

## RAPEX 49 – 06/12/2019



**Alert number:** A12/1838/19

**Category:** Chemical products

**Product:** Tattoo ink

**Brand:** Dynamic

**Name:** BLK

**Type / number of model:** Black

**Batch number / Barcode:** Lot:12026230

**Risk type:** Chemical

The product contains an excessive amount of polycyclic aromatic hydrocarbons PAH among which benzo[a]pyrene (measured values: 1,62 mg/kg and 0,12 mg/kg, respectively).

PAHs and benzo[a]pyrene may cause cancer and are also mutagenic and toxic for reproduction.

The Council of Europe Resolution ResAP (2008)<sup>1</sup> on requirements and criteria for the safety of tattoos and permanent make-up recommends that in tattoo inks the levels of impurities of PAHs does not exceed 0,5 mg/kg and 5 µg/kg of benzo[a]pyrene.

**Measures taken by economic operators:** Withdrawal of the product from the market, Withdrawal of the product from the market (By: Distributor, Importer)

**Measures ordered by public authorities (to: Distributor, Importer):** Withdrawal of the product from the market, Withdrawal of the product from the market

**Description:** 29,6 ml of black tattoo ink in a transparent plastic bottle fitted with a dispensing nozzle and a screw-top. The product was also sold online.

**Country of origin:** United States

**Alert submitted by:** Finland

**Type of alert:** Serious



**Alert number:** A12/1839/19

**Category:** Chemical products

**Product:** Tattoo ink

**Brand:** Bloodline

**Name:** All purpose black

**Type / number of model:** 29,6 ml/ 1 oz

**Batch number / Barcode:** Lot: exp 01/22

**Risk type:** Chemical

The product contains an excessive amount of polycyclic aromatic hydrocarbons PAH among which benzo[a]pyrene (measured values: 1,46 mg/kg and 0,14 mg/kg, respectively). PAHs and benzo[a]pyrene may cause cancer and are also mutagenic and toxic for reproduction.

The Council of Europe Resolution ResAP (2008)<sup>1</sup> on requirements and criteria for the safety of tattoos and permanent make-up recommends that in tattoo inks the levels of impurities of PAHs does not exceed 0,5 mg/kg and 5 µg/kg of benzo[a]pyrene.

**Measures taken by economic operators:** Withdrawal of the product from the market, Withdrawal of the product from the market (By: Distributor, Importer)

**Measures ordered by public authorities (to: Distributor, Importer):** Withdrawal of the product from the market, Withdrawal of the product from the market

**Description:** 29,6 ml of black tattoo ink in a transparent plastic bottle fitted with a dispensing nozzle and a screw-top. The product was also sold online.

**Country of origin:** United States

**Alert submitted by:** Finland

**Type of alert:** Serious



**Alert number:** A12/1844/19

**Category:** Chemical products

**Product:** Tattoo ink

**Brand:** Colour King

**Name:** Orange

**Type / number of model:** Unknown

**Batch number / Barcode:** Unknown

**Risk type:** Chemical

The product contains 4-methyl-m-phenylenediamine (measured concentration 13mg/kg) and barium (measured concentration 5214 mg/kg).

4-methyl-m-phenylenediamine is an aromatic amines that can cause cancer, cell mutations and affect reproduction and it's also a skin sensitizing substance.

Barium can have toxic effects on the body impairing muscle, kidney and heart activity, leading to arrhythmia, paralysis or gastrointestinal alterations.

The Council of Europe Resolution ResAP (2008)1 on requirements and criteria for the safety of tattoos and permanent make-up, recommends that aromatic amines with carcinogenic, mutagenic, reprotoxic or sensitising properties shouldn't be present in tattoos and permanent make-up products and that barium does not exceed 50 mg/kg.

**Measures taken by economic operators:** Notifying about the risk (By: Other)

**Description:** Orange tattoo ink in a transparent plastic bottle with a dispenser cap. The product was sold online (in particular via [lightinthebox.com](http://lightinthebox.com)).

**Country of origin:** China

**Alert submitted by:** Finland

**Type of alert:** Serious



**Alert number:** A12/1845/19

**Category:** Chemical products

**Product:** Tattoo ink

**Brand:** Colour King

**Name:** Black

**Type / number of model:** Unknown

**Batch number / Barcode:** Unknown

**Risk type:** Chemical

The product contains an excessive amount of polycyclic aromatic hydrocarbons (PAHs) (measured total value: 1.88 mg/kg), benzo[a]pyrene, cadmium and lead (measured values: 320 µg/kg, 0.52 mg/kg and 30 mg/kg, respectively).

These PAHs and benzo[a]pyrene may cause cancer and are also mutagenic and toxic for reproduction.

Cadmium is harmful to human health because it accumulates in the body, can damage the kidney and bones, and it may cause cancer.

Lead is harmful to human health, accumulates in the body, can cause developmental neurotoxicity and may also affect breast-fed or unborn children.

The Council of Europe Resolution ResAP (2008)<sup>1</sup> on requirements and criteria for the safety of tattoos and permanent make-up recommends that the levels of impurities of PAHs in tattoo inks do not exceed 0,5 mg/kg, of benzo[a]pyrene 5 µg/kg, of cadmium 0.2 mg/kg and of lead 2 mg/kg.

**Measures taken by economic operators:** Notifying about the risk (By: Other)

**Description:** Black tattoo ink in a transparent plastic bottle with a dispenser cap. The product was sold online (in particular via [lightinthebox.com](http://lightinthebox.com)).

**Country of origin:** China

**Alert submitted by:** Finland

**Type of alert:** Serious



**Alert number:** A12/1847/19

**Category:** Chemical products

**Product:** Tattoo ink

**Brand:** INTENZE

**Name:** The Alex De Pase Series

**Type / number of model:** Magenta

**Batch number / Barcode:** Lot SS265

**Risk type:** Chemical

The product contains the aromatic amines 4-methyl-m-phenylenediamine, o-anisidine (measured values: 13 mg/kg and 7 mg/kg, respectively) and an excessive amount of barium (measured value: 52 mg/kg). 4-methyl-m-phenylenediamine is a skin sensitiser and, as o-anisidine, may cause cancer.

Barium can be easily absorbed and have toxic effects on the body impairing muscle, kidney and heart activity, leading to arrhythmia, paralysis or gastrointestinal alterations.

The Council of Europe Resolution ResAP (2008)<sup>1</sup> on requirements and criteria for the safety of tattoos and permanent make-up, recommends that aromatic amines with carcinogenic mutagenic, reprotoxic or sensitising properties should neither be present in tattoos and permanent make-up products nor released from azo-colourants and that barium does not exceed 50 mg/kg.

**Measures taken by economic operators:** Warning consumers of the risks, Withdrawal of the product from the market (By: Distributor)

**Measures ordered by public authorities (to: Distributor):** Withdrawal of the product from the market

**Description:** 29,6 ml of magenta tattoo ink in a transparent plastic bottle fitted with a dispensing nozzle and a screw-top. The product was also sold online.

**Country of origin:** United States

**Alert submitted by:** Finland

**Type of alert:** Serious



**Alert number:** A12/1848/19

**Category:** Chemical products

**Product:** Tattoo ink

**Brand:** Arte Stylo

**Name:** Cafe

**Type / number of model:** Unknown

**Batch number / Barcode:** Lot: 180624

**Risk type:** Chemical

The product contains nickel (measured value: 22 mg/kg).

Nickel can cause skin irritation, induce sensitisation or elicit allergic responses.

The Council of Europe Resolution ResAP (2008)<sup>1</sup> on requirements and criteria for the safety of tattoos and permanent make-up recommends that the levels of nickel in tattoo inks are as low as technically achievable.

**Measures taken by economic operators:** Ban on the marketing of the product and any accompanying measures, Warning consumers of the risks (By: Distributor)

**Measures ordered by public authorities (to: Distributor):** Ban on the marketing of the product and any accompanying measures

**Description:** Brown tattoo ink in a transparent plastic bottle fitted with a dispensing nozzle and a screw-top. The product was also sold online.

**Country of origin:** United States

**Alert submitted by:** Finland

**Type of alert:** Serious



**Alert number:** A12/1923/19

**Category:** Chemical products

**Product:** Permanent make-up ink

**Brand:** Mastor

**Name:** Pigment Color for Micropigmentation

**Type / number of model:** Dark Pink M307

**Batch number / Barcode:** MGF: 2016.03.12 EXP 2019.03.12

**Risk type:** Chemical

The product contains the aromatic amine o-anisidine and zinc (measured values: 25 mg/kg and 1542 mg/kg, respectively).

O-anisidine may cause cancer and an excessive exposure to zinc might cause neurological disorders.

The Council of Europe Resolution ResAP (2008)1 on requirements and criteria for the safety of tattoos and permanent make-up, recommends that aromatic amines with carcinogenic mutagenic, reprotoxic or sensitising properties should neither be present in tattoos and permanent make-up products nor released from azo-colourants and that zinc does not exceed 50 mg/kg.

**Measures taken by economic operators:** Withdrawal of the product from the market (By: Importer)

**Measures ordered by public authorities (to: Importer):** Withdrawal of the product from the market

**Description:** Red plastic bottle with grey drip cap containing pigment for permanent make-up. The bottle has a white/grey label with the name of the product. The product was also sold online.

**Country of origin:** Unknown

**Alert submitted by:** Finland

**Type of alert:** Serious



**Alert number:** A12/1925/19

**Category:** Chemical products

**Product:** Permanent make-up ink

**Brand:** BioTouch

**Name:** Micro pigment cosmetic color

**Type / number of model:** Black

**Batch number / Barcode:** Lot: 30845

**THE PRODUCT IS COUNTERFEIT**

**Risk type:** Chemical

The product contains an excessive amount of polycyclic aromatic hydrocarbons (PAHs) (measured total value: 1.94 mg/kg), benzo[a]pyrene, cadmium and lead (measured values: 180 µg/kg, 0.42 mg/kg and 26 mg/kg, respectively).

PAHs and benzo[a]pyrene may cause cancer and are also mutagenic and toxic for reproduction.

Cadmium is harmful to human health because it accumulates in the body, can damage the kidney and bones, and it may cause cancer.

Lead is harmful to human health, accumulates in the body, can cause developmental neurotoxicity and may also affect breast-fed or unborn children.

The Council of Europe Resolution ResAP (2008)<sup>1</sup> on requirements and criteria for the safety of tattoos and permanent make-up recommends that the levels of impurities of PAHs in tattoo inks do not exceed 0,5 mg/kg, of benzo[a]pyrene 5 µg/kg, of cadmium 0.2 mg/kg and of lead 2 mg/kg.

**Measures taken by economic operators:** Withdrawal of the product from the market (By: Importer)

**Measures ordered by public authorities (to: Importer):** Withdrawal of the product from the market

**Description:** 28.4 ml of black pigment in a transparent plastic bottle with a white drip cap. The product was also sold online.

**Country of origin:** China

**Alert submitted by:** Finland

**Type of alert:** Serious



**Alert number:** A12/1898/19

**Category:** Cosmetics

**Product:** Skin cleansing product

**Brand:** Unknown

**Name:** Muravjinyj spirt

**Type / number of model:** Unknown

**Batch number / Barcode:** 4603380000255

**Risk type:** Chemical

According to the ingredients list and product information file, the product contains an excessive amount of formic acid (declared value: 1.4%).

Ingestion or contact with an excessive quantity of formic acid may cause inflammation of the skin.

The product does not comply with the Cosmetic Products Regulation.

**Measures ordered by public authorities (to: Importer):** Withdrawal of the product from the market

**Description:** Formic acid packed in 50 ml glass vials with a screw cap.

**Country of origin:** Russian Federation

**Alert submitted by:** Lithuania

**Type of alert:** Serious



**Alert number:** A12/1899/19

**Category:** Cosmetics

**Product:** Skin cleansing products

**Brand:** Unknown

**Name:** Bornaja kislota

**Type / number of model:** Nr. 30416

**Batch number / Barcode:** Unknown

**Risk type:** Chemical

According to the ingredients list and product information file, the product contains an excessive amount of formic acid (declared value: 3%).

Ingestion or contact with an excessive quantity of boron may harm the health by damaging the reproductive system or the unborn child.

The product does not comply with the Cosmetic Products Regulation.

**Measures ordered by public authorities (to: Importer):** Withdrawal of the product from the market

**Description:** Boric acid packed in 25 ml glass vials with a screw ca.

**Country of origin:** Russian Federation

**Alert submitted by:** Lithuania

**Type of alert:** Serious



**Alert number:** A12/1916/19

**Category:** Cosmetics

**Product:** Eyelash growth product

**Brand:** abalico

**Name:** Eyelash Serum

**Type / number of model:** #44.093

**Batch number / Barcode:** 4250737402257, CH 18101 MHD 09/19

**Risk type:** Chemical

The product contains Tafluprost ethyl amide (measured value: 0,0026 %), which should be used under the supervision of an ophthalmologist.

Tafluprost ethyl amide is a prostaglandin analogue, which could cause eye and ophthalmic defects in the user and should not be used by pregnant and breastfeeding women, as it may affect the child.

The product does not comply with the Cosmetic Products Regulation.

**Measures taken by economic operators:** Ban on the marketing of the product and any accompanying measures, Recall of the product from end users, Withdrawal of the product from the market (By: Importer)

**Description:** 3 ml of eyelash growth serum in a transparent plastic flask, with a silver screw cap and built-in application brush. The product is sold in a black and silver cardboard box. The product was also sold online.

**Country of origin:** Austria

**Alert submitted by:** Germany

**Type of alert:** Serious

**Products were found and measures were taken also in:** Slovenia



**Alert number:** A12/1927/19

**Category:** Cosmetics

**Product:** Skin lightening product

**Brand:** Aneeza Cosmetics, Eleven Herbal

**Name:** Ubtan with sunscreen

**Type / number of model:** Unknown

**Batch number / Barcode:** 1143723500019

**Risk type:** Chemical

The product contains mercury (measured value: 9,5 mg/kg).

Mercury accumulates in the body and can damage the kidneys, brain and nervous system. Additionally, it may affect reproduction and the unborn child.

The product does not comply with the Cosmetic Products Regulation.

**Measures ordered by public authorities (to: Importer):** Ban on the marketing of the product and any accompanying measures

**Description:** 70 g of face cream sold in a yellow/gold cardboard box with the face of a man and a woman printed on it.

**Country of origin:** Pakistan

**Alert submitted by:** Norway

**Type of alert:** Serious



**Alert number:** A12/1930/19

**Category:** Cosmetics

**Product:** Skin lightening product

**Brand:** Unknown

**Name:** Rose Cream

**Type / number of model:** Unknown

**Batch number / Barcode:** 041833007002, M : 03.2017 E : 03.2020 B : 7519

**Risk type:** Chemical

The product contains mercury (measured value: 4,8 mg/kg).

Mercury accumulates in the body and can damage the kidneys, brain and nervous system. Additionally, it may affect reproduction and the unborn child.

The product does not comply with the Cosmetic Products Regulation.

**Measures ordered by public authorities (to: Importer):** Ban on the marketing of the product and any accompanying measures

**Description:** 25 g of skin whitening cream sold in a small, pink plastic jar with a gold cap.

**Country of origin:** Lebanon

**Alert submitted by:** Norway

**Type of alert:** Serious