File No.: STD/1676

August 2021

AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS)

PUBLIC REPORT

Benzene, 1,1'-(1,2-ethanediyl)bis[2,3,4,5,6-pentabromo-

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals Act 2019* (the IC Act) and *Industrial Chemicals (General) Rules 2019* (the IC Rules) by following the *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019* (the Transitional Act) and *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019* (the Transitional Rules). The legislations are Acts of the Commonwealth of Australia. The Australian Industrial Chemicals Introduction Scheme (AICIS) is administered by the Department of Health, and conducts the risk assessment for human health. The assessment of environmental risk is conducted by the Department of Agriculture, Water and the Environment.

This Public Report is available for viewing and downloading from the AICIS website. For enquiries please contact AICIS at:

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Executive Director
AICIS

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SUMMARY

The following details will be published on our website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1676	Fibrisol Service Australia Pty Ltd	Benzene, 1,1'-(1,2-ethanediyl)bis[2,3,4,5,6-pentabromo-	ND	≤ 120 tonnes per annum	Flame retardant in articles, films and coatings used in electrical, electronic, building, and automotive applications

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
Based on the available information, the assessed chemical is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard	GHS Classification (Code)	Hazard Statement
Acute Aquatic	Not classified	–
Chronic Aquatic	Category 4 (H413)	May cause long lasting harmful effects to aquatic life

Human Health Risk Assessment
It is expected that substantial quantities of the assessed chemical are already being imported into Australia as components of articles, and the assessed chemical may be released from these articles as dust, leading to indirect human exposure. The overall exposure and risk to human health would be increased through approval of the assessed chemical itself to be introduced into Australia.

Noting the uncertainties in the human health hazards, and provided that control measures are in place to minimise worker exposure to the assessed chemical, the risk to the health of workers from use of the assessed chemical is not considered to be unreasonable.

There are uncertainties regarding the potential long-term effects from exposure to the assessed chemical. The assessed chemical is expected to be persistent in the environment, bioaccumulate, and this could lead to secondary human exposure to the chemical or its degradants.

When used in the proposed manner, the assessed chemical is not considered to pose an unreasonable risk to public health through direct exposure.

Environmental Risk Assessment
It is expected that substantial quantities of the assessed chemical are already being imported into Australia as components of articles, and may be released from these articles, particularly textile articles, leading to indirect environmental exposure. The overall exposure and risk to the environment would be increased through approval of the chemical itself to be introduced into Australia.

Decabromodiphenyl ethane meets the persistence, bioaccumulation, adverse effects in aquatic and terrestrial organisms and long range transport criteria of Annex D of the Stockholm Convention on Persistent Organic Pollutants. Therefore, on the basis of the current hazard information available, the assessed chemical could pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the assessed chemical as introduced and during processing:
  - Enclosed/automated processes if possible
  - Local exhaust ventilation and/or appropriate dust extraction systems when handling the assessed chemical in powder form

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the assessed chemical as introduced and during processing:
  - Avoid inhalation of aerosols/dust
  - Use low-dust handling techniques if possible
  - Clean up spills and waste material promptly

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the assessed chemical as introduced and during processing:
  - Respiratory protection if inhalation exposure to dust or aerosols may occur

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- In the interest of occupational health and safety, the following precautions should be observed for use of the assessed chemical as introduced:
  - The level of atmospheric nuisance dust should be maintained as low as possible. The Safe Work Australia exposure standard for atmospheric dust is 10 mg/m^3 (SWA, 2018).

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015) or relevant State or Territory Code of Practice.

- A copy of the SDS should be easily accessible to employees.

- If products and mixtures containing the assessed chemical are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Environment

- The chemical is hazardous to the environment and should be prioritised for scheduling and the application of appropriate risk management measures under the *Industrial Chemicals Environmental Management (Register) Act 2021*.

Disposal

- Where reuse or recycling is not appropriate, dispose of the assessed chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

- Spills or accidental release of the assessed chemical should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Specific Requirements to Provide Information
This risk assessment is based on the information available at the time of the application. The Executive Director may initiate an evaluation of the chemical based on changes in certain circumstances. Under section 101 of the IC Act the introducer of the assessed chemical has post-assessment regulatory obligations to provide information to AICIS when any of these circumstances change. These obligations apply even when the assessed chemical is listed on the Australian Inventory of Industrial Chemicals (the Inventory).

Therefore, the Executive Director of AICIS must be advised in writing within 20 working days by the applicant or other introducers if:

– the function or use of the chemical has changed from a flame retardant in articles, films and coatings used in electrical, electronic, building, and automotive applications, or is likely to change significantly;
– the amount of chemical being introduced has increased, or is likely to increase, significantly;
– the chemical has begun to be manufactured in Australia;
– additional information has become available to the person as to an adverse effect of the chemical on human health, or the environment.

The Executive Director will then decide whether an evaluation of the introduction is required.

Use Conditions

- The following condition of use applies:
  – This chemical is not to be used in textiles.

Safety Data Sheet
The SDS of the assessed chemical provided by the applicant was reviewed by AICIS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND APPLICATION DETAILS

APPLICANT(S)
Fibrisol Service Australia Pty Ltd (ABN: 57 063 405 121)
53-59 Summer Close
HEATHERTON VIC 3202

APPLICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year)

PROTECTED INFORMATION (SECTION 38 OF THE TRANSITIONAL ACT)
No details are taken to be protected information.

VARIATION OF DATA REQUIREMENTS (SECTION 6 OF THE TRANSITIONAL RULES)
Schedule data requirements are varied for flash point, flammability, autoignition temperature, explosive properties, oxidising properties and eye irritation

PREVIOUS APPLICATION IN AUSTRALIA BY APPLICANT(S)
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
FR-1410

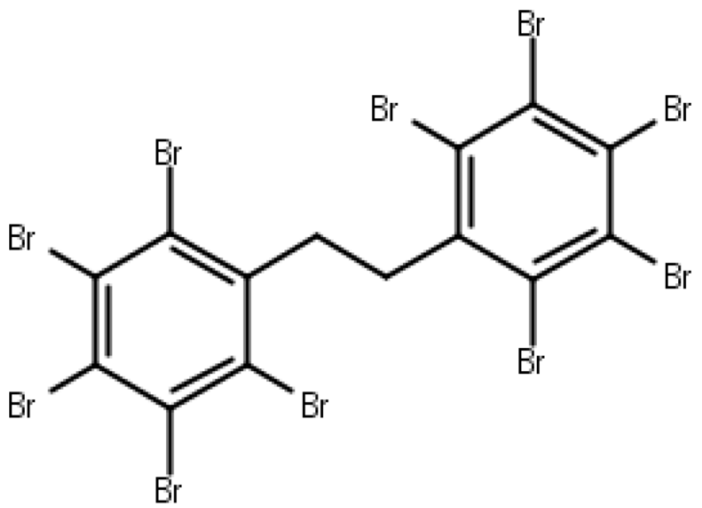
CAS NUMBER
84852-53-9

CHEMICAL NAME
Benzene, 1,1'-(1,2-ethanediyl)bis[2,3,4,5,6-pentabromo-

OTHER NAME(S)
Decabromodiphenyl ethane
DBDPE
1,2-Bis(pentabromophenyl) ethane

MOLECULAR FORMULA
$C_{14}H_4Br_{10}$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
971.22 g/mol

ANALYTICAL DATA
Reference ^{1}H-NMR, ^{13}C-NMR, MS, FT-IR, HPLC, GC and UV-vis spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
99.26%

IDENTIFIED IMPURITIES
Nonabromodiphenylethane I (NonaBDPE I) at 0.08%
Nonabromodiphenylethane II (NonaBDPE II) at 0.28%
Nonabromodiphenylethane III (NonaBDPE III) at 0.06%
Overbrominateddiphenylethane (overBDPE) at 0.32%

The analytical results are derived from high performance liquid chromatography (HPLC). Results using gas chromatography (GC) are not reported, as GC analysis is considered unreliable to determine purity for the assessed chemical due to peak discrimination (against chemicals with low volatility) and the potential for thermal degradation to lower brominated congeners (Kierkegaard A, et al., 2009).

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: white odourless powder

Property	***Value***	***Data Source/Justification***
Melting Point/Freezing Point	~ 350 °C	Measured
Boiling Point	> 350 °C	The chemical decomposes at 350 °C.
Density	945 kg/m^3	Measured
Vapour Pressure	3.14×10^{-14} kPa at 20 °C	Calculated
Water Solubility	$< 5 \times 10^{-5}$ mg/L (< 50 ng/L)	Measured. Solubility was below the limit of quantification (50 ng/L).
Hydrolysis as a Function of pH	Not determined	Contains no hydrolysable functionalities

Property	***Value***	***Data Source/Justification***
Partition Coefficient (n-octanol/water)	log Kow > 6.50	Measured. The partition coefficient exceeds the log Kow for the most lipophilic reference substance used for this measurement.
Adsorption/Desorption	log Koc = 11.84 (log Kow method)	Calculated with KOCWIN v2.00, EPI Suite v4.11 using a calculated log Kow for DBDPE of 13.64 (US EPA 2012).
Dissociation Constant	Not determined	Contains no dissociable functionalities
Particle Size	D_{10} = 1.6 µm; D_{50} = 3.4 µm; D_{90} = 6.8 µm	Measured
Flash Point	Not determined	-
Autoignition Temperature	Not self-ignitable	SDS
Explosive Properties	Unlikely to be explosive	Estimated based on the structure
Oxidising Properties	Unlikely to be oxidising	Estimated based on the structure

DISCUSSION OF PROPERTIES
For details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
The assessed chemical is expected to be stable under normal conditions of use.

Physical Hazard Classification
Based on the submitted physico-chemical data depicted in the above table, the assessed chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF ASSESSED CHEMICAL (100%) OVER NEXT 5 YEARS
The assessed chemical will be imported at 100% concentration.

MAXIMUM INTRODUCTION VOLUME OF ASSESSED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	5	20	60	100	120

PORT OF ENTRY
Sydney, Melbourne and other ports

IDENTITY OF RECIPIENTS
Either distributors or compounders (convertors in the plastic industry)

TRANSPORTATION AND PACKAGING
The assessed chemical will be imported in 25 kg (and possibly 1000 kg) bags and transported by road or rail in Australia.

USE
The applicant proposed that the assessed chemical will be used as a component of articles for electrical and electronics applications, including electronic and electrical home appliances and enclosures. It will also be used for building and construction, as a component of wires, cables and plastic parts in automotive applications at 5 - 30% concentration, and in textile backcoating at < 10% concentration.

The assessed chemical was proposed to be used as an additive in plastics and resins such as:
- LDPE (Low-density Polyethylene) and HDPE (High-density Polyethylene) films and sheets for building and construction
- LDPE, HDPE and PP (Polypropylene) injection moulded parts for electricity and electronics

- ABS (Acrylonitrile/Butadiene/Styrene), HIPS (High Impact Polystyrene), PA (Polyamide), PBT (Polybutylene Terepthalate) and PET (Polyethylene Terephthalate) injection moulded parts for electricity and electronics
- Textile backcoatings, typically used for curtains, and may be a minor use in upholstery fabrics
- UPE (Unsaturated Polyester), vinyl esters, phenolic resins and epoxy resins for building and construction and electricity and electronics

The applicant advised that the chemical will not be used in expanded plastics or polyurethane foam.

Additive flame retardants, such as the assessed chemical, may tend to bleed out of a product and vaporise or collect at the surface, a process known as "blooming". The degree to which blooming may occur is dependent on a number of factors. However the primary release mechanism for brominated flame retardants is expected to be degradation of the matrix and breaking down to small plastic particles containing the chemical. This may occur more easily for certain plastic matrices, depending on their durability.

Laundering of materials that have been coated or treated with additive flame retardants (e.g. curtains) can result in gradual leaching or physical breakdown of fire retardant coatings. Flame retardants applied as surface coatings can also be displaced through physical wear and tear of articles over time.

OPERATION DESCRIPTION

Detailed information on all the proposed uses and processes has not been provided as these could vary at different production facilities. According to the applicant, production of intermediate preparations (such as masterbatches) or articles can be done by extrusion, injection moulding, compression moulding, blown films, blow-moulding, rotational moulding, thermoplastic coatings and thermoset coatings, sometimes through forming pellets and tablets. The chemical would be applied to textiles via a coating.

A typical scenario to make the plastic articles is through compounding and extrusion, followed by formation of the articles. The assessed chemical will be compounded into the final mix or into a masterbatch by mixing it with polymers and other additives in a molten state, which then undergoes an extrusion process. Thermal moulding may also be used to produce the plastic articles.

Compounding and masterbatch production

The imported assessed chemical at 100% concentration will be compounded with polymers and other materials through processes involving weighing and transferring into a mixer, heating, mixing, extruding, Quality assurance (QA) testing, dispensing of granules of the resultant compounded product or masterbatch (containing the assessed chemical at ≤ 40 - 85% concentration) into 25 kg drums, and routine cleaning and maintenance. The mixing and extrusion will be performed in an enclosed system.

Production of plastic articles

The compounded plastic or master batches containing the assessed chemical will be blended with other materials and extruded or thermally moulded to form plastic articles, films or coatings containing the assessed chemical at ≤ 30%. QA testing and routine cleaning and maintenance will also occur. The extrusion or moulding process to produce the finished articles is expected to be performed in a controlled area with local exhaust ventilation.

Textile backcoating

The assessed chemical is usually applied to the fabric by a textile coating machine in the form of liquid dispersion and heated up to cure at around 150 °C. Most common fabrics are PET & cotton/PET blends. The assessed chemical content in a typical textile application is likely to be < 10% of the final article. After backcoating, typical end use application for the textiles will be for curtains and possibly upholstery fabrics.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Stevedores	up to 8	up to 300

Transport	up to 8	up to 300
Warehousing	up to 8	up to 300
Compounding/masterbatch production	up to 8	up to 300
Product QC	up to 8	up to 300
Industrial users	up to 8	up to 300

EXPOSURE DETAILS
Transport and storage workers may come into contact with the assessed chemical at up to 100% concentration only in the unlikely event of an accident.

Compounding/masterbatch production
Worker exposure is more likely while the assessed chemical is in powder form, especially as its particle size is very small (respirable particles of < 10 µm). Compounding and masterbatch production processes may usually be largely enclosed and automated. However, workers may experience dermal, ocular or inhalation exposure to the assessed chemical at up to 100% concentration in powder form during weighing and transfer from the imported bags to the compounding vessels, during quality control testing and maintenance, and during cleaning tasks. It is expected that the potential for inhalation exposure will be highest when the assessed chemical in powder form is weighed and transferred from the import containers to the compounding vessels. Dermal and ocular exposure to workers is expected to be mitigated through the use of personal protective equipment (PPE) including chemical resistant gloves, safety goggles, safety shoes and protective clothing as indicated on the SDS provided. According to the information provided by the applicant, inhalation exposure to dust particles generated from handling the assessed chemical in powder form is expected to be minimised through the use of respiratory protection, mechanical ventilation (according to SDS) and enclosed processes. Once the chemical is incorporated into the masterbatch or compounded plastic mixture, inhalation exposure to particles is not expected.

Production of articles
Processes for the production of articles, films and coated articles are expected to be largely automated; however, in a typical scenario dermal, ocular and inhalation exposure to the assessed chemical at ≤ 30% concentration may occur during transfer of the product containing the assessed chemical to the extruder or moulding machine, during quality control testing and during maintenance and cleaning tasks. According to the applicant, exposure is expected to be minimised by the use of local exhaust ventilation and the use of PPE such as coveralls, impermeable gloves, eye protection and a respirator (if required). Once blended into the articles, the assessed chemical is incorporated in the polymer matrix, but is not chemically reacted into the matrix. Therefore it may be released from the surface of the articles in which it is incorporated.

End use
Workers will handle the finished plastic articles or textile products such as curtains. Workers may have dermal and inhalation exposure to the assessed chemical if cutting of articles occurs at some sites. PPE worn by workers, such as protective clothing and dust masks, are expected to minimise the exposure.

Following incorporation of the assessed chemical into the moulded articles, the chemical is not expected to be available for exposure via the dermal route. Very small amounts of assessed chemical may be available at the surface of the articles due to leaching or blooming. Hence, the dermal exposure from contact with articles is expected to be very low.

Recycling
Another potential source of occupational exposure is from recycling of articles containing the assessed chemical. The assessed chemical was found in the hair and serum of e-waste recyclers in southern China, at levels higher than the general population (Liang S, et al., 2016).

6.1.2. Public Exposure
Public exposure includes direct consumer exposure through use of materials containing the assessed chemical and indirect exposure via the environment.

Direct exposure
The public may have contact with manufactured articles in which the assessed chemical is already incorporated in the article at ≤ 30% concentration.

The assessed chemical is used in consumer products as an additive flame retardant; that is, it is present physically in the articles rather than chemically bonded. It is possible for the chemical to be released to some extent from the treated articles, including through blooming where the chemical migrates to the surface of the article. Consumers who use/handle these treated products may therefore be directly exposed. However it is expected that the majority of the assessed chemical will be incorporated in the article, and will not be available for direct exposure.

It is unlikely that materials detached from articles treated with the assessed chemical will be ingested. Children may mouth articles, however, owing to its low solubility in water, direct systemic exposure through ingestion is considered negligible.

Occasional or infrequent skin contact with some assessed chemical-treated products (for example, insulation panels, curtains at public places and plastic electronic casings) may result in very low dermal exposure. However, direct and frequent skin contact with treated textile articles may result in higher dermal exposure, and potential inhalation exposure of dust.

Due to its low vapour pressure (3.14×10^{-14} kPa at 20 °C), significant emission of assessed chemical vapours from treated articles is not expected.

Hence direct exposure of the public to the assessed chemical is generally expected to be low.

Indirect exposure
Indirect exposure of humans to the assessed chemical and its degradation products through the environment may occur by consumption of food and drinking water, and breast milk in the case of infants, inhalation of air, and ingestion of soil and dust (particularly in children). Indirect exposure through dermal contact, for example, with soil or dust can occur, but the amount absorbed following dermal contact is considered to be negligible (NICNAS 2019).

Similar to decabromodiphenyl ether (decaBDE), the assessed chemical may be released and distributed in the environment through many channels:

- release into the atmosphere or waste water from its industrial uses and disposal;
- emission from treated articles, including breakdown of the article matrix; and
- leaching and emission from landfill.

Dust, indoor air and, to a lesser extent, food were considered to be the most important sources for human exposure to polybrominated diphenyl ethers (US, 2010), and household consumer products were identified as the main source of these chemicals in house dust for decaBDE (NICNAS 2019).

The assessed chemical was found to be prevalent in dust in homes, offices and vehicles in Melbourne, Australia (McGrath TJ, et al., 2018). The authors suggested that this was a result of the propensity for brominated flame retardants to migrate from consumer articles, and contaminate dust. In this study, concentrations of DBDPE were reported in indoor dust from 24 homes, 13 offices and 8 vehicles. The levels ranged from not detected to 10000 ng/g of dust (mean = 2400 ng/g and median = 1800 ng/g, average detection frequency = 80%) with the highest concentrations detected in the offices, where a high density of electronic items are present.

The study indicated that toddlers typically experience a higher body weight adjusted exposure to DBDPE dust than adults. In addition to having body weights five to 10 times lower than adults, toddlers are likely to ingest greater quantities of dust due to mouthing of objects and spending more time in contact with carpets or flooring where dust settles (USEPA, 2017).

The main congener of decaBDE (which like DBDPE has low volatility) was detected in indoor dust in widely scattered highly contaminated particles (Webster TF, et al., 2009). The study authors hypothesised that weathering or abrasion of the polymer matrix rather than volatilisation had resulted in the contaminated particles. It has been suggested that flame-retarded textiles may be a more likely source of particles/fibres than hard plastics (Wilford BH, et al., 2005). This could be due to breakdown of the textile coating related to laundering or embrittlement, or to UV exposure. If this occurred, the levels of resultant dust from this use would be increased.

Indirect exposure through dermal contact outdoors – for example, with soil – can occur. However, exposure via this route is considered to be negligible.

A study conducted in southern China reported that the mean concentrations of DBDPE in hair and serum samples from urban residents were 10.9 ng/g dry weight (dw) and 13.8 ng/g lipid weight (lw), respectively (Liang S, et al., 2016).

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the assessed chemical are summarised in the following table. For details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Acute oral toxicity – rat	LD50 > 2000 mg/kg bw; low toxicity
Acute dermal toxicity – rat	LD50 > 2000 mg/kg bw; low toxicity
Skin irritation – rabbit Eye irritation – rabbit*	non-irritating slightly irritating
Skin sensitisation – mouse local lymph node assay	no evidence of sensitisation (up to 50%)
Repeat dose oral toxicity – rat, 28 days	NOAEL = 1000 mg/kg bw/day**
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* mammalian chromosome aberration test	non genotoxic

*Study summary provided
**Established by the study authors

Toxicokinetics, Metabolism and Distribution

No toxicokinetic data on the assessed chemical were submitted. For dermal and gastrointestinal absorption, molecular weights below 100 g/mol are favourable for absorption and molecular weights above 500 g/mol do not favour absorption (ECHA, 2017). Dermal uptake is likely to be low to moderate if the water solubility is between 1 - 100 mg/L and may be limited if the partition coefficient (log Kow) values are > 4 (ECHA, 2017). Gastrointestinal absorption is also likely to be low if the partition coefficient (log Kow) values are > 4. Absorption of the assessed chemical through the skin and gastrointestinal tract is expected to be low based on the partition coefficient (log Kow > 6.50), very low water solubility ($< 5 \times 10^{-5}$ mg/L) and molecular weight (> 500 g/mol).

DBDPE was poorly absorbed, minimally metabolised and almost exclusively eliminated by the faecal route after single doses administered orally, dermally and intravenously (IV) to female Sprague-Dawley rats or male B6C3F1/Tac mice. The doses used for oral administration (for rats and mice) and IV (for rats only) were 0.02 mg/kg bw. Rats were administered 0.39 mg/kg bw by the dermal route. Repeated oral administration of DBDPE to female Sprague-Dawley rats at 0.02 mg/kg bw/day gave similar results, although increases in [14C]-radioactivity concentrations in liver and adrenal tissues were noted after 10 daily doses (Knudsen GA, et al., 2017).

The bioconcentration and biotransformation of DBDPE after oral exposure were studied and the results were compared with those of decaBDE. Male Sprague-Dawley rats were orally gavaged with corn oil containing 100 mg/kg bw/day of DBDPE or decaBDE for 90 days, after which the levels of DBDPE and decaBDE in the liver, kidney, and adipose tissue were measured. It was reported that DBDPE was found in all tissues with concentrations 3-5 orders of magnitude lower than decaBDE, based on lipid weight. At least seven unknown compounds were noted in the DBDPE-exposed rats, suggesting DBDPE biotransformation. The authors considered a biological response to DBDPE and decaBDE and their metabolites in rats may differ and further studies are needed on the metabolites of DBDPE and their mechanisms of toxicities to assess the potential risks of DBDPE (Wang F-X, et al., 2010).

Acute Toxicity

The assessed chemical is of low acute oral and dermal toxicity based on studies conducted in rats. No acute inhalation toxicity data on the assessed chemical was submitted.

Irritation

Based on the results of a skin irritation study in rabbits, the assessed chemical is not considered to be irritating to the skin.

From a study summary provided by the applicant, the assessed chemical was considered slightly irritating to eyes. The potential of the assessed chemical to cause eye irritation was examined in a study in rabbits according to GLP and OECD test guideline 405. The assessed chemical (100 mg) was instilled into the conjunctival sac of one eye of each of six albino New Zealand rabbits (three males and three females) and the eyes were checked at 1, 24, 48 and 72 hours post-application. No iridial or corneal effects were noted at any of the time points. Conjunctival redness was noted in all of the animals at 1 hour. This persisted until 48 hours in one male only. No effects were noted in any of the animals at 72 hours.

Sensitisation
In a local lymph node assay conducted in mice, the stimulation indices of 1.00, 1.05 and 0.93 were obtained at 10%, 25% and 50% concentrations of the assessed chemical, respectively. Based on the stimulation indices, it could be concluded that the chemical is non-sensitising.

Repeated Dose Toxicity
In a submitted 28-day oral toxicity study (carried out in 2016 according to OECD TG 407) Sprague-Dawley rats received the assessed chemical at doses of 0, 100, 330, 1000 mg/kg bw/day, with a 2-week recovery period (at high dose only). No adverse effects attributed to treatment were reported on clinical condition, haematology parameters, bodyweight or food consumption.

Biochemical examination of the blood plasma at the end of the 4-week treatment period found slight but statistically significantly higher total protein concentration in both sexes receiving the assessed chemical at ≥ 100 mg/kg bw/day. At the end of the 2-week recovery period, total protein output was lower than in control group females and remained slightly higher than in control males. These values were not statistically significant and indicated that complete or partial recovery had occurred.

Urinalysis performed at the end of the 4-week treatment period revealed slightly high but not statistically significant total protein output in males receiving the assessed chemical at ≥ 330 mg/kg bw/day and in females receiving ≥ 100 mg/kg bw/day. At the end of the 2-week recovery period, total protein output was lower than controls in females and remained slightly high in males. These values were not statistically significant, indicating that complete or partial recovery had occurred.

Analysis of organ weights for animals killed after 4-weeks of treatment revealed low mean thymus weights in males given ≥ 330 mg/kg bw/day and in females given ≥ 100 mg/kg bw/day, with only the change in males attaining statistical significance. At the end of the of the 2-week recovery period, adjusted thymus weights remained marginally low for both sexes previously given 1000 mg/kg bw/day, but the magnitude of change was less than that evident at the end of the treatment period, indicating that partial recovery had occurred. Some other Brominated flame retardants (BFRs), also showed effects in the thymus, such as decreased weights (NICNAS 2012 and 2020).

Increased levels of protein in plasma and urine were reported in both males and females, raising a possible effect on renal function. However, mean kidney weights in treated animals were comparable to the control means and the histopathological examination of the kidneys did not reveal any findings related to the treatment. Therefore, these changes were not considered adverse by the study authors. Similarly, effects on thymus weights noted in females given 100 mg/kg/day and in both sexes given 330 or 1000 mg/kg bw/day were also considered non-adverse by the study authors in the absence of any degenerative/corroborative histopathological findings in the thymus.

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study (the highest tested dose).

A 90-day oral gavage study in rats on the assessed chemical (believed to have been carried out in 1991) was reported in a journal article, with dosages of 0, 100, 320 and 1000 mg/kg bw/day. A statistically significant increase in mean absolute and relative liver weights (7% to 12% increase) was seen in high dose females, which resolved after the 28-day recovery period. In male rats there was a dose-related increase in the incidence of abnormal hepatocytes. These changes in hepatocellular vacuolation, hepatocellular degeneration and centrilobular hepatocytomegaly were graded as minimal to slight and were not present in recovery animals. The study authors concluded that the NOAEL for the study was 1000 mg/kg bw/day, the highest dose tested, and commented that the low toxicity was likely related to poor bioavailability (Hardy et al., 2002).

Various recent studies examined additional parameters following administration of DBDPE (by gavage or intragastrically) to rats for a period from 28 to 90 days at varying doses (0, 50, 100, 250, 500, and 1000 mg/kg/day) (Wang F-X, et al., 2010; Sun R-B, et al., 2014; Jing L, et al., 2019; Sun Y-M, et al., 2020; Zheng D, et al., 2021). Some of the parameters investigated in recent studies were not examined in the 28-day study reported above (TG 407 study conducted in 2016). Additional studies have also been reported examining the effect of DBDPE on cardiovascular (Jing L, et al., 2019; Zheng D, et al., 2021) and endocrine functions (Sun R-B, et al., 2018; Wang Y-W, et al., 2019).

Where the assessed chemical was tested at the same time as decaBDE, the latter showed stronger toxicity effects (cardiovascular toxicity, liver toxicity and thyroid toxicity) (Jing L, et al., 2019; Sun Y-M, et al., 2020; Wang Y-W, et al., 2019).

Additional clinical and biochemical parameters were also examined as part of some studies. Among the parameters examined were: expression of the receptors PXR (pregnane X receptor) and CAR (constitutive androstane receptor), drug-metabolising enzymes, including Cytochromes P450 (CYPs) and uridine diphosphate-glucuronosyltransferases (UDPGT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and creatinine (Cr), and total bile acids (TBA). The assessed chemical may induce drug-metabolising enzymes in rats via the CAR/PXR signalling pathway (Sun R-B, et al., 2014). The enzyme UDPGT may conjugate with thyroxine (T4) and increase its removal, resulting in hypothyroid effects related to decreased plasma T4 levels. Thyroid hormone depletion may have a major role in a number of toxicological effects of the closely related PBDEs, particularly the neurodevelopmental effects seen in animal models (NICNAS 2012).

Significant liver toxicity was not observed at relatively low doses (up to 50 mg/kg bw/day) in rats following oral administration of DBDPE for 28 days. However some clinical chemistry parameters were increased after repeated treatment for 28 days at 500 mg/kg bw/day, including glucose levels (Sun R-B, et al., 2014, Sun Y-M, et al., 2020). Pathological changes in the liver in the form of irregular arrangement of hepatic cords, feathery necrosis, and inflammatory cell infiltration occurred in male rats at relatively high DBDPE exposure (500 mg/kg bw/day) following 28 days administration. Indicators of oxidative stress were also seen. Both DBDPE and decaBDE were reported to down-regulate expression of CAR/PXR and CYP3A1 and CYP3A2. The author attributed this effect as a possible result of liver damage (Sun Y-M, et al., 2020). This was not consistent with other findings.

Following oral administration of DBDPE (0, 5, 50, 500 mg/kg bw/day in corn oil) to male rats for 28 days, some histological and ultrastructural damage in the heart and the abdominal aorta was reported as well as effects on endothelial cells in the aorta, predominantly at the highest dose. The ultrastructural effects were determined by transmission electron microscope (TEM). These changes may have occurred through mitochondrial injury and were attributed to the induction of oxidative stress and an inflammation response (Jing L, et al., 2019).

A follow-up study using similar methodology and dosages evaluated the effects of DBDPE on the abdominal aorta of rats (sex not specified). Histological damage in the form of disordered elastin networks was seen at the highest dose of 500 mg/kg bw/day after 28 days intragastric administration. Changes to the ultrastructure were identified at the mid and high doses (50 and 500 mg/kg bw day), including endothelial cell contraction, cell nucleus swelling, and expanded elastic membrane space in the sub-endothelial layer. The study also identified that DBDPE significantly upregulated the protein levels of interleukin IL-1β and IL-18 in mid- and high-dose DBDPE groups compared with the control group. The authors concluded that DBDPE could cause inflammatory reaction in rat abdominal aorta by inducing NLRP3 inflammasome activation and activated caspase-1 (Zheng D, et al., 2021).

Mice were treated orally by gavage with DBDPE at doses of 0, 5, 20, 100 and 200 mg/kg bw/day for 30 days. Significant increases in the drug-metabolising enzymes including CYPs and UDPGT were reported (Sun R-B, et al., 2018). Significant increase in blood glucose levels in the treatment groups (≥ 20 mg/kg bw/day) and histopathologic liver changes (hepatocyte hypertrophy and cytoplasmic vacuolisation, the severity of which was not described) in the high dose group were also noted. There was a weak induction in thyroid stimulating hormone (TSH), only statistically significant in the high dose group. There were significant decreases of serum total triiodothyronine (T3) in the high dose group and serum free T3 (fT3) in 100 and 200 mg/kg bw/day dose groups.

The effect of DBDPE exposure on thyroid hormone levels in serum was investigated in male rats using 100 mg/kg bw/day for 90 days. Significant increases were reported for T3 levels, but not for T4 levels (Wang F-X, et al., 2010).

Rats were treated orally by gavage with DBDPE at doses of 0, 5, 50 and 500 mg/kg bw/day for 28 days (protocol followed in the test was not stated). Exposure to DBDPE for 28 days increased thyroid stimulating hormone (TSH) and thyrotropin-releasing hormone (TRH) levels at the high dose and decreased free T3 level in mid and high dose groups but did not reduce T4 or total T3 levels at any dose group. Histological examination and transmission electron microscope examination showed that exposure to DBDPE led to significant changes in histological structure and ultrastructure of the thyroid with a dose-dependent response from 5 mg/kg bw/day. The assessed chemical affected the expression of hypothalamic-pituitary-thyroid (HPT) axis related genes. The study authors stated that the results suggest the chemical could disrupt thyroid function in the direction of hypothyroidism (Wang Y-W, et al., 2019).

Thyroid hormone deiodinase (DIO) and sulfotransferase (SULT) activity were investigated in five novel brominated flame retardants including DBDPE, using human *in vitro* liver microsomal and cytosolic bioassays. Only DBDPE was reported to inhibit both outer and inner ring deiodination (O and IRD) of T3 and 3,3′-T2 formation from T4, respectively, with an estimated IC50 of 160 nM. However, no statistically significant inhibition of SULT activity was observed. It was reported that outer ring deiodination inhibition of 3,3′-T2 formation from rT3 was also observed with DBDPE (IC50 ~ 100 nM) (Smythe, TA, et al., 2017).

Mutagenicity/Genotoxicity
The assessed chemical was not mutagenic in a bacterial reverse mutation test. The assessed chemical was non-clastogenic in an *in vitro* mammalian chromosome aberration test in human peripheral lymphocytes both with and without metabolic activation.

Toxicity for Reproduction
No studies were submitted for this endpoint. In a submitted 28-day oral toxicity study in Sprague-Dawley rats (carried out according to OECD TG 407), no treatment related changes were reported in reproductive organ weights (testes and ovaries) and histopathology findings.

A 90-day repeated dose toxicity study reported in the literature (Hardy ML, et al., 2002) evaluated testes weights, checked gross reproductive organ changes but not microscopic changes, and measured sperm production (details not reported) following administering the assessed chemical at 0, 100, 320 and 1000 mg/kg bw/day. It was stated that no adverse effects were seen in the parameters evaluated, including the degree of spermatogenesis in the testes of high-dose males and the ovarian activity in the high-dose females. Male reproductive effects were not examined in two other repeated dose toxicity studies from literature (Wang F-X, et al., 2010 and REACH 2021a).

It was reported that DBDPE led to reproductive toxicity by inducing telomere dysfunction and the related cell senescence and apoptosis in the testes of male Sprague-Dawley rats orally dosed with DBDPE for 28 days (study protocol was not stated; doses administered were 0, 5, 50 and 500 mg/kg/day) (Li X-Y, et al., 2021). Histopathological examination of the testis showed effects on the seminiferous epithelium at the mid and high dose. Sperm motility decreased in all treatment groups, sperm numbers reduced in the mid and high dose group, and the sperm malformation rate increased in the high dose group. Increased oxidative stress was seen in the testis at the high dose. DecaBDE showed stronger toxicity in the testis compared to the assessed chemical.

In a perinatal study, female ICR mice were gavaged daily with DBDPE at 100 mg/kg bw/day from gestational day 6 to postnatal day 21. After weaning, male offspring were fed on a low-fat diet (LFD) or a high-fat diet (HFD). Body weight, liver weight, and epididymis fat mass, blood biochemical markers, metabolite changes in the liver, and gene expression involved in lipid and glucose homeostasis were measured and recorded. Observed effects in the male offspring treated with DBDPE that differed from the controls and were statistically significant included: increased body weights, epididymis fat mass and total liver cholesterol, and a reduced serum alanine aminotransferase level in the LFD group. Effects on metabolites and gene expression were also reported. The study authors stated that DBDPE may affect the energy metabolism of offspring by changing the triglyceride synthesis, bile secretion, purine synthesis, mitochondrial function and glucose metabolism, and eventually lead to obesity in offspring (Yan S, et al., 2018).

Female mice (6 mice/group, non-guideline study) orally exposed to DBDPE at 0, 0.05, 0.5, 5, 50 μg/kg bw/day for 30 days (lowest dose was stated to be closer to the environmental exposure concentration), did not show effects on first polar body extrusion (PBE) of oocytes. However, asymmetric division of oocytes was reported to be markedly impaired at 5 and 50 μg/kg bw/day due to the failure of spindle migration and membrane protrusion (Shi F-F and Feng X-Z, 2021).

An *in vitro* study conducted by exposing mouse oocytes to DBDPE at 0, 10 µM, 20 µM, 50 µM, 100 µM for 14 h showed that DBDPE exposure impaired mitochondrial function, causing oxidative damage, autophagy and apoptosis in oocytes (Shi F-F, et al., 2021).

Developmental toxicity
No studies were submitted for this endpoint. The potential embryotoxic and teratogenic effects of the assessed chemical were investigated in prenatal developmental studies using rats and rabbits and performed in accordance with OECD TG 414 (Hardy ML, et al., 2010). Pregnant animals were administered the assessed chemical via oral gavage at dosage levels of 0, 125, 400, or 1250 mg/kg bw/day from gestation day (GD) 6 through 15 for rats and GDs 6 through 18 for rabbits. All female rats and rabbits were sacrificed on GD 20 or GD 29, and subjected to caesarean section. Foetuses were individually weighed, sexed, and examined for external, visceral and skeletal abnormalities. In rats at the 400 mg/kg bw/day dosage, statistically significant increases were noted in the number of litters with hyoid unossified and reduced ossification of the skull. Since similar increases were not observed at the 1250 mg/kg/day level, the differences in the 400 mg/kg bw/day group were not considered to be related to treatment. The NOAELs were established as 1250 mg/kg/day for both rats and rabbits.

A study on the assessed chemical according to OECD TG 426 (Developmental Neurotoxicity Study) was summarised in a REACH dossier (supporting study). The assessed chemical was administered by oral gavage doses of 0, 100, 320, and 1000 mg/kg bw/day in corn oil, once daily to four groups of 25 time-mated female Crl:CD (SD) rats (F0 dams) on gestation day 6 through lactation day 21. There were test substance-related morphometric changes in brains of male offspring on postnatal day (PND) 22 and PND 72 at 100, 320, and 1000 mg/kg bw/day. There were lower group mean morphometric brain measurements in the cortex (Level 1), hippocampus (Level 3), and cerebellum (Level 5) on PND 22 and PND 72. The morphometric changes were not associated with statistically significant changes in brain weight or gross brain measurements, although there was a slight decrement of group mean brain weight in the 1000 mg/kg bw/day group males at PND 22.

It was reported in the REACH dossier, that peer reviewers suggested these changes as ambiguous findings, that may have been an artefact of the sectioning and measuring method. However, a NOAEL for developmental neurotoxicity was not established (REACH 2021b).

Observations on Human Exposure
In a study of two groups of workers in the same region in China, 133 workers occupationally exposed to DBDPE were compared with 169 workers without occupational exposure. A 10-fold increase in levels of DBDPE in serum was associated with increases in mean concentration of thyroid hormones total triiodothyronine (tT3) and total thyroxine (tT4) (2.38% and 4.73% increases, respectively). However the changes were considered to be in the subclinical range. The authors commented that a relationship between DBDPE exposure and thyroid homeostasis required further investigation (Chen T, et al., 2019).

Hair and nail samples were used as non-invasive biomatrices for assessing internal (systemic) BFR exposure levels and health effects in workers. DBDPE was detected in paired hair-serum and nail-serum samples collected from BFR chemical manufacturing workers (0.203-54.4 µg/g lipid weight in serum and 0.106-52.4 mg/g dry weight). However, hair was reported to be more suitable for use as a non-invasive biomatrix to determine the DBDPE exposure level. A series of serum biomarkers reflecting thyroid hormones, and liver and kidney injuries were tested and DBDPE level in hair was reported as significantly and positively correlated with the thyroid hormones fT3 and tT3, and kidney injury markers including blood urea nitrogen, creatinine and cystatin C (Zhao, X-Z, et al., 2020).

Levels of five brominated flame retardants, including DBDPE were determined in 172 serum samples collected from non-occupational residents of a major BFR-producing region in Shandong province, Northern China. All five substances were detected in the samples with DBDPE being the most abundant. The levels of DBDPE detected were reported from limit of detection (LOD) to 1590 ng/g lw, with a median level of 32.5 ng/g lw, indicating significantly higher levels than in studies conducted in the background population. A series of thyroid/liver injury biomarkers indicated a 10-fold increment in the serum DBDPE level was associated with decreased tT3 level (-0.037 nmol/L) [95% CI: -0.070, -0.003] (Zhao, X-Z, et al., 2021).

Health Hazard Classification
Based on the available conflicting data and limited information, the assessed chemical is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),*

as adopted for industrial chemicals in Australia. However, based on some recent publications, adverse effects after repeated exposure to the assessed chemical cannot be ruled out.

6.3. Human Health Risk Characterisation

Studies submitted on the assessed chemical indicated that the assessed chemical is of low acute toxicity, is not irritating to skin, is slightly irritating to eyes, not a skin sensitiser and is not mutagenic or genotoxic. Some repeated dose toxicity studies (including one provided by the applicant) indicated that the assessed chemical has no adverse health effects up to 1000 mg/kg bw/day. However, liver changes, morphological and ultrastructural damage in heart and abdominal aorta, adverse effects in testis and potential endocrine activities in rats/mice have been reported in recent published papers at varying dosages from 5 to 500 mg/kg bw/day. Reductions in thymus weight after repeated exposure are consistent with effects caused by other brominated chemicals (NICNAS 2012 and 2020). Morphometric changes in brains of male pups from 100 mg/kg bw/day were reported in a REACH dossier in a developmental neurotoxicity study for the assessed chemical. Therefore adverse effects after repeated exposure to the assessed chemical cannot be ruled out. In some studies where decaBDE was also tested, the assessed chemical was reported to be causing similar but less severe effects than with decaBDE.

Based on the limited information available, it is uncertain if the assessed chemical may photodegrade to lower brominated congeners (breakdown products), as occurs with decaBDE (NICNAS 2019) (also see section 7.2.6). There could be higher bioavailability and potentially adverse toxicological effects associated with the lower brominated (nonaBDE) impurities of the notified chemical. These were detected at low levels (< 0.5%) in the assessed chemical.

6.3.1. Occupational Health and Safety

Workers may be exposed to the imported assessed chemical up to 100% concentration (powder form) during compounding/masterbatch production operations. Other workers may come into contact with the assessed chemical at ≤ 30% concentration. Should inhalation, dermal or ocular contact occur, the exposure controls and personal protection as stated in the SDS are considered adequate to minimise exposure. These include ventilation requirements, hygiene measures and personal protective equipment (PPE) – gloves, goggles, body covering clothes and boots and respiratory protection.

The powders have a very high proportion (close to 100%) of particles in the respirable size range (< 10 μm). Therefore the greatest concern for exposure and risk to workers relates to inhalation, particularly when the chemical is handled at 100% in powder form (e.g. when being weighed and transferred for compounding). The risk would be reduced by measures that reduce exposure to the assessed chemical (e.g. mechanical ventilation as stated on the SDS).

Noting the uncertainties in human health hazards with repeated exposure, and provided that control measures are in place to minimise worker exposure to the assessed chemical, the risk to the health of workers from use of the assessed chemical is not considered to be unreasonable.

This risk assessment does not cover the exposure of workers during handling of articles containing the assessed chemical and end-of-life activities of articles containing the assessed chemical, such as installation of articles and recycling or removal and disposal of articles from construction. However, these activities are expected to be occurring already in Australia with imported articles containing the assessed chemical.

6.3.2. Public Health

The assessed chemical is intended for industrial use only, however the general public may have limited contact with articles (including curtains or upholstery fabrics) containing the assessed chemical. In addition, the assessed chemical is expected to be already imported into Australia as a component of a range of articles. Indirect human exposure are known to already occur in Australia, presumed to be due to release of dust from imported articles.

Indirect exposure of the public to the assessed chemical and potentially to photodegradation products may occur through the environment, where levels may increase over time due to its persistent and bioaccumulative properties. In particular, a build-up in dust in homes and other indoor environments may lead to public exposure through inhalation or ingestion. The use of the assessed chemical in textiles may increase direct and indirect exposure and therefore risk.

Based on the available hazard data, and noting the uncertainties in the hazard assessment, and likely widespread but low public exposure from the proposed use pattern, (which already occurs from imported articles), the assessed chemical is not considered to pose an unreasonable risk to public health through direct exposure. However, indirect exposure levels could increase over time due to persistent and bioaccumulative properties of the assessed chemical.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure

7.1.1. Environmental Release

Release from articles includes both imported articles and articles manufactured with the imported chemical. Release of the assessed chemical to indoor and outdoor environments is already known to occur in Australia, and is presumed to be due to release from imported articles.

RELEASE OF CHEMICAL AT SITE

The assessed chemical will be imported in neat form. Detailed information on all the proposed processes has not been provided as those could vary at different production facilities. According to the applicant, production of intermediate preparations (such as masterbatches) or articles can be done by extrusion, injection moulding, compression moulding, blown films, blow-moulding, rotational moulding, thermoplastic coatings and thermoset coatings, sometimes through forming pellets and tablets. The applicant estimates up to 20% of the import volume of the assessed chemical would also be applied to textiles via coating. Release of the assessed chemical during import, storage, transport and processing is expected to be collected and disposed of, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The assessed chemical will be used as a flame-retardant component of plastic articles for electrical and electronics applications, including electronic and electrical home appliances and enclosures. It will also be used for building and construction (as a component of films), as a component of wires, cables and plastic parts in automotive applications, and in textile back-coating, typically used for curtains. The assessed chemical is an additive flame retardant and may bloom out of plastic articles over a long time span. Emission factors for flame retardants from indoor service over a lifetime are estimated at 0.05% and for outdoor service at 0.16% per year (OECD, 2009). Since the chemical is used as a replacement for decaBDE, the estimated emission factor from articles for DBDPE is assumed to be similar to that of decaBDE (measured rate to air = 0.03 $\mu g/m^2/h$ and emission factor 1×10^{-7} per year) (OECD, 2019).

Laundering of materials that have been coated or treated with additive flame retardants (e.g., curtains) can result in release of the applied flame retardants by leaching and/or physical breakdown of the coatings. Flame retardants applied as surface coatings can also be displaced during use through physical wear and tear of the coatings over time.

RELEASE OF CHEMICAL FROM DISPOSAL

The assessed chemical will share the fate of articles into which it has been incorporated and is therefore expected to be recycled at approved facilities or disposed of to landfill at the end of the useful lives of the articles. Empty containers containing residues of the assessed chemical are expected to be disposed of in accordance with local government regulations.

No emission factors for non-volatile and hydrophobic flame retardants such as DBDPE are given for the waste disposal stage of the life cycle of a plastic article in the “Emission scenario document on plastic additives” (OECD, 2009). However, wastes in landfill and recycling facilities are known to release dust particles containing the assessed chemical, as demonstrated by several monitoring studies (Kierkegaard A, et al., 2004; Wang J, et al., 2010; McGrath TJ, et al., 2017).

7.1.2. Predicted Environmental Concentration (PEC)

Industrial uses of DBDPE are expected to result in both diffuse and point source emissions into the environment. Environmental concentrations of DBDPE were estimated from available domestic and international monitoring data. The assessed chemical has been detected in the Australian environment indicating that DBDPE is being introduced into Australia, presumably from articles containing the chemical. The assessed chemical is not manufactured in Australia.

The process of blending DBDPE into plastics and other articles/products, and electronic waste recycling facilities can be significant point sources for emissions of DBDPE into the environment (Kierkegaard A, et al., 2004; Wang J, et al., 2010; McGrath TJ, et al., 2017). In Australia, environmental monitoring data indicate DBDPE was present in soils collected from industrial and electronic waste recycling sites in Melbourne with a maximum measured concentration of 384 ng/g dw (McGrath TJ, et al., 2017). The chemical was also detected in soils from industrial sites in Australia specialising in flexible insulation foams and manufacturing construction materials (McGrath TJ, et al., 2017).

A major use of DBDPE is as an additive flame retardant in plastics and textiles. Release of DBDPE may occur through abrasion and wear from these articles. The chemical has been detected in dust collected from households, offices and cars in Australia with average concentrations between 2000 and 3400 ng/g dw (McGrath TJ, et al., 2018). The chemical in indoor dust may be released to wastewater through cleaning and washing of textiles and surfaces. Based on its high octanol-water partition coefficient (log Kow > 6.5), very low water solubility ($< 5 \times 10^{-5}$ mg/L) and recalcitrance towards biodegradation, the majority of the assessed chemical is expected to be removed by partitioning to sludge at sewage treatment plants, and limited release of the assessed chemical to surface water is expected. The major route of exposure resulting from releases of the assessed chemical to waste water is expected to be to the soil compartment as a result of the application of biosolids (treated sewage sludge) to land. Once in the soil compartment, the assessed chemical can be dispersed to other locations and environmental compartments by soil erosion, runoff and through wind borne particulates.

No domestic monitoring data for the assessed chemical in sediments, surface waters, and air (vapour) were identified. A summary of international monitoring data (see Appendix D) is provided in Table 1. A more extensive compilation of data on DBDPE residues in various environmental matrices obtained from the scientific literature is presented in Appendix D. The extensive body of global monitoring data now available for the assessed chemical shows that there have been significant increases in measured concentrations of DBDPE in dust and sewage sludge samples collected from Europe and Asia over the past two decades. This is assumed to reflect increasing global use of DBDPE as an additive flame retardant in various articles and products.

Table 1. Summary of DBDPE residues in various environmental matrices

Matrix	Units	n	Mean	Median	Maximum	Period	Annual trend**
Air (vapour)	pg/m^3	18	91.4	17.9	7000	2006 - 2018	2.12
Air (dust)	ng/g	48	3875	379.0	540000	2006 - 2018	88.8
Soil	ng/g dw	16	33.6	21.4	1612	2006 - 2015	0.83
Water*	ng/L	15	38.8	3.7	920	2009 - 2019	1.37
Sediments	ng/g dw	36	59.3	5.7	2394	2001 - 2020	0.04
Sewage sludge	ng/g dw	21	256.5	48.5	5172	2000 - 2019	6.77

n = number of studies
*Including particulate
**Approximate annual rates of change were obtained by dividing the slope derived from regression of the mean residue values over the specified time period by the number of years

7.2 Environmental Fate and Hazard Assessment

DBDPE has become increasingly important commercially overseas since the 1990s as a flame retardant and as a replacement for decaBDE (Environment Canada, 2019). Based on its low water solubility, very slight volatility and high hydrophobicity, most DBDPE in the environment is expected to partition to soils and sediments.

DBDPE is a member of a group of chemicals known as brominated flame retardants (BFRs). This group of chemicals has come under increased international attention because some members of the group and/or their degradants can have adverse effects on human health and the environment (United Nations, 2017a). DBDPE is a replacement BFR for decaBDE and is structurally very similar to the latter chemical. DecaBDE is a flame retardant of high concern and is a Persistent Organic Pollutant (POP) listed under Annex A (Elimination) of the Stockholm Convention on POPs (United Nations, 2017a). Considering the chemical similarity of decaBDE and DBDPE and the similar industrial uses of both chemicals, the hazard assessment of DBDPE also includes an assessment of whether the assessed chemical has the characteristics of a POP. The assessment of the potential POPs characteristics of DBDPE considers the persistence, bioaccumulation, adverse effects, and the potential for long range transport of the chemical according to criteria specified in Annex D of the Convention. An assessment of the potential for DBDPE to debrominate in the environment was also conducted since the degradants of this chemical may also have the characteristics of POPs.

7.2.1. Persistence

Results from a ready biodegradability study and OECD aerobic and anaerobic transformation studies in soils and sediments demonstrate that DBDPE meets the Persistence criterion in Annex D of the Stockholm Convention.

A ready biodegradability test performed in accordance with OECD TG 301 F determined that DBDPE is not readily biodegradable with no degradation observed over 28 days (ibacon GmbH, 2015b). Since no degradation was observed in 28 days it can be surmised that the half-life of the chemical in water was greater than two months.

Aerobic and anaerobic soil transformation studies, performed in accordance with OECD TG 307, showed no evidence of transformation of radio-labelled DBDPE (^{14}C-DBDPE) during the six-month study period (EAG, 2015a, b). Similarly, no clear evidence of transformation of ^{14}C-DBDPE was observed during a six-month study performed in accordance with OECD TG 308, which examined aerobic and anaerobic transformation in aquatic sediment systems (EAG, 2015c). The half-lives for DBDPE in soils and sediments extrapolated from these studies are both greater than six months which exceeds the criteria for persistence in these compartments under the Stockholm Convention.

7.2.2. Bioaccumulation

The high molecular weight (971.2 g/mol), low water solubility ($< 5 \times 10^{-5}$ mg/L), very slight volatility, and high hydrophobicity (log Kow > 6.5) of DBDPE suggest that this chemical will have very low bioavailability to organisms through the respiring medium (i.e., water for aquatic organisms and air for air-breathing animals). Dietary exposure is expected to be a more environmentally relevant exposure pathway for this very hydrophobic chemical. Numerous studies have demonstrated that DBDPE is present in the tissues of a wide range of aquatic and terrestrial organisms demonstrating that it is bioavailable through dietary exposure (see Appendix E). Additionally, there is evidence that the chemical is bioaccumulative in some food-chains with four studies on animals showing bioaccumulation factors (BAF) > 5000, or biomagnification factors (BMFs) and trophic magnification factors (TMFs) above 1. The relatively high levels of DBDPE found in the muscle tissue of predatory birds and sea eagle eggs provides additional evidence of biomagnification of the chemical through food chains. Maternal transfer of DBDPE was also demonstrated between hens and their eggs and chicks.

Based on the available bioaccumulation data, the chemical meets the bioaccumulation criterion of Annex D of the Stockholm Convention, including section (c)(iii), which is relevant when monitoring data in biota indicates the bioaccumulation potential of the chemical is sufficient to justify consideration within the scope of the Convention.

DBDPE residues in animals and plants

The open scientific literature reports measurable amounts of DBDPE in a wide range of animal and plant species all over the world (see Table 2 and Appendix E). The lowest median concentration was found in marine mammals (0.4 ng/g lw) and the highest median concentration was found in cephalopods (1800 ng/g lw). Among aquatic organisms, the highest residue loads are in predatory fish and cephalopods, with increasing trends for most groups over the past 13 years. The highest residues in terrestrial organisms are found in insects (median 85 ng/g lw).

A summary of the average, median and maximum residues of DBDPE found in different animal taxa and plants can be found in Table 2. A detailed summary of the literature data on DBDPE detected in aquatic and terrestrial biota is presented in Appendix E, tables 6 and 7, respectively.

Table 2. Summary of DBDPE residues in organisms (ng/g lw)

Organisms	n	Mean	Median	Maximum	Period
Aquatic					
Molluscs	12	20.5	1.4	4000	2010 - 2019
Crustaceans	15	595.5	34.2	2700	2006 - 2019
Cephalopods	3	1500.1	1800	2700	2013 - 2019
Other invertebrates	4	1070.4	40.5	4200	2010 - 2019
Fish-plankton feeder	17	14.6	1.4	126	2002 - 2019
Fish-herbivore	4	13.9	8.5	190	
Fish-omnivore	31	190.7	5.2	1800	
Fish-predator	18	450.0	11.1	2000	
Reptiles	5	159.4	30.2	3800	2006 - 2016
Birds-muscle	19	23.5	8.8	800	2006 - 2019
Birds-eggs	14	2.5	0.5	44	
Mammals-blubber	6	0.5	0.4	10	1986 - 2018
Mammals-liver/muscle	5	47.6	27.7	352	
Terrestrial					

Organisms	n	Mean	Median	Maximum	Period
Insects	5	269.3	85.0	1125	2015 - 2016
Amphibians-reptiles	4	16.5	15.9	84	2013 - 2016
Birds-herbivore*	2	14.2	14.2	85.9	2006 - 2019
Birds-omnivore*	13	14.5	12.3	220	
Birds-insectivore*	20	20.6	15.7	149	
Birds-predator*	14	31.9	12.0	800	
Mammals	2	7.7	-	863	2006
Roots	8	17.4	6.2	94	2001 - 2016
Stems	9	4.3	3.4	91.8	
Leaves	12	8.6	3.5	42.3	
Fruits/seeds	4	5.1	3.3	40.2	
Bark	2	54.7	-	100	

n = number of studies
*Muscle tissue

DBDPE levels in the muscle tissue of terrestrial predatory birds are higher than in other birds by a factor of 2 or 3 (Table 3), and levels in the eggs of sea eagles are 4 times higher than in other seabird eggs (de Wit CA, et al., 2020). Residues in eggs of invertebrate feeding birds, most of which prey on insects, are also much higher than in eggs of other birds. Since muscle and egg residues are presumed to arise from dietary exposure, higher levels of DBDPE in predatory birds is taken as evidence of biomagnification through the food chain.

Table 3. Residues of DBDPE in muscle tissue and eggs of birds (ng/g lw)

Feeding group	n	Muscle tissue	Eggs
Scavengers	2	9.7	9.6
Herbivores	2	14.2	0.9
Omnivores	10	14.5	18.3
Invertebrate feeders	11	20.6	56.1
Fish predators	8	29.2	0.2
Other predators	6	35.6	3.2

n = number of data points

Bioaccumulation Studies

DBDPE has been shown to bioaccumulate in some aquatic food webs, with BAF > 5000 reported in one study (He M-J, et al., 2012). Biomagnification of the chemical has been reported to occur in some aquatic food webs. The available evidence indicates that DBDPE is bioavailable through dietary exposure and is also bioaccumulative, and therefore DBDPE meets the Bioaccumulation criterion in Annex D of the Stockholm Convention.

Laboratory Studies

Two laboratory studies examined the dietary uptake of the substance by bluegill fish (*Lepomis machrochirus*) over a 28-day period and determined BMF values in the range 0.001-0.004 (Hardy ML, 2004). Measurements of radiolabelled DBDPE demonstrated that almost all the ingested DBDPE was excreted in the faeces (Eurofins 2020a, b). Other authors have shown that DBDPE bioaccumulation follows a concentration-dependent pattern in zebrafish larvae (Wang X-C, et al., 2019).

Field and Other Studies

Evidence of bioaccumulation was obtained from four monitoring studies and several experimental studies with birds and plant crops. One monitoring study determined log BAF values of 6.1 and 7.1 (= BAF > 10^6 and > 10^7) for fish in the heavily contaminated Dongjiang river of southern China (He M-J, et al., 2012). Biomagnification factors for DBDPE among aquatic organisms in field studies are quite consistent, with BMF values greater than 1 for fish from Lake Winnipeg, Canada (Law K, et al., 2006) and for crabs to fish in the Pearl River delta in China (Sun Y-X, et al., 2015) (Table 4). The only study that reported a BMF < 1 used a non-standard procedure to estimate that factor (Tao L, et al., 2019). Also, trophic magnification of the assessed chemical was identified for seven species in the freshwater food chain in the Lake Winnipeg study (TMF = 2.7; $r^2 = 0.22$, $p = 0.006$), although other studies report trophic dilution (TMF < 1), including one study where TMF = 0.47 for a marine food web in the Bohai Sea of China ($r^2 = 0.53$, $p < 0.001$, 18 species).

Layer hens feeding on a DBDPE-contaminated diet laid eggs that contained this chemical. DBDPE was found in 70% of eggs and 100% of chick tissues, whereas only a trace amount was present in hen muscle. Maternal transfer was the only pathway for contamination of eggs and hatched chicks (Zheng X-B, et al., 2014).

Uptake of DBDPE from contaminated soil or sediment has been reported in a few studies from southern China. The estimated BCFs were in the range 0.1 - 0.36 between roots and soil (Fan Y, et al., 2020; She Y-Z, et al., 2013; Zhang Y, et al., 2015) and 0.027 - 0.09 between mangrove roots and sediment (Hu Y-X, et al., 2020). Despite its high molecular weight and hydrophobicity, transfer of DBDPE between roots, stems and leaves did occur. The estimated ratios between tissues (from 0.11 to 2.09) were significantly higher than the bioconcentration factors between soil and roots (Fan Y, et al., 2020; Hu Y-X, et al., 2020; Zhang Y, et al., 2015).

Bioaccumulation factors between residues in soil and in moss and lichens of Antarctica have been determined as 3.3 and 2.71, respectively (Xiong S-Y, et al., 2021). Other studies, however, indicate lack of correlation between concentrations in soil and plant tissues, which suggest additional contamination sources other than the substrate – presumably through aerial deposition (Zacs D, et al., 2018; Zhang Z-W, et al., 2019).

Table 4. Bioconcentration (BCF), bioaccumulation (BAF), and biomagnification (BMF) factors and trophic magnification factors (TMF) of DBDPE in aquatic and terrestrial organisms

From	To	BCF	BAF	BMF	TMF	Region	Reference
Aquatic organisms							
Food	Fish	-	-	0.001-0.004	-	Experimental	Hardy ML, 2004
Water	Fish	-	6.1 (log) 7.1 (log)	-	-	Dongjiang (China)	He M-J, et al., 2012
Molluscs	Fish	-	-	0.2 1.6 2.0 3.0 9.2	2.7*	Lake Winnipeg (Canada)	Law K, et al., 2006; Law K, et al., 2007
Crabs	Fish	-	-	1.52-2.12	0.85	Pearl river delta (China)	Sun Y-X, et al., 2015
Plankton	Fish	-	-	-	0.37	Lake Taihu (China)	Zheng G-M, et al., 2018
Food	Fish	-	-	0.06	-	Qingyuan (China)	Tao L, et al., 2019
Sediment	Fish	0.005-0.014	-	-	0.9	Fujian (China)	Zhang Z-W, et al., 2019
Plankton	Fish	-	-	-	0.47	Bohai Sea (China)	Liu Y-H, et al., 2021
Terrestrial organisms							
Fish	Kingfisher bird	-	-	0.10-0.77	-	Guangdong (China)	Mo L, et al., 2012
Fish	Kingfisher bird	-	-	0.18-2.40	-	Guangdong (China)	Mo L, et al., 2013
Soil	Earthworms	-	0.02	-	-	Qingyuan (China)	Zhang B-Z, et al., 2013
Insects	Toad	-	-	0.19	-	Guangdong (China)	Liu Y, et al., 2020
Food	Lizard Insectivorous (bird) Omnivore (bird) Predator (bird)	-	-	0.34 0.17 0.24 0.43	-		
Frogs	Snake	-	-	0.22	-	Guangdong (China)	Wu J-P, et al., 2020
Plants							
Soil	Rice leaves	0.14-0.30	-	-	-	Southern China	She Y-Z, et al., 2013

From	To	BCF	BAF	BMF	TMF	Region	Reference
Soil	Rice roots	0.1-0.36	-	-	-	Guangdong (China)	Zhang Y, et al., 2015
Roots	Rice stems	-	0.18-0.45**	-	-		
Stems	Rice leaves	-	0.35-1.83**	-	-		
Sediment	Mangrove roots	0.027-0.09	-	-	-	Shenzhen (China)	Hu Y-X, et al., 2020
Roots	Mangrove stems	-	0.92-2.09**	-	-		
Stems	Mangrove leaves	-	0.91-1.63**	-	-		
Soil	Peanut crop Corn crop	0.31 0.21	-	-	-	Qingyuan (China)	Fan Y, et al., 2020
Roots	Peanut crop Corn crop	-	0.35** 0.11**	-	-		
Soil	Moss Lichen	-	3.30 2.71	-	-	Antarctica	Xiong S-Y, et al., 2021

*Corrected value according to Law, et al., 2007
**Ratios between tissues

Since BMFs indicate dietary exposure alone, values above 1 determined for aquatic organisms (Law K, et al., 2006; Sun Y-X, et al., 2015) and a specialised fish-eating bird (Mo L, et al., 2013) demonstrate that biomagnification is occurring in certain species. This is consistent with high residues of the assessed chemical found in predatory cephalopods and fish (Table 2) and in predatory birds (Table 3), as has been reported elsewhere (Jin X, et al., 2016; de Wit CA, et al., 2020). Uncertainty about the dietary exposure routes, species structure of sampled food webs or insufficient sample sizes can lead to estimating unreliable bioaccumulation metrics, e.g., when toads, lizards and birds feed on multiple insects and other invertebrates (Liu Y-X, et al., 2020), or when other possible prey items for predators are excluded (Wu J-P, et al., 2020).

Most of the TMF values currently available are below 1, which suggests that trophic dilution maybe more common than trophic magnification in many food webs (Table 4). The only TMF value above 1 is for an aquatic food web in Lake Winnipeg which may be related to differences in the bioaccumulation potential between freshwater and marine species. It should be noted that biomagnification of DBDPE can still occur between certain prey-predator combinations within food webs where trophic dilution occurs, which is demonstrated by the BAF and BMF values reported above.

7.2.3. Adverse Effects

DBDPE is not ecotoxic according to the standard acute and chronic ecotoxicity studies conducted on the chemical. However, the chemical is hepatotoxic to fish, and some studies in mice and rats also indicated liver effects although some of these effects were reversible during the recovery period. Furthermore, the chemical upregulates PXR/CAR, with the potential for producing hypothyroidism in rats by hepatic metabolism of thyroxine, and thyroid hormone related effects have been observed in chicken hepatocytes at concentrations that are environmentally relevant. Taken together the evidence indicates that DBDPE does have the potential to have adverse effects on birds, and therefore meets the criterion of Annex D, specifically (e)(ii) which is satisfied if there is ecotoxicity data that indicate the potential for damage to the environment.

Endocrine activity

In chicken hepatocytes, DBDPE up-regulated messenger RNA (mRNA) expression of the deiodinase-1 enzyme (DIO1) at 0.1 µM (= 97 ng/g), which converts the pro-hormone thyroxine (T4) to the active triiodothyronine (T3) (Egloff C, et al., 2011). Furthermore, the *in vitro* inhibition of the DIO1 enzyme from human hepatocytes was estimated at ~160 nM (155 ng/g) and ~100 nM (97 ng/g) for deiodination of T4 and T3, respectively (Smythe TA, et al., 2017). The inhibition of DIO1 is not necessarily incompatible with up-regulation of the genes that codify this enzyme. For example a deficiency of T3 could trigger a positive feedback on the genome resulting in enhanced production of the enzyme. The levels of effect of both processes are comparable. The effects of thyroid hormone imbalance in birds are not as well studied as in mammals, but such metabolic disturbance is expected to impact on processes such as growth, neural development, and thermoregulation in birds.

Monitoring studies show that levels of DBDPE in liver and muscle of birds are similar with an average of 10.7 ng/g lw among different regions (n = 39) (Appendix E). Some references indicate that these levels can reach up to 149 ng/g lw in small passerines (Mo L, et al., 2019), 220 ng/g lw in waterbirds (Luo X-J, et al., 2009), 350 ng/g lw in raptors (Jin X, et al., 2016) and 800 ng/g lw in fish-eating predatory birds (Luo X-J, et al., 2009), all of which are above the effect threshold of 97 ng/g in liver tissues. Since maternal transfer of DBDPE to eggs and hatched chicks has been demonstrated (Zheng X-B, et al., 2014), the above level of effect is relevant and could potentially impair birds' development.

The mode of action of DBDPE in birds is consistent with the target organs of DBDPE exposure in mammals. As with decaBDE, exposure to dietary DBDPE may disrupt thyroid metabolism in the direction of hypothyroidism in rats, with tissue damage in the thyroid but not in pituitary or hypothalamus at 500 mg/kg/d (Wang Y-W, et al., 2019). It appears that the effect on thyroid hormone levels in rats and mice is mediated by constitutive androstane receptor (CAR) pathways and it involves increased hepatic metabolism by CYP and UDPGT enzymes (Sun R-B, et al., 2018). In contrast, exposure of zebrafish larvae to aqueous solutions of DBDPE for 14 days had no obvious effects on hatching, malformation, survival or histopathology of the thyroid. However, levels of T3 and T4 in whole body increased significantly from 30 to 300 nM exposures, while the DIO1 gene was upregulated and DIO2 and DIO3 genes downregulated in a dose-dependent manner, thus disrupting the thyroid function. The authors also reported seven unidentified peaks on the chromatograms, which are thought to be DBDPE metabolites (Wang X-C, et al., 2019).

Acute toxicity
In acute ecotoxicity studies, fish, daphnia and algae were exposed to water accommodated fractions of DBDPE. DBDPE had no acute effect on aquatic invertebrates (48 h NOEC ≥ 110 mg/L), algae (96 h NOEC ≥ 110 mg/L) or fish (96 h NOEC ≥ 110 mg/L) (Hardy ML, et al., 2012). Similarly, DBDPE is not toxic to soil micro-organisms and earthworms (survival NOEC 3720 mg/kg dry soil, and reproduction NOEC 1907 mg/kg dry soil). However, it can impair growth of some crop plants (onions and tomatoes) at concentrations > 2440 mg/kg soil (Hardy ML, et al., 2011).

Chronic toxicity
In a 21-day *Daphnia magna* reproduction study, the chemical did not affect the survival or reproduction of test organisms up to the limit of its solubility in water (EAG Laboratories, 2018). The chemical was found not to affect sediment dwellers at the highest dose level in two chronic studies. The 28 day NOEC was ≥ 5000 mg/kg dry sediment for both chironomids and oligochaetes (Hardy ML, et al., 2012).

DBDPE is not toxic to rats by chronic daily exposure up to 1000 mg/kg body weight for 90 days (Hardy ML, et al., 2002; Wang F-X, et al., 2010). However, higher liver weight and increased incidence of abnormal hepatocytes were observed in females and males respectively, although these effects were resolved during the post-exposure recovery phase (Hardy ML, et al., 2002).

Hepatotoxicity has been observed in fish, and in some studies in mice and rats. *In vitro* experiments with trout hepatocytes showed a significant induction of vitellogenin at 6.3 µg/L, followed by a complete inhibition at 25 µg/L (Nakari and Huhtala, 2010). Several *in vivo* studies with rats and mice indicate that DBDPE affects the liver in the same way as decaBDE, although its effects are not as severe (Sun R-B, et al., 2014; Sun R-B, et al., 2018; Sun Y-M, et al., 2020). Further details on hepatic effects in mice and rats can be found in section 6.2.

Chronic exposures of juvenile goldfish to DBDPE by intra-peritoneal injection triggered some oxidative stress at the highest dose and exposure time tested (100 µg/g bw for 30 days), although this adaptive response was only consistently observed in mixtures with decaBDE (Feng M-B, et al., 2013). DBDPE is neither neurotoxic to zebrafish embryos *in vivo* (Jin M-Q, et al., 2018), nor cytotoxic to chicken hepatocytes *in vitro* (Egloff C, et al., 2011).

GHS classification
In standard acute ecotoxicity studies on fish, invertebrates and algae the chemical did not exhibit any adverse effects, therefore the chemical is not classified for short-term aquatic hazard according to the GHS.

Although the chemical did not exhibit adverse effects in standard acute and chronic ecotoxicity studies the chemical is poorly soluble in water, not rapidly degraded and there is evidence that it can bioaccumulate in aquatic food webs. Therefore, according to the GHS guidance on classification of aquatic hazards (4.1.2.2), the long-term aquatic hazard of this chemical is classified as category Chronic 4 (i.e., the "safety net" classification) (United Nations, 2017b).

Hazard	GHS Classification (Code)	Hazard Statement
Acute Aquatic	Not classified	–
Chronic Aquatic	Category 4 (H413)	May cause long lasting harmful effects to aquatic life

7.2.4. Predicted No-Effect Concentration (PNEC)

DBDPE is bioaccumulative and environmentally persistent. These two hazard characteristics combined have the potential to result in a range of long-term effects on aquatic and terrestrial life exposed to this chemical which cannot be readily identified through standard toxicity tests. For such chemicals, it is not currently possible to estimate a safe exposure concentration using standard extrapolation methods based on laboratory screening level tests. PNECs have therefore not been derived for this substance.

7.2.5. Long-Range Environmental Transport

The available evidence indicates that wet and dry deposition of particulates containing DBDPE results in contamination of soils, moss, lichens, trees and surface waters long distances away from emission sources and that the chemical has reached Antarctica. Therefore, DBDPE fulfills the long-range environmental transport criterion of Annex D of the Stockholm Convention, specifically section (d)(i) and (ii) which are satisfied if measured levels are in locations distant from the sources of its release and monitoring data exist.

DBPDE is not expected to volatilise from moist surfaces (Henry's Law Constant 2.94 $\times 10^{-8}$ atm-m^3/mol), whereas its high hydrophobicity (log Kow > 6.50) indicates that it is expected to adsorb to air-borne particles, soil and other surfaces. Despite its low solubility, DBDPE has been found in precipitation water. Concentrations in rainwater from the Great Lakes in North America are one order of magnitude lower (0.15 - 0.8 pg/m^3) than in air-borne particles from the same region (Ma Y-N, et al., 2013; Salamova A and Hites RA, 2011).

Average concentrations of DBDPE in air samples range from a low of 0.53 pg/m^3 in the Arctic (Salamova A, et al., 2014) to 42 pg/m^3 in households from Indiana (Venier M, et al., 2016) and 460 pg/m^3 in schools from Ireland (Wemken N, et al., 2019).

DBDPE has been detected in the atmosphere in both polar regions: on Svalbard in the Arctic Ocean at 0.04 - 2.2 pg/m^3 (Salamova A, et al., 2014) and from the limit of detection (LOD) to 2.1 pg/m^3 in 94% of samples from King George Island in Antarctica (Zhao J-P, et al., 2020). The aerial residues in Svalbard are linked to the use of flame retardants in the mining community of Longyearbyen. However, air samples that were collected over 8 years from a hilltop near a research station in Antarctica showed that peak concentrations of DBDPE and other novel flame retardants in air were significantly correlated with wind fluxes from the South American continent. This indicates long-range transport of DBDPE (Zhao J-P, et al., 2020).

Dry and wet deposition of DBDPE on surfaces results in contamination of tree bark (Zhu L-Y and Hites RA, 2006), tree leaves and pine needles (Zhu H-K, et al. 2018; Dreyer A, et al. 2019) and mosses (Dreyer A, et al., 2018). The level of contamination of mosses in Europe is two orders of magnitude lower than in Antarctica, where 50% of moss and 72% of lichens had DBDPE residues averaging 254 ng/g dw and 195 ng/g dw, respectively (Xiong S-Y, et al., 2021).

7.2.6. Debromination

The criteria of Annex D are applicable to the transformation products of a chemical. Since modelling has indicated that the degradants of DBDPE are potentially POPs (Environment and Climate Change Canada, 2019), an assessment of the potential for DBDPE to debrominate in the environment was conducted. DBDPE has been shown to debrominate rapidly in several laboratory experiments, however they were conducted with either unnatural light conditions (wavelengths < 290 nm), non-aqueous solvents or both. Three studies conducted under natural light with DBDPE in different matrices gave different results. DBDPE in HIPS showed no clear pattern of degradation in 224 days, while DBDPE on the surface of silica gel showed significant (80 - 100%) degradation in 18 hours. Field studies conducted on sediment in the vicinity of DBDPE production facilities indicated the presence of debromination products, the nonabrominated congeners. Based on the available information it is concluded that DBDPE may debrominate in the environment under certain conditions. The data pertaining to debromination of DBDPE is summarised in Table 5.

In a photolytic degradation study, DBDPE was found to photodegrade under an unfiltered high-pressure mercury lamp in all matrices investigated, including humic acid/water, silica gel, *n*-hexane, tetrahydrofuran and water/methanol, with a half-life in the range of 6 to > 240 minutes. DBDPE was also found to photodegrade under natural sunlight in *n*-hexane, with half-life in the range 20-40 minutes. DBDPE and decaBDE exhibited similar degradation behaviours in *n*-hexane and their degradation rate constants in this matrix were of the same order of magnitude. The degradation products of DBDPE were characterised as nona-, octa- and heptabrominated diphenyl ethanes (Wang J, et al., 2012).

No clear pattern of degradation of DBDPE incorporated in HIPS was found during the experimental period (224 days) in a study conducted under natural sunlight conditions (Kajiwara N, et al., 2008). Throughout this experiment, the measured concentrations of DBDPE remained close to the initial loading concentration with some fluctuation. However, a comparable experiment with decaBDE-loaded HIPS showed a clear pattern of degradation during the same time period, with a half-life of 51 days. Wang J, et al. (2012) suggest the matrices into which DBDPE and decaBDE are incorporated (e.g. HIPs), may play an important role in their photolytic behaviours.

In contrast to the above observations, significant photodegradation (80 - 100%) of DBDPE on the surface of silica gel was observed under simulated sunlight irradiation (400 - 1000 nm) within 18 hours (Li C-G, et al., 2019). Hydroxyl radicals can be generated from silica gel under simulated sunlight irradiation (Qu R-J, et al., 2018) and were the main contributor to the transformation of DBDPE. Nona- and octabrominated DPEs and OH-BDPEs were identified as the major debromination products.

The presence of DBDPE in aquatic sediments in a region where BFRs are manufactured (Arkansas, USA) was studied (Wei H, et al., 2012). Two nonabrominated DPEs were detected in pond sediments. This artificial pond was built in 1952 and had received treated effluent and biosolids from a wastewater treatment facility until 1989. The pond is shallow (< 2 m) and at the time of sampling the pond water was hypereutrophic (overly enriched with nutrients, conducive to algal growth), but still oversaturated with oxygen. It is within a few kilometres from a DBDPE manufacturing plant although has not received the wastewater directly from that plant. The nona-brominated congener concentration was found to increase steadily towards the surface of the sediment. Two samples extracted from sediment depths of less than 5 cm were found to have a nonabrominated/DBDPE ratio significantly greater than 0.7 in the calibration standards, with the highest being 1.3. The enrichment of nonabrominated congeners was attributed to debromination of DBDPE in the upper sediment of the pond. Debromination of decaBDE also occurred in this pond, which was attributed to a complex process likely involving abiotic and biological pathways.

Table 5. Summary of DBDPE debromination studies

Study	**Light source***	**Matrix/Matrices**	**Results**
Wang J, et al., 2012	High pressure mercury lamp (A)	Humic acid/water, silica gel, *n*-hexane, THF, water/methanol	$t_{1/2}$ = 6 to > 240 min
Wang J, et al., 2012	Natural sunlight (N)	*n*-hexane	$t_{1/2}$ = 20 to 40 min
Nadjia L, et al., 2014	200 – 800 nm (A)	THF	Biphasic $t_{1/2}$ = 1.9 min $t_{1/2}$ = 58 min
Klimm A, et al., 2019	200 – 600 nm (A)	Toluene, chlorobenzene, dichloromethane, benzyl alcohol	$t_{1/2}$ = 4.6 to 60 min
Li C-G, et al., 2019	400 – 1000 nm (N)	Surface of silica gel	80 – 100 % photodegradation within 18 h
Wei H, et al., 2012	Natural sunlight (N)	Artificial pond built in 1952 near DBDPE manufacturing facilities.	Nona-BDPE detected in 2009 with increasing concentration towards surface of sediment. Debromination probably due to photolysis and other factors.

*A: artificial, N: natural

7.3. Environmental Risk Assessment

A hazard evaluation according to the criteria of Annex D of the Stockholm Convention on Persistent Organic Pollutants has been conducted. This includes the determination of persistence, bioaccumulation, adverse effects and the potential for long range transport of the assessed chemical. An assessment of the potential for DBDPE to debrominate in the environment was also conducted.

Results from an OECD biodegradability study and aerobic and anaerobic transformation studies in soils and sediments demonstrate that DBDPE meets the Persistence criterion in Annex D of the Stockholm Convention.

There is clear evidence from the open scientific literature of the bioavailability of DBDPE in a wide range of aquatic and terrestrial species, as well as evidence of uptake of soil and sediment residues by plants. In addition, one study with fish has reported values of BAFs > 5000 (log BAF 6.1 and 7.1), and three animal studies reported values of BMFs and TMFs above 1. The relatively high levels of DBDPE found in the muscle tissue of predatory birds and sea eagle eggs is evidence of biomagnification through the food chain. Maternal transfer of DBDPE was demonstrated between hens and their eggs and chicks. Taken together, these findings provide strong evidence that DBDPE bioaccumulates in aquatic and terrestrial food-webs and therefore fulfills the bioaccumulation criterion of Annex D of the Stockholm Convention.

DBDPE is not ecotoxic according to the standard acute and chronic ecotoxicity studies conducted on the chemical. However, the chemical is hepatotoxic to fish, and in some rodent studies. Furthermore, it acts in a way that may produce hypothyroidism in rats and has been shown to affect chicken hepatocytes at relevant environmental concentrations, which provides a plausible pathway for adverse effects in birds at environmentally relevant exposure concentrations. Taken together the evidence indicates that DBDPE meets the adverse effects criterion of Annex D.

The evidence currently available indicates that wet and dry deposition of particles containing DBDPE results in contamination of soils, moss, lichens, trees and surface waters at long distances from likely emission sources and the assessed chemical has been monitored in Antarctica. Therefore, DBDPE fulfills the long-range environmental transport criterion of Annex D of the Stockholm Convention.

Photolytic degradation studies show that DBDPE is debrominated under certain conditions. Field studies conducted on sediment in the vicinity of DBDPE production facilities showed indications of the presence of the debromination products, nonabrominated congeners of DBDPE. This indicates DBDPE can debrominate, under certain environmental conditions. Measured hazard data on DBDPE debromination products are not available. However, modelling data suggest that DBDPE debromination products can have POP characteristics.

In conclusion, based on the available information decabromodiphenyl ethane has the characteristics of a Persistent Organic Pollutant according to Annex D of the Stockholm Convention.

8. OVERSEAS INVESTIGATIONS

The assessed chemical has been the subject of actions in Canada, the EU and the USA.

The final Screening Assessment Report for DBDPE was published in May, 2019 by the Government of Canada, with the conclusion that it meets criteria for toxicity set out in section 64(a) of CEPA (the Canadian Environmental Protection Act, 1999). The final order to add DBDPE to Schedule 1 of CEPA is currently under development, with publication anticipated to be in 2021.

The assessed chemical is currently listed on the EU ECHA CoRAP (Community Rolling Action Plan), due to Suspected PBT/vPvB, high (aggregated) tonnage and wide dispersive use. It is currently the subject of an evaluation.

The assessed chemical is also the subject of a Significant New Use Rule (SNUR) in the USA, with limitations on the manufacturing, processing or use, through a consent order under TSCA. Use of the chemical in a manner inconsistent with the consent order requires notification to the US EPA before the new use begins. The US EPA would review the new use and, if necessary, place restrictions on it.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point ~ 350 °C

Method	Differential Scanning Calorimetry method was used.
Remarks	The average onset temperature was 352.8°C and the peak temperature was 354.7°C.
Test Facility	ICL Industrial Products (2014a)

Density 945 kg/m^3 (relative standard deviation = 1.3%)

Method	Bulk density was measured using the weight of test substance in 100 mL calibrated cylinder divided by the cylinder volume.
Test Facility	ICL Industrial Products (2014b)

Vapour Pressure 3.14×10^{-14} kPa at 20 °C

Method	OECD TG 104 Vapour Pressure
Remarks	The isothermal thermogravimetric effusion method was used. The results were extrapolated from data measured between 240 °C and 270 °C.
Test Facility	ibacon GmbH (2015a)

Water Solubility $< 5 \times 10^{-5}$ mg/L at 20 °C

Method	OECD TG 105 Water Solubility
Remarks	Column Elution Method. A primary stock solution of the test substance was prepared at a concentration of 0.100 g/L in carbon disulfide. Secondary stock solutions were then prepared by successive dilutions (10.0 mg/L and 1.00 mg/L in carbon disulfide, and 0.100 mg/L in toluene). The toluene secondary stock was used to prepare test substance calibration standards. Water samples from a generator column packed with solid support coated with the test substance were collected directly into toluene extraction solvent, extracted once and an aliquot of the toluene extract was directly injected into a gas chromatograph equipped with a mass selective detector (GC/MS). The water solubility of the test substance was determined to be less than the method limit of quantification (5×10^{-5} mg/L = 50 ng/L) at 20.0 °C.
Test Facility	EAG Laboratories (2016a)

Partition Coefficient (n-octanol/water) log Kow > 6.50

Method	OECD TG 117 Partition Coefficient (n-octanol/water) by HPLC Method
Remarks	HPLC Method. A test solution of the test substance was prepared at a nominal concentration of 75.0 mg/L in carbon disulfide from a primary stock solution. Six calibration reference standards of known log Kow were prepared and injected into a HPLC system followed by single injections of three separate aliquots of the test substance. The retention time of the test substance was longer than the most lipophilic and slowest to elute reference substance 'DDT' (log Kow = 6.50). The test substance eluted as a set of two peaks, both corresponding to mean estimated log Kow > 6.50. The minor peak was approximately 5% the height of the major peak.
Test Facility	EAG Laboratories (2016b)

Particle Size D_{10} = 1.6 μm; D_{50} = 3.4 μm; D_{90} = 6.8 μm

Method	Malvern Mastersizer-3000 was used for the measurement. D_{10}: The portion of particles with diameters smaller than this value is 10%. D_{50}: The portions of particles with diameters smaller and larger than this value are 50%. Also known as the median diameter. D_{90}: The portion of particles with diameters below this value is 90%.

Test Facility ICL Industrial Products (2017)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute Oral Toxicity – Rat, Fixed Dose

TEST SUBSTANCE Assessed chemical (99.48% purity)

METHOD OECD TG 420 Acute Oral Toxicity – Fixed Dose Method (2001)
EC Council Regulation No. 440/2008 B.1 bis Acute toxicity (Oral)

Species/Strain Rat/Wistar
Vehicle Arachis oil BP
Remarks – Method GLP Certificate
No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	1F	2000	0/1
2	4F	2000	0/4

LD50 > 2000 mg/kg bw
Signs of Toxicity No signs of systemic toxicity were observed.
Effects in Organs No abnormalities were observed at necropsy.
Remarks – Results Body weight gains were as expected.

CONCLUSION The assessed chemical is of low acute toxicity via the oral route.

TEST FACILITY Envigo (2015a)

B.2. Acute Dermal Toxicity – Rat

TEST SUBSTANCE Assessed chemical (99.48% purity)

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test (1987)
EC Council Regulation No 440/2008 B.3 Acute Toxicity (Dermal) – Limit Test
Species/Strain Rat/Wistar
Vehicle Arachis oil BP
Type of dressing Semi-occlusive.
Remarks – Method GLP Certificate
No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	5 per sex	2000	0/10

LD50 > 2000 mg/kg bw
Signs of Toxicity – Local There were no signs of dermal irritation.
Signs of Toxicity – Systemic There were no deaths or signs of systemic toxicity.
Effects in Organs No abnormalities were observed at necropsy.
Remarks – Results Three females showed body weight loss or no gain in body weight during the first week with expected body weight gain during the second week. The remaining animals showed expected gains in body weight over the study period.

CONCLUSION The assessed chemical is of low acute toxicity via the dermal route.

TEST FACILITY Envigo (2015b)

B.3. Skin Irritation – Rabbit

TEST SUBSTANCE Assessed chemical (99.5%)

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion
EC Council Regulation No 440/2008 B.4 Acute Toxicity (Skin Irritation)

Species/Strain Rabbit/New Zealand White
Number of Animals 2
Vehicle Distilled water
Observation Period 72 hours
Type of Dressing Semi-occlusive
Remarks – Method The following deviations from the Study Plan occurred:
Due to a technician error, the 72-hour observations were not recorded. However, because the study was terminated at the 72-hour time point after recording the body weights, it is reasonable to assume that there was no evidence of erythema or oedema.

This deviation was considered to have not affected the integrity or validity of the study.

Remarks – Results Both animals showed expected body weight gain during the study period (72 hours). The test substance produced a primary irritation index of 0.0. No evidence of skin irritation was noted during the study.

CONCLUSION The assessed chemical is non-irritating to the skin.

TEST FACILITY Envigo (2016a)

B.4. Skin Sensitisation – LLNA

TEST SUBSTANCE Assessed chemical (99.5% purity)

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay (2010)
EC Council Regulation No 440/2008 B.42 Skin Sensitisation (Local Lymph Node Assay)

Species/Strain Mouse/CBA/Ca
Vehicle Acetone:olive oil (4:1)
Preliminary study Yes, at 50%
Positive control α-Hexylcinnamaldehyde, tech., 85%, conducted in parallel with the test substance at a concentration of 25% (v/v) in acetone:olive oil (4:1)
Remarks – Method No significant protocol deviations.
No analysis was conducted to determine the homogeneity, concentration or stability of the test substance formulation. Although not compliant with GLP, this was considered not to affect the purpose or integrity of the study.

RESULTS

Concentration (% v/v)	*Number and Sex of Animals*	*Proliferative Response (DPM/lymph node)*	*Stimulation Index (test/control ratio)*
Test Substance			
0 (vehicle control)	5F	418.50	-
10%	5F	419.61	1.00
25%	5F	437.45	1.05
50%	5F	391.07	0.93
Positive Control			
25%	5F	3169.21	7.57

Remarks – Results	No unscheduled mortalities or signs of systemic toxicity were observed during the study period. Residual test substance was observed on the ears of the study animals receiving the 25% and 50% concentration of test substance. The stimulation indices were 1.00, 1.05 and 0.93 at 10%, 25% and 50% concentrations, respectively, indicating a non-sensitising response. The positive control behaved as expected, confirming the validity of the test system.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the assessed chemical at up to 50% concentration.
TEST FACILITY	Envigo (2016b)

B.5. Repeat Dose Oral Toxicity – Rats

TEST SUBSTANCE	Assessed chemical (99.48% purity)
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents (2008)
Species/Strain	Rats/Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 2 weeks
Vehicle	Corn oil
Remarks – Method	GLP Certificate No significant protocol deviations. Doses for the study were selected in conjunction with the Sponsor based on results from a previous repeat dose oral toxicity study.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw/day)*	*Mortality*
Control	5 per sex	0	0/10
Control Recovery	5 per sex	0	0/10
Low Dose	5 per sex	100	0/10
Mid Dose	5 per sex	330	1/10
High Dose	5 per sex	1000	0/10
High Dose Recovery	5 per sex	1000	0/10

Mortality and Time to Death

One animal (330 mg/kg bw/day) was found dead on day 20 of treatment without exhibiting any clinical signs prior to death. Macroscopic and microscopic examination determined the cause of death to be a result of dosing trauma and not related to treatment.

Clinical Observations

Adverse clinical signs were not observed in association with dose administration and there were no sign observed at the routine physical examinations that was considered related to treatment. A single incident of irregular breathing for one male (1000 mg/kg bw/day) was observed on day 11 of treatment in association with dose administration. This sign was observed at the end of the working day and had resolved by the following morning.

There was no adverse effect of treatment on body weight and food consumption at all doses. There were also no treatment-related effect on sensory reactivity responses and grip strength and on either rearing (high beam) or ambulatory (low beam) motor activity.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

The haematology investigation performed at the end of the 4-week treatment period did not identify any treatment related findings. Biochemical examination of the blood plasma at the end of the 4-week treatment period found slight but statistically significantly higher total protein concentration in both sexes given ≥ 100 mg/kg bw/day. These values (mean) in males were: 55 g/L (control), 57 g/L (100 mg/kg bw/day), 59 g/L (330 mg/kg bw/day), and 57 g/L (1000 mg/kg bw/day); these values being significant only at 330 and 1000 mg/kg bw/day. Values (mean) in females were: 58 g/L (control), 63 g/L (100 mg/kg bw/day), 60 g/L (330 mg/kg bw/day), and 63 g/L (1000 mg/kg bw/day). These values were not significant.

At the end of the 2-week recovery period, total protein output was lower than controls for previously treated females and remained slightly high for previously treated males. These values (mean) in males were 58 g/L (control) and 56 g/L (1000 mg/kg bw/day) and in females were 65 g/L (control) and 66 g/L (1000 mg/kg bw/day). These values were not significant, indicating that complete or partial recovery had occurred.

Urinalysis performed at the end of the 4-week treatment period revealed slightly high total protein output in males given ≥ 330 mg/kg bw/day and in females given ≥ 100 mg/kg bw/day. These values (mean) in males were: 2.674 mg (control), 2.131 mg (100 mg/kg bw/day), 3.137 mg (330 mg/kg bw/day), and 3.937 mg (1000 mg/kg bw/day); being significant only at 1000 mg/kg bw/day. These values (mean) in females were: 0.419 mg (control), 0.554 mg (100 mg/kg bw/day), 0.630 mg (330 mg/kg bw/day), and 0.671 mg (1000 mg/kg bw/day); these values were not significant.

At the end of the 2-week recovery period, total protein output was lower than controls for previously treated females and remained slightly high for previously treated males. These values (mean) in males were 4.448 mg (control) and 5.438 mg (1000 mg/kg bw/day) and in females were 0.709 mg (control) and 0.630 mg (1000 mg/kg bw/day). These values were not significant, indicating that complete or partial recovery had occurred.

Effects in Organs

Analysis of organ weights for animals killed after 4-weeks of treatment revealed low mean thymus weights in males given ≥ 330 mg/kg bw/day and in females given ≥ 100 mg/kg bw/day, with only the change in males attaining statistical significance. These values (mean) in males were: 0.493 g (control), 0.449 g (100 mg/kg bw/day), 0.384 g (330 mg/kg bw/day), and 0.405 g (1000 mg/kg bw/day). These values (mean) in females were: 0.440 g (control), 0.402 g (100 mg/kg bw/day), 0.341 g (330 mg/kg bw/day), and 0.390 g (1000 mg/kg bw/day).

At the end of the of the 2-week recovery period, adjusted thymus weights remained marginally low for both sexes previously given 1000 mg/kg bw/day but, the magnitude of change was less than that evident at the end of the treatment period. These values (mean) in males were 0.448 g (control) and 0.388 g (1000 mg/kg bw/day) and in females were 0.336 g (control) and 0.318 g (1000 mg/kg bw/day). This indicated that partial recovery had occurred.

Remarks – Results

A slight but statistically significantly increase in total protein concentration in both sexes given ≥100 mg/kg bw/day suggests a possible effect on renal function. However, mean kidney weights in treated animals were comparable to the control means and the histopathological examination of the kidneys did not reveal any findings related to treatment; these changes were not considered adverse by the study authors. Plasma biochemistry and urinalysis, possibly indicative of adaptations of metabolism in the kidneys, showed partial or complete recovery after two weeks respite from treatment and were not considered adverse by the study authors. The slightly low thymus weights seen in females given 100 mg/kg/day and both sexes given 330 or 1000 mg/kg bw/day were considered non-adverse by the study authors in the absence of any degenerative/corroborative histopathological findings in the thymus.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study (the highest tested dose).

TEST FACILITY Envigo CRS Limited (2016)

B.6. Genotoxicity – Bacteria

TEST SUBSTANCE Assessed chemical (99.48% purity)

METHOD OECD TG 471 Bacterial Reverse Mutation Test
Species/Strain *Salmonella typhimurium*: TA1535, TA1537, TA98, TA100
Escherichia coli: WP2uvrA (pKM101)
Metabolic Activation System Rat liver S9 fraction
Concentration Range in Main Test a) With metabolic activation: 5 – 5000 µg/plate
b) Without metabolic activation: 2 – 5000 µg/plate
Vehicle DMSO
Remarks – Method There were no deviations from the protocol.

Positive controls:
With metabolic activation: 2-aminoanthracene (TA100, TA1535); Benzo[a]pyrene (TA98, and TA1537)
Without metabolic activation: Sodium azide (TA100, TA1535); 9-aminoacridine (TA1537); 2-nitrofluorene (TA98); 4-Nitroquinoline-1-oxide (WP2 uvrA (pKM101))

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	> 5000	≥ 1500	negative
Test 2	> 5000	≥ 1500	negative
Present			
Test 1	> 5000	not reported	negative
Test 2	> 5000	not reported	negative

Remarks – Results No substantial increases in revertant colonies over control counts were observed for any of the bacterial strains at any concentration, either with or without metabolic activation.

Appropriate positive control chemicals (with S9 mix where required) induced substantial increases in revertant colony numbers with all strains in all reported tests, confirming sensitivity of the cultures and activity of the S9 mix.

CONCLUSION The assessed chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Huntingdon (2015)

B.7. Genotoxicity – *In Vitro* Mammalian Chromosome Aberration Test in Human Lymphocytes

TEST SUBSTANCE Assessed chemical (99.48% purity)

METHOD OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test (2014)
EC Commission Regulation No. 440/2008. Method B.10: Mutagenicity – *In Vitro* Mammalian Chromosome Aberration Test.
Species/Strain Human
Cell Type/Cell Line Peripheral lymphocytes
Metabolic Activation System S9 mix from phenobarbital/β-naphthoflavone (NF) induced rat liver
Vehicle Dimethyl sulfoxide
Remarks – Method GLP Certificate

No significant protocol deviations.
Negative control: Dimethyl sulfoxide
Positive control: Without metabolic activation: Mitomycin C
With metabolic activation: Cyclophosphamide

The dose selection for the main experiments was based on toxicity in a dose range-finding study carried out at 2.52 - 250 µg/mL.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	11.66, 19.44, 32.4, 54*, 90*, 150*	3 hours	21 hours
Test 2	11.66, 19.44, 32.4, 54*, 90*, 150*, 250	21 hours	21 hours
Present			
Test 1	11.66, 19.44, 32.4, 54*, 90*, 150*	3 hours	21 hours

*Cultures selected for metaphase analysis

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 250	> 150	≥ 250	negative
Test 2	≥ 250	> 150	≥ 150	negative
Present				
Test 1	≥ 250	> 150	≥ 150	negative

Remarks – Results

The test substance did not induce any statistically significant increases in the frequency of cells with structural chromosomal aberrations, or in the numbers of polyploid cells, either in the presence or absence of metabolic activation.

The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system.

CONCLUSION

The assessed chemical was not clastogenic to human peripheral lymphocytes treated *in vitro* under the conditions of the test.

TEST FACILITY

Envigo (2015c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready Biodegradability

TEST SUBSTANCE DBDPE (99.5% purity)

METHOD OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test
Inoculum Activated sludge from a domestic wastewater treatment plant
Exposure Period 28 days
Auxiliary Solvent None
Analytical Monitoring Biochemical oxygen demand (BOD) by sensor system
Remarks - Method No major deviations from the test guidelines were reported. The test substance was added directly to the test vessels. A toxicity control was run.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
4	0	4	62
14	0	14	81
21	0	21	85
28	0	28	87

Remarks - Results The pH value of the test substance flasks at the end of the test (8.7 and 8.8) was outside the pH range recommended by the test guideline (6.0 – 8.5). The pH at the start of the test was also slightly higher (7.7) than recommended (7.4 ± 0.2). The high pH values were not found to have a significant effect on the study as the pH values of the controls were in the same range, and all validity criteria were met. The toxicity control exceeded 25% biodegradation after 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The test substance loading rate (103 mg/L) was significantly higher than the measured solubility ($< 5\times10^{-5}$ mg/L). There was no degradation of the test substance observed over the 28 day exposure period.

CONCLUSION The test substance is not readily biodegradable.

TEST FACILITY ibacon GmbH (2015b)

C.1.2. Bioaccumulation (Study 1)

TEST SUBSTANCE ^{14}C-DBDPE (98.6% purity)

METHOD OECD TG 305 Bioaccumulation in Fish: Dietary Exposure

Species Bluegill (*Lepomis macrochirus*)
Exposure Period Uptake: Group 1: 28 days; Group 2: 56 days Depuration: 28 days
Auxiliary Solvent None
Analytical Monitoring Liquid scintillation counter (LSC)
Remarks - Method No major deviations from the test guidelines were reported. Two treatment groups with spiked ^{14}C-DBDPE plus a reference substance PCB-153 were tested. Group 1 was exposed to DBDPE at nominal 100 µg/g plus PCB-153 at nominal 10 µg/g (measured 101 and 10 µg/g, respectively). Group 2 was exposed to DBDPE at nominal 1000 µg/g plus PCB-153 at nominal 100 µg/g (measured 960 and 95.5 µg/g, respectively).

	Each group consisted of one test chamber with initially 110 fish in each chamber. A continuous flow-through test system was used. During both uptake and depuration phases, test organisms were collected and analysed for the test substance.
RESULTS	
Bio-magnification Factor (BMF)	Estimated growth and lipid corrected biomagnification factors (BMF_{KgL}) were 0.003 and 0.001 for groups 1 and 2 respectively. The measured steady-state BMF were identical to the kinetic estimates in the two groups. Depuration half-lives were 0.21 and 0.15 day for the respective groups.
Remarks - Results	All validity criteria were met. No mortalities were observed in any test group.
CONCLUSION	The test substance does not bioaccumulate in whole fish tissue and is primarily retained in the gut tract.
REFERENCE	Eurofins (2020a)

C.1.3. Bioaccumulation (Study 2)

TEST SUBSTANCE	^{14}C-DBDPE (98.9% purity)
METHOD	OECD TG 305 Bioaccumulation in Fish: Dietary Exposure
Species	Bluegill (*Lepomis macrochirus*)
Exposure Period	Uptake: 28 days Depuration: 28 days
Auxiliary Solvent	None
Analytical Monitoring	LSC
Remarks - Method	No major deviations from the test guidelines were reported. Bluegill fish were exposure to five treatment groups: -Group1: DBDPE at nominal 1000 µg/g + PCB-153 at nominal 100 µg/g (measured 966 and 91 µg/g, respectively) -Group2: DBDPE at nominal 1000 µg/g (measured 925 µg/g) -Group3: PCB-153 at nominal 100 µg/g (measured 86 µg/g) -Group4: solvent blue at nominal 100 µg/g (measured 91 µg/g) -Group5: o-terphenyl at nominal 100 µg/g (measured 94 µg/g) Each group consisted of one test chamber with initially 90 fish in each chamber. A continuous flow-through test system was used. During both uptake and depuration phases, test organisms were collected and analysed for the test substance.
RESULTS	
Bio-magnification Factor (BMF)	Estimated growth and lipid corrected biomagnification factors (BMF_{KgL}) were 0.0003 and 0.0014 for groups 1 and 2 respectively. The measured steady-state BMF were 0.003 and 0.004 respectively for the same groups. Depuration half-lives were 0.92 and 0.46 day for the two groups.
Remarks - Results	All validity criteria were met. No mortalities were observed in any test group.
CONCLUSION	The test substance does not bioaccumulate in whole fish tissue and is primarily retained in the gut tract.
REFERENCE	Eurofins (2020b)

C.1.4. Aerobic Transformation in Soils

TEST SUBSTANCE	^{14}C-DBDPE (94.5% purity)
METHOD	OECD TG 307 Aerobic and Anaerobic Transformation in Soil

Soils	Textural Class	pH (1:1 soil:water)	% Organic Carbon	Microbial Biomass (µg/g)	% Organic Matter
Soil 1	Loamy sand	5.2	0.9	211.7	1.6
Soil 2	Sandy clay loam	6.9	1.9	543.2	3.4
Soil 3	Clay loam	5.4	4.0	531.5	6.8
Soil 4	Sandy Clay loam	7.9	2.8	548.3	4.7

Test Duration 182 days

Analytical Monitoring LSC, high performance liquid chromatography (HPLC)

Remarks – Method Soils were dosed with ^{14}C-DBDPE at a nominal test concentration of 1.8 mg/kg dry soil. A stock solution containing the test substance was initially loaded onto freeze-dried sludge which was subsequently added to test soil and homogenised. Test samples were incubated in the dark at approximately 20 °C. Test chambers were attached to a gas flow-through system. Chamber outlets were connected to an ethylene glycol trap followed by a KOH trap. The head space of the test chamber was continuously purged with air to maintain aerobic conditions. Duplicate samples of each test chamber were collected about monthly for chemical analysis. Mass balances were calculated from the sum of ^{14}C-DBDPE in the soil extracts, soil combustion products and products collected in the traps. No reference substance was used to confirm the degradation process.

RESULTS There was no clear pattern of degradation in any of the tested soils, and the half-lives were extrapolated beyond the six-month test period. The mean percentage of radioactivity recovered as ^{14}C-DBDPE at the end of the six-month test was > 94% in all soil extracts. The mean recoveries throughout the study ranged from 87 to 113%. There were no distinct, consistent transformation product peaks observed during the study.

Remarks – Results The recoveries of the test substance directly after addition to soil ranged from 87 to 101% which was slightly lower than the quality criteria of the test guidelines (90-110%). The quality criterion on limit of detection (LOD) was met. LOD of the scintillation counter was the same as limit of quantitation (LOQ), and was equivalent to 0.000108% of the dose or 0.338 ng DBDPE. The LOQ for all samples was < 0.1% of the applied dose. The LOD of the HPLC β-RAM detector was equivalent to 0.000375% of the nominal dose or 0.676 ng DBDPE. LOQ in the concentrated soil extracts was approximately 0.62% of the nominal dose.

CONCLUSION There is no clear evidence that ^{14}C-DBDPE is transformed in aerobic soil during the study period.

TEST FACILITY EAG Laboratories (2015a)

C.1.5. Anaerobic Transformation in Soils

TEST SUBSTANCE ^{14}C-DBDPE (94.5% purity)

METHOD OECD TG 307 Aerobic and Anaerobic Transformation in Soil

Soils	Textural Class	pH (1:1 soil:water)	% Organic Carbon	Microbial Biomass (µg/g)	% Organic Matter
Soil 1	Loamy sand	5.2	0.9	211.7	1.6
Soil 2	Sandy clay loam	6.9	1.9	543.2	3.4
Soil 3	Clay loam	5.4	4.0	531.5	6.8
Soil 4	Sandy Clay loam	7.9	2.8	548.3	4.7

Test Duration 182 days

Analytical Monitoring LSC, HPLC

Remarks – Method

Soils were dosed with ^{14}C-DBDPE at a nominal test concentration of 1.5 mg/kg dry soil. A stock solution containing the test substance was initially loaded onto freeze-dried sludge which was subsequently added to test soil and homogenised. Test samples incubated in the dark at approximately 20 °C. Aerobic conditions were maintained for the first 32 days by purging the headspace in each chamber with air. On day 32, the soils were flooded with oxygen-free water, purged with nitrogen, and sealed to maintain anaerobic conditions. Test chambers were attached to a gas flow-through system. Sample chamber outlets were connected to an ethylene glycol trap followed by a KOH trap. Duplicate samples of each test chamber were collected monthly for chemical analysis. Mass balances calculated from the sum of ^{14}C-DBDPE in the overlying water layers, soil extracts, soil combustion products and products collected in the traps.

The microbial activity of each soil was measured after the four soils had achieved anaerobic conditions (day 62), and at the end of the test (day 182). All test chambers achieved > 50% mineralisation within 28 days after application of ^{14}C glucose indicating viable microbial populations.

RESULTS

There was no clear pattern of degradation in any of the tested soils, and the half-lives were extrapolated beyond the six-month test period. The mean percentage of radioactivity recovered as ^{14}C-DBDPE at the end of the six-month test was > 93% in all soil extracts. The mean recoveries throughout the study ranged from 91 to 108%. There were no distinct, consistent transformation product peaks observed during the study.

Remarks – Results

All the validity criteria were met. The recoveries of the test substance directly after addition to soil were within the test guidelines range (90-110%). LOD of the scintillation counter was the same as LOQ, and was equivalent to 0.000108% of the dose or 0.338 ng DBDPE. The LOQ for all samples was < 0.1% of the applied dose. The LOD of the HPLC β-RAM detector was equivalent to 0.000375% of the nominal dose or 0.676 ng DBDPE. LOQ in the concentrated soil extracts was approximately 0.55% of the nominal dose. The redox potentials (Eh*) for all four soils were < 0 mV by day 46, < -100 mV by day 53, and < -200 mV by day 137. All four soils were considered to have achieved anaerobic conditions by month 2.
*Measured against the Standard Hydrogen Electrode which is defined as 0 mV.

CONCLUSION

There is no clear evidence that DBDPE is transformed in anaerobic soil during the study period.

TEST FACILITY

EAG Laboratories (2015b)

C.1.6. Aerobic and Anaerobic Transformation in Sediments

TEST SUBSTANCE — ^{14}C-DBDPE (94.5% purity)

METHOD — OECD TG 308 Aerobic and Anaerobic Transformation in Aquatic Sediment Systems

Source of Sediment and Associated Water — Brandywine Creek and Choptank River. The two sediment types had sufficiently different organic content and textures as required.

Test Duration — 182 days

Analytical Monitoring — LSC, HPLC

Remarks – Method — Test systems were dosed with ^{14}C-DBDPE at a nominal test concentration of 314 µg per test chamber. A stock solution containing the test substance was initially loaded onto quartz sand which was subsequently added to the test chambers containing sediment/water/headspace. The depths of the sediment layers ranged from 2.1 to 2.8 cm in the transformation test chambers. The depths of the water layers ranged from 8.3 to 10 cm. The water:sediment volume ratio was 3.5:1 in all test vessels. Aerobic conditions were maintained by purging the water layers in each vessel with air, while anaerobic conditions were maintained by purging with nitrogen. Test chambers were incubated in the dark at 20 °C. Sample chamber outlets were connected to an ethylene glycol trap followed by a KOH trap. Duplicate samples of each test chamber were collected monthly for chemical analysis. Mass balances calculated from the sum of ^{14}C-DBDPE in the sediment extracts, combustion products, aqueous phase and products collected in the traps. No reference substance was used to confirm the degradation process.

RESULTS — There was no clear pattern of degradation of the test substance in any of the tested systems and the half-lives were extrapolated beyond the six-month test period. The mean percentage of radioactivity recovered as DBDPE at the end of the six-month test was > 91% in all soil extracts. The mean recoveries throughout the study ranged from 85 to 103%. There were no distinct, consistent transformation product peaks observed during the study.

Remarks – Results — All the validity criteria were met. The recoveries of the test substance directly after addition to soil were within the test guidelines range (90-110%). LOD of the scintillation counter was the same as LOQ, and was equivalent to 0.000108% of the dose or 0.338 ng DBDPE. The LOQ for all samples was < 0.1% of the applied dose. The LOD of the HPLC β-RAM detector was equivalent to 0.000216% of the nominal dose or 0.676 ng DBDPE. LOQ in the concentrated soil extracts was approximately 0.52% of the nominal dose. The redox potentials (Eh) of the aerobic sediment layers were > 200 mV at the start of the test, and declined to < 0 mV at the end of the test. The redox potentials (Eh) of the anaerobic sediment layers were < -80 mV at the start of the test, and declined to < -150 mV at the end of the test.

CONCLUSION — There is no clear evidence that DBDPE is transformed under aerobic or anaerobic aquatic sediment systems during the study period.

TEST FACILITY — EAG Laboratories (2015c)

C.2. Ecotoxicological Investigations

C.2.1. Chronic Toxicity to Aquatic Invertebrates

TEST SUBSTANCE — ^{14}C- DBDPE (98.9% purity)

METHOD — OECD TG 211 *Daphnia magna* Reproduction Test

Species	*Daphnia magna*
Exposure Period	21 days
Auxiliary Solvent	Dimethylformamide (DMF)
Water Hardness	128 - 140 mg $CaCO_3$/L
Analytical Monitoring	LSC
Remarks - Method	No major deviations from the test guidelines were reported. Two test concentrations were selected based on preliminary range finding test results. Each stock solution was prepared by mixing the test substance in DMF at a nominal concentration of 2940 and 5879 ng/mL. The stock solutions were stored refrigerated and aliquots of each stock were placed in a syringe pump every 2 to 4 days for injecting into a diluter mixing chambers to achieve the desired test concentrations. The concentration of DMF in the solvent control and all treatment groups was 0.1 mL/L. Delivery of the test substance to the test chambers was initiated seven days prior to the introduction of daphnids in order to achieve equilibrium of the test substance in the test chambers. The test water was collected from each treatment and control group at the test initiation, at approximately weekly intervals during the test and at test termination, for analysis of the test substance. Ambient laboratory light was used to illuminate the test systems. Fluorescent light bulbs that emit wavelengths similar to natural sunlight were controlled by an automatic timer to provide a photoperiod of 16 hours of light and 8 hours of darkness. A 30-minute transition period of low light intensity was provided when lights went on and off to avoid sudden changes in lighting.

RESULTS

Test Concentration (ng/L)		Survival (% of control)	Total no. offspring released by survived *Daphnia*
Nominal	Mean measured		
Pooled Control	< LOQ*	100	153
360	256	106	172
720	356	111	179

**LOQ: Limit of quantitation of 59.5 ng/L*

21 day EC50	> 356 ng/L (measured concentration)
21 day NOEC	≥ 356 ng/L (measured concentration)
Remarks - Results	All validity criteria for the test were satisfied. Immobility of the parent animals in both negative and solvent controls were ≤ 10% at the test termination. The mean number of living offspring produced per parent animal surviving at the test termination was 161 and 145 in the negative and solvent controls respectively. During the test, DO concentration in the test water was at ≥ 71% saturation. There is no statistically significant reduction in survival and production in any of the treatment groups in comparison to the pooled control ($p > 0.05$).

CONCLUSION	The test substance does not affect the survival and reproduction of aquatic invertebrates up to its water solubility limit.
TEST FACILITY	EAG Laboratories (2018)

APPENDIX D: SUMMARY OF ENVIRONMENTAL MONITORING STUDIES

Table 6. Residues of DBDPE in environmental matrices

A) Residues in air (pg/m^3)

Sampling	Residue range	% detections	Region	Reference
e-waste facility	700	NR	Sweden	Kierkegaard A, et al. 2004
Household	22.9	20	Sweden	Karlsson M, et al. 2007
Household	< 10 - 97	40	UK	Tao F, et al. 2016
Household	< LOD - 74	85	Toronto	Venier M, et al. 2016
Household	< LOD - 71	85	Indiana	Venier M, et al. 2016
Household	15 - 7000	88	Ireland	Wemken N, et al. 2019
Offices	< 15 - 66	NR	Beijing	Newton S, et al. 2016
Offices	< 10 - 54	5	UK	Tao F, et al. 2016
Offices	< 15 - 2800	97	Ireland	Wemken N, et al. 2019
Research Station	< LOD - 2.1	94	Antarctica	Zhao J-P, et al. 2020
Schools	< 15 - 3800	97	Ireland	Wemken N, et al. 2019
Urban	0.077 - 7.9	100	Sweden	Egebäck AL, et al. 2012
Urban	< LOD - 171	38	Tibetan plateau (China)	Liu Y, et al. 2018
Urban	1.2 - 5.2	29	Great Lakes (USA)	Ma Y-N, et al. 2013
Urban	0.04 - 34	79	Great Lakes (USA)	Olukunle OI, et al. 2018
Urban	1.2 - 4.7	23	Great Lakes (USA)	Salamova A and Hites RA (2011)
Urban	0.04 - 2.2	88	Svalbard (Arctic)	Salamova A, et al. 2014
Urban	402 - 3578	100	Pearl river delta (China)	Shi T, et al. 2009
Urban	1 - 22	NR	Great Lakes (USA)	Venier M and Hites RA (2008)

B) Residues in dust (ng/g)

Sampling	Residue range	% detections	Region	Reference
Agricultural	< 2.5 - 139	60	Guangdong (China)	Shi T, et al. 2009
Cars	84 - 8200	100	Kuwait	Ali N, et al. 2013
Cars	6 - 5420	100	Pakistan	Ali N, et al. 2013
Cars	33.2 - 5186	100	Greece	Besis A, et al. 2017
Cars	422 - 3820	100	Brazil	Cristale J, et al. 2018
Cars	< LOD - 3900	88	Melbourne	McGrath TJ, et al. 2018
Cars	< 13 - 190000	88	Ireland	Wemken N, et al. 2019
e-waste facility	13.5 - 1144	100	Guangzhou (China)	Wang J, et al. 2010
Household	< LOD - 121	80	Sweden	Karlsson M, et al. 2007
Household	< 10 - 430	94	California	Dodson RE, et al. 2012
Household	< LOD - 11070	79	USA	Stapleton HM, et al. 2008
Household	< LOD - 3400	NR	UK	Harrad S, et al. 2008
Household	15 - 1600	100	Vietnam	Tue NM, et al. 2013
Household	55 - 2126	100	Belgium	Ali N, et al. 2011
Household	< 20 - 2467	75	UK	Ali N, et al. 2011
Household	9 - 23	NR	New Zealand	Ali N, et al. 2012
Household	18 - 2800	100	California	Dodson RE, et al. 2012
Household	40 - 2175	100	Kuwait	Ali N, et al. 2013
Household	2.5 - 465	100	Pakistan	Ali N, et al. 2013
Household	18 - 490	100	Vancouver	Schreder ED & La Guardia MJ 2014
Household	147	NR	Norway	Cequier E, et al. 2014
Household	47 - 1570	NR	Germany	Fromme H, et al. 2014

Household	< LOD - 3140	97	Indiana	Venier M, et al. 2016
Household	< LOD - 2060	100	Toronto	Venier M, et al. 2016
Household	< LOD - 114	79	Czech Republic	Venier M, et al. 2016
Household	< LOD - 3610	98	China	Zhu H-K, et al. 2018
Household	219 - 3010	100	Beijing	Wang J-D, et al. 2018
Household	< 1.2 - 2300	60	UK	Tao F, et al. 2016
Household	148 - 743	100	Brazil	Cristale J, et al. 2018
Household	< LOD - 9000	71	Melbourne	McGrath TJ, et al. 2018
Household	410 - 460000	91	Ireland	Wemken N, et al. 2019
Household	54 - 2200	100	Hanoi (Vietnam)	Hoang MTT, et al. 2021
Household	< LOD - 6670	97	Latvia	Pasecnaja E, et al.2021
Offices	582 - 1550	100	Beijing	Wang J-D, et al. 2018
Offices	< 1.2 - 17000	96	UK	Tao F, et al. 2016
Offices	839 - 5000	100	Brazil	Cristale J, et al. 2018
Offices	< LOD - 10000	92	Melbourne	McGrath TJ, et al. 2018
Offices	< 13 - 130000	97	Ireland	Wemken N, et al. 2019
Schools	< 40 - 1100	95	Sweden	Larsson K, et al. 2018
Schools	213 - 703	100	Brazil	Cristale J, et al. 2018
Schools	620 - 540000	100	Ireland	Wemken N, et al. 2019
Urban	100 - 47000	100	Guangzhou (China)	Wang J, et al. 2010
e-waste workshop	1300 - 37000	100	Vietnam	Wannomai T, et al. 2021

C) **Residues in soil (ng/g dw)**

Sampling	Residue range	% detections	Region	Reference
Agricultural	< 2.5 - 4.6	25	Guangdong (China)	Shi T, et al. 2009
Agricultural	17.6 - 35.8	100	Pearl river delta (China)	Shi T, et al. 2009
Agricultural	10.4 - 18.9	100	Southern China	She Y-Z, et al. 2013
Agricultural	0.03 - 173	100	Jingjin (China)	Lin Y, et al. 2015
Agricultural	0.12 - 125	100	Hebei (China)	Lin Y, et al. 2015
Agricultural	< LOD - 27	95.4	Shanxi (China)	Lin Y, et al. 2015
Agricultural	0.06 - 1612	100	Shandong (China)	Lin Y, et al. 2015
Agricultural	< LOD - 1612	95.4	North China	Lin Y, et al. 2015
Agricultural	86 - 468	NR	Qingyuan (China)	Fan Y, et al. 2020
e-waste facility	4.6 - 4200	34	Vietnam	Someya M, et al. 2016
e-waste facility	< LOD - 295	50	Melbourne	McGrath TJ, et al. 2017
Forest	0.025 - 18	NR	China	Zheng Q, et al. 2015
Forest	< LOD - 0.56	50	Germany	Dreyer A, et al. 2019
Industrial	< LOD - 384	33.3	Melbourne	McGrath TJ, et al. 2017
NR	< LOD - 7.6	NR	Indonesia	Ilyas M, et al. 2011
NR	< LOD - 1.5	74	Tibetan plateau (China)	Liu Y, et al. 2018

D) **Residues in water (ng/L)**

Sampling	Residue range	% detections	Region	Reference
Estuary	< LOD - 46.4	NR	Bohai Sea (China)	Liu L, et al. 2021
Lake	3.9	68	Great Lakes (USA)	Venier M, et al. 2014
Rain	0.3 - 0.8	61	Great Lakes (USA)	Salamova A, et al. 2011
Rain	0.15 - 0.75	66	Great Lakes (USA)	Ma Y-N, et al. 2013
River	0.013 - 0.038	NR	Dongjiang river (China)	He M-J, et al. 2012
Urban drains	< LOD - 193	74	Vancouver	Schreder ED & La Guardia MJ 2014
WWT effluent	0.2 - 16	NR	Canada	Kim M, et al. 2014
WWT effluent	< 10 - 230	NR	Japan	Suzuki G, et al. 2021
WWT inflow	5.1	33	Norway	Nyholm JR, et al. 2013
WWT inflow	3.7 - 130	NR	Canada	Kim M, et al. 2014

WWT inflow	0.06 - 5.6	NR	Spain	Navarro I, et al. 2018
WWT inflow	11 - 920	NR	Japan	Suzuki G, et al. 2021

E) **Residues in sediment (ng/g dw)**

Sampling	**Residue range**	**% detections**	**Region**	**Reference**
Bay	0.16 - 6.49	NR	Yellow Sea	Zhen X-M, et al. 2016
Bay	0.25 - 39.7	NR	Yellow Sea	Zhen X-M, et al. 2016
Bay	0.069 - 0.85	NR	Beppu Bay (Japan)	Hoang AQ, et al. 2021a
Coast	0.18 - 11	NR	Sweden	Ricklund N, et al. 2010
Estuary	< LOD - 1728	NR	Pearl river delta (China)	Chen S-J, et al. 2013
Estuary	1.13 - 49.9	NR	Qingdao (China)	Zhen X-M, et al. 2016
Estuary	0.18 - 1.6	46	Yangtze river	Zhu B-Q, et al. 2013
Estuary	5.1 - 32	100	Fujian (China)	Zhang Z-W, et al. 2019
Estuary	7.7 - 14.4	100	Shenzhen (China)	Hu Y-X, et al. 2020
e-waste facility	314	NR	Qingyuan (China)	Zhang B-Z, et al. 2013
e-waste facility	< LOD - 20	63	Vietnam	Someya M, et al. 2016
Lake	0.11 - 2.8	46	Great Lakes (USA)	Yang R-Q, et al. 2012
Lake	0.23 - 11	NR	Sweden	Ricklund N, et al. 2010
Lake	10.2 - 280	92	Lake Magiore (Italy)	Poma G, et al. 2014
Lake	0.08 - 22.6	83	Tunisia	Mekni S, et al. 2019
NR	24	NR	Sweden	Kierkegaard A, et al. 2004
Ocean	< LOD - 0.45	NR	Arctic ocean	Cai M-G, et al. 2012
River	37 - 110	NR	Dongjiang river (China)	He M-J, et al. 2012
River	38.8 - 364	100	Pearl river delta (China)	Shi T, et al. 2009
River	19 - 430	100	Dongjiang river (China)	Zhang X-L, et al. 2009
River	1.2	NR	Norway	Nyholm JR, et al. 2013
River	1.7 - 2394	NR	Arkansas	Wei H, et al. 2012
River	< LOD - 1700	NR	Dongjiang river (China)	He M-J, et al. 2012
River	2.42 - 19	100	Yangtze river	Zhu B-Q, et al. 2013
River	91 - 435	10	Spain	Cristale J, et al. 2013
River	< LOD - 30.7	NR	Catalonia (Spain)	Barón E, et al. 2014
River	< LOD - 48.9	100	Germany	Dreyer A, et al. 2019
River	< LOD - 20.8	NR	Slovenia-Bosnia-Croatia	Giulivo M, et al. 2017
Urban rivers	< LOD - 59	90	Hanoi (Vietnam)	Hoang AQ, et al. 2021b

F) **Residues in biosolids from Waste Water Treatment plants (ng/g dw)**

Sampling	**Residue range**	**% detections**	**Region**	**Reference**
Sewage	7.7 - 31	100	Australia	Ricklund N, et al. 2008
Sewage	6 - 30	NR	Canada	McCrindle R, et al. 2004
Sewage	< LOD - 65	89	Canada	Ricklund N, et al. 2008
Sewage	< LOD - 257	77	Catalonia (Spain)	Gorga M, et al. 2013
Sewage	< LOD - 100	NR	Catalonia (Spain)	Barón E, et al. 2014
Sewage	39 -140	100	China	Ricklund N, et al. 2008
Sewage	6 - 140	100	Czech Republic	Ricklund N, et al. 2008
Sewage	< LOD - 220	80	Germany	Ricklund N, et al. 2008
Sewage	1500 - 5172	NR	Japan	Suzuki G, et al. 2021
Sewage	5.1 - 31	100	New Zealand	Ricklund N, et al. 2008
Sewage	1.9 - 6.3	100	Norway	Nyholm JR, et al. 2013
Sewage	266 - 1995	100	Pearl river delta (China)	Shi T, et al. 2009
Sewage	5 - 82	100	Singapore	Ricklund N, et al. 2008
Sewage	55	NR	South Africa	Ricklund N, et al. 2008
Sewage	0.2 - 15	NR	Spain	Eljarrat E, et al. 2005
Sewage	3.3 - 125	100	Spain	de la Torre A, et al. 2012
Sewage	< LOD - 0.15	NR	Spain	Navarro I, et al. 2018
Sewage	32 - 100	NR	Sweden	Kierkegaard A, et al. 2004
Sewage	54	NR	Sweden	Ricklund N, et al. 2008

Sewage	73 -160	100	Switzerland	Ricklund N, et al. 2008
Sewage	34 - 63	100	UK	Ricklund N, et al. 2008
Sewage	1.4 -160	100	USA	Ricklund N, et al. 2008

APPENDIX E: SUMMARY OF MONITORING STUDIES ON BIOTA

Table 7. Residues of DBDPE in aquatic organisms

Animal group	Species	Residue range (ng/g lw)*	% detections	Location	Reference
Tunicates	Sea squirt	< LOD	0	Chile	Barón E, et al. 2013
Cephalopods	Squid	0.17 - 1.9	> 50	Pearl River delta, China	Sun R-X, et al. 2015
Cephalopods	Octopus	< LOD - 0.64	31	South China Sea	Sun Y-X, et al. 2017
Cephalopods	Cuttlefish, octopus	1800 - 2700	87	Bohai Sea, China	Liu Y-H, et al., 2021
Plankton	NR	1.27 - 5.58	NR	Lake Taihu, China	Zheng G-M, et al. 2018
Plankton	Several species	4200	NR	Bohai Sea, China	Liu Y-H, et al., 2021
Echinoderms	Sea urchin	0.29 - 0.8	NR	Portugal	Rocha AC, et al. 2018
Echinoderms	Sea urchin	< LOD	0	Tunisia	Mekni S, et al. 2019
Insects	Dragonfly and water beetle larvae	77.4 - 25400	NR	Qingyuan, China	Tao L, et al. 2019
Crustaceans	Oriental river prawn	84.3	47	Guangdong, China	Wu J-P, et al. 2010
Crustaceans	2 crab sp.	< LOD	0	Chile	Barón E, et al. 2013
Crustaceans	2 crab and 2 shrimp sp.	0.75 - 17.7	> 50	Pearl River delta, China	Sun R-X, et al. 2015
Crustaceans	Xanthid crab	< LOD	0	Southern China	Sun Y-X, et al. 2017
Crustaceans	Crayfish	2.34 - 13.2	NR	Lake Taihu, China	Zheng G-M, et al. 2018
Crustaceans	Oriental river prawn	330 - 900	NR	Guangdong, China	Liu Y, et al. 2018
Crustaceans	1 crab, 1 prawn sp.	11.3 - 140	100	Southern China	Sun R-X, et al. 2018
Crustaceans	Mud crab	< LOD - 15	89	Fujian, China	Zhang Z-W, et al. 2019
Crustaceans	1 crab, 2 shrimp sp.	2300 - 2700	87	Bohai Sea, China	Liu Y-H, et al., 2021
Mollusks	Mussels	< LOD	0	Lake Winnipeg, Canada	Law K, et al. 2006
Mollusks	Mystery snail	< LOD	0	Guangdong, China	Wu J-P, et al. 2010
Mollusks	Mud snail	34 - 1098	NR	China	Wang J, et al. 2010
Mollusks	1 snail, 1 clam sp.	< LOD	0	North Carolina, USA	La Guardia MJ, et al. 2012
Mollusks	2 snails, 3 clam sp.	< LOD	0	Chile	Barón E, et al. 2013
Mollusks	Clams	< LOD	0	Italy	Casatta N, et al. 2015
Mollusks	2 clams	0.34 - 15	>50	Pearl River delta, China	Sun R-X, et al. 2015
Mollusks	Striated cone	< LOD - 0.9	31	South China Sea	Sun Y-X, et al. 2017
Mollusks	2 snails, 1 clam sp.	13.5 - 157	100	Southern China	Sun R-X, et al. 2018

Mollusks	1 mussel, 1 clam, 1 snail sp.	< LOD - 11.9	NR	Lake Taihu, China	Zheng G-M, et al. 2018
Mollusks	2 mussel sp.	< 0.93 - 4.5	33	Germany	Dreyer A, et al. 2019
Mollusks	Green mussel	< LOD - 4.34	91	Southern China	Sun R-X, et al. 2020
Mollusks	4 clams, 1 snail sp.	2900 - 4000	87	Bohai Sea, China	Liu Y-H, et al. 2021
Fish	6 lake sp.	< LOD - 3.3	NR	Lake Winnipeg, Canada	Law K, et al. 2006
Fish	3 river sp.	< LOD	0	Guangdong, China	Shi T, et al. 2009
Fish	3 river sp.	< LOD - 338	47	Guangdong, China	Wu J-P, et al. 2010
Fish	Common sole	< LOD - 0.28	NR	France	Munschy C, et al. 2011
Fish	3 river sp.	< LOD - 230	90	Dongjiang river, China	He M-J, et al. 2012
Fish	2 estuarine sp.	< LOD	0	San Francisco, USA	Klosterhaus SL, et al. 2012
Fish	3 river sp.	15 - 127	100	Guangdong, China	Mo L, et al. 2012
Fish	Several river sp.	< LOD - 130	NR	Spain	Santin G, et al. 2013
Fish	3 marine sp.	< LOD	0	Chile	Barón E, et al. 2013
Fish	3 river sp.	< LOD	0	Canada	Houde M, et al. 2014
Fish	European eel	< LOD	0	Germany	Sühring R, et al. 2015
Fish	8 estuarine sp.	< LOD - 30.6	54.5	Pearl River delta, China	Sun R-X, et al. 2015
Fish	3 estuarine sp.	0.29 - 460	100	Pearl River delta, China	Sun R-X, et al. 2016
Fish	3 marine sp.	< LOD - 0.98	31	South China Sea	Sun Y-X, et al. 2017
Fish	10 river sp.	< LOD	0	Italy, Slovenia, Croatia, Bosnia, Greece	Giulivo M, et al. 2017
Fish	11 river sp.	0.54 - 29.1	100	Southern China	Sun R-X, et al. 2018
Fish	European eel	0.04 - 33	59	Latvia	Zacs D, et al. 2018
Fish	11 lake sp.	< LOD - 4.82	NR	Lake Taihu, China	Zheng G, et al. 2018
Fish	Carp	440 - 1000	NR	Guangdong, China	Liu Y, et al. 2018
Fish	3 estuarine sp.	< LOD - 20	89	Fujian, China	Zhang Z-W, et al. 2019
Fish	4 river sp.	80 - 1700	NR	Qingyuan, China	Tao L, et al. 2019
Fish	Emerald cod	< LOD	0	Antarctica	Dreyer A, et al. 2019
Fish	Atlantic cod	< LOD	0	Barents Sea, Arctic	
Fish	2 marine sp.	< LOD	0	Germany	
Fish	2 lake species	< LOD - 57.8	91	Lake Geneva	Babut M, et al. 2021
Fish	7 species	870 - 2000	87	Bohai Sea, China	Liu Y-H, et al. 2021

Fish	3 river sp.	< LOD - 170	28	Pearl river, China	Liu J, et al. 2021
Reptiles	Water snake	< LOD	0	Guangdong, China	Wu J-P, et al. 2010
Reptiles	Chinese alligator eggs	0.01 - 0.51	100	Anhui, China	Hong B, et al. 2015
Reptiles	Chinese alligator	9.05 - 192			
Reptiles	Water snake eggs	9.9 - 12	NR	Guangdong, China	Liu Y, et al. 2018
Reptiles	Water snake	110 - 3800			
Birds	Herring gull eggs	< LOD - 44	9	Great Lakes	Gauthier LT, et al. 2009
Birds	Waterhen	9.6 - 124	100	Guangdong, China	Shi T, et al. 2009
Birds	4 aquatic sp.	< LOD - 800	91	Pearl river delta, China	Luo X-J, et al. 2009
Birds	8 aquatic sp. eggs	< LOD - 2.2	54	Yellow river, China	Gao F, et al. 2009
Birds	Cormorant eggs	< LOD	0	San Francisco, USA	Klosterhaus SL, et al. 2012
Birds	Guillemot eggs	< LOD - 0.1	14	Greenland	Vorkamp K, et al. 2015
Birds	Glaucous gull	< LOD	0	Greenland	Vorkamp K, et al. 2015
Birds	1 duck, 1 gull sp.	< 7.5 - 56.5	35	Korea	Jin X, et al. 2016
Birds	Waterhen eggs	< LOD	0	Guangdong, China	Liu Y, et al. 2018
Birds	Herring gull eggs	< LOD - 1.64	33	Germany	Dreyer A, et al. 2019
Birds	4 waders, 1 marine sp.	0.21 - 39	58	South China Sea	Zhu C-Y, et al. 2020
Mammals	Ringed seal	< LOD	0	Canadian Arctic	Muir DCG and de Wit CA (2010).
Mammals	3 whales, 1 seal sp.	< LOD	0	North Atlantic	Bavel Bv et al. 2010
Mammals	Polar bear	< 0.02	13	Arctic	McKinney MA, et al. 2011
Mammals	Franciscana dolphin	< LOD - 14.9	40	Brazil	de la Torre A, et al. 2012
Mammals	Franciscana dolphin	< LOD - 352	21	Brazil	Alonso MB, et al. 2012
Mammals	Harbour seal	< LOD	0	San Francisco, USA	Kosterhaus SL, et al. 2012
Mammals	Harbour porpoise	< LOD	0	UK	Law RJ, et al. 2013
Mammals	2 dolphin sp.	< LOD - 10	82	South China Sea	Zhu B-Q, et al. 2014
Mammals	Polar bear, ringed seal	< LOD - 0.3	14	Greenland	Vorkamp K, et al. 2015
Mammals	1 whale, 2 dolphin sp.	< LOD	0	South Spain	Barón E, et al. 2015
Mammals	2 whale sp.	< LOD	0	Canadian Arctic	Simond AE, et al. 2017
Mammals	Striped dolphin	9.1 - 85.6	75 - 100	Mediterranean, Spain	Aznar-Alemany Ò, et al. 2021

* LOD = limit of detection; NR = not reported

Table 8. Residues of DBDPE in terrestrial organisms

Animal group	Species	Residue range (ng/g lw)*	% detections	Location	Reference
Earthworms	Lumbriculus variegatus	364	NR	Qingyuan, China	Zhang B-Z, et al. 2013
Earthworms	Lumbricus terrestris faeces	< LOD	0	Spain	Navarro I, et al. 2016
Earthworms	Lumbricus terrestris faeces	< 0.35	0	Germany	Dreyer A, et al. 2019
Insects	Dragonflies	15 - 5200	NR	Guangdong, China	Liu Y, et al. 2018
Insects	4 herbivorous sp.	0.53 - 420	NR		
Amphibians	1 toad, 1 frog sp.	7.5 - 72	NR	Guangdong, China	Liu Y, et al. 2018 and 2020
Reptiles	Snake	2.26 - 84	100	Guangdong, China	Wu J-P, et al. 2020
Reptiles	Lizard	6.5 - 56	NR	Guangdong, China	Liu Y, et al. 2018 and 2020
Birds	Pheasant eggs	0.9 - 2.4	54	Yellow River, China	Gao F, et al. 2009
Birds	Starling eggs	< LOD	0	Canada	Chen S-J, et al. 2013
Birds	4 insectivore sp. eggs	19 - 609	100	Pearl River delta, China	Sun Y-X, et al. 2014
Birds	Peregrine falcon eggs	< LOD	0	Spain	Guerra P, et al. 2012
Birds	Peregrine falcon eggs	< LOD - 8.2	8	Canada	Guerra P, et al. 2012
Birds	Peregrine falcon plasma	< LOD - 49.7	55	Canada	Fernie KJ, et al. 2017
Birds	Bald eagle eggs	< LOD	0	Canada	Guo J, et al. 2018
Birds	Kingfisher	0.44 - 90	100	Guangdong, China	Mo L, et al. 2012 and 2013
Birds	4 songbird sp.	2.7 - 125	100	Guangdong, China	Peng Y, et al. 2015
Birds	Kingfisher	0.01 - 230	94	Guangdong, China	Peng Y, et al. 2019
Birds	Magpie robin	< LOD - 149	97	Guangdong, China	Mo L, et al. 2019
Birds	2 songbird sp.	4.3 - 27	100	Guangdong, China	Liu Y, et al. 2018 and 2020
Birds	Oriental pranticole	0.54 - 0.99	58	South China	Zhu C-Y, et al. 2020
Birds	3 songbird sp.	2.5 - 130	100	Guangdong, China	Sun Y-X, et al. 2012
Birds	Turtle dove	< LOD - 56.5	35	Korea	Jin X, et al. 2016
Birds	3 raptor sp.	< LOD - 93.3			
Birds	3 owls	< LOD - 350			
Birds	Vulture	< LOD - 27.4			
Mammals	Giant panda	< LOD - 863	87	China	Hu G-C, et al. 2008
Mammals	Red panda	< LOD - 41	71	China	Hu G-C, et al. 2008
Mammals	Roe deer	< LOD	0	Germany	Dreyer A, et al. 2019

* LOD = limit of detection; NR = not reported

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