Gesundheitsdepartement des Kantons Basel-Stadt

Kantonales Laboratorium

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Inks for tattoos and permanent make-up

Preservatives, colourants, primary aromatic amines, poly-aromatic hydrocarbons and nitrosamines

Samples from the cantons of Aargau, Bern, St. Gallen, Thurgau and Basel-Stadt (lead laboratory) as well as samples for private analyses

Number of samples tested:	85 (of which taken for official purposes 63)
Number of non-compliant samples:	52 (64%)
Reasons for objection:	Banned pigments (23), Banned preservatives (28),Limit for preservatives exceeded (2), Nitrosamines (2), Aromatic amines (5), Aromatic amines after reductive splitting (2), Polyaromatic hydrocarbons (3), Fragrances (3), Undeclared preservatives (36), Undeclared pigments (29), Inadequate declaration of ingredients (13).

Background and purposes of testing

Swiss requirements in terms of tattooing inks are based, as were the requirements of other European countries until December 2020, on Council of Europe Resolution 2008[1] . The main difference between the Swiss legislation and the various legislations of other European countries was the regulations applicable to preservatives. In Switzerland, the only preservatives permitted are those which may also be used in leave-on cosmetics. Since December 2020, common regulations on tattooing inks have been applied in the EU as part of the REACH legislation on chemicals. The transition period will expire in July 2021[2] .
In the past, the lack of pan-European regulations, or the lack of consistency in this area, had a negative impact in terms of ensuring inks were legally compliant. This was established as early as 2009 in one of

1 COUNCIL OF EUROPE COMMITTEE OF MINISTERS: Resolution ResAP(2008) on requirements and criteria for the safety of tattoos and permanent make-up (superseding Resolution ResAP(2003) on tattoos and permanent make-up); https://wcd.coe.int/ViewDoc.jsp?Ref=ResAP(2008)1&Language=lanEnglish&Ver=original&Site=COE&BackColorInternet=DBDCF2&BackColorIntranet=FDC864&BackColorLogged=FDC864

2 ECHA: Submitted restriction proposals, Substances used in tattoo inks and permanent make-up; https://echa.europa.eu/de/registry-of-submitted-restriction-proposal-intentions/-/substance-rev/17806/term

the first major Swiss studies[3] . Further studies in 2011[4] and 2014[5] revealed little improvement.
In the years that followed, targeted samples were tested from newly opened studios, and a national customs campaign was launched to make tattoo studios more aware of the problems associated with non-compliant tattooing inks[6].
In December 2020, after years of work, common regulations on tattooing inks were introduced in the EU as part of the REACH legislation on chemicals. All tattooing inks in the EU must satisfy the new requirements by June 2021. This will present a major challenge to most manufacturers, and the tattooing ink market will probably look quite different afterwards.

Legal principles

The specifications for tattooing and PMU inks are defined in the Swiss Human Contact Ordinance (Verordnung über Gegenstände für den Humankontakt – HKV[7]). Many chemical specifications are based on the regulations for cosmetics (forbidden substances, colourants or preservatives) or for consumer goods (aromatic amines).

Parameter	Assessment
Aromatic amines and banned azo dyes	HKV Art. 5, paragraph 3a
Colourants	HKV Art. 5, paragraphs 3b, 3c and 3d
CMR substances* (nitrosamines, phthalates, etc.)	HKV Art. 5, paragraph 3e
Fragrances	HKV Art. 5, paragraph 3f
Preservatives	HKV Art. 5, paragraph 4
Polyaromatic hydrocarbons	HKV Art. 5, paragraph 3 bis
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 colourants and preservatives. However, since very low concentrations of colourants and preservatives can be introduced into tattooing inks from raw materials and some CMR substances are technically virtually impossible to avoid, we do not object to traces of these substances at a safe level, in the interests of reasonableness.

Description of the samples

The inspection of tattoo studios mainly involves the sampling of risky inks. By risky inks, we mean inks from manufacturers with many products listed on the Federal Food Safety and Veterinary Office (FSVO) negative list or with Rapex[8] or which are new to the Swiss market. These tend to be non-European brands. For a private European consumer protection organisation, we tested 20 samples from a country with similar legislation. We also tested another two cheap tattooing inks from China for a court case.

3 Federal Office of Public Health (FOPH) (2009) Unsatisfactory compliance of tattooing and permanent make-up dyes. FOPH Bull 29:535–541
4 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), focus laboratory: Basel-Stadt: Inks for tattoos and PMU (permanent make-up)/Organic pigments, preservatives and impurities such as aromatic amines and nitrosamines: http://www.kantonslabor.bs.ch/dms/kantonslabor/download/berichte/berichte-2011/JB_Tattoo_PMU_2011_4.pdf
5 Joint campaign by the Swiss Association of Cantonal Chemists (Verband der Kantonschemiker der Schweiz – VKCS), focus laboratory: Basel-Stadt: Inks for tattoos and permanent make-up/Pigments, preservatives, aromatic amines, polyaromatic hydrocarbons and nitrosamines; http://www.kantonslabor.bs.ch/dms/kantonslabor/download/berichte/berichte-2014/Tattoo_PMU_2014.pdf
6 Joint campaign by the Swiss Association of Cantonal Chemists (Verband der Kantonschemiker der Schweiz – VKCS) and the Directorate General of Customs, focus laboratory Basel-Stadt: Legal compliance of tattooing inks according to documentation/ Inspection campaign, 29.3.2017, https://www.kantonslabor.bs.ch/dam/jcr:1f67648f-3a5d-4592-9dfc-58c3d11bf686/Zollinspektionskampagne%20Tattoo%202015_2016.pdf
7 SR 817.023.41: Verordnung des EDI über Gegenstände für den Schleimhaut-,Haut- und Haarkontakt sowie über Kerzen,Streichhölzer, Feuerzeuge und Scherzartikel (Verordnung über Gegenstände für den Humankontakt)1 vom 23. November 2005 (Stand am 20. April 2021)
8 https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.listNotifications&lng=de

Test procedures

Parameter group	Method
Preservatives and other UV-active substances:	Three analysis methods were used for the analysis of samples: • Significantly more than 50 UV-active preservatives following extraction with methanolic phosphoric acid by means of an UHPLC/DAD multi-method. This method was also used to screen over 1,000 additional UV-active ingredients. • Polar preservatives such as methylisothiazolinone and methylchloroisothiazolinone following extraction with aqueous phosphoric acid by means of UHPLC/DAD. • Formaldehyde and acetaldehyde following derivatisation with 2,4-Dinitrophenylhydrazine by means of UHPLC/DAD.
Banned azo dyes or free aromatic amines	In Switzerland, the prescribed approach to identifying banned azo dyes is a standard (ISO 14362) method used on textiles. The reduced extracts as well as extracts for establishing free aromatic amines were analysed directly, without cleaning, by means of LC/MS/MS
Organic pigments	Various HPLC/DAD methods following extraction of samples with suitable solvents such as N,N-Dimethylformamide, Chloronaphthalene or N-Methylpyrrolidinone. As required: UV/VIS spectroscopy of samples dissolved in sulphuric acid or chloronaphthalene.
N-Nitrosamine	HPLC-HRMS(/MS) following extraction with water (95%)/methanol (5%)/formic acid (0.1%) for polar and methanol for non-polar nitrosamines
Polyaromatische Kohlenwasserstoffe (PAK)	HPLC coupled to fluorescence detection (FLD) following extraction with toluene at 110°C (microwaves)

Results and measures taken

52 (64%) of the 85 samples tested were not legally compliant. As with recent years, most of these samples were from the USA.
As regards the 63 official samples, objections were raised in 37 cases (59%). For 24 of these products, use or sale was forbidden (38%).

Table 1 – Objection rates and reasons

	No. of samples		Non-compliant		Banned ingredients, limit
Country of origin	Tattoo	PMU	Tattoo	PMU	
USA	61	2	44 (72%)	2 (100%)	46 (75%)
Germany	11	2	0	0	0
China	2	-	2 (100%)	-	2 (100%)
England	2	-	2 (100%)	-	2 (100%)
South Korea	-	2	-	2 (100%)	2 (100%)
Australia	1	-	0	-	0
Italy	1	-	0	-	0
Unknown	-	1	-	0	0
Total	**78**	**7**	**48 (61%)**	**4 (57%)**	

Reasons for objection

Pigments

Although pigments are subject to the same regulations in the legislation of all European countries, 19 samples (22%) contained one or more banned pigments in relevant quantities (C.I. 12370 (3), 21108 (3), C.I. 51319 (3), C.I. 73900 (3), C.I. 73915 (5), C.I 74260 (6). Only two of these 23 pigments were correctly declared. Of these 23 instances only two were correctly declared on the product label. In comparison, legal

pigments which were not declared were only found in six samples. This is a clear indication that manufacturers are knowingly using clandestine banned pigments. Ten of these products were taken during an official survey and for these, a sales ban was imposed. Table 2 contains an overview of the organic pigments identified and the declared inorganic pigments.

Table 2 - Frequency of the organic pigments identified in the 85 tattooing inks as well as the inorganic pigments declared on the packaging ('decl')

Pigment (C.I. number)	Frequency		Frequency without traces*		Legal status
	Number	[%]	Number	[%]	
77891 (decl)	43	50,6%	**43**	**50,6%**	
21095	28	32,9%	**28**	**32,9%**	
77266 (decl)	23	27,1%	**23**	**27,1%**	
74160	16	18,8%	**16**	**18,8%**	
12475**	16	18,8%	**15**	**17,6%**	
56110	13	15,3%	**11**	**12,9%**	
11741	10	11,8%	**8**	**9,4%**	
12477	10	11,8%	**9**	**10,6%**	
21110	8	9,4%	**7**	**8,2%**	
12315	7	8,2%	**4**	**4,7%**	Indirectly 'banned' through azo regulations
56300	7	8,2%	**7**	**8,2%**	
73915	6	7,1%	**5**	**5,9%**	Banned
74260	6	7,1%	**6**	**7,1%**	Banned
77491 (decl)	5	5,9%	**5**	**5,9%**	
21160	4	4,7%	**1**	**1,2%**	
73900	4	4,7%	**2**	**0,0%**	Banned
561170	4	4,7%	**3**	**3,5%**	
11740	3	3,5%	**3**	**3,5%**	
12370	3	3,5%	**3**	**3,5%**	Banned
21108	3	3,5%	**3**	**3,5%**	Banned
51319	3	3,5%	**3**	**3,5%**	Banned
51345	2	2,4%	**2**	**2,4%**	
77492 (decl)	2	2,4%	**2**	**2,4%**	
11767	1	1,2%	**1**	**1,2%**	
15850	1	1,2%	**1**	**1,2%**	
42555	1	1,2%	**0**	**0,0%**	Banned
71130	1	1,2%	**1**	**1,2%**	

* We regard as traces pigment concentrations which barely influence the colour of the samples.
** 12475: On its own or as a component of C.I. 12477

Primary aromatic amines (PAAs) – as an impurity and following reductive splitting

In addition to the explicitly banned pigments, those azo dyes which can be broken down into carcinogenic primary aromatic amines by reductive splitting are also banned. In view of the lack of reference material and the very large number of possible colourants, these substances are detected indirectly by identifying the amines listed in the ordinance which are formed by reductive splitting. Only samples which contained suspicious pigments were tested for PAAs following reductive azo splitting (ISO 14362). In two red inks, we found 281 and 391 mg/kg 2,4-Diaminotoluene and 169 and 212 mg/kg 5-Nitro-o-toluidine following reductive splitting (limit 30 mg/kg). The use or sale of the officially collected sample was prohibited. The positive findings were traced back, in each case, to the pigment C.I. 12315 (Pigment Red 22), which is re-

duced during splitting to 5-Nitro-o-toluidine and 2,4-Diaminotoluene. The results for the other inks were significantly below 30 mg/kg. This was in line with expectations as the pigments contained are barely soluble in the prescribed splitting agent.
Also banned are free PAAs, which may be present as impurities in the inks. The total limit in Switzerland is 30 mg/kg, the same as for textiles. Six samples contained more than the permissible 30 mg/kg of o-toluidine. The use or sale of the two officially collected samples was prohibited. With the new European regulations, the limit for aromatic amines has been reduced to 5 mg/kg. Currently, many of the products tested still are not conform to this limit (Table 3).

Table 3 - Free aromatic amines in 72 tattooing inks tested

	o-toluidine	o-anisidine	Aniline	3,3'Dichlor-benzidine	5-Nitro-o-toluidine
Anzahl > 0.5 mg/kg	27 (38%)	16 (22%)	6 (8%)	3 (4%)	6 (8%)
Anzahl > 5 mg/kg*	18 (25%)	3 (4%)	1 (1.4%)	-	3 (4%)
Anzahl > 30 mg/kg**	6 (8%)	-	-	-	-
Maximum	377 mg/kg	23,7 mg/kg	15,3 mg/kg	0,74 mg/kg	11,4 mg/kg
Median	14,1 mg/kg	1,4 mg/kg	1,5 mg/kg	0,66 mg/kg	1,8 mg/kg

* Future limit in the EU according to REACH
** Current limit in Switzerland

Polyaromatic hydrocarbons (PAHs)

PAHs are formed during the incomplete combustion of organic material. Eight PAHs are officially classified as class 1 carcinogens and therefore banned for use in tattooing inks. A limit of 0.005 mg/kg was set for the carcinogenic lead substance benzo[a]pyrene, while a limit of 0.5 mg/kg applies to total PAHs.
The pigment Carbon Black (C.I. 77266 or C.I. 77288) is responsible for the black dye in almost all black inks. It is used in various quality grades in a wide range of products (rubber, inks and dyes, cosmetics, pharmaceuticals).
Three out of 14 black samples (21%) contained significantly too high levels of PAHs. Containing between 22 and 52 mg/kg, they exceeded the total limit of 0.5 mg/kg by a multiple of 40 to 100. At 0.038 – 0.23 mg/kg, the same samples also contained too much benzo[a]pyrene and exceeded this limit by a multiple of 7 to 40.

Nitrosamines

N-Nitrosamines are impurities made up of secondary amines and nitrite. Many N-Nitrosamines are carcinogenic substances which have been found in animal testing to be liable to cause cancer even in low concentrations and must not therefore be contained in tattooing inks. Two samples contained 97 and 1760 µg/kg N-Nitrosodiethanolamine (NDELA). Objections were raised in respect of both samples. Use of the sample with 1760 µg/kg was prohibited.

Preservatives

Of the officially collected samples in Switzerland, 27 (44%) were subject to objections due to preservatives, with a ban on sale or use being announced in 15 (25%) cases. Bans were announced due to limits being exceeded for the permissible preservative benzyl alcohol (two samples; 1.3 and 1.5%) and due to high concentrations of banned preservatives: benzisothiazolinone (BIT) > 50 mg/kg (12 samples) and methylisothiazolinone > 1.5 mg/kg (one sample). Table 4 contains an overview of the preservatives identified in the samples.

Table 4 - Preservatives in 85 samples tested

Preservative*	Number	Number not decl.**	Min (mg/kg)	Max (mg/kg)	Median (mg/kg)
Benzisothiazolinone***	30 (35%)	23	1	374	58
Benzoic acid	28 (33%)		10	460	101
DMDM hydantoin	20 (24%)	4		Not quantified	
Benzyl alcohol	12 (14%)		3200	14900	4900
Phenoxyethanol	9 (11%)	3	560	3500	1650
Methylisothiazolinone***	8 (9%)	4	0.3	216	1.6
Phenol***	4 (5%)		0.6	21	15
Dehydroacetic acid	2 (2%)		540	870	700
Sorbic acid	2 (2%)		49	78	63
Chlorphenesin	1 (1%)		2200	2200	2200
Methylparaben	1 (1%)	1	1100	1100	1100
Propylparaben	1 (1%)	1	440	440	440

* Based on various methods, the tattooing inks were tested for around 100 technical and cosmetic preservatives.
** Traces of permissible preservatives were tolerated. They had to be declared where the content was more than 10% of the limit value.
*** Banned preservatives Low concentrations based on the typical scope of application were tolerated as traces.

The use of BIT in cosmetics was judged to be unsafe, and therefore not approved, due to its potential sensitising effect. Nine products showed higher content levels than 100 mg/kg and therefore more than was requested for use in cosmetics. In two products, we found very high quantities of methylisothiazolinone (39 and 216 mg/kg). Given its sensitising properties, the substance is only approved in rinse-off products up to a limit of 15 mg/kg.
With the introduction of the new REACH regulation in the EU, it is not yet clear which substances may be used as preservatives in future. Some of the substances previously permissible in Switzerland, e.g. benzoic acid and phenoxyethanol, can no longer be used as preservatives with them being classed as irritating to skin or eyes. In addition, the limit of 100 mg/kg means that previously tolerated quantities will give rise to objections. This means, for example, that all nine products containing phenoxyethanol are no longer fit for sale, even though only three products contain phenoxyethanol at concentrations which we classed as relevant. The situation with benzoic acid is even more extreme. The concentrations found in the 28 products containing benzoic acid were so low that they barely served as preservatives, and we therefore classed them as not relevant. In future, 15 of these products will no longer be fit for sale.
Formaldehyde is something of a special case too. This is not directly used as a preservative but is continuously released in relatively small quantities as a fragment (e.g. from the preservative DMDM hydantoin. Many samples may well also contain formaldehyde as a simple impurity as a result of synthesis, storage or packaging. At least 27 of the 43 products tested (> 60%!) failed to comply with the future EU limit of 0.5 mg/kg.

Declaration and other issues

Three products contained fragrances according to the declaration. This is not permissible in Switzerland. Seven products did not contain ingredients specified ('proprietary'). With six other products, ingredients were declared which clearly could not be correct, e.g. iso alcohol or isopropyl instead of isopropyl alcohol or C.I. 21905 instead of C.I. 21095.

Compliance with future REACH legislation

We assessed the 20 private samples tested, which were purchased in a European country around nine months before the ordinance came into force, in accordance with the new regulations. According to our estimates, all samples were not compliant with this legislation, while 30% of samples did at least satisfy current Swiss legislation. Besides the known reasons, the following findings were decisive:
Benzoic acid, isopropyl alcohol and phenoxyethanol > 100 mg/kg, o-toluidine (limit 5 instead of 30 mg/kg), phenol > 0.5 mg/kg, pigments C.I. 11741, 11767, 12315, 12477, 21095, 21110.
The samples were not tested for formaldehyde. Our experiences with the Swiss samples, as described above, show that this too would have been a common reason for objection according to REACH.

Conclusions

- For years now, we have been finding the same banned preservatives, pigments and impurities in the same brands. These are mainly inks from countries which do not have any legislation of their own, particularly from the USA. These same brands are often also listed with the European early warning system known as Rapex. This year's tests confirm the classification of the brands concerned as risky products. The introduction of European legislation and the intended introduction of legislation in the USA are expected to correct the market in the medium term.
- For the Swiss tattoo industry and in terms of enforcement, the question is whether and then how/when Switzerland will adapt its legislation to that of the European Union. As manufacturers of tattooing inks will not be producing big volumes for the Swiss market, products will be adapted to reflect European legislation. Only time will tell how quickly manufacturers are able to adapt their products to the new requirements. The challenges are nevertheless considerable, as highlighted by our tests of 20 samples. Testing of tattooing inks will therefore remain a high priority in the coming years.