American Chemistry Council | North American Flame Retardant Alliance

January 28, 2022

Washington Department of Ecology
300 Desmond Drive SE
Lacey, Washington 98503

Re: Draft Regulatory Determinations Report to the Legislature: Safer Products for Washington Implementation Phase 3

To Whom It May Concern:

The American Chemistry Council's (ACC) North American Flame Retardant Alliance ("NAFRA")[1] submits the following comments regarding Washington Department of Ecology's ("Department" of "Ecology") Draft Regulatory Determinations Report to the Legislature as part of Safer Products for Washington.[2] NAFRA's comments focus specifically on the draft proposal regarding the use of flame retardants in enclosures and casings for electric and electronic equipment.

NAFRA appreciates the opportunity to comment on the Department's draft report and looks forward to additional opportunities during the regulatory process to discuss with Ecology the benefits of flame retardants in plastic device casings for electrical and electronic equipment. If you have questions or need clarification, please contact me at ben_gann@americanchemistry.com or 202-249-7000.

Sincerely,

Ben Gann
Director
American Chemistry Council

[1] The American Chemistry Council's North American Flame Retardant Alliance represents the leading producers of flame retardants used in wide variety of industrial and consumer applications. NAFRA members represent cutting edge fire-safety chemistry and technology and are dedicated to improving fire safety performance in key product applications. NAFRA members are Albemarle Corporation, ICL Industrial Products, and Lanxess. For more information on NAFRA, visit https://www.americanchemistry.com/industry-groups/north-american-flame-retardant-alliance-nafra.

[2] Draft Regulatory Determinations Report to the Legislature: Safer Products for Washington Implementation Phase 3, November 2021. https://apps.ecology.wa.gov/publications/documents/2104047.pdf

Regulation of Flame Retardants in Casings and Enclosures for Electric and Electronic Equipment

NAFRA supports chemical safety and appreciates the opportunity to comment on the draft regulatory determination of flame retardants in plastic enclosures for electrical and electronic equipment. Flame retardants are used by product manufacturers to meet or exceed flammability standards as part of an overall approach to product safety. Flame retardants offer valuable mitigation against ignition failures in electrical and electronic equipment.

Washington Department of Ecology as part of S*afer Products for Washington* is considering restrictions on the use of all organohalogen flame retardants (OFRs) in device casings and enclosures for electronic and electrical equipment – including but not limited to TVs, laptops, mobile phones, kitchen appliances, washing machines, irons, coffee makers, vacuum cleaners, hair dryers, appliances, power tools, and various other electronic and electric devices – used in both residential and commercial settings.

The Department's draft recommendations extend beyond consumer products to all electronic and electrical products available for sale in Washington State. This is the broadest proposed regulation of its kind in the world and could have implications for a huge range of products used every day by consumers and businesses in the Evergreen State.

Overall, the factors outlined below argue for a more rigorous assessment and a more targeted approach for this important product category. While the underlying law for *Safer Products for Washington* clearly identifies OFRs and non-halogenated flame retardants as priority chemicals for evaluation,[3] there is nothing that prevents Washington State from taking a more targeted approach in its policy recommendations and enhancing its evaluation of certain subcategories of OFRs, as well as narrowing the scope of electrical and electronic products.

Outlined below and expanded upon in greater detail are key issues and concerns that the Department should consider in finalizing its determinations for a diverse set of chemicals used in a wide range of electrical and electronic products.

1. **Identification of electric and electronic device casings utilizing flame retardants as priority products for regulation is <u>not</u> warranted based on the Safer Products for Washington criteria.**

   The law which serves as the basis for *Safer Products for Washington* requires the Department to identify priority consumer products that are significant sources of identified priority chemicals.[4] As part of this effort, the Department is required to consider specific criteria. Electrical and electronic device casings utilizing flame retardants fail to meet the key criteria for identifying priority products, particularly as it relates to exposure, levels found in the environment, the status of various regulatory assessments, and the availability and feasibility of safer alternatives that provide equivalent performance.

[3] Chapter 70A.350 RCW https://app.leg.wa.gov/rcw/default.aspx?cite=70A.350

[4] Ibid.

a. Electrical and electronic equipment with plastic device casings utilizing flame retardants is not a significant source of exposure and should not be designated a priority product.

While it is true that electrical and electronic equipment with plastic device casings utilize OFRs, the relative contribution of electronics to potential flame retardant exposure is small. Ecology's utilization of volume of electronics as a proxy for potential exposure is not accurate and should not be the basis for determining priority products.

Factors related to the availability and potential for migration of additives from plastics depend on the formulation process for specific products. In general, migration is influenced by the following factors:

- compatibility of the polymer and the additive;
- molecular geometry; and,
- partial vapor pressure.

Manufacturers give clear recommendations regarding what flame retardants are compatible with specific polymers, as a mismatch typically also leads to the deterioration of physical properties. Likewise, formulators seek flame retardants with structures similar to the base resin where they will be used. Doing so aids in maintaining the physical characteristics of the base resin and minimizes the potential for migration. There is no advantage to seeking poor performing products, so it is in the best interest of both the manufacturer and the formulator to use highly compatible materials.

All else being equal, more complex molecular geometries are likely to resist migration. The effect is similar to an anchor. An anchor that is just a heavy bowling ball shape would much more easily be pulled along the ocean floor than a more complex anchor with hooked ends or more sophisticated geometry. The geometry of most brominated flame retardants is quite complex and therefore more likely to anchor into the plastic than a smaller or simpler molecule.

The partial vapor pressure of non-polymeric organohalogen flame retardants is negligible. All of this indicates that the potential for migration of OFRs from electronic casings is quite low. Hence potential exposure is quite low.

In this regard, it would also be important for Ecology to distinguish between polymeric, reactive, and additive flame retardants in its assessment. Please see additional information in Section 3 of these comments regarding these distinctions.

Case Study: Research[5] illustrates that the amount of additive TBBPA in acrylonitrile-butadiene-styrene (ABS) has limited potential to migrate. Specifically, the study evaluated the migration potential of TBBPA from the

[5] TBBPA: Quantitation of the potential emissions (blooming) from the surface of ABS (AcrylonitrileButadiene-Styrene), based on ICL internal reports.

surface of acrylonitrile butadiene styrene (ABS) plastic. The research found that TBBPA migration levels from the surface of ABS were below the study limit of quantification.

b. Specific flame retardants used in electronic casings are either not found in the Washington environment or any actual measured levels are extremely low and therefore unlikely to present a risk to human health or the environment.

While there is data demonstrating some level of some specific OFRs in various media and in the environment, this is not the case for all the referenced flame retardants, and, as noted, electronic casings are not likely to be a significant source of any potential releases.

In many cases, Ecology has utilized measurement of a sub-class of older flame retardants, polybrominated diphenyl ethers (PBDEs) – which were used in textiles, upholstered furniture, and electronics – as a proxy for other flame retardants. This data is not indicative or relevant for other flame retardants and should not be used as a basis for making conclusions about other flame retardants, much less an entire class or classes of flame retardants. Further, it is not appropriate as the basis for identifying electronic casings as a priority product category.

As noted by Ecology in earlier assessments, beyond PBDEs, actual monitoring data indicates that some of the other referenced flame retardants (DBDPE, TBBPA, BTBPE, or TTBP-TAZ) are not found in the Washington state environment or they are found at extremely low levels not likely to present a risk.[6]

Case Study: Published research illustrates that specific flame retardants used in electronic casings do not present a risk to human health or the environment. This comprehensive evaluation of TBBPA exposure and toxicity[7] found that margin of safety (MOS) estimates were sufficiently large. Using the most conservative estimates of exposure and toxicity, the total lifetime average daily exposure would have to be increased approximately 80 times or greater for adverse health effects to occur.

Specifically, the study evaluated the available toxicity data and human exposure information using the maximum exposure concentrations of TBBPA in the diet, breast milk, soil/dust, and water and reported that the resulting exposures were many orders of magnitude below any reported adverse effects seen in research animal studies. This information directly reinforces why specific flame retardants used in electronic casings do not meet the criteria for a priority product listing.

[6] WA Department of Ecology, Flame Retardants in Ten Washington Lakes, 2017-2018, December 2019. https://apps.ecology.wa.gov/publications/documents/1903021.pdf

[7] 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.

c. Several government regulatory bodies have assessed specific organohalogen flame retardants used in this product category and determined they do not present a risk and do not warrant additional regulation.

No U.S. federal restrictions currently exist around flame retardants in electric and electronic enclosures. It is also important to note that most state regulation relative to flame retardants has explicitly exempted electronics for some of the reasons noted in these comments.

Case Study: There are specific examples[8] of where government regulators have determined that specific organohalogen flame retardant uses in this product category do not present a risk to human health or the environment. This includes assessments and regulatory determination made by U.S. government authorities, as well as Canada, and the European Union.

2. The identified product category of electronic casings is overly broad and should be narrowed.

The proposed recommendations cover an extremely broad range of products and product categories. It covers hundreds, if not thousands, of products. The draft recommendations emphasize that the list of products currently within the regulatory scope is not exhaustive, so it would ban virtually any product where OFRs are used in plastic enclosures for electrical and electronic equipment even if they are used mostly in commercial and industrial applications. The Department has appropriately excluded internal components from the scope of the regulation, which includes printed circuit boards, internal fans, wires, cables, switches, and connectors.

Ecology's draft report fails to consider the vastly different product design and performance factors for this wide range of products. There is a tremendous difference within and amongst different types of products. As highlighted further relative to the assessment of potential alternatives; different products within this broad product category have different functional and safety needs, so taking a one size fits all approach to this broad range of products does not make sense and likely undermines overall product safety and performance.

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[8] Government of Canada. 1999. Canadian Environmental Protection Act, 1999 (S.C. 1999, c. 33). Available at URL: http://laws-lois.justice.gc.ca/eng/acts/C-15.31/index.html. Accessed Jan. 16, 2016.

Environment Canada and Health Canada. 2013. Screening Assessment Report Phenol, 4,4'-(1-methylethylidene) bis[2,6-dibromo-, Ethanol,2,2' [(1-methylethylidene)bis[(2,6-dibromo-4,1-phenylene)oxy]]bis, Benzene, 1,1'-(1-methylethylidene)bis[3,5-dibromo-4-(2-propenyloxy)-, Available at: http://ec.gc.ca/ese-ees/BEE093E4-8387-4790-A9CD-C753B3E5BFAD/FSAR_TBBPA_EN.pdf.

European Chemicals Bureau. 2006. European Union Risk Assessment Report. 2,2',6,6'-tetrabromo-4,4'isopropylidenediphenol (tetrabromobisphenol-A or TBBP-A) Part II – human health, Available at URL: http://echa.europa.eu/documents/10162/32b000fe-b4fe-4828-b3d3-93c24c1cdd

CONTAM (European Food Safety Authority Panel on Contaminants in the Food Chain). 2011. Scientific Opinion on Tetrabromobisphenol A (TBBPA) and its derivatives in food. EFSA Journal 9(12):2477. Page 54.

Case Study: For example, the materials that are used and feasible for phone and TV enclosures are very different and not interchangeable. If product designers and specifiers tried to use the same materials utilized in the casings for phones for TVs, the weight would make them unfunctional.

In the public session hosted by the Department on January 5, 2022, regarding Safer Products for Washington, a representative with the Department stated that examples of the kinds of products being regulated would be listed later this year but that publication of a formal list was unlikely. In explaining their reasoning for such an approach, the Department official said that the regulatory focus was on plastic casings of electrical and electronic equipment and not specific final goods available for sale to be used by consumers.

This would be misguided for several reasons. First, it incorrectly assumes that all plastic device casings in electrical and electronic equipment used to protect individuals pose the same level of risk. Second, it would place the restriction on parts for final goods – in this instance enclosures for electrical or electronic equipment – rather than on final goods themselves. Third, failing to publish a complete list of products that the Department intends to regulate deprives manufacturers, distributors, and retailers the opportunity to provide valuable feedback regarding design, feasibility of alternatives, and other considerations as part of an overall approach to product safety.

No other regulatory authority has proposed regulations as broad or as out of step with the current state of the science as some of those being considered in Washington. In its preliminary recommendations, Ecology has failed to recognize that several publicly available risk evaluations have found no public health concerns with some of the specific chemical applications identified in its report. The Department also seems to have not considered some of the important criteria outlined in the underlying Safer Products law — in particular, it has not demonstrated that the proposed restrictions could reduce a significant source of exposure.

The draft regulatory proposal would make Washington an outlier. Such a regulation would potentially decrease the availability of electronic and electric products for purchase in the state and potentially increase the fire risk posed by the products that are available. Electronic and electrical equipment present unique fire risks and restricting the use of flame retardants in their plastic enclosures could undermine overall product safety and performance.

Case Study: Electronic and electrical products with larger enclosures can be required by UL 746C[9] to undergo a specific test that assumes a flame threat occurs outside of the enclosure. In these instances, enclosures meeting specific size criteria must pass a larger scale fire test (either ASTM E162 or UL 723 can be used per UL 746C). Using an interior fire barrier (possibly metal) with a horizontal burn "shell" may not be enough to satisfy these additional requirements.

[9] UL 746C specifies standards for parts made of polymeric materials that are used in electrical equipment and describe the various test procedures and their use in the testing of such parts and equipment.

There are hundreds of end-product standards for electrical and electronic equipment. It is common for some of these standards to supersede UL 746C for the devices they cover. Sometimes they reference all or parts of UL 746C. These end product standards can contain additional or stricter requirements than UL 746C, such as an enclosure needing a minimum of UL 94 V-1 or V-0 for flammability.

For example, UL 2158 Standard for Safety: Electric Clothes Dryer has criteria for large mass considerations. Section 28.13 requires a polymeric part that meets the large mass criteria to have a flame spread of 200 or less in either UL 723, UL 94 (which uses the ASTM E162 test), or CAN/ULC-S102.

3. It is not scientifically accurate or appropriate to treat all organohalogen flame retardants as the same.

The draft report takes an overly broad approach in its characterization of, and recommendations for OFRs. In many cases, the draft report makes some extremely broad assumptions and mischaracterizations that are not supported by the science, and in some cases are directly contradicted by the state of the science.

It is not scientifically accurate or appropriate to make broad conclusions or impose a one size fits all approach for all flame retardants or even subclasses of flame retardants. Not all flame retardants are the same. They are a diverse set of chemicals that vary in property and molecular structure. Chemical and toxicological properties vary widely between various flame retardants and even substances of the same family. Specifications, standards, and regulations therefore need to address specific flame retardants and specific applications.

Most notable is the fact that the National Academy of Sciences (NAS) found that this diverse group of chemicals cannot be treated as a single class for purposes of assessment. Instead, the NAS has recommended that OFRs be sorted into 14 subgroups based on chemical structure, physicochemical properties, and predicted biologic activity for purposes of further assessment.[10] Despite this, the Department has stated that "further sub-classification was not required to conduct our hazard analysis of the OFRs class."

Key differences between flame retardants are also highlighted within assessments conducted by regulatory agencies such as the U.S. Environmental Protection Agency (EPA), Environment and Climate Change Canada and Health Canada, the European Chemicals Agency, and the European Food Safety Authority, which have taken approaches consistent with the NAS findings to initially screen and evaluate subcategories or "clusters" of specific flame retardants that may have similar properties but not broad classes or even subclasses.

In many cases, the basis for Ecology's recommendations seems to be based on an older category of flame retardants, PBDEs. Chemical producers have generally supported efforts to discontinue the use of PBDEs and have proactively worked to develop new alternatives, but

[10] National Academies of Sciences, Engineering, and Medicine. 2019. A Class Approach to Hazard Assessment of Organohalogen Flame Retardants. https://doi.org/10.17226/25412

the fact remains that PBDEs are still used globally and may still be in imported products, because of exemptions. This may be an area for specific focus by the Department as it moves forward in the regulatory process.

Finally, the draft recommendations fail to consider the difference between additive, reactive, and polymeric flame retardants. Flame retardants can be liquids or solids that can be physically incorporated into a material (additive) or chemically transformed to create a new fire-resistant material (reactive).

Additive flame retardants are incorporated into compounds via physical mixing. Compounds containing flame retardant elements are mixed with existing polymers without undergoing any chemical reactions. By contrast, reactive flame retardants are incorporated into polymers via chemical reactions. The production of existing polymers is modified so that one or more unsubstituted reactant monomers is replaced with a substituted monomer containing flame-retardant heteroelements. The substituted monomers and their heteroelement components become an integral part of the resulting polymer structure.[11]

Polymeric materials have the added advantage of being very large macromolecules. So large, in fact, that they are unable to interact with cells and therefore possess inherent safety towards biological organisms. OFRs that are created as macromolecules or start as reactive and are transformed into macromolecules exhibit the same inability to interact with biological systems.

State and federal regulatory bodies have differentiated between additive and reactive applications when considering regulations for flame retardants and have focused on additive applications. Washington State has previously recognized this distinction in its 2015 Report to the Legislature on Flame Retardants[12] and should continue to do so. This important distinction has also been recognized by key stakeholders including NGOs, firefighters, and government agencies,[13] as well as national regulatory authorities, including EPA and the U.S. Consumer Product Safety Commission (CPSC).

Polymeric flame retardants are large stable molecules whose sheer size inhibits their migration out of the material to which they have been added, and therefore present little potential for human or environmental exposure. Their large size also prevents them from crossing biological membranes, reducing potential human or environmental health risks. Additionally, there are also types of flame retardants that are chemically reacted or molecularly bonded into the matrix to the material they are intended to protect. In this instance the reacted flame retardant predominantly no longer exists and is therefore not available to migrate out of the product.

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[11] U.S. Environmental Protection Agency, "Flame Retardants in Printed Circuit Boards," Chapter 3, Page 2. https://www.epa.gov/sites/production/files/2015-08/documents/pcb_final_report.pdf

[12] Department of Ecology Report to the Legislature on Flame Retardants, Updated July 2015 Publication no. 14-04-047

[13] Petition HP 15-1 to the U.S. Consumer Product Safety Commission Requesting Rulemaking on Products Containing Organohalogen Flame Retardants

Criteria for polymeric substances developed during the Clinton Administration define specific requirements for molecular weight (i.e., size of the molecule), chemical composition, and other characteristics. The criteria exclude polymers that may substantially degrade, decompose, or depolymerize into smaller substances upon exposure to heat, light, microbial action, or other conditions.

The following statements demonstrate how toxicologists and risk assessors think about reactive and polymeric flame retardants:

- Dr. Linda Birnbaum, Director of the National Institute of Environmental Health Sciences and the National Toxicology Program has said, "Use [of flame retardants] in a reactive mode or in polymers reduces the opportunity for exposure, and hence, reduces risk."[14]

- During the Obama administration, the EPA said of a polymeric flame retardant being evaluated as an alternative to a non-polymeric flame retardant said, "There is no absorption expected for any route of exposure. This polymer is large, with a MW [molecular weight] >1,000. It is expected to have limited bioavailability and is therefore not expected to be readily absorbed, distributed or metabolized in the body."[15]

- Regarding the potential of the same polymeric flame retardant to exhibit reproductive toxicity, EPA said, "Available experimental data indicate a low hazard designation. In addition, this polymer is large, with a MW >1,000. It is expected to have limited bioavailability; therefore, it has low potential for reproductive effects."[16]

- In another Obama era alternatives investigation looking at polymeric flame retardants, EPA said, "Large polymers (greater than 1,000 daltons) were generally designated as low concern compared to discrete chemicals, because the large polymers generally cannot be absorbed or easily metabolized. . . Without absorption there cannot be systemic effects."[17]

Indeed, some polymeric OFRs would likely be considered safer by Ecology and have less migration/exposure than various alternatives outlined in the draft report, and the Department's determinations should recognize this distinction.

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[14] Statement for the Consumer Product Safety Commission, December 9, 2015.

[15] U.S. Environmental Protection Agency. 2014. Flame Retardant Alternatives for Hexabromocyclododecane (HBCD), Publication No. 740R14001, Page 4-112. https://www.epa.gov/sites/default/files/2014-06/documents/hbcd_report.pdf

[16] *Id*. at 4-113.

[17] U.S. Environmental Protection Agency. 2014. An Alternatives Assessment for the Flame Retardant Decabromodiphenyl Ether, Page 6-2. https://www.epa.gov/sites/default/files/2014-05/documents/decabde_final.pdf

4. Electronic casings present unique fire risks and the proposed product category could undermine overall product safety and performance.

Electrical and electronic equipment presents unique fire safety risks because they have a potential ignition source generated by the actual components of the product – circuit boards, transformers, batteries, connectors, and more. Despite fire safety standards for products that are sold in the United States, in the last year alone there were over 6.2 million units that were recalled for a variety of electrical and electronic products due to fire and shock hazards.[18]

Flame retardants are an essential tool for overall electronics safety and performance. One of the most important benefits of flame retardants in product design is they can stop small ignition events from turning into larger fires. Batteries can overheat, and circuit boards and other device components carry electric currents; therefore, electronic products present a higher risk of flammability than non-electronic products. Flame retardants help to reduce the risk of fire and are a critical part of overall product safety.

Electronic device manufacturers must balance the need to meet consumer demand for smaller, lighter, and more powerful electronics with the need to ensure that those devices meet performance and safety standards. Plastics have revolutionized electronic product designs. Manufacturers use plastics to ensure device performance goals, and plastic casings serve as an enclosure that protects from fire and shock risk. If left untreated, these plastics are flammable, so flame retardants serve as a critical line of defense against fire.

Likewise, when designing products, original equipment manufacturers (OEMs) need to consider specific plastic resin types and the flame retardant systems that are appropriate for those resins. Simple substitution is just not possible in many cases. Therefore, the electronics sector needs a broad array of material choices for differing product design needs, including the use of OFRs.

OFRs provide specific fire safety and performance benefits for specific resin systems in a variety of electrical and electronic equipment. These substances also help provide other important performance factors for end-use performance like durability, weight, fire resistance, and sustainability. Banning the use of all OFRs in all electronic casings could undermine fire safety and overall product safety and performance of electronics.

Fire safety standards should be viewed as minimum requirements for flammability and products can go beyond those standards. OEMs use enclosures that meet or exceed minimum flammability requirements based on their own needs for safety and performance. For instance, OEMs may conclude that an external fire threat is a risk for their product (from a candle or other flame source) and want their product to exceed minimum requirements for horizontal burning or may determine that an internal risk may warrant a higher than the minimum flame rating allowed in a standard.

[18] Based on U.S. Consumer Product Safety Commission (CPSC) recall data. https://www.cpsc.gov/Recalls

Case Study: Southwest Research Institute (SwRI) conducted a study[19] to determine through computer fire modeling how much more likely flashover is to occur when a flat screen television (TV) is the first item ignited in a room and the casing is not treated with flame retardants, compared to a flat screen TV that is the first item ignited in a room where the casing is treated with flame retardants. SwRI quantified the risk of flashover in a living room and bedroom by calculating the ratio of the risk measures for TVs with untreated casings versus those treated with a flame retardant casing. The ratio is an indication of the increased likelihood of flashover should flame retardant treated TV casings be replaced with untreated casings.

The results of the risk quantification indicate that a living room fire initiated with a flat screen TV where the casing is not treated with flame retardants, is between 4.2 and 15.2 times more likely to result in flashover compared to a flat screen TV where the where the casing is treated with flame retardants. For a fire in a bedroom, the relative likelihood is between 4.1 and 15.5 times more likely to result in flashover. The relative likelihood of flashover was found to be slightly lower for apartments than for single-family homes.

These broader product safety and design considerations are important to inform Washington State's analysis and any policy recommendations. More direct engagement with relevant downstream users as it relates to flame retardants, alternatives, and overall product safety, design, performance, sustainability, and innovation will be important as Ecology works to finalize its recommendations.

5. Inconsistent and incomplete approach to evaluating OFRs and alternatives.

The Department in the draft report identifies five alternatives to the use of OFRs in enclosures for electrical and electronic equipment, and states that additives that provide an anti-drip function can be used in combination with the OFR alternatives to meet flammability standards. However, some of the alternatives identified by Ecology are on authoritative lists or are being evaluated by regulatory bodies, even though part of the Department's justification for proposing restrictions on OFRs is that some appear on authoritative and screening lists.

Ecology's flawed chemical class approach has led to inconsistent application of its hazard criteria and has chosen an approach that assumes all chemicals within an identified priority chemical class – in this case OFRs – will not qualify as safer. Conversely, in its desire to find acceptable alternatives, the Department has applied a lower level of scrutiny to alternatives. This is likely to lead to regrettable – or, at best, needless and costly – substitution.

For example, the Department has stated in conversations with NAFRA that if an OFR achieves a Benchmark-2 score as part of a GreenScreen Assessment, it still may not meet its

[19] Blais, M., Carpenter, K. Combustion Characteristics of Flat Panel Televisions with and Without Fire Retardants in the Casing. *Fire Technol* 51, 19–40 (2015). https://doi.org/10.1007/s10694-014-0420-7

"safer" criteria. This is because, Ecology claims, such chemicals fail within-class criteria.[20] However, the Department has also concluded that two non-halogenated flame retardants (TPP and RDP) identified as alternatives meet the minimum criteria for "safer" despite having the same Benchmark-2 score as part of a GreenScreen Assessment.[21]

> **Case Study:** For one OFR, decabromodiphenyl ethane ((DBDPE) (CAS RN 84852-53-9)) a GreenScreen Assessment was recently conducted with the chemical assigned a Benchmark-2 score.[22] The assessment updates a GreenScreen Assessment performed in 2017 when the compound was assigned a Benchmark-1 score.[23]
>
> The Department has identified Benchmark-2 as meeting its minimum criteria for safer. However, since DBDPE is an OFR additional within-class criteria applies, and the substance still might not meet Ecology's criteria for safer. This higher bar applies despite no relevant environmental transformation products for this chemical.[24]
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> A copy of the GreenScreen Assessment for DBDPE is included in Appendix I.

The Department's analysis must meaningfully consider the efficacy of alternative chemicals or any product redesign. If a replacement chemical or redesigned product poses an increased fire risk relative to a product that is currently available, the new product is not "safer."

The statute defines a "safer alternative" as "an alternative that is less hazardous to humans or the environment than the existing chemical or chemical process."[25] The legislature did not limit the hazards to those Ecology believes are posed by the priority chemical itself, but Ecology's current criteria for "safer" does not appear to adequately account for the hazards that flame retardants mitigate. Under the statutory language, a product that presents a fire safety risk cannot be a "safer alternative."

Ecology's framework underweights the fire safety hazards of products that can be mitigated with the use of OFRs, and bears the burden, under the statute, for demonstrating that a replacement chemical, or redesigned product, is safer.[26] That analysis must include not only a toxicological perspective but a fire safety perspective as well, which includes the efficacy of

[20] Draft Report at page 36.

[21] Draft Report at page 52.

[22] Gradient. GreenScreen® Assessment for [Decabromodiphenyl ethane; DBDPE (CAS # 84852-53- 9)]; Prepared for: American Chemistry Council: December 2021.

[23] NSF International. GreenScreen® Assessment for [Decabromodiphenyl ethane; DBDPE (CAS # 84852-53- 9)]; Prepared for: Clean Production Action: 2017.

[24] Gradient, *supra* note 22.

[25] RCW 70A.350.010(13).

[26] RCW 70A.350.040(3) .

OFRs and identified alternatives. The Department should balance any hazards associated with the priority chemical within the product, with the hazards that the chemical mitigates.

6. **Washington State should take a more robust and complete approach to assessing alternatives that considers product design factors such as innovation, sustainability, and equivalent performance.**

   a. **The draft recommendations take a very narrow approach to alternatives assessment that could ultimately impact product safety, performance, sustainability, and innovation. Washington State should expand its approach to assessing alternatives to include a more holistic, multi-factor approach.**

   Effective alternatives assessments consider multiple factors that are important for overall product design and performance, including critical attributes related to efficacy and sustainability. Absent a more robust and holistic alternatives assessment process, this new program will foster regrettable substitution and detract from some of the underlying objectives of the program.

   In most cases, the current approach appears to lack practical product design considerations. It is not clear if the alternatives identified in the draft report are practical or would in-fact be options for the broad range of product categories. Moreover, there are a host of sustainability issues to consider in the context of overall electronic product design and performance, including energy efficiency, durability, light, weighting, and material selection, among other factors.

   Case Study: Product manufacturers consider a variety of performance factors, including flammability. Alternatives to OFRs in some instances are not sufficient to meet minimum flammability requirements. Using phosphorus flame retardants in combination with polytetrafluoroethylene (PTFE) to provide the necessary anti-drip function may not be enough to meet flammability standards in some instances, and consequently an additional chemical that appears on authoritative lists may also be needed to meet or exceed flammability requirements.

   Moreover, alternatives to OFRs may not perform adequately in some settings when used in the casings or enclosures of electrical and electronic equipment. According to one resin manufacturer, OFR alternatives cannot be used in LED lights bulbs, charging cables, or outdoor electrical and electronic products due to performance concerns. These examples suggest that the Department has not adequately considered how flame retardants are used in end products and its draft proposal could have unintended consequences for electrical and electronic equipment performance, flammability, circularity, and overall product safety.

   Effective alternatives assessment and chemical regulation needs to consider these factors and overall product safety. While NAFRA appreciates that Safer Products for Washington is focused more narrowly on chemical safety and is not necessarily positioned to assess overall product design and performance factors, including fire

safety, we encourage Ecology to engage more directly with relevant downstream sectors as it relates to flame retardants, available alternatives, and overall product safety, design, and performance. The assumptions in the draft report would benefit from more rigorous analysis and address broader product safety and performance considerations, such as sustainability and life-cycle factors. These product safety and design considerations are important to factor into Department's analysis and any final policy recommendations.

It is clear from NAFRA's outreach to the electronics value-chain that the proposed assessment and draft determinations are insufficient in the following ways:

- Fails to take into account the robust and diverse set of end-product standards for electrical and electronic equipment. These standards extend beyond and often supersede the specific standards that Washington State has used to evaluate potential alternatives.

- Does not recognize that fire safety standards are viewed as minimum requirements for many OEMs and that overall fire safety can often go beyond those standards. In fact, many manufacturers voluntarily use enclosures with higher than the minimum flame requirements based on their own risk assessments.

- Identified alternatives to OFRs in some product applications do not meet fire safety standards.

- Fails to consider equivalent performance for alternatives – especially relative to other performance factors like weight, transparency, hydrophobics – which has specific implications for key uses in certain conditions.

- Does not consider the regulatory environment for the identified alternatives as well as broader circular and safety considerations relevant for product design in the electronics and electrical equipment sectors.

Careful consideration of these issues is also particularly relevant for future phases of the Safer Products program and any proposed regulations as these will require further analysis and justification. So, it is important to consider these issues now to guide effective public policy. To this end, we urge Ecology to hold a follow-up technical workshop to hear directly from manufacturers and suppliers about the diverse and complex issues that need to be considered relative to this product category.

b. The proposed recommendations would limit the availability of materials to manufacturers.

Different end products require different solutions and specific flame retardants are not interchangeable. A variety of flame retardants are necessary because materials that need to be made fire-resistant are very different, as are the end-use performance requirements

of the final product. Specific flame retardants are paired with specific plastic materials to address the unique safety and performance requirements of the product.

A combination of several products is often needed to achieve fire safety while maintaining material performance. For example, one consumer product might contain several types of plastics, and one type of plastic might have to meet different performance requirements. Electronics manufacturers need a broad array of material choices, including various plastics and flame retardants, to help meet product safety and design requirements. Material selection has a direct impact on utility, functionality, safety, cost, and weight of the product.

Flame retardants also enhance product performance and address key technical challenges like assembly temperatures, electrical properties, moisture uptake, mechanical performance, resistance to aging, mouldability, flexibility, and rigidity. In many cases flame retardants help enhance product performance and address key technical design challenges.

Manufacturers include specific flame retardants in their products based on its attributes, properties, usage, and potential ignition threats. The combination of the plastic matrices and the types of flame retardants is always based on the technical compatibility of the two materials. For example, a phosphorus-based flame retardant will only work on specific polymers because they need to react with it by forming a protective layer, whereas inorganic flame retardants are generally only efficient in high concentrations, which is only possible for elastomers.

In comparison, OFRs have a good technical compatibility with a wide range of materials. They are stable during the plastic processing and are efficient at low concentrations. That is why OFRs are in many instances the preferred choice for electronic casings.

Manufacturers need options to meet safety and performance requirements. Although in some instances there might be alternatives to OFRs for use in electronic device casings, substitutes are not always practical. The proposed recommendations may also have the unfortunate effect of deselecting resin systems available for product manufacturers, thereby reducing options for product design.

c. The assessment of alternatives should include relevant sustainability factors including recyclability and circularity.

BSEF, the International Bromine Council, recently released a report[27] regarding waste electrical and electronic equipment (WEEE) plastics flows and recycling efforts. The report, undertaken by a leading consultancy, SOFIES, addresses misperceptions regarding the impact of brominated flame retardants (BFRs) on WEEE plastics recycling

[27] Study on the Impacts of Brominated Flame Retardants on the Recycling of WEEE plastics in Europe," https://www.bsef.com/wp-content/uploads/2020/11/Study-on-the-impact-of-Brominated-Flame-Retardants-BFRs-on-WEEE-plastics-recycling-by-Sofies-Nov-2020.pdf

and presents the successes and overarching challenges in making WEEE plastic streams more circular.

The overarching conclusion from the study is that the presence of brominated flame retardants in WEEE plastics do not reduce recycling yields more than other flame retardants, as plastics containing flame retardants, as well as plastics containing other additives in significant loads (e.g., fillers), are sorted out during the recycling process. Moreover, a switch from brominated flame retardants to other flame retardants would not improve WEEE plastics recycling and would most probably have detrimental impacts on yields and quality.

Ecology has also failed to consider how the state's own electronic recycling program, E-Cycle Washington, could be part of a least burdensome alternative in achieving the state's policy objectives. E-Cycle Washington was established in 2009 and to date has collected over 440 million pounds of electronics through the program for recycling.[28] For 2021, over 15 million pounds of covered electronic products[29] were collected for recycling under the program.[30]

d. The failure to take a more holistic approach to alternatives assessments has the potential to undermine key objectives and drive regrettable substitution.

The overly broad scope of both the priority chemicals and priority product category may also have unintended consequences related to driving regrettable substitution. In some cases, this may force the use of substances that may create more exposure and may also be less effective, thereby undermining overall product safety and performance and driving unintended consequences from a sustainability perspective.

For example, the draft recommendations reference possibly using alternative processes or materials such as metal casings. However, it is not clear that these are realistic or even safer alternatives for the broad range of products. Replacing plastics with materials like metal would not only increase weight, but it would also increase the risk of shock and heat transfer. The fact is that plastics, and specifically flame retarded plastics, are often the best choice for manufacturers seeking overall product safety and performance.

Case Study: Although metal is a materials option available to OEMs, the use of plastics for exterior enclosures is usually driven by a variety of factors, including improved design functionality, corrosion resistance, integrated color without the need to use paints, and increased portability and movability due to the product being

[28] WA Department of Ecology, https://ecology.wa.gov/Waste-Toxics/Reducing-recycling-waste/Our-recycling-programs/Electronics-E-Cycle

[29] Covered electronic products include televisions, computers, laptops, monitors, tablets, e-readers, and portable DVD players

[30] WA Materials Management & Financing Authority, E-Cycle Washington December and YTD 2021, https://ecology.wa.gov/DOE/files/7e/7e15819e-cf21-43e3-addf-2e67f60349d1.pdf.

lighter weight. Plastics are mostly insulative and there are challenges with using metal as an insulative material with respect to shock resistance.

Electrical and electronic devices generally carry a risk of electric shock. Most metals are electrical conductors and therefore need protection from a fault that could cause it to become a shock hazard. Extra insulation and/or spacing from live parts are options to mitigate this risk; however, many product designs may be able achieve a higher level of electrical safety by using flame retardant plastics, which have inherent electrical insulative properties to prevent an internal fault from causing the enclosure or casing from becoming a "live" part. **Product marketing and non-authoritative sources should not be the sole basis for assessing the availability, feasibility, and equivalency of potential alternatives.**

The draft recommendations seem to rely heavily on references to various marketing materials and information from non-authoritative sources. As noted under the more detailed discussions of alternatives, such an approach fails to take into account important considerations related to product safety, performance, innovation, and sustainability.

NAFRA encourages Ecology to engage more directly with relevant downstream users as it relates to flame retardants, alternatives, and overall product safety, design, and performance. The assumptions stated in the draft report would benefit from a more rigorous analysis of alternatives and should more directly address product safety and performance considerations, including sustainability and life-cycle factors. These broader product safety and design considerations are important to factor into Department's analysis and any final policy recommendations.

7. **Any policy recommendations need to accurately and fully assess the important socio-economic considerations required under Safer Products for Washington.**

The Department of Ecology in developing any regulations for priority products must conduct the relevant socio-economic analyses. Important requirements that need to be considered include:

- A cost benefit analysis of the proposed regulation
- Whether the proposed regulation implements the "least burdensome alternative"
- A small business economic impact statement

While these requirements apply to the final rulemaking phase of this new program, it is critical that these factors be considered now at this stage to guide effective policy recommendations.

The Department to-date has failed to meaningfully consider the cost of removing OFRs from the casings and enclosures of electronics and electrical equipment. In Appendix D of the draft report, Ecology states that it will consider cost for scenarios like this. Washington State requires that any significant legislative rule being adopted include a cost-benefit analysis of

the rule and be the least burdensome alternative for those required to comply with it to achieve the general goals.[31]

In addition, the Regulatory Fairness Act (RFA) requires the Department to prepare a small business economic impact statement "if the proposed rule will impose more than minor costs on businesses in an industry" unless the Department as part of its cost-benefit analysis meets the RFA's requirements for a small business economic impact statement.[32]

8. Product manufacturers operate in a complex, global regulatory environment and are required to consider a broad range of product safety and design factors.

Product manufacturers manufacturers operate in a global regulatory environment and must take into account a broad range of product safety and design factors. This includes complex considerations related to product certification, performance, use and end of life, and even chemical registration and use. In addition, electronics manufacturers rely on a global supply chain for components and subcomponents. Any proposed recommendations should take these important global considerations into account.

Any proposed regulations should also seek to align with relevant federal and international regulations. No state, federal, or international regulatory authority has imposed a ban on flame retardants in electronics as broad as the one being considered in Washington State. This would make the state an outlier, potentially both decreasing electronic products available for purchase in the state and potentially impacted broader product safety, innovation, and sustainability.

Electronic products vary widely by power source (e.g., alternating current power, alkaline batteries, lithium batteries, etc.), size and weight requirements (e.g., floor equipment, tabletop equipment, handheld, wearable equipment, etc.), and other key factors impacting performance needs and safety considerations. Electronic equipment accounts for more than a hundred pages of Harmonized Tariff Schedule codes.[33] If the Department were to conclude that restrictions are appropriate for specific electrical and electronic products, it must analyze the feasibility of alternatives for those products.

The current proposed recommendations would also run counter to federal health and safety standards, as well as existing federal chemical and product safety regulations. Such a broad regulatory approach suggests that a more thoughtful approach is needed to align any proposal with existing state and federal programs. The draft recommendations regarding the use of flame retardants in protective enclosures for electrical and electronic equipment would create an unworkable regulatory framework in the state and would undermine interstate commerce.

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[31] Chapter 34.05.328 RCW, https://app.leg.wa.gov/rcw/default.aspx?cite=34.05.328

[32] Chapter 19.85 RCW, https://app.leg.wa.gov/RCW/default.aspx?cite=19.85

[33] *See* Chapters 84-85 of the Harmonized Tariff Schedule of the United States, available at https://hts.usitc.gov/current.

9. A revised approach is needed as the Department of Ecology finalizes its report to the Legislature.

NAFRA has concerns with the draft report, as outlined above in greater detail, and requests that the Department consider these concerns as it develops its regulatory determinations for a diverse set of flame retardant chemicals used in a wide range of electrical and electronic products.

Suggested areas for improvement include 1) a move away from the class-based approach for assessment of OFRs, 2) a narrowed product scope that more comprehensively considers the risk of flame retardant exposure from electronic casings, and 3) a thorough and consistent approach to assessing alternatives to OFRs used in casings and enclosures of electrical and electronic equipment that is based on a range of criteria, including fire safety and overall product performance.

APPENDIX I

Decabromodiphenyl Ethane (CAS RN 84852-53-9) Certified GreenScreen® Assessment

Prepared for
American Chemistry Council, Inc.
700 2nd Street NE
Washington, DC 20002

December 20, 2021

GRADIENT

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Table of Contents

Page

Contents

List of Tables

GreenScreen® Assessment for Decabromodiphenyl Ethane (CAS # 84852-53-9)

Method Version: GreenScreen Version 1.4[1]

Assessment Type:[2] Certified

Chemical Name: Decabromodiphenyl Ethane (CAS # 84852-53-9)

GreenScreen Assessment Prepared By:	GreenScreen Assessment Quality Control Performed By:
Name: Pranav Mashankar	**Name:** Alex Alverson
Title: Chemist	**Title:** Chemist
Organization: Gradient	**Organization:** Gradient
Date: 12/20/21	**Date:** 12/20/21
Name: Steven Boomhower and Ife Bamgbose	**Name:** Kim Reid
Title: Sr. Toxicologist and Environmental Scientist	**Title:** Principal Scientist
Organization: Gradient	**Organization:** Gradient
Date: 12/20/21	**Date:** 12/20/21
Name: Tatiana Manidis	**Name:** Tom Lewandowski, Ph.D. DABT, ERT, ATS
Title: Environmental Scientist	**Title:** Principal and Toxicologist
Organization: Gradient	**Organization:** Gradient
Date: 12/20/21	**Date:** 12/20/21
Assessor Type (Licensed GreenScreen Profiler, Authorized GreenScreen Practitioner, or Unaccredited):	Licensed GreenScreen Profiler

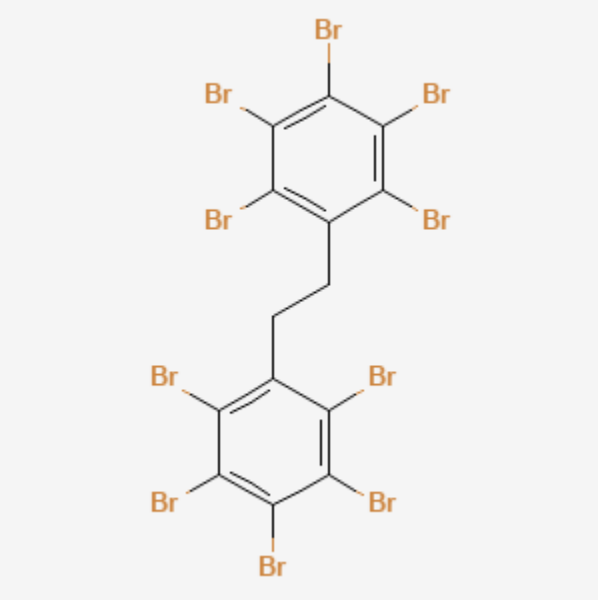
Confirm Application of the Disclosure and Assessment Rules and Best Practice:[3] N/A

Chemical Name (CAS #): Decabromodiphenyl Ethane (CAS # 84852-53-9)

Also Called: 1,2-Bis(perbromophenyl)ethane; 1,2-bis(2,3,4,5,6-pentabromophenyl)ethane; benzene, 1,1'-(1,2-ethanediyl)bis[2,3,4,5,6-pentabromo-; DeBDethane; saytex 8010; EC 284-366-9;

[1] Use GreenScreen Assessment Procedure (Guidance) v1.4 (January 2018).
[2] GreenScreen reports are either "UNACCREDITED" (by unaccredited person), "AUTHORIZED" (by Authorized GreenScreen Practitioner), "CERTIFIED" (by Licensed GreenScreen Profiler or equivalent), or "CERTIFIED WITH VERIFICATION" (Certified or Authorized assessment that has passed GreenScreen Verification Program)
[3] See GreenScreen Guidance v1.4.

Chemical Structure:

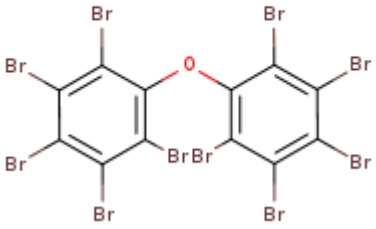


Source: National Library of Medicine (NLM, 2021 221-0618)

Suitable Analogs or Moieties Used in This Assessment (CAS #s):

One possible analog, decabromodiphenyl ether (Deca) (Chemistry Abstracts Service [CAS] # 1163-19-5[4]), was considered for use in this assessment. While both DBDPE and Deca have the same degree of bromine substitution, one is an unsaturated alkane (*i.e.*, ethane) and the other is an ether. The potential for biological/metabolic differences may be significant, as indicated by differing GreenScreen scores obtained for certain endpoints (*e.g.*, developmental neurotoxicity where the analog Deca has demonstrated effects [Washington Ecology, 2015] and DBDPE produced no clear effects, see below). Thus, we only relied upon data for Deca in a supportive role when data for DBDPE were absent and noted reservations with such extrapolation.

Table 1 Chemical Structures of Analogs Considered in the GreenScreen Assessment of DBDPE

Analog Name (CAS #)	Structure[1]	Endpoint(s) Assessed
Decabromodiphenyl ether (Chemistry Abstracts Service [CAS] # 1163-19-5)		Reproductive toxicity

Note:
CAS = Chemistry Abstracts Service.
(1) National Library of Medicine (NLM, 2021).

Notes Related to Production-Specific Attributes:[5]

For Inorganic Chemicals and Relevant Particulate Organics: N/A

Define Properties:

1. **Particle Size:** 2.687 microns (mean particle size of different lots of commercial product, measured June 2011, St. dev: 1.257 µm)

2. **Structure:** N/A

3. **Mobility (*e.g.*, water solubility, volatility):**
    a. Water Solubility: 0.72 µg /L (25 °C) (ECHA, 2021a)
    b. Vapor Pressure: < 1E-4 Pa (20 °C) (ECHA, 2021a)
    c. Adsorption onto soil: Kd: 8.83E+3 (silt loam soil), 4.17E+3 (Sandy soil), 2.37E+4 (sandy loam sediment), 5.89E+3 (sandy sediment). 4.28E+2 and 6.20E+2 (Activated Sludge Soils) (ECHA, 2021a)
    d. Henry's Law Constant: est. 6.42 x 10 -8 (Bond method) and 2.94 x 10-8 (Group method) atm-m3/mole (25˚C, 1 atm) (ECHA, 2021a)

4. **Bioavailability:**
    a. K_{ow}: Log Kow: 3.55 (25 °C) (ECHA, 2021a)
    b. K_{oc}: 3.312E+6 (EPI Module PCKOC v1.66) (ECHA, 2021a)
    c. Bioaccumulation: "Did not bioconcentrate in fish over an 8 week period" and "the substance is not metabolised in the gut and only absorbed to a very little extend from the gut and eliminated unchanged." (ECHA, 2021a)

Identify Applications/Functional Uses:

1. Adhesives and sealants
2. Construction material
3. Thermoplastics used in electronics or automotives
4. Flame retardant
5. Coating products
6. Fillers
7. Putties
8. Plasters

[5] Note any composition or hazard attributes of the chemical product relevant to how it is manufactured. For example, certain synthetic pathways or processes result in typical contaminants, by-products or transformation products. Explain any differences between the manufactured chemical product and the GreenScreen assessment of the generic chemical by CAS #.

9. Modelling clay
10. Inks and toners
11. Leather treatment products
12. Lubricants and greases
13. Polishes and waxes
14. Polymers
15. Washing & cleaning products
16. Cosmetics and personal care products

(ECHA, 2021a)

GreenScreen Benchmark Score and Hazard Summary Table[6]

Decabromodiphenyl ethane (hereafter, "DBDPE") is assigned a Benchmark Score of BM-2 based on *Very High (vH)* persistence and *Moderate (M)* reproductive, developmental and endocrine potential. The *Moderate (M)* score for reproductive toxicity is based on the analog decabromodiphenyl ether which may be unreliable; all other endpoint scores are based on data for DBDPE. The moderate score for developmental toxicity is due to limitations of a developmental neurotoxicity study which indicated no definitive effects and, aside form this uncertainty would otherwise equate to a score of Low. Although a data gap exists for respiratory sensitization, the data requirements were met for BM-2 classification, as shown in Table 2 below.

If we consider a worst-case benchmarking scenario based on reported data gaps (score of **High (H)** for respiratory sensitization), DBDPE would be assigned a score of BM-1. However, there are currently no indications that such a score is likely.

Table 2 GreenScreen (v1.4) Hazard Profile Summary Table – Decabromodiphenyl Ethane

Group I Human					Group II and II* Human									Ecotox		Fate		Phys.	
C	M	R	D	E	AT	ST		N		SnS*	SnR*	IrS	IrE	AA	CA	P	B	Rx	F
						sgl	rpt*	sgl	rpt*										
L	**L**	*M*	*M*	M	**L**	**L**	**L**	**L**	*L*	**L**	DG	**L**	**L**	**L**	*L*	*vH*	**L**	**L**	**L**

Notes:
CAS = Chemistry Abstracts Service.
Hazard levels (Very High [vH], High [H], Moderate [M], Low [L], Very Low [vL]) in *italics* reflect estimated values, authoritative B lists, screening lists, weak analogues, and lower confidence.
Hazard levels in **bold** font are used with good quality data, authoritative A lists, or strong analogues.
Group II Human Health endpoints differ from Group II* Human Health endpoints in that they have four hazard scores (*i.e.*, vH, H, M, and L) instead of three (*i.e.*, H, M, and L) and are based on single exposures instead of repeated exposures.
All acronym definitions are listed in Appendix A.

Environmental Transformation Products and Ratings[10]

Identify feasible and relevant environmental transformation products (*i.e.*, dissociation products, transformation products, valence states) and/or moieties of concern (Table 3).[11]

[6] See Appendix A for a glossary of hazard endpoint acronyms.
[7] See Appendix B for the PHAROS results for Chemical Name and its transformation products.
[8] For inorganic chemicals only, see GreenScreen Guidance v1.4 Section 12. (Exceptions for Persistence).
[9] For Systemic Toxicity and Neurotoxicity, repeated exposure data are preferred. Lack of single exposure data is not a Data Gap when repeated exposure data are available. In that case, lack of single exposure data may be represented as NA instead of DG. See GreenScreen Guidance v1.4 Section V, Annex 2, 2.3 (A2.2.3).
[10] See GreenScreen Guidance v1.4 Sections 11.4 and 11.5.
[11] A moiety is a discrete chemical entity that is a constituent part or component of a substance. A moiety of concern is often the parent substance itself for organic compounds. For inorganic compounds, the moiety of concern is typically a dissociated component of the substance or a transformation product.

Table 3 Environmental Transformation Products and Ratings

Functional Use	Life Cycle Stage	Transformation Pathway	Environmental Transformation Products	CAS #	Feasible and Relevant?	GreenScreen List Translator Score or Benchmark
Polymer additive (*e.g.*, as a flame retardant)	End of Life	Photo-transformation in air	None	N/A	Not feasible. Compound did not undergo photodegradation even after being exposed to sunlight irradiation for 224 days.	N/A
		Hydrolysis	None	N/A	Not feasible due to insolubility in water	N/A
		Biodegradation in water	None	N/A	Not feasible. Compound was not biodegradable by activated sewage sludge over a 28-day period.	N/A
		Biodegradation in soil	None	N/A	Not feasible. Compound did not appear to degrade in 4 test soils over a 6 month period	N/A

Notes:
CAS = Chemistry Abstracts Service; N/A = Not Applicable
Source: ECHA 2021

DBDPE was observed to not undergo photodegradation in air even after being exposed to sunlight irradiation for 224 days in an experimental study (ECHA, 2021a). DBDPE is insoluble in water (0.72 µg/L), making degradation *via* hydrolysis in water highly unlikely (ECHA, 2021a,b). In an experimental biodegradation study in water under aerobic conditions, DBDPE showed no degradation in water or activated sludge after 28 days (ECHA, 2021a). Finally, an experimental study investigating the biodegradability of DBDPE in soil found that it did not appear to degrade in 4 test soils over a 6 month period (ECHA, 2021a). Overall, DBDPE is not expected to transform significantly in aquatic or terrestrial environments, which is partially related to its low solubility in water (ECHA, 2021a,b). As a consequence, it was determined that there are no relevant environmental transformation products for this chemical.

Introduction

DBDPE is an industrial chemical that is used primarily as a flame retardant for the plastics industry (ECHA, 2021b). Table 4 summarizes the physical and chemical properties obtained for DBDPE:

Table 4 Physical and Chemical Properties of Decabromodiphenyl Ethane (CAS # 84852-53-9)

Property	Value	Reference
Molecular Formula	$C_{14}H_4Br_{10}$	Expert judgement
SMILES Notation	C(CC1=C(C(=C(C(=C1Br)Br)Br)Br)Br)C2=C(C(=C(C(=C2Br)Br)Br)Br)Br	Expert judgment
Molecular Weight	971.2 g/mol	NLM 2021 221-10454
Physical State	Solid at 20 °C and 1013 hPa	ECHA 2021a
Appearance	White powder	ECHA 2021a
Melting Point	350 °C	ECHA 2021a
Vapor Pressure	< 1E-4 Pa (20 °C)	ECHA 2021a
Water Solubility	0.72 µg /L (25 °C)	ECHA 2021a
Dissociation Constant	Not applicable	Expert judgement
Density/Specific Gravity	2.67 g/ml (20 °C)	ECHA 2021a
Partition Coefficient, Log Kow	Log Kow: 3.55 (25 °C)	ECHA 2021a

Notes:
SMILES = Simplified Molecular-Input Line-Entry System.
Gradient assessed Chemical Name against GreenScreen version 1.4 (CPA, 2019).

Hazard Classification Summary Section

Hazard classifications for the GreenScreen endpoints evaluated are provided below.

Group I Human Health Effects (Group I Human)

Carcinogenicity (C)

Score: *L*

DBDPE was assigned a score of *Low* (*L*) for carcinogenicity based on a lack of any indication of pre-neoplastic or other tissue damage in a well conducted 90-day study, negative or inadequate results of structure-activity programs for genotoxic or non-genotoxic carcinogenicity, consistently negative results in several genotoxicity assays, and no indication from chronic exposure studies that the chemical might act by other modes of carcinogenicity (*e.g.*, peroxisomal proliferation). The chemical is also not present on any authoritative or screening level lists for this endpoint. The confidence in this determination is low due to the absence of data from a 2-year bioassay specifically designed to assess carcinogenicity and the uncertain relevance of data for decabromodiphenyl ether.

Authoritative and Screening Lists

- **Authoritative**: Not listed.
- **Screening**: Not listed.

Study Data

- In a 90-day repeated dose toxicity study (discussed in more detail below), there was no indication of tissue damage or other lesions in histopathological analysis of exposed animals (ECHA, 2021a).
- As noted below, DBDPE was negative in both bacterial and mammalian genotoxicity testing.
- The structure activity program Toxtree predicts that DBDPE would not be a carcinogen by either genotoxic or non-genotoxic mechanisms. The predictive toxicology program Oncologic indicates a moderate level of concern but this is based solely on DBDPE having halogenated substitution, not on the presence of a reactive functional group or a likely mechanism of carcinogenicity.
- The structurally related decabromodiphenyl ether has indicated some potential for carcinogenic activity in animal studies (NTP, 1986) but the use of this chemical as an analog for read across is uncertain given the difference in structure (an ether *versus* an ethane).

Overall, the weight of the evidence suggests a Low carcinogenic risk. Given the Oncologic predictions and uncertain relevance of the surrogate decabromodiphenyl ether, the level of confidence is considered low. . Note that the United Kingdom Environmental Agency in reviewing DBDPE indicated the chemical unlikely to be carcinogenic (EA, 2007).

Mutagenicity/Genotoxicity (M)

Score (H, M or L): L

DBDPE is assigned a score of **Low (L)** for mutagenicity with high confidence. *In vitro* studies reviewed indicate that DBDPE is not mutagenic or clastogenic. This classification is made with high confidence as it is based on experimental data from well-conducted studies with DBDPE. In addition, DBDPE is not present on any authoritative or screening lists.

Authoritative and Screening Lists

- **Authoritative**: Not listed.
- **Screening**: Not listed.

Studies

- **ECHA (2021a)**
  - DBDPE was not mutagenic in an *in vitro* bacterial reverse mutation assay (1991; similar to OECD 471; K = 1), with and without metabolic activation (arochlor-induced rat liver microsomes), using *Salmonella typhimurium* strains TA1535, TA1537, TA1538, TA98, and TA 100 and *E.coli* strain uvrA at concentrations ranging from 0 to 5,000 µg/plate. Appropriate solvent (dimethyl sulfoxide [DMSO]) and positive controls were evaluated concurrently. Under the test conditions, the substance was negative for mutagenicity both with and without metabolic activation. Control groups responded appropriately, validating the study results.
  - DBDPE was not mutagenic in an *in vitro* bacterial reverse mutation assay (1988; similar to OECD 471; K = 1), with and without metabolic activation (arochlor-induced rat liver microsomes), using *Salmonella typhimurium* strains TA1535, TA1537, TA98, and TA 100 at concentrations ranging from 0 to 5,000 µg/plate. Positive and negative control values were reported to be within acceptable limits. Under the test conditions, the substance was negative for mutagenicity both with and without metabolic activation. Control groups responded appropriately, validating the study results.
  - DBDPE was not clastogenic in an *in vitro* chromosome aberration assay (1991; equivalent to OECD 473; K = 1), with and without metabolic activation (S9 mix), using Chinese hamster lung fibroblasts (V79) at concentrations ranging from 0 to 625 µg/mL (in DMSO) and 0 to 5,000 µg/mL (in 1% carboxymethyl cellulose). Positive controls were evaluated concurrently. DBDPE did not increase the number of cells with chromosome aberrations with and without metabolic activation. Control groups responded appropriately, validating the study results.

Reproductive Toxicity (R)

Score (H, M, or L): *M*

DBDPE is assigned a score of *Moderate (M)* for reproductive toxicity, with low confidence. This score is based on no observed effects on reproductive organ weights from a 90-day subchronic toxicity study with the target chemical. A reproductive toxicity study with the analog chemical decabromodiphenyl ether observed adverse effects on sperm in mice; however use of this chemical as an analog for read-across is

uncertain due to differences in key structural elements. This score is assigned with low confidence as it is based on limited results from a subchronic toxicity study with the target chemical and reproductive toxicity studies with an analog of uncertain relevance. In addition, DBDPE is not present on any authoritative or screening lists.

Authoritative and Screening Lists

- **Authoritative:** Not listed.
- **Screening:** Not listed.

Studies

- **ECHA (2021a,c)**
  - In a 90-day subchronic toxicity study (1992; OECD 408; K = 1), male and female Sprague-Dawley rats were administered 0, 100, 320, or 1,000 mg/kg-day (n = 20/sex for 0 and 1,000 mg/kg-day groups; n = 10/sex for 100 and 320 mg/kg-day groups) of DBDPE in corn oil *via* oral gavage for 90 days. There were no treatment-related adverse effects observed on reproductive organ weights (*i.e.*, testes and ovaries) among the 40 organs measured. Based on these results, a NOAEL of 1,000 mg/kg-day was determined.
  - In a one-generation reproductive toxicity study (1975; equivalent to OECD 415; K = 2), male and female Sprague-Dawley rats were administered 0, 3, 30, or 100 mg/kg-day[12] of the analog chemical decabromodiphenyl ether (CAS # 1163-19-5) *via* diet for 60 days prior to mating, throughout mating, and throughout gestation and lactation. There were no treatment-related adverse effects observed on reproductive or developmental parameters. However, the use of this chemical as an analog for read across is uncertain given the difference in structure (an ether *versus* an ethane).
  - In a reproductive toxicity study (2006; no guideline), male CD-1 mice were administered 0, 10, 100, 500, or 1,500 mg/kg-day of the analog chemical decabromodiphenyl ether *via* oral gavage for 49 days. Decreased amplitude of lateral head displacement (sperm motility) and mitochondrial membrane potential (sperm fertility potential) were observed at the two highest doses. The study authors identified a NOAEL of 100 mg/kg-day. However, the use of this chemical as an analog for read across is uncertain given the difference in structure (an ether *versus* an ethane).

Developmental Toxicity Incl. Developmental Neurotoxicity (D)

Score (H, M or L): *M*

DBDPE is assigned a score of *Moderate (M)* for developmental toxicity, with low confidence. No effects were observed in prenatal developmental toxicity studies (in rats and rabbits) and no clear effects were reported for a developmental neurotoxicity study, although there is some uncertainty as to whether some histopathology effects seen in the developmental neurotoxicity study were treatment related. This score is assigned with low confidence as it is driven by uncertainties in the data which would otherwise suggest a score of Low for DBDPE.

[12] 10 males/dose and 20 females/dose were assigned to the 3 and 30 mg/kg-day dose levels. 15 males and 30 females were assigned to the 100 mg/kg-day dose levels. 20 males and 40 females were assigned to the control condition.

Authoritative and Screening Lists

- **Authoritative:** Not listed.
- **Screening:** Not listed.

Studies

- **ECHA (2021a) and Health Canada (2019)**
  - In a prenatal developmental toxicity study (1992; equivalent to OECD 414; K = 1), Sprague-Dawley rats (n = 25 females/dose) were administered 0, 125, 400, or 1,250 mg/kg-day of DBDPE in corn oil *via* oral gavage from gestational days 6 to 15. No changes in maternal body weight or food consumption were observed. In fetuses, there was a statistically significant increase in the number of litters with unossified hyoid bone and reduced ossification of the skull at 400 mg/kg-day. Because similar effects were not observed at the highest dose, this observation was not considered to be biologically meaningful. Thus, the NOAEL for developmental toxicity is ≥1,250 mg/kg-day (Mercieca, 1992a)
  - In a prenatal developmental toxicity study (1992; equivalent to OECD 414; K = 1), New Zealand White rabbits (n = 20 females/dose) were administered 0, 125, 400, or 1,250 mg/kg-day of DBDPE in carboxymethyl cellulose *via* oral gavage from gestational days 6 to 18. No changes in maternal body weight or food consumption were observed. No treatment-related effects were observed on body weights, live offspring, sex ratio, litter size and weights, survival, or malformations of offspring/fetuses. An increased number of litters with the 27th presacral vertebra were observed at the highest dose; however, this was considered a common finding in rabbits and within the historical range and not considered adverse. Based on the results of this study, the NOAEL for developmental toxicity is 1,250 mg/kg-day (Mercieca, 1992b)
  - In a prenatal developmental toxicity study (2010; OECD 414; K =1), rats and rabbits (numbers unspecified) were administered 0, 125, 400, or 1,250 mg/kg-day of DBDPE *via* oral gavage from gestational days 6-15 (rats) and 6-18 (rabbits). Dams and does were sacrificed on gestational days 20 and 29 respectively, and offspring obtained by caesarean section. No treatment-related mortality, body weight changes, food consumption changes, or abortions were observed in mothers. In offspring/fetuses, no treatment-related effects were observed in terms of malformations or developmental parameters. Based on the results of this study, the NOAEL for developmental toxicity is 1,250 mg/kg-day (Hardy *et al*., 2010).
  - In a developmental neurotoxicity study (2018; OECD 426; K = 2), Sprague-Dawley rats (n = 25 females/dose) were administered 0, 100, 320, or 1,000 mg/kg-day of DBDPE in corn oil *via* oral gavage from gestational day 6 to lactational day 21. No changes in maternal body weight or food consumption were observed. Offspring (n = 10/sex) were divided among four groups for clinical observations, auditory startle response, motor activity, and learning and memory using passive avoidance. There were no effects observed on pup body weight gain, postweaning body weight, or sexual maturation parameters. There were no treatment-related effects observed in terms of clinical observations, auditory startle response, motor activity, or learning and memory tests. Morphometric changes were observed in the brains of male rats; however, the authors stated these were not associated with changes in brain weight or gross brain measurements. Two independent pathology reviews described these results as ambiguous and potentially an artifact of the tissue preparation process. In addition, there were no microscopic changes in brain, spinal cord, nerve roots, or ganglia.

Endocrine Activity (E)

Score (H, M or L): M

DBDPE is assigned a score of **Moderate (M)** for endocrine activity with high confidence. This classification is based on findings from a 90-day toxicity study in rats, a 30-day exposure study in mice, a developmental neurotoxicity in rats, a subacute study in zebrafish and a study in occupationally exposed workers. DBDPE was shown to increase serum thyroid hormone triiodothyronine (T3) levels in male Sprague-Dawley rats and Balb/C mice. However, the thyroxine (T4) levels in males were not altered. It is noteworthy to mention that the Wang *et al*. (2010) study has been challenged for poor study design. A developmental neurotoxicity study in rats involving exposure during gestation and evaluation of pups indicated no changes in sexual maturation. Moreover, no endocrine related effects were observed in the repeated dose studies cited above. This score is assigned with high confidence due to multiple studies in animals suggesting an effect on thyroid hormone concentrations.

Authoritative and Screening Lists

- **Authoritative:** Not listed
- **Screening:** OSPAR - Priority PBTs & EDs & equivalent concern

Studies

- **Wang *et al*. (2010) and Health Canada (2019)**
  - In an oral exposure study, male Sprague-Dawley rats (n = 6/dose) were administrated 100 mg/kg-day of DBDPE in corn oil *via* oral gavage for 90 days. Biochemical parameters, including thyroid hormone levels were evaluated. DBDPE induced an increase in serum triiodothyronine (T3) concentration but not serum thyroxine (T4). Thyroid stimulating hormone in serum was apparently not measured. Tissue histopathology was not examined. According to Health Canada (2019), the study was challenged for poor study design.
- **Bao Sun *et al*. (2019)**
  - In a dietary exposure study, Balb/C mice were administered 5, 20, 100, and 200 mg/kg body weight per day of DBDPE *via* oral gavage for 30 days. Biochemical parameters and hormone levels including insulin and thyroid hormone were assayed. DBDPE weakly induced the thyroid-stimulating hormone (TSH) at the highest dose. The triiodothyronine (T3), and free triiodothyronine (fT3) were reduced at the highest dose, respectively. DBDPE also significantly increased uridine diphosphoglucuronyltransferase (UDPGT), pentoxyresorufin O-dealkylase (PROD), and ethoxyresorufin O-dealkylase (EROD) activities in animals of the high dose group. The study authors concluded that DBDPE "has the activity of endocrine disruptors in Bal/C mice [*sic*], which may induce drug-metabolizing enzymes including CYPs and UDPGT, and interfere with thyroid hormone levels mediated by AhR and CAR signaling pathways. Endocrine disrupting activity of DBDPE could also affect the glucose metabolism homeostasis."
- **Wang *et al*. (2019a)**
  - In an exposure study, zebrafish embryos were exposed to 0, 3, 10, 30, 100, 300 nM of DBDPE for 6 or 14 days. Thyroid endocrine function was evaluated. DBDPE increased whole body

content of triiodothyronine (T3) and thyroxine (T4). However, histological findings and stereological analysis showed no obvious pathological changes in the thyroid gland.

- **Wang *et al*. (2019b)**
  - The same researchers noted above (Wang *et al*. 2019a) also examined the comparative effects of Deca-BDE and DBDPE in the thyroids of rats. Rats were treated with 5, 50 or 500 mg/kg of either chemical for 28 days after which thyroid hormones and thyroid histology were examined. Treatment at 500 mg/kg DBDPE caused an increase in serum TSH and thyrotropin releasing hormone (TRH) whereas serum free T3 (fT3) was decreased at both 50 and 500 mg/kg DBDPE. Serum T4 (total or free) and total T3 were not affected at any dose. Histopathological evaluation of the thyroids showed evidence of cell swelling and vacuolization. The authors noted that the increase in TSH and decrease in fT3 was consistent with hypothyroidism.
- **Chen *et al*. (2019)**
  - A study of human populations exposed to DBDPE was reported by Chen *et al*. (2019), the same research group as Wang *et al*. (2019a and b). The study measured thyroid-related hormone levels in a population occupationally exposed to DBDPE. Serum levels of DBDPE were quite high (mean - 4100 µg/g *versus* 46 ng/g in controls). The authors reported that serum DBDPE in exposed workers was positively correlated with total serum concentrations of the thyroid hormones T3 and T4 but not with serum TSH. Free (unbound) concentrations of T3 and T4 (fT3, fT4) were not significantly increased. Thyroid peroxidase antibodies (TPO-Ab) were also increased although the increase was just outside statistical significance (p=0.052). Concentrations of thyroid hormones in the exposed workers were said to be "predominantly" in the normal clinical range. Moreover, serum DBDPE was also associated with a number of other variables including seafood intake, alcohol consumption, iodized salt intake and number of children (in women). Although the authors attempted to control for these in their regression model, given the small degree of effect, residual confounding cannot be ruled out. The authors also did not consider potential co-exposures (*i.e*., Deca as an impurity). The authors also noted that the findings with respect to thyroid hormone changes were not consistent with the effects observed in their earlier rat study (Wang *et al*. 2019b) where fT3 was decreased and TSH was increased. Overall, this study, with limitations, suggests possible endocrine activity of DBDPE in humans although it provides no evidence of an actual health effect which would lead to a GreenScreen score of high.
- **ECHA (2021a)**
  - In a developmental neurotoxicity study (2018; OECD 426; K = 2), Sprague-Dawley rats (n = 25 females/dose) were administered 0, 100, 320, or 1,000 mg/kg-day of DBDPE in corn oil *via* oral gavage from gestational day 6 to lactational day 21. Among offspring, there were no effects of DBDPE on postweaning body weight or the onset of sexual maturation as indicated by timing of vaginal opening or preputial separation.

Group II and II* Human Health Effects (Group II and II* Human)

Note: *Group II and Group II* endpoints are distinguished in the v1.4 Benchmark system (the asterisk indicates repeated exposure). For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints. When classifying hazard for Systemic Toxicity/Organ Effects and Neurotoxicity endpoints, repeated exposure results are required and preferred. Lacking repeated exposure results in a data gap. Lacking single exposure data does not result in a data gap when repeated exposure data are present*

(shade out the cell in the hazard table and make a note). If data are available for both single and repeated exposures, then the more conservative value is used.

Acute Mammalian Toxicity (AT) Group II

Score (vH, H, M or L): L

DBDPE is assigned a score of **Low (L)** for acute mammalian toxicity, single exposure, with high confidence. This score is based on the results of two OECD guideline acute toxicity studies, in which median lethal doses (LD_{50}) were reported at values greater than would warrant classification per GHS guidelines. No mortalities were observed. The oral and dermal LD50s were > 2,000 mg/kg-bw. Confidence in this score is high because it is based on reliable experimental data for DBDPE for both the dermal and oral routes of exposure. In addition, DBDPE is not present on any authoritative or screening lists.

Authoritative and Screening Lists

- **Authoritative:** Not listed.
- **Screening:** Not listed.

Studies

Oral

- **ECHA (2021a)**
  - In an acute oral toxicity study (1988; equivalent to OECD 420; K = 1), male and female Sprague-Dawley rats (n = 5/sex) were administered a single dose of 5,000 mg/kg-bw of DBDPE (in 0.25% methylcellulose) *via* oral gavage and observed for 14 days. There were no signs of systemic toxicity and no mortality occurred. An LD_{50} was determined to be greater than 5,000 mg/kg-bw. This study indicated that the test substance exhibits low acute toxicity *via* the oral route.

Dermal

- **ECHA (2021a)**
  - In an acute dermal toxicity study (1988; equivalent to OECD 434; K = 1), male and female New Zealand White rabbits (n = 5/sex) were administered 2,000 mg/kg-bw of DBDPE (moistened in saline) *via* dermal application under occlusive conditions for 24 hours and observed for 14 days following exposure. There were no signs of systemic toxicity and no mortality occurred. An LD_{50} was determined to be greater than 5,000 mg/kg-bw. This study indicated that the test substance exhibits low acute toxicity *via* the dermal route.

Inhalation

- None.

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST)

(ST-Single) Group II

Score (vH, H, M or L): L

DBDPE is assigned a score of **Low (L)** for single-exposure systemic toxicity/organ effects including immunotoxicity, with high confidence. This score is based on an acute oral toxicity study in rats and an acute dermal toxicity study in rabbits. No adverse effects were reported at levels requiring classification in any of the studies reviewed. Confidence in this score is high because it is based on reliable experimental data for DBDPE for two routes of exposure. In addition, DBDPE is not present on any authoritative or screening lists.

Authoritative and Screening Lists

- **Authoritative:** Not listed.
- **Screening:** Not listed.

Studies

Oral

- **ECHA (2021a)**
  - In an acute oral toxicity study (1988; equivalent to OECD 420; K = 1), male and female Sprague-Dawley rats (n = 5/sex) were administered a single dose of 5,000 mg/kg-bw of DBDPE (in 0.25% methylcellulose) *via* oral gavage and observed for 14 days. There were no signs of systemic toxicity or effects on organ systems. An LD_{50} was determined to be greater than 5,000 mg/kg-bw. This study indicated that the test substance exhibits low acute toxicity *via* the oral route.

Dermal

- **ECHA (2021a)**
  - In an acute dermal toxicity study (1988; equivalent to OECD 434; K = 1), male and female New Zealand White rabbits (n = 5/sex) were administered 2,000 mg/kg-bw of DBDPE (moistened in saline) *via* dermal application under occlusive conditions for 24 hours and observed for 14 days following exposure. There were no signs of systemic toxicity or effects on organ systems. An LD_{50} was determined to be greater than 5,000 mg/kg-bw. This study indicated that the test substance exhibits low acute toxicity *via* the dermal route.

Inhalation

- None.

(ST-Repeated) Group II*

Score (H, M, L): L

DBDPE is assigned a score of **Low (L)** with high confidence for repeated-exposure systemic toxicity/organ effects including immunotoxicity. This score is based on two subchronic repeated dose studies in rats administered DBDPE *via* oral gavage. No adverse effects were noted at doses up to 1,000 mg/kg-day. Confidence in this score is high because it based on reliable experimental data for DBDPE . In addition, DBDPE is not present on any authoritative or screening lists.

Authoritative and Screening Lists

- **Authoritative:** Not listed.
- **Screening:** Not listed.

Studies

Oral

- **ECHA (2021a)**
  - In a 28-day subchronic toxicity study (1991; OECD 407; K = 1), male and female Sprague-Dawley rats were administered 0, 125, 400, or 1,250 mg/kg-day (n = 12/sex/dose in the control and high dose groups; n = 6/sex/dose in the low and mid dose groups) DBDPE in corn oil *via* oral gavage for 28 days. Animals were observed for 14 days afterward. No treatment-related adverse effects were observed on body weights, weight gain, or food consumption. A dose-dependent increase in liver weights was observed in female rats, but was not considered adverse due to the absence of histopathology and reversal after 14 days. Notably, no effects were observed in terms of thyroid weights. A NOAEL of 1,250 mg/kg-day was determined.
  - In a 90-day subchronic toxicity study (1992; OECD 408; K = 1), male and female Sprague-Dawley rats were administered 0, 100, 320, or 1,000 mg/kg-day (n = 20/sex for 0 and 1,000 mg/kg-day groups; n = 10/sex for 100 and 320 mg/kg-day groups) of DBDPE in corn oil *via* oral gavage for 90 days. No deaths or clinical signs were observed. Statistically significant hematological changes were observed but were not considered toxicologically relevant because they fell within historical control ranges. Increased relative and absolute liver weights were observed in females at the highest dose. Increased relative liver weights were observed in males at the highest dose. The liver weight effects resolved after a 28-day recovery period and, based on histopathological evaluation, were judged to be an adaptive effect. There were no treatment-related adverse effects observed on reproductive organ weights (*i.e.*, testes and ovaries) among the 40 organs measured. Based on these results, a NOAEL of 1,000 mg/kg-day was determined.

Inhalation

- None.

Dermal

- None.

Neurotoxicity (N)

Neurotoxicity (N) Group II – Single

Score (vH, H, M or L): L

DBDPE is assigned a score of **Low (L)** for neurotoxicity *via* single exposure with high confidence. This score is based on a lack of neurotoxic findings observed in OECD guideline acute toxicity tests *via* the oral and dermal routes. Confidence in this score is high because the study data are reliable and there are data for two exposure pathways. In addition, DBDPE is not present on any authoritative or screening lists.

Authoritative and Screening Lists

- **Authoritative:** Not listed.
- **Screening:** Not listed.

Studies

Oral

- **ECHA (2021a)**
  - In an acute oral toxicity study (1988; equivalent to OECD 420; K = 1), male and female Sprague-Dawley rats (n = 5/sex) were administered a single dose of 5,000 mg/kg-bw of DBDPE (in 0.25% methylcellulose) *via* oral gavage and observed for 14 days. There were no signs of systemic toxicity or clinical signs suggestive of neurotoxicity.

Dermal

- **ECHA (2021a)**
  - In an acute dermal toxicity study (1988; equivalent to OECD 434; K = 1), male and female New Zealand White rabbits (n = 5/sex) were administered 2,000 mg/kg-bw of DBDPE (moistened in saline) *via* dermal application under occlusive conditions for 24 hours and observed for 14 days following exposure. There were no signs of systemic toxicity and no clinical signs suggestive of neurotoxicity.

Inhalation

- None.

Neurotoxicity (N) Group II* – Repeated

Score (H, M or L): *L*

DBDPE is assigned a score of *Low (L)* for neurotoxicity *via* repeated exposure with low confidence. This score is based on results from a 90-day subchronic toxicity study and a developmental neurotoxicity study, both of which did not observe any neurotoxic effects in rats at doses up to 1,000 mg/kg-day. Importantly,

no neurological effects were observed in the developmental neurotoxicity study which examined a more sensitive developmental period (*i.e.*, gestational exposure). Confidence in this score is low because specific neurological endpoints (*e.g.*, *via* a functional observation battery) were not examined in adult animals following repeated exposures. In addition, DBDPE is not present on any authoritative or screening lists.

Authoritative and Screening Lists

- **Authoritative:** Not listed.
- **Screening:** Not listed.

Studies

- **ECHA (2021a)**
  - As noted above, in a developmental neurotoxicity study (2018; OECD 426; K = 2), Sprague-Dawley rats (n = 25 females/dose) were administered 0, 100, 320, or 1,000 mg/kg-day of DBDPE in corn oil *via* oral gavage from gestational day 6 to lactational day 21. There were no treatment-related neurological effects observed in terms of clinical observations, auditory startle response, motor activity, and learning and memory. The NOAEL for developmental neurotoxicity is 1,000 mg/kg-day.
  - As noted above, in a 90-day subchronic toxicity study (1992; OECD 408; K = 1), male and female Sprague-Dawley rats were administered 0, 100, 320, or 1,000 mg/kg-day (n = 20/sex for 0 and 1,000 mg/kg-day groups; n = 10/sex for 100 and 320 mg/kg-day groups) of DBDPE in corn oil *via* oral gavage for 90 days. No test article-related clinical signs were observed during the course of the study.

Skin Sensitization (SnS) Group II*

Score (H, M or L): L

DBDPE is assigned a **Low (L)** score for skin sensitization, with high confidence. This score is based on a lack of skin sensitization reactions in a guinea pig maximization test. The predictive toxicology program DEREK NEXUS predicts DBDPE to be a non-sensitizer. Confidence in this score is high due to predictions that DBDPE is a non-sensitizer that are supported by data from an experimental study. DBDPE is not present on any authoritative or screening lists.

Authoritative and Screening Lists

- **Authoritative:** Not listed.
- **Screening:** Not listed.

Studies

- **ECHA (2021a)**
  - In a guinea pig maximization test (GPMT) (2003; OPPTS 870.2600; K = 1), researchers applied DBDPE to male female Dunkin-Hartley guinea pigs at 5% for intradermal induction, 100% for the topical induction, and 1% for the topical challenge exposures. Animals were divided among three groups: test animals (n = 10/sex), positive controls (n = 5/sex), and negative controls (n

= 5/sex). Mild erythema was observed at 24 hours in 90% of animals in all groups. After 48 hrs, 20% of negative control animals and 20% of test group animals showed a positive response; however, 50% of the positive control animals showed a positive response. Because the test group and negative control group had lower responses compared to the positive control group at 48 hrs, the test substance was deemed non-sensitizing under the test conditions. However, because there was a high incidence of reaction in the negative controls, the study is considered to be of low confidence in terms of interpretation.

- **Modeled Data**
  - The predictive toxicology program DEREK NEXUS predicts DBDPE to be a non-sensitizer.

Respiratory Sensitization (SnR) Group II*

Score (H, M or L): DG

No experimental data are available for the target or analog compounds for respiratory sensitization. Therefore, this endpoint was assigned a Data Gap (DG) score. DBDPE is not present on any authoritative or screening lists.

Authoritative and Screening Lists

- **Authoritative:** Not listed.
- **Screening:** Not listed.

Studies

- None.

Skin Irritation/Corrosivity (IrS) Group II

Score (vH, H, M or L): L

DBDPE is assigned a score of **Low (L)** for skin irritation/corrosivity, with high confidence. This score is based on the results of a skin irritation study conducted in rabbits. Confidence in this score is high because it is based on reliable experimental data for DBDPE. In addition, DBDPE is not present on any authoritative or screening lists.

Authoritative and Screening Lists

- **Authoritative:** Not listed.
- **Screening:** Not listed.

Studies

- **ECHA (2021a)**

- In a skin irritation study (1988; OECD 404; K = 1), 0.5 grams of DBDPE was applied to the skin of New Zealand White rabbits (n = 3/sex) for a period of 4 hours under occlusive conditions. Animals were evaluated for skin reactions for four days (1, 24, 48, and 72 hours following application). No dermal reactions (erythema or edema) were noted in any animals throughout the duration of the study and the test substance was determined to be non-irritating to the skin.

Eye Irritation/Corrosivity (IrE) Group II

Score (vH, H, M or L): L

DBDPE is assigned a score of **Low (L)** for eye irritation/corrosivity, with high confidence. This score is based on a lack of effects in an eye irritation study conducted in rabbits. Confidence in this score is high because it is based on reliable experimental data for DBDPE. In addition, DBDPE is not present on any authoritative or screening lists.

Authoritative and Screening Lists

- **Authoritative:** Not listed.
- **Screening:** Not listed.

Studies

- **ECHA (2021a)**
  - In an eye irritation study (1988; OECD 405; K = 1), 0.1 grams of DBDPE (undiluted) was instilled into the right eye of New Zealand White rabbits (n = 3/sex). Observations were conducted at 1, 24, 48, and 72 hrs following treatment. Conjunctival redness (score = 1) was observed in animals at 1 hr, but resolved for all animals at 72 hrs (and for all but one animal in 24 hr). No iridial or corneal effects were observed at any time point. Thus, DBDPE was determined to be non-irritating to the eyes of rabbits under the condition of this study.

Ecotoxicity (Ecotox)

Acute Aquatic Toxicity (AA)

Score (vH, H, M or L): L

DBDPE is assigned a score of **Low (L)** for acute aquatic toxicity, with high confidence. This assignment is based on experimental algae, invertebrate, and fish toxicity data for DBDPE (Table 5). The measured water accommodated fraction (WAF) median lethal/effect concentrations for the three trophic levels are greater than 110 mg/L, which is also above the water solubility of DBDPE (0.72 µg/L at 25°C). Therefore, DBDPE exhibits low acute aquatic toxicity in accordance with GreenScreen guidance. The score is assigned with high confidence because the studies relied upon were conducted following GLP compliance and OECD guidelines and were of good quality with high reliability scores (K = 1).

Authoritative and Screening Lists

- **Authoritative**: Not listed.
- **Screening:**
    - Listed as 'PBT' on International Chemical Secretariat's Substitute It Now (SIN) List (ChemSec/SIN List)

Studies

Table 5 Acute Aquatic Toxicity Data for DBDPE

Trophic Level	Test Species	Method	Test Type (K Score)	Endpoint (Basis)	Value (mg/L)	Source
Test Material: DBDPE						
Algae	Algae (*Scenedesmus capricornutum*)	OECD TG 201	Static freshwater (K = 1)	96-hour ELR_{50} (Growth rate and biomass)	> 110 (WAF)	EA, (2007); ECHA (2021a)
Invertebrate	Water Flea (*Daphnia magna*)	OECD TG 202	Static freshwater (K = 1)	48-hour ELR_{50} (Mobility)	> 110 (WAF)	EA, (2007); ECHA (2021a)
		ISO 6341 (1996)	Semi-static freshwater (K = 3)[1]	48-hour EC_{50} (Mobility)	0.019 (nominal)[2]	ECHA (2021)
Fish	Rainbow trout (*Oncorhynchus mykiss*)	OECD TG 203	Static freshwater (K = 1)	96-hour LLR_{50}	> 110 (WAF)	EA, (2007); ECHA (2021a)
	Japanese medaka (*Oryzias latipes*)	JIS K 0102-1986-71	Semi-static freshwater (K = 1)	48-hour LC_{50}	> 50 (nominal)[3]	EA, (2007); ECHA (2021a)

Notes:
CAS = Chemistry Abstracts Service; EC = European Community; EC_{50} = Median Effect Concentration; ELR_{50} = median effective loading rate; ISO = International Organization for Standardization; JIS = Japanese Industrial Standard; K Score = Klimisch Score; LC_{50} = Median Lethal Concentration; LLR_{50} = Lethal Loading Rate; OECD TG = Organisation for Economic Co-operation and Development Test Guideline; ppm = Parts Per Million; WAF = Water Accommodated Fraction.
(1) The following study was disregarded in the ECHA registration dossier due to "major methodological deficiencies" (ECHA, 2021a).
(2) According to the ECHA registration dossier (2021a), effects are "likely due to the solvent (toluene) and diluent ([dimethyl sulfoxide])".
(3) Concentration is presumed to be nominal and is "over four orders of magnitude higher than the solubility" of DBDPE in pure water (EA, 2007).

Chronic Aquatic Toxicity (CA)

Score (vH, H, M or L): *L*

DBDPE is assigned a score of *Low (L)* for chronic aquatic toxicity, with low confidence. This assignment is based on an experimental toxicity study for DBDPE in algae (Table 6) and an 8-week bioaccumulation study in carp (*Cyprinus carpio*) exposed to 0.05 and 0.5 mg/L, which showed no abnormalities in appearance or behavior. The measured NOEC in algae is greater than 110 mg/L (WAF); therefore, DBDPE exhibits low chronic aquatic toxicity in accordance with GreenScreen guidance.

A 96-hour No Observed Effect Loading Rate (NOELR) was used to inform the chronic endpoint for algae. Due to the short lifespan of *Scenedesmus capricornutum*, a 96-hour NOELR is acceptable to inform this endpoint. The only study in invertebrates showed no effects up to the highest mean measured test concentration, which was 0.000356 mg/L. The only study in fish, which was reported by US EPA (2014), was disregarded in the ECHA registration dossier due to "major methodological deficiencies" and the inability to calculate LOEC/NOEC values, because the median times for these endpoints were not provided (ECHA, 2021a). According to US EPA (2014), this study is "[n]ot a standard test for the determination of hazard for which emphasis is strongly placed on whole organism studies". Therefore, low confidence is assigned due to limited data.

Authoritative and Screening Lists

- **Authoritative:** Not listed.
- **Screening:**
  - Listed as 'PBT' on International Chemical Secretariat's Substitute It Now (SIN) List (ChemSec/SIN List).

Studies

- **EA (2007)**
  - No abnormalities in appearance or behavior were observed in an 8-week bioaccumulation study where carp (*Cyprinus carpio*) were exposed to 0.05 and 0.5 mg/L of DBDPE under continuous flow-through conditions (EA, 2007). These test concentrations "are at least two orders of magnitude higher than" the solubility of DBDPE and were achieved using dispersant (EA, 2007). It should be noted that the fish in this study were not at a sensitive life stage and measured lengths greater than those recommended by OECD TG 203.

Table 6 Chronic Aquatic Toxicity Data for DBDPE

Trophic Level	Test Species	Method	Test Type (K Score)	Endpoint (Basis)	Value (mg/L)	Source
Test Material: DBDPE						
Algae	Algae (*Scenedesmus capricornutum*)	OECD TG 201	Static freshwater (K = 1)	96-hour NOELR (Growth rate and biomass)	110 (WAF)	EA (2007); ECHA (2021a)
Invertebrate	Water Flea (*Daphnia magna*)	OECD TG 211	Flow-through freshwater (K = 1)	21-day NOEC (survival, reproduction, or growth)	0.000356 (arithmetic mean)[1]	ECHA (2021a); AICIS (2021)

Trophic Level	Test Species	Method	Test Type (K Score)	Endpoint (Basis)	Value (mg/L)	Source
Fish	Zebrafish (*Danio rerio*)	ISO 1289 (1999)	Semi-static freshwater larvae-egg study (K = 3)[2]	NOEC/LOEC[3] (Hatching and survival)	NOEC[4] = < 0.0125 LOEC[4] = 0.0125	ECHA (2021a); US EPA (2014)

Notes:
CAS = Chemistry Abstracts Service; NOEC = No Observed Effect Concentration; NOELR = No Observed Effect Loading Rate; OECD = Organisation for Economic Co-operation and Development; WAF = Water Accommodated Fraction.

(1) 0.000356 mg/L was the highest mean measured test concentration.
(2) The following study was disregarded in the ECHA registration dossier due to "major methodological deficiencies" (ECHA, 2021a).
(3) According to the ECHA registration dossier (2021a), LOEC/NOEC calculation is not possible because the median times for these endpoints were not provided.
(4) Values reported by US EPA (2014). According to US EPA (2014), this study is "[n]ot a standard test for the determination of hazard for which emphasis is strongly placed on whole organism studies".

Other Ecotoxicity

The GreenScreen benchmark score is based on toxicity to aquatic organisms (acute and chronic). Toxicity to other organisms (*e.g.*, terrestrial wildlife) is not included in the benchmark calculation although the GreenScreen guidance does allow for consideration of other ecotoxicity studies when available (CPA, 2019). As indicated below, non-aquatic toxicity studies all suggest a low level of concern, consistent with the scores assigned for acute and chronic aquatic toxicity.

Authoritative and Screening Lists

Authoritative: Not listed.
- **Screening:** Not listed.

Studies

- **ECHA (2021b**)
  - In a GLP-compliant earthworm subchronic toxicity study (2003; EPA OPPTS 850.6200; K = 1), earth worms (*Eisenia fetida*) were exposed to nominal test concentrations (0, 313, 625, 1,250, 2,500 and 5,000 mg/kg dry soil) of DBDPE in artificial soil for 28 days to test for survival and 56 to test for reproduction. A 28-day NOEC based on mortality and measured (arithmetic mean) concentrations was 3,720 mg/kg soil dw. A 56-day NOEC based on reproduction and measured (arithmetic mean) concentrations was 1,970 mg/kg soil dw.
  - In a GLP-compliant, static, freshwater, sediment toxicity study (2003; EPA OPPTS 850.1735; K = 1), blackworms (*Lumbriculus variegatus*) were exposed to nominal test concentrations (0, 313, 625, 1,250, 2,500 and 5,000 mg/kg dry sediment) of DBDPE for 28 days in artificial sediment. No effects on mortality or dry weight were observed up to the highest concentration tested, and therefore, a 28-day NOEC of 5,000 mg/kg sediment dw was established.
  - In a GLP-compliant, static, freshwater, sediment toxicity study (2003; EPA OPPTS 850.1735; K = 1), harlequin flies (*Chironomus riparius*) were exposed to nominal test concentrations (0, 313, 625, 1,250, 2,500 and 5,000 mg/kg dry sediment) of DBDPE for 28 days in artificial sediment. No effects on mean development times, emergence or development rates were

observed up to the highest concentration tested, and therefore, a 28-day NOEC of 5,000 mg/kg sediment dw was established.

- In a GLP-compliant, aerobic, static, freshwater, activated sludge respiration inhibition test (2008; OECD 209; K = 1), activated sludge (predominantly domestic sewage) was exposed to 10 mg/L of DBDPE for 3 hours. A 3-hour NOEC of greater than or equal to 10 mg/L was established. According to the ECHA dossier (2021b), DBDPE did not adversely affect sludge respiration.
- In a GLP-compliant avian reproduction test (2013; OECD 206; K = 1), Northern bobwhite (*Colinus virginianus*) were exposed to nominal test concentrations (0, 160, 400, or 1000 ppm) of DBDPE for 20 weeks. No adverse effects were observed up to the highest concentration tested, and therefore, a 20-week NOEC of 1,000 ppm (equivalent to 88.1 mg a.i./kg-bw/day) was established.
- In a GLP-compliant terrestrial plants test (2005; OECD 208; K = 1), corn (*Zea mays*), cucumber (*Cucumis sativus*), soybean (*Glycine max*), ryegrass (*Lolium perenne*), tomato (*Lycopersicon esculentum*), and onion (*Allium cepa*) were exposed to nominal test concentrations (0, 391, 781, 1,563, 3,125 and 6,250 mg/kg dry soil) of DBDPE for 21 days. The 21-day NOEC values for corn (based on seedling emergence and growth), cucumber (based on survival), soybean (based on seedling emergence and growth), ryegrass (based on seedling emergence and growth), tomato (based on height and dry weight), and onion (based on height and dry weight) were determined as 6,250, 3,125, 6,250, 6,250, 3,125, and 1,563 mg/kg soil dw, respectively.

Environmental Fate (Fate)

Persistence (P)

Score (vH, H, M, L, or vL): vH

DBDPE is assigned a score of **Very High (vH)** for persistence, with high confidence. DBDPE is insoluble in water (*i.e.*, water solubility is 0.72 µg/L), thus, it is not available to biotic and abiotic degradation. An OECD 301 C biodegradation study in activated sludge found that DBDPE (CAS # 84852-53-9) is not readily biodegradable under aerobic conditions. DBDPE also showed no biodegradation in activated sludge under anaerobic conditions in an OECD 314C study. Due to its very low vapor pressure ($< 1x10^{-4}$ Pa) and insolubility in water, air and water are not considered environmental compartments of concern for DBDPE, which is supported by fugacity modeling results by EQC v1.01 and EpiSuite v4.11 presented in Tables X and X, respectively. DBDPE is expected to primarily amass in soil and sediment, which is supported by its modeled K_{oc} (3.312E+6) and fugacity modeling results (ECHA, 2021a). DBDPE was determined not to be inherently biodegradable over 90 days under optimized conditions in a GLP-compliant OECD 302 D study. In both GLP-compliant OECD 307 studies of aerobic and anaerobic soil systems and GLP-compliant OECD 308 studies of aerobic and anaerobic aquatic sediment systems, mean percentage of radioactivity recovered as DBDPE was greater than 90% after six months and 50% disappearance time (DT50), calculated as pseudo-first order reaction, was greater than six months. Confidence is high because the score is based on experimental data from several GLP-compliant OECD guideline studies.

Authoritative and Screening Lists

- **Authoritative:** None.
- **Screening:**

- Listed as 'PBT' on International Chemical Secretariat's Substitute It Now (SIN) List (ChemSec/SIN List)

Studies

- **ECHA (2021b**)
  - A GLP-compliant ready biodegradability study (1991; OECD 301 C; K = 1) was conducted using DBDPE under aerobic conditions using activated sludge. After 28 days, an initial concentration of 100 mg/L resulted in 0% degradation measured by O_2 consumption and 2% degradation by analysis of test material. The test substance was determined to be not readily biodegradable under the conditions of the modified MITI test (I).
  - A GLP-compliant biodegradation study (2011; OECD 314 C; K = 1) was conducted using DBDPE under anaerobic conditions using domestic, non-adapted activated sludge. After 63 days, an initial concentration of 0.1 mg/L resulted in 0% degradation measured by both CO_2 evolution and CH_4 evolution, respectively. The test substance was determined not to be biodegradable under the test conditions.
  - A GLP-compliant study (2015; OECD 308; K = 1) was conducted to assess the transformation of DBDPE in aerobic and anaerobic aquatic sediment systems. Samples were taken from Brandywine Creek, Pennsylvania and Choptank River, Maryland, and a total of four test systems or vessels were prepared, one aerobic and one anaerobic for each location. Test vessels were dosed with 14C-ring labeled DBDPE at a nominal concentration of 10.4 μCi/test vessel (or 312 μg/test vessel and left to incubate for up to 182 days at 20°C. DBDPE did not appear to degrade in any of the four test systems, and the mean percentage of radioactivity recovered as DBDPE in all sediment samples was 91% after six months. For all four test systems, the 50% disappearance time (DT50), calculated as pseudo-first order reaction, was greater than six months.
  - A GLP-compliant study (2015; OECD 307; K = 1) was conducted to assess the transformation of DBDPE in aerobic soil systems. The four soil systems were comprised of different soil types: loamy sand, sandy clay loam, clay loam, and sandy clay loam. Each soil system was dosed with a nominal concentration of 1.8 mg/kg dry soil of 14C-ring labeled DBDPE and incubated at 20 ºC for up to 182 days. DBDPE did not appear to degrade in any of the four soil systems under aerobic conditions, and the mean percentage of radioactivity recovered as DBDPE in all soil samples was greater than 94% after six months. For all four soil systems, the DT50, calculated as pseudo-first order reaction, was greater than six months.
  - A GLP-compliant study (2015; OECD 307; K = 1) was conducted to assess the transformation of DBDPE in anaerobic soil systems. The four soil systems were comprised of different soil types: loamy sand, sandy clay loam, clay loam, and sandy clay loam. Each soil system was dosed with a nominal concentration of 1.5 mg/kg dry soil of 14C-ring labeled DBDPE and incubated at 20 ºC for up to 182 days. DBDPE did not appear to degrade in any of the four soil systems under anaerobic conditions, and the mean percentage of radioactivity recovered as DBDPE in all soil samples was greater than 93% after six months. For all four soil systems, the DT50, calculated as pseudo-first order reaction, was greater than six months.
  - A GLP-compliant proposed inherent biodegradability study (2010; OECD 302 D; K = 1) was conducted under aerobic conditions using DBDPE and soil collected from Claiborne, Maryland. Initial concentrations were 20 mg C/L or 70 μg/L and degradation was

measured by inorganic C analysis and radiochemical measurement (*i.e*. theoretical inorganic carbon content [ThIC] and ^{14}C-analysis). After 90 days, degradation was reported as 0% or 'not determinable' for both measurements and no transformation products were reported. The study determined DBDPE is not inherently biodegradable over 90 days under optimized conditions, and therefore, is "unlikely to undergo aerobic biodegradation in the environment or in sewage treatment plants" (ECHA, 2021a).

- **EA (2007)**
  - Fugacity modeling results for DBDPE were modeled using EQC v1.01 and are presented in Table 7. According to the results table presented by EA (2007), DBDPE is expected to primarily amass in sediment (93.9%).
  -

Table 7 Fugacity Modeling Results for DBDPE using EQC v1.01[1]

Compartment	Air	Water	Soil	Air: Water: Soil equally
Air	0.005	<0.001	<0.001	<0.001
Water	0.004	0.86	0.003	0.006
Soil	0.45	94.8	0.35	0.67
Sediment	99.5	4.3	99.7	99.3

Source: EA, 2007
Notes:
(1) Available for use in Organisation for Economic Co-operation and Development(OECD) high production volume (HPV) program

- Environmental partitioning behavior and half-life values for DBDPE were modeled using the EpiSuite Level III fugacity model and are presented in Table 8. DBDPE is expected to primarily amass in soil (93.9%). See Appendix A for modeling results.

Table 8 Modeled Environmental Partitioning and Half-Life for DBDPE using EPISuite v4.11

Compartment	Mass Amount (%)	Half-life (hr)	Half-life (days)	Model	Source
Air	0.113	107	4.5	Level III fugacity model	US EPA (2021)
Water	5.34	4,320	180		
Soil	93.9	8,640	360		
Sediment	0.667	38,900	1,620.8		

Notes:
CAS = Chemistry Abstracts Service
Values were modeled in EPI Suite V4.11 using the CAS and experimental values for water solubility (0.00072 mg/L) and log K_{ow} (3.55)

Bioaccumulation (B)

Score (vH, H, M, L, or vL): vL

DBDPE is assigned a score of **Very Low (L)** for bioaccumulation, with high confidence. In accordance with GreenScreen's guidance for the Very Low score for Bioaccumulation Potential, the Log K_{ow} is ≤ 4 with a reported experimental Log P_{ow} of 3.55. The score is assigned with high confidence because OECD

305 studies conducted in 2020 concluded DBDPE does not bioaccumulate in fish and reported experimental lipid-corrected growth-corrected kinetic and indicative lipid-corrected steady-state biomagnification factors (BMF) values for DBDPE (BMF_{SS} = 0.001 and BMF_K = 0.0003-0.0014, respectively) which indicate low biomagnification potential. Concentrations of DBDPE measured in multiple field and monitoring studies were either nondetect, below detection limits, or considered negligible. In addition, DBDPE is listed as a 'Registered Substances Considered not to be PBT/vPvB' by the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation 1907/2006. DBDPE is also listed as 'low bioconcentration' on Japan's Chemical Substance Control Law (CSCL) list of Examined Existing Chemical Substances.

Authoritative and Screening Lists

- **Authoritative:** None.
- **Screening:**
  - Listed as 'PBT' on International Chemical Secretariat's Substitute It Now (SIN) List (ChemSec/SIN List)

Studies

- **ECHA (2021b)**
  - In a GLP-compliant column elution method study (1999; EPA OPPTS 830.7560; K =1), a log P_{ow} of 3.55 was determined at 25°C for DBDPE.
  - In a GLP-compliant, flow-through, freshwater bioaccumulation study (2020; OECD 305; K = 1) bluegill sunfish (*Lepomis macrochirus*) were exposed to a nominal concentrations of 100 µg/g of DBDPE + 10 µg/g PCB-153 for 28 days and 1,000 µg/g of DBDPE + 100 µg/g PCB-153 for 56 days, respectively, *via* diet. PCB-153 was added to the diet as a positive control and benchmark chemical. Both the lipid-corrected growth-corrected kinetic and indicative lipid-corrected steady-state BMF values for DBDPE were 0.003 for the 100 µg/g treatment group and 0.001 for the 1,000 µg/g treatment group, respectively. According to the ECHA registration dossier (2021b), the results from the uptake and depuration phase indicate that DBDPE did not bioaccumulate in fish tissue and "[a]nalysis of gut track tissue show that the test material was retained in the gut and that no metabolism occurred." Under the conditions of this study, DBDPE did not biomagnify and did not bioaccumulate in fish. In addition, the study results "demonstrated that the uptake was not concentration [dependent]" (ECHA, 2021b).
  - As a follow-up to the preliminary pilot study described above, a GLP-compliant, flow-through, freshwater bioaccumulation study (2020; OECD 305; K = 1) was conducted in bluegill sunfish (*Lepomis macrochirus*). Test organisms were exposed to a nominal concentrations of 1,000 µg/g of DBDPE + 100 µg/g PCB-153 (Treatment Group 1) or 1,000 µg/g of DBDPE (Treatment Group 2) for 28 days *via* diet. PCB-153 was added to the diet as a positive control and benchmark chemical. The lipid-corrected growth-corrected kinetic BMF values were 0.0003 and 0.0014 in Treatment Groups 1 and 2, respectively. Indicative lipid-corrected steady-state BMF values for Treatment Groups 1 and 2 were 0.003 and 0.004, respectively. The study reported minimal uptake of DBDPE in whole fish tissues and rapid depuration. The results of the study indicate that DBDPE "does not bioaccumulate in whole fish tissue and is primarily retained in the gut tract" (ECHA, 2021b).
  - In a static, freshwater bioaccumulation study (2013; GLP compliance was not specified; K = 2), rainbow trout (*Oncorhynchus mykiss*) were exposed to 2 µg/g of DBDPE *via* diet and tissue

concentrations were measured after five days. DBDPE was not measured in tissue but was measured in feces, and therefore, the study concluded that under these conditions, DBDPE is not absorbed into fish tissue.

- A field study conducted by Munschey *et al.* (2011) measured levels of DBDPE using gas chromatography/high-resolution mass spectrometry (GC/HRMS) in muscle and liver tissue in common sole (*Solea L.*) collected along the coast of France between 2007 and 2009. Mean concentrations were 0.0-1.9 ng/g ww (0.28-1.13 ng/g lw) in muscle samples and less than the level of detection (<LOD)-14.2 pg/g ww (<LOD-1.33 ng/g lw) in liver samples, respectively. These concentrations were similar to those collected in the same areas in 2003 and 2004 and were concluded to be negligible.
- A field study collected "sediment and biota samples from three European river basins: a continental river (the Sava, which flows through Slovenia, Croatia, Bosnia and Herzegovina and Serbia), a Mediterranean river (the Evrotas, in Greece) and an Alpine river basin (the Adige, in Italy). DBDPE was not detected in any fish samples (Unnamed publication, 2017 as cited in ECHA, 2021b).
- In a freshwater field study conducted by He *et al*. (2012), sediment samples were collected in July 2009, water sampled were collected in May 2010, and fish samples (mud carp, Nile tilapia, and plecostomus) were collected September 2010. Based on mean values, bioaccumulation factors (BAFs) of 0.73, 0.77, and 1.4 were calculated for mud carp, Nile tilapia, and pleocostomus, respectively. A biota-sediment accumulation factor (BSAF) of 0.034 was calculated based on normalized lipid fraction and sediment and mean pleocostomus concentrations. The ECHA registration dossier (2021b) concluded that DBDPE "did not accumulate in fish whether the exposure was via particulates in the diet or from [exposure] via sediment".
- According to the ECHA registration dossier (2021b), terrestrial bioaccumulation of DBDPE is not expected based on an oral absorption, distribution, metabolism, and excretion (ADME) study in rats using ^{14}C-DBDPE which "demonstrated elimination in the feces as the parent molecule and background levels of radioactivity in the blood, plasma, bile, tissues and urine", limited uptake due to "negligible water and organic solvent solubility of the substance", reduced bioavailability due to high particulate binding, and "an *in vitro* study showing negligible solubility in cell culture media". The ECHA registration dossier (2021b) also reports the solubility of DBDPE in octanol as <0.002 mM x MW, which indicates a low potential for bioaccumulation according to REACH Guidance.
- Guerra *et al.* (2012) did not detect DBDPE in thirteen peregrine falcon eggs collected between 2003 and 2006 in Spain.
- McKinney *et al.* (2011) did not detect DBDPE in samples of polar bear adipose tissue collected between 2005 and 2008 in East Greenland and Svalbard, a Norwegian archipelago.
- In a study conducted by Tlustos *et al.* (2010), DBDPE was not detected *via* GC-HRMS using 13C-labelled surrogates in 30 milk samples, 20 egg samples, 38 samples of carcass fat taken from beef cattle, pigs, lambs, chickens and ducks, and 12 samples of liver (bovine, porcine, ovine, equine and avian) which were sampled in Ireland by the Food Safety Authority of Ireland.
- Fisk *et al.* (2019) reported monitoring results from European studies, which measured levels of DBDPE in birds, eggs and fish muscle and liver "either below detection or quantification limit or in the pg/g range" (ECHA, 2021b). The same study also reported monitoring data for "shellfish at the local marine scale (<0.84 pg/g ww - 20.1 pg/g ww and 29 ± 50 pg/g), zebra

mussel and zooplankton (both <LOD) at the local scale, and bird liver (<0.025 ng/g ww), seal blubber (<0.12 - 0.30 ng/g ww, more than 80% < MDL) and polar bear adipose tissue (<0.13 ng/g ww) at the continental background scale." (ECHA, 2021b)

- **ECHA (2021b)/EA (2007)**
  - In a GLP-compliant, flow-through, freshwater bioaccumulation study (1991; OECD 305D; K = 2) carp (*Cyprinus carpio*) were exposed to 0.05 and 0.5 mg/L of DBDPE for eight weeks. BCFs based on whole body wet weight were determined as < 2.5 for the 0.5 mg/L exposure level and < 25 for the 0.005 mg/L exposure level, respectively. It was concluded that DBDPE did not bioconcentrate in fish. This study was also discussed in Environment Agency's (EA) environmental risk evaluation report of DBDPE and was described as 'invalid' because the actual exposure concentrations are unknown due to the use of dispersant, the sample size was too small, the fish likely did not achieve steady state, the concentrations might not reflect internal tissue levels because whole body homogenate was analyzed, and "[f]ish tissue concentrations were not established with confidence" (EA, 2007). According to EA, "[a]ssuming that [DBDPE] was present in the water phase at around the water solubility limit (~0.72 μg/L), and that the measured fish concentrations represent tissue levels, then the BCF would be 1,600 L/kg."
  - In a freshwater field study conducted by Law *et al*. (2006), six species of fish, one species of mussel, and zooplankton were collected from Canadian lake for two years, and using these samples a trophic magnification factor (TMF) of 2.7 was calculated based on nitrogen isotope measurement. The ECHA registration dossier (2021b) concluded that DBDPE was not measured in the studied biota at levels higher than the limits of detection and that DBDPE did not biomagnify or undergo trophic magnification. According to EA (2007), the TMF of 2.7 was corrected from 8.6 by Law *et al*. in 2007 and that the highest estimated lipid-adjusted biomagnification was 9.2. EA (2007) concludes that "reliable conclusions cannot be drawn due to the low concentrations and detection frequency involved and uncertainties about the state of the system over the study period".

Physical Hazards (Physical)

Reactivity (Rx)

Score (vH, H, M or L): L

DBDPE is assigned a score of **Low (L)** for reactivity with high confidence. This score is based on GHS classifications for explosiveness and oxidizing potential listed in the ECHA database (2021a). This conclusion is supported by use of DBDPE as a flame retardant, and by the fact that the chemical structure of DBDPE does not contain reactive functional groups.

Authoritative and Screening Lists

- **Authoritative:** Not listed.
- **Screening:** Not listed.

Studies

- **ECHA (2021a)**
  - Explosives: data conclusive but not sufficient for classification
  - Self-reactive substances and mixtures: data conclusive but not sufficient for classification
  - Self-heating substances and mixtures: data conclusive but not sufficient for classification
  - Substances and mixtures which in contact with water emit flammable gases: data conclusive but not sufficient for classification
  - Oxidizing gases: data conclusive but not sufficient for classification
  - Oxidising liquids: data conclusive but not sufficient for classification
  - Oxidizing solids: data conclusive but not sufficient for classification
  - Organic peroxides: data conclusive but not sufficient for classification
  - Corrosive to metals: data conclusive but not sufficient for classification
  - Desensitized explosives: data lacking

Flammability (F)

Score (vH, H, M or L): L

DBDPE is assigned a score of **Low (L)** for flammability with high confidence. This score for DBDPE is based on its use as a flame retardant.

Authoritative and Screening Lists

- **Authoritative:** Not listed.
- **Screening:** Not listed.

Studies

- **ECHA (2021a)**
  - Flammable gases and chemically unstable gases: data conclusive but not sufficient for classification
  - Aerosols: data conclusive but not sufficient for classification
  - Flammable liquids: data conclusive but not sufficient for classification
  - Flammable solids: data conclusive but not sufficient for classification
  - Pyrophoric liquids: data conclusive but not sufficient for classification
  - Pyrophoric solids: data conclusive but not sufficient for classification

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Appendix A

Hazard Benchmark Acronyms

Hazard Benchmark Acronyms

AA	Acute Aquatic Toxicity
AT	Acute Mammalian Toxicity
B	Bioaccumulation
C	Carcinogenicity
CA	Chronic Aquatic Toxicity
Cr	Corrosion/ Irritation (Skin/Eye)
D	Developmental Toxicity
E	Endocrine Activity
F	Flammability
IrE	Eye Irritation/Corrosivity
IrS	Skin Irritation/Corrosivity
M	Mutagenicity and Genotoxicity
N	Neurotoxicity
P	Persistence
R	Reproductive Toxicity
Rx	Reactivity
SnS	Sensitization – Skin
SnR	Sensitization – Respiratory
ST	Systemic/Organ Toxicity

Appendix B

PHAROS Results – Chemical Name and Associated Transformation Products

Hazard Export from Pharos for "[84852-53-9] Decabromodiphenyl ethane"
https://pharosproject.net/chemicals/2012834
2021-10-27

Hazard Name	List Name	Hazard Inherited From	Endpoint	Hazard Level	GreenScreen List Translator Score	GreenScreen List Type
PBT / vPvB (Persistent, Bioaccumulative, & Toxic / very Persistent & very Bioaccumulative)	ChemSec - SIN List		PBT (Persistence, Bioaccumulation & Toxicity)	Very High	LT-P1	Screening A
Flame retardant substance class of concern for PB&T & long range transport	EHP - San Antonio Statement on BFRs & CFRs	BROMINATED FLAME RETARDANTS (BFR)	PBT (Persistence, Bioaccumulation & Toxicity)	Very High	NoGS	Not included in GreenScreen
PBT - Chemical for Priority Action	OSPAR - Priority PBTs & EDs & equivalent concern	BROMINATED FLAME RETARDANTS (BFR)	PBT [Persistence, Bioaccumulation, and any of the following: Acute Aquatic Toxicity, Chronic Aquatic Toxicity, Carcinogenicity, Mutagenicity, Reproductive Toxicity, Developmental Toxicity, Systemic Toxicity/Organ Effects repeated exposure]	Unspecified	LT-1	Authoritative A
Acute Tox. 4 - Harmful if swallowed (modeled)	DK-EPA - Danish Advisory List		Acute Mammalian Toxicity	Potential Concern	NoGS	Not included in GreenScreen
Candidate Chemical List	CA SCP - Candidate Chemicals		Restricted List	Potential Concern	NoGS	Not included in GreenScreen
CoHC List (non SVHC)	CPA - Chemical Footprint	BROMINATED FLAME RETARDANTS (BFR)	Restricted List	Potential Concern	NoGS	Not included in GreenScreen
Core Restrictions	Cradle to Cradle Certified® Product Standard Version 4.0 Restricted Substances List (RSL) - Effective July 1, 2021	Halogenated Flame Retardants (HFRs)	Restricted List	Potential Concern	NoGS	Not included in GreenScreen

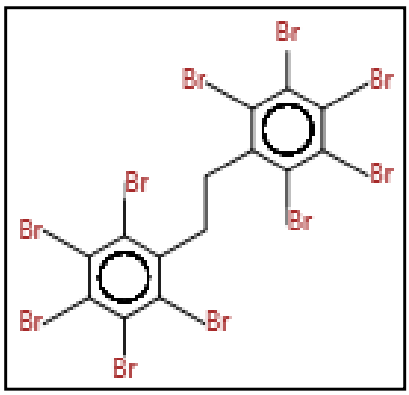
Hazard Name	List Name	Hazard Inherited From	Endpoint	Hazard Level	GreenScreen List Translator Score	GreenScreen List Type
Substances selected for RMOA or hazard assessment	EU - PACT-RMOA Substances		Restricted List	Potential Concern	NoGS	Not included in GreenScreen
Food Contact Chemicals Database Version 5.0	Food Contact Chemicals Database (FCCdb)		Restricted List	Potential Concern	NoGS	Not included in GreenScreen
Flame Retardants	GSPI - Six Classes of Problematic Chemicals	BROMINATED FLAME RETARDANTS (BFR)	Restricted List	Potential Concern	NoGS	Not included in GreenScreen
Declarable and Reference Substance Lists (DSL and RSL)	IEC 62474 - Material Declaration for Products of and for the Electrotechnical Industry		Restricted List	Potential Concern	NoGS	Not included in GreenScreen
Priority for Inclusion in the Living Building Challenge Red List	Living Building Challenge 4.0 - Red List of Materials & Chemicals	Decabromodiphenyl ethane (primary CASRN is 84852-53-9)	Restricted List	Potential Concern	NoGS	Not included in GreenScreen
Red List substances to avoid in Living Building Challenge V4.0 projects	Living Building Challenge 4.0 - Red List of Materials & Chemicals		Restricted List	Potential Concern	NoGS	Not included in GreenScreen
Red List substance to avoid in Living Building Challenge V2.1 projects	Living Future - Living Building Red List 2.1	BROMINATED FLAME RETARDANTS (BFR)	Restricted List	Potential Concern	NoGS	Not included in GreenScreen
Prospective Red List substances to avoid in Living Building Challenge projects	Living Future - Living Building Red List 3.0	BROMINATED FLAME RETARDANTS (BFR)	Restricted List	Potential Concern	NoGS	Not included in GreenScreen
Red List substances to avoid in Living Building Challenge V3 projects	Living Future - Living Building Red List 3.0		Restricted List	Potential Concern	NoGS	Not included in GreenScreen
Red List substances to avoid in Living Building Challenge V3.1 projects	Living Future - Living Building Red List 3.1		Restricted List	Potential Concern	NoGS	Not included in GreenScreen
Chemicals of High Concern	MDH - Chemicals of High Concern and Priority Chemicals		Restricted List	Potential Concern	NoGS	Not included in GreenScreen
Precautionary list of substances recommended for avoidance	P&W - Precautionary List	Halogenated Flame Retardants (HFRs)	Restricted List	Potential Concern	NoGS	Not included in GreenScreen

Hazard Name	List Name	Hazard Inherited From	Endpoint	Hazard Level	GreenScreen List Translator Score	GreenScreen List Type
Substances of Very High Concern (RIVM ZZS)	Substances of Very High Concern (RIVM ZZS)		Restricted List	Potential Concern	NoGS	Not included in GreenScreen
SNUR (Significant New Use Rule)	US EPA - PPT Chemical Action Plans		Restricted List	Potential Concern	NoGS	Not included in GreenScreen
Substance to avoid to fulfill LEED Pilot Credit 11	USGBC - LEED Pilot Credits	BROMINATED FLAME RETARDANTS (BFR)	Restricted List	Potential Concern	NoGS	Not included in GreenScreen
Substance to avoid to fulfill LEED Pilot Credit 54 Option 2	USGBC - LEED Pilot Credits	Halogenated Flame Retardants (HFRs)	Restricted List	Potential Concern	NoGS	Not included in GreenScreen
Chemicals of High Concern to Children	Vermont Chemicals of High Concern to Children		Restricted List	Potential Concern	NoGS	Not included in GreenScreen
Chemicals of High Concern to Children	WA DoE - Chemicals of High Concern to Children		Restricted List	Potential Concern	NoGS	Not included in GreenScreen

Appendix C

Modeling Results

OncoLogic Justification Report



The level of concern for this compound, disregarding any highlighted substituents, is MODERATE. The effect of any highlighted substituents is uncertain.

JUSTIFICATION

Halogenated aromatics include the following type of halogenated compounds: benzenes, naphthalenes, biphenyls, terphenyls, diphenyl ethers, diphenyl sulfides, dibenzo-p-dioxins, dibenzofurans, dibenzothiophenes, and diphenyl alkanes and alkenes. Although a number of halogenated aromatics have been shown to be carcinogenic in experimental animals, the mechanism of their carcinogenic action is not clearly understood.

However, there is a prevalent view that these chemicals may be carcinogenic through epigenetic mechanisms rather than by direct action on DNA. For instance, there is considerable evidence showing that the initial event involved in 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) carcinogenesis is binding to the cytosolic Ah receptor. The subsequent translocation of the TCDD-receptor complex into the nucleus leads to a modulation of gene expression which is believed to be responsible for the various biochemical (e.g. induction of the cytochrome P-450 1A family) and toxicological effects (including tumorigenesis) of the compound.

Since the key requirement for the binding of TCDD to the cytosolic Ah receptor is a planar molecule with the halogens at the lateral position (i.e., 2,3,7,8-position of TCDD), it has been suggested that other halogenated aromatics with a molecular shape isosteric with TCDD may act by a mechanism similar to that of TCDD. Indeed, like TCDD, a number of halogenated biphenyls and naphthalenes with halogens at the lateral positions are also inducers of the cytochrome P-450 1A family.

Other halogenated biphenyls, naphthalenes and benzenes, which induce the cytochrome P-450 2B family, on the other hand, have been postulated to act via inhibition of "intercellular communication" (also called "metabolic cooperation"). Other epigenetic mechanisms that have been linked to carcinogenesis of halogenated aromatics include (i) hormone imbalance (e.g. estrogen mimics), (ii) immunosuppresion, and (iii) cytotoxicity.

Halogenation of the aromatics renders them more lipid-soluble, more slowly metabolized, and therefore more persistent in animal tissues. In general, the rate of oxidative metabolism decreases as the degree of halogenation increases because of steric hindrance by the halogen atoms. Moreover,

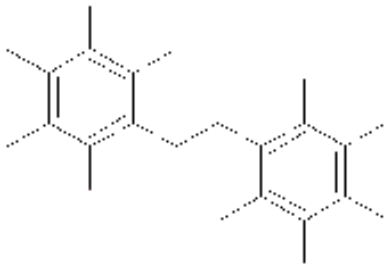
the position of halogenation plays an important role in determining the rate of oxidative metabolism. For instance, it has been shown that chlorinated and brominated benzenes having two adjacent unsubstituted carbon atoms are more rapidly metabolized than those without adjacent unsubstituted carbon atoms, despite a similar degree of halogenation. Hence, in addition to the type of halogens, the degree and position of halogenation are important factors in evaluating the carcinogenicity potential of halogenated aromatics.

The carcinogenicity concern levels of these compounds are determined based on structure-activity relationship analysis as well as metabolism and mechanism considerations.

The halogenated benzene with five Cl, Br and/or Cl, Br has a level of concern of MODERATE.

As a result of the combined substituent modifications, the level of concern remains MODERATE.

The final level of concern for this compound is MODERATE.



SA12_gen = NO
Negative for genotoxic carcinogenicity = YES
SA55_nogen = NO
SA31c_nogen = NO
SA45_nogen = NO
SA11_gen = NO
SA6_gen = NO
SA49_nogen = NO
SA13_gen = NO
SA28ter_gen = NO
Error when applying the decision tree = NO
Negative for nongenotoxic carcinogenicity = YES
SA46_nogen = NO
SA10_gen = NO
SA5_gen = NO
QSAR6,8 applicable? = NO
SA14_gen = NO
mutant.rules.MutantTreeResult#explanation =
,SA1_genN,SA2_genN,SA3_genN,SA4_genN,SA5_genN,SA6_genN,SA7_genN,SA8_genN,SA9_genN,SA11_genN,SA12_genN,SA13_genN,SA14_genN,SA15_genN,SA16_genN,SA18_genN,SA19_genN,SA21_genN,SA22_genN,SA23_genN,SA24_genN,SA25_genN,SA26_genN,SA27_genN,SA28_genN,SA28bis_genN,SA28ter_genN,SA29_genN,SA30_genN,SA37_genN,SA38_genN,SA39_gen_and_nogenN,Genotoxic alert?N,QSAR13
applicable?N,SA10_genN,aN=NaN,ar-N=CH2N,QSAR6,8
applicable?N,SA17_nogenN,SA20_nogenN,SA31a_nogenN,SA31b_nogenN,SA31c_nogenN,SA39_gen_and_nogenN,SA40_nogenN,SA41_nogenN,SA42_nogenN,SA43_nogenN,SA44_nogenN,SA45_nogenN,SA46_nogenN,SA47_nogenN,SA48_nogenN,SA49_nogenN,SA50_nogenN,SA51_nogenN,SA52_nogenN,SA53_nogenN,SA54_nogenN,SA55_nogenN,SA56_nogenN,Nongenotoxic alert?N
SA56_nogen = NO
Structural Alert for nongenotoxic carcinogenicity = NO
SA41_nogen = NO
SA15_gen = NO
SA22_gen = NO
SA31b_nogen = NO
SA4_gen = NO
SA28_gen = NO
SA44_nogen = NO
SA28bis_gen = NO
SA21_gen = NO
For a better assessment a QSAR calculation could be applied. = NO
SA16_gen = NO
SA3_gen = NO
SA29_gen = NO
SA52_nogen = NO
Structural Alert for genotoxic carcinogenicity = NO
SA25_gen = NO
SA47_nogen = NO
SA31a_nogen = NO
ar-N=CH2 = NO
SA2_gen = NO
SA20_nogen = NO

	SA40_nogen = NO SA26_gen = NO SA50_nogen = NO SA18_gen = NO SA43_nogen = NO Unlikely to be a carcinogen based on QSAR = NO SA53_nogen = NO SA27_gen = NO aN=Na = NO Unlikely to be a S. typhimurium TA100 mutagen based on QSAR = NO SA1_gen = NO SA9_gen = NO Potential S. typhimurium TA100 mutagen based on QSAR = NO SA19_gen = NO SA23_gen = NO SA51_nogen = NO SA8_gen = NO SMILES = C(Cc1c(c(c(c(c1Br)Br)Br)Br)c2c(c(c(c(c2Br)Br)Br)Br)Br Potential carcinogen based on QSAR = NO SA48_nogen = NO SA54_nogen = NO cdk:Comment = Created from SMILES SA30_gen = NO SA37_gen = NO SA24_gen = NO SA39_gen_and_nogen = NO SA17_nogen = NO SA38_gen = NO SA7_gen = NO QSAR13 applicable? = NO SA42_nogen = NO