



Government
of Canada

Gouvernement
du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

Propane, 2-nitro-

(2-Nitropropane)

Chemical Abstracts Service Registry Number (CAS RN):
79-46-9

Environment Canada
Health Canada

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Canada

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This proposed risk management approach document builds on the previously released risk management scope document for Propane, 2-nitro-, and outlines the proposed control actions for this substance. Stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Following this consultation period, the Government of Canada will initiate the development of the specific risk management instrument(s) where necessary. Comments received on the proposed risk management approach will be taken into consideration in developing the instrument(s). Consultation will also take place as instrument(s) are developed.

SUMMARY OF RISK MANAGEMENT

1. The Government of Canada plans to implement Significant New Activity provisions under CEPA 1999 to this substance.
2. The Government of Canada will consider delisting Propane, 2-nitro- from table XV, Division 16 (Food Additives) of the *Food and Drug Regulations*.

Note: This summary is an abridged list of the instruments and tools proposed to risk manage this substance. Please see section 9.1 of this document for a complete explanation of risk management.

1. ISSUE

1.1 Categorization and the Challenge to Industry and Other Interested Stakeholders

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health (the Ministers) to categorize substances on the *Domestic Substances List* (DSL). Categorization involves identifying those substances on the DSL that a) are considered to be persistent (P) and/or bioaccumulative (B), based on the criteria set out in the *Persistence and Bioaccumulation Regulations* (Canada, 2000), and “inherently toxic” (iT) to humans or other organisms; or b) present, to individuals in Canada, the greatest potential for exposure (GPE). In addition, the Act requires the Ministers to conduct screening assessments of substances that meet the categorization criteria. The assessment further determines whether the substance meets one or more of the criteria set out in section 64 of the Act.¹

¹ A determination of whether one or more of the criteria of section 64 are met and whether risk management may be required is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes exposures from ambient and indoor air, drinking water, foodstuffs and the use of consumer products. A conclusion under CEPA 1999 on the substances in the Chemicals Management Plan (CMP) Challenge Batches 1–12 is not relevant to nor does it preclude an assessment against the hazard criteria specified in the Workplace Hazardous Materials Information System [WHMIS] *Controlled Products Regulations* for products intended for workplace use.

In December 2006, the Challenge identified 193 chemical substances through categorization which became high priorities for assessment due to their hazardous properties and their potential to pose risks to human health and the environment. In February 2007, the Ministers began publishing, for industry and stakeholder comment, profiles of batches containing 12 to 19 high-priority substances. New batches are released for comment every three months.

In addition, the information-gathering authority in section 71 of CEPA 1999 is being used under the Challenge to gather specific information where it is required. The information that is collected through the Challenge will be used to make informed decisions and appropriately manage any risks that may be associated with these substances.

The substance Propane, 2-nitro-, Chemical Abstracts Service Registry Number (CAS RN)² 79-46-9, referred to throughout this document as “2-nitropropane,” is included in Batch 8 of the Challenge under the Chemicals Management Plan (Canada 2010).

1.2 Final Screening Assessment Report Conclusion for 2-nitropropane

A notice summarizing the scientific considerations of a final screening assessment report was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, for 2-nitropropane on July 31, 2010, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that 2-nitropropane is entering or may be entering the environment in a quantity or a concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

The final screening assessment report also concluded that 2-nitropropane does not meet the criteria for persistence and does not meet the criteria for bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA 1999. The presence of 2-nitropropane in the environment results primarily from human activity.

For further information on the final screening assessment report conclusion for 2-nitropropane, refer to the final screening assessment report, available at <http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-8/index-eng.php>.

1.3 Proposed Measure

As a result of a screening assessment of a substance under section 74 of CEPA 1999, the substance may be found to meet one or more of the criteria under section 64 of CEPA 1999. The Ministers can propose to take no further action with respect to the substance, add the substance to the Priority Substances List (PSL) for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act. Under certain circumstances,

² CAS RN: Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information 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.

the Ministers must make a specific proposal to recommend the implementation of virtual elimination. In this case, the Minister proposed to recommend the addition of 2-nitropropane to Schedule 1. As a result, the Ministers will develop a regulation or instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to this substance.

The final screening assessment report did not conclude that 2-nitropropane meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, 2-nitropropane will not be subject to the virtual elimination provisions under CEPA 1999 and will be managed using a life-cycle approach.

2. BACKGROUND

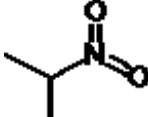
2.1 Substance Information

2-Nitropropane is part of the chemical grouping discrete organics and the chemical sub-grouping nitro compounds.

Table 1 presents other names, trade names, chemical groupings, the chemical formula, the chemical structure and the molecular mass for 2-nitropropane.

Table 1 Identity of 2-nitropropane

Chemical Abstracts Service Registry Number (CAS RN)	79-46-9
DSL name	Propane, 2-nitro-
National Chemical Inventories (NCI) names¹	<i>Dimethylnitromethane</i> <i>Isonitropropane</i> <i>1-Methylnitroethane</i> <i>2-Nitropropane</i> (ECL, EINECS, ENCS) sec-Nitropropane 2-NP NSC 5369 Propane, 2-nitro- (AICS, ASIA-PAC, NZIoC, PICCS, SWISS, TSCA) <i>UN 2608</i> <i>UN 2608 (DOT)</i>
Other names	<i>Nitroisopropane</i> <i>beta-Nitropropane</i>
Chemical group (DSL stream)	Discrete organics
Major chemical class or use	Low molecular weight hydrocarbons
Major chemical sub-class	Nitro compounds
Chemical formula	C ₃ H ₇ NO ₂

Chemical structure	
SMILES²	N(=O)(=O)C(C)C
Molecular mass	89.1 g/mol

¹. National Chemical Inventories (NCI). 2009: AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Asia-Pacific Substances Lists); ECL (Korean Existing Chemicals List); EINECS (European Inventory of Existing Commercial Chemical Substances); ENCS (Japanese Existing and New Chemical Substances); NZIoC (New Zealand Inventory of Chemicals); PICCS (Philippine Inventory of Chemicals and Chemical Substances); SWISS (Swiss Giftlist 1 and Inventory of Notified New Substances); TSCA (Toxic Substances Control Act Chemical Substance Inventory).

². Simplified Molecular Input Line Entry System

3. WHY WE NEED ACTION

3.1 Characterization of Risk

Evaluation of risk to human health involves consideration of data relevant to the estimation of exposure (non-occupational) of the general population, as well as information on health hazards.

Based principally on the weight-of-evidence assessments of international and other national agencies (International Agency for Research on Cancer, the European Commission and the U.S. National Toxicology Program), a critical effect for characterization of risk to human health for 2-nitropropane is carcinogenicity. Increased incidences of liver tumours were observed in experimental animals from various studies. 2-Nitropropane induced benign and malignant liver tumours in rats in a 16-week oral study. Multiple hepatocellular carcinomas were observed in rats exposed to 2-nitropropane via inhalation for 6 months. Metastases were also observed in the lungs of exposed animals. In addition, 2-nitropropane showed initiating activity in rat liver following intraperitoneal injection or inhalation exposure.

In light of the clear evidence in the *in vitro* and *in vivo* genotoxicity assays in the liver of rats, where 2-nitropropane causes tumours, and the evidence that the underlying mechanisms of the genotoxicity of 2-nitropropane in rodent cells and in human cells are apparently identical, it cannot be precluded that 2-nitropropane induces tumours via a mode of action involving direct interaction with genetic material both in experimental animals and in humans.

With respect to non-cancer effects, the lowest lowest-observed-adverse-effect level (LOAEL) for oral exposure to 2-nitropropane was 26 mg/kg-bw (milligrams per kilogram body weight) per day, based on increased hepatic lipid peroxidation, oxidative DNA damage and cell proliferation in the liver of rats in a 2-week study. Comparison of this effect level with the estimated intake from vegetable fats and oils for children aged 6–8 (0.0078 µg/kg-bw per day) results in a predicted margin of exposure of approximately 3.3×10^6 . This margin is considered to be adequately protective against the induction of non-cancer effects in the general population in Canada in light of the very conservative nature of the exposure estimate.

Cigarette smoke represents a significant source of exposure to 2-nitropropane. Although smoking does not provide an appropriate basis on which to assess the risk to the general population, the additional intake of 2-nitropropane as a result of exposure to cigarette smoke would further reduce the margin of exposure for non-cancer effects.

4. CURRENT USES AND INDUSTRIAL SECTORS

According to data submitted in response to section 71 of CEPA 1999, no companies in Canada reported manufacturing 2-nitropropane in a quantity greater than or equal to the threshold of 100 kg for the 2006 calendar year. Information received from Canadian companies indicated that 100-1000 kg of the substance were imported into Canada in 2006 (Environment Canada 2008). One submitter, a waste management company, indicated the importation of 2-nitropropane in 2006 for consolidation and incineration at a hazardous waste facility.

The information provided by industry indicates no domestic manufacture of this substance and importation of only small quantities (100–1000 kg). However, 2-nitropropane may be entering Canada in formulated products including inks, paints, adhesives, varnishes, polymers and synthetic materials (NTP 2005), that may not be captured under section 71 reports.

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

2-Nitropropane is a core substance reportable under the National Pollutant Release Inventory (NPRI) program, meaning that any facility meeting the reporting criteria that has manufactured, processed or otherwise used more than 10 tonnes of material containing greater than 0.1% 2-nitropropane is required to report. No domestic releases were reported to the NPRI between 1997 and 2007 (the most recent data available). In 1994, 1995 and 1996, an Ontario based company, reported total on-site releases of 0.125 tonne/year; the medium of release was not specified (NPRI 2007). Additionally, no releases to the environment were reported for 2006 under section 71 of CEPA 1999 (Environment Canada 2008).

The Great Lakes Commission, representing the Province of Ontario and the eight Great Lakes states, publishes annual reports on toxic air emissions in the Great Lakes region. Total estimated releases of 2-nitropropane to air in the region in 2001 and 2002 were 71.7 kg and 83.0 kg, respectively. Ontario's contribution to these release estimates was approximately 10.4 kg in 2001 and 11.3 kg in 2002 (GLC 2004, 2006). Release estimates in Ontario are based on two sources: a per capita emission factor intended to address releases of solvents from consumer and commercial use of adhesives and sealants, and an emission factor for wastewater treatment. Both emission factors are derived from guidance published by the U.S. EPA (2009 personal communication from Ontario Ministry of the Environment to Risk Assessment Bureau, Health Canada; unreferenced).

2-Nitropropane is identified as a high production volume chemical in the United States. Quantity information submitted under the Inventory Update Reporting system in the United States

indicates that between 4.5 million and 22.7 million kilograms of the chemical were produced or imported in 2002; however, 2-nitropropane does not appear in the non-confidential 2006 Inventory Update Report (US EPA 2009). In the United States, the Toxics Release Inventory (TRI) database indicates on-site releases from eight facilities totalling 11 725 kg in 2007. The manufacturing facility in Sterlington, Louisiana, accounts for more than 96% of the total releases (TRI 2009).

5.2 Exposure Sources

Evaluation of risk to human health involves consideration of data relevant to the estimation of exposure (non-occupational) of the general population, as well as information on health hazards. The two most significant sources of potential exposure include the inhalation of tobacco smoke and the possibility of ingesting vegetable oils containing residual concentrations of the substance.

In an investigation of tobacco smoke composition, Hoffman and Rathkamp (1968) reported concentrations of 2-nitropropane of 1.1 to 1.2 μg in the smoke from one 85-mm USA-blended unfiltered cigarette. The authors suggested that production of nitroaliphatic substances such as 2-nitropropane is a result of the interaction between hydrocarbons and nitrogen dioxide in the combustion zone. Based on a review of the available literature (Hoffman and Rathkamp 1968; Hoffman and Hoffman 1997; Hoffman et al. 2001; Rodgman 2003; Gaworski et al. 2008; Patskan et al. 2008), 1.2 μg /cigarette was deemed to be a reasonable worst-case estimate of 2 nitropropane emissions in mainstream smoke, as it was obtained from a study of United States blended, unfiltered cigarettes. Using the mean smoking frequency data collected through the Canadian Tobacco Use Monitoring Survey (CTUMS 2008), the estimated exposure of smoking youths (aged 15–19; 12.2 cigarettes/day), young adults (aged 20–24; 12.2 cigarettes/day) and adults (aged > 25; 14.9 cigarettes/day) to 2-nitropropane in Canada is predicted to be 0.25, 0.21 and 0.25 $\mu\text{g}/\text{kg-bw}$ per day, respectively (see Appendix 2 of the screening assessment report). Cigarette smoke represents a significant source of exposure to 2-nitropropane. Although smoking does not provide an appropriate basis on which to assess the risk to the general population, the additional intake of 2-nitropropane as a result of exposure to cigarette smoke would further reduce the margin of exposure for non-cancer effects.

The next most significant source is possibly the ingestion of vegetable oil that may contain residual concentrations of this substance. In Canada, 2-nitropropane is permitted for use as a carrier or extraction solvent for vegetable oils, with a maximum residue level of up to 0.5 mg/kg (0.5 ppm) of 2-nitropropane. However, because industry stakeholders have indicated that it is no longer used for this purpose in North America, exposure estimates based on the permitted maximum residue specified in the *Food and Drug Regulations* were not generated (2009 personal communication from Food Directorate, Health Canada, to Risk Assessment Bureau, Health Canada; unreferenced). Indeed, the use of 2-nitropropane as a food processing solvent is also discouraged internationally. Nonetheless, to account for the possibility that 2-nitropropane may be present in vegetable oils imported into Canada, an assessment of the potential exposure from vegetable fats and oils was conducted. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has previously characterized the potential exposure associated with consumption of vegetable oil processed with 2-nitropropane. At its 35th meeting in 1989, the

JECFA noted that procedures used at that time for the processing of fats and oils with 2-nitropropane did not lead to detectable levels of this substance in the finished product, and thus their assessment was based on the assumption that all oil may contain 2-nitropropane at the detection limit of 10 µg/kg (10 ppb) (WHO 1990). It was very conservatively assumed that all vegetable fats and oils from all food sources ingested by Canadians may contain this concentration of 2-nitropropane. The estimated intake from vegetable fats and oils for children aged 6–8 (0.0078 µg/kg-bw per day) results in a predicted margin of exposure of approximately 3.3×10^6 . This margin is considered to be adequately protective against the induction of non-cancer effects in the general population in Canada in light of the very conservative nature of the exposure estimate.

Other Potential Sources of Exposure.

2-Nitropropane has been reported to be used in printing inks for flexible food packaging, as a solvent in coatings for beer and beverage cans, and in film laminating adhesives (WHO 1992; NTP 2005). However, there have been no recent food packaging submissions received by Health Canada's Food Directorate that include the use of 2-nitropropane. It is therefore likely that 2-nitropropane has been replaced by other alternative solvents in food packaging applications (2009 personal communication from Food Directorate, Health Canada, to Risk Assessment Bureau, Health Canada; unreferenced). Consequently, no exposure scenario was generated for food packaging applications of 2-nitropropane.

In Canada, 2-nitropropane is not listed in the Drug Product Database (DPD), the Therapeutic Products Directorate's internal Non-Medicinal Ingredients Database, the Natural Health Products Ingredients Database (NHPID) or the Licensed Natural Health Products Database (LNHPD) as a medicinal or non-medicinal ingredient present in final pharmaceutical products, natural health products or veterinary drugs manufactured in Canada. As 2-nitropropane is marketed as a chemical intermediate for pharmaceutical synthesis (ANGUS 2009), it may be present in trace amounts in pharmaceuticals. No information was identified on what products, if any, might contain residual concentrations of 2-nitropropane. The International Conference on Harmonization Guideline Q3C (R4) (ICH 2009) for residual solvents, which has been adopted by the Therapeutic Products Directorate, the Natural Health Products Directorate and the Veterinary Drugs Directorate, does not specify solvent residue limits specific for 2-nitropropane.

A potential source of consumer product exposure considered was the use of 2-nitropropane in paints and coatings. Bollmeier (2000) suggests that use of 2-nitropropane in these applications has largely been eliminated. In a search of the publicly available literature, products identified as containing 2-nitropropane were intended for industrial applications.

2-Nitropropane may enter the environment as a result of anthropogenic activities. The role natural processes might play in the formation of 2-nitropropane is unclear. The substance may be formed during the combustion of nitrogen-rich organic material, as is the case with cigarette smoke (Hoffman and Rathkamp 1968); however, no studies characterizing this potential exposure source were identified.

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

2-Nitropropane is subject to the following risk management:

- the *Food and Drug Regulations*, Division 16 (Food Additives), where it is permitted for use as a carrier or extraction solvent for vegetable oils, with a maximum residue level of up to 0.5 mg/kg (0.5 ppm) of 2-nitropropane (Canada 1985)
- the *Food and Drug Regulations*, Division 23, which controls the safety of all materials used for packaging foods
- reporting under the National Pollutant Release Inventory (NPRI 2007)
- the *Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations* (SOR/2005-149) under CEPA 1999

6.2 Existing International Risk Management

In 1989, the Joint FAO/WHO Expert Committee on Food Additives (JECFA), at its 35th meeting, decided that its previous temporary acceptance of 2-nitropropane as a fractionating solvent in the production of fats and oils should not be extended (WHO 1990).

In the European Union, 2-nitropropane is listed on Annex II (List of Substances Prohibited in Cosmetic Products) under Regulation (EC) No 1223/2009 of the European Parliament and of the Council of November 30, 2009, on cosmetic products.

2-Nitropropane is approved in the United States for use in food packaging adhesives under 21CFR 175.105. (US FDA 2009)

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

It is likely that 2-nitropropane has been replaced by other alternative solvents in food packaging applications (2009 personal communication from Food Directorate, Health Canada, to Risk Assessment Bureau, Health Canada; unreferenced).

Based on recent discussions that Health Canada has had with its stakeholders, 2-nitropropane is not used in vegetable oil processing in North America and, indeed, its use as a food processing solvent is discouraged internationally.

It is important to note that substitutes may not have undergone an assessment to determine whether they meet the criteria under section 64 of CEPA 1999.

7.2 Alternative Technologies and/or Techniques

No alternative technologies and/or techniques were identified that would minimize or eliminate the use and/or release of the substance.

7.3 Socio-economic Considerations

Socio-economic factors will be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Streamlining Regulation* (TBS 2007) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action*.

7.4 Children's Exposure

The Government of Canada considered, where available, risk assessment information relevant to children's exposure to this substance. As part of the Challenge, the Government asked industry and interested stakeholders to submit any information on the substance that may be used to inform risk assessment, risk management and product stewardship. In particular, stakeholders were asked through a questionnaire if any of the products containing the substance were intended for use by children. Given the information received, it is proposed that no risk management actions to specifically protect children are required for this substance at this time.

8. PROPOSED OBJECTIVES

8.1 Environmental or Human Health Objective

An environmental or human health objective is a quantitative or qualitative statement of what should be achieved to address environmental or human health concerns identified during a risk assessment.

The proposed human health objective for 2-nitropropane is to minimize human exposure to the greatest extent practicable.

8.2 Risk Management Objective

A risk management objective is a target expected to be achieved for a given substance by the implementation of risk management regulations, instrument(s) and/or tool(s).

The proposed risk management objective for 2-nitropropane is to prevent exposure to the Canadian population from increasing.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management Tool and Regulation

As required by the Government of Canada's *Cabinet Directive on Streamlining Regulation*³ and criteria identified in the Treasury Board document entitled *Assessing, Selecting, and Implementing Instruments for Government Action*, the proposed risk management tool and regulation were selected using a consistent approach, and took into consideration the information that was received through the Challenge and other information available at the time.

The principal focus of risk management actions is to address the prioritized sources.

In order to achieve the risk management objective and to work towards achieving the environmental or human health objective(s), the risk management being considered for 2-nitropropane includes the following measures: **(1) The Government of Canada plans to implement Significant New Activity provisions under CEPA 1999 to this substance.** This would require that any proposed new manufacture, import or use be subject to further assessment, and would determine if the new activity requires further risk management consideration. **(2) The Government of Canada will consider delisting 2-nitropropane from table XV, Division 16 (Food Additives) of the *Food and Drug Regulations*** so that the potential for exposure to the Canadian population does not substantially increase.

9.2 Implementation Plan

The proposed regulation or instrument respecting preventative or control actions in relation to 2-nitropropane will be published in the *Canada Gazette*, Part I, no later than July 2012.

³ Section 4.4 of the *Cabinet Directive on Streamlining Regulation* states that "Departments and agencies are to: identify the appropriate instrument or mix of instruments, including regulatory and non-regulatory measures, and justify their application before submitting a regulatory proposal".

10. CONSULTATION APPROACH

The risk management scope for 2-nitropropane, which summarized the proposed risk management under consideration at that time, was published on January 30, 2010. Industry and other interested stakeholders were invited to submit comments on the risk management scope during a 60-day comment period. Comments received on the risk management scope document were taken into consideration in the development of this proposed risk management approach document.

Consultation for the proposed risk management approach document will involve publication on July 31, 2010, and a 60-day public comment period.

The primary stakeholders include

- the food sector
- the paint and coating sector
- Health Canada and Environment Canada

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on proposed risk management approach document	July 31, 2010 to September 29, 2010
Response to comments on the proposed risk management approach document	No later than at the time of publication of the proposed instrument
Consultation on the draft instrument	Spring/summer 2011
Publication of the proposed instrument	No later than July 2012
Formal public comment period on the proposed instrument	No later than fall 2012
Publication of the final instrument	No later than January 2014

Industry and other interested stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Please submit comments prior to September 29, 2010, since the risk management of 2-nitropropane will be moving forward after this date. During the development of regulations, instrument(s) and/or tool(s), there will be opportunity for consultation. Comments and information submissions on the proposed risk management approach should be submitted to the address provided below:

Chemicals Management Division
Gatineau (QC) K1A 0H3
Tel: 1-888-228-0530 / 819-956-9313
Fax: 819-953-7155
Email: Existing.Substances.Existantes@ec.gc.ca

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