

Screening Assessment for the Challenge

Butane

Chemical Abstracts Service Registry Number

106-97-8

Containing 1,3-Butadiene

Chemical Abstracts Service Registry Number

106-99-0

and

Propane, 2-methyl (Isobutane)

Chemical Abstracts Service Registry Number

75-28-5

Containing 1,3-Butadiene

Chemical Abstracts Service Registry Number

106-99-0

**Environment Canada
Health Canada**

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Synopsis

Butane (Chemical Abstracts Service Registry Number (CAS RN) 106-97-8) and isobutane (CAS RN 75-28-5) were identified in the categorization of the Domestic Substances List as high priorities for action under the Ministerial Challenge as they were considered to pose greatest potential for exposure to individuals in Canada and had been classified by the European Commission on the basis of carcinogenicity when they contain 1,3-butadiene (CAS RN 106-99-0) at a concentration greater than or equal to 0.1%. 1,3-Butadiene was assessed in Canada under the Priority Substances List 2 (PSL 2) of the *Canadian Environmental Protection Act, 1999* and it was determined that 1,3-butadiene was likely to be carcinogenic in humans, and may also be associated with genotoxicity and reproductive toxicity. It was not found to present a risk to the environment, but was found to contribute to the photochemical formation of ground-level ozone. Therefore, the focus of this investigation is to evaluate the exposure to and potential risk to human health from 1,3-butadiene in butane and isobutane in Canada. A screening assessment of the chemical substances butane and isobutane, in the absence of 1,3-butadiene, will be conducted with the group of substances that are of medium priority for assessment as a result of categorization. In addition, end-use fuels (e.g., motor vehicle gasoline, liquefied petroleum gas) formulated with butane and isobutane will be addressed under the Petroleum Sector Stream Approach of the Chemicals Management Plan.

Butane and isobutane containing residual amounts of 1,3-butadiene are both manufactured in and imported into Canada in high volumes. The presence of 1,3-butadiene in butane and isobutane exists as a refinery by-product. While the residual amount of 1,3-butadiene in both butane and isobutane ranged from 0.0 to <1 w/w%, levels were typically below 0.1 w/w%. However, in some cases, the levels of 1,3-butadiene were simply reported as “unknown”.

Major use patterns reported for butane and isobutane in the section 71 survey include its use as a propellant/blowing agent, fuel or fuel additive, solvent carrier, and formulation component. In terms of non-fuel uses, butane is used in various applications including insulating polyurethane foam, aerosol sprays and coatings, paint dyes and automotive spray waxes in which the concentration of butane can range up to 60 w/w %. Isobutane is used in consumer products such as cosmetic/beauty preparations, air freshener, cleaners, activator/primers and various coatings in which the concentration of isobutane may range up to 70 w/w %. The presence of residual 1,3-butadiene in butane and isobutane containing products is not due to intentional addition of 1,3-butadiene.

To estimate potential risk to human health from 1,3-butadiene in butane or isobutane-containing consumer products, a modelled exposure estimate to 1,3-butadiene from hairspray (product composition of 70% isobutane containing 0.1 w/w % 1,3-butadiene) was compared to cancer potency estimates and benchmark concentrations derived for carcinogenicity and reproductive toxicity of 1,3-butadiene. The hairspray scenario was chosen because it represented the upper-end of the isobutane concentration in a propellant, the typical upper-bound levels of 1,3-butadiene in the isobutane, and the most

frequent use pattern. This comparison resulted in exposure potency indexes which indicate that the priority for investigation of options to reduce potential exposures to 1,3-butadiene from this source is low to moderate. Some of the consumer products contain slightly higher levels of 1,3-butadiene in butane or isobutane (up to < 1.0 w/w %). These products would contribute to overall exposure to 1,3-butadiene. Also, there is potential for multiple products to be used successively, increasing exposure to 1,3-butadiene.

Comparing this modelled exposure estimate for consumer product use to data from Canadian indoor air studies, estimated concentrations of 1,3-butadiene attributable to consumer product use are 50 times lower than the average indoor levels measured in “non-smoking” homes. Other potential indoor air sources include fuel combustion (e.g. natural gas, oil or wood), and infiltration of automobile exhaust. In addition, higher levels of 1,3-butadiene are found in “smoking” homes. Therefore, exposure to 1,3-butadiene from consumer products that contain butane and isobutane, including multiple use scenarios, should be considered in relation to ongoing risk management activities for 1,3-butadiene.

Since the PSL 2 determination that 1,3-butadiene poses a low ecological risk, no data have come to the attention of Environment Canada to suggest an increase in its ecotoxicological effects. The quantities of 1,3-butadiene considered for that PSL 2 assessment surpass the quantities identified in the section 71 survey of 1,3-butadiene as a trace contaminant in butane and isobutane. Previously unconsidered environmental releases of 1,3-butadiene (e.g., from the use of butane as an aerosol propellant) are not expected to add significantly to the exposures to aquatic or terrestrial organisms. It is therefore concluded that the ecological risks associated with concentrations of 1,3-butadiene in butane and isobutane in Canada are low.

Based on the information available, it is concluded that the exposure to 1,3-butadiene from the uses of butane and isobutane identified in this investigation should be considered in relation to ongoing risk management activities undertaken for 1,3-butadiene under CEPA 1999. Risk management activities for 1,3-butadiene are in place and will be revisited in the context of any new exposure information available.

Introduction

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health to conduct screening assessments of substances that have met the categorization criteria set out in the Act to determine whether these substances present or may present a risk to the environment or human health.

Based on the information obtained through the categorization process, the Ministers identified a number of substances as high priorities for action. These include substances that

- met all of the ecological categorization criteria, including persistence (P), bioaccumulation potential (B) and inherent toxicity to aquatic organisms (iT), and were believed to be in commerce; and/or
- met the categorization criteria for greatest potential for exposure (GPE) or presented an intermediate potential for exposure (IPE), and had been identified as posing a high hazard to human health based on classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity or reproductive toxicity.

The Ministers therefore published a notice of intent in the *Canada Gazette*, Part I, on December 9, 2006 (Canada 2006), that challenged industry and other interested stakeholders to submit, within specified timelines, specific information that may be used to inform risk assessment, and to develop and benchmark best practices for the risk management and product stewardship of those substances identified as high priorities.

The substances butane (CAS RN 106-97-8) and isobutane (CAS RN 75-28-5) were identified as high priorities for assessment of human health risk because they were considered to present GPE and had been classified by other agencies on the basis of carcinogenicity when they contain 1,3-butadiene at concentrations greater than or equal to 0.1%.

Although butane and isobutane were determined to be high priorities for assessment with respect to human health and they also met the ecological categorization criterion for persistence, they did not meet the criteria for bioaccumulation potential or inherent toxicity to aquatic organisms. Therefore, this investigation focuses principally on information relevant to the evaluation of risk to human health.

The Ministerial Challenge for butane and isobutane was published in the *Canada Gazette* on November 17, 2007 (Canada 2007), and requested stakeholders to submit information on butane and isobutane only when they contained 1,3-butadiene, at any concentration. A substance profile was released at the same time. The substance profile presented the technical information available prior to December 2005 that formed the basis for

categorization of this substance. As a result of the Challenge, submissions of information were received.

As a result of a previous assessment of 1,3-butadiene under the Priority Substances List 2 (PSL 2), it was concluded that 1,3-butadiene was entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to life or health, and is considered to be “toxic” as defined in section 64 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Environment Canada and Health Canada 2000).

Therefore, the focus of this investigation is to evaluate the exposure to and potential risk to human health from 1,3-butadiene in butane and isobutane in Canada. A screening assessment of the chemical substances butane and isobutane, in the absence of 1,3-butadiene, will be conducted with the group of substances that are of medium priority for assessment as a result of categorization. In addition, end-use fuels (e.g., motor vehicle gasoline, liquefied petroleum gas) formulated with butane and isobutane will be addressed under the Petroleum Sector Stream Approach of the Chemicals Management Plan.

This report was prepared by staff in the Existing Substances Programs at Health Canada and Environment Canada and incorporates input from other programs within these departments. Additionally, the draft of this evaluation was subject to a 60-day public comment period. The critical information and considerations upon which the report is based are summarized below.

Sources

The main sources of butane are from the refinery of crude oil and from the processing of natural gas (WLPGA 2007). Isobutane is found naturally in oil and natural gas deposits, and it is produced as a by-product when crude oil is refined (Cheminfo 2006).

1,3-Butadiene may be present at very low levels in crude oil refinery products such as gasoline and in liquefied petroleum gas, and its presence in butane and isobutane is also likely as a refinery by-product.

Based on information reported for the calendar year 2006, pursuant to section 71 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Environment Canada 2007), a total of 13 Canadian companies reported manufacturing a combined total of between 100 000 and 1 000 000 tonnes of butane containing residual amounts of 1,3-butadiene and a total of 21 Canadian companies and 3 foreign companies reported importing into Canada a combined total of between 100 and 1000 tonnes of butane containing residual amounts of 1,3-butadiene. In addition, a total of 3 Canadian companies reported importing the substance in quantities below the reporting threshold. A total of 12 Canadian companies reported manufacturing a combined total of between 100 000 and 1 000 000 tonnes of isobutane containing residual amounts of 1,3-butadiene and a total of 22 Canadian companies and 2 foreign companies reported importing into

Canada a combined total between 1000 and 10 000 tonnes of isobutane containing residual amounts of 1,3-butadiene. In addition, a total of 2 Canadian companies reported importing the substance in quantities below the reporting threshold. While the residual amount of 1,3-butadiene in both butane and isobutane ranged from 0.0 to <1 w/w%, levels were typically below 0.1 w/w%. However, in some cases, the levels of 1,3-butadiene were simply reported as “unknown” (Environment Canada 2007). The presence of residual 1,3-butadiene in butane and isobutane containing products is not due to intentional addition of 1,3-butadiene.

Uses

Major Use Patterns for Butane and Isobutane

Butane and isobutane have a number of industrial uses. They are commonly blended into motor vehicle gasoline to increase the volatility of the fuel to make engine starting easier, while isobutane is also alkylated with unsaturated hydrocarbons to produce highly branched hydrocarbons that in turn are added to gasoline to boost the octane value (Mears and Eastman 1995). Butane and isobutane are both components of liquefied petroleum gas (LPG) and as such they are used in a wide variety of fuel applications for both recreational and leisure use, including heating and air conditioning, refrigeration, cooking and lighters (Mears and Eastman 1995, LPGA 2007, Inchem 1997). A large market for butane is its use as a chemical intermediate in the synthesis of maleic anhydride, but it is also used to manufacture ethylene, methyl tertiary-butyl ether (MTBE), synthetic rubber and acetic acid and by-products (Lewis 2002, Mears and Eastman 1995). Butane is also used as a solvent in liquid-liquid extraction of heavy oils in a deasphalting process (Mears and Eastman 1995). Isobutane may also be used as an intermediate in chemical manufacturing (Mears and Eastman 1995), as a calibration standard in laboratories and as a non-ozone-depleting refrigerant in refrigerators and freezers (Cheminfo 2006).

In terms of internationally identified consumer uses, butane and isobutane are commonly used, alone or in mixtures, as hydrocarbon propellants in aerosol-based products that fall into the following use categories: arts and crafts, automotive, home maintenance, landscape/yard, personal care, pesticides and pet care. This would include products such as hair care sprays, deodorants and antiperspirants, shaving creams, edible oil, cleaners, pesticides and coatings (Mears and Eastman 1995, Sciarra and Sciarra 2001, HPD 2005).

Canadian Use Patterns for Butane and Isobutane

Based on information reported pursuant to section 71 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Environment Canada 2007), the major use patterns for butane and isobutane include solvent/carrier, propellant/blowing agent, fuel or fuel additive and formulation component. End-use fuels (e.g., motor vehicle gasoline, liquefied petroleum gas) formulated with butane and isobutane will be addressed under the Petroleum Sector Stream Approach of the Chemicals Management Plan. In terms of non-fuel uses, butane is used in various applications including insulating polyurethane foam, aerosol sprays and coatings, paint dyes and automotive spray waxes in which the concentration of butane can range up to approximately 60 w/w%. Isobutane is used in consumer products such as cosmetic/beauty preparations, air freshener, cleaners, activator/primers and various coatings in which the concentration of isobutane may range up to 70 w/w%. All of these products also contain residual levels of 1,3-butadiene within the concentration ranges indicated above, but typically at levels below 0.1 w/w% in butane or isobutane (Environment Canada 2007). In a number of cases, the concentrations are specified as unknown or not analyzed.

In addition to information collected in the section 71 survey, the following uses for butane and isobutane have also been identified by other programs within Health Canada.

Isobutane and butane have an approved use as a propellant permitted in edible vegetable oil-based or lecithin-based pan coatings or a mixture of both. Good manufacturing practice is recommended for the maximum level of use (Table VIII, Division 16 of the *Food and Drug Regulations*) (Canada 1994). However, no such provision exists for 1,3-butadiene, which therefore cannot be directly added to the propellant preparation. Isobutane and butane, if used as food additives in accordance with the *Food and Drug Regulations*, must be of food-grade quality and meet their respective Food Chemicals Codex (FCC) specifications. FCC purity specifications for these propellants (not less than 97.0% butane and not less than 95.0% isobutane) do not specify 1,3-butadiene. Based on the limited information collected to date, it is expected that levels are much less than 0.1%. Due to the volatile nature of 1,3-butadiene and a hot pan, 1,3-butadiene in the propellant (if any) would evaporate immediately (Health Canada 2008a). Therefore, levels of 1,3-butadiene in finished foods from a propellant use in pan coatings will also be extremely low and negligible.

Butane is used as a blowing agent/foaming gas in the manufacture of foam plastics such as polypropylene and polystyrene-based packaging materials that are used in direct contact with foods. Similarly, isobutane is used as a component in blowing agents/foaming gases that are used in the manufacture of polyethylene foam and low-density polyethylene (LDPE) packaging materials that are used in direct contact with food. However, because of their high volatility, residual levels of butane and isobutane are not expected to be present in the finished packaging materials. Butane and isobutane are also used as a propellant in aerosol spray products such as lubricants where contact with food is only incidental or there is no food contact, and cleaners where treated surfaces are rinsed with potable water under well-ventilated conditions in food plants.

Unfortunately, no data on the concentration of 1,3-butadiene in either butane or isobutane used in the above applications are currently available (Health Canada 2008a).

Butane and isobutane propellants are also reported to be used in some natural health products, as well as some marketed therapeutic products such as aerosol antiperspirants and foot sprays, but concentrations of 1,3-butadiene in the propellant mixtures are not known (Health Canada 2008b, c). Isobutane and butane are not listed on the Health Canada Cosmetic Ingredient Hotlist (Health Canada 2007). Isobutane is used in cosmetics, alone or in mixtures, as a hydrocarbon propellant in aerosol-based consumer products such as hairstyling and fixative sprays, deodorants and shaving creams. It is considered safe as a cosmetic ingredient at the appropriate concentration and right circumstances of use. From cosmetic notification, no information is currently available on the concentration of 1,3-butadiene in isobutane used in the above cosmetic applications. However, 1,3-butadiene is not intentionally added to these personal care products (Health Canada 2008d). Finally, butane and isobutane are used in certain pest control product formulations as propellants, but the sources supplying the propellants have indicated that they do not contain 1,3-butadiene in excess of 0.1% (Health Canada 2008e).

Potential to Cause Ecological Harm

Environment Canada has previously assessed the ecological risks associated with the production and use of 1,3-butadiene (Environment Canada and Health Canada 2000) and found that the substance presents a low risk to aquatic organisms, terrestrial plants, soil invertebrates and wildlife. No ecotoxicological data suggesting that this conclusion should be modified have come to the attention of Environment Canada since that assessment. The quantities of the substance considered for that assessment also far surpass the quantities identified in a recent survey (Environment Canada 2007) of 1,3-butadiene as a trace contaminant in butane and isobutane. Previously unconsidered environmental releases of 1,3-butadiene (e.g., from the use of butane as an aerosol propellant) are not expected to add significantly to the exposures of aquatic or terrestrial organisms. It is therefore concluded that the ecological risks associated with concentrations of 1,3-butadiene in butane and isobutane in Canada are low.

Potential to Cause Harm to Human Health

Exposure Assessment

Butane and isobutane both have very high vapour pressures and any indoor emissions from the above products would be expected to partition rapidly to air and contribute to the indoor air levels of these substances. Similarly, 1,3-butadiene also has a very high vapour pressure and when present in butane and isobutane propellants as an impurity, would also be expected to partition rapidly to air once released, thus contributing to the background levels of this substance typically found in the indoor air of Canadian homes. For example, a recent air monitoring study conducted in non-smoking homes in Windsor, Ontario reported that the arithmetic mean concentrations of 1,3-butadiene in indoor air were $0.134 \mu\text{g}/\text{m}^3$ (summer) and $0.170 \mu\text{g}/\text{m}^3$ (winter), while maximum levels were $0.900 \mu\text{g}/\text{m}^3$ (summer) and $2.833 \mu\text{g}/\text{m}^3$ (winter) (Health Canada 2008f). In addition, higher levels of 1,3-butadiene are found in “smoking” homes (Environment Canada and Health Canada 2000). Thus, exposure to 1,3-butadiene resulting from the use of the various products containing butane and isobutane propellants would be expected to occur mainly through inhalation of indoor air. However, because of the difficulty of distinguishing levels of 1,3-butadiene associated with these products from background levels, it is not possible to accurately estimate the contribution of 1,3-butadiene arising from the use of butane and isobutane propellants in consumer products. However, if one assumes that background levels of 1,3-butadiene are zero, then consumer exposure models such as ConsExpo (RIVM 2006) can be used to estimate exposure resulting from the use of a specific product, provided that the concentration of 1,3-butadiene is known. For example, as shown in Appendix A, the upper-bounding estimated inhalation mean event concentration and inhalation air concentration year average associated with the use of hair spray containing isobutane propellant (70% isobutane containing 0.1% w/w 1,3-butadiene) (Environment Canada 2007) is $0.00097 \text{ mg}/\text{m}^3$ and $4.03 \times 10^{-6} \text{ mg}/\text{m}^3/\text{day}$ respectively. The hairspray scenario was chosen because it represented the upper-end of the isobutane concentration in a propellant, the typical upper-bound levels of 1,3-butadiene in the isobutane, and the most frequent use pattern. Some of the consumer products contain slightly higher levels of 1,3-butadiene in the butane or isobutane (up to $< 1.0 \text{ w/w } \%$). These products would contribute to overall exposure to 1,3-butadiene. Also, there is the potential for multiple products to be used successively, increasing exposure to 1,3-butadiene (e.g. multiple cosmetic/beauty preparations such as hairspray, deodorant, shaving cream).

Estimated exposure levels from one cosmetic product outlined above are still 200–700 times lower than the measured maximum level of 1,3-butadiene in Canadian homes, and around 50 times lower than mean measured levels, but the exposure scenario does not account for potential simultaneous exposure from the use of multiple aerosol propellants. Propellant uses of isobutane and butane are potential contributors to the reported indoor air levels, but their contribution to overall exposure to 1,3-butadiene via indoor air is considered limited. Other potential indoor air sources include fuel combustion (e.g. natural gas, oil or wood), and infiltration of automobile exhaust. In addition, higher

levels of 1,3-butadiene are found in “smoking” homes (Environment Canada and Health Canada 2000).

Outside the home, any releases of 1,3-butadiene associated with the use of products containing hydrocarbon propellants (e.g., garden pesticide sprays, automotive cleaners) would rapidly disperse into ambient air and concerns regarding inhalation exposure would be low.

Exposure to 1,3-butadiene through other sources was previously assessed under the PSL 2 assessment and will not be readdressed in this report.

Potential to Cause Harm to Human Health

Classification of Butane and Isobutane

The European Commission has classified butane and isobutane as Category 1 for carcinogenicity (substance known to be carcinogenic to man) and Category 2 for genotoxicity (substance which should be regarded as if it is mutagenic to man). These classifications for butane and isobutane are based on each substance containing a concentration of $\geq 0.1\%$ butadiene (CAS RN 106-99-0) (European Commission 2001a, b; ESIS 2006).

Summary of Health Effects of 1,3-Butadiene (CAS 106-99-0)

The following information was taken from the PSL 2 report for 1,3-butadiene (Environment Canada and Health Canada 2000).

Based on critical evaluation of the extensive database available on the health effects, it was concluded that 1,3-butadiene is highly likely to be carcinogenic in humans, and may also be associated with genotoxicity and reproductive toxicity (Environment Canada and Health Canada 2000).

Epidemiological studies conducted on workers in the styrene-butadiene rubber industry revealed an association between occupational exposure to 1,3-butadiene and incidence of leukemia (Delzell et al. 1995). There is also limited evidence that 1,3-butadiene is genotoxic in exposed workers. Based on available data, it is likely that there is a significant variation in sensitivity within human populations, possibly due to genetic polymorphism for the gene that codes for enzymes related to metabolism of 1,3-butadiene (Krause et al. 1997).

Based on the results of long-term animal studies, inhaled 1,3-butadiene is a multi-site carcinogen in mice and rats for all the concentrations tested. A study conducted by the National Toxicology Program (NTP 1993) revealed that, in mice exposed to

concentrations ranging from 6.25 to 625 ppm (13.8 to 1383 mg/m³) for up to 2 years, there were increases in the incidences of malignant lymphomas, histiocytic sarcomas, cardiac hemangiosarcomas and tumours of the Harderian gland, liver, lung, mammary glands, ovary and forestomach. Although 1,3-butadiene also induced multi-site tumours in rats, the exposure concentrations were greater (≥ 1000 ppm or ≥ 2212 mg/m³) than those noted in mice. Mice also showed a higher incidence of tumours compared to rats. Available data suggests that the marked species difference in sensitivity of 1,3-butadiene is due to quantitative differences in absorption of the substance, rate of metabolism and the proportion of metabolites generated (Bond 1986). According to in-vitro studies, mice metabolize a greater proportion of 1,3-butadiene to active epoxide metabolites. 1,3-Butadiene is also genotoxic in both somatic and germ cells in a wide variety of in vivo and in vitro studies. Similar to carcinogenic potency, genotoxic potency in mice is greater than that of rats.

The assessment of 1,3-butadiene (Environment Canada and Health Canada 2000) developed estimates of carcinogenic potency (tumourigenic concentration (TC)) from both epidemiological and long-term animal bioassays (see summary in Table 1).

1,3-Butadiene-induced non-cancer adverse effects in the reproductive organs were observed in mice but not in rats. A 2-year chronic bioassay conducted by the NTP (NTP 1993) showed ovarian atrophy in female mice at relatively low concentrations (6.25 ppm or 13.8 mg/m³). Effects on reproductive organs of male mice were seen only at higher concentrations than that of female mice (NTP 1993). In the PSL 2 assessment of 1,3-butadiene (Environment Canada and Health Canada 2000), benchmark concentrations (BMC₀₅) for 5% increase in ovarian atrophy were derived on the basis of the results from the 2-year bioassay conducted by the NTP (1993) (see summary in Table 2). As well, the PSL 2 assessment concluded that the mode of induction of ovarian atrophy is unknown and assumed that the mode of action is related to that by which tumours are induced (i.e., direct interaction with genetic material).

Characterization of Risk to Human Health

Based on a previous critical evaluation of the extensive database available on the health effects of 1,3-butadiene, it was concluded that 1,3-butadiene is highly likely to be carcinogenic in humans, and may also be associated with genotoxicity and reproductive toxicity (Environment Canada and Health Canada 2000).

Comparison of the estimates of carcinogenic potency (TC₀₁ or TC₀₅) with the upper-bounding estimate for chronic exposure to consumer product containing a weight fraction of 0.0007 of 1,3-butadiene, results in exposure potency indices (EPI) between 8.6×10^{-7} and 4.0×10^{-5} (Table 1). In addition, comparison of the BMC₀₅ for non-cancer effects with the same upper-bounding estimate for chronic exposure to consumer products results in margins of exposure of 110 000 to 141 000 (Table 2).

These comparisons indicate that the priority for investigations of options to reduce exposure for this particular exposure scenario is low to moderate. Some of the consumer

products contain slightly higher levels of 1,3-butadiene in the butane or isobutane (up to < 1.0 w/w %). These products would contribute to overall exposure to 1,3-butadiene. Also, there is the potential for multiple products to be used successively, increasing exposure to 1,3-butadiene (e.g. multiple cosmetic/beauty preparations such as hairspray, deodorant, shaving cream).

However, compared to data from Canadian indoor air studies, estimated concentrations of 1,3-butadiene attributable to consumer product use are approximately 50 times lower than the average indoor levels measured in “non-smoking” homes. Other potential indoor air sources include fuel combustion (e.g. natural gas, oil or wood), and infiltration of automobile exhaust. In addition, higher levels of 1,3-butadiene are found in “smoking” homes. Therefore, exposure to 1,3-butadiene from products, including multiple use scenarios, should be considered in relation to ongoing risk management activities for 1,3-butadiene.

Table 1: Comparison of estimates of carcinogenic potency with exposure levels

Exposure	Potency (TC ₀₁ or TC ₀₅)	Margin between effect level and exposure	Priority for further action*
		Exposure Potency Index (EPI)	
4.03 × 10 ⁻⁶ mg/m ³ (upper- bounding estimate for chronic exposure to consumer product containing weight fraction of 0.0007 1,3-butadiene)	0.1 mg/m ³ (TC ₀₁ for leukemia in humans)	24 800	Moderate
		4.0 × 10 ⁻⁵	
	2.3 mg/m ³ (TC ₀₅ for most sensitive tumour site in mice [Harderian gland])	570 000	Low
		1.7 × 10 ⁻⁶	
	1.7 mg/m ³ (95% LCL ¹ of TC ₀₅ for most sensitive tumour site in mice)	420 000	Moderate
		2.4 × 10 ⁻⁶	
	6.7 mg/m ³ (TC ₀₅ for most sensitive tumour site in rats [mammary gland])	1 660 000	Low
		6.0 × 10 ⁻⁷	
	4.7 mg/m ³ (95% of LCL of TC ₀₅ for most sensitive tumour site in rats)	1 170 000	Low
		8.6 × 10 ⁻⁷	

* For EPIs calculated on the basis of a TC₀₁ derived from epidemiological data, the priority for investigation of options to reduce exposure is considered to be high, moderate or low if the EPI values are determined to be 1×10⁻³ or greater, between 1×10⁻⁵ and 1×10⁻³, or less than 1×10⁻⁵, respectively. If EPI is calculated on the basis of a TC₀₅ derived from data in laboratory animals, the priority for investigation of options to reduce exposure is considered to be high, moderate or low if the EPI values are determined to be 2×10⁻⁴ or greater, between 2×10⁻⁶ and 2×10⁻⁴, or less than 2×10⁻⁶, respectively.

¹ Lower Confidence Level

Table 2: Comparison of estimates of non-cancer effects with exposure levels

Exposure	Potency (BMC ₀₅)	Margin between effect level and exposure*	Priority for further action*
		Exposure Potency Index (EPI)*	
4.03 × 10 ⁻⁶ mg/m ³ (upper-bounding estimate for chronic exposure to consumer product containing weight fraction of 0.0007 1,3-butadiene)	0.57 mg/m ³ (BMC ₀₅ for ovarian atrophy in mice)	141 000	Moderate
		7.1 × 10 ⁻⁶	
	0.44 mg/m ³ (95th percentile of BMC ₀₅ for ovarian atrophy in mice)	110 000	Moderate
		9.1 × 10 ⁻⁶	

* If the mode of action involves interaction with genetic material. See the PSL 2 assessment on 1,3-butadiene for discussion.

Uncertainties in Evaluation of Risk to Human Health

Uncertainties with regards to the health effects evaluation of 1,3-butadiene are outlined in the PSL 2 assessment of that substance.

The main uncertainty with regard to exposure to 1,3-butadiene from butane and isobutane containing 1,3-butadiene as a residual, are data gaps regarding the levels of residual 1,3-butadiene in butane and isobutane, particularly in some propellants with general population use.

Conclusion

Based on the information available, it is concluded that exposure to 1,3-butadiene from the uses of butane and isobutane identified in this investigation should be considered in relation to ongoing risk management activities undertaken for 1,3-butadiene under CEPA 1999. Risk management activities for 1,3-butadiene are in place and will be revisited in the context of any new exposure information available.

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Appendix A: Upper-Bounding Estimate of Exposure to 1,3-butadiene from Isobutane-Containing Consumer Products

Product composition is 70% isobutane (containing 0.1w/w% 1,3-butadiene)

ConsExpo 4.1 report

Product

hair spray

Compound

compound name	1,3-butadiene	
CAS number	106-99-0	
molecular weight	54	g/mol
vapour pressure	2.81E5	Pascal
K _{ow}	1.99	10Log

General Exposure Data

exposure frequency	438	1/year
body weight	61	kilogram

Inhalation model: Exposure to spray

weight fraction compound	0.00070	fraction
exposure duration	5	minute
room volume	10	m ³
ventilation rate	2	1/hr
mass generation rate	0.47	g/sec
spray duration	0.24	minute
airborne fraction	1	fraction
weight fraction non-volatile	0.03	fraction
density non-volatile	1.5	g/cm ³
room height	2.5	meter
inhalation cut-off diameter	15	micrometer
cloud volume	0.0625	m ³
non-respirable uptake fraction	0	fraction
spraying towards exposed person		

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	16.2	m ³ /day

Dermal model: Direct dermal contact with product: instant application

weight fraction compound	0.00070	fraction
exposed area	565	cm ²
applied amount	0.6	gram

Output

Inhalation (point estimates)

inhalation mean event concentration	0.000967	mg/m ³
inhalation mean concentration on day of exposure	4.03E-6	mg/m ³
inhalation air concentration year average	4.03E-6	mg/m ³ /day
inhalation acute (internal) dose	8.91E-7	mg/kg
inhalation chronic (internal) dose	1.07E-6	mg/kg/day

Dermal : point estimates

dermal load	-	mg/cm ²
dermal external dose	-	mg/kg
dermal acute (internal) dose	-	mg/kg
dermal chronic (internal) dose	-	mg/kg/day

Oral non-respirable: point estimates

oral external dose	0	mg/kg
oral acute (internal) dose	0	mg/kg
oral chronic (internal) dose	0	mg/kg/day

Integrated (point estimates)

total external dose	0.00716	mg/kg
total acute dose (internal)	0.00689	mg/kg
total chronic dose (internal)	0.00826	mg/kg/day