Safety Data Sheet

National Institute of Advanced Industrial Science and Technology
AIST

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 (NMIJ)
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 : March 1, 2017
		Revised on : November 13, 2017
		ID Number : 6209001
Identity of Substance/Mixture	:	Certified Reference Material NMIJ CRM 6209-a Human Insulin Solution
Recommended Use of the Chemical and Restriction on Use	:	This reference material can be used in the calibration and validation of analytical methods and instruments for the determination of human insulin by instrumental analyses such as amino acid analysis, chromatography, and spectrophotometry. It can be also used controlling the precision of analytical methods and instruments. In addition, this CRM can be used in the validation of analytical instruments, and for evaluating the accuracy of quantitative values in the analysis of human insulin by the immunoassay, after the commutability has been verified by the user. Do not use this reference material for other purposes than testing/research.

2. Hazards Identification

GHS classification	:	Not classifiable
GHS label element	:	-
Signal word	:	-
Hazard and toxicity	:	-
Precautionary statement	:	[Safety Precaution] Avoid ocular instillation, oral ingestion or dermal injection. When handling, use protective mask, protective gloves, eye protection, etc. and take thorough precautions to prevent this reference material from getting into mouth and contacting with skin. [First-Aid Measure] 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: Seek medical examination/treatment.

If on skin: Rinse skin with plenty of water.
If swallowed: Rinse mouth thoroughly with water.
［Storage］
Store in a freezer at a temperature of about -20 ºC.
［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
Ingredient 1		
Chemical name	:	Human insulin
Synonym	:	Insulin
Chemical formula	:	$C_{257}H_{383}N_{65}O_{77}S_6$
Molecular weight	:	5807.6
CAS number	:	11061-68-0
Content	:	0.01 %
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	:	Monosodium dihydrogen phosphate
Synonym	:	Sodium dihydrogenorthophosphate
Chemical formula	:	NaH_2PO_4
Molecular weight	:	119.97
CAS number	:	7558-80-7
Content	:	0.094 %
Reference Number in Gazetted List in Japan	:	Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. : 1-497
	:	Industrial Safety and Health Act : Published
Ingredient 3		
Chemical name	:	Disodium monohydrogenphosphate
Synonym	:	Disodium hydrogen phosphate
Chemical formula	:	Na_2HPO_4
Molecular weight	:	141.95
CAS number	:	7558-79-4
Content	:	0.18 %
Reference Number in Gazetted List in Japan	:	Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. : 1-497

: Industrial Safety and Health Act : Published

Ingredient 4

Chemical name	:	Water
Synonym	:	—
Chemical formula	:	H_2O
Molecular weight	:	18.02
CAS number	:	7732-18-5
Content	:	99 % or above
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 him/her warm and at rest. Seek medical examination/treatment.
If on skin	:	Rinse skin thoroughly with clean water. Remove/Take off contaminated clothing/shoes, etc. Seek medical examination/ treatment.
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: Seek medical examination/treatment.
If swallowed	:	Rinse mouth thoroughly with water. Call doctor/physician.
Protection of First-Aid Responder	:	Use personal protective equipment.

5. Fire-fighting Measures

Extinguishing Media	:	Extinguishing media appropriate for surrounding facilities
Fire-Specific Hazards	:	Nothing special
Specific Fire-Fighting Method	:	Eliminate ignition sources at the origin of a fire and put out fire by using extinguishing media. Remove movable containers promptly to a safe place. In the case of immovable containers, cool their surroundings with sprayed water.
Protection of Fire-Fighters	:	Carry out fire-fighting 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.

6. Accidental Release Measures

Personal Precaution	:	Use appropriate personal protective equipment to avoid contamination of skin, eyes and personal clothing.
Personal Protective Equipment and	:	Ventilate the affected areas thoroughly, if it is in an indoor environment, until the clean-up operation is completed.

Emergency Procedures		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 spillage 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 spilled liquid in empty containers by making it 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	:	Avoid contact with eyes. Use appropriate personal protective equipment when handling this reference material. Do not use this reference material for other purposes than testing/research.
Local and General Ventilation	:	If emitting vapor or mist, keep the emission sources tightly closed and use local ventilation system.
Precautions for Safe Handling	:	Avoid rough handling such as turning over, dropping, giving a shock to or dragging containers. Prevent spillage, overflow and scattering, and avoid vapor emission. Keep container tightly closed after using this reference material. Wash hands, face, etc. thoroughly and gargle after handling this reference material. Restrict drinking, eating and smoking to designated areas. Do not bring gloves and other contaminated personal protective equipment into staff room. Make a place handling this reference material a restricted area to keep out unauthorized people. Use appropriate personal protective equipment to avoid inhalation and contact with eyes, skin and clothing. Use local ventilation system in indoor handling areas.

Storage

Appropriate Storage Conditions	:	Store in a freezer at a temperature of about −20 ºC.
Safe Container Packaging Material	:	Glass

※ See the Certificate for the details on appropriate storage conditions and instructions for use as a reference material.

8. Exposure Controls/Personal Protection

Threshold Limit Value
Not specified
Permissible Concentration
- 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 container tightly closed. Keep away from flammable substances, reducing substances and strong oxidizers.

Personal Protective Equipment (PPE)
Respiratory System : Protective mask
Hands : Protective gloves
Eyes : Safety spectacles
Skin and Body : Protective clothing

Hygiene Controls
Handle this reference material in accordance with industrial health and safety standards.

9. Physical and Chemical Properties

- Appearance, etc. : Liquid
- Color : Colorless transparent
- Odor : No data
- pH : 7.4 (21 °C)
- Melting point : No data
- Boiling point : No data
- Flashing point : No data
- Explosive range : No data
- Vapor pressure : No data
- Relative vapor density(Air=1) : No data
- Specific gravity or bulk specific gravity : 0.9995 g/cm^3 (25 °C)
- Solubility : Miscible in water
- *n*-Octanol/water partition coefficient (Log Po/w) : No data
- Auto-ignition temperature : No data
- Decomposition temperature : No data
- Flammability : No data

10. Stability and Reactivity

◇Stability
- Stable in normal storage conditions

◇Reactivity

・No data

◇Possibility of hazardous reactions

・No data available

◇Conditions to Avoid

・High temperature and direct sunlight

◇Incompatible material

・No data

◇Hazardous Decomposition Products

・No data

11. Toxicological Information

Serious Eye Damage/ Eye Irritation: May cause eye irritation.

Others

※The above toxicological information is prepared based on the information on the raw materials since there is no information on the mixture available.

Under the normal conditions, this reference material is stable and it does pose a risk for elution of hazardous additive components. In the case of special handling, such as use at a high temperature, however, thorough precautions must be taken.

12. Ecological Information

Toxicity

・No data available

Persistence and Degradability

・No data available

Bioaccumulative Potential

・No data available

Mobility in soil

・No data available

Ozone depletion potential

・No data available

13. Disposal Considerations

Residual Waste	:	Dispose of this reference material in accordance with applicable legislation and local government ordinance. Entrust disposal of residual waste to a professional waste disposal company licensed by prefectural governor or to a local government, if it provides such services. Identify as a medical waste or an industrial waste when disposing this reference material.
Contaminated Container and Package	:	Dispose of containers after thoroughly removing their contents.

14. Transport Information

UN number	:	Not applicable
UN classification	:	-
Material name	:	-
Container grade	:	-
ICAO/IATA	:	Not applicable
Marine pollutant	:	Not applicable
Precautions	:	Avoid direct sunlight, pay attention to leaks due to falling, overturning, etc. and flames carefully. Transport this reference material carefully.

15. Regulatory Information

・No applicable laws and regulations

◎ **This SDS is originally prepared for the use of the material in Japan, thus the stated laws and regulations are stipulated and carried out in Japan. The use of the material in other countries should be referred to and by application of the relevant laws and regulations of the country in which the material will be 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.