

## Procleix Positive & Negative External Controls

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier Product Identifier

**Product Name** Procleix Positive & Negative External Controls

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

**Specific use(s)** Procleix Babesia Assay

**Recommended Use** For Investigational Use/Performance Evaluation Only

#### 1.3. Details of the supplier of the safety data sheet Details of the supplier of the safety data sheet

**Manufacturer Address** Hologic, Inc.  
10210 Genetic Center Drive  
San Diego, CA 92121-4362

**Australian Supplier** Hologic (Australia) Pty Ltd  
Suite 402, Level 4  
2 Lyon Park Road  
North Ryde NSW 2113  
+61 2 9888 8000

**New Zealand Supplier** Pharmaco (NZ) Ltd.  
4 Fisher Crescent, Mount Wellington  
Auckland, New Zealand  
+64 9 377 3336

#### 1.4. Emergency telephone number

**Emergency Telephone - Australia  
- New Zealand**

**24 Hour Emergency Phone Number** Chemtrec, Australia (Sydney) +(61)-290372994, Chemtrec, New Zealand (Auckland)  
+(64)-98010034, Chemtrec International + 1-703-741-5970

**For further information, please contact:** MolecularSupport@hologic.com

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

*Regulation (EC) No 1272/2008*

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [GHS].

**Classification according to Directive 67/548/EEC or 1999/45/EC**

*Full text of R-phrases: see section 16*

#### Hazard symbols

Not dangerous

#### 2.2. Label elements

##### **Product Identifier**

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [GHS].

##### **Signal word**

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None

### 2.3. Other hazards

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Not applicable.

### 3.2 Mixtures

Mixtures

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

<b>Eye contact</b>	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. If symptoms persist, call a physician.
<b>Skin Contact</b>	If symptoms persist, call a physician. Wash skin with soap and water.
<b>Ingestion</b>	If symptoms persist, call a physician. Clean mouth with water and drink afterwards plenty of water.
<b>Inhalation</b>	Remove to fresh air. If symptoms persist, call a physician.

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

**Symptoms** None known.

### 4.3. Indication of any immediate medical attention and special treatment needed

**Note to physicians** Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Use extinguishing agent suitable for type of surrounding fire.

### 5.2. Special hazards arising from the substance or mixture

**Special Hazard** None known based on information supplied.

### 5.3. Advice for firefighters

**Special protective equipment for fire-fighters** As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** Use personal protective equipment as required.

### 6.2. Environmental precautions

**Environmental precautions** See Section 12 for additional ecological information.

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Cover with absorbent or contain.

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**Methods for cleaning up** Soak up with inert absorbent material. Dispose of contents/containers in accordance with local regulations.

### 6.4. Reference to other sections

**Reference to other sections** See Section 12: Ecological Information.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

**Precautions for safe handling** No known effects under normal use conditions.

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Wash hands thoroughly after handling. Use personal protection recommended in Section 8.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store in accordance with local regulations. Use appropriate containment to avoid environmental contamination.

### 7.3. Specific end use(s)

**Specific use(s)** In vitro diagnostic.

## SECTION 8: Exposure Controls/Personal Protection.

### 8.1. Control parameters

**Exposure Limits** This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

### 8.2. Exposure controls

**Engineering Controls** Provide adequate ventilation. Showers. Eyewash stations.

### Personal protective equipment

<b>Eye/face protection</b>	Wear safety glasses with side shields (or goggles).
<b>Hand Protection</b>	Wear protective gloves.
<b>Skin and body protection</b>	Wear suitable protective clothing.
<b>Respiratory protection</b>	Not applicable.

**Environmental exposure controls** No information available.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

<b>Physical State @20°C</b>	Liquid
<b>Appearance</b>	Frozen
<b>Color</b>	Colorless
<b>Odor threshold</b>	No information available

<u>Property</u>	<u>Values</u>
<b>pH</b>	7.5
<b>Melting point/freezing point</b>	No information available
<b>Boiling point / boiling range</b>	No information available
<b>Flash point</b>	
<b>Method</b>	No information available
<b>Evaporation rate</b>	No information available
<b>Flammability (solid, gas)</b>	No information available

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### Flammability Limits in Air

Upper flammability limits

No information available

Lower flammability limit

No information available

Vapor pressure

No information available

Vapor density

No information available

Relative density

Not determined

Water solubility

No information available

Solubility(ies)

No information available

Autoignition temperature

No information available

Decomposition temperature

No information available

Kinematic viscosity

No information available

Dynamic viscosity

No information available

### 9.2. Other information

None

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Reactivity

None under normal use conditions.

### 10.2. Chemical stability

Stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

Possibility of Hazardous Reactions None under normal use conditions.

### 10.4. Conditions to avoid

Conditions to avoid

None under normal use conditions.

### 10.5. Incompatible materials

Materials to avoid

None under normal use conditions.

### 10.6. Hazardous decomposition products

Hazardous Decomposition Products None under normal use conditions.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

#### Acute toxicity

Product Information

Product does not present an acute toxicity hazard based on known or supplied information.

Inhalation

None under normal use conditions.

Eye contact

Risk of serious damage to eyes

Skin Contact

None under normal use conditions.

Ingestion

None under normal use conditions.

Component name	LD50/oral/rat - NO UNITS (Wizards mg/kg)	LD50/dermal/rat - NO UNITS (Wizards mg/kg)	Inhalation LC50
Lithium Hydroxide, Monohydrate	= 120 mg/kg ( Rat )		

#### Chronic toxicity

Carcinogenicity

No information available.

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Sensitization	No information available
Reproductive toxicity	No information available.
Germ cell mutagenicity	No information available.
Target Organ Effects	No information available.

### Precautionary Statements - Disposal

No information available

## SECTION 12: Ecological information

### 12.1. Toxicity

#### Ecotoxicity

20 - 50% of the mixture consists of components(s) of unknown hazards to the aquatic environment.

### 12.2. Persistence and degradability

No information available

### 12.3. Bioaccumulative potential

No information available

### 12.4. Mobility in soil

No information available.

### 12.5. Results of PBT and vPvB assessment

No information available.

### 12.6. Other adverse effects

No information available.

## SECTION 13: Disposal Considerations.

### 13.1. Waste treatment methods

#### Waste from Residues / Unused Products

Disposal should be in accordance with applicable regional, national and local laws and regulations.

#### Contaminated packaging

Dispose of in accordance with federal, state and local regulations.

## SECTION 14: Transport information

### ADG

Not Classified as dangerous goods.

### IMDG

Not regulated

### IATA

Not regulated

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### Regulatory information

Component name	New Zealand - GHS Classifications - HSNO Chemical Classification Information Database (CCID)
Lauryl Sulfate Lithium Salt 2044-56-6	HSNO Approved
Lithium Hydroxide, Monohydrate 1310-66-3	HSNO Approved

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Succinic Acid 110-15-6	HSNO Approved

### International Inventories

Component name	TSCA	EINECS/ELINCS	DSL/NDSL	PICCS
Water 7732-18-5	Present	X	X	X
HEPES 7365-45-9	Present	X	X	X
Lauryl Sulfate Lithium Salt 2044-56-6	Present	X	X	-
Lithium Hydroxide, Monohydrate 1310-66-3	-	-	-	X
Succinic Acid 110-15-6	Present	X	X	X

Component name	ENCS	IECSC	AICS	KECL
Water 7732-18-5	-	X	X	Present
HEPES 7365-45-9	-	X	X	-
Lauryl Sulfate Lithium Salt 2044-56-6	Present	X	X	Present
Lithium Hydroxide, Monohydrate 1310-66-3	Present	X	X	-
Succinic Acid 110-15-6	Present	X	X	Present

### Legend

X - Present  
- Not Listed

*TSCA - United States Toxic Substances Control Act Section 8(b) Inventory*

*EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances*

*DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List*

*PICCS - Philippines Inventory of Chemicals and Chemical Substances*

*ENCS - Japan Existing and New Chemical Substances*

*IECSC - China Inventory of Existing Chemical Substances*

*AICS - Australian Inventory of Chemical Substances*

*KECL - Korean Existing and Evaluated Chemical Substances*

*NZIoC - New Zealand Inventory of Chemicals*

### National Regulations

*Australia*

### 15.2. Chemical safety assessment

**Chemical Safety Report** No information available.

## SECTION 16: Other information

### Full text of R-phrases referred to under sections 2 and 3

R25 - Toxic if swallowed

**Revision Date** 22-Feb-2017

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

