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Safety Data Sheet

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1. IDENTIFICATION

Product Identifier

NDC Number(s): 64938-009-01, 64938-010-12
Product Name: 0.9% Sodium Chloride Sterile Solution

Other Means of Identification

Product Codes: 64938-009-01, 64938-040-06, 64938-010-12
Trade Name (s): Saljet 30ml Sterile Saline Topical Solution
Saljet Rinse (sodium chloride 0.9% w/v)

Recommended use of the chemical and restrictions on use

Product Use: Pharmaceutical
Type: Topical irrigation solution
Uses advised against: No information

Supplier of the SDS

Winchester Laboratories, LLLP
1177 Blue Heron Blvd. west,
Suite B106
Riviera Beach, FL 33404-4267
(630)-377-7880

2. Hazards Identification

Classification

OSHA regulatory status: This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.122)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Hazards not otherwise classified (HNOC): None known

Emergency overview: The product contains no substances which at their given concentration, are considered to be hazardous to health.

3. Composition/Information on Ingredients

Component	CAS No.	Weight %
Sodium Chloride	7647-14-5	0.9%
Water	7732-18-5	99.1%

4. First Aid Measures

General Advice:	Treat symptomatically and supportively
Eye contact:	None recommended
Skin contact:	None Recommended
Inhalation:	None Recommended
Ingestion:	None Recommended

5. Fire Fighting Measures

Specific Hazards:	Product is non flammable
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6. Accidental Release Measures

Personal precautions:	None Recommended
Environmental Precautions:	See Section 12
Methods for containment And clean up:	Clean spills with absorbent mop or other suitable device

7. Handling and Storage

Precautions for safe handling:	Wash thoroughly after handling
Conditions for safe storage:	Keep containers tightly closed in a cool ventilated place. Store at room temperature. Avoid excessive heat.
Incompatible products:	No special restrictions on storage with other products

8. Exposure Controls/Personal Protection

Occupational exposure limits: This product as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

Component	OSHA Time Weighted Avg.	OSHA Short Term Exposure Limit	OSHA Ceiling Limit	ACGIH Time Weighted Avg.	ACGIH Short Term Exposure Limit	ACGIH Ceiling Value
Sodium Chloride (7647-14-5)	None	None	None	None	None	None
Water (7732-18-5)	None	None	None	None	None	None

8. Exposure Controls/Personal Protection Cont.

Individual protection

Measures:

Eye Protection:	Eye protection not required for normal final product use
Hand Protection:	Not Required
Skin and Body:	Not required
Respiratory Protection:	No personal respiratory protective equipment required

9. Physical and Chemical Properties

Physical state:	Liquid
Appearance:	Aqueous solution
Color:	Colorless, clear
Odor:	Odorless
pH:	4.5 – 7.0
Melting point:	32 degrees F
Boiling point:	Lowest known value is 212 degrees F
Density:	Only known value is 1 (Same as water)
Vapor pressure:	Highest known value is 2.3 kPa (@ 20°C) (Water)
Vapor density:	The highest known value is 0.62 (Air=1) (Water)
Flammability:	Not flammable

10. Stability and Reactivity

Reactivity:	No data available
Chemical Stability:	Stable under recommend storage conditions
Possibility of Hazardous Reactions:	None under normal use
Conditions to avoid:	None known
Incompatible materials:	None Known
Hazardous Decomposition Products:	No data available

11. Toxicological Information

Component	LC50 Inhalation	LD50 Dermal	LD50 Oral
Sodium Chloride (7647-14-5)	> 42 g/m ³ (rat) 1h	-	= 3 g/kg (Rat)
Water (7732-18-5)	-	-	-



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11. Toxicological Information Cont.

Likely routes of exposure

Inhalation: Inhalation not likely under normal use
 Eye contact: Not expected to cause eye irritation
 Skin Contact: Not expected to cause skin irritation
 Ingestion: Not expected to be hazardous by ingestion

Toxicological effects

Symptoms: No information available

Delayed and immediate effects or chronic effects from Long/short term exposure

Irritation: Not Classified
 Corrosivity: Not classified
 Sensitization: Not Classified
 Mutagenic effects: Not Classified
 Carcinogenic effects: Not Classified

Component	ACGIH	IARC	NTP	OSHA
Sodium Chloride (7647-14-5)	-	-	-	-
Water (7732-18-5)	-	-	-	-

Reproductive Toxicity: Not classified
 STOT – Single exposure: Not classified
 STOT – Repeated exposure: Not classified
 Aspiration Hazard: Not Classified



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12. Ecological Information

Ecotoxicity: Not Available

BOD5 and COD: Not Available

Products of Degradation: Possibly hazardous short term degradation products are not likely.

Toxicity of the products of degradation: The products of degradation are more toxic

13. Disposal Considerations

Waste disposal: Waste must be disposed of in accordance with federal, state and local environmental control regulations.

14. Transport Information

DOT Classification: Not a DOT controlled material (United States)

Identification: Not applicable

Special provisions for Transport: Not applicable

TDG: Not a TDG controlled material (Canada)

15. Other Regulatory Information

US regulations

TSCA inventory list: The product is exempt from TSCA, it is FDA regulated

Other regulations:

Japanese Inventory (ENCS); Product complies with JPENCS

State Regulations:

Component	California Prop. 65	Minnesota Right to Know	Florida Right to Know	Rhode Island Right to Know	Mass. Right to Know	Pennsylvania Right to Know	New Jersey Right to Know
Sodium Chloride (7647-14-5)	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Water (7732-18-5)	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed



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15. Other Regulatory Information Cont.

Canadian Regulations:

Canada DSL Inventory
List:

This product complies with DSL

EU EINECS List:

This product complies with EINECS

Risk Phrases:

None

Safety Phrases:

None

16. Other Information

Prepared By: Winchester Laboratories LLLP.

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 the accuracy or completeness of the information contained 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.

End of Safety Data Sheet