SAFETY DATA SHEET

1st Edition: 25 Oct 2018
6th Edition: 09 Sep 2026

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name: Celltac Chemi HbA1c N

Product code: HA-420W, HA-421W

1.2 Relevant identified uses of the substance or mixture and uses advised against

Measurement of Glycohemoglobin A1c in whole blood

1.3 Details of the supplier of the safety data sheet

Nihon Kohden Corporation
1-31-4 Nishiochiai, Shinjuku-ku, Tokyo 161-8560, Japan
Tel: +81 3-5996-8041
Fax: +81 3-5996-8085

1.4 Emergency telephone number

+1 800-424-9300; CHEMTREC (US)
+1 613-996-6666; CANUTEC (Canada)
+81 3-5996-8022 (Outside US and Canada)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Skin sensitisation Category 1A

2.2 Label elements

Hazard pictogram:



Signal word: Warning

Hazard statements:	H317	May cause an allergic skin reaction.
Precautionary statements:	P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
	P272	Contaminated work clothing should not be allowed out of the workplace.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P302 + P352	IF ON SKIN:Wash with plenty of water.
	P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362 + P364	Take off contaminated clothing and wash it before reuse.
	P501	Dispose of contents/container in accordance with local and national regulations.

Supplemental Hazard Information (EU):

EUH032	Contact with acids liberates very toxic gas
EUH071	Corrosive to the respiratory tract

2.3 Other hazards

No data available

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Reagent Name	Chemical Name	Concentration or Its Ranges	CAS Number	EC Number REACH Registration No.	Classification according to Regulation (EC) No. 1272/2008 [CLP]
A1c diluent	Sodium azide	< 0.1%	26628-22-8	247-852-1	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410
	Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) *Proclin300	0.0021%	55965-84-9	911-418-6	Acute Tox. 2; H330 Acute Tox. 2; H310 Acute Tox. 3; H301 Skin Corr. 1C [1]; H314 Eye Dam. 1 [2]; H318 Skin Sens. 1A [3]; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410
A1c latex reagent	Sodium hydroxide; caustic soda	< 0.5%	1310-73-2	215-185-5	Skin Corr. 1A [4]; H314
	2-methylisothiazol-3 (2H)-one *Proclin950	0.0095%	2682-20-4	220-239-6	Acute Tox. 2; H330 Acute Tox. 3; H301 Acute Tox. 3; H311 Skin Corr. 1B; H314 Eye Dam. 1; H318 Skin Sens. 1A [3]; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410
A1c rinse solution	Sodium azide	< 0.1%	26628-22-8	247-852-1	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410
	Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) *Proclin300	0.0021%	55965-84-9	911-418-6	Acute Tox. 2; H330 Acute Tox. 2; H310 Acute Tox. 3; H301 Skin Corr. 1C [1]; H314 Eye Dam. 1 [2]; H318 Skin Sens. 1A [3]; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410
A1c antibody reagent	Hydrochloric acid ...%	< 1.0%	7647-01-0	231-595-7	STOT SE 3 [5]; H335 Skin Corr. 1B [6]; H314
	2-methylisothiazol-3(2H)-one *Proclin950	0.0038%	2682-20-4	220-239-6	Acute Tox. 2; H330 Acute Tox. 3; H301 Acute Tox. 3; H311 Skin Corr. 1B; H314 Eye Dam. 1; H318 Skin Sens. 1A [3]; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410

[1] Skin Corr. 1C Concentration limit is ≥ 0.6%, Skin Irrit. 2; Concentration limit is ≥ 0.06% and < 0.6%.

[2] Eye Dam Concentration limit is ≥ 0.6%, Eye Irrit. 2; Concentration limit is ≥ 0.06% and < 0.6%.

[3] Concentration limit is ≥ 0.0015%.

[4] Skin Corr. 1A; Concentration limit is ≥ 5%, Skin Corr. 1B. 2; Concentration limit is ≥ 2% and < 5%, Skin Irrit. 2; Concentration limit is ≥ 0.5% and < 2%, Eye Irrit. 2; 1B. 2; Concentration limit is ≥ 0.5% and < 2%.

[5] Concentration limit is ≥ 10%.

[6] Skin Corr. 1B; Concentration limit is ≥ 25%, Skin Irrit. 2; Concentration limit is ≥ 10% and < 25%, Eye Irrit. 2; Concentration limit is ≥ 10% and < 25%.

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation:	This product is nonvolatile. No risk of inhalation.
Skin contact:	Immediately wash with soap and running water and see a physician.
Eye contact:	Wash thoroughly with running water and see a physician.
Ingestion:	Wash the mouth thoroughly with water, do not force vomiting and see a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

No data available

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:	Water, powder extinguisher, foam extinguisher
Unsuitable extinguishing media:	No data available

5.2 Special hazards arising from the substance or mixture

The product is nonflammable, but when fire occurs, immediately remove the product away from fire.

5.3 Advice for firefighters

Aqueous solutions is nonflammable, but when fire occurs, spray extinguishing media.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

To avoid skin contact, wear protection such as gloves, mask, protective clothing and goggles when handling.

6.2 Environmental precautions

Do not drain a large amount of the product into public drainage or waterway.

6.3 Methods and material for containment and cleaning up

Recover with nonflammable absorbent. After recovery, wash away hazard area with a lot of water.

6.4 Reference to other sections

See “SECTION 8: Exposure controls/personal protection” and “SECTION 13: Disposal considerations”.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures:	Wear appropriate protective gear for eyes and skin.
Precautions:	Only use the product in prescribed facilities and procedures. Do not inject or drink the product. Not to contact with eyes and skin, wear protection.
Hygiene measures:	Do not eat, drink or smoke while handing the product. Wash hands thoroughly after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions:	Store at temperatures between 2 and 8°C (36 to 46°F) and avoid direct sunlight.
Packing material:	Styrene form, Polyethylene terephthalate, Paper
Container material:	Polypropylene, Polyethylene terephthalate, Polyethylene, Polyester, Aluminum

7.3 Specific end use(s)

No relevant information available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Chemical Name	ACGIH (TLV)	OSHA (PEL)
Sodium hydroxide	STEL: 2 mg/m^3	TWA: 2 mg/m^3
Sodium azide	STEL: (as Sodium azide) 0.29 mg/m^3 (as Hydrazoic acid vapor) 0.11 ppm (Card impair; lung dam)	Not applicable
Hydrochloric acid	STEL: 2 ppm	STEL: C 5 ppm, 7 mg/m^3

8.2 Exposure controls

Appropriate engineering controls

Washing and drainage. No need for a special ventilation system.

Individual protection measures

Eye/face protection: Wear eye protection/face protection.

Skin protection: Wear protective gloves. Wear protective clothing.

Respiratory protection: If necessary, wear respiratory protection.

Thermal hazards: No data available

Environmental exposure controls

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

	A1c diluent	A1c latex reagent	A1c rinse solution	A1c antibody reagent
Physical state	Liquid	Liquid	Liquid	Liquid
Color	Colorless	Milky-white	Colorless	Colorless
Odor	None	None	None	None
Melting point/freezing point	No data available	No data available	No data available	No data available
Boiling point or initial boiling point and boiling range	No data available	No data available	No data available	No data available
Flammability	Noncombustible	Noncombustible	Noncombustible	Noncombustible
Lower and upper explosion limit	No data available	No data available	No data available	No data available
Flash point	No data available	No data available	No data available	No data available
Auto-ignition temperature	Noncombustible	Noncombustible	Noncombustible	Noncombustible
Decomposition temperature	No data available	No data available	No data available	No data available
pH	Neutrality	7.5 to 7.8 (25°C, 77°F)	Neutrality	5.5 to 6.5 (25°C, 77°F)
Kinematic viscosity	No data available	No data available	No data available	No data available
Solubilities	Soluble in water	Soluble in water	Soluble in water	Soluble in water
Partition coefficient n-octanol/water	No data available	No data available	No data available	No data available
Vapour pressure	No data available	No data available	No data available	No data available
Density and/or relative density	0.997 g/cm^3	0.999 g/cm^3	0.997 g/cm^3	1.016 g/cm^3
Relative vapour density	No data available	No data available	No data available	No data available
Particle characteristics	No data available	0.05µm to 0.50µm polystyrene lattex	No data available	No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended handling and storage conditions.

10.3 Possibility of hazardous reactions

Explosive substance is created when sodium azide comes in contact with metals.

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Metal or metallic compound (The product includes less than 0.1% of sodium azide.)

10.6 Hazardous decomposition products

No data available

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (Oral):	Category 3: 55965-84-9 (Oral - Rat LD_{50} 66 mg/kg)
	Category 3: 2682-20-4 (Oral - Rat LD_{50} 285.5 mg/kg)
	Category 2: 26628-22-8 (Orl-rat LD_{50} 45 mg/kg)
	Classification result: Not classified
Acute toxicity (Dermal):	Category 2: 55965-84-9 (Dermal - Rabbit LD_{50} 87.12 mg/kg)
	Category 3: 2682-20-4 (Dermal - Rat LD_{50} 242 mg/kg)
	Classification result: Not classified
Acute toxicity (Inhalation: gas):	Does not fall under gas based on GHS definitions.
Acute toxicity (Inhalation: vapour):	Unable to classify due to insufficient data.
Acute toxicity (Inhalation: dust/mist):	Category 2: 55965-84-9 (Inhalation - Rat 4 h LC_{50} 0.171 mg/L)
	Category 2: 2682-20-4 (Inhalation – Rat 4 h LC_{50} 0.11 mg/L)
	Classification result: Not classified
Skin corrosion/irritation:	Category 1C: 55965-84-9
	Category 1B: 2682-20-4
	Category 1B: 7647-01-0
	(10 × Category 1) + Category 2 < 10%
	Classification result: Not classified
Serious eye damage/eye irritation:	Category 1: 55965-84-9
	Category 1: 2682-20-4
	(10 × Category 1) + Category 2 < 10%
	Classification result: Not classified
Respiratory sensitisation:	Unable to classify due to insufficient data.
Skin sensitisation:	Category 1A: 2682-20-4 (Category 1A ≥ 0.0015%)
	Category 1A: 55965-84-9 (Category 1A ≥ 0.0015%)
Germ cell mutagenicity:	Unable to classify due to insufficient data.
Carcinogenicity:	Unable to classify due to insufficient data.
Reproductive toxicity:	Unable to classify due to insufficient data.
STOT-single exposure:	Category 3: 7647-01-0 (STOT SE 3 ≥ 10%)
	Classification result: Not classified
STOT-repeated exposure:	Unable to classify due to insufficient data.
Aspiration hazard:	Unable to classify due to insufficient data.

11.2 Information on other hazards

No data available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment short-term (Acute):

A1c diluent/A1c rinse solution

Category 1: 55965-84-9 (M=100), 26628-22-8

(M × 10 × Category 1) + Category 2 < 25%

Classification result: Not classified

A1c latex reagent

2682-20-4 (M=10)

(M × 10 × Category 1) + Category 2 < 25%

Classification result: Not classified

A1c antibody reagent

2682-20-4 (M=10)

(M × 10 × Category 1) + Category 2 < 25%

Classification result: Not classified

Hazardous to the aquatic environment long-term (Chronic):

A1c diluent/A1c rinse solution

Category 1: 55965-84-9 (M=100), 26628-22-8

(M × 100 × Category 1) + (10 × Category 2) + Category 3 < 25%

Classification result: Not classified

A1c latex reagent

2682-20-4 (M=1)

(M × 100 × Category 1) + (10 × Category 2) + Category 3 < 25%

Classification result: Not classified

A1c antibody reagent

2682-20-4 (M=1)

(M × 100 × Category 1) + (10 × Category 2) + Category 3 < 25%

Classification result: Not classified

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available

12.6. Endocrine disrupting properties

No data available

12.7. Other adverse effects

Hazardous to the ozone layer: No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste of the remainder: Dispose of the product according to your local laws and your facility's guidelines for waste disposal.

Pollution container and wrapping: Dispose of the product according to your local laws and your facility's guidelines for waste disposal.

13.2 Instruction for disposal to prevent the release of microplastics

This product contains synthetic polymer microparticles (microplastics) to ensure its diagnostic functionality. To prevent the release of microparticles into the environment, this product and its waste (including used reaction mixtures and wash fluids) must not be discharged into the sewage system or the natural environment. Dispose of as clinical or hazardous waste in accordance with local, regional, and national regulations.

SECTION 14: Transport information

14.1 UN number or ID number

Not regulated

14.2 UN proper shipping name

Not regulated

14.3 Transport hazard class (es)

Not regulated

14.4 Packing group

Not regulated

14.5 Environmental hazards

Not regulated

14.6 Special precautions for user

Make sure that there is no damage or leakage on the product containers. Do not turn over, drop or damage the product containers when loading. Tie down the product containers to prevent load shifting.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU - REACH (1907/2006): Article 59(1) Candidate List of Substances Subject to Authorization

Annex XVII Restrictions of Certain Dangerous Substances, Mixtures and Articles

Annex XVII, Entry 78:This product contains synthetic polymer microparticles (microplastics) intentionally added. It is subject to the information requirements under Regulation (EU) 2023/2055.

15.2 Chemical safety assessment

See “SECTION 8: Exposure controls/personal protection” and “SECTION 11: Toxicological information”.

SECTION 16: Other information

Abbreviations and acronyms

ACGIH:	American Conference of Governmental Industrial Hygienists
TLV:	Threshold Limit Values
OSHA:	Occupational Safety and Health Administration
PEL:	Permissible Exposure Limits
REL:	Recommended Exposure Limits
TWA:	Time-Weighted Average
STEL:	Short-Term Exposure Limits
Acute Tox. 2:	Acute toxicity Category 2
Acute Tox. 3 :	Acute toxicity Category 3
Skin Corr. 1A :	Skin corrosion/irritation Category 1-1A
Skin Corr. 1B :	Skin corrosion/irritation Category 1-1B
Eye Dam. 1 :	Serious eye damage/eye irritation Category 1
Skin Sens. 1A:	Skin sensitisation Category 1-1A
STOT SE 3:	Specific target organ toxicity-single exposure 3
Aquatic Acute 1:	Hazardous to the aquatic environment short-term (Acute) Category 1
Aquatic Chronic 1:	Hazardous to the aquatic environment long-term (Chronic) Category 1
EUH032	Contact with acids liberates very toxic gas
EUH071	Corrosive to the respiratory tract
H300	Fatal if swallowed.
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H330	Fatal if inhaled.
H335	May cause respiratory irritation

H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Literature references

NITE GHS
ECHA
EU CLP Regulation, Annex VI

Amendment

This safety data sheet has been revised in accordance with REACH (EC 1907/2006) and CLP (EC 1272/2008) regulations.

Changes made in the most recent edition are indicated by a bar in the left margin of each page.

This data sheet is complete and accurate to the best of our knowledge but all information may not be covered. Any product may contain unknown harmful substances. This product must be handled carefully and used under the responsibility of the user, taking appropriate safety measures.