

A372 and A872 HPV SurePath

Doc. No.: SDS-ACRN-07

Rev. Number: 6

Rev. Date: Jun 17, 2022

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

1.1 Product Identifier Trade name: ACCURUN® Product Code Product Description Product Code ACCURUN® 372 Series 400 2025-0037, ACCURUN 372 Series 600 2025-0041 ACCURUN 872 2035-0009 REACH Registration number: Not relevant Image: Not relevant 1.2 Relevant identified uses of the substance or mixture and uses advised against: Product category: For In Vitro Diagnostics Use Image: Not relevant

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

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.

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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

3.1 Substances

Not applicable

3.2 Mixtures – Chemical characterization:

Description: Mixture of substances listed below with nonhazardous additions.

Composition:		
CAS No.	Components	% Weight
64-17-5 (EC no. 603-002-00-5)	Ethanol	< 50
67-56-1	Methanol	< 2
67-63-0	Isopropanol	< 2
N/A	Cultured Human cells in buffer	
Hazard Information:		
Flammable liquids Category 2	GHS02 Danger	
Precautionary Statement	P210: Keep away from heat, hot surfaces, sparks, open flames and other sources of ignition. No smoking.	

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

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SECTION 4: Composition/information on ingredients

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:** The vapor mixes well with air, explosive mixtures are easily formed.

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

Wear appropriate personal protective clothing to prevent skin contact. Remove: Work clothing that becomes wet should be immediately removed due to its flammability hazard (i.e.for liquids with flash point < 100°F)Avoid breathing vapors, mist or gas. Avoid prolonged contact with eyes, skin, and clothing.

6.2 Environmental precautions: Not available.

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.

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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. Keep sparks, flames, and other sources of ignition away. Keep material out of water sources and sewers. Build dikes to contain flow as necessary. Attempt to stop leak if without undue personnel hazard. Use water spray to knock-down vapor.

Land spill: Dig a pit, pond, lagoon, holding area to contain liquid or solid material. Dike surface flow using soil, sandbags, foamed polyurethane, or foamed concrete. Absorb bulk liquid with fly ash, cement powder, or commercial sorbents. Water spill: Use natural barriers or oil spill control booms to limit spill travel. Remove trapped material with suction hoses. (AAR, 2003

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

- 7.2 Conditions for safe storage, including any incompatibilities
 Storage: Store at 2-8 °C separated from strong oxidants
 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. 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.

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.

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8.3 Environmental exposure controls: None

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:	:	Slightly cloudy
Form	:	Liquid
Colour	:	Colorless
Odour	:	Mild alcohol odor
pH value @ 20 °C	:	6-8
Change in condition:	:	
Melting point/freezing point	:	Not determined
Boiling Point		86 °C
Flash point	:	35 °C
Flammability (solid, gas)	:	Not applicable
Ignition temperature	:	Not applicable
Decomposition temperature	:	Not determined
Auto-ignition temperature	:	Product is not self-igniting contains ethyl alcohol (363°C)
Explosive properties	:	Ethyl Alcohol: vol% in air 3.3-19 Upper Explosive Limit: 19.0 % (NIOSH, 2003)
Explosion limits	:	
Lower	:	Not determined
Upper	:	19.0 % (NIOSH, 2003)
Vapour pressure	:	44 mm Hg
Density @ 20 °C	:	0.8 g/cm ³
Relative density	:	Not determined (Ethyl Alcohol=0.8)
Vapour density	:	Not determined (Ethyl Alcohol: (air = 1): 1.6
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

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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, is a mild oxidizing agent, and polymerization will not occur.

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

Possibility of hazardous reactions: Ethyl Alcohol: Reacts slowly with calcium hypochlorite, silver oxide and ammonia, causing fire and explosion hazard. Reacts violently with strong oxidants such as nitric acid, silver nitrate, mercuric nitrate or magnesium perchlorate, causing fire and explosion hazard No dangerous reactions known.

- **10.3** Conditions to avoid: No further relevant information available.
- **10.4 Incompatible materials:** Strong oxidizing agents, Peroxides, Acids, Acid Chlorides, Acid Anhydrides, Alkali Metals, and Ammonia g agents, acids and bases.

10.5 Hazardous decomposition products:

Carbon Monoxide, Carbon Dioxide

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity The toxicological risks are minor due to the low concentration of hazardous ingredients. The following toxicological information is for the hazardous ingredient in pure form.

LD50/LC50 values relevant for classification:

LD50 Oral Rat: 343450 mg/kg

LD50 Dermal Rat iv: 1440 mg/kg

LD Dermal Rat iv: 1973 mg/kg

LC50 Inhalation mouse: 39 mg/cu m/4 hr

LC50 Inhalation Rat: Inhalation 20000 ppm/ 10 hrs

Primary irritant effect:

Skin corrosion/irritation: Skin irritant

Serious eye damage/irritation: Eye irritant

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 MAK COMMISSION Germ Cell Mutagenic- Category 5 (Substance with minimal effect)

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Carcinogenicity MAK-COMMISSION - Category 5 (No considerable risk).

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 the substance irritates the eyes. Inhalation of high concentration of vapor may cause irritation of the eyes and respiratory tract. The substance may cause effects on the central nervous system are not met.

STOT (Specific target organ toxicity)-repeated exposure

The liquid defats the skin. The substance may have effects on the upper respiratory tract and central nervous system, resulting in irritation, headache, fatigue and lack of concentration.

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.

Crustacean (Daphnia magna) EC50 (IMM) 48 hr 9.300 mg/L; NOEC (Reproduction Rate) 9 day 9.6 mg/L (Slightly harmful in the aquatic environment or otherwise designed for biocidal action) Glycerin (56-81-5)

- **12.2 Persistence and degradability:** Readily biodegradable (74% after 5 days)
- 12.3 Bioaccumulative potential: Data for 100% Ethanol: Not likely to bioaccumulate (calculated log BCF=0.5).
- **12.4** Mobility in soil: No further relevant information available.

Additional ecological information:

General notes: Not available.

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.

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14.1	UN-Number	
14.1		
	ADR/ADN, IMDG, IATA	UN1992; Flammable Liquids, Toxic, n.o.s (Ethanol), 3(6.1), E1, Excepted quantity label
14.2	UN proper shipping name	
	ADR/ADN, IMDG, IATA	UN1992; Flammable Liquids, Toxic, n.o.s (Ethanol), 3(6.1), E1, Excepted quantity labelNon-Regulated Material
14.3	Transport hazard class(es)	
	ADR/ADN, ADN, IMDG, IATA	
	Class	Flammable Liquids, Toxic, n.o.s (Ethanol), 3(6.1), E1, Excepted quantity label
14.4	Packing group	
	ADR/ADN, IMDG, IATA	Flammable Liquids, Toxic, n.o.s (Ethanol), 3(6.1), E1, Excepted quantity label
14.5	Not applicable	
14.6	Special precautions for user:	Not applicable
14.7	Transport in bulk according to Annex II of Marpol and the IBC Code:	Not applicable
	UN "Model Regulation":	UN1992

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 Ethanol, Ethyl alcohol

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:

US Federal Regulations

SARA Section 302 Threshold Planning Quantity

500 (this material is reactive solid. (The TPQ does not default to 10000 pounds for non-powder, non-molten, non-solution form)

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

Chemical Name:	Ethanol
Massachusetts:	Listed
New Jersey:	Listed
Pennsylvania:	Listed
Pennsylvania:	Listed
New York:	Listed
Rhode Island:	Not Listed

International Inventories

Ethanol
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:

H225: Highly flammable liquid and vapor.

P210: Keep away from heat, hot surfaces, sparks, open flames and other sources of ignition. No smokingAbbreviations 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

IATA: International Air Transport Association

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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

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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