

Alertas RAPEX enero 2021

Referencia: SOFM/MJA/apf

Fecha: 13/01/2021

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

RAPEX es un sistema unificado de alertas de productos peligrosos para los consumidores de la Unión Europea. Abarca todo tipo de productos no alimentarios, excepto los farmacéuticos, y pretende asegurar un rápido intercambio de información entre los estados miembros y la Comisión sobre las medidas tomadas para prevenir, restringir o imponer condiciones específicas en el márketing o uso de productos por razones de serio riesgo para la salud y seguridad de los consumidores.

Se adjuntan las últimas alertas RAPEX referentes a mascarillas de filtración para protección frente al contagio por COVID19. Dichas mascarillas tienen la consideración, bien de higiénicas, bien de EPI (equipo de protección individual) o bien son falsas mascarillas quirúrgicas (con marcado CE no válido) y ese es el motivo de su inclusión en un sistema de alerta destinado en principio a productos no farmacéuticos.

La alertas calificadas como INFO presentan un incumplimiento documental sin haberse realizado ensayos analíticos acerca de la seguridad del producto. La alerta A11/120/2020 ha sido categorizada como de riesgo no grave por la autoridad notificante.

Le solicitamos que consulten frecuentemente las alertas emitidas por las autoridades europeas sobre MASCARILLAS EPIS 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, 13 de enero de 2021



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FARMACÉUTICA Y MEDICAMENTOS.



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

Gobierno de La Rioja
Oficina Auxiliar de Registro
Salud

Fecha: 13 ENE. 2021

Hora: S- 5124

Número:



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
KN95 Filtering half mask

Brand (on the product or the packaging)
• Welooo

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

Is the product also sold online?
No

Professional product?
No

Product description
Single use particle half-face filter mask for protection against particles and aerosols, labelled KN95 and FFP2. The product is embossed with "KN95" on the side.

Packaging description
The product is sold in a white and blue folding box, with black/blue labelling. A box contains 10 masks, each of which is wrapped in a foil sachet.

Product Recall

Type/number of models
• KN95 / FFP2

Batch number
• 2020041

Bar code
• 897310994021

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A12/01886/20

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The particle filter retention of the material is insufficient (measured value 44,1%)

Consequently, an excessive amount of particles or microorganisms may pass through the mask, increasing the risk of infection if not combined with additional protective measures.

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 Personal Protective Equipment Regulation and with the relevant European standard EN 149.

(Overall) risk level
Serious

Product category
Protective equipment

Measures

Voluntary measures Voluntary measures



Case number
A12/01887/20

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The particle filter retention of the material is insufficient (measured value 64,6%). Consequently, an excessive amount of particles or microorganisms might pass through the mask, increasing the risk of infection if not combined with additional protective measures.

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

(Overall) risk level
Serious

Product category
Protective equipment

Measures

Compulsory measures

Importer

**Recall of the product from end users
14/12/2020**

Product (what the product is)
Particle filter mask

Product Recall

Name (on the product or the packaging)
KN95 Mask

Type/number of models
• KN95

Brand (on the product or the packaging)
• purvigor

Batch number
• 2020032

OECD Portal category (if known)
85000000 - Safety Protection - PPE

Bar code
**• 697312975001 (single)
• 697312975002 (10-items pack)**

Is the product (also) sold online?
Unknown - Unknown

Is the product counterfeit?
Unknown

Professional product?
No

Is this notification linked to a Business Gateway case?

Product description
Single use particle half-face filter mask for protection against particles and aerosols, labelled KN95 and FFP2. The brand's name is embossed on the side.

Packaging description
The product is sold in a transparent foil sachet with black labelling, containing one item, with barcode 6973129750016. The product can be found in an additional outer packaging for 10 individual packets, with a different barcode on the outer packaging (6973129750023).



Case number
A12/01888/20

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 37%). Consequently, an excessive amount of particles or microorganisms might pass through the mask, increasing the risk of infection if not combined with additional protective measures.

Applicable provisions (at EU level) and European standards against which the product was tested and does not comply
The product does not comply with the Personal Protective Equipment Regulation.

(Overall) risk level
Serious

Product category
Protective equipment

Measures

Voluntary measures

Other

Withdrawal of the product from the market
18/11/2020

Product (what the product is)
Particle filter mask

Product Recall

Type/number of models
• KN95

Name (on the product or the packaging)
Face mask - high-efficiency protective mask filter

Batch number
Unknown

Bar code
Unknown

Brand (on the product or the packaging)
Unknown

Is the product counterfeit?
Unknown

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

Is this notification linked to a Business Gateway case?
Unknown

Is the product (and its packaging) sold online?
Unknown - unknown

Professional product?
No

Product description
White protective respiratory filtration half-face mask, embossed with "KN95" on the side.

Packaging description

Year

Country of origin

Alert submitted by

2020

People's Republic of China

Germany



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Particle-filtering half mask

Brand (on the product or the packaging)
Unknown

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

Is the product (also) sold online?
No

Professional product?
No

Product description
White protective respiratory filtration half-face mask, embossed with "KN95" on the side.

Packaging description
The product is sold in a polythene bag containing 5 items.

Product Recall

Type/number of model
• KN95-A

Batch number
Unknown

Bar code
Unknown

Is the product counterfeit?
No

Is this notification linked to a Business Gateway case?

Case number
A12/01889/20

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 67,6%). Consequently, an excessive amount of particles or microorganisms might pass through the mask, increasing the risk of infection if not combined with additional protective measures.

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 Personal Protective Equipment Regulation.

(Overall) risk level
Serious

Product category
Protective equipment

Measures

Voluntary measures

Other

Withdrawal of the product from the market
18/11/2020

Year

Country of origin

Alert submitted by

2020

People's Republic of China

Germany



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Particle-filtering half mask

Brand (on the product or the packaging)
• SUNLU

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

Is the product (also) sold online?
Unknown - unknown

Professional product?
No

Product description
White protective respiratory filtration half-face mask, embossed with "KN95" on the side.

Packaging description

Year

Country of origin

Alert submitted by

2020

People's Republic of China

Germany

Case number
A12/01890/20

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 31,5%). Consequently, an excessive amount of particles or microorganisms might pass through the mask, increasing the risk of infection if not combined with additional protective measures.

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 Personal Protective Equipment Regulation.

(Overall) risk level
Serious

Product category
Protective equipment

Measures

Voluntary measures

Other

Withdrawal of the product from the market
18/11/2020



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Disposable Non Sterile Mask

Brand (on the product or the packaging)
• **Simbio**

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

Is the product (also) sold online?
No

Professional product?
No

Product description
Respiratory protective half-face mask.

Packaging description
The product is sold in a white and blue cardboard box containing 50 pieces.

Product Recall

Type/number of model
• **SBH4819**

Batch number
• **REF 9608
2020051501**

Bar code
• **5 943805 044563**

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
A11/00120/20

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product bears a CE marking but is not certified as protective equipment by a relevant body. Consequently, the product might not fulfil the health and safety requirements and thus not properly protect if not combined with additional measures.

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 Personal Protective Equipment Regulation and with the relevant European standard EN 149.

(Overall) risk level
Unknown

Product category
Protective equipment

Measures

Compulsory measures

Retailer

**Withdrawal of the product from the market
13/11/2020**

Year

Country of origin

Alert submitted by

2020

People's Republic of China

Romania



<p>Product (what the product is) Particle filter mask</p> <p>Name (on the product or the packaging) FACE MASK PARTICULATE RESPIRATOR</p> <p>Brand (on the product or the packaging) • Ouleok</p> <p>OECD Portal category (if known) 85000000 - Safety / Protection - DIY</p> <p>Is the product (also) sold online? Unknown - No in-depth investigations have been carried out in this respect.</p> <p>Professional product? No</p> <p>Product description White protective respiratory filtration half-face mask.</p> <p>Packaging description The product is packed in individual small plastic pouches. The European standard EN 149 is printed on the packaging.</p>	<p>Product Recall</p> <p>Type/number of model Unknown</p> <p>Batch number Unknown</p> <p>Bar code • 789849136593</p> <p>Is the product counterfeit? Unknown</p> <p>Is this notification linked to a Business Gateway case?</p>	<p>Case number INFO/00179/20</p> <p>Type of risk Health risk / other</p> <p>Risk description (technical defect and consequences) The product bears a CE marking but is not certified as protective equipment by a relevant body. Consequently, the product might not fulfil the health and safety requirements and thus not properly protect if not combined with additional measures.</p> <p>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 Personal Protective Equipment Regulation and with the relevant European standard EN 149.</p> <p>(Overall) risk level Unknown</p> <p>Product category Protective equipment</p> <p>Measures</p> <p>Compulsory measures</p> <p>Distributor</p> <p>Ban on the marketing of the product and any accompanying measures</p>
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Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Face Mask Surgical Disposable

Brand (on the product or the packaging)
Unknown

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

Is the product (also) sold online?
No

Professional product?
No

Product description
Face mask surgical disposable.

Packaging description
The masks are packed in a white and blue cardboard box containing 50 pieces with the product description in English with black characters. The packaging bears the CE marking.

Product Recall

Type/number of model
Unknown

Batch number
Unknown

Bar code
Unknown

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
INFO/00180/20

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product bears a CE marking and claims to meet the requirements of a surgical mask but it has not been certified as such by a relevant European body. Consequently, the product might not fulfil the health and safety requirements and thus not properly protect if not combined with additional measures.

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 requirements of the Medical Devices Directive and of the relevant European standard EN 14683.

(Overall) risk level
Unknown

Product category
Protective equipment

Measures

Compulsory measures

Importer

Withdrawal of the product from the market
20/11/2020

Year

Country of origin

Alert submitted by





Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Disposable Protective Mask

Brand (on the product or the packaging)
• RIXIN™

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

Is the product (also) sold online?
No

Professional product?
No

Product description
Blue-coloured disposable protective mask.

Packaging description
The product is sold in a white and blue cardboard box containing 50 pieces.

Product Recall

Type/number of model
• Earhook

Batch number
Unknown

Bar code
• 6973215750012

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
INFO/00181/20

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product bears the CE marking but it is certified by a relevant body. Consequently, the product might not fulfil the health and safety requirements and thus not properly protect if not combined with additional measures.

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 Personal Protective Equipment Regulation.

(Overall) risk level
Unknown

Product category
Protective equipment

Measures

Compulsory measures

Retailer

Withdrawal of the product from the market 05/11/2020

Year

Country of origin

Alert submitted by

2020

People's Republic of China

Romania



Product (what the product is)
Particle filter mask

Name (on the product or the packaging)
Medical mask with two layers

Brand (on the product or the packaging)
• **PRIMA**

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

Is the product (also) sold online?
No

Professional product?
No

Product description
Green medical mask with two layers. Masks are described as Class 1 medical devices, but in the same time, as „General purpose face mask suitable for medical, food processing as well as industrial use.“

Packaging description
The product is sold in a white and blue cardboard box containing 50 pieces.

Product Recall

Type/number of model
Unknown

Batch number
• **LHP – 1283**
02/2028

Bar code
• **6422125003911**

Is the product counterfeit?
Unknown

Is this notification linked to a Business Gateway case?

Case number
INFO/00182/20

Type of risk
Health risk / other

Risk description (technical defect and consequences)
The product bears a CE marking and claims to meet the requirements of a surgical mask but it has not been certified as such by a relevant European body. Consequently, the product might not fulfil the health and safety requirements and thus not properly protect if not combined with additional measures.

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 requirements of the Medical Devices Directive and with the relevant European standard EN 14683.

(Overall) risk level
Unknown

Product category
Protective equipment

Measures

Compulsory measures

Retailer

Withdrawal of the product from the market
04/11/2020

Year

Country of origin

Alert submitted by