CHEMICAL SAFETY REPORT

Substance Name: magnesium chloride

EC Number: 232-094-6

CAS Number: 7786-30-3

Registrant's Identity: Macco Organiques, s.r.o., Czech Republic

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Part A

Annex I, 0.13 of REACH regulation “General Provisions for Assessing substances and preparing chemical safety reports” indicates that Part A of the chemical safety report should include a declaration that the risk management measures outlined in the relevant exposure scenarios for the manufacturer's or importer's own use(s) are implemented by the manufacturer or importer and that those exposure scenarios for the identified uses are communicated to distributors and downstream users in the safety data sheet(s).

As the substance $MgCl_2$ does not meet the criteria for classification as dangerous according to Directive 67/548/EEC or Regulation 1272/2008 and is not assessed as being a PBT or vPvB substance, an exposure assessment and a risk characterisation have not been performed. Thus, no specific risk management measures, in compliance with REACH regulation, have to be implemented by the manufacturer and the downstream users and no safety data sheet is required.

Nevertheless, all relevant information will be communicated by the manufacturer to the downstream user as required in article 32 of REACH (first aid measures, fire-fighting measures, accidental spillage…).

Part B

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1. Name and other identifiers of the substance

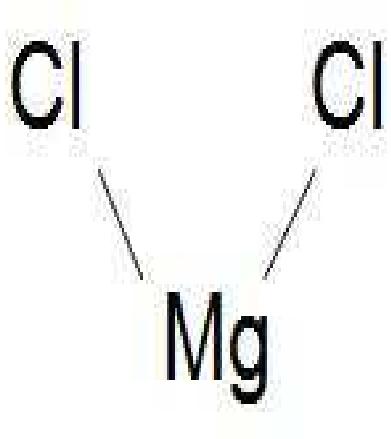
The substance **magnesium chloride** is a mono constituent substance (origin: inorganic) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).

The following public name is used: Magnesium Chloride.

Table 1. Substance identity

EC number:	232-094-6
EC name:	magnesium chloride
CAS number (EC inventory):	7786-30-3
CAS name:	Magnesium Chloride
IUPAC name:	Magnesium Chloride
Description:	At 20°C and 101,3 kPa, colour of Magnesium Chloride is white to gray granules and/or flakes. Crystalline structure of magnesium chloride (anhydrous form) : rhomboedric
Molecular formula:	Cl2Mg
Molecular weight range:	>= 95.206 — <= 95.216

Structural formula:



1.2. Composition of the substance

Name: Magnesium Chloride

According to the REACH Guidance for identification and naming of substances under REACH, hydrates and water free (anhydrous) forms of compounds shall be regarded as the same substance. Therefore this dossier includes information on anhydrous substance, as well hexahydrate forms of magnesium chloride. The majority of information included in this dossier is considered to be applicable to all forms, unless stated otherwise.

Various forms of magnesium chloride are manufactured and imported in the EU:

- magnesium chloride anhydrous
- magnesium chloride hexahydrate

Name: Magnesium chloride (anhydrous)

Table 2. a) Constituents

Constituent	Typical concentration	Concentration range	Remarks
Magnesium chloride	99,5	> 99 % - 100%	

Table 3. a) Impurities

Impurity	Typical concentration	Concentration range	Remarks
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Name: Magnesium chloride (hexahydrate)

Table 4. b) Constituents

Constituent	Typical concentration	Concentration range	Remarks
Magnesium chloride	47 %	46 – 48 %	

Table 5. b) Impurities

Impurity	Typical concentration	Concentration range	Remarks
water	53 %	52 – 54 %	Crystallic water

1.3. Physico-chemical properties

Table 6. Overview of physico-chemical properties

Property	Results	Value used for CSA / Discussion
Physical state at 20°C and 1013 hPa	Several independent sources indicate that MgCl2 is solid at 20°C and 101.3 kPa. Colour is white, and the product is odorless	**Value used for CSA:** solid Several independent sources indicate that

Property	Results	Value used for CSA / Discussion
	(based on experience in handling and use).	$MgCl_2$ is solid at 20°C and 101.3 kPa. Different studies indicate the following appearance for chloride magnesium : - thin white to gray granules and/or flakes - lustrous hexagonal crystals - soft leaflets - colourless or white crystals - white lustrous hexagonal crystals
Melting / freezing point	The melting point of chloride magnesium is reported to be 712°C (The Merck Index, CRC Handbook of Chemistry and Physics).	**Value used for CSA:** 712 °C at 101.3 kPa Several independent sources indicate that melting point of MgCl2is 712°C at 101.3 kPa. On the basis of Annex XI, section 1.2, a weight of evidence approach can be used. Several independent sources indicate that the endpoint is 712°C at 101,3 kPa. Therefore, we assume, that the results are valid and that testing does not appear necessary.
Relative density	Relative density at 20°C is 2.316	**Value used for CSA:** 2.316 at 20°C Density and relative density have been determined according to guideline EC method A.3, OECD 109. The density of Magnesium Chloride Anhydrous was determined to be 2.316 g/cm^3 at 20°C. The relative density of Magnesium Chloride was determined to be 2.316
Water solubility	The water solubility of magnesium chloride anhydrous was determined according to OECD Guideline 105 and EC method A.6 (92/69/EC).	**Value used for CSA:** 468.7 g/L at 20 °C The water solubility of magnesium chloride anhydrous was determined according to OECD Guideline 105 and EC method A.6 (92/69/EC). The water solubility of Magnesium Chloride Anhydrous was determined in bidistilled water (being in equilibrium with atmospheric carbon dioxide) at 20°C +/- 0.5°C. The water solubility of Magnesium Chloride Anhydrous in bidistilled water (being in equilibrium with atmospheric carbon dioxide) at 20 °C +/- 0.5°C is determined to be 468.7 g/L. The pH of the saturated solution was pH 4.3
Flammability	Magnesium chloride is non flammable	**Value used for CSA:**

Property	Results	Value used for CSA / Discussion
		non flammable Magnesium chloride is reported to be non-flammable (Source : ICSC) This result can be confirmed by the chemical structure of MgCl2. Since magnesium is in its most stable oxidation state, the substance is incapable of further reactions with oxygen. For water flammability, testing can be waived based on experience in handling and use : magnesium chloride is not flammable
Self-ignition temperature	No self-ignition temperature was observed up to the maximum test temperature of 404°C.	No self-ignition temperature was observed up to the maximum test temperature of 404°C, according to the testing guideline for auto-flammability (solids-determination of relative self-ignition temperature) in the sense of the European Commission Regulation (EC) n°440/2208, Method A.16.

Data waiving

Information requirement: Boiling point

Reason: other justification

Justification: On the basis of column 2 on Annex VII of Regulation REACH, the study does not need to be conducted for solids which melt above 300°C

Information requirement: Vapour pressure

Reason: other justification

Justification: According to column 2 of Annex VII of Regulation REACH, the study does not need to be conducted if the boiling point is above 300°C

Information requirement: Surface tension

Reason: other justification

Justification: On the basis of column 2 on Annex VII of Regulation REACH, the study needs only to be conducted if:

- based on structure, surface activity is expected or can be predicted; or

- surface activity is a desired property of the material

which is not the case of MgCl2

Information requirement: Partition coefficient n-octanol/water (log value)

Reason: other justification

Justification: On the basis of column 2 on Annex VII of Regulation REACH, the study does not need to be conducted if the substance is inorganic

Information requirement: Flash point

Reason: other justification

Justification: On the basis of column 2 on Annex VII of Regulation REACH, the study does not need to be conducted if the substance is inorganic

Information requirement: Explosive properties

Reason: other justification

Justification: On the basis of column 2 on Annex VII of Regulation REACH, the study does not need to be conducted if there are no chemical groups associated with explosive properties present in the molecule

Information requirement: Oxidising properties

Reason: other justification

Justification: On the basis of column 2 on Annex VII of Regulation REACH, the study does not need to be conducted if the substance is incapable of reacting exothermically with combustible materials, for example on the base of the chemical structure. MgCl2 is thermodynamically stable as magnesium is in its highest oxidation state.

Information requirement: Granulometry

Reason: study scientifically unjustified

Justification: Magnesium chloride is deliquescent, which means that it tends to undergo gradual dissolution and liquefaction by the attraction and the absorption of the moisture from the air.

Essays have been conducted on magnesium chloride to assess percentage of moisture depending on time.

It has to be noticed that:

- after one day, the rate of moisture already reached more than 20%,

- after leaving the sample several days at ambient atmosphere, the sample became completely liquid

Granulometry is a parameter that applies to granular form. As magnesium chloride does not stay under a granular form and hydrates quickly, study appears scientifically unjustified.

Information requirement: Stability in organic solvents and identity of relevant degradation products

Reason: other justification

Justification: On the basis of column 2 on Annex VII of Regulation REACH, the study does not need to be conducted if the substance is inorganic

Information requirement: Dissociation constant

Reason: study scientifically unjustified

Justification: Dissociation constant is a specific type of equilibrium constant that measures the propensity of a larger object to separate reversibly into smaller components, as when a complex falls apart into its component molecules, or when a salt splits up into its component ions. Given that chemical structure f chloride magnesium and its properties of solubilities, dissociation constant is equal to water solubility constant. Besides, dissociation constant is an important property for ionisable organic substances since it indicates which chemical species will be present at a particular pH, which is not the case of chloride magnesium.

Information requirement: Viscosity

Reason: study scientifically unjustified

Justification: Viscosity is the property of a fluid substance of absorbing a stress during deformation which depends on the rate of deformation. Viscosity is relevant only for liquids, therefore for many substances this determination is not required (Guidance on information requirements and chemical safety assessment, chapter R.7a: Endpoint specific guidance)

Discussion of physico-chemical properties

Magnesium chloride is a deliquescent solid. It can be found under different forms: granules, flakes, crystals, soft leaflets...

Physical and chemical properties of this substance are:

- melting point: 712°C
- boiling point: 1412°C
- relative density: 2.316
- water solubility: 468.7 g/L

The substance is not flammable, and has neither explosive properties nor oxidising properties. Magnesium chloride is not classified for its physical and chemical properties.

2. MANUFACTURE AND USES

Quantities

Table 7. Overview of quantities (in tonnes/year)

Year	Total tonnage	Own use	Used for article	Used as intermediate under strictly controlled conditions	Used for research purposes
2008	1700	0	0	0	0
2009	1900	0	0	0	0
2010	2200	0	0	0	0

2.1. Manufacture

Manufacturing process

Acid-magnesite production

This process is based on the direct reaction of HCl with natural magnesite according to the following equation:

$MgCO3 + 2\ HCl \rightarrow MgCl2 + H2O + CO2$

This may occur as a deliberate direct process or indirectly when the magnesite is used in HCl acid fume abatement technology.

The quality and strength of the solution produced will depend on the purity of the raw materials and the concentration of the acid used.

Purification steps (e.g. addition of magnesium hydroxide slurry) allow precipitating impurities like iron and other metals, which are then separated by filtration.

Liquor produced via this route may be used in the production of flakes, prills or crystals.

2.2. Identified uses

The main uses of magnesium chloride are as follows :

- for industrial processing
- for magnesium salt production
- food processing agent
- food additives
- medication
- laboratory chemicals

Percentages of the uses are different among member countries and may vary from year to year.
In addition, magnesium chloride was evaluated to be a food substance of very low toxicity and thus the establishment of the acceptable daily intake (ADI) for calcium chloride has not been deemed necessary by the Joint FAO/WHO Expert Committee on Food Additives (1974, 2001).

Table 8. Uses by workers in industrial settings

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
	1	production of magnesium chloride		**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 15: Use as laboratory reagent PROC 19: Hand-mixing with intimate contact and only PPE available. PROC 26: Handling of solid inorganic substances at ambient temperature **Environmental release category (ERC):** ERC 1: Manufacture of substances **Sector of end use (SU):** SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) **Subsequent service life relevant for that use?:** no
	2	Use of magnesium chloride as chemical intermediate		**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
				PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 15: Use as laboratory reagent PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature PROC 26: Handling of solid inorganic substances at ambient temperature **Environmental release category (ERC):** ERC 1: Manufacture of substances ERC 2: Formulation of preparations ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) **Sector of end use (SU):** SU 1: Agriculture, forestry and fishing SU 4: Manufacture of food products SU 5: Manufacture of textiles, leather, fur SU 6b: Manufacture of pulp, paper and paper products SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals **Subsequent service life relevant for that use?:** no
	3	Formulation and/or distribution of magnesium chloride		**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
				PROC 6: Calendering operations PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent PROC 19: Hand-mixing with intimate contact and only PPE available. PROC 26: Handling of solid inorganic substances at ambient temperature **Environmental release category (ERC):** ERC 1: Manufacture of substances ERC 2: Formulation of preparations ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) ERC 7: Industrial use of substances in closed systems **Sector of end use (SU):** SU 1: Agriculture, forestry and fishing SU 4: Manufacture of food products SU 5: Manufacture of textiles, leather, fur SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 20: Health services SU 11: Manufacture of rubber products SU 12: Manufacture of plastics products, including compounding and conversion SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
				Subsequent service life relevant for that use?: no
	4	Handling of aqueous magnesium chloride		**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature **Environmental release category (ERC):** ERC 1: Manufacture of substances ERC 2: Formulation of preparations ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) ERC 8b: Wide dispersive indoor use of reactive substances in open systems **Sector of end use (SU):** SU 1: Agriculture, forestry and fishing SU 4: Manufacture of food products SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
				SU 20: Health services SU 14: Manufacture of basic metals, including alloys **Subsequent service life relevant for that use?:** no

Table 9. Uses by professional workers

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
	1	Professional use of magnesium chloride		**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 15: Use as laboratory reagent PROC 19: Hand-mixing with intimate contact and only PPE available. PROC 26: Handling of solid inorganic substances at ambient temperature **Environmental release category (ERC):** ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8d: Wide dispersive outdoor use of processing aids in open systems ERC 1: Manufacture of substances

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
				ERC 2: Formulation of preparations **Sector of end use (SU):** SU 1: Agriculture, forestry and fishing SU 4: Manufacture of food products SU 9: Manufacture of fine chemicals SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 20: Health services **Subsequent service life relevant for that use?:** no
	2	Handling of aqueous magnesium chloride		**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature **Environmental release category (ERC):** ERC 1: Manufacture of substances ERC 2: Formulation of preparations

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
				ERC 8b: Wide dispersive indoor use of reactive substances in open systems **Sector of end use (SU):** SU 1: Agriculture, forestry and fishing SU 4: Manufacture of food products SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 14: Manufacture of basic metals, including alloys SU 20: Health services **Subsequent service life relevant for that use?:** no

Most common technical function of substance (what it does):

Food/feedstuff additives

Intermediates

Laboratory chemicals

Pharmaceutical substance

2.3. Uses advised against

No uses advised against were identified.

3. CLASSIFICATION AND LABELLING

3.1. Classification and labelling according to CLP / GHS

Name: Magnesium Chloride

Implementation: EU

State/form of the substance: solid

Related composition: Magnesium Chloride

Classification

The substance is classified as follows:

- for physical-chemical properties:

Explosives:	Reason for no classification: data lacking
Flammable gases:	Reason for no classification: data lacking
Flammable aerosols:	Reason for no classification: data lacking
Oxidising gases:	Reason for no classification: data lacking
Gases under pressure:	Reason for no classification: data lacking
Flammable liquids:	Reason for no classification: data lacking
Flammable solids:	Reason for no classification: data lacking
Self-reacting substances and mixtures:	Reason for no classification: data lacking
Pyrophoric liquids:	Reason for no classification: data lacking
Pyrophoric solids:	Reason for no classification: data lacking
Self-heating	Reason for no classification: data lacking

substances and mixtures:	
Substances and mixtures which in contact with water emits flammable gases:	Reason for no classification: data lacking
Oxidising liquids:	Reason for no classification: data lacking
Oxidising solids:	Reason for no classification: data lacking
Organic peroxides:	Reason for no classification: data lacking
Corrosive to metals:	Reason for no classification: data lacking

- for health hazards:

Acute toxicity - oral:	Reason for no classification: conclusive but not sufficient for classification
Acute toxicity - dermal:	Reason for no classification: conclusive but not sufficient for classification
Acute toxicity - inhalation:	Reason for no classification: data lacking
Skin corrosion/irritation:	Reason for no classification: conclusive but not sufficient for classification
Serious damage/eye irritation:	Reason for no classification: conclusive but not sufficient for classification
Respiration sensitization:	Reason for no classification: data lacking
Skin sensitation:	Reason for no classification: conclusive but not sufficient for classification
Aspiration hazard:	Reason for no classification: data lacking
Reproductive Toxicity:	Reason for no classification: conclusive but not sufficient for classification
Reproductive Toxicity: Effects on or via lactation:	Reason for no classification: data lacking
Germ cell mutagenicity:	Reason for no classification: conclusive but not sufficient for classification
Carcinogenicity:	Reason for no classification: conclusive but not sufficient for classification
Specific target organ	Reason for no classification: conclusive but not sufficient for classification

toxicity - single:

Specific target organ toxicity - repeated: Reason for no classification: conclusive but not sufficient for classification

- for environmental hazards:

Hazards to the aquatic environment: Reason for no classification: conclusive but not sufficient for classification

Hazardous to the atmospheric environment: Reason for no classification: data lacking

Labelling

Signal word: No signal word

3.2. Classification and labelling according to DSD / DPD

3.2.1. Classification and labelling in Annex I of Directive 67/548/EEC

Not classified

3.2.2. Self classification(s)

Not classified

3.2.3. Other classification(s)

Status: 67/548/EEC self classification

Chemical name: Magnesium Chloride

Table 10. Status not specified

Endpoints	Classification	Reason for no classification	Justification for (non) classification can be found in section
Explosiveness		data lacking	6.1
Oxidising properties		data lacking	6.3
Flammability		data lacking	6.2
Thermal stability		data lacking	
Acute toxicity		conclusive but not sufficient for classification	5.2
Acute toxicity- irreversible damage after single exposure		conclusive but not sufficient for classification	5.2
Repeated dose toxicity		conclusive but not sufficient for classification	5.6
Irritation / Corrosion		conclusive but not sufficient for	5.3.4 and 5.4.3

Endpoints	Classification	Reason for no classification	Justification for (non) classification can be found in section
		classification	
Sensitisation		conclusive but not sufficient for classification	5.5.3
Carcinogenicity		conclusive but not sufficient for classification	5.8.3
Mutagenicity - Genetic Toxicity		conclusive but not sufficient for classification	5.7.3
Toxicity to reproduction-fertility		conclusive but not sufficient for classification	5.9.3
Toxicity to reproduction-development		conclusive but not sufficient for classification	5.9.3
Toxicity to reproduction - breastfed babies		conclusive but not sufficient for classification	5.9.3
Environment		conclusive but not sufficient for classification	7.6

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4. ENVIRONMENTAL FATE PROPERTIES

General discussion of environmental fate and pathways:

Hydrolisis:

In aqueous solution, Magnesium Chloride is readily ionised under aqueous conditions (see conclusion on water solubility) to form Magnesium and Chloride ions which will combine to form various inorganic complexes.

$$MgCl_2 + H_20 \rightarrow Mg^{2+} + 2\ Cl^-$$

Therefore, hydrolysis is scientifically not relevant for $MgCl_2$ which will rapidely dissociate in water at environmentally relevant pH.

Biodegradation:

Magnesium Chloride is inorganic and can therefore not undergo any microbial degradation.

Bioaccumulation:

Magnesium Chloride dissociates into Magnesium (Mg^{2+}) and chloride (Cl^-) ions at environmental pH. These are essential to all living organisms (flora and fauna) and their intracellular and extra-cellular concentrations are actively regulated. Hence, bioaccumulation is thus not expected.

Adsorption/Desorption:

Relating to the Kd values, Magnesium Chloride displays a moderate affinity for the solid phase of the sediment particles.

4.1. Degradation

4.1.1. Abiotic degradation

4.1.1.1. Hydrolysis

Data waiving

Reason: study scientifically unjustified

Justification: A hydrolysis study does not need to be conducted as the substance is readily ionised under aqueous conditions (see conclusion on water solubility) in the environment to form Magnesium and Chloride ions which will combine to form various inorganic complexes. Therefore, hydrolysis is scientifically not relevant for MgCl2 which will rapidly dissociate in water at environmentally relevant pH

4.1.1.2. Phototransformation/photolysis

No information is available and is not required under REACH.

4.1.1.2.1. Phototransformation in air

No information is available and is not required under REACH.

4.1.1.2.2. Phototransformation in water

No information is available and is not required under REACH.

4.1.1.2.3. Phototransformation in soil

No information is available and is not required under REACH.

4.1.2. Biodegradation

4.1.2.1. Biodegradation in water

4.1.2.1.2. Screening tests

Data waiving

Reason: other justification

Justification: According to column 2 of Annex VII of Regulation no. 1907/2006, the study does not need to be conducted as Magnesium Chloride is an inorganic substance.

4.1.2.1.3. Simulation tests (water and sediments)

Data waiving

Reason: other justification

Justification: According to column 2 of Annex VII of Regulation no. 1907/2006, a simulation test on the

ultimate degradation does not need to be performed as Magnesium Chloride is an inorganic substance.

4.1.2.1.4. Summary and discussion of biodegradation in water and sediment

Magnesium Chloride is an inorganic substance, no biodegradation will occur.

4.1.2.2. Biodegradation in soil

Data waiving

Reason: other justification

Justification: According to column 2 of Annex VII of Regulation no. 1907/2006, the study does not need to be conducted as Magnesium Chloride is inorganic.

4.1.3. Summary and discussion of degradation

Abiotic degradation

Once released into the environment Magnesium Chloride is unlikely to remain in its original form, but will rapidly react with water (or moist sediments) to form Magnesium and Chloride ions which will combine to form various inorganic complexes.

Biotic degradation

Magnesium Chloride is inorganic and can therefore not undergo any microbial degradation. Therefore, it is scientifically unjustified to study and consider the biodegradation of Magnesium Chloride. In that context, tests on biodegradation in water, sediment and soil are waived.

4.2. Environmental distribution

4.2.1. Adsorption/desorption

The studies on adsorption/desorption are summarised in the following table:

Table 11. Overview of studies on adsorption/desorption

Method	Results	Remarks	Reference
Study type: Monitoring study (sediment) monitoring study Sediment samples are collected from three sites at two rivers near Hanoi, Vietnam, at three depths (0-10, 10- 20 and 20-30 cm). Pore water is extracted and filtered through a 0.45 µm nylon filter.	Adsorption coefficient: Kd: 234.4 at 20 °C (% Org. C: 1.2) Kd: 1819.7 at 20 °C (% Org. C: 10.6)	2 (reliable with restrictions) key study experimental result **Test material (CAS name): Magnesium**	Marcussen, Helle; Dalsgaard, Anders ; Holm, Peter E. (2008)

Method	Results	Remarks	Reference
Sediments are then totally digested using a closed vessel microwave system. Metal contents (in both pore water and digested sediment) are measured by ICP-MS. Distribution coefficients (logKd) were calculated as the ratio between sediment (mg/kg d.w.) and pore water (mg/L) concentrations.			
Study type: Monitoring study (sediment) Monitoring study Sediment samples (23 stream water and 18 sediments samples) were collected from Onion Creek, Ohio (near a lead-zinc mine in USA). No paired observations of Mg concentrations in solid (sediments) and solution phases were made : - Water samples were collected using sample bottles immersed upside-down below the water surface (0-20 cm) on the upstream side, inverted and allowed to fill. - Sediments samples were scooped from the middle of Onion Creek so that samples collected were representative of the entire drainage area Mg concentrations were measured (ICP-MS and EAAS) in the 23 stream water and 18 sediments samples. Distribution coefficient (Kd) values were calculated based on the average concentration of trace metals (including Mg) in Onion Creek water and sediments.	Adsorption coefficient: Kd: 1288.2 (Field study)	3 (not reliable) disregarded study experimental result **Test material (CAS name): Magnesium**	Routh, J. ; Ikramuddin, M. (1996)

Discussion

There are 2 studies with relevant information on adsorption/desorption, reporting distribution coefficients (Kd values, i. e. ratio of Mg concentration in solid phase over Mg concentration in solution phase) for sediments. Only one study (Marcussen et al., 2008), reporting Kd values for sediment ranging between 234 and 1820 L/kg (Koc = 4680 and 36400 L/kgoc respctively), based on monitoring data, is judged reliable (Klimisch 2 - No guideline study, but well performed and well described). The other study (Routh et al. 1996) is considered as unreliable (Klimisch 3) since no paired observations of Mg concentrations in solid and solution phases were made.

All the information available is based on measurement of elemental Mg in sediment and water and these results can be used for Magnesium Chloride (Magnesium chloride is readily dissociated into magnesium and chloride ions in water).

The following information is taken into account for any environmental exposure assessment:

Key study from Marcussen et al. (2008) reported Kd values for sediment ranging between 234 and 1820 L/kg, based on monitoring data.

Sediment samples collected from three sites at two rivers near Hanoi, Vietnam, at three depths (0-10, 10-20 and 20-30 cm). Pore water extracted and filtered through a 0.45 μm nylon filter. Sediment totally digested using a closed vessel microwave system. Metal content measured by ICP-MS.

Value used for CSA:

log Kp (solids-water in sediment): 2.37 L/kg at 20 °C

log Kp (solids-water in sediment): 3.26 L/kg at 20 °C

4.2.2. Volatilisation

Not relevant at normal conditions of temperature and pressure.

4.2.3. Distribution modelling

No information is available.

4.2.4. Summary and discussion of environmental distribution

Once released into the environment Magnesium Chloride is unlikely to remain in its original form, but will rapidly react with water (or moist sediments) to form Magnesium and Chloride ions which will combine to form various inorganic complexes.

4.3. Bioaccumulation

4.3.1. Aquatic bioaccumulation

Data waiving

Reason: other justification

Justification: Magnesium Chloride dissociates into the Magnesium (Mg^{2+}) and chloride (Cl^-) ions at environmental pH. These are essential to all living organisms (flora and fauna) and their intracellular and extra-cellular concentrations are actively regulated. Bioaccumulation is thus not expected.

4.3.2. Terrestrial bioaccumulation

No information is required under REACH.

4.3.3. Summary and discussion of bioaccumulation

See information above

4.4. Secondary poisoning

Based on the available information, there is no indication of a bioaccumulation potential and, hence, secondary poisoning is not considered relevant (see CSR chapter 7.5.3 "Calculation of PNEC oral (secondary poisoning) ").

Justification for no PNEC oral derivation: Magnesium Chloride dissociates into the magnesium Mg2+ and chloride Cl- ions at environmental pH. These are essential to all living organisms (flora and fauna) and their intracellular and extra-cellular concentrations are actively regulated. Bioaccumulation is thus not expected.

5. HUMAN HEALTH HAZARD ASSESSMENT

5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

5.1.1. Non-human information

No information is required under REACH (human information available)

5.1.2. Human information

The exposure-related observations in humans are summarised in the following table:

Table 12. Overview of exposure-related observations on basic toxicokinetics and/or dermal absorption in humans

Method	Results	Remarks	Reference
Study type: bibliographic study with clinical case studies and studies with volunteers Type of population: general Subjects: This bibliographic study included different studies with children, pregnant women, tetanic, hypertensive and cardiac patients and volunteers. Endpoint addressed: basic toxicokinetics	Magnesium kinetics represent an open system consisting of several compartments: the intestinal tract (absorption compartment), blood (central compartment), cells, skeleton, central nervous system (deep compartments) and faeces, urine, sweat and milk during lactation (excretion). Mg balance is positive when the input is greater than the output in urine and faeces. This calculation seems simple at a first glance but becomes highly variable aiming to the following individual factors: - At low dietary Mg intakes, enteral absorption considerably increases from the normal level of 30-40% up to 80% probably via an active transport system (although this has not yet been prooved); this system can, however, be completely defective (so-called “primary Mg deficiency”) or insufficient (“poor absorbers”). - As in the latter cases Mg uptake depends mostly or exclusively on passive	2 (reliable with restrictions) supporting study **Test material (This bibliographic study is based on magnesium and magnesium salt as dichloride, sulphate....): null**	Scientific Committee on Food (2001)

Method	Results	Remarks	Reference
	diffusion (10-30%), a Mg deficit will result at intake levels which are sufficient for normal individuals (Durlach, 1988; Schimatschek et al., 1997; Seelig, 1980; Wörwag et al., 1999). - Mg turnover also differs individually, depending for example on age, growth, physical activity, pregnancy-lactation, fluid consumption, stress exposure, drugs and diseases (Classen, 1990). Estimates of requirement have therefore been performed on healthy individuals under strictly standardized essentially steady state conditions (FNB, 1997). - Mg losses represent an important variable: diarrhea or bowel diseases adversely affect excretion? Under physiological conditions, the healthy kidney can reduce daily Mg excretion from 5 mmol to less than 0.5 mmol within a few days of low Mg intake. However, this Mg-sparing mechanism could be disturbed genetically, or affected by diseases associated with polyuria such as diabetes mellitus or by drugs (e.g. most diuretics) or alcohol. Outcome of incidence: No data		
Study type: study with volunteers Type of population: general Subjects: 16 male volunteers aged 27-38 years Endpoint addressed: basic toxicokinetics	Fractional absorption was assessed by comparison of blood concentration after i.v. with oral dose. Fractional absorption was stated with 41.8 % of dose. Outcome of incidence: No data	4 (not assignable) disregarded study **Test material (EC name): magnesium chloride**	Danielson BG, Johansson G, Jung B, Ljunghall S, Lundqvist H and Malmborg P (1979)
Study type: study with volunteers Type of population: general Subjects: 23 human volunteers (12M and 11F) Endpoint addressed: basic toxicokinetics	Net oral absorption decreased with increasing dose, starting with 70 % absorption at 0.3 mmol Mg by day and ending at 14 % at 41.7 mmol Mg by day. 10 % of the net absorption was attributed by the authors to a saturable process (passive diffusion), whereas the remaining absorption was postulated to be associated with facilitated diffusion. Outcome of incidence: No data	4 (not assignable) disregarded study **Test material (EC name): magnesium chloride**	Roth P and Werner E (1979)
Study type: study with volunteers Type of population: general Subjects: Four men, fully ambulant and in good health.	Mean absorption varied between subjects form 46.5-53.1 %. True absorption ranged from 46.1-54.9 %. Outcome of incidence: No data	4 (not assignable) disregarded study **Test material (EC name):**	Schwartz R., Spencer H. and Wentworth R.A. (1978)

Method	Results	Remarks	Reference
Endpoint addressed: basic toxicokinetics		**magnesium chloride**	

5.1.3. Summary and discussion of toxicokinetics

Basic toxicokinetics

Magnesium chloride is deliquescent, which means that it tends to undergo gradual dissolution and liquefaction by the attraction and the absorption of the moisture from the air. Consequently, in biological liquid, the magnesium chloride is dissociated into the chlorine ion and the magnesium cation: it is hence appropiate to use data from magnesium salt for read-across to magnesium chloride. Moreover, the first adverse effect (mild diarrhoea) to occur is triggered by magnesium concentration rather than by an effect of the chloride ion (SCF, 2001).

In this context, the toxicokinetic information are mainly based on the opinion of the Scientific Committee on Food on the tolerable Upper Intake level of Magnesium (SCF, 2001).

The principal data are:

- Magnesium kinetics represent an open system consisting of several compartments: intestinal tract (absorption compartment), blood (central compartment), cells, skeleton, central nervous system (deep compartments) and faeces, urine, sweat and milk during lactation (excretion).
- At low dietary Mg intakes, enteral absorption considerably increases from the normal level of 30-40% up to 80% probably via an active transport system (although this has not yet been proved); this system can, however, be completely defective (so-called “primary Mg deficiency”) or insufficient (“poor absorbers”).
- As in the latter cases, Mg uptake depends mostly or exclusively on passive diffusion (10-30%). A Magnesium deficit will result intake levels which are sufficient for normal individuals.
- Mg losses represent an important variable: diarrhoea or bowel disease adversely affect excretion. Under physiological conditions, healthy kidney can reduce daily Mg excretion from 5 mmol to less than 0.5 mmol within a few days of low Mg intake.

These data are confirmed by some publications and only few are presented as disregarded studies. Indeed, these sources provide valuable information in humans on oral bioavailability of dietary magnesium or of soluble magnesium salts (as MgCl2), which confirm the SCF data (European document).

Concerning dermal absorption, no human data are available and on the basis of:

- The Health Risk Assessment Guidance for metal (HERAG, 2006) indicating that the penetration of the dermis by dissolved metal cations is generally low, i. e. in the range of 0.1 -1%.
- The result for acute dermal toxicity with no systemic effect to the limit test.

This dermal absorption can be considered minor compared to oral absorption.

The following information is taken into account for any hazard / risk assessment:

Magnesium chloride is an easily dissociable magnesium salt and in biological liquid, it is dissociated into the chlorine ion and the magnesium cation. In this context the toxicokinetic information is based on the magnesium cation following oral administration.

The principal information is: to be completed

- Magnesium kinetics represent an open system consisting of several compartments: the intestinal tract (absorption compartment), blood (central compartment), cells, skeleton, central nervous system (deep compartments) and faeces, urine, sweat and milk during lactation (excretion).
- At low dietary Mg intakes enteral absorption considerably increases from the normal level of 30-40% up to 80% probably via an active transport system.

- As in the latter cases Mg uptake depends mostly or exclusively on passive diffusion (10-30%) a Mg deficit will result at intake levels which are sufficient for normal individuals.
- Mg losses represent an important variable and affect excretion.
- The dermal absorption can be considered minor compared to oral absorption (in the range of 0.1-1 %).

Value used for CSA: no bioaccumulation potential

5.2. Acute toxicity

5.2.1. Non-human information

5.2.1.1. Acute toxicity: oral

The results of experimental studies are summarised in the following table:

Table 13. Overview of experimental studies on acute toxicity after oral administration

Method	Results	Remarks	Reference
rat (Wistar) female oral: gavage OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method)	LD50: > 5000 mg/kg bw (female) based on: test mat. (LD50 cut off)	1 (reliable without restriction) key study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Dr. Philip Allingham (2009a)
rat oral: gavage No data	LD50: ca. 8100 mg/kg bw	4 (not assignable) disregarded study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Smith H.F., Carpenter C.P. and Weil C.S (1969)
rat oral: unspecified No data	LD50: ca. 2800 mg/kg bw	4 (not assignable) disregarded study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Ulrich J.L. and Shternov V.A (1929)
mouse oral: unspecified No data	LD50: ca. 4700 mg/kg bw	4 (not assignable) disregarded study **Test material (CAS name): magnesium chloride hexahydrate**	Iyakuhin Kenkyu (1990)

5.2.1.2. Acute toxicity: inhalation

Data waiving

Reason: other justification

Justification: On the basis of column 2 of annex VIII, the study does not need to be conducted as the inhalation route is not appropriate.

5.2.1.3. Acute toxicity: dermal

The results of experimental studies are summarised in the following table:

Table 14. Overview of experimental studies on acute toxicity after dermal administration

Method	Results	Remarks	Reference
rat (Wistar) male/female Coverage: semiocclusive OECD Guideline 402 (Acute Dermal Toxicity)	LD50: > 2000 mg/kg bw (male/female) based on: test mat.	1 (reliable without restriction) key study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Dr. Anne-Laure Leoni (2010)

5.2.1.4. Acute toxicity: other routes

No information is required under REACH.

5.2.2. Human information

No data are required.

5.2.3. Summary and discussion of acute toxicity

The acute toxicity studies were conducted for the oral and dermal route. The inhalation route is not appropriate due to the nature of the substance (magnesium chloride is deliquescent; it does not stay under a granular form and hydrates quickly).

For oral acute toxicity

All the studies indicate a LD50 higher than 2000 mg/kg bw. The key study (Allingham, 2009 - Reliablity 1) is a acute toxic class method (OECD 423) in female Wistar rats. The LD50 cut off was > 5000 mg/kg bw for the hydrate form. For the anhydrous form, the LD50 is considered to be > 2330 mg/kg bw.

For dermal acute toxicity

The key study (Leon, 2010 - Reliability 1) is a limit test of the acute dermal method (OECD 402) in male and female Wistar rats. The LD50 was > 2000 mg/kg bw for the hydrate form. For the anhydrous form, on the basis of :

- no significant effect (clinical signs, bodyweight, gross pathology) observed on the 5 male and 5 female rats under the conditions of the OECD 402 study,
- The LD50 > 932 mg/kg bw for the anhydrous form and no mortality observed (for ten rats) under the conditions of the OECD 402 study,
- no irritation effect (local effect) of MgCl2 under the condition of GPL studies (402 and Episkin),
- for several metals (Zn, Ni, Cd, Sb, Cu, Pb), the penetration of the dermis by dissolved metal cations generally low, i. e. in the range of 0.1 -1% (HERAG, Helth Risk Assessment Guidance for metals, 2006),

it was concluded that LD50 was > 2000 mg/kg bw.

The following information is taken into account for any hazard / risk assessment:

Acute toxicity studies have been conducted with magnesium chloride hexahydrate via the oral and dermal route. The results have been corrected to magnesium chloride anhydrous and the LD50:

For oral acute toxicity, was > 2330 mg/kg bw for Wistar rats (OECD 423).

For dermal acute toxicty, was considered as > 2000 mg/kg bw for Wistar rats (OECD 402 and toxicity data).

Justification for classification or non classification

On the basis of LD50 values and some data for the dermal acute toxicity (toxicity and toxicokinetics data), the MgCl2 was not classified for acute toxicity under the CLP regulation 1272/2008 and the Directive 67/548.

5.3. Irritation and Corrosion

5.3.1. Skin

5.3.1.1. Non-human information

The results of experimental studies on skin irritation are summarised in the following table:

Table 15. Overview of experimental studies on skin irritation

Method	Results	Remarks	Reference
in vitro study human (epidermal keratinocytes) EU method B46 (irritation)	not irritating Absorbance (550 nm): ca. 0.831 of max. 0.937 (mean) (Time point: 15 mn)	1 (reliable without restriction) key study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Dr. Dominik Stuhlmann (2010)
rabbit OECD Guideline 404	not irritating Not irritating:	4 (not assignable) disregarded study	Anon (1988a)

Method	Results	Remarks	Reference
(Acute Dermal Irritation / Corrosion)		experimental result **Test material (CAS name): magnesium chloride hexahydrate**	

Data waiving

Reason: other justification

Justification: On the basis of column 2 of annex VIII, the study does not need to be conducted as an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (see Acute Tox. derm-1-2010-LEON).

Furthermore, a validated in vitro test method (Episkin-SM - EU method B46) is used as key study and shows no irritation (Skin Irr. -1-2010-STUH)

5.3.1.2. Human information

No data are required

5.3.2. Eye

5.3.2.1. Non-human information

The results of experimental studies on eye irritation are summarised in the following table:

Table 16. Overview of experimental studies on eye irritation

Method	Results	Remarks	Reference
rabbit (New Zealand White) OECD Guideline 405 (Acute Eye Irritation / Corrosion)	not irritating Cornea score: ca. 0 of max. 0 (mean) (Time point: 24, 48, 72 hours) Iris score: ca. 0 of max. 0 (mean) (Time point: 24, 48, 72 hours) Conjunctivae score: ca. 1.67 of max. 2 (animal #1) (Time point: 24, 48, 72 hours) (fully reversible within: 6 days) ca. 1.33 of max. 2 (animal #2) (Time point: 24, 48, 72 hours) (fully reversible within: 4 days) ca. 0 of max. 2 (animal #3) (Time point: 24, 48, 72 hours) (fully reversible within: 48 hours) Chemosis score: ca. 0.67 of max. 3 (animal #1) (Time	1 (reliable without restriction) key study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Dr. Varun Ahuja (2010a)

Method	Results	Remarks	Reference
	point: 24, 48, 72 hours) (fully reversible within: 72 hours) ca. 1 of max. 2 (animal #2) (Time point: 24, 48, 72 hours) (fully reversible within: 4 days) ca. 0.33 of max. 2 (animal #3) (Time point: 24, 48, 72 hours) (fully reversible within: 48 hours)		
rabbit OECD Guideline 405 (Acute Eye Irritation / Corrosion)	not irritating	4 (not assignable) disregarded study **Test material (CAS name): magnesium chloride hexahydrate**	Anon (1988b)
rabbit		4 (not assignable) disregarded study experimental result **Test material (CAS name): Magnesium**	Grant W.M. (1974)

5.3.2.2. Human information

No data are required

5.3.3. Respiratory tract

5.3.3.1. Non-human information

No data are required under REACH.

5.3.3.2. Human information

No data are required under REAC

5.3.4. Summary and discussion of irritation and corrosion

Irritation/corrosion studies have been conducted with magnesium chloride hexahydrate.

Skin irritation / corrosion.

Two studies indicate no skin irritant effects for MgCl2, 6H20. The study of Stuhlmann D., 2010 (reliability 1) is selected as key study. In this study, Magnesium Chloride Hexahydrate was applied topically to the EPISKIN-SM tissue for 15 min followed by a 42 h postincubation period and immediate determination of cytotoxic effects via MTT reduction assay (EU method B46). Irritant potential was predicted from the relative mean tissue viabilities obtained compared to the corresponding negative control tissues concurrently treated with sterile water. MgCl2, 6H2O showed no irritant effect

Eye irritation

Two studies indicate no eye irritant effects for MgCl2, 6H20. The study of Ahuja V., 2010 (reliability 1) is selected as key study. Under the conditions of this study (OECD 405), single ocular instillation of the test item Magnesium chloride hexahydrate to New Zealand white rabbits at a dose of 0.1 g produced irritant effects,

which were fully reversible. MgCl2, 6H2O is not irritating on eyes.

The following information is taken into account for any hazard / risk assessment:

Irritation/corrosion studies have been conducted with magnesium chloride hexahydrate. The results can be extrapolated to magnesium chloride anhydrous and were:

For skin irritation, the MgCl2 is not irritating on skin (EU metho B46)

For eye irritation, the MgCl2 is not irritating on eyes (OECD 405)

Value used for CSA:

Skin irritation / corrosion: not irritating

Eye irritation: not irritating

Justification for classification or non classification

On the basis of study results, the MgCl2 was not classified for skin and eye irritation under the CLP regulation 1272/2008 and the directive 67/548

5.5. Sensitisation

5.5.1. Skin

5.5.1.1. Non-human information

The results of experimental studies on skin sensitisation are summarised in the following table:

Table 17. Overview of experimental studies on skin sensitisation

Method	Results	Remarks	Reference
guinea pig (Hartley) female Guinea pig maximisation test Induction: intradermal and epicutaneous Challenge: epicutaneous, occlusive OECD Guideline 406 (Skin Sensitisation)	not sensitising No. with positive reactions: 1st reading: 0 out of 10 (test group); 24 h after chall.; dose: 50% 1st reading: 0 out of 10 (test group); 48 h after chall.; dose: 50% 1st reading: 1 out of 5 (negative control); 24 h after chall.; dose: 50% 1st reading: 0 out of 5 (negative control); 48 h after chall.; dose: 50%	1 (reliable without restriction) key study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Dr. Varun Ahuja (2010b)
guinea pig (Dunkin-Hartley) female Guinea pig maximisation test OECD Guideline 406 (Skin Sensitisation)	No. with positive reactions: not sensiting:	4 (not assignable) disregarded study experimental result **Test material (CAS name): magnesium**	Witte F., Abeln I., Switzer E., Kaese V., Meyer-Lindenberg A. and (2008)

5.5.1.2. Human information

No data are required.

5.5.2. Respiratory system

5.5.2.1. Non-human information

No data are required under REACH

5.5.2.2. Human information

No data are required under REACH

5.5.3. Summary and discussion of sensitisation

Skin sensitisation

There is only one study available for MgCl2: Ahuja V., 2010 (reliability 1). This key study was performed on the guinea pig (OECD 406). The following concentrations were determined by a preliminary test:

- Intradermal induction: 5% of the test item, vehicle: physiological saline 0.9% NaCl
- Dermal induction: 50% of the test item, vehicle: vaseline
- Challenge exposure (the highest non-irritating dose): 50% of the test item, vehicle: vaseline.

After the challenge exposure, no erythema was observed in any of the test animals at any time and no oedema was observed in any animal at any time. There was no evidence of sensitisation at the challenge and the percentage of animals sensitised was 0%.

The following information is taken into account for any hazard / risk assessment:

Skin sensitisation study has been conducted with magnesium chloride hexahydrate. The result can be extrapolated to magnesium chloride anhydrous and there was no evidence of sensitisation in the MgCl2 group at the challenge and the percentage of animals sensitised was 0 %.

Value used for CSA: not sensitising

Justification for classification or non classification

On the basis of study result, the MgCl2 was not classified for skin sensitisation under the CLP regulation 1272/2008 and the Directive 67/548.

5.6. Repeated dose toxicity

5.6.1. Non-human information

5.6.1.1. Repeated dose toxicity: oral

The results of experimental studies are summarised in the following table:

Table 18. Overview of experimental studies on repeated dose toxicity after oral administration

Method	Results	Remarks	Reference
rat (Wistar) male/female combined repeated dose and reproduction / developmental	NOAEL: > 1000 mg/kg bw/day (actual dose received) (male/female) based on: test mat.	1 (reliable without restriction) key study	Dr. Shivakumar Rudragowda (2010a)

Method	Results	Remarks	Reference
screening (oral: gavage) 250 mg/kg bw/day (actual ingested) 500 mg/kg bw/day (actual ingested) 1000 mg/kg bw/day (actual ingested) Exposure: 28-29 days for males maximum 54 days for females (14 days pre mating, 14 days mating, during gestation period and up to post natal day 3) (7 days per week) OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)		experimental result **Test material (CAS name): magnesium chloride hexahydrate**	
rat (Wistar) male/female subacute (oral: gavage) 500 mg/kg bw/day (actual ingested) 1000 mg/kg bw/day (actual ingested) 1500 mg/kg bw/day (actual ingested) Exposure: 14 days (7 days per week) (Test item was administered by gavage in a single dose to the animals using a gavaging canula. The dose volume was 5 mL/ kg bw.) This stuyd is a dose range finding study to determine the dose level of the 28 days study (Rep. Dose Tox. oral-1-2010-RUDR)	NOAEL: > 1500 mg/kg bw/day (nominal) (male/female) based on: test mat.	2 (reliable with restrictions) supporting study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Dr. Philip Allingham (2009b)
rat (Fischer 344/DuCrj) male/female subchronic (oral: feed) 0.1% (nominal in diet) 0,5% (nominal in diet) 2,5% (nominal in diet) Exposure: 90 days (Daily) equivalent or similar to OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)	NOAEL: ca. 0.5 % (male/female) based on: test mat. LOAEL: ca. 2.5 % (male/female) based on: test mat. (Transient soft stool and sustained increase in water consumption were observed both in males and females of the 2.5% group and slight reduction in body weight gain was noted in the high-dose males.)	2 (reliable with restrictions) supporting study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Takizawa T., Yasuhara K., Mitsumori K., Onodera H., Koujitani T., (2000)
mouse (B6C3F1) male/female subchronic (oral: feed) 0.3% (nominal in diet) 0.6% (nominal in diet)	NOAEL: > 5 % (female) based on: test mat. NOAEL: ca. 2.5 % (male) based on: test mat. LOAEL: ca. 5 % (male) based	2 (reliable with restrictions) supporting study experimental result	Tanaka H., Hagiwara A., Kurata Y., Ogiso T., Futakuchi M. and Iti N. (1993)

Method	Results	Remarks	Reference
1.25% (nominal in diet) 2.5% (nominal in diet) 5% (nominal in diet) Exposure: 13 weeks (daily) equivalent or similar to OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)	on: test mat. (vacualation of kidney tubular cells)	**Test material (CAS name): magnesium chloride hexahydrate**	
mouse (B6C3F1) male/female combined repeated dose and carcinogenicity (oral: feed) 0.5% (nominal in diet) 2% (nominal in diet) Exposure: 96 weeks and 8 weeks of post exposure period (104 weeks) (Daily) equivalent or similar to OECD Guideline 453 (Combined Chronic Toxicity / Carcinogenicity Studies)	NOAEL: ca. 2000 mg/kg diet (male/female) based on: test mat. NOAEL: ca. 2810 mg/kg bw/day (nominal) (male) based on: test mat. NOAEL: ca. 3930 mg/kg bw/day (nominal) (female) based on: test mat.	2 (reliable with restrictions) supporting study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Kurata Y., Tamano S., Shibata MA., Hagiwara A., Fukushima S. and Iti N. (1989)
rat (SHRSP) female chronic (oral: drinking water) 0.2% (nominal in water) Exposure: 17 months (Daily) No data		4 (not assignable) disregarded study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Saito N., Okada T., Moriki T., Nishiyama S. and Matsubayashi K. (1980)
mouse subchronic (oral: unspecified) No data Exposure: 13 weeks (No data) No data	NOAEL: ca. 114 mg/kg bw/day (nominal) based on: test mat. (13 weeks)	4 (not assignable) disregarded study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Anon (1984)

5.6.1.2. Repeated dose toxicity: inhalation

Data waiving

Information requirement (Test type):

Reason: other justification

Justification: On the basis of column 2 of REACH annex VIII, the repeated dose toxicity study need to be conducted to the most appropriate route of administration. For Magnesium Chloride, the most appropriate route of administration is oral.

5.6.1.3. Repeated dose toxicity: dermal

Data waiving

Information requirement (Test type):

Reason: other justification

Justification: On the base of column 2 of REACH annex VIII, the repeated dose toxicity study need to be conducted to the most appropriate route of administration. For Magnesium Chloride, the most appropriate route of administration is oral.

5.6.1.4. Repeated dose toxicity: other routes

No data are required under REACH

5.6.2. Human information

The exposure-related observations in humans are summarised in the following table:

Table 19. Overview of exposure-related observations on repeated dose toxicity in humans

Method	Results	Remarks	Reference
Study type: bibliographic study with clinical case studies and studies with volunteers Type of population: general Subjects: This bibliographic study included different studies with children, pregnant women, tetanic, hypertensive and cardiac patients and volunteers. Endpoint addressed: repeated dose toxicity: oral	Magnesium in foods derived from plant or animal sources has not been demonstrated to induce diarrhoea nor other adverse effects in healthy persons, probably as Mg is bound to matrices and hence is mostly not easily dissociable. On the other hand, easily dissociable magnesium salts (e.g. chloride or sulphate; included are compounds like MgO becoming readily dissociable after the reaction with gastric hydrochloric acid) which are present in water, many supplements and drugs, exert dose-dependent laxative effects.	2 (reliable with restrictions) supporting study **Test material (This bibliographic study is based on magnesium and magnesium salt as dichloride, sulphate....): null**	Scientific Committee on Food (2001)

Method	Results	Remarks	Reference
	In conclusion, mild diarrhoea is the most sensitive non-desirable effect of orally administrated easily dissociable magnesium salts.		

5.6.3. Summary and discussion of repeated dose toxicity

Discussion

The repeated dose toxicity studies were conducted for the oral route.

The inhalation and dermal routes are not appropriate due to, respectively, the nature of the substance (magnesium chloride is deliquescent, it does not stay under a granular form and hydrates quickly) and the low potential of absorption through the skin (the penetration of the dermis by dissolved metal cations was generally low, i. e. in the range of 0.1 -1% [HERAG, Helth Risk Assessment Guidance for metals, 2006]).

Oral route

There are many reliable studies available and all indicated a low toxicological effect or no toxicological effect. The table below summarised these data:

Table 18. Overview of experimental study on repeated dose toxicity after oral administration

Reference	Reliability	Time exposure	Animal/sex	NOAEL (mg/kg bw/day)	LOAEL (mg/kg bw/day)	
					Level	Effect
Rudragowda et al., 2010	1	28 days	Wistar rat (male)	1000		
		54 days	Wistar rat (female)	1000		
Allingham et al., 2009	2	14 days	Wistar rat (male/female)	1500		
Tanaka H. et al, 1993	2	13 weeks	B6C3F, mice (male)	5410	12830	Decrease in body weight
			B6C3F, mice (male)	12 830		
Takizawa T. et al., 2000	2	13 weeks	Fischer rat (male)	308	1600	slight reduction in body weight and sustained increase in water consumption
			Fischer rat (female)	299	1531	

Reference	Reliability	Time exposure	Animal/sex	NOAEL (mg/kg bw/day)	LOAEL (mg/kg bw/day)	
					Level	Effect
Kurata Y. et al., 1989	2	96 weeks	B6C3F1 mice (male)	3930		
			B6C3F1 mice (female)	2810		

The Rudragowda et al. 2010 is selected as key study and the other studies support this study in the fact that no oral toxicity is observed for repeated exposure, expect a decrease in body weight in two studies (Tanaka H. et al, 1993 and Takizawa T. et al., 2000). Although this effect is not regarded as a major toxic effect, the LOAEL are deduced from it.

On the basis of the results, rats being the more sensitive species and the LOAEL and NOAEL were deduced on it (expect for 2 years study, only data available for mice) and presented below:

Table 19. Overview of experimental studies on repeated dose toxicity after oral administration

Value	Exposure time	Dose for MgCl2 hexahydrate (mg/kg bw/day)	Dose for MgCl2 anhydrous (mg/kg bw/day)	Basis for effect level
NOAEL	28 days	1000	466	
NOAEL	90 days	299	140	
LOAEL	90 days	1531	713	slight reduction in body weight
NOAEL	2 years	2810	1309	

The following information is taken into account for any hazard / risk assessment:

Repeated dose toxicity studies have been conducted with magnesium chloride hexahydrate via the oral route. The results have been corrected to magnesium chloride anhydrous.

The key study (OECD 422) and the supporting studies observed no oral toxicity for repeated exposure expect a decrease in body weight. The rats being the more sensitive species and the LOAEL and NOAEL, for MgCl2 anhydrous, were deduced on it expect for 2 years study (only data available for mice).

- NOAEL (28 days) = 466 mg/kgbw/day - rat
- NOEAL (90 days) = 140 mg/kgbw/day - rat
- LOAEL (90 days) = 713 mg/kgbw/day - rat
- NOAEL (2 years) = 1309 mg/kgbw/day - mice

Value used for CSA (route: oral):

- NOAEL: 1309 mg/kg bw/day (chronic; mouse)

Justification for classification or non classification

On the basis of the studies, the only effect observed is a decreased in bodyweight for a dose level of 713 mg/kg bw/day for MgCl2 anhydrous. As indicated in the CLP regulation 1272/2008, this effect is not considered to support classification for specific target organ toxicity, following repeated exposure and the highest guidance values by oral exposure for a classification is 100 mg/kgbw/day for 90 days exposure. In conclusion, the MgCl2 was not classified for repeated dose toxicity under the CLP regulation 1272/2008 and the Directive 67/548.

5.7. Mutagenicity

5.7.1. Non-human information

5.7.1.1. In vitro data

The results of experimental studies are summarised in the following table:

Table 20. Overview of experimental in vitro genotoxicity studies

Method	Results	Remarks	Reference
mammalian cell gene mutation assay (gene mutation) mouse lymphoma L5178Y cells (met. act.: with and without) Doses: 36,000 - 32,000 - 30,000 - 28,000 - 26,000 - 24,000 - 22,000 µg/ml. equivalent or similar to OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test)	Evaluation of results: negative Test results: negative for mouse lymphoma L5178Y cells(strain/cell type: Thymidine kinase +/-); met. act.: with and without; cytotoxicity: yes (See table in "any other information")	2 (reliable with restrictions) key study experimental result **Test material (EC name): magnesium chloride**	Oberly T.J. , Piper C.E. and McDonald D.S. (1982)
mammalian cell gene mutation assay (gene mutation) S. typhimurium TA 102 Doses: 0.1-1M No data	Test results: negative for S. typhimurium TA 102	4 (not assignable) disregarded study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Bronzetti G., Cini M. and Della Croce C (1995)
bacterial reverse mutation assay (e.g. Ames test) (gene mutation) S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 (met. act.: with) Doses: 6 dose levels, highest dose: 100 mg/plate, duplicate cultures equivalent or similar to OECD Guideline 471 (Bacterial Reverse Mutation Assay)	Test results: Negative for S. Typhimurium TA 1535, TA 1537, TA 98, TA 92 and TA 100; met. act.: with	4 (not assignable) disregarded study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Ishidate, M., Sofuni, T., Yoshikawa, K., Hayashi, M., Nohmi, T., Sawada (1984)
in vitro mammalian chromosome	Evaluation of results:	1 (reliable without	M. Sc. Shailendra

Method	Results	Remarks	Reference
aberration test (chromosome aberration) lymphocytes: human peripheral blood lymphocytes (met. act.: with and without) Doses: Duplicate cultures were treated at each concentration. The selection of the concentrations used in the experiment I and II was based on data from the pre-experiment. The following concentrations were used in the main experiments: Experiment I: with and without metabolic activation: 0.31, 0.62, 1.25, 2.5, 5 and 10 mM Experiment II: with metabolic activation: 5, 6, 7, 8, 9 and 10 mM and without metabolic activation: 0.078, 0.16, 0.31, 0.62, 1.25, 2.5, 5 and 10 mM The following concentrations were selected in the main experiments for the microscopic analysis: Experiment I: with and without metabolic activation, 4 h treatment, 24 h preparation interval: 2.5, 5 and 10 mM Experiment II: with metabolic activation, 4 h treatment, 24 h preparation interval: 8, 9, and 10 mM and without metabolic activation, 24 h treatment, 24 h preparation interval: 2.5, 5 and 10 mM OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test)	negative Test results: negative (all dose groups treated (with or without metabolic activation) with the test item were within the historical control data (0-4%) for clastogenicity effect.) for lymphocytes: human peripheral blood lymphocytes; met. act.: with and without; cytotoxicity: no	restriction) key study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Singh (2010)
in vitro mammalian chromosome aberration test (chromosome aberration) mammalian cell line, other: Chinese hamster fibroblast, CHL (met. act.: without) Doses: 3 dose levels, maximum dose MgCl2: 2mg/mL equivalent or similar to OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test)	Evaluation of results: negative Test results: negative for Chinese hamster lung fibroblasts (V79); met. act.: without	4 (not assignable) disregarded study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Ishidate, M., Sofuni, T., Yoshikawa, K., Hayashi, M., Nohmi, T., Sawada (1984)

Method	Results	Remarks	Reference
in vitro mammalian chromosome aberration test (chromosome aberration) Chinese hamster lung fibroblasts (V79) (met. act.: without) Doses: 0, 2, 4, 8, 12 mg/mL No data	Evaluation of results: negative Test results: positive (Chromosomal aberrations observed at dose levels of 8mg/mL and above.) for Chinese hamster lung fibroblasts (V79); met. act.: without	3 (not reliable) disregarded study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Ashby J. and Ishidate M. (1986)
Bacillus subtilis recombination assay (DNA damage and/or repair) bacteria, other: Bacillus subtilis strain H17, M45 Doses: No data No data	Evaluation of results: negative Test results: negative for bacteria, other: Bacillus subtilis strain H17, M45	4 (not assignable) disregarded study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Kada T., Hirano K. and Shirasu Y. (1980)

5.7.1.2. In vivo data

Data waiving

Information requirement (Test type):

Reason: other justification

Justification: In accordance with column 2 of Annex X, n vivo mutagenicity studies shall not be considered: the available information indicates that there is a negative result in any of the in vitro genotoxicity studies in Annex VII and or VIII.

5.7.2. Human information

No data are required

5.7.3. Summary and discussion of mutagenicity

Discussion

In vitro data

MgCl2 has been examined in numerous tests including bacterial, mammalian test systems. All these studies failed to demonstrate mutagenic activity.

Concerning the Ames test, different studies indicate a negative result. But there is a high prevalence of false negatives for metal compounds in this test (due to limited capacity for uptake of metal ions). Consequently, the results of this test will not be taken into account.

Concerning the chromosome aberration test, different studies indicate a negative result. The study of Singh S, 2010 (reliability 1) is selected as key study. In this study, the potential of Magnesium Chloride Hexahydrate for its ability to induce structural chromosome aberrations in Human Lymphocytes was investigated (OECD

473). The treatment interval was 4 h with and without metabolic activation (experiment I) and 4 h with and 24 h without metabolic activation (experiment II). In experiment I and II, no biologically relevant increase of the aberration rates and in the frequencies of polyploid cells were found. In conclusion, MgCl2, 6H2O did not induce structural chromosomal aberrations in human lymphocyte cells

Concerning the gene mutation test. The study of Oberly, Piper CE and McDonald DS, 1982 (reliability 2) is selected as key study. In this study, MgCl2 was examined for its potential to induce forward mutations at the TK locus in L5178Y mouse lymphoma cells. Test doses of MgCI2 evoked little or no enhancement of mutation compared to the solvent control. These results were not altered by metabolic activation of the test system. In conclusion, MgCl2, 6H2O showing no treatment related increase in mutation frequency.

In vivo data

No data is available for in vivo mutagenicity. Under the REACH regulation, this data are not considered because the available information indicates that there are negative results in any of the in vitro genotoxicity studies.

The following information is taken into account for any hazard / risk assessment:

Genetic toxicity studies have been conducted with magnesium chloride hexahydrate. The results can be extrapolated to magnesium chloride anhydrous and were:

For in vitro Mammalian Chromosome Aberration Test (OECD 473), negative on human peripheral blood lymphocytes with/without S9

For In vitro Mammalian Cell Gene Mutation Test (OECD 476), negative on TK +/- of L5178 mouse lymphoma cells with/without S9

Value used for CSA: Genetic toxicity: negative

Justification for classification or non classification

On the basis of studies results, the MgCl2 was not classified for genetic toxicity under the CLP regulation 1272/2008 and the Directive 67/548.

5.8. Carcinogenicity

5.8.1. Non-human information

5.8.1.1. Carcinogenicity: oral

The results of experimental studies are summarised in the following table:

Table 21. Overview of experimental studies on carcinogenicity after oral administration

Method	Results	Remarks	Reference
mouse (B6C3F1) male/female oral: feed 0.5% (nominal in diet) 2% (nominal in diet) Exposure: 96 weeks (Daily) equivalent or similar to OECD Guideline 453 (Combined Chronic Toxicity / Carcinogenicity Studies)	NOAEL (carcinogenicity): ca. 2 % (male/female) based on: test mat. NOAEL (toxicity): ca. 2 % (male/female) based on: test mat. Neoplastic effects: no effects (see details on results)	2 (reliable with restrictions) supporting study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Kurata Y., Tamano S., Shibata MA., Hagiwara A., Fukushima S. and Iti N. (1989)

5.8.1.2. Carcinogenicity: inhalation

No data are available

5.8.1.3. Carcinogenicity: dermal
No data are available

5.8.1.4. Carcinogenicity: other routes
No data are available

5.8.2. Human information

No data are available.

5.8.3. Summary and discussion of carcinogenicity

Discussion

MgCl2 is not classified as a mutagen category 3 and there is no evidence from the repeat dose studies that MgCl2 is able to induce hyperplasia and/or pre-neoplastic lesions. According to annex X, section 8.9.1, column 2 of REACH regulation, a carcinogenicity study is not warranted.

Kurata Y. et al, 1982 support this information in the fact that there is no evidence of compound-related carcinogenicity. In this study, groups of 50 male and 50 female B6C3F1 mice were given MgCl2, 6H20 at dose levels of 0.5 and 2% (3930 mg/kgbw/day for female and 2810 mg/kgbw/day for male) in the diet for 96 week, after which all animals received the control diet for 8 wk and were then necropsied.

The following information is taken into account for any hazard / risk assessment:

The repeated dose and carcinogenicity available show no evidence of compound-related carcinogenicity.

Justification for classification or non classification

On the basis of the dose repeated studies, the MgCl2 was not classified for carcinogenic toxicity under the CLP regulation 1272/2008 and the Directive 67/548.

5.9. Toxicity for reproduction

5.9.1. Effects on fertility

5.9.1.1. Non-human information

The results of experimental studies are summarised in the following table:

Table 22. Overview of experimental studies on fertility

Method	Results	Remarks	Reference
rat (Wistar) male/female screening oral: gavage 250 mg/kgbw/day (actual ingested) 500 mg/kgbw/day 1000 mg/kgbw/day (actual ingested) Exposure: 28-29 days for males maximum 54 days for females (14 days pre mating, 14 days mating, during gestation period and up to	NOAEL (P): > 1000 mg/kg bw/day (actual dose received) (male/female) based on: test mat. NOAEL (F1): > 1000 mg/kg bw/day (actual dose received) (male/female) based on: test mat.	1 (reliable without restriction) key study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Dr. Shivakumar Rudragowda (2010b)

Method	Results	Remarks	Reference
post natal day 3) (7 days per week) OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)			

Data waiving

Reason: other justification

Justification: On the basis of column 1 of annex IX, the study does not need to be conducted as the 28-day and 90-day studies do not indicate adverse effects on reproductive organs or tissues.

5.9.1.2. Human information

No data are required

5.9.2. Developmental toxicity

5.9.2.1. Non-human information

The results of experimental studies are summarised in the following table:

Table 23. Overview of experimental studies on developmental toxicity

Method	Results	Remarks	Reference
rat (Wistar) oral: gavage 200 mg/kgbw/day (actual ingested (with doses based on the body weight at day 6 of gestation)) 400 mg/kgbw/day (actual ingested (with doses based on the body weight at day 6 of gestation)) 800 mg/kgbw/day (actual ingested (with doses based on the body weight at day 6 of gestation)) Exposure: From day 6 through 15 of pregnancy (10 days) (By gavage (one by day)) equivalent or similar to OECD Guideline 414 (Prenatal Developmental Toxicity Study)	NOAEL (teratogenicity): > 800 mg/kg bw/day based on: test mat. NOAEL (maternal toxicity): > 800 mg/kg bw/day based on: test mat.	2 (reliable with restrictions) key study experimental result **Test material (CAS name): magnesium chloride hexahydrate**	Usami M., Sakemi K., Tsuda M. and Ohno Y. (1996)

5.9.2.2. Human information

No data are required

5.9.3. Summary and discussion of reproductive toxicity

Discussion

Effects on fertility

No data is available for fertility endpoint (one or two generation reproductive study). Under the REACH regulation, this data is not considered because the available information (Rudragowda et al. 2010 as key study and the other supporting repeated dose studies) indicates no adverse effects on reproductive organs or tissues.

The following information is taken into account for any hazard / risk assessment:

The available information indicates no adverse effects on reproductive organs or tissues.

Developmental toxicity

Two key studies are available: Rudragowda et al., 2010 (OECD 422) and Usami et al., 1994 (OECD 414).

The study of Rudragowda et al. 2010 is based on the data generated from a combined repeated dose toxicity and reproduction/ developmental toxicity screening test with Magnesium chloride hexahydrate, the no observed adverse effect level (NOAEL) is believed to be 1000 mg/kg bodyweight for Magnesium chloride hexahydrate (eq. 466 mg/kg/bw for Magnesium Chloride anhydrous) in male and female Wistar rats. This study indicates no adverse effects on reproductive organs or tissues.

The other dose repeated studies indicate no adverse effects on reproductive organs or tissues for differents exposure times:

- Tanaka H. et al., 1993 (male and female B6C3F mice, 90 days)
- Takizawa T. et al., 2000 (male and female Fischer rat, 90 days)
- Kurata Y. et al., 1989 (male and female B6C3F mice, 96 weeks)

The study of Usami et al., 1996 is a teratogenicity study on Wistar rats. Magnesium chloride hexahydrate was given to pregnant Wistar rats by gavage once a day from day 6 through 15 of pregnancy. The pregnant rats were sacrificed on day 20 of pregnancy and their foetuses were examined for malformation. Magnesium chloride hexahydrate caused no increased incidences of foetal malformation, and no toxic signs in the pregnant rats and the foetuses. The no observed adverse effect level was estimated to be over 800 mg/kg/day (eq 373 mg/kgbw/day for MgCl2 anhydrous) for both pregnant rats and rat foetuses.

The following information is taken into account for any hazard / risk assessment:

Developmental toxicity/teratogenicity toxicity studies have been conducted with magnesium chloride hexahydrate via the oral route. The results have been corrected to magnesium chloride anhydrous.

Two key studies are available:

- Rudragowda et al., 2010 (OECD 422) on Wistar rat indicates no adverse effect and the NOAEL is over 1000 mg/kg bodyweight for MgCl2 hexahydrate (eq. 466 mg/kg/bw for Magnesium Chloride anhydrous).
- Usami et al. 1994 (OECD 414) on Wistar rat indicates no adverse effect and the NOAEL is over 800 mg/kg/day (eq 373 mg/kgbw/day for MgCl2 anhydrous).

Justification for classification or non classification

On the basis of studies results, the MgCl2 was not classified for reproduction toxicity under the CLP regulation 1272/2008 and the directive 67/548

5.10. Other effects

5.10.1. Non-human information

5.10.1.1. Neurotoxicity

No data are available.

5.10.1.2. Immunotoxicity

No data are available.

5.10.1.3. Specific investigations: other studies

No data are available.

5.10.2. Human information

No data are available.

5.11. Derivation of DNEL(s) / DMEL(s)

5.11.1. Overview of typical dose descriptors for all endpoints

Table 24. Available dose-descriptor(s) per endpoint for the submission substance as a result of its hazard assessment

Endpoint	Dose descriptor	Qualitative assessment	Remarks on study
Acute toxicity oral			Acute toxicity studies have been conducted with magnesium chloride hexahydrate via the oral and dermal route. The results have been corrected to magnesium chloride anhydrous and the LD50: For oral acute toxicity, was > 2330 mg/kg bw for Wistar rats (OECD 423). For dermal acute toxicty, was considered as > 2000 mg/kg bw for Wistar rats (OECD 402 and toxicity data).
Acute toxicity dermal			
Acute toxicity inhalation			
Irritation / Corrosivity skin		not irritating	Irritation/corrosion studies have been conducted with magnesium chloride hexahydrate. The results can be extrapolated to magnesium chloride anhydrous and were: For skin irritation, the MgCl2 is not irritating on skin (EU method B46) For eye irritation, the MgCl2 is not irritating on eyes (OECD 405)
Irritation / Corrosivity eye		not irritating	
Irritation / Corrosivity respiratory tract			
Sensitisation skin		not sensitising	Skin sensitisation study has been conducted with magnesium chloride hexahydrate. The result can be extrapolated to magnesium chloride anhydrous and there was no evidence of sensitisation in the MgCl2 group at the challenge and the percentage of animals sensitised was 0 %.
Repeated dose toxicity: sub-acute / sub-chronic / chronic oral	NOAEL: 1309 mg/kg bw/day (chronic; mouse)		Repeated dose toxicity studies have been conducted with magnesium chloride hexahydrate via the oral route. The results have been corrected to magnesium chloride anhydrous. The key study (OECD 422) and the supporting studies observed no oral toxicity for repeated exposure expect a decrease in body weight. The rats being the more sensitive species and the LOAEL and NOAEL, for MgCl2 anhydrous, were deduced on it expect for 2 years study (only data available for mice).
Repeated dose toxicity: sub-acute / sub-chronic / chronic dermal			
Repeated dose toxicity: sub-acute / sub-chronic / chronic inhalation			

Endpoint	Dose descriptor	Qualitative assessment	Remarks on study
			NOAEL (28 days) = 466 mg/kgbw/day - rat NOEAL (90 days) = 140 mg/kgbw/day - rat LOAEL (90 days) = 713 mg/kgbw/day - rat NOAEL (2 years) = 1309 mg/kgbw/day - mice
Mutagenicity in vitro / in vivo		Genetic toxicity: negative	Genetic toxicity studies have been conducted with magnesium chloride hexahydrate. The results can be extrapolated to magnesium chloride anhydrous and were: For in vitro Mammalian Chromosome Aberration Test (OECD 473), negative on human peripheral blood lymphocytes with/without S9 For In vitro Mammalian Cell Gene Mutation Test (OECD 476), negative on TK +/- of L5178 mouse lymphoma cells with/without S9
Carcinogenicity oral			The repeated dose and carcinogenicty available show no evidence of compound-related carcinogenicity.
Carcinogenicity dermal			
Carcinogenicity inhalation			
Reproductive toxicity: fertility impairment oral			The available information indicates no adverse effects on reproductive organs or tissues.
Reproductive toxicity: fertility impairment dermal			
Reproductive toxicity: fertility impairment inhalation			
Reproductive toxicity: developmental toxicity oral			Developmental toxicity/teratogenicity toxicity studies have been conducted with magnesium chloride hexahydrate via the oral route. The results have been corrected to magnesium chloride anhydrous. Two key studies are available:
Reproductive toxicity: developmental toxicity dermal			

Endpoint	Dose descriptor	Qualitative assessment	Remarks on study
			- Rudragowda et al., 2010 (OECD 422) on Wistar rat indicates no adverse effect and the NOAEL is over 1000 mg/kg bodyweight for MgCl2 hexahydrate (eq. 466 mg/kg/bw for Magnesium Chloride anhydrous). - Usami et al. 1994 (OECD 414) on Wistar rat indicates no adverse effect and the NOAEL is over 800 mg/kg/day (eq 373 mg/kgbw/day for MgCl2 anhydrous).
Reproductive toxicity: developmental toxicity inhalation			

5.11.2. Selection of the critical DNEL(s)/DMEL(s) and/or qualitative/semi-quantitative descriptor for critical health effects

Table 25. DN(M)ELs for workers

Exposure pattern	Route	Descriptor	DNEL / DMEL	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
Acute - systemic effects	Dermal	No-threshold effect and/or no dose-response information available				There is no acute toxicity effect (leading to C&L), so no acute/short-term DNEL was derived. See discussion below.
Acute - systemic effects	Inhalation	No data available: testing technically not feasible				No DNEL derivation. Scientifically unjustified. See discussion below.
Acute - local effects	Dermal	No-threshold effect and/or no dose-response information available				There is no acute toxicity effect (leading to C&L), so no acute/short-term DNEL was derived. See discussion below.
Acute - local effects	Inhalation	No data available: testing technically not feasible				No DNEL derivation. Scientifically unjustified. See discussion below.
Long-term - systemic effects	Dermal	No-threshold effect and/or no dose-response information available				No DNEL derivation. Scientifically unjustified. See discussion below.
Long-term - systemic effects	Inhalation	No data available: testing technically not feasible				No DNEL derivation. Scientifically unjustified. See discussion below.
Long-term - local effects	Dermal	No-threshold effect and/or no dose-response information available				No DNEL derivation. Scientifically unjustified. See discussion below.
Long-term - local effects	Inhalation	No data available: testing technically not feasible				No DNEL derivation. Scientifically unjustified. See discussion below.

**) The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and "Assessment factor" provided in the Endpoint summary of IUCLID section 7. Toxicological information. It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of assessment factors.*

Discussion

Acute DNEL

For dermal route, there is no acute toxicity hazard (leading to C&L), so no acute/short-term DNEL was derived. (Refer to ECHA Guidance on IR&CSA R.8 p.16).

For inhalation route, this route is not appropriate indeed magnesium chloride is deliquescent, which means that it tends to undergo gradual dissolution and liquefaction by the attraction and the absorption of the moisture from the air.

Long term DNEL

Inhalation DNEL

This route is not appropriate indeed magnesium chloride is deliquescent, which means that it tends to undergo gradual dissolution and liquefaction by the attraction and the absorption of the moisture from the air.

Dermal DNEL

First of all, no information of dose response relationship were available and no adverse effects were observed, for local and systemic effects. Indeed, based on acute toxicological studies identified (limit test OECD 402 and in vitro skin irritation EU B46), there are no statistically or biologically adverse effects induced by MgCl2. In addition, the Health Risk Assessment Guidance for metal (HERAG, 2006) indicated that the penetration of the dermis by dissolved metal cations is generally low, i. e. in the range of 0.1 - 1%: this substance is quasi not available for the organisms (by demal route), toxic effects are hence negligible.

In these conditions, a DNEL cannot be elaborated for the dermal route, except via a route to route extrapolation.

A route to route extrapolation is proposed for the systemic effect on the basis of guidance on information requirements and chemical safety assessment R8. The NOAEL and the mean oral absorption (250 mg Mg per day and 35%) defined by the SCF (2001) and the estimate skin absorption defined by HERAG (2006) are used. For more details, see discussion for general population.

Assuming a human body weight of 70 kg and converted the value to magnesium chloride, the long-term oral NOAEL of workers is:

250 mg Mg per day = 981 mg MgCl2 per day

981 / 70 = 14 mg MgCl2/kg bw/day

The corrected dermal NOAEL is

Long term oral NOAEL * Oral absorption / skin absorption

14 * 35/1 = 490 mg/kg bw/day

For workers, no overall assessment factor was retained:

- For intra-species variability, the studies used by SCF (2001) are based on a large number of subjects including sensitive sub-populations; consequently no assessment factor was retained.
- For the duration study, the maximum duration is 76 weeks but the NOAEL is based on a mild, transient laxative effect, without pathological sequelae, which is readily reversible. It seems therefore appropriate not to assign an extra assessment factor for study duration, although none of the studies covers a chronic exposure time.
- For the quality of data: the different clinical studies were reviewed by an European Commission expert group. There may be smaller deficiencies in individual studies but altogether they present an evident dose-response relationship. It does not seem therefore appropriate to introduce an additional assessment factor for data quality

In conclusion:

The long term dermal DNEL for workers is 490 mg/kg bw/day.

Otherwise because of the skin behaviour of MgCl2 (very low absorption) and the high level of the DNEL reached, this dermal DNEL was not considered relevant. Indeed for a worker (bodyweight of 70 kg), the level of exposition for a “theoretical” adverse effect is 34300 mg per day (of the anhydrite form) for a long term exposition. This exposition is not realistic.

Table 26. DN(M)ELs for the general population

Exposure pattern	Route	Descriptor	DNEL / DMEL	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
Acute - systemic effects	Dermal	No-threshold effect and/or no dose-response information available				There is no acute toxicity hazard (leading to C&L), so no acute/short-term DNEL was derived. See discussion below
Acute - systemic effects	Inhalation	No data available: testing technically not feasible				No DNEL derivation. Scientifically unjustified. See discussion below
Acute - systemic effects	Oral	No-threshold effect and/or no dose-response information available				There is no acute toxicity hazard (leading to C&L), so no acute/short-term DNEL was derived. See discussion below.
Acute - local effects	Dermal	No-threshold effect and/or no dose-response information available				There is no acute toxicity hazard (leading to C&L), so no acute/short-term DNEL was derived. See discussion below.
Acute - local effects	Inhalation	No data available: testing technically not feasible				No DNEL derivation. Scientifically unjustified. See discussion below.
Long-term - systemic effects	Dermal	No-threshold effect and/or no dose-response information available				No DNEL derivation. Scientifically unjustified. See discussio below.
Long-term - systemic effects	Inhalation	No data available: testing technically not feasible				No DNEL derivation. Scientifically unjustified. See discussion below.
Long-term - systemic effects	Oral	DNEL (Derived No Effect Level)	7 mg/kg bw/day	NOAEL: 14 mg/kg bw/day (based on AF of 2)		See discussion below.
Long-term - local effects	Dermal	No-threshold effect and/or no dose-response information available				No DNEL derivation. Scientifically unjustified. Ssee discussion below
Long-term -	Inhalation	No data available:				No DNEL derivation. Scientifically unjustified. See

Exposure pattern	Route	Descriptor	DNEL / DMEL	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
local effects		testing technically not feasible				discussion below.

**) The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and "Assessment factor" provided in the Endpoint summary of IUCLID section 7. Toxicological information. It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of assessment factors.*

Discussion

Acute DNEL

There is no acute toxicity hazard (leading to C&L), so no acute/short-term DNEL was derived. (Refer to ECHA Guidance on IR&CSA R.8 p.16).

For inhalation route, this route is not appropriate indeed magnesium chloride is deliquescent, which means that it tends to undergo gradual dissolution and liquefaction by the attraction and the absorption of the moisture from the air.

Long term DNEL

Inhalation DNEL

This route is not appropriate indeed magnesium chloride is deliquescent, which means that it tends to undergo gradual dissolution and liquefaction by the attraction and the absorption of the moisture from the air.

Oral DNEL

A long-term oral DNEL for general population was elaborated on the basis of animal and human studies. Both elaborations are presented below.

On the basis of animal studies

The DNEL is based on a NOAEL from a 96 weeks oral study. In this study, groups of 50 male and 50 female B6C3F1 mice were given MgCl2, 6H20 at dose levels of 0, 0 5 and 2 % in the diet. The NOAELs for female and male mice were, respectively 3930 mg/kg bw/day (2 % in the diet) and 2810 mg/kg bw/day (2 % in the diet). These results were corrected to magnesium chloride anhydrous: 1830 mg/kg bw/day for female mice and 1309 mg/kg bw/day for male mice.

The overall assessment factor was obtained as follows:

- For interspecies: 7 for allometric scaling factor for mice as compared to humans (for mice and 70 kg for man) and 2.5 for remaining interspecies differences
- For intraspecies: 10 for intraspecies differences in the general population.

No other factors were applied as the quality of the information was good and consistency.

The derived long term oral DNEL is

$$1309 / (7 \times 2.5 \times 10) = 7.5 \text{ mg/kgbw/day}$$

On the basis of human studies

The Opinion of the Scientific Committee on Food of the European Commission (SCF 2001) summarized 20 different clinical studies on oral uptake of magnesium compounds. Considering these clinical studies, the SCF has set a human NOAEL of 250 mg/day for additional intakes (above diatery) based on mild diarrhoea (the most sensitive, non-desirable effect following oral administration of magnesium occurring at oral doses of 360/365 mg Mg per day, the LOAEL) and the absence of such at 250 mg Mg per day (NOAEL).

It seems applicable to use data from other easily bioavailable magnesium salts for read-across to magnesium chloride, based on the assumption that the first adverse effect to occur (mild diarrhoea) is triggered by magnesium concentration rather than by an effect of the chloride ion.

An overall assessment factor of 2 was obtained as follows:

- For intra-species variability, a factor of 2 was appropriate. The studies used regard a large number of subjects including sensitive sub-populations (such as children, elderly, pregnant women, patients) but excluding in particular infants (<4 years). This factor seems therefore appropriate than 2.

- For the duration study, the maximum duration is 76 weeks but the NOAEL is based on a mild, transient laxative effect, without pathological sequelae, which is readily reversible. It seems therefore appropriate not to assign an extra assessment factor for study duration, although none of the studies covers a chronic exposure time.

- For the quality of data: the different clinical studies were reviewed by an European Commission expert group. There may be smaller deficiencies in individual studies but altogether they present an evident dose-response relationship. It does not seem therefore appropriate to introduce an additional assessment factor for data quality

Assuming a human body weight of 70 kg and converted the value to magnesium chloride, the long-term oral DNEL of the general population is:

250 mg Mg per day = 981 mg MgCl2 per day

981 / (70 * 2) = 7 mg MgCl2/kg bw/day

Conclusion

Both elaborations (for long-term oral DNEL) gave an equivalent result:

- 7.5 mg/kg bw/day on the basis of animal studies.

- 7 mg/kg bw/day on the basis of human studies.

These results confirm theread-across between magnesium and magnesium chloride.

The final long term oral DNEL for the general population is hence7 mg/kg bw/day.

Dermal DNEL

First of all, no information of dose response relationship were available and no adverse effects were observed, for local and systemic effects. Indeed, based on acute toxicological studies identified (limit test OECD 402 and in vitro skin irritation EU B46), there are no statistically or biologically adverse effects induced by MgCl2. In addition, the Health Risk Assessment Guidance for metal (HERAG, 2006) indicated that the penetration of the dermis by dissolved metal cations is generally low, i. e. in the range of 0.1 - 1%: this substance is quasi not available for the organisms (by demal route), toxic effects are hence negligible.

In these conditions, a DNEL cannot be elaborated for the dermal route, except via a route to route extrapolation.

A route to route extrapolation is proposed for the systemic effect on the basis of guidance on information requirements and chemical safety assessment R8. The NOAEL and the mean oral absorption (250 mg Mg per day and 35%) defined by the SCF (2001) and the estimate skin absorption defined by HERAG (2006) are used.

Assuming a human body weight of 70 kg and converted the value to magnesium chloride, the long-term oral NOAEL:

250 mg Mg per day = 981 mg MgCl2 per day

981 / 70 = 14 mg MgCl2/kgbw/day;

The corrected dermal NOAEL is

= Long term oral NOAEL * Oral absorption / skin absorption

= 14 * 35/1 = 490 mg/kgbw/day

As the oral route, an overall assessment factorof 2 was appropriate for general population.

In conclusion:

The long term dermal DNEL for general population is 245 mg/kgbw/day.

Otherwise because of the skin behaviour of MgCl2 (very low absorption) and the high level of the DNEL reached, this dermal DNEL was not considered relevant. Indeed for an adult (bodyweight of 70 kg), the level of exposition for a "theoretical" adverse effect is 17150 mg per day (of the anhydrite form) for a long term exposition. This exposition is not realistic

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

6.1. Explosivity

Data waiving: see CSR section 1.3 Physico-chemical properties.

Classification according to GHS

Name: magnesium chloride

Reason for no classification: data lacking

Classification according to DSD / DPD

Classification status: (Magnesium Chloride)

Reason for no classification: data lacking

6.2. Flammability

The available information on flammability is summarised in the following table:

Table 27. Overview of information on flammability

Method	Results	Remarks	Reference
Methodological details are not reported	Evaluation of results: non flammable Study results: Ignition on contact with air: no	2 (reliable with restrictions) key study experimental result **Test material (EC name): magnesium chloride**	International Programme on Chemical Safety, (2010)

Magnesium chloride is reported to be non-flammable (Source: ICSC)

This result can be confirmed by the chemical structure of MgCl2. Since magnesium is in its most stable oxidation, the substance is incapable of further reactions with oxygen.

For water flammability, testing can be waived based on experience in handling and use: magnesium chloride is not flammable

The following information is taken into account for any hazard / risk assessment:

Magnesium chloride is non flammable

Data waiving: see CSR section 1.3 Physico-chemical properties.

Classification according to GHS

Name: magnesium chloride

Reason for no classification (Flammable gases): data lacking

Reason for no classification (Flammable aerosols): data lacking

Reason for no classification (Flammable liquids): data lacking

Reason for no classification (Flammable solids): data lacking

Classification according to DSD / DPD

Classification status: (Magnesium Chloride)

Reason for no classification: data lacking

Justification for classification or non-classification:

No classification is proposed since the substance is non flammable

6.3. Oxidising potential

Data waiving: see CSR section 1.3 Physico-chemical properties.

Classification according to GHS

Name: magnesium chloride

Reason for no classification (Oxidising gases): data lacking

Reason for no classification (Oxidising liquids): data lacking

Reason for no classification (Oxidising solids): data lacking

Classification according to DSD / DPD

Classification status: (Magnesium Chloride)

Reason for no classification: data lacking

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic compartment (including sediment)

7.1.1. Toxicity test results

For the 3 trophic levels, several studies on the short-term toxicity are available, and one study is available for the long-term toxicity to invertebrates:

Fishes :

Short-term acute toxicity tests with MgCl2 have been performed on freshwater fathead minnows (*Pimephales promelas*), saltwater Mysid shrimp (*Mysidopsis bahia*), salwater sheepshead minnows (*Cyprinodon variegatus*), and salwater inland silverside minnows (*Menidia beryllina*). All the observed LC50 were higher than 100 mg/L with the lowest value obtained for freshwater fathead minnows (*Pimephales promelas* LC50= 2119 mg/L), and *Menidia beryllina* being the most sensitive salwater fish (LC50=10968 mg/L).

Invertebrates :

Reliable data are available for the acute and chronic effects of MgCl2 over a wide range of freshwater and marine water invertebrates, including *Daphnia magna* (LC50 = 548 mg/L, EC10= 341 mg/L), *Ceriodaphnia dubia* (LC50= 1328 mg/L) and *Americamysis bahia* (LC50= 3259 mg/L). All reliable LC50 values were higher than 100 mg Mg/L, with the lowest 48 h LC50 value for *Daphnia magna* (548 mg/L), and 832 mg Mg/L for marine invertebrates.

Algae :

A GLP guideline study was performed to assess the acute toxicity of Magnesium Chloride to the Single Cell Green Algae (*Desmodesmus subspicatus)* in a limit test. The 72 h EC50 was found to be >100 mg/L. No mortalities or adverse effects were noted at this concentration: NOEC = 100 mg of MgCl2/L.

Another literature study (den Dooren de Jonget al., 1965) on the toxicity of Magnesium Chloride to the algal species *Chlorella vulgaris* reports a NOEC of 980 mg Mg/L. Finally two other published data, reported in the IUCLID Dataset present two EC50s to *Scenedesmus subspicatus* of 562 and 1195 mg Mg/L. These three last data were not judged reliable since there was not enough available information on the test conditions to assess the reliability.

In conclusion, the lowest values observed for short-term and long-term studies are related to tests conducted with *Daphnia magna*:

- Short-term : 48h LC50= 548 mg/L
- Long-term : 21d EC10= 321 mg/L

7.1.1.1. Fish

7.1.1.1.1. Short-term toxicity to fish

The results are summarised in the following table:

Table 28. Overview of short-term effects on fish

Method	Results	Remarks	Reference
Pimephales promelas freshwater static	LC50 (96 h): 541 mg/L element (meas. (initial)) LC50 (96 h): 2119.3 mg/L test mat. (meas. (initial))	2 (reliable with restrictions) key study experimental result	Mount DR, Gulley DD, Hockett JR, Garrison TD and Evans JM (1997)

Method	Results	Remarks	Reference
U.S. Environmental Protection Agency. 1991. Methods for measuring the acute toxicity of effluents to freshwater and marine organisms, 4th ed. EPA/600/4-90/027. Cincinnati, OH.		**Test material (EC name): magnesium chloride**	
Gambusia affinis freshwater static Data were collected on the toxicity of 86 pure chemicals (including MagnesiumChloride) to the mosquito fish Gambusia affinis.	LC50 (96 h): 4212 mg/L element (nominal) LC50 (96 h): 16500 mg/L test mat. (nominal)	3 (not reliable) disregarded study experimental result **Test material (EC name): magnesium chloride**	Wallen, I.E., Greer, W.C., Lasater, R. (1957)
Menidia beryllina saltwater static EPA OPPTS 850.1075 (Freshwater and Saltwater Fish Acute Toxicity Test)	LC50 (48 h): 2800 mg/L element (nominal) LC50 (48 h): 10968 mg/L test mat. (nominal)	2 (reliable with restrictions) supporting study **Test material (EC name): magnesium chloride**	Pillard, D.A., DuFresne, D.L., Caudle, D., D., Tietge, J., E., Evans (2000)

Discussion

Relevant information is available on the acute toxicity of magnesium compounds to fish.

(i) In total, **2 studies were judged reliable with restriction** (Klimisch 2):

- Mount et al. (1997) investigated the acute toxicity of Magnesium Chloride to freshwater fathead minnow (Pimephales promelas). The 96 h LC50 for Magnesium Chloride was 2119.5 mg/L (or 541 mg of Mg/L). This study was performed following the standard protocols developed by the Environmental Protection Agency (EPA, 1991), and thus were judged as reliable with restrictions (No guideline study, but well documented and scientifically acceptable)

- Pillard et al. (2000) investigated the acute toxicity of Magnesium Chloride to saltwater silverside minnows (Menidia beryllina). The 48 h LC50 for Magnesium Chloride was 10968 mg of MgCl2/L (or 2800 mg of Mg/L). This study was performed following the standard protocols developed by the Environmental Protection Agency (EPA, 1991), and thus were judged as reliable with restrictions (water characteristics measured but not reported)

(ii) **1 study was unreliable** (Klimisch 3)

- Wallen et al. (1957) investigated the acute toxicity of Magnesium Chloride*Gambusia affinis.* The 96 h LC50 for Magnesium Chloride was 16 500 mg of MgCl2/L (or 4212 mg of Mg/L). This study was no tperformed following the standard protocols(e. g. tests were performed using waters collected in a highly turbidity farm pond), and thus were judged not reliable (Relevant methodological deficiencies)

=> All reliable LC_{50}values were higher than 100 mg mg/L, with the lowest LC_{50}value for *Pimephales promelas* of 2119.5 mg of MgCl2/L (Mount*et al.,* 1997).

The following information is taken into account for acute fish toxicity for the derivation of PNEC:

Two reliable studies are available for the acute toxicity of Magnesium Chloride for freshwater and seawater fishes:

- The 96 h LC50 of magnesium chloride to Pimephales promelas was 2119.5 mg of MgCl2/L. (Mount et al. (1997))
- The lowest LC50 obtained for Menidia beryllina was 10968 mg MgCl2/L. (Pillard et al. (2000))

Value used for CSA:

- LC50 for freshwater fish: 2119.5 mg/L
- LC50 for marine water fish: 10968 mg/L

7.1.1.1.2. Long-term toxicity to fish

Data waiving

Reason: other justification

Justification: On the basis of column 2 of annexes IX and X, long-term toxicity testing shall be proposed if the chemical safety assessment (CSA) indicates the need to investigate further the effects on aquatic organisms, which is not the case. Because of their widespread occurrence in rocks and soils, and its ready solubility, magnesium and chloride ions are present in nearly all waters.

Hence, if Magnesium and Chloride ions are ubiquitous in water, then long term exposure of fish to magnesium chloride should not be of concern.

Moreover, Long-term toxicity test on invertebrates (Biesinger et al., 1972) reports a 21 days EC10 (for Daphnia magna reproduction) of 321 mg/L, indicating that the substance is not chronically toxic for aquatic invertebrates. Similar results are expected for fish, since short-term toxicity values for fish and invertebrates are in the same order of magnitude.

7.1.1.2. Aquatic invertebrates

7.1.1.2.1. Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 29. Overview of short-term effects on aquatic invertebrates

Method	Results	Remarks	Reference
Daphnia magna freshwater static A bioassay procedure was developed for Daphnia magna to serve as a representative aquatic invertebrate test species to evaluate the toxicity of selected inorganic pollutants (including MgCl2.6H2O).	LC50 (48 h): 140 mg/L element (Mg) (meas. (initial)) based on: mortality LC50 (48 h): 548.4 mg/L test mat. (meas. (initial)) based on: mortality	2 (reliable with restrictions) key study experimental result **Test material (CAS name): Magnesium Chloride hexahydrate**	Biesinger, K.E., Christensen, G.M. (1972)

Method	Results	Remarks	Reference
The toxicities of various metals to Daphnia magna were evaluated on the basis of a 48-hr 50% lethal concentration (LC50).			
Daphnia magna and Ceriodaphnia dubia freshwater static U.S. Environmental Protection Agency. 1991. Methods for measuring the acute toxicity of effluents to freshwater and marine organisms, 4th ed. EPA/600/4-90/027. Cincinnati, OH.	LC50 (48 h): 225 mg/L element (meas. (initial)) based on: mortality LC50 (48 h): 841.4 mg/L test mat. (meas. (initial)) based on: mortality LC50 (48 h): 339 mg/L element (meas. (initial)) based on: mortality LC50 (48 h): 1328 mg/L test mat. (meas. (initial)) based on: mortality	2 (reliable with restrictions) supporting study experimental result **Test material (EC name): magnesium chloride**	Mount, D.R., Gulley, D.D., Hockett, J.R., Garrison, T.D., J.M., E. (1997)
Americamysis bahia saltwater static The study was conducted to evaluate the toxicity of six major seawater ions (bicarbonate, borate, calcium, magnesium, potassium, and sulfate) to the mysid shrimp, Americamysis bahia, at salinities of 10, 20 and 31‰. Mysid shrimp were tested in 100-ml glass beakers with a volume of 50 ml. Five organisms were placed into each chamber, three replicates per test concentration were used. The test photoperiod was 16:8 h light:dark, and test temperature ranged from 25 to 278C. Mysid shrimp were fed ,24-h-old Artemia nauplii (ø0.1 ml/chamber) three times a day (in order to discourage cannibalism). The exposure period was 48 h without renewal, and observations of mortality were made daily. The criteria for death were no visible movement and no response to prodding with a blunt probe.	LC50 (48 h): 832 mg/L element (nominal) based on: mortality LC50 (48 h): 3259.2 mg/L test mat. (nominal) based on: mortality LC50 (48 h): 1705 mg/L element (nominal) based on: mortality LC50 (48 h): 6679 mg/L test mat. (nominal) based on: mortality LC50 (48 h): 2650 mg/L element (nominal) based on: mortality LC50 (48 h): 10381 mg/L test mat. (nominal) based on: mortality	2 (reliable with restrictions) supporting study experimental result **Test material (EC name): magnesium chloride**	Pillard, D.A., DuFresne, D.L., Caudle, D., D., Tietge, J., E., Evans (2000)

Discussion

There is substantial relevant information on the acute toxicity of magnesium compounds to aquatic invertebrates. In total, 3 studies were judged reliable with restriction (Klimisch 2).

Reliable data are available on the effect of MgCl2 to a range of aquatic invertebrates, including Daphnia magna, in both freshwater and marine water. All reliable L(E) C50 values were larger than 100 mg Mg/L, with the lowest 48 h LC50 value for Daphnia magna 140 mg Mg/L (or 548.4 mg of MgCL2 / L) for freshwater, and 832 mg Mg/L (or 3259 mg of MgCl2/L) for marine invertebrates (Americamysis bahia).

The following information is taken into account for short-term toxicity to aquatic invertebrates for the derivation of PNEC:

- The key study: Biesinger et al. (1972)
- Ten 12±12h old daphnids (Daphnia magna) were pleaced in each test and control vessel, i. e. 20 animal per concentration test. After 48 h the number of animals in the control and test solutions that could swim was counted.
- The test was considered as valid when fewer than 10% of the animals in the control solutions were unable to swim, when the pH value was not below 7.0 and the measured oxygen concentration was near-saturation.
- The 48 h LC50 was calculated arithmetically from the concentration/effect ratio.
- Thus calculated 48 h LC50 value for Daphnia magna was 140 mg Mg/L (or 548.4 mg of MgCl2/L).

Value used for CSA:

- EC50/LC50 for freshwater invertebrates: 548.4 mg/L
- EC50/LC50 for marine water invertebrates: 3259 mg/L

7.1.1.2.2. Long-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 30. Overview of long-term effects on aquatic invertebrates

Method	Results	Remarks	Reference
Daphnia magna freshwater semi-static A bioassay procedure was developed for Daphnia magna to serve as a representative aquatic invertebrate test species to evaluate the effect of MgCl2 on the reproduction of Daphnia magna of selected inorganic substances (including MgCl2.6H2O) . The study reports a 21 days EC10 of 82 mg Mg/L for the effect of MgCl2 on the reproduction of Daphnia magna (or 321 mg of MgCl2 /L).	EC10 (21 d): 82 mg/L element (meas. (initial)) based on: reproduction EC10 (21 d): 321 mg/L test mat. (meas. (initial)) based on: reproduction	2 (reliable with restrictions) key study experimental result **Test material (CAS name): Magnesium chloride hexahydrate**	Biesinger, K.E., Christensen, G.M. (1972)

Discussion

Only one study is judged reliable (Klimisch 2) and reports a 21 day EC10 of 321 mg/L for the effect of MgCl2 on the reproduction of Daphnia magna (Biesinger and Christensen, 1972).

This EC10 value is larger than 100 mg/L for freshwater invertebrates, indicating that Magnesium Chloride showed no long-term toxicity to aquatic invertebrates and is therefore not chronically toxic to aquatic invertebrates.

The following information is taken into account for long-term toxicity to aquatic invertebrates for the derivation of PNEC:

- The key study: Biesinger et al. (1972)
- Five 12±12h old dauphins (Daphnia magna) were pleased in each test and control vessel, i. e. 20 animal per concentration test (4 replicate per concentration). At the end of the test, the total number of living offspring produced per parent animal alive at the end of the test was assessed.
- The 21 days EC10 was arithmetically calculated from the concentration/effect ratio. Thus calculated 21 days EC10 value for Daphnia magna was 82 mg of Mg/L (or 321 mg of MgCl2/L).
- The test was considered as valid when less than 10% of the animals in the control solutions were unable to swim, when the pH value was not below 7 and the measured oxygen concentration was near-saturation.
- The 48 h LC50 was calculated arithmetically from the concentration/effect ratio.
- Thus calculated 48 h LC50 value for Daphnia magna was 140 mg Mg/L (or 548.40 mg of MgCl2/L).

Value used for CSA:

- EC10/LC10 or NOEC for freshwater invertebrates: 321 mg/L

7.1.1.3. Algae and aquatic plants

The results are summarised in the following table:

Table 31. Overview of effects on algae and aquatic plants

Method	Results	Remarks	Reference
Desmodesmus subspicatus (algae) freshwater static OECD Guideline 201 (Alga, Growth Inhibition Test)	EC50 (3 d): > 100 mg/L test mat. (meas. (geom. mean)) based on: growth rate NOEC (3 d): 100 mg/L test mat. (meas. (geom. mean)) based on: growth rate	1 (reliable without restriction) key study experimental result **Test material (EC name): magnesium chloride**	Detlef Dengler (2010a)
Chlorella vulgaris (algae) freshwater static The toxicity of a number of salts (including Magnesium Chloride) to Chlorella vulgaris. NOEC/LOEC were assessed on the basis of the observed growth rates.	NOEC (90 d): 980 mg/L element (nominal) based on: growth rate NOEC (90 d): 3838 mg/L test mat. (nominal) based on: growth rate LOEC (90 d): 1230 mg/L element (nominal) based on: growth rate LOEC (90 d): 6777 mg/L test mat. (nominal) based on: growth rate	3 (not reliable) disregarded study experimental result **Test material: >>>??? Inconsistent identities: "EC number" same, but "CAS name" not same as in section 1.1<<<**	den Dooren de Jong, L., Roman, W. (1965)
Scenedesmus subspicatus (new name: Desmodesmus subspicatus) (algae) freshwater	EC50 (72 h): 562 mg/L element based on: biomass EC10 (72 h): 156 mg/L	4 (not assignable) disregarded study experimental result	Anon, (1994)

Method	Results	Remarks	Reference
No data	element based on: biomass	**Test material (EC name): magnesium chloride**	
Scenedesmus subspicatus (new name: Desmodesmus subspicatus) (algae) freshwater No data	EC50 (24 h): 1195 mg/L element	4 (not assignable) disregarded study experimental result **Test material (EC name): magnesium chloride**	Anon, no data

Discussion

Effects on algae / cyanobacteria

A GLP guideline study was performed to assess the acute toxicity of Magnesium Chloride (DENG, 2010) to the Single Cell Green Alga *Desmodesmus subspicatus* in a limit test (0 -100 mg of MgCl2/L). The 72 h EC50 was found to be >100 mg/L. No mortalities or adverse effects were noted at this concentration: NOEC = 100 mg of MgCl2/L.

A further literature study (den Dooren de Jong*et al.*, 1965) which assessed the toxicity of Magnesium Chloride to the algal species *Chlorella vulgaris* reports a NOEC of 980 mg Mg/L (or 3838 mg of MgCl2/L).

Two further studies, reported in the IUCLID Dataset (2000) present two EC50s to *Scenedesmus subspicatus* of 562 and 1195 mg Mg/L.

The following information is taken into account for effects on algae / cyanobacteria for the derivation of PNEC:

Data is available on the acute toxicity of magnesium chloride to algae. No short-term toxicity was observed at the concentrations tested.

Value used for CSA:

- EC10/LC10 or NOEC for freshwater algae: 100 mg/L

7.1.1.4. Sediment organisms

Data waiving

Reason: other justification

Justification: According to Section 9.5.1 of REACH Regulation 1907/2006, a long-term toxicity test to sediment organisms is required. However, such a study is not justified for Magnesium Chloride for the following reasons:

- Magnesium and chloride ions are ubiquitous in the environment and are found naturally in soil, water and sediment (Mg in soils/sediments is at a 50th percentile level in the range of 0.9-1.2 %). Magnesium will be assimilated by species residing in the sediment and is necessary to maintain a good chemical balance in soils, water and sediment. The chloride will become part of the chloride cycle and/or be assimilated by microorganisms and other species that require chloride as an essential substance in their biological systems/ processes.

- Natural magnesium minerals are quite soluble, and so differences in bioavailability between natural magnesium sources and anthropogenic added magnesium are not expectable.

Due to the natural occurrence of Magnesium chloride in the environment, it is expected that Magnesium

chloride would not be toxic to sediment organisms and hence, long-term toxicity tests are scientifically unjustified.

Discussion

According to Section 9.5.1 of REACH Regulation 1907/2006, a long-term toxicity test to sediment organisms is required. However, such a study is not justified for Magnesium Chloride for the following reasons:

- Magnesium and chloride ions are ubiquitous in the environment and are found naturally in soil, water and sediment (Mg in soils/sediments are at a 50th percentile level in the range of 0.9-1.2 %). Magnesium will be assimilated by species residing in the sediment and is necessary to maintain a good chemical balance in soils, water and sediment. The chloride will become part of the chloride cycle and/or be assimilated by microorganisms and other species that require chloride as an essential substance in their biological systems/ processes.

- Natural magnesium minerals are quite soluble, and so differences in bioavailability between natural magnesium sources and anthropogenic added magnesium are not expected.

Due to the natural occurrence of Magnesium chloride in the environment, it is expected that Magnesium chloride would not be toxic to sediment organisms and hence, long-term toxicity tests are scientifically unjustified.

7.1.1.5. Other aquatic organisms

No data are required.

7.1.2. Calculation of Predicted No Effect Concentration (PNEC)

7.1.2.1. PNEC water

Table 32. PNEC water

PNEC	Assessment factor	Remarks/Justification
PNEC aqua (freshwater): 3.21 mg/L	100	Extrapolation method: assessment factor The lowest chronic EC10 is 321 mg/l for Daphnia magna. An assessment factor of 100 has been used since data are available from a wide selection of species covering the three taxonomic groups for the acute toxicity and one taxonomic group (invertebrates) for the chronic toxicity
PNEC aqua (marine water): 0.32 mg/L	1000	Extrapolation method: assessment factor The lowest chronic EC10 is 321 mg/l for Daphnia magna. An assessment factor of 1000 has been used since data are available from a wide selection of species covering three taxonomic groups for the acute toxicity and one taxonomic group (invertebrates) for the chronic toxicity
PNEC aqua (intermittent releases): 5.48 mg/L	100	Extrapolation method: assessment factor The PNECaqua-intermittent was derived by application of an assessment factor of 100 to the lowest L(E)C50 of the 7 L(E)C50 available (548 mg of MgCl2/L, Biesinger etal., 1972).

7.1.2.2. PNEC sediment

Table 33. PNEC sediment

PNEC	Assessment factor	Remarks/Justification
PNEC sediment (freshwater): 288.9 mg/kg sediment dw		Extrapolation method: partition coefficient The PNEC sediment was derived from the PNEC water using the equilibrium partitioning method. The following Imput paramaters were used : Fsolid = 0.2m3/m3 ; Foc = 5% ; Koc = 4680 (worst case) ; RHOsolid 2500 ; RHOsed = 1300.
PNEC sediment (marine water): 28.89 mg/kg sediment dw		Extrapolation method: partition coefficient The PNEC sediment was derived from the PNEC water using the equilibrium partitioning method. The following Imput paramaters were used : Fsolid = 0.2m3/m3 ; Foc = 5% ; Koc = 4680 L/Kgoc (worst case) ; RHOsolid 2500 ; RHOsed = 1300.

7.2. Terrestrial compartment

7.2.1. Toxicity test results

Short-term and long-term toxicity tests to terrestrial organisms (macoorganisms, plants, microoganisms, birds...) are required. However, such studies are not justified for Magnesium Chloride for the following reasons:

- Magnesium and chloride ions are ubiquitous in the environment and are found naturally in soil, water and sediment (Mg in soils/sediments is at a 50th percentile level in the range of 0.9-1.2 %). Magnesium will be assimilated by species residing in the soil and is necessary to maintain a good chemical balance in soils, water and sediment. The chloride will become part of the chloride cycle and/or be assimilated by microorganisms and other species that require chloride as an essential substance in their biological systems/ processes.

- Natural magnesium minerals are quite soluble, and so differences in bioavailability between natural magnesium sources and anthropogenic added magnesium are not expected.

For these reasons, it is expected that Magnesium chloride would not be toxic to soil organisms and hence, short-term and long-term toxicity tests to terrestrial organisms are scientifically unjustified.

7.2.1.1. Toxicity to soil macro-organisms

Data waiving

Information requirement: Toxicity to soil macro-organisms except arthropods

Reason: other justification

Justification: According to Section 9.4.1 and 9.4.4 of REACH Regulation 1907/2006, short-term and long-term toxicity tests to terrestrial macroorganisms (excepted arthropods) is required. However, such a study is not justified for Magnesium Chloride for the following reasons:

- Magnesium and chloride ions are ubiquitous in the environment and are found naturally in soil, water and sediment (Mg in soils/sediments are at a 50th percentile level in the range of 0.9-1.2 %). Magnesium will be assimilated by species residing in the soil and is necessary to maintain a good chemical balance in soils, water and sediment. The chloride will become part of the chloride cycle and/or be assimilated by

microorganisms and other species that require chloride as an essential substance in their biological systems/ processes.

- Natural magnesium minerals are quite soluble, and so differences in bioavailability between natural magnesium sources and anthropogenic added magnesium are not expected.

Due to these reasons, it is expected that Magnesium chloride would not be toxic to soil organisms and hence, short-term and long-term toxicities test to terrestrial macroorganisms (excepted arthropods) are scientifically unjustified.

Information requirement: Toxicity to terrestrial arthropods

Reason: other justification

Justification: According to Section 9.4.1 and 9.4.4 of REACH Regulation 1907/2006, short-term and long-term toxicity tests to terrestrial arthropods is required. However, such a study is not justified for Magnesium Chloride for the following reasons:

- Magnesium and chloride ions are ubiquitous in the environment and are found naturally in soil, water and sediment (Mg in soils/sediments are at a 50th percentile level in the range of 0.9-1.2 %). Magnesium will be assimilated by species residing in the soil and is necessary to maintain a good chemical balance in soils, water and sediment. The chloride will become part of the chloride cycle and/or be assimilated by microorganisms and other species that require chloride as an essential substance in their biological systems/ processes.

- Natural magnesium minerals are quite soluble, and so differences in bioavailability between natural magnesium sources and anthropogenic added magnesium are not expected.

Due to these reasons, it is expected that Magnesium chloride would not be toxic to soil organisms and hence, short-term and long-term toxicitys test to terrestrial arthropods are scientifically unjustified.

7.2.1.2. Toxicity to terrestrial plants

Data waiving

Reason: other justification

Justification: According to Sections 9.4.3 and 9.4.6 of REACH Regulation 1907/2006, short-term and long-term toxicity tests to terrestrial plants is required. However, such a study is not justified for Magnesium Chloride for the following reasons:

- Magnesium and chloride ions are ubiquitous in the environment and are found naturally in soil, water and sediment (Mg in soils/sediments are at a 50th percentile level in the range of 0.9-1.2 %). Magnesium will be assimilated by species residing in the soil and is necessary to maintain a good chemical balance in soils, water and sediment. The chloride will become part of the chloride cycle and/or be assimilated by microorganisms and other species that require chloride as an essential substance in their biological systems/ processes.

- Natural magnesium minerals are quite soluble, and so differences in bioavailability between natural magnesium sources and anthropogenic added magnesium are not expected.

Due to these reasons, it is expected that Magnesium chloride would not be toxic to soil organisms and hence, short-term and long-term toxicitys test to terrestrial plants are scientifically unjustified.

7.2.1.3. Toxicity to soil micro-organisms

Data waiving

Reason: other justification

Justification: According to Section 9.4.2 of REACH Regulation 1907/2006, a study is required to investigate the effects on soil microorganisms. However, such a study is not justified for Magnesium Chloride for the following reasons:

- Magnesium and chloride ions are ubiquitous in the environment and are found naturally in soil, water and sediment (Mg in soils/sediments are at a 50th percentile level in the range of 0.9-1.2 %). Magnesium will be assimilated by species residing in the soil and is necessary to maintain a good chemical balance in soils, water and sediment. The chloride will become part of the chloride cycle and/or be assimilated by microorganisms and other species that require chloride as an essential substance in their biological systems/ processes.

- Natural magnesium minerals are quite soluble, and so differences in bioavailability between natural magnesium sources and anthropogenic added magnesium are not expected.

Due to these reasons, it is expected that Magnesium chloride would not be toxic to soil microorganisms and hence, short-term and long-term toxicities test to terrestrial microorganisms are scientifically unjustified.

7.2.1.4. Toxicity to other terrestrial organisms

No data are required.

7.2.2. Calculation of Predicted No Effect Concentration (PNEC soil)

Table 34. PNEC soil

PNEC	Assessment factor	Remarks/Justification
PNEC soil: 662.77 mg/kg soil dw		Extrapolation method: partition coefficient The PNEC soil was derived from the PNEC water using the equilibrium partitioning method. The following Imput paramaters were used : Fsolid = 0.6m3/m3 ; Foc = 2% ; Koc = 11700 L/Kgoc (worst case) ; RHOsolid 2500 ; RHOsed = 1700.

7.3. Atmospheric compartment

No data are available and is not required under REACH.

7.4. Microbiological activity in sewage treatment systems

7.4.1. Toxicity to aquatic micro-organisms

The results are summarised in the following table:

Table 35. Overview of effects on micro-organisms

Method	Results	Remarks	Reference
activated sludge of a predominantly domestic sewage freshwater static OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test)	EC50 (3 h): > 900 mg/L test mat. (nominal) based on: respiration rate	1 (reliable without restriction) key study experimental result **Test material (EC name): magnesium chloride**	Detlef Dengler (2010b)
Vibrio fisheri freshwater	EC50 (15 min): 5.1 mg/L element based on: bioluminescence EC50 (15 min): 20 mg/L test mat. based on: bioluminescence	3 (not reliable) disregarded study experimental result **Test material (EC name): magnesium chloride**	Newman, M., McCloskey, J. (1996)
Photobacterium phosphoreum German Standard methods for the analysis of water and sludge ; bio-assays (group L) ; determination of the effect of the inhibitory effect of waste water on the light emission of Photobacterium Phoshoreum (L34).	EC50 (30 min): 9266 mg/L element EC50 (30 min): 23968 mg/L element	4 (not assignable) disregarded study experimental result **Test material (EC name): magnesium chloride**	ANON (1994)

Discussion

An Activated Sludge, Respiration Inhibition (ASRI) test has been performed on Magnesium Chloride in accordance with GLP and OECD 209.

No short-term toxicity to microorganisms was observed at the concentration tested (12 -900 mg/L).

Hence, the effect of the test material on the respiration of activated sewage sludge micro-organisms gave a 3-Hour EC50 of greater than 900 mg/L. The No Observed Effect Concentration (NOEC) after 3 hours exposure was 900 mg/L.

The following information is taken into account for effects on aquatic micro-organisms for the derivation of PNEC:

An Activated Sludge, Respiration Inhibition Test test has been performed on magnesium chloride according to OECD 209.

Value used for CSA:

- EC10/LC10 or NOEC for aquatic micro-organisms: 900 mg/L

7.4.2. PNEC for sewage treatment plant

Table 36. PNEC sewage treatment plant

Value	Assessment factor	Remarks/Justification
PNEC STP: 90 mg/L	10	Extrapolation method: assessment factor The EC50 for STP micro-organisms is >900 mg/L, with a NOEC reported to be 900 mg/L. The PNEC for STP micro-organisms is derived by applying an assessment factor of 10 to the NOEC. The PNEC for STP is therefore equal to 90 mg/L.

7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

7.5.1. Toxicity to birds

Data waiving

Information requirement: Toxicity to birds

Reason: other justification

Justification: According to Section 9.6.1 of REACH Regulation 1907/2006, a long-term or reproductive toxicity study in birds is required. However, such a study is not justified for magnesium chloride for the following reasons:

Comprising about 0.1 % of a bird's weight, magnesium is one of the predominant mineral in the body. Magnesium is used for bone formation, egg shell production and blood clotting. Most of the body's magnesium is found in the skeleton where it comprises about 2 % of the weight of the dried bone.

For this reason, magnesium is generally considered as an essential element for birds, justifying that toxicity tests to birds are scientifically unjustified.

7.5.2. Toxicity to mammals

No data are available and is not required under REACH.

7.5.3. Calculation of PNECoral (secondary poisoning)

Table 37. PNEC oral

PNEC	Assessment factor	Remarks/Justification
No potential for bioaccumulation		Magnesium Chloride dissociates into the magnesium Mg2+ and chloride Cl- ions at environmental pH. These are essential to all living organisms (flora and fauna) and their intracellular and extra-cellular concentrations are actively regulated. Bioaccumulation is thus not expected.

7.6. Conclusion on the environmental hazard assessment and on classification and labelling

Environmental classification justification

Magnesium Chloride is not classified as dangerous for the environment under the CLP regulation 1272/2008 and the Directive 67/548.

General discussion

In accordance with the "Guidance on information requirements and chemical safety assessment, Chapter R.10":

- an AF of 100 is applied to the long-term toxicity value EC10 (321 mg/L) for the derivation of the freshwater $PNEC_{aqua.}$
- an AF of 1000 is applied to the long-term toxicity value EC10 (321 mg/L) for the derivation of the marine water $PNEC_{aqua.}$
- an AF of 100 is applied to the lowest short-term toxicity value LC50 (548 mg/L) for the derivation of the intermitent release $PNEC_{aqua.}$

8. PBT AND VPVB ASSESSMENT

8.1. Assessment of PBT/vPvB Properties

As explained before, Magnesium Chloride is an inorganic substance quite soluble in contact with water, and that immediately dissociate into ions Mg^{2+} and Cl^- :

$$MgCl_2 \rightarrow Mg^{2+} + Cl^-$$

The relevant PBT (persistent, bioaccumulative, toxic) criteria according to the REACH regulation and the corresponding properties of Magnesium Chloride are compiled in the following Table:

Table 38 : PBT and vPvB criteria and the corresponding properties of Magnesium Chloride.

Criterion	PBT criteria	vPvB criteria	Magnesium Chloride	Criterion fulfilled?
P	Half-life in marine water > 60 d, or half-life in fresh- or estuarine water > 40 d, or half-life in marine sediment > 180 d, or half-life in fresh- or estuarine water sediment > 120 d, or half-life in soil > 120 d	Half-life in marine, fresh or esturarine water > 60 d, or Half-life in marine, fresh or esturarine sediment > 180 d, or Half-life in soil > 180 d	Not relevant for Magnesium Chloride (inorganic salt which immediately dissociates into its ions Mg^{2+} and Cl^-)	no
B	BCF > 2000	BCF > 5000	Not relevant as Magnesium and Chloride ions are essentials elements which are bioregulated (homeostatic mechanism)	no
T	Long-term NOEC for marine or freshwater organisms < 0.01 mg/l		Not relevant : Magnesium Chloride is not classified as a toxic substance for the environment	no
T	CMR	n.a.	Not classified as CMR	no
T	Other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC	n.a.	Not classified as T, R48, or Xn, R48 according to Directive 67/548/EEC	no

8.1.1. Persistence Assessment

The table demonstrates that the substance $MgCl_2$ do not fulfil the P or vP criteria.

8.1.2. Bioaccumulation Assessment

The table demonstrates that the substance $MgCl_2$ do not fulfil the B or vB criteria.

8.1.3. Toxicity Assessment

The table demonstrates that the substance $MgCl_2$ do not fulfil the criteria for T classification.

8.2. Summary and overall conclusions on PBT or vPvB properties

A substance is identified as a PBT substance if it fulfils all three PBT criteria described above. Here, the substance $MgCl_2$ does not fulfil the P, B and T criteria. Therefore the substance cannot be classified as PBT.
A substance is identified as a vPvB substance if it fulfils both vPvB criteria described above. The P and the B criteria are not fulfilled for $MgCl_2$.

8.2. Emission Characterisation

Magnesium Chloride is neither a PBT nor a vPvB substance. Accordingly, an Emission Characterisation under Section 4.2 of Annex I is not required.

9. EXPOSURE ASSESSMENT AND RISK CHARACTERISATION

As the substance $MgCl_2$ does not meet the criteria for classification as dangerous according to Directive 67/548/EEC or Regulation 1272/2008 and is not assessed as being a PBT or vPvB substance, an exposure assessment and a risk characterisation have not been performed.

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