

Allergenic ingredients in nail polishes

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It has been known since the 1940s that nail polishes contain allergenic ingredients. The aim of this study was to clarify whether the nail polishes on the market today contain significant amounts of allergens, and what the solvents are. The following ingredients were determined: toluene, toluene sulfonamide formaldehyde resins, free formaldehyde, acrylates, methacrylates and certain organic solvents. The study comprised 20 brands and 42 samples. All the nail polishes analysed contained allergenic toluene sulfonamide formaldehyde resins (TSFR), in concentrations from 0.08 to 11.0%. The concentration of total formaldehyde varied from 0.02% to 0.5%. The more TSFR a nail polish contained, the higher was its formaldehyde content. Probably not only TSFR-allergic but also formaldehyde-allergic persons may get dermatitis from many of the nail polishes studied. The concentrations of acrylates and methacrylates were so small that they are of practical significance only to those previously sensitized to acrylates. Of the organic solvents, toluene was still widely used, whereas xylene was found in only 1 product. The nail polishes on the market today are not safe for all consumers. However, according to the regulations of the European Union, the packaging labeling of all cosmetic products must be supplied with a list of ingredients from the beginning of 1998. This will help the consumer to avoid allergenic products. A better alternative could, however, be to substitute the most allergenic ingredients with substances possessing minor allergy potency.

Key words: nail polish; formaldehyde; toluene sulfonamide; toluene sulfonamide formaldehyde resin; acrylates; methacrylates; organic solvent; cosmetics; allergic; solvents. © Munksgaard, 1997.

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Nail polishes have been in general use for decades, and it has been known for more than 50 years that they cause allergic contact dermatitis (ACD)(1–3). It has been estimated that some 1–3% of the population have nail polish allergy (1). In patients seeking medical advice because of cosmetic allergies, the incidence of allergy caused by nail polishes has been estimated to be as high as 6–13% (2). On the other hand, according to an American study, the risk of allergy caused by nail polish is modest (1 case in every 1700 users) (1).

Nail polish allergy often appears at a location other than the actual contact site, i.e. the fingers. 80% of the symptoms appear on the neck, face, lips and eyelids (4, 5). The commonest allergen in nail polish is toluene sulfonamide formaldehyde resin (TSFR, Fig. 1) (6, 7). Other components such as formaldehyde, polyester resin, ethylene dichloride, pigments, amyl acetate, phthalates, guanine, (meth)acrylates and nitrocellulose have also been

reported to cause allergy (1–9). Although it has been known for 50 years that nail polishes cause allergies, product development aimed at resolving allergy-related problems has been limited. It is

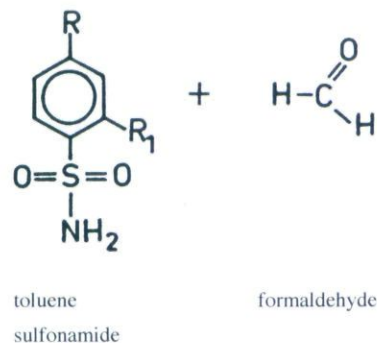


Fig. 1. Components of toluene sulfonamide formaldehyde resin (TSFR) *p*-toluene sulfonamide (R=CH₃, R₁=H); *o*-toluene sulfonamide (R=H, R₁=CH₃).

only recently that TSFR has been replaced in some products by ester resins, which may have less allergenic potential. The resulting preparations are often referred to as "hypoallergenic", although a number of other allergenic constituents still remain in such nail polishes.

Table 1. Concentrations of toluene sulfonamide (TSA) and toluene sulfonamide formaldehyde resin (TSFR) in nail polishes

Product	Liquid nail polish		Dried nail polish	
	TSA (%)	TSFR (%)	TSA (%)	TSFR (%)
1. Almay 10	0.05	9.80	0.01	18.50
2. Almay 03	0.06	2.80	<0.01	6.02
3. Anytime 065	0.14	7.20	0.35	17.80
4. Anytime 081	0.15	6.40	0.38	16.90
5. Arcancil 285	0.20	6.60	0.62	16.50
6. Arcancil 082	0.18	6.10	0.57	15.90
7. Christian Dior 934	0.14	7.00	0.31	17.90
8. Christian Dior 164	0.10	6.50	0.26	19.40
9. Clarins 38	0.05	0.16	<0.01	0.12
10. Clarins 98	0.03	0.10	0.02	0.13
11. Clinique 04	0.23	3.40	0.68	13.00
12. Clinique 02	0.30	4.80	0.72	13.90
13. Elisabeth Arden 106	0.09	0.49	<0.01	1.07
14. Elisabeth Arden 103	0.04	0.77	0.03	2.40
15. Ellen Betrix 19	0.38	6.70	1.51	18.70
16. Ellen Betrix 18	0.56	7.50	1.77	24.30
17. Gemey 23	0.19	7.30	0.36	18.30
18. Gemey 86	0.11	11.10	0.44	24.30
19. Givenchy 305	0.02	2.20	<0.01	5.90
20. Givenchy 307	0.02	2.00	<0.01	6.30
21. Guerlain 128	0.26	7.00	0.76	18.40
22. Guerlain 134	0.13	6.00	1.29	16.20
23. Isadora 63	0.05	0.13	<0.01	0.17
24. Isadora 04	0.04	0.10	<0.01	0.15
25. Lancaster 11	0.29	5.60	1.06	16.60
26. Lancaster 64	0.26	5.80	0.91	15.60
27. Lancome 152	0.19	6.30	0.52	18.20
28. Lancome 181	0.13	5.80	0.48	17.30
29. Lumene 25	0.05	0.08	<0.01	0.11
30. Lumene 8	0.04	0.09	<0.01	0.10
31. Mavala 3	0.10	6.70	0.29	19.30
32. Mavala 10	0.17	6.90	0.63	20.90
33. Max Factor 549	0.17	8.90	0.50	24.10
34. Max Factor 518	0.14	8.60	0.41	24.60
35. Revlon 23	0.15	7.20	0.41	21.00
36. Revlon 91	0.15	9.20	0.40	23.30
37. Rimmel 33	0.09	6.10	0.26	15.30
38. Rimmel 60	0.08	6.40	0.24	19.50
39. Yves Rocher 03	0.14	6.60	0.45	16.90
40. Yves Rocher 11	0.17	7.20	0.54	18.40
41. Gemey 05	0.15	7.50	0.47	21.80
42. Gemey 34	0.21	7.20	0.60	22.10

Nail polishes consist of about 60% (w/w) of various organic solvents (e. g., toluene), which may have a detrimental effect on the central nervous system. Many manufacturers are therefore currently aiming at developing toluene-free products.

The objective of the study was to assess the safety of nail polishes. Answers were sought to the following questions: (1) In what quantities are toluene sulfonamide and TSFR present in nail polishes? (2) Are the concentrations of these constituents in the liquid nail polish the same as in dried nail polish? (3) How much formaldehyde do nail polishes contain? (4) What are the concentrations of (meth)acrylate monomers in liquid and dried nail polishes? (5) What solvents are used? Questions (1)–(4) are associated with allergenic potential. Question (5) is important from the viewpoint of general safety, particularly as the term "toluene-free" is currently used to promote sales.

Materials and Methods

Nail polish samples were purchased from well-known department stores in Helsinki in December 1995. 2 colors of each brand were chosen randomly. 42 samples of 20 brands were examined in the study (Table 1).

Dried nail polish. About 12–20 drops of each nail polish were spread on separate microscope slides. The slides were allowed to dry in a fume cupboard for 3 days, after which samples of dried nail polish were scratched off.

Chemical determinations

Toluene sulfonamide compounds

Homogenous samples of 100 mg of liquid products were mixed with 5 ml of acetonitrile. In the case of dried nail polishes, 30–100 mg samples were scratched off and mixed with acetonitrile to obtain sample concentrations of 10 mg/ml for analysis. 5-fold stronger concentrations were prepared from products containing very small amounts of resin. After the samples had been shaken and centrifuged, they were analyzed within 3 days by means of reverse-phase liquid chromatography, using a diode array detector. The column was Hypersil 5 ODS (250 mm×4.6 mm ID). Acetonitrile-water was used as eluent at a flow-rate of 1.2 ml/min. The starting acetonitrile concentration was 35%, which was increased to 95% in 20 min. An autosampler was used for injection with an injection volume of 10 µl. Toluene sulfonamide formaldehyde resin (Chemotechnique Diagnostics), o-toluene sulfonamide and *p*-toluene sulfonamide (*p*-TSA) (Aldrich; purity grade 98%) were used as reference compounds. *p*-TSA was used as an external

standard for quantification at a wave length of 227 nm, as we could not be sure that all TSFR oligomers in the reference material were fully eluted from the column during the used conditions. Both *p*-TSA and the TSFR peaks with retention times of more than 8 min had UV spectra with the maximum absorbance at 227–228 nm. The other absorbance peak, which had only about 7% of the maximum absorbance, occurred at 262 nm for *p*-TSA and at 267 nm for the TSFR oligomers. TSFR in the samples were identified on the basis of retention times. Other peaks with retention times of more than 8 min were considered to be TSFR if their UV spectra were identical to that of the control resin. UV spectra in the range 220–350 nm were recorded for each peak during the liquid chromatographic analysis. Results were calculated in terms of *p*-toluene sulfonamide, and resins consisting of oligomers. The detection limit for individual monomers/oligomers was 0.01%.

Formaldehyde determination using the acetyl acetone method (90/207/EEC)

Analysis was based on a colorimetric method in which formaldehyde reacts with acetyl acetone to form a colored lutidine complex (pH 6.4). This complex was extracted into butyl alcohol and the absorbance was measured at a wavelength of 410 nm.

Formaldehyde determination using the dinitrophenylhydrazine method (10)

Samples of 50 mg and 100 mg of the product were added to 5 ml of water. The water-soluble formaldehyde and formaldehyde-releasing compounds were allowed to react with dinitrophenylhydrazine (DNPH) (1 h, 70°C) in acid solution, adopted from the method of Benassi and Semenzato (10). The resulting hydrazone was determined by means of liquid chromatography using a reverse-phase method and a diode array detector (352 nm), and quantified against an external standard (formaldehyde hydrazone in acetonitrile, 98% purity as determined using liquid chromatography and a diode array detector). The detection limit was 0.003%, and the relative standard deviation (SD) of the method was $\pm 8\%$.

Acrylate residue monomers

Acetone-soluble acrylates (200 mg nail polish/10 ml acetone) were determined by gas chromatography with autosampler splitless injection of 2 μ l (240°C) on 2 parallel columns (NB 54 and NB 1701, 25 m $\times$ 0.32 mm ID, film thickness 1 μ m); each column was coupled to a flame ionization de-

tector (300°C). The oven temperature was held at 35°C for 5 min and was subsequently increased at 5°C/min to 210°C. Samples of dried nail polish were also scratched off for residue monomer analysis (20–30 mg/ml of acetone). Quantification was performed against 14 external standards (methyl methacrylate, allyl acrylate, ethyl ethacrylate, sec-butyl acrylate, i-butyl acrylate, allyl methacrylate, n-butyl acrylate, sec-butyl methacrylate, hydroxyethyl acrylate, i-butyl methacrylate, hydroxypropyl acrylate, n-butyl methacrylate, hydroxyethyl methacrylate, hydroxypropyl methacrylate) using the results of the NB 54 column. The retention times from the results of the other columns were used to confirm the identification of the acrylates. The detection limit was 0.002%. Standards were obtained from Polyscience Corp (USA); their purity was 98%.

Solvents

Homogenous samples of 100 mg of the products were dissolved in 5 ml of dimethylformamide. For analysis, the dissolved samples were diluted with dimethylformamide to concentrations of 1 mg/ml. Solvents were determined by gas chromatography with split injection on 2 parallel columns (NB 54 and NB 1701); each column was coupled to a flame ionization detector. For quantification, pentrane was used as an internal standard. The purity of the solvent standards exceeded 98%. The relative SD varies from ± 0.5 to $\pm 7\%$, depending on the solvent being analyzed. The detection limit for this method was 0.1%. The analytical method is adopted from a method (11) that is used to determine solvent concentrations in workplace air.

Results

Toluene sulfonamide compounds

Toluene sulfonamides and TSFR were determined in nail polish and dried nail polish (Table 1). The TSFR concentrations varied in the bottles within the range of 0.08% (Lumene 25) to 11% (Gemey 86). In dried nail polish (Table 1), the lowest concentration was 0.10% (in Lumene 8), the highest in the Max Factor product 518, which contained 25% TSFR. The % of toluene sulfonamide in the products varied between 0.04% (Lumene 8) and 0.56% (Ellen Betrix, 18) (Table 1). Many dried nail polishes exhibited no trace of toluene (Almay 03, Clarins 38, Elizabeth Arden 106, Givenchy 305, 307, Isadora 63, 04, Lumene 25, 8). The highest concentration, 1.7%, was found in an Ellen Betrix product. A chromatogram of TSFR used to identify the oligomers, and chromatograms of 2 nail

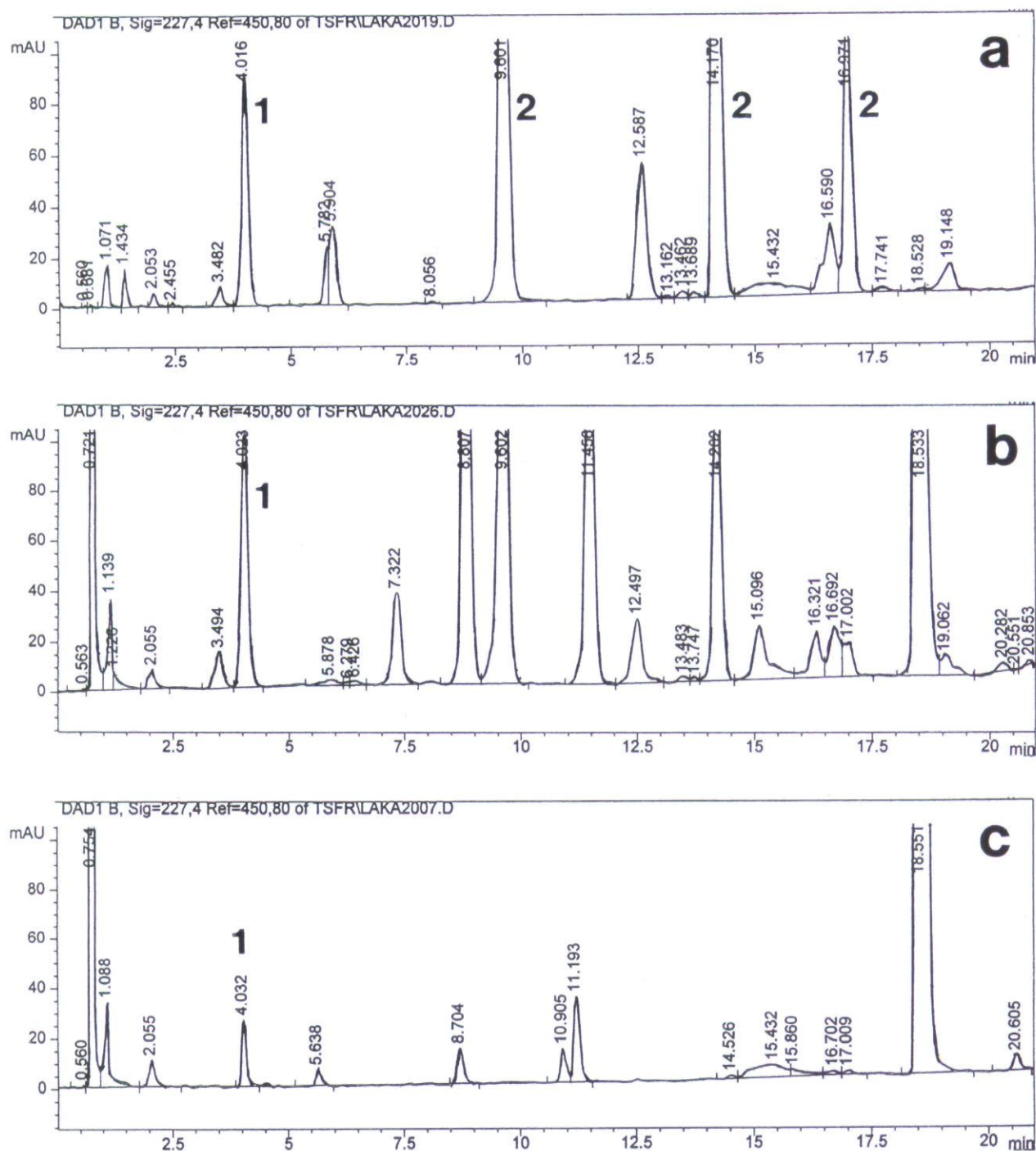


Fig. 2. Liquid chromatographic separation of toluene sulfonamide (1) toluene sulfonamide formaldehyde resin (TSFR) oligomers (2) in two nail polishes (b and c). Peaks with retention times of more than 8 min were considered TSFR oligomers if their UV spectrum was identical to the UV spectra of the peaks (2) from the TSFR (a). a=reference TSFR, b=Lancaster 11, c=Almay 10.

polishes containing different types of TSFR, are shown in Fig 2.

Formaldehyde

Only 7 out of 20 products were completely free from formaldehyde (Table 2), namely products

from Almay, Clarins, Clinique, Elizabeth Arden, Givenchy, Isadora and Lumene. Of 2 Ellen Betrix products, 1 was marketed as being formaldehyde-free. In many products, formaldehyde concentrations markedly exceeded the maximum for preservatives in the cosmetic regulations (0.2%). These included, e.g., Christian Dior, Gemey, Lancaster,

Lancôme, Mavala, Max Factor, Rimmel and Yves Rocher. The results relate to analyses based on methods referred to 90/207/EEC. Formaldehyde determinations were also undertaken by means of a liquid chromatography method (10). There were no significant differences between the results.

Table 2. Concentrations of formaldehyde in nail polishes

Product	Formaldehyde % (1)	Formaldehyde % (2)
1. Almay 10	<0.003	—
2. Almay 03	<0.003	—
3. Anytime 065	0.12	0.12
4. Anytime 081	0.13	0.10
5. Arcancil 285	0.17	0.17
6. Arcancil 082	0.20	0.17
7. Christian Dior 934	0.23	0.23
8. Christian Dior 164	0.21	0.20
9. Clarins 38	<0.003	—
10. Clarins 98	<0.003	—
11. Clinique 04	<0.003	—
12. Clinique 02	<0.003	—
13. Elisabeth Arden 106	<0.003	—
14. Elisabeth Arden 103	<0.003	—
15. Ellen Betrix 19	0.02	0.15
16. Ellen Betrix 18	<0.003	—
17. Gemey 23	0.27	0.33
18. Gemey 86	0.42	0.43
19. Givenchy 305	<0.003	—
20. Givenchy 307	<0.003	—
21. Guerlain 128	0.13	0.45
22. Guerlain 134	0.21	0.23
23. Isadora 63	<0.003	—
24. Isadora 04	<0.003	—
25. Lancaster 11	0.49	0.42
26. Lancaster 64	0.47	0.41
27. Lancome 152	0.28	0.33
28. Lancome 181	0.28	0.28
29. Lumene 25	<0.003	—
30. Lumene 8	<0.003	—
31. Mavala 3	0.19	0.20
32. Mavala 10	0.31	0.28
33. Max Factor 549	0.22	0.19
34. Max Factor 518	0.14	0.17
35. Revlon 23	0.23	0.32
36. Revlon 91	0.18	0.20
37. Rimmel 33	0.31	0.28
38. Rimmel 60	0.23	0.22
39. Yves Rocher 03	0.26	0.22
40. Yves Rocher 11	0.30	0.30
41. Gemey 05	0.44	0.64
42. Gemey 34	0.19	0.62

1=formaldehyde determined by means of the method described in resolution 97/93 of the Ministry for Trade and Industry (90/207 EEC). 2=formaldehyde determined by liquid chromatography. <0.003=detection limit, —=not determined.

Table 3. Concentrations of *n*-butyl methacrylate in dried nail polishes

Product	<i>n</i> -butyl methacrylate %
13. Elisabeth Arden 106	0.014
14. Elisabeth Arden 103	0.025
19. Givenchy 305	0.046
20. Givenchy 307	0.067
21. Guerlain 128	0.037
22. Guerlain 134	0.019

Acrylates and methacrylates

Low amounts of acrylates or methacrylates were observed in liquid or dried (Table 3) nail polishes. The highest concentrations of (meth)acrylates in the liquid nail polishes were: methyl methacrylate 0.013%; (product 13), *n*-butyl acrylate 0.028% (product 40) and *n*-butyl methacrylate 0.049% (product 20). Up to 0.067% of *n*-butyl methacrylate was present in dried nail polish (product 20; Table 3).

Organic solvents

The solvent concentrations ranged from 61 to 72% (w/w) (Table 4). The concentrations of aromatic solvents, such as toluene, were relatively high (approx. 20%) in products from Anytime, Arcancil, Christian Dior, Gemey, Guerlain, Lancaster, Mavala, Revlon, Rimmel, Yves Rocher, Gemey.

Xylene was found in only 2 products (Christian Dior, Rimmel), in very small amounts, 0.3–0.4%. The most commonly used solvents besides toluene were *n*-butyl acetate (in all products, in concentrations of 15–52%) and ethyl acetate (in all products, in concentrations of 4–42%). All products contained isopropanol (2.7–7.7%). Other solvents used included isobutyl acetate, ethanol (in very low concentrations), isopropyl acetate and *n*-butanol.

Discussion

Various TSFR constituents have been shown to have different allergenic potential (12). Monomers and dimers are likely to be the most potent allergens (12). The differences between the allergenic potential of monomers and oligomers are thought to be up to 1000-fold. According to our results, the chemical composition of the resin did not change after the nail polish had dried. This can result in allergy if the nail comes in direct contact with the skin, e.g. during sleep, as is clinically well-known. Nail polish is sometimes used to cover the metal parts of a watch, to protect the skin. A case has

Table 4. Concentrations of solvents in nail polishes (%); an empty space indicates that the solvent was not detected

Product	Solvent (76)									Total
	iso-propanol	ethyl-acetate	toluene	iso-butyl acetate	n-butyl acetate	ethanol %	iso-propylene-acetate	n-butanol	xylene	
1. Almay 10	6.1	29.5			25.8	0.2	0.3			62.0
2. Almay 03	6.0	28.9	0.1		26.8	0.2				61.9
3. Anytime 065	5.0	14.5	19.3		26.6		0.3			65.7
4. Anytime 081	5.2	13.1	19.5		26.5					64.2
5. Arcancil 285	4.7	13.6	17.7		25.2	0.1	0.3			61.7
6. Arcancil 082	5.1	12.7	19.2		26.6		0.4			64.0
7. Christian Dior 934	6.7	19.8	23.3		15.3			0.7	0.4	66.2
8. Christian Dior 164	6.8	21.0	24.0		14.8			0.7	0.4	67.8
9. Clarins 38	5.4	23.7		5.7	30.3	0.3	0.5	0.6		66.4
10. Clarins 98	4.9	27.8		6.3	30.7	0.4	0.6	0.8		71.6
11. Clinique 04	4.7	29.8			23.4	0.2	0.3	7.1		65.7
12. Clinique 02	4.4	24.5			21.3	0.3	0.5	12.5		63.4
13. Elisabeth Arden 106	3.4	36.3			27.6	0.6	0.9	0.7		69.7
14. Elisabeth Arden 106	2.7	30.2			29.8	1.0	1.6	1.2		66.5
15. Ellen Betrix 19	4.9	25.7			20.1	0.1		11.6		62.3
16. Ellen Betrix 18	5.2	31.5			22.0			7.6		66.3
17. Gemey 23	7.5	41.1			21.1					69.6
18. Gemey 86	6.1	9.3	27.5		24.6					67.5
19. Givenchy 305	6.0	7.1			50.8	0.1	0.4	1.7		66.1
20. Givenchy 307	6.1	4.9			51.6		0.4	1.9		64.9
21. Guerlain 128	5.0	12.7	18.4		24.4	0.2	0.4			61.6
22. Guerlain 134	4.5	13.5	20.1		24.4					62.5
23. Isadora 63	4.7	23.6	0.1	5.4	29.9	0.4	0.7	0.7		65.5
24. Isadora 04	5.0	22.9	0.1	6.0	30.4	0.4	0.7	0.7		66.1
25. Lancaster 11	6.0	9.8	19.0		31.6	0.1	0.4	1.2		68.2
26. Lancaster 64	5.7	9.4	17.9		31.2		0.3	1.3		65.7
27. Lancome 152	7.5	20.9			40.6					69.0
28. Lancome 181	7.7	21.8			39.7					69.1
29. Lumene 25	5.7	23.4		5.7	31.1					65.9
30. Lumene 8	5.6	22.2		5.8	30.9					64.4
31. Mavala 3	5.1	19.1	20.0		20.4					64.2
32. Mavala 10	4.8	18.4	20.9		21.6					65.6
33. Max Factor 549	5.7	21.7	7.0		29.1	0.3				63.8
34. Max Factor 518	5.5	20.1	7.2		31.5	0.2				64.6
36. Revlon 91	5.2	18.6	18.8		18.9			1.5		63.0
37. Rimmel 33	5.5	9.1	20.4		24.9			0.7	0.3	61.0
38. Rimmel 60	5.7	11.0	23.8		24.6			0.9	0.4	66.5
39. Yves Rocher 03	5.7	13.4	19.0		28.4			0.9		67.5
40. Yves Rocher 11	5.4	10.9	20.4		28.2			0.9		65.8
41. Gemey 05	5.8	8.9	26.8		23.9					65.5
42. Gemey 34	7.3	42.4			22.2					72.0

been reported in which nickel allergy was suspected but the patient had in fact developed hypersensitivity to TSFR (13). TSFR in nail hardeners has also caused allergies (14).

Formaldehyde concentrations as low as 0.003% have been reported to cause symptoms in sensitized subjects (15, 16). Formaldehyde is a component of nearly all nail polishes. In Engelhardt and

Klinker's study (17) free formaldehyde was present at concentrations of 100 ppm or less, whereas in our study the concentration of total formaldehyde varied from 0.02% to 0.5%. Engelhardt & Klinker (17) showed that formaldehyde is easily released from the resin in contact with water. Accordingly, formaldehyde can easily be released in contact with body fluids and the skin, causing allergic con-

tact dermatitis. Our results obtained by the acetyl acetone method, in which all extractions and reactions occur in neutral solution, reflect the allergy risk of nail polishes. We also determined formaldehyde by another method. The results were very close to each other, indicating that the determinations are reliable. To summarize, allergy to formaldehyde is common, and nail polish may cause relapsing dermatitis in both TSFR-sensitive and formaldehyde-sensitive persons. The amounts of formaldehyde detected in this study are high enough to cause primary sensitization.

Hardened plastic polymers only rarely cause acrylate allergy. Occasionally, however, a product may contain residues of unhardened allergenic monomer (18). The concentrations of acrylate and methacrylate were low in the products studied. It is not known what quantities of acrylates have allergenic potential. However, some manufacturers have taken this possible danger into account in product labeling. A package may be marked: "contains acrylates" (e.g., Lumene). Products with high acrylate concentrations are also available (18) but were not included in the present study.

Most of the constituents of nail polishes are organic solvents (60%). All solvents may irritate the skin. In large quantities they have narcotic effects. Butyl acetate, which gives nail polish its typical smell, irritates the eyes and dries the skin (19). The irritation can also affect the respiratory tract. High concentrations of solvents can be absorbed through the skin. Solvents, however, very seldom cause allergies. The aromatic solvents in toluene and xylene should be substituted by less hazardous agents, even though toluene is not allergenic (20). Because of the well-known harmful properties of toluene, some nail polishes are marked "toluene-free".

Although the solvents used in nail polish can be hazardous in large quantities, minor exposure associated with evaporation of the solvent during normal use of nail polish is not hazardous to health. Sniffing from the bottle should, however, be avoided.

Although the allergenic properties of nail polishes have been recognized for nearly 50 years, few products free from the allergen TSFR are marketed. In the European Union, requirements for labeling TSFR on the package have occasionally been suggested (21), but not before 1 January 1998 will all consumer packs have to include statements about TSFR, toluene sulfonamide, and other constituents, in the product declaration (as tosyl amide/formaldehyde resin) (22).

Cosmetics face increasing safety requirements. During the development of nail-polish products, constituents with allergenic properties are likely to

be replaced by safer agents. At present, however, consumers allergic to TSFR have difficulties in finding a safe nail polish.

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