

Field Safety Notice

Sterimar – Isotonic 100ml

FSCA identifier: S001/2011

Type of action: Return of all batches identified – not to be used.

Date: 12th January 2012 (update)

Details on affected devices:

Sterimar Isotonic 100ml

Batch Numbers FE1248b and FE1249 – displayed on base of can & base of carton and shipper labels (see identification notice for details)

Description of the problem:

It has become apparent that a limited amount of quarantined product deemed unsuitable for sale by Church & Dwight UK Ltd was erroneously released into the supply chain and shipped to customers by Church & Dwight UK Ltd's designated third-party warehouse and distribution carrier despite Church & Dwight's clear instructions to destroy the products. The batch numbers affected are FE1248b & FE1249.

These batches (FE1248b and FE1249) may contain some microbiological contamination (*Pseudomonas stutzeri* and *Sphingomonas paucimobilis*) which would have no impact for the majority of users but could cause some users (for example, those who have had nasal or sinus surgery or who have a weaker immune system) to experience symptoms in which case they should consult a Healthcare professional. Possible symptoms may be nasal or facial tenderness, discoloured mucus or fever. As such the product should not be used.

Church & Dwight UK Ltd would in the interest of public safety, wish to remove all of the product with these batch numbers from any recipient. No other batches of Sterimar brand products including Sterimar Isotonic in the UK market are affected.

Advise on action to be taken by the user:

We are requesting that any product with these batch identification quoted (i.e. FE1248b & FE1249) is not to be shipped, but should be identified, quarantined and that you contact your customer services contact at Church & Dwight UK Ltd to arrange uplift of the affected batches (i.e. FE1248b & FE1249). If you have shipped any of these batches of products with the batch numbers quoted, please have these products sent back to your storage facility as soon as possible.

If you are experiencing any of the symptoms contact a Healthcare professional.

Additionally if product from either of the affected batches (FE1248b & FE1249) is found to be on sale to consumers we request that this stock is removed from sale and returned to the original point of supply.

A credit will be provided for all affected product returned from batches FE1248b and FE1249. No other product should be returned. We cannot provide a credit for any returned product that is not part of the recalled batch numbers.

As there is likelihood that some of batches FE1248b & FE1249 that has been sold through to consumers, we will be placing information bulletins out to all retailers.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected units have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Geoff Parsons

Sales Director

Church & Dwight UK Ltd

Folkestone

CT19 6PG

Tel: 07852 204621 email: geoff.parsons@churchdwight.co.uk

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

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How to identify recalled product



Carton

Batch Code



Can

Batch Code



How to identify recalled product

Pallet Label

Batch code

STORAGE LOCATION
0050

FE1234 123456

STERIMAR
100ml UK

050 10724 81506 9

Code : **010601486** Pallet No: **02**
20012466

Conf. No: 0000012345 Quant No: Qty / Pallet **01920**

Conf.No: 0050 Qty / Pallet
0000012345 010601486 20012466 **02** 01920

Shipper Label

Batch Code

DESTINATION: **UK**

SOMIBEL-LAB. FUMOUZE STERIMAR
100ml UK

05010724815069

REF. PRODUCT. : 0 6014 80 20012466

CONTENT : 48 EXPIRY DATE : 2014/05
WEIGHT : 8,4 kg BATCH : **FE1234** 123456

CARTON NUMBER : **0002**