SAFETY DATA SHEET

In accordance with 1907/2006 annex II and 1272/2008 (All references to EU regulations and directives are abbreviated into only the numeric term)

Revision date 2022-01-03 Replaces SDS issued 2021-10-20 Version number 2.0



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

1.1. Product identifier

Trade name Article number Red D-dimer Latex Reagent C3004, C3017

1.2. Relevant identified uses of the substance or mixture and uses advised against Identified uses Laboratory chemicals

1.3. Details of the supplier of the safety data sheet

Company	Nordic Biomarker
	Vildmannavägen 1
	903 47 Umeå
	Sweden
Telephone	+46 90718601
E-mail	info@nordicbiomarker.com

1.4. Emergency telephone number

Phone number for emergencies: 999 or 112. The numbers are available 24/7.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Upon assessment, this mixture is not classified as hazardous according to 1272/2008

2.2. Label elements

Hazard pictogram	Not applicable
Signal word	Not applicable
Hazard statement	Not applicable
Precautionary statement	Not applicable

Supplemental hazard information

EUH210 Safety data sheet available on request. EUH208 Contains 2-METHYLISOTHIAZOL-3(2H)-ONE. May produce an allergic reaction.

2.3. Other hazards

This product does not contain any substances that are assessed to be a PBT or a vPvB

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Note that the table shows known hazards of the ingredients in pure form. These hazards are reduced or eliminated when mixed or diluted, see Section 16d.

Constituent	Classification	Concentration
2-METHYLISOTHIAZOL-3(2H)-ONE		
CAS No: 2682-20-4 EC No: 220-239-6	Acute Tox. 2, Acute Tox. 3, Acute Tox. 3, Skin Corr. 1B, Eye Dam. 1, Skin. Sens. 1A, Aquatic Acute 1, M = 10, Aquatic Chronic 1; H330, H311, H301,	0.001463 %
	H314, EUH071, H318, H317, H400, H410	
REACH: 01-2120764690-50		

Explanations to the classification and labelling of the ingredients are given in Section 16e. Official abbreviations are printed in normal font. Text in italics are specifications and/or complements used in the calculation of the classification of this mixture, see Section 16b.

SECTION 4: First aid measures

4.1. Description of first aid measures

Generally

In case of concern, or if symptoms occur, call a doctor/physician.

Upon breathing in

Fresh air and rest. If symptoms persist seek medical advice.

Upon eye contact

Remove contact lenses immediately if possible.

Rinse the eye for several minutes with lukewarm water. If irritation persists call a doctor.

Upon skin contact

Normal washing of the skin is considered sufficient; If nevertheless symptoms do occur, contact a physician.

Upon ingestion

Rinse nose, mouth and throat with water. Get medical attention if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

Upon skin contact

May cause an allergic skin reaction.

4.3. Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Extinguish with water mist, powder, carbon dioxide or alcoholresistant foam.

5.2. Special hazards arising from the substance or mixture

In case of fire, substances hazardous to health, or substances harmful in other respects, may be dispersed.

5.3. Advice for firefighters

Protective measures should be taken regarding other material at the site of the fire. In case of fire use proper breathing apparatus. Wear full protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid inhalation and exposure to skin and eyes. Use recommended safety equipment, see section 8. Ensure good ventilation. Note that there is a risk of slipping if product is leaking/spilling.

6.2. Environmental precautions

Avoid release to drains, soil or watercourses.

6.3. Methods and material for containment and cleaning up

Small spills can be wiped up with a cloth or similar. Then flush the spill site with water. Larger spills should first be covered with sand or earth and then be collected. Collected material should be disposed according to Section 13.

6.4. Reference to other sections

See section 8 and 13 for personal protection equipment and disposal considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Store this product separately from food items and keep it out of the reach of children and pets. Avoid spillage and contact with eyes and skin.
Do not eat, drink or smoke in premises where this product is handled.
Wash your hands after using the product.
Handle in premises which have modern ventilation standards.
Remove contaminated clothing.
Wash contaminated clothing before reuse.
Use recommended safety equipment, see section 8.
Implement appropriate engineering controls if necessary, see Section 8.

7.2. Conditions for safe storage, including any incompatibilities

The product should be stored in a manner which prevents hazards to health and the environment. Avoid exposure to humans and animals and do not discharge the product in a sensitive environment.

Store separately from food products.

Keep out of reach for children.

Always use sealed and visibly labeled packages.

Store in dry and cool area.

7.3. Specific end use(s)

See identified uses in Section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters 8.1.1. National limit values SODIUM AZIDE

United Kingdom (EH40/2005)

Time-weighted-average exposure limit (TWA) 0.1 mg/m³ Short term exposure limit (STEL) 0.3 mg/m³ Note Sk

SODIUM HYDROXIDE

United Kingdom (EH40/2005)

Short term exposure limit (STEL) 2 mg/m³

Note

Explanations of abbreviations are given in Section 16b

DNEL 2-METHYLISOTHIAZOL-3(2H)-ONE

	Type of exposure	Route of exposure	Value
Worker	Acute Local	Inhalation	0.043 mg/m ³
Worker	Chronic Local	Inhalation	0.021 mg/m ³
Consumer	Acute Local	Inhalation	0.043 mg/m ³
Consumer	Acute Systemic	Oral	0.053 mg/kg bw
Consumer	Chronic Local	Inhalation	0.021 mg/m ³
Consumer	Chronic Systemic	Oral	0.027 mg/kg bw

PNEC

2-METHYLISOTHIAZOL-3(2H)-ONE

Environmental protection target	PNEC value
Fresh water	3.39 µg/L
Marine water	3.39 µg/L
Microorganisms in sewage treatment	230 µg/L
Soil (agricultural)	0.0471 mg/kg dw
Intermittent	3.39 µg/L

8.2. Exposure controls

The risks posed by the product or its constituents must be considered in the task specific risk assessment, in accordance with current working environment legislation. The risk assessment should be reviewed regularly and updated if necessary.

8.2.1. Appropriate engineering controls

The ventilation in the workplace must ensure an air quality that meets the requirements of the current working environment legislation. Local exhaust ventilation should be used to remove airborne contaminants at the source.

Eye/face protection

Eye protection should be worn if there is any danger of direct exposure or splashing.

Skin protection

Wear suitable protective clothing when necessary.

During continuous contact use gloves with a minimum breakthrough time of at least 240 minutes, preferably over 480 minutes.

The most suitable protective glove should be chosen in consultation with the glove supplier, taking into account the risk assessment for the specific task and the properties of the chemicals involved. Note that the breakthrough time of the material is affected by the duration of the exposure, temperature conditions, abrasion, etcetera.

Based on the chemical properties of the product, the following glove materials are recommended (EN 374):. – Nitrile rubber.

Respiratory protection

Use appropriate respiratory protective equipment in case of insufficient ventilation.

The most appropriate respiratory protective equipment should be decided in consultation with the appointed safety representative, taking into account the risk assessment for the specific task.

8.2.3. Environmental exposure controls

For limiting environmental exposure, see section 12.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

(a) Physical state	liquid
	Form: liquid
(b) Colour	Not indicated
(c) Odour	Not indicated
(d) Melting point/freezing point	Not indicated
(e) Boiling point or initial boiling point and boiling range	Not indicated
(f) Flammability	Not indicated
(g) Lower and upper explosion limit	Not indicated
(h) Flash point	Not indicated
(i) Auto-ignition temperature	Not indicated
(j) Decomposition temperature	Not indicated
(k) pH	Not indicated
(l) Kinematic viscosity	Not indicated
(m) Solubility	Not indicated
(n) Partition coefficient n-octanol/water (log value)	Not indicated
(o) Vapour pressure	Not indicated
(p) Density and/or relative density	Not indicated
(q) Relative vapour density	Not indicated
(r) Particle characteristics	Not indicated

9.2. Other information

9.2.1. Information with regard to physical hazard classes Not indicated

9.2.2. Other safety characteristics

Not indicated

SECTION 10: Stability and reactivity

10.1. Reactivity

The product contains no substances which can lead to hazardous reactions at normal use.

10.2. Chemical stability

The product is stable at normal storage and handling conditions.

10.3. Possibility of hazardous reactions

No hazardous reactions known during normal use.

10.4. Conditions to avoid

None in particular.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None under normal conditions.

SECTION 11: Toxicological information

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

Information on possible health hazards are based on experience and / or toxicological properties of several components in the product.

Acute toxicity

The product is not classified as acutely toxic.

2-METHYLISOTHIAZOL-3(2H)-ONE

LD50 rat 24h: > 2000 mg/kg Dermally LD50 rat 24h: > 2000 mg/kg Orally

Skin corrosion/irritation

The product is not classified for skin corrosion/irritation.

Serious eye damage/irritation

The product is not classified for serious eye damage/eye irritation.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

Germ cell mutagenicity

The product is not classified as mutagen.

Carcinogenicity

The product is not classified as carcinogenic.

Reproductive toxicity

The product is not classified as a reproductive toxicant.

STOT-single exposure

The product is not classified for specific organ toxicity after single exposure.

STOT-repeated exposure

The product is not classified for specific organ toxicity after repeated exposure.

Aspiration hazard

The product is not classified as being toxic for aspiration.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

The product does not have any known endocrine-disrupting properties.

11.2.2. Other information

Not indicated.

SECTION 12: Ecological information

12.1. Toxicity

Avoid larger spills in soil, water and drains.

The product is not classified as hazardous to the environment.

2-METHYLISOTHIAZOL-3(2H)-ONE

LC50 Rainbow trout (Oncorhynchus mykiss) 96h: 6 mg/l EC50 Freshwater water flea (Daphnia magna) 48 h: 1.68 mg/l EC50 Algae (Scenedesmus subspicatus) 72h: 0.445 mg/l

12.2. Persistence and degradability

There is no information regarding persistence or degradability.

12.3. Bioaccumulative potential

There is no information regarding bioaccumulation.

12.4. Mobility in soil

Information about mobility in nature is not available.

12.5. Results of PBT and vPvB assessment

This product does not contain any substances that are assessed to be a PBT or a vPvB.

12.6. Endocrine disrupting properties

The product does not have any known endocrine-disrupting properties.

12.7. Other adverse effects

No known effects or hazards.

SECTION 13: Disposal considerations

13.1. Waste treatment methods Waste handling of the product

The product is not classified as hazardous waste. Empty, rinsed packaging is sent for recycling where practicable. Avoid discharge into sewers. See directive 2008/98/EC on waste. Observe national or regional provisions on waste management.

SECTION 14: Transport information

Where not otherwise stated the information applies to all of the UN Model Regulations, i.e. ADR (road), RID (railway), ADN (inland waterways), IMDG (sea), and ICAO (IATA) (air).

14.1. UN number or ID number

Not classified as dangerous goods

- **14.2. UN proper shipping name** Not applicable
- 14.3. Transport hazard class(es)

Not applicable

14.4. Packing group Not applicable

14.5. Environmental hazards Not applicable

14.6. Special precautions for user

Not applicable

14.7. Maritime transport in bulk according to IMO instruments Not applicable

14.8 Other transport information

Not applicable

SECTION 15: Regulatory information

- **15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture** Not indicated.
- 15.2. Chemical safety assessment

Not indicated.

SECTION 16: Other information

16a. Indication of where changes have been made to the previous version of the safety data sheet Revisions of this document

Earlier versions

2021-10-20 Changes in section(s) 1, 8.

16b. Legend to abbreviations and acronyms used in the safety data sheet Full texts for Hazard Class and Category Code mentioned in section 3

Acute Tox. 2	Acute toxicity (inhal.), Hazard Category 2 - Acute Tox. 2, H330 - Fatal if inhaled
Acute Tox. 3	Acute toxicity (oral), Hazard Category 3 - Acute Tox. 3, H301 - Toxic if swallowed
Skin Corr. 1B	Skin corrosion/irritation, Hazard Category 1B - Skin Corr. 1B, H314 - Causes severe skin
	burns and eye damage
Eye Dam. 1	Serious eye damage/eye irritation, Hazard Category 1 - Eye Dam. 1, H318 - Causes serious eye damage
Skin. Sens. 1A	Respiratory or skin sensitisation, Sensitisation — Skin, hazard category 1A - Skin. Sens. 1A, H317 - May cause an allergic skin reaction
Aquatic Acute 1, $M = 10$	Hazardous to the aquatic environment — Acute Hazard, Category 1 - Aquatic Acute 1, M = 10, H400 - Very toxic to aquatic life
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1 - Aquatic Chronic 1, H410 - Very toxic to aquatic life with long lasting effects

Explanations of the abbreviations in Section 8 United Kingdom

Sk Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity

Explanations of the abbreviations in Section 14

- ADR European Agreement concerning the International Transport of Dangerous Goods by Road
- RID Regulations concerning the International Transport of Dangerous Goods by Rail
- IMDG International Maritime Dangerous Goods Code
- ICAO International Civil Aviation Organization (ICAO, 999 University Street, Montreal, Quebec H3C 5H7, Canada)
- IATA The International Air Transport Association

16c. Key literature references and sources for data Sources for data

Primary data for the calculation of the hazards has preferentially been taken from the official European classification list, 1272/2008 Annex I, as updated to 2022-01-03.

Where such data was not available, alternative documentation used to establish the official classification was used, e.g. IUCLID (International Uniform Chemical Information Database). As a second alternative, information was used from reputable international chemical industries, and as a third alternative other available information was used, e.g. material safety data sheets from other suppliers or information from non-profit associations, where reliability of the source was assessed by expert opinion. If, in spite of this, reliable information could not be sourced, the hazards were assessed by expert opinions based on the known hazards of similar substances, and according to the principles in 1907/2006 and 1272/2008.

Full texts for Regulations mentioned in this Safety Data Sheet

1907/2006 REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

1272/2008 REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

2008/98/EC DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008 on waste and repealing certain Directives

16d. Methods of evaluating information referred to in 1272/2008 Article 9 which was used for the purpose of classification

Hazard calculation for this mixture has been performed as a cumulative assessment with the aid of expert assessments in accordance with 1272/2008 Annex I, where all available information which may be significant to establishing the hazards of the mixture was assessed together, and in accordance with 1907/2006 Annex XI.

16e. List of relevant hazard statements and/or precautionary statements

Full texts for hazard statements mentioned in section 3

- H330 Fatal if inhaled
- H311 Toxic in contact with skin
- H301 Toxic if swallowed
- H314 Causes severe skin burns and eye damage
- EUH071 Corrosive to the respiratory tract
- H318 Causes serious eye damage
- H317 May cause an allergic skin reaction
- H400 Very toxic to aquatic life
- H410 Very toxic to aquatic life with long lasting effects

16f. Advice on any training appropriate for workers to ensure protection of human health and the environment Warning for misuse

Not indicated.

Other relevant information

Not indicated

Editorial information



This material safety data sheet has been prepared and checked by KemRisk®, KemRisk Sweden AB, Platensgatan 8, SE-582 20 Linköping, Sweden, <u>www.kemrisk.se</u>