Safety Data Sheet

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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 ™ Super Rapid Readout Biological Indicator 1491 & 1492V

Product Identification Numbers
70-2007-6356-6

1.2. Recommended use and restrictions on use

Recommended use
To indicate attainment or 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
Plastic Tube	111211-39-3	50 - 60
Polypropylene Cap	9003-07-0	20 - 25
Growth media solution	None	10 - 15
Borosilicate Glass ampule	Mixture	5 - 10
Process Aid	17833-43-1	< 5
Nylon Nonwoven	Mixture	< 2
Label	65996-61-4	< 2
Geobacillus stearothermophilius spores	None	0.01 - 0.05

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
Use a fire fighting agent suitable for the surrounding fire.

5.2. Special hazards arising from the substance or mixture
None inherent in this product.

Hazardous Decomposition or By-Products

Substance	Condition
Carbon monoxide.	During combustion.
Carbon dioxide.	During combustion.

5.3. Special protective actions for fire-fighters
No special protective actions for fire-fighters are anticipated.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Observe precautions from other sections. Use PPE - Exposure Assessment Use personal protective equipment based on the results of an exposure assessment. Refer to Section 8 for PPE recommendations. If anticipated exposure resulting from an accidental release exceeds the protective capabilities of the PPE listed in Section 8, or are unknown, select PPE that offers an appropriate level of protection. Consider the physical and chemical hazards of the material when doing so. Examples of PPE ensembles for emergency response could include wearing bunker gear for a release of flammable material; wearing chemical protective clothing if the spilled material is a corrosive, a sensitizer, a significant dermal irritant, or can be absorbed through the skin; or donning a positive pressure supplied-air respirator for chemicals with inhalation hazards. For information regarding physical and health hazards, refer to sections 2 and 11 of the SDS.

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. Remember, adding an absorbent material does not remove a physical, health, or environmental hazard. 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 release to the environment.

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
Not applicable.

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.
Color	Multicolor
Odor	Nearly Odorless
Odour threshold	*Not applicable.*
pH	7.5 [*Details:*(applies to media)]
Melting point/Freezing point: NA	*Not applicable.*
Boiling point/Initial boiling point/Boiling range	100 ºC [*Details:*applies to media]
Flash point	No flash point
Evaporation rate	*No data available.*
Flammability	Not applicable.
Flammable Limits(LEL)	*Not applicable.*
Flammable Limits(UEL)	*Not applicable.*
Vapour pressure	*Not applicable.*
Relative Vapor Density	*Not applicable.*
Density	1 g/ml
Relative density	1 [*Ref Std:*WATER=1]
Water solubility	Negligible
Solubility- non-water	*Not applicable.*
Partition coefficient: n-octanol/water	*Not applicable.*
Autoignition temperature	*Not applicable.*
Decomposition temperature	*Not applicable.*
Kinematic Viscosity	*No data available.*
Volatile organic compounds (VOC)	*No data available.*
Percent volatile	*No data available.*
VOC less H2O & exempt solvents	*No data available.*
Molecular weight	*No data available.*

Particle Characteristics	*Not applicable.*

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	Condition
None known.	

Refer to section 5.2 for hazardous decomposition products during combustion.

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
No health effects are expected.

Eye contact
No health effects are expected.

Ingestion
No health effects are expected. 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
Plastic Tube	Dermal	Professional judgement	LD50 > 2,000 mg/kg
Plastic Tube	Ingestion	Professional judgement	LD50 > 5,000 mg/kg
Polypropylene Cap	Dermal		LD50 estimated to be > 5,000 mg/kg
Polypropylene Cap	Ingestion	Mouse	LD50 > 8,000 mg/kg
Label	Ingestion	similar compounds	LD50 > 5,000 mg/kg

Label	Dermal	similar health hazards	LD50 estimated to be > 5,000 mg/kg

ATE = acute toxicity estimate

Skin Corrosion/Irritation

Name	Species	Value
Plastic Tube	similar compounds	No significant irritation
Polypropylene Cap	Human and animal	No significant irritation
Label	similar compounds	No significant irritation

Serious Eye Damage/Irritation

Name	Species	Value
Plastic Tube	similar compounds	Mild irritant
Polypropylene Cap	Professional judgement	No significant irritation
Label	similar compounds	Mild irritant

Sensitization:

Skin Sensitisation

Name	Species	Value
Plastic Tube	similar compounds	Not classified
Polypropylene Cap	Human and animal	Not classified
Label	similar compounds	Not classified

Respiratory Sensitisation

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

Germ Cell Mutagenicity

Name	Route	Value
Polypropylene Cap	In Vitro	Not mutagenic
Label	In Vitro	Not mutagenic

Carcinogenicity

Name	Route	Species	Value
Polypropylene Cap	Not specified.	Rat	Some positive data exist, but 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
Plastic Tube	111211-39-3	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Polypropylene Cap	9003-07-0	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Process Aid	17833-43-1	N/A	Data not available or insufficient for classification	N/A	N/A	N/A
Label	65996-61-4	N/A	Data not available or insufficient for classification	N/A	N/A	N/A

12.2. Persistence and degradability

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Plastic Tube	111211-39-3	Data not	N/A	N/A	N/A	N/A

		available-insufficient				
Polypropylene Cap	9003-07-0	Data not available-insufficient	N/A	N/A	N/A	N/A
Process Aid	17833-43-1	Estimated Biodegradation	28 days	BOD	41 %BOD/ThOD	OECD 301F - Manometric respirometry
Label	65996-61-4	Data not available-insufficient	N/A	N/A	N/A	N/A

12.3 : Bioaccumulative potential

Material	CAS Nbr	Test type	Duration	Study Type	Test result	Protocol
Plastic Tube	111211-39-3	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Polypropylene Cap	9003-07-0	Data not available or insufficient for classification	N/A	N/A	N/A	N/A
Process Aid	17833-43-1	Experimental Bioconcentration		Log Kow	-0.66	
Label	65996-61-4	Data not available or insufficient for classification	N/A	N/A	N/A	N/A

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.

SECTION 14: Transport Information

Not hazardous for transportation.

Air Transport (IATA)Regulations

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

Marine Transport (IMDG)
UN No Not applicable
Proper Shipping Name Not applicable
Hazard Classs/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 manufacturer for more information This product complies with Measures on Environmental Management of New Chemical Substances. All ingredients are listed on or exempt from on China IECSC inventory.

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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