SGM BIOTECH®
BIOLOGICAL INDICATOR SPECIALISTS

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Introducing SterilFlex®

One of SGM's more popular biological indicators is the SterilAmp®II, which was designed for monitoring the steam sterilization of liquid products. SGM began receiving requests from the food industry for producing a glass-free version of the SterilAmp II. After experimenting with nearly forty different prototype lots, we are happy to announce the arrival of the SterilFlex biological indicator.

The driving force behind the requests for the SterilFlex BI was a glass-free biological indicator. Many producers of thermally processed food products to be aseptically packaged forbid the presence of glass in their manufacturing lines. This practice eliminates the possibility of the end products becoming contaminated with glass chards from broken biological indicators. For these companies, finding an appropriate liquid submersible BI to monitor the sterilization process that was both convenient to use, and glass-free was a significant problem.

SterilFlex was developed for the manufacturers of liquid foods and pharmaceutical products, sterilized by moist heat processes. The bacterial spores in this unit respond predictably to specific F_o exposures measured in the product or product containers by certified thermocouples. SterilFlex is a totally self-contained unit, easy to use, and requires no sophisticated laboratory testing or analysis.

SterilFlex biological indicators contain spores of *Geobacillus stearothermophilus* 7953[(1)] suspended in a specially formulated culture medium. The growth medium has a color (pH) indicator to aid in the early detection of growth. The indicator is purple when the biological indicators are manufactured. To test for surviving spores, simply incubate the SterilFlex BI at 60ºC. Spores that have survived the sterilization process will turn the culture medium from purple to yellow within 48 hours of incubation.

Early SterilFlex prototypes were constructed of polypropylene, and worked well at common sterilization temperatures, but a study performed by the USDA and the Department of Food Science at North Carolina State University revealed a problem with the BI. In this study, the SterilFlex BIs were fed through a continuous-flow microwave heating system. The higher temperatures in combination with the mechanical mixing caused many of the SterilFlex units to rupture. Complete details of this study, titled "Feasibility of Utilizing Bioindicators for Testing Microbial Inactivation in Sweetpotato Purees Processed with a Continuous-Flow Microwave System" can be found in the Journal of Food Science (Vol.72, Nr. 5, 2007)

The results of this study indicated the need for a more robust plastic. SterilFlex is now manufactured with a food grade "thermoplastic" that can withstand temperatures well above those typically used for thermal processing with moist heat sterilization.

The SterilFlex BI has comparable performance characteristics to the SterilAmp biological indicator. SterilFlex has been produced with D_{121}-values ranging from 1.2 minutes to 3.2 minutes, depending on the spore crop used (see Table 1).

Table 1. D-value and z-value Data From Five Lots of SterilFlex BIs

Lot	Spore crop	population	D_{121}-value	D_{124}-value	D_{127}-value	z-value	F_0-value	
							Survival	Kill
SF-029	A	1.4×10^6	3.2 min	1.3 min	0.6 min	8.0ºC	18.5 min	21.5 min
SF-035	B	3.9×10^6	1.4 min	0.5 min	0.3 min	9.0ºC	8 min	12 min
SF-036	C	4.3×10^5	1.2 min	0.5 min	0.2 min	8.5ºC	5 min	10 min
SF-037	B	1.3×10^6	1.4 min	0.6 min	0.2 min	7.9ºC	7 min	13 min
SF-041	D	1.7×10^6	2.6 min	1.2 min	0.6 min	10.0ºC	14 min	20 min

The physical characteristics of SterilFlex allow it to be used more universally than the SterilAmp product. It is smaller in size which may allow for easier placement in the load. It is more robust, minimizing the threat of a compromised unit that may result in the release of the test organism into the environment. And lastly and in many cases most importantly, it is glass-free. A summary of the physical characteristics of SterilFlex is presented in Table 2.

Table 2. Summary of SterilFlex Physical Characteristics

Average length of unit	17mm
Average width of unit	10mm
Average thickness of unit	3mm
Average mass of unit	0.21g
Average volume displacement of unit	0.2ml
Average internal volume of unit	50µl
Approximate density	1.05g/ml*

*Water = 1.0

In summary, the use of SterilFlex is an ideal monitoring system due to its small size and easy post processing read out. It can be easily placed into a container or it can be used in continuous flow aseptic fill systems. Additional information on SterilFlex and other biological indicators can be found at www.sgmbiotech.com.

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