

SAFETY DATASHEET

CareStart™ Malaria Rapydtest®



This Safety Datasheet complies with the requirements of Regulation (EC) No 1907/2006

SECTION 1 IDENTIFICATION OF THE SUBSTANCE/ MIXTURE AND THE COMPANY/UNDERTAKING

1.1 Product Identifier: 1630 / 16305

CareStart™ Malaria Rapydtest®

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

TEST: Medical device for professional in vitro diagnostic use only. Use for detection of malaria HRP2 and pLDH in human blood.

BUFFER: For use only with the supplied CareStart™ Malaria Rapydtest®.

1.3 Details of the supplier of the Safety Data Sheet:

Apacor Limited, Unit 5 Sapphire Centre, Fishponds Road, Wokingham, Berkshire, RG41 2QL, England

+44 (0) 118 979 5566

technical@apacor.com

1.4 Emergency telephone number:

+44 (0)118 979 5566

(Monday-Friday 0900-1700 excluding UK Public Holidays)

SECTION 2 HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

No significant health effects are anticipated from using this product when used under normal operating conditions and in accordance with the kit specific instructions for use.

Although sodium azide is included as a preservative in the assay buffer solution, it is not considered as hazardous at this concentration (<0.1%) according to the latest edition of Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

Repeated or prolonged exposure is not known to aggravate any medical condition.

2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]: Non-hazardous

Eye Contact: Irritation. Tears.

Skin Contact: Irritation.

Ingestion: No known significant effect or critical hazard upon ingestion of assay buffer solution in the kit.

Inhalation: None known.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Hazard statement(s): -

Precautionary statements: -

2.3 Other hazards

No information available.

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous ingredients according to Regulation (EC) No 1272/2008

Component: Sodium Azide

CAS No: 26628-22-8

Concentration: <0.1%

Hazard statement: non-hazardous at this concentration

SECTION 4 FIRST AID MEASURES

4.1 Description of first aid measures

If inhaled: not applicable.

If in case of skin contact: wash off immediately with soap and plenty of water.

If in case of eye contact: rinse thoroughly with plenty of water for at least 15 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Consult a physician immediately.

If swallowed rinse mouth with water. Consult a physician immediately.

If symptoms persist, call a physician or poison control center.

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

Treat symptomatically.

SECTION 5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

No combustible materials are contained in this product.

5.2 Special hazards arising from the substance or mixture

None.

5.3 Advice for firefighters

Wear approved self-contained breathing apparatus for firefighting if necessary and full protective gear.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Prevent contact with skin, eyes and clothes. Use personal protective equipment. Ensure adequate ventilation

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Contain spillage, soak up with inert absorbent material then collect and place in container for disposal according to local regulations.

6.4 Reference to other sections

See Sections 8 and 13 as appropriate.

SECTION 7 HANDLING AND STORAGE

7.1 Precautions for safe handling

Follow Good Laboratory Practice, wear disposable gloves. Avoid contact and contamination with skin, eyes and clothes. Wash hands and any other exposed area with soap and water before eating, drinking, smoking, and leaving work place.

7.2 Conditions for safe storage, including any incompatibilities

Store at room temperature, not above 40°C and not below 1°C.

7.3 Specific end use(s)

No other specific uses are specified apart from those listed in Section 1.2.

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SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

No data available

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday. Specimen collection and preparation: all the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

8.2.2 Personal protective equipment

(a) Eye/face protection: Tightly fitting safety goggles.

Faceshield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

(b) Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves should satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

(c) Body Protection: The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

(d) Respiratory protection: no specific requirement when used under normal operating conditions.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Appearance Test: White solid reaction strip in a plastic cassette.

Buffer: brown liquid.

b) Odour No data available

c) Odour threshold Not applicable

d) pH Buffer: 9.2

e) Melting point / freezing point Not applicable

f) Initial boiling point and boiling range Buffer 100°C

g) Flash point Not applicable

h) Evaporation rate Not applicable

i) Flammability (solid, gas) Not applicable

j) Upper/lower flammability or explosive limits Not applicable

k) Vapour pressure Not applicable

l) Vapour density Not applicable

m) Relative density No data available

n) Solubility (ies) No data available

o) Partition coefficient: n-octanol/water No data available

p) Auto-ignition temperature Not applicable

q) Decomposition temperature Not applicable

r) Viscosity No data available

s) Explosive properties No risk

t) Oxidising properties Not applicable

9.2 Other information

No data available

SECTION 10 STABILITY AND REACTIVITY

10.1 Reactivity

Not applicable.

10.2 Chemical stability

Under storage at normal ambient temperatures the product is stable.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

None.

10.5 Incompatible materials

None.

10.6 Hazardous decomposition products

None.

SECTION 11 TOXICOLOGICAL INFORMATION

11.1 Information of toxicological effects

Acute toxicity: Product does not present an acute toxicity hazard based on known or supplied information.

Skin corrosion/irritation: irritation.

Serious eye damage/eye irritation: irritation.

Respiratory or skin sensitisation: no data available

Germ cell mutagenicity: no effects are known.

Carcinogenicity: no effects are known.

Reproductive toxicity: no effects are known.

Specific target organ toxicity - single exposure: no data available

Specific target organ toxicity - repeated exposure: no data available

Aspiration hazard: no data available

SECTION 12 ECOLOGICAL INFORMATION

12.1 Toxicity

No data available. The product should be discarded in a proper biohazard container after testing. Do not allow product to reach ground water, water bodies or sewage system.

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 Other adverse effects

No data available

12.7 Additional information

Do not allow to enter waters, drains or soil.

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SECTION 13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

This material is not regarded as hazardous waste.

Product: Dispose of in accordance with all federal, state, and local regulations.

Contaminated packaging: Dispose of as unused product.

Sodium azide (<0.1%) may react with lead or copper found in plumbing drains to form explosive compounds. Drain with copious amount of water to dilute solutions to prevent the buildup of shock sensitive compound.

SECTION 14 TRANSPORT INFORMATION

14.1 UN number: -

14.2 UN proper shipping name: Not dangerous goods.

14.3 Transport hazard class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user: -

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

Not intended to be transported in bulk.

SECTION 15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/ legislation specific for the substance or mixture

This product does not require special labelling, in accordance with the appropriate EC directives. This product is for in vitro diagnostic use therefore must comply with the European Directive 98/79/EC regarding bearing the CE label prior to placing on the market.

15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out for this product.

SECTION 16 OTHER INFORMATION

For professional in vitro diagnostic use only. Consult instructions for use.

References: Directives 1999/45/EC, 98/79/EC, 91/155/EC, 67/548/EEC

Amended sections are indicated by a line in the border.

The information supplied in this SDS is correct to the best of our knowledge. We do not accept any liability for loss, injury or damage, which may result from its use.