

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations And According To The Hazardous Products Regulation (February 11, 2015).

Date of Issue: 03/26/2021 Version: 1.0

# **SECTION 1: IDENTIFICATION**

# 1.1. Product Identifier

Product Form: Mixture

Product Name: 5% Dextrose and 0.45% Sodium Chloride Injection, USP

#### 1.2. Intended Use of the Product

Sterile solution for intravenous administration

## 1.3. Name, Address, and Telephone of the Responsible Party

#### Manufacturer

Fresenius Kabi Deutschland GmbH

Freseniusstraße 1 Friedberg, Hesse 61169

Germany

General Phone Number: +49 6172 686 0

Customer Service Phone Number: (888) 386-1300 Health Issues Information: (800) 551-7176

Technical Product Information: +49 6172 686 8599

Emergency Phone Number: 8475502300

## Distributor

Fresenius Kabi USA, LLC Three Corporate Drive Lake Zurich, Illinois 60047

USA

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300 Health Issues Information: (800) 551-7176

# 1.4. Emergency Telephone Number

Emergency Number : ChemTel LLC

Domestic: 1-800-255-3924 International: +1-813-248-0585 Australia: 1-300-954-583 Brazil: 0-800-591-6042 China: 400-120-0751 India: 000-800-100-4086 Mexico: 800-099-0731

## SECTION 2: HAZARDS IDENTIFICATION

# 2.1. Classification of the Substance or Mixture

## **GHS-US/CA Classification**

Not classified

#### 2.2. Label Elements

#### **GHS-US/CA Labeling**

No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2015-17.

#### 2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

## 2.4. Unknown Acute Toxicity (GHS-US/CA)

No data available

# **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

# 3.1. Substance

Not applicable

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#### 3.2. Mixture

Name	Synonyms	Product Identifier	%	GHS Ingredient Classification
Water	AQUA / water	(CAS-No.) 7732-18-5	94.55	Not classified
D-Glucose, monohydrate	D-Glucose monohydrate / Dextrose monohydrate / Glucose hydrate	(CAS-No.) 77938-63-7	5	Comb. Dust
Sodium chloride	Sea salt / Sodium chloride (NaCl) / Salt / Sodium salt of hydrochloric acid	(CAS-No.) 7647-14-5	0.45	Not classified

Full text of H-phrases: see section 16

## **SECTION 4: FIRST AID MEASURES**

## 4.1. 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:** When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

**Skin Contact:** Remove contaminated clothing. Wash immediately with plenty of soap and water. Obtain medical attention if irritation develops or persists.

**Eye Contact:** Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

# 4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Not expected to present a significant hazard under anticipated conditions of normal use.

Inhalation: Prolonged exposure may cause irritation.

**Skin Contact:** Prolonged exposure may cause skin irritation.

**Eye Contact:** Prolonged exposure may cause slight irritation to eyes. **Ingestion:** Ingestion of large quantities may have adverse effects. **Chronic Symptoms:** None expected under normal conditions of use.

## 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

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

# 5.1. Extinguishing Media

Suitable Extinguishing Media: Carbon dioxide, dry chemical, foam, water spray, fog.

Unsuitable Extinguishing Media: None known.

## 5.2. 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. Contains substances that are combustible dusts. If dried and allowed to accumulate, may form combustible dust concentrations in air that could ignite and cause an explosion. Take appropriate precautions.

Reactivity: Hazardous reactions will not occur under normal conditions.

#### 5.3. 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, CO<sub>2</sub>). Chlorine compounds.

#### 5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

# 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).

#### 6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Personnel

**Protective Equipment:** Equip cleanup crew with proper protection.

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**Emergency Procedures:** Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

#### **6.2.** Environmental Precautions

Prevent entry to sewers and public waters.

# 6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

## 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

## **SECTION 7: HANDLING AND STORAGE**

# 7.1. Precautions for Safe Handling

**Precautions for Safe Handling:** Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

# 7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

**Storage Conditions:** Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

**Storage temperature:** Avoid excessive heat. Store at 20-25 °C / 68-77 °F [see USP Controlled Room Temperature]; brief exposure up to 40 °C / 104 °F does not adversely affect the product.

## 7.3. Specific End Use(s)

Sterile solution for intravenous administration

# SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

#### 8.2. Exposure Controls

**Appropriate Engineering Controls:** Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles.







Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles.

Skin and Body Protection: Wear suitable protective clothing.

**Respiratory Protection:** If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

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

#### 9.1. Information on Basic Physical and Chemical Properties

Physical State : Liquid

Appearance : Clear and colourless to slightly yellowish

Odor : Not available

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Odor Threshold	:	Not available
рН	:	Not available
<b>Evaporation Rate</b>	:	Not available
Melting Point	:	Not available
Freezing Point	:	Not available
<b>Boiling Point</b>	:	Not available
Flash Point	:	Not available
Auto-ignition Temperature	:	Not available
<b>Decomposition Temperature</b>	:	Not available
Flammability (solid, gas)	:	Not applicable
Lower Flammable Limit	:	Not available
Upper Flammable Limit	:	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
Partition Coefficient: N-Octanol/Water	:	Not available
Viscosity	:	Not available

## **SECTION 10: STABILITY AND REACTIVITY**

- 10.1. Reactivity: Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid: Direct sunlight, extremely high or low temperatures, and incompatible materials.
- **10.5. Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- **10.6.** Hazardous Decomposition Products: Thermal decomposition may produce: Carbon oxides (CO, CO<sub>2</sub>). Chlorine compounds.

## **SECTION 11: TOXICOLOGICAL INFORMATION**

11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral): Not classified
Acute Toxicity (Dermal): Not classified
Acute Toxicity (Inhalation): Not classified
LD50 and LC50 Data: Not available
Skin Corrosion/Irritation: Not classified
Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

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

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation. **Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation.

**Symptoms/Injuries After Eye Contact:** Prolonged exposure may cause slight irritation to eyes. **Symptoms/Injuries After Ingestion:** Ingestion of large quantities may have adverse effects.

**Chronic Symptoms:** None expected under normal conditions of use.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

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Sodium chloride (7647-14-5)	
LD50 Oral Rat	3550 mg/kg (Species: Wistar)
LD50 Dermal Rabbit > 10000 mg/kg (Species: New Zealand White)	
LC50 Inhalation Rat > 42 g/m³ (Exposure time: 1 h)	

# SECTION 12: ECOLOGICAL INFORMATION

## 12.1. Toxicity

Ecology - General: Not classified.

Sodium chloride (7647-14-5)		
LC50 Fish 1	5560 (5560 – 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through]	
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)	
LC50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])	
EC50 - Crustacea [2]	- <b>Crustacea [2]</b> 340.7 (340.7 – 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])	
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)	

## 12.2. Persistence and Degradability

2.5% Dextrose and 0.45% Sodium Chloride Injection, USP	
Persistence and Degradability	Not established.

## 12.3. Bioaccumulative Potential

2.5% Dextrose and 0.45% Sodium Ch	e and 0.45% Sodium Chloride Injection, USP	
Bioaccumulative Potential	Not established.	
Sodium chloride (7647-14-5)		
BCF Fish 1	(no bioaccumulation)	

**12.4. Mobility in Soil** Not available

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

# **SECTION 13: DISPOSAL CONSIDERATIONS**

## 13.1. Waste treatment methods

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Ecology - Waste Materials: Avoid release to the environment.

# **SECTION 14: TRANSPORT INFORMATION**

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

Not regulated for transport

14.1. In Accordance with DOT Not regulated for transport
 14.2. In Accordance with IMDG Not regulated for transport
 14.3. In Accordance with IATA Not regulated for transport

# **SECTION 15: REGULATORY INFORMATION**

In Accordance with TDG

# 15.1. US Federal Regulations

14.4.

Sodium chloride (7647-14-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

# 15.2. US State Regulations

Neither this product nor its chemical components appear on any US state lists, or its chemical components are not required to be disclosed

## 15.3. Canadian Regulations

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Sodium chloride (7647-14-5)		
Listed on the Canadian DSL (Domestic Substances List)		
Water (7732-18-5)		
Listed on the Canadian DSL (Domestic Substances List)		

# SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

**Date of Preparation or Latest** 

: 03/26/2021

Revision

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA

Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products

Regulations (HPR) SOR/2015-17.

**GHS Full Text Phrases:** 

Comb. Dust Combustible Dust

**HMIS III Rating:** 

Health: 0 Minimal HazardFlammability: 0 Minimal HazardPhysical: 0 Minimal Hazard

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

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