

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	D-dimer Calibrator
Product code	DD-CAL

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

Calibrator for Nihon Kohden Automated Hematology and Clinical Chemistry Analyzer

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

Not classified

2.2 Label elements

Hazard pictogram	None
Signal word	None
Hazard statements	None
Precautionary statements	None

2.3 Other hazards

No data available

SECTION 3: Composition/information on ingredients

3.2 Mixtures

It does not contain substances referred to in accordance with applicable regulations.

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 | Water spray, Dry powder extinguisher, Foam extinguisher |
| Unsuitable extinguishing media | Strong running water should not be used as a fire extinguisher. |
- 5.2 Special hazards arising from the substance or mixture
- Toxic gas may be produced when fire occurs.
- 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 with suitable absorbent material and collect for disposal.
- 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. Although tested negative for HBsAg, HIV, and HCV, this product contains human blood components and must be handled as potentially infectious. |
| 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 | Flexible polyurethane foam, Paper |
| Container material | Glass |
- 7.3 Specific end use(s)
- No relevant information available

SECTION 8: Exposure controls/personal protection

- 8.1 Control parameters
- No data available
- 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

Physical state	Solid
Color	White
Odor	No data available
Melting point/freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability	No data available
Lower and upper explosion limit	No data available
Flash point	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
pH	No data available
Kinematic viscosity	No data available
Solubilities	No data available
Partition coefficient n-octanol/water	No data available
Vapour pressure	No data available
Density and/or relative density	No data available
Relative vapour density	No data available
Particle characteristics	No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not react under recommended handling, storage, and transportation conditions.

10.2 Chemical stability

Stable under recommended handling and storage conditions.

10.3 Possibility of hazardous reactions

No possibility of hazardous reactions under the recommended conditions of handling and storage.

10.4 Conditions to avoid

None under recommended handling and storage conditions.

10.5 Incompatible materials

No data available

10.6 Hazardous decomposition products

No hazardous decomposition products are formed under the recommended conditions for handling and storage.

SECTION 11: Toxicological information

11.1 Information on hazard classes

Acute toxicity (Oral)	Unable to classify due to insufficient data
Acute toxicity (Dermal)	Unable to classify due to insufficient data
Acute toxicity (Inhalation: gas)	Not classified
Acute toxicity (Inhalation: vapour)	Not classified
Acute toxicity (Inhalation: dust/mist)	Unable to classify due to insufficient data
Skin corrosion/irritation	Unable to classify due to insufficient data
Serious eye damage/eye irritation	Unable to classify due to insufficient data
Respiratory sensitisation	Unable to classify due to insufficient data
Skin sensitisation	Unable to classify due to insufficient data
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	Unable to classify due to insufficient data
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)
No data available

Hazardous to the aquatic environment long-term (Chronic)
No data available

12.2. Persistence and degradability

Not readily biodegradable

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 regulated

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	No main regulation
15.2 Chemical safety assessment	See "SECTION 8: Exposure controls/personal protection" and "SECTION 11: Toxicological information".

SECTION 16: Other information

Literature references	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.