Safety Data Sheet

1. Identification of the Substance/Mixture and the Supplier

Supplier	:	National Institute of Advanced Industrial Science and Technology (AIST)
Address	:	1-3-1 Kasumigaseki, Chiyoda, Tokyo, Japan
Office in charge	:	Reference Materials Office, Center for Quality Management of Metrology, National Metrology Institute of Japan
Person in charge	:	Certified Reference Material Staff
Telephone No.	:	+81-29-861-4059 Fax No. : +81-29-861-4009
Emergency contact	:	Same as above
		Prepared on : April 1, 2021
		Revised on :
		Reference No. : 6208001
Identity of substance/mixture	:	Reference Material, NMIJ RM 6208-a Monoclonal Antibody Solution、AIST-MAB （Monoclonal Antibody Solution, AIST-MAB）
Recommended use of the chemical and restriction on use	:	This reference material is intended for use in the characterization of monoclonal antibody including validation of analytical procedures in quantification, analytical method development and its evaluation. It also can be used for the internal and external quality control of analyses. Do not use this reference material for other purposes than testing/research.

2. Hazard Identification

GHS classification	:	Not classifiable
GHS-labeling element	:	－
Signal word	:	－
Hazard statement	:	－
Precautionary statement	:	［Precaution］ Use personal protective equipment when handling. ［Response］ Rinse cautiously with clean water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. ［Storage］ Store in a freezer at −80 °C. ［Disposal］ Dispose of this reference material in accordance with applicable

legislation and local government ordinance.
Entrust disposal of this reference material to a professional waste disposal company licensed by prefectural governor.

The other hazards than the above do not result in classification or are not classifiable

3. Composition/Information on Ingredients

Substance or mixture	:	Mixture
Chemical name	:	Reference Material, NMIJ RM 6208-a Monoclonal Antibody Solution

Ingredient 1

Chemical name	:	Monoclonal Antibody
Synonym	:	_
Chemical formula	:	—
Molecular weight	:	—
CAS number	:	—
Content	:	5.0 g/L
Reference number in gazetted list in Japan	:	Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. : — Industrial Safety and Health Act : —

Ingredient 2

Chemical name	:	Dipotassium monohydrogen phosphate
Synonym	:	Dipotassium hydrogen phosphate
Chemical formula	:	K_2HPO_4
Molecular weight	:	174.2
CAS number	:	7758-11-4
Content	:	10 mmol/L
Reference number in gazetted list in Japan	:	Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. : (1)-452 Industrial Safety and Health Act : Published

Ingredient 3

Chemical name	:	Monopotassium dihydrogen phosphate
Synonym	:	Potassium dihydrogen phosphate
Chemical formula	:	KH_2PO_4
Molecular weight	:	136.1
CAS number	:	7778-77-0
Content	:	2 mmol/L
Reference number in gazetted list in Japan	:	Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. : (1)-452 Industrial Safety and Health Act : Published

Ingredient 4

Chemical name	:	Sodium acetate
Synonym	:	−
Chemical formula	:	CH_3COONa
Molecular weight	:	82.03
CAS number	:	127-09-3
Content	:	0.5 mmol/L (approximately 0.004 %)
Reference number in gazetted list in Japan	:	Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. : (2)-692 Industrial Safety and Health Act : 2-4-581

Ingredient 5

Chemical name	:	Sodium chloride
Synonym	:	−
Chemical formula	:	NaCl
Molecular weight	:	58.44
CAS number	:	7647-14-5
Content	:	2 mmol/L (approximately 0.012 %)
Reference number in gazetted list in Japan	:	Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. : (1)-236 Industrial Safety and Health Act : Published

Ingredient 6

Chemical name	:	Water
Synonym	:	−
Chemical formula	:	H_2O
Molecular weight	:	18.02
CAS number	:	7732-18-5
Content	:	Over 99 %
Reference number in gazetted list in Japan	:	Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. : − Industrial Safety and Health Act : −

4. First-Aid Measures

If inhaled	:	Remove victim to fresh air and keep warm and at rest. Get medical advice/attention.
If on skin	:	Rinse thoroughly with clean water. Remove/Take off contaminated clothing/shoes, etc. Get medical advice/attention.
If in eyes	:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
If swallowed	:	Rinse mouth thoroughly with water. Call doctor/physician.
Protection of first-aiders	:	Use personal protective equipment.

5. Fire-Fighting Measures

Suitable extinguishing media	:	Use powder, carbon dioxide, dry chemical fire extinguisher or fire extinguishing tools for initial firefighting activities.
Unsuitable extinguishing media	:	No data available
Fire-specific hazards	:	May emit irritating or toxic fume (or gas) at the time of fire.
Specific fire-fighting method	:	Fight fire from the windward in order to avoid breathing hazardous gas. Use personal protective equipment such as fire-proof clothing, fire-resistant clothing, protective clothing, compressed air open-circuit self-contained breathing apparatus, compressed oxygen closed-circuit self-contained breathing apparatus, rubber gloves and rubber boots.
Protection of fire-fighters		

6. Accidental Release Measures

Personal precautions, personal protective equipment and emergency procedures	:	Eliminate ignition source in the vicinity immediately. Make fire extinguishing media/equipment available to prepare for potential ignition. Use appropriate personal protective equipment during the operation to avoid eyes contact, skin contact, and contamination of clothes. Ventilate the affected areas thoroughly, if it is in an indoor environment, until the clean-up operation is completed. Use appropriate personal protective equipment during the operation to avoid skin contact of splash, etc. and inhalation of dust and gas.
Environmental precautions	:	Take precautions to prevent spillages from draining into rivers etc. to adversely impact the environment. Make it sure to appropriately treat contaminated wastewater in order to prevent untreated wastewater from being released into the surrounding environment.
Recovery and neutralization	:	Collect spillages in empty containers by making them adsorbed to wiping cloth/rag or soil/sand, etc. Rinse away the remains with plenty of water.
Prevention of secondary disaster	:	Mark the restricted area with rope, etc. to keep out unauthorized people. Carry out the clean-up operation from the windward and make people on the leeward side evacuate.

7. Handling and Storage

Handling

Engineering precautions/Local and general ventilation	:	Handle in a well-ventilated place. Install safety showers, hand-washing facilities and eye-washers near a handling place. Prevent this reference material from leaking, overflowing and

scattering. Do not allow vapors to be emitted.
Avoid breathing vapors (dust).
Keep away from hot surface, sparks and open flames.
Avoid rough handling such as knocking over, dropping, giving a shock to and dragging container.
Handle in a place equipped with local exhaust equipment.

Precautions for safe handling : Do not allow aerosol and vapors to be emitted.

Hygiene controls : Handle this reference material in accordance with industrial health and safety codes.
Wash hands, face, etc. thoroughly and gargle after handling this reference material.
Restrict drinking, eating and smoking to a designated area.
Do not bring gloves and other contaminated personal protective equipment into staff room.
Keep out unauthorized people.
Use appropriate personal protective equipment to avoid inhalation and contact with eyes, skin, and clothing.

Storage

Appropriate storage conditions : Store in a freezer at temperature of about −80 ºC.

Safe container packaging material : Polypropylene, Glass, Plastic

※Refer to the Certificate for appropriate storage conditions and instructions for use as reference material.

8. Exposure Controls/Personal Protection

Threshold limit value :
Not specified

Permissible concentration (Phosphate buffer solution)

・ACGIH TLV-TWA : Not specified

・Values recommended by Japan Society for Occupational Health : Not specified

・OSHA PEL TWA : Not specified

Engineering controls

・Ventilation/Exhaust : Local ventilation system or General ventilation system

・Safety control/Gas detection : Measuring equipment, Detecting tube

・Storage precaution : Keep away from strong oxidizers.

Personal Protective Equipment (PPE)

・Respiratory system : Protective mask

・Hands : Protective gloves

・Eyes : Eye protector, Safety goggle

・Skin and body : Protective clothing, Face protection

9. Physical and Chemical Properties and Safety Characteristics

Appearance, etc.	:	Liquid at room temperature
Color	:	Colorless
Odor	:	No data available
Melting point	:	No data available
Boiling point	:	No data available
Flammability	:	No data available
Explosive range	:	No data available
Flashing point	:	No data available
Auto-ignition temperature	:	No data available
pH	:	pH 7
Kinematic viscosity		No data available
Solubility	:	Miscible with water
n-Octanol/water partition coefficient (log Po/w)	:	No data available
Vapor pressure	:	No data available
Density and/or relative density	:	No data available
Relative vapor density (air=1)	:	No data available
Particle characteristics	:	No data available

10. Stability and Reactivity

Reactivity	:	No data available
Stability	:	Stable stored or handled under recommended condition
Possibility of hazardous reactions	:	No data available
Conditions to avoid	:	Sunlight, Heat, Contact with hot surfaces or oxidizers
Incompatible material	:	Strong oxidizers
Hazardous decomposition products	:	Phosphorus oxide

11. Toxicological Information

Note: No information on toxicity is available. However, care should be taken when handling it as it may feature unknown toxicity.
※Section "Toxicological Information" is prepared based on the information on the raw material because no information on the mixture is available.
This reference material is stable under normal conditions and there is no risk of elution of harmful additives. In case of handling this material under special conditions, such as high temperatures, however, it is recommended to take sufficient safety precautions.

12. Ecological Information

Ecotoxicity	:	No data available
Persistence and degradability	:	No data available
Bioaccumulative potential	:	No data available
Mobility in soil	:	No data available
Harmful effects on ozone layer	:	No data available

13. Disposal Considerations

Residual wastes	:	Dispose of this reference material in accordance with applicable legislation and local government ordinance. When the above-mentioned treatments are not possible, entrust disposal of residual waste to a professional waste disposal company licensed by prefectural governor.
Contaminated container and package	:	Dispose of containers after thoroughly removing their contents.

14. Transport Information

International regulations

UN number	:	Not applicable
Shipping name	:	Not applicable
UN classification	:	—
Packing group	:	—
Marine pollutant	:	—

Japanese domestic regulations

Transport by road/rail	:	Comply with Fire Service Act, Poisonous and Deleterious Substances Control Act, High Pressure Gas Safety Act
Transport by sea	:	Comply with Ship Safety Act and Act on Port Regulations
Transport by air	:	Comply with Civil Aeronautics Act

15. Regulatory Information

・No applicable laws and regulations

◎ **This SDS was originally prepared for the use of the reference material in Japan, and therefore Section 15 "Regulatory Information" covers only those laws and regulations which are enacted and enforced in Japan. In case of using this reference material, it is necessary to refer to and apply relevant laws and regulations of the country in which it is used.**

16. Other Information

Others

The information in this document is not intended to be exhaustive and is based on currently available information and data. The measures given in this document are applicable only to normal handling conditions. When handling this reference material under special conditions etc., it is recommended to take safety measures appropriate to each specific application and context of use. This document is intended to provide information and not intended to guarantee anything in handling this reference material.