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Inks for tattoos and PMU (permanent make-up) / Organic pigments, preservatives and impurities such as primary aromatic amines and nitrosamines

Joint campaign by the Swiss Association of Cantonal Chemists (Verband der Kantonschemiker der Schweiz – VKCS) with financial support from the FOPH (Swiss Federal Office of Public Health), laboratory in charge : Basel City

Number of samples tested:		*Total samples objected to*	*Banned from use*
Total:	190	96 (51%)	63 (33%)
Tattooing inks:	167	88 (53%)	61 (37%)
PMU dyes:	23	8 (35%)	2 (9%)

Reasons for objection:*	*Total*	*Tattoo*	*PMU*
Banned due to declaration of prohibited substances	*21*	*21*	*-*
Banned due to analysis results	*59*	*57*	*2*
Objection due to high nitrosamine content	*17*	*15*	*2*
Objection due to undeclared ingredients	*98*	*90*	*8*
Objection due to declaration	*83*	*79*	*4*

** More than one reason for objection is possible per sample.*

Summary

- The national campaign to investigate the inks in tattoos and permanent make-up showed a pleasing and significant reduction in the number of objections, down by 25% compared with the 2009 campaign. The reason for this must surely be that many manufacturers and studios have taken action following the poor results. Unfortunately, this good news story is tarnished by the fact that objections were still raised concerning one in two samples, which is unacceptable from the point of view of consumer protection. While the situation regarding the use of azo dyes and the nitrosamine content as well as the use of banned preservatives has improved greatly in the last two years, banned colourants are still being used far too often in tattooing studios. As our investigations showed, unfortunately studios cannot always rely on the manufacturers. On the other hand, many studios pay too little attention to carrying out their own checks and use products which are obviously not legal, either because the declared ingredients are not permitted or because exact details about pigments or the preservatives that have been used are missing.
- Furthermore, differences or omissions in legislation do not make it easy for manufacturers to produce products that comply with regulations. A further complication is that the manufacturers are unable to find any suppliers of pigments of "tattooing quality", with the result that they use contaminated and poorly defined pigments which are often mixed with other unknown additives. Often the manufacturer is not really familiar with his product, and so cannot provide a complete declaration of the ingredients and may well run the risk of contaminants such as nitrosamines being formed. In some cases, however, the manufacturer makes a conscious decision not to declare the ingredients in order to protect his commercial secrets. At best, the ingredients are then listed under catch-all terms such as "Preservatives" or "Detergents". In the interests of consumer protection, this should be a clear indication to the studios to steer clear of these products.
- Many consumers are not aware that the ingredients of tattooing and PMU dyes are not subject to any kind of testing or licensing by national health authorities. Whereas cosmetics manufacturers have to restrict themselves when choosing colourants to a list of permitted, toxicologically assessed substances (a positive list), this is not the case for the producers of tattooing inks. The pigments that are used are not tested toxicologically for use in tattooing inks. Furthermore, some pigments can be broken down into toxic substances by exposure to UV light or if tattoos are removed by laser. These aspects are also not (yet) taken into account in legislation.
- In view of these unsatisfactory results, it is obvious that tattooing inks and PMU dyes must continue to be tested regularly over the coming years.

- **Initial situation**

Tattoos are fashionable and have been so for years. According to a survey [1] by the University of Leipzig, every fourth person between the ages of 15 and 35 in Germany in 2009 had at least one tattoo. There is no comparable data about the situation in Switzerland.
Permanent make-up is a special form of tattooing which is mainly used to highlight the eyebrows or lips, or to conceal scarring after operations. In view of how widespread tattooing is, it is surprising that the dyes used for it were not legally supervised until recently, and that to this day they are still not regulated in many countries in Europe.

In Switzerland, tattooing and the inks used for it and PMU were made subject to the Swiss Food Act (Lebensmittelgesetz – LMG) in 2006 and specifications were defined for the microbiological and chemical quality of the products that are used, and for how they should be declared. The Swiss requirements are based on a European Council Resolution [2] of 2003, which was modified in 2008 (European Council Resolution 2008) [3]. However, the European Union has no standardised regulatory system and national regulations vary greatly (e.g. Germany, Netherlands) or are non-existent (e.g. UK, Sweden).
The inadequate or inconsistent regulations have a negative effect on the standard of quality control regarding the dyes that are used, as was confirmed in 2009 by a Swiss market survey. Bans had to be imposed on the use of 54% of the dyes, most of which were collected from tattooing studios, and on 11% of PMU dyes. Only one in five products (21%) was legally compliant. On the basis of the results of this study, which were reported on in detail in the Bulletin [4, 5] produced by the FOPH, the general public were informed and the banned products were listed on the FOPH website. In this way the tattooing studios were able to find out which products they would no longer be allowed to use in future. Subsequently, guidelines for assessing tattooing inks were published by both the FOPH and the State Laboratory of the Canton Basel City (FOPH, KLBS).

Purposes of the investigation

The purpose of repeating the national campaign involving the FOPH and all the cantons was to find out whether the studios' self-regulation of tattooing and PMU dyes had improved and whether the proportion of non-compliant products had fallen noticeably.

Legal principles

The specifications for tattooing and PMU dyes are defined in the Swiss Human Contact Ordinance (Verordnung über Gegenstände für den Humankontakt – HKV). Most of the chemical specifications are based on the regulations for cosmetics (CMR substances, colourants, preservatives) or for consumer goods (aromatic amines).

Parameters	Assessment
Aromatic amines and banned azo dyes	HKV Art. 5, paragraph 3a
Colourants	HKV Art. 5, paragraph 3b and 3c
Fragrances	HKV Art. 5, paragraph 3d
CMR substances* (nitrosamines, phthalates, etc.)	HKV Art. 5, paragraph 3e
Preservatives	HKV Art. 5, paragraph 4
Requirements for the declaration	HKV Art. 8, 1a-f

**CMR substances: Substances which are categorised as carcinogenic (C), mutagenic (M) or toxic to reproduction (R)*

There is zero tolerance of substances with CMR properties and of banned dyes and preservatives. However, since very low concentrations of preservatives can be introduced into the products by the raw materials and some CMR substances are technically virtually impossible to avoid, traces of these substances at a safe level were not objected to, in the interests of commensurability.

Description of the samples

A total of 190 samples were collected from 72 tattooing and PMU studios and from 3 importers in all the Swiss cantons and in the Principality of Liechtenstein. The samples came from 34 tattooing ink manufacturers and 9 producers of PMU dyes.

Origin	No. of samples	Tattooing inks	PMU dyes
Germany	62	48	14
USA	58	56	2
Australia	17	17	0
Switzerland*	9	7	2
Italy	9	9	0
Japan	9	9	0
Brazil	9	9	0
England	6	6	0
Unknown	4	4	0
Austria	3	0	3
Holland	2	0	2
France	1	1	0
China	1	1	0
Total	**190**	**167**	**23**

** The Swiss tattooing inks that were investigated have not been available from retailers for a considerable time now.*

Colour	No. of samples
Red	31
Black	24
Green	24
Yellow	22
Violet/purple/lilac	19
Brown	19
Blue	19
Orange	14
Pink/rose/magenta	12
Grey	4
White	2
Total	**190**

Test procedures

Preservatives and other UV-active substances

In analysing the tattooing and PMU inks, three methods from the field of cosmetics were used to identify the preservatives.

Well over 50 UV-active preservatives were screened for, following extraction using acidic methanol, by using a UHPLC/DAD multi method. This method was also used to screen for dibutyl, benzylbutyl and diethylhexyl phthalates, UV-active fragrances and other ingredients (tensides, impurities, etc.).

The polar preservatives methylisothiazolinone, methylchloroisothiazolinone and benzisothiazolinone were identified and quantified using HPLC/DAD, after being extracted using aqueous and aqueous-methanoic formic acid.

Formaldehyde was also detected by HPLC/DAD following derivatisation with 2,4-dinitrophenylhydrazine. The same method was used to screen for glutardialdehyde and glyoxal. Glyoxal was measured using UHPLC/DAD after converting it with o-phenylenediamine to quinoxaline.

Organic pigments

The main method used for qualitative analysis of organic pigments was MALDI-TOF mass spectrometry. This allowed most of the pigments that were used to be analysed directly from the dyes themselves, without adding a matrix. Wherever possible, results were verified using the UHPLC/DAD multi method, with the pigments being extracted from the samples using N,N dimethylformamide or dichloromethane. Along with poor solubility, the biggest problem in the analysis lay in obtaining reference substances.

Carcinogenic aromatic amines as evidence of banned azo pigments

Evidence of banned azo dyes was obtained by using a standard method used on textiles. [6]. The reduced extracts were analysed directly with no purification using LC/MS/MS (as described in [7]).

Carcinogenic N nitrosamines

An LC/MS/MS method was used to analyse ten carcinogenic N nitrosamines. The substances were extracted from the samples using water, and in the case of quantifying nitrosodibutylamine using methanol/water. To quantify N-nitrosodiethanolamine, positive samples were analysed in a second LC/MS/MS process using column switching, in order to keep precursors away from

the actual separation column and achieve additional selectivity. N-nitrosomorpholine and N-nitrosodibutylamine were also measured using a further LC/MS/MS process.

Results and measures taken

Summary

Objections were raised in 96 (51%) of the 190 tattooing and PMU dyes that were investigated. Compared with the first national campaign in 2009, this is a slight improvement, especially with regard to tattooing inks (Table 1). Samples however were not examined microbiologically in 2011. Even though considerably more tattooing inks than PMU dyes were collected this year, the overall proportion giving grounds for complaint fell from 76 to 51%. The proportion of products banned from use fell from 41 to 33%. In general, the same improving trend could be observed in both tattooing inks and PMU dyes, although the small number of samples of PMU dyes meant that the survey was not representative.

Table 1 – Comparison between the numbers of objections in 2011 and in 2009

	Number of samples tested:		*Total samples objected to*		*Banned from use*	
	2011	*2009*	*2011*	2009	2011	2009
Total:	190	152	51%	76%	33%	41%
Tattooing inks:	167	105	53%	87%	37%	54%
PMU dyes:	23	47	35%	60%	9%	11%

When it comes to the reasons for imposing a ban on use, it is noticeable that the situation regarding the main ingredients, the pigments, has not improved (Table 2). On the other hand, thanks to multiple inspections of the manufacturers, hardly any products containing banned azo dyes were found this time. Far fewer banned preservatives were found, too, and there was also a clear improvement regarding nitrosamines. While many samples did still contain nitrosamines (12% compared with 15% in 2009), this year we observed no serious contamination of more than 150 µg/kg. The number of cases where the limits for permitted preservatives had been exceeded has increased slightly.

Table 2 – Comparison between the numbers of bans on use in 2011 and in 2009

Reason for the ban on use	**2011**	**2009**
Banned colourants	29%	23%
Banned preservatives***	8%	14%
Exceeding of limits for preservatives	3%	0.7%
Aromatic amines / azo dyes	0.5%	6%
N-nitrosamines**	0%	7%
Microbiology	*	3%

** No analysis carried out; ** Content > 150 µg/kg; *** Content > 50 mg/kg*

Pigments

Organic pigments

Even though Swiss legislation on colourants is in line with the European Council resolution from 2003 and the German Tattooing Inks Ordinance (Tätowiermittel-Verordnung), more than a quarter of the samples (50 samples, 56 reasons for objection; Table 3) had to be banned from use because they contained prohibited organic pigments. In one sample we found the explicitly banned colourants C.I. 45160 and C.I. 45170, while the other samples contained colourants which are not permitted for all purposes in cosmetics, and therefore are not permitted in tattooing and PMU dyes (C.I. 11680, C.I. 11710, C.I. 12370, C.I. 21108, C.I. 51319, C.I. 73900, C.I. 73915 and C.I. 74260).

Table 3 – Organic pigments – Reasons for objection

Reason for objection	No. of samples	Frequency
Missing declaration (of which failures to declare colourants)	23 [11]	12 [6%]
Declared *banned* colourants	28	15%
Detection of *banned*, undeclared colourants (analysis)	34	18%
Detection of *permitted*, undeclared colourants (analysis)	11	6%
Samples objected to in connection with the colourants	61	32%
Samples objected to because of undeclared *permitted* colourants	10	5%
Samples banned from use because of *prohibited* colourants	50	26%

While the white, grey and black colours presented no problem with regard to the pigments that were used, a third of the coloured products contained banned pigments. In over half of the cases, this was easy to detect by looking at the declaration: either the banned pigments were declared (22 samples, 28 pigments), or no colourants at all were declared (10 samples), meaning that the products were not fit for sale in any case. This clearly indicates that a considerable number of the studios were not carrying out their own controls properly.
The situation among the manufacturers also gives cause for concern. Not only did some old products, which have apparently been in use for years, contain banned pigments, this was even the case with some new products. In some cases, it is claimed on the Internet that the products meet European requirements, and this is confirmed by certificates of analysis for impurities. However, it would have only taken a careful look at the declaration to see that these products certainly do not comply with the European Council Resolution!
Our analysis revealed 34 banned pigments used in 30 samples. The fact that banned pigments are either not declared, or incorrectly declared, in so many cases suggests that some products were being deliberately labelled incorrectly in order to be able to offer consumers an apparently legal product.
For example, in three cases of green inks, the pigment C.I. 74265 was declared, but the samples contained the banned pigment C.I. 74260. Similarly, for one ink a yellow and a blue pigment were declared, but again C.I. 74260 was responsible for the colour. The declaration on a violet ink was obviously incorrect: according to the declaration, the ink contained the white pigment titanium dioxide and the blue pigment C.I. 74160 – together these would make light blue. However, the violet colour came from the banned pigment C.I. 51319. Incorrect declarations were also found on other purple inks. Two of them contained C.I. 51319 even though the pigments declared were red and blue. In another sample containing C.I. 51319, a mixture of a white and a red pigment containing manganese violet (C.I. 77742) was declared. Declaring a red and a black pigment was supposed to conceal the presence of C.I. 73915.
One German manufacturer whose product range otherwise contained legal pigments was unlucky. Our analysis of samples containing the pigment Red 282 tested positive for C.I. 73915, which, as mentioned above, is banned. According to the safety data sheets, the pigment Red 282 is not a single substance but a mixture of quinacridone pigments. The main ingredient in this mixture is in fact the banned pigment C.I. 73915, which is sold as an unblended substance called Pigment Red 122. This was not known to either the tattoo manufacturer or ourselves. The manufacturer was able to show us an older safety data sheet on which this information did not yet appear.

We regard the regulation of colourants using negative lists to be unsatisfactory, because the indirect consequence of this is that all colourants whose use is not regulated by the Cosmetics Ordinance, and which do not release carcinogenic aromatic amines following reductive splitting in accordance with EN 14362, are permitted for use in tattooing and PMU dyes. This means that colourants are permitted that have not been subjected to toxicology testing for either cosmetics or tattooing use, with the result that organic pigments are being used in 56% of the dyes (Table 4). This is a definite increase compared with 2009.

Table 4: Organic pigments in tattooing and PMU dyes: frequency of use and legal status

Proportion of samples containing colourants*:		Legal basis
Permitted	24%	Cosmetics Ordinance, Appendix 2, Column 1
Banned	32%	Cosmetics Ordinance, Appendix 2, Columns 2-4 (31%); Human Contact Ordinance, Appendix 2 (1%);
Unregulated	56%	Not listed in either the Cosmetics Ordinance or the Human Contact Ordinance

***** *Totals do not add up to 100% because some dyes may contain colourants in more than one category.*

Pigment	Colour	Frequency in samples	Legal status	Comments
C.I. 74160	Blue	18%	Permitted	
C.I. 74260	Green	8%	Banned	
C.I. 12475	Red	7%	Not regulated	
C.I. 11741	Yellow	7%	Not regulated	May release o-anisidine*
C.I. 11767	Yellow	7%	Not regulated	
C.I. 51319	Violet	7%	Banned	
C.I. 73915	Magenta	7%	Banned	5 colourants declared as Pigment Red 282
C.I. 561170	Orange	6%	Not regulated	
C.I. 56110	Red	5%	Not regulated	
C.I. 12477	Red	4%	Not regulated	
C.I. 21110	Orange	4%	Not regulated	May release 3,3'-dichlorobenzidine
C.I. 74265	Green	4%	Not regulated	
C.I. 11680	Yellow	3%	Banned	
C.I. 56300	Yellow	3%	Not regulated	
C.I. 12490	Red	3%	Permitted	
C.I. 11710	Yellow	2.1%	Banned	
C.I. 11740	Yellow	2.1%	Not regulated	May release o-anisidine*
C.I. 12370	Red	2.1%	Banned	May release o-toluidine
C.I. 12085	Red	1.6%	Permitted	
C.I. 13980	Yellow	1.6%	Not regulated	
C.I. 12510	Brown	1.1%	Not regulated	
C.I. 51345	Violet	1.1%	Not regulated	
C.I. 73907	Magenta	1.1%	Not regulated	
C.I. 12485	Red	0.5%	Not regulated	
C.I. 15580	Red	0.5%	Permitted	
C.I. 15850	Red	0.5%	Permitted	
C.I. 21095	Yellow	0.5%	Not regulated	May release 3,3'-dichlorobenzidine and o-toluidine*
C.I. 21108	Yellow	0.5%	Banned	May release 3,3'-dichlorobenzidine
C.I. 45160	Pink	0.5%	Banned	
C.I. 45170	Pink	0.5%	Banned	
C.I. 47005	Yellow	0.5%	Permitted	
C.I. 73360	Red	0.5%	Permitted	
C.I. 73900	Magenta	0.5%	Banned	

** aromatic amines not azo-linked*

The unregulated organic pigments include those which do contain carcinogenic aromatic amines as a structural element (C.I. 11740, 11741, 21095 and 21110) but which often prove negative when tested under the prescribed azo-dyes standard EN 14362, because they are not readily soluble. We see as problematic the fact that, both in new in vitro experiments to test photo-stability and also in previous, unpublished studies using laser radiation, carcinogenic amines were sometimes released. There is therefore good reason to fear that these pigments could release harmful substances either under the influence of light or if tattoos are removed by laser radiation.

Inorganic pigments

Except where they are used for shading, inorganic pigments have all but disappeared from coloured tattooing inks. Almost all black pigments, on the other hand, contain Carbon Black (C.I. 77266). White inks contain titanium dioxide (C.I. 77891).

Table 5 lists the inorganic pigments declared in 167 tattooing inks. The list only includes tattooing inks, because most PMU dyes come with a "may contain" list of colourants.

Table 5: Declared inorganic pigments in tattooing inks

Pigment	Frequency	Legal status	Comments
C.I. 77891	36%	Permitted	Titanium dioxide, used in a very large number of dyes for shading
C.I. 77266	19%	Permitted	Carbon Black, black pigment
C.I. 77491	4%	Permitted	Iron (III) oxide, red-brown shade
C.I. 77492	2%	Permitted	Iron (III) oxide hydrate, yellow-brown shade
C.I. 77499	1%	Permitted	Triiron tetraoxide, black shade
C.I. 77742	1%	Permitted	Manganese violet, Pigment Violet 16

Aromatic amines

In addition to the explicitly banned pigments, those azo dyes which can be broken down into carcinogenic aromatic amines by reductive splitting are also banned. In view of the lack of reference material and the very large number of possible substances, these substances are detected indirectly by identifying the listed amines which are formed by reductive splitting. Also banned are free carcinogenic aromatic amines, which may be present as impurities in the inks. Since this problem in tattooing has been known about for years, many manufacturers have their products tested for these substances and then provide certificates of analysis with the products. It is pleasing to note that this has now resulted in a situation where hardly any products can be found giving rise to objections in this regard. The only sample which had to be withdrawn from sale because of too high an aromatic amine content was a green dye containing approx. 130 mg/kg o-toluidine. o-toluidine was present in this dye as an impurity, and reductive splitting did not increase the level of o-toluidine any further.

Table 6: Detecting banned azo dyes - aromatic amines after reductive splitting

Aromatic amine after azo splitting	No. of samples containing > 2 mg/kg		Lowest value [mg/kg]	Highest value [mg/kg]	Average value [mg/kg]	Banned from use (total > 30 mg/kg)	
3,3'-dichlorobenzidine	1	1%			3	0	0%
o-toluidine	7	4%	2	134	27	1	0.5%
o-anisidine	7	4%	2	32	11	0	0%
2,4-diaminotoluene	1	1%			2	0	0%
2,4-dimethylaniline	1	1%			2	0	0%
Total no. banned from use (total > 30 mg/kg)						1	1%

The no. of complaints based on aromatic amines fell compared with the previous survey from 6 to 0.5%.

N-nitrosamines

N-nitrosamines are impurities formed by the reaction of secondary amines with nitrite. Many N-nitrosamines are carcinogenic substances which have been found in animal testing to be liable to cause cancer even in low concentrations.

In 16 (8%) of the samples tested, either N-nitrosodiethanolamine (NDELA), N-nitrosomorpholine or N-nitrosodibutylamine were found at levels of more than 10 µg/kg (Table 7).

Table 7: N-nitrosamines in tattooing inks and PMU dyes

N-nitrosamine	No. of samples		Lowest value [µg/KG]	Highest value [µg/KG]	Average value [µg/KG]
Nitrosodiethanolamine	16	8%	13	152	46
Nitrosomorpholine	4	2%	81	87	85
Nitrosodibutylamine	2	1%	53	93	73
Objection (> 15 µg/kg)	18	9%			
Banned from use (> 150 µg/kg)	0	0%			

The situation has improved markedly compared with the survey in 2009. Both the number of samples found to contain nitrosamines and the levels detected were significantly lower. Unlike in the previous survey, this year only objections were raised, with no bans on use being imposed, because the levels found were below 150 µg/kg. In 2009, we found a number of samples with over 1,000 µg/kg NDELA.

Preservatives

The investigations in 2009 showed that relatively few tattooing inks contained preservatives, even though this is legally permitted in Switzerland, provided that those preservatives which are permitted for all purposes in cosmetics are used. However, the implementation of the European Council Resolution of 2003 or the Dutch legislation did not allow any preservatives at all. On the other hand, the revised European Council Resolution of 2008 was no longer as restrictive regarding preservatives. Preservatives are permitted if they are only used to preserve the product after opening, the lowest possible effective concentration is used and a safety assessment has been carried out.

In some products, the high ethanol or isopropanol content, sometimes combined with other ingredients, will act as an adequate preservative. Other products are preserved using glass powder or γ-ray radiation. Experience suggests that tattooing inks are not a good culture medium for bacteria [5] and in 2009 only 3% of the samples had to be banned from use because the number of bacteria was too high.

Banned preservatives

Although preservatives were only found in a quarter of the samples that we studied, in 35 (18%) of the samples we found other banned technical preservatives such as phenol (5), octylisothiazolinone (1) or benzisothiazolinone (BIT; 27). These were either not declared at all or, at best, declared as "preservatives". 16 samples (8%) had to be banned from use because the level exceeded 50 mg/kg (FOPH directive). It is striking that, unlike in the last survey, only one sample contained octylisothiazolinone (last survey: 14). There is a simple explanation for this. Whereas in 2009, products from the manufacturer in question were among the most frequently used (22; 14%), this year only 2 samples were still to be found in tattooing studios (1%).

Exceeding the limits for permitted preservatives

Surprisingly, this year we also found two tattooing inks which exceeded the limit for phenoxyethanol (1.5 and 1.2%; limit 1%). An objection was raised regarding one sample which exceeded the limit for methyl- and methylchloro-isothiazolinone (MI/MCI: 20 mg/kg; limit: 15 mg/kg). We also found one sample which greatly exceeded the limit for glyoxal (0.02%; limit 0.01%). Whereas MI/MCI and phenoxyethanol are standard preservatives in cosmetics, glyoxal is more frequently used as a disinfectant in cleaning agents and medical products. One sample contained 0.23% formaldehyde, slightly more than the permitted level (0.2%).

Table 8: Preservatives in tattooing inks and PMU dyes

Preservatives	No. of samples		Lowest value	Highest value	Average value	Objection due to missing declaration*		Banned due to exceeding the limit**	
BIT	29	15%	2.6 mg/kg	178 mg/kg	49 mg/kg	11	6%	11	6%
Formaldehyde	22	12%	0.004%	0.23%	0.02%	17	9%	1	0.5%
Benzoic acid	5	3%	0.007%	0.04%	0.02%				
Glyoxal	5	3%	0.010%	0.02%	0.013%	4	2%	1	0.5%
Phenoxyethanol	4	2%	0.059%	1.49%	0.980%	1	0.5%	2	1%
Phenol	5	2%	0.004%	0.39%	0.290%	5	3%	4	2%
MCI	4	2%	1.3 mg/kg	14 mg/kg	5.6 mg/kg				
MI	4	2%	0.36 mg/kg	11 mg/kg	4.5 mg/kg				
Total MI/MCI	3	2%	2.5 mg/kg	20 mg/kg	9.9 mg/kg	2	1%	1	0.5%
2-n-octyl-4-isothiazoline-3-on	1	1%			83 mg/kg	1	0%	1	1%
Chlorhexidine	1	1%			0.018%	1	1%		
o-phenylphenol	1	1%			0.060%	1	1%		
4-chloro-3,5-dimethylphenol	1	1%			0.25%	1	1%		
Objections due to missing declaration, total						44	23%		
Banned from use, total								21	11%

* Traces of preservatives are tolerated. They had to be declared where the content was more than 10% of the limit value. For formaldehyde the limit is 0.005% (this is 10% of the limit value, upwards of which a warning notice is required).
** Objections were raised about banned preservatives upwards of 50 mg/kg.

Failure to declare preservatives
Preservatives are still rarely declared. As well as banned preservatives not being declared, in one of the four products that were preserved with phenoxyethanol, and two of the three products preserved with MI/MCI, these were not declared. For the first time in tattooing inks, we found chlorhexidine (0.02%), o-phenylphenol (0.06%) and 4-chloro-3,5-dimethylphenol (0.25%), each in one sample. These substances were not declared. Some samples contained glyoxal below the limit value of 0.01%.

Other impurities and additives
In general, and depending on the manufacturer, the inks contained far more ingredients than were declared. This was particularly striking with American manufacturers and related particularly to tensides and agents for improving the consistency of inks, such as glycols.

Formulating aids
Undeclared beta-naphthol-ethoxylate was found in two samples at a level of 3%-4%. However, beta-naphthol, which is released from beta-naphthol-ethoxylate in the body, is not permitted in cosmetics.
In five samples we found 0.7%-1.2% undeclared octylphenolethoxylate. This substance is better known under the trade name Triton X-100. In five samples, we found nonylphenol ethoxylate, ethoxylated to varying degrees, at levels between 1.2% and 3.9%.
Objections were made about all samples containing undeclared tensides.
We also found many undeclared glycols and glycol ethers. In particular, many samples contained diethylene glycol (DEG). This substance has been banned in cosmetics since 2010, although traces up to 0.1% are tolerated and a transitional period is in place until 2012. Six samples contained between 0.4% and 13% DEG, and only on the sample containing 13% DEG was this properly declared. The studio was informed that this substance must not be used.

Colourant educts
4-chloro-2,5-dimethoxyaniline is an impurity which occurs in colourants with the structural element 4-chloro-2,5-dimethoxyacetoacetanilide (e.g. C.I. 21108, C.I. 11767). Following animal testing, the compound was judged by the MAK Commission of the German Research Foundation to be possibly carcinogenic (Carc. Cat. 3). The manufacturers of five samples containing between 50 und 370 mg/kg of this substance were asked to provide an explanation. One yellow-orange PMU dye containing the undeclared pigment C.I. 11767 contained 120 mg/kg of the coupling component 4-chloro-2,5-dimethoxy acetoacetanilide. Another coupling component was found in two yellow tattooing inks (pigments C.I. 11740 and C.I. 11741). The

products contained 90 and 450 mg/kg o-acetoacetaniside respectively. One of the two dyes also contained 27 mg/kg of the degradation product 2-anisidine (Carc. Cat. 2; limit value 30 mg/kg).
Naphthol AS is a known contact allergen and a coupling component used in the manufacture of red azo pigments. One red tattooing ink contained 0.22% of this substance. Another red tattooing ink contained 80 mg/kg of the substance beta-naphthol, which is banned in cosmetics. The same sample also contained traces of chinolin (approx. 10 mg/kg; Carc. Cat. 2).

Defective declarations

42 samples (22%) were found to have defective declarations, for example:

- Missing contents list: 17 (9%)
- Catch-all terms used such as "Organic pigments", "Preservatives", "Emulsifiers", "Dispersing agents" or "Proprietary": 22 (12%)
- Missing use-by date or date after opening: 19 (10%)
- Missing batch number: 10 (5%)

The studios themselves should have been able to recognise that these defective declarations were not legally compliant, when carrying out their own checks. Consequently, objections were raised because of the defective declarations.

References

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[2] “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; Council of Europe, Strasbourg, 2003

[3] “Resolution ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up (superseding ResolutionResAP(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; Council of Europe, Strasbourg

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[7] Urs Hauri, Beat Lütolf, Urs Schlegel and Christopher Hohl: Determination of carcinogenic aromatic amines in dyes, cosmetics, finger paints and inks for pens and tattoos with LC/MS; Mitt. Lebensm. Hyg. 96, 321–335 (2005)