Gesundheitsdepartement des Kantons Basel-Stadt
Kantonales Laboratorium

Dr. Urs Hauri

Kids' Cosmetics

Contaminants and ingredients such as preservatives and colourants

Joint campaign of the cantons Aargau and Basel-City (expert laboratory)

Number of analysed samples/sets:	23 (137 subsamples)
Number of non-conformities:	13 (57%), of which 9 were banned from sales
Non-conformities:	unauthorised colourants (48), unauthorised preservatives (2), other banned substances (22), undeclared preservatives (19), undeclared colourants (82), undeclared fragrance allergens (8), undeclared other substances (13), labelling (4).


Foto: Archivbild

Background and aims

For almost 20 years, the State Laboratory of Basel-Stadt has been testing attractively presented cosmetic products for children. These products are produced almost exclusively in the Far East. We first became aware of this product category in 2007 and 2008, when we detected high levels of phthalates in shower gels that were packaged in imaginative but unsuitable soft PVC containers. In the following years, the non-conformity rate for kids' cosmetics varied between 39% and 68% (2023), with many products containing unauthorised ingredients and impurities, resulting in sales bans for up to 50% of the samples.
Although the continuously high non-conformity rate does not suggest this, some companies have indeed achieved improvements in the quality of their products. The high non-conformity rates are, however, still concerning. But they do not reflect the market compliance in general; they are a result of our risk-based sampling. In particular, products from brands newly introduced to the Swiss market often show lower conformity. Since many responsible companies are based in the EU, members of the European network of official cosmetics control laboratories (Official Cosmetics Control Laboratories (OCCL)) were informed and encouraged to pay more attention to this product category. As part of this campaign, we also examined three kids' cosmetics kits consisting of 18 individual samples for the Slovenian authorities. One sample was found not to be compliant.
With this year's market monitoring, we have, for the first time, focused specifically on the Swiss online retail sector, as non-food products are increasingly purchased online.

Legal context

The requirements for cosmetic products are regulated in the Swiss Ordinance on Cosmetic Products (VKos; SR 817.23.31) and the Swiss Food and Utility Articles Ordinance (LGV; SR 817.02). Since Swiss cosmetics legislation has been largely harmonized with the EU, many legal requirements refer directly to appendices of the European Cosmetics Regulation (EC 1223/2009).

Parameter	Legal requirements	
Banned substances e.g. nitrosamines, formaldehyde, acetaldehyde, dimethylformamide, N-methylpyrrolidone, styrene, colourants)	LGV, Art. 54, Abs. 1	EU KosV, Anhang 2
Restricted substances e.g. fragrance allergens	LGV, Art. 54, Abs. 2	EU KosV, Anhang 3
Colourants	LGV, Art. 54, Abs. 3	EU KosV, Anhang 4
Preservatives	LGV, Art 54, Abs. 4	EU KosV, Anhang 5
Labelling	VKos, Art. 8 und 9	

Samples

Based on the results of the past years, almost exclusively decorative cosmetics (make-up) for children were sampled. Due to their presentation, these products are often given as presents. The products usually are kits comprising several different items such as nail varnishes, lipsticks, eye shadows and the like. Many products are also classified as toys and carry the respective required warnings. With a few exceptions, the products were made in China. Though this is typical for toys, cosmetics made in China are unusual on the Swiss market.
Four individual samples and 19 sets were collected from retail and importers, in the cantons of Aargau and Basel-Stadt, as well as in web shops with a Swiss top-level domain (.ch).

Origin	Number of Samples
Swiss web shops («.ch» Domain)	15
Retail	5
Importer	3
Total	**23**

Methods

Parameter class	Method	Analysed subsamples
Multimethod for UV/Vis-light absorbing substances: • preservatives • fragrances • UV-filters • contaminants	UHPLC-DAD after extraction with 0,1% phosphoric acid in methanol or methanol	80
Colourants	HPLC-DAD after extraction with DMF, chloronaphthalene or NMP	121
Multimethod for problematic substances (targeted screening, e.g. aromatic amines)	HPLC-HRMS after extraction with 0,1% phosphoric acid in methanol or methanol	45
Formaldehyde and other aldehydes and ketones	HPLC-DAD after pre-column in-line derivatisation with 2,4-dinitrophenylhydrazine	61
N-nitrosamines (polar)	HPLC-MS/MS after extraction with acidic water/methanol mixture	62
Alkanolamines	HILIC-LC-HRMS(/MS) after extraction with water/methanol mixture	7

Results and measures

Proportion of non-compliant products and sales bans

Of the 23 products sampled based on risk, 13 (57%) were found to have at least one non-compliance. A sales ban was issued for nine products (39%). For samples from web shops this means the samples could be recalled from the end consumers, as there is good traceability. The rate of non-compliance was comparable to the last market surveys.
Lip products and blushes were the only categories, for which more than half the analysed samples complied with the legal provisions.

Non-compliances by product category

Product-category	Number of sub-samples	Non-compliances	
Hair care products	1	1	100%
Temporary hair dyes	5	5	100%
Skin cleaning	5	4	80%
Eye shadows	41	26	63%
Nail varnishes	27	17	63%
Body and face paints/pens	21	11	52%
Perfumes	2	1	50%
Blushes	5	2	40%
Lip products	30	6	20%
Total	**137**	**73**	**53%**

Banned ingredients

Colourants:

Manufacturers can choose their colourants from a positive list with over 150 different colourants, although not all of them are approved for leave-on products (products that are not washed off immediately). Although only approved colourants may be used, there are also colourants which are explicitly prohibited, for example the rhodamine dye C.I. 45170 (rhodamine B) or the triarylmethane colourants C.I. 42535 (methyl violet) and C.I. 42555 (crystal violet). The colourants we report to be problematic are not impurities, but rather the colouring agents of the products and, as such, are present in significant quantities. On the other hand, the colourants declared on the packaging were often not detectable in the samples with problematic colourants. Overall, we detected 48 unauthorised colourants in 30 sub-samples, 23 in eye shadows, 13 in nail varnishes, nine in hair chalk, and one colourant each in a lipstick, a shower gel and a soap. The detected colourants are listed in the table colourants under „Incorrect declaration". By far the highest number of cases involved the magenta-coloured rhodamines C.I. 45160 (7), C.I. 45161 (2), C.I. 45170 (6) and C.I. 45174 (10).

Preservatives:

The isothiazolinones methyl- and methylchloroisothiazolinone are effective preservatives even at low concentrations. Unfortunately, they are also potent sensitising substances. Therefore, their approval for use in leave-on products was withdrawn several years ago. Nevertheless, we regularly find these preservatives in kids' cosmetics, in this year's case in a body perfume (total of 13 mg/kg) and a nail polish (13 mg/kg methylisothiazolinone). In both products, the substances were not labelled.

Impurities and other prohibited substances:

Prohibited substances must not be deliberately added to products. However, certain prohibited substances cannot be avoided as impurities in cosmetics. For such impurities, it must be ensured that their concentration does not endanger health and does not exceed technically unavoidable trace levels. However, the manufacturer must be able to explain why the substance could not be avoided in the product and which measures have been taken, to reduce the concentration of the substance as much as possible.

Nitrosamines and secondary alkanolamines:
Many N-nitrosamines are potent genotoxic substances even at low concentrations.
The by far most frequently detected nitrosamine in cosmetics is N-nitrosodiethanolamine (NDELA). It may enter cosmetics as a reaction product of the equally prohibited precursor substance diethanolamine (DEA), or it may be formed there. DEA cannot be avoided as an impurity of the ingredients triethanolamine (TEA) and cocamide DEA and is limited by a purity requirement for the two raw materials in Annex 3 of the Cosmetics Regulation.
NDELA:

- In two tattoo pen sets, we detected NDELA. In one set, three colours contained concentrations between 16 and 158 µg/kg. The three tested colour pens contained both TEA (not declared) and the prohibited impurity DEA, with a wide range of concentrations: 0.01 % TEA and 0.68 % DEA, 0.52 % TEA and 0.25 % DEA, and > 0.5 % TEA and 0.03 % DEA. If we assume that the raw material TEA was used in all the products, this suggests a possible degradation of TEA in the ink.
- In the other set, concentrations were below 10 µg/kg, which we accepted in line with current knowledge.
- A red hair chalk contained a high amount of NDELA at 2600 µg/kg. The other tested colours in the set were all free of NDELA.
- In one cosmetic set, both the shower gel (690 µg/kg) and the bath confetti (290 µg/kg) contained elevated NDELA concentrations:
- The source in the shower gel was the undeclared ingredient TEA (0.69 %) or its impurity DEA, which was present in an excessive concentration (0.12 %). Legally, 0.0035 % DEA (0.5 % in relation to TEA) would be permitted.
- In the case of the bath confetti, the cause was the equally undeclared surfactant cocamide DEA (approximately 1 %) or again its impurity DEA, which was present in the product at a very high concentration of 0.7 %.
- In a water-based nail polish, we found 0.07 % DEA and 0.12 % TEA (not declared). Here too, the raw material requirements were not met. However, the NDELA concentration was below the detection limit.

Nitrosamines in nail varnish:
While most cosmetics contain less than 10 µg/kg of nitrosamines, this is not the case for solvent-based nail polishes containing the film former nitrocellulose and the stabilizers stearalkonium hectorite or bentonite. The nitrosamine concentrations in these nail varnishes could and should be significantly reduced, as they are up to 1000 times higher than is typical for cosmetics. Most children's nail polishes are water-based and usually contain neither nitrocellulose nor stearalkonium and therefore also no nitrosamines. However, we found two sets with solvent-based nail polishes in this campaign. In both sets, individual nitrosamines were found in all six tested nail polishes in quantities that are technically avoidable, since 90% of the nail varnishes we examined showed lower concentrations. The following concentrations were found in the tested samples: total nitrosamines (one set; 6800–7500 µg/kg), NDELA (all varnishes; 230–690 µg/kg), N-nitrosodimethylamine (NDMA; up to 280 µg/kg), N-nitrosomethylbenzylamine (all varnishes; 320–440 µg/kg), N-nitrosomethyltetradecylamine (all varnishes; 160–220 µg/kg), N-nitrosomethyloctadecylamine (all varnishes of one set; 3560–3940 µg/kg), N-nitrosodibenzylamine (NDBzA; up to 160 µg/kg) and N-nitrosodiphenylamine (all varnishes of one set; 230–260 µg/kg).

Formaldehyde and acetaldehyde:
Formaldehyde and acetaldehyde are common carcinogenic substances that are undesirable in kids' cosmetics. Formaldehyde can also cause allergies. Acetaldehyde may be detected in cosmetics due to oxidation of ethanol or as a breakdown product of ethoxylated surfactants. We often found elevated concentrations of acetaldehyde in water-based nail polishes, which is why we are currently prepared to tolerate higher levels in these products. The manufacturers have not yet been able to explain the reasons for these high concentrations to us.
We detected acetaldehyde in 23 (38 %) of the 61 sub-samples tested, at concentrations exceeding 1 mg/kg. As in previous years, water-based nail polishes contained the highest concentrations (190–420 mg/kg). Three of these nail varnishes with concentrations above 320 mg/kg were deemed unsatisfactory, as 90% of comparable products in previous years had lower concentrations. We also considered 94–120 mg/kg of acetaldehyde in three solvent-based nail varnishes to be technically avoidable. Here too, it seems perfectly feasible to produce products with lower acetaldehyde concentrations.
Formaldehyde was found in 7 (11 %) of the products tested this year at concentrations between 8 and 33 mg/kg. We did not have to issue any complaints this year regarding excessive formaldehyde concentrations.

Non-compliant labelling

The correct declaration of ingredients is especially important for people with allergies. In addition, an incorrect declaration indicates shortcomings in production and/or quality control. Product safety assessments cannot be carried out correctly in such cases. The high rate of undeclared colourants or preservatives in cosmetics produced in China is not new. It should also be noted that some products are obviously incorrectly labelled: The colour of the declared pigments does not match the actual product colour.

Substances not declared:	Preservatives	Colourants	Fragrances	Other
Number of substances	19	82	8	13
Number of subsamples	18 (23%) *	49 (41%) *	6 (8%) *	13 (16%) *
Number of products/sets	5 (22%)	12 (52%)	2 (9%)	5 (22%)

* With respect to the number of analysed subsamples (preservatives 80, fragrances 80; colourants 121)

Preservatives:

In 22 % (or one in five) of the collected children's cosmetic products, the declaration of a preservative was missing 19 times:

Preservative	# of detects	Not declared	Concentration range (mg/kg) All samples	not labelled	Legal limit (mg/kg)
Benzoic acid	16	11 (69%)	11 – 1650	530 – 1650	5000
Chlorphenesin	1	1 (100%)	970	970	3000
Methylparaben	1	1 (100%)	770	770	4000
MI*	1	1 (100%)	13	13	Banned in leave-on
MI/MCI**	1	1 (100%)	13	13	Banned in leave-on
Phenoxyethanol	53	1 (2%)	170 – 7600	6400	10000
Propylparaben	4	3 (75%)	230 – 450	350 – 450	1400
Sorbic acid	2	-	3200 – 3600	-	6000

* MI: Methylisothiazolinone, ** MCI: Methylchloroisothiazolinone

Colourants:

More than half of the cosmetic products for children tested (52%) were non-compliant due to a total of 82 colourants, which were not declared on the product:

Colourant	# of detects	Not declared	Not permissible		Legal requirement
Total	**206**	**82**			
C.I. 11670	2	2	-	-	Not regulated in hair dye
C.I. 11710	1	-	-	-	Approved, except in contact with mucous membrane
C.I. 12075	1	1	1	Hair dye	Banned
C.I. 12085	1	1	-	-	Approved, except for hair dye
C.I. 12300	1	1	1	Lipstick	Unapproved
C.I. 12310	1	1	1	Nail varnish	Unapproved
C.I. 12360	1	1	1	Eye shadow	Unapproved
C.I. 12474	1	1	-	-	Not regulated in hair dye
C.I. 12475	1	1	-	-	Not regulated in hair dye
C.I. 12485	1	1	1	Nail varnish	Unapproved
C.I. 15850	25	6	-	-	Approved
C.I. 15865	2	2	-	-	Approved, except for hair dye
C.I. 15880	2	-	-	-	Approved, except for hair dye
C.I. 16035	14	1	-	-	Approved
C.I. 17200	10	-	-	-	Approved
C.I. 19140	9	-	-	-	Approved
C.I. 21090	5	5	5	Hair dye, Eye shadow (3), Nail varnish	Unapproved, banned in hair dye
C.I. 21095	2	2	2	Eye shadow, Nail varnish	Unapproved
C.I. 42000	1	1	1	Eye shadow	Unapproved
C.I. 42090	35	-	-	-	Approved
C.I. 42535	1	1	1	Hair dye	Banned
C.I. 42555	1	1	1	Hair dye	Banned
C.I. 42595	1	1	1	Eye shadow	Unapproved
C.I. 45160	7	7	7	Eye shadow (3), Nail varnish (3), Soap (1)	Unapproved
C.I. 45161	2	2	2	Eye shadow	Unapproved
C.I. 45170	6	6	6	Hair dye (1), eye shadow (5)	Banned
C.I. 45174	10	10	10	Eye shadow (6), nail varnish (3), shower gel (1)	Unapproved
C.I. 45410	33	6	-	-	Approved
C.I. 47005	9	5	-	-	Approved
C.I. 51319	3	3	3	Eye shadow (1), nail varnish (2)	Approved only for rinse-off
C.I. 55165	1	1	1	Nail varnish	Unapproved
C.I. 73360	1	-	-		Approved, except for hair dye
C.I. 74160	14	11	2	Hair dye	Approved, except for hair dye
C.I. 74260	1	1	1	Hair dye	Unapproved for products used near the eyes, banned in hair dye

Fragrances:

Although the samples were examined using a method that does not cover all allergenic fragrances, we found undeclared allergenic fragrance substances in two tested sets: benzyl alcohol (2; 23 and 314 mg/kg), benzyl benzoate (5; 139 - 472 mg/kg) and coumarin (1; 20 mg/kg)

Other ingredients that were not declared on the label:

Five samples contained the stabiliser BHT. The declaration of the substance was missing in one eye shadow (510 mg/kg) and one blush (185 mg/kg). In the three other samples, the substance was also not declared, but it is likely that it was subsumed as a perfume stabiliser under the terms „Fragrance" or „Perfume". In the six samples of a tattoo gel pen set, approximately 0.19 % benzotriazole was present without the substance being declared. The European database COSING lists the function of the substance as „antimicrobial". However, benzotriazole would not be approved as a preservative.

As already mentioned above, three tattoo pens and a nail varnish contained undeclared triethanolamine between 0.12 and 0.7%, and bath confetti contained more than 1% cocamide DEA.

Conclusions

- The consistently high rate of non-compliant products is partly a result of our risk-based sampling. While we have observed significant improvements from certain manufacturers over the years, products from brands being checked for the first time often contain above-average amounts of prohibited substances. The legal situation regarding kids' cosmetics is therefore clearly worse than for make-up intended for adults. Despite ten years of market surveillance with high non-compliance rates and numerous sales bans, far too many products are still on the market that fall significantly short of legal requirements. Some manufacturers have withdrawn from the market over the years. As long as there is a demand, however, new companies continue to fill the resulting market gap.
- Product information files and safety assessments can provide important insights into cosmetics. However, these documents are largely worthless, if there are such significant differences between the declared and the actual ingredients. Responsible business operators, in particular importers, are required to carry out analytical testing of such products as part of their self-monitoring obligations.
- There is still need for action for a large part of the industry. It is obvious that costs for production and quality assurance are being saved at the expense of children.
- Given the high non-compliance rate, further market controls are clearly needed.