

SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Contact information

General



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Product identifier	Sodium Tetradecyl Sulfate Injection 3% (30 mg/mL) (in vials)
Synonyms	7-Ethyl-2-Methyl-4-undecyl sulfate sodium salt; 4-Undecanol, 7-ethyl-2-methyl, hydrogen sulfate, sodium salt
Trade names	None assigned
Chemical family	Mixture - anionic surfactant
Relevant identified uses of the substance or mixture and uses advised against	Bulk formulated pharmaceutical mixture/Formulated pharmaceutical product/mixture packaged in final form for patient use; used in the treatment of varicose veins and hemorrhoids
Note	This SDS is written to address potential worker health and safety issues associated with the handling of the active pharmaceutical ingredient. The pharmacologic, ecologic and toxicologic properties of this product/mixture have not been fully characterized; this SDS will be revisited as more data become available.

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Globally Harmonized System [GHS] Irritant (skin) - Category 2.

Label elements

SECTION 2 - HAZARDS IDENTIFICATION ...continued

GHS hazard pictogram**GHS signal word**

Warning

GHS hazard statements

H315 - Causes skin irritation.

GHS precautionary statements

P264 - Wash hands thoroughly after handling. P280 - Wear eye/face protection. P302 + P352 - IF ON SKIN: Wash with plenty of soap and water. P321 - Specific treatment (see First Aid information on product label and/or Section 4 of the SDS). P332 + P313 - If skin irritation occurs: Get medical advice/attention. P362 + P364 - Take off contaminate clothing and wash it before reuse.

Other hazards

Sodium tetradecyl sulfate injection is an anionic surfactant, sclerosing agent. Common adverse effects include pain, itching, or ulceration at the injection site. Sloughing and necrosis of tissue may occur following extravasation. Mild systemic effects of headache, nausea, and vomiting have been reported. Less commonly, allergic reactions such as hives, asthma, hay fever, and anaphylactic shock have been reported.

No well-controlled studies in pregnant women taking sodium tetradecyl sulfate or developmental toxicity studies in animals were identified. Epidemiology data are conflicting, as congenital anomalies in infants were observed twice as frequently as expected in one report of 95 women treated during the first four months of pregnancy, while no significant increases in anomalies were found among the infants of 606 women treated throughout pregnancy.

Note

This product/mixture is classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA).

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ ELINCS#</u>	<u>Amount</u>	<u>GHS Classification</u>
Sodium Tetradecyl Sulfate	139-88-8	205-380-3	3%	SC1: H314; ATO4: H302
Benzyl alcohol	100-51-6	202-859-9	2%	ATO4: H302; ATI4: H332; ATD4: H312; FL4; H227

Note

The ingredient(s) listed above are considered hazardous and/or are the active ingredient. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of GHS classifications.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

Immediate Medical Attention Needed	Yes
Eye Contact	If easy to do, remove contact lenses if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
Skin Contact	Wash exposed area with soap and water and remove contaminated clothing/shoes. Rinse skin with water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
Inhalation	Avoid inhalation. Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
Ingestion	Avoid ingestion. If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
Protection of first aid responders	See Section 8 for Exposure Controls/Personal Protection recommendations.
Most important symptoms and effects, both acute and delayed	See Sections 2 and 11
Indication of immediate medical attention and special treatment needed, if necessary	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

SECTION 5 - FIREFIGHTING MEASURES

Extinguishing media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Specific hazards arising from the substance or mixture	No information identified. May emit carbon monoxide, carbon dioxide, oxides of sodium, and sulfur-containing compounds.
Flammability/Explosivity	No explosivity or flammability data identified. High concentrations of finely divided airborne organic particles can potentially explode if ignited.
Advice for firefighters	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment (see section 8). Area should be adequately ventilated. If exposed or concerned, get medical advice/attention.
Environmental precautions	Do not empty into drains. Avoid release to the environment.
Methods and material for containment and cleaning up	DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice.
Reference to other sections	See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling	Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing dust. 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.
Conditions for safe storage including any incompatibilities	Store in a dry, cool and well-ventilated place. Protect from heat and direct sunlight. Store at 20-25°C (68-77°F)
Specific end use(s)	No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Note Dispose of broken vials/syringes in a sharps container.

Control Parameters/ Occupational Exposure Limit Values

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Sodium Tetradecyl Sulfate	--	--	--
Benzyl alcohol	AIHA	TWA-8 HR	10 ppm
	Bulgaria, Latvia	TWA-8 HR	5 mg/m ³
	Czech Republic	TWA-8 HR	40 mg/m ³

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued

**Control Parameters/
Occupational Exposure
Limit Values**

...continued

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
	Czech Republic	Ceiling	80 mg/m ³
	Lithuania	TWA-8 HR	5 mg/m ³ (skin)
	Poland	TWA-8 HR	240 mg/m ³

**Exposure/Engineering
controls**

None required for normal handling of packaged product. If vials are crushed or broken, or if handling bulk formulation: Control exposures to below the OEL (for the active ingredient(s) if available). Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Utilize closed and sealed systems whenever possible. Solutions used for procedures where aerosolization may occur (e.g., spraying, pumping, open transfers,) must be handled using an engineered local exhaust ventilation (LEV) and/or enclosure or isolator system. Control the potential for spills and leaks by securing all connections. Use clean-in-place systems.

**Respiratory
protection**

None required for normal handling of packaged product. If vials are crushed or broken, or if handling bulk formulation: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. A powered air-purifying respirator (PAPR) with HEPA filters and head cover is required when performing aerosol generating operations. An airline respirator or self-contained breathing apparatus (SCBA) and disposable outerwear is required for spill cleanup.

Hand protection

None required for normal handling of packaged product. If vials are crushed or broken, or if handling bulk formulation: Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Skin protection

Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

**Environmental
Exposure Controls**

Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued

Other protective measures	Wash hands in the event of contact with this product/mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). Decontaminate all protective equipment following use.
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SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Liquid in vials
Color	Clear, colorless
Odor	No information identified.
Odor threshold	No information identified.
pH	7.2-8.4
Melting point/ freezing point	0°C (32°F)
Initial boiling point and boiling range	100°C (212°F)
Flash point	No information identified.
Evaporation rate	No information identified.
Flammability (solid, gas)	No information identified.
Upper/lower flammability or explosive limits	No information identified.
Vapor pressure	No information identified
Vapor density	No information identified.
Relative density	No information identified.
Water solubility	No information identified.
Solvent solubility	No information identified.
Partition coefficient (<i>n</i>-octanol/water)	No information identified.
Auto-ignition temperature	No information identified.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

Decomposition temperature	No information identified.
Viscosity	No information identified.
Explosive properties	No information identified.
Oxidizing properties	No information identified.
Other information	
Molecular formula	Not applicable (Mixture)
Molecular weight	Not applicable (Mixture)

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	No information identified.
Chemical stability	Stable when stored as recommended.
Possibility of hazardous reactions	No information identified.
Conditions to avoid	No information identified.
Incompatible materials	No information identified.
Hazardous decomposition products	No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Note As limited data were identified for the product/mixture, toxicology data for the individual ingredients are described below where applicable.

Information on toxicological effects

Route of entry May be absorbed by inhalation, skin contact and ingestion.

Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Sodium Tetradecyl Sulfate	LD ₅₀	Oral	Rat	1250 mg/kg
	LD ₅₀	Dermal	Rabbit	3 mL/kg
	LD ₅₀	Intravenous	Rat	72 mg/kg
Benzyl alcohol	LC ₅₀	Inhalation	Rat	8.8 mg/L/4 hours
	LD ₅₀	Oral	Rat	1230 - 3100 mg/kg
	LD ₅₀	Dermal	Rabbit	2000 mg/kg
	LD ₅₀	Oral	Mouse	1150 - 1580 mg/kg

SECTION 11 - TOXICOLOGICAL INFORMATION ...continued

Irritation/Corrosion	Sodium tetradecyl sulfate is mildly irritating to rabbit eyes and severely irritating to rabbit skin. Benzyl alcohol was slightly irritating to rabbit skin and irritating to rabbit eyes.
Sensitization	No data available.
STOT-single exposure	No data available.
STOT-repeated exposure/Repeat-dose toxicity	No appreciable toxicity was observed in a 30-day study in rats administered 0.15 g/kg in drinking water, although some growth inhibition was discernable.
Reproductive toxicity	No data available.
Developmental toxicity	No data available.
Genotoxicity	Sodium tetradecyl sulfate was negative in a mouse lymphoma assay.
Carcinogenicity	No data available.
Aspiration hazard	No data available.
Human health data	See "Section 2 - Other Hazards"

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Sodium Tetradecyl Sulfate	--	--	--
Benzyl alcohol	LC ₅₀ /48h	<i>Leuciscus idus</i> (freshwater fish)	646 mg/L
	LC ₅₀ /96h	Fathead minnow	460 mg/L
	EC ₅₀ /48h	Daphnia magna	23 mg/L
	EC ₅₀ /48h	Bacteria (<i>E.coli</i>)	1000 mg/L
	LC ₅₀	Lepomis macrochirus	10 mg/mL

Additional toxicity information	No data identified.
Persistence and Degradability	No data identified.
Bioaccumulative potential	No data identified.
Mobility in soil	No data identified.
Results of PBT and vPvB assessment	No data identified.
Other adverse effects	No data identified.

SECTION 12 - ECOLOGICAL INFORMATION ...continued

Note The environmental characteristics of this product/mixture have not been fully investigated. Releases to the environment should be avoided.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods Used product should be disposed of according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

SECTION 14 - TRANSPORT INFORMATION

Transport This product/mixture is not regulated as a hazardous material/dangerous goods under EU ADR/RID, IATA, IMDG, US DOT, or Canada TDG.

UN number None assigned.

UN proper shipping name None assigned.

Transport hazard classes and packing group None assigned.

Environmental hazards Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.

Special precautions for users Due to lack of data, avoid release to the environment.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

SECTION 15 - REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.

Chemical safety assessment Not conducted.

SECTION 15 - REGULATORY INFORMATION ...continued

TSCA status	Sodium tetradecyl sulfate and benzyl alcohol are listed in TSCA, but the 3% sodium tetradecyl sulfate injection solution is not.
SARA section 313	Not listed.
California proposition 65	Not listed.
Additional information	No other information identified.

SECTION 16 - OTHER INFORMATION

Full text of H phrases and GHS classifications	ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. ATi4 - Acute Toxicity (Inhalation) Category 4. H332 - Harmful if inhaled. ATD4 - Acute Toxicity (Dermal) Category 4. H312 - Harmful in contact with skin. H315 - Causes skin irritation. SI2 - Skin irritant Category 2. SC1 - Skin corrosion Category 1. H314 - Causes severe skin burns and eye damage. FL4 - Flammable Liquid Category 4. H227 - Combustible liquid.
Sources of data	Information from published literature and internal company data.
Abbreviations	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System
Issue Date	22 February 2019
Revisions	This is the first version of this SDS.

SECTION 16 - OTHER INFORMATION ...continued

Disclaimer

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a chemical substance. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.