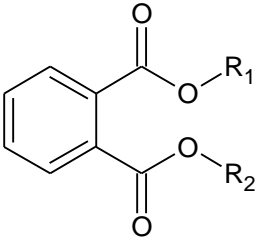


INITIAL TARGETED ASSESSMENT PROFILE

CAS No.	68515-42-4												
Chemical Name	1,2-Benzenedicarboxylic acid, di-C₇₋₁₁-branched and linear alkyl esters (Di(heptyl, nonyl, undecyl) phthalate)												
Structural Formula	 <p style="text-align: center;"> $R_1 = C_7H_{15}$ or C_9H_{19} or $C_{11}H_{23}$ $R_2 = C_7H_{15}$ or C_9H_{19} or $C_{11}H_{23}$ R_1 and R_2 can be linear or branched </p>												
SUMMARY CONCLUSIONS OF THE TARGETED ASSESSMENT													
<p>NOTE: The present assessment is targeted to address the following human health endpoints: reproductive and developmental toxicity. It cannot be considered as a full SIDS Initial Assessment. Summary information on exposure is also reported here. Other endpoints for human health and the environment are included in the Canadian screening assessment but have not been agreed upon by OECD member countries, and thus are not included in this profile.</p> <p>The final screening assessment has been published under the responsibility of the Government of Canada. [http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-6/index-eng.php#final]</p> <p>Rationale for Targeting the Assessment</p> <p>The Government of Canada "categorized" or prioritized all 23,000 chemical substances on its Domestic Substances List (DSL) from 1999 to September 2006, as required by its <i>Canadian Environmental Protection Act, 1999</i> (CEPA 1999). Using information from Canadian industry, academic research and other countries, Government of Canada scientists applied a set of rigorous tools to the 23,000 chemical substances on the DSL. They were categorized to identify those that were: inherently toxic to humans or to the environment and that might be persistent and/or bioaccumulative; and substances to which people might have greatest potential for exposure. During this priority-setting exercise, distinct approaches were taken for identifying substances of likely concern for human health and the environment, and subsequent assessment activities may have focused on either human health or ecological endpoints. Through categorization, the Government of Canada has identified approximately 4,000 of the 23,000 chemical substances on the DSL as priorities for further assessment, research and/or measures to control their use or release.</p> <p>The substance 1,2-Benzenedicarboxylic acid, di-C₇₋₁₁-branched and linear alkyl esters or di(heptyl, nonyl, undecyl) phthalate, abbreviated as DHNUP, was identified as a high priority for assessment of human health risk because it was considered to present intermediate potential for exposure and had been classified by the European Commission on the basis of reproductive and developmental toxicity (Category 2 for developmental toxicity with risk phrase R61 ("May cause harm to the unborn child") and as a Category 3 for reproductive toxicity with risk phrase R62 ("Possible risk of impaired fertility").</p> <p>Substance Identity</p> <p>DHNUP, Chemical Abstracts Service Registry Number (CAS RN) 68515-42-4, is a mixture of phthalates containing the following six components:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">CAS RN</th> <th style="text-align: left;">Name</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> </tr> </tbody> </table>		CAS RN	Name										
CAS RN	Name												

3648-20-2	1,2-Benzenedicarboxylic acid, diundecyl ester, linear only
68515-44-6	1,2-Benzenedicarboxylic acid, diheptyl ester, branched and linear
68515-45-7	1,2-Benzenedicarboxylic acid, dinonyl ester, branched and linear
111381-89-6	1,2-Benzenedicarboxylic acid, heptyl nonyl ester, branched and linear
111381-90-9	1,2-Benzenedicarboxylic acid, heptyl undecyl ester, branched and linear
111381-91-0	1,2-Benzenedicarboxylic acid, nonyl undecyl ester, branched and linear

There is variation regarding the nomenclature used to represent this mixture. In Europe, the composite CAS RN 68515-42-4 is used most commonly to represent DHNUP. However, CAS RNs in the list above are also made reference to in Europe. In the United States, DHNUP is more frequently represented by listing together all the individual CAS RNs provided above. The US EPA considers the test substance for commercial DHNUP to be a mixture of the above six CAS RNs and not described by CAS RN 68515-42-4.

It should be noted that some common names or trade names for DHNUP may also represent different CAS RNs for similar mixtures of phthalates or individual phthalates. For example, the common name 711P may refer to DHNUP or to 1,2-benzenedicarboxylic acid, (C7,C11) ester, branched and linear (CAS RN 111381-90-9). The components of DHNUP, except for CAS RN 111381-90-9, are known to be commercially sold as separate products. It is notable that, due to the variable composition of DHNUP, no single discrete molecular structure may be considered truly representative of DHNUP, and thus use of the representative structure provided above was limited to physicochemical property modelling.

Physical-chemical properties

The substance, DHNUP, is a liquid at room temperature with a measured melting point of -57°C , measured boiling points of 235 to 278°C and measured vapour pressure of <10 Pa at 20°C . The measured octanol-water partition coefficient ($\log K_{ow}$) is 4.8, and the measured water solubility is 0.1 mg/L at 20°C .

Human Health Targeted Endpoints

Most of the *in vivo* studies were conducted in rats, and only a few of them were conducted in mice. Whereas most of the studies were reported on CAS RN 68515-42-4, there are some that pertain to CAS RN 3648-20-2, which is just one of the six components of DHNUP. No toxicological data were identified for the remaining components of DHNUP.

No guideline studies on reproductive toxicity were identified. Data on potential effects on fertility were obtained from repeated-dose studies. Reproductive toxicity in the form of slight testicular atrophy and reduced testis weights following dietary administration of CAS RN 68515-42-4 to rats for 21 days was observed at 2416 mg/kg-bw per day (LOEL= 2416 mg/kg bw/day), suggesting an LOAEL > 2416 mg/kg bw/day. No effects were observed at 1159 mg/kg-bw per day (no-observed-effect level [NOEL]). For CAS RN 3648-20-2, the NOEL in rats was reported at 2495 mg/kg-bw per day.

High incidences of teratogenic and embryotoxic effects were observed following oral administration of di-711-phthalate (considered to comprise the following CAS RNs: 111381-89-6, 111381-90-9, 111381-91-0, 68515-44-6, 68515-45-7 and 3648-20-2) to female rats at 1000 mg/kg-bw per day (lowest-observed-adverse-effect level [LOAEL]) during gestation (in a developmental toxicity study). Other effects observed at this dose included reduced maternal body weight and body weight gain, increased relative liver and kidney weights and markedly reduced uterus weight. These effects were not observed at 200 mg/kg-bw per day (no-observed-adverse-effect level [NOAEL]). Another study on rats using Santicizer 711 (Santicizer 711 has been ascribed CAS RN 68515-42-4 by the authors of the study) reported a lowest-observed-effect level (LOAEL) of 5000 mg/kg-bw per day based on significant mean fetal body weight reduction in the absence of maternal toxicity.

DHNUP possesses properties indicating a hazard for the human health endpoints, developmental and reproductive toxicity (teratogenic and embryotoxic effects, testicular atrophy and reduced testes weights).

Exposure Summary Information

DHNUP is used principally for plasticizing applications. A single use was identified in Canada as on-going after the 2006 reporting year, namely plasticization of electrical and communication wire insulation. As a plasticizer, DHNUP is compatible with several polymer resins, including copolymer and homopolymer vinyl resins, nitrile, chlorinated and styrene-butadiene rubber, cellulose, neoprene, polyurethane, acrylic latex, alkyd resins and rosin-modified polyester resins of maleic anhydride and glycerine.

DHNUP was introduced worldwide in the early 1970s. The following uses of DHNUP were identified as global or historical in nature; however, they were not determined to be on-going in Canada after the 2006 reporting year. For vinyl applications, DHNUP plasticizes polyvinyl chloride (PVC) coatings of mine brattice cloth and

metal coils. Industrially, DHNUP plasticizes polyurethane prepolymers for foam applications. For automotive use, DHNUP is used as a low-volatility sealant in addition to functioning as a plasticizer in primerless urethane adhesive, glass and transmission adhesive, vibration-damping coatings and exterior trim. In terms of construction materials, DHNUP has been used as a plasticizer in elastomeric roof and barrier coatings, geomembranes, tarpaulins, flashing cement, wood filler, wood and stone hardener, caulk, sanding sealer and high-solids lacquer. Finally, DHNUP has been reported to be used to plasticize high-end luggage.

In response to a survey conducted in Canada, less than 10 kg of DHNUP was reported to be released to each of air and water in the 2006 calendar year. Some transfers of DHNUP to non-hazardous waste facilities occurring in the 2006 calendar year were also reported. DHNUP is not reportable to the National Pollutant Release Inventory in Canada or to the US Toxics Release Inventory Program; therefore, no release information was available from these sources.