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# **Consultation on Proposed Code of Practice for a Recommended Concentration of 2-(2-Methoxyethoxy) Ethanol (DEGME) in Surface Coating Materials Available to Consumers in Canada**

May 9, 2015

Document for Public Comment

Consultation period ends July 8, 2015

**Canada**

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## 1.0 Purpose of Consultation

The purpose of this consultation document is to:

- Inform interested stakeholders of the proposed code of practice for 2-(2-methoxyethoxy) ethanol (DEGME) (herein referred to as the proposed code), as published on May 9, 2015 in *Canada Gazette*, Part I.
- Provide an opportunity for interested stakeholders to comment on the proposed code.

## 2.0 Introduction

The Chemicals Management Plan (CMP) was launched by the Government of Canada on December 8, 2006. A key element in the CMP was the initiative known as the "Challenge".

2-(2-Methoxyethoxy) ethanol (Chemical Abstracts Service Registry Number (CAS RN) 111-77-3, also known as DEGME) was included in Batch 3 of the Challenge.

## 3.0 Background

### 3.1 Final Screening Assessment

The conclusion of the final screening assessment for DEGME was published in the *Canada Gazette*, Part I on March 7, 2009; the full report was published on the [Chemicals Management Plan website](#) (Canada, 2009a). The report concludes that DEGME is 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 conclusion is based on the potential inadequacy of the margin between exposure and critical effect levels. Specifically, the margin between conservative estimates of dermal exposure to DEGME during use of consumer products and critical effect levels for developmental toxicity in experimental animals was considered inadequate.

DEGME was therefore concluded to meet the criteria in paragraph 64(c) of the [Canadian Environmental Protection Act, 1999](#) (CEPA 1999). It did not meet the criteria in paragraphs 64(a) and (b): it 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.

### 3.2 Risk Management Approach Document

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The [proposed Risk Management Approach for DEGME](#), published in March 2009, outlined the risk management objective and human health objective for DEGME (Canada, 2009b). The proposed risk management objective for DEGME is to ensure that the concentrations of DEGME in cosmetics and consumer products do not exceed levels that are adequately protective of human health. In 2011, the Government took action to address exposure to DEGME in cosmetics by adding the substance to the List of Prohibited and Restricted Cosmetic Ingredients (more commonly referred to as the [Cosmetic Ingredient Hotlist](#) or simply the [Hotlist](#)). This is an administrative tool that Health Canada uses to communicate to manufacturers and others that products containing certain substances are unlikely to be classified as a cosmetic under the *Food and Drugs Act* (FDA), and in addition, that certain substances, when present in a cosmetic at certain concentrations, may contravene the general prohibition found in section 16 of the FDA, or may contravene one or more provisions of the *Cosmetic Regulations*. In 2012, the Government published an Order amending the [Domestic Substances List to apply the Significant New Activity \(SNAc\) provisions to DEGME](#). Application of the SNAc provisions requires industry to notify the Government of plans for significant new manufacture, import or use of DEGME so that the Government can assess human health risk before new activities commence.

The purpose of the proposed code is to further help reduce Canadians' exposure to DEGME in consumer products. In the risk management approach for DEGME, the Government committed to investigating whether certain consumer products identified as sources of exposure of concern in the final screening assessment, required risk management. Product testing completed by Health Canada identified the need to reduce the exposure of Canadians to DEGME in surface coating materials that are consumer products. The proposed code targets levels of DEGME in those products. A voluntary code of practice as per section 55 of CEPA 1999 is considered to be an appropriate tool for addressing levels of DEGME in surface coating materials that are consumer products, given that the industry has already moved to reduce the use of DEGME in these products.

### 3.3 Proposed Risk Management – Code of Practice

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The proposed code will recommend a concentration threshold of 10,000 mg/kg (also expressed as 1.0 % (w/w)) for DEGME in consumer products that are surface coating materials (please see Annex A for the definition of 'surface coating materials' and 'consumer product'). This threshold was developed through an analysis of levels of DEGME in consumer products that are surface coating materials that would be protective of human health while minimizing harmful impacts on Canadian industry.

## 4.0 Next Steps

The Government of Canada is committed to providing interested and affected parties with the opportunity to take part in consultations at all stages of development of the proposed code. All comments will be taken into consideration in the drafting of the final code. The Government of Canada welcomes the distribution of this consultation document to any interested and affected parties.

Please submit comments on the proposed code, presented in Annex A of this consultation document, by **July 8, 2015**.

Comments on the consultation document are to be submitted to the Minister of Health by email, mail or fax. Addresses are below. Please type: **"Consultation on Proposed Code of Practice for DEGME"** in the subject line of your message.

**E-mail:** [chemicalsubstanceschimiques@hc-sc.gc.ca](mailto:chemicalsubstanceschimiques@hc-sc.gc.ca)

**Mail:** Chemical Substances Website  
c/o Health Canada  
269 Laurier Avenue West, Address Locator 4905B  
Ottawa (ON) K1A 0K9

**Fax:** 613-952-8857

The final code of practice will be published in the *Canada Gazette*, Part I, and on the Health Canada Web site. Please note that there is no comment period after such a publication.

## 5.0 References

Canada. 2009a. Screening assessment for the Challenge – Ethanol, 2-(2-methoxyethoxy), Chemical Abstract Service Registry Number 111-77-3. Available from <http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-3/index-eng.php>

Canada. 2009b. Risk Management Approach for Ethanol, 2-2(methoxyethoxy), Chemical Abstract Service Registry Number 111-77-3. Available from <http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-3/index-eng.php>.

## **Annex A - Proposed Code of Practice for a Recommended Concentration of 2-(2-Methoxyethoxy) Ethanol (DEGME) in Surface Coating Materials Available to Consumers in Canada**

### **Glossary of Terms**

CEPA 1999	<i>Canadian Environmental Protection Act, 1999</i>
Surface Coating Material	For the purposes of this proposed code of practice (herein referred to as the proposed code), the definition of a surface coating material is the same as in the <i>Surface Coating Materials Regulations</i> under the <i>Canada Consumer Product Safety Act (CCPSA)</i> , as amended from time to time: a paint or other similar material that dries to a solid film when a layer of it is applied to a surface. It does not include a material that becomes a part of the substrate.
Consumer Product	For the purposes of this proposed code, a consumer product is a product that may reasonably be expected to be obtained by an individual to be used for non-commercial purposes.

### **1. Purpose of the Proposed Code of Practice**

The risk management objective for the proposed code for DEGME is to further protect human health by reducing the concentrations of DEGME in consumer products that are surface coating materials. The proposed code will help meet this objective by facilitating a reduction in exposure of the general public to DEGME during application of surface coating materials. All applicable municipal, provincial, territorial and federal legal requirements pertaining to this substance must still, however, be met and a commitment by any person to adopt the practices and procedures set out in the proposed code does not remove obligations to comply with all applicable statutory and regulatory requirements. This proposed code outlines the following recommended practice:

***The concentration of total DEGME present in a surface coating material available to a consumer in Canada should not be more than 10,000 mg/kg (also expressed as 1.0% w/w).***

### **2. Background**

DEGME (CAS# 111-77-3) was assessed as part of Batch 3 of the Challenge to industry under the Chemicals Management Plan. The final screening assessment for DEGME can be found on the [Chemicals Management Plan website](#). The report concludes that DEGME is 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 conclusion is based on the potential inadequacy of the margin between exposure and critical effect levels. Specifically, the margin between conservative estimates of dermal exposure to DEGME during use of consumer products and critical effect levels for developmental toxicity in experimental animals was considered inadequate.

The proposed risk management approach document describes the various uses of and exposure sources to DEGME. The principal source of exposure to DEGME in the general population is expected to be through inhalation and dermal contact during the use of consumer products containing the substance and, in particular, during the use of various surface coating materials in which DEGME is used as a solvent.

### 3. Exposure Mitigation

It is recommended that the concentration of total DEGME present in a surface coating material available to a consumer in Canada not exceed 10,000 mg/kg when a wet sample is tested in accordance with a method that conforms to good laboratory practices (see Appendix 1). Note: 10,000 mg/kg = 1.0% w/w.

### 4. Applicability

This proposed code may be adopted by any person who manufactures in Canada or imports into Canada surface coating materials that are consumer products containing DEGME.

### 5. Applicable Products

This proposed code is applicable to consumer products that are surface coating materials containing DEGME.

### 6. Products Excluded from the Proposed Code

Surface coating materials for industrial and/or commercial use only are not included in the proposed code.

### 7. Declaration

Canadian manufacturers and importers of consumer products that are surface coating materials containing DEGME who have adopted the measures in this proposed code are advised to communicate, in writing, to the Minister of Health no later than six months after publication of the proposed code or six months after they start to use DEGME in their products or import products containing DEGME. The Minister of Health should also be notified in writing when anyone who has adopted the proposed code permanently ceases to manufacture or import applicable products containing DEGME.

Please see Appendix 2 for a declaration form that can be submitted to the Minister of Health.

### 8. Contact Information to Submit Declarations

Declarations should be submitted to the Minister of Health either by mail, email or fax to the following addresses. Please type: **"Declaration for Code of Practice for DEGME"** in the subject line of your message.

**E-mail:** [chemicalsubstanceschimiques@hc-sc.gc.ca](mailto:chemicalsubstanceschimiques@hc-sc.gc.ca)

**Mail:** Chemical Substances Website  
c/o Health Canada  
269 Laurier Avenue West, Address Locator 4905B  
Ottawa (ON) K1A 0K9

**Fax:** 613-952-8857

## 9. Confidentiality

In this section, "confidential business information" in respect of a person to whose business or affairs the information relates, refers to business information:

- that is not publicly available;
- in respect of which the person has taken measures that are reasonable in the circumstances to ensure that it remains not publicly available;
- that has actual or potential economic value to the person or their competitors because it is not publicly available and its disclosure would result in a material financial loss to the person or a material financial gain to their competitors.

A person who provides information to the Minister of Health under this proposed code may submit a written request that the information or part of it be treated as confidential business information. If the Minister considers that the information does not meet the definition of confidential business information, a written notice will be given to this effect to the person who provided the information to the Minister.

The Minister of Health will use and disclose confidential business information in respect of which a request for confidentiality has been made as permitted by law. For greater certainty, personal information as defined in section 3 of the *Privacy Act* will be used and disclosed in accordance with that Act.

## 10. Verification and Reporting

The Minister of Health will evaluate the effectiveness of the proposed code. To that end, baseline data on concentrations of DEGME in consumer products that are surface coating materials have been collected in 2014. Approximately 2 years after the publication of the final code, information on the concentrations of DEGME in consumer products that are surface coating materials will again be requested. Future information requests, whether mandatory or voluntary, may also be made to determine whether the code of practice is effective or whether additional risk management is required.

## 11. Coming into Effect

The proposed code will come into effect on the day of its final publication in the *Canada Gazette*, Part I.

## Appendix 1. Definition of Good Laboratory Practices

The Principles of Good Laboratory Practice (GLP) have been developed to promote the quality and validity of test data used for determining the safety of chemicals and chemical products. It is a managerial concept (i.e. Quality Management System) covering the organisational process and the conditions under which laboratory studies are planned, performed, monitored, recorded and reported. Its principles are required to be followed by test facilities carrying out studies to be submitted to national authorities for the purposes of assessment of chemicals and other uses relating to the protection of man and the environment. (From: [Good Laboratory Practice - OECD Principles and Guidance for Compliance Monitoring](#), 2005.)

## Appendix 2. Example Declaration Form

### 1. Contact Information:

a) Name and civic address of the person providing information or duly authorized representative:

Name of Contact:  
Name of Company/Corporation:  
Civic and Postal Address:  
E-mail Address:  
Telephone Number:  
Fax Number:

b) General/Technical contact for the company/facility (if different from authorized representative). This contact information will be used by Health Canada to correspond with your company/facility on items related to your submission.

Name of Contact:  
Name of Company/Corporation:  
Civic and Postal Address:  
E-mail Address:  
Telephone Number:  
Fax Number:

### 2. Declaration:

I declare that [Insert Company Name] has adopted the *Code of Practice for a Recommended Concentration of 2-(2-Methoxyethoxy) Ethanol (DEGME) in Surface Coating Materials Available to Consumers in Canada*.

**Signature:**

**Date:**