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

- **1.1 Product identifier:**
- **Trade name: ACCURUN®**

<table>
<thead>
<tr>
<th>Product Description:</th>
<th>Product Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCURUN 106 Series 1000</td>
<td>2015-0065, 2015-0066</td>
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<tr>
<td>ACCURUN 810</td>
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<td>ACCURUN 145</td>
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<td>ACCURUN 140</td>
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<td>ACCURUN 136</td>
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<td>2015-0082</td>
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<td>ACCURUN 132</td>
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<td>ACCURUN 119</td>
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<td>ACCURUN 117</td>
<td>2015-0071</td>
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<tr>
<td>ACCURUN 115</td>
<td>2015-0070</td>
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<tr>
<td>ACCURUN 113</td>
<td>2015-0068</td>
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<tr>
<td>ACCURUN 21 Series 1000</td>
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<tr>
<td>ACCURUN 800</td>
<td>2010-0018</td>
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<td>ACCURUN 52</td>
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<td>ACCURUN 52 Series 3000</td>
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<td>ACCURUN 51</td>
<td>2000-0040, 2000-0041</td>
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<tr>
<td>ACCURUN 51 Series 3000</td>
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<td>ACCURUN 51 Series 2000</td>
<td>2000-0063, 2000-0065</td>
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<td>2000-0039</td>
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<td>ACCURUN 25</td>
<td>2000-0034</td>
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<td>2000-0074</td>
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<tr>
<td>ACCURUN 24</td>
<td>2000-0032</td>
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</table>
Safety Data Sheet

Product Description:
- ACCURUN Anti-SARS-CoV-2 Series 1000
- ACCURUN Anti-SARS-CoV-2 Series 2000
- ACCURUN Anti-SARS-CoV-2 IgM Controls Kit
- ACCURUN 1 Negative
- ACCURUN 2 Series 2700
- ACCURUN 2 Series 2900
- ACCURUN 1 Series 8100
- ACCURUN 1 Series 5600
- ACCURUN 1 Series 5100
- ACCURUN 1 Series 4400
- ACCURUN 1 Series 4000
- ACCURUN 1 Series 2700
- ACCURUN 1 Series 2500
- ACCURUN 1 Series 2400
- ACCURUN 3 Multi-Marker Positive Control
- ACCURUN 4 Multi-Marker Positive Control
- ACCURUN 5 Multi-Marker Positive Control
- ACCURUN 6 Multi-Marker Positive Control

Product Code
- 2015-0222
- 2015-0225
- 2015-0232
- 2010-0013, 2010-0015
- 2000-0023, 2000-0024
- 2000-0080
- 2000-0022
- 2000-0018
- 2000-0016, 2000-0017
- 2000-0010
- 2000-0008
- 2000-0005
- 2000-0002
- 2000-0001
- 2000-0092
- 2000-0093
- 2000-0094
- 2000-0095

- **REACH Registration number**: Not relevant
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**: 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
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.

<table>
<thead>
<tr>
<th>CAS No.</th>
<th>Components</th>
<th>% Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 55965-84-9 EC list No: 911-418-6 Index No. 613-167-00-5</td>
<td>5-Chloro-2-methyl-3(2H)-isothiazolone with 2-methyl-3(2H)-isothiazolone</td>
<td>0.001-0.005%</td>
</tr>
<tr>
<td>N/A</td>
<td>Human Plasma</td>
<td>&gt;99.9%</td>
</tr>
</tbody>
</table>

Hazard Information: CAS: 55965-84-9

<table>
<thead>
<tr>
<th>Hazard classification</th>
<th>Hazard Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Danger</td>
<td>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, &gt;= 1 - &lt; 5 %</td>
</tr>
</tbody>
</table>

Symbols:
- GHS05: Corrosion
- GHS09: Environment
- GH06: Acute Toxicity
Precautionary statements

<table>
<thead>
<tr>
<th>Precautionary statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>P261: Avoid breathing dust/fume/gas/mist/vapors/spray.</td>
</tr>
<tr>
<td>P273: Avoid release to the environment.</td>
</tr>
<tr>
<td>P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...</td>
</tr>
<tr>
<td>P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].</td>
</tr>
<tr>
<td>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</td>
</tr>
<tr>
<td>P310: Immediatly call a POISON CENTER/doctor/...</td>
</tr>
<tr>
<td>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</td>
</tr>
</tbody>
</table>

**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 wash 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.
**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:**
    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:**
    - **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

· **8.2.3 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:**
    
    Liquid

  · **Colour:**
    
    Pale amber

  · **Odour:**
    
    Odourless

  · **pH-value @ 20 °C:**
    
    6-8

  · **Change in condition**
    
    **Melting point/freezing point:**
    
    Not determined.

  · **Flash point:**
    
    Not applicable.

  · **Flammability (solid, gas):**
    
    Not applicable.

  · **Ignition temperature:**
    
    Not applicable.

  · **Decomposition temperature:**
    
    Not determined.

  · **Auto-ignition temperature:**
    
    Product is not self-igniting.

  · **Explosive properties:**
    
    Product does not present an explosion hazard.

  · **Explosion limits:**
    
    **Lower:**
    
    Not determined.

    **Upper:**
    
    Not determined.

  · **Vapour pressure:**
    
    Not determined.

  · **Density @ 20 °C:**
    
    1.846 g/cm³

  · **Relative density:**
    
    Not determined.

  · **Vapour density:**
    
    Not determined.

  · **Evaporation rate:**
    
    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.
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.
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: Non-Regulated Material
- 14.4 Packing group
  - ADR/ADN, IMDG, IATA: Non-Regulated Material
- 14.5 Environmental hazards:
  - Class: Not applicable.
- 14.6 Special precautions for user
  - Marpol and the IBC Code: Not applicable.
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
  - 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.
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
NDSSL: Not Listed
EINECS: Not Listed
CHINA: Not Listed KECL: Not Listed
JAPAN: Not Listed AICS: Not Listed
**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:**
- AD: 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
- 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 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: Mar 22, 2022 / 9*