



Pfizer Ireland
Grange Castle Business Park,
Clondalkin, Dublin 22
Ireland

Michelle Kelly
Contract Operations QA
Tel: +35314694490
email: michelle.kelly1@pfizer.com

To: To whom this may concern
CC: File

From: Michelle Kelly


Subject: Presence of Latex in rubber stoppers FM 27
Pfizer Reference: COQA - 839

Date: 08 Jan 2013

To whom this may concern:

I, the undersigned hereby declare that the rubber stoppers used in FRAGMIN pre-filled syringes may contain natural rubber latex which may cause allergic reactions. This is based on the information provided by the manufacturer of the stoppers (reference document PSI.S.0079v2 07/02/2011).

Kind regards,


Michelle Kelly, COQA Manager


Karl Blumberg, Senior Director Technical External Supply

MARVA SIWIEC
Director TL Global Manufacturing Services

PRODUCT SUPPORT INFORMATION

Prepared for: General Distribution
Author: Bram Jongen



CONFIRMATION: LATEX FREE & FM27

According to the formulation and manufacturing recipe of rubber compound FM27, Datwyler does not intentionally use or add natural rubber in its formulation. However, this does not exclude the presence of negligible traces due to among other things impurities in the components supplied by external parties.

FM27 contains epoxyprene as one of the raw materials, which is not a natural rubber latex but synthetically synthesized with using natural rubber as starting material.

FDA RECOMMENDATION:

Since last year, the FDA does not accept a "latex free" labelling for FM27 anymore and proposes following labelling to be used:

"May contain natural rubber latex which may cause allergic reactions in latex sensitive individuals "

Datwyler,

Bram Jongen
Product Support Manager