



SOTRADECOL® (SODIUM TETRADECYL SULFATE INJECTION)

SAFETY DATA SHEET

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

Product Identifier

Product name: Sotradecol® (Sodium Tetradecyl Sulfate Injection)

Intended Use of the Product

Use of the substance/mixture: Pharmaceutical. For intravenous use as a sclerosing agent. Refer to product insert for usage instructions and product information.

Name, Address, and Telephone of the Responsible Party

Supplier:

Mylan Institutional LLC
1718 Northrock Court
Rockford, IL 61103 USA
800.848.0462

www.mylan.com

Manufacturer:

Mylan Teoranta
Galway, Ireland

Emergency Telephone Number

Emergency number : +1 877-446-3679

2. HAZARDS IDENTIFICATION

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

Classification of the Substance or Mixture

Classification (GHS-US)

Skin Irrit. 2 H315
Eye Dam. 1 H318

Label Elements

GHS-US labeling

Hazard pictograms (GHS-US)



Signal word (GHS-US)

: Danger

Hazard statements (GHS-US)

: H315 - Causes skin irritation
H318 - Causes serious eye damage

Precautionary statements (GHS-US)

: P264 - Wash hands and forearms thoroughly after handling.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 - Immediately call a POISON CENTER or doctor/physician.
P321 - Specific treatment (see Section 4).
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P362 - Take off contaminated clothing and wash before reuse.

Other Hazards

Other hazards not contributing to the classification: May produce an allergic reaction.

Unknown acute toxicity (GHS-US) Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Name	Product identifier	% (w/w)	Classification (GHS-US)
4-Undecanol, 7-ethyl-2-methyl-, hydrogen sulfate, sodium salt	(CAS No) 139-88-8	1 - 3	Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311 Skin Corr. 1B, H314 Eye Dam. 1, H318
Benzyl alcohol	(CAS No) 100-51-6	2	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 3 (Inhalation:vapour), H331 Aquatic Acute 2, H401

Full text of H-phrases: see section 16

4. FIRST AID MEASURES

Description of First Aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

Skin Contact: Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

Eye Contact: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

Most Important Symptoms and Effects Both Acute and Delayed

General: Please refer to the package insert for more detailed information. Causes skin irritation. Causes serious eye damage.

Inhalation: Inhalation is not considered a potential route of exposure.

Skin Contact: Causes skin irritation. Exposure may produce an allergic reaction.

Eye Contact: Causes serious eye damage.

Ingestion: Ingestion is likely to be harmful or have adverse effects.

Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. In the event of accidental injection, go immediately to the nearest emergency room.

5. FIREFIGHTING MEASURES

Extinguishing Media

Suitable extinguishing media: Dry chemical powder, alcohol foam, carbon dioxide, water spray, fog.

Unsuitable extinguishing media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

Special Hazards Arising From the Substance or Mixture

Fire hazard: Not considered flammable but may burn at high temperatures.

Explosion hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

Advice for Firefighters

Precautionary measures fire: Exercise caution when fighting any chemical fire.

Firefighting instructions: Use water spray or fog for cooling exposed containers.

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂).

Other information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

General measures: Avoid all eye and skin contact and do not breathe vapor and mist.

For Non-Emergency Personnel

Protective equipment: Use appropriate personal protection equipment (PPE).

Emergency procedures: Evacuate unnecessary personnel.

For Emergency Personnel

Protective equipment: Equip cleanup crew with proper protection.

Environmental Precautions

Prevent entry to sewers and public waters.

Methods and Material for Containment and Cleaning Up

Methods for cleaning up: For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Hygiene measures: This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

Conditions for Safe Storage, Including Any Incompatibilities

Storage conditions: Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight.

Storage temperature: 20-25°C (68-77°F)

Special rules on packaging: Examine the vial for particulate matter and discoloration prior to administration. If the solution is discolored or contains solid particles (precipitate), do not use.

Specific End Use(s)

Pharmaceutical. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

No Occupational Exposure Limits (OELs) have been established for this product or its chemical components.

Exposure Controls

Appropriate engineering controls: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal protective equipment: Protective clothing. Gloves. In case of splash hazard: safety glasses.

Hand protection: Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

Eye protection: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

Skin and body protection: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

Respiratory protection: When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties

Physical state	: Liquid
Appearance	: Clear
Odor	: Not available
Odor threshold	: Not available
pH	: 7-8
Relative evaporation rate (butyl acetate=1)	: Not available
Melting/Freezing point	: 0°C (32°F)
Boiling point	: 100°C (212°F)
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Upper/Lower flammable limits	: Not available
Vapor pressure	: Not available
Relative vapor density at 20 °C	: Not available
Relative density	: Not available

Specific gravity	: Not available
Solubility	: Not available
Log Pow/Kow	: Not available
Viscosity (kinematic, dynamic)	: Not available
Explosion data - sensitivity to mechanical impact	: Not available
Explosion data - sensitivity to static discharge	: Not available

10. STABILITY AND REACTIVITY

Reactivity Hazardous reactions will not occur under normal conditions.

Chemical Stability Stable under normal conditions.

Possibility of Hazardous Reactions Hazardous polymerization will not occur.

Conditions to Avoid Direct sunlight. Extremely high or low temperatures.

Incompatible Materials Strong oxidizers. Strong bases. Strong acids.

Hazardous Decomposition Products Carbon oxides (CO, CO₂).

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects - Product

Acute toxicity: Not classified

LD50 and LC50 Data: Not available

Skin Corrosion/Irritation: Causes skin irritation. (pH: 7-8)

Serious Eye Damage/Irritation: Causes serious eye damage. (pH: 7-8)

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Teratogenicity: Not available

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Benzyl alcohol (100-51-6)	
LD50 oral rat	1230 mg/kg
LD50 dermal rabbit	2 g/kg
LD50 Intravenous Rat	53 mg/kg
LC50 inhalation rat (mg/l)	8.8 mg/l/4h

12. ECOLOGICAL INFORMATION

Toxicity

Benzyl alcohol (100-51-6)	
LC50 fish 1	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	23 mg/l (Exposure time: 48 h - Species: water flea)
LC50 fish 2	10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

Persistence and Degradability Not available

Bioaccumulative Potential

Benzyl alcohol (100-51-6)	
Log Pow	1.1

13. DISPOSAL CONSIDERATIONS

Waste disposal recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not dispose of waste into sewer.

Additional information: Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

14. TRANSPORT INFORMATION

In Accordance With ICAO/IATA/DOT/TDG

UN Number Not regulated for transport

UN Proper Shipping Name Not regulated for transport

15. REGULATORY INFORMATION**US Federal Regulations****Sotradecol® (Sodium Tetradecyl Sulfate Injection)**

SARA Section 311/312 Hazard Classes Immediate (acute) health hazard

4-Undecanol, 7-ethyl-2-methyl-, hydrogen sulfate, sodium salt (139-88-8)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Benzyl alcohol (100-51-6)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

US State Regulations**Benzyl alcohol (100-51-6)**

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Water Quality - Ground Water Quality Criteria
U.S. - New Jersey - Water Quality - Practical Quantitation Levels (PQLs)
U.S. - Pennsylvania - RTK (Right to Know) List
U.S. - Texas - Effects Screening Levels - Short Term

Canadian Regulations**Sotradecol® (Sodium Tetradecyl Sulfate Injection)**

WHMIS Classification Class E - Corrosive Material
Class D Division 2 Subdivision B - Toxic material causing other toxic effects

**4-Undecanol, 7-ethyl-2-methyl-, hydrogen sulfate, sodium salt (139-88-8)**

Listed on the Canadian DSL (Domestic Substances List) inventory.

Listed on the Canadian Ingredient Disclosure List

Benzyl alcohol (100-51-6)

Listed on the Canadian DSL (Domestic Substances List) inventory.

Listed on the Canadian Ingredient Disclosure List

WHMIS Classification Class B Division 3 - Combustible Liquid
Class D Division 2 Subdivision B - Toxic material causing other toxic effects

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by CPR.

16. OTHER INFORMATION**Revision date** : 02/11/2014**Data sources** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.**Other information** : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.**GHS Full Text Phrases:**

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation:vapour)	Acute toxicity (inhalation:vapour) Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Flam. Liq. 4	Flammable liquids Category 4
Skin Corr. 1B	Skin corrosion/irritation Category 1B
Skin Irrit. 2	Skin corrosion/irritation Category 2
H227	Combustible liquid
H302	Harmful if swallowed
H311	Toxic in contact with skin
H312	Harmful in contact with skin

H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H331	Toxic if inhaled
H401	Toxic to aquatic life

Party Responsible For The Preparation Of This Document:

Mylan Global Environmental, Health, and Safety Department

Phone Number: 304-599-2595

This MSDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

North America Mylan Pharmaceuticals