

Alertas RAPEX mascarillas
Referencia: SOFM/MJA/apf
Fecha: 20/05/2021

ALERTAS EUROPEAS SOBRE MASCARILLAS QUE PRESENTAN RIESGOS PARA LA SALUD DE LOS USUARIOS

RAPEX es un sistema unificado de alerta e intercambio de información de productos peligrosos para la salud de los consumidores de la Unión Europea. Algunos de los productos notificados puede que no se encuentren disponibles en nuestro país, salvo que se adquieran a través de comercio electrónico.

Se adjuntan las últimas alertas RAPEX referentes a mascarillas de filtración para protección frente al contagio por COVID19. La citas alertas son las A12/00540/21, A12/00541/21, A12/00542/21 y la A12/00556/21 todas ellas notificadas desde Alemania.

En todos los casos se han realizado los ensayos previstos en la Norma UNE-EN 149:2001+A1:2010 reguladora de los requisitos y ensayos de los dispositivos de protección respiratoria obteniendo en los cuatro casos NO conformidad por insuficiente capacidad de filtración, por lo que y ha de procederse a su cese de uso y retirada del mercado.

Le solicitamos que consulten frecuentemente las alertas emitidas por las autoridades europeas sobre mascarillas en el siguiente enlace, porque existen muchas en vigor en la actualidad y se incorporan continuamente.

https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.search&lng=es

Para cualquier duda puede dirigirse al Servicio de Ordenación Farmacéutica y Medicamentos: Tfno: 941 299 923 - mail: alertas.productossanitarios@larioja.org - Carta: Servicio de Ordenación Farmacéutica y Medicamentos - Productos Sanitarios C/ Obispo Lepe s/n 26071 Logroño

Logroño, 20 de mayo de 2021



Beatriz Barrio García
JEFA DE SECCIÓN DE
ATENCIÓN FARMACÉUTICA



**Gobierno
de La Rioja**
Salud y Portavocía del Gobierno
Humanización, Prestaciones
y Farmacia

Gobierno de La Rioja
Oficina Auxiliar de Registro
Salud

Fecha

20 MAYO 2021

Hora:

S- 107759

Número:



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
KN95 mask - respiratory protective face mask

Brand (on the product or the packaging)
Unknown

OECD Portal category (if known)
85000000 - Safety / Protection - DIY

Is the product (also) sold online?
Yes - Other

Professional product?
No

Product description
White respiratory protective face mask in a transparent plastic bag (1 piece) with packaging indicating only the KN95 standard; according to the printing on the mask itself, both standard KN95 GB2626-2006 and also EU standard EN 149:2001+A1:2009 are met

Packaging description
Plastic bag with black inscription. The product was sold online, in particular via

Product Recall

Type/number of model
• **KN95 MASK**

Batch number
• **20201019M**

Bar code
• **650226559983**

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00540/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The particle/filter retention of the material is insufficient

(measured value: as low as 82 %). Consequently, an excessive amount of particles or microorganisms might pass through the mask; thus, even if combined with other recommended measures, it may not properly protect.

Legal provisions (at EU level) and European standards against which the product was tested and did not comply
The product does not comply with the PPE Regulation and the relevant European standard EN 149.

(Overall) risk level
Serious

Product category
Protective equipment

Measures

Voluntary measures Voluntary measures

Retailer

Importer

eBay.

Recall of the product
from end users

Removal of this
product listing by
the online
marketplace

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Germany

DRAFT



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Ear brand folding anti particulate Mask

Brand (on the product or the packaging)
• AND MAGPIE

OECD Portal category (if known)
85000000 - Safety / Protection - DIY

Is the product (also) sold online?
Yes - Other

Professional product?
No

Product description
Respiratory protective face mask. The product is also sold online.

Packaging description
The product is sold in a white box with turquoise printing.

Product Recall

Type/number of models
• KN95

Batch number
Unknown

Bar code
• 6971044293892

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00541/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The particle/filter retention of the material is insufficient (measured values: as low as 93 %). Consequently, an excessive amount of particles or microorganisms might pass through the mask; thus, even if combined with other recommended measures, it may not properly protect.

Legal provisions (at EU level) and European standards against which the product was tested and did not comply
The product does not comply with the PPE Regulation and the European standard EN 149.

(Overall) risk level
Serious

Product category
Protective equipment

Measures

Voluntary measures Voluntary measures

Retailer Distributor

**Removal of this
product listing by
the online
marketplace**

**Destruction of the
product**

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Germany

DRAFT



Case number
A12/00542/21

Type of risk
**Health risk / other
Microbiological**

Risk description (technical defect and consequences)
The particle/filter retention of the material is insufficient (measured values: 92%). Consequently, an excessive amount of particles or microorganisms might pass through the mask; thus, even if combined with other recommended measures, it may not properly protect.

Legal provisions (at EU level) and European standards against which the product was tested and did not comply
EN 149, Clause 7.9.1 Regulation (EU) 2016/425

(Overall) risk level
High

Product category
Protective equipment

Measures

Compulsory measures

Other

**Recall of the product from end users
29/03/2021**

Product (what the product is)
Particle filter mask

Product Recall

Type/number of model
• KN95/FFP2

Name (on the product or the packaging)
Daily Protective Face Mask

Batch number
Unknown

Brand (on the product or the packaging)
• Highlight

Bar code
• 4064011489489

Is the product counterfeit?
Unknown

OECD Portal category (if known)
85000000 - Safety / Protection - DIY

Is this notification linked to a Business Gateway case?

Is the product (also) sold online?
No

Professional product?
No

Product description
20 individually packed face masks

Packaging description
Blue and white cardboard box

Year

Country of origin

Alert submitted by

2021

People's Republic of China

The Netherlands



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
KN95 Children's Masks

Brand (on the product or the packaging)
SHUFANG

OECD Portal category (if known)
85000000 - Safety / Protection - DIY

Is the product (also) sold online?
Yes - eBay

Professional product?
No

Product description
Particle filter mask, labelled as "for children". The product is also sold online, in particular via eBay.

Packaging description
The product is sold in transparent-and-blue plastic pouches, containing each 10 pieces.

Product Recall

Type/number of model
Unknown

Batch number
YM200227

Bar code
6973078310033

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/00556/21

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The particle/filter retention of the material is insufficient (measured values: as low as 53%). Consequently, the product does not fulfil the health and safety requirements; thus, even if combined with other recommended measures, it may not properly protect.

Legal provisions (at EU level) and European standards against which the product was tested and did not comply
The product does not comply with the PPE Regulation and with the relevant European standard EN 149.

(Overall) risk level
Serious

Product category
Protective equipment

Measures

Voluntary measures

Retailer

Recall of the product from end users

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Germany