Gesundheitsdepartement des Kantons Basel-Stadt

Kantonales Laboratorium

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Toy cosmetics

Preservatives, colourants, UV-filters, nitrosamines and other banned substances

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

Number of analysed samples/sets:	31 (169 subsamples)
Number of non-conformities:	21 (68%), of which 14 were banned from sales and for 3 more the sale was stopped voluntarily
Non-conformities:	unauthorised colourants (28 subsamples), unauthorised preservatives (14), other banned substances (34), undeclared preservatives (13), undeclared colourants (45), undeclared fragrance allergens (19), undeclared other substances (4).

Foto: Archivbild

Background and aims

For the last fifteen years, we have regularly analysed and enforced regulation on toy cosmetics. In these campaigns, we do not mean children's cosmetics as products for small children under the age of three or care products for children. Rather, we mean attractively packaged products marketed directly at children, sometimes designed with well-known characters from the world of films, and that may also be toys. These products are almost exclusively manufactured in the Far East. In 2007 and 2008, we criticised the packaging of many shower gels, which were imaginative but unsuitable soft PVC with excessive phthalate contents[1]. In the years 2011 to 2019, the non-compliance rates were between 39 and 65% (2019[2]).

1 Judith P. Amberg-Müller, Urs Hauri, Urs Schlegel, Christopher Hohl and Beat J. Brüschweiler: Migration of phthalates from soft PVC packaging into shower and bath gels and assessment of consumer risk; Journal für Verbraucherschutz und Lebensmittelsicherheit, Volume 5, Numbers 3 & 4, 429-442

2 Hauri, U. Kinderkosmetik 2019; Gemeinsame Kampagne der Kantone Aargau und Basel-Stadt (Schwerpunktslabor) und amtliche Untersuchungen für die nationalen Untersuchungsbehörden Sloweniens; https://www.kantonslabor.bs.ch/dam/jcr:2ed71d47-3cea-4e80-ad4e-ffd4980422be/Kinderkosmetik-2019.pdf

Many products contained unauthorized or banned ingredients and impurities, which led to bans on the sale of up to 50% of the samples.
Although the consistently high non-compliance rates do not indicate this, some companies have certainly achieved improvements in the quality of their products. The recurring very high rates are less a reflection of the market, but rather evidence of the success of our risk-based sampling. In particular, products from companies, which are new to the Swiss market, generally have poorer compliance. Because many relevant business operators are based in the EU, the members of the European network of official testing laboratories for cosmetics (Official Cosmetics Control Laboratories; OCCL) were informed and urged to pay increased attention to this product category[3,4]. While working on this campaign, we also tested colourants in ten bath bombs with 20 sub-samples for the Norwegian authorities. Five subsamples (25%) were found to be non-compliant.

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; SR817.02). 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 acetaldehyd, dimethylformamide, N-methylpyrrolidone, styrene, colourants)	LGV, art 54, p. 1	EC 1223/2009, Annex 2
Restricted substances e.g. fragrance allergens	LGV, art 54, p. 2	EC 1223/2009, Annex 3
Colourants	LGV, art 54, p. 3	EC 1223/2009, Annex 4
Preservatives	LGV, art 54, p. 4	EC 1223/2009, Annex 5
Labelling	VKos, art. 8 and 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. In many cases one product is a cosmetic set with many subsamples. 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 on the Swiss market, which are made in China, are unusual.
Six individual samples and 25 sets were collected in department stores, toy shops and mail order companies in the cantons of Aargau and Basel-Stadt as well as in internet shops with a Swiss top-level domain.

Origin	Number of samples	Of which were sets
China	26	24
Italy	2	1
Europe	2	
USA	1	
Total	**31**	**25**

3 EDQM (European Directorate for the quality of medicines & health care); Summary report Care products for children and kids' cosmetics - Market surveillance study conducted by Official Cosmetics Control Laboratories; https://www.kantonslabor.bs.ch/dam/jcr:947561d7-1117-426c-b361-efe61c8c1f2a/OCCL-Kinderkosmetik.pdf
4 EDQM (European Directorate for the quality of medicines & health care): OCCL study reports low compliance of "kids' cosmetics; https://www.edqm.eu/en/-/edqm-occl-study-reports-low-compliance-of-kids-cosmetics-

Methods

Parameter class	Method	Analysed subsamples
Multimethod for UV-active substances: • preservatives • UV-active fragrances • UV-filters • impurities	UHPLC-DAD after extraction with 0,1% phosphoric acid in methanol	UV-active-substances: 108 colourants: 123
Colourants and pigments	UHPLC-DAD after extraction with 0,1% phosphoric acid in methanol (U) HPLC-DAD after extraction with DMF, chloro-naphthalene or NMP	123
Multimethod for problematic substances (targeted screening, e.g. aromatic amines)	HPLC-HRMS after extraction with an acidic water/methanol mixture	76
Formaldehyde und other aldehydes and ketones	HPLC-DAD after pre-column in-line derivatisation with 2,4-dinitrophenyl-hydrazine	42
Isothiazolinones / polar preservatives	UHPLC-DAD after extraction with 0,1% phosphoric acid	76
N-nitrosamines (polar and apolar)	HPLC-MS/MS after extraction with acidic water/methanol mixture and methanol	76

Results and measures

Proportion of non compliant products and sales bans

Of the 31 products sampled based on risk and surveyed, 21 (68%) were found to have at least one non-compliance. A sales ban was issued for 14 products (45%). Based on our anayses, a further three products (10%) were voluntarily withdrawn from the market by the companies. The rate of non-compliance was comparable to the last market survey in 2019. As in recent years, nail polishes in particular were responsible for the high rate of non-compliance.

Non-compliances by product category

Product-type	Number of samples	Non-compliances	
Perfume	1	1	100%
Nail varnishes	49	40	82%
Cosmetics for lips	48	17	35%
Temporary hair dye	3	1	33%
Body and face paints/pens	33	8	24%
Eye shadow	29	2	7%
Other make-up products	3	0	0%
Skin cleaning	2	0	0%
Face mask	1	0	0%
Total	**169**	**69**	**41%**

Banned ingredients

Perservatives:

- Methylisothiazolinone and methylchloroisothiazolinone are effective as preservatives even at low concentrations, but unfortunately they are also potent sensitizing substances. That is why they have not been allowed in leave-on products (products that are not washed off immediately) for many years. Nevertheless, we regularly find these preservatives in toy cosmetics: this year in seven nail polish sets in concentrations between 1 and 40 mg/kg. The highest concentration is clearly above the previous limit of 15 mg/kg. None of the products contained the substances in the declaration of ingredients.

- A hair mascara contained the two unauthorized preservatives anisic acid (0.7%) and levulinic acid (0.56%). The concentrations detected were the highest we have ever determined in cosmetics. There were no approved preservatives in the product. The substances that are often used in natural cosmetics under the guise of perfume, masking or pH-regulating were deliberately added for preservation.

Colourants:

Manufacturers can choose their colourants from a positive list of over 150 different substances, however not all colourants are approved for leave-on products. Eventhough only approved colourants may be used, there are some substances that the law has explicitly banned, such as Rhodamine B (C.I. 45170) or the triarylmethane colourants methyl violet (C.I. 42535) and crystal violet (C.I. 42555).
The colourants, due to which we took measures against companies, were not impurities, but rather the actual colouring substances. On the other hand, the colourants declared on the packaging were not detectable in most samples.
A total of 22 nail polishes and two face paints, out of 12 samples, contained illegal colourants. The detected but not declared colourants can be found in the table below with the title "Not declared colourants".

Impurities and other prohibited substances:

- We detected the reproductively toxic solvent N-methylpyrrolidone in three sets of nail polishes. In three subsamples from two sets, the concentrations of 3.5 – 7.5% were so high that the substance must have been deliberately added as a solvent. Two further subsamples contained significantly smaller amounts of 222 and 379 mg/kg (0.02 and 0.04 %).
- We detected N,N-dimethylformamide, also a reproductively toxic solvent, in two eye shadows in relatively low concentrations of 13 and 14 mg/kg. The manufacturer's clarifications revealed that the solvent in the eyeshadows was from the packaging.
- Formaldehyde is an almost ubiquitous contaminant that may not be contained in cosmetics. We considered the amount of 130 mg/kg. which we detected in a solvent-based nail polish without an obvious source of formaldehyde (e.g. formaldehyde resin), to be technically avoidable.
- Four sets contained nail polishes containing the carcinogenic and mutagenic substance acetaldehyde in elevated concentrations of 240 - 380 mg/kg. These concentrations are technically avoidable.
- Nitrosamines: Many N-nitrosamines are genotoxic substances that act even in low concentrations. Two body tattoo pen sets contained a total of six pens containing 15 to 455 µg/kg N-nitrosodiethanolamine (NDELA).
- While nitrosamines are technically avoidable in most cosmetics and concentrations below 10 µg/kg can be expected, this does not apply to solvent-based nail polishes based on the film former nitrocellulose and the stabilizer stearalkonium. The levels of nitrosamines in these nail polishes should urgently be reduced, as they are up to 1000 times higher than in other cosmetics. Most nail polishes for children are water-based and usually contain neither nitrocellulose nor stearalkonium and therefore no nitrosamines. In this campaign, we also found two manufacturers with solvent-based nail polishes for children. Nitrosamines were present in both samples in quantities that are technically avoidable. In one set we detected the substances NDELA (370 µg/kg), nitrosodiethylamine (NDEA; 95 to 480 µg/kg), nitrosodibenzylamine (NDBzA; 100 to 150 µg/kg) and nitrosodiphenylamine (NDPhA; 350 – 1050 µg/kg). In the other set we found NDPhA (205 µg/kg) and NDEA (59 µg/kg).

Non-compliant labelling

The correct declaration of ingredients is important for all consumers, and particularly important for consumers with allergies. In addition, an incorrect declaration indicates deficiencies in production and/or quality assurance. It indicates that the safety assessment of the products is also incorrect.
The high rate of undeclared colourants or preservatives in cosmetics produced in China is not new. Products are often found, which are obviously not labelled correctly because the colour of the declared pigments does not match to the colour of the product.

Substances not declared:	Perservatives	Colourants	Fragrances
Number of detected undeclared substances	17	62	40
Number of subsamples with undeclared substances	13 (12%)*	45 (36%)*	19 (18%)*
Number of procucts/sets with undeclared substances	5 (16%)	14 (45%)	6 (19%)

* With respect to the number of analysed subsamples (preservatives 108, fragrances 108; colourants 123)

A total of 17 undeclared preservatives were detected in 16% of the toy cosmetic products in this campaign – or almost every sixth sample examined:

Not declared preservatives:

Preservative	# of detects	Concentration range	Limit
MI/MCI	10	1,1 – 40 mg/kg	Banned in Leave-on
MI	3	1,3 – 1,6 mg/kg	Banned in Leave-on
Bronopol	4	180 – 226 mg/kg	1000 mg/kg

Across almost half of the toy cosmetic products surveyed (45%), a total of 62 colourants were not declared. This affected a third of all the subsamples examined:

Not declared colourants:

Colourant	# of detects	Colourant	# of detects	Colourant	# of detects
C.I. 11741	1	C.I. 15865	1	C.I. 47005	4
C.I. 12310	2	C.I. 21095	4	C.I. 51319	2
C.I. 12315	1	C.I. 21108	1	C.I. 55165	2
C.I. 12317	2	C.I. 42535	1	C.I. 73900	2
C.I. 12335	3	C.I. 42555	1	C.I. 73915	2
C.I. 12360	2	C.I. 45160	1	C.I. 74160	8
C.I. 12370	1	C.I. 45161	3	Solvent Yellow 172	1
C.I. 12485	5	C.I. 45170	2		
C.I. 15850	5	C.I. 45174	5	**Total**	**62**

Although the samples were examined using a method that does not cover all allergenic fragrances, we found undeclared allergenic fragrances in six sets examined.

Not declared fragrance allergens:

Fragrance allergens	# of detects	Concentration range	Declaration limit
Amyl cinnamal	8	28 - 44 mg/kg	10 mg/kg
Benzyl alcohol	13	78 – 1110 mg/kg	10 mg/kg
Benzyl benzoate	4	58 – 175 mg/kg	10 mg/kg
Benzyl salicylate	7	27 – 33 mg/kg	10 mg/kg
Hexyl cinnamal	8	28 – 383 mg/kg	10 mg/kg

One sample was non-compliant due to the missing declaration of the stabilizer BHT (165 mg/kg). Three others based on the banned solvent N-methylpyrrolidone as mentioned above.

Conclusions

- The continued high rate of non-compliance in toy cosmetics is mainly due to our improved risk-based sampling. Nevertheless, we note that after more than 10 years of market controls, far too often decorative cosmetics for children do not meet the legal requirements. We have seen improvements from some manufacturers over the years. These manufacturers demonstrate the effectiveness of our controls and that it is possible to manufacture compliant products in China. However, we often find that products from brands we analyse for the first time often contain banned ingredients.
- Product information files and safety assessments can provide important insights into products. However, without analytical testing of the products, these documents are largely worthless. In particular, the colourants and preservatives used are not sufficiently checked.
- There is still a need for action in a large part of the industry.
- Due to the high rate of non-compliance, more controls will be carried out in the future.