SECTION 1. IDENTIFICATION

1.1 Product Identifier

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Other Means of Identification. Catalog #:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRYOcheck™ Normal Reference Plasma</td>
<td>CCNRP-05, CCNRP-10</td>
</tr>
<tr>
<td>CRYOcheck Reference Control Normal</td>
<td>RCN-05, RCN-10</td>
</tr>
<tr>
<td>CRYOcheck Abnormal 1 Reference Control</td>
<td>ARP1-05, ARP1-10</td>
</tr>
<tr>
<td>CRYOcheck Abnormal 2 Reference Control</td>
<td>ARP2-10</td>
</tr>
<tr>
<td>CRYOcheck Lupus Positive Control</td>
<td>CCLP-05, CCLP-10</td>
</tr>
<tr>
<td>CRYOcheck Weak Lupus Positive Control</td>
<td>CCWLP-05, CCWLP-10</td>
</tr>
<tr>
<td>CRYOcheck Low Fibrinogen Control</td>
<td>CCF-10</td>
</tr>
<tr>
<td>CRYOcheck Abnormal 1 Control</td>
<td>CCA1-10</td>
</tr>
<tr>
<td>CRYOcheck Abnormal 2 Control</td>
<td>CCA2-10</td>
</tr>
<tr>
<td>CRYOcheck Heparin Control</td>
<td>CCH-10</td>
</tr>
<tr>
<td>CRYOcheck APCR Positive Control</td>
<td>APCR-05</td>
</tr>
<tr>
<td>CRYOcheck Pooled Normal Plasma</td>
<td>CCN-10, CCN-10, CCN-15, CCN-40</td>
</tr>
<tr>
<td>CRYOcheck Factor 2 Deficient Plasma</td>
<td>FDP02-10, FDP02-15</td>
</tr>
<tr>
<td>CRYOcheck Factor 5 Deficient Plasma</td>
<td>FDP05-10, FDP05-15</td>
</tr>
<tr>
<td>CRYOcheck Factor 7 Deficient Plasma</td>
<td>FDP07-10, FDP07-15</td>
</tr>
<tr>
<td>CRYOcheck Factor 8 Deficient Plasma</td>
<td>FDP08-10, FDP08-15, FDP08-40</td>
</tr>
<tr>
<td>CRYOcheck Factor 9 Deficient Plasma</td>
<td>FDP09-10, FDP09-15</td>
</tr>
<tr>
<td>CRYOcheck Factor 10 Deficient Plasma</td>
<td>FDP10-10, FDP10-15</td>
</tr>
<tr>
<td>CRYOcheck Factor 11 Deficient Plasma</td>
<td>FDP11-10, FDP11-15</td>
</tr>
<tr>
<td>CRYOcheck Factor 12 Deficient Plasma</td>
<td>FDP12-10, FDP12-15</td>
</tr>
<tr>
<td>CRYOcheck Prekallikrein Deficient Plasma</td>
<td>FDPK-10</td>
</tr>
<tr>
<td>CRYOcheck Platelet Lysate</td>
<td>PNP-10</td>
</tr>
<tr>
<td>CRYOcheck Clot S , Protein S Deficient Plasma Component</td>
<td>CCS-15, PS Deficient Component, CCS-30, PS Deficient Component</td>
</tr>
<tr>
<td>CRYOcheck Clot C, Protein C Deficient Plasma Component</td>
<td>CCC-15, PC Deficient Component, CCC-30, PC Deficient Component</td>
</tr>
<tr>
<td>CRYOcheck Factor VIII Inhibitor Kit, Positive Control Component</td>
<td>CCIK8, Pos Control Component</td>
</tr>
<tr>
<td>CRYOcheck Factor VIII Inhibitor Kit, Negative Control Component</td>
<td>CCIK8, Neg Control Component</td>
</tr>
</tbody>
</table>

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
SECTION 2. HAZARD IDENTIFICATION

2.1 Classification of the mixture

This product is not hazardous according to Regulations (EC) No 1272/2008 and OSHA 29CFR 1910.1200

Product definition: Mixture
Classification of the mixture: Not classified

This product is classified according to Regulations (EC) No 1272/2008 [CLP/GHS], (US) OSHA Hazard classification of ingredients listed in section 3 in accordance with 29 CFR 1910.1200, and Hazardous Product Regulation HPR (WHMIS 2015)

2.2 Label Elements:

Signal Word: No signal words
Hazard statement: None
Others: Biohazard – Handle as if capable of transmitting infectious agents

Adverse Human Health Effects and Symptoms: No data available

Pictograms: None
Others: Biohazard labelling

Precautionary Statements: No data available

Other hazards not otherwise classified: Not known

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance/Mixtures: Mixture

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section

Occupational exposure limits, if available, are listed in Section 8
SECTION 4. FIRST AID MEASURES

4.1 Description of First Aid Measures

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

Skin Contact: Remove contaminated clothes and shoes. Wash affected area immediately with soap or mild detergent and plenty of water. Get medical attention if symptoms occur.

Eye Contact: Rinse immediately with plenty of water. Keep eyelid open with fingers while rinsing. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Ingestion: Rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Get medical attention if symptoms occur.

4.2 Most Important Symptoms and Effects, Acute and Delayed

No known significant effects or critical hazards.

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.

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 dioxide, carbon monoxide, and other organic compounds.

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

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

6.3 Methods for Containment and Cleaning Up

Pre-treat the spill with a disinfectant with full biocidal activity. Soak up with inert absorbent material, and clean with plenty of water. Collect spilled material in appropriate biohazard 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.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling

All blood products should be treated as potentially infectious. Human blood-based products should be handled and discarded as recommended for any potentially infectious human specimen.

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

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

Skin Protection: 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

Respiratory Protection: Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification

Body Protection: Personal protective equipment (PPE) should be selected based on the task being performed and the risks involved

Other skin protection: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved

8.2.3 Environmental Exposure Controls

Avoid any release into the environment

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties

Physical state: Liquid
Odor: Odorless
Odor Threshold: No applicable
Color: Yellowish
pH: Neutral pH
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
9.1 Information on Basic Physical and Chemical Properties

- Flammability: Not applicable
- Upper/lower flammability or explosive limits: Not applicable
- Vapor Pressure: Not available
- Vapor density: Not applicable
- Relative Density: Not applicable
- Solubility: Not applicable
- Partition coefficient: n-octanol/water: Not applicable
- Auto-ignition temperature: 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.

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 applicable

10.5 Incompatible Materials

Avoid strong acids, avoid alkalis or strong bases

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

Acute toxicity: Not available
Skin corrosion/irritation: Not available
Serious eye damage/irritation: Not available
Respiratory or skin sensitization: Not available
Germ cell mutagenicity: Not available
Carcinogenicity: Not available
Reproductive toxicity: Not available
Summary of evaluation of the CMR properties: Not available
STOT-single exposure: Not available
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 be a potential carcinogen by OSHA: Not found

SECTION 12. ECOLOGICAL INFORMATION

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

Special Precautions

The product is a human blood-based product and should be handled and discarded as recommended for any potentially infectious human specimen

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

14.6 Special Precautions for User

Transport within user premises: Always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage

Not a dangerous good. Biohazard labelling is applicable for transport

14.7 Transport in Bulk According to Annex II of MARPOL and the IBC Code: Not applicable
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 EPA List of Lists: Not applicable, no products were found
- Massachusetts: No components listed
- New Jersey: No components listed
- Pennsylvania: No components listed
- California Prop. 65: No components listed

EU Regulations and Lists:
  - Annex XIV List of substances subject to authorisation: No components listed
  - Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixture and articles: Not applicable
- C&L Inventory: All components are listed

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
Not applicable

Key literature References and Sources for Data
This SDS was prepared on the basis of sheets 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]
Hazardous Product Regulation HPR (WHMIS 2015)

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
- NPR=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**

<table>
<thead>
<tr>
<th>Revision</th>
<th>Revision Date</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>00</td>
<td>March 19, 2019</td>
<td>Not applicable</td>
</tr>
<tr>
<td>01</td>
<td>May 1, 2019</td>
<td>added PNP, Clot C and Clot S Deficient plasmas to sheet.</td>
</tr>
</tbody>
</table>