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

November 2016

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## 1.0 Purpose of the Code of Practice

The risk management objective for the Code for DEGME is to further protect human health by reducing the concentration of DEGME in consumer products that are surface coating materials (see Appendix 1). The 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 Code does not remove obligations to comply with all applicable statutory and regulatory requirements. This 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).*

## 2.0 Background

DEGME (CAS# 111-77-3) was assessed as part of Batch 3 of the Challenge under the Government of Canada's 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 and can be found on the Chemicals Management Plan website. 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.

The proposed Code for DEGME was subjected to a 60-day public comment period in which a single correspondent acknowledged the proposed Code with no further comment aside from requesting additional engagement in future risk management activities.

## 3.0 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 2). Note: 10,000 mg/kg = 1.0% w/w.

## 4.0 Persons to which the Code Applies

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

## 5.0 Products to which the Code Applies

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

## 6.0 Products Excluded from the Code

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

## 7.0 Declaration

Canadian manufacturers and importers of consumer products that are surface coating materials containing DEGME who have adopted the measures in this Code are advised to communicate, in writing, to the Minister of Health no later than six months after publication of the 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 Code permanently ceases to manufacture or import applicable products containing DEGME.

Please see Appendix 3 for a declaration form that can be submitted to the Minister of Health.

## 8.0 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

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

**Fax:** 613-952-5354

## 9.0 Confidentiality

In this section, "confidential business information" in respect of a person to whose business or affairs the information relates, means 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; and
- 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 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.

## 10.0 Verification and Reporting

The Minister of Health has evaluated the degree to which the concentration limit stated in the proposed Code has already been adopted by manufacturers and importers. To that end, baseline data on concentrations of DEGME in consumer products that are surface coating materials have been collected in 2014 and again in 2016. Approximately 2 years after the publication of this Code, information on the concentrations of DEGME in consumer products that are surface coating materials may 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.

## 11.0 Coming into Effect

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

## Appendix 1. Glossary of Terms

| | |
|---|---|
| CEPA | *Canadian Environmental Protection Act, 1999* |
| Surface Coating Material | For the purposes of this Code of Practice (herein referred to as the "Code"), the definition of a surface coating material is the same as in the *Surface Coating Materials Regulations* under the *Canada Consumer Product Safety Act* (CCPSA), 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 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. |

## Appendix 2. 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 organizational 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 human health and the environment. (From: Good Laboratory Practice - OECD Principles and Guidance for Compliance Monitoring, 2005. Available online at:www.oecd-ilibrary.org/environment/good-laboratory-practice_9789264012837-en).

## Appendix 3. Example Declaration Form

This form may be used as a template to provide information to Health Canada in respect to Section 7 of the Code of Practice.

**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*.

| | |
|---|---|
| _____ | _____ |
| Submitter Name (print) | Submitter Title |
| _____ | _____ |
| Telephone | Email |
| _____ | _____ |
| Submitter Signature | Date of Signature |

Request for Confidentiality

Please identify specific sections that are requested to be treated as confidential.