Ecolab Temizleme Sistemleri Ltd. Şti.
Esentepe Cevizli E5 Yanyol Cad Vizyon
bulvar No:13/65 Kat:1 Kartal İstanbul
Tel : 0 216 458 69 00
Faks : 0 216 458 69 07
www.tr.ecolab.eu/

To Healthcare Organisation Name
Address

URGENT
FIELD SAFETY NOTICE

Date: *06/12/2019*

Object:
☒ *Batch recall*
☐ *Information and/or recommendations*

Affected products:

Device Commercial Name	Packaging	Reference Number	Batch number
DERSOL K2CA3G-Y45 ACIDIC HEMODIALYSIS CONCENTRATE	10 Liter	86350	141D1903139110 141D1903139111 141D19072410590 141D19072410591 141D19072410593

Primary clinical purpose of device: Hemodialysis solutions are used in dialysis treatment for acute and chronic renal failure patients and toxicity due to toxic substances.

Madam, Sir,

We have identified that you received products in the above table, and we are recalling the all batches stated on the above table as they do not comply with our quality expectations. First, we performed chemical and microbiological analysis of the samples received from the end user internally. It has been found that both analyses of the samples comply with the specifications. After that, according to the external laboratory results, the precipitates were found in the mentioned batches due to Sodium Chloride (NaCl) which is one of the product's raw materials.

Corrective actions to eliminate the precipitates are being implemented. We have checked our process and maintenance records and noticed that at the manufacturing dates of the affected products, product filter failures have been occurred in the mixers. After we have received the external laboratory results, we have increased the filter changing period. Also, it was decided that employee from our Quality department will join filter changing operation as an observer. We decide that in case of any filter failures in the future, we will put the batch in quarantine to check precipitate formation. Another action we take is after all batches we produce, the filter on the transfer line will be backwashed.

For precautionary reasons, we ask that you stop immediately using the recalled products that you may have in stock, as they may cause the risk of blockage of the hemodialysis machines.

We ask you to block and isolate these products. In addition, we need you to inform immediately your end customers and ask them to notify you of the quantities they have in stock and ask them to provide the affected products back to you for the destruction of the affected batches. You will be required to collect the completed response form (Annex I) from your customers and share a consolidated form with us of all the products you have recalled to the following e-mail address: selin.sahin1@ecolab.com. Any quantity declared can be subject of verification.

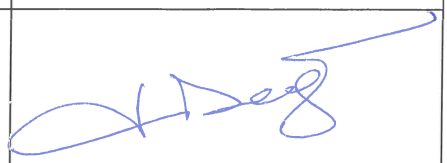
Please acknowledge receipt of this communication by returning at your earliest convenience - but no later than 25/12/2019 - the completed and signed reply form.
The proof of products' destructions will be requested from you.

Your Ecolab representative will contact you to discuss the destruction of the recalled product you have in stock. We remain at your entire disposal for any question or assistance that you may need.

The undersigns confirm that this notice has been reported to the appropriate Regulatory Agency.

Please accept our apologies for the inconvenience it may have caused.

Yours faithfully,

Berfu Ergüney Quality Manager	Selin Şahin Regulatory Affairs Specialist	Lütfi Doğan MEA Supply Chain Manager
		

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

This means, if you are a distributor, that this information has to be forwarded to any customers which was delivered with one of the affected batches.

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

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ANNEX I
CUSTOMER REPLY FORM

1.Field Safety Notice (FSN)

FSN Reference: ECL-FSN-001

FSN Date: 06/12/2019

Affected products:

Device Commercial Name	Packaging	Reference Number	Batch number
DERSOL K2CA3G-Y45 ACIDIC HEMODIALYSIS CONCENTRATE	10 Liter	86350	141D1903139110 141D1903139111 141D19072410590 141D19072410591 141D19072410593

2.Customer Details

Customer Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	

Email*	
Print Name*	
Signature*	
Date*	

Mandatory fields are marked with *

3. Customer action undertaken on behalf of Healthcare Organisation

☐ I confirm receipt of the Field Safety Notice (FSN) and that I read and understood its content.

☐ I performed all actions requested by the FSN.

☐ The information and required actions have been brought to the attention of all relevant users and executed, including end customers in case of distribution of those products

☐ I have destroyed affected devices – number of devices destroyed is documented in the table below (proof of destruction have to be provided to close the current action to selin.sahin1@ecolab.com)

Device Commercial Name	Reference Number	Batch N°	Packages Quantity (units)

☐ No affected devices are available for destruction

☐ Other Action (Define):

4. Return acknowledgement to sender

Email	selin.sahin1@ecolab.com
Postal Address	Ecolab Temizleme Sistemleri Ltd. Şti. Cevizli-Esentepe E-5 Yanyol Cad. Vizyon Blv. N.13 K.1 N.65 Kartal/Istanbul/Turkey
Fax	+90 216 458 69 07
Deadline for returning the customer reply form	25/12/2019

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.
Your organisation's reply is the evidence we need to monitor the progress of the corrective actions