

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

1.1. Product identifier

| | |
|---|---|
| Trade name or designation of the mixture | Sekisui RapidTesta® Strep A Extraction Reagent (Ampule) |
| Registration number | - |
| Synonyms | None. |
| Kit number | 408731 |
| Issue date | 22-May-2012 |
| Version number | 01 |
| Revision date | - |
| Supersedes date | - |

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

| | |
|-----------------------------|--|
| Identified uses | For In Vitro Diagnostic use only. |
| Uses advised against | Use in accordance with supplier's recommendations. |

1.3. Details of the supplier of the safety data sheet

| | |
|--|---|
| Corporate Headquarters | Sekisui Diagnostics, LLC 31 New York Avenue, Framingham, MA 01701 USA www.sekisuidiagnostics.com Phone: 800-332-1042 |
| Distributor | Sekisui Diagnostics (UK) Limited 50 Gibson Drive, Kings Hill, West Malling Kent ME19 4AF UK www.sekisuidiagnostics.com Phone: 44 (0) 1732 220022 info@sekisuidiagnostics.com |
| Contact person | Americas 1-760-476-3962 |
| 1.4. Emergency telephone number | Europe, Middle East & Africa +1-760-476-3961 Asia Pacific +1-760-476-3960 |
| Access code | 333512 |

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

This preparation does not meet the criteria for classification according to Directive 1999/45/EC as amended.

Classification according to Regulation (EC) No 1272/2008 as amended

This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

Hazard summary

| | |
|------------------------------|--|
| Physical hazards | Not classified for physical hazards. |
| Health hazards | Not classified for health hazards. |
| Environmental hazards | Not classified for hazards to the environment. |
| Specific hazards | Avoid contact with eyes and skin. Do not ingest or inhale. |
| Main symptoms | Ingestion may cause irritation and malaise. |

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

| | |
|--------------------------|--|
| Hazard pictograms | None. |
| Signal word | None. |
| Hazard statements | The mixture does not meet the criteria for classification. |

Precautionary statements

| | |
|-------------------|-------|
| Prevention | None. |
| Response | None. |

| | |
|---------------------------------------|---|
| Storage | None. |
| Disposal | None. |
| Supplemental label information | Not applicable. |
| 2.3. Other hazards | Not a PBT or vPvB substance or mixture. |

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

| Chemical name | % | CAS-No. / EC No. | REACH Registration No. | INDEX No. | Notes |
|------------------------|---|----------------------|------------------------|--------------|-------|
| Acetic acid | 1 - < 3 | 64-19-7 200-580-7 | - | 607-002-00-6 | # |
| Classification: | DSD: R10, C;R35 | | | | |
| | CLP: Flam. Liq. 3;H226, Skin Corr. 1A;H314 | | | | |

DSD: Directive 67/548/EEC.

CLP: Regulation No. 1272/2008.

#: This substance has been assigned Community workplace exposure limit(s).

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. The full text for all R-phrases is displayed in Section 16.

SECTION 4: First aid measures

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

4.1. Description of first aid measures

| | |
|---------------------|--|
| Inhalation | Move to fresh air. Call a physician if symptoms develop or persist. |
| Skin contact | Wash skin thoroughly with soap and water. Get medical attention if irritation develops and persists. |
| Eye contact | In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists. |
| Ingestion | Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Get medical attention if irritation develops and persists. |

4.2. Most important symptoms and effects, both acute and delayed Ingestion may cause irritation and malaise.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards The product is not flammable.

5.1. Extinguishing media

| | |
|---------------------------------------|---|
| Suitable extinguishing media | Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire. |
| Unsuitable extinguishing media | None known. |

5.2. Special hazards arising from the substance or mixture None known.

5.3. Advice for firefighters

| | |
|--|---|
| Special protective equipment for firefighters | Self-contained breathing apparatus and full protective clothing must be worn in case of fire. |
| Special fire fighting procedures | Use standard firefighting procedures and consider the hazards of other involved materials. |

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

| | |
|------------------------------------|--|
| For non-emergency personnel | Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. |
| For emergency responders | Use personal protection as recommended in section 8 of the SDS. |

6.2. Environmental precautions Do not allow to enter drains, sewers or watercourses.

6.3. Methods and material for containment and cleaning up

Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

6.4. Reference to other sections

For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

Store in a closed container away from incompatible materials.

7.3. Specific end use(s)

For In Vitro Diagnostic use only.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

EU. Indicative Exposure Limit Values in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU

| Components | Type | Value |
|---------------------------|------|--------------------------------|
| Acetic acid (CAS 64-19-7) | TWA | 25 mg/m ³ 10 ppm |

Biological limit values

No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures

Follow standard monitoring procedures.

Derived no-effect level (DNEL)

| Components | Type | Route | Value | Form |
|---------------------------|---------|------------|----------------------|-------------------------|
| Acetic acid (CAS 64-19-7) | Workers | Inhalation | 25 mg/m ³ | Acute Local effects |
| | | Inhalation | 25 mg/m ³ | Long term Local effects |

Predicted no effect concentrations (PNECs)

| Components | Type | Route | Value | Form |
|---------------------------|------------------------------|----------------|-------------|------|
| Acetic acid (CAS 64-19-7) | Aqua (freshwater) | Water | 3.058 mg/l | |
| | Aqua (intermittent releases) | Water | 30.58 mg/l | |
| | Aqua (marine water) | Water | 0.3058 mg/l | |
| | Sediment (freshwater) | Not applicable | 11.36 mg/kg | |
| | Sediment (marine water) | Not applicable | 1.136 mg/kg | |
| | Sewage Treatment Plant | Not applicable | 85 mg/l | |
| | Soil | Soil | 0.47 mg/kg | |

8.2. Exposure controls

Appropriate engineering controls

Provide adequate ventilation. Observe Occupational Exposure Limits and minimise the risk of inhalation of vapours.

Individual protection measures, such as personal protective equipment

General information

Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eye/face protection

Wear approved safety glasses or goggles.

Skin protection

- Hand protection

Wear appropriate chemical resistant gloves.

- Other

Remove contaminated clothing promptly.

Respiratory protection

In case of inadequate ventilation or risk of inhalation of vapours, use suitable respiratory equipment.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

Hygiene measures

Handle in accordance with good industrial hygiene and safety practices.

Environmental exposure controls

Inform appropriate managerial or supervisory personnel of all environmental releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|---|
| Appearance | Colourless liquid. |
| Physical state | Liquid. |
| Form | Liquid. |
| Colour | Colourless, clear. |
| Odour | No data available. |
| Odour threshold | Not available. |
| pH | Not applicable. |
| Melting point/freezing point | Not available. |
| Initial boiling point and boiling range | Not available. |
| Flash point | Not applicable. |
| Evaporation rate | Not applicable. |
| Flammability (solid, gas) | Not applicable. |
| Upper/lower flammability or explosive limits | |
| Flammability limit - lower (%) | Not available. |
| Flammability limit - upper (%) | Not available. |
| Vapour pressure | Not applicable. |
| Vapour density | Not applicable. |
| Relative density | Not available. |
| Solubility(ies) | Soluble. |
| Partition coefficient (n-octanol/water) | Not applicable. |
| Decomposition temperature | Not available. |
| Viscosity | Not applicable. |
| Explosive properties | Not available. |
| Oxidizing properties | Not available. |
| 9.2. Other information | No relevant additional information available. |

SECTION 10: Stability and reactivity

| | |
|---|---|
| 10.1. Reactivity | The product is stable and non reactive under normal conditions of use, storage and transport. |
| 10.2. Chemical stability | Material is stable under normal conditions. |
| 10.3. Possibility of hazardous reactions | Polymerization will not occur. |
| 10.4. Conditions to avoid | Heat, sparks, flames, elevated temperatures. |
| 10.5. Incompatible materials | Strong oxidising agents. |
| 10.6. Hazardous decomposition products | No data available. |

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

| | |
|---------------------|--|
| Ingestion | May cause discomfort if swallowed. |
| Inhalation | In high concentrations, vapours may be irritating to the respiratory system. |
| Skin contact | May cause skin irritation. |
| Eye contact | May cause eye irritation. |

Symptoms Ingestion may cause irritation and malaise.

11.1. Information on toxicological effects

Acute toxicity May cause discomfort if swallowed.

| Components | Species | Test results |
|---------------------------|----------------|---------------------|
| Acetic acid (CAS 64-19-7) | | |
| Acute | | |
| <i>Dermal</i> | | |
| LD50 | Rabbit | 1060 mg/kg |

| Components | Species | Test results |
|---|---|--------------------|
| <i>Inhalation</i> | | |
| LC50 | Rat | 11.4 mg/l, 4 Hours |
| <i>Oral</i> | | |
| LD50 | Rat | 3.31 g/kg |
| Skin corrosion/irritation | May cause skin irritation. | |
| Serious eye damage/irritation | May cause eye irritation. | |
| Respiratory sensitisation | Not classified. | |
| Skin sensitisation | Not classified. | |
| Germ cell mutagenicity | Not classified. | |
| Carcinogenicity | Not classified. | |
| Reproductive toxicity | Not classified. | |
| Specific target organ toxicity - single exposure | Not classified. | |
| Specific target organ toxicity - repeated exposure | Not classified. | |
| Aspiration hazard | Not classified. | |
| Mixture versus substance information | Not available. | |
| Other information | No other specific acute or chronic health impact noted. | |

SECTION 12: Ecological information

12.1. Toxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

| Components | Species | Test results |
|---------------------------|---------|---|
| Acetic acid (CAS 64-19-7) | | |
| Aquatic | | |
| Crustacea | EC50 | Water flea (<i>Daphnia magna</i>) 65 mg/l, 48 hours |
| Fish | LC50 | Bluegill (<i>Lepomis macrochirus</i>) 75 mg/l, 96 hours |
| | | Fathead minnow (<i>Pimephales promelas</i>) 79 mg/l, 96 Hours |

12.2. Persistence and degradability No data is available on the degradability of this product.

12.3. Bioaccumulative potential Not available.

Partition coefficient n-octanol/water (log Kow) Not applicable.

Acetic acid -0.17

Bioconcentration factor (BCF) Not available.

12.4. Mobility in soil Not available.

Mobility in general The product is soluble in water.

12.5. Results of PBT and vPvB assessment Not a PBT or vPvB substance or mixture.

12.6. Other adverse effects The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

| | |
|-------------------------------------|---|
| Residual waste | Dispose in accordance with all applicable regulations. Contract with a licensed chemical disposal agency. |
| Contaminated packaging | Empty containers should be taken to an approved waste handling site for recycling or disposal. |
| EU waste code | The Waste code should be assigned in discussion between the user, the producer and the waste disposal company. |
| Disposal methods/information | Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions. |

SECTION 14: Transport information

ADR

The product is not covered by international regulation on the transport of dangerous goods.

RID

The product is not covered by international regulation on the transport of dangerous goods.

ADN

The product is not covered by international regulation on the transport of dangerous goods.

IATA

The product is not covered by international regulation on the transport of dangerous goods.

IMDG

The product is not covered by international regulation on the transport of dangerous goods.

SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 143/2011 Annex XIV Substances Subject to Authorisation

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not regulated.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not regulated.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not regulated.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Acetic acid (CAS 64-19-7)

Directive 94/33/EC on the protection of young people at work

Acetic acid (CAS 64-19-7)

Other regulations

This product does not meet the criteria for classification according to Regulation (EC) 1272/2008 (CLP Regulation) and Directive 1999/45/EC and their amendments respectively. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006. In the European Union this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

National regulations

The product has not been classified as dangerous according to the legislation in force.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

DNEL: Derived No-Effect Level.
PNEC: Predicted No-Effect Concentration.
PBT: Persistent, bioaccumulative and toxic.
vPvB: Very Persistent and very Bioaccumulative.

References

Not available.

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R10 Flammable.
R35 Causes severe burns.

H226 - Flammable liquid and vapour.
H314 - Causes severe skin burns and eye damage.

Training information

Follow training instructions when handling this material.

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