



Tristel Solutions Ltd
Unit 1a
Lynx Business Park
Fordham Road
Snailwell
UK
CB8 7NY
18TH February

URGENT FIELD SAFETY NOTICE

Type of Action	Recall
Tristel Reference	TSLFSN ₁
Commercial Name	Tristel Duo ULT
Product Code	Lot Number
TSL022601	P833206

Dear Customer

Details of affected devices

Tristel Solutions Ltd. has initiated a voluntary Field Safety Corrective Action for the above listed product.

Description of the problem

Tristel Solutions Ltd. is recalling this product due to an incorrect expiry date printed on the in transit label that is placed on the outer carton. The expiry date of the product should be 2020/11/20. The label has the expiry date printed as 2021/11/20 which could result in product being used beyond its shelf life expiry. All bottles contained within the cartons have the expiry date printed correctly.

Our records indicate that you have potentially received products that are subject to this recall. We are notifying our customers to take the following actions;

FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF

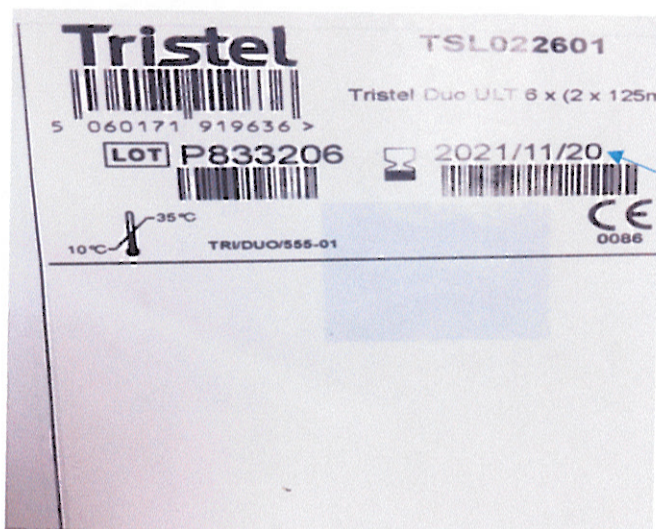
1. We request that you check your inventory for product within scope of this field action. Please assess the pictures below that illustrates the issue. Users should cease use and distribution of stock of the affected product batch and quarantine immediately.

Fig 1. Correct in transit label expiry date



Correct expiry date 2020/11/20

Fig 2. Incorrect in transit label expiry date



Incorrect expiry date 2021/11/20



2. If you do not have stock in scope of this field action as referred to in the table on Page 1 then mark the according checkbox on the Acknowledgement form, Appendix 1, and return the form to mail@tristel.com
3. If you have stock from the affected product as referred to in the table on Page 1 mark the according checkbox on the Acknowledgement form, Appendix 1. Contact Customer Service by calling the phone number mentioned on the Acknowledgement Form, Appendix 1. They will allocate a returns number for adding into the form.
4. Complete Appendix 1 for all products in your possession and under control. Return this form to mail@tristel.com
5. Tristel Solutions Ltd. will issue a credit note upon receipt of the affected product.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT

1. If you are a distributor, provide this field safety notice to all of your customers who have received product in scope of this Field Action. Your customer is then required to complete the Acknowledgement Form, Appendix 1, and return this to you.
2. As a Distributor you are required to confirm to Tristel Solutions Ltd. that you have completed the field safety outlined above. Upon completion of your actions, please forward the completed Acknowledgement form to mail@tristel.com
3. Please be aware that EEA/Switzerland (EEA/CH) AND Turkey Member State Competent Authorities in which Tristel Solutions Ltd. distribute directly will be notified by Tristel Solutions Ltd.
4. If you are a distributor and/or have a reporting responsibility outside the EEA/CH/TK area please notify your local Competent Authority of this action. Please forward this correspondence to Tristel Solutions Ltd.

Tristel Solutions Ltd.

Tristel Solutions Ltd. informs all customers, employees of Tristel Solutions Ltd. and distributors of this field action.

Transmission of this Field Safety Notice

This notice should be passed to all persons who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in circulation of this notice.

Maintain awareness of this notice until all required actions have been completed in your organization.

Contact Reference Person

Customer Service; Laura Smith

Telephone; 01638 721500

Tristel

Email; mail@tristel.com

We sincerely apologize for any inconvenience this action may have caused to your operations. If you have any further questions please contact your local sales rep or Customer Service.

For and on behalf of Tristel Solutions Ltd.

A handwritten signature in dark ink, appearing to read "Steve", followed by a large, horizontal, oval-shaped flourish.

Steve Garrod

Quality Director



APPENDIX 1- FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM

IMMEDIATE ACTION REQUIRED

REF; **TSLFSN₁**

EMAIL; mail@tristel.com

<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm that our inventory does NOT include products affected by this field action	<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm our inventory does include products affected by this Field Action. The use and further distribution of the affected products is stopped. All products are put on hold and the amount below will be returned Return Authorisation Number;
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Ref; TSLFSN₁

Commercial Name	Tristel Duo Ult	
Product Code	Lot Number	QUANTITY
TSLo22601	P833206	

Include a copy of the completed Acknowledgement Form in the returns package with any returned units.

Please label as "Field Action Returns"

INSTITUTION NAME EG. HOSPITAL/HEALTHCARE ORGANISATION	
INSTITUTION ADDRESS	
PHONE NUMBER	
SIGNATURE	
PRINT NAME	

Tristel

DATE	
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