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Screening Assessment

Cyclohexene, 4-ethenyl-
(4-Vinylcyclohexene)

Chemical Abstracts Service Registry Number
100-40-3

Environment and Climate Change Canada
Health Canada

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Canada

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Synopsis

Pursuant to section 68 of the Canadian Environmental Protection Act, 1999 (CEPA), the Minister of the Environment and the Minister of Health have conducted a screening assessment of cyclohexene, -4 ethenyl-, hereafter referred to as 4-vinylcyclohexene (4-VCH). The Chemical Abstracts Service Registry Number (CAS RN[1]) for 4-VCH is 100-40-3. This substance is among those substances identified as priorities for assessment on the basis of other human health concerns.

4-VCH does not occur naturally in the environment. It is used primarily as an industrial intermediate and is chemically consumed in the manufacture of flame retardants, plastic/rubber materials and other specialty chemicals. 4-VCH may also be found as a residual in styrene-butadiene latex adhesives used in the manufacture or installation of manufactured items, such as carpets and laminated building materials. Concentrations of 4-VCH in the environment are expected to be very low due to rapid oxidation in the atmosphere and the potential for polymerization. In 2008, less than 100 kg of 4-VCH were manufactured in Canada, and between 1000 and 10 000 kg were imported into Canada.

The ecological risk of 4-VCH was characterized using the ecological risk classification of organic substances (ERC). The ERC is a risk-based approach that employs multiple metrics for both hazard and exposure based on weighted consideration of multiple lines of evidence for determining risk classification. Hazard profiles based principally on metrics regarding mode of toxic action, chemical reactivity, food web-derived internal toxicity thresholds, bioavailability, and chemical and biological activity are established. Metrics considered in the exposure profiles include potential emission rate, overall persistence, and long-range transport potential. A risk matrix is used to assign a low, moderate or high level of potential concern for substances based on their hazard and exposure profiles. The ERC identified 4-VCH as having low potential to cause ecological harm.

Considering all available lines of evidence presented in this screening assessment, there is low risk of harm to organisms and the broader integrity of the environment from 4-VCH. It is concluded that 4-VCH does not meet the criteria under paragraphs 64(a) or (b) of CEPA as it is not entering the environment in a quantity or concentration or under

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conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

The critical health effects for 4-VCH are carcinogenicity and reproductive toxicity as demonstrated in laboratory studies. Low toxicity was observed in short-term inhalation studies.

Exposure of the general population to 4-VCH is expected to be low. Exposure from environmental media is not expected, given that industry uses 4-VCH in closed systems. Quantities in commerce are also low. 4-VCH may be found as a residual in manufactured products containing styrene-butadiene adhesives. Available information indicates a potential for exposure as a result of off-gassing from a limited number of manufactured items containing these adhesives, but exposures would be limited, occurring only over a short period of time. Given the nature of potential exposure, risk to human health is considered to be low.

On the basis of the information presented in this screening assessment, it is concluded that 4-VCH does not meet the criteria under paragraph 64(c) of CEPA as it is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

It is concluded that 4-VCH does not meet any of the criteria set out in section 64 of CEPA.

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1. Introduction

Pursuant to section 68 of the Canadian Environmental Protection Act, 1999 (CEPA) (Canada 1999), the Minister of the Environment and the Minister of Health conducted a screening assessment of cyclohexene, -4 ethenyl- to determine whether this substance presents or may present a risk to the environment or to human health. Cyclohexene, -4 ethenyl-, hereafter referred to as 4-vinylcyclohexene (4-VCH), was identified as a priority for assessment under CEPA on the basis of other human health concerns (ECCC, HC [modified 2007]).

4-VCH was previously assessed internationally by the European Chemicals Agency (ECHA 2012) and by the International Agency for Research on Cancer (IARC 1994). These assessments undergo rigorous review and approval processes. Health Canada and Environment and Climate Change Canada accept these assessments as reliable. These reports were used to inform the health effects characterization in this screening assessment.

The ecological risk of 4-VCH was characterized using the ecological risk classification of organic substances (ERC) (ECCC 2016a). The ERC describes the hazard of a substance using key metrics, including mode of toxic action, chemical reactivity, food web-derived internal toxicity thresholds, bioavailability, and chemical and biological activity, and considers the possible exposure of organisms in the aquatic and terrestrial environments based on such factors as potential emission rates, overall persistence and long-range transport potential in air. The various lines of evidence are combined to identify substances as warranting further evaluation of their potential to cause harm to the environment or as having a low likelihood of causing harm to the environment.

This screening assessment includes consideration of information on chemical properties, environmental fate, hazards, uses, and exposures. Relevant data were identified up to April 2016. Empirical data from key studies as well as results from models were used to reach the conclusions. When available and relevant, information presented in assessments from other jurisdictions was considered.

This screening assessment was prepared by staff in the CEPA Risk Assessment Programs at Health Canada and Environment and Climate Change Canada and incorporates input from other programs within these departments. The ecological portion of this assessment is based on the ERC document (published July 30, 2016), which was peer-reviewed and subject to a 60-day public comment period. Additionally, the draft of this screening assessment (published February 25, 2017) was also subject to 60-day public comment period.

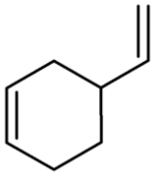
While external comments were taken into consideration, the final content and outcome of the screening assessment remain the responsibility of Environment and Climate Change Canada and Health Canada.

This screening assessment focuses on information critical to determining whether the substance meets the criteria as set out in section 64 of CEPA by examining scientific information and incorporating a weight–of-evidence approach and precaution.[2] The screening assessment presents the critical information and considerations that form the basis of the conclusion.

2. Substance identity

4-Vinylcyclohexene is an organic chemical belonging to a substance class known as alkenes. The Chemical Abstracts Service Registry Number (CAS RN[3]), Domestic Substances List (DSL) name and common name for 4-VCH are presented in Table 2-1.

Table 2-1: substance identity

CAS RN	DSL name (common name)	Chemical structure and molecular formula	Molecular weight (g/mol)
100-40-3	Cyclohexene, 4-ethenyl- (4-vinylcyclohexene)	 $C_8H_6O_3$	108.18

3. Physical and chemical properties

A summary of physical and chemical properties of 4-VCH is presented in Table 3-1. Additional physical and chemical properties are presented in ECCC (2016b).

[2] A determination of whether one or more of the criteria of section 64 of CEPA are met is based upon an assessment of potential risks to the environment and/or human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products available to consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazardous Products Regulations*, which are part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

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Table 3-1: physical and chemical property values for 4-VCH (at standard temperatures and pressures)

Property	Value	Type of data	Reference
Melting point (^{o}C)	-108.9	experimental	US EPA 2006
Boiling point (^{o}C)	128.9	experimental	US EPA 2006
Water solubility (mg/L)	50	experimental	US EPA 2006
Density (g/mL)	0.8299 @ 20 ^{o}C	experimental	US EPA 2006
Vapour pressure (kPa)	2.09 @ 25 ^{o}C (15.7 mm Hg)	experimental	US EPA 2006
Henry's law constant (Pa m^3/mol)	4.54×10^{3}	experimental	EPI Suite c2010-2012
log K_{ow} (dimensionless)	3.93	experimental	EPI Suite c2010-2012

Abbreviations: K_{ow}, octanol–water partition coefficient; K_{oc}, organic carbon–water partition coefficient

4. Sources and uses

4-VCH does not occur naturally in the environment. It is the reaction product of the catalytic dimerization of 1,3-butadiene, with production and use occurring in closed systems (US EPA 2006).

4-VCH has been surveyed pursuant to section 71 of CEPA. Table 4-1 presents a summary of the total manufacture and total import quantities for 4-VCH (Canada 2009).

Table 4-1: summary of information on Canadian manufacturing and imports of 4-VCH submitted pursuant to a CEPA section 71 survey

Common Name	Total manufacture (kg)	Total imports[4] (kg)	Reporting year	Survey reference
4-VCH	<100	1000 to 10 000	2008	Canada 2009

4-VCH is used primarily as an intermediate in the production of other chemicals and products including flame retardants, plastic and rubber materials, and adhesives and solvents (US EPA 2006; IARC 1994; ECHA 2012). Additional information on uses in Canada is presented in Table 4-2.

Table 4-2: additional uses in Canada for 4-VCH

Use	
Food additive[a]	N

[4] Values reflect quantities reported in response to surveys conducted under section 71 of CEPA. See survey for specific inclusions and exclusions (schedule 2 and 3).

Use	
Food packaging materials[a]	Y
Internal Drug Product Database as medicinal or non-medicinal ingredients in disinfectant, human or veterinary drug products in Canada[b]	N
Natural Health Products Ingredients Database[c]	N
Licensed Natural Health Products Database as medicinal or non-medicinal ingredients in natural health products in Canada[c]	N
List of Prohibited and Restricted Cosmetic Ingredients[d]	N
Notified to be present in cosmetics, based on notifications submitted under the Cosmetic Regulations to Health Canada[d]	N
Formulant in pest control products registered in Canada[e]	N

Abbreviations: [Y -Yes; N - No]

[a] Email communication from Food Directorate to Existing Substances Risk Assessment Bureau; unreferenced.

[b] Email communication from Therapeutic Products Directorate to Existing Substances Risk Assessment Bureau; unreferenced.

[c] Email communication from Natural and Non-prescription Health Products Directorate to Existing Substances Risk Assessment Bureau; unreferenced.

[d] Email communication from Consumer Product Safety Directorate to Existing Substances Risk Assessment Bureau; unreferenced.

[e] Email communication from Pest Management Regulatory Agency to Existing Substances Risk Assessment Bureau; unreferenced.

In Canada, 4-VCH has been identified as an impurity in a component used in the manufacture of some food packaging materials. It is not directly or intentionally added to food packaging materials (email communication from Food Directorate to Existing Substances Risk Assessment Bureau; unreferenced).

Additional searches of material safety data sheets (MSDS) identified a small number of specialty products that listed 4-VCH as a component, typically from less than 0.02% to less than 0.1%. These products include specialized adhesives for electronics and electrical boards as well as bulk polymer materials that are further processed at an industrial level (styrene-butadiene copolymers) (MSDS 2015a, MSDS 2009, MSDS 2015b). 4-VCH may also be found as a residual in the adhesive component of manufactured items, such as carpets and laminated building materials (US EPA 2006).

In the United States, the national production volume of 4-VCH for the year 2012 was reported as 1.41 million kilograms (3.11 million pounds) (CDAT 2014). A search of the

Household Products Database did not identify any products available to consumers associated with the CAS RN for 4-VCH (Household Products Database 2016).

5. Potential to cause ecological harm

5.1 Characterization of ecological risk

The ecological risks of 4-VCH were characterized using the ecological risk classification of organic substances (ERC) (ECCC 2016a). The ERC is a risk-based approach that considers multiple metrics for both hazard (potency) and exposure based on weighted consideration of multiple lines of evidence for determining risk classification. The various lines of evidence are combined to discriminate between substances of lower or higher potency and lower or higher potential for exposure in various media. This approach reduces the overall uncertainty with risk characterization compared to an approach that relies on a single metric in a single medium (e.g., LC_{50}) for characterization. The following paragraphs in this section summarize the approach, which is described in detail in ECCC (2016a).

Data on physical-chemical properties, fate (chemical half-lives in various media and biota, partition coefficients, fish bioconcentration), acute fish ecotoxicity, and chemical import or manufacture volume in Canada were collected from scientific literature, from available empirical databases (e.g., OECD QSAR Toolbox) and from responses to surveys under section 71 of CEPA, or were generated using selected quantitative structure-activity relationship (QSAR) or mass-balance fate and bioaccumulation models. These data were used as inputs to other mass-balance models or to complete the substance hazard and exposure profiles.

Hazard profiles based principally on metrics regarding mode of toxic action, chemical reactivity, food web-derived internal toxicity thresholds, bioavailability, and chemical and biological activity were established. Exposure profiles were also composed of multiple metrics including potential emission rate, overall persistence, and long-range transport potential. Hazard and exposure profiles were compared to decision criteria in order to classify the hazard and exposure potentials for each organic substance as low, moderate, or high. Additional rules were applied (e.g., classification consistency, margin of exposure) to refine the preliminary classifications of hazard or exposure.

A risk matrix was used to assign a low, moderate or high classification of potential risk for each substance based on its hazard and exposure classifications. ERC classifications of potential risk were verified using a two-step approach. The first step adjusted the risk classification outcomes from moderate or high to low for substances that had a low estimated rate of emission to water after wastewater treatment, thus representing a low potential for exposure. The second step reviewed low risk potential classification outcomes using relatively conservative, local-scale (i.e., in the area immediately surrounding a point-source of discharge) risk scenarios, designed to be

protective of the environment to determine whether the classification of potential risk should be increased.

ERC uses a weighted approach to minimize the potential for both over- and under-classification of hazard and exposure and subsequent risk. The balanced approaches for dealing with uncertainties are described in greater detail in ECCC 2016a. The following describes two of the more substantial areas of uncertainty. Error with empirical or modeled acute toxicity values could result in changes in classification of hazard, particularly metrics relying on tissue residue values (i.e., mode of toxic action), many of which are predicted values from QSAR models. However, the impact of this error is mitigated by the fact that overestimation of median lethality will result in a conservative (protective) tissue residue used for critical body residue (CBR) analysis. Error with underestimation of acute toxicity is mitigated through the use of other hazard metrics, such as structural profiling of mode of action, reactivity and/or estrogen binding affinity. Changes or errors in chemical quantity could result in differences in classification of exposure as the exposure and risk classifications are highly sensitive to emission rate and use quantity. The ERC classifications thus reflect exposure and risk in Canada based on what is believed to be the current use quantity, and may not reflect future trends.

Critical data and considerations used to develop the substance-specific profiles for 4-VCH and to determine the hazard, exposure and risk classification results are presented in ECCC (2016b).

Based on low hazard and low exposure classifications according to ERC for 4-VCH, this substance was classified as having a low potential for ecological risk and is therefore unlikely to result in concerns for organisms or the broader integrity of the environment in Canada.

6. Potential to cause harm to human health

6.1 Exposure assessment

6.1.1 Environmental media

4-Vinylcyclohexene is used primarily as an intermediate in the manufacture of other chemicals and products, including flame retardants and polymer plastics and rubbers. It is produced and used in closed production systems because it is reactive and readily oxidizes in air.

Exposure of the general population to 4-VCH from environmental media is not expected, given that industry produces and uses 4-VCH in closed systems. Additionally, any releases to air would oxidize in the atmosphere with an approximate half-life of 1.4 hours (US HPV 2006). The substance may also polymerize in air at temperatures above 26.6 ºC, leading to a gum-polymer type material and further limiting the potential for

environmental accumulation (ECHA 2006). 4-VCH is unlikely to be found in soil due to its relatively high vapour pressure (US EPA 2006) and low-moderate K_{ow}. It is readily removed from wastewater effluent from wastewater treatment systems[5], with an estimated removal of 92% by secondary level treatment based on the SimpleTreat model (Struijs et al. 1991).

6.1.2 Products available to consumers

Limited concentrations of 4-VCH have been reported in a small number of speciality products that may be available to the consumer. Given the nature of product uses and the physical-chemical properties of 4-VCH, there is the potential for limited inhalation exposure to 4-VCH.

Newly manufactured items, such as carpets and laminated building materials (where styrene-butadiene latex adhesives have been used in the manufacturing or installation process) can contain residual levels of 4-VCH (US EPA 2006). Off-gassing from such products can occur inside a residence, and this may result in inhalation exposure to 4-VCH.

The extent of off-gassing of 4-VCH from installation of new manufactured items has been explored in chamber studies. The National Research Council of Canada (NRC Material Emissions Database) quantified the air concentration of 4-VCH over 24 hours inside a closed chamber after simulated installation of new manufactured items (NRC 2011). The chamber air concentration of 4-VCH was found to range from 2.84 µg/m^3 to 0.12 µg/m^3, with an arithmetic mean value of 1.48 µg/m^3 (NRC 2011).

Similarly, other chamber studies suggest that airborne concentrations of 4-VCH from freshly milled and installed carpet could be on the order of a few parts per billion (6 ppb) immediately after installation, decreasing rapidly over the first 6 hours (to 2 ppb) (from 0.027 to 0.009 mg/m^3) (Hodgson 1993).

These low initial levels and the reduction in concentration over a short time course reaffirm that the residual levels of 4-VCH in manufactured items are low and are rapidly

[5] In this assessment, the term “wastewater treatment system” refers to a system that collects domestic, commercial and/or institutional household sewage and possibly industrial wastewater (following discharge to the sewer), typically for treatment and eventual discharge to the environment. Unless otherwise stated, the term wastewater treatment system makes no distinction of ownership or operator type (municipal, provincial, federal, indigenous, private, partnerships). Systems located at industrial operations and specifically designed to treat industrial effluents will be identified by the terms “on-site wastewater treatment systems” and/or “industrial wastewater treatment systems.

removed from the indoor environment. Therefore, exposure to 4-VCH is expected to be limited in nature.

Potential exposure to 4-VCH from its presence as a residual in components used in the manufacture of certain food packaging materials is expected to be negligible (email communications from the Food Directorate to Existing Substances Risk Assessment Bureau; unreferenced).

In summary, exposure of the general population to 4-VCH through environmental media is not expected and exposure through food is expected to be negligible. The use of manufactured items that contain residual 4-VCH may result in a limited post-installation exposure. Further exposure is not expected after materials off-gas residual 4-VCH.

6.2 Health effects assessment

The European Chemicals Agency (ECHA), as well as other groups and agencies, summarized the health effects literature and/or characterized the toxicity of 4-VCH (NTP 1986; IARC 1994; TCEQ 2011; ECHA 2012; Kappeler and Hoyer 2012; OEHHA 2013). Health effects studies indicate that repeated oral exposure of laboratory animals to 4-VCH may result in carcinogenicity. The International Agency for Research on Cancer (IARC) classifies 4-VCH as a group 2B carcinogen ('possibly carcinogenic to humans'), and the European Commission under the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals classifies it as a Category 2 carcinogen ("suspected human carcinogen") (IARC 1994; European Union 2008, 2009; UN 2013). Carcinogenicity studies in mice have produced ovarian and adrenal tumours in females and lymphoma and tumours of the lung in males. Carcinogenicity studies in rats showed increased incidences of skin tumours in males and clitoral gland tumours in females (IARC 1994).

Adverse effects on reproduction have also been observed in animal studies conducted in mice and rats demonstrating ovotoxcitiy conducted using 4-vinyl-1-cyclohexene diepoxide (vinyl cyclohexane dioxide), the primary bioactive metabolite of 4-VCH (Kappeler and Hoyer 2012; OEHHA 2013).

Mice exposed to 4-VCH via inhalation at 250, 490 or 1000 ppm (4425 mg/m^3) over two days and rats exposed at 500, 1000 or 2000 ppm (8850 mg/m^3) did not show increased micronuclei formation, and mice did not exhibit clinical signs of toxicity (no observed adverse effect concentration (NOAEC) = 4425 mg/m^3), although male mice exhibited significantly reduced weight gain (Bevan et al. 2001). Rats exhibited a decrease in responsiveness to sound as well as narcosis, both of which reversed after cessation of exposure in all exposed groups (lowest observed effect concentration (LOEC) = 500 ppm; 2212 mg/m^3). In a 10-day range finding study of inhalation exposure in mice and rats, a NOAEC of 3185 mg/m^3 was established (US EPA 1994).

6.3 Characterization of risk to human health

4-Vinylcyclohexene is an industrial chemical intermediate that is produced and used in closed systems during the production of other chemicals and products. Exposure of the general population to 4-VCH from environmental media is not expected and, therefore, the risk to human health is low. The risk to human health from potential dietary exposure to 4-VCH, where it may be present as a residual in components used in the manufacture of food packaging materials, is considered negligible.

Off-gassing from new carpets and laminated building materials that contain styrene-butadiene adhesives may result in limited inhalation exposure to 4-VCH inside residences. Any potential exposure is expected to be limited (i.e., occurring on a time scale of minutes to hours, immediately following product installation), as indicated by chamber studies. In laboratory animals, carcinogenicity has been established as a critical effect for repeated exposure to 4-VCH. However, this critical effect is not considered relevant for risk characterization of limited inhalation exposure to manufactured products. Similarly, reproductive effects from inhalation exposure are only seen in animals that have been exposed to very high concentrations of 4-VCH for longer durations (i.e., 90 days). Studies more representative of the duration of exposure relevant to the general population showed limited, reversible effects at doses that were several orders of magnitude higher than potential general population exposures. Therefore, risk to human health is considered to be low.

While exposure of the general population to 4-VCH is not of concern at current levels, this substance is considered to have a health effect of concern based on its potential carcinogenicity. Therefore, there may be a concern for human health if exposures were to increase.

6.4 Uncertainties in evaluation of risk to human health

Overall confidence in the inhalation exposure database is moderate, with uncertainties derived from a lack of Canadian air monitoring data inside residences. However, chamber studies that simulate an indoor air scenario provide context for potential exposure from off-gassing from manufactured items.

7. Conclusion

Considering all available lines of evidence presented in this screening assessment, there is low risk of harm to organisms and the broader integrity of the environment from 4-VCH. It is concluded that 4-VCH does not meet the criteria under paragraphs 64(a) or (b) of CEPA as it is not entering 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 or that constitute or may constitute a danger to the environment on which life depends.

On the basis of the information presented in this screening assessment, it is concluded that 4-VCH does not meet the criteria under paragraph 64(c) of CEPA as it is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Therefore, it is concluded that 4-VCH does not meet any of the criteria set out in section 64 of CEPA.

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