

| Product Name: | Other Means of Identification. Catalog #: |
|----------------------------|---|
| CRYO <i>check</i> ™ Hex LA | HEXLA, HEXLA7 |

| Product Manufacturer: | |
|---|---|
| Precision BioLogic 140 Eileen Stubbs Avenue Dartmouth, NS B3B 0A9 Canada | Phone: +1.902.468.6422 Toll-free in US and CA: +1.800.267.2796 Fax: +1.902.468.6421 Toll-free in US and CA: +1.800.267.0796 www.precisionbiologic.com |

CRYOcheck Hex LA consists of three components. This Safety Data Sheet contains information for each component of CRYOcheck Hex LA listed in the table below.

| cryo <i>check</i> Hex LA Component | Component Type | Kit Configuration | Mixture Classification According to 1272/2008/EC Regulation | Mixture Classification According to OSHA hazard classification in accordance with 29 CFR 1910.1200, and Hazardous Product Regulation HPR (WHMIS 2015) | Page Reference |
|--|-------------------|---|---|---|-------------------|
| LA Start | Mixture | 2 x 1.5 mL | Not classified | Not classified | Page 2 |
| LA Correct | Mixture | 2 x 1.5 mL | Not classified | Not classified | Page 2 |
| LA APTT | Mixture | 2 x 3.0 mL (HEXLA) 3 x 3.0 mL (HEXLA7) | Not classified | Not classified | Page 11 |



SECTION 1. IDENTIFICATION

1.1 Product Identifier

| | Product Name: | Other Means of Identification. Lot # Format: |
|-----|--|---|
| | CRYO <i>check</i> Hex LA: LA Start | HXXX-ST |
| | CRYO <i>check</i> Hex LA: LA Correct | HXXX-CT |
| I | Product type: | Liquid |
| 1.2 | Relevant Identified Uses of the Substance or Mixture and | d Uses Advised Against |
| I | Recommended Use: | For use with the other components of CRYO <i>check</i> Hex LA. CRYO <i>check</i> Hex LA is a medical device for in vitro diagnostic use |
| F | Restrictions on Use: | For professional use only |
| 1.3 | Details of the Supplier of the Safety Data Sheet | |
| I | Manufacturer Contact Information: | Precision BioLogic Inc., 140 Eileen Stubbs Ave, Dartmouth, NS B3B 0A9, Canada |
| I | Email: | techsupport@precisionbiologic.com |
| F | Precision BioLogic Inc. Telephone Number: | <u>1-800-267-2796</u> |
| 1.4 | Emergency Telephone Number | |
| I | USA Poison Control: | 1-800-222-1222 |
| (| Canada Provincial Poison Control Centers: | www.capcc.ca |
| I | 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:

2.3

| Signal Word: | No signal words |
|--|-------------------|
| Hazard statement: | None |
| Adverse Human Health Effects and Symptoms: | No data available |
| Pictograms: | None |
| Precautionary Statements: | No data available |
| Other hazards not otherwise classified: | Not known |

LA Start and LA Correct contain human plasma. Source plasma used in these products was found to be negative when



tested in accordance with current FDA required tests for communicable disease. However, 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. 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

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: | Products are non-flammable, low risk of fire by the inflammability characteristics of the products 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, these products do 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 if 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

These products are 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 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 these mixtures are handled, stored and processed. Wash hands with soap and water after handling the mixtures and before eating, drinking or smoking. Remove contaminated |

PrecisionBioLogic Safety Data Sheet

Doc. ID: SDS-009 EN Revision: 01 Revision date: April 27, 2020

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 products are for use with the other components of CRYOcheck Hex LA. CRYOcheck Hex LA is a medical device for in vitro diagnostic use. Use in accordance with Good Laboratory Practice.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

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.

None

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: | Respiratory protection is not required. |
| 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 |



9.1 Information on Basic Physical and Chemical Properties

| | Odor Threshold: | Not applicable |
|-------|---|--|
| | Color: | LA Start: Clear, straw color LA Correct: Milky, light straw color |
| | pH: | Neutral pH |
| | Melting point/freezing point: | Not available |
| | Initial boiling point and boiling range: | Not available |
| | Flash point: | Products do not sustain combustion |
| | Evaporation rate: | Not available |
| | 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 these products or their 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



Not available

Not available

Not applicable

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:

12.4 Mobility in Soil:

12.5 Results of PBT and vPvB Assessment:



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 these products, 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 products are human blood-based 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

14.7 Transport in Bulk According to Annex Not applicable II of MARPOL and the IBC Code: Not applicable

Safety Data Sheet

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: | |
| EU Regulation (EC) No.1907/2006 (REACH): | |
| 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] Hazard Communication Standard, 29 CFR 1910.1200 (HCS) Hazardous Product Regulation HPR (WHMIS 2015)

Training Advice

Safety Data Sheet

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

| Revision: 00 | Revision Date: January 15, 2020 | Changes: Not applicable |
|--------------|---------------------------------|--------------------------------|
| Revision:01 | Revision Date: April 27, 2020 | Changes: Revisions for clarity |



SECTION 1. IDENTIFICATION

1.1 Product Identifier

| | Product Name: | Other Means of Identification. Lot# Format: |
|---|--|---|
| | CRYO check Hex LA: LA APTT | HXXX-AP |
| F | Product type: | Liquid |
| 1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against | | |
| F | Recommended Use: | For use with the other components of CRYO <i>check</i> Hex LA. CRYO <i>check</i> Hex LA is a medical device for in vitro diagnostic use |
| F | Restrictions on Use: | For professional use only |
| 1.3 | Details of the Supplier of the Safety Data Sheet | |
| P | Manufacturer Contact Information: | Precision BioLogic Inc., 140 Eileen Stubbs Ave. Dartmouth, NS B3B 0A9, Canada |
| E | Email: | techsupport@precisionbiologic.com |
| F | Precision BioLogic Inc. Telephone Number: | <u>1-800-267-2796</u> |
| 1.4 | Emergency Telephone Number | |
| ι | JSA Poison Control: | 1-800-222-1222 |
| (| Canada Provincial Poison Control Centers: | www.capcc.ca |
| E | 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 |
| Adverse Human Health Effects and Symptoms: | No data available |
| Pictograms: | None |
| Precautionary Statements: | No data available |

2.3 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: | Symp | tomatic treatment |
|--------------------|------|-------------------|
|--------------------|------|-------------------|

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 | Due to its non-flammable nature, the product does not present a fire risk |
|-----------------------------------|---|
| chemical/substance or mixture: | under normal conditions of storage, manipulation and use |

PrecisionBioLogic Safety Data Sheet

Doc. ID: SDS-009 EN Revision: 01 Revision date: April 27, 2020

| 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 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

| 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



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For use with the other components of CRYOcheck Hex LA. CRYOcheck Hex LA is a medical device for in vitro diagnostic use. Use in accordance with Good Laboratory Practice.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

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.

None

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8.2.2 Individual Protection Measures

| Eye/Face Protection: | 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: | Respiratory protection is not required. |
| 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 |

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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: | White, turbid |
| pH: | Neutral pH |
| Melting point/freezing point: | Not available |
| Initial boiling point and boiling range: | Not available |



9.1 Information on Basic Physical and Chemical Properties

| | Flash point: | Product does not sustain combustion |
|-------|---|-------------------------------------|
| | Evaporation rate: | Not available |
| | 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



Not applicable

No known significant effects or critical hazards.

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:

12.6 Other Adverse Effects:



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 |
| 14.6 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 |

14.7 Transport in Bulk According to Annex II of MARPOL and the IBC Code:

Not applicable

accident or spillage

Safety Data Sheet

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: | | |
| EU Regulation (EC) No.1907/2006 (REACH): | | |
| 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] Hazard Communication Standard, 29 CFR 1910.1200 (HCS) Hazardous Product Regulation HPR (WHMIS 2015)

Training Advice

Safety Data Sheet

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

| Revision: 00 | Revision Date: January 17, 2020 | Changes: Not applicable |
|--------------|---------------------------------|------------------------------|
| Revision: 01 | Revision Date: April 27, 2020 | Changes: Updates for clarity |