



**Government  
of Canada**    **Gouvernement  
du Canada**

## **Screening Assessment**

**Acetic acid, anhydride  
(Acetic anhydride)**

**Chemical Abstracts Service Registry Number  
108-24-7**

**Environment and Climate Change Canada  
Health Canada**

**November 2017**

**Canada**<sup>ca</sup>

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## Synopsis

Pursuant to section 74 of the *Canadian Environmental Protection Act, 1999* (CEPA), the Minister of the Environment and the Minister of Health have conducted a screening assessment of acetic acid, anhydride, hereinafter referred to as acetic anhydride. The Chemical Abstracts Service Registry Number (CAS RN) for acetic anhydride is 108-24-7. This substance is among those substances identified as priorities for assessment as it met categorization criteria under subsection 73(1) of CEPA.

Acetic anhydride does not occur naturally in the environment. In Canada, it is used as an intermediate in the preparation of other chemicals, as a laboratory reagent and as a plasticizer in commercial building or construction materials, including certain silicone sealants. In 2011, there were no reports of manufacture above the reporting threshold of 100 kg for acetic anhydride, but between 10 000 and 100 000 kg of acetic anhydride were imported into Canada.

Acetic anhydride is a permitted food additive that is used to modify starches, which are food ingredients, and as a non-medicinal ingredient in pharmaceuticals.

The ecological risk of acetic anhydride was characterized using the ecological risk classification (ERC) of organic substances. The ERC is a risk-based approach that employs multiple metrics for both hazard and exposure on the basis of weighted consideration of multiple lines of evidence for determining risk classification. Hazard profiles based primarily on metrics regarding mode of toxic action, chemical reactivity, food web-derived internal toxicity thresholds, bioavailability, and chemical and biological activity were 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 on the basis of their hazard and exposure profiles. The ERC identified acetic anhydride as having a low potential to cause ecological harm.

Considering all available lines of evidence presented in this screening assessment, there is a low risk of harm to organisms and the broader integrity of the environment from acetic anhydride. It is concluded that acetic anhydride does not meet the criteria under paragraph 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.

Acetic anhydride is not identified as posing a high hazard to human health on the basis of classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity or reproductive toxicity. Assessment by the Organisation for Economic Co-operation and Development (OECD) Cooperative Chemicals Assessment Programme did not identify effects of concern for human health.

The general population is not expected to be exposed to acetic anhydride via environmental media due to its rapid hydrolysis. Dietary exposure, if any, to acetic anhydride from consuming modified food starches used as food ingredients is expected to be negligible. Exposure from use of products available to consumers is likewise limited. Overall, exposure of the general population to acetic anhydride is expected to be negligible and the potential risk to human health is considered to be low.

On the basis of the information presented in this screening assessment, it is concluded that acetic anhydride 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 acetic anhydride does not meet any of the criteria set out in section 64 of CEPA.

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## 1. Introduction

Pursuant to section 74 of the *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999), the Minister of the Environment and the Minister of Health have conducted a screening assessment of acetic anhydride to determine whether this substance presents or may present a risk to the environment or to human health. This substance was identified as a priority for assessment as it met categorization criteria under subsection 73(1) of CEPA (ECCC, HC [modified 2007]).

Acetic anhydride was reviewed internationally through the Organisation for Economic Co-operation and Development (OECD) Cooperative Chemicals Assessment Programme, and an OECD Screening Information Dataset (SIDS) Initial Assessment Report (SIAR) is available. These assessments undergo rigorous review and endorsement by international governmental authorities. Health Canada and Environment and Climate Change Canada are active participants in this process and consider these assessments reliable. The OECD SIAR is used to inform the health effects characterization in this screening assessment.

The ecological risk of acetic anhydride 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 on the basis of factors including 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 exposure, including additional information submitted by stakeholders. Relevant data were identified up to January 2016. Empirical data from key studies, as well as some results from models, were used to reach the conclusions. When available and relevant, information from other jurisdictions was considered.

This screening assessment was prepared by staff in the CEPA Risk Assessment Program at Health Canada and Environment and Climate Change Canada and incorporates input from other programs within these departments. The draft of this screening assessment (published July 30, 2016) was subject to a 60-day public comment period. The ERC approach (published July 30, 2016) was peer reviewed, and was also subject to a 60-day public comment period.

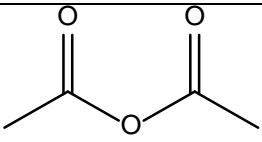
While external comments were taken into consideration, the final content and outcome of the screening assessment remain the responsibility of Environment and Climate Change Canada and Health Canada.

This screening assessment focuses on information critical to determining whether a substance meets the criteria as set out in section 64 of CEPA. Scientific information was examined and a conclusion was developed by incorporating a weight-of-evidence approach and precaution.<sup>1</sup> The screening assessment presents the critical information and considerations that form the basis of the conclusion.

## 2. Substance Identity

The substance acetic acid, anhydride, herein referred to as acetic anhydride, is an organic chemical belonging to a substance class known as anhydrides. The Chemical Abstracts Service Registry Number (CAS RN<sup>2</sup>), *Domestic Substances List* (DSL) name and common name for this substance, as well as additional information regarding substance identity, is presented in Table 2-1.

**Table 2-1. Substance identity for acetic anhydride**

CAS RN	DSL name (common name)	Chemical structure and molecular formula	Molecular weight (g/mol)
108-24-7	Acetic acid, anhydride (acetic anhydride)	 C <sub>4</sub> H <sub>6</sub> O <sub>3</sub>	102.09

<sup>1</sup> A determination of whether one or more of the criteria of section 64 of CEPA are met is on the basis of 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 on the basis of the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

<sup>2</sup> The Chemical Abstracts Service Registry Number (CAS RN) is the property of the American Chemical Society, and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior written permission of the American Chemical Society.

### 3. Physical and Chemical Properties

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

**Table 3-1. Physical and chemical property values for acetic anhydride (at standard temperatures and pressures)**

Property	Value	Type of data	Reference
Melting point (°C)	-73	experimental	Lind 2012
Boiling point (°C)	140	experimental	Lind 2012
Water solubility (mg/L)	$1.2 \times 10^5$	experimental	EPI Suite c2010-2012
Density (g/mL)	1.082	experimental	Lind 2012
Vapour pressure (Pa)	$6.80 \times 10^2$ (5.1 mm Hg)	experimental	Lind 2012
Henry's law constant (Pa m <sup>3</sup> /mol)	3.61	modelled (bond method)	EPI Suite c2010-2012
Henry's law constant (Pa m <sup>3</sup> /mol)	$5.79 \times 10^{-1}$	experimental	EPI Suite c2010-2012
log K <sub>ow</sub> (dimensionless)	-0.58	modelled	EPI Suite c2010-2012
log K <sub>oc</sub> (dimensionless)	0.00	modelled (MCI method)	EPI Suite c2010-2012
log K <sub>oc</sub> (dimensionless)	0.15	modelled (Kow method)	EPI Suite c2010-2012

Abbreviations: K<sub>ow</sub>, octanol–water partition coefficient; K<sub>oc</sub>, organic carbon–water partition coefficient

### 4. Sources and Uses

Acetic anhydride does not occur naturally in the environment.

On the basis of information submitted pursuant to section 71 of CEPA , there were no reports of manufacture above the reporting threshold of 100 kg for acetic anhydride in Canada in 2011. Between 10 000 and 100 000 kg of acetic anhydride was imported into Canada during the same calendar year<sup>3</sup>. (Canada 2012)

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<sup>3</sup> Values reflect quantities reported in response to surveys. See survey for specific inclusions and exclusions (Schedules 2 and 3).



In the United States, the national production volume for acetic anhydride was between 0.45 and 2.27 billion kg (between 1 and 5 billion pounds) for the year 2011 (CDAT [modified 2014]).

In Canada, acetic anhydride is used as an intermediate in the manufacture of other chemicals and products, as a laboratory reagent, and as a plasticizer in commercial building or construction materials (OECD 2002; Sigma-Aldrich 2015; Canada 2012).

Globally, acetic anhydride is an acetylating and dehydrating agent and is used as an intermediate in the manufacture of cellulose acetates.

Acetic anhydride is a Class A precursor for the purposes of the *Controlled Drugs and Substances Act* and the *Precursor Control Regulations* (Canada 2002; Canada 1996).

Additional uses for acetic anhydride are listed in Table 4-1.

**Table 4-1. Additional uses in Canada for acetic anhydride**

Use	Acetic anhydride
Food additive <sup>a</sup>	Y (starch modifying agent)
Food packaging materials <sup>b</sup>	Y (manufacture of paper trays and paper with negligible residual levels in the finished product)
Internal Drug Product Database <sup>c</sup>	N (non-medicinal ingredient, it is not listed in database)
Natural Health Products Ingredients Database <sup>d</sup>	Y (non-medicinal ingredient)
Licensed Natural Health Products Database as medicinal or non-medicinal ingredients	N
List of Prohibited and Restricted Cosmetic Ingredients <sup>f</sup>	N
Reported to be present in cosmetics, on the basis of notifications submitted under the <i>Cosmetic Regulations</i> to Health Canada <sup>g</sup>	N
Formulant in pest control products registered in Canada <sup>h</sup>	Y

Abbreviations: Y, YES; N, NO

<sup>a</sup> Health Canada (modified 2013)

<sup>b</sup> October 2015 email from the Food Directorate, Health Canada, to the Risk Management Bureau, Health Canada; unreferenced

<sup>c</sup> DPD (modified 2015)

<sup>d</sup> NHPID (modified 2016)

<sup>e</sup> LNHPD (modified 2016)

<sup>f</sup> Health Canada (modified 2015)

<sup>g</sup> December 2014 email from the Consumer Product Safety Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada; unreferenced

<sup>h</sup> August 2015 email from the Risk Management Bureau, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada; unreferenced

Acetic anhydride is used in manufacturing certain types of modified food starches (deMan 1999; FCC 2016; JECFA 2014). In Canada, modified food starches are used as food ingredients, and Canada regulates the modifying agents (e.g., acetic anhydride) used in their manufacture as food additives. Acetic anhydride is permitted for this use in Canada at a level consistent with good manufacturing practice (GMP), which is the minimum amount needed to manufacture the modified starch. Food-grade specifications have been established for four modified starches manufactured with acetic anhydride, namely starch acetate, acetylated distarch adipate, acetylated distarch phosphate, and acetylated oxidized starch (FCC 2016; JECFA 2014).

## **5. Potential to Cause Ecological Harm**

### **5.1 Characterization of Ecological Risk**

The ecological risk of acetic anhydride was 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 and exposure on the basis of 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<sub>50</sub>) 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 they 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 primarily 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 and 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 on the basis of 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 in 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 value used for critical body residue (CBR) analysis. Error of underestimation of acute toxicity will be 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 on the basis of 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 acetic anhydride and the hazard, exposure and risk classification results are presented in ECCC (2016b).

Owing to low hazard and exposure classifications according to ERC for acetic anhydride, this substance was classified as having a low potential for ecological risk. It 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

Acetic anhydride is mainly used as an intermediate in the manufacture of other chemicals and products, including certain silicone sealants. General population exposure to acetic anhydride in the environment is not expected as it is readily hydrolyzed to acetic acid, which is normally present in the environment. As such, exposure of the general population to acetic anhydride through environmental media is not expected.

In the manufacture of modified food starches, acetic anhydride reacts with the starch in a substitution reaction that replaces hydroxyl groups on the starch with acetyl esters (deMan 1999; JECFA 2014). Recognized food-grade specifications for modified food starches limit the amount of introduced acetyl groups to 2.5% (FCC 2016; JECFA 2014), and Canada restricts the amount of acetic anhydride that is used to the minimum amount that is needed to make the desired modified starch (i.e., a level consistent with good manufacturing practice). For these reasons, as well as the fact that acetic anhydride will be consumed in the substitution reaction and that modified food starch is used as a food ingredient and is not consumed directly, the dietary exposure, if any, to acetic anhydride as a result of this permitted food additive use is likely to be negligible (personal communication, email from Food Directorate, Health Canada, to Existing Substances Risk Assessment Bureau, Health Canada, dated July 6, 2016; unreferenced).

Acetic anhydride is also used in the manufacture of paper trays and paper for food packaging. However, exposure of the general population is not expected due to negligible residual levels in the finished packaging materials (personal communication, email from Food Directorate, Health Canada, to Risk Management Bureau, Health Canada, dated October 9, 2015; unreferenced).

Acetic anhydride is used as a non-medicinal ingredient in three prescription drugs (personal communication, email from Risk Management Bureau, Health Canada, to Existing Substances Risk Assessment Bureau, Health Canada, dated October 13, 2015; unreferenced). Given the low quantities (< 3 kg/year) in reported sales data for Canadian hospitals and pharmacies (IMS 2013) and the rapid hydrolysis of acetic anhydride, exposure from use of prescription drugs is expected to be limited. Although it is listed as a non-medicinal ingredient in the Natural Health Products Ingredients Database, acetic anhydride is not currently found in any licensed natural health products.

According to information in publicly available Material Safety Data Sheets (MSDSs), acetic anhydride may be present in certain silicone sealants in low concentrations ( $\leq$  0.1%) as a residual (MSDS 2015a; MSDS 2015b). Some of these silicone sealants are available to consumers as do-it-yourself products, with suggested applications in

residential kitchens or bathrooms. Due to the low concentration of acetic anhydride and the limited nature of its use, general population exposure to acetic anhydride from products available to consumers is expected to be minimal.

In summary, exposure of the general population to acetic anhydride through environmental media, food and products available to consumers is expected to be negligible.

## **6.2 Health Effects Assessment**

Acetic anhydride has been previously reviewed (OECD 2002), and that review was used to inform the health effects characterization in this assessment. Acetic anhydride was not identified as posing a high hazard to human health on the basis of classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity or reproductive toxicity. It is also not on the European Chemicals Agency's Candidate List of Substances of Very High Concern for Authorisation (ECHA [modified 2015]).

The critical effects for acetic anhydride are irritancy and corrosivity at the site of contact. In animals and humans, acetic anhydride is known to be highly corrosive to the respiratory and gastrointestinal tracts, but generally only at high concentration (OECD 2002). Other health effects were not observed following repeated exposure by the inhalation route, and there are no repeated-dose studies for acetic anhydride following oral or dermal exposure (OECD 2002). The reported health effects of acetic acid (the primary metabolite of acetic anhydride) were also primarily site-of-contact effects (generally at high concentrations) or were secondary to the corrosive nature of the substance (AGDH 2013). OECD (2002) did not identify any concerns for carcinogenicity, genotoxicity, developmental or reproductive toxicity.

## **6.3 Characterization of Risk to Human Health**

Acetic anhydride is an industrial chemical that is used primarily as an intermediate in the manufacture of other chemicals and products. Releases of acetic anhydride to the environment are expected to be minimal due to hydrolysis to acetic acid; consequently, no exposure to acetic anhydride is expected for the general population via environmental media. Dietary exposure, if any, to acetic anhydride from consuming modified food starches used as food ingredients is expected to be negligible. Exposure is also not expected from acetic anhydride in food packaging due to negligible residual levels in the packaging material. It is not expected to be a significant source of exposure to the general population as a non-medicinal ingredient in prescription drugs or as a residual in certain silicone sealants. Overall exposure of the general population to acetic anhydride is expected to be negligible, and the potential risk to human health is considered to be low.

## 6.4 Uncertainties in Evaluation of Risk to Human Health

Although there are some uncertainties in the health effects database (e.g., no repeated exposure studies by the oral and dermal routes) and some limitations in the exposure databases (e.g., no environmental monitoring), given that the sources, uses, and properties of acetic anhydride are well characterized, a qualitative approach to risk characterization is considered appropriate for this assessment.

## 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 acetic anhydride. It is concluded that acetic anhydride 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 acetic anhydride 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 acetic anhydride does not meet any of the criteria set out in section 64 of CEPA.

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