

Doc. ID: SDS-004 EN

Revision: 00 Revision. date: May 3, 2019

SECTION 1. IDENTIFICATION

1.1 Product Identifier

| Product Name: | Other Means of Identification. Catalog #: | | |
|--------------------------------|---|--|--|
| CRYO <i>check™</i> C&S Diluent | CSD | | |

Product type: Liquid

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

Recommended Use: Medical device for in vitro diagnostic use

Restrictions on Use: For professional use only

1.3 Details of the Supplier of the Safety Data Sheet

Manufacturer Contact Information: Precision BioLogic Inc., 140 Eileen Stubbs Ave Dartmouth,

NS B3B 0A9, Canada

Email: techsupport@precisionbiologic.com

Precision BioLogic Inc. Telephone Number: 1-800-267-2796

1.4 Emergency Telephone Number

USA Poison Control: 1-800-222-1222

Canada Provincial Poison Control Centers: www.capcc.ca

EU National Helpdesks: https://echa.europa.eu/support/helpdesks



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SECTION 2. HAZARD IDENTIFICATION

2.3 Other Hazards not Otherwise Classified:

| 2.1 | Classification of the Mixture | | | | | |
|-----|---|---|---|--|--|--|
| | This product is classified according to Regulations (EC) No 1272/2008 and OSHA 29CFR 1910.1200 | | | | | |
| | Product definition: | Mixture | | | | |
| | Classification of the mixture: | Reproductive to | xicity (Category 1B), H360 | | | |
| 2.2 | 2 Label Elements: | | | | | |
| | Signal Word: | Danger | | | | |
| | Hazard statement: | H360: May damage fertility or the unborn child | | | | |
| | Adverse Human Health Effects and Symptoms: | Presumed human reproductive toxicant – largely based on animal evidence | | | | |
| | Pictograms: | | | | | |
| | Precautionary Statements: | | | | | |
| | | P201 | Obtain special instructions before use | | | |
| | Precautionary Statement Prevention: | P202 | Do not handle until all safety precautions have been read and understood. | | | |
| | | P280 | Wear protective gloves/ protective clothing/ eye protection/ face protection | | | |
| | Precautionary Statement Response: | P308 + P313 | IF exposed or concerned get medical advice/attention. | | | |
| | Precautionary Statement Storage: | P405 | Store in location with controlled access | | | |
| | Precautionary Statement Disposal: | P501 | Dispose of contents/container to a licensed disposal company | | | |
| | Precautionary Statement Prevention: Precautionary Statement Prevention: Precautionary Statement Response: Precautionary Statement Storage: | P202 P280 P308 + P313 P405 | Do not handle until all safety precautions have been read and understood. Wear protective gloves/ protectic clothing/ eye protection/ face protection IF exposed or concerned get meadvice/attention. Store in location with controlled access Dispose of contents/container to | | | |

Not known



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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance/Mixtures: Mixture

| Component Name | EC-No | CAS-No | Concentration | Classification |
|----------------|-----------|----------|--|--|
| Imidazole | 206-019-2 | 288-32-4 | 0.1 <c<1%< td=""><td>Acute toxicity, Oral (Category 4), H302 Skin corrosion (Category 1C), H314 Serious eye damage (Category 1), H318 Reproductive toxicity (Category 1B), H360</td></c<1%<> | Acute toxicity, Oral (Category 4), H302 Skin corrosion (Category 1C), H314 Serious eye damage (Category 1), H318 Reproductive toxicity (Category 1B), H360 |

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4. FIRST AID MEASURES

4.1 Description of First Aid Measures

If inhaled, move person to fresh air. Get medical attention if adverse Inhalation:

symptoms appear

Remove contaminated clothes and shoes. Wash affected area immediately Skin Contact:

with soap or mild detergent and plenty of water. Get medical attention if

symptoms occur

Rinse immediately with plenty of water. Keep eyelid open with fingers while Eye Contact:

rinsing. Check for and remove any contact lenses. Get medical attention if

irritation occurs

Rinse mouth with plenty of water provided person is conscious. Do not Ingestion:

induce vomiting. Get medical attention if symptoms occur

4.2 Most Important Symptoms and Effects, Acute and Delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3 Immediate Medical Attention and Special Treatment

Note to physician: In case of exposure, the symptoms might be delayed. The exposed person

may need to be kept under medical surveillance for 48 hours

No action shall be taken involving any personal risk or without suitable training



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SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media

Suitable Extinguishing Media: Product is non-flammable, low risk of fire by the inflammability

characteristics of the product in normal conditions of storage, manipulation and use. In the case of the existence of sustained combustion as a result of improper manipulation, storage or use any type of extinguishing agent

can be used

Unsuitable Extinguishing Media: Not applicable

5.2 Specific Hazards Arising from the substance or mixture

Specific hazards arising from the chemical/substance or mixture:

Due to its non-flammable nature, the product does not present a fire risk

under normal conditions of storage, manipulation and use

Hazardous thermal decomposition

products:

Thermal decomposition may generate toxic and hazardous fumes of

carbon oxides, nitrogen oxides, hydrogen cyanide

5.3 Special Protective Equipment and Precautions/Advice for Fire-Fighters

Protective actions: Isolate the scene by removing all persons from the vicinity of the incident if

there is fire. No action shall be taken involving any personal risk or without

suitable training

Equipment for self-protection: Depending on the magnitude of the fire it may be necessary to use full

protective clothing and individual respiratory equipment. Minimum

emergency facilities and equipment should be available.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment, and Emergency Procedures

For non-emergency personnel: Isolate leaks provided that there is no additional risk for the people

performing this task. Do not walk through spilled material. Put on

appropriate personal protective equipment

For emergency responders: Wear appropriate protective equipment (see Section 8). See also the

information in "For non-emergency personnel"

6.2 Environmental Precautions

Keep product away from drains, surface and underground water

6.3 Methods for Containment and Cleaning Up

Soak up with inert absorbent material, and clean with plenty of water. Collect spilled material in appropriate waste disposal container. Dispose of via a licenced waste disposal contractor

6.4 Reference to Other Sections

See Section 1 for emergency contact information

See Section 8 for information on appropriate personal protective equipment

See Section 13 for additional waste treatment information



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SECTION 7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling

Protective measures: Put on appropriate personal protective equipment (see Section 8)

Advice on general occupational hygiene: Do not eat, drink or smoke in areas where this mixture is handled, stored

> and processed. Wash hands with soap and water after handling the mixture and before eating, drinking or smoking. Remove contaminated clothing and protective equipment before entering eating areas. See Section 8 for additional information on hygiene measures

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Store at temperature indicated on the product label. Keep container tightly closed and sealed until ready for use. Avoid environmental release. Keep away from food and drinks. Store in accordance with local regulations

7.3 Specific End Uses

The product is intended for in vitro diagnostic use. Use the product in accordance with Good Laboratory Practice

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters: None

8.2 Exposure Controls: No exposure limit value known.

8.2.1 Appropriate Engineering Controls

Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

8.2.2 Individual Protection Measures

Skin Protection:

Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to Eye/Face Protection:

liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher

degree of protection: safety glasses with side-shields

Handle with chemical-resistant, impervious gloves complying with an

approved standard. 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

Based on the hazard and potential for exposure, select a respirator that Respiratory Protection:

meets the appropriate standard or certification

Personal protective equipment (PPE) should be selected based on the **Body Protection:**

task being performed and the risks involved

Appropriate footwear and any additional skin protection measures should Other skin protection:

be selected based on the task being performed and the risks involved

8.2.3 Environmental Exposure Controls Avoid any release into the environment



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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties

Physical state: Liquid Odor: Odorless

Odor Threshold: Not applicable

Color: Clear pH: Neutral

Melting point/freezing point: Not available Initial boiling point and boiling range: Not available

Flash point: Product does not sustain combustion

Evaporation rate: Not available Flammability: Not applicable

Upper/lower flammability or explosive

limits:

Relative Density:

Auto-ignition temperature:

Not applicable

Not applicable

Not applicable

Vapor Pressure: Not available

Vapor density: Not applicable

Solubility: Not applicable

Partition coefficient: n-octanol/water: Not applicable

Decomposition temperature: Not applicable

Viscosity: Not applicable

Explosive properties: Not applicable

Oxidizing properties: Not applicable

9.2 Other Information: Not applicable

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity

No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical Stability

Chemically stable under recommended conditions of storage, handling and use.

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Not available

10.3 Possibility of Hazardous Reactions

Under the normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to Avoid, Including Static Discharge, Shock or Vibration

Not available

Acute toxicity:

10.5 Incompatible Materials

Strong oxidizing agents.

10.6 Hazardous Decomposition Products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects

Skin corrosion/irritation: Not available Serious eve damage/irritation: Not available Respiratory or skin sensitization: Not available Not available Germ cell mutagenicity: Not available Carcinogenicity: Reproductive toxicity: Not available Summary of evaluation of the CMR properties: Not available Not available STOT-single exposure: STOT-repeated exposure: Not available Aspiration hazard: Not available Symptoms related to the physical, chemical and toxicological characteristics: No specific data Delayed and immediate effects, and chronic effects from short-term and long-term exposure: Not available Numerical measures of toxicity, including Acute Toxicity Estimates (ATEs): Not available Indication of whether the chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest editions) or found to Not applicable be a potential carcinogen by OSHA:

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity: Not available 12.2 Persistence and Degradability: Not available 12.3 Bioaccumulative Potential: Not available Not available 12.4 Mobility in Soil:



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12.5 Results of PBT and vPvB Assessment: Not applicable

12.6 Other Adverse Effects: No known significant effects or critical hazards.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Disposal Methods and Special Precautions for Product Disposal

The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licenced waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

13.2 Disposal Methods for Packaging

The generation of waste should be avoided or minimized wherever possible. Incineration or landfill should only be considered when recycling is not feasible.

Special Precautions

This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14. TRANSPORT INFORMATION

(ADR/RID, ADN, IMDG and ICAO, TDG&DOT Classification, IATA)

14.1 UN Number: Not regulated

14.2 UN Proper Shipping Name: Not applicable

14.3 Transport Hazard Class: Not applicable

14.4 Packing Group: Not applicable

14.5 Environmental Hazards: Not applicable

14.6 Additional Information: Not applicable

14.7 Special Precautions for User

Always transport in closed containers that are upright and secure. Transport within user premises:

Ensure that persons transporting the product know what to do in the

event of an accident or spillage.

14.8 Transport in Bulk According to Annex II of

MARPOL and the IBC Code:

Not applicable

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SECTION 15. REGULATORY INFORMATION

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

Canada Regulations and Lists:

NPRI: No components listed CEPA Toxic substances: No components listed

DSL/NDSL: All components are listed or exempt

US Regulations and Lists:

TSCA: All components are listed or exempt

SARA 302/304 and

SARA 311/312 Not a subject to reporting requirements

Massachusetts Sodium azide, CAS# 26628-22-8

New Jersey Imidazole, CAS# 288-32-4; Sodium azide, CAS# 26628-22-8 Pennsylvania Imidazole, CAS# 288-32-4; Sodium azide, CAS# 26628-22-8

California Prop. 65 No components listed

EU Regulations and Lists:

EU Regulation (EC) No.1907/2006 (REACH):

Annex XIV List of substances subject to
 No components listed

authorisation

Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances,

mixture and articles

Not applicable

C&L Inventory, REACH # All components are listed or exempt

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16. OTHER INFORMATION

Full text of H-Statements Referred to Under Section 2 and 3

H360: May damage fertility or the unborn child

Repr: Reproductive toxicity H302: Harmful if swallowed

H314: Causes severe skin burns and eye damage

H318: Causes serious eye damage

Key literature References and Sources for Data

This SDS was prepared on the basis of SDS of individual components and online databases (e.g. ECHA, RTECS) as well as our knowledge and experience, taking into account current legislation.

Procedure Used to Derive the Classification for Mixtures

(EU) Classification for mixtures according to Regulation (EC) 1272/2008 [CLP] Hazard Communication Standard, 29 CFR 1910.1200 (HCS) Hazardous Product Regulation HPR (WHMIS 2015)

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Training Advice

Provide workers with adequate training to assure that the product is handled safely in accordance with national and community legislation.

Abbreviations and Acronyms:

WHMIS=Workplace Hazardous Materials Information System

GHS=Globally Harmonized System of Classification and Labelling of Chemicals

OSHA=Occupational Safety and Health Administration

CLP= Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]

FDA=Food and Drug Administration

STOT=Specific Target Organ Toxicity

PBT=Persistent, Bioaccumulative and Toxic

vPvB= Very Persistent and very Bioaccumulative

ADR=European Agreement concerning the International Carriage of Dangerous Goods by Road

RID=European Agreement Concerning the International Carriage of Dangerous Goods by Rail

ADN=International Carriage of Dangerous Goods by Inland Waterways

IMDG=International Maritime Dangerous Goods

ICAO= International Civil Aviation Organization

TDG=Transportation of Dangerous Goods Act

DOT=Department of Transportation

UN=United Nations

IATA=International Air Transport Association

NPRI=National Pollutant Release Inventory

CEPA=Canadian Environmental Protection Act

DSL=Canada Domestic Substances List

NDSL= Canada Non-Domestic Substances List

TSCA=Toxic Substances Control Act

SARA=Superfund Amendments and Reauthorization Act

DEA Lists=United States Drug Enforcement Administration Lists

EPA=United States Environmental Protection Agency

REACH=Registration, Evaluation, Authorisation and Restriction of Chemicals

ECHA=European Chemical Agency

RTECS=Registry of Toxic Effects of Chemical Substances

Notice to Reader:

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Preparation Information

Precision Biologic Inc.

Revision History

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