

SAFETY DATA SHEET

1st Edition: 14 Aug 2025

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

1.1 Product identifier

Product name Celltac chemi D-dimer
 Product code DD-421W

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

Measurement of D-dimer in whole blood and plasma

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

+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]
DD hemolysis reagent	Ethyleneglycolmonophenyl ether	0.50%	122-99-6	204-589-7	Acute Tox. 4 ¹ ; H302 STOT SE 3; H335 Eye Dam. 1; H318
	Hydrochloric acid...%	< 0.01%	7647-01-0	231-595-7	Skin Corr. 1B ² ; H314 STOT SE 3 ³ ; H335
	2-methylisothiazol-3(2H)-one *Proclin950	0.0095%	2682-20-4	220-239-6	Acute Tox. 2; H330 Acute Tox. 3; H311 Acute Tox. 3; H301 Skin Corr. 1B; H314 Eye Dam. 1; H318 Skin Sens. 1A ⁴ ; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH071
DD latex reagent	Sodium azide	< 0.1%	26628-22-8	247-852-1	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032
DD diluent	Sodium azide	< 0.1%	26628-22-8	247-852-1	Acute Tox. 2; H300 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032

¹ oral: ATE = 1394 mg/kg bw

² Skin Corr. 1B; Concentration limit is $\geq 25\%$, Skin Irrit. 2; Concentration limit is $\geq 10\%$ and $< 25\%$, Eye Irrit. 2; Concentration limit is $\geq 10\%$ and $< 25\%$.

³ Concentration limit is $\geq 10\%$.

⁴ Concentration limit is $\geq 0.0015\%$.

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation	Move to fresh air and get rest.
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	Use appropriate extinguishing media suitable for surrounding facilities.
Unsuitable extinguishing media	No data available

5.2 Special hazards arising from the substance or mixture

Fire may produce irritating, corrosive and/or toxic gases.

5.3 Advice for firefighters

Wear appropriate protective equipment such as self-contained breathing apparatus and full protective clothing.

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

Avoid release into the environment. In case of a spill, promptly report to the appropriate authorities.

6.3 Methods and material for containment and cleaning up

Absorb spill with inert material (dry sand, earth, et al), then place in a chemical waste container. For large spill, dike for later disposal. Fill the disposal into labelled, closable containers.

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 personal protective equipment

Precautions

Ensure proper ventilation. Wear protective gloves. Use personal protective equipment as required.

Hygiene measures

Do not eat, drink or smoke while handling 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, Polypropylene film, 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)
Hydrochloric acid	STEL: 2 ppm	STEL: C 5 ppm, 7 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

8.2 Exposure controls

Appropriate engineering controls

Ensure adequate ventilation and install hand-washing and drainage facilities nearby.

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

	DD hemolysis reagent	DD latex reagent	DD diluent
Physical state	Liquid	Liquid	Liquid
Color	colorless to pale yellow or brown	milky white	colorless to pale yellow
Odor	None	No data available	No data available
Melting point/freezing point	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
Flammability	Noncombustible	No data available	No data available
Lower and upper explosion limit	No data available	No data available	No data available
Flash point	No data available	No data available	No data available
Auto-ignition temperature	Noncombustible	No data available	No data available
Decomposition temperature	No data available	No data available	No data available
pH	7.4 to 7.6 (25°C, 77°F)	Neutrality	7.15 to 7.25
Kinematic viscosity	No data available	No data available	No data available
Solubilities	No data available	No data available	No data available
Partition coefficient n-octanol/water	No data available	No data available	No data available
Vapour pressure	No data available	No data available	No data available
Density and/or relative density	1.002 g/cm ³	0.998 g/cm ³	1.044 g/cm ³
Relative vapour density	No data available	No data available	No data available
Particle characteristics	No data available	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

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

No data available

10.6 Hazardous decomposition products

Irritating gases and/or vapors are produced by pyrolysis.

SECTION 11: Toxicological information

11.1 Information on hazard classes

Acute toxicity (Oral):	Category 4: 122-99-6 (Oral - Rat LD ₅₀ 1394 mg/kg) Category 3: 2682-20-4 (Oral - Rat LD ₅₀ 285.5 mg/kg) Category 2: 26628-22-8 (Oral - Rat LD ₅₀ 45 mg/kg) Classification result: Not classified
Acute toxicity (Dermal)	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: 2682-20-4 (Inhalation - Rat 4h LC ₅₀ 0.11 mg/L) Classification result: Not classified
Skin corrosion/irritation	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: 122-99-6 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%)
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: 122-99-6 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)

DD hemolysis reagent 2682-20-4 (M=10) (M×10×Category 1) + Category 2 < 25% Classification result: Not classified
DD latex reagent 26628-22-8 (M×10×Category 1) + Category 2 < 25% Classification result: Not classified
DD diluent 26628-22-8 (M×10×Category 1) + Category 2 < 25% Classification result: Not classified

Hazardous to the aquatic environment long-term (Chronic)

DD hemolysis reagent
2682-20-4 (M=1)
 $(M \times 100 \times \text{Category 1}) + (10 \times \text{Category 2}) + \text{Category 3} < 25\%$
Classification result: Not classified

DD latex reagent
26628-22-8
 $(M \times 100 \times \text{Category 1}) + (10 \times \text{Category 2}) + \text{Category 3} < 25\%$
Classification result: Not classified

DD diluent
26628-22-8
 $(M \times 100 \times \text{Category 1}) + (10 \times \text{Category 2}) + \text{Category 3} < 25\%$
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.

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 Subject to Authorization
Annex XVII Restrictions of Certain Dangerous Substances, Mixtures and Articles

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
Acute Tox. 4:	Acute toxicity Category 4
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
H300	Fatal if swallowed
H301	Toxic if swallowed
H302	Harmful if swallowed
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
EUH032	Contact with acids liberates very toxic gas
EUH071	Corrosive to the respiratory tract

Literature references

NITE GHS
ECHA
EU CLP Regulation, AnnexVI

Amendment

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

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.