NORMAL SALINE I. V. FLUSH SYRINGE

Safety Data Sheet

According to 29 CFR 1910.1200 (g) [Federal Register Vol. 77, No. 58 Dated March 26, 2012]

MEDEFIL, INC.

Date of Issue: 09/14/2020 Revision: 002

1. IDENTIFICATION

(a) **Product Identifier**:

Product Name: Normal Saline I. V. Flush Syringe
Trade Name: Normal Saline I. V. Flush Syringe

(b) **Intended Use of the Product**: Normal Saline I. V. Flush Syringe is indicated for use as a sterile isotonic solution for flushing compatible intravenous tubing and/or in-dwelling access devices only.

(c) **Name, Address, Telephone of the Manufacturer**:

Medefil, Inc.
405 Windy Point Drive
Glendale Heights, IL. 60139
(630) 682 – 4600
www.medefilinc.com

(d) **Emergency Telephone Number**: 1-630-682-4600

2. HAZARDS IDENTIFICATION

(a) **Classification of the Substance of Mixture**

GHS-US Classification: Not classified as hazardous

(b) **Label Elements**

Signal Word (GHS-US): Not applicable
Hazard Statements (GHS-US): Not applicable
Precautionary Statements (GHS-US): Not applicable

(c) **Other Hazards:** No data available
(d) **Unknown Acute Toxicity (GHS-US):** No data available

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 **Substance**

Name	CAS Number	%	GHS-US Classification
Sodium Chloride, USP	7647-14-5	9 mg/mL	Not classified

Name	CAS Number	%	GHS-US Classification
Hydrochloric Acid, NF	7647-01-0	Quantity sufficient	Not classified

Name	CAS Number	%	GHS-US Classification
Sodium Hydroxide, NF	1310-73-2	Quantity sufficient	Not classified

Name	CAS Number	%	GHS-US Classification
Water for Injection	7732-18-5	100	Not classified

3.2 **Mixture** Not applicable

4. FIRST AID MEASURES

4.1 **Description of First-aid Measures**

General: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reaction from prescribed doses and overdoses are described in the package insert.

Skin Contact: No reactions expected under normal conditions of use, first aid is not normally required.

Eye Contact: No reactions expected under normal conditions of use, first aid is not normally required.

Ingestion: No reactions expected under normal conditions of use, first aid is not normally required.

Inhalation: Not an expected route of exposure.

4.2 **Most Important Symptoms and Effects Both Acute and Delayed**

Symptoms/Injuries: None expected under normal conditions of use.
Chronic Symptoms: None expected under normal conditions of use.
Aggravation of Pre-Existing Conditions: Individuals with hypernatremia or fluid retention.

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.

5. FIRE-FIGHTING MEASURES

5.1. **Extinguishing Media**: Use extinguishing media as for primary cause of fire.

5.2. **Special Hazards Arising From the Substance or Mixture:**
Fire Hazard: Not flammable.
Explosion Hazard: Product is not explosive.
Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. **Advice for Firefighters:** Not applicable.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures
Not applicable.

6.2. Environmental Precautions

None.

6.3. Methods and Materials for Containment and Cleaning Up

Wipe with a damp cloth and place in container for disposal.

7. HANDLING AND STORAGE

7.1. **Precautions for Safe Handling**

No special handling requirements for normal use of this material.

7.2. **Conditions for Safe Storage, Including Any Incompatibilities**

Storage Conditions: Store as directed by product packaging.
Incompatible Products: None Known.

7.3 **Specific End Use(s):**

No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 **Control Parameters:** No Occupational Exposure Limit (OEL) or short term exposure limit (STEL) has been identified.

8.2 **Exposure Controls:**

Appropriate Engineering Controls: Engineering controls should be used as the primary means to control exposure.

Personal Protective Equipment: Not generally required. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hand Protection: Not required for normal use of this product.
Eye Protection: Not required under normal conditions of use.
Skin and Body Protection: Not required for the normal use of this product.
Respiratory Protection: Not required under normal conditions of use.
Other Information: Not applicable.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State:	Liquid
Appearance:	Clear, colorless solution
Odor:	Odorless
Odor Threshold:	No data available
pH:	4.5 - 7.0
Evaporation Rate:	No data available
Melting Point:	Not established
Boiling Point:	Not established
Flash Point:	No data available
Auto-ignition Temperature:	No data available
Decomposition Temperature:	No data available
Flammability (solid, gas):	No data available

Vapor Pressure:	Not established
Relative Vapor Density at 20°C:	No data available
Specific Gravity:	1.0
Solubility:	Soluble in water
Partition Coefficient:	No data available
Viscosity:	No data available

9.2. **Other Information** No additional information available.

10. STABILITY AND REACTIVITY

10.1. **Reactivity:** No data available.
10.2. **Chemical Stability:** Stable under recommended handling and storage conditions.
10.3. **Possibility of Hazardous Reactions:** None.
10.4. **Conditions to Avoid:** None.
10.5. **Incompatible Materials:** None.
10.6. Hazardous Decomposition Products: No data available.

11 TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: Mild eye irritant in experimental animals (based on components)
Chronic Toxicity: None known

Hydrochloric Acid:

Eye: Eye – Rabbit Total particulate/dust (T): 5 mg/30S (RTECS)
Skin: Administration onto the skin – Human Standard Draize test.: 4%/24H (RTECS)

Inhalation: Inhalation – Rat LC50: 3124 ppm/1H [Sense Organs and Special Senses (Olfaction) – effect not otherwise specified Sense Organs and Special Senses (Eye) – Iritis]
Inhalation – Mouse LC50: 1108 ppm/1H [Sense Organs and Special Senses (Eye) – Effect, not otherwise specified, Lungs, Thorax, or Respiration – Respiratory stimulation Skin and Appendages – Dermatitis, other (After systemic exposure)]
Inhalation – Rat LC50: 4500 mg/m3/5M [Lungs, Thorax, or Respiration – Acute pulmonary edema].
Inhalation – Rat LC50: 8300 mg/m3/30M [Lungs, Thorax, and Respiration – Acute pulmonary edema].
Inhalation – Mouse LC50: 8300 mg/m3/30M [Lungs, Thorax, and Respiration – Acute pulmonary edema].
Inhalation – LC50: 0.1 gm/m3 [Details of toxic effects not reported other than lethal dose value]
Inhalation – Rat LC50: 60938 mg/m3/5M [Lungs, Thorax, and Respiration – Acute pulmonary edema].
Inhalation – Mouse LC50: 20487 mg/m3/5M [Lungs, Thorax, and Respiration – Acute pulmonary edema].
Inhalation – Rat LC50: 7004 mg/m3/30M [Lungs, Thorax, and Respiration – Acute pulmonary edema].
Inhalation – Mouse LC50: 3940 mg/m3/30M [Lungs, Thorax, and Respiration – Acute pulmonary edema].
Inhalation – Rat LC50: 3700 ppm/30M [Details of toxic effect not reported other than lethal dose value].
Inhalation – Mouse LC50: 2644 ppm/30M [Details of toxic effect not reported other than lethal dose value] (RTECS).

Ingestion: Oral – Rabbit LD50: 900 mg/kg [Details of toxic effect not reported other than lethal dose value] (RTECS).

Sodium Hydroxide:

Eye: Eye – Rabbit Standard Draize test.: 400 µg
Eye – Rabbit Standard Draize test.: 50 µg/24 H (RTECS):

Skin: Administration on to the skin – Rabbit Standard Draize test.: 500 mg/24H

Ingestion: Oral – Rabbit LDLo: 500 mg/kg [Details of toxic effect nor reported other than lethal dose value].

Sodium Chloride:

Eye: Rabbit Standard Draize test,: 10 mg [Moderate]

Skin: Administration on to the skin – Rabbit LD50: > 10 gm/kg [Details of toxic effects no reported other than lethal dose value].
Administration onto the skin – Rabbit Standard Draize test.: 50 mg/24 H [mild].
Administration onto the skin – Rabbit Standard Draize test.: 500 mg/24 H [mild].

Inhalation: Inhalation – Rat LC50: > 42 gm/m3/1H [Details of toxic effects not reported other than lethal dose value].

Ingestion: Oral – Mouse LD50: 4 gm/kg [Details of toxic effects not reported other than lethal dose value].
Oral – Rat LD50: 3000 mg/Kg [Details of toxic effects not reported other than lethal dose value].

Other Toxicological Information:
Intravenous – Mouse LD50: 645 mg/kg [Details of toxic effects not reported other than lethal dose value].
Intravenous – Rabbit LDLo: 1100 mg/kg [Behavioral – convulsions or effect on seizure threshold behavioral – muscle contraction or spasticity Cardiac – Other changes].
Intravenous – Guinea pig LDLo: 300 mg/kg [Details of toxic effects not reported other than lethal dose value].
Intravenous – Mouse TDLo: 2.1 mg/kg [Vascular – other changes blood – hemorrhage Skin and Appendages – dermatitis, irritative (after systemic exposure)].
Intravenous – Rabbit LDLo: 1.5 mg/kg [Details of toxic effects not reported other than lethal dose value].
Intravenous – Rabbit TDLo: 0.04 mg/kg [Vascular – other changes blood – hemorrhage Skin and Appendages – dermatitis, irritative (after systemic exposure)].
Subcutaneous – Rat LDLo: 3500 mg/kg [Behavioral – irritability].
Subcutaneous – Mouse LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value].
Subcutaneous – Guinea pig LDLo: 2160 mg/kg [Details of toxic effects not reported other than lethal dose value].
Subcutaneous – Rabbit TDLo: 0.04 mg/kg [Vascular – other changes Skin and Appendages – dermatitis, irritative (after systemic exposure)].
Subcutaneous – Mouse TDLo: 1900 mg/kg [Reproductive – Effects on Embryo or Fetus – fetal death].
Subcutaneous – Mouse TDLo: 1900 mg/kg [Reproductive – Specific Developmental Abnormalities – musculoskeletal system].
Subcutaneous – Mouse TDLo: 2500 mg/kg [Reproductive – Effects on Embryo or Fetus – fetotoxicity (except death, e.g., stunted fetus)].
Subcutaneous – Mouse TDLo: 13440 mg/kg [Reproductive – Fertility – Abortion].
Intraperitoneal – Mouse LD50: 2602 mg/kg kg [Details of toxic effects not reported other than lethal dose value].

Intraperitoneal – Rat LD50: 2600 mg/kg kg [Details of toxic effects not reported other than lethal dose value].
Intraperitoneal – Rat LDLo: 3.72 gm/kg [Behaviral – tremor Behavioral – convulsions or effect on seizure threshold].
Intraperitoneal – Rat LDLo: 1710 mg/kg [Reporoductive – Effect on Embryo or Fetus – fetotoxicity (except death, e.g., stunted fetus) Reproductive – Effects on Embryo or Fetus – fetal death Reproductive – Specific Developmental Abnormalities – musculoskeletal system].
Intraperitoneal – Rat TDLo: 10 gm/kg [Reproductive – Effects on Newborn – Behavioral].
Intraperitoneal – Rat Cytogenetic analysis: 2338 mg/kg.

12 ECOLOGICAL INFORMATION

Environmental Overview: No harmful effects to aquatic organisms are expected.

12.1 Toxicity: No data available.

12.2 Persistence and Degradability: No data available.

12.3 Bio-accumulative Potential: No data available **.**

12.4 Mobility in Soil: No data available.

13 DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods: Dispose of contents/container in accordance with local, regional, national, and international regulations.

14 TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below

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.

15 REGULATORY INFORMATION

Sodium Chloride, USP

CERCLA/SARA313 Emission reporting	Not listed
California Proposition 65	Not listed
Inventory – United States TSCA – Sec. 8(b)	Present

Water for Injection, USP

CERCLA/SARA313 Emission reporting	Not listed
California Proposition 65	Not listed
Inventory – United States TSCA – Sec. 8(b)	Present

16 OTHER INFORMATION

Date of Preparation of Latest Information: September 14, 2020

Date of Issue: 09/14/2020 Revision: 002

Other Information: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

Refer to Prescribing Information for further information at www.medefilinc.com

The above information is believed to be accurate and represents the best information currently available to Medefil, Inc. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations.

Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Medefil, Inc. be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Medefil, Inc. has been advised of the possibility of such damages.

WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE.

END OF SAFETY DATA SHEET