

# Safety Data Sheet

ACCURUN® Babesia Positive Molecular Control Kit

SDS-ACRN-025

Rev. Number: 1

Rev. Date: Oct 9, 2023

## 1. PRODUCT AND COMPANY IDENTIFICATION

Product Description:	Product Code
ACCURUN® Babesia Positive Molecular Control Kit	2020-0155

Kit Components	Part Code
ACCURUN® Babesia Negative Diluent	2020-0156
ACCURUN® Babesia Positive	2020-0157
ACCURUN® Babesia Lysis Buffer	2020-0158

**Recommended Use:** Control

**Contact Manufacturer:** LGC Clinical Diagnostics, Inc.  
37 Birch Street  
Milford, MA 01757

**Phone #:** (508) 244-6400  
US Toll Free: (800) 676-1881

**Fax #:** (508) 634-3394

**Web:** [www.seracare.com](http://www.seracare.com)

**Email:** [CDx-CustomerService@LGCGroup.com](mailto:CDx-CustomerService@LGCGroup.com)

**Emergency Telephone Numbers:**

AUSTRALIA – POISONS INFORMATION CENTER	Telephone: 13 11 26 - Hours: 24 hours
CANADIAN TRANSPORT EMERGENCY CENTER	Telephone: (1 ) 613 996 6666 - Hours: 24 hours/day, 7 days/week
UK – THE NATIONAL FOCUS	Telephone: (44) 029 2041 6388 - Hours: 09:00-17:00 GMT
USA - NATIONAL RESPONSE CENTER	Telephone: (1 ) 800 424 8802 - Hours: 24 hours/day, 7 days/week

**CHEMTREC:** CHEMTREC Customer Number:- CCN12505\*  
For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident  
Call CHEMTREC Day or Night  
Within USA and Canada: 1-800-424-9300 CCN12505 or  
+1 703-527-3887 (collect calls accepted)

# Safety Data Sheet

ACCURUN® Babesia Positive Molecular Control Kit

Doc. No.: SDS-ACRN-025

Rev. Number: 1

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

### 1.1 Product Identifier

**Trade name: ACCURUN® Babesia Positive Molecular Control Kit**

Product Description	Product Code
ACCURUN® Babesia Positive Molecular Control Kit	2020-0155
ACCURUN® Babesia Negative Diluent	2020-0156
ACCURUN® Babesia Positive	2020-0157

**REACH Registration number:** Not relevant

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

**Product category:** Controls (for In Vitro Diagnostics Use) and Reference materials/Panels (Research Use Only)

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

**Manufacturer/Supplier:**

LGC Clinical Diagnostics, Inc  
37 Birch Street  
Milford, MA 01757  
Phone #: (508) 244-6400  
US Toll Free: (800) 676-1881  
Fax #: (508) 634-3394  
www.seracare.com  
Email: CDx-CustomerService@LGCGroup.com

**EU Authorized Representative:**

MediMark Europe Sarl.  
11 rue Emile Zola. BP 2332  
38033 Grenoble cedex 2 – France  
Phone #: +33 (0)4 76 86 43 22  
Fax #: +33 (0)4 76 17 19 82  
info@medimark-europe.com

### 1.4 Emergency telephone number:

For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident  
Call CHEMTREC Day or Night  
Within USA and Canada: 1-800-424-9300 or +1 703-527-3887 (collect calls accepted)  
Account number: CCN12505

AUSTRALIA – POISONS INFORMATION CENTER Telephone: 13 11 26

CANADIAN TRANSPORT EMERGENCY CENTER Telephone: (1) 613 996 6666

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

#### Classification according to Regulation (EC) No 1272/2008 and GHS classification (29 CFR 1910 HCS)

The product is not classified, according to the CLP Regulation.

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS): The product contains no substances which at their given concentration, are considered to be hazardous to health or the environment.

### 2.2 Label elements

#### Labelling according to Regulation (EC) No 1272/2008

**Hazard pictograms:** Not applicable

**Signal word:** Not applicable

**Hazard statements:** Not applicable

#### Additional information:

This value refers to knowledge of known, established toxicological or ecotoxicological values.

0 % of the mixture consists of component(s) of unknown toxicity.

Contains 0 % of components with unknown hazards to the aquatic environment.

### 2.3 Other hazards: Contains materials of human origin - Potentially Biohazardous material: The positive control contains non-viable Babesia parasites.

#### Results of PBT and vPvB assessment

**PBT:** Not applicable.

**vPvB:** Not applicable.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Not applicable

### 3.2 Mixtures

**Description:** Stabilised human whole blood.

**Dangerous components:** The product does not contain reportable quantities of dangerous components.

**Additional information:** Each donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV-1 HIV-2, HCV, and non-reactive for HBsAg, HBV DNA, HIV-1 RNA, HCV RNA, Syphilis, WNV RNA and anti-T. Cruzi.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### General information:

Remove contaminated clothing and was before reuse. If symptoms persist, call a physician.

**After inhalation:** Supply fresh air; consult physician in case of complaints.

**After skin contact:** Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

**After eye contact:** Remove contact lenses. Protect unharmed eye. Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician in case of complaint.

Doc. No.: SDS-ACRN-025

Rev. Number: 1

Rev. Date: Oct 9, 2023

**After swallowing:** If accidentally swallowed obtain immediate medical attention. Rinse mouth with water. Never give anything by mouth to an unconscious person.

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

No further relevant information available.

**4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

**SECTION 5: Firefighting measures****5.1 Extinguishing media**

**Suitable extinguishing agents:** CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

**For safety reasons unsuitable extinguishing agents:** No further relevant information.

**5.2 Special hazards arising from the substance or mixture:** In case of fire, the following can be released: Carbon oxides (CO<sub>x</sub>), nitrogen oxides (NO<sub>x</sub>), sulphur oxides (SO<sub>x</sub>).**5.3 Advice for firefighters** Use fire extinguishing methods suitable to surrounding conditions.

**Protective equipment:** As in any fire, wear self-contained breathing apparatus pressure-demand and full protective gear to prevent contact with skin and eyes.

**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

Avoid breathing vapors, mist or gas. Use personal protective equipment.

**6.2 Environmental precautions:**

Prevent entry to sewers and public waters.

**6.3 Methods and material for containment and cleaning up**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Keep in suitable, closed containers for disposal. Swab down area with Chlorox or other disinfecting agent.

**6.4 Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

This product should be handled as a potentially infectious material, as no known test method procedure can offer complete assurance that products derived from materials of human origin will not transmit infectious agents. Refer to Directive 2000/54/EC or Biosafety recommendations of the United States Center for Disease Control (HHS Publ. No. (CDC) 300859 revised June 2020 for information on handling biohazardous materials.

Avoid contact with the eyes, skin and mucous membranes.

Keep out of the reach of children.

Wear appropriate PPE. Refer to section 8.

Doc. No.: SDS-ACRN-025

Rev. Number: 1

Rev. Date: Oct 9, 2023

**Information about fire and explosion protection:** No special measures required.

## 7.2 Conditions for safe storage, including any incompatibilities

**Storage:** Store as labeled at -20°C or lower until use. Store in a dry, cool and well-ventilated place. Keep container tightly closed when not in use.

**Requirements to be met by storerooms and receptacles:** No special requirements.

**Information about storage in one common storage facility:** Not required.

**Further information about storage conditions:** None.

## 7.3 Specific end use(s)

See section 1.2

# SECTION 8: Exposure controls/personal protection

## 8.1 Control parameters

Contains no substances with occupational exposure limit values.

## 8.2 Exposure controls

**Personal protective equipment:**

**General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling biological materials. Wash hands before breaks and at the end of work. Do not eat, drink or smoke during use. Emergency eye wash stations and safety showers should be available in the immediate vicinity of any potential exposure.

Clean work areas with hypochlorite or other disinfecting agent.

**Respiratory protection:** Use suitable respiratory protective device in case of insufficient ventilation.

Protection of hands

:



Protective gloves

Material of gloves

:

The selection of the suitable gloves depends on the material, and marks of quality, and varies from manufacturer to manufacturer.

Penetration time of glove material

:

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection

:



Goggles recommended during use

Body protection

:



Protective work clothing

## 8.3 Environmental exposure controls: None

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Red
Odour	: Characteristic
Melting point/freezing point	: Not determined
Boiling point or initial boiling point and boiling range	: Not determined
Flammability (solid, gas)	: Not flammable
Lower and upper explosion limit	: Not determined
Flash point	: Not determined
Auto-ignition temperature	: Not determined
Decomposition temperature	: Not determined
pH(@ 20 °C)	: Not determined
Kinematic viscosity	: Not determined
Solubility	
Solubility in / Miscibility with water	: Fully miscible
Partition coefficient n-octanol/water (log value)	: Not determined
Vapour pressure	: Not determined
Density and/or relative density	: Not determined
Relative vapour density	: Not determined
Particle characteristics	: Not applicable
Evaporation rate	: Not available
Partition coefficient: n-octanol/water	: Not available

### 9.2 Other information

- 9.2.1 Information with regard to physical hazard classes  
Not applicable
- 9.2.2 Other safety characteristics  
No further relevant information available.

## SECTION 10: Stability and reactivity

- 10.1 Reactivity:** No further relevant information available.
- 10.2 Chemical stability:** Product is stable under recommended storage conditions.  
**Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions:** No dangerous reactions known.
- 10.4 Conditions to avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5 Incompatible materials:** Strong oxidizing agents, acids and bases.
- 10.6 Hazardous decomposition products:**  
No decomposition if stored and applied as directed.

**SECTION 11: Toxicological information****11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

**Acute toxicity:** Based on available data, the classification criteria are not met.

**Skin corrosion/irritation:** Based on available data; the classification criteria are not met.

**Serious eye damage/irritation:** Based on available data, the classification criteria are not met.

**Respiratory or skin sensitization:** Based on available data, the classification criteria are not met.

**Germ cell mutagenicity:** Based on available data, the classification criteria are not met.

**Carcinogenicity:** Based on available data, the classification criteria are not met.

**Reproductive toxicity:** Based on available data, the classification criteria are not met.

**STOT (Specific target organ toxicity)-single exposure:**

Based on available data, the classification criteria are not met.

**STOT (Specific target organ toxicity)-repeated exposure:**

Based on available data, the classification criteria are not met.

**Aspiration hazard:** Based on available data, the classification criteria are not met.

**11.2 Information on other hazards****11.2.1 Endocrine disrupting properties**

No endocrine disrupting properties anticipated.

**11.2.2 Other information**

Not applicable

**SECTION 12: Ecological information****12.1 Toxicity**

**Aquatic toxicity:** No further relevant information available.

**12.2 Persistence and degradability:** Contains dimethyl sulfoxide which is not readily biodegradable

**12.3 Bioaccumulative potential:** No further relevant information available.

**12.4 Mobility in soil:** No further relevant information available.

**Additional ecological information:**

**General notes:** Generally not hazardous for water.

**12.5 Results of PBT and vPvB assessment**

**PBT:** Not applicable

**vPvB:** Not applicable

**12.6 Endocrine disrupting properties**

Does not contain substances with identified endocrine disrupting properties.

**12.7 Other adverse effects** No further relevant information available.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

**Recommendation:**

Dispose and treat as biohazardous waste. Observe all federal, state and local environmental regulations when disposing of this material.

**Uncleaned packaging:** Avoid contact with skin and clothing. Dispose of in compliance with the respective national and local regulations.

**Recommendation:** Unused portions and product evaluated using this reagent are to be disposed of as biohazardous waste and incinerated.

**Recommended cleansing agents:** Water, if necessary together with cleansing agents.

## SECTION 14: Transport information

### 14.1 UN-Number or ID number

ADR/ADN/RID, IMDG, IATA, DOT

Not applicable

### 14.2 UN proper shipping name

ADR/ADN/RID, IMDG, IATA, DOT

Not applicable

### 14.3 Transport hazard class(es)

ADR/ADN/RID, IMDG, IATA, DOT

Non-Regulated Material. Not classified as dangerous goods.

### 14.4 Packing group

ADR/ADN/RID, IMDG, IATA, DOT

Not applicable

### 14.5 Environmental hazards:

Not applicable

### 14.6 Special precautions for user:

Not applicable

### 14.7 Maritime transport in bulk according to IMO instruments: Not applicable

## SECTION 15: Regulatory information

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

**DIRECTIVE 2012/18/EU on the control of major accidents**

**Named dangerous substances - Annex I** None of the ingredients are listed.

**DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients are listed.

**REGULATION (EU) 2019/1148 on Explosives Precursors**

**Annex I - Restricted Explosives Precursors (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients are listed.

**Annex II - Reportable Explosives Precursors**

None of the ingredients are listed.



Doc. No.: **SDS-ACRN-025**Rev. Number: **1**Rev. Date: **Oct 9, 2023****REGULATION (EC) No 273/2004 on drug precursors**

None of the ingredients are listed.

**REGULATION (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients are listed.

**National regulations:****US Federal Regulations**

Listed on the US TSCA inventory

**CERCLA Reportable Quantity**

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

**SARA Section 302**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312**

No SARA Hazards

**SARA 313**

This product does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**State Regulations****California Proposition 65:**

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

**State Right to Know Act**

<b>Massachusetts:</b>	None of the components are listed
<b>New Jersey:</b>	None of the components are listed
<b>Pennsylvania:</b>	None of the components are listed
<b>New York:</b>	None of the components are listed
<b>Rhode Island:</b>	None of the components are listed
<b>Massachusetts:</b>	None of the components are listed
<b>New Jersey:</b>	None of the components are listed

**15.2 Chemical safety assessment:**

A Chemical Safety Assessment has not been carried out.

**Abbreviations and acronyms:**

ADR: Agreement concerning the International Carriage of Dangerous Goods by Road

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

RID: Regulations concerning the International Carriage of Dangerous Goods by Rail

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Doc. No.: **SDS-ACRN-025**Rev. Number: **1**Rev. Date: **Oct 9, 2023****SECTION 16: Other Information**

The above information is believed to be accurate, complete and current but does not purport to be all inclusive and shall be used as a guide. LGC Clinical Diagnostics makes no representation or warranties with respect to the product described herein, including but not limited to any implied warranties or merchantability or fitness for a particular use. LGC Clinical Diagnostics assumes no liability or responsibility and authorizes no other person to assume any additional liability or responsibility as a result of the use of this product or the information contained in the Safety Data Sheet.

Date of preparation / last revision: Aug 30, 2023 / N/A

# Safety Data Sheet

ACCURUN® Babesia Positive Molecular Control Kit

Doc. No.: SDS-ACRN-025

Rev. Number: 1

Rev. Date: Oct 9, 2023

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

### 1.1 Product Identifier

**Trade name: ACCURUN® Babesia Positive Molecular Control Kit**

#### Product Description

ACCURUN® Babesia Lysis Buffer

#### Product Code

2020-0158

**REACH Registration number:** Not relevant

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

**Product category:** Controls (for In Vitro Diagnostics Use) and Reference materials/Panels (Research Use Only)

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

#### Manufacturer/Supplier:

LGC Clinical Diagnostics, Inc  
37 Birch Street  
Milford, MA 01757  
Phone #: (508) 244-6400  
US Toll Free: (800) 676-1881  
Fax #: (508) 634-3394  
www.seracare.com  
Email: CDx-CustomerService@LGCGroup.com

#### EU Authorized Representative:

MediMark Europe Sarl.  
11 rue Emile Zola. BP 2332  
38033 Grenoble cedex 2 – France  
Phone #: +33 (0)4 76 86 43 22  
Fax #: +33 (0)4 76 17 19 82  
info@medimark-europe.com

### 1.4 Emergency telephone number:

For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident  
Call CHEMTREC Day or Night  
Within USA and Canada: 1-800-424-9300 or +1 703-527-3887 (collect calls accepted)  
Account number: CCN12505

AUSTRALIA – POISONS INFORMATION CENTER Telephone: 13 11 26

CANADIAN TRANSPORT EMERGENCY CENTER Telephone: (1) 613 996 6666

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

#### Classification according to Regulation (EC) No 1272/2008 and GHS classification (29 CFR 1910 HCS)

The product is not classified as hazardous, according to the CLP Regulation.

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS): The product contains no substances which at their given concentration, are considered to be hazardous to health or the environment.

### 2.2 Label elements

#### Labelling according to Regulation (EC) No 1272/2008

**Hazard pictograms:** Not applicable

**Signal word:** Not applicable

**Hazard statements:** Not applicable

#### Additional information:

This value refers to knowledge of known, established toxicological or ecotoxicological values.

0 % of the mixture consists of component(s) of unknown toxicity.

Contains 0 % of components with unknown hazards to the aquatic environment.

### 2.3 Other hazards

#### Results of PBT and vPvB assessment

**PBT:** Not applicable.

**vPvB:** Not applicable.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Not applicable

### 3.2 Mixtures

**Description:** Aqueous solution containing the following hazardous components

Component	CAS No. EC No.	Classification	% Weight
Guanidine hydrochloride	50-01-1 200-002-3	Acute Tox 4; H302 Skin Irrit 2; H315 Eye Irrit 2; H319	5 - 10
Na <sub>2</sub> EDTA	139-33-3 205-358-3	Acute Tox 4; H332	1 - 2
Triton X-100*	9002-93-1	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Chronic 2; H411	0.1 - 0.5

**Additional information:** For the wording of the listed hazard phrases refer to section 15

\* Candidate List of Substances of Very High Concern for Authorisation (SVHC)

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### General information:

Remove contaminated clothing and wash before reuse. If symptoms persist, call a physician.

Doc. No.: SDS-ACRN-025

Rev. Number: 1

Rev. Date: Oct 9, 2023

**After inhalation:** Supply fresh air; consult physician in case of complaints.

**After skin contact:** Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. If symptoms persist, call a physician.

**After eye contact:** Remove contact lenses. Protect unharmed eye. Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

**After swallowing:** If accidentally swallowed obtain immediate medical attention. Rinse mouth with water. Never give anything by mouth to an unconscious person.

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

May cause mild eye irritation.

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

No further relevant information available.

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

**Suitable extinguishing agents:** CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

**For safety reasons unsuitable extinguishing agents:** No further relevant information.

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

In case of fire, the following can be released: Carbon oxides (CO<sub>x</sub>), nitrogen oxides (NO<sub>x</sub>).

#### 5.3 Advice for firefighters

Use fire extinguishing methods suitable to surrounding conditions.

**Protective equipment:** As in any fire, wear self-contained breathing apparatus pressure-demand and full protective gear to prevent contact with skin and eyes.

### SECTION 6: Accidental release measures

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

Avoid breathing vapors, mist or gas. Use personal protective equipment.

#### 6.2 Environmental precautions:

Prevent entry to sewers and public waters.

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

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Keep in suitable, closed containers for disposal.

#### 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Avoid contact with the eyes, skin and mucous membranes.

Keep out of the reach of children.

**Information about fire and explosion protection:** No special measures required.

Doc. No.: SDS-ACRN-025

Rev. Number: 1

Rev. Date: Oct 9, 2023

**7.2 Conditions for safe storage, including any incompatibilities**

**Storage:** Store as labeled at -20°C or lower until use. Store in a dry, cool and well-ventilated place. Keep container tightly closed when not in use.

**Requirements to be met by storerooms and receptacles:** No special requirements.

**Information about storage in one common storage facility:** Not required.

**Further information about storage conditions:** None.

**7.3 Specific end use(s)**

See section 1.2

**SECTION 8: Exposure controls/personal protection****8.1 Control parameters**

Contains no substances with occupational exposure limit values.

**8.2 Exposure controls****Personal protective equipment:****General protective and hygienic measures:**

Specimens should be handled as potentially infectious materials. Refer to Directive 2000/54/EC or Biosafety recommendations of the United States Center for Disease Control (HHS Publ. No. (CDC) 300859 revised June 2020 for information on handling biohazardous materials.

Wash hands before breaks and at the end of work. Do not eat, drink or smoke during use. Emergency eye wash stations and safety showers should be available in the immediate vicinity of any potential exposure.

Clean work areas with hypochlorite or other disinfecting agent.

**Respiratory protection:** Not normally required.

Protection of hands

:



Protective gloves

Material of gloves

:

The selection of the suitable gloves depends on the material, and marks of quality, and varies from manufacturer to manufacturer.

Penetration time of glove material

:

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection

:



Goggles recommended during use

Body protection

:



Protective work clothing

**8.3 Environmental exposure controls:** None

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colorless
Odour	: Characteristic
Melting point/freezing point	: Not determined
Boiling point or initial boiling point and boiling range	: Not determined
Flammability (solid, gas)	: Not flammable
Lower and upper explosion limit	: Not relevant
Flash point	: Not relevant
Auto-ignition temperature	: Not determined
Decomposition temperature	: Not determined
pH(@ 20 °C)	: 8.0
Kinematic viscosity	: Not determined
Solubility	
Solubility in / Miscibility with water	: Fully miscible
Partition coefficient n-octanol/water (log value)	: Not determined
Vapour pressure	: Not determined
Density and/or relative density	: 1.03 g/cm <sup>3</sup> @ 20 °C
Relative vapour density	: Not determined
Particle characteristics	: Not applicable
Evaporation rate	: Not available
Partition coefficient: n-octanol/water	: Not available

### 9.2 Other information

9.2.1 Information with regard to physical hazard classes

Not applicable

9.2.2 Other safety characteristics

No further relevant information available.

## SECTION 10: Stability and reactivity

**10.1 Reactivity:** No further relevant information available.

**10.2 Chemical stability:** Product is stable under recommended storage conditions.

**10.3 Possibility of hazardous reactions:** No dangerous reactions known.

**10.4 Conditions to avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.

**10.5 Incompatible materials:** Strong oxidizing agents, acids and bases.

**10.6 Hazardous decomposition products:**

No decomposition if stored and applied as directed.

**SECTION 11: Toxicological information****11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

**Acute toxicity:** Based on available data, the classification criteria are not met.

LD50/LC50 values relevant for classification: ATE (Oral) = > 10,000 mg/kg

**Skin corrosion/irritation:** Based on available data; the classification criteria are not met.

**Serious eye damage/irritation:** Based on available data, the classification criteria are not met.

**Respiratory or skin sensitization:** Based on available data, the classification criteria are not met.

**Germ cell mutagenicity:** Based on available data, the classification criteria are not met.

**Carcinogenicity:** Based on available data, the classification criteria are not met.

**Reproductive toxicity:** Based on available data, the classification criteria are not met.

**STOT (Specific target organ toxicity)-single exposure:**

Based on available data, the classification criteria are not met.

**STOT (Specific target organ toxicity)-repeated exposure:**

Based on available data, the classification criteria are not met.

**Aspiration hazard:** Based on available data, the classification criteria are not met.

**11.2 Information on other hazards****11.2.1 Endocrine disrupting properties**

No information available

**11.2.2 Other information**

Not applicable

**SECTION 12: Ecological information****12.1 Toxicity**

**Aquatic toxicity:** No further relevant information available.

**12.2 Persistence and degradability:** The organic components are readily biodegradable

**12.3 Bioaccumulative potential:** Bioaccumulation is not anticipated.

**12.4 Mobility in soil:** No further relevant information available.

**Additional ecological information:**

**General notes:** Generally not hazardous for water.

**12.5 Results of PBT and vPvB assessment**

**PBT:** Not applicable

**vPvB:** Not applicable

**12.6 Endocrine disrupting properties**

Decomposition product of Triton X-100: 4-tert-octylphenol.

**12.7 Other adverse effects** No further relevant information available.



## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

**Recommendation:**

Dispose of used product as biohazardous waste. Observe all federal, state and local environmental regulations when disposing of this material.

**Uncleaned packaging:** Avoid contact with skin and clothing. Dispose of in compliance with the respective national and local regulations.

**Recommendation:** Unused portions and product evaluated using this reagent are to be disposed of as biohazardous waste and incinerated.

**Recommended cleansing agents:** Water, if necessary together with cleansing agents.

## SECTION 14: Transport information

### 14.1 UN-Number or ID number

ADR/ADN/RID, IMDG, IATA, DOT Not applicable

### 14.2 UN proper shipping name

ADR/ADN/RID, IMDG, IATA, DOT Not applicable

### 14.3 Transport hazard class(es)

ADR/ADN/RID, IMDG, IATA, DOT Non-Regulated Material. Not classified as dangerous goods.

### 14.4 Packing group

ADR/ADN/RID, IMDG, IATA, DOT Not applicable

### 14.5 Environmental hazards:

Not applicable

### 14.6 Special precautions for user:

Not applicable

### 14.7 Maritime transport in bulk according to IMO instruments: Not applicable

## SECTION 15: Regulatory information

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

**DIRECTIVE 2012/18/EU on the control of major accidents**

**Named dangerous substances - Annex I** None of the ingredients are listed.

**DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients are listed.

**REGULATION (EU) 2019/1148 on Explosives Precursors**

**Annex I - Restricted Explosives Precursors (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients are listed.

**Annex II - Reportable Explosives Precursors**

None of the ingredients are listed.

Doc. No.: SDS-ACRN-025

Rev. Number: 1

Rev. Date: Oct 9, 2023

**REGULATION (EC) No 273/2004 on drug precursors**

None of the ingredients are listed.

**REGULATION (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients are listed.

**National regulations:****US Federal Regulations**

Listed on the US TSCA inventory

**CERCLA Reportable Quantity**

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

**SARA Section 302**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312**

No SARA Hazards

**SARA 313**

This product does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**California Proposition 65:**

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

**State Right to Know Act**

<b>Massachusetts:</b>	None of the components are listed
<b>New Jersey:</b>	None of the components are listed
<b>Pennsylvania:</b>	None of the components are listed
<b>New York:</b>	None of the components are listed
<b>Rhode Island:</b>	None of the components are listed
<b>Massachusetts:</b>	None of the components are listed
<b>New Jersey:</b>	None of the components are listed

**15.2 Chemical safety assessment:**

A Chemical Safety Assessment has not been carried out.

**Abbreviations and acronyms:**

ADR: Agreement concerning the International Carriage of Dangerous Goods by Road

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

RID: Regulations concerning the International Carriage of Dangerous Goods by Rail

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

DOT: US Department of Transport Dangerous Goods Regulations

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

Doc. No.: SDS-ACRN-025

Rev. Number: 1

Rev. Date: Oct 9, 2023

vPvB: very Persistent and very Bioaccumulative  
Acute Tox 4: Acute toxicity, Category 4  
Skin Irrit 2: Skin Irritant, Category 2  
Eye Irrit 2: Eye Irritant, Category 2  
Eye Dam 1: Eye damage, Category 1  
Aquatic Chronic 2: Dangerous for the environment, Chronic, Category 2

**Relevant H-statements**

H302: Harmful if swallowed.  
H315: Causes skin irritation.  
H318: Causes serious eye damage.  
H319: Causes serious eye irritation.  
H332: Harmful if inhaled.  
H411: Toxic to aquatic life with long lasting effects.

**SECTION 16: Other Information**

The above information is believed to be accurate, complete and current but does not purport to be all inclusive and shall be used as a guide. LGC Clinical Diagnostics makes no representation or warranties with respect to the product described herein, including but not limited to any implied warranties or merchantability or fitness for a particular use. LGC Clinical Diagnostics assumes no liability or responsibility and authorizes no other person to assume any additional liability or responsibility as a result of the use of this product or the information contained in the Safety Data Sheet.

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