



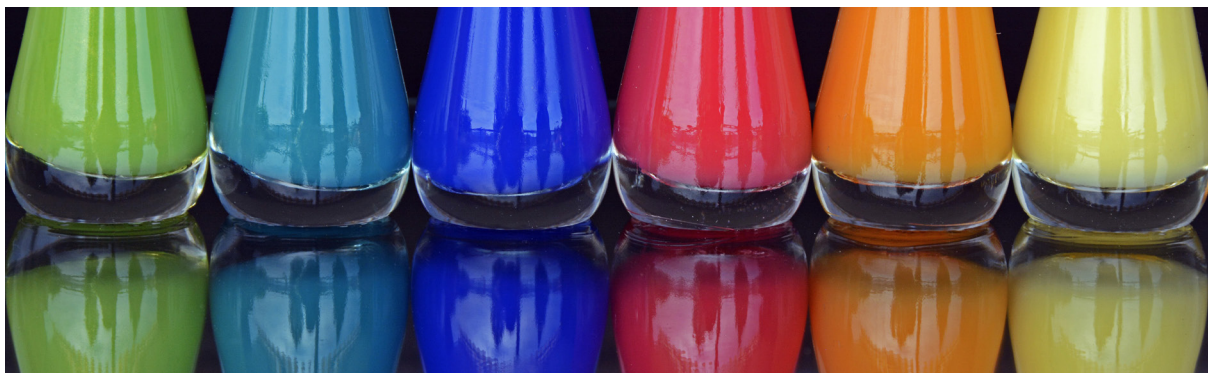
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Gel and UV light-cured nail varnishes

Colourants, monomers and oligomers, stabilisers, photo-initiators, plasticisers, preservatives and impurities

Joint campaign of the cantons of Aargau and Basel-Stadt (specialised laboratory)

Number of samples tested:	26 samples/32 individual samples
Number of samples objected to:	24 (92%)
Reasons for objection:	Unauthorised use of colourants (20), limit for stabilisers exceeded (7), limit for photoinitiators exceeded (4), N-nitrosamines (3), undeclared colourants (21), undeclared mono- and oligomers (7), undeclared stabilisers (16), undeclared photoinitiators (13), missing or insufficient warnings (15)



Background and purposes of testing

When nails are artfully decorated in nail studios, the polish should not flake off again after just a few days. Therefore, instead of the conventional nitrocellulose-based nail varnishes, longer-lasting varnishes are applied, usually acrylic-based varnishes, which can be cured under UV light or LED light depending on the type. Many of these varnishes are intended for professional use only. However, it is well-known that these products are also used privately at home.

In 2016, we tested acrylate-based nail varnishes in addition to conventional nail varnishes and objected to many products due to colourants, solvents, stabilisers and impurities (phenol). In contrast to the conventional nail varnishes, these nail products contained hardly any carcinogenic nitrosamines¹. A further investigation in 2020 confirmed the poor legal compliance of this product category: for 13 products (65%), either a sales ban was imposed or the responsible parties voluntarily took the products off the market after being presented with our findings. The main reason for the sales bans was the presence of unauthorised colourants. Objection had to be raised on account of a limit for a stabiliser also being exceeded and its unlawful use in products for personal use. Furthermore, one product contained an unauthorised preservative².

In the current campaign samples were tested from department stores, health/beauty/household stores, perfumeries, wholesalers, online trade and nail salons.

¹ Nail varnishes/dyes, preservatives, nitrosamines, formaldehyde, phenol, ethyl pyrrolidone, hydroquinones and phthalates; focus programme at the border SPP 2016_6; joint campaign of the Federal Food Safety and Veterinary Office, the customs authorities and the cantons of Aargau and Basel-Stadt (specialised laboratory) https://www.kantonlabor.bs.ch/dam/jcr:cb1159e9-b594-418a-ad43-154188a3fcbd/Nagellack-2017_en.pdf

² Gel and UV light-cured nail varnishes: Colourants and preservatives, stabilisers, nitrosamines, formaldehyde, phenol; joint campaign of the cantons of Aargau and Basel-Stadt (specialised laboratory) <https://www.kantonlabor.bs.ch/dam/jcr:f37e6116-8d3b-48fb-a7d8-f38a92864ee4/2020-Nagellacke.pdf>

Statutory bases

The requirements for cosmetic products are regulated in the Foodstuffs and Utility Articles Ordinance (FUAO) and in the FDHA Cosmetics Ordinance (CosmO).

Parameter	Assessment
Prohibited substances e.g. nitrosamines, formaldehyde, phenol)	FUAO, Art. 54, para. 1; EU Cosmetics Regulation, Annex 2
Substances authorised with restrictions (e.g. stabilisers, photoinitiators)	FUAO, Art. 54, para. 2; EU Cosmetics Regulation, Annex 3
Colourants	FUAO, Art. 54, para. 3; EU Cosmetics Regulation, Annex 4
Preservatives	FUAO, Art. 54, para. 4; EU Cosmetics Regulation, Annex 5
Labelling	CosmO, Art. 8 and 9

Description of the samples

The 26 products collected from 21 brands were all acrylate-based nail varnishes. With two exceptions, all the varnishes were intended exclusively for professional use. The products were collected from department stores, perfumeries or health/beauty/household stores (4), wholesalers (3), online shops (2) and nail salons (7) in the cantons of Aargau (11) and Basel-Stadt (15).

Origin	No. of samples/sets
USA	6
China	4
Germany	4
Poland	3
Estonia	2
Austria	2
Switzerland	2
Czech Republic	2
European Union	1
Total	26

Test procedures

Parameter group	Method
Multi-method for problematic substances (targeted screening, e.g. aromatic amines) Multi-methods for UV-active substances: <ul style="list-style-type: none"> • Preservatives • UV-active fragrances • UV filters • Stabilisers • Film former • Impurities (e.g. phenol) • Colourants 	HPLC-HRMS after extraction with acidic water/ methanol mixture UHPLC-DAD at pH 2.7 after extraction with 0.1% methanolic phosphoric acid and further solvents (UV filters; colourants) & UHPLC-DAD at pH 6.0 after extraction with methanol and further solvents (colourant)
Formaldehyde and other aldehydes and ketones	HPLC-DAD after in-line pre-column derivatisation with 2,4-dinitrophenylhydrazine
Isothiazolinones/polar preservatives	UHPLC-DAD after extraction with 0.1% phosphoric acid
N-nitrosamines	HPLC-MS/ MS after extraction with acidic water/ methanol mixture

Results and measures taken

Objections were raised in respect of 24 of the 26 products investigated (92%). A ban on sale or, in salons, a ban on use had to be imposed for 21 (81%) of the products because of banned ingredients being used or limits being exceeded. The reasons for the bans were unauthorised colourants, unauthorised use of monomers and oligomers in consumer products, and exceeding of limits for stabilisers and film formers. Furthermore, many ingredient declarations did not correspond to the substances found and some products were assessed as not fit for sale due to obviously incomplete ingredient declarations. One nail varnish was used in a salon even though, according to the label, it is not supposed to be a cosmetic product.

Colourants

In 21 of the 26 products, we found 46 colourants that were not declared on the packaging. In one case it turned out that the supplier had given us the wrong declaration. The remaining 20 nail varnishes (77%) contained 45 unauthorised pigments. With the exception of six samples, authorised pigments were declared instead of the unauthorised pigments found. Of the six exceptions, in one case the ingredient declaration was missing altogether. In the other cases, no colour pigments were declared or the colour pigments were only declared as a group ("pigments", "UV pigment", "natural mineral pigments" or "fluorescent pigment").

Non-declared colourants in the samples tested

Colourants	Colour	No. of individual samples
C.I. 12370*	Red	1
C.I. 12475**	Red	2
C.I. 12485**	Red	1
C.I. 21100*	Yellow	2
C.I. 21108*	Yellow	2
C.I. 21110**	Orange	1
C.I. 45100*	Magenta	1
C.I. 45160**	Magenta	2
C.I. 45161**	Magenta	5
C.I. 45174**	Magenta	6
C.I. 45220*	Magenta	1
C.I. 48013**	Violet	1
C.I. 60725	Violet	1
C.I. 56110**	Red	3
C.I. 73900*	Magenta	11
C.I. 73915*	Magenta	3
Solvent Yellow 172**	Yellow	3
Total		46 of which 45 are unauthorised

* Not permitted in leave-on cosmetics

** Not permitted in cosmetics

Acrylates

As monomers or oligomers, the substances HEMA and di-HEMA trimethylhexyl dicarbamate are frequently used in acrylate-based nail varnishes. The use of these sensitising substances is only authorised for professional products. The declaration of HEMA and di-HEMA trimethylhexyl dicarbamate, the two main ingredients, was missing for two products investigated from a health/beauty/household store. Consequently, these products also did not have the mandatory warning that the products are only permitted for professional use. Furthermore, two products for professional use contained undeclared di-HEMA trimethylhexyl dicarbamate and three other products for professional use contained undeclared HEMA. Conversely, according to their ingredient lists, six products should contain di-HEMA trimethylhexyl dicarbamate as the main ingredient, but the substance could not be detected in the products. The declaration of isobornyl acrylate and hydroxypropyl acrylate was missing on the respective product in which each substance was found.

Monomers and oligomers, stabilisers and photoinitiators in the samples tested

Analyte	No. of samples	Missing declaration	Limit (L)	Limit exceeded	Range
Benzophenone	1				1,2%
Benzoyl isopropanol	3	1			n.q.**
Benzoyl peroxide	2	1	0.7%		ca. 0,7%
BHT	12	5			0,01% - 0,4%
Bis-trimethylbenzoyl phenylphosphine oxide	2				0,47 - 0,84%
p-hydroxyanisole*	19 (26)	10 (16)	0.02%	7	0,005 - 0,085%
Di-HEMA trimethylhexyl dicarbamate*	5	4			5,8% - >30%
Ethyl trimethylbenzoyl phenylphosphinate	7	2			1,1 - 3,3%
HEMA*	13	3			8% - 28%
Hydroxycyclohexyl phenyl ketone	13 (15)	1 (3)			0,1 - 8,4%
Hydroxypropyl methacrylate	5	1			n.q.**
Isobornyl acrylate	3	1			n.q.**
Phenyldimethoxyacetophenone	2				
Trimethylbenzoyl diphenylphosphine oxide*	17 (23)	10 (16)	5%	4	0,5% - 7,8%

* Only to be used in products for professional use

** n.q.: not quantified

Stabilisers

To prevent premature polymerisation in the bottle, acrylate nail varnishes need to be stabilised. The first choice for this is p-hydroxyanisole. However, the use of this stabiliser is only permitted in professional products up to a limit of 0.02%. Ten products (38%) did not have the declaration of p-hydroxyanisole. In seven products, the limit was even exceeded, and in the worst case by up to four times the limit (0.085%). Butylated hydroxytoluene (BHT) is a common stabiliser in cosmetics and is also used to prevent premature polymerisation in nail varnishes. There are no restrictions on its use, but the declaration of this substance was missing on five of the twelve ingredient lists.

Photoinitiators

Photoinitiators are needed to start the polymerisation of the nail varnish by UV or LED light. The use of most photoinitiators is not restricted. They are sometimes present in products at very high concentrations (usually between 0.5 and 10%).

Trimethylbenzoyl diphenylphosphine oxide is classified as reprotoxic. Its use in nail varnishes is only permitted up to a concentration of 5%. 16 of the individual samples and all tested subsamples of the set contained this photoinitiator at concentrations of between 0.5 and 7.8%. Four of the products tested clearly exceeded the limit of 5%. Ten products (38%) did not have the necessary declaration.

Three samples in a set contained between 0.1 and 1% hydroxycyclohexyl phenyl ketone, which was not declared. However, the declared photoinitiator benzophenone could not be detected. In twelve other samples, the substance was correctly declared.

Ethyl trimethylbenzoyl phenylphosphinate was present in seven products at concentrations of between 1.1 and 3.3%. The declaration was missing in two cases.

For one product, the declaration of benzoyl isopropanol was missing, while another was missing the declaration of benzoyl peroxide.

Nitrosamines

In 2016 and 2020, we did not detect any relevant amounts of N-nitrosamines in acrylate-based nail varnishes (< 20 µg/kg), compared to conventional nitrocellulose-based nail varnishes. This year, on the other hand, we found N-nitrosamines in three of the products tested, the origin being not yet clear. One product from the Czech Republic contained a high amount (3'130 µg/kg) of N-nitrosodiethanolamine (NDELA). We

detected 113 µg/kg of N-nitrosodimethylamine in a nail varnish from the USA, and 46 µg/kg of N-nitrosodimethylamine and 21 µg/kg N-nitrosomorpholine in a nail varnish from Poland.

Phenol

Unlike in the last two market surveys, we did not find the banned substance phenol in any of the products tested.

Phthalates

To avoid nail polishes becoming brittle too quickly, plasticisers are added to the products. Dibutyl phthalate (DBP) used to be frequently used for this purpose. However, since the classification of DBP and other phthalates as reprotoxic substances, the use of these plasticisers has been banned. While EU products have long been phthalate-free, non-EU products containing DBP keep appearing on the market. As in the last two campaigns, fortunately no products with a CMR phthalate content of more than 100 mg/kg were detected this year.

Aromatic amines

No elevated levels (greater than 5 mg/kg) of free aromatic amines were detected.

Formaldehyde

Formaldehyde was formerly used as a nail hardener. Today, its use in cosmetics is banned. Since formaldehyde is a ubiquitous impurity, cosmetic products often contain detectable amounts of this substance in any case. This therefore raises the question as to what quantities should still be tolerated in nail varnishes, since they are considered technically unavoidable.

Formaldehyde in acrylate-based nail varnishes	
No. of identified instances	34
Values greater than 2 mg/kg (identification threshold)	25 (71%)
Maximum measurement value	0,019% (190 mg/kg)
90% percentile	0,014% (140 mg/kg)
Median	0,0014% (14 mg/kg)

None of the samples declared typical formaldehyde sources such as formaldehyde-releasing preservatives or formaldehyde-based resins. An examination of the measurement values shows that four nail varnishes contained significantly higher amounts of formaldehyde (> 0.01% = 100 mg/kg) than the rest of the samples, where the formaldehyde concentrations were all below 0.005% (50 mg/kg). The degree of difficulty in determining the origin of formaldehyde is shown in two products that, on paper, supposedly only differ in the pigments they contain. In one colour, there is a high formaldehyde content of 0.019%, whereas in the second sample the formaldehyde content was < 0.0005%. More measurement data are needed to assess the extent to which it is technically feasible to avoid formaldehyde in products.

Preservatives

Apart from small amounts of benzoic acid, we did not detect any preservatives in the products tested. In these concentrations, the benzoic acid no longer has a preservative effect but is an impurity from the synthesis/ degradation product of the initiator benzoyl peroxide.

Declaration and warnings

In addition to undeclared ingredients and missing obligatory warnings pertaining to the use of certain ingredients, the packaging had a number of other issues. Among them were also a few particular cases: as mentioned above, two products did not feature the warning "for professional use". This warning was present on a product sold in a department store, albeit hidden on the inside of a double sticker, which was additionally protected under a blister film and in amongst other text in a font size of < 1 mm. It is obvious that this crucial information is not available to the buyer before purchase of the product and does not meet the requirements for warnings at all. In addition, in the case of two other products sold in a perfumery, the warnings were hidden on the inside of a double label, and therefore the warning that the product was only intended for professional use was barely visible to a potential buyer.

A product containing benzoyl peroxide not only failed to include the warning "avoid contact with skin"; the instructions actually indicated that the products were easy to apply by dipping the fingers directly into the powder!

In one salon, a nail varnish from Germany was being used and the manufacturer had printed on the label that it must not be used for cosmetic purposes. The product was indistinguishable from a "normal" nail

varnish and otherwise fulfilled the declaration requirements (ingredient declaration, warnings, lot number, shelf life) of a cosmetic product. It is difficult to imagine any other use for it than for painting nails.

Conclusions

Unfortunately, we confirmed the results of the last campaign that acrylate-based nail varnishes, most of which cure under UV light, perform very poorly in terms of conformity to applicable regulations.

The expansion of our analyses to include monomers and oligomers as well as other stabilisers and photo-initiators revealed many other deficiencies in addition to unauthorised colourants. Besides breaches of limits and generally inadequate ingredient declaration, the detection of substances that are not permitted for use in products for the general public was particularly noticeable.

Many manufacturers have completely insufficient control over the raw materials used and/or are not sufficiently aware of the legislation. In some cases, it cannot be ruled out that unauthorised colourants are deliberately used or that unauthorised substances are used in nail varnishes for personal use.

Due to the high rate of objections, further tests are urgently needed.