

# SAFETY DATA SHEET



Glucalmax

Version 1.0      Revision Date: 24.06.2020      SDS Number: 122000017685      Date of last issue: -  
Date of first issue: 24.06.2020

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## Section 1: Identification

### 1.1 Product identifier

Glucalmax

HSNO Approval Number : HSR002399

ACVM number : A001441

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

### 1.3 Details of the supplier of the safety data sheet

#### Company

Elanco New Zealand  
Unit A, 123 Ormiston Road  
AUCKLAND  
NEW ZEALAND  
+64-9-272 5420  
elanco\_sds@elanco.com

### 1.4 Emergency telephone number

**In case of emergency:** CHEMTREC International: +1 703-527-3887 (24 hours)  
or +64-0800 425 459 (Local toll free)

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## Section 2: Hazard identification

### GHS Classification

Toxic to Reproduction : 6.8B

### GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H361 Suspected of damaging fertility or the unborn child.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P264 Wash skin thoroughly after handling.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ eye protection/ face protection.

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## Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

## Other hazards which do not result in classification

None known.

## Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Boric acid	10043-35-3	>= 2 -< 10
Magnesium chloride	7786-30-3	>= 1 -< 10
D-gluconic acid, cyclic 4,5-ester with boric acid, calcium salt	Not Assigned	25

## Section 4: First-aid measures

- General advice : Take off all contaminated clothing immediately.
- You should call the National Poisons Centre if you feel that you may have been harmed or irritated by this product. The number is 0800 764 766 (0800 POISON) (24hr emergency service).
- If inhaled : Remove to fresh air.  
Call a physician immediately.
- In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.  
If skin reactions occur, contact a physician.
- In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- If swallowed : If swallowed, seek medical advice immediately and show this container or label.
- Most important symptoms and effects, both acute and delayed : No information available.
- Notes to physician : No information available.

## Section 5: Fire-fighting measures

- Suitable extinguishing media : Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

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- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire-fighting : Fire may cause evolution of:  
Carbon monoxide (CO)  
Carbon dioxide (CO<sub>2</sub>)
- Specific extinguishing methods : Prevent fire extinguishing water from contaminating surface water or the ground water system.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
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### Section 6: Accidental release measures

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Use with adequate ventilation.
- Environmental precautions : Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : Suppress (knock down) gases/vapours/mists with a water spray jet.  
Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).  
Place in closed containers. Label for proper disposal.
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### Section 7: Handling and storage

- Advice on protection against fire and explosion : No special protective measures against fire required.
- Advice on safe handling : Industrial uses:  
Avoid formation of aerosol.  
Use with local exhaust ventilation.  
Avoid contact with skin, eyes and clothing.
- Hygiene measures : Cleanliness Guidelines (GMP) for manufacturing of drugs must be observed!
- Conditions for safe storage : For storage suitable stores with adequate product-reception volume must be used.  
During handling local official regulations must be observed in order to avert impairment of water by the product.
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### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis

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Boric acid	10043-35-3	TWA (Inhalable fraction)	2 mg/m <sup>3</sup> (Borate)	ACGIH
		TWA (Inhalable fraction)	2 mg/m <sup>3</sup> (Borate)	ACGIH
		STEL (Inhalable fraction)	6 mg/m <sup>3</sup> (Borate)	ACGIH
		STEL (Inhalable fraction)	6 mg/m <sup>3</sup> (Borate)	ACGIH

### Personal protective equipment

Respiratory protection : Recommended respiratory protection: full mask with filter ABEK-ST (ABEK-P3)

Hand protection  
Material : Hand protection: protective gloves for chemicals made of Baypren, nitrile rubber or PVC wear

Remarks : Breakthrough time not tested; dispose of immediately after contamination. Advice: The gloves should not be reused.

Eye protection : Safety glasses

Protective measures : No special safety precautions are required during handling of pharmaceuticals in their intended finished form (tablets or liquid formulations) by chemists, the hospital's medical staff or patients.  
For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet.  
The personal protective equipment is applicable for the handling of bulk material without packaging and for incidents if an exposure by the active ingredient or hazardous components can be expected.  
Wear suitable protective equipment.

### Section 9: Physical and chemical properties

Appearance : liquid

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Explosive properties : No data available

Oxidizing properties : No data available

Impact sensitivity : No data available

Minimum ignition energy : No data available

### Section 10: Stability and reactivity

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Reactivity : No data available  
Chemical stability : No data available  
Possibility of hazardous reactions : No data available  
Conditions to avoid : No data available  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : Carbon monoxide (CO)  
Carbon dioxide (CO<sub>2</sub>)

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### Section 11: Toxicological information

#### Acute toxicity

##### Product:

Acute oral toxicity : Acute toxicity estimate (ATE): > 5.000 mg/kg  
Method: Calculation method

##### Components:

##### **Boric acid:**

Acute oral toxicity : LD50 (Rat): 2.660 mg/kg  
Assessment: The component/mixture is minimally toxic after single ingestion.

Acute inhalation toxicity : LC50 (Rat): > 2,12 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist/aerosol  
Method: OECD 403  
Assessment: No adverse effect has been observed in acute toxicity tests.

##### **Magnesium chloride:**

Acute oral toxicity : LD50 (Rat): 2.800 mg/kg

#### Skin corrosion/irritation

##### Components:

##### **Boric acid:**

Species : Rabbit  
Exposure time : 24 h  
Result : No skin irritation

##### **Magnesium chloride:**

Species : Rabbit  
Result : No skin irritation

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## Serious eye damage/eye irritation

### Components:

#### **Boric acid:**

Species : Rabbit  
Result : No eye irritation  
Exposure time : 24 h  
Method : OECD 405

#### **Magnesium chloride:**

Species : Rabbit  
Result : No eye irritation

## Respiratory or skin sensitisation

### Components:

#### **Boric acid:**

Species : Guinea pig  
Method : OECD 406  
Result : Does not cause skin sensitisation.

## Chronic toxicity

## Germ cell mutagenicity

### Components:

#### **Boric acid:**

Genotoxicity in vitro : Test Type: DNA damage and/or repair  
Test system: Hamster V79-cells  
Metabolic activation: with and without metabolic activation  
Result: negative

Test Type: Ames test  
Test system: Salmonella typhimurium  
Metabolic activation: with and without metabolic activation  
Method: OECD 471  
Result: negative

Test Type: In vitro gene mutation study in mammalian cells  
Test system: mammalian cells  
Metabolic activation: with and without metabolic activation  
Method: OECD 476  
Result: negative

Genotoxicity in vivo : Test Type: Chromosome aberration test in vivo  
Species: Mouse (male and female)  
Application Route: Oral  
Exposure time: Multiple dose  
Method: OECD 474  
Result: negative

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## Magnesium chloride:

Genotoxicity in vitro : Test Type: Bacterial mutagenicity  
Result: negative

## Carcinogenicity

### Components:

#### Boric acid:

Species : Mouse  
Application Route : Oral  
Exposure time : 721 days  
Method : OECD 451  
Result : Animal testing did not show any carcinogenic effects.

## Reproductive toxicity

### Components:

#### Boric acid:

Effects on fertility : Test Type: Two-generation study  
Species: Rat  
Application Route: Oral  
Frequency of Treatment: 1 daily  
General Toxicity - Parent: NOAEL: 100 mg/kg  
General Toxicity F1: NOAEL: 100 mg/kg  
General Toxicity F2: NOAEL: 100 mg/kg  
Result: No toxicity to reproduction

Reproductive toxicity - Assessment : Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies., Positive evidence of adverse effects on development from human epidemiological studies.

## Repeated dose toxicity

### Components:

#### Boric acid:

Species : Rat, male and female  
NOAEL : 17,5 mg/kg  
LOAEL : 334 mg/kg  
Application Route : Oral

## Further information

### Components:

#### Boric acid:

Remarks : If swallowed  
Nausea  
Vomiting

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Diarrhoea

Remarks : After absorption of large quantities  
Ataxia  
drowsiness  
Ataxia (uncontrolled movements)

### **Magnesium chloride:**

Remarks : After absorption of large quantities  
Nausea  
Vomiting  
Diarrhoea

Remarks : Systemic toxicity  
hypotension  
Cardiovascular disorders  
Tiredness

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## Section 12: Ecological information

### **Ecotoxicity**

#### **Components:**

#### **Boric acid:**

Toxicity to fish : LC50 (Gambusia affinis (Mosquito fish)): 5.600 mg/l  
Exposure time: 96 h

LC0 (Lepomis macrochirus (Bluegill sunfish)): > 1,021 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 133 mg/l  
Exposure time: 48 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : (Daphnia magna (Water flea)): 53,2 mg/l  
Exposure time: 21 d  
Test Type: Reproductive toxicity

#### **Ecotoxicology Assessment**

Acute aquatic toxicity : slightly hazardous to water

#### **Magnesium chloride:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 2.120 mg/l  
Exposure time: 96 h  
Test Type: static test  
Method: US-EPA

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 548,4 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : IC50 (Desmodesmus subspicatus (green algae)): 2.200 mg/l  
Exposure time: 72 h

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Toxicity to microorganisms : EC50 (Photobacterium phosphoreum): 36.300 mg/l  
Exposure time: 0,5 h

## Persistence and degradability

### Components:

#### **Boric acid:**

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

## Bioaccumulative potential

### Components:

#### **Boric acid:**

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-octanol/water : log Pow: 0,757

#### **Magnesium chloride:**

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

## Mobility in soil

No data available

## Other adverse effects

### Product:

Additional ecological information : Do not allow to enter surface waters or groundwater.

### Components:

#### **Magnesium chloride:**

Results of PBT and vPvB assessment : This substance is not considered to be persistent, bioaccumulating and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulating (vPvB).

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## Section 13: Disposal considerations

### **Disposal methods**

Waste from residues : Dispose of as hazardous waste in compliance with local and national regulations.

Contaminated packaging : Contaminated, empty containers are to be treated in the same way as the contents.

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## Section 14: Transport information

### IATA-DGR

Not regulated as a dangerous good

### IMDG-Code

Not regulated as a dangerous good

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

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## Section 15: Regulatory information

### Safety, health and environmental regulations/legislation specific for the substance or mixture

#### HSNO Approval Number

HSR002399

#### HSW Controls

Approved handler certificate not required.

HSNO tracking not required.

Refer to EPA user guide to the HSNO control regulations for further information.

Montreal Protocol (Ozone Depleting Substances) : Not applicable

Rotterdam Convention (Prior Informed Consent) : Not applicable

Stockholm Convention (Persistent Organic Pollutants) : Not applicable

#### The components of this product are reported in the following inventories:

NZIoC : On the inventory, or in compliance with the inventory

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## Section 16: Other information

Date format : dd.mm.yyyy

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

ACGIH / STEL : Short-term exposure limit

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA

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- International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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