

SECTION 1: Identification

1.1. Identification

Product form : Mixture
 Product name : Strep A Extraction Reagent (Ampule)
 Product code : 147

1.2. Recommended use and restrictions on use

Use of the substance/mixture : in vitro diagnostics
 Restrictions on use : Restricted to professional users

1.3. Supplier

Sekisui Diagnostics, LLC
 6659 Top Gun Street, San Diego, CA 92121, USA
 Tel. +1-858-777-2600
 Sekisui Diagnostics P.E.I. Inc.
 70 Watts Avenue, Charlottetown Prince Edward Island, C1E 2B9 Canada
 Tel. 800-565-0265
 Sekisui Diagnostics (UK) Limited
 Liphook Way, Allington, Maidstone, Kent ME16 0LQ
 Tel. +44 (0) 1622 607800
 www.sekisuidiagnostics.com
 Contact person: info@sekisuidiagnostics.com

1.4. Emergency telephone number

Emergency number : Americas 1-760-476-3962
 Europe, Middle East & Africa +1-760-476-3961
 Asia Pacific +1-760-476-3960
 Access code 333512

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Skin corrosion/irritation Category 2 H315 Causes skin irritation
 Serious eye damage/eye irritation Category 2A H319 Causes serious eye irritation
 Full text of H statements : see section 16

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Hazard pictograms (GHS US) :



Signal word (GHS US) : Warning
 Hazard statements (GHS US) : H315 - Causes skin irritation
 H319 - Causes serious eye irritation
 Precautionary statements (GHS US) : P264 - Wash hands, forearms and face thoroughly after handling.
 P280 - Wear protective gloves/protective clothing/eye protection/face protection.
 P302+P352 - If on skin: Wash with plenty of water.
 P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P321 - Specific treatment (see supplemental first aid instruction on this label).
 P332+P313 - If skin irritation occurs: Get medical advice/attention.
 P337+P313 - If eye irritation persists: Get medical advice/attention.
 P362+P364 - Take off contaminated clothing and wash it before reuse.

2.3. Other hazards which do not result in classification

No additional information available

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2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS US classification
Acetic acid	(CAS No) 64-19-7	1-5	Flam. Liq. 3, H226 Skin Corr. 1A, H314

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
- First-aid measures after skin contact : Wash skin with plenty of water. Take off contaminated clothing. If skin irritation occurs: Get medical advice/attention.
- First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
- First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects (acute and delayed)

- Symptoms/effects after skin contact : Irritation.
- Symptoms/effects after eye contact : Irritation to eyes.

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Specific hazards arising from the chemical

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Special protective equipment and precautions for fire-fighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Exercise caution. Spill area may be slippery. Avoid contact with skin and eyes.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Take up liquid spill into absorbent material.
- Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Wear personal protective equipment.
- Hygiene measures : Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a well-ventilated place. Keep cool.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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No additional information available	
Acetic acid (64-19-7)	
USA - ACGIH - Occupational Exposure Limits	
Local name	Acetic acid
ACGIH TWA (ppm)	10 ppm
ACGIH STEL (ppm)	15 ppm
Remark (ACGIH)	TLV® Basis: URT & eye irr; pulm func
Regulatory reference	ACGIH 2020
USA - OSHA - Occupational Exposure Limits	
Local name	Acetic acid
OSHA PEL (TWA) (mg/m ³)	25 mg/m ³
OSHA PEL (TWA) (ppm)	10 ppm
Regulatory reference (US-OSHA)	OSHA Annotated Table Z-1

8.2. Appropriate engineering controls

- Appropriate engineering controls : Ensure good ventilation of the work station.
- Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Hand protection:

Protective gloves

Type	Material	Permeation	Thickness (mm)	Penetration
Disposable gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0.11	

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment.

Personal protective equipment symbol(s):



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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear.
Color	: Colorless.
Odor	: No data available
Odor threshold	: No data available
pH	: No data available
pH solution	: 2.6
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: Not applicable.
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble.
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: Product is not explosive.
Oxidizing properties	: Not oxidising.

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

Acetic acid (64-19-7)

LD50 oral rat	3310 mg/kg body weight
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Acetic acid (64-19-7)	
LC50 Inhalation - Rat	11.4 mg/l (OECD 403, 4 h)
ATE US (oral)	3310 mg/kg body weight
ATE US (vapors)	11.4 mg/l/4h
ATE US (dust, mist)	11.4 mg/l/4h

Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified

Acetic acid (64-19-7)	
NOAEL (oral, rat, 90 days)	290 mg/kg body weight

Aspiration hazard	: Not classified
Viscosity, kinematic	: No data available
Symptoms/effects after skin contact	: Irritation.
Symptoms/effects after eye contact	: Irritation to eyes.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.
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Acetic acid (64-19-7)	
LC50 fish 1	> 1000 mg/l <i>Oncorhynchus mykiss</i> (<i>Salmo gairdneri</i>)
EC50 Daphnia 1	> 1000 mg/l <i>Daphnia magna</i>
LC50 fish 2	> 300.82 mg/l <i>Oncorhynchus mykiss</i> (<i>Salmo gairdneri</i>)
EC50 Daphnia 2	> 300.82 mg/l <i>Daphnia magna</i>

12.2. Persistence and degradability

Acetic acid (64-19-7)	
Persistence and degradability	Readily biodegradable in the soil. Readily biodegradable in water.
Biochemical oxygen demand (BOD)	0.6 – 0.74 g O ₂ /g substance
Chemical oxygen demand (COD)	1.03 g O ₂ /g substance
ThOD	1.07 g O ₂ /g substance

12.3. Bioaccumulative potential

Acetic acid (64-19-7)	
BCF fish 1	3.16
Partition coefficient n-octanol/water (Log Pow)	-0.17 (25 °C)
Bioaccumulative potential	Not bioaccumulative.

12.4. Mobility in soil

Acetic acid (64-19-7)	
Surface tension	26.3 mN/m (30 °C)
Ecology - soil	Highly mobile in soil. May be harmful to plant growth, blooming and fruit formation.

12.5. Other adverse effects

No additional information available

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SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

Transportation of Dangerous Goods

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are listed, or excluded from listing, on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

Acetic acid (64-19-7)	
CERCLA RQ	5000 lb

15.2. International regulations

CANADA

Acetic acid (64-19-7)	
Listed on the Canadian DSL (Domestic Substances List) inventory.	

EU-Regulations

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

Reference code	Applicable	Entry title or description
3(a)	Acetic acid	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F
3(b)	Strep A Extraction Reagent (Ampule) ; Acetic acid	Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10
40.	Acetic acid	Substances classified as flammable gases category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or not.

Contains no REACH candidate substance

Contains no REACH Annex XIV substances.

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance(s) subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

National regulations

No additional information available

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15.3. US State regulations

Component	State or local regulations
Acetic acid(64-19-7)	U.S. - Delaware - Pollutant Discharge Requirements - Reportable Quantities; U.S. - New York City - Right to Know Hazardous Substances List

SECTION 16: Other information

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Revision date : 07/31/2020

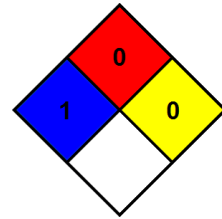
Full text of H-phrases:

H226	Flammable liquid and vapor
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H319	Causes serious eye irritation

NFPA health hazard : 1 - Materials that, under emergency conditions, can cause significant irritation.

NFPA fire hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA reactivity : 0 - Material that in themselves are normally stable, even under fire conditions.



Hazard Rating

Health : 1 Slight Hazard - Irritation or minor reversible injury possible

Flammability : 0 Minimal Hazard - Materials that will not burn

Physical : 0 Minimal Hazard - Materials that are normally stable, even under fire conditions, and will NOT react with water, polymerize, decompose, condense, or self-react. Non-Explosives.

Personal protection : B
B - Safety glasses, Gloves

Indication of changes:

Section	Changed item	Change	Comments
3	Composition/Information on ingredients	Modified	

SDS US (GHS HazCom 2012)

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