



## SAFETY DATA SHEET

(REACH regulation no. 1907/2006 and 453/2010)

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**SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

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**1.1 Product Identifier**

Product name: Prevomax 10 mg/ml solution for injection

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

Use: Anti-emetic veterinary medicinal product

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

Registered company name: Le Vet Beheer B.V.

Address: Wilgenweg 7, 3421 TV Oudewater, The Netherlands

Telephone: +31-(0)348-565858.

Fax: +31-(0)348-565454

info@levetpharma.com

www.levetpharma.com

**1.4 Emergency telephone number:****+31-(0)6-10203326**

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**SECTION 2: HAZARDS IDENTIFICATION**

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**Appearance:****Classification of the Substance or Mixture****GHS – Classification**

Serious Eye Damage/Eye Irritation: Category 2A

Skin Sensitization: Category 1

Specific target organ systemic toxicity (repeated exposure): Category 2

Acute aquatic toxicity: Category 3

Chronic aquatic toxicity: Category 3

**EU Classification:**

EU Indication of danger: Irritant

**Label Elements****Signal Word:** Warning**Hazard Statements:**  
H319 – Causes serious eye irritation  
H317 – May cause an allergic skin reaction  
H373 – May cause damage to organs through prolonged or repeated exposure (cardiovascular, kidneys, liver)  
H412 – Harmful to aquatic life with long lasting effects**Precautionary Statements:** P264 – Wash hands thoroughly after handling  
P261 – Avoid breathing dust/fume/gas/mist/vapors/spray  
P272 – Contaminated work clothing should not be allowed out of the workplace  
P280 – Wear protective gloves/protective clothing/eye protection/face protection  
P260 – Do not breathe dust/fume/gas/mist/vapors/spray  
P273 – Avoid release to the environment  
P302 + P352 – IF ON SKIN: Wash with plenty of soap and water  
P333 + P313 – If skin irritation or rash occurs: Get medical advice/attention  
P362 – Take off contaminated clothing and wash before reuse  
P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P314 – Get medical attention/advice if you feel unwell

P501 – Dispose of contents/container in accordance with all local and national regulations

**Other Hazards**

<b>Short Term:</b>	May cause eye irritation. Not expected to cause skin irritation (based on components). May cause respiratory tract irritation.
<b>Long Term:</b>	Based on findings in animal studies, this compound may cause rare but potentially serious cardiac effects in human clinical use.
<b>Known Clinical Effects:</b>	-

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**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**


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**3.1 Substances**

No substances fulfill the criteria set forth in annex II section A of the REACH regulation (EC) no. 1907/2006

**3.2 Mixtures****Composition:**

Ingredient	CAS-no.	Quantity
Maropitant	147116-67-4	10.0 mg/ml
Betadex sulfobutyl ether sodium	182410-00-0	11.1 mg/ml
Benzyl alcohol (E1519)	100-51-6	Classified
Citric acid, anhydrous	77-92-9	Classified
Sodium hydroxide	1310-73-2	Classified
Water for injections	7789-20-0	ad 1 ml

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**SECTION 4: FIRST AID MEASURES**


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**Description of First Aid Measures**

<b>Eye Contact:</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Skin Contact:</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion:</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Most important Symptoms and Effects, Both Acute and Delayed****Symptoms and Effects**

<b>of Exposure:</b>	For information on potential signs and symptoms of exposure, See section 2 – Hazards Identification and/or Section 11 – Toxicological Information.
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**Name: PREVOMAX 10 MG/ML SOLUTION FOR INJECTION****Medical Conditions****Aggravated by Exposure:** None known**Indication of the Immediate Medical Attention and Special Treatment Needed****Notes to Physician:** None

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**SECTION 5: FIREFIGHTING MEASURES**

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**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, dry chemical or water spray**Special hazards arising from the substance or mixture****Hazardous Combustion****Products:** Emits toxic fumes of carbon monoxide, carbon dioxide and nitrogen oxides**Fire/Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.**Advice for firefighters**

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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**SECTION 6: ACCIDENTAL RELEASE MEASURES**

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**Personal Precautions, Protective Equipment and Emergency Procedures**

Personnel involved in clean-up should wear appropriate personal protective equipment (See section 8). Minimize exposure.

**Environmental Precautions**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Methods and Material for Containment and Cleaning up****Measures for Cleaning /****Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.**Additional Consideration****for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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**SECTION 7: HANDLING AND STORAGE**

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**Precautions for Safe Handling**

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**Conditions for Safe Storage, including any Incompatibilities****Storage Conditions:** Store as directed by product packaging

## Specific end use(s)

No data available.

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**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

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**Control Parameters****Occupational****Exposure Limits:** No data available.**Exposure controls****Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate, unless the process generates dust, mist or fumes.**Personal Protective****Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).**Hands:** Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.**Eyes:** Wear safety glasses or goggles if eye contact is possible.**Skin:** Impervious, disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

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**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

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**Physical State:** Liquid  
**Odor:** Odourless  
**Colour:** Colourless  
**Molecular formula:** Mixture  
**Molecular weight:** Mixture

**Solvent Solubility:** Not applicable  
**Water Solubility:** Not applicable  
**pH:** 4.1 – 4.7  
**Melting/Freezing Point:** No data available  
**Boiling Point (°C):** No data available  
**Partition Coefficient:** No data available  
**Evaporation Rate:** No data available  
**Vapor Pressure:** No data available  
**Vapor Density:** No data available  
**Viscosity:** No data available

**Flammability:**

**Autoignition Temperature (Solid):** No data available  
**Flammability (Solids):** No data available  
**Flash Point (Liquid):** No data available  
**Upper Explosive Limits (Liquid):** No data available  
**Lower Explosive Limits (Liquid):** No data available

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**SECTION 10: STABILITY AND REACTIVITY**

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**Reactivity**

No data available

**Chemical stability**

Stable under normal conditions of use.

**Possibility of hazardous reactions**

No data available

**Conditions to avoid**

Fine particles (such as dust and mists) may fuel fires/explosions.

**Incompatible materials**

As a precautionary measure, keep away from strong oxidizers.

**Hazardous decomposition products**

No data available

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**SECTION 11: TOXICOLOGICAL INFORMATION**

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**Information on Toxicological Effects****General Information:**

Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation. Routes of exposure: eye contact , skin contact.

**Carcinogen Status:**

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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**SECTION 12: ECOLOGICAL INFORMATION**

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**Environmental Overview:**

Environmental properties have not been investigated. Releases to the environment should be avoided.

**Toxicity:**

No data available.

**Persistence and Degradability:**

No data available

**Bio-accumulative Potential:**

No data available

**Mobility in Soil:**

No data available

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**SECTION 13: DISPOSAL CONSIDERATIONS**

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**Waste treatment methods:**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

**Name: PREVOMAX 10 MG/ML SOLUTION FOR INJECTION**

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**SECTION 14: TRANSPORT INFORMATION**

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The following refers to all modes of transportation, unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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**SECTION 15: REGULATORY INFORMATION**

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

<b>Particular provisions:</b>	Veterinary medicinal product, under the scope of 2001/82/EC as amended
<b>Chemical safety assessment:</b>	No data available

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**SECTION 16: OTHER INFORMATION**

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Data Sources: The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.