
Safety Assessment of Polyurethanes as Used in Cosmetics

Status: Scientific Literature Review for Public Comment
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All interested persons are provided 60 days from the above date to comment on this safety assessment and to identify additional published data that should be included or provide unpublished data which can be made public and included. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings, will be available at the CIR office for review by any interested party and may be cited in a peer-reviewed scientific journal. Please submit data, comments, or requests to the CIR Director, Dr. Lillian J. Gill.

The 2017 Cosmetic Ingredient Review Expert Panel members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Ronald A. Hill, Ph.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Director is Lillian J. Gill, D.P.A. This report was prepared by Lillian C. Becker, Scientific Analyst/Writer.

INTRODUCTION

This is a review of the available scientific literature and unpublished data provided by industry relevant to assessing the safety of polyurethanes as used in cosmetics. According to the *International Cosmetic Dictionary and Handbook (Dictionary)*, the functions of these 66 ingredients include artificial nail builders, binders, film formers, hair fixatives, plasticizers, and surface modifiers (Table 1).¹ The ingredients in this group are:

| | | |
|-----------------|-----------------|-----------------|
| Polyurethane-1 | Polyurethane-25 | Polyurethane-51 |
| Polyurethane-2 | Polyurethane-26 | Polyurethane-52 |
| Polyurethane-4 | Polyurethane-27 | Polyurethane-53 |
| Polyurethane-5 | Polyurethane-28 | Polyurethane-54 |
| Polyurethane-6 | Polyurethane-29 | Polyurethane-55 |
| Polyurethane-7 | Polyurethane-32 | Polyurethane-56 |
| Polyurethane-8 | Polyurethane-33 | Polyurethane-57 |
| Polyurethane-9 | Polyurethane-34 | Polyurethane-58 |
| Polyurethane-10 | Polyurethane-35 | Polyurethane-59 |
| Polyurethane-11 | Polyurethane-36 | Polyurethane-60 |
| Polyurethane-12 | Polyurethane-39 | Polyurethane-61 |
| Polyurethane-13 | Polyurethane-40 | Polyurethane-62 |
| Polyurethane-14 | Polyurethane-41 | Polyurethane-63 |
| Polyurethane-15 | Polyurethane-42 | Polyurethane-64 |
| Polyurethane-16 | Polyurethane-43 | Polyurethane-65 |
| Polyurethane-17 | Polyurethane-44 | Polyurethane-66 |
| Polyurethane-18 | Polyurethane-45 | Polyurethane-67 |
| Polyurethane-19 | Polyurethane-46 | Polyurethane-68 |
| Polyurethane-20 | Polyurethane-47 | Polyurethane-69 |
| Polyurethane-21 | Polyurethane-48 | Polyurethane-70 |
| Polyurethane-23 | Polyurethane-49 | Polyurethane-71 |
| Polyurethane-24 | Polyurethane-50 | Polyurethane-72 |

The polyurethane ingredients in this report are copolymers comprising, in part, carbamate (i.e., urethane) linkages.

Several precursors and moieties of these polymers have been reviewed by the Cosmetic Ingredient Review (CIR) Expert Panel (Panel). Table 2 lists the previously reviewed ingredients and connects them to the relevant polyurethanes in this report. Acetic Acid, 1,2-Butanediol, Butylene Glycol, Ethylhexylglycerin, Hexylene Glycol, Glycine Soja (Soybean) Oil, Hexylene Glycol, Adipic Acid, Hexanedioic Acid, Bis-Hydroxyethoxypropyl Dimethicone, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isostearic Acid (Sorbitan Isostearate), Methyl Gluceth-10, Polyethylene, Triethylene Glycol, Toluene, and PEGs ≥ 4 are safe as used.²⁻¹⁸ Alkyl PEG Ethers, Diethanolamine, Propylene Glycol, and PPGs are safe when formulated to be non-irritating.¹⁹⁻²¹ Isopropanolamine is safe as used if not used in products containing *N*-nitrosating agents.^{3,22} Hydroxypropyl Methacrylate, HEMA (Hydroxyethyl Methacrylate), and Isopropylidenediphenyl Bisoxhydroxypropyl Methacrylate are safe in nail enhancement products when skin contact is avoided.²³ PPG-30 Butyl Ether was found to be safe when formulated to avoid irritation in a 2001 safety assessment; this report (with the addition of PPG-3 Butyl Ether) is currently under re-review and an insufficient data announcement has been issued.^{24,25} 1,4-Butanediol, 1,5-Pentanediol, and Hexanediol are currently under review by the Panel; an insufficient data announcement has been issued.^{26,27} Chemicals and cosmetic ingredients that have not been reviewed by the Panel and are precursors or moieties of the polyurethanes in this safety assessment are presented in Table 3.

Quantification of residual monomers in the cosmetic ingredients addressed in this report is important for determining safety (Table 4). For example, these ingredients are copolymers, each of which is synthesized, in part, from isocyanate analogs.^{28,29} Exposure to diisocyanates in the work place is one of the leading causes of occupational asthma and other related issues; diisocyanates have also been associated with irritant and allergic contact dermatitis, as well as skin and conjunctival irritation.

The ingredients in this report are not isocyanates, but are end products of a polymerization process that includes isocyanate or an analog of isocyanate as one of the starting materials (monomers). The CIR Panel has reviewed Hexamethylene diisocyanate (HDI) polymers, which are polymers that also contain isocyanates, and found that 17 of these ingredients are safe in cosmetics in the present practices of use and concentration and that the available data are insufficient to make a determination that 2 of these ingredients are safe.³⁰

Data on polyurethanes that are not listed in the *Dictionary* as cosmetic ingredients have been included below for potential supporting information.

CHEMISTRY

Definition and Structure

The structures, definitions, and functions of the polyurethanes in this safety assessment are provided in Table 1. Some of the definitions may give insight into the method of manufacture.

The polyurethane ingredients in this report are copolymers comprising, in part carbamate (i.e., urethane) linkages (Figure 1). Polyurethanes are formed by reacting a polyol (e.g., a glycol) with a diisocyanate or polyisocyanate.

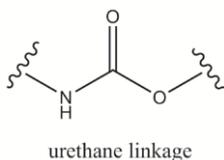


Figure 1. Urethane residue

Some of these polymers are linear, but when multi-functional monomers (e.g., glycerin) are used as reactants, branched or cross-linked structures are probable. The degree of polymerization of these ingredients can be controlled to obtain a product having a desired functionality, such as rheology modifier. Accordingly, the molecular weights and molecular volumes of these ingredients could vary widely, unless otherwise noted in specifications. These polymers, by virtue of their monomers, contain both hydrophilic and hydrophobic groups. The ratio of hydrophilic and hydrophobic groups may vary within one ingredient name. In the absence of ingredient-explicit specifications, estimating some of the chemical and physical properties of these ingredients is challenging. These ingredients can potentially range from liquid to solid, soluble to insoluble, and non-penetrating to readily penetrating the skin. Aside from the potential presence of a diisocyanate or end-capping agent residue, these ingredients are likely to be similar to unmodified polyurethane-type polymers.

Physical and Chemical Properties

Chemical and physical properties are provided in Table 5.

A supplier reported that Polyurethane-14 was supplied in a 30% aqueous ethanol solution at a concentration of 28% solids.³¹ Based on the monomer composition and general hydrophobic properties of this polymer, it is not expected to be significantly soluble in water. It is not expected to undergo significant hydrolysis at a pH range of 4-9. Polyurethane-14 partitions primarily in the organic phase in octanol-water separation systems.

Another supplier reported that Polyurethane-35 was supplied in a 40% aqueous solution. Based on the high molecular weight (>1000 g/mol) and predominantly hydrophobic structure, Polyurethane-35 is expected to have low solubility in water. This polymer is stable under normal environmental conditions and will not degrade in cosmetic products at 5%-15%.

A supplier reported that the particle size of Polyurethane-62 was 50-1000 μm and the average molecular weight is >70,000 Da.³² Polyurethane-62 is stable under normal environmental conditions and yields no degradation products under normal conditions of use.

Method of Manufacture

Polyurethanes are formed by reacting a polyol (e.g., a glycol) with a diisocyanate or polyisocyanate.

The U.S. Food and Drug Administration (FDA) stipulates that polyurethane resins that are used in adhesives that may come in contact with food must be produced by:

- (1) reacting diisocyanates with one or more of the polyols or polyesters named in this paragraph [this is a large list and is not provided here], or
- (2) reacting the chloroformate derivatives of one or more of the polyols or polyesters named in this paragraph with one or more of the polyamines named in this paragraph, or
- (3) reacting toluene diisocyanate or 4,4' methylenebis(cyclohexylisocyanate) with:
 - (i) one or more of the polyols or polyesters named in this paragraph [not listed here] and with either *N*-methyl-diethanolamine and dimethyl sulfate or dimethylolpropionic acid and triethylamine, or
 - (ii) a fumaric acid-modified polypropylene glycol or fumaric acid-modified tripropylene glycol, triethylamine, and ethylenediamine, or
- (4) reacting meta-tetramethylxylene diisocyanate with one or more of the polyols and polyesters listed in this paragraph [not listed here] and with dimethylolpropionic acid and triethylamine, *N*-methyl-diethanolamine, 2-dimethylaminoethanol, 2-dimethylamino-2-methyl-1-propanol, and/or 2-amino-2-methyl-1-propanol. [21CFR175.105]

Impurities/Constituents

4,4'-Diaminodiphenylmethane (MDA) is classified as a carcinogen and is used in the production of methylene diphenyl diisocyanate (MDI).³³ MDI, or an analog, is a component of some of the polyurethanes in this safety assessment (e.g., Polyurethane-2, -17, -29, -33, -40, -60, and -61).¹ No residual MDA was detected in the production of MDI.³³

Furthermore, any remaining MDI would be expected to be further reduced when MDI is further processed in the manufacture of polyurethanes.

Medical devices constructed of polyurethane (compositions not provided) were tested for the presence of isocyanates using Swype pads (detection limit 3-5 µg).³⁴ Isocyanates were detected in adhesive films, wound dressings, foam-backed electrodes, adhesive oximetry sensors, and phototherapy eye protectors, but not in catheters, feeding tubes, chest drains, limb boards, plaster/band aids, disposable diapers, and suction catheters.

USE **Cosmetic**

The safety of the cosmetic ingredients addressed in this assessment is evaluated based on data received from the FDA and the cosmetics industry on the expected use of this ingredient in cosmetics. Use frequencies of individual ingredients in cosmetics are collected from manufacturers and reported by cosmetic product category in FDA's Voluntary Cosmetic Registration Program (VCRP) database. Use concentration data are submitted by the cosmetic industry in response to a survey, conducted by the Personal Care Products Council (Council), of maximum reported use concentrations by product category.

According to VCRP survey data received in 2016, Polyurethane-11 was reported to be used in 272 formulations, 261 in leave-on formulations and 11 in rinse-off formulations (Table 6).³⁵ An additional 15 ingredients had reported uses in 30 or fewer formulations.

The VCRP has an entry for "polyurethane" with 15 uses in a pattern similar to the polyurethanes in this safety assessment. It is unknown to what extent, if any, "polyurethane" is the same as, or similar to, one or more of the polyurethane ingredients in this safety assessment.

The results of the concentration of use survey conducted by the Council in 2016 indicate that Polyurethane-1 has the highest reported maximum concentration of use; it is used at up to 15% in nail products.³⁶ The highest maximum concentration of use reported for products resulting in leave-on dermal exposure is 7.5% for Polyurethane-33 in the category of other skin care preparations. The other reported concentrations of use were at up to 9% (in nail, hair, or rinse-off dermal preparations) or less.

In some cases, uses were reported to the VCRP, but concentration of use data were not provided. For example, Polyurethane-7 was reported to be used in 14 cosmetic formulations, but no use concentration data were reported. In other cases, no uses were reported to the VCRP, but concentration of use data were received from industry; for example, Polyurethane-10 had no reported uses in the VCRP, but use concentrations in the categories of mascara; tonics, dressings, and other hair grooming aids; and foundations were provided in the industry survey. Therefore, it should be presumed there is at least one use in every category for which a concentration is reported.

The ingredients not in use according to the VCRP and industry survey are listed in Table 7.

Polyurethane-1, -2, -10, -11, -14, -33, -34, -35, and -40 were reported to be used in products that are applied around the eye at up to 7% in mascara. Polyurethane-11, -15, and -34 were reported to be used in products that may be ingested and come in contact with mucous membranes at up to 2.9% in lipsticks.

Several of the polyurethanes are used in cosmetic sprays and could possibly be inhaled. Polyurethane-1, -6, -11, -14, -18, -24, and -33 were reported to be used in spray products, at a maximum of 6% in pump hair sprays. These ingredients are reportedly used at concentrations up to 6% in spray products. In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters >10 µm.³⁷⁻⁴⁰ Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and bronchial regions and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount.^{37,39} Polyurethane-2, -7, -11, -14, -35, and -40 were reported to be used in face powders at concentrations up to 3.2%. Conservative estimates of inhalation exposures to respirable particles during the use of loose-powder cosmetic products are 400-fold to 1000-fold less than protective regulatory and guidance limits for inert airborne respirable particles in the workplace.⁴¹⁻⁴³

Polyurethane-17 and -21 are restricted in Europe in that the amount of residual trialkylamines is limited to 2.5% in ready-for-use preparations.^{44,45} Also, trialkylamines are not to be used with nitrosating systems, have a minimum purity of 99%, a maximum secondary amine content of 0.5%, a maximum nitrosamine content of 50 µg/kg, and must be kept in nitrite-free containers.

Non-Cosmetic

Table 8 gives the provisions in the Code of Federal Regulations (CFR) for the use of polyurethanes that come in contact with food, use in food packaging, and use in medical devices.

Polyurethane foam or porous polyurethane films are used to make wound dressings.⁴⁶⁻⁴⁸ Polyurethane prostheses are being developed for soft tissue scaffolds of blood vessels and tissues of the cardiovascular system; some of these are impregnated with drugs to control smooth muscle cell proliferation.⁴⁹ Polyurethanes are used to coat medical implants, including percutaneous leads, catheters, tubing, and intra-aortic balloons.^{50,51} Polyurethane has been used as a coating on breast implants.⁵²

Sprayed polyurethane foam is used for roofing material and other protective applications such as truck bed liners.⁵³

TOXICOKINETIC STUDIES

Toxicokinetic studies were not found in the published literature and no unpublished data were submitted.

TOXICOLOGICAL STUDIES

Acute Dose Toxicity

Acute dermal and inhalation toxicological studies were not found in the published literature and no unpublished data were submitted.

Oral

The oral LD₅₀ of Polyurethane-35 in rats was reported to be 4890 mg/kg.⁵⁴ The test was conducted in accordance with the Organisation for Economic Co-operation and Development test guideline (OECD TG) 423. No further details were provided.

Short-Term Toxicity Studies

Short-term dermal and inhalation toxicity studies were not found in the published literature and no unpublished data were submitted.

Oral

Male Swiss albino mice (n=6) were received a polyurethane solution (0, 2, 5, or 10 mg/kg in saline) by gavage daily for 10 days.⁵⁵ The polyurethane tested was manufactured with a natural triol, diisocyanate, and olive oil that were added to a solution of tween 80 while stirring at room temperature. The polyurethane particles had a diameter of 249 ± 5.7 nm and a polydispersity index (PDI) of 0.3 ± 0.04 . All mice survived the study and there were no behavioral changes observed. At necropsy, there were no differences in body weights or organ weights between the groups. There was increased visceral fat accumulation in the treated mice in all groups compared to controls. The lungs of mice in the 5 and 10 mg/kg/day groups (4 and 6 mice, respectively) showed inflammation, and inflammatory infiltrate was observed in all treatment groups. The kidneys of mice in the 5 and 10 mg/kg/day groups (5 and 6 mice, respectively) showed glomerular necrosis and glomerular atrophy. Histological examination of the adipose tissue did not reveal any alterations in morphology in any group. Oral polyurethane administration induced an increase in alanine aminotransferase (ALT) levels (58 ± 7.7 , 69 ± 15 , and 78 ± 4.5 IU/L in the 2, 5, and 10 mg/kg groups, respectively, versus control mice 34 ± 3.5 IU/L). Mice in the 5 and 10 mg/kg groups also showed an increase in alkaline phosphatase activities (ALP) (20 ± 4 and 24 ± 2 IU/L, respectively, versus controls, 8.5 ± 1.7 IU/L). Hematological evaluation revealed no changes in any parameter. There was an increase in TNF- α level (approximately 80-fold) in mice in the 10 mg/kg group. The authors concluded that oral administration of polyurethane particles generates an inflammation response in mice.

Subchronic Toxicity Studies

Subchronic toxicity studies were not found in the published literature and no unpublished data were submitted.

Chronic Toxicity Studies

Chronic toxicity studies were not found in the published literature and no unpublished data were submitted.

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY (DART) STUDIES

DART studies were not found in the published literature and no unpublished data were submitted.

GENOTOXICITY STUDIES

In Vitro

Polyurethane-35 was not mutagenic in a bacterial reverse mutation assay conducted in accordance with OECD TG 471 (Bacterial Reverse Mutation Test).⁵⁴ No further information was provided.

In Vivo

In vivo genotoxicity studies were not found in the published literature and no unpublished data were submitted.

CARCINOGENICITY STUDIES

Carcinogenicity studies were not found in the published literature and no unpublished data were submitted.

DERMAL IRRITATION AND SENSITIZATION STUDIES

Irritation

In Vitro

In an in vitro dermal corrosion assay conducted in accordance with OECD TG 431 (In Vitro Skin Corrosion: Human Skin Model Test), Polyurethane-35 was not corrosive.⁵⁴ No further information was provided.

Animal

In a skin irritation study conducted in accordance with OECD TG 404 (Acute Dermal Irritation/Corrosion), Polyurethane-35 (40% in water) was slightly irritating to the skin of rabbits (n=3).⁵⁴ The author noted that the removal of the patch was not possible without altering the response or the integrity of the epidermis in one rabbit. All irritation effects were reversible within 7 days. The irritant effects were not sufficient to warrant classification of the notified polymer as a skin irritant. No further information was provided.

Human

Human irritation studies were not found in the published literature and no unpublished data were submitted

Sensitization

Animal

In Buehler and maximization tests conducted in accordance with OECD TG 406 (Skin Sensitization), Polyurethane-35 showed no evidence of sensitization.⁵⁴ No further information was provided.

Human

Human sensitization studies were not found in the published literature and no unpublished data were submitted

OCULAR IRRITATION STUDIES

Animal

In an eye irritation study conducted in accordance with OECD TG 405, two of the rabbits (n=3) exhibited redness in the conjunctivae in one treated eye 1 h after instillation of Polyurethane-35, and the remaining rabbit exhibited these effects in 1 treated eye 24 h after instillation.⁵⁴ All irritation responses were reversible within 48 h and were not sufficient to warrant classification of the polymer as an eye irritant.

Human

Human ocular irritation studies were not found in the published literature and no unpublished data were submitted

SUMMARY

This is a review of the available scientific literature and unpublished data provided by industry relevant to assessing the safety of polyurethanes as used in cosmetics. According to the *Dictionary*, the functions of these 66 ingredients include artificial nail builders, binders, film formers, hair fixatives, plasticizers, and surface modifiers. The polyurethane ingredients in this report are copolymers, which are comprised of carbamate (i.e., urethane) linkages within the respective polymer backbone.

Quantification of residual monomers or precursors of concern in the final cosmetic ingredient is important for determining safety. For example, the ingredients in this report are copolymers, each of which is synthesized, in part, from isocyanate analogs. Exposure to diisocyanates in the work place is one of the leading causes of occupational asthma.

In the production of MDI, there is no evidence of residual MDA, which is classified as a carcinogen. Furthermore, processing of MDI in the manufacture of polyurethanes would further consume any undetected residual MDA and would therefore be negligible in the final polymer.

According to the VCRP survey data received in 2016, Polyurethane-11 was reported to be used in 272 formulations, 261 in leave-on formulations and 11 in rinse-off formulations. The other ingredients that had reported uses were reported to be used in 30 or fewer formulations. The results of the concentration of use survey conducted by the Council in 2016 indicate Polyurethane-1 has the highest reported maximum concentration of use; it is used at up to 15% in nail products. The highest maximum concentration of use reported for products resulting in leave-on dermal exposure is 7.5% Polyurethane-33 in the category of other skin care preparations. The rest of the ingredients that had reported concentrations of use are used at up to 9% (in nail, hair, or rinse-off dermal preparations) or less.

The oral LD₅₀ of Polyurethane-35 in rats was reported to be 4890 mg/kg.

The oral administration of polyurethane particles at 5 and 10 mg/kg/day for 10 days generated an inflammation response in mice. There was increased visceral fat accumulation in the treated mice in all groups (2, 5, 10 mg/kg/d) compared to controls. The lungs of mice in the 5 and 10 mg/kg/day groups showed inflammation, and inflammatory infiltrate was observed in all treatment groups.

Polyurethane-35 was not mutagenic in a bacterial reverse mutation assay.

In an in vitro dermal corrosion assay, Polyurethane-35 was not corrosive to human skin cells.

In a skin irritation study, Polyurethane-35 (40% in water) had a slight irritating effect to the skin of rabbits. All irritation effects were reversible within 7 days.

In Buehler and maximization tests, Polyurethane-35 showed no evidence of sensitization.

In an eye irritation study conducted with rabbits, the irritant effects were not sufficient to warrant classification of Polyurethane-35 as an eye irritant.

DATA NEEDS

CIR welcomes any toxicological data, especially from dermal exposure for these ingredients. Chemical and physical properties are also desirable. These data would supplement the current information and help the CIR Expert Panel assess the safety of the use of these ingredients in cosmetics. These data include, but are not limited to:

- Chemical and physical properties, including molecular weight
- Method of manufacture
- Impurity data, especially on the monomers
- Dermal penetration
- Chronic dermal toxicity
- Inhalation toxicity
- Carcinogenicity
- Dermal irritation and sensitization

TABLES

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.^{1, CIR Staff}

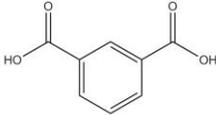
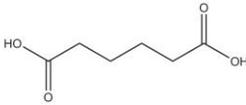
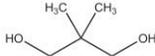
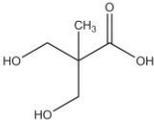
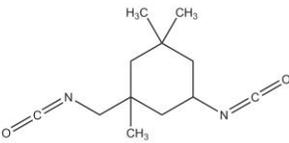
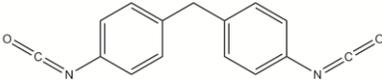
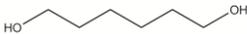
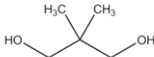
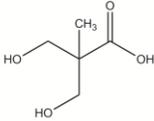
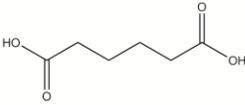
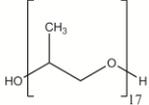
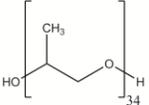
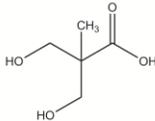
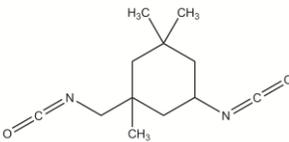
| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|-----------------------|--|------------------------------------|
| Polyurethane-1 | <p>Polyurethane-1 is a copolymer of isophthalic acid, adipic acid, hexylene glycol, neopentyl glycol, dimethylolpropanoic acid, and isophorone diisocyanate monomers. [Monomers:]</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p>isophthalic acid</p> </div> <div style="text-align: center;">  <p>adipic acid</p> </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;">  <p>hexylene glycol</p> </div> <div style="text-align: center;">  <p>neopentyl glycol</p> </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;">  <p>dimethylolpropanoic acid</p> </div> <div style="text-align: center;">  <p>isophorone diisocyanate</p> </div> </div> | Binder; film former; hair fixative |
| Polyurethane-2 | <p>Polyurethane-2 is a copolymer of hexylene glycol, neopentyl glycol, adipic acid, saturated methylene diphenyldiisocyanate (SMDI), and dimethylolpropanoic acid monomers. [Monomers:]</p> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;">  <p>SMDI</p> </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;">  <p>hexylene glycol</p> </div> <div style="text-align: center;">  <p>neopentyl glycol</p> </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;">  <p>dimethylolpropanoic acid</p> </div> <div style="text-align: center;">  <p>adipic acid</p> </div> </div> | Film former |
| Polyurethane-4 | <p>Polyurethane-4 is a copolymer of PPG-17, PPG-34, isophorone diisocyanate and dimethylolpropanoic acid monomers. [Monomers:]</p> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;">  <p>PPG-17</p> </div> <div style="text-align: center;">  <p>PPG-34</p> </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;">  <p>dimethylolpropanoic acid</p> </div> <div style="text-align: center;">  <p>isophorone diisocyanate</p> </div> </div> | Film former |

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.^{1, CIR Staff}

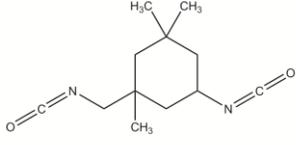
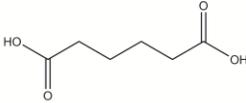
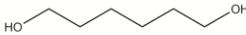
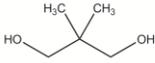
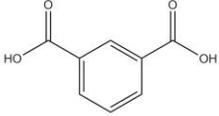
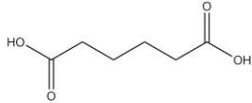
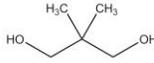
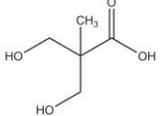
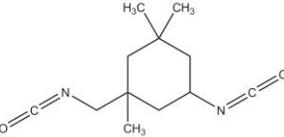
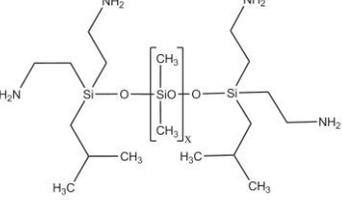
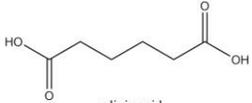
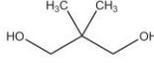
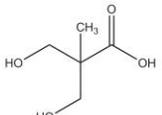
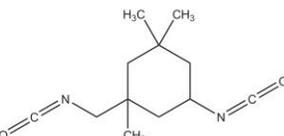
| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|-----------------------|--|------------------------------------|
| Polyurethane-5 | <p data-bbox="256 216 1287 264">Polyurethane-5 is a copolymer of hexylene glycol, neopentyl glycol, adipic acid and isophorone diisocyanate monomers. [Monomers:]</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p data-bbox="618 415 760 436">isophorone diisocyanate</p> </div> <div style="text-align: center;">  <p data-bbox="930 415 995 436">adipic acid</p> </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;">  <p data-bbox="621 541 719 562">hexylene glycol</p> </div> <div style="text-align: center;">  <p data-bbox="914 541 1011 562">neopentyl glycol</p> </div> </div> | Film former |
| Polyurethane-6 | <p data-bbox="256 569 1317 642">Polyurethane-6 is a copolymer of isophthalic acid, adipic acid, hexylene glycol, neopentyl glycol, dimethylolpropanoic acid, isophorone diisocyanate and bis-ethylaminoisobutyl-dimethicone monomers. [Monomers:]</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p data-bbox="597 772 686 793">isophthalic acid</p> </div> <div style="text-align: center;">  <p data-bbox="898 772 963 793">adipic acid</p> </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;">  <p data-bbox="597 898 686 919">hexylene glycol</p> </div> <div style="text-align: center;">  <p data-bbox="881 898 979 919">neopentyl glycol</p> </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;">  <p data-bbox="589 1098 735 1119">dimethylolpropanoic acid</p> </div> <div style="text-align: center;">  <p data-bbox="881 1119 1027 1140">isophorone diisocyanate</p> </div> </div> <div style="text-align: center; margin-top: 10px;">  <p data-bbox="695 1371 898 1392">bis-ethylaminoisobutyl-dimethicone</p> </div> | Binder; film former; hair fixative |
| Polyurethane-7 | <p data-bbox="256 1392 1190 1465">Polyurethane-7 is a copolymer of hexylene glycol, neopentyl glycol, adipic acid, isophorone diisocyanate and dimethylolpropanoic acid monomers. [Monomers:]</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p data-bbox="768 1560 833 1581">adipic acid</p> </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;">  <p data-bbox="597 1669 686 1690">hexylene glycol</p> </div> <div style="text-align: center;">  <p data-bbox="881 1669 979 1690">neopentyl glycol</p> </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;">  <p data-bbox="589 1858 735 1879">dimethylolpropanoic acid</p> </div> <div style="text-align: center;">  <p data-bbox="881 1879 1027 1900">isophorone diisocyanate</p> </div> </div> | Film former |

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.^{1, CIR Staff}

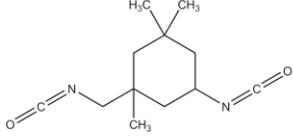
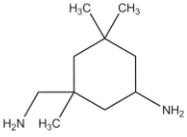
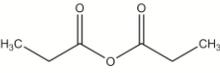
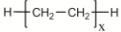
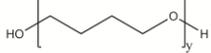
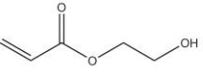
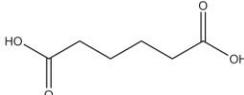
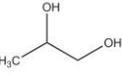
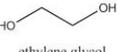
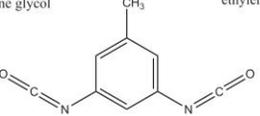
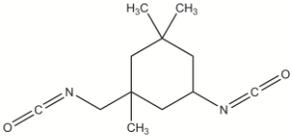
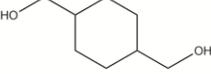
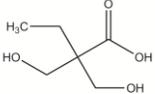
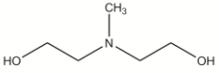
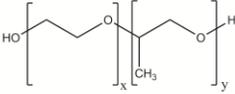
| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|------------------------------|--|----------------------------------|
| Polyurethane-8 69011-31-0 | <p>Polyurethane-8 is a copolymer of polyethylene, poly(1,4-butanediol), isophorone diisocyanate, and isophorone diamine. [Monomers:]</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p>isophorone diisocyanate</p> </div> <div style="text-align: center;">  <p>isophorone diamine</p> </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 20px;"> <div style="text-align: center;">  <p>propanoic anhydride</p> </div> <div style="text-align: center;">  <p>polyethylene</p> </div> </div> <div style="text-align: center; margin-top: 20px;">  <p>poly(1,4-butanediol)</p> </div> | Binder; film former; plasticizer |
| Polyurethane-9 69011-31-0 | <p>Polyurethane-9 is the copolymer of adipic acid, toluene diisocyanate, propylene glycol, ethylene glycol and hydroxyethyl acrylate monomers. [Monomers:]</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p>hydroxyethyl acrylate</p> </div> <div style="text-align: center;">  <p>adipic acid</p> </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 20px;"> <div style="text-align: center;">  <p>propylene glycol</p> </div> <div style="text-align: center;">  <p>ethylene glycol</p> </div> </div> <div style="text-align: center; margin-top: 20px;">  <p>toluene diisocyanate</p> </div> | Artificial nail builder |
| Polyurethane-10 | <p>Polyurethane-10 is a copolymer of isophorone diisocyanate, cyclohexanedimethanol, dimethylolbutanoic acid, polyalkylene glycol and <i>N</i>-methyl diethanolamine monomers. [Monomers:]</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p>isophorone diisocyanate</p> </div> <div style="text-align: center;">  <p>cyclohexane 1,4-dimethanol</p> </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 20px;"> <div style="text-align: center;">  <p>dimethylolbutanoic acid</p> </div> <div style="text-align: center;">  <p><i>N</i>-methyl diethanolamine</p> </div> </div> <div style="text-align: center; margin-top: 20px;">  <p>polyalkylene glycol</p> </div> | Film former; hair fixative |

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. ¹, CIR Staff

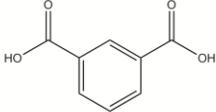
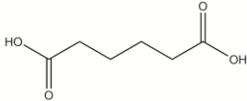
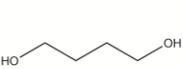
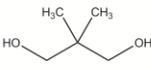
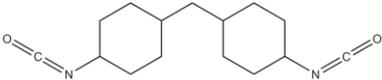
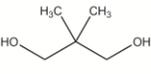
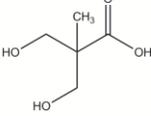
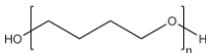
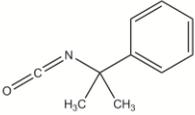
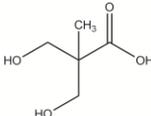
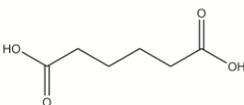
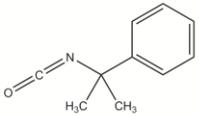
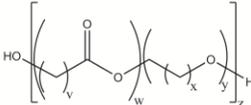
| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|-------------------------------|---|---------------------|
| Polyurethane-11 68258-82-2 | <p data-bbox="256 216 1287 289">Polyurethane-11 is a copolymer of adipic acid, 1,4-butanediol, isophthalic acid, methylene bis-(4-cyclohexylisocyanate), neopentyl glycol and trimethylolpropane monomers. [Monomers:]</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p data-bbox="613 422 709 436">isophthalic acid</p> </div> <div style="text-align: center;">  <p data-bbox="915 422 982 436">adipic acid</p> </div> </div> <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 10px;"> <div style="text-align: center;">  <p data-bbox="542 543 630 558">1,4-butanediol</p> </div> <div style="text-align: center;">  <p data-bbox="776 543 863 558">neopentyl glycol</p> </div> <div style="text-align: center;">  <p data-bbox="954 543 1068 558">trimethylolpropane</p> </div> </div> <div style="text-align: center; margin-top: 10px;">  <p data-bbox="704 669 930 684">methylene bis-(4-cyclohexylisocyanate)</p> </div> | Film former |
| Polyurethane-12 | <p data-bbox="256 695 1287 768">Polyurethane-12 is a copolymer of trimethylolpropane, neopentyl glycol, dimethylolpropanoic acid, polytetramethylene ether glycol and isocyanato methylethylbenzene monomers. [Monomers:]</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p data-bbox="646 852 734 867">neopentyl glycol</p> </div> <div style="text-align: center;">  <p data-bbox="824 852 938 867">trimethylolpropane</p> </div> </div> <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 10px;"> <div style="text-align: center;">  <p data-bbox="623 1020 776 1035">dimethylolpropanoic acid</p> </div> <div style="text-align: center;">  <p data-bbox="802 1020 982 1035">polytetramethylene ether glycol</p> </div> </div> <div style="text-align: center; margin-top: 10px;">  <p data-bbox="683 1178 883 1192">1-isocyanato-1-methylethylbenzene</p> </div> | Binder; film former |
| Polyurethane-13 | <p data-bbox="256 1199 1287 1272">Polyurethane-13 is a copolymer of trimethylolpropane, dimethylol propionic acid, hexanediol, adipic acid, polyester diol, and isocyanato methylethylbenzene monomers. [Monomers:]</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p data-bbox="586 1419 737 1434">dimethylol propionic acid</p> </div> <div style="text-align: center;">  <p data-bbox="850 1419 917 1434">adipic acid</p> </div> </div> <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 10px;"> <div style="text-align: center;">  <p data-bbox="597 1551 711 1566">trimethylolpropane</p> </div> <div style="text-align: center;">  <p data-bbox="818 1551 906 1566">1,6-hexanediol</p> </div> </div> <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 10px;"> <div style="text-align: center;">  <p data-bbox="565 1713 773 1728">1-isocyanato-1-methylethylbenzene</p> </div> <div style="text-align: center;">  <p data-bbox="867 1719 946 1734">polyester diol</p> </div> </div> | Binder; film former |

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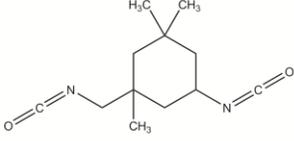
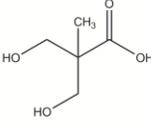
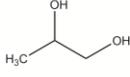
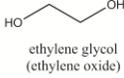
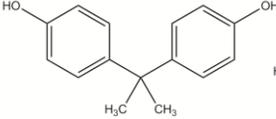
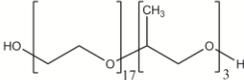
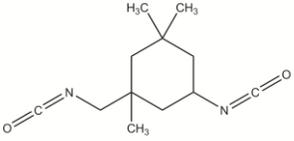
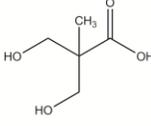
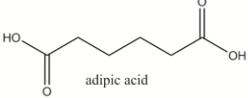
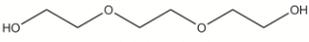
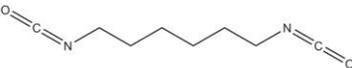
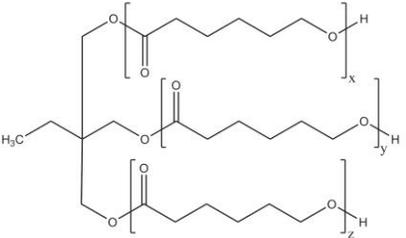
| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|-----------------------|---|---|
| Polyurethane-14 | <p>Polyurethane-14 is a copolymer of isophorone diisocyanate, dimethylol propionic acid, and 4,4'-isopropylidenediphenol reacted with propylene oxide, ethylene oxide and PEG/PPG-17/3. [Monomers:]</p> | Film former; hair conditioning agent |
| | <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p>isophorone diisocyanate</p> </div> <div style="text-align: center;">  <p>dimethylol propionic acid</p> </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 20px;"> <div style="text-align: center;">  <p>propylene glycol (propylene oxide)</p> </div> <div style="text-align: center;">  <p>ethylene glycol (ethylene oxide)</p> </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 20px;"> <div style="text-align: center;">  <p>4,4'-isopropylidenediphenol</p> </div> <div style="text-align: center;">  <p>PEG/PPG-17/3</p> </div> </div> | |
| Polyurethane-15 | <p>Polyurethane-15 is a copolymer of isophorone diisocyanate, adipic acid, triethylene glycol, and dimethylolpropanoic acid. [Monomers:]</p> | Film former |
| | <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p>isophorone diisocyanate</p> </div> <div style="text-align: center;">  <p>dimethylol propionic acid</p> </div> </div> <div style="text-align: center; margin-top: 20px;">  <p>adipic acid</p> </div> <div style="text-align: center; margin-top: 20px;">  <p>triethylene glycol</p> </div> | |
| Polyurethane-16 | <p>Polyurethane-16 is a cross-linked condensation polymer formed from the addition polymerization of 2 [stoichiometric equivalents] of hexamethylene diisocyanate with 1 [stoichiometric equivalent] of polycaprolactonetriol terminated with 3 hydroxyl groups. [Members:]</p> | Anticaking agent; emulsion stabilizer; film former; slip modifier; surface modifier |
| | <div style="text-align: center;">  <p>hexamethylene diisocyanate</p> </div> <div style="text-align: center; margin-top: 20px;">  <p>polycaprolactonetriol</p> </div> | |

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.^{1, CIR Staff}

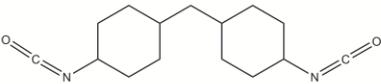
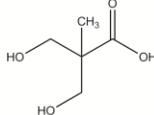
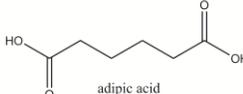
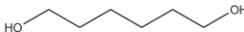
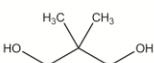
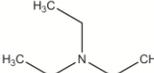
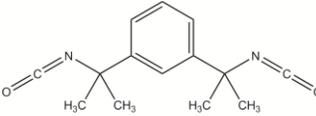
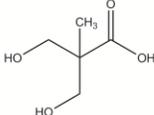
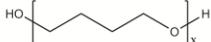
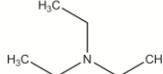
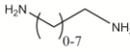
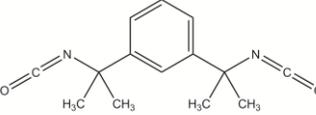
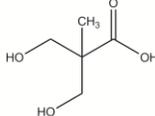
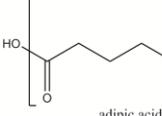
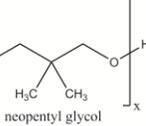
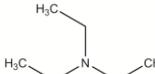
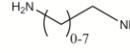
| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|--------------------------------|--|-----------------------|
| Polyurethane-17 347175-78-4 | <p>Polyurethane-17 is a complex polymer made by neutralizing Hexylene Glycol/Neopentyl Glycol/Adipic Acid/SMDI/DMPA Copolymer with triethylamine in the presence of water. Further chain extension is achieved by reacting the polymer with ethylenediamine.</p> <p>[Monomers/reactants:]</p> <div style="display: flex; flex-wrap: wrap; justify-content: space-around;"> <div style="text-align: center; margin: 5px;">  <p>SMDI</p> </div> <div style="text-align: center; margin: 5px;">  <p>dimethylol propionic acid</p> </div> <div style="text-align: center; margin: 5px;">  <p>adipic acid</p> </div> <div style="text-align: center; margin: 5px;">  <p>1,6-hexanediol</p> </div> <div style="text-align: center; margin: 5px;">  <p>neopentyl glycol</p> </div> <div style="text-align: center; margin: 5px;">  <p>triethylamine</p> </div> <div style="text-align: center; margin: 5px;">  <p>ethylenediamine</p> </div> </div> | Film former |
| Polyurethane-18 | <p>Polyurethane-18 is a complex polymer formed by the reaction of m-tetramethylene diisocyanate, polybutylene glycol and dimethylol propionic acid. The pre-polymer is neutralized with triethylamine and condensed with a combination of hydrazine and C1-8 diamines to achieve chain extension.</p> <p>[Monomers/reactants:]</p> <div style="display: flex; flex-wrap: wrap; justify-content: space-around;"> <div style="text-align: center; margin: 5px;">  <p>m-tetramethylene diisocyanate</p> </div> <div style="text-align: center; margin: 5px;">  <p>dimethylol propionic acid</p> </div> <div style="text-align: center; margin: 5px;">  <p>polybutylene glycol</p> </div> <div style="text-align: center; margin: 5px;">  <p>triethylamine</p> </div> <div style="text-align: center; margin: 5px;">  <p>hydrazine</p> </div> <div style="text-align: center; margin: 5px;">  <p>C1-8 diamines</p> </div> </div> | Binder; hair fixative |
| Polyurethane-19 | <p>Polyurethane-19 is a complex polymer formed by the reaction of m-tetramethylene diisocyanate, neopentyl glycol, trimethylol propane, dimethylol propionic acid and a polyester formed by condensing neopentyl glycol and adipic acid. The pre-polymer is neutralized with triethylamine and condensed with a combination of hydrazine and C1-8 diamines to achieve chain extension.</p> <p>[Monomers/reactants:]</p> <div style="display: flex; flex-wrap: wrap; justify-content: space-around;"> <div style="text-align: center; margin: 5px;">  <p>m-tetramethylene diisocyanate</p> </div> <div style="text-align: center; margin: 5px;">  <p>dimethylol propionic acid</p> </div> <div style="text-align: center; margin: 5px;">  <p>adipic acid</p> </div> <div style="text-align: center; margin: 5px;">  <p>neopentyl glycol</p> </div> <div style="text-align: center; margin: 5px;">  <p>hydrazine</p> </div> <div style="text-align: center; margin: 5px;">  <p>triethylamine</p> </div> <div style="text-align: center; margin: 5px;">  <p>C1-8 diamines</p> </div> </div> | Binder; hair fixative |

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. ¹, CIR Staff

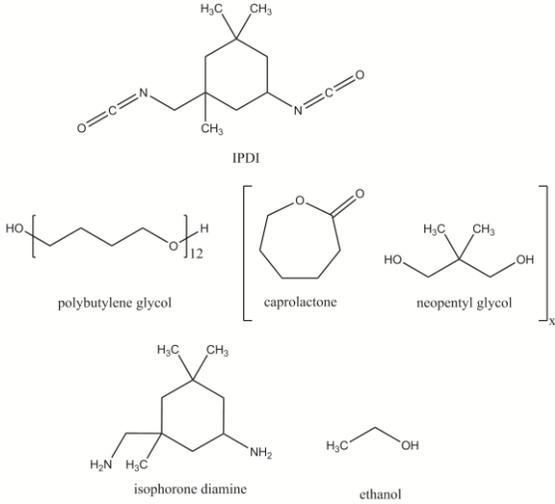
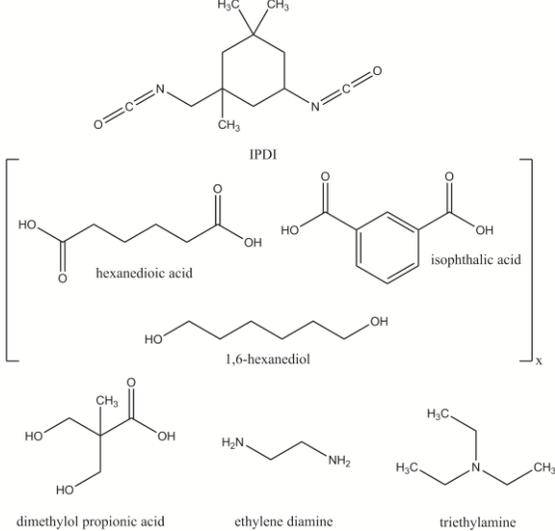
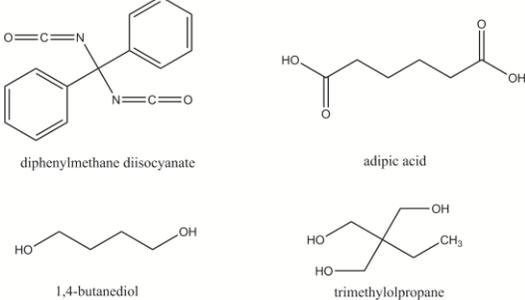
| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|---|--|----------------------------------|
| Polyurethane-20 | <p>Polyurethane-20 is a complex polymer formed by the reaction of isophorone diisocyanate (IPDI), and two polyols: The first polyol is polybutylene glycol containing approximately 12 butylene glycol units. The second polyol is formed by the reaction of approximately 10 [stoichiometric equivalents] of caprolactone [with 1 stoichiometric equivalent of] neopentyl glycol. The urethane polymer is then reacted with isophorone diamine to build molecular weight and the resulting polymer is capped with ethanol to eliminate residual isocyanate groups.</p> <p>[Monomers/reactants:]</p> | Binder; film former; plasticizer |
|  <p>The image shows the chemical structures for the monomers and reactants of Polyurethane-20. At the top is IPDI (isophorone diisocyanate), a six-membered ring with two isocyanate groups and three methyl groups. Below it are polybutylene glycol (a chain of butylene glycol units), caprolactone (a seven-membered lactone ring), and neopentyl glycol (a central carbon with two methyl groups and two hydroxyl groups). At the bottom are isophorone diamine (a six-membered ring with two amino groups and three methyl groups) and ethanol (a two-carbon chain with one hydroxyl group).</p> | | |
| Polyurethane-21 | <p>Polyurethane-21 is a urethane copolymer prepared by reacting isophorone diisocyanate (IPDI) with dimethylol propionic acid (DMPA), a polyester of hexanedioic acid, isophthalic acid and 1,6-hexanediol, and ethylene diamine, neutralized with triethylamine.</p> <p>[Monomers/reactants:]</p> | Film former |
|  <p>The image shows the chemical structures for the monomers and reactants of Polyurethane-21. At the top is IPDI. Below it are hexanedioic acid (a six-carbon chain with two carboxylic acid groups), isophthalic acid (a benzene ring with two carboxylic acid groups in the meta position), and 1,6-hexanediol (a six-carbon chain with two hydroxyl groups). At the bottom are dimethylol propionic acid (a three-carbon chain with two hydroxyl groups and one carboxylic acid group), ethylene diamine (a two-carbon chain with two amino groups), and triethylamine (a nitrogen atom bonded to three ethyl groups).</p> | | |
| Polyurethane-23 | <p>Polyurethane-23 is a copolymer of adipic acid, 1,4 butanediol, diphenylmethane diisocyanate, and trimethylolpropane.</p> <p>[Monomers:]</p> | Film former |
|  <p>The image shows the chemical structures for the monomers of Polyurethane-23. At the top left is diphenylmethane diisocyanate (two benzene rings connected by a methylene group, with two isocyanate groups). At the top right is adipic acid (a six-carbon chain with two carboxylic acid groups). At the bottom left is 1,4-butanediol (a four-carbon chain with two hydroxyl groups). At the bottom right is trimethylolpropane (a central carbon bonded to three hydroxymethyl groups and one methyl group).</p> | | |

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.^{1, CIR Staff}

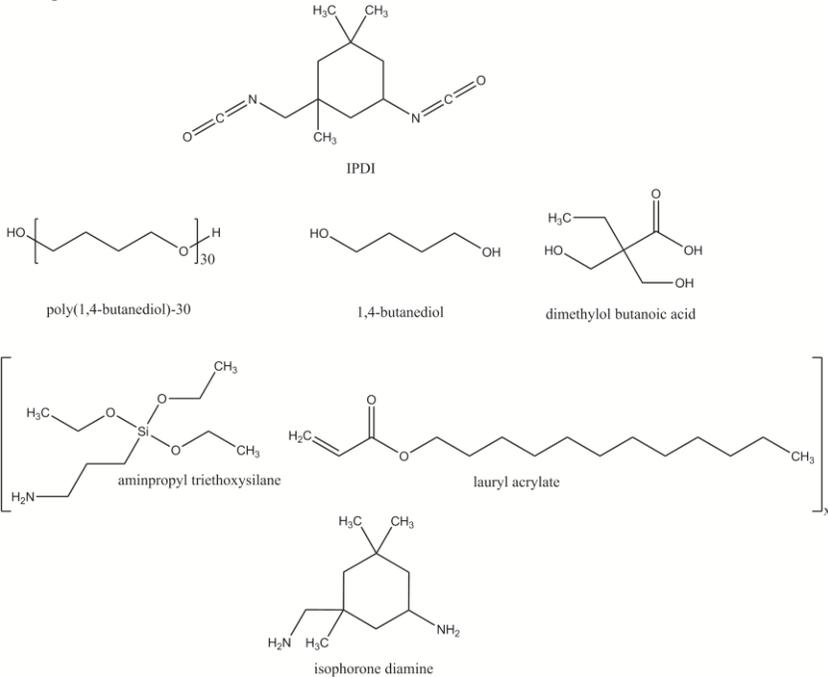
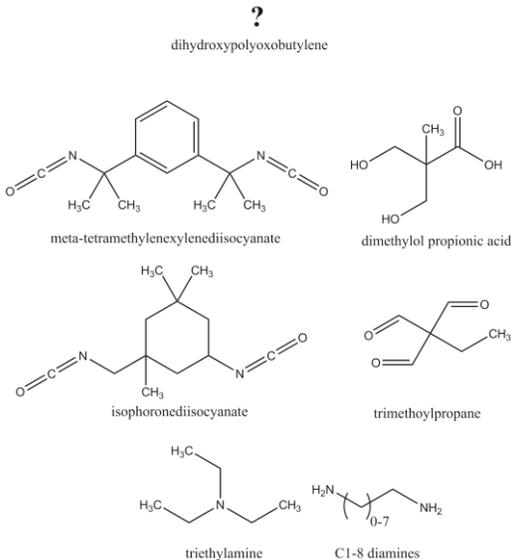
| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|-----------------------|---|--|
| Polyurethane-24 | <p>Polyurethane-24 is a complex polymer prepared via the following multi-step synthesis. First, isophorone diisocyanate (IPDI) is reacted with three different polyols: poly(1,4-butanediol)-30, 1,4-butanediol, and dimethylol butanoic acid. This pre-polymer is then reacted with a reagent formed by the reaction between aminopropyl triethoxysilane and lauryl acrylate. The resulting polymer is subsequently chain extended by reaction with isophorone diamine in aqueous solution to produce Polyurethane-24. [Monomers/reactants:]</p> | Hair conditioning agent; hair fixative |
| |  <p>The structures shown are: IPDI (isophorone diisocyanate), poly(1,4-butanediol)-30 (represented as a repeating unit with subscript 30), 1,4-butanediol, dimethylol butanoic acid, aminopropyl triethoxysilane, lauryl acrylate, and isophorone diamine.</p> | |
| Polyurethane-25 | <p>Polyurethane-25 is a complex polymer formed by the reaction of dihydroxypolyoxobutylene (degree of polymerization 12-30), dimethylol propionic acid, meta-tetramethylenexylenediisocyanate, isophoronediiisocyanate and trimethylpropane. The prepolymer is neutralized with triethylamine and chain extended with C1-8 alkyl diamine. [Monomers/reactants:]</p> | Binder; hair-waving/straightening agent; skin-conditioning agent-occlusive |
| |  <p>The structures shown are: dihydroxypolyoxobutylene (represented with a question mark), meta-tetramethylenexylenediisocyanate, dimethylol propionic acid, isophoronediiisocyanate, trimethylpropane, triethylamine, and C1-8 diamines (represented as a repeating unit with subscript 0-7).</p> | |

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.^{1, CIR Staff}

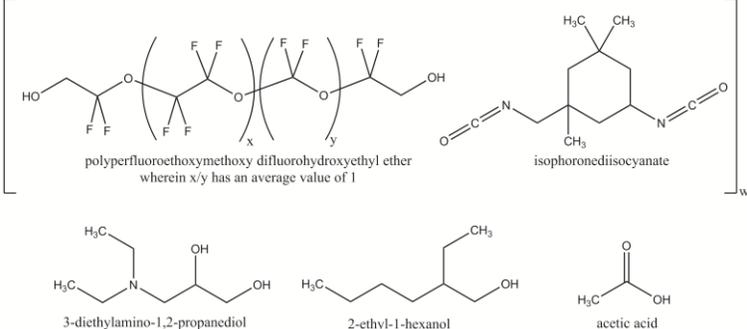
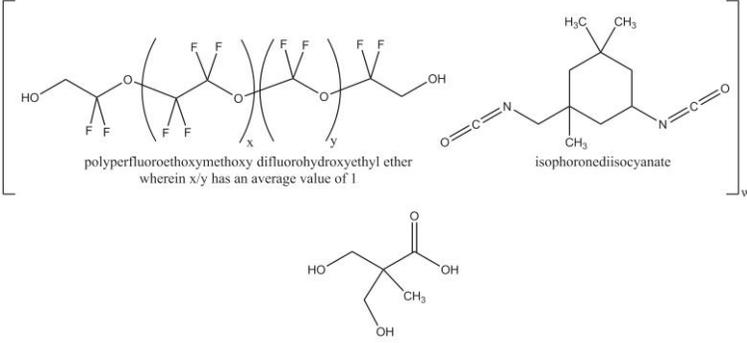
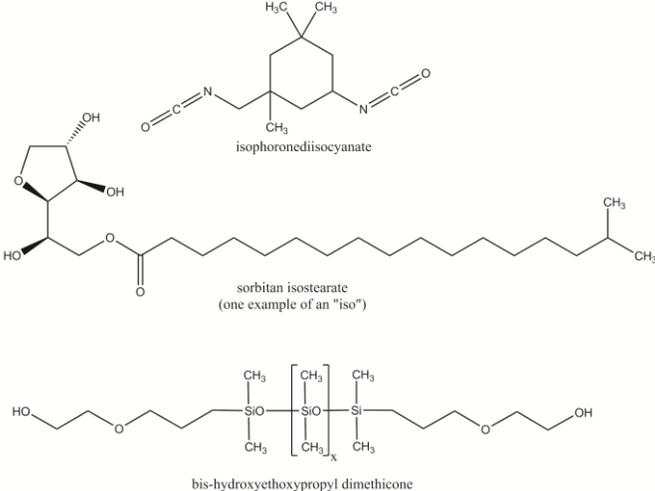
| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|--------------------------------|---|---|
| Polyurethane-26 328389-90-8 | <p>Polyurethane-26 is a complex polymer that is formed by the reaction of polyperfluoroethoxymethoxy difluorohydroxyethyl ether and isophorone diisocyanate (IPDI) to form a prepolymer. The prepolymer is further reacted with 3-diethylamino-1,2-propanediol followed by the capping of any residual isocyanate groups with 2-ethyl-1-hexanol. The resulting polymer is neutralized with acetic acid.</p> <p>[Monomers/reactants:]</p>  <p>polyperfluoroethoxymethoxy difluorohydroxyethyl ether wherein x/y has an average value of 1</p> <p>isophorone diisocyanate</p> <p>3-diethylamino-1,2-propanediol</p> <p>2-ethyl-1-hexanol</p> <p>acetic acid</p> | Film former; hair conditioning agent; skin protectant |
| Polyurethane-27 328389-91-9 | <p>Polyurethane-27 is a complex polymer that is formed by the reaction of polyperfluoroethoxymethoxy difluorohydroxyethyl ether and isophorone diisocyanate (IPDI) to form a prepolymer. The prepolymer is further reacted with the triethylamine salt of 3-hydroxy-2-(hydroxymethyl)-2-methyl-1-propionic acid.</p> <p>[Monomers/reactants:]</p>  <p>polyperfluoroethoxymethoxy difluorohydroxyethyl ether wherein x/y has an average value of 1</p> <p>isophorone diisocyanate</p> <p>3-hydroxy-2-(hydroxymethyl)-2-methyl-1-propionic acid</p> | Film former; hair conditioning agent; skin protectant |
| Polyurethane-28 | <p>Polyurethane-28 is a complex polymer formed by the reaction of bis-hydroxyethoxypropyl dimethicone with isophorone diisocyanate (IPDI) and Sorbitan Isostearate.</p> <p>[Monomers/reactants:]</p>  <p>isophorone diisocyanate</p> <p>sorbitan isostearate (one example of an "iso")</p> <p>bis-hydroxyethoxypropyl dimethicone</p> | Surfactant-emulsifying agent |

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.^{1, CIR Staff}

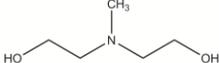
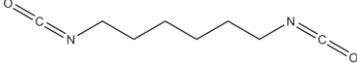
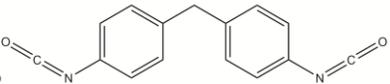
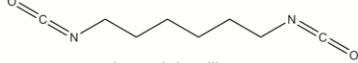
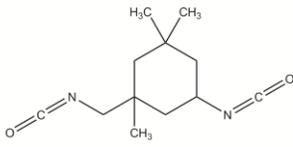
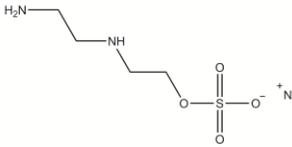
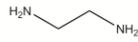
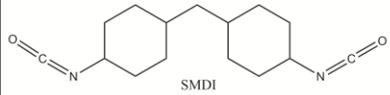
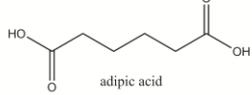
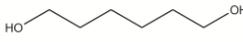
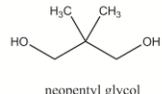
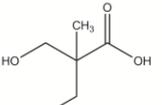
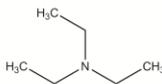
| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|-----------------------|---|---|
| Polyurethane-29 | <p data-bbox="256 216 1214 289">Polyurethane-29 is a copolymer of methyl diethanolamine (MDEA), polytetramethylene ether glycol (PTMEG), hexamethylene diisocyanate (HDI), and saturated methylene diphenyldiisocyanate (SMDI). [Monomers:]</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p data-bbox="597 464 644 485">MDEA</p> </div> <div style="text-align: center;">  <p data-bbox="963 443 1010 464">PTMEG</p> </div> </div> <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 20px;"> <div style="text-align: center;">  <p data-bbox="609 579 639 600">HDI</p> </div> <div style="text-align: center;">  <p data-bbox="971 569 1008 590">SMDI</p> </div> </div> | Emulsion stabilizer; film former; hair conditioning agents; hair fixative |
| Polyurethane-32 | <p data-bbox="256 604 1214 678">Polyurethane-32 is a copolymer of 1,4-butanediol, ethylenediamine, hexamethylene diisocyanate, isophorone diisocyanate, and sodium <i>N</i>-(2-aminoethyl)-3-aminoethane sulfonate monomers. [Monomers:]</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p data-bbox="565 743 732 764">hexamethylene diisocyanate</p> </div> <div style="text-align: center;">  <p data-bbox="922 737 1003 758">1,4-butanediol</p> </div> </div> <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 20px;"> <div style="text-align: center;">  <p data-bbox="570 947 711 968">isophorone diisocyanate</p> </div> <div style="text-align: center;">  <p data-bbox="824 947 1117 968">sodium <i>N</i>-(2-aminoethyl)-3-aminoethane sulfonate</p> </div> </div> <div style="text-align: center; margin-top: 20px;">  <p data-bbox="743 1060 841 1081">ethylenediamine</p> </div> | Binder |
| Polyurethane-33 | <p data-bbox="256 1087 1214 1182">Polyurethane-33 is a complex polymer formed by reacting dimethylolpropionic acid and a polyester composed of adipic acid, hexylene glycol, neopentyl glycol with methylene dicyclohexyldiisocyanate (SMDI) to form a prepolymer. The prepolymer is neutralized with triethylamine and then chain-extended with hydrazine. [Monomers/reactants:]</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p data-bbox="641 1283 688 1304">SMDI</p> </div> <div style="text-align: center;">  <p data-bbox="971 1283 1034 1304">adipic acid</p> </div> </div> <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 20px;"> <div style="text-align: center;">  <p data-bbox="613 1402 717 1423">hexylene glycol</p> </div> <div style="text-align: center;">  <p data-bbox="959 1402 1063 1423">neopentyl glycol</p> </div> </div> <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 20px;"> <div style="text-align: center;">  <p data-bbox="553 1583 699 1604">dimethylol propionic acid</p> </div> <div style="text-align: center;">  <p data-bbox="792 1583 873 1604">triethylamine</p> </div> <div style="text-align: center;">  <p data-bbox="971 1583 1034 1604">hydrazine</p> </div> </div> | Binder |

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.^{1, CIR Staff}

| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|-----------------------|---|-------------|
| Polyurethane-34 | <p data-bbox="256 216 1333 289">Polyurethane-34 is a complex polymer that is formed in a multi-step reaction. A copolymer of hexanediol, neopentyl glycol, and adipic acid is reacted with hexamethylene diisocyanate. The resulting polymer is further reacted with <i>N</i>-(2-aminoethyl)-3-aminoethanesulfonic acid and ethylenediamine.</p> <p data-bbox="256 291 370 312">[Monomers:]</p> <div data-bbox="479 312 1120 747"> <p>The monomers for Polyurethane-34 are: adipic acid (HOOC(CH₂)₄COOH), hexanediol (HO(CH₂)₆OH), neopentyl glycol (HO-C(CH₃)₂-CH₂-OH), hexamethylene diisocyanate (OCN(CH₂)₆NCO), sodium <i>N</i>-(2-aminoethyl)-3-aminoethane sulfonate (H₂N-CH₂-CH₂-NH-CH₂-CH₂-O-SO₃⁻Na⁺), and ethylenediamine (H₂N-CH₂-CH₂-NH₂).</p> </div> | |

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.^{1, CIR Staff}

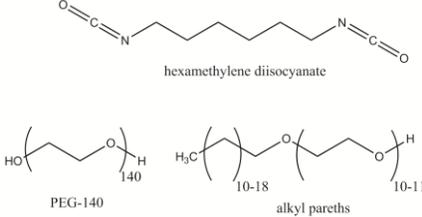
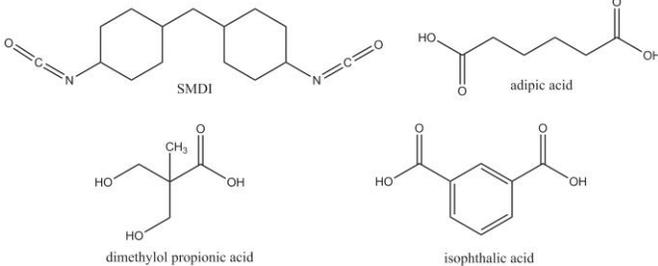
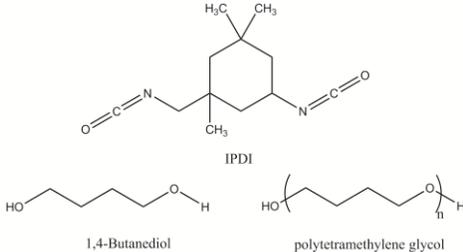
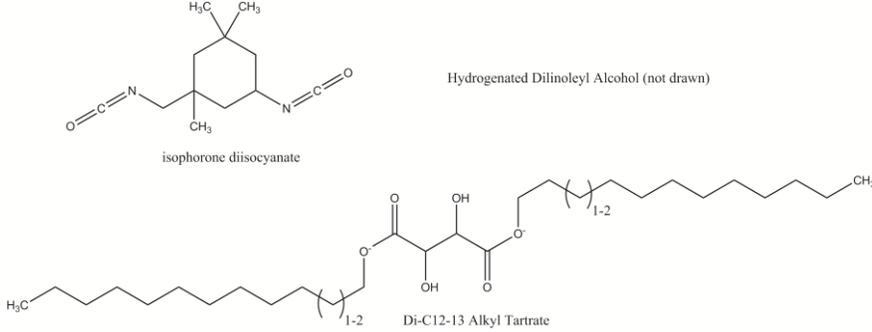
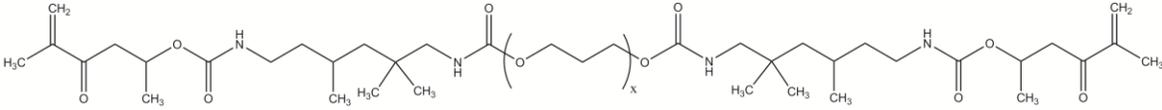
| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|--|---|--|
| Polyurethane-39 | Polyurethane-39 is a copolymer of PEG-140 and hexamethylene diisocyanate end-capped with C12-14 Pareth-10, C16-18 Pareth-11, and C18-20 Pareth-11. [Monomers:] | Hair conditioner |
|  <p style="text-align: center;">hexamethylene diisocyanate</p> <p style="text-align: center;">PEG-140 alkyl pareths</p> | | |
| Polyurethane-40 | Polyurethane-40 is a copolymer of Adipic Acid, dimethylolpropanoic acid (DMPA), isophthalic acid and saturated methylene diphenyldiisocyanate (SMDI) monomers. [Monomers:] | Film former; surface modifier |
|  <p style="text-align: center;">SMDI adipic acid</p> <p style="text-align: center;">dimethylol propionic acid isophthalic acid</p> | | |
| Polyurethane-41 | Polyurethane-41 is a copolymer of 1,4-Butanediol, polytetramethylene glycol and isophorone diisocyanate (IPDI) monomers. [Monomers:] | Film former; hair conditioning agent; skin protectant |
|  <p style="text-align: center;">IPDI</p> <p style="text-align: center;">1,4-Butanediol polytetramethylene glycol</p> | | |
| Polyurethane-42 1184186-26-2 | Polyurethane-42 is a copolymer of Di-C12-13 Alkyl Tartrate, Hydrogenated Dilinoleyl Alcohol and isophorone diisocyanate. [Monomers:] | Film former |
|  <p style="text-align: center;">isophorone diisocyanate Hydrogenated Dilinoleyl Alcohol (not drawn)</p> <p style="text-align: center;">Di-C12-13 Alkyl Tartrate</p> | | |
| Polyurethane-43 | Polyurethane-43 is the polymer that conforms generally to the formula: | Film former |
|  | | |

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.^{1, CIR Staff}

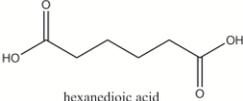
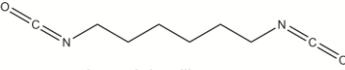
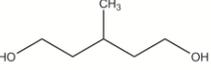
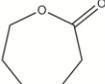
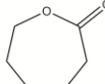
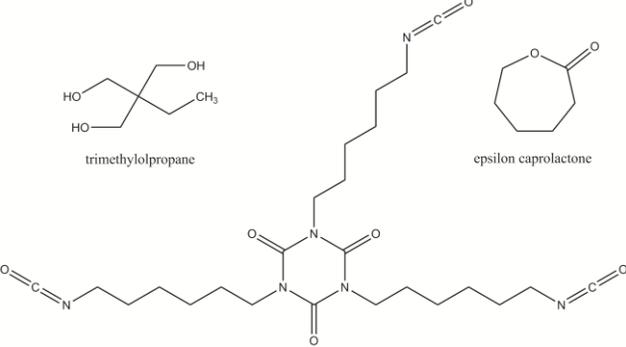
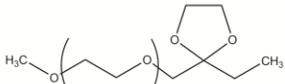
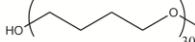
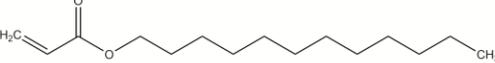
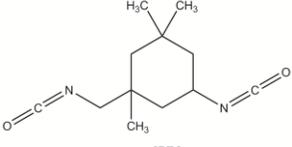
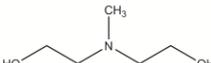
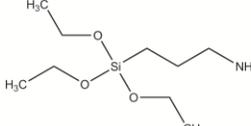
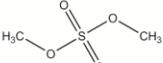
| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|-----------------------|---|------------------------------------|
| Polyurethane-44 | <p data-bbox="256 216 1317 264">Polyurethane-44 is a copolymer of hexanedioic acid, hexamethylene diisocyanate (HDI), trimethylolpropane, 3-methyl-1,5-pentanediol (MPD), and caprolactone monomers.</p> <p data-bbox="256 264 375 285">[Monomers:]</p> <div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="text-align: center;">  <p data-bbox="553 380 673 394">hexanedioic acid</p> </div> <div style="text-align: center;">  <p data-bbox="846 380 1019 394">hexamethylene diisocyanate</p> </div> </div> <div style="display: flex; justify-content: space-around; align-items: flex-start; margin-top: 10px;"> <div style="text-align: center;">  <p data-bbox="553 527 673 541">trimethylolpropane</p> </div> <div style="text-align: center;">  <p data-bbox="846 527 992 541">3-methyl-1,5-pentanediol</p> </div> </div> <div style="text-align: center; margin-top: 20px;">  <p data-bbox="721 688 800 703">caprolactone</p> </div> | Anticaking agent; bulking agent |
| Polyurethane-45 | <p data-bbox="256 716 1317 764">Polyurethane-45 is a polymer made by the reaction of epsilon caprolactone and Trimethylolpropane with the cyclic trimer of hexamethylene diisocyanate.</p> <p data-bbox="256 764 375 785">[Monomers:]</p> <div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="text-align: center;">  <p data-bbox="553 947 691 961">trimethylolpropane</p> </div> <div style="text-align: center;">  <p data-bbox="959 936 1081 951">epsilon caprolactone</p> </div> </div> <div style="text-align: center; margin-top: 20px;">  <p data-bbox="683 1146 935 1161">cyclic trimer of hexamethylene diisocyanate</p> </div> | Film former |
| Polyurethane-46 | <p data-bbox="256 1171 1317 1289">Polyurethane-46 is a complex urethane-based polymer. Initially, a pre-polymer is made by the reaction of isophorone diisocyanate (IPDI) with three different polyols. The polyols are poly(1,4-butanediol)-30, methoxy PEG-20 terminated with a 2,2 dimethyl butoxy group, and Methyl Diethanolamine. The pre-polymer is capped with the product formed by the reaction of lauryl acrylate and aminopropyl triethoxysilane (via Michael addition), and finally the amine groups from the methyl diethanolamine are quaternized with dimethylsulfate.</p> <p data-bbox="256 1289 456 1310">[Monomers/reactants:]</p> <div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="text-align: center;">  <p data-bbox="256 1440 618 1455">methoxy PEG-20 terminated with a 2,2 dimethyl butoxy group</p> </div> <div style="text-align: center;">  <p data-bbox="659 1440 789 1455">poly(1,4-butanediol)-30</p> </div> <div style="text-align: center;">  <p data-bbox="1065 1419 1154 1434">lauryl acrylate</p> </div> </div> <div style="display: flex; justify-content: space-around; align-items: flex-start; margin-top: 10px;"> <div style="text-align: center;">  <p data-bbox="407 1619 440 1633">IPDI</p> </div> <div style="text-align: center;">  <p data-bbox="626 1608 756 1623">methyl diethanolamine</p> </div> <div style="text-align: center;">  <p data-bbox="1016 1608 1179 1623">aminopropyl triethoxysilane</p> </div> </div> <div style="text-align: center; margin-top: 20px;">  <p data-bbox="797 1734 894 1749">dimethylsulfate</p> </div> | Hair conditioning agent |

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| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|-----------------------|--|---|
| Polyurethane-47 | <p data-bbox="256 216 1304 310">Polyurethane-47 is a copolymer made by reacting a polyester polyol with isophorone diisocyanate (IPDI) and then bis-hydroxypropyl dimethicone. The polyester polyol is made by reacting Epoxidized Soybean Oil with a polyol. [Soybean oil consists essentially of triglycerides of oleic, linoleic, linolenic and saturated acids. Monomers:]</p> <div data-bbox="370 352 1247 814"> <p data-bbox="1057 478 1247 499">undisclosed polyol (not drawn)</p> <p data-bbox="570 594 816 615">one example of an epoxidized soybean oil</p> <p data-bbox="589 793 621 814">IPDI</p> <p data-bbox="889 793 1073 814">bis-hydroxypropyl dimethicone</p> </div> | Binder; film former; hair fixative; skin-conditioning agent-occlusive |
| Polyurethane-48 | <p data-bbox="256 825 1304 898">Polyurethane-48 is a copolymer of hexanediol, neopentyl glycol, adipic acid, isophorone diisocyanate, isophorone diamine and sodium <i>N</i>-(2-aminoethyl)-3-aminoethanesulfonic acid monomers. [Monomers:]</p> <div data-bbox="500 898 1101 1329"> <p data-bbox="597 1035 743 1056">isophorone diisocyanate</p> <p data-bbox="938 1035 1003 1056">adipic acid</p> <p data-bbox="621 1140 686 1161">hexanediol</p> <p data-bbox="922 1140 1019 1161">neopentyl glycol</p> <p data-bbox="524 1308 833 1329">sodium <i>N</i>-(2-aminoethyl)-3-aminoethane sulfonic acid</p> <p data-bbox="914 1308 1027 1329">isophorone diamine</p> </div> | Film former |
| Polyurethane-49 | <p data-bbox="256 1339 1304 1413">Polyurethane-49 is a copolymer of poly(1,4-butanediol), 1,3-bis(isocyanatomethyl)benzene, ethoxylated 4,4'-isopropylidenediphenol and 4-hydroxybutyl acrylate. [Monomers:]</p> <div data-bbox="524 1413 1076 1848"> <p data-bbox="654 1549 881 1570">ethoxylated 4,4'-isopropylidenediphenol</p> <p data-bbox="573 1696 703 1717">poly(1,4-butanediol)</p> <p data-bbox="865 1696 995 1717">4-hydroxybutyl acrylate</p> <p data-bbox="686 1833 881 1854">1,3-bis(isocyanatomethyl)benzene</p> </div> | Artificial nail builder |

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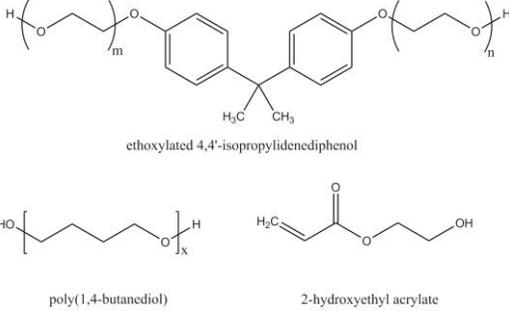
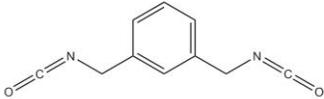
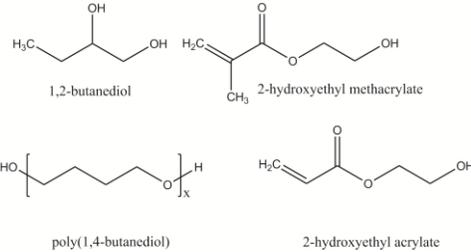
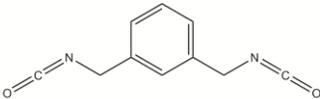
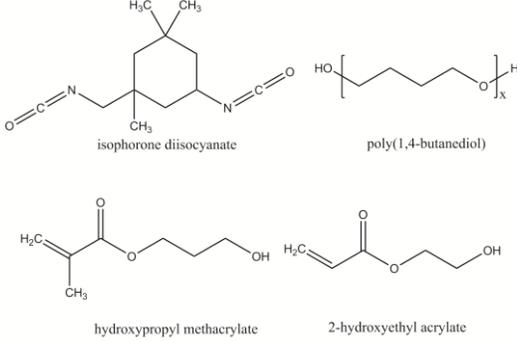
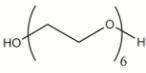
| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|--|--|-------------------------|
| Polyurethane-50 | <p>Polyurethane-50 is a copolymer of poly(1,4-butanediol), 1,3-bis(isocyanatomethyl)benzene, ethoxylated 4,4'-isopropylidenediphenol and 2-hydroxyethyl acrylate. [Monomers:]</p> | Artificial nail builder |
|  <p style="text-align: center;">ethoxylated 4,4'-isopropylidenediphenol</p> <p style="text-align: center;">poly(1,4-butanediol) 2-hydroxyethyl acrylate</p> | | |
|  <p style="text-align: center;">1,3-bis(isocyanatomethyl)benzene</p> | | |
| Polyurethane-51 | <p>Polyurethane-51 is a copolymer made by reacting 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate (HEMA), 1,2-Butanediol, poly(1,4-butanediol) and 1,3-bis(isocyanatomethyl)cyclohexane. [Monomers:]</p> | Artificial nail builder |
|  <p style="text-align: center;">1,2-butanediol 2-hydroxyethyl methacrylate</p> <p style="text-align: center;">poly(1,4-butanediol) 2-hydroxyethyl acrylate</p> | | |
|  <p style="text-align: center;">1,3-bis(isocyanatomethyl)benzene</p> | | |
| Polyurethane-52 | <p>Polyurethane-52 is a copolymer of poly(1,4-butanediol), isophorone diisocyanate, PEG-6, 2-hydroxyethyl acrylate and hydroxypropyl methacrylate. [Monomers:]</p> | Artificial nail builder |
|  <p style="text-align: center;">isophorone diisocyanate poly(1,4-butanediol)</p> <p style="text-align: center;">hydroxypropyl methacrylate 2-hydroxyethyl acrylate</p> | | |
|  <p style="text-align: center;">PEG-6</p> | | |

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. ¹, CIR Staff

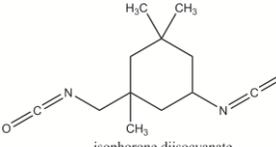
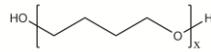
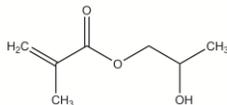
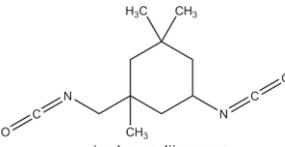
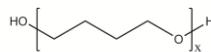
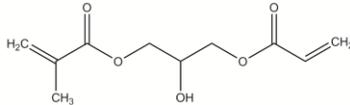
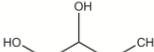
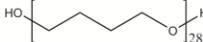
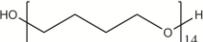
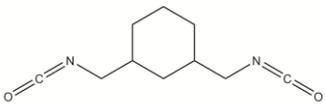
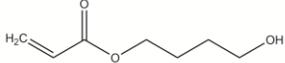
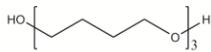
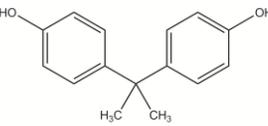
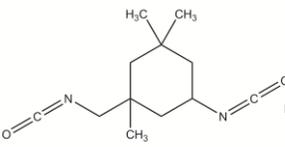
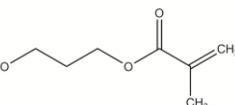
| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|---------------------------------|---|-------------------------|
| Polyurethane-53 | <p data-bbox="256 216 1214 262">Polyurethane-53 is a copolymer of poly(1,4-butanediol), isophorone diisocyanate and 2-hydroxypropyl acrylate. [Monomers:]</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p data-bbox="633 399 779 420">isophorone diisocyanate</p> </div> <div style="text-align: center;">  <p data-bbox="901 399 1023 420">poly(1,4-butanediol)</p> </div> </div> <div style="text-align: center; margin-top: 10px;">  <p data-bbox="738 546 917 567">2-hydroxypropyl methacrylate</p> </div> | Artificial nail builder |
| Polyurethane-54 | <p data-bbox="256 573 1214 640">Polyurethane-54 is a copolymer of poly(1,4-butanediol)-4, 1,2-butanediol, 3-(acryloyloxy)-2-hydroxypropyl methacrylate and isophorone diisocyanate. [Monomers:]</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p data-bbox="625 777 771 798">isophorone diisocyanate</p> </div> <div style="text-align: center;">  <p data-bbox="893 777 1015 798">poly(1,4-butanediol)</p> </div> </div> <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 10px;"> <div style="text-align: center;">  <p data-bbox="576 934 844 955">3-(acryloyloxy)-2-hydroxypropyl methacrylate</p> </div> <div style="text-align: center;">  <p data-bbox="941 934 1031 955">1,2-butanediol</p> </div> </div> | Artificial nail builder |
| Polyurethane-55 | <p data-bbox="256 961 1214 1029">Polyurethane-55 is the polymer formed by the reaction of Poly(1,4-Butanediol)-28, Poly(1,4-Butanediol)-14, and 1,3-bis(isocyanatomethyl)cyclohexane. The polymer is capped with 4-hydroxybutyl acrylate. [Monomers:]</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p data-bbox="625 1123 763 1144">poly(1,4-butanediol)-28</p> </div> <div style="text-align: center;">  <p data-bbox="852 1123 990 1144">poly(1,4-butanediol)-14</p> </div> </div> <div style="text-align: center; margin-top: 10px;">  <p data-bbox="706 1281 901 1302">1,3-bis(isocyanatomethyl)cyclohexane</p> </div> <div style="text-align: center; margin-top: 10px;">  <p data-bbox="730 1428 885 1449">4-hydroxybutyl acrylate</p> </div> | Artificial nail builder |
| Polyurethane-56 1342288-58-7 | <p data-bbox="256 1455 1214 1522">Polyurethane-56 is a copolymer of 4,4'-Isopropylidenediphenol, poly(1,4-butanediol)-3, Hydroxypropyl Methacrylate, and isophoronediiisocyanate (IPDI). [Monomers:]</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p data-bbox="584 1648 722 1669">poly(1,4-butanediol)-3</p> </div> <div style="text-align: center;">  <p data-bbox="812 1648 974 1669">4,4'-isopropylidenediphenol</p> </div> </div> <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 10px;"> <div style="text-align: center;">  <p data-bbox="673 1858 706 1879">IPDI</p> </div> <div style="text-align: center;">  <p data-bbox="836 1858 1006 1879">hydroxypropyl methacrylate</p> </div> </div> | Binder |

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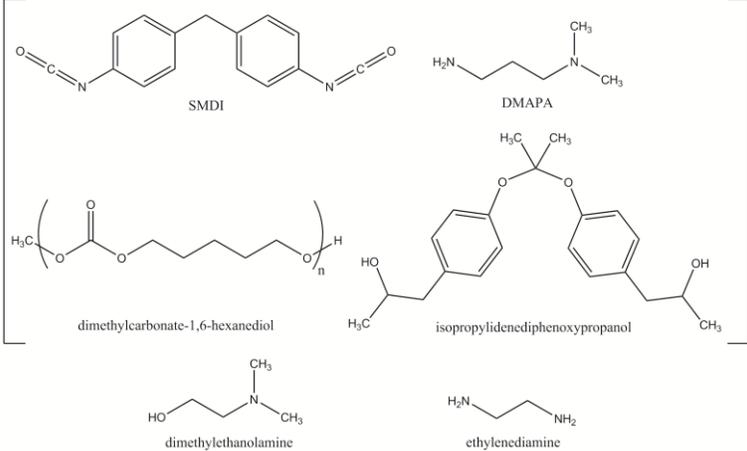
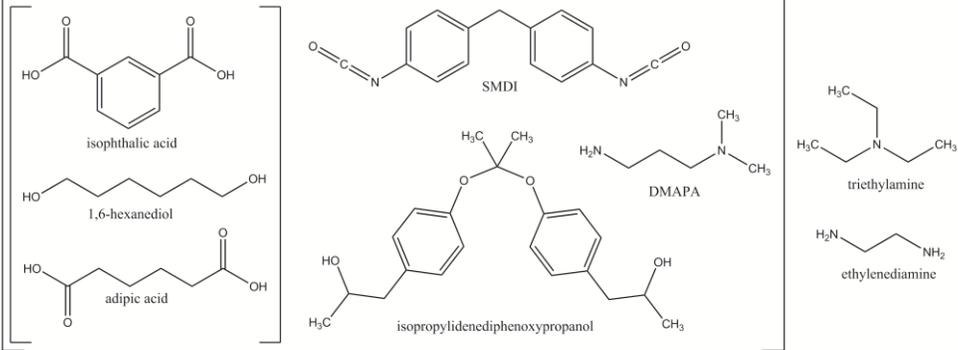
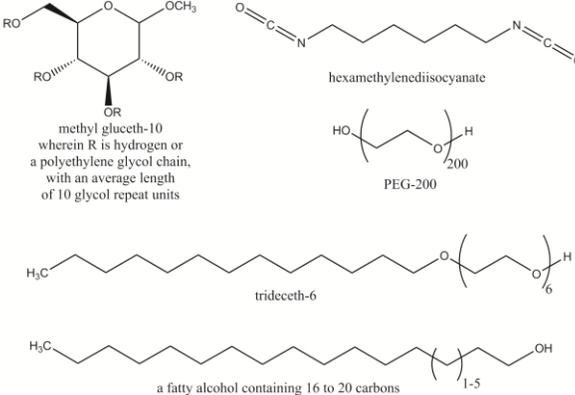
| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|-----------------------|--|--|
| Polyurethane-60 | <p>Polyurethane-60 is the complex polymer made by first reacting saturated methylene diphenyldiisocyanate (SMDI), dimethyl aminopropylamine (DMAPA), isopropylidenediphenoxypropanol, and dimethylcarbonate-1,6-hexanediol to form a prepolymer, followed by dispersion in water with dimethylethanolamine and subsequent chain extension with ethylenediamine.</p> <p>[Monomers/reactants:]</p>  <p>The structures shown are: SMDI (saturated methylene diphenyldiisocyanate), DMAPA (dimethyl aminopropylamine), dimethylcarbonate-1,6-hexanediol, isopropylidenediphenoxypropanol, dimethylethanolamine, and ethylenediamine.</p> | Nail conditioning agent |
| Polyurethane-61 | <p>Polyurethane-61 is the complex polymer made by first reacting saturated methylene diphenyldiisocyanate (SMDI), dimethyl aminopropylamine (DMAPA), isopropylidenediphenoxypropanol and the polyester polyol derived from isophthalic acid/1,6-hexanediol/adipic acid to form a prepolymer, followed by dispersion in water with triethylamine and subsequent chain extension with ethylenediamine.</p> <p>[Monomers:]</p>  <p>The structures shown are: isophthalic acid, 1,6-hexanediol, adipic acid, SMDI (saturated methylene diphenyldiisocyanate), DMAPA (dimethyl aminopropylamine), isopropylidenediphenoxypropanol, triethylamine, and ethylenediamine.</p> | Nail conditioning agent |
| Polyurethane-62 | <p>Polyurethane-62 is a copolymer of hexamethylene diisocyanate, PEG-200, Methyl Gluceth-10 and Trideceth-6 monomers, end-capped with a fatty alcohol containing 16 to 20 carbons.</p> <p>[Monomers:]</p>  <p>The structures shown are: methyl gluceth-10 (wherein R is hydrogen or a polyethylene glycol chain, with an average length of 10 glycol repeat units), hexamethylenediisocyanate, PEG-200, trideceth-6, and a fatty alcohol containing 16 to 20 carbons.</p> | Binder; viscosity increasing agent-aqueous |

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.^{1, CIR Staff}

| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|-----------------------|--|--------------------------|
| Polyurethane-63 | <p>Polyurethane-63 is a complex polymer formed by first reacting dimethylolpropionic acid (DMPA) and isophorone diisocyanate (IPDI) with a polyester diol made with Adipic Acid, isophthalic acid, and Hexanediol. The resulting prepolymer is then neutralized with triethylamine and finally, chain-extended with ethylenediamine.</p> <p>[Monomers/reactants:]</p> | Film former |
| | | |
| Polyurethane-64 | <p>Polyurethane-64 is a urethane copolymer formed by a multi-step reaction. First, isophorone diisocyanate (IPDI) is reacted with a mixture of polytetrahydrofurans (PTHFs), also known as polybutylene glycols or polytetramethylene glycols. One of the PTHFs contains an average of 14 mols and the other an average of 28 mols of butylene glycol. The resulting polyurethane is reacted with 4,4'-methylenebis(cyclohexylamine) and finally the residual isocyanate groups are reacted with ethanol.</p> <p>[Monomers/reactants:]</p> | Film former |
| | | |
| Polyurethane-65 | <p>Polyurethane-65 is a complex urethane copolymer made by reacting Isophorone Diisocyanate (IPDI) with a combination of dimethylolpropionic acid (DMPA) and a copolymer composed of Neopentyl Glycol and Adipic Acid. The resulting polymer is chain extended with ethylene diamine and neutralized with trimethylamine.</p> <p>[Monomers:]</p> | Artificial nail builders |
| | | |
| Polyurethane-66 | <p>Polyurethane-66 is a urethane polymer formed by reacting a polymer of 1,4-butanediol that contains an average of 28 moles of butylene oxide with a combination of isophorone diisocyanate (IPDI) and 1,3-bis(isocyanomethyl)cyclohexane. The polymer is end-blocked with hydroxybutyl acrylate.</p> <p>[Monomers:]</p> | Binder |
| | | |

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.^{1, CIR Staff}

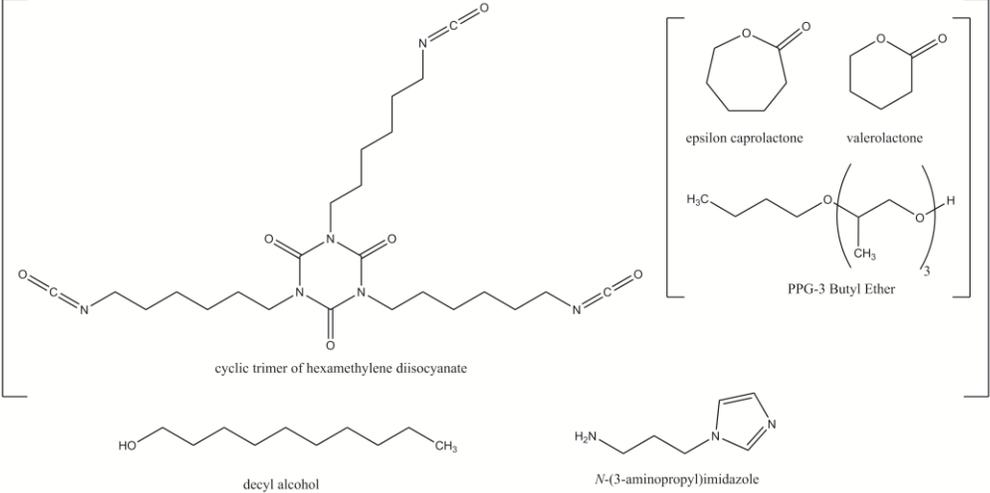
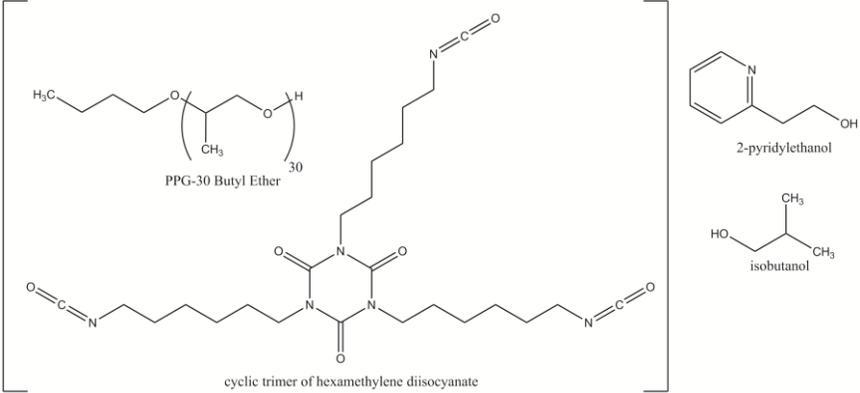
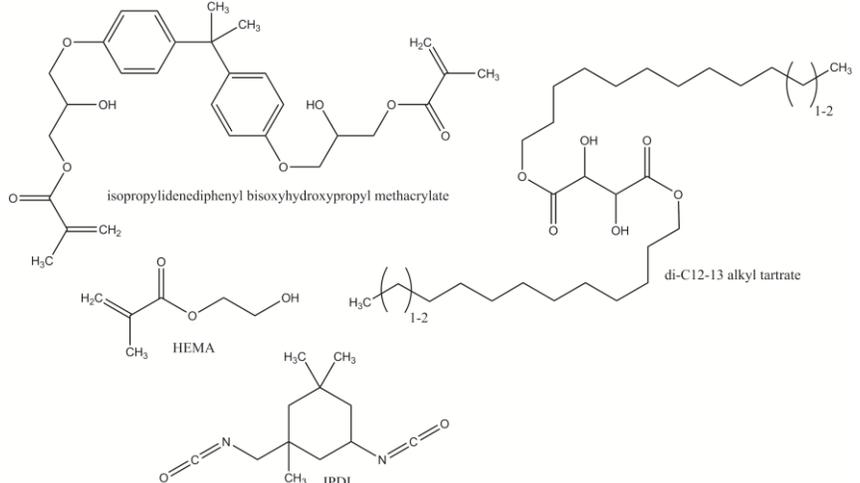
| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|---------------------------------|--|--|
| Polyurethane-67 1334242-38-4 | <p data-bbox="256 216 1333 310">Polyurethane-67 is a complex polymer made by reacting the trimer of hexamethylene diisocyanate (HDI isocyanurate trimer) with a copolymer that is made by reacting PPG-3 Butyl Ether with a mixture of epsilon-caprolactone and valerolactone. Some of the remaining isocyanate groups from the first reaction are reacted with Decyl Alcohol and in a third step, the remaining isocyanate groups are reacted with <i>N</i>-(3-aminopropyl)imidazole.</p> <p data-bbox="256 312 370 333">[Monomers:]</p>  <p>The structures shown are: cyclic trimer of hexamethylene diisocyanate (a central six-membered ring with three carbonyl groups and three isocyanate groups); epsilon caprolactone (a seven-membered lactone ring); valerolactone (a six-membered lactone ring); PPG-3 Butyl Ether (a polyether chain with a methyl group and a terminal hydrogen); decyl alcohol (a ten-carbon primary alcohol); and <i>N</i>-(3-aminopropyl)imidazole (an imidazole ring with a three-carbon propyl chain ending in an amino group).</p> | Surface modifier |
| Polyurethane-68 157420-46-7 | <p data-bbox="256 842 1333 915">Polyurethane-68 is a complex polymer that is made by reacting the trimer of hexamethylene diisocyanate (HDI isocyanurate trimer) with PPG-30 Butyl Ether. Some of the remaining isocyanate groups from the first reaction are reacted with 2-pyridylethanol and in a third step, the remaining isocyanate groups are reacted with 1-isobutanol.</p> <p data-bbox="256 917 370 938">[Monomers:]</p>  <p>The structures shown are: PPG-30 Butyl Ether (a polyether chain with a methyl group and a terminal hydrogen, with a subscript of 30); cyclic trimer of hexamethylene diisocyanate (same as above); 2-pyridylethanol (a pyridine ring with a two-carbon ethyl chain ending in a hydroxyl group); and isobutanol (a three-carbon primary alcohol with a methyl branch on the second carbon).</p> | Surface modifier |
| Polyurethane-69 1668562-30-8 | <p data-bbox="256 1341 1333 1390">Polyurethane-69 is a copolymer of Isopropylidenediphenyl Bisoxhydroxypropyl Methacrylate, Isophorone Diisocyanate (IPDI), and Di-C12-13 Alkyl Tartrate, end-capped with hydroxyethyl methacrylate (HEMA).</p> <p data-bbox="256 1392 370 1413">[Monomers:]</p>  <p>The structures shown are: isopropylidenediphenyl bisoxhydroxypropyl methacrylate (a complex molecule with two phenyl rings connected by an isopropylidene group, and two hydroxypropyl chains, one of which is part of a methacrylate group); HEMA (hydroxyethyl methacrylate, a methacrylate with a hydroxyethyl group); di-C12-13 alkyl tartrate (a long-chain tartrate derivative with a subscript of 1-2); and IPDI (isophorone diisocyanate, a six-membered ring with two isocyanate groups and two methyl groups).</p> | Skin-conditioning agent- miscellaneous |

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment. ¹, CIR Staff

| Ingredient CAS No. | Definition & Monomers Structures | Function(s) |
|--------------------------------|--|--|
| Polyurethane-70 | <p data-bbox="261 216 1341 331">Polyurethane-70 is a complex polymer that is formed by a multi-step synthesis. First, a mixture of polyester diols (a copolymer of Adipic Acid and 1,4-Butanediol; and a copolymer of Adipic Acid and Hexanediol; and Neopentyl Glycol and 1,4-Butanediol) are reacted with Isophorone Diisocyanate and hexamethylene diisocyanate (HDI). The resulting urethane polymer is reacted with the sodium salt of N-(2-aminoethyl)-3-aminoethanesulfonic acid, ethylene diamine, and Diethanolamine. The final polymer is dispersed in water.</p> <p data-bbox="261 338 451 359">[Monomers/reactants:]</p> <div data-bbox="337 363 1279 716"> </div> | Film former |
| Polyurethane-71 | <p data-bbox="261 730 1341 825">Polyurethane-71 is a complex polymer that is formed by a multi-step synthesis. First, a polyester diol made by condensing Hexanediol, Adipic Acid, and isophthalic acid is reacted with isophorone diisocyanate and dimethylolpropionic acid. The resulting pre-polymer is neutralized with Triethylamine. The neutralized polymer is dispersed in water with Isopropanolamine and ethylene diamine.</p> <p data-bbox="261 831 451 852">[Monomers/reactants:]</p> <div data-bbox="407 856 1208 1192"> </div> | Binder; film former |
| Polyurethane-72 502761-95-7 | <p data-bbox="261 1207 1341 1262">Polyurethane-72 is a urethane polymer made by reacting Hydrogenated Acetophenone/Oxymethylene Copolymer with Isophorone Diisocyanate (IPDI), dimethylolpropanoic acid, and Dimethyl MEA. The resulting polymer is dispersed in water.</p> <p data-bbox="261 1268 451 1289">[Monomers/reactants:]</p> <div data-bbox="537 1293 1062 1556"> </div> | Binder; film former; nail conditioning agent |

Table 2. Previous reports on precursors, monomers, moieties, and related ingredients of polyurethanes in this safety assessment.

| Moiety | Conclusion; year | Highest concentration of use | Ingredients | Reference |
|--|--|--|---|------------------|
| Acetic Acid | Safe as used; 2012 | Acetic Acid-0.3% in nail products Isopropyl Alcohol-100% Methyl Acitrate-60% | Polyurethane-26 | ¹⁷ |
| Adipic Acid; Hexanedioic Acid | Safe as used; 2012 | Adipic Acid-18% in rinse-off, 0.00001% in leave-on products Succinic Acid-26% in rinse-off; Disodium Succinate-0.4% in leave-on products | Polyurethane-1, -2, -5, -6, -7, -9, -11, -13, -15, -17, -19, -21, -23, -33, -34, -35, -40, -48, -61, -63, -65, -70, -71 | ⁸ |
| Alkyl PEG Ethers | Safe when formulated to be non-irritating; 2012 | C12-13 Pareth 3-32% in products diluted for the bath, 25% in leave-on products | Polyurethane-39, -62 | ²⁰ |
| Butylene Glycol, Hexylene Glycol | Safe as used; 1985, 2006 | Hexylene Glycol-4% in rinse-off; 6% in leave-on products Butylene Glycol-12% in rinse-off; 89% in leave-on products | Polyurethane-1, -2, -5, -6, -7, -17, -33 | ^{3,7} |
| 1,4-Butanediol; 1,5-Pentadiol; Hexanediol | Insufficient Data Announcement; 2016 | 1,4-Butanediol-none reported Hexanediol-0.5% in leave-on; 0.45% in rinse-off products Propanediol-39.9% in leave-on products | Polyurethane-8, -11, -13, -21, -23, -24, -32, -34, -35, -41, -46, -48, -49, -50, -51, -52, -53, -55, -56, -57, -60, -61, -63, -66, -70, -71 | ^{26,27} |
| 1,2-Butanediol | Safe as used; 2012 | 1,2-Butanediol-none reported 1,2-Hexanediol-10% in leave-on products | Polyurethane-51, -54 | ⁹ |
| Diethanolamine | Safe when formulated to be non-irritating; 2011 | Diethanolamine-0.3% in rinse-off; 0.06% in leave-on products | Polyurethane-10, -29, -46, -70 | ²¹ |
| Ethylhexylglycerin | Safe as used; 2013 | Ethylhexylglycerin-2% in leave-on; 8% in rinse-off products Batyl Alcohol-3% in leave-on products | Polyurethane-59 | ¹⁰ |
| Glycine Soja (Soybean) Oil | Safe as used; 2011 | Glycine Soja (Soybean) Oil-95% in leave-on products | Polyurethane-47 | ¹² |
| HDI Polymers | 17 are safe as used, 2 insufficient data; 2016 | HDI/Trimethylol Hexyllactone Crosspolymer-31% in leave-on products | All | ³⁰ |
| Bis-Hydroxyethoxypropyl Dimethicone | Safe as used; 2014 | Bis-Hydroxyethoxypropyl Dimethicone-12% in leave-on products Stearoxy Dimethicone-22% in rinse-off products Cetyl PEG/PPG-10/1 Dimethicone-15% in leave-on products | Polyurethane-28 | ^{2,4} |
| Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer | Safe as used; 2016 | Hydroxyethyl Acrylate/ Sodium Acryloyldimethyl Taurate Copolymer-4.3% in rinse-off, 3.6% in leave-on products | Polyurethane-9 | ¹⁵ |
| Hydroxypropyl Methacrylate; Isopropylidenediphenyl Bisoxhydroxypropyl Methacrylate; HEMA (Hydroxyethyl Methacrylate) | Safe in nail enhancement products when skin contact is avoided | Hydroxypropyl Methacrylate-25% in nail products Isopropylidenediphenyl Bisoxhydroxypropyl Methacrylate-none reported Methoxydiglocol Methacrylate and Ethoxyethyl Methacrylate-85% in nail products HEMA-30% in nail products | Polyurethane-51, -52, -54, -56, -69 | ²³ |
| Isopropanolamine | Safe as used if not used in products containing <i>N</i> -nitrosating agents; 1987, 2006 | Isopropanolamine-1% in leave-on hair products | Polyurethane-71 | ^{3,22} |
| Isostearic Acid (Sorbitan Isostearate) | Safe as used; 2014 | Sorbitan Isostearate-6.5% in leave-on; 1% in rinse-off products Sorbitan Triisostearate-9.1% in leave-on products | Polyurethane-28 | ⁵ |
| Methyl Gluceth-10 | Safe as used; 2013 | Methyl Gluceth-10-15% in leave-on and rinse-off products | Polyurethane-62 | ¹³ |
| PEGs; Triethylene Glycol | Triethylene Glycol and PEGs ≥ 4 are safe as used, 2010 | PEG-200-none reported-85% in leave-on hair products; 45% in other personal care products | Polyurethane-14, -39, -46, -52, -59, -62 | ¹⁸ |
| Polyethylene | Safe as used; 2007, 2015 | Polyethylene-67.6% in leave-on products Hydrogenated Polyisobutene 95% in leave-on products | Polyurethane-8 | ¹⁴ |

Table 2. Previous reports on precursors, monomers, moieties, and related ingredients of polyurethanes in this safety assessment.

| Moiety | Conclusion; year | Highest concentration of use | Ingredients | Reference |
|---------------------------------------|--|---|--|------------------|
| PPG-3 Butyl Ether; PPG-30 Butyl Ether | Safe when formulated to avoid irritation; 2001 Insufficient Data Announcement; 2016 | PPG-3 Butyl Ether and PPG-30 Butyl Ether –none reported PPG-40 Butyl Ether -60.5% in leave-on hair products PPG-14 Butyl Ether-17.5% leave-on dermal products | Polyurethane-67, -68 | ^{24,25} |
| Propylene Glycol; PPGs | Propylene Glycol and PPGs ≥ 3 are safe when formulated to be non-irritating, 2012 | Propylene Glycol-73% in leave-on products; 99% in products diluted for the bath | Polyurethane-4, -9, -14, -36, -67, -68 | ¹⁹ |
| Toluene | Safe in the present practices of use; 1987, 2006 | Toluene-26% in nail products | Polyurethane-9 | ^{11,16} |

Table 3. Precursors, monomers, moieties, and related ingredients of polyurethanes in this safety assessment that are either cosmetic ingredients that have not been reviewed or chemicals that are not cosmetic ingredients.¹

| | | |
|---|---|---|
| Acetophenone* | <i>N</i> -(3-Aminopropyl)imidazole | Aminopropyl triethoxysilane |
| bis-Ethylaminoisobutyl-dimethicone monomers | Butylene oxide | Caprolactone* |
| Cyclohexanedimethanol* | Decyl Alcohol* | Di-C12-13 Alkyl Tartrate* |
| 3-Diethylamino-1,2-propanediol | Dihydroxypolyoxobutylene | Dilinoleyl Alcohol* |
| 2-Dimethylamino-2-methylpropanol | Dimethyl aminopropylamine (DMAPA) | Dimethylcarbonate-1,6-hexanediol |
| Dimethylethanolamine* | Dimethyl MEA | Dimethylolbutanoic acid |
| Dimethylolpropanoic acid | Dimethylolpropionic acid (DMPA) | Dimethylsulfate |
| Ethoxylated 4,4'-isopropylidenediphenol | 2-Ethyl-1-hexanol | Ethylene Carbonate* |
| Ethylene diamine | Ethylene glycol* | Ethylene oxide |
| Ethylenediamine | Hydrazine | 4-Hydroxybutyl acrylate |
| 3-Hydroxy-2-(hydroxymethyl)-2-methyl-1-propionic acid | Hydroxypropyl dimethicone* | Hydroxybutyl acrylate |
| Hydroxyethyl acrylate | 1-Isobutanol | Isophthalic acid |
| Isophorone diamine | 4,4'-Isopropylidenediphenol* | Isopropylidenediphenoxypropanol |
| Lauryl Acrylate* | 4,4'-Methylenebis(cyclohexylamine) | <i>N</i> -(2-Aminoethyl)-3-aminoethanesulfonic acid |
| Neopentyl glycol* | Oxymethylene | Propylene oxide |
| Polyalkylene glycol | Polybutylene glycol | Polycaprolactonetriol |
| Polyester diol | Polyperfluoroethoxymethoxy Difluorohydroxyethyl Ether* | Polytetrahydrofurans (PTHFs) |
| Polytetramethylene ether glycol | Polytetramethylene glycol | Propanoic anhydride |
| Propylene oxide | 2-Pyridylethanol | Sodium <i>N</i> -(2-aminoethyl)-3-aminoethane sulfonate |
| Tetradecyloctadeceth | Trimethylamine* | Trimethylolpropane* |
| Valerolactone* | | |

*Cosmetic ingredient or closely related to a cosmetic ingredient listed in the *Dictionary* that has not been reviewed.

Table 4. Diisocyanates used in manufacturing polyurethanes in this safety assessment.¹

| | |
|---|---|
| bis(Isocyanatomethyl)benzene | 1,3-bis(Isocyanatomethyl)cyclohexane |
| Diphenylmethane diisocyanate | Cyclic trimer of hexamethylene diisocyanate |
| Hexamethylenediisocyanate | Isocyanato methylethylbenzene |
| Isophorone diisocyanate (IPDI) | Methylene bis-(4-cyclohexylisocyanate) |
| m-Tetramethylene diisocyanate | meta-Tetramethylenexylenediisocyanate |
| Saturated methylene diphenyldiisocyanate (SMDI) | Toluene diisocyanate |

Table 6. Frequency of use according to duration and exposure of polyurethanes.^{35,36}

| Use type | Maximum Concentration (%) | | Maximum Concentration (%) | | Maximum Concentration (%) | | Maximum Concentration (%) | |
|-------------------------------|---------------------------|----------|---------------------------|----------|---------------------------|-----------------------------|------------------------------------|-------------------|
| | Uses | | Uses | | Uses | | Uses | |
| | Polyurethane-24 | | Polyurethane-33 | | Polyurethane-34 | | Polyurethane-35 | |
| Total/range | NR | 0.0018-2 | 24 | 0.04-7.5 | 6 | 0.36-3.2 | 9 | 0.84-7 |
| <i>Duration of use</i> | | | | | | | | |
| Leave-on | NR | 0.0018-2 | 24 | 0.04-7.5 | 6 | 0.36-3.2 | 9 | 0.84-7 |
| Rinse-off | NR | NR | NR | NR | NR | NR | NR | NR |
| Diluted for (bath) use | NR | NR | NR | NR | NR | NR | NR | NR |
| <i>Exposure type</i> | | | | | | | | |
| Eye area | NR | NR | 2 | 0.5-1.8 | 6 | 3.2 | 9 | 2-7 |
| Incidental ingestion | NR | NR | NR | NR | NR | 2.9 | NR | NR |
| Incidental Inhalation-sprays | NR | 0.0018 | NR | 0.04 | NR | 0.36-0.75; 0.5 ^e | NR | NR |
| Incidental inhalation-powders | NR | NR | NR | NR | NR | NR | NR | 0.84 ^d |
| Dermal contact | NR | NR | 1 | 0.5-7.5 | NR | NR | 3 | 0.84-2.9 |
| Deodorant (underarm) | NR | NR | NR | NR | NR | NR | NR | NR |
| Hair-noncoloring | NR | 0.0018-2 | NR | 0.04 | NR | 0.36-0.75 | NR | NR |
| Hair-coloring | NR | NR | NR | NR | NR | NR | NR | NR |
| Nail | NR | NR | 22 | 0.3-7.5 | NR | NR | NR | NR |
| Mucous Membrane | NR | NR | NR | NR | NR | 2.9 | NR | NR |
| Baby | NR | NR | NR | NR | NR | NR | NR | NR |
| <hr/> | | | | | | | | |
| | Polyurethane-39 | | Polyurethane-40 | | Polyurethane-46 | | Polyurethane ^e | |
| Total/range | 8 | NR | 8 | NR | NR | 0.2 | 15 | NS |
| <i>Duration of use</i> | | | | | | | | |
| Leave-on | 4 | NR | 8 | NR | NR | NR | 14 | NS |
| Rinse-off | 4 | NR | NR | NR | NR | 0.2 | 1 | NS |
| Diluted for (bath) use | NR | NR | NR | NR | NR | NR | NR | NS |
| <i>Exposure type</i> | | | | | | | | |
| Eye area | NR | NR | 2 | NR | NR | NR | 2 | NS |
| Incidental ingestion | NR | NR | NR | NR | NR | NR | 1 | NS |
| Incidental Inhalation-sprays | 3 ^b | NR | 2 ^b | NR | NR | NR | 3; 1 ^b ; 2 ^c | NS |
| Incidental inhalation-powders | NR | NR | 1 | NR | NR | NR | 2 ^c | NS |
| Dermal contact | NR | NR | 8 | NR | NR | NR | 5 | NS |
| Deodorant (underarm) | NR | NR | NR | NR | NR | NR | NR | NS |
| Hair-noncoloring | 8 | NR | NR | NR | NR | 0.2 | 5 | NS |
| Hair-coloring | NR | NR | NR | NR | NR | NR | NR | NS |
| Nail | NR | NR | NR | NR | NR | NR | 3 | NS |
| Mucous Membrane | NR | NR | NR | NR | NR | NR | 1 | NS |
| Baby | NR | NR | NR | NR | NR | NR | NR | NS |

NR = Not Reported; NS = Not surveyed; Totals = Rinse-off + Leave-on + Diluted for Bath Product Uses.

Note: Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure type uses may not equal the sum total uses.

^a Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.

^b It is possible these products may be sprays, but it is not specified whether the reported uses are sprays.

^c Not specified whether a powder or a spray, so this information is captured for both categories of incidental inhalation.

^d It is possible these products may be powders, but it is not specified whether the reported uses are powders.

^e Not a cosmetic ingredient in the *Dictionary* but reported in the VCRP.

Table 7. Polyurethanes that have no reported uses in the VCRP or from an Industry survey.^{35,36}

| | | |
|-----------------|-----------------|-----------------|
| Polyurethane-4 | Polyurethane-5 | Polyurethane-12 |
| Polyurethane-13 | Polyurethane-17 | Polyurethane-19 |
| Polyurethane-20 | Polyurethane-21 | Polyurethane-23 |
| Polyurethane-25 | Polyurethane-26 | Polyurethane-27 |
| Polyurethane-28 | Polyurethane-29 | Polyurethane-32 |
| Polyurethane-36 | Polyurethane-41 | Polyurethane-42 |
| Polyurethane-43 | Polyurethane-44 | Polyurethane-45 |
| Polyurethane-47 | Polyurethane-48 | Polyurethane-49 |
| Polyurethane-50 | Polyurethane-51 | Polyurethane-52 |
| Polyurethane-53 | Polyurethane-54 | Polyurethane-55 |
| Polyurethane-56 | Polyurethane-57 | Polyurethane-58 |
| Polyurethane-59 | Polyurethane-60 | Polyurethane-61 |
| Polyurethane-62 | Polyurethane-63 | Polyurethane-64 |
| Polyurethane-65 | Polyurethane-66 | Polyurethane-67 |
| Polyurethane-68 | Polyurethane-69 | Polyurethane-70 |
| Polyurethane-71 | Polyurethane-72 | |

Table 8. Code of Federal Regulations for the use of polyurethanes in materials that come in contact with food.

| Code | Regulation |
|----------------|--|
| 21 CFR 174.5 | <p>FOOD FOR HUMAN CONSUMPTION: General provisions applicable to indirect food additives.</p> <p>(a) Regulations prescribing conditions under which food additive substances may be safely used predicate usage under conditions of good manufacturing practice. For the purpose of this part and parts 175, 176, and 177 of this chapter, good manufacturing practice shall be defined to include the following restrictions:</p> <p>(1) The quantity of any food additive substance that may be added to food as a result of use in articles that contact food shall not exceed, where no limits are specified, that which results from use of the substance in an amount not more than reasonably required to accomplish the intended physical or technical effect in the food-contact article; shall not exceed any prescribed limitations; and shall not be intended to accomplish any physical or technical effect in the food itself, except as such may be permitted by regulations in parts 170 through 189 of this chapter.</p> <p>(2) Any substance used as a component of articles that contact food shall be of a purity suitable for its intended use.</p> <p>(b) The existence in the subchapter B of a regulation prescribing safe conditions for the use of a substance as an article or component of articles that contact food shall not be construed to relieve such use of the substance or article from compliance with any other provision of the Federal Food, Drug, and Cosmetic Act. For example, if a regulated food-packaging material were found on appropriate test to impart odor or taste to a specific food product such as to render it unfit within the meaning of section 402(a)(3) of the Act, the regulation would not be construed to relieve such use from compliance with section 402(a)(3).</p> <p>(c) The existence in this subchapter B of a regulation prescribing safe conditions for the use of a substance as an article or component of articles that contact food shall not be construed as implying that such substance may be safely used as a direct additive in food.</p> <p>(d) Substances that under conditions of good manufacturing practice may be safely used as components of articles that contact food include the following, subject to any prescribed limitations:</p> <p>(1) Substances generally recognized as safe in or on food.</p> <p>(2) Substances generally recognized as safe for their intended use in food packaging.</p> <p>(3) Substances used in accordance with a prior sanction or approval.</p> <p>(4) Substances permitted for use by regulations in this part and parts 175, 176, 177, 178 and 179.45 of this chapter.</p> <p>(5) Food contact substances used in accordance with an effective premarket notification for a food contact substance (FCN) submitted under section 409(h) of the act.</p> |
| 21 CFR 175.105 | <p>INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS - Subpart B--Substances for Use Only as Components of Adhesives: Adhesives.</p> <p>(a) Adhesives may be safely used as components of articles intended for use in packaging, transporting, or holding food in accordance with the following prescribed conditions:</p> <p>(1) The adhesive is prepared from one or more of the optional substances named in paragraph (c) of this section, subject to any prescribed limitations.</p> <p>(c) Subject to any limitation prescribed in this section and in any other regulation promulgated under section 409 of the Act which prescribes safe conditions of use for substances that may be employed as constituents of adhesives, the optional substances used in the formulation of adhesives may include the following:</p> <p>(5) Substances permitted for use in adhesives by other regulations in this subchapter and substances named in this subparagraph: <i>Provided, however,</i> That any substance named in this paragraph and covered by a specific regulation in this subchapter, must meet any specifications in such regulation.</p> <p>3-Aminopropanediol, Glycerol polyoxypropylene triol, minimum average molecular weight, and a-Hydro-omega-hydroxypoly-(oxytetramethylene) can only be use or use the preparation of polyurethane and polyurethane resins. Dibutyltin dilaurate for use only as a catalyst for polyurethane resins.</p> <p>Polyurethine resins produced by: (1) reacting diisocyanates with one or more of the polyols or polyesters named in this paragraph, or (2) reacting the chloroformate derivatives of one or more of the polyols or polyesters named in this paragraph with one or more of the polyamines named in this paragraph, or (3) reacting toluene diisocyanate or 4,4' methylenebis(cyclohexylisocyanate) with: (i) one or more of the polyols or polyesters named in this paragraph and with</p> |

Table 8. Code of Federal Regulations for the use of polyurethanes in materials that come in contact with food.

| Code | Regulation |
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| 21 CFR 176.170 | <p>either N-methyldiethanolamine and dimethyl sulfate or dimethylolpropionic acid and triethylamine, or (ii) a fumaric acid-modified polypropylene glycol or fumaric acid-modified tripropylene glycol, triethylamine, and ethylenediamine, or (4) reacting meta-tetramethylxylene diisocyanate with one or more of the polyols and polyesters listed in this paragraph and with dimethylolpropionic acid and triethylamine, N-methyldiethanolamine, 2-dimethylaminoethanol, 2-dimethylamino-2-methyl-1-propanol, and/or 2-amino-2-methyl-1-propanol.</p> <p>Components of paper and paperboard in contact with aqueous and fatty foods.</p> <p>Substances identified in this section may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packaging, processing, preparing, treating, packing, transporting, or holding aqueous and fatty foods, subject to the provisions of this section. Components of paper and paperboard in contact with dry food of the type identified under Type VIII of table 1 in paragraph (c) of this section are subject to the provisions of 176.180.</p> <p>(a) Substances identified in paragraph (a) (1) through (5) of this section may be used as components of the food-contact surface of paper and paperboard. Paper and paperboard products shall be exempted from compliance with the extractives limitations prescribed in paragraph (c) of this section: <i>Provided</i>, That the components of the food-contact surface consist entirely of one or more of the substances identified in this paragraph: <i>And provided further</i>, That if the paper or paperboard when extracted under the conditions prescribed in paragraph (c) of this section exceeds the limitations on extractives contained in paragraph (c) of this section, information shall be available from manufacturing records from which it is possible to determine that only substances identified in this paragraph (a) are present in the food-contact surface of such paper or paperboard.</p> <p>(1) Substances generally recognized as safe in food.</p> <p>(2) Substances generally recognized as safe for their intended use in paper and paperboard products used in food packaging.</p> <p>(3) Substances used in accordance with a prior sanction or approval.</p> <p>(4) Substances that by regulation in parts 170 through 189 of this chapter may be safely used without extractives limitations as components of the uncoated or coated food-contact surface of paper and paperboard in contact with aqueous or fatty food, subject to the provisions of such regulation.</p> <p>(5) Substances identified in this paragraph, as follows: Anionic polyurethane, produced by reacting the preliminary adduct formed from the reaction of glyceryl monostearate and 2,4-toluenediisocyanate with not more than 10 mole percent N-methyldiethanolamine and not less than 90 mole percent dimethylolpropionic acid. The final product is a 15 to 20 percent by weight aqueous solution, having a Brookfield viscosity of 25 to 100 centipoises at 24 deg. C (75 deg. F) - For use only as a surface sizing agent at a level not to exceed 0.1 percent by weight of dry paper and paperboard.</p> |
| 21 CFR 177.1210 | <p>INDIRECT FOOD ADDITIVES: POLYMERS - Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces: Closures with sealing gaskets for food containers</p> <p>Closures with sealing gaskets may be safely used on containers intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:</p> <p>(5) Substances that may be employed in the manufacture of closure-sealing gaskets include:</p> <p>Polyurethane resins manufactured from diphenylmethane diisocyanate, 1,4-butanediol, and adipic acid - For use only: No limitation on amount used, but for use only in closure gasket compositions used in contact with food types VI-A and VI-C (up to 15 percent alcohol) under conditions of use D, E, F, and G, as described in §176.170(c) of this chapter, tables 1 and 2, respectively.</p> |
| 21 CFR 177.1390 | <p>INDIRECT FOOD ADDITIVES: POLYMERS-Subpart B—Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces: Laminate structures for use at temperatures of 250 °F and above.</p> <p>(c) Urethane cross-linking agent comprising no more than 14 percent weight of the cured adhesive and formulated from 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate cyanurate.</p> <p>(vi) Polyurethane-polyester resin-epoxy adhesives formulated from the following mixture:</p> <p>(a)(1) Polyester-polyurethanediol resins prepared by the reaction of a mixture of polybasic acids and polyhydric alcohols listed in §175.300(b)(3)(vii) of this chapter and 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate.</p> <p>(2) Polyester resin formed by the reaction of polybasic acids and polyhydric alcohols listed in §175.300(b)(3)(vii) of this chapter. Additionally, azelaic acid and 1,6-hexanediol may also be used as reactants in lieu of a polyhydric alcohol.</p> <p>(3) Epoxy resin listed in §175.300(b)(3)(viii)(a) of this chapter and comprising not more than 5 percent by weight of the cured adhesive.</p> <p>(4) Optional trimethoxy silane curing agents, containing amino, epoxy, ether, or mercapto groups not in excess of 3 percent of the cured adhesive.</p> <p>(b) Urethane cross-linking agent, comprising not more than 20 percent by weight of the cured adhesive, and formulated from trimethylol propane adducts of 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate or 1,3-bis(isocyanatomethyl)benzene.</p> <p>(vii) Polyester-polyurethane resin-acid dianhydride adhesives for use at temperatures not to exceed 121 °C (250 °F), in contact only with food Types I, II, VIA, VIB, VIIB, and VIII as described in Table I of §176.170 of this chapter, and formulated from the following mixture:</p> <p>(a)(1) Polyesterpolyurethanediol resins prepared by the reaction of a mixture of polybasic acids and polyhydric alcohols listed in §175.300(b)(3)(vii) of this chapter and 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate. Additionally, dimethylol propionic acid and 1,6-hexanediol may be used alone or in combination as reactants in lieu of a polybasic acid and a polyhydric alcohol.</p> <p>(2) Acid dianhydride formulated from 3a,4,5,7a-tetrahydro-7-methyl-5-(tetrahydro-2,5-dioxo-3-furanyl)-1,3-isobenzofurandione, comprising not more than one percent of the cured adhesive.</p> <p>(b) Urethane cross-linking agent, comprising not more than twelve percent by weight of the cured adhesive, and formulated from trimethylol propane adducts of 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate and/or 1,3-bis(isocyanatomethyl)benzene.</p> |

Table 8. Code of Federal Regulations for the use of polyurethanes in materials that come in contact with food.

| Code | Regulation |
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| 21 CFR 177.1395 | <p>INDIRECT FOOD ADDITIVES: POLYMERS-Subpart B—Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces: Laminate structures for use at temperatures between 120°F and 250°F.</p> <p>(a) The laminates identified in this section may be safely used at the specified temperatures. These articles are layered structures that are optionally bonded with adhesives. In these articles, the food-contact layer does not function as a barrier to migration of components from non-food-contact layers. The layers may be laminated, extruded, coextruded, or fused.</p> <p>(b) Laminate structures may be manufactured from:</p> <ol style="list-style-type: none">(1) Polymers and adjuvants complying with §177.1390 of this chapter.(2) Any polymeric resin listed in these regulations so long as the use of the resin in the structure complies with the conditions of use (food type and time/temperature) specified in the regulation for that resin.(3) Optional adjuvant substances used in accordance with §174.5 of this chapter. |
| 21 CFR 177.1680 | <p>INDIRECT FOOD ADDITIVES: POLYMERS-Subpart B—Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces: Polyurethane resins.</p> <p>The polyurethane resins identified in paragraph (a) of this section may be safely used as the food-contact surface of articles intended for use in contact with bulk quantities of dry food of the type identified in §176.170(c) of this chapter, table 1, under Type VIII, in accordance with the following prescribed conditions:</p> <p>(a) For the purpose of this section, polyurethane resins are those produced when one or more of the isocyanates listed in paragraph (a)(1) of this section is made to react with one or more of the substances listed in paragraph (a)(2) of this section:</p> <ol style="list-style-type: none">(1) Isocyanates:<ul style="list-style-type: none">Bis(isocyanatomethyl) benzene.Bis(isocyanatomethyl) cyclohexane.4,4'-Diisocyanato-3,3'-dimethylbiphenyl (bi-tolylene diisocyanate).Diphenylmethane diisocyanate.Hexamethylene diisocyanate.3-Isocyanatomethyl - 3,5,5 - trimethylcyclohexyl isocyanate.4,4-Methylenebis(cyclohexyl isocyanate).Toluene diisocyanate.(2) List of substances:<ul style="list-style-type: none">Adipic acid.1,4-Butanediol.1,3-Butylene glycol.1,4-Cyclohexane dimethanol.2,2-Dimethyl-1,3-propanediol.Ethylene glycol.1,6-Hexanediol.α-Hydro-ω-hydroxypoly(oxy-1,4-butanediyl).α-Hydro-<i>omega</i>-hydroxypoly (oxytetramethylene).α,α'-(Isopropylidenedi-<i>p</i>-phenylene)bis[<i>omega</i>-hydroxypoly (oxypropylene)(3-4 moles)], average molecular weight 675.Maleic anhydride.Methyl oxirane polymer with oxirane.Methyl oxirane polymer with oxirane, ether with 1,2,3-propanetriol.α,α',α''-Neopentanetetrayltetrakis [<i>omega</i>-hydroxypoly (oxypropylene) (1-2 moles)], average molecular weight 400.Pentaerythritol-linseed oil alcoholysis product.Phthalic anhydride.Polybutylene glycol.Polyethyleneadipate modified with ethanolamine with the molar ratio of the amine to the adipic acid less than 0.1 to 1.Poly(oxycarbonylpentamethylene).Polyoxypropylene ethers of 4,4'-isopropylidenediphenol (containing an average of 2-4 moles of propylene oxide).Polypropylene glycol.α,α',α''-1,2,3-Propanetriyltris [<i>omega</i>-hydroxypoly (oxypropylene) (15-18 moles)], average molecular weight 3,000.Propylene glycol.α,α',α''-[Propylidynetris (methylene)] tris [<i>omega</i>-hydroxypoly (oxypropylene) (minimum 1.5 moles)], minimum molecular weight 400.α-[<i>p</i>(1,1,3,3-Tetramethylbutyl) - phenyl]-<i>omega</i>-hydroxypoly(oxyethylene) (5 moles), average molecular weight 425.Trimethylol propane. <p>(b) Optional adjuvant substances employed in the production of the polyurethane resins or added thereto to impart desired technical or physical properties may include the following substances:</p> <p style="text-align: center;">Substance and Restriction</p> <ul style="list-style-type: none">1-[(2-Aminoethyl)amino]2-propanol - as a curing agent.1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride - As a preservative.Colorants used in accordance with §178.3297 of this chapter.Dibutyltin diacetate - as a catalyst.Dibutyltin dichloride - as a catalyst.Dibutyltin dilaurate - as a catalyst.<i>N,N</i>-Dimethyldodecylamine - as a catalyst.<i>N</i>-Dodecylmorpholine - as a catalyst.α,α'-[Isopropylidenebis[<i>p</i>-phenyleneoxy(2-hydroxytrimethylene)]][bis[<i>omega</i>-hydroxypoly-(oxyethylene) (136-170 moles)], average molecular weight 15,000 - as a stabilizer.4,4'-Methylenedianiline - as a curing agent.1,1',1''-Nitrioltri-2-propanol - as a curing agent.2,2'-(<i>p</i>-Phenylenedioxy) diethanol - as a curing agent. |

Table 8. Code of Federal Regulations for the use of polyurethanes in materials that come in contact with food.

| Code | Regulation |
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| | <p>Polyvinyl isobutyl ether Polyvinyl methyl ether Soyaalkyd resin - conforming in composition with §175.300 of this chapter and containing litharge not to exceed that residual from its use as the reaction catalyst and creosol not to exceed that required as an antioxidant. Tetrakis [methylene-(2,5-di-<i>tert</i>-butyl-4-hydroxyhydrocinnamate)]methane (CAS Reg. No. 6683-19-8) - Stabilizer. <i>N,N,N'</i>-Tetrakis (2-hydroxypropyl)ethylenediamine - as a curing agent. Triethanolamine - as a curing agent. Trimethyleneglycol di (<i>p</i>-aminobenzoate) (CAS Reg. No. 57609-64-0) - as a curing agent. (c) An appropriate sample of the finished resin in the form in which it contacts food, when subjected to ASTM method D968-81, "Standard Test Methods for Abrasion Resistance of Organic Coatings by the Falling Abrasive Tester," which is incorporated by reference (Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA)).</p> |
| 21 CFR 177.2600 | <p>INDIRECT FOOD ADDITIVES: POLYMERS - Subpart C—Substances for Use Only as Components of Articles Intended for Repeated Use: Rubber articles intended for repeated use. Rubber articles intended for repeated use may be safely used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section. (a) The rubber articles are prepared from natural and/or synthetic polymers and adjuvant substances as described in paragraph (c) of this section. (b) The quantity of any substance employed in the production of rubber articles intended for repeated use shall not exceed the amount reasonably required to accomplish the intended effect in the rubber article and shall not be intended to accomplish any effect in food. (c) Substances employed in the preparation of rubber articles include the following, subject to any limitations prescribed: (1) Substances generally recognized as safe for use in food or food packaging. (2) Substances used in accordance with the provisions of a prior sanction or approval. (3) Substances that by regulation in parts 170 through 189 of this chapter may be safely used in rubber articles, subject to the provisions of such regulation. (4) Substances identified in this paragraph (c)(4), provided that any substance that is the subject of a regulation in parts 174, 175, 176, 177, 178 and §179.45 of this chapter conforms with any specification in such regulation. (i) <i>Elastomers.</i> Polyurethane resins (CAS Reg. Nos. 37383-28-1 or 9018-04-6) derived from the reaction of diphenylmethane diisocyanate with 1,4-butanediol and polytetramethylene ether glycol. Polyurethane resins derived from reactions of diphenylmethane diisocyanate with adipic acid and 1,4-butanediol.</p> |
| 21 CFR 189.280 | <p>FOOD FOR HUMAN CONSUMPTION - Subpart D--Substances Prohibited From Indirect Addition to Human Food Through Food-Contact Surfaces: 4,4'-Methylenebis (2-chloroaniline). (a) 4,4'-Methylenebis (2-chloroaniline) has the molecular formula, C₁₃H₁₂Cl₂N₂. It is a synthetic chemical not found in natural products and has been used as a polyurethane curing agent and as a component of food packaging adhesives and polyurethane resins. (b) Food containing any added or detectable level of this substance is deemed to be adulterated in violation of the act based upon an order published in the Federal Register of December 2, 1969 (34 FR 19073).</p> |
| 21 CFR 874.3695 | <p>MEDICAL DEVICES – EAR, NOSE, AND THROAT DEVICES – Subpart D—Prosthetic Devices: Mandibular implant facial prosthesis (a) <i>Identification.</i> A mandibular implant facial prosthesis is a device that is intended to be implanted for use in the functional reconstruction of mandibular deficits. The device is made of materials such as stainless steel, tantalum, titanium, cobalt-chromium based alloy, polytetrafluoroethylene, silicone elastomer, polyethylene, polyurethane, or polytetrafluoroethylene with carbon fibers composite. (b) <i>Classification.</i> Class II.</p> |
| 21 CFR 878.3540 | <p>MEDICAL DEVICES – GENERAL AND PLASTIC SURGERY DEVICES – Subpart D—Prosthetic Devices: Silicone gel-filled breast prosthesis (3) <i>Polyurethane covered silicone gel-filled breast prosthesis.</i> A polyurethane covered silicone gel-filled breast prosthesis is an inner silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane, with an outer silicone adhesive layer and an outer covering of polyurethane; contained within the inner shell is a fixed amount of cross-linked polymerized silicone gel, fillers, and stabilizers and an inert support structure compartmentalizing the silicone gel. The device is intended to be implanted to augment or reconstruct the female breast. (b) <i>Classification.</i> Class III. (c) <i>Date premarket approval application (PMA) is required.</i> A PMA is required to be filed with the Food and Drug Administration on or before July 9, 1991 for any silicone gel-filled breast prosthesis that was in commercial distribution before May 28, 1976, or that has on or before July 9, 1991 been found to be substantially equivalent to a silicone gel-filled breast prosthesis that was in commercial distribution before May 28, 1976. Any other silicone gel-filled breast prosthesis shall have an approved PMA in effect before being placed in commercial distribution.</p> |
| 21 CFR 878.4020 | <p>MEDICAL DEVICES – GENERAL AND PLASTIC SURGERY DEVICES – Subpart E—Surgical Devices: Occlusive wound dressing (a) <i>Identification.</i> An occlusive wound dressing is a nonresorbable, sterile or non-sterile device intended to cover a wound, to provide or support a moist wound environment, and to allow the exchange of gases such as oxygen and water vapor through the device. It consists of a piece of synthetic polymeric material, such as polyurethane, with or without an adhesive backing. This classification does not include an occlusive wound dressing that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources. (b) <i>Classification.</i> Class I (general controls). The device is exempt from the premarket notification procedures in part 807, subpart E of this chapter subject to the limitations in 878.9.</p> |

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