

**Resolution ResAP(2008)1
on requirements and criteria for the safety of tattoos and permanent make-up (superseding
Resolution ResAP(2003)2 on tattoos and permanent make-up)**

*(Adopted by the Committee of Ministers on 20 February 2008
at the 1018th meeting of the Ministers' Deputies)*

The Committee of Ministers, in its composition restricted to the representatives of Austria, Belgium, Bulgaria, Cyprus, Finland, France, Germany, Ireland, the Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland and the United Kingdom, member states of the Partial Agreement in the Social and Public Health Field,

Recalling Resolution (59) 23 of 16 November 1959, on the extension of the activities of the Council of Europe in the social and cultural fields;

Having regard to Resolution (96) 35 of 2 October 1996 revising the above-mentioned partial agreement, whereby it revised the structures of the Partial Agreement and resolved to continue, on the basis of revised rules replacing those set out in Resolution (59) 23, the activities hitherto carried out and developed by virtue of that resolution, these being aimed in particular at:

- a. raising the level of health protection of consumers in its widest sense, including the making of a constant contribution to harmonising – in the field of products having a direct or indirect impact on the human food chain as well as in the fields of pesticides, pharmaceuticals and cosmetics – legislation, regulations and practices governing, on the one hand, quality, efficiency and safety controls for products, and, on the other hand, the safe use of toxic or noxious products;
- b. integrating people with disabilities into the community; defining and contributing to the implementation, at a European level, of a model of coherent policy for people with disabilities, which takes account simultaneously of the principles of full citizenship and independent living; contributing to the elimination of barriers to people's integration whatever their nature, whether psychological, educational, family-related, cultural, social, professional, financial or architectural;

Having regard to the action carried out for several years for the purpose of harmonising their legislation, in particular with a view to promoting consumer health as regards the use of cosmetic products;

Considering the increasing popularity of body adornment through tattoos or permanent make-up (PMU);

Considering that tattoos and PMU may pose a risk to human health due to microbiological contamination and/or the presence of harmful substances in the products used for tattoos and PMU and/or the possibility of being tattooed under questionable hygienic conditions;

Considering that colorants not restricted by this resolution have not been evaluated for safe use in tattoos and PMU by an independent scientific body;

Considering that risk assessment is an essential part of the decision-making process on preventive measures aimed at protecting public health;

Taking into account the fact that in most member states tattoos, tattooing and PMU are covered neither by specific national nor European Community regulations;

Aware of the need to fill this gap in legislation and thus to adopt specific legislation on the composition of the products used for tattoos and PMU and the assessment of their safety, including in particular the harmonisation of methods for the analytical determination of possibly harmful substances in colorants, and ensuring that practices for tattoos and permanent make-up are carried out under appropriate hygienic conditions;

Considering the fact that implementing specific legislation on tattoos and PMU may have a substantial positive impact on health risks related to product quality;

Taking the view that each member state, faced with the need to introduce regulations governing this matter, would find it beneficial for such regulations to be harmonised at European level;

Considering that this resolution follows a negative list approach by listing the substances which must not be used in tattooing products and PMU, based on current knowledge in this field;

Considering further that using a negative list-approach is only a first step towards ensuring that hazardous substances are avoided,

Recommends that the governments of the member states of the Partial Agreement in the Social and Public Health Field:

- take into account in their national laws and regulations on tattoos and PMU the principles set out thereafter in the appendix to this resolution, in particular on the composition of tattoos and PMU, and modes and criteria of the safety assessment with a view to public health protection;
- regulate the use of substances in tattoos and PMU by taking steps towards establishing – on the basis of safety assessments carried out by the competent bodies and harmonised at European level – an exhaustive list of substances proved safe for this use under certain conditions (“positive list”).

Each government remains free to impose stricter regulations.

Appendix to Resolution ResAP(2008)1

1. Field of application

This resolution applies to:

- the composition and labelling of products used for tattoos and PMU;
- the risk evaluation required before products used for tattoos and PMU are placed on the market;
- the conditions of the application of tattoos and PMU;
- the obligation to inform the public and the consumer of the health risks of tattoos and PMU and tattooing practices.

2. Definitions

Tattooing is a practice whereby a permanent skin marking or design (a “tattoo”) is administered by intradermal injection of products consisting of colorants and auxiliary ingredients.

“Colorant” is the commonly used denomination for pigments, lakes and dyes that are coloured molecules. Pigments are in general very poorly soluble in water and application media, and unlike most dyes, they have low solubility in organic solvents. For this reason they remain essentially in the solid state, including in live tissues. Dyes are organic molecules that are soluble in general. Certain substances like titanium dioxide (TiO₂) or barium sulphate (BaSO₄) can be used as carriers for dyes used in tattoos, thereby forming “lakes” which are insoluble in water.

Auxiliary ingredients are necessary to obtain ready-to-use tattooing products. They are of different kinds like solvents, stabilisers, “wetting agents”, pH-regulators, emollients and thickeners.

A permanent make-up (PMU) consists of colorants and auxiliary ingredients which are injected intradermally for the purposes of enhancing the contours of the face.

“Sterile” in this context means the absence of viable organisms, including viruses.

3. Specifications

3.1. When applied and used as intended, tattoo and PMU products must not endanger the health or safety of persons or the environment. To this end, the manufacturer or person responsible for placing the product on the market should perform a risk evaluation based on recent toxicological data and knowledge. This evaluation should be set out in a file which is readily available to the competent authorities.

3.2. Notwithstanding, and in addition to the requirements set out in paragraph 3.1, tattoo and PMU products must only be used if they comply with all the following requirements:

- they do not contain or release the aromatic amines listed in Table 1 of this appendix in concentrations that are technically avoidable according to good manufacturing procedures; the presence or release of these aromatic amines should be determined by using appropriate test methods which should be harmonised across the member states in order to ensure comparable health protection of the consumer and to avoid divergent enforcement, drawing on existing methods which can serve as models (see Tables 4.a-c);
- they do not contain the substances listed in Table 2 of this appendix;
- they do not contain substances listed in Directive 76/768/EEC (Annex II);
- they do not contain substances specified in Directive 76/768/EEC (Annex IV, columns 2 to 4);
- they do not contain carcinogenic, mutagenic and reprotoxic substances of categories 1, 2 or 3 which are classified under Directive 67/548/EEC;
- they comply with maximum allowed concentrations of impurities listed in Table 3 and the minimum requirements for further organic impurities for colorants used in foodstuffs and cosmetic products as set out in Directive 95/45/EEC;
- they are sterile and supplied in a container which maintains the sterility of the product until application, preferably in a packaging size appropriate for single use. In case multi-use containers are used, their design should ensure that the contents will not be contaminated during the period of use;
- preservatives should only be used to ensure the preservation of the product after opening and by no means as a correction of insufficient microbiologic purity in the course of manufacture and of inadequate hygiene in tattooing and PMU practice;
- preservatives should only be used after a safety assessment and in the lowest effective concentration.

3.3. Tattoo and PMU products should contain the following information on the packaging:

- the name and address of the manufacturer or the person responsible for placing the product on the market;
- the date of minimum durability;¹
- the conditions of use and warnings;
- the batch number or other reference used by the manufacturer for batch identification;
- the list of ingredients according to their International Union of Pure and Applied Chemistry (IUPAC) name, CAS number (Chemical Abstract Service of the American Chemical Society) or Colour Index (CI) number;
- the guarantee of sterility of the contents.

3.4. Tattooing and the application of PMU – including treatment and maintenance of the instruments, in particular their sterilisation and disinfection – must be carried out by the tattooist in conformity with the hygiene regulations laid down by national public health services.

¹ The date of minimum durability of a tattoo and PMU product should be the date until which this product, stored under appropriate conditions, continues to fulfil its initial function and, in particular, remains in conformity with the requirements that such products must not endanger the health or safety of people or the environment. The date of minimum durability should be indicated by the words: "To be used before the end of ...", followed by either the date itself (month and year) or details of where the date appears on the packaging. If necessary, this information should be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

4. Data for the safety assessment of substances which are used in tattoos and PMU

In order to ensure the use of only safe substances in tattoos and PMU, the competent authorities should evaluate specific safety data as set out below, with a view to excluding the use of harmful substances and to establishing gradually and publishing a list of substances shown to be safe in use. Priority should be given to the evaluation of colorants.

In doing so, the competent authorities may use amongst other sources the files which manufacturers are required to keep readily available to the authorities in accordance with paragraph 3.1 of this appendix and should exchange relevant data and conclusions.

Manufacturers should be encouraged to make data on the composition of the product and on the toxicology of the substances available to the competent authorities.

The competent authorities should continuously take steps towards establishing an exhaustive positive list of safe substances with a view to replacing negative lists of harmful substances. Pending the achievement of this goal, authorities should set up and publish non-exhaustive lists of substances shown to be safe in use.

Pigments forbidden in tattoos and PMU included in Table 2 of this appendix or Annex IV, columns 2 to 4 of Directive 76/768/EEC, but relevant for producers may be included in national positive lists if their safety is proven on the basis of additional data obtained under conditions of use in tattoos and PMU.

Safety data required for the assessment of substances used in tattoos and PMU

- Data on physico-chemical properties:

- purity;
- impurities (heavy metals, amines, etc.);
- auxiliary ingredients;
- stability (UV, laser, enzymes, bacteria);
- cleavage products (aromatic amines, etc.).

- Toxicological data:

- corrosion;
- irritation (skin, mucous membranes);
- phototoxicity;
- immunotoxicity (sensitisation, photo-sensitisation, etc.);
- genotoxicity *in vitro* including test of cleavage products; photo-genotoxicity.

- Additionally:

further relevant data or tests in agreement with competent authorities.

Toxicological data for safety assessment should be obtained from test methods using guidelines whenever they exist (for example, Organisation for Economic Co-operation and Development, European Union).

5. Public information

5.1. Governments should issue regulations constituting the legal basis for the information obligations incumbent upon the various players concerned. In this context, the tattooist should necessarily provide the consumer with complete, reliable and comprehensible information on the risks entailed by those practices,² including the potential occurrence of sensitisation, care following the application of a tattoo, reversibility and removal of tattoos, and the advice of consulting a physician in case of medical complications.

5.2. Potential consumers should be provided with reliable and evidence-based information about the risks of tattooing or PMU by all appropriate means, for example, through mass information campaigns or via the Internet.

² See Resolution ResAP(2003)2 on tattoos and permanent make-up, Note B.

Table 1 – List of aromatic amines, particularly with regard to their carcinogenic, mutagenic, reprotoxic and sensitising properties, which should neither be present in tattoos and PMU products nor released from azo-colorants

CAS ³ number	EC-number	Substances
293733-21-8		6-amino-2-ethoxynaphthaline
		4-amino-3-fluorophenol
60-09-3		4-aminoazobenzene
97-56-3	202-591-2	o-aminoazotoluene
90-04-4	201-963-1	o-anisidine
92-87-5	202-199-1	Benzidine
92-67-1	202-177-1	Biphenyl-4-ylamine
106-47-8	203-401-0	4-chloroaniline
95-69-2	202-411-6	4-chloro-o-toluidine
91-94-1	202-109-0	3,3'-d-dichlorobenzidine
119-90-4	204-355-4	3,3'-dimethoxybenzidine
119-93-7	204-358-0	3,3'-dimethylbenzidine
120-71-8	204-419-1	6-methoxy-m-toluidine
615-05-4	210-406-1	4-methoxy-m-phenylenediamine
101-14-4	202-918-9	4,4'-methylenebis(2-chloroaniline)
101-77-9	202-974-4	4,4'-methylenedianiline
838-88-0	212-658-8	4,4'-methylenedi-o-toluidine
95-80-7	202-453-1	4-methyl-m-phenylenediamine
91-59-8	202-080-4	2-naphtylamine
99-55-8	202-765-8	5-nitro-o-toluidine

Other substances classified as carcinogens in Categories 1, 2, and 3 by the European Commission and mentioned in the Council Directive 1967/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

101-80-4	202-977-0	4,4'-oxydianiline
106-50-3	2003-404-7	Para-phenylenediamine
139-65-1	205-370-9	4,4'-thiodianiline
95-53-4	202-429-0	o-toluidine
137-17-7	205-282-0	2,4,5-trimethylaniline
87-62-7		2,6-xylidine
95-68-1		2,4-xylidine

³ Chemical Abstract Service of the American Chemical Society.

Table 2 – Non-exhaustive list of substances, particularly with regard to their carcinogenic, mutagenic, reprotoxic and/or sensitising properties, which tattoo and PMU products should not contain (BC/CEN/97/29.11)

CI⁴ Name	CAS⁵ Number	CI Number
Acid Green 16	12768-78-4	44025
Acid Red 26	3761-53-3	16150
Acid Violet 17	4129-84-4	42650
Acid Violet 49	1694-09-3	42640
Acid Yellow 36	587-98-4	13065
Basic Blue 7	2390-60-5	42595
Basic Green 1	633-03-4	42040
Basic Red 1	989-38-8	45160
Basic Red 9	569-61-9	42500
Basic Violet 1	8004-87-3	42535
Basic Violet 10	81-88-9	45170
Basic Violet 3	548-62-9	42555
Disperse Blue 1	2475-45-8	64500
Disperse Blue 106	12223-01-7	
Disperse Blue 124	61951-51-7	
Disperse Blue 3	2475-46-9	61505
Disperse Blue 35	12222-75-2	
Disperse Orange 3	730-40-5	11005
Disperse Orange 37	12223-33-5	
Disperse Red 1	2872-52-8	11110
Disperse Red 17	3179-89-3	11210
Disperse Yellow 3	2832-40-8	11855
Disperse Yellow 9	6373-73-5	10375
Pigment Orange 5	3468-63-1	12075
Pigment Red 53	2092-56-0	15585
Pigment Violet 3	1325-82-2	42535:2
Pigment Violet 39	64070-98-0	42555:2
Solvent Blue 35	17354-14-2	61554
Solvent Orange 7	3118-97-6	12140
Solvent Red 24	85-83-6	26105
Solvent Red 49	509-34-2	45170:1

⁴ Colour Index.

⁵ Chemical Abstract Service of the American Chemical Society.

Solvent Violet 9	467-63-0	42555:1
Solvent Yellow 1	60-09-3	11000
Solvent Yellow 2	60-11-7	11020
Solvent Yellow 3	97-56-3	11160

Table 3 – Maximum allowed concentrations of impurities in products for tattoos and PMU

Element or compound	ppm	ppb
Arsenic (As)	2	
Barium (Ba)	50	
Cadmium (Cd)	0.2	
Cobalt (Co)	25	
Chromium (Cr) (VI) ⁶	0.2	
Copper (Cu) soluble ⁷	25	
Mercury (Hg)	0.2	
Nickel (Ni) ⁸	As low as technically achievable	
Lead (Pb)	2	
Selenium (Se)	2	
Antimony (Sb)	2	
Tin (Sn)	50	
Zinc (Zn)	50	
Polycyclic aromatic hydrocarbons (PAH)	0.5	
Benzene-a-pyrene (BaP)		5

⁶ The presence of traces of chromium (VI) in products for tattoos and PMU should be mentioned on the package together with a warning (for example, "Contains chromium. Can cause allergic reactions.").

⁷ Soluble copper should be determined after extraction to an aqueous solution with pH 5.5.

⁸ The presence of traces of nickel in products for tattoos and PMU should be mentioned on the package together with a warning (for example, "Contains nickel. Can cause allergic reactions.").

Tables 4.a-c – Methods which can serve as models for harmonising test methods

1. Summary of the method provided by the Dutch Food and Consumer Product Safety Authority

Table 4.a – Determination of aromatic amines in tattoos and permanent make-up using GC-MS (SIG01-ND428)

1. Principle	<p>This procedure describes a method⁹ for determination of aromatic amines in tattoo and permanent make-up. It is derived from method EN 14362-1 for textile products. The method is validated for aniline, o-toluidine, o-anisidine, p-chloraniline, 4-chloro-o-toluidine, 2,4-diaminotoluene, 2-naphtylamine, 2-amino-4-nitrotoluene and 3,3'-dichloro-benzidine.</p> <p>Azo-dyes are characterised by a structure containing an azo-unit (-N=N-) which splits off aromatic amines. In this method, azo-dyes are reduced to release primary aromatic amines using sodium dithionite. The aromatic amines are then extracted with t-butylmethylether and analysed with GC-MS.</p>
2. Operating procedures	
2.1. Preparation	Tattoo colorants and PMUs: homogenise the sample by shaking or mixing with a spatula.
2.2. Extraction	Weigh 500 mg sample in a tube. Add 5 ml dithionite solution (5%) in phosphate buffer. Mix with a vortex mixer for 20 seconds. Place the tubes in a water bath at 70°C for 90 minutes. After 30 minutes, mix the solution again with a vortex mixer. Cool the solution to room temperature. Add 5 ml internal standard solution. Mix the extract for 20 seconds with a vortex mixer. Centrifuge the tube at 2 500 g for 15 minutes. Filtrate the upper layer using a microfilter and put the extract in a vial.
2.3. Screening and quantification	Perform a screening with GC-MS by comparing the spectra of the peaks in the extract with a library. Positive samples are quantified in SIM-mode using calibration standards. For calculation an internal standard is used.
3. Validation	
Overview of validation data	See Analysis of aromatic amines in tattoos and permanent make-up by GC-MS in Table 4.b.

⁹ Report of the Dutch Food and Consumer Product Safety Authority.

Table 4.b – Analysis of aromatic amines in tattoos and PMU by GC-MS (Matrix: tattoo products)

Component	Aniline	o-anisidine	4-chloro-o-toluidine	2,4-diaminotoluene	2-naphtylamine	2-amino-nitrotoluene	3,3'-dichlorbenzidine	o-toluidine	p-chlor-aniline	Benzidine
C _{Detection limit} (mg/kg)	1.5	1.8	2.5	1.6	2.6	1.7	1.4	0.9	2.0	1.5
C _{Determination limit} (mg/kg)	3.0	3.6	5.0	3.2	5.2	3.4	2.8	1.8	4.0	3.0
Working range of the method (mg/kg)	0-250	0-250	0-250	0-250	0-250	0-250	0-250	0-250	0-250	50-750
Recovery (%)	97.5	96.4	108.5	65	114.2	101.1	100.8	102.0	111.1	91.6
RSD _r within working range (n=--)	5.2	5.8	9.1	3.5	5.6	5.6	4.6	3.1	7.5	9.4

2. Summary of the method provided by the Swiss Federal Office of Public Health included in the report on analysis of tattoo and PMU inks collected on the Swiss market in 2005

Table 4.c – Determination of aromatic amines in tattoos and PMU with LC/MS

1. Principle	The method is based on EN 71-7:2002. ¹⁰ The azo-compounds are reduced to release primary aromatic amines using sodium dithionite.
2. Operating procedures	
2.1. Sample preparation for aromatic amines as impurities	50 µl of tattoo ink are weighed into a HPLC vial. 1 ml of 0.07 M hydrochloric acid are added and the solution vortexed thoroughly for one minute. The sample solution is then sonicated for 15 minutes in an ultrasonic bath at room temperature and filtered through a 0.2 µm syringe filter into an HPLC glass vial. 5 µl of this solution are injected.
2.2. Sample preparation for aromatic amines after reductive cleavage	Reductive cleavage is performed according to EN 71-7:2002 ¹¹ with sodium dithionite. Instead of 1 g of sample, only 50 mg are used. Amounts of reagents are adapted proportionally. After reductive cleavage, samples are diluted with methanol and sonicated for 15 minutes. Afterwards extracts are filtered through a 0.2 µm syringe filter and 2 µl are injected without further clean-up.
2.3. HPLC analysis	For aromatic amines: HPLC/MS analysis is performed according to note. ¹¹
3. Additional information	Additional information is included in Hauri et al., 2005. ¹¹

¹⁰ EN 71-7:2002 Safety of toys – Part 7: Finger paints – requirements and test methods.

¹¹ Hauri U., Lütolf, B., Schlegel, U. and Hohl C., Determination of carcinogenic aromatic amines in dyes, cosmetics, finger paints and inks for pens and tattoos with LC/MS. Mitt. Lebensm. Hyg. 2005; 06:321-335.