

Summary of Risk Assessment Conducted Pursuant to subsection 83(1) of the *Canadian Environmental Protection Act, 1999*

New Substances Notification 16734: Magnesium hydroxide sulfate (Chemical Abstracts Service registry number 124343-14-2)

Regulatory decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA), and pursuant to section 83 of the Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance, and have determined based on the available information, that when used as notified, the substance is not anticipated to enter 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, constitute or may constitute a danger to the environment on which life depends, or constitute or may constitute a danger in Canada to human life or health.

The significant new activity (SNAc) provisions of CEPA were applied to the substance because of potential environmental and human health impacts that could arise as a result of potential new activities. [Order 2012-87-12-01 Amending the Domestic Substances List](#) outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 147, No. 7 on March 27, 2013. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substance undergoes further assessment and risk management consideration.

Substance identity

The notified chemical is magnesium hydroxide sulfate (Chemical Abstracts Service registry number¹ 124343-14-2).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as a plastics additive. Potential uses may include as a reinforcement, insulator and friction material in a wide variety of applications.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to water. The substance is not expected to be persistent as it is expected to readily dissociate to form inorganic oxides and sulfates. However, the magnesium ion will be persistent in water

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because it cannot degrade any further. The substance is not expected to bioaccumulate because it is an inorganic solid.

Environmental risk assessment

Based on the available hazard information, the substance is expected to have low toxicity in fish, aquatic invertebrates and algae (no adverse effects observed in saturated solutions). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

The notified and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activities is expected to be mainly from formulation and use by release of the substance to water at low rates given that the substance will be used in a contained industrial environment, and the substance will be encapsulated within a polymer matrix in end-use products with very little leaching expected. For potential activities such as use as an additive in resins or other materials, environmental exposure is expected to be low, similar to the notified use. A predicted environmental concentration was not calculated due to the low potential for environmental exposure.

Based on the low potential for ecotoxicity and environmental exposure, the substance is unlikely to cause ecological harm in Canada when not manufactured at the nanoscale.

However, should the substance be manufactured as a nanomaterial, it may have different properties and behaviours, and so additional information is required to further evaluate potential environmental risks. See “Nanomaterial considerations” section below for further information. For more information on the use of the term “manufactured” in relation to the engineering of nanomaterials, see the [Health Canada’s working definition for nanomaterial](#).

Human health risk assessment

Based on the available hazard information, the substance is expected to have a low acute toxicity by the inhalation route ($LC_{50} > 5 \text{ mg/L/4hr}$). It is not a dermal sensitizer ($>10\%$ estimated concentration required to produce a stimulation index of 3 (local lymph node assay)). It is not mutagenic *in vitro* or clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage. Similar substances have been found to cause kidney toxicity and cancer if inhaled.

When the notified substance is used as an additive in plastics, consumers may come into contact with end-use products containing the substance; however, direct exposure is expected to be low because the substance will be encapsulated within the stable matrix of the product and leaching is expected to be minimal. Indirect exposure of the general population from environmental media such as drinking water is expected to be at levels that do not pose a concern, given the low potential for release to the environment from industrial uses, and the low potential for leaching from end-use products during consumer use. However, potential uses of the substance include use as reinforcement, insulator and friction materials in a wide variety of applications, which may result in significantly different exposure.

Based on the low potential for exposure when used as notified, the substance is not likely to pose a significant health risk to the general population, and is therefore unlikely to be harmful to human health.

However, based on indications that the substance causes inhalation toxicity, the potential use of the substance in applications causing inhalation exposure could significantly alter the exposure and/or conditions of use resulting in the substance becoming harmful to human health. In addition, the potential manufacturing of the substance at the nanoscale could significantly alter the exposure and/or conditions of use resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with these activities.

Nanomaterial considerations

While the substance was not notified with a particle size on the nanometer scale, there is evidence that it may be available industrially, commercially, or in consumer products in the form of nanoparticles, nanoplates, nanoflowers, nanowhiskers, nanoribbons and nanobelts. Substances in the 1-100 nanometer size range may exhibit significantly different physical and chemical properties, environmental fate, toxicity, and exposure potential. More information is necessary to better characterize potential environmental and health risks.

Assessment conclusion

When the substance is used as notified, it is not suspected to be harmful to human health or the environment within the meaning of the criteria under section 64 of the Act. However, it is suspected that a significant new activity in relation to the substance could result in the substance meeting those criteria.

Due to the potential risk to human health related to inhalation toxicity if the substance were to be used in applications causing inhalation exposure, and due to the identified potential for engineering or use of the substance at the nanometer scale and the uncertainty predicting environmental fate, hazard and exposure in those scenarios, the SNAC provisions under CEPA were applied to the substance in order to obtain information to ensure that the substance undergoes further assessment before these potential activities are undertaken. Order 2012-87-12-01 was published in the *Canada Gazette* Part II, Vol. 147, No. 7 on March 27, 2013.

A conclusion under CEPA, on this substance, is not relevant to, nor does it preclude an assessment against the hazard criteria for Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or *Hazardous Products Regulations* for products intended for the workplace.