



Material Safety Data Sheet

Section 1: Identification of the Substance/Preparation and of the Company/Undertaking

Section 1.1 Product Identifier/Details of the Supplier

Product Name: OneStep HCV RapidCard InstaTest (Serum/Plasma/Whole Blood)
Part Number: 118773-1-44
Manufactured by: Diagnostic Automation/Cortez Diagnostics, Inc.
Street Address: 21250 Califa St. Suite 102 and 116,
City, State, Zip: Woodland Hills, CA 91367 USA
Telephone Number: 818-591-3030
Fax Number: 818-591-8383

Section 1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Rapid Test Kit for In Vitro Diagnostic

Section 1.3 Emergency Telephone Number

Contact the Regional Poison Control Center

Section 2: Hazards Identification

Section 2.1 Classification of the Substance or Mixture

Classification according to regulation (EC) No. 1272/2008 appendix VII: Not applicable
Chemical Ingredient Chemical Data / Information
Classification according to regulation 67/548/EEC or regulation 1999/45/EC: Not applicable

Section 2.2 Label Elements

Labelling according to regulation (EC) No. 1272/2008

The product does not need to be labelled in accordance with EC directives or respective national laws.

Hazard pictograms and Signal word: No

Hazardous components for labeling: No

Hazard statements: No

Precautionary statements: No

Section 2.3 Other Hazards

At this concentration, this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested (quantities above those found in the kit).. ProClin 300 is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals [H317].

Section 3: Composition/Information on Ingredients

Section 3.1 Substances

This product is a mixture

Section 3.2 Mixtures

Hazardous ingredients	CAS No.	EINECS No.	REACH Registration No.	Classification: Category Codes/ Hazard statement	W/W %
Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1)	55965-84-9	N/A	Not available	Acute Tox. 3: H301-H311-H331 Skin Corr. 1B: H314 Skin Sens. 1: H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	<0,001 %

Lowest generic cut-off value according to Table 1.1 Annex I: ≥ 0.1

Lowest specific concentration limits according to Table 3.1 Annex VI:

Skin Corr. 1B; H314 $C \geq 0.6 \%$

Skin Irrit. 2; H315: $0,06 \% \leq C < 0.6 \%$

Eye Irrit. 2; H319: $0,06 \% \leq C < 0.6 \%$

Skin Sens. 1; H317: $C \geq 0.0015 \%$

Section 4: First-Aid Measures

Section 4.1 Description of First Aid Measures

After inhalation	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is not a significant inhalation hazard in the kit volumes and concentrations present.
After skin contact	Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
After eye contact	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
After Ingestion	If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

Section 4.2 Most Important Symptoms and Effects, both Acute and Delayed

Not applicable.

Section 4.3 Indication of any Immediate Medical Attention and Special treatment needed

Not applicable.

Section 5: Fire-Fighting Measures

Section 5.1 Extinguishing Media

Suitable extinguishing media:

The common fire extinguish media can be used

Unsuitable extinguishing media:

Not investigate

Section 5.2 Special Hazards Arising from the Substance or Mixture

Not find yet

Section 5.3 Advice for Fire Fighters

Dry-chemical fire extinguisher

Section 6: Accidental Release Measures

Section 6.1 Personal Precautions, Protective Equipment and Emergency Procedures

Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.

Section 6.2 Environmental Precautions

Avoid release to the environment.

Section 6.3 Methods and Material for Containment and Cleaning Up

Clean up with broom.

Section 6.4 Reference to Other Sections

Collect material and dispose of waste according to section 13.

Section 7: Handling and Storage

Section 7.1 Precautions for Safe Handling

General hygiene measures: Do not eat, drink or smoke in the area where specimens and kits are handled. Wash hands after use.

Contaminated clothing and protective equipment must be removed before entering eating areas.

Section 7.2 Conditions for Safe Storage, Including any Incompatibilities

Information about storage conditions: Note the storage conditions on product packaging.

Requirements for storage rooms and containers: Store in a cool dry place.

Section 7.3 Specific End Uses

Rapid chromatographic immunoassay for the qualitative detection of antibody to HCV in human whole blood, serum or plasma specimen.

Section 8: Exposure Controls/Personal Protection

Section 8.1 Control Parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

Section 8.2 Exposure Control

Section 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.

Section 8.2.2 Personal Protective Equipment

<i>General protective and hygienic measures:</i>	Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work.
<i>Respiratory protection</i>	Not required
<i>Protective gloves</i>	Disposable gloves
<i>Material of gloves</i>	Latex/natural rubber
<i>Penetration time of glove material</i>	Gloves resistance is not critical when the product is handled according to the instruction for use.
<i>Eye Protection</i>	Safety glasses
<i>Body protection</i>	Lab coat

Section 8.2.3 Environmental Exposure Controls

There are no special precautions and measures. See section 6 and 7

Section 9: Physical and Chemical Properties

Section 9.1 Information on Basic Physical and Chemical Properties

Physical State:	Solid
Colour:	White appearance and some content of the test strip is purple
Odour:	tasteness
Odour threshold:	Not established
Flash point:	Not established
Self-igniting:	Product is not known to be self-igniting
Danger of explosion:	There is no substances in the kit could lead to the danger of explosion
Melting point:	Not established
Boiling point:	Not established
Vapour pressure:	Not established
Density (20°C):	Not established
pH-value at 20°C:	Not established
Solubility in water:	The product almost could not solute in the water

Section 9.2 Other Safety Information

No

Section 10: Stability and Reactivity

Section 10.1 Reactivity

The product is stable in accordance with the recommended storage conditions.

Section 10.2 Chemical Stability

All the chemicals in the test kits are stable.

Section 10.3 Possibility of Hazardous Reactions

Almost Impossible

Section 10.4 Conditions to Avoid

High humidity and the temperature out of 2-30°C



Section 10.5 Incompatible Materials

No

Section 10.6 Hazardous Decomposition Products

No

Section 11: Toxicological Information

Section 11.1 Information on Toxicological Effects (Mixture)

Acute toxicity:	Quantitative data on the toxic effects of this product is not available.
Irritation:	Irritating to skin and severely irritating or corrosive to eyes and, with greater exposures, can cause eye damage, including permanent impairment of vision or blindness.
Corrosivity:	Corrosive to eyes; with greater exposures may cause eye injury. Harmful if swallowed.
Sensitisation:	Contains a small volume of a very dilute, sensitizing preservative (ProClin™ 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.
Repeated dose toxicity:	Not yet investigate
Carcinogenicity:	Not yet investigate
Mutagenicity:	Not yet investigate
Toxicity for reproduction:	No reproductive toxic effect known.

Section 12: Ecological Information

Section 12.1 Toxicity

No data available

Section 12.2 Persistence and Degradability

No data available

Section 12.3 Bio accumulative Potential

No data available

Section 12.4 Mobility in Soil

No data available

Section 12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

Section 12.6 Other Adverse Effects

No data available

Section 13: Disposal Considerations

Section 13.1 Waste Treatment Methods

<i>Product:</i>	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
<i>European waste catalogue:</i>	18 01 03 wastes whose collection and disposal is subject to special requirements in order to prevent infection.
<i>Packaging:</i>	Disposal must be made in accordance with local waste management regulations. Contaminated packaging must be disposed of in the same manner as the product. Non-Contaminated packaging materials may be recycled. Contact your local service providers for further information.

Section 14: Transport Information

Section 14.1 UN Proper Shipping Name

ADR/RID: Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods

Section 14.2 Transport Hazard Class

ADR/RID: - IMDG: - IATA: -

Section 14.3 Packing Group

ADR/RID: - IMDG: - IATA: -

Section 14.4 Environmental Hazards

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: yes / no ✓
Marine Pollutant : yes / no ✓

Section 14.5 Special Precautions for User

See sections 6-8

Section 14.6 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code

Delivery will only be taken in suitable and regulatory approved packaging

Section 15: Regulatory Information

Section 15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

EU regulations: This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Section 15.2 Chemical Safety Assessment


The mixture was not subjected to security assessment

Section 16: Other Information

General information

The potential for adverse health effects is unknown for the highly diluted, small volume of ProClin 300 in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations [P501].

The information and recommendations presented in this MSDS are based on sources believed to be accurate. It is the user's responsibility to determine the suitability of the information for their particular purposes.

<p style="color: red; font-weight: bold;">ISO 13485 ISO 9001</p> 	
<p>Diagnostic Automation/Cortez Diagnostics, Inc. 21250 Califa Street, Suite 102 and 116, Woodland Hills, California 91367 USA</p>	
Date Adopted	2016-09-30
REF 118773-1-144	<p>OneStep HCV RapidCard InstaTest (Serum/Plasma/Whole Blood)</p>