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Here are the comments from the Swedish Contact Dermatitis Research Group concerning the call for data on ingredients 'Di-HEMA Trimethylhexyl Dicarbamate' (CAS 41137-60-4), 'HEMA' (CAS 868-77-9), and on the class of compounds 'Urethane acrylates' used in cosmetic products in the framework of Regulation (EC) 1223/2009 on Cosmetic Products.

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All 3 substances have been implicated in LED/UV-curing nail polish marketed and sold in Sweden. Some of the background to the comments on these 3 substances are found in a recent publication (1).

'Di-HEMA Trimethylhexyl Dicarbamate': This is a polymer component, defined as a mixture of two larger methacrylates, both containing the HEMA structure in the molecule.

Types of cosmetic products in which they are used: Nail enhancement products such as LED/UV-curing nail polish marketed for home use.

The concentration level at which they are used in specific products: In the mentioned LED/UV-curing nail polish the active concentration was 27% in the product.

Their function: Polymer component which undergoes rapid polymerization to form a hard material and speeds up polymerization and/or form cross-links.

'HEMA': This is the short word for the small monomeric methacrylate 2-hydroxyethylmethacrylate.

Types of cosmetic products in which they are used: This compound is used in nail elongating chemicals (in gels) and UV-curing nail polish.

The concentration level at which they are used in specific products: In the mentioned LED/UV-curing nail polish the active concentration was 4.5% in the product.

Their function: To form a film on the nail plate.

Type of exposure: Via direct skin contact and exposed groups are nail technicians and lay people using the UV-curing nail polishes containing HEMA.

Type of symptoms: May range from paraesthesia of the fingertips with/without allergic contact dermatitis, allergic contact dermatitis, pulpitis of the fingertips, paronychia, nail dystrophy, onycholysis, facial dermatitis, eyelid dermatitis (airborne or contaminated hands), irritant contact dermatitis, and allergic conjunctivitis.

'Urethane acrylates': This is a mixed isocyanate-acrylate polymer. In the case of the aforementioned LED/UV-curing nail polish, the acrylate was hydroxyethyl acrylate.

Types of cosmetic products in which they are used: In UV-curing nail polish.

The concentration level at which they are used in specific products: In the mentioned LED/UV-curing nail polish the active concentration was 6% in the product.

Their function in general: Aliphatic Urethane Acrylate is used as a component (<30%) of industrial coatings, adhesives, inks and in plastic manufacture.

Background to the comments:

Nail polish containing UV-curing acrylates and methacrylates is currently used as an alternative to common nail polish. These products are marketed as more durable and long-lasting than conventional nail polishes and should be applied every second or third week. These methacrylate-containing nail polishes are applied directly to the nail plate in several layers by the use of a brush. Between applications, each layer is to be cured using UV-light. When these nail polishes first were launched, they were only offered by professional nail-technicians in nail salons, but recently different kits for non-professional use at home have appeared on the market, which means that anyone can use them. They contain highly sensitizing acrylates and methacrylates of more or less the same type that are used industrially, and in dentistry and orthopaedic surgery.

The use of acrylates and methacrylates in industry is controlled by legislation but this is not the case in beauty care, and the risk of skin sensitization is not obvious to the user of the nail polish. The concentration of acrylates and methacrylates in UV-curing nail polishes can be above 90 %.

Severe skin reactions from nail polish

The most commonly reported problem in those that had used a special brand of LED/UV-curing nail polish in Sweden and that the Medical Product's Agency prohibited the sale of was eczema starting around the nails (1). Nail injuries and loss of nails were also quite common, sometimes in combination with eczema. Consumers were on sick leave and in one case hospitalized. Several of those customers that had had skin problems from the use of the LED/UV-curing nail polish were investigated with patch testing by the author of this document and another member of the Swedish Contact Dermatitis Research Group, Mihály Matura. Eight of these cases are reported in detail in the attached scientific publication (1).

It was found that all 8 tested individuals except one had contact allergy against one or several of the acrylate or methacrylate ingredients in the nail polish. Six individuals reacted to the small monomeric 2-hydroxyethylmethacrylate (HEMA), but allergic reactions were also obtained in 7 individuals to the larger and more polymerized acrylate di-HEMA trimethylhexyl dicarbamate and in 6 to Urethane acrylates. Six reacted to the product itself diluted in an appropriate concentration (base coat and top coat). It is possible that HEMA is the main sensitizer, and the other reactions are cross reactions due to the structural similarities. However, one patient reacted only to di-HEMA-trimethylhexyl dicarbamate with a weak allergic reaction, speaking against this.

## Conclusion

From previous experience it is well known that both acrylates and methacrylates are potent skin sensitizers, and that they cause severe skin disease in industry workers, dental workers, and orthopaedic personell ( 2-4) .

Cosmetics should not cause disease. It is the opinion of the Swedish Contact Dermatitis Research Group that lay people (e.g. consumers that use the UV-curing nail polish themselves) as well as “nail technicians” are at a very high risk of skin sensitization (induction and elicitation) when exposed to such potent skin sensitizers as acrylates and methacrylates when present in cosmetic products. The above mentioned 3 substances are such chemicals.

Moreover, several (meth)acrylates are used in other applications and sensitization caused by this type of products may affect the future life of the patients, for example in the choice of career or considerations in for example dental treatment, where a lot of different (meth)acrylates are used.

## References:

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