



Safety Gate: Rapid Alert System for dangerous non-food products

Alert number	A12/00112/20
Category	Chemical products
Type of alert	Products with serious risks
Product user	Consumer
Product	Tattoo ink
Brand	Icolor
Name	Product for permanent makeup
Type / number of model	Nude Pink
Batch number / Barcode	
OECD Portal Category	58000000 - Cross Segment
Description	10 ml of pink ink for lip permanent make-up.
Country of origin	United States
Alert submitted by	Sweden
Risk type	Chemical
Technical defect	<p>The product contains the aromatic amines 4-methyl-m-phenylenediamine and o-toluidine (measured values up to: 1.5 mg/kg and 1.0 mg/kg, respectively), nickel as well as an excessive amount of lead (measured values: 47 mg/kg and 4.5 mg/kg, respectively).
 4-methyl-m-phenylenediamine is a skin sensitiser, may cause cancer and might induce mutations and/or affect fertility. O-toluidine is genotoxic and may cause cancer. Nickel can cause skin irritation, induce sensitisation or elicit allergic responses. 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)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, that the levels of nickel are as low as technically achievable and that impurities of lead do not exceed 2 ppm.</p>
Risk	
Measures adopted by notifying country	Withdrawal of the product from the market

Images

