

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

1.1. Product Identifier

Product Name	Other Means of Identification (including GHS Product Identifier if applicable); Product Code
CRYOcheck™ Normal Reference Plasma	CCNRP-05, CCNRP-10
CRYOcheck Reference Control Normal	RCN-05, RCN-10
CRYOcheck Abnormal 1 Reference Control	ARP1-05, ARP1-10
CRYOcheck Abnormal 2 Reference Control	ARP2-10
CRYOcheck Lupus Positive Control	CCLP-05, CCLP-10
CRYOcheck Weak Lupus Positive Control	CCWLP-05, CCWLP-10
CRYOcheck Low Fibrinogen Control	CCLF-10
CRYOcheck Abnormal 1 Control	CCA1-10
CRYOcheck Abnormal 2 Control	CCA2-10
CRYOcheck Heparin Control	CCH-10
CRYOcheck APCR Positive Control	APCR-05
CRYOcheck Pooled Normal Plasma	CCN10-10, CCN-10, CCN-15, CCN-40
CRYOcheck Factor II Deficient Plasma	FDP02-10, FDP02-15
CRYOcheck Factor V Deficient Plasma	FDP05-10, FDP05-15
CRYOcheck Factor VII Deficient Plasma	FDP07-10, FDP07-15
CRYOcheck Factor VIII Deficient Plasma	FDP08-10, FDP08-15, FDP08-40
CRYOcheck Factor VIII Deficient Plasma with VWF	FDP08VWF-10, FDP08VWF-15
CRYOcheck Factor IX Deficient Plasma	FDP09-10, FDP09-15
CRYOcheck Factor X Deficient Plasma	FDP10-10, FDP10-15
CRYOcheck Factor XI Deficient Plasma	FDP11-10, FDP11-15
CRYOcheck Factor XII Deficient Plasma	FDP12-10, FDP12-15
CRYOcheck Prekallikrein Deficient Plasma	FDPK-10
CRYOcheck Platelet Lysate	PNP-10
CRYOcheck Clot C, Protein C Deficient Plasma Component	CCC-15, PCdP-15, CCC-30, PCdP-30
CRYOcheck Factor VIII Inhibitor Kit, Positive Control Component	CCIK08, POS
CRYOcheck Factor VIII Inhibitor Kit, Negative Control Component	CCIK08, NEG
CRYOcheck Lupus Negative Control	CCLN-05, CCLN-10

Unique Formula Identifier (UFI) Not applicable

Nanoform The product does not contain nanoparticles.

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

Identified Use(s) Medical device or components of medical devices for in vitro diagnostic use.

Restrictions on Use For Professional Use Only

1.3. Details of the supplier of the safety data sheet

Company Identification	Precision BioLogic Inc. 140 Eileen Stubbs Ave Dartmouth, NS B3B 0A9 Canada
Telephone	1-800-267-2796
E-mail (competent person)	techsupport@precisionbiologic.com

Distributors

Company Identification	Alpha Laboratories 40 Parham Drive Eastleigh Hampshire SO50 4NU United Kingdom
Telephone	+44 2380 487212
E-mail (competent person)	export@alphalabs.co.uk

Company Identification	CoaChrom Diagnostica Hauptstraße 5 2344 Maria Enzersdorf Austria
Telephone	+43 1 236 222 1
E-mail (competent person)	info@coachrom.com

Company Identification	Cryopep 83 rue Yves Montand – Parc 2000 34080 Montpellier France
Telephone	+33 (0)4 67 10 71 20
E-mail (competent person)	contact@cryopep.com

Company Identification	ELITech Group 65 Mills Road Braeside, VIC, 3195 Australia
Telephone	+61 2 9894 6988
E-mail (competent person)	elitechaustralia@elitechgroup.com

Company Identification	Endotell AG Gewerbstrasse 25 4123 Allschwil Switzerland
Telephone	+41 61 482 20 70

E-mail (competent person) info@endotell.ch

Company Identification Fannin
 Fannin House
 South County Business Park
 Leopardstown
 Dublin 18
 Ireland

Telephone +353 1 290 7000

E-mail (competent person) enquiries@fannin.eu

Company Identification MoreBio Inc.
 #F810, Testa Tower, 25, Misagangbyeonse-ro
 Hanam-si, Gyeonggi-do
 Republic of Korea, 12918

Telephone +82 02 406 2942

E-mail (competent person) info@morebio.co.kr

Company Identification Tokyo Future Style, Inc.
 TCI A-13, 1-6, Sengen 2-Chome
 Tsukuba City, Ibaraki
 Japan, 305 – 0047

Telephone +81 29 851 9222

E-mail (competent person) info@tokyofuturestyle.com

1.4. Emergency Telephone Number

Alpha Laboratories

Emergency Telephone +44 2380 487212 Monday to Friday, 9am-5pm
 (Office hours)

Language(s) Spoken English

CoaChrom Diagnostica

Emergency Telephone +43 1 236 222 1 Monday to Friday, 8am-5pm
 (Office hours)

Language(s) Spoken German, English, Danish, Swedish, Spanish, Italian,
 Hungarian

Cryopep

Emergency Telephone +33 (0)4 67 10 71 20 Monday to Friday, 8am-5pm
 (Office hours)

Language(s) Spoken French, English, Dutch

ELITech Group

Emergency Telephone +61 2 9894 6988 Monday to Friday, 8am-5pm
 (Office hours)

Language(s) Spoken English

Endotell AG

Emergency Telephone	+41 61 482 20 70	Monday to Friday, 8am-5pm (Office hours)
Language(s) Spoken	French, German, English, Italian	

Fannin

Emergency Telephone	+353 1 290 7000	Monday to Friday, 9am-5pm (Office hours)
Language(s) Spoken	English	

MoreBio Inc.

Emergency Telephone	+82 02 406 2942	Monday to Friday, 9am-5pm (Office hours)
Language(s) Spoken	Korean, English	

Tokyo Future Style, Inc.

Emergency Telephone	+81 29 851 9222	Monday to Friday, 9am-5pm (Office hours)
Language(s) Spoken	Japanese, English	

SECTION 2: HAZARD IDENTIFICATION**2.1. Classification of the substance or mixture**

These products are classified as not hazardous, according to Regulations (EC) No 1272/2008 [CLP/GHS], (US) 29 CFR 1910.1200, and Hazardous Product Regulation HPR (WHMIS 2015).

2.2. Label Elements

Contains	Not applicable
Hazard Pictogram(s)	None
Signal Word(s)	None assigned
Hazard Statement(s)	None assigned
Precautionary Statements	None assigned
Supplemental Information	Not applicable

2.3. Other hazards which do not result in classification

These products contain human plasma or platelets. All blood products should be treated as potentially infectious. Source material used in these products was found to be negative when tested in accordance with current required tests for transfusion-transmitted diseases. No known test methods can offer complete assurance that products derived from human blood will not transmit infectious agents. Accordingly, any human blood-based component should be handled and discarded as recommended for any potentially infectious human specimen.

SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS**3.1. Substances**

Not applicable

3.2. 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.



SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Self-protection of the first aider	No action should be taken involving personal risk. Use personal protective equipment as required. Ensure adequate ventilation. Avoid breathing vapours. Avoid contact with skin, eyes or clothing. Remove contaminated clothing and wash it before reuse.
Inhalation	IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a doctor if you feel unwell.
Skin Contact	IF ON SKIN: Wash with plenty of water and soap. If irritation (redness, rash, blistering) develops, get medical attention.
Eye Contact	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If symptoms persist, obtain medical attention.
Ingestion	IF SWALLOWED: Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Immediately call a doctor.

4.2. Most important symptoms and effects, both acute and delayed

The product contains human plasma and is therefore a potential biohazard.

4.3. Indication of any immediate medical attention

Treat symptomatically.

SECTION 5: FIRE FIGHTING MEASURES

5.1. Extinguishing Media

Suitable extinguishing media	Not flammable. Use fire-extinguishing media appropriate for surrounding materials.
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Unsuitable extinguishing media

Do not use water jet. Direct water jet may spread the fire.

5.2. Specific hazards arising from the substance or mixture

In case of fire may be liberated: Oxides of carbon and other organic compounds.

5.3. Special protective actions for fire-fighters

Fight fire with normal precautions from a reasonable distance. Evacuate area. Remove persons to safety. Fire fighters should wear complete protective clothing including self-contained breathing apparatus. Use water spray jet to protect personnel and to cool endangered containers. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

No action should be taken involving personal risk. Do not eat, drink or smoke when using this product. Use good personal hygiene practices. Ensure adequate ventilation. Avoid breathing vapours. Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Remove contaminated clothing and wash it before reuse.

For emergency responders

Wear appropriate protective equipment (see Section 8).

6.2. Environmental Precautions

Avoid release to the environment. Do not allow to enter drains, sewers or watercourses.

6.3. Methods and material containment

Contain spillages with sand, earth or any suitable adsorbent material. Transfer to a lidded container for disposal or recovery. Wash away spilled liquid (remainder) with plenty of water. Dispose of waste according to applicable legislation.

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

Do not eat, drink or smoke when using this product. Use personal protective equipment as required. Ensure adequate ventilation. Avoid breathing vapours. Avoid contact with skin, eyes or clothing. Remove contaminated clothing and wash it before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. Keep containers tightly closed. Keep container in an upright position. Keep in a cool, dry place. Keep away from food, drink and animal feeding stuffs.

Storage temperature	Store at temperature indicated on the product label.
Incompatible materials	Keep away from: strong acids, strong bases, alkalis.

7.3. **Specific end use(s)** See Section 1.2.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

8.1. Control Parameters

Occupational exposure limits	None
Biological limit value	Not established
PNECs and DNELs	Not established

8.2. Exposure Controls

Appropriate engineering controls	Ensure adequate ventilation. Store in a cool/low-temperature, well-ventilated (dry) place away from heat and ignition sources.
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Individual protection measures, such as personal protective equipment	Do not eat, drink or smoke when using this product. Use personal protective equipment as required. Keep good industrial hygiene. Wash hands and exposed skin thoroughly after handling. Use personal protective equipment as required. Avoid breathing vapors. Avoid contact with skin, eyes or clothing. Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier
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Eye / face protection



Wear eye protection with side protection (EN 166). Eyewash bottles / station should be available.

Skin protection



Hand protection

Wear impervious gloves (EN 374).

Use cryogenic gloves when handling product in frozen state.

Body protection

Wear suitable protective clothing. Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved.

Respiratory protection

Respiratory protection is not necessary if room is well ventilated. In case of inadequate ventilation wear respiratory protection.



Thermal hazards	None known
Environmental exposure controls	Avoid release to the environment. Do not allow to enter drains, sewers or watercourses.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties**

Physical state	Liquid (or frozen liquid)
Color	Clear straw / light straw
Odor	Odorless
Melting point/freezing point	Not established
Boiling point or initial boiling point and boiling range	Not established
Flammability	Not established
Lower and upper explosion limit	Not established
Flash point	Product does not sustain combustion
Auto-ignition temperature	Not established
Decomposition temperature	Not established
pH	Neutral
Kinematic viscosity	Not established
Solubility	Not established
Partition coefficient: n-octanol/water (log value)	Not established
Vapour pressure	Not established
Density and/or relative density	Not established
Relative vapour density	Not established
Particle characteristics	Not established

9.2. Other Information None known

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity Stable under normal conditions.

10.2. Chemical stability	Stable under normal conditions.
10.3. Possibility of hazardous reactions	None anticipated
10.4. Conditions to avoid	Keep away from food, drink and animal feeding materials.
10.5. Incompatible materials	Keep away from: strong acids, strong bases, alkalis.
10.6. Hazardous decomposition products	In case of fire may be liberated. Oxides of carbon and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION**11.1. Information on hazard classes / toxicological health effects**

Acute toxicity – Ingestion	Based upon the available data, the classification criteria are not met. Acute Toxicity Estimate Mixture Calculation: LD50 >2000 mg/kg bw
Acute toxicity – Inhalation	Based upon the available data, the classification criteria are not met. Acute Toxicity Estimate Mixture Calculation: LC50 >20 mg/L (vapors)
Acute toxicity – Skin contact	Based upon the available data, the classification criteria are not met. Acute Toxicity Estimate Mixture Calculation: LD50 >2000 mg/kg bw
Skin corrosion / irritation	Based upon the available data, the classification criteria are not met.
Serious eye damage / irritation	Based upon the available data, the classification criteria are not met.
Respiratory or skin sensitization	Based upon the available data, the classification criteria are not met.
Germ cell mutagenicity	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Reproductive toxicity	Based upon the available data, the classification criteria are not met.
STOT – Single exposure	Based upon the available data, the classification criteria are not met.

STOT – Repeated exposure Based upon the available data, the classification criteria are not met.

Aspiration hazard Based upon the available data, the classification criteria are not met.

11.2. Information on other hazards / likely routes of exposure

Endocrine disrupting properties This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets this criterion.

11.3. Symptoms related to the physical, chemical and toxic characteristics No specific data

11.4. Delayed and immediate effects and also chronic effects from short- and long-term exposure Not available

11.5. Numerical measures of toxicity, including acute toxicity estimate (ATE) Not available

11.6. Interactive effects Not available

11.7. Mixtures Not applicable

11.8. Mixtures and ingredient info Not applicable

11.9. Listed on National Toxicology Program (NTP) Report on Carcinogens or International Agency for Research on Cancer (IARC) Monographs or by OSHA Not found

SECTION 12: ECOLOGICAL INFORMATION

12.1. Ecotoxicity Based upon the available data, the classification criteria are not met.

12.2. Persistence and degradability No data available

12.3. Bio-accumulative 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. Endocrine disruption properties This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no component meets the criteria.

12.7. Other adverse effects None known

SECTION 13: DISPOSAL CONSIDERATIONS**13.1. Disposal methods, including wastewater treatment**

Waste treatment method	Do not allow to enter surface water or drains. Dispose of contents/container to an appropriate recycling or disposal facility. Disposal should be in accordance with local, state or national legislation. The product contains human plasma. Any human blood-based component should be handled and discarded as recommended for any potentially infectious human specimen.
Product disposal	The generation of waste should be avoided or minimized wherever possible. Dispose of surplus and non-recyclable products via a licensed 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.

SECTION 14: TRANSPORT INFORMATION

Not classified according to the United Nations' 'Recommendations on the Transport of Dangerous Goods'.

	ADR/RID	ADN	IMDG	IATA/ICAO
14.1. UN number or ID number	None assigned	None assigned	None assigned	None assigned
14.2. UN proper shipping name	None assigned	None assigned	None assigned	None assigned
14.3. Transport hazard class(es)	None assigned	None assigned	None assigned	None assigned
14.4. Packing group	None assigned	None assigned	None assigned	None assigned
14.5. Environmental hazards	Not classified	Not classified	Not classified as a marine pollutant	Not classified
14.6. Special precautions for user	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.			
14.7. Maritime transport in bulk according to IMO instruments	Not applicable			
14.8. Additional information	Product is shipped on dry ice.			

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 applicable, no products were found
EPA List of Lists	
Massachusetts	No components listed
New Jersey	No components listed
Pennsylvania	No components listed
California Prop. 65	No components listed

EU Regulations

EU Regulation (EC) No. 1907/2006 (REACH)	
Authorisations and/or restrictions on use	Not restricted
CoRAP Substance Evaluation	None listed
EUON - Nanomaterials Currently on the EU Market	Not applicable
To follow:	Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work.
EU National regulations	
Germany	
Water hazard class (WGK)	Water hazard class: non-hazardous to water (nwg) (self-classification).

UK Regulations and Lists

UK Regulation 2021 No. 904 (REACH)	
Control of Substances Hazardous to Health Regulations (COSHH) 2002	No components listed

15.2. Chemical Safety Assessment

A REACH chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION**References**

EU Classification: This Safety Data Sheet was prepared in accordance with EC Regulation (EC) 1907/2006 (REACH), 1272/2008 (CLP) & 2020/878

Hazard Communication Standard, 29 CFR 1910.1200 (HCS)

Hazardous Product Regulation HPR (WHMIS 2015)

Canada SOR-2015-17

Globally Harmonized System of Classification and Labelling of Chemicals (GHS 7th Revised Edition, Annex 4)

Legend

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CAS	Chemical Abstracts Service
CEPA	Canadian Environmental Protection Act
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DNEL	Derived no effect level
DOT	Department of Transportation
DSL	Canada Domestic Substance List
EC	European Community
ECHA	European Chemicals Agency
EN	European Standard
EU	European Union
EPA	United States Environmental Protection Agency
FDA	Food and Drug Administration
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HSE	Health and Safety Executive
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
LC50	Lethal concentration at which 50% of the population is killed
NDSL	Canada Non-Domestic Substances List
NPRI	National Pollutant Release Inventory
OECD	Organisation for Economic Cooperation and Development
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No Effect Concentration
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STOT	Specific Target Organ Toxicity
TDG	Transportation of Dangerous Goods Act
TSCA	Toxic Substances Control Act
vPvB	very Persistent and very Bioaccumulative
UN	United Nations

WHMIS Workplace Hazardous Materials Information System

Training advice: Consideration should be given to the work procedures involved and the potential extent of exposure as they may determine whether a higher level of protection is required.

Disclaimers

Information contained in this publication or as otherwise supplied to Users is believed to be accurate and is given in good faith, but it is for the Users to satisfy themselves of the suitability of the product for their own particular purpose. Precision BioLogic Inc. gives no warranty as to the fitness of the product for any particular purpose and any implied warranty or condition (statutory or otherwise) is excluded except to the extent that exclusion is prevented by law. Precision BioLogic Inc. accepts no liability for loss or damage (other than that arising from death or personal injury caused by defective product, if proved), resulting from reliance on this information. Freedom under Patents, Copyright and Designs cannot be assumed.

Preparation Information

Precision BioLogic Inc.

Revision History

Revision Number	Revision Date	Description of Changes Made
Revision 00	Revision Date: March 19, 2019	Changes: Not applicable.
Revision 01	Revision Date: May 1, 2019	Changes: Added PNP and added Clot C and Clot S deficient plasma components.
Revision 02	Revision Date: April 27, 2020	Changes: Added Lupus Negative Control; clarifications.
Revision 03	Revision Date: August 20, 2021	Changes: Added Factor VIII Deficient Plasma with VWF.
Revision 04	Revision Date: April 18, 2022	Changes: Corrected typographical error (updated CCIK8 to CCIK08 and CCN-10-10 to CCN10-10).
Revision 05	Revision Date: Sept 27, 2023	Changes: Updated Emergency Contact Information.
Revision 06	Revision Date: June 14, 2024	Changes: Updated to harmonize translated versions; typographical corrections.
Revision 07	Revision Date: 22 September 2025	Changes: Decommission Clot S and move to new template