



Tristel Solutions Ltd

Unit 1a

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Fordham Road

Snailwell

UK

CB8 7NY

26<sup>th</sup> April 2019

## URGENT FIELD SAFETY NOTICE

Type of Action	Information Purposes
Tristel Reference	TSLFSN2
Commercial Name	Tristel Trio Wipes System, Tristel Rinse Wipe
Product Code	Lot Number
TSL030601	Rinse Wipe Batch- 832400/1 within Trio Wipes System Batches P900101, P900301, P900302, P900304, P900400

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 informing customers, distributors and medical professionals, due to a Rinse Wipe, as part of the Trio Wipes System, displaying a small area of contamination on the wipe. The instructions on the wipe sachet state do not use if damaged, which would cover this type of issue, as the wipe isn't in the condition intended, and the customer reporting this issue has discarded this wipe as per the IFU instruction. Our records indicate that you have received products that have the same batch number as the affected rinse wipe batch. We are notifying our customers to take the following actions;

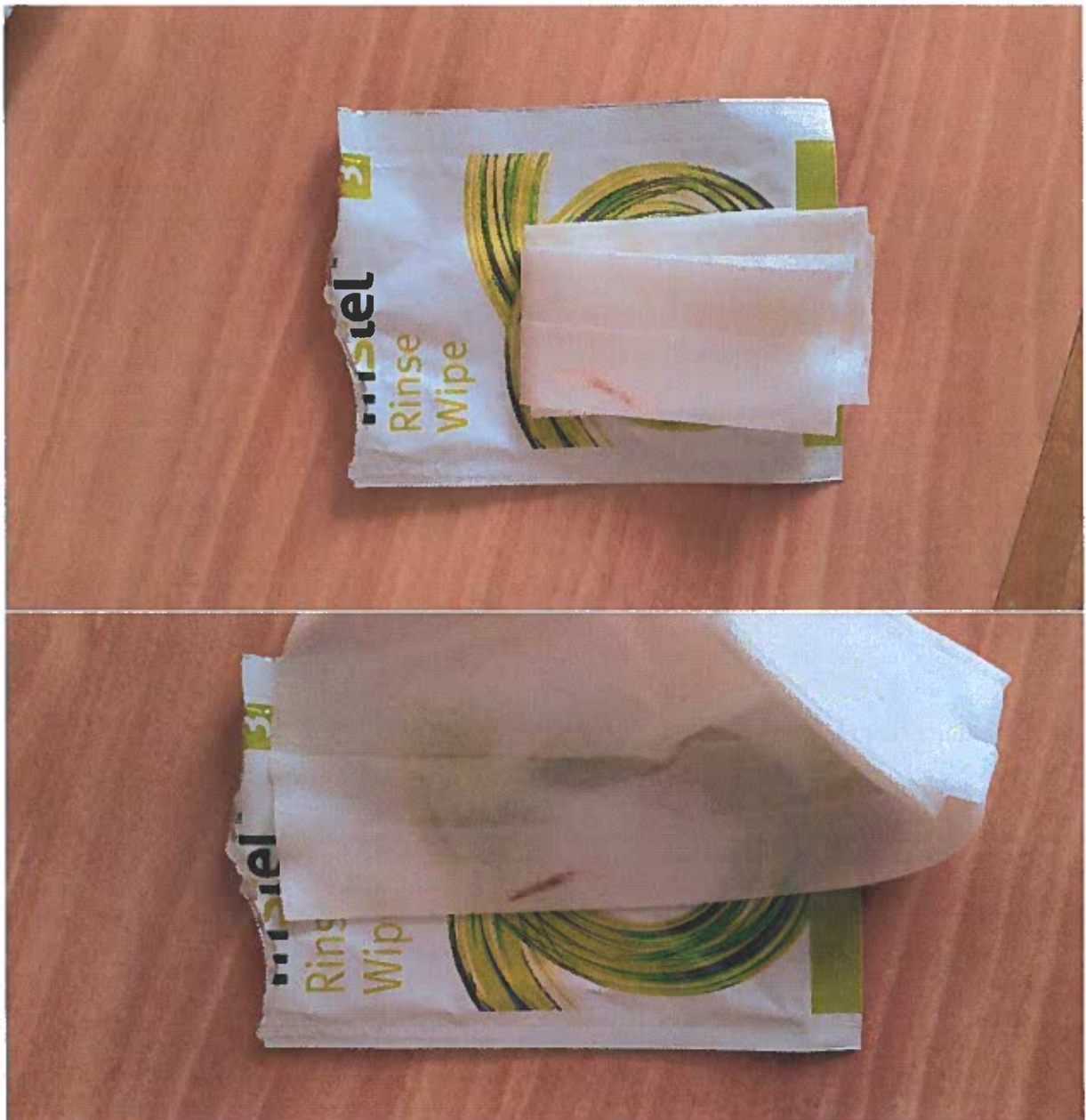


## FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS

### 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. As per the instructions on the sachet regarding damage, if this brown streak is seen on the wipe when opening the sachet in usage, the wipe is to be discarded. If this isn't present on the wipe then the wipe can be used as per normal instructions for use.

**Fig 1. Brown Streak seen on 1 Rinse Wipe**





2. If you have stock with the brown streak evident then please contact Customer Service by calling the phone number mentioned on the Acknowledgement Form, Appendix 1. They will advise upon action to be taken.
3. Complete Appendix 1 for all products in your possession and under control and confirm that you understand and will apply the actions recommended. Return this form to [mail@tristel.com](mailto:mail@tristel.com)

#### **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](mailto: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

**Email;** [mail@tristel.com](mailto: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 black ink, appearing to read 'Steve Garrod', followed by a large, stylized oval flourish.

Steve Garrod  
Quality Director



**APPENDIX 1- FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGEMENT FORM**

**IMMEDIATE ACTION REQUIRED**

**REF; TSLFSN2**

**EMAIL; [mail@tristel.com](mailto:mail@tristel.com)**

We confirm receipt of this FSN and understand the action recommended, whereby product will be checked upon opening of the sachet and discarded if brown streaks are evident.

**Ref; TSLFSN2**

<b>Commercial Name</b>	<b>Tristel Trio Wipes System</b>	
<b>Product Code</b>	<b>Lot Number</b>	<b>QUANTITY</b>
TSLo30601	Rinse Wipe batch 832400/1 within Trio batches P900101 P900301 P900302 P900304 P900400	79,100 total Rinse Wipes within these 5 batches.

Include a copy of the completed Acknowledgement Form.

<b>INSTITUTION NAME EG. HOSPITAL/HEALTHCARE ORGANISATION</b>	
<b>INSTITUTION ADDRESS</b>	
<b>PHONE NUMBER</b>	
<b>SIGNATURE</b>	
<b>PRINT NAME</b>	
<b>DATE</b>	

