

# COUNCIL OF EUROPE

## COMMITTEE OF MINISTERS

### **Resolution ResAP(2003)2 on tattoos and permanent make-up**

*(Adopted by the Committee of Ministers on 19 June 2003  
at the 844th meeting of the Ministers' Deputies)*

1. The Committee of Ministers, in its composition restricted to the representatives of Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, 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,

2. 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;

3. Having regard to Resolution (96) 35 revising the Partial Agreement in the Social and Public Health Field of 2 October 1996, 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:

– raising the level of health protection of consumers in its widest sense, including 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 field 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;

– integrating people with disabilities into the community: defining – and contributing to the implementation at 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 integration, whatever their nature, whether psychological, educational, family-related, cultural, social, professional, financial or architectural;

4. Having regard to the action carried out over several years for the purposes of harmonising their legislation in the public health field and, in particular, to specific issues in the cosmetics sector;

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

6. 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 the possibility of unhygienic practices and premises;

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

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

9. 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 ensuring hygienic management for tattooing and PMU practices;

10. 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,

11. 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 permanent make-up the principles set out thereafter in the Appendix to this resolution, each government remaining free to impose stricter regulations.

## **Appendix to Resolution ResAP(2003)2**

### **1. Field of application**

This resolution applies to:

- the risk evaluation required before products used for tattoos and PMU are placed on the market;
- the composition and labelling of products used for tattoos and PMU;
- 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 tattooing and PMU.

### **2. Definition**

Tattooing is a practice whereby a permanent skin marking or design (a “tattoo”) is administered by the intradermal injection of colouring products.

A PMU consists of colouring products 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<sup>1</sup>**

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 dossier readily available to the competent authorities.

3.2. Notwithstanding, and in addition to the requirements set out in 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 under the conditions of appropriate test methods;
- 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 category 1, 2 and 3 which are classified under Directive 67/548/EEC;
- they do not contain preservatives;
- they are sterile and supplied in a container which maintains the sterility of the product until application;
- they are supplied in a packaging size appropriate for single use on an individual consumer.

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 minimal date of durability<sup>2</sup>;
- the conditions of use and warnings;
- the batch number or 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.

#### **4. Public information**

4.1. 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<sup>3</sup>, including the potential occurrence of sensitisation.

4.2. 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, via the Internet.

#### **References**

Dr H.R.Reus and Dr R.D. van Buuren: Tattoo and Permanent Make-up Colorants. Report number ND COS 012 (November 2001)

#### **Note A**

This resolution is based on negative lists, drawn up on the basis of current knowledge in this field. Positive lists are likely to be drawn up in the future, thus entailing a revision of this instrument.

**Note B**

In addition to inorganic colorants, which have been traditionally used for tattoos, an extensive series of organic colorants are currently applied in tattoos and PMU. At least forty-one colorants have been identified in the member states. All the colorants in use would appear to be of industrial grade. A large proportion are azo-colorants give rise to aromatic amines. Many colorants are not permitted for use in cosmetic products. Manufacturers do not produce colorants specially formulated for tattooing and PMU. They do not appear to be aware of the possible use of their standard colorants for these purposes. A series of different colourant-related medical complications have been reported in the medical literature. Traditional inorganic colorants have been replaced in recent years by organic colorants. The long-term health effects of this marked change in the use of colorants remain unknown.

The results from a survey carried out in the Netherlands (see the above-mentioned reference) on the chemical composition and microbiological contamination of products used for tattoos and PMU give a glimpse of the health risks involved: sixty-three samples of products used for tattoos and PMU from the Dutch market and taken from opened and sealed containers were analysed for the presence of carcinogenic aromatic amines and for the presence of several heavy metals. In addition, the samples were also examined for the total bacteria count and the presence of pathogenic bacteria, yeasts and moulds.

Eleven samples (18%) were found to be microbiologically contaminated. Of these eleven samples, eight samples had been taken from opened containers and three from sealed containers. In seven samples, more than 100 000 bacteria/ml were found. Six samples (10%) contained the species *Pseudomonas*. The pathogen *Pseudomonas aeruginosa* was identified in three samples (5%). Intradermal injection of these contaminated products could result in serious infections. Azo-pigments, based on carcinogenic aromatic amines, were identified in ten samples (17%).

Several samples contained one or more heavy metals in comparatively high concentrations.

The removal of a tattoo or PMU by means of laser treatment may result in decomposition of azo-colorants into aromatic amines.

**Table 1 – List of aromatic amines, particularly with regard to their carcinogenic, mutagenic, reprotoxic and sensitising properties, which should not be present in or released from azo-colorants in tattoo and PMU products**

CAS <sup>4</sup> number	Catalogue number	EC-numb	Substances
92-67-1	612-072-00-6	202-177-1	Biphenyl-4-ylamine
92-87-5	612-042-00-2	202-199-1	Benzidine
95-69-2		202-411-6	4-chloro-o-toluidine
91-59-8	612-022-00-3	202-080-4	2-naphtylamine

97-56-3	611-006-00-3	202-591-2	o-aminoazotoluene
99-55-8		202-765-8	5-nitro-o-toluidine
106-47-8		203-401-0	4-chloroaniline
615-05-4		210-406-1	4-methoxy-m-phenylenec
101-77-9	612-051-00-1	202-974-4	4,4'-methyleendianiline
91-94-1	612-068-00-4	202-109-0	3,3'-dichlorobenzidine
119-90-4	612-036-00-X	204-355-4	3,3'-dimethoxybenzidine
119-93-7	612-041-00-7	204-358-0	3,3'-dimethylbenzidine
838-88-0	612-085-00-7	212-658-8	4,4'-methyleendi-o-toluidine
120-71-8		204-419-1	6-methoxy-m- toluidine
101-14-4	612-078-00-9	202-918-9	4,4'-methylenebis(2-chlor
101-80-4		202-977-0	4,4'-oxydianiline
139-65-1		205-370-9	4,4'-thiodianiline
95-53-4	612-091-00-X	202-429-0	o- toluidine
95-80-7	612-099-00-3	202-453-1	4-methyl-m-phenylenedia
137-17-7		205-282-0	2,4,5-trimethylaniline

90-04-4	612-035-00-4	201-963-1	o-anisidine
60-09-3	X	X	4-aminoazobenzene
	X	X	4-amino-3-fluorphenol
95-68-1	X	X	2,4-xylydine
87-62-7	X	X	2,6-xylydine
293733-21-8	X	X	6-amino-2-ethoxynaphtha

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

CI <sup>5</sup> Name	CAS <sup>6</sup> 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 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
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

Note <sup>1</sup> See Note A.

Note <sup>2</sup> The date of minimum durability of a tattooing and PMU product should be the date until which stored under appropriate conditions, continues to fulfil its initial function and, in particular, remains, in accordance with the requirements that such products must not endanger the health or safety of man or the environment. The date of minimum durability should be indicated by the words: "To be used before the end of...." Followed either: the date itself (month and year), or details of where the date appears on the packaging. If no information should be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

Note <sup>3</sup> See Note B.

Note <sup>4</sup> Chemical Abstract Service of the American Chemical Society.

Note <sup>5</sup> Colour Index.

Note <sup>6</sup> Chemical Abstract Service of the American Chemical Society.

Top ▲

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### Related Documents (Meetings, URL, multimedia, ...)



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844 meeting of the Ministers' Deputies / 19 June 2003

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CM(2003)39E / 21 May 2003

CM/Del/Dec(2003)844/6.1E / 24 June 2003

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