

Technical & Safety Data Sheet

Sodium Citrate 4% / Ethanol 30%

PRODUCT INFORMATION

Product Name:

Sodium Citrate 4% / Ethanol 30%

Product Code(s):

3844, 38443, 38443-1, 38453, 38455

Brand Name(s):

CitraFlow Plus™ (brand name may vary by region)

Application: Manufacturer: Lock solution for vascular access devices. Sterile. Single use. MedXL Inc., 285 Av Labrosse, Pointe-Claire, QC, H9R 1A3, Canada

Telephone: +1.514.695.7474, Fax: +1.514.695.1511

COMPOSITION & INGREDIENT INFORMATION

Solution: Anticoagulant Sodium Citrate and Antimicrobial Ethanol Solution

Ingredients:

Trisodium citrate dihydrate ($Na_3C_6H_5O_7.2H_2O$), CAS-No 6132-04-3 (or 68-04-2)

Citric acid (C₆H₈O₇), CAS-No 77-92-9

Water for injection (WFI)

Ethanol (CH₃-CH₂-OH), CAS-No 64-17-5

Composition:

40 mg/mL trisodium citrate and 0.3mL/mL ethanol in water,

pH adjusted with citric acid (pH 6.4 to 7.5)

Incompatible with:

Strong oxidizers

Syringe:

Volume

5mL (5cc); 10mL (10cc)

Nozzle type

Male Luer Lock fitting
Barrel: Polypropylene (PP)

Material(s)

Barrel: Po

Plunger: Polypropylene (PP)
Gasket: Bromobutyl Rubber + silicone lubricant

Label Material(s)

Polypropylene (PP)

Label Graduations

0 to 5mL (5cc) at 0.1mL increments; 0 to 10mL (10cc) at 0.2mL increments

Compliance Standard(s)

ISO 7886-1

Syringe Cap:

Type

Female Luer Lock, non-vented

Material(s)

Acrylonitrile Butadiene Styrene (ABS)

Compliance Standard(s)

ISO 594-2 or equivalent

HAZARDS IDENTIFICATION

Eye Contact:

May cause irritation

Skin Contact:

May cause irritation

Inhalation:

None None

Ingestion:

FIRST AID MEASURES

Wash eyes with water

Eye Contact: Skin Contact:

Wash skin with water and soap.

Inhalation:

N/A

Ingestion:

N/A

FIRE FIGHTING MEASURES

The product or its components are not fire or explosion hazards when used as intended.

ACCIDENTAL RELEASE MEASURES

Personal precautions during spill:

N/A

Precautions to protect environment:

N/A

Spill cleanup methods:

Clean with water and soap



MedXL Inc. | 285 Av Labrosse, Pointe-Claire, QC, H9R 1A3, Canada T:+1.514.695.7474 | F:+1.514.695.1511 | www.medxl.com

HANDLING & STORAGE

Usage precautions

Store between 15°C and 30°C in original syringe, protect from direct sunlight Storage precautions

EXPOSURE CONTROLS / PERSONAL PROTECTION

Does not require any specific protection.

PHYSICAL AND CHEMICAL PROPERTIES

Physical State

Liquid

N/A

Appearance:

Colourless/Clear

Odour/Taste:

Neutral/Metal/Alcohol

Solubility:

Soluble in water

Boiling Point: Melting Point: N/A N/A

pH Value:

6.4 - 7.5

STABILITY & REACTIVITY

Stability:

Stable under normal conditions of use and storage

Incompatible Materials:

Strong oxidizers

Hazardous Reaction:

None under normal use

Hazardous Decomposition Products:

None under normal use

TOXOLOGICAL INFORMATION

Non toxic

ECOLOGICAL INFORMATION

Not regarded as dangerous for the environment. Solution components are bio-degradable, and soluble. No bioaccumulation.

DISPOSAL CONSIDERATIONS

Consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

TRANSPORT INFORMATION

N/A

Special Shipping Information: **REGULATORY INFORMATION**

Risk phrases

R36 Irritating to eyes

Safety phrases

S2 Keep away from the reach of children

S25 Avoid contact with eyes

OTHER INFORMATION

The information provided is believed to be accurate and represents the best data currently available. The information given is designed only as guide and is not to be considered as a warranty or quality specification.

When handled properly by qualified personnel, the product described herein does not present a significant health or safety hazard. Alteration of its characteristics may present hazards addressed herein and must be evaluated by the user.

Prepared by:

Lee-Anne Hosein

Title:

Products Manager

Signature & Date:

Revised by:

Premala Premanathan

Title:

Regulatory Affairs Associate

Signature & Date:

Omar Boulanouar

01-02-17 Title:

Quality Operations Supervisor

Approved by: Signature & Date:

01-02-17

01-02-17