

DEPARTMENT OF THE ENVIRONMENT

CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

Significant New Activity Notice No. 16734

Significant New Activity Notice

(Section 85 of the *Canadian Environmental Protection Act, 1999*)

Whereas the Minister of the Environment and the Minister of Health have assessed information in respect of the substance magnesium hydroxide sulfate ($\text{Mg}_6(\text{OH})_{10}(\text{SO}_4)$), Chemical Abstracts Service Registry No. 124343-14-2, under section 83 of the *Canadian Environmental Protection Act, 1999*;

Whereas the substance is not specified on the *Domestic Substances List*;

And whereas the ministers suspect that a significant new activity in relation to the substance may result in the substance becoming toxic within the meaning of section 64 of the *Canadian Environmental Protection Act, 1999*,

Therefore, the Minister of the Environment indicates, pursuant to section 85 of the *Canadian Environmental Protection Act, 1999*, that subsection 81(4) of that Act applies with respect to the substance in accordance with the Annex.

PETER KENT
Minister of the Environment

ANNEX

Information Requirements

(Section 85 of the *Canadian Environmental Protection Act, 1999*)

1. In relation to the substance magnesium hydroxide sulfate ($\text{Mg}_6(\text{OH})_{10}(\text{SO}_4)$), a significant new activity is

- (a) its use in architectural coatings, friction materials, insulation or construction materials intended to be used by consumers, in a quantity that exceeds 100 kg per calendar year; or
- (b) any use where the substance is engineered to contain particles of particle size ranging from 1 to 100 nanometres in one or more dimensions, in a quantity that exceeds 10 kg per calendar year.

2. The following information must be provided to the Minister at least 90 days before the commencement of each proposed significant new activity:

- (a) a description of the proposed significant new activity in relation to the substance;
- (b) for a significant new activity described in paragraph 1(a):

- (i) the information specified in item 7 of Schedule 4 to the *New Substances Notification Regulations (Chemicals and Polymers)*,
- (ii) the information specified in item 8 of Schedule 5 to those Regulations,
- (iii) the information specified in item 11 of Schedule 6 to those Regulations,
- (iv) the test data and a test report on the subchronic inhalation toxicity of the substance, including a satellite (reversibility) study, conducted according to the methodology described in the Organisation for Economic Co-operation and Development (OECD) Test Guideline Test No. 413 (Test Guideline) titled *Subchronic Inhalation Toxicity: 90-day study*, and where the Test Guideline is current at the time the test data are developed, and
- (v) the test data and a test report on bronchoalveolar lavage conducted immediately following the last exposure and recovery in the subchronic inhalation toxicity test required in subparagraph (iv), conducted according to the methodology described in the OECD Series on Testing and Assessment, Number 125 (Guidance Document), titled *Guidance Document on Histopathology for Inhalation Toxicity Studies, Supporting TG 412 (Subacute Inhalation Toxicity: 28-Day Study) and TG 413 (Subchronic Inhalation Toxicity: 90-Day Study)*, and where the Guidance Document is current at the time the test data are developed;
- (c) for a significant new activity described in paragraph 1(b):
 - (i) the information specified in Schedule 6 to the *New Substances Notification Regulations (Chemicals and Polymers)*,
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 - (ii) the analytical information to determine the primary and secondary particle size of the substance,
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 - (iii) the information describing the agglomeration and aggregation state, shape, surface area and surface charge of the substance,
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 - (iv) the analytical information to determine the leachability potential of the substance and its precursors from any final product resulting from the new activity;
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 - (v) the test data and a test report on the water solubility of the substance conducted in accordance with the OECD Series on Testing and Assessment, Number 29, *Guidance Document on Transformation/Dissolution of Metals and Metal Compounds in Aqueous Media*, and that is current at the time the test is developed,

- (vi) the analytical information to determine the primary and secondary particle size of the test substance as administered in the health and ecological toxicity tests required under subparagraph (i), and
- (vii) the information describing the agglomeration and aggregation state, shape, surface area and surface charge of the test substance as administered in the health and ecological toxicity tests required under subparagraph (i); and
- (d) all other information or test data in respect of the substance that are in the possession of the person who intends to use the substance for the proposed significant new activity, or to which they have access, and that are relevant to determining whether the substance is toxic or capable of becoming toxic.

3. The test data and the test reports described in subparagraphs 2(b)(iv) and (v) must be in conformity with the practices described in the *OECD Principles of Good Laboratory Practice* (Principles of GLP) set out in Annex 2 of the *Decision of the Council Concerning the Mutual Acceptance of Data in the Assessment of Chemicals*, adopted on May 12, 1981, and where the Test Guideline, Guidance Document and Principles of GLP are current at the time the test data are developed.

4. The above information will be assessed within 90 days after the day on which it is received by the Minister.

EXPLANATORY NOTE

(This explanatory note is not part of the Significant New Activity Notice.)

A Significant New Activity Notice is a legal instrument issued by the Minister of the Environment pursuant to section 85 of the *Canadian Environmental Protection Act, 1999*. The Significant New Activity Notice sets out the appropriate information that must be provided to the Minister for assessment prior to the commencement of a new activity as described in the Notice.

Substances that are not listed on the *Domestic Substances List* can be manufactured or imported only by the person who has met the requirements set out in section 81 of the *Canadian Environmental Protection Act, 1999*. Under section 86 of the *Canadian Environmental Protection Act, 1999*, in circumstances where a Significant New Activity Notice is issued for a new substance, it is the responsibility of every person who transfers the physical possession or control of the substance to notify all persons to whom the possession or control is transferred of the obligation to comply with the Significant New Activity Notice and of the obligation to notify the Minister of the Environment of any new activity and all other information as described in the Notice. It is the responsibility of the users of the substance to be aware of and comply with the Significant New Activity Notice and to submit a Significant New Activity notification to the Minister prior to the commencement of a significant new activity associated with the

substance. However, as mentioned in subsection 81(6) of the *Canadian Environmental Protection Act, 1999*, a Significant New Activity notification is not required when the proposed new activity is regulated under an act or regulations listed on Schedule 2 to the *Canadian Environmental Protection Act, 1999*.

A Significant New Activity Notice does not constitute an endorsement from Environment Canada or the Government of Canada of the substance to which it relates, or an exemption from any other laws or regulations that are in force in Canada and that may apply to this substance or activities involving the substance.