SAFETY DATA SHEET

Posatex

Section 1: Identification of the Substance and Supplier

Product name	**Posatex**
Recommended use	For the treatment of acute otitis externa and acute exacerbations of recurrent otitis externa.
Company details	**Schering-Plough Animal Health Ltd** **33 Whakatiki Street, Upper Hutt 5018, New Zealand** **Phone: 0800 800 543 Fax: 0800 808 100** **Website: www.msd-animal-health.co.nz** **Hours: 8 am – 5 pm, Mon – Fri**
Emergency telephone	**0800 764 766 (0800 POISON) 24 hours human health** **0800 243 622 (0800 CHEMCALL) 24 hours**
Date of preparation	April 2019

Section 2: Hazards Identification

Hazard classifications	6.8B: Reproductive/developmental toxicant 6.9B: Target organ systemic toxicant 9.1C: Aquatic ecotoxicant
GHS Pictogram:	
Signal word	Warning
Hazard statement	H361: Suspected of damaging fertility or the unborn child from repeated oral exposure. H373: May cause damage to nervous system, through prolonged or repeated oral or inhalation exposure. H412: Harmful to aquatic life with long lasting effects.
Prevention statement	P102: Keep out of the reach of children. P202: Do not handle until all safety precautions have been read and understood. P260: Do not breathe mist. P273: Avoid release to the environment. P281: Use personal protective equipment as required.
Response statement	P308 + P313: IF exposed or concerned: Get medical advice/ attention.
Storage	P405: Store locked up.
Disposal	P501: Dispose of product, packaging and waste at an approved landfill or other approved facility.

Section 3: Composition/Information on Ingredients

Chemical name	CAS number	Concentration
Mometasone furoate monohydrate	141646-00-6	0.1%
Posaconazole	171228-49-2	0.1%
Orbifloxacin	113617-63-3	1%

Section 4: First Aid Measures

Necessary first aid measures	**SKIN CONTACT** While wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a doctor. **EYE CONTACT** Immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a doctor. **INGESTION** Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or National Poisons Centre. If symptoms persist, consult a doctor. **INHALATION** Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a doctor.
Required instructions	For advice contact the National Poisons Centre 0800 POISON (0800 764 766) or a doctor.
Notes for medical personnel	**Inhalation**: Remove to fresh air & provide oxygen if breathing is difficult. **Skin contact:** Symptoms: Tingling and pruritus with blotchy erythema on the face or other exposed areas, exacerbated by sweating or touching. Symptoms usually resolve within 24 hours without specific treatment. Treatment: Topical vitamin E (tocopherol acetate) has been shown to reduce skin irritation if applied soon after exposure.
Workplace facilities	Emergency showers and eyewashes may be warranted depending on quantity and type of use.

Section 5: Fire Fighting Measures

Type of hazard	Not classified as flammable
Fire hazard properties	Not applicable
Regulatory requirements	Not applicable
Extinguishing media and methods	Carbon dioxide (CO_2), extinguishing powder or water spray
Hazchem code	Not applicable
Recommended protective clothing	Wear self-contained breathing apparatus (SCBA) plus protective gloves.

Section 6: Accidental Release Measures

Personal Precautions	Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Environmental Precautions	Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes. Avoid release to the environment.
Emergency procedures	Wear chemical resistant gloves and overalls, face mask or goggles. Prevent further spillage. Adsorb spilled product and place in sealable container for disposal. Wash down affected area with water plus detergent. Absorb and

collect washings and place in the same sealable container for disposal. Seek advice from the local authority regarding disposal. Avoid contamination of any water source or soil with product or empty container.

Section 7: Handling and Storage

Precautions for safe handling	Avoid contact with skin, eyes, and mucosa. Keep containers adequately sealed during material transfer, transport, or when not in use. See Section 8 (Exposure Controls) for additional guidance.
Regulatory requirements	Signage required where quantities greater than 1000 L are present. Emergency Plan required where quantities greater than 1000 L are present.
Handling practices	Avoid contact with skin. Keep containers adequately sealed during material transfer, transport, or when not in use.
Certified handlers	Not required.
Conditions for safe storage	Store in original container in a cool, dry, ventilated place away from direct heat or direct sunlight. Keep container sealed when not in use. Keep out of reach of children.
Store site requirements	Store in the original bottle and carton at room temperature. Once opened use within 7 days.
Packaging	Schedule 4

Section 8: Exposure Control/Personal Protection

Occupational exposure limits	No WES is set for this substance at this time.
Application in the workplace	Ensure adequate ventilation. Keep container sealed when not in use.
Exposure standards outside the workplace	No TEL or EEL is set for this substance at this time.
Personal protection	Wear chemical resistant gloves, facemask or goggles.
Engineering controls	The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

Section 9: Physical and Chemical Properties

Appearance	White to off white cream
Boiling Point	Not determined
Melting/Softening point	Not determined
Vapour Pressure	Not determined

Specific Gravity	0.8-0.9
Solubility (H_2O)	Not applicable
Percent Volatiles	Not determined
Evaporation Rate	Not determined

Section 10: Stability and Reactivity

Stability of the substance	Stable under normal conditions.
Conditions to avoid	Avoid high temperatures
Material to avoid	Avoid food products
Hazardous decomposition products	Carbon oxides (COx), Sulphur oxides (SOx), and Nitrogen oxides (NOx).

Section 11: Toxicological Information

Acute effects for individual ingredients only

ORAL	LD50 > 2000 mg/kg rat
TEL	No TEL is set for this substance at this time.

Chronic/long term effects for individual ingredients only

Reproductive / Developmental Toxicity
Mometasone furoate – Oral doses of 700 mcg MF/kg in rabbits caused increased incidences of resorptions, cleft palate and head malformations. Following oral doses of 2800 mcg MF/kg, rabbits failed to become pregnant.
In reproductive and developmental studies, posaconazole increases gestation duration, causes fetotoxicity (reduced number of live pups and decreased mean pup weights), and causes increases in skeletal variations and malformations.

Mutagenicity /Genotoxicity
Orbifloxacin was positive in a mouse lymphoma assay and in an in vitro assay in human peripheral blood lymphocytes.
At cytotoxic doses, mometasone furoate produced an increase in chromosome aberrations in vitro but not in the presence of microsomal activation (rat liver S9 fraction).
In the mouse micronucleus assay, bone marrow toxicity was observed in male and female mice indicating that posaconazole can reach and affect the bone marrow; however, increases in micronucleus frequency was not observed in test animals at any dose administered.

Section 12: Ecological Information

Effects for individual ingredients only

AQUATIC	Posaconazole: 96-hr EC50 (rainbow trout):0.95 mg/L 96-hr EC50 (algae): >0.119 mg/L (growth rate) 48-hr EC50 (daphnid): 0.276 mg/L
EEL	No EEL is set for this substance at this time.

Section 13: Disposal Considerations

Disposal information

Disposal
Dispose of unused product through AgRecovery Chemicals. Avoid contamination of any water source or the environment with product or empty container.

Container Disposal
Triple rinse empty container, puncture and recycle through AgRecovery. Do NOT burn.

Reference

Current version of NZS 8409 Management of Agrichemicals.

Section 14: Transport Information

Relevant information

Not considered a Dangerous Good for transport

Section 15: Regulatory Information

Regulatory status

HSNO Approval Code: HSR100642
For full listings of controls see www.epa.govt.nz

ACVM registration number: A010701
For conditions of registration see www.foodsafety.govt.nz

Section 16: Other Information

Additional information

Posatex is a registered trademark