



SAFETY DATA SHEET

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

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

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.

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

SECTION 2: HAZARDS IDENTIFICATION

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**

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

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**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

SECTION 4: FIRST AID MEASURES**Description of First Aid Measures**

Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion:	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.
Inhalation:	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 of Exposure:	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

SECTION 5: FIREFIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, 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.

SECTION 6: ACCIDENTAL RELEASE MEASURES

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.

SECTION 7: HANDLING AND STORAGE

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.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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

SECTION 10: STABILITY AND REACTIVITY

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

SECTION 11: TOXICOLOGICAL INFORMATION

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.

SECTION 12: ECOLOGICAL INFORMATION

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

SECTION 13: DISPOSAL CONSIDERATIONS

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.

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SECTION 14: TRANSPORT INFORMATION

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

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

SECTION 15: REGULATORY INFORMATION

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

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

SECTION 16: OTHER INFORMATION

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