



Government
of Canada

Gouvernement
du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

Benzene, 1-methyl-2-nitro

(2-Nitrotoluene)

Chemical Abstracts Service Registry Number (CAS RN):
88-72-2

Environment Canada
Health Canada

July 2010

CanadaThe wordmark for Canada, with a small red maple leaf icon integrated into the letter 'a'.

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This proposed risk management approach document builds on the previously released risk management scope document for 2-nitrotoluene 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

The Government of Canada plans to implement Significant New Activity provisions under CEPA 1999 to this substance.

Note: This summary is an abridged list of the 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

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

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.

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 Benzene, 1-methyl-2-nitro, Chemical Abstracts Service Registry Number (CAS RN)² 88-72-2, referred to throughout this document as “2-nitrotoluene,” is included in Batch 8 of the Challenge under the Chemicals Management Plan.

1.2 Final Screening Assessment Report Conclusion for 2-nitrotoluene

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-nitrotoluene on July 31, 2010, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that on the basis of the carcinogenic potential of 2-nitrotoluene, for which there may be a probability of harm at any exposure level, 2-nitrotoluene is a substance that is entering or may be 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.

The final screening assessment report also concluded that 2-nitrotoluene meets 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-nitrotoluene in the environment results primarily from human activity.

For further information on the final screening assessment report conclusion for 2-nitrotoluene, 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, 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-nitrotoluene to Schedule 1. As a result, the Ministers will develop a regulation or instrument respecting

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.

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-nitrotoluene meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, 2-nitrotoluene will not be subject to the virtual elimination provisions under CEPA 1999 and will be managed using a life-cycle approach, to prevent or minimize its release into the environment.

2. BACKGROUND

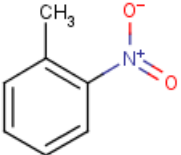
2.1 Substance Information

2-Nitrotoluene is part of the chemical grouping discrete organics and the chemical sub grouping benzene compounds, or more specifically, nitrobenzenes.

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

Table 1. Identity of 2-nitrotoluene

Chemical Abstracts Service Registry Number (CAS RN)	88-72-2
DSL name	Benzene, 1-methyl-2-nitro-
National Chemical Inventories (NCI) names¹	<i>Benzene, 1-methyl-2-nitro-</i> (AICS, ASIA-PAC, ENCS, NZIoC, PICCS, SWISS, TSCA) <i>1-Methyl-2-nitrobenzene</i> (ECL) <i>2-Nitrotoluene</i> (EINECS) <i>o-Nitrotoluene</i> (PICCS) <i>Toluene, 2-nitro-</i> (PICCS)
Other names	<i>Benzene, 1-methyl-2-nitro;</i> <i>2-Methyl-1-nitrobenzene;</i> <i>2-Methylnitrobenzene;</i> <i>1,2-Methylnitrobenzol;</i> <i>1-Methyl-2-nitrobenzol;</i> <i>2-Methylnitrobenzol;</i> <i>alpha-Methylnitrobenzene;</i> <i>o-Methylnitrobenzene;</i> <i>o-Methylnitrobenzol;</i> <i>o-Mononitrotoluene;</i> <i>Mononitrotoluole;</i> <i>2-Nitro-1-methyl-benzol;</i> <i>2-Nitro-1-methylbenzol;</i> <i>o-Nitrotoluene;</i> <i>2-Nitrotoluol;</i> <i>o-Nitrotoluol;</i> <i>o-Nitrotoluol D;</i> <i>NSC 9577;</i> <i>ONT;</i> <i>UN 1664 (DOT)</i> ²
Chemical group (DSL stream)	Discrete organics
Major chemical class or use	Benzene compounds
Major chemical sub-class	Nitrobenzenes
Chemical formula	C ₇ H ₇ NO ₂

Chemical structure	
SMILES³	O=[N+]([O-])c1ccccc1C
Molecular mass	137.14 g/mol

¹. National Chemical Inventories (NCI). 2007: 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 Giftliste 1 and Inventory of Notified New Substances); TSCA (Toxic Substances Control Act Chemical Substance Inventory).

². U.S. Department of Transportation

³. Simplified Molecular Input Line Entry System

3. WHY WE NEED ACTION

3.1 Characterization of Risk

As 2-nitrotoluene was classified on the basis of carcinogenicity by other national and international agencies (e.g., European Commission and National Toxicology Program), carcinogenicity was a key focus for the screening assessment. An increased incidence of tumours was reported in multiple tissues, such as the mesothelium, skin, mammary gland, liver or lungs, in rats exposed in the diet. Tumours in the circulatory system, large intestine and liver were reported in mice exposed via the dietary route. Furthermore, 2-nitrotoluene has been reported to be a weak skin tumour initiator in the mouse skin painting model. 2-Nitrotoluene was genotoxic in a range of *in vitro* and *in vivo* assays, was notably clastogenic in human peripheral lymphocytes, and formed DNA adducts in exposed rodents. Although the mode of induction of tumours has not been fully elucidated, based on the genotoxicity of 2-nitrotoluene, the tumours observed in the experimental animals are considered to have resulted from direct interaction with genetic material. (Canada 2010)

Exposure to 2-nitrotoluene has also been associated with a range of non-cancer effects in experimental animals. Non-neoplastic lesions in multiple target tissues have been observed in rats chronically exposed to relatively low doses of 2-nitrotoluene. A dose of 25 mg/kg-bw (milligram per kilogram body weight) per day was the lowest dose tested in these studies. At the same dose and under the same exposure conditions, reproductive changes, such as atrophy of the germinal epithelium and interstitial cell hyperplasia of the testes, were observed in male rats. The most sensitive non-cancer effects occurred at 25 mg/kg-bw per day. Margins of exposure were not calculated for non-cancer effects in this assessment since non-cancer effects occurred at a dose level at which tumours were observed and because the available information indicates that exposures to 2-nitrotoluene in the Canadian general population from either environmental media or consumer products is expected to be negligible (Canada 2010).

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.

4. CURRENT USES AND INDUSTRIAL SECTORS

According to submissions made under section 71 of CEPA 1999 and from the Challenge questionnaire submissions (Canada 2010), only 100–1000 kilograms of 2-nitrotoluene were imported and used in Canada in 2006. The majority of 2-nitrotoluene currently used in Canada is for the manufacturing of explosives (Canada 2010). 2-Nitrotoluene uses in Canada are expected to be limited to this industrial application.

Previously received information from the DSL nomination (1984–1986) showed that the total quantity of 2-nitrotoluene (as imported, manufactured, or in commerce) in Canada during the 1986 calendar year was 10 000 000–100 000 000 kg (Canada 1988). The amount of 2-nitrotoluene in commerce in Canada has decreased significantly since that time.

The use of 2-nitrotoluene for the manufacture of explosives, such as dinitrotoluene and trinitrotoluene (TNT), has also been reported outside of Canada (EURAR 2008). Other possible 2-nitrotoluene uses have not been identified or are no longer practiced in Canada.

It should also be noted that in Canada, there are no registered pesticides that contain this substance either as an active ingredient or a formulant. When judging the current risks to human health arising from indirect exposure to 2 nitrotoluene via the environment, concern is considered to be very low (EURAR 2008).

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

2-Nitrotoluene is an anthropogenic substance and does not occur naturally in the environment (IARC 1996). Environmental releases are not reportable to the National Pollutant Release Inventory (NPRI 2007) in Canada or to the Toxics Release Inventory Program (TRI 2006) in the United States. Therefore, no release information is available from these sources. Additionally, based on the section 71 information received, there were no reported releases to environmental media in Canada.

5.2 Exposure Sources

Monitoring data indicate that the only identifiable routes of exposure to the general population would be via inhalation of ambient air and ingestion of drinking water in the vicinity of production sites (HSDB 2010). No such facilities have been identified in Canada.

Exposure to Canadians from consumer products is not expected. 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.

Outside of Canada, 2-nitrotoluene is predominantly used in the production of intermediates such as o-toluidine (EURAR 2008). These intermediates are used primarily in the manufacture of dyestuffs but may also be used in the production of rubber, other chemicals and pesticides, and as a curing agent for epoxy resin systems (OECD 1994; INCHEM 2009). European production of 2 nitrotoluene has decreased significantly since the 1980s due to decreasing market demands (EURAR 2008).

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

Federal:

- 2-Nitrotoluene is listed on the *Regulations for the Prevention of Pollution from Ships and for Dangerous Chemicals* (SOR/2007-86) as part of the *Canada Shipping Act, 2001* (Canada 2009).
- Nitrotoluenes (all isomers including 2-nitrotoluene) are dangerous goods and are listed in Schedule 1 of the *Transportation of Dangerous Goods Regulations* (Canada 2008).

Provincial:

- 2-Nitrotoluene is listed in Section 1 of the *Contaminated Sites Regulation, B.C. Reg. 375/96*, as part of the *Environmental Management Act*, where quantities and concentrations must meet certain environmental standards (British Columbia 2009).
- 2-Nitrotoluene is listed on Ontario's Jurisdictional Screening Level list, developed by the Ministry of the Environment to provide an additional screening tool for *Ontario Regulation 419: Air Pollution – Local Air Quality* (Ontario 2008).

6.2 Existing International Risk Management

- In the European Union, 2-nitrotoluene is listed on Annex II (List of Substances Prohibited in Cosmetic Products) under the *Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products* (European Commission 2005).
- The United States Environmental Protection Agency lists 2-nitrotoluene as a hazardous substance, which is reportable at quantities exceeding 454 kg under part 302 of the *Comprehensive Environmental Response, Compensation, and Liability Act* (CERCLA). CERCLA provides broad federal authority to respond directly to releases or threatened releases of hazardous substances that may endanger public health or the environment (USA 2008).
- 2-Nitrotoluene is subject to subchapter D, Development of protective concentration levels, under Chapter 350 – Texas Risk Reduction Program from the Texas Commission on Environmental Quality (TEXAS 2009).
- 2-Nitrotoluene was added, in 1998, to *Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986*, as a chemical known to the state to cause cancer (California 2006).

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

No information on potential substitutes for 2-nitrotoluene was brought forward in the voluntary Challenge Questionnaire submissions or during the public comment period on the Risk Management Scope document.

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*.

No production of 2-nitrotoluene occurred in Canada in 2006. In Europe, the number of producers of 2-nitrotoluene has decreased in the last years, and the use pattern has changed due to fluctuations in the demand for 2-nitrotoluene (EURAR 2008). 2-Nitrotoluene is used in the manufacturing of explosives (NAICS 32592 – Explosives Manufacturing).

The Canadian explosives manufacturing industry comprises enterprises primarily engaged in the manufacturing of explosive preparations, detonators for explosives, and explosive devices, except ammunition. Examples of final products include azides explosive materials, blasting accessories (for example, blasting caps, fuses, igniters, squibs), blasting powders, caps (blasting and detonating), detonators (except ammunition), dynamite, fuses (detonating and safety), gunpowder, nitroglycerin explosives and TNT (trinitrotoluene) (Industry Canada 2010).

In 2008, there were 28 establishments in the Canadian explosives manufacturing industry. The number of establishments in the industry fluctuated between 20 and 40 establishments over the 1998–2008 period, reaching a high of 40 establishments in 2004. The Canadian industry is composed primarily of micro and small establishments. In 2008, 64% of Canadian establishments had between 5 and 99 employees, 29% had 1–4 employees and 7% had 100–499 employees. No Canadian establishments had more than 500 employees. In 2008, 34% of establishments were located in Quebec, 24% in British Columbia and 14% in Ontario. The remaining establishments were located in Alberta, the Northwest Territories, Manitoba, New Brunswick, Newfoundland and Labrador, and Nova Scotia (Industry Canada 2010).

The number of employees in the Canadian explosives manufacturing industry decreased from 1498 employees in 1998 to 681 employees in 2007. In 2007, 82% of positions were in

production and 18% were in administration. Average salaries in 2008 were \$45,515 for production workers and \$73,397 for administrative workers (Industry Canada 2010).

Manufacturing revenues for the Canadian explosives manufacturing industry were \$217.7 million in 2007, a decrease from 311 million in both 2005 and 2006 and 338 million in 2004 (Industry Canada 2010).

Total exports from the industry were \$182 million in 2009, a 16% increase from the previous year and a 36% increase from 2005. The top destinations for Canadian exports were the United States, Australia, Mexico and Chile. During the same period, total imports were \$135 million, a 19% decrease from 2008 and a 10% overall decrease from 2005. The top sources of Canadian imports were the United States, Mexico, Germany and Sweden. In 2009, 88% of exports originated in Quebec and 43% of imports went to Quebec.

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 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-nitrotoluene 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-nitrotoluene is to prevent exposure to the Canadian population from increasing.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management Tool

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 was selected using a consistent approach, and took into consideration the information that was received through the Challenge and other information available at the time.

In order to achieve the risk management objective and to work towards achieving the human health objective, **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.**

9.2 Implementation Plan

The proposed regulation or instrument respecting preventative or control actions in relation to 2-nitrotoluene will be published in the *Canada Gazette*, Part I, no later than July 2012, as per the timelines legislated in CEPA 1999.

10. CONSULTATION APPROACH

The risk management scope for 2-nitrotoluene, 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 document 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 risk management approach document will involve publication on July 31, 2010, and a 60-day public comment period.

The primary stakeholders include

- importers of 2-nitrotoluene
- non-governmental organizations
- company(ies) involved in the manufacture of explosives using a technology associated with 2-nitrotoluene

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".

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-nitrotoluene 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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