



PRIVATE LABEL CHEMISTRY

GESELLSCHAFT FÜR DENTALE
FORSCHUNG UND INNOVATIONEN

GDF GmbH • Dieselstr. 5-6 • D-61191 Rosbach v.d.H. • Germany

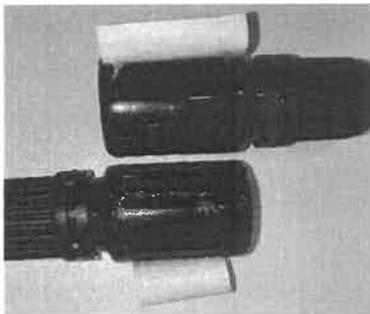
Rosbach, February 13, 2019

Dear ,

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 Zirkon 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.



The following batch numbers are affected:

2018005600

2018004873

2017009080

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.



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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.

Best regards

