



ACCURUN®

SDS-ACRN-01 Rev. Number: 11 Rev. Date: Mar 29, 2022

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

· 1.1 Product identifier:

· Trade name: ACCURUN®

Product Description:	Product Code
ACCURUN 106 Series 1000	2015-0065, 2015-0066
ACCURUN 810	2010-0020
ACCURUN 190	2015-0097
ACCURUN 156	2015-0094
ACCURUN 155 Series 5000	2015-0092, 2015-0093
ACCURUN 155 Series 2000	2015-0090
ACCURUN 146	2015-0088
ACCURUN 145	2015-0087
ACCURUN 141	2015-0086
ACCURUN 140	2015-0084
ACCURUN 136	2015-0083
ACCURUN 135	2015-0082
ACCURUN 132	2015-0081
ACCURUN 130	2015-0080
ACCURUN 127	2015-0079
ACCURUN 125	2015-0077, 2015-0078
ACCURUN 121	2015-0074, 2015-0076
ACCURUN 120	2015-0073
ACCURUN 119	2015-0072
ACCURUN 117	2015-0071
ACCURUN 115	2015-0070
ACCURUN 113	2015-0068
ACCURUN 21 Series 1000	2000-0027, 2000-0028
ACCURUN 800	2010-0018
ACCURUN 52	2000-0043
ACCURUN 52 Series 3000	2000-0071
ACCURUN 51	2000-0040, 2000-0041
ACCURUN 51 Series 3000	2000-0062, 2000-0067
ACCURUN 51 Series 2000	2000-0063, 2000-0065
ACCURUN 40	2000-0039
ACCURUN 31	2000-0038
ACCURUN 30	2000-0037
ACCURUN 26	2000-0035
ACCURUM 25 Series 1000	2000-0034
ACCURUN 25 Series 1000 ACCURUN 25 Series 2000	2000-0073 2000-0074
ACCURUN 24 ACCURUN 24	2000-0074
ACCURUN 21 Series 2000	2000-0030, 2000-0031





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Product Description:	Product Code
ACCURUN Anti-SARS-CoV-2 Series 1000	2015-0222
ACCURUN Anti-SARS-CoV-2 Series 2000	2015-0225
ACCURUN Anti-SARS-CoV-2 IgM Controls Kit	2015-0232
ACCURUN 1 Negative	2010-0013, 2010-0015
ACCURUN 2 Series 2700	2000-0023, 2000-0024
ACCURUN 2 Series 2900	2000-0080
ACCURUN 1 Series 8100	2000-0022
ACCURUN 1 Series 5600	2000-0018
ACCURUN 1 Series 5100	2000-0016, 2000-0017
ACCURUN 1 Series 4400	2000-0010
ACCURUN 1 Series 4000	2000-0008
ACCURUN 1 Series 2700	2000-0005
ACCURUN 1 Series 2500	2000-0002
ACCURUN 1 Series 2400	2000-0001
ACCURUN 3 Multi-Marker Positive Control	2000-0092
ACCURUN 4 Multi-Marker Positive Control	2000-0093
ACCURUN 5 Multi-Marker Positive Control	2000-0094
ACCURUN 6 Multi-Marker Positive Control	2000-0095

- · **REACH Registration number:** Not relevant
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against:
- · Product category: For in-vitro diagnostics use.
- · 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

· 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





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SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008

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

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008 Non-Regulated Material
- · Hazard pictograms Non-Regulated Material
- · Signal word: Non-Regulated Material
- · Hazard statements: Non-Regulated Material
- · 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: Potentially Biohazardous material: This material has the potential to transmit infectious agents and should be handled according to Biosafety recommendations of the United States Center for Disease Control (HHS Publ. No. (CDC)300859 revised June 2020.
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

· Composition:		
CAS No.	Components	% Weight
CAS: 55965-84-9 EC list No: 911-418-6 Index No. 613-167-00-5	5-Chloro-2-methyl-3(2H)-isothiazolone with 2-methyl-3(2H)-isothiazolone	0.001- 0.005%
N/A	Human Plasma	>99.9%
Hazard Information	CAS: 55965-84-9	_
Hazard classification	Danger	
	GHS05: Corrosion GHS09: Environment GH06: Acute Toxicity	
Hazard Statements	Acute Tox. 3; Acute Tox. 2; Skin Corr. 1C; Eye Dam. 1; Skin Sens. 1A; Aquatic Acute 1; Aquatic Chronic 1; H301, H330, H310, H314, H318, H317, >= 1 - < 5 %	





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Precautionary statements	P261: Avoid breathing dust/fume/gas/mist/vapors/spray. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/ P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P310: Immediately call a POISON CENTER/doctor/ P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	
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· Additional information: For the wording of the listed hazard phrases refer to section 16.

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 doctor in case of complaints.
- · After skin contact:

Generally the product does not irritate the skin.

If skin irritation occurs, consult a doctor.

· After eye contact:

If eye irritation occurs, consult a doctor.

Rinse opened eye for several minutes under running water.

- · After swallowing: If swallowed and symptoms occur, consult a doctor.
- · 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: Use fire extinguishing methods suitable to surrounding conditions.
- · For safety reasons unsuitable extinguishing agents: No further relevant information.
- 5.2 Special hazards arising from the substance or mixture: No further relevant information available.
- · 5.3 Advice for firefighters
- · 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 Not required.
- · 6.2 Environmental precautions: Dilute with plenty of water.
- · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of cleaning materials contaminated with the product as biohazardous and incinerated. Use Disinfectant.





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· 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 Handle as potentially infectious. No special precautions are necessary if used correctly. Wear appropriate PPE. Refer to section 8.
- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage: Store as labeled
- · 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
- · Additional information about design of technical facilities: No further data; see item 7.
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists valid during the making were used as basis.
- · 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.

- · 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:



Gogales recommended during use





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· Body protection:



Protective work clothing

· 8.2.3 Environmental exposure controls: None

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

Appearance: The serum or plasma may be in liquid or solid (if frozen) form; its

normal appearance is a pale amber liquid.

Form: LiquidColour: Pale amberOdour: Odourless

• **pH-value @ 20 °C**: 6-8

· Change in condition

Melting point/freezing point:
 Flash point:
 Flammability (solid, gas):
 Ignition temperature:
 Decomposition temperature:
 Not applicable
 Not applicable
 Not determined.

• Auto-ignition temperature: Product is not self-igniting.

• Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

Lower:
Upper:
Not determined.
Not determined.

Vapour pressure:
Not determined.

Density @ 20 °C:
Relative density:
Vapour density:
Not determined.
Not determined.
Not determined.
Not determined.

· Solubility in / Miscibility with

water: Fully miscible.Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not determined. **Kinematic:** Not determined.

· Solvent content:

VOC content: 0.00 %

0.0 g/l / 0.00 lb/gal

 VOC (EC)
 0.00 %

 Solids content:
 0.0 %

• **9.2 Other information** No further relevant information available.





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SECTION 10: Stability and reactivity

- 10.1 Reactivity: No further relevant information available.
- · 10.2 Chemical stability: Product is stable under normal 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: No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products:

Carbon Monoxide, Carbon Dioxide, Nitrogen Oxides, Sulphur Oxides, Hydrogen Chloride gas

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · LD50/LC50 values relevant for classification:

Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3- one

Oral LD50 66 mg/kg (Rat)

Dermal LD50 87.12 mg/kg (Rabbit)

- · Primary irritant effect:
- · 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.
- · Sensitisation: Based on available data, the classification criteria are not met.
- · Additional toxicological information:
- · CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):
- · 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.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability: No further relevant information available.
- 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 Other adverse effects No further relevant information available.





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SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation:

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

· ADR/ADN, IMDG, IATA Non-Regulated Material

· 14.2 UN proper shipping name

· ADR/ADN, IMDG, IATA Non-Regulated Material

· 14.3 Transport hazard class(es)

· ADR/ADN, ADN, IMDG, IATA

· Class Non-Regulated Material

· 14.4 Packing group

· ADR/ADN, IMDG, IATA Non-Regulated Material

14.5 Environmental hazards:
 14.6 Special precautions for user
 Not applicable.
 Not applicable.

· 14.7 Transport in bulk according to Annex II of

Marpol and the IBC Code Not applicable.

· UN "Model Regulation": Non-Regulated Material

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU Substance is not listed.
- · 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
- · 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.

· 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.





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· National regulations:

The product is not subject to be labelled according with the prevailing version of the regulations on hazardous substances.

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product contains no chemical or chemicals which are subject to the reporting requirements of the Act and Title 40n of the Code of Federal Regulations, Part 372. SARA Section 311/312

Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs) (See 40 CFR 61)
This product contains no chemicals which are subject to the reporting requirements of the Clean Air Act

California Proposition 65: This product contains the following Proposition 65 chemicals: None Listed

State Right to Know Act US / North America

Chemical Name: None Listed
Massachusetts: Not Listed
New Jersey: Not Listed
Pennsylvania: Not Listed
New York: Not Listed
Rhode Island: Not Listed

International Inventories

Chemical Name None Listed

TSCAL: Not Listed DSL: Not Listed NDSL: Not Listed EINECS: Not Listed

CHINA: Not Listed KECL: Not Listed JAPAN: Not Listed AICS: Not Listed





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· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases

H301: Toxic if swallowed.

H311: Toxic in contact with skin.

H310: Fatal in contact with skin.

H314: Causes severe skin burns and eye damage.

H330: Fatal if inhaled.

H317: May cause an allergic skin reaction.

H410: Very toxic to aquatic life with long lasting effects.

H318: Serious eye damage

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International

Carriage of Dangerous Goods by Road)

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

IMDG: International Maritime Code for Dangerous Goods

INDEX: International Markine Code to 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

Acute Tox. 2: Acute toxicity – Category 2

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1

Data compared to the previous version altered.

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 quide. 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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