Gesundheitsdepartement des Kantons Basel-Stadt

Kantonales Laboratorium

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Gel nail varnishes

Colourants, monomers, oligomers, stabilisers, photoinitiators, plasticisers, preservatives and contaminants

Joint campaign of the cantons of Aargau, Basel-Landschaft, Bern, Solothurn and Basel-Stadt (coordination and analyses)

Number of samples examined:	54 samples
Number of non-conforming Products:	50 (93%)
Reasons for non-conformities:	Unauthorized use of colourants (24), exceeding allowed limits of stabilisers (7), exceeding allowed limit of photoinitiators (4), N-nitrosamines (3), undeclared colourants (21), undeclared monomers and oligomers (7), undeclared stabilisers (16), undeclared photoinitiators (13), missing or insufficient warning labels (15)

Background and objectives

When people have their nails treated in nail salons, the results should last longer than a few days. That is why salons use longer-lasting varnishes instead of the classic home use nitrocellulose-based ones. Usually salons use methacrylate-based varnishes which are hardened under UV or visible light depending on the type. They are normally referred to as gel nail varnishes or UV nail varnishes. Many of these products are intended only for commercial use in salons because of the sensitising substances they contain. However, the products can often be purchased freely by the public, particularly from online shops, and are therefore increasingly used by consumers at home. Online shops rarely point out that the products are for commercial use. A lack of knowledge and skills when using them, as well as poor ventilation in private homes, increases the risk of allergic reactions or harm. Various articles in the press have reported on increased health problems when using these varnishes. In addition to dermatological problems, respiratory diseases, known as „dip flu", can also be triggered.

In recent years, we have repeatedly examined methacrylate-based nail varnishes and found many products to be non-compliant with legislation due to unauthorized colourants, solvents, stabilisers and impurities. In a 2022 campaign, 24 out of 26 samples were non-compliant (92%). For 21 (81%) of the products, a sales or application ban were imposed, due to prohibited ingredients or limit exceedances[1]. The current campaign examined samples from department stores, drugstores, perfumeries, supermarkets, online shops and nail salons in northwestern Switzerland.

1 Gel and UV light-cured nail varnishes / Colourants, monomers and oligomers, stabilisers, photoinitiators, plasticisers, preservatives and impurities. Zenodo. https://doi.org/10.5281/zenodo.11566779

Legal considerations

The requirements for cosmetic products are regulated in the Swiss Food and Utility Articles Ordinance (LGV) and the Swiss and EU Cosmetic Products Ordinance (VKos and EU VKos).

Parameters	Limits in
Banned substances e.g. Nitrosamines, formaldehyde, phenol)	LGV, art 54, par. 1 / EU KosV, Annex 2
Approved substances with limits (e.g. stablisers, photoinitiators)	LGV, art 54, par 2 / EU KosV, Annex 3
Colourants	LGV, art 54, par. 3 / EU KosV, Annex 4
Preservatives	LGV, art 54, par. 4 / EU KosV, Annex 5
Labelling	VKos, art. 8 and 9

Sample description

The 54 sampled products from 23 brands were all acrylate- or methacrylate-based nail varnishes, all of which were intended for professional use only. Half the products were collected from nail salons, the rest from manufacturers, online shops, department stores, perfumeries and wholesalers in the cantons of Aargau, Basel-Land, Bern, Basel-Stadt and Solothurn.

Samples taken from	Number of samples
Nail salons	28
Producers	12
Internet-shops with impressums (“legal notices”) in north western Switzerland	7
Department stores / Perfume shops	5
Supermarkets	2
Total	**54**

A total of 15 products were sampled from three manufacturers in Switzerland. The remaining products originated from various European countries, the USA and China.

Origin	Number of samples or sets
Switzerland	15
USA	11
Germany	7
Austria	5
United Kingdom	4
China	3
Czech Republic	2
The Netherlands	2
Europe	2
Italy	2
Hungary	1
Total	**54**

Measurement methods

Parameter group	Methods
Multimethodes for UV-active substances: • Preservatives • UV-active fragrants • UV-filters • Stabilisers • Film forming agents • Impurities (e.g. phenols) • Colourants	UHPLC-DAD at pH 2.7 after extraction with 0.1% phosphoric acid & UHPLC-DAD at pH 6.0 after extraction with methanol and dimethylformamide rsp. N-methylpyrrolidone (colourants)
Pigments (apolar)	HPLC-DAD after extraction with chloronaphthalene
Multimethod for problematic substances (e.g. aromatic amines)	HPLC-HRMS after extraction with methanol
Formaldehyde, acetaldehyde and other aldehydes and ketones	HPLC-DAD after in-line pre column derivatisation with 2,4-dinitrophenylhydrazine
N-nitrosamines	HPLC-HRMS(/MS) after extraction with an acidic mixture of water and methanol (polar) and methanol (apolar)

Results and measures

50 of the 54 products (93%) were found to be non-compliant. 31 (57%) of the products had to be banned from sales or from application in salons, due to prohibited ingredients or limit exceedances for stabilisers, photoinitiators and film forming agents or increased concentrations of carcinogenic substances such as nitrosamines, acetaldehyde and formaldehyde. Furthermore, the labelling of ingredients for many products did not match the substances found. Several products were deemed unmarketable due to the obviously incomplete listing of ingredients. Two nail varnishes from a German manufacturer were used in a nail salon, despite the fact that the label stated that they were not a cosmetic product.

Prohibited CMR substances and preservatives in the samples examined

Substance	Toxicity	# of detects	Result
Nitrosodimethylamine	carcinogenic	1	30 mg/kg
Nitrosodiethylamine	carcinogenic	2	3,5 & 35 mg/kg
Nitrosomorpholine	carcinogenic	1	5,8 mg/kg
N-Ethylpyrrolidone	reprotoxic	1	7900 mg/kg
N,N-Dimethylformamide	reprotoxic	1	8300 mg/kg
Acetaldehyde	carcinogenic	3	57 - 3400 mg/kg
Formaldehyde	carcinogenic, sensitising	4	205 – 278 mg/kg
Methylisothiazolinone	sensitising	1	37 mg/kg
Styrene	reprotoxic	1	32 mg/kg

Nitrosamines

In contrast to classic nitrocellulose-based nail varnishes, gel nail varnishes rarely contain relevant amounts of genotoxic N-nitrosamines (>10 µg/kg). However, this year we discovered very high amounts in two products: one from Switzerland contained 35 000 µg/kg nitrosodiethylamine (NDEA). In another product from the USA, we found 30 000 µg/kg nitrosodimethylamine as well as 3 500 µg/kg NDEA and 5 700 µg/kg nitrosomorpholine. Why the two products contained such high amounts of these nitrosamines has not yet been conclusively clarified.

Formaldeyde and acetaldehyde

In the past, formaldehyde was used to harden nails. Today, its use in cosmetics is prohibited. Both formaldehyde and acetaldehyde are ubiquitous contaminants, which is why many cosmetics contain detectable amounts of these substances. The question, therefore, arises, as to which amounts can still be tolerated in nail varnishes and which amounts may be considered technically unavoidable. For this purpose, the

90th percentile of measured values for comparable products is usually used. If samples show a higher concentration of these substances, it can be assumed that technically avoidable levels are present and the manufacturer must take measures to reduce the amounts in his products.

Aldehydes in Acrylate-based nail varnishes	Formaldehyde	Acetaldehyde
Number of analysed samples	53	53
Number of results > 2 mg/kg (limit of quantification)	21 (40%)	36 (78%)
Highest measured result	0,028% (280 mg/kg)	0,34% (3400 mg/kg)
90th percentile	0.015% (150 mg/kg)	0,0007% (7 mg/kg)
Median	< 0,0002% (< 2 mg/kg)	0,0002% (2 mg/kg)

Four nail varnishes contained 205 - 278 mg/kg formaldehyde, significantly more than 90% of comparable products. Only one of these products declared a possible formaldehyde source: „Polymer with formaldehyde and 1,3,5-Triazine-2,4,6-triamine".
Three other nail varnishes contained 54, 112 and 3 400 mg/kg acetaldehyde, significantly more than 90% of comparable products. The product with 112 mg/kg acetaldehyde contained ethanol, a possible cause of the increased concentration.

Preservatives

Our investigations show, in accordance with the declarations, that this product category does not need to be preserved with traditional preservatives. Nevertheless, one product contained 37 mg/kg of methylisothiazolinone. This sensitizing preservative is not permitted in leave-on cosmetics and even the limit for rinse-off products of 15 mg/kg would be massively exceeded. Two products also containeded 0.2% benzyl alcohol each. We assume that this is a contaminant or a degradation product of the benzyl methacrylate present in the products. In addition, we found small amounts of benzoic acid in all products containing benzoyl peroxide.

Other impurities and banned substances

In contrast to the last two market surveillance studies, we did not find more than 20 mg/kg of the banned substance phenol in any of the products examined. This was despite the fact that two products contained triphenyl phosphate, which is often contaminated with phenol or releases this substance.
To prevent nail polishes from becoming brittle, plasticisers are added to the products. In previous years, dibutyl phthalate (DBP) had often been used for this purpose. However, since DBP and other phthalates were classified as reproductive toxic substances, the use of these plasticisers has been banned. While European products have long been phthalate-free, non-European products containing DBP have repeatedly appeared on the market. As in the more recent campaigns, this year, fortunately, no products with phthalate contents of more than the permissible 100 mg/kg were detected.
One product containing the colourant C.I. 12370, which is not permitted for nail varnishes, contained traces (< 5 mg/kg) of the carcinogenic primary aromatic amine o-toluidine.

Colourants

In 24 of the 54 products examined, we found 58 colorants that were not declared on the lable. With one exception, their use in nail varnishes is not permitted. In one sample, the two colorants C.I. 73900 and C.I. 73915 were correctly declared on the lable, but are not allowed in nail varnish. On the ingredients list of another product from the same manufacturer, several prohibited colorants were listed, but the product actually contained different colourants altogether and these were not declared on the lable. In addition to the two products mentioned above, the responsible Swiss business operator did not realise that the declaration of colourants was obviously insufficient for twelve other products. There were eight cases where no colourants were declared, although the products were coloured. In three more cases, only general information was provided such as „Cosmetic colorants". And in two cases the declared white colourant could not explain the colour of the products.

Colourants in the samples examined

Colourant	Non-approved (not in Annex IV)	Non-permitted (in leave-on products)	Banned (Anhang II)	Not listed as ingredient
C.I. 12370 / pigment red 112		2		2
C.I. 12475 / pigment red 170	1			1
C.I. 15850 / pigment red 57				2
C.I. 21160 / pigment orange 16	1			1
C.I. 45160 / basic red 1	5			5
C.I. 45161 / basic red 1:1	8			8
C.I. 45170 / basic violet 10			7	7
C.I. 45174 / basic violet 11:1	13			13
C.I. 48013 / basic violet 16	2			2
C.I. 55165 / disperse yellow 232	1			1
C.I. 56110 / pigment red 254	6			6
C.I. 73900 / pigment violet 19		2		1
C.I. 73915 / pigment red 122		6		5
C.I. basic yellow 40	2			2
C.I. solvent yellow 172	4			4
not identified	1			1
Total	**44**	**10**	**7**	**61, of which 59 not permissible**

Acrylates

The substances HEMA (2-hydroxyethyl methacrylate; 30 samples) and Di-HEMA trimethylhexyl dicarbamate (20 samples) are still used most frequently as monomers and oligomers. The median concentrations were 16% and 6% respectively. The declaration of HEMA was missing in 11 samples (37%) and of Di-HEMA trimethylhexyl dicarbamate in 7 samples (35%). The use of these sensitizing substances is only permitted in products for professional application. The required warning for these substances was missing in three products. On the other hand, four products should contain Di-HEMA trimethylhexyl dicarbamate as their main ingredient according to the list of ingredients. However, the substance was not detectable in the products (< 0.1%). Many other products contained undeclared acrylates (see table "Monomers, oligomers stabilisers and photoinitiators in the samples"). Isopropylidene diphenyl bisoxyhydroxy propyl methacrylate was often not declared conspicuously (4 out of 5 products containing 11 – 29%). Isobornyl acrylate, the American Contact Dermatitis Society's „Allergen of the Year 2020", was not declared in two out of four products. We only detected traces of ethyl methacrylate in one dipping product (0.4%).

Monomers, oligomers stabilisers and photoinitiators in the samples

Analyt	# of samples	Not listed as ingredient	Limit	# of exceedances	Concentration range
1,6-Hexanediol Diacrylate	4	1			0,2% - 5,8%
Benzophenone*	1				1,2%
Benzoyl Isopropanol	7	2			0,13% - 14%
Benzoyl Peroxide	4	1	0,7%	1	0,7 – 1,4%
Benzyl alcohol	2	2			0,20% - 0,22%
Benzyl Methacrylate	1				22%
BHT	26	6			0,02% - 0,48%
Bis-Trimethylbenzoyl Phenylphosphine Oxide	6	1			0,14% - 2,3%
p-Hydroxyanisole**	33	18	0,02%	8	0,0014%-0,064%
Di-HEMA Trimethylhexyl Dicarbamate**	20	7			0,07%- 78%
Ethyl Methacrylate	2	2			0,36% - 0,37%
Ethyl Trimethylbenzoyl Phenylphosphinate	15				0,58% – 4,3%
HEMA**	30	11			0,11% - 29%
Hydrochinon**	1	1	0,02%	1	0,053%
Hydroxycyclohexyl Phenyl Ketone	27	1			0,01% - 12%
Hydroxypropyl Methacrylate	16	4			0,14% - 23%
Isobornyl Acrylate	4	2			13% - 24%
Isobornyl Methacrylate	3				4,9% - 7,9%
Isopropylidenediphenyl bisoxyhydroxypropyl methacrylate	5	4			11 – 29%
Methyl Benzoylformate	4				n.q.***
Phenyldimethoxyacetophenone	2				0,13 – 1,3%
Tetrahydrofurfuryl Methacrylate	4	1			12% - 14%
p-Toluolsulfonamid	1	1			0,15%
Triethylene glycol dimethacrylate	5				0,5% - 16%
Trimethylbenzoyl Diphenylphosphine Oxide**	27	14	5%	3	0,25% - 8,2%
Trimethylolpropane Triacrylate	2				n.q.***
Triphenyl Phosphate	2	2			0,44% - 0,96%

* Legal at time of sampling, banned since 1/8/2023
** Permissible only in products for professional use

Stabilisers

To prevent premature polymerization in the container, acrylate nail varnishes must be stabilised. The most common choice for this is p-hydroxyanisole. However, the use of this stabiliser is only permitted in products for professional application up to a limit of 0.02%. In 18 products (33%), or more than half of the products containing p-hydroxyanisole, the declaration of this substance was missing. In eight products, the limit was even exceeded, in the most extreme case up to three times (0.064%).
The same application restrictions apply to hydroquinone. This substance used to be more commonly used to stabilise. We found it only in one product this year. At 0.053%, the limit was significantly exceeded, and the substance was not even declared.
Butylated hydroxy toluene, or BHT for short, is also often used as a stabiliser in gel nail varinshes. All concentrations were within the legal limit of 0.8% but the substance was not listed as an ingredient in six out of 26 products containing BHT.

Photoinitiators and plasticisers

Photoinitiators start the polymerisation of the varnishes when they are exposed to UV radiation or „visible light". The use of most photoinitiators is not restricted. Typical concentrations in gel nail varnishes are between 0.5 and 10%.
Trimethylbenzoyl diphenylphosphine oxide is classified as toxic to reproduction. Its use in nail varnishes is only permitted up to a concentration of 5%. 27 varnishes contained this photoinitiator in concentrations between 0.25 and 8.2%. Three of the products examined clearly exceeded the limit of 5%. The substance was not listed on 14 products (38%) containing it. Interestingly, unregulated photoinitiators are declared on the lable much better: Ethyl trimethylbenzoyl phenylphosphinate was correctly declared in all 15 samples that contained the substance (concentrations ranging from 0.6% to 4.3%), and in the case of hydroxycyclohexyl phenyl ketone (0.01 - 12%), the declaration was missing in only one of 26 products.
We detected benzoyl peroxide in four acrylic powders, three of which contained approx. 0.7%, which corresponds to the limit. However, one product contained 3.5%, which is significantly too much. Two of these products were so-called „dipping" products. When using the product, the fingertips are dipped into the acrylic powder. This is obviously a contradiction to the mandatory warning „avoid skin contact".
One gel varnish contained 1.2% benzophenone. The substance was not banned at the time the sample was taken but is now.

Labelling and warnings

Due to the numerous deficiencies in the composition of the products, the legal conformity of the declaration was not conclusively investigated. In addition to the undeclared ingredients mentioned above, the following deficiencies were particularly noticeable (see also table "Reason for non-complaint labelling").
In the case of 16 coloured products without declared colorants, it would have been possible for the importer, reseller or nail artist to recognize that the products were not compliant without the need for any analyses.
According to the legal requirements, the ingredients must be listed according to the common name in the annex to Implementing Decision (EU) 2022/677. In a further twelve products, it was not clear from the ingredient lists which substances were contained in the products. This deficiency often affected the main ingredients, i.e. the acrylates. For example, the name urethane dimethacrylates was often listed, instead of the correct name Di-HEMA trimethylhexyl dicarbamate. The group name „urethane acrylates" was also often listed instead of the specific acrylates. Finally, the spelling was frequently incorrect.
Ingredients in nail varnishes up to a concentration of 1% must be listed on the label in descending order. The order was incorrect for at least eight products. In two products, the two main ingredients on the label, were not actually in the product in relevant quantities.
Warnings are required for some ingredients. These were either inadequate or missing entirely for ten products.

Reason for non-compliant labelling	# of samples
No colourant labelled in coloured samples	16
Incorrect list of ingredients	12
Lack of or erronious warnings	10
Wrong order of listed ingredients	8
Ingredient list with substances that are not permissible	3
Missing lot number	3
Main ingredient listed not in product	2
No ingredient list	2
Product with lable "not for cosmetic use"	2

Two German nail varnishes were used in a studio, on the label of which the manufacturer had indicated that the product may not be used for cosmetic purposes. The products were indistinguishable from „normal" nail varnishes in appearance and otherwise met the declaration requirements (list of ingredients, warnings, lot number, shelf life) of a cosmetic product. It is difficult to imagine any other use than colouring nails. Manufacturers may not circumvent the safety requirements for nail varnishes by adding "not for cosmetic use" to the label. The intended use of the product was abundantly clear.
Apparently, the motto of a Basel nail studio is „bring your own". Only products that customers bring with them are applied, in an attempt not to be held responsible for the use of non-compliant products.

Conclusions

Unfortunately, we rediscovered in this campaign that too many UV hardening (meth)acrylate-based nail varnishes do not meet the legal requirements for these products. The poor compliance of this product category is unacceptable: The detection of illegal colourants in almost half of the samples examined, as well as exceedances of limit values for stabilisers and photoinitiators and non-compliant labelling for most products, indicate absolutely inadequate quality assurance with regard to the raw materials used and/or insufficient knowledge of the legislation. Unfortunately, it cannot be ruled out that illegal colourants are sometimes used deliberately.

Practically all of the products examined are not consumer products, intended for use by anyone. Nevertheless, such products are increasingly being used in people's homes. Allergic reactions and complications are increasing. The products are easily available in stores and online shops without any checks as to the training of the purchaser. In online shops, customers often do not find any warning that the products are only intended for professional users/appliers. On products sold in shops, this warning, if included as required, is overlooked and in some cases hidden on the back of double labels. However, it is also conceivable that the warning is perceived as an advertisement, as it promises a particularly good product.

Due to the high rate of non-compliance, further checks will be carried out.