

Solventum Germany GmbH – Edisonstr. 6 – 59174 Kamen

Field Safety Notice

Name of the affected product: 3M™ Transbond™ Plus Self-Etching Primer, catalogue number 712-090 and 712-091

FSCA-identifier: 2024-11 FSCA 1098106 Transbond SEP

Type of action: Disposal of affected products

Date: November 29th, 2024

Attention: Solventum and 3M Healthcare Customers

Dear Customer,

Solventum, as distributor of the above-mentioned products, is notifying all distributors and end users of the above-named products of a field safety corrective action.

Our records indicate you have received the affected product and if you are a distributor may have shipped the product to your customers. Therefore, Solventum is requesting your active participation in taking the appropriate actions below. This is a potential safety issue.

Description of the problem and potential hazard and risk for the patient/user:

Eight lots of 3M™ Transbond™ Plus Self-Etching Primer below had a manufacturing issue, resulting in the potential for an increased occurrence of skin irritation/blistering and for reduced bracket bonding strength.

Details on affected devices:

The following lots of 3M Transbond Plus Self-Etching Primer, catalogue number 712-090 and 712-091, are subject of this field safety corrective action:

REF	Description	UDI	LOT
712-090	Transbond Plus Self-Etching Primer - 100-unit box	00652221109170	11093917
			11106533
			11120254
			11153742
			11155372
			11173412
712-091	Transbond Plus Self-Etching Primer - 20-unit box	00652221109187	11165780
			11165793

Action to be taken by end users:

1. Ensure all your internal users are informed about this field safety corrective action.
2. Please identify the affected products listed above and immediately cease use and distribution of affected lots of 3M™ Transbond™ Plus Self-Etching Primer 712-090 and 712-091.
3. Please discard all remaining affected products listed above per facility procedures.
4. Complete and return by e-mail to fsca-emea@solventum.com the enclosed Acknowledgement Form, indicating that the corrective action was understood and executed. Please also indicate the number of devices of which you have disposed. With receipt of this certificate of destruction, Solventum will arrange for product replacement.

Action to be taken by distributors:

1. Ensure all your customers are informed about this field safety corrective action.
2. Send this FSN to all affected customers.
3. Please inform us if you supplied the affected items to customers outside your home country to ensure completeness of competent authority notification.
4. Please identify the affected products listed above and immediately cease use and distribution of affected lots of 3M™ Transbond™ Plus Self-Etching Primer 712-090 and 712-091.
5. Please discard all remaining affected products listed above per facility procedures.
6. Complete and return by e-mail to fsca-emea@solventum.com the enclosed Acknowledgement Form, indicating that the corrective action was understood and executed. Please also indicate the number of devices of which you have disposed. With receipt of this certificate of destruction, Solventum will arrange for product replacement.

Transmission of this Field Safety Notice:

Please pass on this notice immediately to all departments who might use the concerned products. In addition, ensure that the information is provided to any organisation where the concerned products potentially have been distributed.

Thank you for your immediate attention and cooperation. We apologise for any inconvenience this matter may cause.

If you have questions, please contact your local Solventum representative or your distributor.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Karin Watzek
Senior Regulatory Affairs Specialist, CHVR
Mail: fsca-emea@solventum.com

Acknowledgement Form – 2024-11 FSCA 1098106 Transbond SEP

Email completed form to: fsca-emea@solventum.com

Please examine your inventory to determine if you have any of the 3M™ Transbond™ Plus Self-Etching Primer, catalogue number 712-090 and 712-091, listed. Note, this corrective action only applies to the affected catalogue number, and lots listed. It does NOT apply to any other Transbond™ products.

- ☐ Acknowledge that you have read and understood this letter and will complete the actions requested.
- ☐ We have examined our inventory and identified and disposed of the following number of 3M™ Transbond™ Plus Self-Etching Primer, catalogue number 712-090 and 712-091:

Catalogue number	Lot number	Number of boxes that have been disposed
712-090	11093917	
	11106533	
	11120254	
	11153742	
	11155372	
	11173412	
712-091	11165780	
	11165793	

- ☐ We have examined our inventory and do not have the affected 3M™ Transbond™ Plus Self-Etching Primer, catalogue number 712-090 and 712-091, in stock.

Email completed form to: fsca-emea@solventum.com

Person completing this form:

Name		Facility Name	
Signature		Address, City, Country	
Date		Phone/ E-mail	