



SUPPLIER CHANGE NOTIFICATION REVISION

Issue Date: October 9, 2024

Change Number: 22140-050, Rev. 6

Revision History:

Revision	Issue Date	Revision Description
1	July 11, 2022	No Changes, Original Issue
2	August 18, 2022	1. Changes: <ul style="list-style-type: none"> a. Table 2 – ISO Certifications b. Table 2 – Product Drawings c. Table 2 – Manufacturing Environment Classification d. Table 2 – Product Certifications Assigned Risk 2. Additions: <ul style="list-style-type: none"> a. Table 2 – Mold Tech Transfer b. Table 2 – Product Claims c. Table 2 – Product Packaging d. Table 3 – Mechanical Properties Testing e. Table 3 – Extractables – Note f. Table 3 – Shelf Life Studies
3	December 22, 2022	1. Customer Strategy – Customer Portal Link Provided 2. Transfer Timeline – Dates updated 3. Table 2 – Clarifications provided 4. Addition of Attachment 4 – Updated Drawings List
3.1	March 03, 2023	1. Change Impact and Risk Assessment – Product Drawings – Updated to reflect changes to Attachment 4 2. Attachment 4 – Revised with updated part dimensions
3.2	April 13, 2023	1. Change Impact and Risk Assessment – Labels 2. Attachment 1 – Parts added to scope: <ul style="list-style-type: none"> a. Phase 1 Group 1 – TAD150-08M b. Phase 2 – GAS-S010, TBC08F-EPDM, and TER150-100 3. Attachment 4 – Revised with updated part dimensions
3.3	March 25, 2024	1. Updating Saint-Gobain's internal target nominal dimensions as applicable. 2. Notify of the release of the common Regulatory Information Overview for SaniTech® RIGID Polyvinylidene Fluoride Connectors (RIO-00001) and SaniTech® RIGID Polypropylene Connectors (RIO-00002) manufactured in Garden Grove and Beaverton. Update SaniTech® RIGID PVDF Connectors shelf-life from 40 year to 5 years
4	June 26, 2024	Update SaniTech® RIGID Part Number Discontinuation from Garden Grove
5	October 9, 2024	Update Additional SaniTech® RIGID Part Numbers in scope for Discontinuation from Garden Grove.
6	October 9, 2024	Scope and project plan for all remaining Rigid Part Numbers transferring to SG Beaverton site. Communicate part numbers no longer in the scope of this CN as they are transferring to the SG Mickleton site. Clarify part numbers that are not in scope of the Extractables Test Strategy, Revision 7 as they are intended for use as utility parts.

Change Types: Listed by Part Number in Attachment 1

Change Level: Level 1 (High Risk)

Change Categorization: Routine

Change Approval Required: No Change Approval Required

CONFIDENTIAL AND PROPRIETARY

Saint-Gobain Performance Plastics
3910 Terry-Diane St., Beaverton, MI, 48612



SUPPLIER CHANGE NOTIFICATION REVISION

Change Description: The change types and change descriptions vary by part number. Refer to Attachment 1 for part numbers impacted by this change, change description(s) and change type(s). **Attachment 1** is a **Master List** of part numbers currently manufactured at the Saint-Gobain Garden Grove location that will be transferred to a 3rd party manufacturing location managed by **Saint-Gobain Beaverton**. **Attachment 2** is a Master list of part numbers currently manufactured at the Saint-Gobain Garden Grove location that were listed in the original CN22140-050, Revision 1 scope but are now being transferred to the **Saint-Gobain Mickleton** location. Refer to **Attachment 2** for a comprehensive listing of the parts in scope and respective customer notification letter detailing the change.

Change Impact / Risk Assessment:

Process Element	Comparison	Risk Assigned	Actions to be taken to Mitigate Risk
Product Drawings	Saint-Gobain internal manufacturing drawings will be updated as part of our internal change control process.	Low	None Required
Product Claims	There is no change to the raw materials. The worst-case process conditions for Single Use Systems (SUS) Components transferred to Beaverton were already substantiated under validations PQ-2022-01019 and PQ-2022-01096. The process changes in scope are expected to remain within the validation ranges substantiated in validations PQ-2022-01019 and PQ-2022-01096. Therefore, there is no expected impact to the SUS component product claims. For Rigid Utility parts identified as such in Attachments I and II, this notification is to clarify that extractables testing has not been performed on these parts given their intended use. The Extractables Strategy document will be updated to clarify which Rigid part numbers are in scope for the extractable testing program.	Low	Update the Extractables Test Strategy to clarify parts in and out of scope for the Rigid product line.
Certificate of Conformity	None. The global certificate of conformity is used by all SG manufacturing sites involved in the change. Therefore, there is no impact to the CoC template. The data in the fields will reflect the manufacturing location change from the Garden Grove site to Beaverton site.	Low	None Required
Shelf Life	There is no expected impact to the five-year shelf-life as there is no change to the raw materials and the critical process parameters are not expected to exceed the worst-case scenario previously substantiated.	Low	None Required
Process or Product Validation	Any modifications to the existing molds and any new mold will undergo a scientific mold study, OQ and PV/PQ (see attachment for further details).	Low	Scientific Mold Study OQ PV or PQ
Equipment Qualification	The presses at the manufacturing location have already undergone IQ/OQ. No modifications are required to the existing presses to manufacture the parts in scope. There is no impact on the equipment qualifications.	Low	None Required
Manufacturing Environment Classification	Molding at the Saint-Gobain Garden Grove facility is currently done in a CNC environment. The new manufacturing location will mold in an ISO 8 clean room.	Low	None Required
Supplier Qualification	The current suppliers and associated supplier files in use at Garden Grove will transfer to Saint-Gobain Beaverton. The Approved Supplier list (ASL) will be updated accordingly under internal change control. The 3 rd party manufacturer is ISO 13485 and 9001 certified. There is no change to the suppliers.	Low	Under change control, set up suppliers, supplier files and ASL to use the current suppliers in use at SG Garden Grove.

CONFIDENTIAL AND PROPRIETARY

Saint-Gobain Performance Plastics
3910 Terry-Diane St., Beaverton, MI, 48612



SUPPLIER CHANGE NOTIFICATION REVISION

Transport and Packaging Integrity	There will be no change the current packaging materials, processes, and mode of transporting product from SG to the customers. Therefore, there is no expected impact on the transport and package integrity of the product. The current packaging process is already validated for the poly bag thickness in scope.	Low	None Required
Extractables	The worst-case parts have already been evaluated for impact to extractables profile: https://www.biopharm.saint-gobain.com/validation-technical/extractables-information	Low	None Required
Form, Fit and Function	Form, fit and function will be assessed as part of the validation activities. There is no expected impact on the current validated state because of this change.	Low	Scientific Mold Study OQ PV or PQ
Customer Sample Availability	The completion date of the validation is listed by part number in the attachment. Customers may place sample POs now if there is a need to evaluate samples as part of the customer's change acceptance process.	Low	Refer to the Attachment for dates by part number.

Implementation Dates:

- Based on Garden Grove's current lead times, Garden Grove will stop accepting purchase orders for Sani-Tech® Rigid parts on **April 30, 2025**. Customers needing parts with a delivery date through **August 29, 2025**, must ensure all purchase orders have been received by Saint-Gobain Garden Grove on or before **April 30, 2025**.
- Saint-Gobain Garden Grove will stop shipping Sani-Tech® Rigid parts on or before **August 29, 2025**.
- Starting **May 1, 2025**, all Sani-Tech® Rigid purchase orders will be confirmed for order fulfillment out of the Saint-Gobain Beaverton location. Lead times will be as follows:
 - Parts that have completed validation → **6 weeks**
 - Parts that still require validation → **16 weeks**
 - Future updates to the Attachment 1 Master Plan will be included in each subsequent communication update until the project is closed to clearly indicate when parts have completed validation and converted to a 6-week lead time. Until such time, all received purchase orders will continue to reflect a 16-week lead time.
- By **September 1, 2025**, Saint-Gobain Beaverton will be shipping all Sani-Tech® Rigid parts listed in **Attachment 1**.

Action to Take:

- Saint-Gobain to update the Extractables Test Strategy document to clarify which part numbers are in scope for the extractables reports. Target completion date is November 2024.
- Please complete your internal change control requirements according to the attached project plan to ensure no supply disruptions because of these changes.
- April 30, 2025** = Last day to place purchase orders with the Saint-Gobain Garden Grove facility for all Sani-Tech® Rigid part numbers **listed in Attachments 1 and 2**.
- May 1, 2025** = First day 100% of all customer purchase orders will **ONLY** be order entered for the Saint-Gobain Beaverton site (**Attachment 1**) or Saint-Gobain Mickleton Site (**Attachment 2**).
- August 29, 2025** = Last shipment out of Saint-Gobain Garden Grove facility for all Sani-Tech® Rigid part numbers listed in **Attachments 1 and 2**.

CONFIDENTIAL AND PROPRIETARY

Saint-Gobain Performance Plastics
3910 Terry-Diane St., Beaverton, MI, 48612



SUPPLIER CHANGE NOTIFICATION REVISION

Next Communication:

Saint-Gobain acknowledges that the communication regarding this change need to be vastly improved. As such, we will provide regular project updates of the progress made against the transfer plan outlined in Attachment 1. The next scheduled communication will be sent to our customers by **December 20, 2024**.

Please take this opportunity to contact your respective Customer Service Representative or Business Development Manager should you have any questions / concerns.

Sincerely,

Allison Vereb
BPS Quality Director
Allison.Vereb@Saint-Gobain.com

Hannah Hertrick
Product Manager, BPS
Hannah.C.Hertrick@Saint-Gobain.com

Enclosure:

Attachment 1 – Master Transfer Plan of Part Numbers Transferring to Saint-Gobain Beaverton Site
Attachment 2 – Master Transfer Plan of Part Numbers Transferring to the Saint-Gobain Mickleton Site

CONFIDENTIAL AND PROPRIETARY

Saint-Gobain Performance Plastics
3910 Terry-Diane St., Beaverton, MI, 48612



SUPPLIER CHANGE NOTIFICATION REVISION

Attachment 1: Master Transfer Plan of Part Numbers Transferring to Saint-Gobain Beaverton Site

Part Number	Manufacturing Location Change	In Scope of the Extractables Program After Transfer	Part Number Change	Existing Tool Transfer	New Tool	Existing Process	Modified Process	Validation Strategy	Transfer Completion Date	Inventory in SG Garden Grove	Target Date to Place POs with SG Beaverton
SKM90-150-NT	Yes	Yes	No	Yes	No	Yes	No	PV	Oct-24	Yes	TBA**
T90100L	Yes	Yes	No	Yes	No	Yes	No	PV	Oct-24	Yes	TBA**
KEC075	Yes	Yes	No	Yes	No	Yes	No	PV	Nov-24	Yes	TBA**
TEC075	Yes	Yes	No	Yes	No	Yes	No	PV	Nov-24	Yes	TBA**
TCT150	Yes	Yes	No	Yes	No	Yes	No	PV	Dec-24	Yes	2-Jan-25
K-SCREWCAPH	Yes	Yes	Yes	Yes	No	Yes	No	PV	Feb-25		2-Apr-25
K-SCREWCAPHDB	Yes	Yes	Yes	Yes	No	Yes	No				
I113406-PS2	Yes	N/A	No	Yes	No	Yes	No	PV			
KAD075-02H	Yes	Yes	No	No	Yes	Yes	No	PV	Hold for PO		Sep-25
KAD075-04H	Yes	Yes	No					PV	Hold for PO		Sep-25
KAD075-06H	Yes	Yes	No					PV	Hold for PO		Sep-25
KAD075-08H	Yes	Yes	No					PV	Hold for PO		Sep-25
KAD075-12H	Yes	Yes	No					PV	Hold for PO		Sep-25
TAD075-02H	Yes	Yes	No					PV	Hold for PO		Sep-25
TAD075-04H	Yes	Yes	No					PV	Jul-25		Jul-25
TAD075-06H	Yes	Yes	No					PV	Hold for PO		Sep-25
TAD075-08F	Yes	Yes	No					PV	Hold for PO		Sep-25
TAD075-08H	Yes	Yes	No					pV	Hold for PO		Sep-25
TAD075-08H-10	Yes	Yes	No						Hold for PO		Sep-25
TAD075-08H-TFS-PKG	Yes	Yes	No						Hold for PO		Sep-25
TAD075-12H	Yes	Yes	No						PV	Jul-25	
CL300TU	Yes	Yes	No	No	Yes	No	Yes	PQ	Mar-25		2-Apr-25
TCA2	Yes	Yes	No	No	Yes	No	Yes	PQ			
TCA2DB	Yes	Yes	No	No	Yes	No	Yes	PQ			
TEC300	Yes	Yes	No	No	Yes	No	Yes	PQ	May-25		May-25
TAD200-08H	Yes	Yes	No	No	Yes	No	Yes	PQ	Q2, 2025		Sep-25
KAD200-12H	Yes	Yes	No	Yes	No	Yes	No	PV	Hold for PO		Sep-25
KAD200-150	Yes	Yes	No					PV	Hold for PO		Sep-25
TAD200-075	Yes	Yes	No					PV	Q2, 2025		Sep-25
TAD200-12H	Yes	Yes	No					PV	Hold for PO		Sep-25
TAD200-150	Yes	Yes	No					PV	Q2, 2025		Sep-25
TAD200-150-CONE	Yes	Yes	No					PV	Q2, 2025		Sep-25
KSB150	Yes	Yes	No	No	New Insert	No	Yes	PQ	Q4, 2025	Sep-25	
TSB150	Yes	Yes	No					PQ	Hold for PO	Sep-25	
KT075	Yes	Yes	No	No	New Insert	Yes	No	PV	Q3, 2025		Sep-25
TT075	Yes	Yes	No					PV	Q3, 2025		Sep-25
TSB100L	Yes	Yes	No	No	New Insert	No	Yes	PQ	Q3, 2025		Sep-25
TT100L	Yes	Yes	No	Yes	No	Yes	No	PV	Q3, 2025		Sep-25
STV-GEL	Yes	N/A	No	NA	NA	Yes	No	NA	31-Dec		2-Jan-25
TAD400-300	Yes	No*	No	NA	NA	Yes	No	NA	31-Dec		2-Jan-25
TER150-075	Yes	Yes	No	NA	NA	Yes	No	NA	31-Dec		2-Jan-25
CL075SW	No - Distribution Location Change Only	N/A	No	No	No	No	No	No	31-Dec		2-Jan-25
CL100SW		N/A									
CL150SW		N/A									
CL200SW		N/A									
CL250SW		N/A									
CL300SW		N/A									
K-LL075		No*									
K-LL3W		No*									
T-LL075		No*									
TSF006		No*									

*These part numbers are not covered by the current Extractables Test Strategy, Revision 7. They are intended for use as utility parts and not single use system components. The Extractables Test Strategy will be updated to clarify these parts are out of scope.

**TBA = To Be Announced in a future update to this change notification letter. Orders will be fulfilled by Garden Grove to deplete inventory on hand.

N/A = These part numbers did not meet the original part number scheme outlined in the Extractables Test Strategy. Therefore, they have always been out of scope and will continue to be out of the scope of the extractables program.

PV = one Performance Verification run

PQ = Performance Qualification consisting of three runs

CONFIDENTIAL AND PROPRIETARY

Saint-Gobain Performance Plastics
3910 Terry-Diane St., Beaverton, MI, 48612



SUPPLIER CHANGE NOTIFICATION REVISION

Attachment 2: Master Transfer Plan of Part Numbers Transferring to the Saint-Gobain Mickleton Site

Part Number	In Scope for the Original Extractables Program After Transfer	Change Notification Letter	Implementation Date
K003	N/A	Refer to CN 520-L4-200-0519	30-Dec-24
K006			
K100			
K150			
K200			
K250			
K300			
T003			
T006			
T075			
T100			
T150			
T200			
T250			
T300			
TT006			
T012-60-ST45	N/A	Refer to CN 520-L4-200-0565	31-Mar-25
CP-11142018-1	N/A	Forthcoming	TBA - To Be Announced
CP-222016-1			
CP-4232010-1			
CP-5282020-1			
CP-852010-1			
CP-9192016-2ANNEAL			
KBC075	No*		

*This part number is not covered by the current extractables test strategy. It is intended for use as utility parts and not single use system components. The Extractables Test Strategy, Revision 7 will be updated to clarify this part is out of scope.

N/A = These part numbers did not meet the original part number scheme outlined in the Extractables Test Strategy, Revision 7. Therefore, they have always been out of scope and will continue to be out of the scope of the extractables program.

CONFIDENTIAL AND PROPRIETARY

Saint-Gobain Performance Plastics
3910 Terry-Diane St., Beaverton, MI, 48612