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Presence of 2-hydroxyethyl methacrylate (HEMA) and other (meth)acrylates in nail cosmetics, and compliance with EU legislation: An online market survey

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Abstract

Background: During the last 15–20 years, allergic contact dermatitis from acrylates-containing nail cosmetics (acrylic nails, gel nails, gel nail polish) has been increasingly reported. 2-Hydroxyethyl methacrylate (HEMA) is considered to be the major allergenic culprit; few data on its presence in nail cosmetics are available.

Objectives: To investigate (1) the frequency in which HEMA and di-HEMA trimethylhexyl dicarbamate are present in nail cosmetics; (2) whether nail cosmetics comply with EU regulations; (3) which other (meth)acrylates are present in nail cosmetics and how often.

Methods: One-line market survey.

Results: HEMA was present in nearly 60% of 394 cosmetic nail products and di-HEMA trimethylhexyl dicarbamate in 34%. Mandatory warnings on the packages of products containing HEMA were absent in 35% ('For professional use only') resp. 55% ('Can cause an allergic reaction'). Forty-five other (meth)acrylates were identified, of which the most frequent were hydroxypropyl methacrylate (25%), isobornyl methacrylate (16%) and trimethylolpropane triacrylate (12%). Some ingredient lists mentioned non-INCI names or non-specific names.

Conclusions: HEMA was by far the most common ingredient of nail cosmetics, being present in nearly 60% of the products. Violations of EU legislation occurred in >30% (mandatory warnings missing) resp. 10% (mislabelling) of nail cosmetics.

KEYWORDS

2-hydroxyethyl methacrylate (HEMA), acrylic nail, di-HEMA trimethylhexyl dicarbamate (di-HEMA TMHDC), EU legislation, gel nail, gel nail polish, hydroxypropyl methacrylate, ingredient labelling, ingredient list, isobornyl methacrylate, market survey, nail cosmetic, trimethylolpropane triacrylate

1 | INTRODUCTION

During the last 15–20 years, allergic contact dermatitis (ACD) from acrylates-containing nail cosmetics such as acrylic nails, gel nails and gel nail polish has been increasingly reported.[1] Many of these patients had positive patch tests to 2-hydroxyethyl methacrylate (INCI name HEMA), either tested in a baseline series or in a (meth)acrylate series. In most patients, the reactions to HEMA were considered to be relevant (indicating that HEMA had either caused the allergic contact dermatitis or contributed to it), although the presence of HEMA in the

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culprit nail cosmetics had not been ascertained, for example, from information on the material safety data sheet, ingredient label, from information obtained from the manufacturer or from chemical analyses.[1]

Few data are available on the qualitative and quantitative presence of HEMA and other acrylates in nail cosmetics.[2] In some case series of ACD from cosmetic nail products, ingredient labels had confirmed the presence of patch test-positive (meth)acrylates in the cosmetics responsible for the allergic reactions.[3–5] The largest study was performed in 2015 by the Netherlands Food and Consumers Product Safety Authority.[6] The ingredient labels of 91 gel nail polishes were screened for the presence of (meth)acrylates. HEMA was the most frequently identified, being present in 46 products (51%), followed by 2-hydroxypropyl methacrylate (HPMA) (44/91, 48%) and di-HEMA trimethylhexyl dicarbamate (43/91, 47%).[6]

At that time, HEMA and di-HEMA trimethylhexyl dicarbamate (di-HEMA TMHDC) were allowed in all cosmetic nail products for both professional nail stylists and for consumers (home use). However, in November 2020, in the European Union, the use of HEMA and di-HEMA TMHDC in nail cosmetics was restricted in the context of the EU Cosmetics Regulation (EC 1223/2009), permitting only professional use. The warnings 'for professional use only' and 'can cause an allergic reaction' must be stated on the package of nail products containing HEMA, di-HEMA TMHDC or both.[7]

Because of the current lack of data on the (meth)acrylates ingredients in nail cosmetics, we decided to perform an online market survey on this topic with the following aims:

1. Investigate the frequency in which HEMA and di-HEMA TMHDC are present in nail cosmetics.
2. Assess whether currently available nail cosmetics comply with the EU regulation as mentioned above
3. Investigate which other (meth)acrylates are present in nail cosmetics and how often.

2 | METHODS

Data on the presence of HEMA, di-HEMA TMHDC and other (meth) acrylates in nail cosmetics was collected from the website of bol.com, one of the largest web shops in The Netherlands, between 5 June 2023 and 10 July 2023. Products in the categories 'gel polish' and 'fake nails', present in the beauty, makeup and nails section were screened for ingredient listings and, when available, were included in the study. Within these categories all brands and their products were examined. Relevant product types included primers, base coats, base gels, poly base/bonders, top coats, sealer/topcoat gels, base and top 2-in-1 products, gel nail polish, builder/fibre gels, poly gel/acryl gels, and dip solutions (acrylic liquids). The following data was collected for each product: brand name, country of origin, product type, number of available colour types, presence or absence of the ingredient list on the brand's website, the full ingredients list, and precautions and warnings listed on bol.com, the brand's website or the package of the product.

For each brand and product, the producers' or importers' official website was searched and checked for the availability of ingredient listing. In cases of discrepancies between bol.com and the official websites, the ingredient information from the latter was used. For products containing HEMA and/or di-HEMA TMHDC, images of the packaging were searched on Google.

Data collection was scheduled to close when ingredient lists for approximately 400 nail cosmetics had been collected.

3 | RESULTS

3.1 | Frequency of HEMA and di-HEMA TMHDC in nail cosmetics

Data on the (meth)acrylates ingredients were collected for 394 nail products. Many of these cosmetics were available in multiple colours, resulting in 5233 commercially available nail cosmetics, which are covered by the 394 products for which results are presented here.

In 128 of the 394 (32%) products, the ingredients shown on www.bol.com could be verified by data available on the websites of the manufacturers'/importer's online stores. The 394 nail products included 59 brands, with numbers of products per brand ranging from 1 to 10. All but 3 brands (country unknown) originated from Europe (7 countries), China, or USA. The Netherlands headed the list with 20 brands (113 products), followed by Poland (12 brands, 146 products), China (11 brands, 57 products), and USA (8 brands, 44 products).

Of the 394 products, 259 were (components of) gel nail polish (primer, base coat, gel nail polish, top coat, base coat/top coat 2-in-1), 96 were components of gel nails (base gel, base gel/top gel 2-in-1, builder/fibre gel, sealer/topcoat gel), 14 were components of acrylic nails (acrylic liquid) and 25 poly gel nails (poly gel/acryl gel, poly base/bonder) (Table 1). HEMA was present in 229 of 394 (58%) cosmetics, di-HEMA TMHDC in 134 (34%), and one or both of these methacrylates were found in 264 of the 394 cosmetic products (67%). The frequency of HEMA in the 4 cosmetic categories ranged from 36% to 63%, with the highest percentages in gel nails (63%) and gel nail polish (59%). Di-HEMA TMHDC had lower scores with 0% in acrylic nails, 24% in poly gel nails (both low number of products), 30% in gel nail polish and 52% in gel nails. However, one or both methacrylates were present in 65% of 259 gel nail polishes and even 82% of 96 gel nails.

When looking at the 3 layers of the products (base layer, the body and the top layer), HEMA was present in 48%–73%, most frequently in the base layer (73%). Again, di-HEMA TMHDC had far lower scores with 32%–37%. One or both methacrylates were present in 71% of the top layer and 80% of the base layer (Table 2).

The data of the various countries shows, for the 4 largest contributors (Poland, Netherlands, China, USA) some differences. One or both methacrylates were present in 55%–80% of the products, the lowest for the Netherlands (55%) and the highest for Poland (80%) and USA (77%). The presence of HEMA ranged from 47% (Netherlands) to 70% (Poland). di-HEMA TMHDC was present in 37%–61% in 3 countries, but only 4% in Chinese cosmetics. In the other countries, di-HEMA TMHDC was also infrequently found (15%), with 4 of 6 countries scoring 0% in 26 products.

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3.2 | Complying with EU regulations: Warnings 'For professional use only' and 'Can cause an allergic reaction'

Of 264 products containing HEMA and/or di-HEMA TMHDC, 89 (34%) showed the mandatory warning 'For professional use only' and 78 (30%) the mandatory warning 'Can cause an allergic reaction' on the website www.bol.com, the producers'/importers' website, the product label, and/or the product package. For HEMA the corresponding numbers were 71/229 (31%) (professional) and 68/229 (30%) (allergic) and for di-HEMA TMHDC 58/134 (43%) (professional) and 46/134 (34%).

For products of which the ingredients could be verified on the website of the manufacturer or importer, the percentages

TABLE 1 Presence of HEMA, Di-HEMA TMHDC or both in 394 nail cosmetics.

Type of product	Number of products	Number of products containing HEMA	%	Number of products containing di-HEMA TMHDC	%	Number of products containing HEMA, di-HEMA TMHDC or both	%
Gel nail polish	**259**	**154**	**59%**	**78**	**30%**	**168**	**65%**
Primer	27	16	59%	0	0	16	59%
Base coat	51	38	75%	21	41%	40	78%
Gel nail polish	108	56	52%	32	30%	60	56%
Top coat	68	40	59%	22	32%	48	71%
Base coat/top coat 2-in-1	5	4	80%	3	60%	4	80%
Gel nails	**96**	**60**	**63%**	**50**	**52%**	**79**	**82%**
Base gel	31	26	84%	16	52%	30	97%
Base gel/top gel 2-in-1	3	2	67%	3	100%	3	100%
Builder gel/fibre gel	49	24	49%	24	49%	37	76%
Sealer/topcoat gel	13	8	62%	7	54%	9	69%
Acrylic nails	**14**	**5**	**36%**	**0**	**0%**	**5**	**36%**
Dip solution (acrylic liquid)	14	5	36%	0	0%	5	36%
Poly gel nails	**25**	**10**	**40%**	**6**	**24%**	**12**	**48%**
Poly gel/acryl gel	18	5	28%	4	22%	6	33%
Poly base/bonder	7	5	71%	2	29%	6	86%
Total	**394**	**229**	**58%**	**134**	**34%**	**264**	**67%**

TABLE 2 Presence of HEMA, Di-HEMA TMHDC or both in base layer, body and top layer of 394 nail cosmetics.

Type of product	Number of products	Number of products containing HEMA	%	Number of products containing di-HEMA TMHDC	%	Number of products containing HEMA, di-HEMA TMHDC or both	%
Base layer	119	87	73%	42	35%	95	80%
Body	189	90	48%	60	32%	108	57%
Top layer	86	52	60%	32	37%	61	71%
Total	**394**	**229**	**58%**	**134**	**34%**	**264**	**67%**

TABLE 3 Presence of warnings 'For professional use only' and 'Can cause an allergic reaction' on packages of products containing HEMA, di-HEMA TMHDC or both.

Methacrylates	Nr. products with methacrylates	Nr. products with warning professional use (%)	Nr. products with warning allergic reaction (%)
HEMA + di-HEMA	25	18 (72%)	16 (64%)
HEMA	20	13 (65%)	9 (45%)
di-HEMA	15	12 (80%)	11 (73%)

Abbreviation: di-HEMA, di-HEMA trimethylhexyl dicarbamate.

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TABLE 4 Acrylates and methacrylates found in the ingredient lists of 394 nail cosmetics.

Name of (meth)acrylate	CAS number	Frequency ($n = 394$)	%
HEMA	868-77-9	229	58.1%
di-HEMA trimethylhexyl dicarbamate	72869-86-4	134	34.0%
Hydroxypropyl methacrylate	27813-02-1	100	25.4%
Isobornyl methacrylate	7534-94-3	61	15.5%
Trimethylolpropane triacrylate	15625-89-5	47	11.9%
PEG-9 dimethacrylate	25852-47-5 (generic)	29	7.4%
Ethyl methacrylate	97-63-2	28	7.1%
Glycol HEMA-methacrylate	97-90-5	26	6.6%
Trimethylolpropane trimethacrylate	3290-92-4	24	6.1%
Urethane acrylate[a]		20	5.1%
Tetrahydrofurfuryl methacrylate	2455-24-5	17	4.3%
Isopropylidenediphenyl bisoxyhydroxypropyl methacrylate	1565-94-2	14	3.6%
Acrylic acid	79-10-7	13	3.3%
Special tertiary amine acrylate[a]		13	3.3%
Dipentaerythrityl hexaacrylate	29570-58-9	11	2.8%
PEG-4 dimethacrylate (in 5 cases the name on the cosmetic was tetraethylene glycol dimethacrylate)	109-17-1	10	2.5%
PPG-3 glyceryl ether triacrylate (in 2 cases termed glyceryl propoxy triacrylate)	52408-84-1	8	2.0%
Triethylene glycol dimethacrylate	109-16-0	7	1.8%
Dipropylene glycol diacrylate	57472-68-1	6	1.5%
Isobornyl acrylate	5888-33-5	6	1.5%
Methacrylic acid	79-41-4	6	1.5%
Butyl methacrylate	97-88-1	5	1.3%
Glyceryl dimethacrylate	1830-78-0	5	1.3%
PPG-5 methacrylate	39420-45-6 (generic)	5	1.3%
Tripropylene glycol diacrylate	42978-66-5	5	1.3%
Aliphatic urethane acrylate[a]	68 987-79-1	4	1.0%
Aliphatic urethane methacrylate[a]	82339-26-2	3	0.8%
Ditrimethylolpropane tetraacrylate	94108-97-1	3	0.8%
Acrylic monomer[a]		2	0.5%
Bisphenol A dimethacrylate[a]	3253-39-2	2	0.5%
Ethylhexyl acrylate	103-11-7	2	0.5%
4-*tert*-Butylcyclohexyl acrylate[a]	84100-23-2	2	0.5%
Methoxydiglycol methacrylate (name on 1 cosmetic: diethylene glycol monomethylacrylate)	45103-58-0	2	0.5%
Caprolactone acrylate[a]	110489-05-9	1	0.3%
Dipentaerythrityl pentaacrylate	60506-81-2	1	0.3%
Epoxy methacrylate[a]		1	0.3%
Ethoxyethyl methacrylate	2370-63-0	1	0.3%
Methacryloylethyl phosphate (name on cosmetic: HEMA phosphate)	24599-21-1	1	0.3%
Methyl methacrylate	80-62-6	1	0.3%
Neopentyl glycol dimethacrylate	1985-51-9	1	0.3%
PEG-15 trimethylolpropane triacrylate	28961-43-5 (generic)	1	0.3%
PEG-5 methacrylate[a]	25736-86-1 (generic)	1	0.3%
Pentaerythrityl tetraacrylate	4986-89-4	1	0.3%

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TABLE 4 (Continued)

Name of (meth)acrylate	CAS number	Frequency ($n = 394$)	%
Phenoxyethyl methacrylate	10595-06-9	1	0.3%
PPG methacrylate	39420-45-6 (generic)	1	0.3%
PPG-4 dimethacrylate[a]	25852-49-7 (generic)	1	0.3%
HEMA maleate	51978-15-5	1	0.3%

[a]Not present in the INCI nomenclature database https://ec.europa.eu/growth/tools-databases/cosing/.

with the warnings were higher: 'May cause an allergic reaction' 52% for one or both methacrylates, 55% for HEMA and 53% for di-HEMA TMHDC. Warning 'For professional use only' 65% for one or both methacrylates, 62% for HEMA and 70% for di-HEMA TMHDC.

Images of the entire packages of the cosmetics containing 1 or both methacrylates could be found for 25 products, of which 20 contained HEMA and 15 di-HEMA TMHDC. They were screened for the presence of the mandatory warnings on professional use and allergic reactions, which should both be present in all cases. The results are shown in Table 3. For both methacrylates together, 72% of the products showed the 'professional' warning and 64% the 'allergic reaction' warning. For HEMA, the percentages were 65% ('professional') and 45% ('allergic'). Thus, 55% and 35% of the products lacked the mandatory warnings 'allergic reactions' resp. 'professional'.

3.3 | Other (meth)acrylates in nail cosmetics

In the ingredient lists of 394 nail products, we found 47 (meth) acrylates, of which 18 were acrylates and 29 methacrylates (Table 4). By far the most frequently found ingredient was HEMA, which was present in 229 products (58.1%). HEMA was followed by di-HEMA TMHDC with 134 products (34.0%), hydroxypropyl methacrylate ($n = 100$, 25.4%), isobornyl methacrylate ($n = 61$, 15.5%) and trimethylolpropane triacrylate ($n = 47$, 11.9%). These 5 were the only ones present in >10% of all cosmetic products. Twenty-six (meth)acrylates (55%) were present in only 1–5 products, of which fourteen (29.8% of the total of 47) in a single nail cosmetic. Eleven chemicals could not be found in the INCI nomenclature database (https://ec.europa.eu/growth/tools-databases/cosing/), of which some had non-specific names such as urethane acrylate, special tertiary amine acrylate, acrylic monomer, and epoxy methacrylate.

In nine products, non-INCI names were used: 5× tetraethylene glycol dimethacrylate (INCI name PEG-4 dimethacrylate), 2× glyceryl propoxy triacrylate (INCI name PPG-3 glyceryl ether triacrylate), 1× diethylene glycol monomethylacrylate (INCI name methoxydiglycol methacrylate) and 1× HEMA phosphate (INCI name methacryloylethyl phosphate). Thus, mislabelling from using non-specific names ($n = 36$) and non-INCI names ($n = 9$) occurred in 45 of 394 (11%) products (Table 4).

4 | DISCUSSION

4.1 | Frequency of HEMA and di-HEMA TMHDC in nail cosmetics

This study shows that HEMA was present in nearly 60% of the 394 investigated nail cosmetics, the great majority of which were gel nails and gel nail polish. HEMA was by far the most frequent (meth) acrylate. Although not investigated in this study, we feel that this favours the generally made assumption that HEMA is the most important allergenic ingredient. Second was di-HEMA trimethylhexyl dicarbamate with 34% in the total group and >50% in gel nails. The products originated from seven European countries, China and the USA. There are some variations between countries, for example, that HEMA is used somewhat less frequently in these cosmetics in The Netherlands (47%) and USA (52%) than in Poland 70%) and China (63%). Nevertheless, nearly or at least half of the products from these countries contain HEMA. Di-HEMA TMHDC, however, is very little used in Chinese products. This also applied to some European countries, but here the numbers of products investigated were small.

4.2 | Compliance with EU regulations

European law requires that products containing HEMA, di-HEMA TMHDC or both are used only by professionals. These products must have warnings on their product package stating 'For professional use only' and 'Can cause an allergic reaction'. We could find these mandatory warnings in only 30%–40% of products containing these methacrylates on the website www.bol.com, the producers'/importers' website, the product label, and/or the product package. These figures rose to 50%–70% in a subgroup of products for which data were available on the websites of the producers or importers. This does not necessarily imply that a large portion of 30%–50% of the products are in violation of EU legislation. Both warnings must be shown on the package of the cosmetics and complete packages were available for only 25 products containing HEMA, di-HEMA DMHDC or both.

Quite interestingly, of 20 products containing HEMA, only 45% contained the allergic reaction warning and 65% the professional use warning. Thus, it was shown that in this small group of products, over half was in violation of EU regulations, lacking the warning 'Can cause an allergic reaction'. Whether this also applies to nail cosmetics in general is a matter of speculation. However, in our study, over 2/3 of

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all products contained one of both methacrylates, with frequencies of 97% in base gels of gel nails and 78% in base coats of gel nail polishes. It is hardly conceivable that all these products are intended for professional use only. Some manufacturers appear to make no efforts for complying to EU legislation at all. Three products of one manufacturer containing HEMA and di-HEMA TMHDC were advertised as 'the perfect gel manicure for home use' and were recommended with 'whether you are a novice or a professional in the field of nail polishes, you can be your own nail stylist in a few simple steps'. Another brand actually did have both warnings on its packages and online, but still these products were advertised with 'we would like to propose you "Do It Yourself" solutions of quality. Don't waste time and money in a nail salon, apply a nice gel nail polish at home when it suits you'. Such misleading advertising may well stimulate the use of these products by teenagers who do not seem to take the warnings seriously, as evidenced by their reviews.

4.3 | Nature and frequency of other (meth) acrylates in nail cosmetics

Apart from HEMA and di-HEMA TMHDC, we found 45 (meth)acrylates in the ingredient lists, of which only three were present in >10% of the products: hydroxypropyl methacrylate (25%), isobornyl methacrylate (16%) and trimethylolpropane triacrylate (12%) (Table 3). In nine products non-INCI names were used and non-specific undetermined chemical names were found in 36 ingredient labels. Thus, mislabelling occurred in 45 of 394 (11%) products, which are also violations of EU law requirements.

4.4 | Limitations

The main limitation of this study is that the information on our study website could be confirmed on the websites of the manufacturers'/importer's online stores in only some 30% of the products. By comparing the 2 websites, some faulty ingredient listings were found. This concerned mostly wrong listing of *all* colour types (10%) or *some* of the colour types (8%). Although this was largely limited to two particular brands which had a large number of products, it cannot be excluded that such errors may also have occurred in other products that could not be verified.

A final assessment of whether products containing HEMA, di-HEMA TMHDC or both show the mandatory warnings could only be made for 25 products. Direct inspection of products would solve this problem, but we have been unable to locate any physical stores in The Netherlands where a large number of these nail cosmetics are shown. Apparently, a large proportion of nail products are sold and purchased online. This makes it very difficult for The Netherlands Food and Consumers Product Safety Authority and their counterparts in other countries to check whether the nail cosmetics sold in the European Community conform to European legislation and, if not, take restrictive and when necessary legal actions.

AUTHOR CONTRIBUTIONS

Iemke M. Steunebrink: Conceptualization; methodology; data curation; formal analysis; investigation; writing – original draft; writing – review and editing. **Anton de Groot:** Conceptualization; supervision; methodology; visualization; project administration; writing – original draft; writing – review and editing. **Thomas Rustemeyer:** Resources; supervision; writing – review and editing.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Research data are not shared.

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