

MSDS: Balanced Salt Solution

Material Safety Data Sheet

Manufacturer: Akorn Incorporated
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Section 1 - IDENTIFICATION

TRADE NAME: Balanced Salt Solution

Description: A sterilized physiologic balanced salt solution for irrigating purposes, which may be used during intraocular surgical procedures. The solution is isotonic to ocular tissue and contains electrolytes required for normal cellular metabolic functions.

Composition	CAS#	TLV (mg/m³)	PEL (mg/m³)	%Content
Calcium Chloride	10035-04-8	NE	NE	0.048
Sodium Chloride	7647-14-5	NE	NE	0.640
Magnesium Chloride	7791-18-6	NE	NE	0.030
Potassium Chloride	7447-40-7	NE	NE	0.075
Sodium Acetate	6131-90-4	NE	NE	0.390
Sodium Citrate	6132-04-3	NE	NE	0.170
Water for Injection	7732-18-5	NE	NE	QS
Sodium Hydroxide	1310-73-2	NE	NE	QS
Hydrochloric Acid	7647-01-0	NE	NE	QS

Common names of active ingredients: *see above*
Chemical Formula: NA
Molecular Weight: NA
Legal Category: Prescription Only

Section 2 - HAZARDOUS INGREDIENTS

Principal Hazardous Ingredients: None
Carcinogenicity: None
Mutagenicity: None
Developmental Toxicity: None

This product is non-hazardous and is approved by the FDA. It is an aqueous solution and is not considered to constitute a hazard.

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Section 3 - PHYSICAL AND CHEMICAL CHARACTERISTICS

Appearance and color:	Clear, colorless solution
Boiling Point:	NE
Melting/Freezing Point:	NE
Vapor Pressure (mm Hg):	NE
Vapor Density:	NE
Evaporation Rate:	NE
Solubility:	Aqueous solution
Specific Gravity:	~1.006 @ 25°C
Viscosity:	Water (Approximate)
pH:	6.5 to 8.0

Section 4 - FIRE AND EXPLOSION HAZARD DATA

Flash Point:	Non-flammable		
Flash Point Method:	NA		
Lower Explosive Limit (%):	NA		
Upper Explosive Limit (%):	NA		
Auto-ignition Temperature:	NA		
Extinguisher Media:	Water spray, carbon dioxide, dry chemical, or foam as appropriate for surrounding fire and materials		
Auto Ignition Temperature:	NA	Method:	NA
Special Firefighting Procedures:	Wear protective clothing		
Unusual Fire and Explosion Hazards:	None expected		
Explosion Sensitivity to Mechanical Impact:	Not sensitive		
Explosion Sensitivity to Static Discharge:	Not sensitive		
Specific Hazards:	NE		

Section 5 - REACTIVITY DATA

Chemical Stability:	Stable
Conditions to Avoid:	NA
Incompatibility:	Generally compatible with other common materials in a medical facility
Hazardous Decomposition Products:	None known
Hazardous Polymerization:	Will not occur

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Section 6 - HEALTH HAZARDS

Emergency Overview: Material is a physiological irrigating solution for eyes, ears, nose and/or throat during a variety of surgical procedures. Do not use this solution unless it is clear, seal is intact and container is undamaged.

Symptoms of Overexposure by Route of Exposure: There are no specific contraindications for this preparation.

Ingestion: Not an anticipated route of occupational exposure. Do not taste. Harmful effects from swallowing are not expected.

Inhalation: Inhalation of significant amounts of the product is not anticipated

Injection: Do not administer by intravenous route.

Contact with Skin or Eyes: Corneal swelling or bullous keratopathy may result when abnormal corneal endothelium is irrigated or subjected to any other trauma. Post-operative inflammatory reactions as well as incidents of corneal edema and corneal decompensation have been reported.

Pre-Existing Medical Conditions: Studies suggest that intraocular irrigating solutions which are iso-osmotic with normal aqueous fluids should be used with caution in diabetic patients undergoing vitrectomy since intraoperative lens changes have been observed.

Chemical Listed as Carcinogen or Potential Carcinogen:

National Toxicology Program:	Yes _____	No <u> x </u>
I.A.R.C. Monographs:	Yes _____	No <u> x </u>
OSHA:	Yes _____	No <u> x </u>

Emergency and First Aid Procedures:

Inhalation: Remove from source of exposure and into fresh air. If victim is not breathing, clear airway and immediately begin artificial respiration. Seek medical attention.

Eyes: Flush with copious amount of water.

Skin: Remove from source of exposure. Remove contaminated shoes and clothing and cleanse affected areas thoroughly with mild soap and copious amounts of water. Wash contaminated clothing before reusing.

Ingestion: If swallowed seek medical attention immediately. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and do not give anything by mouth. Do not induce vomiting. Do not leave person unattended and observe for adequacy of breathing. Seek medical attention.

Note to physicians: Treat symptomatically and supportively.

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Section 7 - PROTECTION INFORMATION

Engineering Controls: No special provisions are required under normal use conditions.
Respiratory Protection: Respiratory protection is not needed during normal product use.
Skin Protection: If skin contact is likely, impervious gloves are recommended.
Wash hands before and after using.
Eye Protection: Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended if contact is likely.

Section 8 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

Handling: Open under aseptic conditions only
Storage: Store under normal room conditions at temperature ranges from 59°F to 77°F (15°C to 25°C). Avoid exposure to excessive heat and do not allow to freeze.
Steps to be taken in case material is released or spilled:
Dispose of in accordance with local, state, and federal regulations

Section 9 - DISPOSAL CONSIDERATIONS

Waste Disposal Methods:
Dispose of in accordance with county, regional, federal, state, and local regulations
Appropriate Method of Disposal of Product, Preparation, Packaging:
Consult state, local and national governmental requirements

Section 10 - TOXICOLOGY INFORMATION

Special Target Organ Effects: NE
Reproductive Toxicity Information: NE
Embryotoxicity/Teratogenicity/Reproductive Toxicity: NE
ACGIH Biological Exposure Indices:
Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

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Section 11 - REGULATORY and ECOLOGICAL INFORMATION

Environmental Stability: Stable under ambient environmental conditions
Effect of chemicals on Aquatic Life: NE
Effect of chemicals on plants or animals: NE
SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304 and 313 of Title II of the Superfund Amendments and Reauthorization Act.
SARA Threshold Planning Quantity: NA
CERCLA Reportable Quantities (RQ): NA
TSCA Inventory Status: Balanced Salt Solution is a “drug” as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.
California Safe Drinking Water and Toxic Enforcement Act (Proposition 65):
This product does NOT contain a chemical known to the State of California to cause developmental and reproductive effects.
OSHA: The requirements of the Bloodborne Pathogen Standard (29 CFR 1910.1030) are not applicable.
DOT: This product does not pose an unreasonable risk to health and safety or property when transported in commerce. The Hazard class definitions of 49CR, Part 173 are not applicable.
EPA: This product does not meet the definition of a hazardous waste as defined in 40CFR, Part 261.11

OTHER INFORMATION

Legend: NE = Not Established
NA = Not Applicable

The information given herein is in good faith and to the best of our knowledge but no warranty, expressed or implied, is made.