

GKE Steri-Record® Spore Suspension

Art.-No.*	Product Code	Biological Indicator Germ	Sterilization Process	Concentration [CFU/ml]	Pop./bottle [CFU/10 ml]	Incubation temperature
226-107	B-E-H-SUS-10-7**	<i>B. atrophaeus</i> 9372	Ethylene oxide, Dry heat	10 ⁷	10 ⁸	33 – 37 °C
226-108	B-E-H-SUS-10-8**			10 ⁸	10 ⁹	
226-109	B-E-H-SUS-10-9**			10 ⁹	10 ¹⁰	
227-107	B-S-SUS-10-7	<i>B. subtilis</i> 5230	Low Temperature Steam	10 ⁷	10 ⁸	
227-108	B-S-SUS-10-8			10 ⁸	10 ⁹	
227-109	B-S-SUS-10-9			10 ⁹	10 ¹⁰	
228-107	B-S-F-SUS-10-7***	<i>Geob. Stearothermophilus</i> 7953	Steam, Formaldehyde	10 ⁷	10 ⁸	55 – 60 °C
228-108	B-S-F-SUS-10-8***			10 ⁸	10 ⁹	
228-109	B-S-F-SUS-10-9***			10 ⁹	10 ¹⁰	
229-107	B-V-SUS-10-7****		Hydrogen Peroxide	10 ⁷	10 ⁸	
229-108	B-V-SUS-10-8****			10 ⁸	10 ⁹	

Art.-No.	Product Code	
226-999	Determination Dry Heat	Determination D-value for dry heat
228-998	Determination LTSF	Determination D-value for formaldehyde (LTSF)

(*) To all article numbers a 3-digit alpha code is added. The additional letter code refers to the language and/or customized version. It is only added on the outside label; the inside of the pack is identical to the article numbers on the above table.

(**) The D-value for ethylene oxide is specified in the certificate, not the D-value for dry heat, which can be determined at extra cost (226-999).

(***) The D-value for steam is specified in the certificate, not the D-value for formaldehyde which can be determined at extra cost (228-998).

(****) The D-value for hydrogen peroxide is specified in the certificate.

Application

The GKE Steri-Record® spore suspension is used for inoculation of products for the biological performance evaluation of sterilization processes. For inoculation and incubation, a microbiological laboratory is required.

Product Description

The GKE Steri-Record® spore suspension vial contains 10 ml resistant bacterial spore suspension.

Performance Characteristics

All GKE spore suspensions are produced in accordance to the EN ISO 11138 standard series and the current European and United States Pharmacopoeia (EP + USP). Population and D-value are measured and certified for each batch documented in the certificate of analysis. According to EP the D-value and z-value (if appropriate) of the spores of the inoculated test items / products must be determined by the user as this may be different from the spores in suspension.

For hydrogen peroxide a standard does not yet exist since no appropriate resistometers/test sterilizers are available to measure D-values. Therefore, most manufacturers have their own test procedures that are not comparable. GKE has developed a test method for hydrogen peroxide in liquid H₂O₂ solution. This test method has been published in Central Service 3/2016, page 171-176. By using this method, it will be possible to compare resistance of BIs from different manufacturers for the first time.

Handling Information

1. Select the spore suspension of appropriate organism and population. If working with spore suspensions always keep the suspensions cooled. Any temperature rise may lead to a loss of population. Therefore, it is recommended to work on crushed ice or to use a temperature cooling block. In this way, the stability of population is ensured until the end of the shelf life.
2. Before use, vigorously shake suspension vial. Keep vial closed. (It may be useful to put the closed vial for 5 minutes into an ultrasonic bath to disaggregate possible agglutinations of spores prior to population determination).
3. Use a sterile dispenser or syringe to withdraw suspension.
4. Put suspension onto or into the product. The area to be inoculated should be the most difficult to sterilize.
5. Place the inoculated products in the sterilizer and run the program.

6. Culturing:

Geob. stearothermophilus: When incubated in nutrient broth or appropriate solid media, growth occurs aerobically within 24 hours at 55 to 60 °C.

B. atrophaeus/ B. subtilis 5230: When incubated aerobically in appropriate media at 33 to 37 °C, growth occurs within 24 hours

If used for validation purposes a 7 days incubation period is advisable depending on the used growth medium. Otherwise, possible late out growing of pre-damaged spores due to the sterilization process could influence the final results.

Microscopy: Under microscopic examination it consists of gram-positive rods with oval endospores in subterminally swollen cells.

Biochemical Analysis: When examined under conventional biochemical tests for microbial characterization it shows a delayed weak positive catalase reaction, it does not utilize citrate, propionate or hippurate, but it reduces nitrate, it does not liquefy gelatine, it gives a negative result with the Voges-Proskauer test. It also shows negative egg yolk and starch hydrolysis reactions.

Storage and Disposal

1. Store at 2-8°C, away from sterilizing agents.
2. Sterilize spore suspension before disposal.
3. Do not use after expiry date.

For further technical details please contact your local dealer or the GKE application laboratory. We will assist you with any technical questions. Also visit our website www.gke.eu for more information.

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