



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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

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Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Tixocortol Pivalate Nasal Spray

Trade Name: PIVALONE®
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of colds, hayfever, and allergies

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Tixocortol Pivalate	55560-96-8	259-706-4	1.0%
Sodium chloride	7647-14-5	231-598-3	*
Sodium hydroxide	1310-73-2	215-185-5	*

Ingredient	CAS Number	EU EINECS List	%
Cetylpyridinium chloride	123-03-5	204-593-9	*
Sodium dihydrogen phosphate dihydrate	13472-35-0	Not listed	*
Water, purified	7732-18-5	231-791-2	*
Benzyl Alcohol	100-51-6	202-859-9	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Aqueous solution
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Additional Hazard Information:
Short Term: May cause allergic skin reaction (based on animal data) . May cause irritation (based on components) . Acute toxicity following ingestion is not expected. Accidental ingestion may cause effects similar to those seen in clinical use.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include skin rash and gastrointestinal disturbances.

EU Indication of danger: Irritant

EU Hazard Symbols:

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EU Risk Phrases:

R43 - May cause sensitization by skin contact.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

- Eye Contact:** Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.
- Skin Contact:** Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.
- 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.

5. FIRE FIGHTING MEASURES

- Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.
- Hazardous Combustion Products:** Toxic or corrosive gases including oxides of carbon and oxides of sulfur
- Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
- Fire / Explosion Hazards:** Not applicable

6. ACCIDENTAL RELEASE MEASURES

- Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
- 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.
- Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
- 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.

7. HANDLING AND STORAGE

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General Handling: Use appropriate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Tixocortol Pivalate

Pfizer OEL TWA-8 Hr: 2 mg/m³

Sodium hydroxide

OSHA - Final PELs - TWAs: 2 mg/m³
ACGIH Ceiling Threshold Limit: = 2 mg/m³ Ceiling
Australia PEAK = 2 mg/m³ Peak

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Wear two layers of disposable gloves.
Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Wear protective clothing when working with large quantities.
Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Aqueous solution	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Cetylpyridinium chloride

Rat Oral LD50 200 mg/kg
Rat Inhalation LC50/4h 90 mg/m³

Benzyl Alcohol

Rat Oral LD50 1.23 g/kg
Rat Intravenous LD50 53 mg/kg

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Sodium chloride

Rat Oral LD50 3000 mg/kg
Mouse Oral LD 50 4000 mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Tixocortol Pivalate

Skin Sensitization - GPMT Guinea Pig Positive

Cetylpyridinium chloride

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Benzyl Alcohol

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Moderate
Skin Irritation Guinea Pig Moderate

Sodium chloride

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Tixocortol Pivalate

6 Day(s) Rat Oral 1620 mg/kg/day LOAEL Endocrine system

Sodium chloride

10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

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

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

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14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: Xi
EU Indication of danger: Irritant

EU Risk Phrases:
R43 - May cause sensitization by skin contact.

EU Safety Phrases:
S24 - Avoid contact with skin.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING
May cause allergic skin reaction.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, and Subdivision B.



Tixocortol Pivalate
EU EINECS List 259-706-4

Sodium chloride
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 231-598-3

Cetylpyridinium chloride
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 204-593-9

Sodium dihydrogen phosphate dihydrate
Australia (AICS): Present

Sodium hydroxide
CERCLA/SARA Hazardous Substances and their Reportable Quantities: = 1000 lb final RQ
= 454 kg final RQ

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Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
EU EINECS List	Schedule 6
	215-185-5
Water, purified	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2
Benzyl Alcohol	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-859-9

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet