

**SAFETY DATA SHEET****SECTION 1: IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING**

**Product name** NORUDIA N HbA<sub>1c</sub> Reagent 1  
**Manufacturer/Supplier** SEKISUI MEDICAL CO., LTD. Tsukuba Plant  
**Address** 3-1 Koyodai 3-Chome, Ryugasaki-shi, Ibaraki 301-0852, Japan  
**Phone** +81-297-62-7551  
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**Emergency phone number** +81-297-62-7551 (Office hour: 9:00am to 5:00pm in Japan time)  
**Recommended uses and restrictions on use:** For in vitro diagnostic use.

**SECTION 2: HAZARDS IDENTIFICATION****GHS classification :**

<b>SKIN SENSITIZER</b>	Category 1
<b>CARCINOGENICITY</b>	Category 1B
<b>TOXIC TO REPRODUCTION</b>	Category 1B
<b>SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE)</b>	Category 1 (liver)
<b>SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE)</b>	Category 1 (liver)

Items without a category description are those not classified, not applicable or classification not possible into GHS category.

**Hazard Symbol****Signal word**

Danger

**Hazard statements**

H317 : May cause an allergic skin reaction  
H350 : May cause cancer  
H360 : May damage fertility or the unborn child  
H370 : Cause damage to organs (liver)  
H372 : Cause damage to organs through prolonged or repeated exposure (liver)

**Precautionary Statements-(Prevention)**

P201 : Obtain special instructions before use.  
P202 : Do not handle until a safety precautions have been read and understood.  
P260 : Do not breathe dust/fume/gas/mist/vapours/spray.  
P270 : Do not eat, drink or smoke when using this product.

P272 : Contaminated work clothing should not be allowed out of the workplace.

P280 : Wear protective gloves/protective clothing/eye protection/face protection.

**Precautionary Statements-(Response)**

P302 + P352 : If on skin: Wash with plenty of soap and water.

P333 + P313 : If skin irritation or rash occurs: get medical advice/attention.

P362 + P364 : Take off contaminated clothing and wash it before reuse.

P308 + P311 : If exposed or concerned: call a poison center/doctor/physician.

H314 : Get medical advice/attention if you feel unwell.

**Precautionary Statements-(Storage)**

P405 : Store locked up.

**Precautionary Statements-(Disposal)**

P501 : Dispose of contents/container to a located point (in accordance with local/regional/international regulation).

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS****Single Substance or Mixture****Mixture**

Chemical name	Weight-%	ENCS	CAS No.
N,N-Dimethylformamide	<1	2-680	68-12-2
Calcium chloride	<0.2	1-176	10043-52-4
ProClin 300	<0.1	5-5235 9-378	55965-84-9
Sodium azide	<0.01	1-482	26628-22-8

**SECTION 4: FIRST AID MEASURES****Inhalation**

Remove to fresh air. If you feel unwell, call a POISON CENTER or doctor/physician.

**Skin contact**

Wash off immediately with soap and plenty of water. Get medical attention if irritation develops and persists.

Remove contaminated clothes and wash them before reuse.

**Eye contact**

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing. Immediate medical attention is required.

**Ingestion**

Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without medical advice.

**Acute effect and delayed effect**

Acute effect: May cause an allergic skin reaction, Cause damage to organs (liver)

Delayed effect: May cause cancer, May danger fertility or the unborn child, Cause damage to organs through prolonged or repeated exposure (liver)

**Protection of first-aiders**

Use personal protective equipment as required.

**SECTION 5: FIRE FIGHTING MEASURES****Suitable extinguishing media**

Use powder, carbon dioxide, dry sand, or other extinguishing media depending on the type of fire in the surrounding area.

**Unsuitable extinguishing media**

Pouring straight streams of water

**Specific hazards arising from the product**

Container may burst due to fire. Irritant, corrosive or toxic gases may be generated due to the fire.

**Special extinguishing method**

Remove the containers if it is not dangerous. Even after extinguishment, cool the containers sufficiently with large quantities of water.

**Protection of fire-fighter**

Perform fire fighting from the windward. Use personal protective equipment as required.

**SECTION 6: ACCIDENTAL RELEASE MEASURES****Personal precautions, protective equipment and emergency procedures**

For indoor, provide adequate ventilation process until the end of working. Deny unnecessary entry other than the people involved by, for example, using a rope. While working, wear appropriate protective equipments to avoid adhering it on skin, or inhaling the gas. Work from windward, and retract the people downwind. Let the workers wear appropriate protective gear (see the "8. EXPOSURE CONTROLS/PERSONAL PROTECTION" section) to prevent contact with eyes and skin and inhalation.

**Environmental precautions**

To be careful not discharge to the environment without being properly handled waste contaminated. See the "12. ECOLOGICAL INFORMATION" section for additional information.

**Methods and materials for containment and methods and materials for cleaning up**

Absorb dry sand, earth, sawdust and the waste rug. Collect empty container that can be sealed. Stop the leakage, if it is not dangerous.

**Recovery, neutralization**

Remove the contaminated objects and wipe off the rest using waste rug.

**Secondary disaster prevention measures**

Clean contaminated objects and areas thoroughly observing environmental regulations. Prevent inflow into sewers, drains, basements, or closed places.

**SECTION 7: HANDLING AND STORAGE****Handling****Technical measures**

Carry out the engineering control (see the "8. EXPOSURE CONTRL/PERSONAL PROTECTION" section) and use personal equipment as required.

**Precautions**

Do not rough handling containers, such as upsetting, falling, giving a shock, and dragging. Prevent leakage, overflow, and scattering. Not generate steam and dust in vain. Seal the container after use. Wash hands after handling. In places other than those specified, should not be smoking or eating or drinking.

**Safety handling precautions**

Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

**Avoidance of contact**

Refer to the "10. STABILITY and REACTIVITY" section

**Storage****Technical measures**

Prohibit the use of frozen product, because accurate results may not obtained due to qualitative change.

**Safe storage conditions**

Store away from sunlight in a cool place (2-10°C).

**Incompatible substances**

Refer to the "10. STABILITY and REACTIVITY" section

**Safe packing material**

Keep in the product original container.

**SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION****Exposure limits**

Chemical name	ISHL Working Environmental Evaluation Standards-Administrative Control level	JSOH	ACGIH TLV-TWA
N,N-Dimethylformamide (CAS : 68-12-2)	N/A	10ppm	10ppm (skin)
Sodium azide (CAS : 26628-22-8)	N/A	N/A	0.29mg/m <sup>3</sup>

**Engineering control**

In case of indoor workplace, use a local exhaust system. Provide the safety shower facility, and hand- and eye-wash facility. And display their position clearly.

**Personal protective equipment**

**Respiratory protection** Protective mask  
**Hand protection** Protection gloves  
**Eye protection** Protective eyeglasses or chemical safety goggles  
**Skin and body protection** Wear suitable protective clothing, protective boots.

**General hygiene considerations**

Do not eat, drink or smoke when using this product

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

<b>Appearance</b>	liquid
<b>Color</b>	Pale blue to Colorless
<b>Odor</b>	No data available
<b>pH</b>	6.0 (25°C)
<b>Melting point/freezing point</b>	No data available
<b>Boiling point, initial boiling point and boiling range</b>	No data available
<b>Flash point</b>	No data available
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Upper/lower flammability or explosive limit</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Specific Gravity/Relative density</b>	1.004
<b>Solubility</b>	No data available
<b>n-Octanol/water partition coefficient</b>	No data available
<b>Auto-ignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Viscosity (coefficient of viscosity)</b>	No data available
<b>Dynamic viscosity</b>	No data available

**SECTION 10: STABILITY AND REACTIVITY****Stability**

Stable under usual handling conditions.

**Hazardous reactions**

No information available

**Conditions to avoid**

Extremes of temperature and direct sunlight.

**Incompatible materials**

No information available

**Hazardous decomposition products**

No information available

**SECTION 11: TOXICOLOGICAL INFORMATION**

<b>ACUTE TOXICITY: ORAL</b>	N,N-Dimethylformamide (CAS : 68-12-2); LD <sub>50</sub> : 3000mg/kg (Rat, EHC 114 (1991)) ProClin 300 (CAS : 55965-84-9); LD <sub>50</sub> : 53mg/kg (Rat, ChemIDPlus) Calcium chloride (CAS : 10043-52-4); LD <sub>50</sub> : 2045mg/kg (Rat, SIDS (Access on Dec. 2008)) Sodium azide (CAS : 26628-22-8); LD <sub>50</sub> : 45mg/kg (Rat, DFGOT Vol.20 (2003)) <u>Product : Not classified</u>
<b>ACUTE TOXICITY: SKIN</b>	N,N-Dimethylformamide (CAS : 68-12-2); LD <sub>50</sub> : 3500mg/kg (Rat, EHC 114 (1991)) Calcium chloride (CAS : 10043-52-4); LD <sub>50</sub> > 5000mg/kg (Rat, SIDS (Access on Dec. 2008)) Sodium azide (CAS : 26628-22-8); LD <sub>50</sub> : 20mg/kg (Rat, ACGIH (2001)) <u>Product : Not classified</u>
<b>ACUTE TOXICITY: INHALATION</b>	N,N-Dimethylformamide (CAS : 68-12-2); LC <sub>50</sub> : 4.7mg/L (HSDB, 2005) Calcium chloride (CAS : 10043-52-4); LC <sub>50</sub> : 0.16mg/L (Rat, SIDS (Access on Dec. 2008)) Sodium azide (CAS : 26628-22-8); LC <sub>50</sub> : 37mg/kg (Rat, RTECS (2008)) <u>Product : Not classified</u>
<b>SKIN CORROSION/ IRRITATION</b>	Sodium azide (CAS : 26628-22-8); Category 1 (DFGOT Vol.20 (2003)) <u>Product : Not classified</u>
<b>SERIOUS EYE DAMAGE/ EYE IRRITATION</b>	N,N-Dimethylformamide (CAS : 68-12-2); Category 1 (EHC 114 (1991)) Calcium chloride (CAS : 10043-52-4); Category 1 (SIDS (Access on Dec. 2008), OECD TG404 GLP) Sodium azide (CAS : 26628-22-8); Category 1 (DFGOT Vol.20 (2003)) <u>Product : Not classified</u>
<b>RESPIRATORY SENSITIZATION</b>	<u>Product : Classification not possible</u>
<b>SKIN SENSITIZATION</b>	ProClin 300 (CAS : 55965-84-9); Category 1 (EC CLP, C <sub>50</sub> ≥ 0.0015%) <u>Product : Category 1</u>
<b>GERM CELL MUTAGENICITY</b>	N,N-Dimethylformamide (CAS : 68-12-2); Category 2 (CERI Hazard assessment report No.8 (2005)) <u>Product : Not classified</u>
<b>CARCINOGENICITY</b>	N,N-Dimethylformamide (CAS : 68-12-2); Category 1B (IARC 71 (1999)) <u>Product : Category 1B</u>
<b>TOXIC TO REPRODUCTION</b>	N,N-Dimethylformamide (CAS : 68-12-2); Category 1B (CERI Hazard assessment report No.8 (2005)) <u>Product : Category 1B</u>
<b>SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE)</b>	N,N-Dimethylformamide (CAS : 68-12-2); Category 1 (liver), Category 2 (respiratory organs) (CERI Hazard assessment report No.8 (2005)) Calcium chloride (CAS : 10043-52-4); Category 3 (respiratory tract irritation) (SIDS (Access on Dec. 2008)) Sodium azide (CAS : 26628-22-8); Category 1 (cardiovascular system, lung, central nervous system, systemic toxicity) (NTP TR.389 (1991), HSDB (2009), DFGOT Vol.20 (2003), ACGIH (2001), PATTY (5th. 2001)) <u>Product : Category 1 (liver)</u>

<b>SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE)</b>	N,N-Dimethylformamide (CAS : 68-12-2); Category 1 (liver) (NTP TOX22 (1992), (IRIS (1990), CERI Hazard assessment report No.8 (2005)) Calcium chloride (CAS : 10043-52-4); Category 2 (blood circulatory system) (SIDS (2008)) Sodium azide (CAS : 26628-22-8); Category 1 (central nervous system, cardiovascular system, lung) (NTP TR389 (1991), HSDB (2009)) <u>Product : Category 1 (liver)</u>
<b>ASPIRATION HAZARD</b>	<u>Product : Classification not possible</u>

**SECTION 12: ECOLOGICAL INFORMATION**

<b>Ecotoxicity</b>	N,N-Dimethylformamide (CAS : 68-12-2); Oryzias latipes LC <sub>50</sub> > 100mg/L/96h (Environmental ecological effect test, 1995) ProClin 300 (CAS : 55965-84-9); Brachydanio rerio LC <sub>50</sub> : 0.27mg/L/96h (e-ChemPortal; HSNO) Calcium chloride (CAS : 10043-52-4); Fish, Algae, Crustacea LC <sub>50</sub> > 100mg/L (SIDS (2005)) Sodium azide (CAS : 26628-22-8); Pseudokirchneriella subcapitata ErC <sub>50</sub> : 0.348mg/L/96h (AQUIRE, 2010) <u>Product :</u> <u>ACUTE HAZARDS TO THE AQUATIC ENVIRONMENT: Not classified,</u> <u>CHRONIC HAZARDS TO THE AQUATIC ENVIRONMENT: Not classified</u>
<b>Persistence and degradability</b>	No information available
<b>Bioaccumulative potential</b>	No information available
<b>Mobility in soil</b>	No information available

**SECTION 13: DISPOSAL CONSIDERATION****Waste from residue**

Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated container and contaminated packing**

Disposal should be in accordance with applicable regional, national and local laws and regulations.

**SECTION 14: TRANSPORT INFORMATION**

<b>International Regulations</b>	
<b>Maritime Regulatory Information</b>	in accordance with IMO regulations
<b>Aviation regulatory information</b>	in accordance with ICAO/IATA regulation
<b>UN No.</b>	Not applicable
<b>Proper Shipping Name</b>	Not applicable
<b>Class</b>	Not applicable
<b>Packing Group</b>	Not applicable
<b>Marine Pollutant</b>	Not applicable
<b>Pictogram</b>	Not applicable
<b>Japanese Regulations</b>	
<b>Class</b>	Not applicable
<b>UN No.</b>	Not applicable
<b>Proper Shipping Name</b>	Not applicable
<b>Packing Group</b>	Not applicable
<b>Land transportation: Fire Service Act</b>	Not applicable
<b>Maritime transport: Ship Safety Act</b>	Not applicable

<b>Air transport: Civil Aeronautics Law</b>	Not applicable
<b>Special precautions for user</b>	In compliance with the “7. HANDLING AND STORAGE” 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.

**SECTION 15: REGULATORY INFORMATION**

<b>Industrial Safety and Health Act: Notifiable Substances (Enforcement Order Art. 18-2 Attached Table No.9)</b>	N,N-Dimethylformamide (CAS : 68-12-2); No.299, Threshold $\geq 0.1$ weight %
<b>Poisonous and Deleterious Substances Control Act</b>	Not applicable
<b>Pollutant Release and Transfer Register Law</b>	Poly (oxyethylene) alkyl ether (C12-C15) (CAS: 84133-50-6): Class 1, Threshold $\geq 1$ weight %
<b>Pharmaceutical and Medical Device Act</b>	In vitro diagnostic
<b>Fire Service Act</b>	Not applicable
<b>Ship Safety Act</b>	Not applicable
<b>Civil Aeronautics Law</b>	Not applicable

**SECTION 16: OTHER INFORMATION**

<b>Literature and references</b>	1. GHS (Rev.4 and Rev.5) 2. JIS Z 7252-2014 3. JIS Z 7253-2012 4. National Institute of Technology and Evaluation: <a href="http://www.safe.nite.go.jp/ghs/list.html">http://www.safe.nite.go.jp/ghs/list.html</a> 5. Ministry of Health, Labour and Welfare Workplace Safety Site <a href="http://anzeninfo.mhlw.go.jp/anzen_pg/GHS_MSD_FND.aspx">http://anzeninfo.mhlw.go.jp/anzen_pg/GHS_MSD_FND.aspx</a>
<b>Revision history of SDS</b>	1st: 01/07/2013 2nd: 01/06/2016 3rd: 24/06/2016
<b>Revision version</b>	3
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.	

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