

# Safety Data Sheet

## **Product Identifier**

### **SECTION 1. IDENTIFICATION**

Product Identifier: Dexamethasone Omega (4 and 10 mg/mL) (Dexamethasone Sodium Phosphate Injection USP) Other Means of Identification: Code L0010026 (1mL), L0010066 (5mL) DIN: 02204266 (4mg/mL) Code: L0010067 (10mL), L0010094 (1mL) DIN: 02204274 (10mg/mL) Recommended Use: N/A Restrictions on Use: N/A Initial Supplier Identifier: Omega Laboratories, Ltd. 11177 Hamon St. Montreal, Canada H3M 3E4 Emergency Telephone Number: (514) 335-0310

#### **SECTION 2. HAZARD IDENTIFICATION**

Classification: N/A Label Elements: N/A Other Hazards: N/A

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	Concentration	Common name / Synonyms	Other identifiers
Benzyl Alcohol	100-51-6	1.0%	N/A	N/A
Sodium Sulfite	7757-83-7	-	N/A	N/A
Dexamethasone	2392-39-4	0.4/1%	N/A	N/A
Sodium Phosphate	N/A	N/A	N/A	N/A
Sodium Citrate	6132-04-3	-	N/A	N/A
Dihydrate	N/A	N/A	N/A	N/A
Water for Injection	7732-18-5	q.s.	N/A	N/A

Notes

## **SECTION 4. FIRST-AID MEASURES**

Inhalation: Remove to fresh air. Oxygen administration, if needed.
Skin Contact: Rinse with water and soap for at least 15 minutes.
Eye Contact: Rinse with water for at least 15 minutes.
Ingestion: Flush out mouth with water. If conscious, do not induce vomiting.



Most Important Symptoms and Effects, Acute and Delayed: Chronic: effects on the adrenal glands and immune system. Acute: Eyes and skin irritation. Immediate Medical Attention and Special Treatment: N/A

### **SECTION 5. FIRE-FIGHTING MEASURES**

Extinguishing Media Suitable Extinguishing Media: N/A Unsuitable Extinguishing Media: N/A Specific Hazards Arising from the Product: N/A Special Protective Equipment and Precautions for Fire-Fighters: N/A

### SECTION 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment, and Emergency Procedures:** Wear disposable latex, nitrile or rubber gloves and a lab coat. **Methods for Containment and Cleaning Up:** Contain spill and soak up liquid with absorbent material.

#### **SECTION 7. HANDLING AND STORAGE**

**Precautions for Safe Handling and Conditions for Safe Storage:** Store between 15 and 30°C protected from light, heat and freezing.

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### **Control Parameters**

Chemical Name	ACGIH® TLV®		OSHA PEL	
N/A	TWA	STEL	TWA	STEL
N/A				
N/A				

#### Notes

Appropriate Engineering Controls: N/A Individual Protection Measures Eye/Face Protection: N/A Skin Protection: Disposable latex, nitrile, or rubber gloves and a lab coat. Respiratory Protection: N/A



#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance: Clear, colorless to pale yellow liquid. Odour: Odorless liquid. **Odour Threshold: N/A pH:** 7.0-8.5 Melting Point and Freezing Point: N/A Initial Boiling Point and Boiling Range: >100°C (>212°F). Flash Point: N/A Evaporation Rate: Approximately water rate. Flammability (solid, gas): Not consider to be a fire hazard. Upper and Lower Flammability or Explosive Limit: N/A Vapour Pressure: N/A Vapour Density (air = 1): N/A Relative Density (water = 1): >1.000 Solubility in Water: Totally soluble. Solubility in Other Liquids: N/A Partition Coefficient, n-Octanol / Water (Log Kow): N/A Auto-ignition Temperature: N/A **Decomposition Temperature: N/A** Viscosity: N/A

#### SECTION 10. STABILITY AND REACTIVITY

Reactivity

**Chemical Stability:** This product is stable when store between 15 and 30°C, protected from light, heat and freezing.

Possibility of Hazardous Reactions: Will not occur. Conditions to Avoid: Heat, freezing, light exposure and contact with incompatible chemicals. Incompatible Materials: Oxidizing agents, strong acids and caustics. Hazardous Decomposition Products: N/A

#### SECTION 11. TOXICOLOGICAL INFORMATION

#### Likely Routes of Exposure

<u>x</u> Inhalation <u>x</u> Skin contact <u>x</u> Eye contact <u>x</u> Ingestion and Injection

#### **Acute Toxicity**

LD50 (IV) : Dexamethasone: mouse 1800 mg/kg, mouse 112mg/kg, Benzyl Alcohol: rat 1230 mg/kg, Sodium Sulfite: mouse 820 mg/kg

LD50 (IV) : rabbit 449mg/kg, mouse 170 mg/kg

**Notes:** Benzyl Alcohol→ considered as tumorigenic and mutagen agent and may cause reproductive effects.

Skin Corrosion / Irritation: Mild irritation. Itching, burning sensation on skin. May cause allergic reaction



Serious Eye Damage / Irritation: Mild irritation. Stinging, watering and redness of the eyes. May cause allergic reaction.

STOT (Specific Target Organ Toxicity) - Single Exposure

**Ingestion Hazard:** Slightly toxic based on animal data. Possible allergic reaction due to the sulfite present in the solution.

## STOT (Specific Target Organ Toxicity) - Repeated Exposure Respiratory and/or Skin Sensitization: N/A

**Notes:** Injection: Local redness and pain. Cushing's syndrome, water retention, electrolyte imbalance, hypertension, hyperglycemia, myopathy and suppression of adrenal gland secretions may occur.

#### Carcinogenicity

Chemical Name	IARC	ACGIH®	OSHA
N/A			
N/A			
N/A			

#### Notes

Reproductive Toxicity Development of Offspring: N/A Sexual Function and Fertility: N/A Effects on or via Lactation: N/A Germ Cell Mutagenicity: N/A Interactive Effects: N/A

#### **SECTION 12. ECOLOGICAL INFORMATION**

Ecotoxicity Persistence and Degradability: N/A Bioaccumulative Potential: N/A Mobility in Soil: N/A Other Adverse Effects: N/A

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

Disposal Methods: Dispose of waste in respect with all regulatory agencies and laws.



## **SECTION 14. TRANSPORT INFORMATION**

Regulation	UN No.	Proper Shipping Name	Technical Name (for N.O.S. entry)	Transport Hazard Class(es)	Packing Group

Special Precautions: N/A Environmental Hazards: N/A Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: N/A

#### **SECTION 15. REGULATORY INFORMATION**

Safety, Health and Environmental Regulations: N/A

### **SECTION 16. OTHER INFORMATION**

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