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PROPOSED RISK MANAGEMENT APPROACH

for

Oxirane, (butoxymethyl)-

(*n*-butyl glycidyl ether)

Chemical Abstracts Service Registry Number (CAS RN):
2426-08-6

Environment Canada
Health Canada

March 2010

Canada

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This proposed risk management approach document builds on the previously released risk management scope document for *n*-butyl glycidyl ether, 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 will require notification regarding any potential changes in the use pattern of *n*-butyl glycidyl ether.

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

1. ISSUE

1.1 Challenge to Industry and Other Interested Stakeholders

The substance Oxirane, (butoxymethyl)-, Chemical Abstracts Service Registry Number (CAS RN)[1] 2426-08-6, will be referred to throughout this document as "*n*-butyl glycidyl ether", is included in Batch 7 of the Challenge under the Chemicals Management Plan. The Ministers of the Environment and of Health (the Ministers) have conducted an assessment under section 68 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999)[2] to assess whether the substance meets one or more of the criteria as set out in section 64 of CEPA 1999.

[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.

[2] 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, but is not limited to, 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 Controlled Products Regulations, which is part of regulatory framework for the Workplace Hazardous Materials Information System [WHMIS] for products intended for workplace use.

This substance was identified in the categorization of the Domestic Substances List as a high priority for action under the Ministerial Challenge. n-Butyl glycidyl ether was identified as a substance presenting an intermediate potential for exposure of individuals in Canada and had been classified by other agencies on the basis of carcinogenicity and genotoxicity. As n-butyl glycidyl ether did not meet the criteria for persistence, bioaccumulation or inherent toxicity to aquatic organisms, the focus of this assessment relates primarily to human health aspects.

Information–gathering authority in section 71 of CEPA 1999 is used to gather specific information where it is required. The information that is collected is used to make informed decisions and appropriately manage any risks that may be associated with these substances.

1.2 Final Assessment Report Conclusion for *n*-butyl glycidyl ether

A notice summarizing the scientific considerations of a final assessment report was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, for *n*-butyl glycidyl ether on March 6, 2010, under paragraphs 68(*b*) and 68(*c*) of CEPA 1999. The final report concluded that *n*-butyl glycidyl ether 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.

Based principally on the weight-of-evidence assessment of the European Commission, a critical effect for characterization of risk to human health for *n*-butyl glycidyl ether is carcinogenicity. Although *n*-butyl glycidyl ether has not been tested in a long-term cancer bioassay, exposure to analogous substances via inhalation, topical application or ingestion increased the incidence of tumours in various organs in rodents. *n*-Butyl glycidyl ether was also genotoxic in a range of *in vivo* and *in vitro* assays; likewise, the structural analogues allyl glycidyl ether and glycidol also tested positive for various endpoints in both *in vivo* and *in vitro* genotoxicity assays. Therefore, in light of the genotoxicity of *n*-butyl glycidyl ether and the carcinogenicity and genotoxicity of structurally similar compounds, it cannot be precluded that *n*-butyl glycidyl ether would induce tumours via a mode of action involving direct interaction with genetic material (Canada 2010). For substances for which the critical health effect is assumed to have no threshold of exposure for induction, it is assumed that there is a probability of harm to human health at any level of exposure.

It is therefore concluded that *n*-butyl glycidyl ether does not meet the criteria in paragraphs 64(*a*) and 64(*b*) of CEPA 1999, but it does meet the criteria in paragraph 64(*c*) of CEPA 1999.

The final report also concluded that *n*-butyl glycidyl ether 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 *n*-butyl glycidyl ether in the environment results primarily from human activity.

For further information on the final report conclusion for *n*-butyl glycidyl ether, refer to the final report, available at http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-7/index-eng.php.

1.3 Proposed Measure

As a result of an assessment of a substance under section 68 of CEPA 1999, the substance may be found to meet one or more of the criteria under section 64 of CEPA 1999. In that case, either Minister can provide information and make recommendations respecting any matter in relation to the substance. While not subject to section 74 to section 77 the Ministers may choose to do such actions as add the substance to the Priority Substances List (PSL) for further assessment, recommend the addition of the substance to Schedule 1 of the Act or take no further action. In this case, the Ministers proposed to recommend the addition of *n*-butyl glycidyl ether to Schedule 1. As a result, the Ministers may 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.

n-Butyl glycidyl ether is not subject to the virtual elimination and may be managed using a life-cycle approach.

2. BACKGROUND

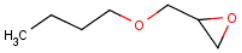
2.1 Substance Information

n-Butyl glycidyl ether is part of the chemical grouping discrete organics and the chemical sub-grouping alkyl epoxides; glycidyl ethers.

Table 1 presents other names, trade names, chemical groupings, the chemical formula, the chemical structure and the molecular mass for *n*-butyl glycidyl ether.

Table 1. Identity of *n*-butyl glycidyl ether

CAS RN	**2426-08-6**
DSL name	**Oxirane, (butoxymethyl)-**
NCI names	(Butoxymethyl)oxirane (ECL) Butyl 2,3-epoxypropyl ether (EINECS) Butylglycidylether (ENCS) Butyl glycidyl ether (PICCS) *n*-Butyl glycidyl ether (ENCS, PICCS) Normal butyl glycidyl ether (PICCS) Oxirane, (butoxymethyl)- (AICS, ASIA-PAC, NZIoC, PICCS, SWISS, TSCA)
Other names	BGE; *n*-BGE; BGE-C; BGE-R; 1-Butoxy-2,3-epoxypropane; 3-Butoxy-1,2-epoxypropane; 2-(Butoxymethyl)oxirane; 1-Butyl glycidyl ether; (±)-Butyl glycidyl ether; DY-BP; DY-BP (epoxide); Epi-Rez 501; Epodil 741; Epodil 741HP; ERL 0810; 2,3-Epoxypropyl butyl ether; Glycidyl butyl ether; Glycidyl *n*-butyl ether; N 10; N 10 (ether); NSC 83413; Propane, 1-butoxy-2,3-epoxy-

Chemical group (DSL stream)	Discrete organics
Major chemical class or use	Epoxides
Major chemical subclass	Alkyl epoxides; glycidyl ethers
Chemical formula	$C_7H_{14}O_2$
Chemical structure	
SMILES	O(C1COCCCC)C1
Molecular mass	130.185 g/mol

Abbreviations: AICS, Australian Inventory of Chemical Substances; ASIA-PAC, Asia-Pacific Substances Lists; CAS RN, Chemical Abstracts Service Registry Number; DSL, Domestic Substances List; ECL, Korean Existing Chemicals List; EINECS, European Inventory of Existing Commercial Chemical Substances; ENCS, Japanese Existing and New Chemical Substances; NCI, National Chemical Inventories; NZIoC, New Zealand Inventory of Chemicals; PICCS, Philippine Inventory of Chemicals and Chemical Substances; SMILES, simplified molecular input line entry specification; SWISS, Swiss Giftliste 1 and Inventory of Notified New Substances; TSCA, Toxic Substances Control Act Chemical Substance Inventory.
Source: NCI 2007

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.

Based principally on the weight-of-evidence assessment of the European Commission, a critical effect for characterization of risk to human health for *n*-butyl glycidyl ether is carcinogenicity. Although *n*-butyl glycidyl ether has not been tested in a long-term cancer bioassay, exposure to analogous substances via inhalation, topical application or ingestion increased the incidence of tumours in various organs in rodents (Canada 2010).

n-Butyl glycidyl ether was also genotoxic in a range of *in vivo* and *in vitro* assays; likewise, the structural analogues allyl glycidyl ether and glycidol also tested positive for various endpoints in both *in vivo* and *in vitro* genotoxicity assays. Considering that the glycidyl ether functional group is present in each of the analogues, that the epoxide moiety contained therein is known to alkylate DNA, that all analogues have tested positive in several *in vitro* genotoxicity assays and some have tested positive in *in vivo* assays, that all show some evidence for carcinogenicity, and that similar health effects were observed for other endpoints (irritation, sensitization and reproductive toxicity), it can be reasonably concluded that *n*-butyl glycidyl ether and the selected analogues cause similar health effects and that the use of such analogues is appropriate to better inform understanding of the hazards associated with exposure to *n*-butyl glycidyl ether. Therefore, in light of the genotoxicity of *n*-butyl glycidyl ether and the carcinogenicity and genotoxicity of structurally similar compounds, it cannot be precluded that *n*-butyl glycidyl ether

would induce tumours via a mode of action involving direct interaction with genetic material (Canada 2010).

With respect to non-cancer effects, the lowest LOEC (lowest-observed-effect concentration) for inhalation exposure was 400 mg/m^3 based on testicular atrophy observed in rats exposed 5 days/week for 10 weeks (Shell Oil Company 1957). Comparison of this effect level with the modelled estimate of outdoor air concentration for *n*-butyl glycidyl ether (i.e., <1 ng/m^3) results in a predicted margin of exposure of approximately eight orders of magnitude. Although *n*-butyl glycidyl ether is used in the manufacture of epoxy resins and other formulations that are used in various products, the available information indicates that consumer exposure is expected to be minimal. Therefore, in light of the low predicted exposures, the margin of exposure is considered sufficient to be protective against the induction of non-cancer effects in the general population in Canada (Canada 2010).

4. CURRENT USES AND INDUSTRIAL SECTORS

Based upon a Canadian survey conducted under section 71 of CEPA 1999, no company manufactured *n*-butyl glycidyl ether at quantities greater than or equal to 100 kg in 2006. However, the total quantity imported into Canada in 2006 was reported to be in the range of 10 000 to 100 000 kg (Environment Canada 2008).

n-Butyl glycidyl ether is used as a reactive diluent for epoxy resins, as a chemical intermediate and as an acid acceptor for stabilizing chlorinated solvents (Bingham et al. 2001; NTP 2004). The reactive diluent functions in epoxy resin systems as a viscosity lowering agent, allowing easier handling of the resin in the uncured state (Bosch et al. 1985; Lee 1989). Due to the presence of the epoxide functional group, *n*-butyl glycidyl ether participates in polymerization and cross-linking reactions, allowing it to become covalently bound into the epoxy network during the curing process (Bosch et al. 1985; Lee 1989; Hamerton 1996).

According to data submitted under section 71 of CEPA 1999, *n*-butyl glycidyl ether is used in Canada in the formulation of epoxy resins, which have applications as coatings, adhesives, binders, sealants, fillers and resins (Environment Canada 2008). A small quantity (2 kg) was imported as an impurity in a material preservative for paint (Environment Canada 2008). The substance is neither an active ingredient nor a formulant in pest control products registered in Canada, but it may be present as a formulant impurity (PMRA 2009).

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

n-Butyl glycidyl ether is not manufactured in reportable quantities in Canada; however, releases to the environment may occur from industrial facilities processing, handling or storing imported material. Information gathered under section 71 of CEPA 1999 indicates that Canadian importers of this substance released 100 to 1000 kg to the air in 2006 (Environment Canada 2008). No releases of it to water or land were disclosed (Environment Canada 2008).

With respect to exposure from environmental sources, no Canadian environmental monitoring data were identified. *n*-Butyl glycidyl ether is not reportable to Canada's National Pollutant Release Inventory (NPRI 2007); therefore, no release information is available from this source.

5.2 Exposure Sources

n-Butyl glycidyl ether is not reported to occur naturally. This substance is produced by condensation of epichlorohydrin and *n*-butyl alcohol to form an intermediate chlorohydrin, which is then dehydrochlorinated to form an epoxide group (Bosch et al. 1985; NTP 2004).

Emissions of *n*-butyl glycidyl ether into the ambient environment would likely come from anthropogenic sources, specifically commercial production and use of epoxy resins. Modelled environmental exposure estimates, based on the upper end of the range of releases reported under the recent section 71 notice (Environment Canada 2008) predict that concentrations of *n*-butyl glycidyl ether would be low. Based on reported releases, uses, and physical and chemical properties, the principal route of exposure for the general population will likely be through inhalation of air. Exposure from other media is not expected (Canada 2010).

In Canada, *n*-butyl glycidyl ether is primarily identified to be used in the formulation of epoxy resins, which have applications as coatings, adhesives, binders, sealants, fillers and resins (Environment Canada 2008). However, no consumer products containing *n*-butyl glycidyl ether as an intentional ingredient were identified in an extensive search of the publicly available literature, nor through consultations with various Health Canada programs (Canada 2010). In addition, once cured, it is generally assumed that the glycidyl ether is no longer present in the cured product (IARC 1989) and thus, exposure to *n*-butyl glycidyl ether from contact with cured epoxies is not expected (Canada 2010).

A small quantity of *n*-butyl glycidyl ether, imported as an impurity in a material preservative for paint, was also reported (Environment Canada 2008). However, due to the reactive nature of *n*-butyl glycidyl ether, it is likely that levels remaining in the paint product used by the end consumer are lower than the worst-case concentration estimate of 336 mg/kg. Additionally, given the very small amount of the substance imported in this type of product as an impurity, consumer exposure would not be widespread across the general population of Canada (Canada 2010).

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

n-Butyl glycidyl ether is subject to
- an Ontario Jurisdictional Screening Level (JSL) value which is used as a screening tool for local air quality (Ontario MOE 2008).

6.2 Existing International Risk Management

n-Butyl glycidyl ether is subject to
- European Commission Directive 2004/93/EC amending Council Directive 76/768/EEC as a substance prohibited in cosmetic products due to the European Commission classification as carcinogenic category 3 and classification as mutagenic category 3 (European Council 2004);
- classification by the Swedish Chemicals Agency (KEMI) as a *priority risk reduction substance* (KEMI 2008);
- air screening levels in several U.S. states, where if levels are exceeded, further evaluation is needed (e.g., State of Washington Department of Ecology 1998; Michigan Department of Environmental Quality 2005; TCEQ 2009).

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

No information on potential substitutes for *n*-butyl glycidyl ether 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* (Treasury Board of Canada Secretariat 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 *n*-butyl glycidyl ether 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 the current exposures of Canadians to *n*-butyl glycidyl ether were considered to be low under the current use conditions, the risk management objective is to prevent increases in exposure.

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 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 human health objective, the risk management being considered for *n*-butyl glycidyl ether is **the requirement for notification of the federal government regarding any potential changes in the use pattern for *n*-butyl glycidyl ether** 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 *n*-butyl glycidyl ether will be published in the *Canada Gazette*, Part I, no later than March 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 document for *n*-butyl glycidyl ether, which summarized the proposed risk management under consideration at that time, was published on September 5, 2009. 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 proposed risk management approach document will involve publication on March 6, 2010, and a 60-day public comment period.

The primary stakeholders include

- manufacturers of epoxy resins containing *n*-butyl glycidyl ether

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on proposed risk management approach document	March 6, 2010, to May 5, 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	Fall-winter 2010–2011
Publication of the proposed instrument	No later than March 2012
Formal public comment period on the proposed instrument	No later than spring 2012
Publication of the final instrument	No later than September 2013

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 May 5, 2010, since the risk management of *n*-butyl glycidyl ether 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 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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