



v 1.2 08-2023

Safety Data Sheet

according to 1907/2006/EC, Article 31

Printing date 03.06.2022 Revision: 08.08.2023

1 Identification of substance**Product details****Trade name:** PhoenixDx® SARS-CoV-2 Multiplex IVD, PhoenixDx® SARS-CoV-2 Multiplex RUO**Article number:** PCCSKU15263 (50 tests, IVD), PCCSKU15292 (500 tests, IVD), PCCSKU15262 (RUO)**Manufacturer/Supplier:**
PROCOMCURE Biotech GmbH
Breitwies 1
5303 Thalgau
Österreich
FN 289033z**2 Hazards identification****Hazard designation:** void**Information pertaining to particular dangers for man and environment:** void**Classification system:** The classification is in line with current EC lists. It is expanded, however, by information from technical literature and by information furnished by supplier companies.**3 Composition/information on ingredients****Chemical characterization****Description:** Aqueous enzyme solution**Dangerous components:**

CAS: 216699-35-3 5-Carboxy-X-rhodamine

Weight % < 0.1

Exposure Limit: None

4 First aid measures**General information:**

Remove contaminated clothing.

No special measures required.

After inhalation:

Supply fresh air; consult doctor in case of symptoms.

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After skin contact:

Instantly wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.

After eye contact:

Rinse opened eye for several minutes under running water.

After swallowing:

Do not induce vomiting; instantly call for medical help.

5 Firefighting measures**Suitable extinguishing agents:**

Extinguishing powder, foam or water jet. Fight larger fires with water jet or alcohol-resistant foam.

Special hazards caused by the material, its products of combustion or resulting gases:

Formation of toxic gases is possible during heating or in case of fire.

Protective equipment:

Wear self-contained breathing apparatus.

6 Accidental release measures**Person-related safety precautions:**

Observe information for safe handling (item 7) and personal protective equipment (item 8).

Measures for environmental protection:

Do not allow to enter drainage system, surface or ground water.

Inform respective authorities in case product reaches water or sewage system.

Measures for cleaning/collecting:

Send for recovery or disposal in suitable containers.

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).

7 Handling and storage**Handling****Information for safe handling:**

Store in cool, dry place in tightly closed containers.

Keep away from heat and direct sunlight.

Avoid contact with eyes and skin.

Information about protection against explosions and fires:

No special measures required.

Storage**Requirements to be met by storerooms and containers:**

Store only in the original container.

Prevent any penetration into the ground.

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Information about storage in one common storage facility:

Keep away from strong oxidizing, alkalis and acidic materials.

Further information about storage conditions:

Store in the dark. Protect from the effects of light.

8 Exposure controls and personal protection
Components with limit values that require monitoring at the workplace:
56-81-5 glycerol

 WEL Long-term value: 10 mg/m³
Additional information: The lists that were valid during the compilation were used as basis.

Personal protective equipment
General protective and hygienic measures

The usual precautionary measures should be adhered to general rules for handling chemicals.

Breathing equipment: Not required.

Protection of hands: Use gloves of stable material (i.e. nitrile rubber).

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable: Nitrile rubber, NBR

Eye protection: Safety glasses recommended during refilling.

Body protection: Wear suitable protective clothing.

9 Physical and chemical properties
General Information
Form: Liquid

Colour: Colourless

Odour: odourless

Change in condition
Melting point/Melting range: Not determined

Boiling point/Boiling range: > 100°C

Flash point: Not applicable

Self-inflammability: Product is not selfigniting.

Danger of explosion: Product is not explosive.

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Solubility in / Miscibility with Water: Fully miscible
pH-value at 20°C: ca. 8
Solvent content
Organic solvents: 0.0 %
Water: >90 %

10 Stability and reactivity

Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

Dangerous reactions: No dangerous reactions known

Dangerous products of decomposition:

None in case of intended use and storage in compliance with instructions.

11 Toxicological information

Acute toxicity

Primary irritant effect:

on the skin: No irritant effect.

on the eye: No irritant effect.

Sensitization: No sensitizing effect known.

Additional toxicological information: The product is not subject to classification according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version.

12 Ecological information

Information about elimination (persistence and degradability)

Other information: There are no data available about the preparation.

General notes: Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

13 Disposal considerations

Recommendation:

Disposal must be made according to official regulations.

Dispose of packaging according to regulations on the disposal of packaging.

Recommended cleaning agent: Water, if necessary with cleaning agent.

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14 Transport information

Land transport ADR/RID (cross-border)
ADR/RID-GGVSE Class: No hazardous good.
Maritime transport IMDG:
IMDG Class: No hazardous good.
Marine pollutant: No
Air transport ICAO-TI and IATA-DGR:
ICAO/IATA Class: Not Restricted.
Transport/Additional information: Not dangerous according to the above specifications.

15 Regulatory information

Designation according to EC guidelines:
Observe the normal safety regulations when handling chemicals.
The product is not subject to identification regulations under EC Directives and the Ordinance on Hazardous Materials.
National regulations
Technical instructions (air):

Class	Share in %
NK	25-50

Water hazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water.

16 Other information

This version replaces all previous versions. The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.