Safety Data Sheet for Chemical Products (SDS)

Standard Solution D & B set for dyalysis

Date Prepared: 05/09/2016
Date Revised: 17/08/2020

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name	Standard Solution D & B set for dialysis
Product Code	J10040
Chemical substance or mixture	Mixture
Company Name	JOKOH CO.,LTD.
Address	731-1, Unane, Takatsu-ku, Kawasaki, Kanagawa Pref., 213-8588, Japan
Department	Medical Device Development Department
TEL	044-811-9211
Emergency TEL	044-811-9211(ext.3)
FAX	044-811-9249
Recommended usage and restriction in use	Never use other instruments than Tokyo JOKOH's designated instruments.

2. SUMMARY OF HAZARDS

GHS Classification	
Substance or mixture	It does not include an applicable material.
Other hazard not classified in GHS	No information.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Pure substance or mixture	Mixture
Chemical formula (only covered in laws and regulations)	The legal target material is not included.
Impurities and Stabilizing additives	N/A

4. FIRST AID MEASURES

INHALATION	No possibility to inhale it (aqueous solution).
SKIN CONTACT	Wash skin with water.
EYE CONTACT	Wash eyes immediately with fresh water for 15 minutes or more, seek medical advice/attention.
INGESTION	Immediately rinse out mouth and drink water or milk, then get them out, seek medical advice.
Protection of First Aiders	Nothing in particular
Most Important Sign and Symptom of acute and delayed	No information

5. FIRE FIGHTING MEASURES

This is non-inflammable. In surrounding fire, extinguishing media including water is available to use.

Extinguishing Media Not to be Used	No information
Special Firefighting Method	No information
Specific Hazards in fire	No information
Protection of Firefighters	Extinguishing should be operated from windward side, avoid breathing vapors or smoke. Firefighters must wear appropriate individual protective clothing.

6. ACCIDENTAL RELEASE MEASURES

Precautions for Human health, Protective Equipment and Emergency Measures	Workers must wear appropriate protective equipment
Environmental Precautions	Prevent spilled materials from entering sewers or streams. Take care not to contaminate the environment. Prevent discharge into the environment.
Containment and Cleaning Method/Equipment	Nothing in particular
Recovery/Neutralization	Recover as much spill as possible, absorb remaining spill by cloth, etc., then, burn them. Spill which cannot be recovered should be diluted by a plenty of water and washed out.
Measures of Secondary Accident Prevention	No information

7. PRECAUTION IN HANDLING AND STORAGE

Handling	
Technical Measures	Wear protection equipment not to touch eyes, skin, and clothes.
Precaution	Do not drink by mistake. Wash hands and face well after handling. Do not handle roughly such as turnover, falling, and impact.
Precautions for Safety Handling	Do not eat or drink while using. Avoid contact to skin, eyes, and nose. Wash hands and face thoroughly after handling.
Storage	
Safety storage condition	
Storage condition	Avoid direct sunshine, high temperature substance. Store not to turnover, nor fall.
Safety container packaging material	No information
Banned substance for mixture	Nothing in particular

8. EXPOSURE CONTROLS AND PROTECTION MEASURE

Facility measure	Make hand washing facility, indicate the location clearly.
Control concentration	Not decided
Exposure limit	Not decided
Protective Equipment	
Respiratory Protection	Protection mask
Hand Protection	Protective gloves
Eyes Protection	Protective glasses
Skin and Body Protection	Protective boots, clothes, rubber apron, if necessary.

Hygienic Measures	No information

9. PHYSICAL AND CHEMICAL PROPERTY

Physical State, Shape, Color, etc.	Colorless, clear liquid
Odor	Slight smell
pH	Dialysate D 7.4±0.2、Dialysate B 8.6±0.2
Melting Point, Freezing Point	Approx. 0°C (aqueous solution)
Boiling Point, Initial Boiling Point, and Boiling Range	Approx.100°C (aqueous solution)
Flash Point	Non-combustibility (aqueous solution)
Vapor Velocity	No data (aqueous solution)
Combustibility (Sold, Gas)	Not applicable (aqueous solution)
Range of combustion or explosion(upper/lower limit)	Not applicable (aqueous solution)
Vapor Pressure	No data (aqueous solution)
Vapor Density	No data (aqueous solution)
Specific Gravity (Density)	1.00~1.02 g/cm^3 (25°C)
Solubility	No data (aqueous solution, dissolved by water arbitrarily.)
n-Octanol/Water Partition Coefficient	No data (aqueous solution)
Spontaneous Ignition Temperature	Not applicable (aqueous solution)
Resolution temperature	Not applicable (aqueous solution)
Viscosity (Rate of viscosity)	No data (aqueous solution)

10. STABILITY AND REACTIVITY

Stability	
Stability	Stable under normal use conditions
Reactivity	Non-reactive under normal use conditions
Possible hazards reaction	
Dangerous polymerizing	No dangerous polymerizing
Conditions to Avoid	No data
Mixture hazard substance	Nothing in particular

11. TOXICOLOGICAL INFORMATION

Acute Toxicity	
Oral Route	For both Dialysate D and B, not classified because the product does not contain ingredients that exceed the cut-off value of 1%.
Dermal Route	Same as above.
Inhalation: Gas	Same as above.
Inhalation: Vapor	Same as above.
Inhalation: Mine dust, mist	Same as above.
Skin Corrosion and Irritation	Same as above.
Severe Eye Damage and Eye Irritation	Same as above.
Respiratory or Skin Sensitization	For both Dialysate D and B, although the product contains ingredients that exceed the cut-off value of 0.1%, there is no data for all ingredients, so the substance was considered as "Not classified".
Germ Cell Mutagenicity	Same as above.
Carcinogenicity	Same as above.
Reproductive Toxicity	Same as above.
Specific Target Organ/Systemic Toxicity	For both Dialysate D and B, not classified because the product

(Single Exposure)	does not contain ingredients that exceed the cut-off value of 1%.
Specific Target Organ/Systemic Toxicity (Repeated Exposure)	Same as above.
Aspiration Hazard	For both Dialysate D and B, not classified because the product does not contain ingredients that exceed the cut-off value of 10%.

12. ENVIRONMENTAL HAZARD

Biology hazard	
Acute Hazard to the Aquatic Environment	For both Dialysate D and B, not classified because the product does not contain ingredients that exceed the cut-off value of 1%.
Chronic Hazard to the Aquatic Environment	Same as above.
The toxicity to other creatures	No data
Residual property and degradability	No data
Creature accumulation characteristics	No data
Mobility in the soil	No data
Hazardousness to the ozone layer	Because I did not include a material listed by an affiliated book of Montreal Protocol, it cannot be classified.

13. DISPOSAL CONSIDERATIONS

Residual Wastes	On the occasion of discharge, please exhaust it in a large quantity of water in diluted form.
Contaminated Container and Package	Clean it and recycle it or perform appropriate disposal according to the standard of the law concerned and the local government. When you discard an empty container, completely remove contents.

14. TRANSPORT CONSIDERATIONS

ADR/RID(Land)	
UN No.	N/A
Name	N/A
UN Class	N/A
Sub hazard	N/A
Label	N/A
Container class	N/A
ERG code	N/A

IMDG(Sea)	
UN No.	N/A
Name	N/A
UN Class	N/A
Sub hazard	N/A
Container class	N/A
EmS No.	N/A
Sea pollution substance	N/A

IATA(Air)	
UN No.	N/A
Name	N/A
UN Class	N/A
Sub hazard	N/A
Container class	

15. APPLICABLE LAWS AND REGULATIONS

International Inventory

REACH (SVHC)	N/A
TSCA, Chapter 6	N/A
Montreal Protocol	N/A
Stockholm Convention on Persistent Organic Pollutants (POPs)	N/A
Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (PIC)	N/A

Domestic Law

Industrial Safety and Health Act	N/A
Act on Confirmation, etc. of Release Amounts of Specific Chemical Substance in the Environment and Promotion of Improvements to the Management Thereof (Law concerning Pollutant Release and Transfer Register / PRTR Law)	N/A
Poisonous and Deleterious Substance Control Law	N/A
The Fire Services Act	N/A
Road Traffic Act	N/A
Ship Safety Law	N/A
Civil Aeronautics Act	N/A
Water Pollution Prevention Act	N/A
Marine Water Protection Law	N/A
Air Pollution Control Law	N/A
Law Concerning the Examination and Regulation of Manufacture	N/A
Pharmaceutical and Medical Device Act	N/A
Stimulants Control Law	N/A
Narcotics and Psychotropics Control Law	N/A
Infectious Diseases Control Law	N/A
Law on the Prohibition of Chemical Weapons and the Regulation of Specific Chemicals	N/A
Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms	N/A
Organization (serum, plasma, organization) containing presence derived from Homo sapiens	Nothing

Harmful ingredient

Export Trade Control Order	Pertinence (Clause 16 of 1 of the separate table first: 90th optical goods of the Customs Tariff Law, the apparatus for the photograph, an apparatus, measuring equipment, inspection equipment, the precision instrument for the movie and a medical device and these components and accessories)

16. OTHER INFORMATION

Reference cited

1）With Shinsuke Aoyagi and others, the electrode method electrolyte analyzer (product made in EX-180 Jokoh Co., Ltd.) have been prepared; examination of the density of dialytic fluid and sodium bicarbonate water solution (B liquid) administration, Japanese dialysis medical society magazine, Vol.34 No. 5 Page 339-343

(2001.05.28)

2）Patent 4440329th "proofreading liquid for exclusive use of the dialytic fluid" in application date 2009.05.20, concessioner Jokoh Co., Ltd., Eiji Akiyama

3）Patent 4440330th "electrode method electrolyte metering equipment having automatic proofreading and a measurement mode for exclusive use of the dialytic fluid" in application date 2009.05.20, concessioner Co., Ltd. Jokoh, Eiji Akiyama

4）Japanese chemical substance security, information center "collection of chemical substance control law existing chemical substance safety check data"

5）Association of prevention of danger, noxious manual center disaster (1992) of the chemical substance 6）GHS classification result (NITE) (classification result (2008 by Ministry of Health, Labour and Welfare and Ministry of the Environment and 2013))

7）Making guideline (Japan Chemical Industry Association) of the Material Safety Data Sheet

8）Transmission method - label of the dangerous noxious information of the chemical article based on GHS, indication in the workshop and security data sheet (SDS) JIS Z 7,253:2,012

Revision No.	No information
Meaning of abbreviation, acronym in SDS	No information

Disclaimer

This SDS is in accordance with “JIS Z 7253:2012”. The statements are based on normal handling, and if you handle as particular way such as combine with other substance, please follow the safety procedure suitable for operation circumstance. The contents are based on the latest information at the revision date, but this does not mean all the information is covered. Therefore, in case we obtain new information, there is a possibility of addition and correction. Also, we do not warrant the accuracy or completeness of the information, as the purpose of this SDS is for informing safety handling information. In all the products, there may be a possibility of having unknown hazard, therefore, please pay attention when you treat this SDS.