

Technical & Safety Data Sheet

Sodium Citrate 4%

PRODUCT INFORMATION

Product Name:

Sodium Citrate 4%

Product Code(s):

3854E1, 38543, 38543-1, 38553, 38555

Brand Name(s)

CitraFlow[™] (brand name may vary by region)

Application:

Lock solution for vascular access devices. Sterile. Single use.

Manufacturer:

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 Solution

Ingredients

Trisodium citrate dihydrate (Na₃C₆H₅O₇.2H₂O), CAS-No 6132-04-3 (or 68-04-2)

Citric acid ($C_6H_8O_7$), 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 ethanol (excipient) 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: Polypropylene (PP)

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: Skin Contact: May cause irritation

Inhalation:

May cause irritation

Ingestion:

None None

FIRST AID MEASURES

Eye Contact:

Wash eyes with water

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.

ACCIDENTAL RELEASE MEASURES

Personal precautions during spill:

N/A

Precautions to protect environment:

N/A

Spill cleanup methods:

Clean with water and soap



HANDLING & STORAGE

N/A Usage precautions

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

EXPOSURE CONTROLS / PERSONAL PROTECTION

Does not require any specific protection.

PHYSICAL AND CHEMICAL PROPERTIES

Physical State

Liquid

Appearance:

Colourless/Clear

Odour/Taste:

Solubility:

Neutral/Metal Soluble in water

Boiling Point:

N/A

Melting Point: pH Value:

N/A 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

Special Shipping Information:

N/A

Goods are not regulated for transport by the International Air Transport

Association (IATA).

REGULATORY INFORMATION

Risk phrases

R36 Irritating to eyes

Safety phrases

S2 Keep away from the reach of children

S25 Avoid contact with eyes

FC Directives

Directive 93/42/EEC, Annex II (3).

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

31-01-17

26-01-17

Title:

Regulatory Affairs Associate

Signature & Date: Approved by:

Omar Boulanouar

Title:

Signature & Date:

Mu

01-02-17

Quality Operations Supervisor