



Government
of Canada

Gouvernement
du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

Thiourea

Chemical Abstracts Service Registry Number (CAS RN):
62-56-6

Environment Canada
Health Canada

January 2009

Canada

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This proposed risk management approach document builds on the previously released risk management scope document for thiourea, 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.

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*, 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 the definition of “toxic” set out in section 64 of CEPA 1999.

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 15 to 30 high-priority substances.

In addition, the information-gathering provisions under section 71 of CEPA 1999 are 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 thiourea, Chemical Abstracts Service Registry Number (CAS RN)¹ 62-56-6, was included in Batch 2 of the Challenge under the Chemicals Management Plan.

¹ 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.

1.2 Final Screening Assessment Report Conclusion for Thiourea

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 thiourea on January 31, 2009, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that thiourea 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.

Based on the available information, it is concluded that thiourea 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 carcinogenicity of thiourea, for which there may be a probability of harm at any level of exposure, as well as the potential inadequacy of the margins of exposure for non-cancer effects, it is concluded that thiourea is a substance that 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.

It is concluded that thiourea does not meet the criteria in paragraph 64(a) and 64(b) of CEPA 1999, but it does meet the criterion in paragraph 64(c) of CEPA 1999.

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

For further information on the final screening assessment report conclusion for thiourea, refer to the final screening assessment report, available at www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot_2_e.html.

1.3 Proposed Measure

Following a screening assessment of a substance under section 74 of CEPA 1999, a substance may be found to meet 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 CEPA 1999. Under certain circumstances, the Ministers must make a specific proposal either to recommend addition to the List of Toxic Substances or to recommend the implementation of virtual elimination (or both). In this case, the Ministers proposed to recommend the addition of thiourea to the List of Toxic Substances in Schedule 1 of CEPA 1999. 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 thiourea meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, thiourea 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.

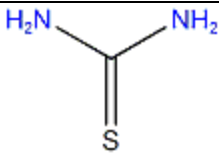
2. BACKGROUND

2.1 Substance Information

Thiourea is part of the chemical grouping discrete organics and the chemical sub grouping amines, thio compounds.

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

Table 1. Identity of thiourea

Chemical Abstracts Service Registry Number (CAS RN)	62-56-6
Name on Domestic Substances List (DSL)	Thiourea
Other names²	β -Thiopseudourea; 2-Thiourea; Isothiourea; NSC 5033; Pseudothiourea; Pseudourea (NH ₂ .C(OH):NH), thio-; Pseudourea, 2-thio-; Thiocarbamide; THU; TsIZP 34; UN 2810; Urea, 2-thio; Urea, thio-
Chemical formula	CH ₄ N ₂ S
Chemical group (DSL stream)	Discrete organics
Chemical structure	
Simplified Molecular Input Line Entry System (SMILES)	C(=S)NN
Molecular mass	76.12 g/mol

² National Chemical Inventories (NCI). 2006: AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Combined Inventories from the Asia-Pacific Region); ECL (Korean Existing Chemicals List); EINECS (European Inventory of Existing Chemical Substances); ENCS (Japanese Existing and New Chemical Substances); NZIoC (New Zealand Inventory of Chemicals); PICCS (Philippine Inventory of Chemicals and Chemical Substances); and TSCA (Toxic Substances Control Act Chemical Substance Inventory).

3. WHY WE NEED ACTION

3.1 Characterization of Risk

Based principally on the weight-of-evidence assessments or classifications of several international or national agencies (IARC, IPCS, EC and NTP), a critical effect for characterization of risk to human health for thiourea is carcinogenicity. The substance induced tumours at multiple sites in male and female rats and in the mammary gland in mice. The modes of action for induction of the various tumour types observed in exposed rats and mice have not been fully elucidated, and such analyses are beyond the scope of the screening assessment under the Challenge. Therefore, a mode of induction involving direct interaction with genetic material cannot be precluded.

Data were insufficient to quantify exposure from the general environment, although it is expected to be negligible; therefore, to characterize the risk for non-cancer effects, the estimated inhalation and dermal exposures (combined) from consumer products during the use of metal cleaners (0.023 mg/kg-bw per day) and photographic toning solutions (0.11 mg/kg-bw per day), were compared to the lowest short-term oral toxicity values (lowest-observed-effect level [LOEL] 70 mg/kg-bw/day). The resulting margin of exposure (MOE) for silver polish is approximately 3000, while that for photographic toning solution is approximately 600. These margins for consumer product exposure scenarios, although conservative in nature, may not be adequate to account for uncertainties in the databases on exposure and effects, particularly in view of the uncertainties regarding the mode(s) of action for the induction of tumours as well as the steepness of the relationship between toxicity and duration of exposure (i.e., LOELs for short-term, subchronic and chronic exposure were 70, 50 and 27.5 mg/kg-bw per day, respectively) (Canada 2008).

4. CURRENT USES AND INDUSTRIAL SECTORS

Based on a survey conducted under section 71 of CEPA 1999, no Canadian companies reported manufacturing thiourea in a quantity greater than or equal to the 100-kg threshold in 2006. However, results from the same survey and from voluntary data submitted by industry indicated that the total quantity of thiourea that was imported into Canada in 2006 ranged between 10 000 and 100 000 kg.

According to submissions made under section 71 of CEPA 1999, thiourea is used in metal finishing solutions and in etch treatments used for printed circuit boards, as a reducing agent in the production of thiourea dioxide, and as a chemical intermediate. Thiourea is used as a reactant in the copper refinery industry, and as an accelerant in rubber production. It is also a component of products used at pulp and paper mills that manufacture paper and paperboard used to make food containers where treated surfaces are thoroughly rinsed with potable water to ensure no contamination of food. Thiourea is also used in the composition of a cleaner and scale remover followed by the potable water rinse, and there will be no contamination of food as a result of their uses in food plants. In addition, thiourea may be used as rust inhibitor, in silver polish, tarnish removers and metal cleaners, as an auxiliary agent in the textile industry, as a photographic fixing agent and as an agent to remove stains from negatives and in pharmaceutical synthesis.

Thiourea may be used in insecticides and agrochemicals, and is a mould inhibitor. However, according to the Pest Management Regulatory Agency (PMRA), no pesticides in Canada contain this chemical as an active ingredient or as a formulant (Canada 2008).

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

According to the submissions made under section 71 of CEPA 1999, releases of thiourea from industry to air, water and soil are considered to be negligible. However, between 100 and 1000 kg of thiourea were reported as being transferred to an off-site waste management facility.

Under the National Pollutant Release Inventory (NPRI), thiourea has had no reportable on-site emissions since 1994, except in 2002 when 50 kg of thiourea were released to air as fugitive emissions. From 1999 to 2002, there was a reported increase in the quantity of thiourea, from 12 kg to 23.55 kg, being sent to off-site municipal sewage treatment plants prior to final disposal. Since 2002 there has been no reported off-site disposal of thiourea (Canada 2008).

5.2 Exposure Sources

No measured concentrations were available to estimate the intake of thiourea for any environmental media or food in Canada or elsewhere. There is limited potential for the general population in Canada to be exposed to thiourea through the use of consumer products such as silver polish, metal cleaners, or textiles.

According to the results from CEPA 1999 section 71 notice and the National Pollutant Release Inventory, the reported uses of thiourea were mainly for industrial purposes. Releases to air, water and soil are considered to be negligible and therefore unlikely to result in exposure of the general population (Canada 2008).

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

Thiourea is subject to

- the Cosmetic Ingredients Hotlist under the *Food and Drugs Act*;
- the *Consumer Chemicals and Containers Regulations, 2001* established under the *Hazardous Products Act*, which require consumer chemical products to be classified against criteria based on short-term exposure situations, with the results determining the appropriate product labelling and packaging requirements (Canada 2001);

- the *Controlled Products Regulations* established under the *Hazardous Products Act*, which require any chemical ingredient on the Ingredient Disclosure List to be disclosed on the Material Safety Data Sheet that must accompany workplace chemicals if present above a certain prescribed concentration (Canada 1988);
- reporting under the National Pollutant Release Inventory (NPRI); and
- The *Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations*—Listed on Schedule 7 (Hazardous Waste and Hazardous Recyclable Material Chemicals).

6.2 Existing International Risk Management

In the US:

- The *Superfund Amendments and Reauthorization Act* (SARA): Sections 311, 312 and 313 – listed
- U.S. Environmental Protection Agency (EPA) *Toxic Substances Control Act* (TSCA) section 8 (b) Chemical Inventory
- California Proposition 65 – listed
- *Resource Conservation and Recovery Act* (RCRA) – listed as a hazardous constituent of waste
- *Food and Drugs Act* (FDA) – Thiourea is not permitted in food for human consumption

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

No information is available on alternative chemicals or substitutes.

7.2 Alternative Technologies and/or Techniques

No information is available on alternative technologies and/or techniques.

7.3 Socio-economic Considerations

Socio-economic factors have been considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objective(s). Socio-economic factors will also be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Streamlining Regulation* (Treasury Board of Canada Secretariat 2007) and the guidance provided in the

Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action*.

Thiourea was not manufactured in Canada in a quantity greater than or equal to the 100-kg threshold, but was imported in a total quantity ranging between 10 000 kg and 100 000 kg in 2006. Many uses for thiourea have been identified in Canada; for example, it is a component of products used on surfaces at pulp and paper mills that manufacture paper and paperboard food packaging and as a component of cleaner and scale remover in food plants. The draft screening assessment report for thiourea proposed that the potential exposure of the general Canadian population is limited.

If the proposed risk management approach on future uses is adopted, the socio-economic impacts may not have a large immediate effect on the costs to Canadian industry. Further analysis on importers of products containing thiourea will need to be assessed. Potential chemical and product alternatives that are identified for thiourea will be examined as part of the socio-economic analysis of any proposed instrument(s).

An analysis of benefits and costs will be conducted as part of instrument development for thiourea. This analysis will identify economic factors as they relate to the use and production of thiourea in Canada, and where data are available may include employment, and regional dispersion of industries that use thiourea. The benefits associated with any instruments developed will be identified, with a valuation of benefits conducted where possible.

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 thiourea is to minimize, to the extent practicable, exposure to thiourea, and hence risk to human health associated with this substance.

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, instruments(s) and/or tool(s). As the current exposures of Canadians to thiourea were considered to be negligible under the current use conditions, the risk management objective is to prevent increases in exposure.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management Instrument

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 instrument was selected using a consistent approach, and took into consideration the information that has been 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 environmental or human health objective(s), the risk management being considered for thiourea is a provision whereby any future potential changes in the use-pattern for thiourea do not substantially increase the potential for exposure of the general Canadian population and would require that the federal government be notified.

9.2 Implementation Plan

The proposed risk management approach developed under CEPA 1999 will be published in the *Canada Gazette*, Part I, no later than January 2011, as per the timelines legislated in CEPA 1999. Releases of thiourea will continue to be monitored under the National Pollutant Release Inventory. Other monitoring will be considered to assess the performance of the risk management instrument and to determine whether further action needs to be taken with respect to thiourea.

10. CONSULTATION APPROACH

The risk management scope for thiourea, which summarized the proposed risk management under consideration at that time, was published on May 17, 2008, and is available at www.ec.gc.ca/TOXICS/EN/detail.cfm?par_substanceID=236&par_actn=s1. 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

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."

taken into consideration in the development of this proposed risk management approach document.

Consultation for the risk management approach will involve publication on January 31, 2009, and a 60-day public comment period.

The primary stakeholders include

- manufacturers, importers and retailers of silver polish and metal cleaners products
- Health Canada and Environment Canada.

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on proposed risk management approach	January 31, 2009, to April 1, 2009
Response to comments on the risk management approach	At time of publication of proposed instrument
Consultation on the draft instrument	Spring-Summer 2009
Publication of the proposed instrument	No later than January 2011
Formal public comment period on the proposed instrument	No later than Spring 2011
Publication of the final instrument	No later than July 2012

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 April 1, 2009, since the Government of Canada will be moving forward with the risk management of thiourea after this date. Pursuant to section 313 of CEPA 1999, any person who provides information to the Minister of the Environment under CEPA 1999 may submit with the information a request that it be treated as confidential. During the development of the risk management 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:

Existing Substances Division
 Gatineau QC K1A 0H3
 Tel: 1-888-228-0530 / 819-956-9313
 Fax: 1-800-410-4314 / 819-953-4936
 Email: Existing.Substances.Existantes@ec.gc.ca

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