



## Change Notice and Communication Policy

Date: November 16, 2016

Saint-Gobain Performance Plastics understands that product(s) supplied to distributors, OEMs and/or end users pursuant to our specifications or Purchase Agreement, will be used in potentially critical applications. In order to maintain compliance to regulatory expectations relevant to the quality management of the supply chain and the Quality Agreements established with customers, Saint-Gobain has developed this policy on change notifications and the communication of Quality information.

### CHANGE NOTIFICATION

In order to enable the supply chain in determining if changes to the product(s) will have an effect on the safety and/or efficacy of the product(s), Saint-Gobain agrees to notify all impacted distributor(s), OEM(s) and/or end user(s) that buy direct from Saint-Gobain in writing prior to making a change via a change notification. The recipient of such information must immediately communicate the change notification provided by Saint-Gobain to all of its affected supply chain purchasing the product(s). The change notifications will occur as follows:

Saint-Gobain shall provide 6-12 months advance notice (based on risk assessment) of a significant change that has the potential to impact:

- the validated state of an item
- the regulatory filing status of an item
- critical quality parameters of the item (safety, identity, purity, quality)
- Form, Fit, or Function of the item
- Change in manufacturing site location
- Change in raw materials
- Change in critical manufacturing steps

Saint-Gobain will provide 90 days' notification for less significant changes that require customer notification. Examples of these changes include:

- CoC/CoA change with no impact to product quality criteria
- Product brand name
- Document Corrections (e.g. Regulatory Information Overview, Label)

Unplanned changes are communicated as soon as Saint-Gobain is aware of a change from a sub-supplier or if there is an urgent quality need to make a change.



For change notifications associated with custom items, the change must be approved by the customer prior to implementation. For change notifications associated with standard items, customer approval is not required.

Saint-Gobain supplies a very diverse range of markets (e.g. aerospace, automotive, medical, pharmaceutical, industrial, micro-e, etc.). The risk assessment referenced above includes evaluation of impact according to the product's intended use documented in our product literature. Notification of changes may not be required to customers in some markets based upon this evaluation. This will be documented in the Change Control documentation at Saint-Gobain.

#### COMPLAINT, NONCONFORMITY, CRITICAL EVENT

Communication of complaint investigations, nonconforming material, or critical events with potential to impact the safety, quality, or efficacy of the product(s) manufactured by Saint-Gobain shall meet the requirements of Saint-Gobain policies and procedures and any current Quality Agreements. Saint-Gobain policy requires notification to our channel as follows:

- Critical events: Notification within three (3) business days
- Complaints:
  - 24 hours to acknowledge receipt of the complaint
  - 20 business days for investigation response (45 calendar days for investigations requiring microbiological analysis)

For nonconformities or critical events, the channel will receive a Quality Alert detailing all pertinent information (correction, containment, risk assessment, root cause analysis and CAPA plan). Recipients of complaints and/or quality alerts have a key responsibility in the timely and accurate communication of this information to their distributors, OEMs and/or end-users. It is recommended that complaint responses and quality alert reports are forwarded within 24 hours of receipt from Saint-Gobain.

Polly M. Hanff  
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