



Government
of Canada

Gouvernement
du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

Oxirane, 2,2',2'',2'''-[1,2-ethanediylidenetetrakis(4,1-phenyleneoxymethylene)]tetrakis-

(TGOPE)

Chemical Abstracts Service Registry Number (CAS RN):
7328-97-4

Environment Canada
Health Canada

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This proposed risk management approach document builds on the previously released risk management scope document for TGOPE, 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 PROPOSED RISK MANAGEMENT

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

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, in accordance with the criteria at section 73 of the Act, a) are considered to be persistent (P) 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) may 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 Act¹.

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 comments, profiles of batches containing 12 to 19 high-priority substances. New batches are released for comments every three months.

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.

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 is used to make informed decisions and appropriately manage any risks that may be associated with these substances.

The substance Oxirane, 2,2',2'',2'''-[1,2-ethanediyliidenetetrakis(4,1-phenyleneoxymethylene)]tetrakis-, Chemical Abstracts Service Registry Number (CAS RN)² 7328-97-4, referred to throughout this document as “TGOPE”, is included in Batch 9 of the Challenge under the Chemicals Management Plan.

1.2 Final Screening Assessment Report Conclusion for TGOPE

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 TGOPE on September 18, 2010, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that TGOPE, on the basis of the carcinogenic potential, for which there may be a probability of harm at any level of exposure, 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 (Canada 2010).

The final screening assessment report also concluded that TGOPE 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. The final screening assessment report also concluded that TGOPE does not meet the criteria for persistence, but does meet the criteria for bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA 1999. The presence of TGOPE in the environment results primarily from human activity (Canada 2010).

For further information on the final screening assessment report conclusion for TGOPE, refer to the final screening assessment report, available at <http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-9/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

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.

elimination. In this case, the Ministers proposed to recommend the addition of TGOPE to the List of Toxic Substances in 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.

TGOPE is not subject to the virtual elimination provisions under CEPA 1999 and will be managed using a lifecycle approach, to prevent or minimize human exposure to this substance.

2. BACKGROUND

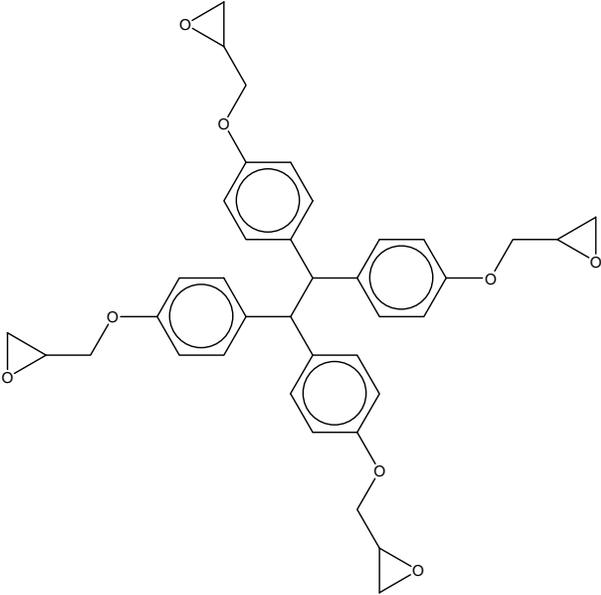
2.1 Substance Information

TGOPE is part of the chemical grouping discrete organics and the chemical sub grouping epoxides, or more specially tetraphenyls and tetraglycidyl ethers.

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

Table 1. Identity of TGOPE

Chemical Abstracts Service Registry Number (CAS RN)	7328-97-4
DSL name	Oxirane, 2,2',2'',2'''-[1,2-ethanediylidenetetrakis(4,1-phenyleneoxymethylene)]tetrakis-
National Chemical Inventories (NCI) names¹	<i>Oxirane, 2,2',2'',2'''-[1,2-ethanediylidenetetrakis(4,1-phenyleneoxymethylene)]tetrakis-</i> (TSCA, PICCS, ASIA-PAC, NZIoC, AICS); <i>2,2',2'',2'''-[ethane-1,2-diylidenetetrakis(p-phenyleneoxymethylene)]tetraoxirane</i> (EINECS)
Other names	<i>1,1,2,2-(4,4',4'',4'''-tetraglycidyoxyphenyl)ethane;</i> <i>1,1,2,2-tetra(p-hydroxyphenyl)ethane tetraglycidyl ether;</i> <i>1,1,2,2-tetrakis(4-glycidoxyphenyl)ethane;</i> <i>1,1,2,2-tetrakis(p-glycidyoxyphenyl)ethane;</i> <i>1,1,2,2-tetrakis(p-hydroxyphenyl)ethane tetraglycidyl ether;</i> <i>ethane, 1,1,2,2-tetrakis[p-(2,3-epoxypropoxy)phenyl]-;</i> <i>tetraglycidyl ether of 1,1,2,2-tetrakis(p-hydroxyphenyl)ethane;</i> <i>tetraphenylolthane, epichlorohydrin epoxy resin</i>
Chemical group (DSL Stream)	Discrete organics
Major chemical class or use	Epoxides

Major chemical sub-class	Tetraphenyls; tetraglycidyl ethers
Chemical formula	C ₃₈ H ₃₈ O ₈
Chemical structure	
SMILES²	O(C1COc(ccc(c2)C(c(ccc(OCC(O3)C3)c4)c4)C(c(ccc(OC(C(O5)C5)c6)c6)c(ccc(OCC(O7)C7)c8)c8)c2)C1
Molecular mass	622.72 g/mol

¹ National Chemical Inventories (NCI), 2007: AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Asia-Pacific Substances Lists); EINECS (European Inventory of Existing Commercial 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).

² Simplified Molecular Line Input Entry System

3. WHY WE NEED ACTION

3.1 Characterization of Risk

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

Empirical data identified for TGOPE suggested direct-mutagenic potential *in vitro*. The 4 epoxy rings contained in TGOPE are the critical hazard concern, as each epoxy ring can bind covalently with DNA. Four aromatic glycidyl ether analogues that contained epoxy ring(s) were identified and aided in assessing the risks to human health of TGOPE. Some of the analogues were classified by national and international regulatory agencies for carcinogenicity and mutagenicity. The analogues, which contained the alkylating epoxy ring(s), had similar direct-mutagenic genotoxicity profiles as TGOPE *in vitro*. Some analogues were also shown to be carcinogenic in animal studies although *in vivo* genotoxicity data were mixed. The collective evidence from genotoxicity and carcinogenicity data for TGOPE and its analogues suggested

that TGOPE has a potential for genotoxicity and carcinogenicity. Therefore it cannot be precluded that TGOPE could induce tumours via a mode of action involving direct interaction with genetic material (Canada 2010).

The potential for exposure of the general population to TGOPE from environmental media is expected to be negligible. There is no expected exposure from food. In addition, exposure to TGOPE from consumer products (e.g., epoxy adhesives) is expected to be low. Exposure of the general population in Canada based on the use of the substance as an epoxy adhesive is expected to be low to negligible (Canada 2010).

4. CURRENT USES AND INDUSTRIAL SECTORS

Information was collected through surveys conducted for the years 2005 and 2006 under Canada Gazette notices issued pursuant to section 71 of CEPA 1999 (Canada 2006, Canada 2009a). These notices requested data on the Canadian manufacture, import and uses of TGOPE. Information gathered from the survey notices indicates that TGOPE was not manufactured in Canada in 2005 or 2006. Fewer than four companies reported import of this substance in the 1000 – 10 000 kg/year range in 2006 and 1000-100,000 kg/year range in 2005.

Products containing TGOPE may enter the country even if they are not identified as such in the section 71 survey, because they may be imported unknowingly in manufactured items, or in quantities below the 100 kg reporting threshold for the survey (Canada 2009b). The substance uses that were reported were primarily in industrial settings and would likely not result in any exposure to the public.

The following North American Industry Classification System (NAICS) code was reported for TGOPE in 2005 (Canada 2006): 32551 – Paint, Coating and Adhesive Manufacturing. This industry comprises establishments primarily engaged in: (1) mixing pigments, solvents and binders into paints and other coatings, such as stains, varnishes, lacquers, enamels, shellacs, and water repellent coatings for concrete and masonry; and/or (2) manufacturing allied paint products, such as putties, paint and varnish removers, paint brush cleaners, and frit. More specific usage information was reported in 2006 but this is considered to be confidential business information (Canada 2009b). This confidential information was taken into consideration in the risk assessment and for the proposed risk management approach.

The substance uses that were reported were primarily in industrial settings and would likely not result in any exposure to the public. However, based on one submission received, TGOPE is found in an adhesive product that may have consumer uses. Uses listed for the DSL nomination in 1986 included codes 80 (paints and coatings) and 87 (plastics and synthetic resins).

In the United States, TGOPE has been used as an adhesive and binding agent in semiconductor and other electronic component manufacturing, and in the resin and synthetic rubber manufacturing sectors (US EPA 2006). In addition, 15 tonnes of TGOPE were used in Sweden in 2005 as an adhesive/binding agent (SPIN 2009).

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

TGOPE is not known to be naturally produced in the environment. No empirical data on releases of TGOPE to the environment were found nor were any releases reported from the section 71 surveys. TGOPE is not reportable to the National Pollutant Release Inventory (NPRI 2008) or to the United States Toxics Release Inventory Program (TRI 2007).

The potential releases of TGOPE to the environment may result from various losses of the substance during its industrial use and consumer/commercial use. TGOPE is not expected to be released to the environment via routes other than wastewater. During the manufacturing of items containing TGOPE, virtually all of the TGOPE will chemically react and therefore become chemically transformed and unavailable for release. The very small amount of unreacted TGOPE remaining in manufactured items is assumed to be disposed of in landfill sites. TGOPE disposed of in landfill has very low potential to migrate into groundwater, since TGOPE released to soil is expected to be virtually immobile and remain in soil (Canada 2010).

5.2 Exposure Sources

From the literature, TGOPE has been reported to be used in manufacturing high-performance epoxy systems, specially formulated for high-accuracy, elevated-temperature transducer applications (Davidson Measurement 2005). TGOPE has been used in the production of multifunctional epoxy resins, which can be used to improve the properties of cured epoxy resin systems, particularly at elevated temperatures. These epoxy resins may find application in electrical laminates, high-performance composites, and adhesives (Canada 2010).

While the possibility exists for consumers to order these highly specialized products directly from the distributor, these products are not widely available to the general population of Canada as they are designed for specialized and industrial purposes.

The intake estimates for environmental media and food, in addition to total intake for each age group, were found to be negligible (Canada 2010).

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

No existing Canadian risk management was identified.

6.2 Existing International Risk Management

No existing international risk management was identified.

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

No information on potential substitutes for TGOPE has been identified.

7.2 Alternative Technologies and/or Techniques

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

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*.

Socio-economic considerations for TGOPE include:

- TGOPE was not manufactured above the threshold of 100kg/yr in 2005 or 2006 in Canada, and the total quantity imported into Canada was in the range of 1 000-10 000 kg in 2005 and 1 000-100 000 in 2006 (Environment Canada 2006, Environment Canada 2009).
- TGOPE is listed on the 2004 and 2007 OECD High Production Volume (HPV) chemicals lists (OECD 2004, OECD 2009), the 1994 U.S. EPA HPV List (US EPA 1994) but is not listed as an HPV or low production volume chemical (LPV) in Europe (ESIS 2010)
- In 2005, the Paint and Coatings Manufacturing NAICS code (32551) was reported for TGOPE (Environment Canada 2006). This industry comprises establishments primarily engaged in mixing pigments, solvents and binders into paints, stains, and other coatings; and manufacturing related products (Industry Canada 2010).
- The revenue of the Canadian Paints and Coatings industry was \$2.4 billion in 2008, with 272 establishments employing approximately 6 600 employees (Statistics Canada). The number of employees increased over the 2004-2008 period, while the number of establishments and total revenue decreased over the same period (Statistics Canada 2010).
- In 2008, approximately 47 percent of establishments were in Ontario, 22 percent in Quebec, 14 percent in British Columbia and 11 percent in Alberta (Statistics Canada 2010).
- The value of Canadian annual exports for Paints and Coatings products was \$257 million in 2009, a 38 percent decrease from 2000. The top destination for Canadian products in 2009 was the United States, representing 89 percent of exports. During the same period, Canadian annual imports were \$884 million, a nine percent decrease from 2000. The major source of

Canadian imports was the United States representing 93 percent of imports in 2009 (Industry Canada 2010b).

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

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

The proposed human health objective for TGOPE 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). As exposures of the Canadian public to TGOPE are considered to be negligible under current use conditions, the proposed risk management objective for TGOPE 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 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.

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".

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 Significant New Activity provisions for TGOPE will be published in the *Canada Gazette*, Part I, no later than September 2010, as per the timelines legislated in CEPA 1999.

10. CONSULTATION APPROACH

The risk management scope document for TGOPE, which summarized the proposed risk management under consideration at that time, was published on March 20, 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 September 18, 2010 and a 60-day public comment period.

The primary stakeholders include

- Importers, users and distributors of TGOPE
- non-governmental organizations
- Paints, Coatings and Adhesives manufacturing industries

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on proposed risk management approach document	September 18, 2010 to November 17, 2010
Response to comments on proposed the risk management approach document	No later than at the time of publication of the proposed instrument
Consultation on the draft instrument	2011-2012
Publication of the proposed instrument	No later than September 2012
Formal public comment period on the proposed instrument	No later than fall 2013
Publication of the final instrument	No later than March

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 November 17, 2010, since the risk management of TGOPE will be moving forward after this date. During the development of regulations, instrument(s) and 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 Quebec 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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