Bilaga 9

Cosmetic product safety report.

L.Y.X. One-Step Gel Polish, 39669213.
55 colour shades.
The present update includes the report on colour shade no 5.

2015-02-20
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Cosmetic product safety report

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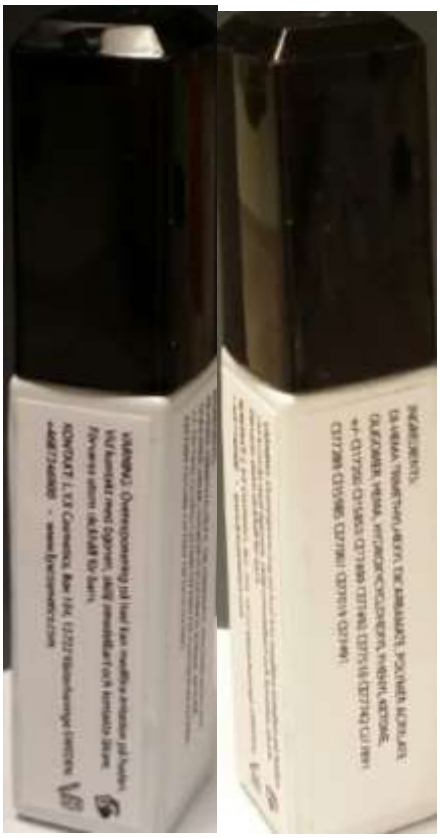
Summary

Cosmetic products should be safe under normal or reasonably foreseeable conditions of use.[1]

In the present safety assessment, an appropriate weight-of-evidence approach is used for reviewing the data from existing sources on the ingredients and on the finished product L.Y.X. One-Step Gel Polish, 39669213, including 55 colour shades, L.Y.X. Cosmetic AB. The intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in the final formulation are also taken into account.

Based upon the information found in the open literature and data from the responsible person, it is concluded that sufficient information is obtained on the ingredients and the finished products to be able to assess its potential risks to human health under normal and reasonable foreseeable use. The information gives no evidence that L.Y.X. One-Step Gel Polish, 39669213 will pose any significant risk to the consumers. There are no ingredients of human or bovine origin and none are classified as having Carcinogenic, Mutagenic or Reproductive (CMR) toxicity. The product can be expected to be well tolerated and only potentially induce reactions in sensitive individuals if the instructions for use are not followed. Like any cosmetic product that may be hazardous if misused, it is important that L.Y.X. One-Step Gel Polish, 39669213 carries the directions for safe use on the label. The present product is instructed not to be used outside the nail plate and if used inadvertently in the eyes they should be rinsed with water and medicinal professionals contacted. Case reports also suggest the product to be safer than similar products on the market.



A. Cosmetic product safety information

Responsible Person: L.Y.X. Cosmetics AB, Allévägen 38, Tungelsta Box 104, 137 22 Västerhaninge, Sweden

Quantitative composition L.Y.X. One-Step Gel Polish, 39669213

INGREDIENTS (INCI)	FUNCTION	CAS /EC	Interval or max%
POLYURETHANE ACRYLATE OLIGOMER (DI-HEMA TRIMETHYLHEXYL DICARBAMATE)	FILMFORMING	41137-60-4	[redacted]
ETHYLENE GLYCOL METHACRYLATE. 2-Hydroxyethyl Methacrylate (HEMA)	FILMFORMING	868-77-9/ 212-782-2	[redacted]
POLYMER ACRYLATE OLIGOMER	FILMFORMING	152187-46-	[redacted]
1-HYDROXYCYCLOHEXYL PHENYLKETONE, (1-Hydroxycyclohexyl) phenylmethanone (HYDROXYCYCLOHEXYL PHENYL KETONE)	BINDING	947-19-3/ 213-426-9	[redacted]
CI 15850	Colour		[redacted]
CI 15985	Colour		[redacted]
CI 17200	Colour		[redacted]
CI 77007	Colour		[redacted]
CI 77019	Colour		[redacted]
CI 77289	Colour		[redacted]
CI 77491	Colour		[redacted]
CI 77492	Colour		[redacted]
CI 77499	Colour		[redacted]
CI 77510	Colour		[redacted]
CI 77742	Colour		[redacted]
CI 77891	Colour		[redacted]

Physical/chemical characteristics and stability of the cosmetic product

L.Y.X. One Step Gel Polish is a monophasic UV-light curable polish for nails. The physical / characteristics of the ingredients are briefly described below along with the toxicological profile of the ingredients. Additional information is to be found in other parts of the product information dossier.

The finished cosmetic product is a colored and almost odorless liquid, for more information see product information file. The stability of the cosmetics product has been investigated using standard techniques for cosmetic products and found to be adequate under reasonably foreseeable storage conditions. The Period After Opening (12 M) is labeled on the product.

Microbiological quality

The product is water-fee and does not allow growth of microorganisms.

Impurities, traces, information about the packaging material

The packaging is suitable for its use. The purity of the colours is reported to be at the highest standard possible and those with purity restrictions for food use are also manufactured to be used in food.

The container is a standard white glass container with plastic applicator made of polypropylene and polyethylene. The polypropylene part fulfils the harmonized requirements on materials used for articles or components of articles intended to come into contact with food as described in the European Directive 2002/72/EC and other appropriate directives.[A] The LDPE part of the applicator complies with the applicable restrictions set by the REACH Regulation (CE) No 1907/2006, annex XVII "Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles" and following amendments, including Regulation (CE) No 552/2009. The Riblene is a Low Density Polyethylene (LDPE), produced with approved components (monomer, additives, etc.) under a third party certified ISO 9001:2008 Quality Management System.[B]

Normal and reasonably foreseeable use

L.Y.X. One-Step Gel Polish, 39669213, is packed in a 5 and 10 ml containers. The users of the product is carefully instructed to use the product on the nails and to prevent the skin to be exposed to the polish. A thin layer of the product should be applied to the nails which then is hardened for 30 s under a LED lamp. The LED lamp promote polymerization. Thereafter a second layer can be applied which is hardened for 60 s beneath the lamp. The nails are treated separately (one or two at a time) to facilitate the curing process beneath the lamp. This procedure will reduce the risks for inadvertent exposure to non-hardened nail polish. The users are also instructed not to overdose the polish.

The possibility of secondary exposure to the product (e.g. inhalation and ingestion) is unlikely or negligent. The product presentation does not mimic the presentation of food, which reduces the risks for the product to be ingested. The product should be kept away from children.

Exposure to the cosmetic product

There are no SCCS estimates on the daily exposure to the present type of nail polish.[2] A reasonable estimate would be 2 mg per sq cm once a week, i.e. ca 20 mg, which would be roughly 0.05 mg/kg bw /day). The normal and reasonably foreseeable use of the product is considered not to exceed this exposure.

Exposure to the substances

The relative daily exposure (mg/kg bw/day) of each ingredient can be calculated from daily exposure, the bioavailability and the concentration in the product. The bioavailability and systemic exposure is not known, but the penetration via the nail is usually considered negligible. In the table a typical exposure to the ingredients is given; in this case represented by the example colour shade no 5, which is covered in a separate safety report.

INGREDIENTS (INCI)	**CONC %**	**Weekly applied dose (20 mg)**	**Topical exposure (mg) per kg bw and day (20 mg/60kg 7 d)**
DI-HEMA TRIMETHYLHEXYL DICARBAMATE	[redacted]	[redacted]	[redacted]
ETHYLENE GLYCOL METHACRYLATE. 2-Hydroxyethyl Methacrylate (HEMA)	[redacted]	[redacted]	[redacted]

[A] Total Petrochemicals Research Feluy, December 7, 2009. Polypropylene PPH 10099 grade as produced in Europe.

[B] Versalis, Italy. Product stewardship regulatory statement. Revision May 21, 2012

POLYMER ACRYLATE OLIGOMER	[redacted]	[redacted]	[redacted]
1-HYDROXYCYCLOHEXYL PHENYLKETONE, (1-Hydroxycyclohexyl) phenylmethanone (HYDROXYCYCLOHEXYL PHENYL KETONE)	[redacted]	[redacted]	[redacted]
CI 77510	[redacted]	[redacted]	[redacted]
CI 77742	[redacted]	[redacted]	[redacted]
CI 77891	[redacted]	[redacted]	[redacted]
Total	**100**	**20**	**0.047**

Toxicological profile of the substances

The toxicological profile of the ingredients in the cosmetic product is briefly summarized below, with particular focus on local toxicity evaluation (skin and eye irritation) and skin sensitisation. Further information, detailing MSDS, raw material specifications, certificates and other technical information is available in the Product Information File, stored at the manufacturer, or in the open scientific literature cited below.

DI-HEMA TRIMETHYLHEXYL DICARBAMATE /HEMA /POLYMER ACRYLATE OLIGOMER

In the present product DI-HEMA Trimethylhexyl Dicarbamate (Polyurethane Acrylate Oligomer, CAS 41137-60-4), HEMA (Ethylene Glycol Methacrylate. 2-Hydroxyethyl Methacrylate, CAS 868-77-9, EC 212-782-2) and Polymer Acrylate Oligomer (CAS 152187-46-7) are used as filmforming substances.

Methacrylate ester monomers are used as artificial nail builders in nail enhancement products, They undergo rapid polymerization to form a hard material on the nail that is then shaped. While Ethyl Methacrylate has been used as the primary monomer in nail enhancement products, other methacrylate esters are also used in the polymerization in the formation of cross-links to build the stiff layer.

CIR has evaluated the safety of methacrylates.[3] The polymerization rates of methacrylate esters evaluated by CIR are within the same range as Ethyl Methacrylate. While data are not available on all of these methacrylate esters, the available data demonstrated little acute oral, dermal, or i.p. toxicity. In a 28-day inhalation study on rats, Butyl Methacrylate caused upper airway irritation; the NOAEL was 1801 mg/m3. In a 28-day oral toxicity study on rats, t-Butyl Methacrylate had a NOAEL of 20 mg/kg/day. Beagle dogs dosed with 0.2 to 2.0 g/kg/day of C12 to C18 methacrylate monomers for 13 weeks exhibited effects only in the highest dose group: weight loss, emesis, diarrhea, mucoid feces, or salivation were observed.

Butyl Methacrylate (0.1 M) and Isobutyl Methacrylate (0.1 M) are mildly irritating to the rabbit eye. HEMA is corrosive when instilled in the rabbit eye, while PEG-4 Dimethacrylate and Trimethylolpropane Trimethacrylate are minimally irritating to the eye. Dermal irritation caused by methacrylates is documented in guinea pigs and rabbits. In guinea pigs, HEMA, Isopropylidene-diphenyl Bisglycidyl Methacrylate, Lauryl Methacrylate, and Trimethylolpropane Trimethacrylate are strong sensitizers; Butyl Methacrylate, Cyclohexyl Methacrylate, Hexyl Methacrylate, and Urethane Methacrylate are moderate sensitizers; Hydroxypropyl Methacrylate is a weak sensitizer; and PEG-4 Dimethacrylate and Triethylene Glycol Dimethacrylate are not sensitizers. Ethylene Glycol Dimethacrylate was not a sensitizer in one guinea pig study, but was a strong sensitizer in another. There is cross-reactivity between various methacrylate esters in some sensitization tests. Inhaled Butyl Methacrylate, HEMA, Hydroxypropyl Methacrylate, and Trimethylolpropane Trimethacrylate can be developmental toxicants at high exposure levels (1000 mg/kg/day). None of the methacrylate ester monomers that were tested were shown to have any endocrine disrupting activity.

These methacrylate esters are mostly non-mutagenic in bacterial test systems, but weak mutagenic responses were seen in mammalian cell test systems. Chronic dermal exposure of mice to PEG-4 Dimethacrylate (25 mg, 2 x weekly for 80 weeks) or Trimethylolpropane Trimethacrylate (25 mg, 2 x weekly for 80 weeks) did not result in increased incidence of skin or visceral tumors. The carcinogenicity of Triethylene Glycol Dimethacrylate (5, 25, or 50%) was assessed in a mouse skin painting study (50 microl for 5 days/week for 78 weeks), but was not carcinogenic at any dose level tested. The Expert Panel was concerned about the strong sensitization and co-reactivity potential of the methacrylate esters reviewed in this report. However, data demonstrated the rates of polymerization of these Methacrylates were similar to that of Ethyl Methacrylate and there would be little monomer available for exposure to the skin.

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.[3] In the present product Di- HEMA Trimethyl Dicarbamate is used in a higher concentration than in the reported CIR assessment.[3] Furthermore, Kanerva (1989) did not found any of 7 patients occupationally sensitized to dental resin products to react to Di-HEMA Trimethylheyl Dicarbamate.[3] Also Tucker (1999)[3] 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.[3] Polymers and oligomers are even less likely to diffuse into the viable tissue and cause unwanted reactions.

According to CLP HEMA is classified as:

- Eye Irrit. 2, H319 : Causes serious eye irritation
- Skin Irrit. 2, H315 : Causes skin irritation
- Skin Sens. 1, H317 : May cause an allergic skin reaction,

whereas DI-HEMA Trimethyl Dicarbamate is not classified as an irritant or sensitizers.

In consideration of the animal toxicity data, the CIR Expert Panel decided that these methacrylate esters should be restricted to the nail and must not be in contact with the skin. Accordingly, these methacrylate esters are safe as used in nail enhancement products when skin contact is avoided.[3] Polymer Acrylate Oligomer is an already formed polymer without any toxicological relevance.

HYDROXYCYCLOHEXYL PHENYL KETONE

Hydroxycyclohexyl Phenyl Ketone (1-Hydroxycyclohexyl Phenylketone, (1-Hydroxycyclohexyl) phenylmethanone) CAS 947-19-3, EC 213-426-9. The substance is a photoinitiator and is reported to function as a binding substance in CosIng. Data in Epa reports the oral acute toxicity rat to be 2895 mg/kg and at the substance to be irritating to the eyes.[C] Noted classification as Eye Irrit 2 and Aquatic Chronic 1 in Echa.[D] Furthermore, DNEL (Deriverd No Effect Level) is 21.16 mg/m^3 and the oral NOAEL is set at 300 mg/kg bw/day,[E] as the oral administration of by gavage over a period of 3 months revealed no signs of systemic toxicity in male and female animals at dose levels up to 300 mg/kg bw/d.

CI 77510

CI 77510, Ferric Ammonium Ferrocyanide, is a synthetic blue pigment and allowed to be used in cosmetic products. The pigments must conform to the EU Regulation and be free from cyanide ions.

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

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

[E] 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

The supplier conforms purity in accordance to EU Cosmetic Directive, which corresponds to the requirement of the Regulation.[F]

CI 77742

Manganese violet, CI 77742 (CAS 10101-66-3), is an inorganic salt manganese ammonium pyrophosphate functioning as a colorant. The pigment is insoluble in water, whereas contact with strong alkali liberates ammonia. MSDS suggests irritation in eyes and in sensitive skin.[G] Manganese violet is approved as a colouring agent in EU and is also considered as safe by FDA for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.[H] The present quality is manufactured for use in food, drug, and cosmetic applications and are produced to the highest purity standards possible.

CI 77891

CI 77891, titanium dioxide, is used to impart a whiteness to color cosmetics and personal care products that are applied to the skin (including the eye area), nails, lips, and it helps to increase the opacity, and reduce the transparency of a product formula. Titanium Dioxide absorbs, reflects, or scatters light (including ultraviolet radiation in light), which can help protect products from deterioration. Titanium Dioxide has a long history of use in body care products. CI 77891 may be used without restriction according to the purity requirements that have been established for the quality of the same material used in foods. The present quality conforms to the purity requirements and is manufactured for use in food, drug and cosmetics and are produced to het highest purity standards possible (SunChemical Corporation, C47-051 01.01.05)

Titanium Dioxide is also allowed in EU to be used as a sunscreen active ingredient (25%) to protect against the adverse effects of ultraviolet radiation found in sunlight. The particles, irrespectively of size, are not considered to penetrate the skin and induce toxic effects.[4]

CI 17200

CI 17200 (CAS 3567-66-6, D&C Red 33) is a red azo dye with mw 467. The color is listed in Annex IV (colorants allowed in cosmetic products) and may be used without restriction.[1] As with other azo-colours it may be linked to discussions on adverse reactions when used at high concentrations in food.

CI 15985

The colouring agent CI 15985 (FDC yellow 6, E110, CAS 2783-94-0, EINICS/ELINCS 220-491-7) is a synthetic dye classed chemically as a monoazo color. The color is listed in Annex IV (colorants allowed in cosmetic products) and may be used without restriction when purity criteria as set out in Commission Directive 95/45/EC (E 110) is fulfilled. The present quality is supplied by the international company Sun Chemical Corporation and are manufactured for use in food, drugs and cosmetics and a produced to the highest purity standards possible (MSDS C19-6619, 01.01.03/C70-5270 01.01.03).

CI 15850

[F] C385410 PIGMENT 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

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

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

CI 15850 (Pigment Red 57:1, Red 7 Lake 5281-04-9) / Disodium 3-hydroxy-4-[(4-methyl-2-sulphonatophenyl)azo]-2-naphthoate and its insoluble barium, strontium and zirconium lakes, salts and pigments (CAS 5858-81-1, EINECS/ELINCS 227-497-9, E180, D&c Red No. 6, pigment red 57) is classed chemically as a monoazo color. The color is listed in Annex IV (colorants allowed in cosmetic products) and may be used without restriction when purity criteria as set out in Commission Directive 95/45/EC (E 180) is fulfilled. The present quality from SunChemical Corp include U.S. Certified Organic Colorants, Purified Inorganic Colorants, and Non-Certified Organic Colorants, and are produced to the highest purity standards possible (Code C19-6619, 01/01/03).

CI 77491, CI 77492, CI 77499

Iron Oxides are listed as red CI 77491 (CAS 1309-37-1 / 1317-61-9 / 1345-27-3 / 52357-70-7 / 1345-25-1, E172(2)), yellow CI 77492 (CAS 51274-00-1 / 1345-27-3 / 20344-49-4 / 52357-70-7, E172(2)) and black CI 77499 (CAS 12227-89-3 / 1309-37-1 / 1317-61-9 / 1345-25-1 / 1345-27-3 / 52357-70-7) in Annex IV, Part I (colouring agent allowed for use in cosmetic products) of the Cosmetics regulation and may be used without restriction when purity requirements are fulfilled.

The Joint FAO/WHO Expert Committee on Food Additives has established an Acceptable Daily Intake of 0-0.5 mg/kg body weight for Iron Oxides. When used in cosmetic products in the European Union, the ingredients must listed on the label by its CI (Color Index) number.

These compounds are used as coloring pigments in a variety of applications. Iron oxides and iron hydroxides are produced synthetically and consist essentially of anhydrous and/or hydrated iron oxides. The range of hues includes yellows, reds, browns and blacks. Food quality iron oxides are primarily distinguished from technical grades by the comparatively low levels of contamination by other metals.

Because some of the starting materials for synthetic Iron Oxide may come from the earth there may be trace amounts of heavy metals present. The levels of heavy metals in Iron Oxides are regulated by the FDA and EU, and the small amounts that may eventually be in cosmetic or personal care products do not pose a risk to human health. The following criteria is applied to iron oxides on cosmetics in EU (by total dissolution):

- Water soluble matter: Not more than 1,0 %
- Arsenic: Not more than 5 mg/kg
- Barium: Not more than 50 mg/kg
- Cadmium: Not more than 5 mg/kg
- Chromium: Not more than 100 mg/kg
- Copper: Not more than 50 mg/kg
- Lead: Not more than 20 mg/kg
- Mercury: Not more than 1 mg/kg
- Nickel: Not more than 200 mg/kg
- Zinc: Not more than 100 mg/kg

The present raw materials are supplied by the international company Sun Chemical Corporation and are manufactured for use in food, drugs and cosmetics and a produced to the highest purity standards possible (MSDS C33-5198 08.21.03 /C33-115 01.01.05/C33-8073 01.01.05/oxide 08.08.12, C33-5138 01.01.03).

CI 77019

Mica (CAS 12001-26-2, EINECS 310-127-6) (muscovite) belongs to the mica-group of earth minerals and typically contains 43-48% SiO2 and 30-36% Al2O3. Mica is used as an opacifier and to

give products sparkle and shine. Mica based pigments are also approved as food additive.[I] As it is obtained from natural sources it can be subjected to a sterilization process (by ethylene oxide) in order to reduce its microbiological content to an acceptable level. CIR Expert Panel has concluded that mica and other similar silicates are safe as currently used in cosmetic formulations.[5]

CI 77289

Chromium hydroxide CI 77289 CAS 12001-99-9) is a mineral colorant Cr(OH)3 used in a variety of products. This ingredient contains trivalent chromium, a form of chromium that functions as an essential trace element in human metabolism. The pigment is allowed to be used in EU cosmetics and should be free from chromate ion. The present quality is manufactured by SunChemical Corporation and is produced to the highest purity standards possible (C61-6735 01.01.03).

CI 77007

This substance, named lazurite or ultramarine, is identified in the Colour Index by Colour Index Constitution Number CI 77007 (CAS 12769-96-9 / 1302-83-6 / 57455-37-5) as a mineral-derived blue pigment composed of sodium, aluminum, silicate and sulfate. Ultramarines may be produced synthetically.

Undesirable effects and serious undesirable effects

There are no reports on adverse skin reactions or other undesirable effects from the use of the present product. Instead case reports suggest the product to be safer than similar nail polishes. Nail hardeners have been supplied to the market in the long term although some of the have been shown to cause serious adverse skin reactions and been withdrawn from the Swedish market as is was found to pose a chemical risk due to a high amount of sensitizing acrylate monomer.[J] However, it is not clear which monomer the withdrawal refers to and methylmetacrylate is not recommended by neither CIR, nor FDA to be used in certain cosmetics for the nails.

After its launch, the cosmetic product will be further monitored by the responsible person, a distributor or relevant national authorities. This obligation arises from Articles 6 and 23 of the Regulation. If any serious undesired effects on consumer health appear, the relevant authorities will be informed about it without any delay and corrective measures will be adopted in accordance with the Regulation. At the same time, the responsible person will notify the Safety Assessor about this fact who will update the Cosmetic Product Safety Report based on the new findings and the adopted corrective measures.

Information on the cosmetic product

L.Y.X. One-Step Gel Polish, 39669213 has not been tested on animals, but similar products have been available for long on the market without any evidence of safety issues other than contact eczema if exposed to the skin. Furthermore, in a pilot study on 14 patients only one of the patients, previously diagnosed for allergic contact dermatitis due to exposure to polyphasic 3-steps gels, reacted with erythema and pruritus on left index finger after treatment with the present gel polish.[K]

[I] http://www.fda.gov/ForIndustry/ColorAdditives/GuidanceComplianceRegulatoryInformation/ColorAdditiveListingRegulations/ListingofColorAdditivesExemptfromCertification/ucm108158.htm

[J] http://www.cosmeticobs.com/pro/news/recalls-of-products/recalls-of-products-august-8-2014-centifolia-hema-&-depend-2534. , http://www.lakemedelsverket.se/Alla-nyheter/NYHETER-2014/Lakemedelsverket-forbjuder-forsaljningen-av-nagellacket-Depend-GelLack/ Accessed dec 2014.

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

Other Swedish case reports also suggest the product to be safe for use in consumers with allergy to 3-steps nail hardeners without any evidence of adverse reactions after usages several times.[L]

[L] Testperson A, började använda LYX One Step 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.

B. Cosmetic product safety assessment

Assessment conclusion

The cosmetic product, including up to 55 different shades, assessed in the present report, L.Y.X. One-Step Gel Polish, 39669213, 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 polishes for adults are used to provide a hard colored layer on the nail plate. In total 55 number of different shades are evaluated, containing different proportions of the individual ingredients to achieve the desired cosmetic properties, such as e.g. viscosity and colour. Thus, the safety evaluation is made on concentrations which are allowed to vary ±5% without affecting the present reasoning and conclusion.

The formed layer on the nail plate is composed by reacting together the acrylate ester monomers in a suitable mix with pigments and polymer acrylate oligomer using a photoinitiator. The reaction is activated by the use of a light emitting diode (LED) lights, or equivalent light source. Also ordinary outside UV-light will harden the layer. The nail polishes do 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.[3] Proper toxicological data on the important metacrylate ester monomers and also the other ingredients (Hydroxycyclohexyl Phenyl Ketone, Polymer Acrylate Oligomer, CI 15850, CI 15985, CI 17200, CI 77007, CI 77019, CI 77289, CI 77491, CI 77492, CI 77499, CI 77510, CI 77742 and CI 77891) have been retrieved by careful data search in relevant data bases (e.g. PubMed, ToxNet, CosIng)[M] and been obtained from the raw material suppliers (see data on the Toxicological profile of the ingredients denoted in Part A). The colour pigments are allowed to be used in the present type of product. No further data which could reverse the important assessment made by CIR has been

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

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

[M] 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

[M]SunChemical. PERFORMANCE PIGMENTS 5000 SPRING GROVE AVENUE CINCINNATI, OH, USA 45232

identified in the literature since the publication of the CIR report. The purity of the ingredients and the packaging are satisfactory.

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[3]). 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.[3]

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,[N] 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.[3] 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.[3] In the present product Di- HEMA Trimethyl Dicarbamate is used in a higher concentration than in the reported CIR assessment.[3] Furthermore, Kanerva (1989) did not found any of 7 patients occupationally sensitized to dental resin products to react to Di-HEMA Trimethylheyl Dicarbamate.[3] Also Tucker (1999)[3] 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.[3]

The formed polymers and the polymer acrylate oligomer are even less likely to diffuse into the viable tissue and cause unwanted reactions and are therefore considered to be without toxicological significance.

It is concluded that sufficient information is obtained on the ingredients and the formulation L.Y.X Cosmetics One Step Gel Polish, 55 different shades, 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 L.Y.X. One-Step Gel Polish, 39669213, carries

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

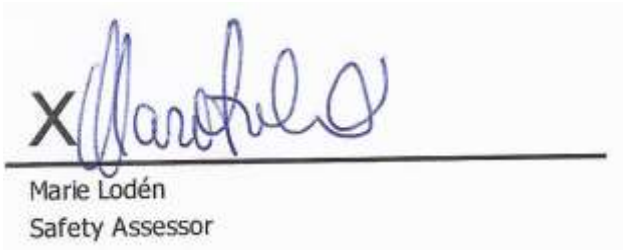
the appropriate warnings and directions for safe use which also are applied to the product. One Step Gel should not to be used outside the nail plate but exposure to the skin, although not intended – may sometimes be inevitable in normal and reasonably foreseeable conditions of use. If the eyes are exposed 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.[O] 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".[P]

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.[Q] 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: February 20, 2015
Signature:



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

[O] 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

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

[Q] 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.

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