

Waregem, 18/02/2019

Re: recall / defective packaging CEKA Multi Primer

Dear Business Partner,

The manufacturer of CEKA Multi Primer has informed us about a defect in the material of the bottle requiring a product recall (see full text on next page).

This means that the primers sold individually or in the CEKA Multi Set may have been affected. We therefore ask you to dispose of the primers that you still have in stock.
DO NOT RETURN THEM TO US!

We also request that you inform your customers who bought the primer about the defective product / packaging.

The defect has no negative impact on the performance of the product.
Any injuries of patients can be excluded.

We will replace the primers free of charge by products in a new bottle.

Below you will find a list of the primers sold to you that are affected by the defect.
Please indicate how many primers you want to have replaced.

Order date	Order amount	Product
5/12/18	2	CEKA Multi Primer
26/10/18	2	CEKA Multi Primer
31/08/18	2	CEKA Multi Primer
18/01/19	2	CEKA Multi Set
15/01/19	2	CEKA Multi Set
29/11/18	2	CEKA Multi Set
12/10/18	2	CEKA Multi Set

Please do not hesitate to contact us for any further information.

With kind regards,

ALPHADENT NV

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MANUFACTURER NOTICE REGARDING PRIMER RECALL

During control of retained samples conducted on a regular basis we noticed a material defect requiring a product recall.

What is this about

As a long-term effect the solvent ethanol contained in CEKA Multi Primer damages the plastic of the bottle (primary packaging).

So far, we were unable to detect a diffusion but cannot entirely exclude it.

As a worst case scenario this could even cause an increasing risk of fire. The partial swellings become visible as shown in below picture taken by our test laboratory.



Until today we have not received any customer complaints. This is probably due to the fact that the detected partial swellings are covered by the label.

We do not assume any negative impact on the performance of the product. At present, we can therefore exclude any injuries of patients.

What do you have to take into consideration

We need to ask you to dispose of all bottles of above referenced batch numbers as indicated in the Safety Data Sheet as hazardous waste and to instruct your end customers to take measures accordingly. Since we cannot entirely exclude the risk of leakage of the flammable ethanol we ask you not to dispatch the concerned goods.

Please give us information on the quantities disposed of. You will, of course, receive a replacement in correct bottles.

Which measures have been taken

We are currently producing a replacement shipment and will inform you of the exact delivery date under separate cover.

Do you have further questions

We will be happy to answer all your questions in relation to this recall.

We regret any inconvenience caused by these measures and thank you for your understanding and support in view of product safety. We have informed the competent authority BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte / Federal Institute for Drugs and Medical Devices) of this voluntary safety measure.