



Safety Data Sheet

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| Document group: | 11-2863-6 | Version number: | 1.00 |
| Issue Date: | 17/09/2025 | Supersedes date: | Initial issue. |

This Safety Data Sheet has been prepared in accordance with the GHS guidelines & India Hazardous substances (Classification, Labeling & Packaging) Draft Rules 2011.

SECTION 1: Identification

1.1. Product identifier

Attest™ Biological Indicators for Steam 1261, 1261P, 1262, 1262P & 1262-S

Product Identification Numbers

70-2005-0348-3 70-2007-5058-9

1.2. Recommended use and restrictions on use

Recommended use

Sterilization process indicator , To indicate attainment of conditions for sterilization.

1.3. Supplier's details

Address: KCI Medical India Private Limited, S - 327, Greater Kailash - II, New Delhi, Delhi, 110048, India
Telephone: 1-855-423-6725
E Mail: psops_supportteam@solventum.com
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1.4. Emergency telephone number

CHEMTREC 1-800-424-9300 OR 1-703-527-3887, Contract number# 1015211

SECTION 2: Hazard identification

Under MSIHC Rules, information is noted below on flammability, acute toxicity and explosivity relevant to this product. In line with international standards, information on other hazard classes and associated precautionary statements relevant to this product are included as well.

2.1. Classification of the substance or mixture

Not classified as hazardous according to UN GHS criteria.

2.2. Label elements

Signal Word

Not applicable.

Symbols

Not applicable

Pictograms

Not applicable

2.3. Other hazards

None known.

SECTION 3: Composition/information on ingredients

This material is a mixture.

| Ingredient | CAS Nbr | % by Wt |
|--|----------------|----------------|
| Water | 7732-18-5 | 99.8 |
| Glucose | 50-99-7 | < 0.19 |
| L-Tyrosine | 60-18-4 | < 0.01 |
| L-ALANINE | 56-41-7 | < 0.004 |
| BROMOCRESOL PURPLE, MONOSODIUM SALT | 62625-30-3 | < 0.001 |
| Inosine | 58-63-9 | < 0.001 |

SECTION 4: First aid measures**4.1. Description of first aid measures****Inhalation**

No need for first aid is anticipated. If symptoms develop, remove the affected person to fresh air. Get medical attention.

Skin contact

If exposed, wash with soap and water. If signs/symptoms develop, get medical attention.

Eye contact

If exposed, flush eyes with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If signs/symptoms develop, get medical attention.

If swallowed

Rinse mouth. If you feel unwell, get medical attention.

4.2. Most important symptoms and effects, both acute and delayed

No critical symptoms or effects. See Section 11.1, information on toxicological effects.

4.3. Indication of any immediate medical attention and special treatment required

Not applicable

SECTION 5: Fire-fighting measures**5.1. Suitable Extinguishing media**

In case of fire: Use a fire fighting agent suitable for ordinary combustible material such as water or foam to extinguish.

5.2. Special hazards arising from the substance or mixture

None inherent in this product.

5.3. Special protective actions for fire-fighters

Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus,

bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ventilate the area with fresh air. Observe precautions from other sections.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Contain spill. Working from around the edges of the spill inward, cover with bentonite, vermiculite, or commercially available inorganic absorbent material. Mix in sufficient absorbent until it appears dry. Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Clean up residue with an appropriate solvent selected by a qualified and authorised person. Ventilate the area with fresh air. Read and follow safety precautions on the solvent label and Safety Data Sheet. Seal the container. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid skin contact with hot material.

7.2. Conditions for safe storage including any incompatibilities

No special storage requirements.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

No occupational exposure limit values exist for any of the components listed in Section 3 of this Safety Data Sheet.

8.2. Exposure controls

8.2.1. Engineering controls

No engineering controls required.

8.2.2. Personal protective equipment (PPE)

Eye/face protection

None required.

Skin/hand protection

PPE No chemical protective gloves are required.

Respiratory protection

None required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|----------------|---------|
| Physical state | Liquid. |
|----------------|---------|

| | |
|--|---|
| Specific Physical Form: | Glass ampule with test strip and media, enclosed in a covered plastic vial. |
| Color | Multicolor |
| Odor | Nearly Odorless |
| Odour threshold | <i>Not applicable.</i> |
| pH | ± 7.5 [<i>Details:(applies to media)</i>] |
| Melting point/Freezing point: NA | <i>No data available.</i> |
| Boiling point/Initial boiling point/Boiling range | ± 100 °C [<i>Details:(applies to media)</i>] |
| Flash point | 121.1 °C |
| Evaporation rate | <i>No data available.</i> |
| Flammability | Not applicable. |
| Flammable Limits(LEL) | <i>Not applicable.</i> |
| Flammable Limits(UEL) | <i>Not applicable.</i> |
| Vapour pressure | <i>Not applicable.</i> |
| Relative Vapor Density | <i>Not applicable.</i> |
| Density | 1 g/ml |
| Relative density | ± 1 [<i>Ref Std:WATER=1</i>] |
| Water solubility | Negligible |
| Solubility- non-water | <i>Not applicable.</i> |
| Partition coefficient: n-octanol/water | <i>No data available.</i> |
| Autoignition temperature | <i>Not applicable.</i> |
| Decomposition temperature | <i>Not applicable.</i> |
| Kinematic Viscosity | <i>No data available.</i> |
| Volatile organic compounds (VOC) | <i>Not applicable.</i> |
| Percent volatile | ± 0 % |
| VOC less H₂O & exempt solvents | <i>No data available.</i> |
| Molecular weight | <i>No data available.</i> |

| | |
|---------------------------------|------------------------|
| Particle Characteristics | <i>Not applicable.</i> |
|---------------------------------|------------------------|

SECTION 10: Stability and reactivity

10.1 Reactivity

This material is considered to be non reactive under normal use conditions

10.2 Chemical stability

Stable.

10.3 Possibility of hazardous reactions

Hazardous polymerisation will not occur.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Substance

Not applicable.

Condition

Not specified.

SECTION 11: Toxicological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. In addition, toxicological data on ingredients may not be reflected in the material classification and/or the signs and symptoms of exposure, because an ingredient may be present below the threshold for labelling, an ingredient may not be available for exposure, or the data may not be relevant to the material as a whole.

11.1 Information on Toxicological effects

Signs and Symptoms of Exposure

Based on test data and/or information on the components, this material may produce the following health effects:

Inhalation

No health effects are expected.

Skin contact

Contact with the skin during product use is not expected to result in significant irritation.

Eye contact

Contact with the eyes during product use is not expected to result in significant irritation.

Ingestion

Physical Blockage: Signs/symptoms may include cramping, abdominal pain, and constipation.

Toxicological Data

If a component is disclosed in section 3 but does not appear in a table below, either no data are available for that endpoint or the data are not sufficient for classification.

Acute Toxicity

| Name | Route | Species | Value |
|-----------------|-----------|---------|--|
| Overall product | Ingestion | | No data available; calculated ATE >5,000 mg/kg |

ATE = acute toxicity estimate

Skin Corrosion/Irritation

For the component/components, either no data are currently available or the data are not sufficient for classification.

Serious Eye Damage/Irritation

For the component/components, either no data are currently available or the data are not sufficient for classification.

Sensitization:

Skin Sensitisation

For the component/components, either no data are currently available or the data are not sufficient for classification.

Respiratory Sensitisation

For the component/components, either no data are currently available or the data are not sufficient for classification.

Germ Cell Mutagenicity

For the component/components, either no data are currently available or the data are not sufficient for classification.

Carcinogenicity

For the component/components, either no data are currently available or the data are not sufficient for classification.

Reproductive Toxicity

Reproductive and/or Developmental Effects

For the component/components, either no data are currently available or the data are not sufficient for classification.

Target Organ(s)**Specific Target Organ Toxicity - single exposure**

For the component/components, either no data are currently available or the data are not sufficient for classification.

Specific Target Organ Toxicity - repeated exposure

For the component/components, either no data are currently available or the data are not sufficient for classification.

Aspiration Hazard

For the component/components, either no data are currently available or the data are not sufficient for classification.

Please contact the address or phone number listed on the first page of the SDS for additional toxicological information on this material and/or its components.

SECTION 12: Ecological information

The information below may not be consistent with the material classification in Section 2 if specific ingredient classifications are mandated by a competent authority. Additional information leading to material classification in Section 2 is available upon request. In addition, environmental fate and effects data on ingredients may not be reflected in this section because an ingredient is present below the threshold for labelling, an ingredient is not expected to be available for exposure, or the data is considered not relevant to the material as a whole.

12.1. Toxicity**Acute aquatic hazard:**

Not acutely toxic to aquatic life by GHS criteria.

Chronic aquatic hazard:

Not chronically toxic to aquatic life by GHS criteria.

No product test data available.

| Material | CAS Nbr | Organism | Type | Exposure | Test endpoint | Test result |
|-------------------------------------|------------|-------------|---|----------|---------------|-------------|
| BROMOCRESOL PURPLE, MONOSODIUM SALT | 62625-30-3 | N/A | Data not available or insufficient for classification | N/A | N/A | N/A |
| Glucose | 50-99-7 | N/A | Data not available or insufficient for classification | N/A | N/A | N/A |
| Inosine | 58-63-9 | N/A | Data not available or insufficient for classification | N/A | N/A | N/A |
| L-ALANINE | 56-41-7 | N/A | Data not available or insufficient for classification | N/A | N/A | N/A |
| L-Tyrosine | 60-18-4 | Green algae | Experimental | 72 hours | ErC50 | >100 mg/l |
| L-Tyrosine | 60-18-4 | Water flea | Experimental | 48 hours | EC50 | >100 mg/l |
| L-Tyrosine | 60-18-4 | Green algae | Experimental | 72 hours | ErC10 | >100 mg/l |

12.2. Persistence and degradability

| Material | CAS Nbr | Test type | Duration | Study Type | Test result | Protocol |
|-------------------------------------|------------|---------------------------------|----------|------------|---------------|----------|
| BROMOCRESOL PURPLE, MONOSODIUM SALT | 62625-30-3 | Data not available-insufficient | N/A | N/A | N/A | N/A |
| Glucose | 50-99-7 | Data not available-insufficient | N/A | N/A | N/A | N/A |
| Inosine | 58-63-9 | Data not available-insufficient | N/A | N/A | N/A | N/A |
| L-ALANINE | 56-41-7 | Data not available-insufficient | N/A | N/A | N/A | N/A |
| L-Tyrosine | 60-18-4 | Experimental Biodegradation | 5 days | BOD | 60.8 %BOD/COD | |

12.3 : Bioaccumulative potential

| Material | CAS Nbr | Test type | Duration | Study Type | Test result | Protocol |
|-------------------------------------|------------|---|----------|------------|-------------|---------------------------------|
| BROMOCRESOL PURPLE, MONOSODIUM SALT | 62625-30-3 | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| Glucose | 50-99-7 | Experimental Bioconcentration | | Log Kow | -3.24 | |
| Inosine | 58-63-9 | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| L-ALANINE | 56-41-7 | Data not available or insufficient for classification | N/A | N/A | N/A | N/A |
| L-Tyrosine | 60-18-4 | Experimental Bioconcentration | | Log Kow | <-2 | OECD 107 log Kow shke flask mtd |

12.4. Mobility in soil

Please contact manufacturer for more details

12.5 Other Adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Disposal methods

Dispose of contents/ container in accordance with the local/regional/national/international regulations.

Prior to disposal, consult all applicable authorities and regulations to insure proper classification. Dispose of waste product in a permitted industrial waste facility. As a disposal alternative, incinerate in a permitted waste incineration facility. Proper destruction may require the use of additional fuel during incineration processes. Empty and clean product containers may be disposed as non-hazardous waste. Consult your specific regulations and service providers to determine available options and requirements.

SECTION 14: Transport Information

Not hazardous for transportation.

Air Transport (IATA) Regulations

UN No Not applicable
Proper Shipping Name Not applicable
Hazard Class/Division Not applicable
Subsidiary Risk Not applicable
Packing Group: Not applicable

Marine Transport (IMDG)

UN No Not applicable
Proper Shipping Name Not applicable
Hazard Class/Division Not applicable
Subsidiary Risk Not applicable
Packing Group: Not applicable
Environmental Hazards: Not applicable

SECTION 15: Regulatory information

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

Global inventory status

Contact 3M for more information.

Applicable Environmental, Health and Safety Regulations

The Manufacture, Storage and Import of Hazardous Chemical Rules, 1989

The following ingredients are listed as hazardous on Part II of Schedule I of the India Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) rules

None.

The following ingredients are classified as hazardous based on the criteria listed under Part I of Schedule I of the India Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) rules:

The product is classified as Non-hazardous as per MSIHC Rules, 1989.

SECTION 16: Other information

NFPA Hazard Classification

Health: 0 **Flammability:** 1 **Instability:** 0 **Special Hazards:** None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

Revision information:

No revision information

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