



**specializing in sterilization
design, validation and monitoring**

Material Safety Data Sheet for **gke-Steri-Record®** Biological Indicators

Review 02.07.17

I General Information

Manufacturer's Name	gke-mbH
Emergency Telephone Number	0049-(0)6126-9432-50
Address	Auf der Lind 10 65529 Waldems-Esch
Chemical Name or Synonyms	Biological Indicator
Tradename	gke-Steri-Record® Biological Indicators
Formula	Non-pathogenic spores of <i>Bacillus stearothermophilus</i> , <i>Bacillus subtilis</i> or <i>Bacillus pumilus</i> in different variations (see Section III).

II Hazardous Ingredients

Paints, Preservatives & solvents	n/a
Alloys and Metallic coatings	n/a
Hazardous Mixtures of other liquids, solids, or gases	n/a

III Physical Data

Boiling Point	n/a
Vapor Pressure	n/a
Vapor Density	n/a
Solubility in Water	n/a
Specific Gravity	n/a
Percent Volatile	n/a
Evaporation Rate	n/a
Appearance and Odor	

The **gke-Steri-Record®** Biological Indicators (BI) are supplied as

1. Suspensions (BI suspended in 40 % Ethanol or pure water solution and packaged in 10 ml glass vial)
2. Spore Strips (BI on a paper filter strip packaged in blue glassine envelopes)
3. Ampoules (BI suspended in Tryptic Soy Broth with pH indicator and packaged in a hermetically sealed glass ampoule)
4. Selfcontained BI "Bio Plus" (BI inoculated on a paper filter disc and a glass media ampoule in a covered plastic vial)

No specific odor is associated with these products.

IV Fire and Explosion Hazard Data

flash point	n/a
flammable limits	n/a



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V Health Hazard Data

Eye Contact	No irritation is expected. In case of contact, flush with water.
Skin Contact	No skin irritation is expected from accidental contact. In case of contact, flush with water.
Inhalation	Inhalation is not a likely route of exposure to this product. No health hazards are expected from accidental inhalation of the microorganisms.
If Swallowed	Ingestion is not a likely route of exposure. No health hazards have been associated with accidental exposure to these products.
Other Health Hazard Information	The microorganisms contained in these biological indicators are non-pathogenic organisms.
Protective Clothing	Safety glasses and gloves should be used when removing ampoules with biological indicators from the sterilizer. In all other cases, the use of gloves, moisture impervious aprons, and other protective clothing must be dictated by the standard operational procedures of each individual laboratory.

VI Reactivity Data

Stability	The product is stable if the proper storage conditions are met.
Incompatibility	n/a
Hazardous Decomposition Products	n/a
Hazardous Polymerization	n/a

VII Spill or Leak Procedures

Steps to be taken in case material is spilled or released	Clean and disinfect exposed surface.
Waste Disposal Method	Precautions should be taken against microbial hazard. Sterilize at 121°C 15 minutes or incinerate any materials that have been used during processing of these materials.

VIII Special Protection Information

Respiratory Protection	The use of biohazardous hoods and the prevention of aerosols must be dictated by the standard operational procedures of each individual laboratory.
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IX Special Precautions

The Product Certificate of Analysis, which accompanies the distribution of each product, contains specific information regarding specific precautions.

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