Bilaga 2

Cosmetic product safety report, Part B

One Step Gel Polish, 5

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Cosmetic product safety report

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B. Cosmetic product safety assessment

Assessment conclusion

The cosmetic product assessed in the present report, One Step Gel Polish, 5, is considered to be safe for human health when used under normal and reasonably foreseeable conditions of use, taking into account the presentation, labelling and instructions for use (Article 3 of Regulation (EC) No 1223/2009).

Labelled warnings and instructions of use

There is no need to label any particular warnings and instructions of use in accordance with the regulation. However, the users are carefully instructed on how to use the product and that they should **avoid exposure of the skin and the eyes**. Furthermore, if the eyes are exposed to the product, then the eyes should be rinsed with water and a medicinal practitioner be consulted. The product should also be kept away from children.

Reasoning

The present monophasic UV-light curable nail polish for adults is used to provide a hard colored layer on the nail plate. The formed layer on the nail plate is composed by reacting together acrylic monomers with acrylic polymers using a photoinitiator. The reaction is activated by the use of a light emitting diode (LED) lights, or equivalent light source. Also ordinary outside light will harden the layer. The nail polish does not contain any prohibited substances and there are no ingredients of human or bovine origin and none are classified as having Carcinogenic, Mutagenic or Reproductive (CMR) toxicity. The formulation is not prone to microbiological contamination.

The largest part of the ingredients in One Step Gel Polish are metacrylate ester monomers (HEMA and Di-HEMA Trimethylhexyl Dicarbamate) commonly used in the present type of formulations and they have also been assessed by expert committees for consumer products (CIR), and found to be adequately safe. The most important reference for the assessment - the CIR report (45p) - was published in the International Journal of Toxicology year 2005 and includes data from 147 references.[1] Proper toxicological data on the important metacrylate ester monomers and also the other ingredients (Hydroxycyclohexyl Phenyl Ketone, Polymer Acrylate Oligomer, CI 77510, CI 77742, CI 77891) have been retrieved by careful data search in relevant data bases (e.g. PubMed, ToxNet, CosIng)[N] and been obtained from the raw material suppliers (see data on the Toxicological profile of the ingredients denoted in Part A). No further data which could reverse the important assessment made by CIR has been identified in the literature since the publication of the CIR report. The purities

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[N] http://www.epa.govt.nz/search-databases/Pages/ccid-details.aspx?SubstanceID=6552, accessed 2014-12-25

[N] http://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/cl-inventory/view-notification-details/229976/28766972, retrieved at 2014-12-25

[N] http://apps.echa.europa.eu/registered/data/dossiers/DISS-975e8192-4649-058b-e044-00144f67d031/AGGR-6055fbc6-7cc0-47e7-8aa2-91615da9f22a_DISS-975e8192-4649-058b-e044-00144f67d031.html#AGGR-6055fbc6-7cc0-47e7-8aa2-91615da9f22a, accessed 2014-12-25

[N] C385410 PIGMEN BLUE 27. COLORANT MEETS ALL REQUIREMENTS OF US 21CFR, PARTS 70-82 AND EU COSMETIC DIRECTIVE 76/768/EEC, ANNEX IV, PART 1 AND AMMENDMENTS. SunChemical. PERFORMANCE PIGMENTS 5000 SPRING GROVE AVENUE CINCINNATI, OH, USA 45232

[N] MSDS Natural Sourcing Manganese violet, http://www.naturalsourcing.com/msds/MSDS_Manganese_Violet.pdf accessed Aug 2013.

[N] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=73.2775, accessed Aug 27, 2103

of two of the restricted ingredients (colours CI 77891, CI 77510) do also fulfill the regulation. The purity of the packaging is also satisfactory (see above).

In the CIR report the rate of polymerization of a large number of monomethacrylates, dimethacrylates and trimethacrylates and ethyl methacrylate were discussed. Thermal data showed polymerisation 22 metacrylates at 50% to be within 5 min (Table 4 in the CIR-report[1]). The present formulation with not less than 50% acrylates has a set time and maximum exothermic reaction shorter than 30 s, measured with a thermal imaging camera[0]. Hence, there are no data in the report that suggest the present composition to be more associated with increased risks, due to for example higher concentration of monomers such as e.g. Di-HEMA Trimethylhexyl Dicarbamate than reported to be found in other nail hardening products.

The calculated daily topical exposure to the nail polish is roughly 0.05 mg/kg bw. The Systemic Exposure Dosage (SED) of the ingredients can be used to compare this value with the Threshold of Toxicological Concern (TTC) or reported no observed adverse effects level (NOAEL); Despite absence of generally agreed values on chronic toxicity of all ingredients in the present product, the ingredients are considered to have Margin of Safety well above the necessary ratio (>>100), as the systemic exposure is almost negligible when the product is used as foreseeable. A more frequent use will thus not reduce the Margin of Safety to unacceptable levels. Local skin reactions are considered to be more toxicological relevant than systemic toxicity from the use of the present formulation. It might be worth noting that metacrylates are used in other type of products in close contact or advertently places inside humans, such as for example in indirect food additives, drug delivery systems, contact lenses, dental technology.[1]

The stability of the ingredients is considered to be satisfactory in the container and no hazardous degradation products are expected to be formed during storage. Upon application of the product on the nails, the liquid will polymerize and form a hard surface within 20 s,[0] but the polymerization will continue for another 40 s to complete the hardening of the product. The formed polymers themselves are typically safe, but traces of the reactive monomers may remain in the polymer and have been reported to be able to result in an adverse reaction, such as redness, swelling, and pain in the nail bed, among people who are sensitive to methacrylates. However, methyl methacrylate monomers are more frequently associated with these injuries than the acrylates found in the present product. Methyl metacrylate is not used in the present product, which instead uses a suitable combination of larger molecular-weight metacrylate ester monomers which are considered to be safer than methyl metacrylate.[1] For example, in studies addressed in the CIR-report, a cosmetician with a wide cross-reactivity to several different methacrylates, did not react to Di-HEMA Trimethyl Dicarbamate used in the present product.[1] In the present product Di- HEMA Trimethyl Dicarbamate is used in a higher concentration than in the reported CIR assessment.[1] Furthermore, Kanerva (1989) did not found any of 7 patients occupationally sensitized to dental resin products to react to Di-HEMA Trimethylheyl Dicarbamate.[1] Also Tucker (1999)[1] reported data on 440 patients which suggest that Di-HEMA Trimethylhexyl Dicarbamate to have caused less contact allergy than other tested acrylates in the Chemotechnique series, as 2 of 268 patients elicited a positive response, where 29 or 337 elicited a positive response to HEMA.[1] Polymers and oligomers are even less likely to diffuse into the viable tissue and cause unwanted reactions.

It is concluded that sufficient information is obtained on the ingredients and the formulation L.Y.X Cosmetics One Step Gel Polish, no 5, to be able to assess its potential risks to human health under normal and reasonable foreseeable use. Data on the ingredients capacity to induce adverse skin reactions show absence of significant risks. However, like any cosmetic product that may be hazardous if misused, it is important that One Step Gel Polish, 5, carries the appropriate warnings and directions for safe use which also are applied to the product. One Step Gel should not to be used outside the nail plate but exposure to the skin, although not intended – may sometimes be inevitable

[0] Polymerisering av L.Y.X. Cosmetics nagellack. Eviderm Institute, Teknisk Rapport 2015-03-29.

in normal and reasonably foreseeable conditions of use. If the eyes are exposed they should be rinsed with water and medical attention should be sought. If inadvertently applied to the skin outside the nail plate, then the user will remove the product, which reduces the exposure time to the non-polymerized liquid. When the product is used on the nail plate and the instructions for use is followed, then the information gives no evidence that the product is will pose any risk to the consumers. Instead the product can be expected to be well tolerated and only in rare circumstances induce reactions in sensitive individuals. Individuals with a known sensitivity to certain potential allergens (e.g. acrylate monomers) in the formulation may be at a higher risk. Furthermore, case reports and data from open studies also support the safety of the present formulation and suggest it to be less troublesome than similar products on the market.[P] Other open safety reports on similar one-step nail formulations also support the safety of the present type of product as it concludes that the nail polish "will give users the level of safety they can reasonably expect when used as directed".[Q]

Assessor's credentials and approval

The present safety assessment has been carried out in accordance to article 3 of Regulation (EC) No 1223/2009by the undersigned person, which has a diploma in pharmacy and toxicology. Furthermore the assessor is Doctor in Medicinal Sciences and Associate Professor in Experimental Dermatology.[R] A copy of the references is also available within the Responsible Person.

After analysis of submitted information on the formulation and publicly available information of the toxicological profile of the ingredients, it is concluded that, according to the current state of scientific knowledge, the product is not expected to cause damage to the human health and can be marketed for the intended and foreseeable use as a cosmetic product. New scientific evidence and new regulatory opinions may change the conclusions made in the present assessment.

Eviderm Institute AB, Bergshamra Allé 9, SE-17077 Solna, Sweden.
Date: March 30, 2015
Signature:

Marie Lodén
Safety Assessor

[P] Ventseslav Garow, Clinical Dermatology test, East Diagnostic and consultation center, Bulgaria, dated 14.01.2014

[P] Testperson A, började använda LYX One Stp 9/12-2013, Testperson B, började använda LYX One step 12/210-2013, Testperson C; började använda LYX One Step 7/1-2014, Testperson D Började använda LYX One Step Gel Polish 22/1-2013

[Q] Intertek Toxicology Assessment, http://media.wix.com/ugd/c9596b_42c4a08404e7407d9180ad0ec83a45d6.pdf, accessed 2015-03-30.

[R] CV Marie Lodén, see http://www.eviderm.se/startsida/curriculum-vitae-marie-lodn-254246

General Notes

The product assessed in the present report must be manufactured in accordance with EU Guidance on Good Manufacturing Practice and comply with the relevant purity standards for cosmetic ingredients. It is assumed that the ingredients do not contain any undisclosed impurities/contaminants that would affect the conclusions reached.

The product must be In order to ensure that the cosmetic product safety report is kept up to date as required by Article 10(1)(c) of Regulation (EC) No 1223/2009, the safety of the finished product should be reassessed regularly. When changes in the legal requirements occur (e.g. restrictions of one of the substances included in the formulation), it should be checked, amongst others (e.g. labelling), whether the formulation still complies with the law, and the safety assessment should be reviewed and, if necessary, updated.

The safety assessment should also be reviewed and, if necessary, updated, where one or more of the following circumstances apply:

(a) new scientific findings and toxicological data on the substances are available which could modify the result of the existing safety assessment;

(b) changes occurring in the formulation or specifications of raw materials;

(c) changes occurring in the conditions of use;

(d) a rising trend in terms of the nature, severity and frequency of undesirable effects, both under reasonably foreseeable conditions of use and in the case of misuse.

In supplying this safety assessment Eviderm Institute makes no assurances that the individual raw materials are registered or exempt under REACH, which is usually not an issue if the substances are sourced within the EU. Importers into the EU of products containing any botanical ingredients derived from endangered species should also be aware of any restrictions in this field.

References

1. CIR. Final report of the safety assessment of methacrylate ester monomers used in nail enhancement products. Int J Toxicol. 2005;24 Suppl 5:53-100.