (called "R" in Figures 1 and 2). The resulting substances are soluble in oils and alcohol, but relatively insoluble in water. The chemistry is similar to phthalates, and the central moieties – chemical reactants – were previously assessed together (trimellitic and phthalic, as well as maleic anhydrides).[5] Generally, the trend is that larger aliphatic side-chains (R-groups) result in compounds that are more refractory to environmental breakdown, and with lower acute toxicities.

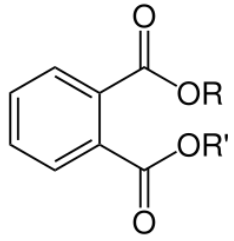
In various products, trimellitates are similar to phthalates, and are increasingly used as phthalate substitutes in plastics, cosmetics, etc. Phthalates are noted for endocrine disruption at low concentrations, as we previously commented and referenced.[6] The chemical similarities, and unknown endocrine disruption potential of partially degraded trimellitates, pose a concern.

Figure 1. General Structure for Trimellitates. "R" represents an organic chemical substituent.



[4] https://www.canada.ca/en/health-canada/services/chemical-substances/other-chemical-substances-interest/microbeads.html
[5] https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/screening-assessment-caa-group.html#toc18
[6] http://www.preventcancernow.ca/wp-content/uploads/2017/12/Phthalates-PCN-Submission.pdf

Figure 2. General Structure for Phthalates. "R" represents an organic chemical substituent.



ENVIRONMENTAL FATE NOT REPORTED: TEHT, BTIT and TTDT are large molecules that do not occur in nature. The environmental end fate of the substances is not reported; long term build-up of novel chemicals in the environment is always of concern, particularly when thousands of tonnes are introduced to Canada annually and the production and use of this type of chemical has been identified as an "acceptable" substitute for phthalates (common, ubiquitous additives in plastics, cosmetics, receipt paper, etc. Phthalates are endocrine disruptors.[7]

Trimellitates are not volatile and do not dissolve easily in water, so they may reside in solid and oily environmental compartments (e.g. sediments); however, not mentioned is that trimellitates are the same density as water. This means that they will neither sink nor float, and potentially could linger in the water column. Trimellitates would be expected to tend to combine with or concentrate other persistent pollutants, and be taken in by small organisms, in a manner similar to their larger solid "cousins," microbeads. Microbeads were banned due to persistence, and adverse effects on aquatic organisms.[4]

As indicated in the US Environmental Protection Agency screening level hazard assessment, despite steric hindrance from the large side-chains, initial breakdown is via hydrolysis / "de-esterification" resulting in removal of an alcohol side-chain.[8] This will most likely occur at the carboxyl on carbon 4 of the ring, leaving chemical degradation products more closely resembling phthalates. Phthalates have gained close scrutiny as a result of endocrine disrupting activities, and there is great interest in "phthalate-free" products.

Smaller molecules may be more biologically active, so it is of great concern that a lack of complete environmental fate reporting is a common shortcoming in Chemicals Management Plan assessments. We see this here, with high-volume replacements for phthalates.

LIMITED TOXICITY DATA: There is limited toxicity data for one trimellitate (TEHT), the chemical that was reported in the draft screening assessment to be in the largest quantities in commerce (up to 20 million kilograms in 2011).

There is no toxicity data available for BTIT and TTDT – the hazard assessment was based on modeling, and read-across from phthalate data. These were not reported to be present in as great quantities as TEHT in 2011. Reporting is only necessary when manufacturing, use or importation by a particular company exceeds 100 kg, leaving open the possibility of substantial quantities in commerce within the vast array of imported plastics, cosmetics and other products by many companies.

[7] Prevent Cancer Now, Chemical Sensitivities Manitoba and Canadian Environmental Law Association. http://www.preventcancernow.ca/wp-content/uploads/2017/12/Phthalates-PCN-Submission.pdf
[8] Prevent Cancer Now, Chemical Sensitivities Manitoba and Canadian Environmental Law Association. http://www.preventcancernow.ca/wp-content/uploads/2017/12/Phthalates-PCN-Submission.pdf

Trimellitates are large molecules that are said to be poorly absorbed through the skin or in the intestine. We emphasize, however, that toxicity of metabolites of compounds that are of high and increasing volumes must also be considered – the hazard assessment is silent on this topic.

HAZARD ASSESSMENT VERSUS RISK ASSESSMENT: We generally advocate that chemicals should be restricted based upon hazard when exposures are low, instead of waiting until Canadians are determined to be exposed to high enough levels to pose substantial risks. In this light, we were initially intrigued to see trimellitates being assessed on the basis of hazard. In the event, this approach was chosen because there is no exposure data available, so risk assessment was untenable; nevertheless, hazard assessment must be well informed. We were unable to identify research indicating:

- whether trimellitates remain in the water column and pose hazards similar to microbeads, concentrating pollutants that then move up the food chain (there is no lower limit to the size of microbeads,[9] so trimellitates may effectively be very small plastic-like beads in the water, collecting toxicants and jump-starting bioaccumulation up the food chain);
- identities and environmental profiles of trimellitate metabolites, and their hazards, including endocrine endpoints; or
- environmental and body burden levels of trimellitate metabolites.

In summary, trimellitates are expected to be a lucrative, rapidly growing sector in the chemicals industry. The present assessment is incomplete and probably omits important considerations that may adversely affect environmental and human health now and in the future.

The realization that plasticizers and certain functions in cosmetic ingredients are being filled by endocrine disrupting chemicals should lead first to consideration of alternative approaches (e.g. polyvinyl chloride requires a substantial segment of plasticizers in commerce – an alternative plastic, that incidentally would be more readily recyclable, should be supported in policies and regulations). A more rational, protective, environmental assessment approach would include examining uses and alternatives via rethinking and redesigning, such as “green chemistry.”

We thank you for consideration. Please do not hesitate to ask, should you wish assistance or clarifications in this matter.

Prevent Cancer Now is a Canadian national civil society organization that works to stop cancer before it starts, with scientific research, education and advocacy.

Respectfully submitted,

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[9] Government of Canada. Microbeads. https://www.canada.ca/en/health-canada/services/chemical-substances/other-chemical-substances-interest/microbeads.html