

SAFETY DATA SHEET

In accordance with 1907/2006 Annex II (2015/830) and 1272/2008
(All references to EU regulations and directives are abbreviated into only the numeric term)

Issued 2017-01-12

Replaces issued SDS 2015-08-10

Version number 1.2



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

1.1. Product identifier

Trade name Prostatype® RT-qPCR kit

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 Chundsell Medicals AB

Industrivägen 19

SE-171 48 Solna

Sweden

Contact person

Rong Cao

Telephone

+46 (0) 704 32 6125

E-mail

rong.cao@chundsell.com

1.4. Emergency telephone number

Acute cases: Call 112, request poison information.

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

2.3. Other hazards

Not indicated.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

The product contains no substances, nor concentration levels thereof, that require marking or that need to be declared.

SECTION 4: First aid measures

4.1. Description of first aid measures

Generally

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

Upon breathing in

Not applicable.

Upon eye contact

Rinse eyes with plenty of water. If symptoms persist, seek medical advice.

Upon skin contact

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

Upon ingestion

Upon ingestion of larger amounts, consult a doctor/physician.

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

No further relevant information available.

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

No further relevant information is available.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Extinguish with materials intended for the surrounding fire.

5.2. Special hazards arising from the substance or mixture

The product is not hazardous in the flammable sense.

5.3. Advice for fire-fighters

In case of fire use a respirator mask.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes.

Use recommended safety equipment, see section 8.

Ensure good ventilation.

6.2. Environmental precautions

Avoid release of large quantities of undiluted product to drains.

6.3. Methods and material for containment and cleaning up

Wipe up and rinse area with water.

6.4. Reference to other sections

Not indicated.

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.

Read and follow the manufacturer's instructions.

Wash your hands after using the product.

The usual precautions for handling chemicals should be observed.

7.2. Conditions for safe storage, including any incompatibilities

Stored at -20°C.

Store tightly, in original packaging.

7.3. Specific end uses

Not relevant.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. National limit values

All ingredients (cf. Section 3) lack occupational exposure limit values.

DNEL

No data available.

PNEC

No data available.

8.2. Exposure controls

In terms of minimizing risks, no special attention is needed for this product besides the general obligations that follow EU directive 89/391 and national occupational legislation.

Eye/face protection

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

Skin protection

Special measures for protection of the skin are necessary only in rare working situations. In case of doubt, consult occupational expertise. Show this safety data sheet.

Normal working-clothes of cotton or synthetic material should be adequate. Clothing contaminated with this product should be washed immediately; avoid contact with the skin.

Protective gloves are normally not needed due to the properties of this product, but may be necessary for other reasons, e.g. mechanical risks, temperature conditions or microbiological risks.

Respiratory protection

Use proper protective breathing equipment in case of insufficient ventilation.

8.2.3. Environmental exposure controls

For limitation of environmental exposure, see Section 12.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

a) Appearance	Form: liquid.
b) Odour	Not indicated
c) Odour threshold	Not indicated
d) pH	Not indicated
e) Melting point/freezing point	Not indicated
f) Initial boiling point and boiling range	Not indicated
g) Flash point	Not indicated
h) Evaporation rate	Not indicated
i) Flammability (solid, gas)	Not applicable
j) Upper/lower flammability or explosive limits	Not indicated
k) Vapour pressure	Not indicated
l) Vapour density	Not indicated
m) Relative density	Not indicated
n) Solubility	Not indicated
o) Partition coefficient: n-octanol/water	Not applicable
p) Auto-ignition temperature	Not indicated
q) Decomposition temperature	Not indicated
r) Viscosity	Not indicated
s) Explosive properties	Not applicable
t) Oxidising properties	Not applicable

9.2. Other information

No data available

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 toxicological effects

Not indicated.

Acute toxicity

The criteria for classification cannot be considered fulfilled based on available data.

Skin corrosion/irritation

The criteria for classification cannot be considered fulfilled based on available data.

Serious eye damage/irritation

The criteria for classification cannot be considered fulfilled based on available data.

Respiratory or skin sensitisation

The criteria for classification cannot be considered fulfilled based on available data.

Germ cell mutagenicity

The criteria for classification cannot be considered fulfilled based on available data.

Carcinogenicity

The criteria for classification cannot be considered fulfilled based on available data.

Reproductive toxicity

The criteria for classification cannot be considered fulfilled based on available data.

STOT-single exposure

The criteria for classification cannot be considered fulfilled based on available data.

STOT-repeated exposure

The criteria for classification cannot be considered fulfilled based on available data.

Aspiration hazard

The criteria for classification cannot be considered fulfilled based on available data.

SECTION 12: Ecological information

12.1. Toxicity

The product is not to be labelled as an environmental hazard. However, it is not inconceivable that large emissions, or repeated small emissions, can have a harmful effect on the environment.

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

No chemical safety report has been executed.

12.6. Other adverse effects

Data lacking.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste handling of the product

The product is not classified as hazardous waste.

This product is not suited for recycling.

Also take local regulations for dealing with waste into account.

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

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. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

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

Assessment and chemical safety report in accordance with 1907/2006 Annex I has not yet been performed.

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

2015-08-10 Changes in section(s) 1, 4, 11.

16b. Legend to abbreviations and acronyms used in the safety data sheet

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 2017-01-12.

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 Annex II (2015/830)	COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
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
89/391	COUNCIL DIRECTIVE (89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work
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

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

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

This product is not expected to cause severe harm to humans or the environment. However the manufacturer, the distributor or the supplier cannot be responsible for unusual or criminal use of the product.

Other relevant information

Editorial information



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