11673-11673/JLCG

SISTEMA COORDINADO DE INTERCAMBIO RAPIDO DE INFORMACION

Asunto: Expediente: ES2021/441 - ÓXIDO DE ETILENO EN CARBONATO CÁLCICO UTILIZADO EN COMPLEMENTO ALIMENTICIO MULTICENTRUM INMUNO C FABRICADO EN ITALIA

Las Autoridades sanitarias competentes de la Comunidad de Madrid , en el marco del Sistema Coordinado de Intercambio de Información (SCIRI), han comunicado una notificación de alerta en relación a la presencia de oxido de etileno en carbonato cálcico utilizado en complementos alimenticios Multicentrum, en concreto los siguientes a continuación detallados:

- MULTICENTRUM INMUNO C 14 sobres (C.N. 202019.1) lotes AUB19 (no ha llegado a comercializarse), MU129 y MU130.
- MULTICENTRUM INMUNO C 28 sobres (C.N. 202020.7) lotes AUB17, AUB18, MU719 y MU131.

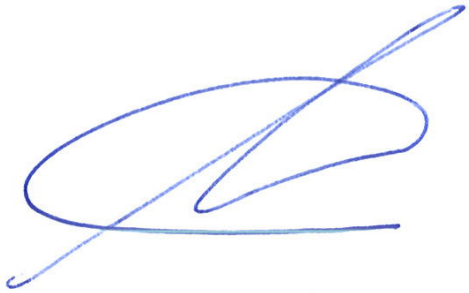
Se ha tenido conocimiento de que dichos productos están distribuidos en oficinas de farmacia.

La empresa responsable de la comercialización, ha contactado con los clientes para la recuperación de la mercancía, que será almacenada para su posterior destrucción.

Se da traslado de la presente información para su conocimiento y efectos oportunos.

Madrid, 21 de diciembre de 2021

Subdirectora General de Coordinación de Alertas y Programación del Control Oficial,



Fdo.: Paloma Cervera Lucini

Annexure 1

GBA

GBAGROUP FOOD

GBA Gesellschaft für Bioanalytik mbH · Goldtschmidtstr. 5 · 21073 Hamburg

Kappa Ingredients GmbH
Herr Selle
Friesenweg 4 Haus 13
22763 Hamburg

QS Ihr Prüfsystem für Lebensmittel. ilac-MRA DAkkS Deutsche Akkreditierungsstelle D-PL-14170-01-00

Contact person:
Laura Wogan
Phone +49 40 797172-442
l.wogan@gba-group.de

Certificate of analysis 21041681 - 002

Sample name	:	Calciumcarbonat Pulver 100
Marking of sample	:	Nr. 800100-25, Batch No: 20J/CP/GH/176-368
Customer No.	:	none
Packaging	:	Plastic vessel
Sample amount	:	285 g
Shipping of sample	:	Courier service
Sample entry	:	27.07.2021
Entrance temperature	:	Room temperature
Sample taken	:	by sender
Begin/end of analysis	:	27.07.2021 / 30.07.2021

The results are only based on the items tested. The GBA test report may not be published without the express written consent of the GBA Group, nor may excerpts of it be reproduced without permission. GBA decision rules can be seen in the general terms and conditions.

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HypoVereinsbank
IBAN DE45 2003 0000 0050 4043 92
SWIFT BIC HYVEDEMM300
Commerzbank Hamburg
IBAN DE67 2004 0000 0449 6444 00
SWIFT-BIC COBADEHHXXX

Sitz der Gesellschaft:
Hamburg
Handelsregister:
Hamburg HRB 42774
USt-Id.Nr. DE 118 554 138
St.-Nr. 47/723/00196

Geschäftsführer:
Ralf Murzen,
Dr. Roland Bernerth,
Kai Plinke,
Dr. Dominik Obeloer

30 Jahre 1989–2019

GBA

GBAGROUP
FOOD

Certificate of analysis : 21041681 002
Sample name : Calciumcarbonat Pulver 100

Test Results

Pesticides and related substances	*Result*	*Unit*
Ethylene oxide		
2-chloroethanol	17	mg/kg
Ethylene oxide, free	<0,010	mg/kg
Ethylene oxide, total	9,4	mg/kg

Hamburg, 30.07.2021

J. Kronberg

i.A. J. Kronberg
(Certified Food Chemist / Customer Service)

Methods

Parameter	*Method*
Ethylene oxide	HH-MA-M 03-064, GC-MS/MS: 2021-02[a]0

With [a] marked methods are accredited.
Testing laboratory: 0GBA Hamburg

Sudeep Pharma Pvt. Ltd. VADODARA

20/10/2021

Annexure 2

GBA

GBAGROUP FOOD

GBA Gesellschaft für Bioanalytik mbH · Goldtschmidtstr. 5 · 21073 Hamburg

Kappa Ingredients GmbH

Friesenweg 4 Haus 13
22763 Hamburg

QS Ihr Prüfsystem für Lebensmittel. ilac-MRA DAkkS Deutsche Akkreditierungsstelle D-PL-14170-01-00

Contact person:
Laura Wogan
Phone +49 40 797172-442
l.wogan@gba-group.de

Certificate of analysis 21039112 - 005

Sample name	:	Calcium Carbonat Powder 100
Marking of sample	:	Batch Nr.: 20H/CP/GH/157
Customer No.	:	none
Packaging	:	plastic package
Sample amount	:	94 g
Shipping of sample	:	Courier service
Sample entry	:	14.07.2021
Entrance temperature	:	Room temperature
Sample taken	:	by sender
Begin/end of analysis	:	14.07.2021 / 21.07.2021

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Geschäftsführer:
Ralf Murzen,
Dr. Roland Bernerth,
Kai Plinke,
Dr. Dominik Obeloer

30 Jahre 1989–2019

GBA

GBAGROUP
FOOD

Certificate of analysis : 21039112 005
Sample name : Calcium Carbonat Powder 100

Test Results

Pesticides and related substances	*Result*	*Unit*
Ethylene oxide		
2-chloroethanol	51	mg/kg
Ethylene oxide, free	<0,010	mg/kg
Ethylene oxide, total	28	mg/kg

Hamburg, 21.07.2021

i. A. L. Wogan
(Certified Food Chemist / Customer Service)

Methods

Parameter	*Method*
Ethylene oxide	HH-MA-M 03-064, GC-MS/MS: 2021-02[a]$_0$

With [a] marked methods are accredited.
Testing laboratory: $_0$GBA Hamburg

Sudeep Pharma Pvt. Ltd. VADODARA
20/11/2021