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Complying with 1907/2006/EEC Regulation of 18 December 2006 ("REACH Regulation") and REGULATION (EC) No 1272/2008 (CLP)

Section 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Identification of the substance/preparation

Product name: Triamcinolone Acetonide Nasal Spray

Trade names: N/A

Synonyms: N/A

Common/important uses of the substance/preparation: Medicine. Triamcinolone Acetonide Nasal Spray is corticosteroid indicated for the treatment of nasal symptoms of seasonal and perennial allergic rhinitis in adults and children 2 years of age and older.

Company/undertaking identification

Supplier/Manufacturer:
Perrigo Israel Pharmaceuticals Ltd.,
P.O.Box 16
Yerucham 80500
Israel
Tel: (972)-523-667-422

E-mail address of person responsible for this SDS: N/A

Emergency telephone number (including hours of operation): (972)-523-667-422, Zeev Goldstein

Section 2. HAZARDS IDENTIFICATION

According to EC Directive 2001/58/EC

Most Important Hazards

Not classified

Classification

Not required

GHS-Classification

Hazards Statements

Not classified

Signal Word

Not required

See section 11 for more detailed information on health effects and symptoms.

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Section 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance/preparation:

Ingredient name	CAS number	%	EC number	EU Classification	GHS Classification
Triamcinolone Acetonide USP Micronized	76-25-5	0.055	200-948-7	Xn; R22 Repr. Cat. 2; R61	Acute Tox. 4 H302 Repr. 1B H360D
Dextrose USP Anhydrous Granular	50-99-7	-	200-075-1	-	-
Avicel® CL-611 (Microcrystalline Cellulose and Carboxymethylcellulose Sodium, NF)	9004-34-6 9004-32-4	-	232-674-9 -	-	-
Titriplex® III (Edetate Disodium USP Dihydrate)	6381-92-6	-	-	-	-
Stepanquat 50 (Benzalkonium Chloride Solution, NF)	8001-54-5	<0.05	-	Xn; R21/22 C; R34 N; R50	Acute Tox. 4 H302, H312 Skin Corr. 1B H314 Aquatic Acute 1 H400
Tween™ 80V Pharma (Polysorbate 80, NF)	9005-65-6	-	500-019-9	-	-
Hydrochloric Acid NF Fuming 37% Extra Pure	7647-01-0	Q.S. to adjust pH to 5	231-595-7	C; R34 Xi; R37	Skin Corr. 1B H314 STOT SE 3 H335
Sodium Hydroxide NF Pellets Extra Pure	1310-73-2	Q.S. to adjust pH to 5	215-185-5	C; R35	Skin Corr. 1A H314
Purified Water, USP	7732-18-5	Q.S. to 100%	231-791-2	-	-

See section 16 for the full text of the R-phrases declared above

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in section 8.

Section 4. FIRST AID MEASURES

- Eyes contact:** In case of contact with eyes rinse thoroughly with plenty of water and seek medical advice.
- Skin contact:** In case of contact with skin wash off immediately with soap and plenty of water, and seek medical advice.
- Inhalation:** Remove from exposure, lie down. If breathing is difficult, give oxygen. If not breathing, give artificial respiration.
- Ingestion:** Wash mouth thoroughly with plenty of water and give water or milk to drink. Get medical attention immediately.

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Expected delayed effects: Not available

See section 11 for more detailed information on health effects and symptoms.

Section 5: FIRE-FIGHTING MEASURES

Extinguishing media

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

Not suitable: N/A.

Special exposure hazards arising from the substance/preparation including combustion products and gases: Thermal decomposition can lead to release of irritating and toxic fumes.

Special protective equipment for fire fighters: Fire fighters should wear full protective clothing and self-contained breathing apparatus in positive pressure mode.

Further information: Move containers from fire area if possible to do so without risk. Cool containers with water spray.

Section 6: ACCIDENTAL RELEASE MEASURES

Personal precautions: Wear protective clothing. Avoid contact with skin and eyes. Avoid breathing vapors, mist or gas. Ventilate area of spill.

Environmental precautions: Prevent entry into waterways, sewers, basements or confined areas.

Methods for cleaning up

Absorb the chemical onto sand, vermiculite, or any other non-combustible absorbent, and scoop into containers for later disposal.

Section 7: HANDLING AND STORAGE

Handling: Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Do not breathe vapors/dust.

Storage: Keep tightly closed, in dry, cool and well-ventilated place. Store at controlled room temperature, 20°C to 25°C (68°F to 77°F)

Section 8: EXPOSURE CONTROL / PERSONAL PROTECTION

Exposure limit values:

Ingredient name	Occupational exposure limits
Hydrochloric acid	OSHA-PEL 5 ppm (CEIL) TLV-ACGIH 2 ppm (CEIL) REL-NIOSH 5 ppm (CEIL) MAK-GER 3 mg/m ³ (TWA)
Sodium hydroxide	OSHA-PEL 2 mg/m ³ (TWA) TLV-ACGIH 2 mg/m ³ (CEIL) REL-NIOSH 2 mg/m ³ /15M (CEIL)

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Exposure controls

Occupational exposure controls:

Use process enclosures, local exhaust ventilation, or others engineering controls to keep airborne levels below recommend exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Respiratory protection: Suitable respirator. Be sure to use an approved/certified or equivalent. Wear appropriate respirator when ventilation is inadequate.

Hand protection: Chemically compatible gloves.

Eye protection: Wear protective safety glasses.

Skin protection: Wear appropriate long-sleeved clothing to minimize skin contact.

Hygiene measures: Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment may be necessary to reduce emissions to acceptable levels.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

General information:

Physical state: Milky suspension
 Colour: White to off -white
 Odour: Odorless

Safety data

pH: 4.5-5.5
 Boiling point/boiling range: N/A
 Flash point: N/A
 Flammability: N/A
 Explosive properties: N/A
 Oxidizing properties: N/A
 Vapor pressure: N/A
 Water solubility: N/A
 Solubility: N/A
 Relative density: N/A
 Octanol/Water partition coefficient: N/A
 Viscosity: N/A
 Vapor density: N/A
 Evaporation rate (butyl acetate=1): N/A

Other information:

Melting point/melting range: N/A
 Auto-ignition temperature: N/A

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Section 10: STABILITY AND REACTIVITY

Stability: Stable under normal conditions.

Conditions to avoid: Keep away from heat, flames and sparks.

Materials to avoid: Strong oxidizing agents.

Hazardous Decomposition products: Irritating and toxic fumes.

Hazard polymerization: Hazardous polymerization does not occur.

Section 11: TOXICOLOGICAL INFORMATION

Potential acute health effects

Acute toxicity:

Product/ingredient name	Test	Species	Dose
Triamcinolone Acetonide	LD50, Oral	Rat	1451 mg/kg
	LD50, Oral	Mouse	2168 mg/kg
Benzalkonium Chloride	LD50, Oral	Rat	240 mg/kg
Hydrochloric acid	LC50, Inhalation	Rat	3124 ppm/1H
	LC50, Inhalation	Mouse	1108 ppm/1H

Inhalation: N/A

Ingestion: N/A

Skin contact: N/A

Eyes contact: N/A.

Irritation and Corrosivity: N/A.

Sensitization: N/A

CMR Effects

Carcinogenicity: In a two-year study in rats, triamcinolone acetonide caused no treatment-related carcinogenicity at oral doses up to 1.0mcg/kg. In a two-year study in mice, triamcinolone acetonide caused no treatment-related carcinogenicity at oral doses up to 3.0mcg/kg.

Mutagenicity: No evidence of mutagenicity was detected from in-vitro tests (a reverse mutation test in Salmonella bacteria and a forward mutation test in Chinese hamster ovary cells) conducted with triamcinolone acetonide.

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Reproductive toxicity: Triamcinolone acetonide did not impair fertility in rats given oral doses up to 15mcg/kg. However, triamcinolone acetonide caused increased fetal resorptions and stillbirths and decreased pup weight and survival at 5 mcg/kg. These effects were not produced at 1 mcg/kg. Triamcinolone acetonide was teratogenic in rats, rabbits and monkeys. In reproduction studies in rats and rabbits, triamcinolone acetonide administered by inhalation produced cleft palate and/or internal hydrocephaly and axial skeletal defects at exposures less than and 2 times, respectively, the maximum recommended daily intranasal dose in adults on a mcg/m² basis. In a monkey reproduction study, triamcinolone acetonide administered by inhalation produced cranial malformations at an exposure approximately 37 times the maximum recommended daily intranasal dose in adults. Dose-related teratogenic effects in rats and rabbits included cleft palate and/or internal hydrocephaly and axial skeletal defects, whereas the effects observed in the monkey were cranial malformations. Hypoadrenalism may occur in infants born of mothers receiving corticosteroids during pregnancy. Such infants should be carefully observe.

Other effects

May cause: Headache, Back Pain, Pharyngitis, Asthma, Cough Increased, Dyspepsia, Nausea, Vomiting, Taste Perversion, Conjunctivitis, Myalgia.

Target organs: N/A

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: N/A

Mobility: N/A

Persistence and Degradability: For Triamcinolone Acetonide: Hazard persistence may be possible.

Bioaccumulative potential: For Triamcinolone Acetonide: Bioaccumulation may be possible.

Result of PBT assessment (if CSR is required): N/A

Other adverse effects:

Substances which have an unfavorable influence on the oxygen balance and can be measured using parameters such as BOD, COD, etc.: N/A

Substances, which contribute to eutrophication: N/A

Remarks: N/A

Section 13: DISPOSAL CONSIDERATIONS

Methods of disposal: Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Hazardous waste: N/A

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Section 14: TRANSPORT INFORMATION

International transport regulations: Not regulated.

Section 15: REGULATORY INFORMATION

Classification and labeling according to EU Directives 67/548/EEC and 1999/45/EC (including amendments) and take into account the intended product use:

Labeling in accordance with EC directives: No symbol required.

Risk phrases: Not classified.

Safety phrases: Not classified.

Classification and labeling according to EU Regulation (EC) 1272/2008 (CLP Regulation) and Globally Harmonized System (GHS):

Signal Word: Not required.

Hazards Statements: Not classified.

Precautionary Statements: Not classified.

Section 16: OTHER INFORMATION

Full text of R-phrases referred to in sections 2 and 3:

- R22: Harmful if swallowed.
- R34: Causes burns.
- R35: Causes severe burns.
- R37: Irritating to respiratory system.
- R50: Very toxic to aquatic organisms.
- R61: May cause harm to the unborn child.
- R21/22: Harmful in contact with skin and if swallowed.

Full text of Hazards Statements referred to in sections 2 and 3:

- H302: Harmful if swallowed.
- H312: Harmful in contact with skin.
- H314: Causes severe skin burns and eye damage.
- H335: May cause respiratory irritation.
- H360: May damage fertility or the unborn child.
- H400: Very toxic to aquatic life.

Training advice: Before using/handling the product one must read carefully present MSDS.

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National Fire Protection Association Hazard Ratings- NFPA (R):

Health Hazard - 1

Flammability - 0

Stability - 0

National Paint & Coating Hazardous Materials Identification System – HMIS (R):

Health Hazard Rating - 1

Flammability Rating - 0

Instability Rating - 0

Personal Protection - A

Recommended restriction:

Key Legend Information:

ACGIH- American Conference of Governmental Industrial Hygienists

OSHA- Occupational Safety and Health Administration

NTP- National Toxicology program

IARC- International Agency for Research on Cancer

ND- Not Determined

N/A- Not available

R-phrases- Risk phrases

S-phrases- Safety phrases

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According to Regulation (EC) No. 1907/2006 (REACH), Annex II, Commission Directive 2001/59/EC and REGULATION (EC) No 1272/2008 (CLP).

The information herein is based on the present state of our knowledge. It is believed to be correct but is not necessarily all inclusive and shall be used only as a guide. Perrigo Israel Pharmaceuticals Ltd. and Haz-Mat Ltd. shall not be held liable for any damage resulting from handling or from contact with the above product. For further information, contact Perrigo Israel Pharmaceuticals Ltd. or contact Haz-Mat at hazmat@hazmat.co.il.