

GRASS Assessment Report
MAGNESIUM HYDROXIDE (H₂MgO₂)

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1. SUBSTANCE DESCRIPTION SUMMARY

Substance name		Magnesium hydroxide
1.1.	Alternative names and synonyms	Magnesium dihydroxide; Milk of magnesia; Brucite; Magnesium hydroxide suspension; Magmex; Magnesiumhydroxid
1.2	Pubchem Database link	https://pubchem.ncbi.nlm.nih.gov/compound/73981#section=Top
1.3	TOXNET database link	http://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+hsdb:@term+@DOCNO+659
1.4	Chemical formula	Mg(OH) ₂
1.5	Molar mass	58.31968 g/mol
1.6	IUPAC ID	magnesium dihydroxide
1.7	CAS number	1309-42-8
1.8	Melting point	350 °C (decomposition)
	Boiling point	decomposition
1.9	Specific Migration limit	No Information Available from any designated sources for all synonyms
1.10	Density:	2.36 g/ml
	Particle size distribution (D10)	Whilst no specific size distribution data is available from any sources, review of the literature suggests that particle size distribution of 6.0–30.0 µm are standard although various reports of nano-scale powders exist.
	Particle size distribution (D50)	
	Particle size distribution (D90)	
1.11	Solubility in water	0.0009 g in 100cm ³ of H ₂ O (18°C) 0.004 g in 100cm ³ of H ₂ O (100°C) 13 mol/L
	Solubility in acids	Soluble (Solubilised with chemical reaction)
	Solubility in alkalines	Soluble (Solubilised with chemical reaction)
	Solubility in solvent	Insoluble in organic solvents
	Solubility partition coefficient (Log P)	-0.87

2. HARMFUL EFFECTS TO HEALTH

H318: Causes serious eye damage.^{1,2}

- Eye irritation
- Exposure route: Direct eye contact
- Concentration required for toxicity: unknown

H319: Causes serious eye irritation ^{1,2}

- Eye irritation
- Exposure route: Direct eye contact
- Concentration required for toxicity: unknown

H315: Causes skin irritation ^{1,2}

- Skin irritation
- Exposure route: Direct dermal contact
- Concentration required for toxicity: unknown

OCH3: Un-Coded Human Health Hazard ^{1,2}

- Magnesium CNS effects
- Exposure route: Oral
- Concentration required for toxicity: unknown

OCH3: Un-Coded Human Health Hazard ^{1,2}

- Respiratory tract irritation
- Exposure route: Inhalation, nasal
- Concentration required for toxicity: 10mg/m3 (old PEL)

OCH3: Un-Coded Human Health Hazard ^{1,2}

- Kidney and digestive damage
- Exposure route: Oral intake
- Concentration required for toxicity: unknown

H335: May cause respiratory irritation ¹

- Respiratory tract irritation
- Exposure route: Inhalation, nasal
- Concentration required for toxicity: unknown

Accumulative effects: Bioconcentration factor of 2.48 according to CompTox.³

Combinatory effects: --

3. HARMFUL EFFECTS TO ENVIRONMENT

Not applicable

4. REGULATORY LIMITS AND RESTRICTIONS

ADI / TDI EU	Not specified (for magnesium 6 mg/kg BW/day) / ADI of 350mg for magnesium. Exposure route: Oral. ^{4,5}
ADI / TDI WHO	Not limited. Exposure route: Oral. ⁴
ADI / TDI USA	Not specified
OSHA PEL	15 mg/m ³ (total dust) TWA for Magnesium oxide fume. "Effective" IDLH = 7,500 mg/m ³ . Exposure route: Inhalation. ⁶
Safety of substance according to CDC NIOSH website	Only available for Magnesium oxide https://www.cdc.gov/niosh/npg/npgd0374.html
ICSC card if available	Only available for Magnesium oxide: http://www.cdc.gov/niosh/ipcsneng/neng0504.html
Haz-Map link	https://hazmap.nlm.nih.gov/category-details?id=5891&table=copytblagents
OSHA.gov link	None - see Magnesium oxide above

5. PI SUMMARY STATEMENTS

Primary PI statement on human health

With some basic limits and restrictions, Magnesium hydroxide can be considered as safe to human health to a GRASS Class C, and there is sufficient evidence to establish a class outcome with reasonable scientific confidence.

At present there are no doubts or any lack of certainty, to the safety of the substance with regards to human health and due to the extensive and long-established history of use of the substance, it can be generally accepted as safe for use in production and manufacturing

Basic handling safety measures are required to mitigate any harmful effects in occupational environments and even though no limit description has been determined, limits described by the CDC for magnesium oxide fumes - enforce a TWA of 15mg/m³ (total dust).

Magnesium hydroxide is considered as safe for the use as food additive. Whilst no ADI has been specifically established for the substance, Magnesium Hydroxide, exposure should never exceed 350mg/ day as specified for magnesium, or 6 mg/kg BW/day.

Magnesium intake may be harmful if inhaled, and a PEL of 10mg/m³ is advised.

Oral magnesium overdose is highly rare, although data report that extreme overdose may cause GI disturbance, potential CNS depression and kidney damage realistic risks. Due to the identification of high alert human health hazard codes, Organics Council[®] considers having enough evidence to support that the maximum applicable GRASS class for this substance is Class C.as these effects arise from extreme overdose/magnesium intake/repetitive exposure (GHS H305), which should be fully avoided using basic limits and restrictions.

Concerns might arise from the use of magnesium hydroxide as pH adjuster in cosmetics since eye/skin irritation effects have been reported for this substance (H318, H319, H315). Therefore Organics Council[®] do not approve the use of this substance in any product where direct eye contact or inhalation may occur.

No natural magnesium hydroxide NP compounds exists; only synthetic NPs, which are not approved for use by Organics Council[®] as outlined in our NP position statement.

Additional secondary PI notes on human health

While there is extensive and long-established history of use of Magnesium hydroxide, showing that it is generally accepted as safe for use in production and manufacturing. Due to the identification of high alert human health hazard codes, the maximum applicable GRASS class for this substance is Class C. Whilst an ADI has not been specifically established, exposure should never exceed 350mg/ day as specified for magnesium, or 6 mg/kg BW/day. Inhalation should never exceed 10mg/m³, due to its association with respiratory tract irritation. Direct eye contact should be avoided completely. Magnesium hydroxide demonstrates a 15% bioavailability and it constitutes a clinically relevant option for oral Mg supplementation and from this, no severe side effects are known. Although, daily use of magnesium hydroxide can result in fluid and electrolyte disturbances. Not to be used by individuals with any form of kidney disease or renal failure. Not to be used by women who are about to deliver as magnesium crosses the placenta and is excreted in small amounts in breast milk.

Primary PI statement on environmental health

With some basic limits and restrictions, magnesium hydroxide can be considered as safe to environmental health to a GRASS Class A, although it is of concern that there is very little available information on the environmental impact of this substance.

At present there are no doubts or any lack of certainty, to the safety of the substance with regards to human health.

There are no associated sustainability impacts that have been reported as a result of sourcing, processing, usage or disposal of this substance.

There are no serious or irreversible effects on environmental health associated with overdose, misuse or unconventional use.

No high alert or banned H codes exist. This substance can be considered as safe to the environment ensuring some basic restrictions avoid excessive release into the atmosphere, aquatic resources or soils.

Additional secondary PI notes on environmental health

There is no evidence of any negative impact or harmful effect on the environment due to the use, processing or disposal of this substance. Nor is there any evidence of lack of sustainability for this substance. Therefore Magnesium Hydroxide may be considered a Class A GRASS substance.

6. FINAL CLASS

Human health - Class C

Environmental health – Class A

7. RESEARCHER NAME AND DATES OF ASSESSMENT

Researcher: Dr. Olga Snurnikova

Primary review PI: Dr. Nicolas Goffette

Secondary review PI: Dr. Esme L Purdie

Date of assessment completion: 13.06.2017

8. REFERENCES

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- ¹ PubChem. NIH - U.S. National Library of Medicine. <https://pubchem.ncbi.nlm.nih.gov/compound/73981#section=Top>
- ² ToxNet. NIH - U.S. National Library of Medicine. <http://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+hsdb:@term+@DOCNO+659>
- ³ ChemNet. Global Chemical Network. <http://www.chemnet.com/cas/supplier.cgi?terms=1309-42-8&l=en&exact=dict&f=plist&mark=&submit.x=46&submit.y=13&submit=search>
- ⁴ WHO. Joint FAO/WHO Expert Committee on Food Additives (JECFA). <http://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=2881>
- ⁵ EUROPEAN FOOD SAFETY AUTHORITY. Scientific Opinion on Dietary Reference Values for magnesium. <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4186/full>
- ⁶ <http://www.cdc.gov/niosh/idlh/1309484.html>