2013/07/01

Safety Data Sheet

1. IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND OF THE SUPPLIER

Product name HbA1c Calibrator for NORUDIA N HbA1c

Company name SEKISUI MEDICAL CO., LTD.

Address 2-1-3 Nihonbashi, Chuo-ku, Tokyo, Japan

Supplier

Address 3-3-1 Koyodai, Ryugasaki, Ibaraki, Japan Division in charge Quality Assurance Unit, Tsukuba Plant

Telephone +81-297-62-7551 Fax +81-297-62-5238

Reference No. 81-26-01

2. HAZARDS IDENTIFICATION

SDS number: 81-26-01

GHS classification Out of the classification criteria

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical or mixture Mixture (this product does not contain any hazardous

substances at concentrations which are higher than those

specified by laws and regulations).

4. FIRST AID MEASURES

Inhalation Remove the victim to a place with fresh air. Let him gargle

and keep him quiet and warm. If the victim feels ill, get

medical advice.

Skin contact Wash the skin immediately with large quantities of water.

If itching, inflammation, or other symptoms occur, get medical advice. Remove contaminated clothes and wash

them before reuse.

Eye contact Wash the eye immediately with large quantities of water for

at least 15 min and get medical advice. Remove the contact lens if it can be removed easily. Continue the eye

washing subsequently.

Swallowing Rinse mouth and dilute this product by letting the victim

drink large quantities of water. Immediately get medical

advice.

Protection of first aid givers Wear protective gear, such as globes, to avoid contact with

harmful substances.

Special precautions for doctors None.

5. FIREFIGHTING MEASURES

Extinguishing media This product is incombustible, because it is packed by glass

bottle. Use powder, carbon dioxide, dry sand, or other materials depending on the type of fire in the surrounding

area.

Prohibited extinguishing media

Special hazards arising from the

product

Pouring straight streams of water.

Container breakage may occur due to heat. Irritant,

corrosive, and toxic gases may be produced due to the fire.

HbA1c Calibrator for NORUDIA N HbA1c

2013/07/01

Specific methods of fire fighting If it is not dangerous, remove the containers from the fire.

Even after extinguishment, cool the containers sufficiently

with large quantities of water.

Perform fire fighting from the windward. Wear appropriate Protection of fire fighters

protective gear depending on the case.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

SDS number: 81-26-01

Isolate the people immediately from the leakage zone which should be appropriately separated in all directions from the origin of the leakage.

If leakage occurs indoors, continue adequate ventilation until the place is cleared up completely.

Take appropriate measures, such as stretching a rope around the leakage zone, to forbid persons except authorized personnel to enter the leakage zone.

Take measures for leakage from the windward, and remove the people from the lee.

Caution should be observed to prevent slipping on the leaks.

Keep out people except authorized personnel.

Let the operators wear appropriate protective gear (see the "8. EXPOSURE CONTROLS/PERSONAL PROTECTION" section) to prevent contact with eyes and skin and inhalation.

Forbid the operators without appropriate protective gear to

touch broken containers or leaks.

Ventilate closed places.

Caution must be exercised to prevent the outflow of drug **Environmental precautions**

leaks or concentrated effluents into rivers or other places. When leaks are diluted with large quantities of water, caution must be exercised to avoid the outflow of contaminated water which has failed to be treated

adequately into the environment.

Collection and neutralization Wipe the leaks with rags or the like and then clean the

affected area with a damp cloth.

Methods and materials for

containment and cleaning up

Stop the leakage, if it is not dangerous.

Measures against secondary disasters Prevent inflow into sewers, drains, basements, or closed

places.

7. HANDLING AND STORAGE

Handling

Technical measures

(Local ventilation/general

Ventilation)

Take the facility measures mentioned in the "8. EXPOSURE CONTROLS/PERSONAL PROTECTION" section and wear appropriate protective gear. Ventilate closed places.

Precautions for safe handling Avoid contact with eyes and skin.

Avoid swallowing.

Avoid breathing mist, vapor, and spray. After use, seal the container tightly.

2013/07/01

Avoid leakage, overflow, and scattering.

Avoid rough handling of containers, such as inverting,

dropping, strongly pressurizing, and pulling.

Avoidance of contact See the "10. STABILITY AND REACTIVITY" section.
Sanitation measures After handling, wash the hands thoroughly.

Avoid eating and drinking or smoking when this product is

used.

Storage

Conditions for safe storage Place in a tightly closed container and store in a cool place

(2-10°C), protected from direct sunlight. Store separately

from oxidants, acidic substances, and metals.

Prohibit the use of frozen product, because accurate results

may not be obtained due to qualitative change.

Safe container and package

SDS number: 81-26-01

materials

Keep in the dedicated containers.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Facility measures When using indoors, ventilate the workplace. Install a

restroom with washbasins in the workrooms where this product is stored or handled and show clearly where it is.

Control parameters Not specified

Acceptable concentration

Japan Society for Occupational

Helth

Not specified

ACGIH Not specified

Personal protective equipment

Respiratory protection Wear appropriate personal protective gear for breathing as

necessary.

Hand protection Wear appropriate personal protective globes. Eye protection Wear appropriate personal safety goggles.

Skin/body protection Wear appropriate personal protective gear, such as

protective clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Арре	earance	рН	Flashing point	Upper/lower	Specific gravity (relative density)	Solubility
Physical state	Color			flammability or explosive limits		
Lyophilized	Reddish brown	Data not available	Non flammable	Non explosive	1	Data not available

10. STABILITY AND REACTIVITY

Chemical stability Stable under usual handling conditions. Possibility of hazardous reactions Nonreactive under usual conditions.

Conditions to avoid Direct sunlight, heat, and air.

Incompatible materials Data not available. Hazardous decomposition products Data not available.

SDS number: 81-26-01 2013/07/01

11. TOXICOLOGICAL INFORMATION

This product does not contain any hazardous substances at concentrations which are higher than those specified by laws and regulations.

12. ECOLOGICAL INFORMATION

Data not available. **Ecotoxicity** Persistence and degradability Data not available. Bioaccumulative potential Data not available.

Mobility in soil Though this product is solid, become a liquid after

dissolution and its ingredients could be transported into

water and soil after dissolution.

Results of PBT and vPvB assessment Data not available.

13. DISPOSAL CONSIDERATIONS

Surplus or waste (residues) When extremely small quantities of waste is discarded

> through a drainage outlet, let it flow together with large quantities of water to avoid damage to water pipes. When large quantities of waste is discarded, commission their disposal to a waste disposal company licensed by the

prefectural governor.

Contaminated containers and

packaging

Rinse contaminated containers thoroughly with water,

classify them, and discard.

14. TRANSPORT INFORMATION

UN number	UN proper shipping name	Transport hazard class	Packaging group	Environmental hazards
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

In compliance with the "7. HANDLING AND STORAGE" Special precautions for user

> section. Before transportation, confirm the absence of breakage, corrosion, leakage, etc. in the containers. Place the containers on board in a manner that will cause no tumbling, falling, and damage and take reliable measures

against container collapsing on board.

15. REGULATORY INFORMATION

Law concerning Pollutant Release and Transfer Register (PRTR Law) Not applicable. Industrial Safety and Health Law Not applicable.

Poisonous and Deleterious

Substances Control Law Not applicable.

Pharmaceutical and Medical

Device Act Not applicable. Ship Safety Law Not applicable. Civil Aeronautics Act Not applicable.

16. OTHER INFORMATION

SDS number: 81-26-01

References

Other

The date of issue: July 1, 2013 Revised date: January 1, 2017

(1) National Institute of Technology and Evaluation: http://www.safe.nite.go.jp/ghs/list.html

- (2) Ministry of Health, Labour and Welfare Workplace Safety Site: http://anzeninfo.mhlw.go.jp/anzen_pg/GHS_MSD_FND.aspx
- (3) All data about the substances covered by the Law concerning Pollutant Release and Transfer Register (PRTR) MSDS (The Chemical Daily Co., Ltd.)
- (4) All data about the substances covered by the Industrial Safety and Health Law MSDS (The Chemical Daily Co., Ltd.) The information of this product safety data sheet is based on the present state of our knowledge. It does not include all information. If new information is obtained, it may be added or the original information may be corrected. The information is applicable to the product with regard to appropriate safety precautions and does not represent any guarantee of the properties of the product. It is requested that the user be responsible for ensuring conditions for safe use.