

Alertas RAPEX mascarillas  
Referencia: SOFM/BBG/apf  
Fecha: 22/09/2021

### 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. Las alertas del sistema RAPEX son notificadas por un Estado Miembro. Algunos de los productos notificados puede que no se encuentren disponibles en nuestro país, salvo que se adquirieran a través de comercio electrónico.

Se adjuntan las últimas alertas referentes a mascarillas de filtración para protección frente al contagio por COVID19:

- A12/01097/21
- A12/01202/21
- A12/01203/21
- A12/01205/21
- A12/01206/21
- A12/01223/21
- A12/01224/21
- A12/01248/21

Estas alertas han sido calificadas como A12 por haber sido sometidos los productos a ensayos y presentar en todos los casos una capacidad de filtrado insuficiente acorde a lo dispuesto en la Norma Europea EN 149:2009 sobre dispositivos de protección respiratoria, por ello se ha dispuesto la **retirada del mercado** de las mascarillas afectadas.

La alerta nº 01224 corresponde a la mascarilla de protección tipo FFP2 del fabricante Shandong Shenquan New Materials Co. Ltd. China, modelo SNN70369B, lote: EXP 2023/10. En el Acuerdo Marco del INGESA 2020/70 resultó adjudicado este modelo de mascarilla de protección a las empresas AMEVISA e ITURRI. Puestos en contacto con ambas empresas, nos comunican que no se ha distribuido esta mascarilla con base en el Acuerdo marco del INGESA.

Le solicitamos que consulten frecuentemente las alertas emitidas por las autoridades europeas en:

[https://ec.europa.eu/consumers/consumers\\_safety/safety\\_products/rapex/alerts/?event=main.search&lng=es](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](mailto:alertas.productossanitarios@larioja.org)

Logroño, 22 de septiembre de 2021



*P.A.*  
  
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Salud

Fecha: 22 SET. 2021

Hora:  
Número:





Product (what the product is)  
**Particle filter mask**

Name (on the product or the packaging)  
**FFP2 NR D fine dust mask**

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

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

Is the product (also) sold online?  
**Yes - Amazon**

Professional product?  
**No**

Product description  
**White masks marked with FFP2 and with the CE marking printed on, with a very large number of threads in the fringes, knotted to the headbands. The product was also sold online, in particular via Amazon, under ASIN B08P7XYD47.**

Packaging description  
**The product is sold in white-blue cardboard packages containing 20 masks; each mask is individually packed in a transparent plastic pouch. The product is marked with**

Product Recall

Type/number of model  
• **C-267**

Batch number  
**Unknown**

Bar code  
• **7629999206564**

Is the product counterfeit?  
**No**

Is this notification linked to a Business Gateway case?

Case number  
**A12/01197/21**

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 74%).**

**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 Personal Protective Equipment (PPE) Regulation and with the relevant European standard EN 149.**

(Overall) risk level  
**Serious**

Product category  
**Protective equipment**

Measures

**Voluntary measures**      **Compulsory measures**

the FFP2 indication and the CE marking.

Other

Other

**Ban on the marketing of the product and any accompanying measures**

**Ban on the marketing of the product and any accompanying measures**

Year

Country of origin

Alert submitted by

2021	Turkey	Germany
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Product (what the product is)  
**Particle filter mask**

Name (on the product or the packaging)

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

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

Is the product (also) sold online?  
**Yes - Amazon**

Professional product?  
**No**

Product description  
**White protective respiratory filtration half-face mask, marked with FFP2 and with the CE marking printed on. Product sold online, in particular via Amazon, with the ASIN code B08T1T71QZ.**

Packaging description  
**The product is sold in a blue/white cardboard box, containing 30 masks. The packaging makes reference to EN 149 and is marked with FFP2, as well as with the CE marking.**

Product Recall

Type/number of model  
• **3199061**

Batch number  
• **20210201R1**

Bar code  
• **X0001AW4RW7**

Is the product counterfeit?  
**Unknown**

Is this notification linked to a Business Gateway case?

Case number  
**A12/01202/21**

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 92%).**

**Furthermore, the mask does not properly adapt to the face. Consequently, the product does not fulfil the health and safety requirements, and an excessive amount of particles or microorganisms might pass through the mask, increasing the risk of infection; 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 Personal Protective Equipment (PPE) Regulation and with the relevant European standard EN 149.**

(Overall) risk level

**Serious**  
Product category  
**Protective equipment**

**Measures**

**Compulsory measures**

**Voluntary measures**

**Other**

**Manufacturer**

**Stop of sales**

**Recall of the product from end users**

**Voluntary measures**

**Compulsory measures**

**Manufacturer**

**Other**

**Stop of sales**

**Recall of the product from end users**

Year

Country of origin

Alert submitted by

2021

Unknown

Germany



Product (what the product is)  
**Particle filter mask**

Name (on the product or the packaging)  
**KN95 Professional Protection**

Brand (on the product or the packaging)  
**Unknown**

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

Is the product (also) sold online?  
**Yes - Amazon**

Professional product?  
**No**

Product description  
**White protective respiratory filtration half-face mask with hybrid labelling (KN95 and CE2163). Product sold online, in particular via Amazon, with the ASIN code: B08SW4XNGN.**

Packaging description  
**The masks are packaged in white plastic bearing turquoise lettering "respiratory protective face-masks KN95". The packaging also bears a sticker with hybrid labelling (KN95 and FFP2/CE), but does not**

Product Recall

Type/number of model  
**Unknown**

Batch number  
**• 2020-3DG**

Bar code  
**Unknown**

Is the product counterfeit?  
**Unknown**

Is this notification linked to a Business Gateway case?

Case number  
**A12/01203/21**

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 29%). Furthermore, the mask does not properly adapt to the face. Consequently, the product does not fulfil the health and safety requirements, and an excessive amount of particles or microorganisms might pass through the mask, increasing the risk of infection; 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 Personal Protective Equipment (PPE) Regulation and with the relevant European standard EN 149.**

(Overall) risk level

state the manufacturer's name, any details concerning the model, an EAN code or other information.

**Serious**  
Product category  
**Protective equipment**

**Measures**

**Voluntary measures**      **Compulsory measures**

**Distributor**

**Other**

**Removal of this product listing by the online marketplace 02/07/2021**

**Removal of this product listing by the online marketplace 02/07/2021**

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Germany





Product (what the product is)  
**Particle filter mask**

Name (on the product or the packaging)  
**KN95 PROTECTIVE MASK**

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

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

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

Professional product?  
**No**

Product description  
**White protective respiratory filtration half-face mask, with elastic ear bands and nose strip, marked with "KN95". The product is also sold online.**

Packaging description  
**The product is sold in transparent cellophane pouches containing 1 item, packed in a white and blue cardboard box containing a total of 10 masks.**

Product Recall

Type/number of model  
**Unknown**

Batch number  
**Unknown**

Bar code  
• **6936384100552**

Is the product counterfeit?  
**Unknown**

Is this notification linked to a Business Gateway case?

Case number  
**A12/01205/21**

Type of risk  
**Health risk / other**

Risk description (technical defect and consequences)  
**The total filtration capacity of the mask is insufficient (measured mean values: as low as 67%). 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 Personal Protective Equipment (PPE) Regulation and with the relevant European standard EN 149.**

(Overall) risk level  
**Serious**

Product category  
**Protective equipment**

Measures

**Compulsory measures**

**Distributor**

**Withdrawal of the product from the market 14/07/2021**

Year

Country of origin

Alert submitted by





Product (what the product is)  
**Particle filter mask**

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

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

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

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

Professional product?  
**No**

Product description  
**White protective respiratory filtration half-face mask, marked with KN95. Product sold online, in particular on eBay with the article number 174739874669.**

Packaging description  
**Masks are packed in a white-green cardboard box of 20, marked with KN95.**

Product Recall

Type/number of model  
**Unknown**

Batch number  

- **RW2004-15**
- **Manufacture: 04/15/2020**
- **Exp.: 04/14/2023**

Bar code  
**Unknown**

Is the product counterfeit?  
**Unknown**

Is this notification linked to a Business Gateway case?

Case number  
**A12/01206/21**

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 73%).**

**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 Personal Protective Equipment (PPE) Regulation and with the relevant European standard EN 149.**

(Overall) risk level  
**Serious**

Product category  
**Protective equipment**

Measures

**Voluntary measures      Compulsory measures**

**Retailer**

**Other**

**Withdrawal of the  
product from the  
market  
09/08/2021**

**Withdrawal of the  
product from the  
market  
09/08/2021**

**Voluntary measures**

**Retailer**

**Recall of the product  
from end users  
09/08/2021**

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Germany



Product (what the product is)  
**Particle filter mask**

Name (on the product or the packaging)  
**KN95 Disposable Respirator 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 - eBay**

Professional product?  
**No**

Product description  
**Protective respiratory filtration half-face mask, with "KN95" embossed on the side. Product sold online, in particular via eBay, with the number 174550990651.**

Packaging description  
**White and blue cardboard box with 20 masks. Each mask is singularly packaged in a transparent foil, with green markings.**

Product Recall

Type/number of model  
**Unknown**

Batch number  
• **20200506**  
• **Production date: 2020/05/06**

Bar code  
• **4036730085891**

Is the product counterfeit?  
**Unknown**

Is this notification linked to a Business Gateway case?

Case number  
**A12/01223/21**

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 31%).**

**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 Personal Protective Equipment (PPE) Regulation and with the relevant European standard EN 149.**

(Overall) risk level  
**Serious**

Product category  
**Protective equipment**

Measures

**Voluntary measures**      **Compulsory measures**

**Retailer**

**Other**

**Withdrawal of the  
product from the  
market  
04/08/2021**

**Withdrawal of the  
product from the  
market  
04/08/2021**

**Voluntary measures**

**Retailer**

**Recall of the product  
from end users  
04/08/2021**

Year

Country of origin

Alert submitted by

2021

Unknown

Germany



Product (what the product is)  
**Particle filter mask**

Name (on the product or the packaging)

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

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

Is the product (also) sold online?  
**Unknown - It is not known whether the batch (EXP 2023/10) of Shengquan SNN70369B FFP2 Particle Filtering Half Masks that was examined is being sold online by other distributors or on other platforms.**

Professional product?  
**Yes**

Product description  
**Protective respiratory filtration half-face mask marked with FFP2 / KN95 and with the CE 2834 marking printed on.**

Product Recall

Type/number of model  
• **SNN70369B**

Batch number  
• **EXP 2023/10**

Bar code  
• **6970266961305**

Is the product counterfeit?  
**No**

Is this notification linked to a Business Gateway case?

Case number  
**A12/01224/21**

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 89%). 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. As a result of the labelling, the mask may be worn in areas where hazardous substances are in use or during activities involving asbestos; since the mask fails to offer sufficient protection, this could lead to asbestosis with fatal consequences.**

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 (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  
**21/07/2021**

Packaging description  
**Transparent plastic pouches with green decorations and marked with FFP2 and the CE marking.**

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Germany





Product (what the product is)  
**Particle filter mask**

Name (on the product or the packaging)  
**Unihope KN95 Maske – Face Mask 3D Pro**

Brand (on the product or the packaging)  
**Unihope**

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

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

Professional product?  
**No**

Product description  
**10 white masks per box, with 'KN95' printed on both sides of each mask. Product sold online, in particular via eBay with the identification code #274871075226.**

Packaging description  
**The secondary packaging is a yellow and blue cardboard box.**

Product Recall

Type/number of model  
**• Rxn-001**

Batch number  
**• 20200402160105**

Bar code  
**• 6934933806474**

Is the product counterfeit?  
**Unknown**

Is this notification linked to a Business Gateway case?

Case number  
**A12/01248/21**

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 62%).**

**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 Personal Protective Equipment (PPE) Regulation and with the relevant European standard EN 149.**

(Overall) risk level  
**Serious**

Product category  
**Protective equipment**

Measures

Compulsory measures

Voluntary measures

**Other**

**Retailer**

**Withdrawal of the product from the market  
16/08/2021**

**Withdrawal of the product from the market  
16/08/2021**

**Voluntary measures**

**Retailer**

**Recall of the product from end users  
16/08/2021**

Year

Country of origin

Alert submitted by

2021

People's Republic of China

Germany

Confidential