

PRODUCT CHANGE NOTIFICATION

17 December 2019

Notification ID: 191201

Notification Type: Product Packaging Change

Dear Customer,

We would like to take this opportunity to update you on the status of our glassine transition. Per customer notification #CN-190901 we notified you of an impending change to the packaging of our paper strip biological indicators due to the discontinuation of the adhesive that was used to bond the two pieces of glassine together.

The intent of this notification is to provide an update on that transition, including any changes to the appearance/packaging of our paper strip biological indicator products and the lot numbers associated with the change in adhesive. The products listed below will transition to two pieces of zone coated glassine bonded together. Changes to the outward appearance will include:

- The glue pattern on the glassine will appear different.
- There will be a black register mark on both sides of the envelope
- Minor changes to the font, formatting and/or placement of the text printed on the glassine.

Part #	Description	Transition Lot #
3-4100, 3-5100, 3-1000, 3-6100	SporeStrip <i>Geobacillus stearothermophilus</i>	GSS-015
5-5100T, 5-1000T, 5-1000C	SporeStrip Dual Species	DSS-028
SGMS/3, SGMS/5, SGMS/6	MesaStrip <i>Geobacillus stearothermophilus</i>	GST-496
S1X25/6G, S2X10/6G	MesaStrip - Custom <i>Geobacillus stearothermophilus</i>	CGST-339
DS6R/6G	MesaDisc <i>Geobacillus stearothermophilus</i>	DGST-177

The products listed below will transition to the glassine coated with the new adhesive and continue to be manufactured using a zone coated front-webbing glassine and a flood coated back-webbing glassine. Changes to the outward appearance will include:

- Minor changes to the font, formatting and/or placement of the text printed on the glassine.

Part #	Description	Transition Lot #
1-4100, 1-6100, 1-6500, 1-1000	SporeStrip <i>Bacillus atrophaeus</i>	BAS-007
SGMG/6	Mesa Strip <i>Bacillus atrophaeus</i>	BATR-465
A1X25/6G, A2X10/6G	MesaStrip - Custom <i>Bacillus atrophaeus</i>	CBATR-207
RG/100	Releasat Kit	RG-318
SGMR/6, SGMR/7	MesaStrip <i>Bacillus pumilus</i>	BPUM-295
SGMSU/6	MesaStrip <i>Bacillus subtilis</i> '5230'	B5230-162
PCD2.5, 3.5, 4.5, 5.5, 6.5, 7.5	PCDs containing MesaStrip SGMG/6	BATR-465*


*Represents the BI lot number contained within the PCD.

In addition to the changes outlined above we've also attached a summary report detailing the result of comparison testing performed on glassine coated with the new adhesive as compared to our existing glassine/adhesive.

As always, if you have any questions, please contact your Mesa Laboratories Representative.



Robert Bradley, Sr. Director – Bozeman Operations 17 Dec 2019
Date



Nicole Dewald, QA Manager 17 Dec 2019
Date



Glassine Change Testing Summary Rev. B

Executive Summary

This report summarizes the impact of a change to the cold contact adhesive used on the glassine for Mesa's paper strip biological indicators.

Revision History

Revision B of this summary was issued to correct a typographical error with one of the lot numbers listed in the '*Rationale for the Selection of Products*' section. A clarification statement was also added to the performance testing section.

Qualification Protocols

This material change was evaluated under the following protocols:

- 190604P; Study to Evaluate the Impact of Changes to the Glassine Packaging Configuration and Adhesive on Performance of Paper Carrier Biological Indicators
- 190801P; Growth Inhibition Testing – Paper Carriers in Glassine Envelopes Exposed to Steam Sterilization
- 190802P; Growth Inhibition Testing – Paper Carriers in Glassine Envelopes Exposed to Chemical Vapor Sterilization
- 190803P; Growth Inhibition Testing – Paper Carriers in Glassine Envelopes Exposed to EO Sterilization
- 190804P; Growth Inhibition Testing – Paper Carriers in Glassine Envelopes Exposed to Dry Heat Sterilization
- 190901P; Growth Inhibition Testing – Paper Carriers in Glassine Envelopes Exposed to Steam Sterilization – *B. subtilis* 5230
- 191004P; Study to Evaluate the Impact of Changes to the Glassine Packaging Configuration and Adhesive on Performance of Paper Carrier Biological Indicators

Rationale for selection of products

The product configurations evaluated for this study and the part numbers they represent are detailed below:

- #903 paper inoculated with *Geobacillus stearothermophilus* (GST), Lot #GST-487
 - Catalog #s: SGMS/3, SGMS/5, SGMS/6, S1X25/6G, S2X10/6G, DS6R/6G
- #903 paper inoculated with *Bacillus atrophaeus* (BATR), Lot #s BATR-462 & BATR-102416/S15
 - Catalog #s: SGMG/6, SGMG/6R, RG/100, A1X25/6G, A2X10/6G
 - Catalog #s: PCD2.5, PCD3.5, PCD4.5, PCD5.5, PCD6.5, PCD7.5
- #903 paper inoculated with *Bacillus subtilis* '5230' (BSUB), Lot #B5230-161
 - Catalog #s: SGMSU/6

- #903 paper inoculated with *Bacillus pumilus* (BPUM), Lot #BPUM-294
 - Catalog #s: SGMR/6, SGMR/7
- #470 paper inoculated with *Geobacillus stearothermophilus* (GST), Lot # GSS-008 & GSS-010
 - Catalog #s: 3-4100, 3-5100, 3-1000, 3-6100, 5-5100T, 5-1000T, 5-1000C
- #470 paper inoculated with *Bacillus atrophaeus* (BATR), Lot # BAS-006 & BAS-007
 - Catalog #s: 1-4100, 1-6100, 1-6500, 1-1000, 5-5100, 5-1000T, 5-1000C

As compared to the packaging prior to the adhesive change, Mesa evaluated two packaging configurations

- Zone coated front-webbing glassine bonded to flood coated back-webbing glassine.
 - The front-webbing glassine contains adhesive around the periphery of the envelop and the back-webbing glassine is flood coated with adhesive.
 - The strip is in direct contact with the adhesive on the flood coated back-webbing.
 - This is how Mesa's paper strip products have historically been packaged.
- Zone coated front-webbing glassine bonded to zone coated back-webbing glassine
 - Both pieces of glassine only have adhesive around the periphery of the envelope. The center of the envelop where the strip resides contains no adhesive.
 - The strip is not in direct contact with the adhesive.

The paper/bacteria configurations chosen for this study represent all of the configurations of paper strip biological indicators that Mesa packages in glassine envelopes.

Results

Growth Inhibition Test Results

Mesa evaluated the three core organisms used for its biological indicators and the glassine with the new adhesive in five different sterilization modalities per Annex B of ISO 11138-1.

Growth Inhibition Testing		
Acceptance Criteria	Sterilization Modality	Pass/Fail
<i>Geobacillus stearothermophilus</i> (Study 190801R)	Steam	PASS
<i>Geobacillus stearothermophilus</i> (Study 190802R)	Chemical Vapor	PASS
<i>Bacillus atrophaeus</i> (Study 190803R)	Ethylene Oxide	PASS
<i>Bacillus atrophaeus</i> (Study 190804R)	Dry Heat	PASS
<i>Bacillus subtilis</i> '5230' (Study 190901R)	Steam	PASS

Performance Testing Results

Results were obtained by running both packaging configurations side-by-side in the same resistometer cycle. As a result, the data obtained might not directly correlate with the certified label claim for the respective lot.

Study 190604R –Zone Coated Front-Webbing to Flood Coated Back-Webbing Packaging Configuration						
Organism	Paper	Lot	Process	D-value Control	D-value New	% Difference
BATR	#470	BAS-006	DH 160C	1.3min	1.6min	+19%
BATR	#470	BAS-006	EO	2.9min	3.0min	+3%
BATR	#903	EBATR-102416/S15	DH 160C	1.6min	1.7min	+6%
BATR	#903	BATR-462	EO	3.2min	3.3min	+3%
BSUB	#903	B5230-161	Steam 121C	0.7min	0.6min	-14%

Study 191004R – Zone Coated Front-Webbing to Zone Coated Back-Webbing Packaging Configuration						
Organism	Paper	Lot	Process	D-value Control	D-value New	% Difference
GST	#470	GSS-008	Steam 121C	2.0min	2.2min	+9%
GST	#470	GSS-008	Chemiclave	S/K = Pass	S/K = Pass	0%
GST	#903	GST-487	Steam 121C	1.6min	1.6min	0%
BATR	#470	BAS-007	DH 160C	1.7min	1.5min	-12%
BATR	#470	BAS-007	EO	2.7min	2.9min	+7%

Acceptance Criteria

Paper Carriers Inoculated with <i>B. atrophaeus</i>			
Zone Coated Front-Webbing to Flood Coated Back-Webbing Packaging Configuration			
Acceptance Criteria	Lot #	Results	Pass/Fail
Dry Heat resistance testing shall have a minimum D-value of 1.0 minutes	EBATR-102416/S15	1.7 min	Pass
	BAS-006	1.6 min	Pass
EO resistance testing shall have a minimum D-value of 2.0minutes	BATR-462	3.3 min	Pass
	BAS-006	3.0 min	Pass
The glassine must remain bonded together after exposure Dry Heat.	EBATR-102416/S15	Bonded	Pass
	BAS-006	Bonded	Pass
The glassine must remain bonded together after exposure EO.	BATR-462	Bonded	Pass
	BAS-006	Bonded	Pass

Paper Carriers Inoculated with B. subtilis 5230			
Zone Coated Front-Webbing to Flood Coated Back-Webbing Packaging Configuration			
Acceptance Criteria	Lot #	Results	Pass/Fail
The glassine must remain bonded together after exposure.	B5230-161	Bonded	

Paper Carriers Inoculated with G. stearothermophilus			
Zone Coated Front-Webbing to Zone Coated Back-Webbing Packaging Configuration			
Acceptance Criteria	Lot #	Results	Pass/Fail
Steam resistance testing shall have a minimum D-value of 1.5minutes	GST-487	1.6 min	Pass
	GSS-008	2.2 min	Pass
The glassine must remain bonded together after exposure to steam.	GST-487	Bonded	Pass
	GSS-008	Bonded	Pass

Paper Carriers Inoculated with G. stearothermophilus			
Zone Coated Front-Webbing to Zone Coated Back-Webbing Packaging Configuration			
Acceptance Criteria	Lot #	Results	Pass/Fail
The glassine must remain bonded together after exposure to Chemiclave sterilization process.	GSS-008	Bonded	Pass

Paper Carriers Inoculated with B. atrophaeus			
Zone Coated Front-Webbing to Zone Coated Back-Webbing Packaging Configuration			
Acceptance Criteria	Lot #	Results	Pass/Fail
Dry Heat resistance testing shall have a minimum D-value of 1.0minutes	BAS-007	1.7 min	Pass
EO resistance testing shall have a minimum D-value of 2.0minutes	BAS-007	2.8 min	Pass
The glassine must remain bonded together after exposure Dry Heat.	BAS-007	Bonded	Pass
The glassine must remain bonded together after exposure EO.	BAS-007	Bonded	Pass

CONCLUSIONS

The proposed packaging configuration of zone coated front-webbing to zone coated back-webbing glassine, utilizing the new cold contact adhesive, performs comparable to the control configuration. The packaging change has no negative impact on the performance of the product and is suitable to serve as a direct replacement for the following product types:

- #903 paper inoculated with *Geobacillus stearothermophilus* (GST)
 - Catalog #s: SGMS/3, SGMS/5, SGMS/6, S1X25/6G, S2X10/6G, DS6R/6G
- #470 paper inoculated with *Geobacillus stearothermophilus* (GST)
 - Catalog #s: 3-4100, 3-5100, 3-1000, 3-6100
- #470 paper inoculated with *Geobacillus stearothermophilus* (GST) & *Bacillus atrophaeus* (BATR)
 - Catalog #s: 5-5100T, 5-1000T, 5-1000C


The proposed packaging configuration of zone coated front-webbing to flood coated back-webbing glassine, utilizing the new cold contact adhesive, performs comparable to the control configuration. The packaging change has no negative impact on the performance of the product and is suitable to serve as a direct replacement for the following product types:


- #903 paper inoculated with *Bacillus atrophaeus* (BATR)
 - Catalog #s: SGMG/6, SGMG/6R, RG/100, A1X25/6G, A2X10/6G
 - Catalog #s: PCD2.5, PCD3.5, PCD4.5, PCD5.5, PCD6.5, PCD7.5
- #903 paper inoculated with *Bacillus subtilis* '5230' (BSUB)
 - Catalog #s: SGMSU/6
- #470 paper inoculated with *Bacillus atrophaeus* (BATR)
 - Catalog #s: 1-4100, 1-6100, 1-6500, 1-1000


Based on the results obtained with the other mesophilic organisms (*Bacillus atrophaeus* and *Bacillus subtilis*) Mesa has determined that the proposed packaging configuration of zone coated front-webbing to flood coated back-webbing glassine, utilizing the new cold contact adhesive, is acceptable for use with the following products:


- #903 paper inoculated with *Bacillus pumilus* (BPUM)
 - Catalog #s: SGMR/6, SGMR/7

Approvals:

Operations:  Date: 19 Dec 2019
 Nick Spain – Sr. Manager of Manufacturing

Operations:  Date: 19 Dec 2019
 Gabrielle Benjamin – Sr. Manager of Manufacturing

Operations:  Date: 19 Dec 2019
 Robert Bradley – Sr. Director of Operations

QA:  Date: 19 Dec 2019
 Kira Gardner – QA Manager