



SAFETY DATA SHEET

PureFlow-B Solutions RFP-4XX

NC1855
Rev B
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1. PRODUCT AND COMPANY IDENTIFICATION

Product name : NxStage® **PureFlow-B Solution RFP-4XX** (*Sterile Bicarbonate Premixed Dialysate*)

Product Number: RFP-400, RFP-401, RFP-402, RFP-403, RFP-404, RFP-405, RFP-406
RFP-453, RFP-454, RFP-455, RFP-456

Brand: NxStage® PureFlow-B Solution RFP-4XX

Company: NxStage Medical Inc.
350 Merrimack Street
Lawrence, Ma 01843

Telephone: 978-687-4700

Fax: 978-687-4800

Emergency Phone #: 1-866-NXSTAGE

Recommended use of the chemical and restrictions on use

Chemical Family: Hemodialysis solution

Product Type: Regulated Medical Device

Container Information: Primary package is overwrapped plastic bags stored and shipped in corrugated boxes.

Product Use: Acute Renal Care. For use with renal replacement therapy systems that utilize sterile premixed dialysate during hemodialysis.

2. HAZARDS IDENTIFICATION

Emergency Overview

OSHA Hazard Classification - None

Signal Word - None

Symbol(s) (pictogram(s)) - None

Hazard statement(s) - None

Precautionary statement(s) - The ingredients in the NxStage® PureFlow-B Solution at the concentrations present are not considered hazardous per the requirements of OSHA's 29 CFR 1910.1200 Toxic and Hazardous Substances. NxStage® PureFlow-B Solution is a physiologic fluid that contains the ingredients in the quantities described below and in the product labeling.

Hazards not otherwise classified

HMIS Classification

Health hazard: None
Chronic effects: None
Flammability: None
Physical hazards: None

NFPA Rating

Health hazard: None
Fire: None
Reactivity Hazard: None
Special hazards: None

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms: PureFlow-B Solutions, Premixed Dialysate, Hemodialysis Fluid, Dialysate

Formula: Reference Component Table

Molecular Weight: Not Applicable

Ingredient:	CAS No:	Concentration:
		Weight %
SMALL FLUID COMPARTMENT:		
Sodium Chloride	7647-14-5	< 1
Potassium Chloride	7447-40-7	< 0.1
Calcium Chloride, Dihydrate	10043-52-4	< 0.1
Magnesium Chloride, Hexahydrate	7791-18-6	< 0.1
Glucose Monohydrate	50-99-7	< 1
Water	7732-18-5	> 90
LARGE FLUID COMPARTMENT:		
Sodium Bicarbonate	144-55-8	< 1
Sodium Chloride	7647-14-5	< 1
Water	7732-18-5	> 90

4. FIRST AID MEASURES

General advice

If inhaled – none known

In case of skin contact – may cause drying of skin and irritation. Rinse thoroughly in water.

In case of eye contact –, with eye damage possible if contact is prolonged. Flush eyes thoroughly for fifteen minutes and contact a physician.

If ingested – contact a physician

5. FIREFIGHTING MEASURES

Suitable extinguishing media:

Not applicable; Use suitable means to extinguish surrounding fire.

Specific hazards from combustion:

None- there is no fire or explosion hazard

Special protective equipment for fire-fighters:

None

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: See Section 7

Protective equipment: See Section 7

Emergency procedures: See Section 5

Environmental precautions: No information available

Methods and materials for containment and cleaning up:

Spills can be contained and cleaned up with absorbent materials. Place spilled material in an appropriate container for wet materials for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling:

Protective eyewear is recommended to reduce risk of eye contact. Gloves are recommended to minimize risk of exposure to solution. Store in protective carton until ready for use.

Conditions for safe storage:

Do not freeze to reduce risk of bag damage and subsequent leakage.

Incompatibilities:

None

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

OSHA permissible exposure limit (PEL)

None

American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV)

None

Any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available

None

Appropriate engineering controls:

None. Store in original container per package requirements.

Personal protective equipment

Respiratory protection – None required

Hand protection – protective gloves recommended

Eye protection – Glasses with splash guard

Skin and body protection – None required

Hygiene measures – None required

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear aqueous solution
Odor:	Odorless
Odor threshold:	Not Available
pH: Small fluid compartment	1.0 – 2.0
pH: Large fluid compartment	7.5 – 8.6
pH: Mixed solution	7.0 – 8.0
Melting point/freezing point:	Not Available
Initial boiling point and boiling range:	Not Available
Flash point:	Not Available
Evaporation rate:	Not Available
Flammability:	Not Available
Upper/lower flammability or explosive limits:	Not Available
Vapor pressure:	Not Available
Relative density:	Not Available
Solubility:	Soluble in Water
Partition coefficient: n-octanol/water:	Not Available

Auto-ignition temperature:	Not Available
Viscosity:	Not Available
Safety data:	See Section 4 & 11

10. STABILITY AND REACTIVITY

Reactivity:	None
Chemical stability:	Stable
Possibility of hazardous reactions:	None
Conditions to avoid:	None
Incompatible materials:	None
Hazardous decomposition products:	None

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:

Inhalation – May cause respiratory tract irritation. The toxicological properties of this substance have not been fully investigated.

Ingestion – May cause gastrointestinal irritation with nausea, vomiting and diarrhea. The toxicological properties of this substance have not been fully investigated.

Skin – May cause skin irritation

Eye contact – May cause mild eye irritation

Symptoms of exposures

Ingestion may cause irritation to the mouth, throat and stomach and may cause vomiting.

Skin contact may cause drying of the skin and irritation.

Eye contact may cause chemical burns.

Delayed and immediate effects

Chronic effects from short- and long-term exposure: Not Available

Numerical measures of toxicity

Not Available. Not classified or listed by NTP, IARC, or by OSHA

12. ECOLOGICAL INFORMATION*

Ecotoxicity (Aquatic and terrestrial):	No data available
Persistence and degradability:	No data available
Bioaccumulative potential:	No data available
Mobility in soil:	No data available
PBT and vPvB assessment:	No data available
Other adverse effects:	No data available

13. DISPOSAL CONSIDERATIONS*

- Waste residue:
Dispose of waste in accordance with appropriate Federal, State, and Local Regulations.
- Handling of waste residue
Dispose of waste in accordance with appropriate Federal, State, and Local Regulations.
- Methods of disposal
Dispose of waste in accordance with appropriate Federal, State, and Local Regulations.
- Disposing of contaminated packaging:
Dispose of waste in accordance with appropriate Federal, State, and Local Regulations.

14. TRANSPORT INFORMATION*

UN number:	None
UN proper shipping name:	None
Transport hazard class(es):	None
Packing group, if applicable:	Not Applicable
Environmental hazards (e.g., Marine pollutant):	No data available
Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code):	Not Applicable
Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises:	None

15. REGULATORY INFORMATION*

Safety, health and environmental regulations which apply to this chemical:
Contains no EPA listed toxic ingredients per 40 CFR 372.65

US Regulations:
FDA Regulated product

16. OTHER INFORMATION

Date of preparation/version of the data sheet

September 18, 2015 Revision B

Further Information:

None

*Note: Since other Agencies regulate this information, OSHA will not be enforcing Sections 12 through 15 (29CFR 1910.1200(g)(2)).

Employers must ensure that SDS's are readily accessible to employees.
See Appendix D of 1910.1200 for a detailed description of SDS contents.