

Summary of Risk Assessment Conducted Pursuant to subsection 83(1) of the *Canadian Environmental Protection Act, 1999*

Ministerial Condition No. 18111: 1,2-Benzenedicarboxylic acid, mixed C₈₋₁₁-alkyl and 2-ethylhexyl and hexyl and isononyl diesters; Chemical Abstracts Service Registry No. 1415043-91-2

Regulatory Decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act* (CEPA), and pursuant to section 83 of that Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance, and determined that the substance is anticipated to enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long term harmful effect on the environment or its biological diversity and constitute or may constitute a danger in Canada to human life or health.

In order to ensure that the substance does not cause harm to the Canadian environment or human health, its manufacture and import is authorized subject to conditions on its use, handling, and disposal as described in [Ministerial Condition No. 18111](#) published in the *Canada Gazette* Part I, Vol. 149, No. 42 on October 17, 2015.

Substance Identity

The substance is a mixture of phthalate diesters with C₆₋₁₁ carbon chain lengths.

Notified Activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10,000 kg/yr for use as a plasticizer in polyvinyl chloride (PVC) applications.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water, soil and sediment. Based on half-life information in these compartments, the substance is not expected to be persistent. The substance is not expected to be bioaccumulative in organisms with high metabolic capacity, based on low bioaccumulation factor (BAF) and bioconcentration factor (BCF) values.

Ecological Assessment

Based on the available hazard information on a structurally related chemical, di(2-ethylhexyl)phthalate (DEHP), which is a component of the notified substance, the substance has low (LC₅₀ and EC₅₀ > 100 mg/L) acute toxicity with no effects up to its water saturation limit in

fish, invertebrates and algae. However, based on data for DEHP, the substance may cause chronic adverse effects, possibly by endocrine-mediated mechanisms. The predicted no effect concentration was calculated to be highly toxic ($< 0.1 \mu\text{g/L}$) based on a non-standardized endpoint for embryo reproduction in the most sensitive organism (fish), which was used to estimate the ecological risk.

The notified and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activities is expected to be mainly from disposal of the substance by release to water. The predicted environmental concentration for notified activities is estimated to be 0-54 $\mu\text{g/L}$.

Based on the potential for exposure by release to water in conjunction with the chronic adverse effects, the substance is anticipated to cause ecological harm in Canada. The risks have been identified with release of the substance to water when cleaning transportation vessels.

Human Health Assessment

The notified substance is a phthalate mixture, which contains DEHP and di(isononyl)phthalate (DINP) among its components. Data from DEHP was used to fulfill the hazard information requirements. Based on this information, the substance is expected to show low acute toxicity by the oral and dermal routes of exposure (oral $\text{LD}_{50} > 2000 \text{ mg/kg bw}$; dermal $\text{LD}_{50} > 2000 \text{ mg/kg bw}$). The substance is expected to be non-irritating to skin (dermal PII = 0.0), and to be negative for dermal sensitization, in a Buehler assay (0% response). Oral repeated-dose testing on DEHP indicated moderate toxicity to mice (NOAEL 30-300 mg/kg bw/day ; 28-day) and low toxicity to rats (NOAEL $> 100 \text{ mg/kg bw/day}$; 90-day). Repeated-dose inhalation studies showed high inhalation toxicity to rats (NOEL $> 0.05 \text{ mg/L /6h}$; 28 days). Based on data for the larger class of phthalate esters, the substance is not expected to be mutagenic or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage. DEHP is linked to reproductive and developmental effects, with a consensus NOAEL of 5 mg/kg bw/day . Therefore, based on data from DEHP (read-across), the notified substance may show the same effects to reproduction and development.

When the notified substance is used as a plasticizer in PVC articles which are vinyl children's toys or child care articles as defined under the *Phthalates Regulations*, direct exposure of children or infants is expected to occur through ingestion of dust and mouthing of toys. Indirect exposure of the general population from environmental media such as drinking water is expected to be low. No additional potential uses were identified.

The notified substance is considered to have the same effects to reproduction and development as DEHP. Based on the risk of developmental and reproductive effects, resulting from direct exposure and low level of indirect exposure from child care articles, the substance is considered likely to pose a significant health risk to infants or children.

Other Considerations

DEHP is subject to several Canadian health and safety regulations, which are all relevant to the notified substance because it is a mixture that contains DEHP.

- DEHP (CAS RN 117-81-7) is on the List of Toxic Substances under CEPA (Schedule 1)
- DEHP is on the list of ingredients prohibited for use in cosmetic products (the Cosmetics Hotlist); under the definitions found on the Hotlist ([How to Read the Cosmetic Ingredient Hotlist](#)), its synonyms, salts and related compounds must not be present in cosmetic products at any time. Consequently, on the basis of its DEHP content, the notified substance cannot be used in cosmetics.
- The [Phthalates Regulations, 2011](#), under the *Canada Consumer Product Safety Act*, apply to a range of phthalates including DEHP, DINP, DnOP, dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), and diisodecyl phthalate (DIDP). The *Phthalate Regulations* restrict the presence of all of these phthalates in the soft vinyl of all children's toys and child care articles to not more than 0.1 wt%. As the notified substance contains certain of these phthalates, it is subject to these Regulations.
- Similarly, as the notified substance contains DEHP, it is subject to the [Medical Devices Regulations](#). The *Medical Devices Regulations* require that the import or manufacture of medical devices containing more than or equal to 0.1% DEHP be reported.
- Fourteen phthalate esters are presently being assessed under the Substance Grouping Initiative of the Chemicals Management Plan, and a Cumulative Risk Assessment of phthalates is also under way. As the notified substance falls within the same class of chemicals (phthalate esters), the outcome of these assessments could have bearing on future risk management actions for the notified substance and other similar substances.

Assessment Conclusion

The substance is suspected to be harmful to the environment according to the criteria under paragraph 64(a) of CEPA and to have the potential to be harmful to human health according to the criteria under paragraph 64(c) of CEPA.

Due to the identified risks to the environment and human health if the substance were released to water or used as a plasticizer in toys and child care articles, [Ministerial Condition No. 18111](#) was published in the *Canada Gazette* Part I, Vol. 149, No. 42 on October 17, 2015, to restrict the manner in which the notifier may use, handle and dispose of the substance in order to mitigate these risks.

A conclusion under CEPA on this substance does not concern, nor does it preclude an assessment against the hazard criteria for Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or *Hazardous Products Regulations* for products intended for workplace use.