

Customer Communication

Important Notification: Face Fit Test Solution A and Face Fit Test Solution B (50 ml bottles, Saccharin and Bitrex)

AlphaSolway has identified and confirmed a quality issue affecting AlphaSolway™ Face Fit Test Solution A and AlphaSolway™ Face Fit Test Solution B (50 ml bottles, Saccharin and Bitrex) ('Products'). Please see details of the Products below:

Description	Manufacturer Product Code	Supply Chain NPC
Bitter Sensitivity Solution FFK Solution A - Bitrex	MAFTSOLA-SENA50ML	BTP85032 and BTP85040
Bitter Sensitivity Solution FFK Solution B - Bitrex	MAFTSOLB-TESTB50ML	BTP85031
Sweet Sensitivity Solution FFK Solution A - Saccharin	MAFTSACA-SENA50ML	BTP85038
Sweet Sensitivity Solution FFK Solution B - Saccharin	MAFTSACB-TESTB50ML	BTP85035

This notification affects Products whose shelf life expires between 07/03/2026 and 19/02/2028.

In some Products, we have observed visible premature degradation over time, including discolouration and/or particulate. This results in the reduction of the declared shelf life.

Test carried out:

Microbiological screening (culture) has been carried out and no trace was found of waterborne pathogens, Legionella, E.coli, Coliforms, Enterococci or Clostridia. Subsequent findings indicate predominantly a yeast contamination, most likely derived from environmental exposure.

Corrective Actions carried out:

Following our and our supplier's ISO 9001:2015 and ISO 13485:2016 procedures, a full root cause analysis was undertaken, and a comprehensive corrective action plan has been implemented to ensure that the quality issue is resolved.

Action - Product Replacement/Disposal

The quality of our product(s) and the satisfaction of our customers being our priority, we kindly ask for your support in managing the affected Products.

- Globus will replace the affected Products with expiry dates set out above at no charge to you.
- Dispose of existing stock following your recommended disposal procedures.
- To arrange replacement, kindly provide details of existing stock to our customer service team by 01/03/2025.
- Contact details: sales@globusgroup.com - +44 (0)161 877 4747

Globus and Alpha Solway will provide on-going support with this process.

We sincerely apologise for the inconvenience this may cause and thank you for your understanding and prompt attention to this matter.

Yours sincerely,

A Owen

Andy Owen
International Business Development Manager

Note: If you require additional information, please do not hesitate to contact your dedicated Sales representative. Alternatively, you contact one of our offices: contact details can be found on our website at www.globusgroup.com/contact