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www.coopervision.co.uk

[BP Number]
[Ship To Account Site Name]
[Ship To Account Site Address Line 1]
[Ship To Account Site City]
[Ship To Account Site Postal Code]

11 August 2022

ACTION REQUIRED - COMPANY-INITIATED FIELD SAFETY NOTICE

All in One Light® (60ml) Multipurpose Contact Lens Care Solution 60ml Bottle Configuration - Lot 162046

Dear Eye Care Practitioner,

CooperVision is voluntarily recalling a single lot (Lot 162046) of All in One Light® (60ml) Multipurpose Contact Lens Care Solution 60ml Bottle Configuration from the market, effective immediately.

Routine quality testing is performed on retained samples. For the affected lot, sterility test results conducted on some of the retained samples failed to meet criteria at the 12-month time interval. Although no complaints have been received for the affected lot and there have been no adverse events, we are acting out of an abundance of caution. **No other lots of All in One Light® are impacted by this action.**

Our records indicate you have received product from the affected lot.

Order Number	Product	No of bottles ordered
[Order number]	[Product]	[Bottles]
[Order number]	[Product]	[Bottles]

We would appreciate your assistance in taking the following actions:

- Please immediately examine your inventory/product shelf for **All in One Light® multipurpose 60ml affected lot 162046**;
- Stop any further distribution of product from the designated lot;
- Record the quantity of bottles specific to this lot from your inventory using the **'Recall Inventory Record' form enclosed**. If you have no bottles of this specified lot, please put '0' in 'Quantity';
- Scan this completed form and email to: credits@coopervision.co.uk – **please complete and return even if you have no bottles remaining in your inventory**;
- Dispose of the solution through waste-water systems and recycle the primary packaging. If you do not wish to dispose of the product in this way, you may return the product to CooperVision through your normal means.

Please note that if a credit is due to you, this will automatically be applied to your account once we have received and validated your 'Recall Inventory Record' form.

We would appreciate your support in notifying customers to whom you have distributed affected product. Please send/email them the following:

- Field Safety Notice (Distributor to Customer);
- Product Recall Notification Template – for your customers to make consumers aware as referenced in the Field Safety Notice (Customer to Patient).

We appreciate your assistance and apologise for any inconvenience to you or your customers. Should you wish to discuss this action, please contact our customer services team at: +44 (0)870 9000 055*.

Yours sincerely,



Doug Bairner
Country Manager – UK & Ireland

Enclosure/attachment:

1. Distributor Recall Inventory Record Form (Distributor to send back to CooperVision)
2. Field Safety Notice (Distributor to send to Customer) enclosed with Patient Product Recall Notification Template (Customer to Patient)

RECALL INVENTORY RECORD FORM

All in One Light® (60ml) Multipurpose Contact Lens Care Solution

60ml Bottle Configuration

Lot 162046

Please complete, scan and email this form to

credits@coopervision.co.uk

NOTE: THIS AFFECTS ONLY THE 60ml BOTTLE CONFIGURATION OF THE ABOVE LOTS.

Do you have any stock of the affected product?

Yes

No

If yes, how many affected 60ml bottles do you have? If you have no bottles, please put '0' in 'Quantity'.

Lot	Quantity (x60ml bottles)	Order number/s (if known)
162046		

Please note that if a credit is due to you, this will automatically be applied to your account once we have received and validated this form.

Account Name:	
Account/BP Number:	
Account Phone Number:	
Signed:	
Name:	
Date:	

[DISTRIBUTOR ADDRESS]
[DISTRIBUTOR ADDRESS]
[DISTRIBUTOR ADDRESS]
[DISTRIBUTOR ADDRESS]
[DISTRIBUTOR TEL]

[EMAIL]
[CUSTOMER NAME]
[COMPANY]
[ADDRESS]
[CITY, REGION]
[DATE]

[Date]

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Our records indicate you have received product from the affected lot.

Order Number	Product	No of bottles ordered
[Order number]	[Product]	[Bottles]
[Order number]	[Product]	[Bottles]

We would appreciate your assistance in taking the following actions:

- Please immediately examine your inventory/product shelf for **All in One Light® multipurpose 60ml affected lot 162046**;
- Stop any further distribution of product from the designated lot;
- Dispose of the solution through waste-water systems and recycle the primary packaging. If you do not wish to dispose of the product in this way, you may return the product to us through your normal means.

As part of this action, we will be asking consumers to cease use and dispose of any product from the affected lot in their possession. We would appreciate your support in making them aware of this recall by:

- Notifying consumers who may have product from the affected lot using the text in the enclosed 'Product Recall Notification Template'. This information can be used in the channels you deem appropriate (such as by email or letter; posted on your website; displayed in store).

For any consumers who have product from the affected lot, the 'Product Recall Notification Template' text will link them to a recall website, where they will be given instructions on how to dispose of their solution and how to claim a reimbursement if they purchased the product.

We appreciate your assistance and apologise for any inconvenience to you or your customers. Should you wish to discuss this action, please don't hesitate to contact us on (contact number).

Yours sincerely,

Enclosure/attachment:

- Patient Product Recall Notification Template (Customer to Patient)

NOTIFICATION – CUSTOMER TO PATIENT

[FOR CUSTOMERS TO PLACE ON THEIR WEBSITE / COMMUNICATE DIRECTLY TO INFORM PATIENTS OF THE ACTION AND WHAT TO DO]

PRODUCT RECALL

All in One Light® (60ml) Multipurpose Contact Lens Care Solution

60ml Bottle Configuration

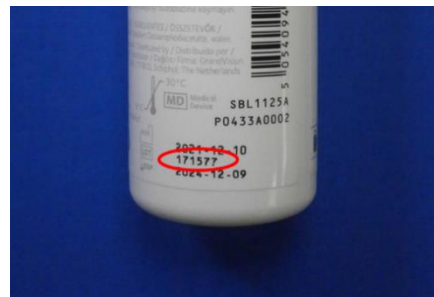
Lot 162046

We have been advised of a limited voluntary recall by the manufacturer, CooperVision, of a single lot of All in One Light® multipurpose contact lens solution (60ml bottle).

The affected lot number is 162046.

Note only 60ml bottles are affected and no other bottle sizes are included in this action.

Lot numbers are printed on the back of each bottle, towards the bottom.



The manufacturer has advised the following:

Routine quality testing is performed on retained product samples. For the affected lot, sterility test results conducted on some of the retained samples failed to meet criteria at the 12-month time interval. Although no complaints have been received for the affected lot and there have been no adverse events, this limited voluntary recall is being taken out of an abundance of caution.

If you possess product from the affected lot of All in One Light® 60ml multipurpose contact lens solution, please cease use and retain the bottle. The manufacturer will soon provide a recall website where impacted consumers can receive further information. This website will be found at:

www.infoCV.expertinquiry.com and is anticipated to be live on 12th August 2022.