

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: **Intersol Solution**
Manufacturer Name: Fenwal France SAS - A Fresenius Kabi Company
Address: Etaillé
 36400 La Chatre
 France
General Phone Number: + 33 2 54 06 25 25
General Fax Number: + 33 2 54 06 25 00
Emergency Phone Number: Chemtrec: 800-424-9300
Distributor Name: Fresenius Kabi AG
Address: 61346 Bad Homburg/Germany
 Germany
General Phone Number: +49 (0) 61 72 686-0
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SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Class: Not considered a hazardous substance.

Potential Health Effects:

Potential Health Effects: Irritation, nausea, headache

Eye: May cause eye irritation.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Disodium phosphate anhydrous	7558-79-4	0.3 mg/mL	
Sodium dihydrogen phosphate dihydrate	13472-35-0	0.1 mg/mL	
Sodium citrate	6132-04-3	0.3 mg/mL	
Sodium chloride	7647-14-5	0.4 mg/mL	
Sodium acetate trihydrate	6131-90-4	0.4 mg/mL	
Water for Injection	7732-18-5	Amount Sufficient	

SECTION 4 : FIRST AID MEASURES

Eye Contact: Immediately flush eyes with plenty of water for 15 to 20 minutes. Get medical attention, if irritation or symptoms of overexposure persists.

Skin Contact: Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

Ingestion: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Other First Aid: For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point: Not established.

Flash Point Method: Not established.

Auto Ignition Temperature: Not established.

Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Avoid dust formation. Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store in a cool, dry, well ventilated area away from sources of heat, combustible materials, and incompatible substances. Keep container tightly closed when not in use.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended topical purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended topical purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid
Color:	White
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	No Data
Vapor Density:	Not established.
Vapor Pressure:	No Data
Percent Volatile:	Not established.
pH:	No Data

Molecular Formula:	Mixture
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Keep away from heat, ignition sources and incompatible materials.
Incompatible Materials:	Strong oxidizers, Acids.

SECTION 11 : TOXICOLOGICAL INFORMATION

Disodium phosphate anhydrous :

Acute Toxicity:	Acute Toxicity: LD50 IV Rat: 21 mg/kg LD50 IV Mouse: 15 mg/kg
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Sodium citrate :

NTP:	NTP: Reasonably anticipated to be a human carcinogen.
Teratogenicity:	Pregnancy Category B: Reproductive studies have been performed in rats at doses up to 6,6 times the human dose and have revealed no evidence of harm to the fetus caused by lidocaine HCl. However, there are no adequate well-controlled studies in pregnant women.

Disodium phosphate anhydrous :

Ingestion:	Oral - Rat LD50: 317 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 220 mg/kg [Behavioral - Convulsions or effect on seizure threshold Behavioral - Rigidity (including catalepsy) Lungs, Thorax, or Respiration - Respiratory stimulation]
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Sodium dihydrogen phosphate dihydrate :

Skin:	Administration onto the skin - Rabbit LD50 : >2 gm/kg [Details of toxic effects not reported other than lethal dose value]
Inhalation:	Inhalation - Rat LC50 : >5800 mg/m3/4H [Details of toxic effects not reported other than lethal dose value]
Ingestion:	Oral - Rat LD50 : 27000 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50 : >27 gm/kg [Details of toxic effects not reported other than lethal dose value]

Sodium citrate :

RTECS Number:	DE4550000
Ingestion:	Oral - Rat LD50 : 14200 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50 : 17500 mg/kg [Details of toxic effects not reported other than lethal dose value]

Sodium chloride :

Skin:	Administration onto the skin - Rabbit Standard Draize test.: 0.1 mL/24H Administration onto the skin - Rabbit Standard Draize test.: 0.5 mL/21D (Intermittent) Administration onto the skin - Rat TDLo: 374.92 gm/kg/13W (Intermittent) [Nutritional and Gross Metabolic - Weight loss or decreased weight gain Blood - Other changes]
Ingestion:	Oral - Mouse LD50: >8 gm/kg [Peripheral Nerve and Sensation - Flaccid paralysis without anesthesia (usually neuromuscular blockage) Behavioral - Ataxia] Oral - Mouse LD50: >8000 mg/kg [Behavioral - Ataxia] Oral - Rat LD50: 2100 mg/kg [Details of toxic effects not reported other than lethal dose value]

Sodium acetate trihydrate :

Ingestion:	Oral - Mouse LD50: 6332 mg/kg [Details of toxic effects not reported other than lethal dose value]
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SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.
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SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Disodium phosphate anhydrous :

TSCA Inventory Status: Listed

Canada DSL: Listed

Sodium dihydrogen phosphate dihydrate :

TSCA Inventory Status: Listed

Canada DSL: Listed

Sodium citrate :

TSCA Inventory Status: Listed

California PROP 65: Listed: cancer.

Canada DSL: Listed

Sodium chloride :

TSCA Inventory Status: Listed

Canada DSL: Listed

Sodium acetate trihydrate :

TSCA Inventory Status: Listed

Canada DSL: Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 1

HMIS Fire Hazard: 0

HMIS Reactivity: 0

HMIS Personal Protection: X

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