Amended Safety Assessment of Acrylates Copolymers as Used in Cosmetics

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ABSTRACT

The Cosmetic Ingredient Review (CIR) Expert Panel (Panel) assessed the safety of 126 acrylates copolymers; 56 of these ingredients were previously reviewed by the Panel, and 70 are reviewed herein for the first time. Many of these ingredients are reported to have several functions in cosmetics, with the function of film former being the most commonly reported cosmetic function for members of this family; many of the ingredients also may function in cosmetics as viscosity increasing agents. The Panel reviewed relevant new data, including frequency and concentration of use, and considered the data from previous CIR reports. The Panel concluded the 126 acrylates copolymers named in this report are safe in cosmetics in the present practices of use and concentration described in the safety assessment when formulated to be non-irritating.

INTRODUCTION

CIR published the Final Report on the Safety Assessment of Acrylates Copolymer and 33 Related Cosmetic Ingredients in 2002.[1] Based on the available data, the Panel concluded that the acrylates copolymers named in that report are safe for use in cosmetics when formulated to avoid irritation.

According to its Procedures, the CIR evaluates the conclusions of previously-issued reports every 15 years. As part of the re-review process, in addition to reassessing the existing conclusion, CIR also determines whether other ingredients are appropriate for inclusion in the re-review document. The Panel determined that it is appropriate to include all the copolymers (including crosslinked copolymers (i.e., crosspolymers)) prepared from monomers that comprise, in part, acrylic acid and/or methacrylic acid; the methyl, ethyl, propyl, or butyl ester(s) of these acids; or the salts of one or both of these two acids, with a few exceptions, as described below. Based on this rationale, the 126 ingredients described below, and listed in Table 1, are included in this re-review.

Some of the ingredients deemed appropriate for inclusion have previously been reviewed by CIR in other assessments. In 2017, the Panel published a safety assessment with the conclusion that 23 crosslinked alkyl acrylates included in the safety assessment are safe in the present practices of use and concentration, except when polymerized in benzene.[2] Acrylates C10-30 Alkyl Acrylate Crosspolymer may be polymerized in benzene, and the available data were insufficient to make a determination of safety, specifically with regard to carcinogenicity, for this ingredient when polymerized in benzene. Accordingly, this assessment only addresses the safety of Acrylates C10-30 Alkyl Acrylate Crosspolymer when polymerized in solvents other than benzene.

In 2011, the Panel published a safety assessment of Polymethyl Methacrylate (PMMA), Methyl Methacrylate Crosspolymer, and Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer, and concluded that these ingredients are safe in the practices of use and concentration that were described in the report.[3] The Food and Drug Administration (FDA) had made a determination of safety of PMMA use in several medical devices, which included human and animal safety data. The Panel used that information as the basis of safety of PMMA and related polymers as used in cosmetics.

Another report on similar ingredients is the 1982 CIR Final Report on the Safety Assessment of Carbomers-934, -910, -934P, 940, -941, and -962; the Panel concluded that these ingredients are safe in the present practices of use and concentration that were described in that report.[4] These ingredient names no longer exist as INCI names. Instead, they are now identified in the web-based *International Cosmetic Ingredient Dictionary and Handbook* (wINCI; *Dictionary*) as technical names for one ingredient, Carbomer.[5] In 2003, the Panel reaffirmed that Carbomer is safe as used.[6]

In addition to the ingredients that have been previously reviewed by the Panel, an additional 70 acrylates copolymers that have not yet been reviewed are named in the *Dictionary*.[5] These ingredients are also included in this safety assessment.

The Panel determined that it was appropriate to exclude five ingredients that were part of the initial safety assessment on the Acrylates Copolymers in this re-review because they are either already part of a recent or a concurrent safety assessment. Sodium Styrene/Acrylates Copolymer and Styrene/Acrylates Copolymer were reviewed in 2014 (and found safe as used in cosmetics),[7] and the safety of Acrylates/VP Copolymer, Vinyl Caprolactam/VP/Dimethylaminoethyl Methacrylate Copolymer, and VP/Dimethyl-aminoethylmethacrylate Copolymer are part of the concurrent safety assessment of Vinylpyrrolidone Polymers.

According to the *Dictionary*, the ingredients included in this report have an array of functions in cosmetics, with the function of film former being the most commonly reported cosmetic function for members of this family (Table 2).[5] Many of the ingredients also may function in cosmetics as viscosity increasing agents.

This safety assessment includes relevant published and unpublished data that are available for each endpoint that is evaluated. Published data are identified by conducting an exhaustive search of the world's literature. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that CIR typically evaluates, is provided on the CIR website (https://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites; https://www.cir-safety.org/supplementaldoc/cir-report-format-outline). Unpublished data are provided by the cosmetics industry, as well as by other interested parties.

Excerpts from the summaries of previous reports on Acrylates Copolymer and related ingredients, and all other previously-reviewed ingredients, are disseminated throughout the text of this re-review document, as appropriate, and are identified by *italicized text*. (This information is not included in the tables or the summary section.) Additionally, the Discussions from these reports are also included in this document. For complete and detailed information, please refer to the original documents, which are available on the CIR website (https://www.cir-safety.org/ingredients). Please note that information on the monomers is found in several of the original reports, but not in this document.

Much of the new data included in this safety assessment was published by Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS).[8-14] Please note that NICNAS provides summaries of information generated by industry, and it is that summary data that are brought into this safety assessment when NICNAS is cited.

CHEMISTRY

Definition and Structure

The definitions and structures of the ingredients included in this report are provided in Table 2.

Copolymers are polymers synthesized from two or more different monomers, and crosspolymers are copolymers that are crosslinked (i.e., individual polymer chains are connected by bridging molecules [crosslinking agents]).[2] As stated in the Introduction, this report comprises a large number of copolymers and crosspolymers, most of which are prepared from monomers that include, in part, acrylic acid and/or methacrylic acid; the methyl, ethyl, propyl, or butyl ester(s) of these acids; or the salts of one or both of these two acids (Figure 1).

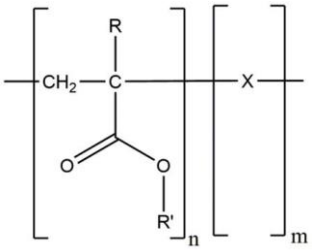


Figure 1. Acrylates copolymers, wherein R is hydrogen or methyl; R' is hydrogen, methyl, ethyl, propyl, butyl, or a salt cation (e.g., sodium); and X is one or more co-monomer residues.

However, a few of these ingredients are the polymerization products of monomers that comprise acrylate esters that are not methyl, ethyl, propyl, or butyl; but instead, these esters are the products of different alkoxyl or polyalkoxyl groups (Figure 1). Also, these other ingredients are all essentially homopolymers.

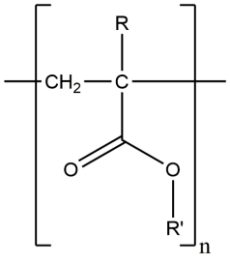


Figure 2. Other polyacrylates, wherein R is hydrogen or methyl; and R' is alkoxyl or polyalkoxyl (e.g., PEG-23).

Physical and Chemical Properties

From the Safety Assessment of Crosslinked Alkyl Acrylates[2]

Crosslinked polymers are generally less chemically reactive and less soluble (if not totally insoluble) than their respective non-crosslinked counterparts. Because of the manner in which these polymers are created and the mixture of monomers and cross-linking agents that can be used, 2 polymers that have the same INCI name can have very different physical consistencies.

Physical and chemical properties of several acrylates copolymers are described in Table 3. Primarily, physical form is identified therein.

Methods of Manufacture

From the Original Safety Assessment of Acrylates Copolymers[1]

Linear polymers of acrylic acid are produced by combining the monomer with a free-radical initiator, which is generally largely consumed by the reaction. The size of the polymer is determined by controlling the environment in which the polymerization occurs. Polymers of acrylic acid are characterized by their average molecular weight, but many species of greater and lesser molecular weight are present and unreacted monomer and catalysts can also be present. Additionally, hydroquinone and monomethyl ester of hydroquinone are often incorporated into acrylic acid and its esters as an inhibitor.[1]

Specific method of manufacture information for several ingredients is found in the original report.

From the Safety Assessment of Crosslinked Alkyl Acrylates[2]

Cross-linked alkyl acrylates are typically produced via free radical, head-to tail chain propagation polymerization. Ethyl acetate + cyclohexane, water, n-hexane, and benzene are all named as solvents.

From the Safety Assessment of PMMA and related ingredients[3]

The manufacturing process for PMMA beads used in medical devices and in cosmetic products is the same. The only difference is the size of the PMMA spheres, which are provided according to the specifications of the purchaser. Polymethyl methacrylate beads or powders in cosmetics are precipitated out from a polymerization reaction. The average bead size can be controlled within the 4 to 50 μm specifications. In nail products, polymer powders are made from methyl or ethyl methacrylate or their copolymers.

From the Safety Assessment of [Carbomer][4]

Carbomer is manufactured by reflux polymerization of acrylic acid in an inert solvent in the presence of a catalyst. In doing this, a closed system, free of oxygen and water, is used.

Acrylates Copolymer

Acrylates Copolymer, as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate, with a quantitative composition described as poly(ethyl acrylate-co-methyl methacrylate) 2:1, is produced by emulsion polymerization.[15] A redox-initiated polymerization of the monomers ethyl acrylate and methyl methacrylate occurs through the use of a free radical donor redox initiator system. Polyethylene glycol monostearyl ether is used as an emulsifier in the process, and an alkyl mercaptan is used as a chain modifying agent. At the end of the process, an emulsifier is added to reduce foaming. Residual monomers and excess water are removed by water vapor distillation, and the pH of the reaction mixture is adjusted with sodium hydroxide.

A similar emulsion polymerization process is used to synthesize Acrylates Copolymer as a fully polymerized copolymer of methyl acrylate, methyl methacrylate, and methacrylic acid, with a quantitative composition described as poly(methyl acrylate-co-methyl methacrylate-co-methacrylic acid) 7:3:1 in an aqueous (aq.) medium.[16] Polymerization is by means of a free radical initiator. Sodium lauryl sulfate (SLS) and polysorbate 80 are used as emulsifiers, and an alkyl mercaptan is used as a chain-modifying agent. Small amounts of dimethicone (polydimethyl siloxane) are added to reduce foam formation. Water vapor distillation removes the residual monomers to a level of less than 100 mg/kg total. After the reaction product is cooled and filtered, the dry substance content is approximately 30%.

Composition/Impurities

From the Original Safety Assessment of Acrylates Copolymers[1]

Linear polymers of acrylic acid may contain unreacted starting material and catalysts. Ten companies representing the majority of the production of polymers sold for cosmetic use indicated that residual acrylic acid concentrations in polymers are typically between 10 and 1000 ppm, with an upper limit of 1500 ppm.

One source reported Acrylates Copolymer can contain residual amounts of ≤ 20 ppm ethyl acrylate, methyl methacrylate, methacrylic acid, and acrylic acid; another source reported that three samples analyzed using gas chromatography (GC) contained < 0.2 to 0.8 ppm acrylic acid, 0.8 to 2.6 ppm methyl methacrylate, and 1.3 to 3.9 ppm ethylene glycol dimethacrylate. Additionally, it was reported to CIR that two polymers, both defined as Acrylates Copolymer, contained different residual monomers; the first contained 36, 20, and 45 ppm n-butyl acrylate, methyl methacrylate, and methacrylic acid, respectively, and the second contained 1500 and 200 ppm stearyl acrylate and methacrylic acid, respectively. Acrylates/VA Copolymer can contain, as reported by two polymer producers, 100 to 1000 ppm residual 2-ethylhexyl acrylate. However, the 10 respondents of the survey described previously reported that they did not produce acrylate polymers with 2-ethylhexyl acrylate for use in the cosmetic industry. Using UV spectroscopy with a limit of detection of 300 mg/kg (ppm), acrylic acid was detected in Polyacrylic Acid at 195 nm. A 90,000-Da molecular weight sodium hydroxide-neutralized Polyacrylic Acid contained 77.5% Sodium Polyacrylate, 3.3% free acrylic acid, and 18.1% water, whereas a 4500-Da molecular weight compound contained 43.3% solids and 0.09% residual monomer.

From the Safety Assessment of Crosslinked Alkyl Acrylates[2]

Small amounts of residual monomer and/or solvent may be present in the crosspolymers.

From the Safety Assessment of PMMA and related ingredients[3]

The impurity of concern in PMMA is the monomer, methyl methacrylate (MMA). Analysis of PMMA beads used in cosmetic formulations found MMA to be present at < 100 ppm. The Nail Manufacturers Council reported that the residual monomer is typically < 1.5%; averages of 0.7% and 1.2% have been reported. Residual MMA in Methyl Methacrylate Crosspolymer is similar to that found in PMMA, i.e., < 100 ppm.

From the Safety Assessment of [Carbomer][4,6]

Reported impurities for the Carbomer resins include water, benzene, propionic acid, acetic acid, acrylic acid, heavy metals, iron, arsenic, and lead. The Panel calls attention to the presence of benzene as an impurity in Carbomer and recommends that every effort be made to reduce it to the lowest possible value. However, when the safety of Carbomer was reassessed in 2003, the Panel acknowledged the industry practice of removing benzene from Carbomer.

Acrylates Copolymer

Specifications for Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate) state that it contains < 100 mg/kg total monomer (sum of methyl methacrylate and ethyl acrylate); 0.7% residual emulsifier (polyethylene glycol monostearyl ether); < 0.5% ethanol; and < 0.1% methanol.[17] Additionally, limits on heavy metals are: < 2 mg/kg arsenic; < 2 mg/kg lead; < 2 mg/kg mercury; < 10 mg/kg zinc; and < 10 mg/kg copper.

Approximately 0.3% SLS and 1.2% polysorbate 80, both w/w based on the solid substance, are residual in the polymer as a result of the emulsion polymerization process used to synthesize Acrylates Copolymer as a fully polymerized copolymer of methyl acrylate, methyl methacrylate, and methacrylic acid.[16]

Acrylates/Steareth-20 Methacrylate Copolymer

Acrylates/Steareth-20 Methacrylate Copolymer contains < 100 ppm residual monomer.[18]

Polyacrylate-1 Crosspolymer

Polyacrylate-1 Crosspolymer is reported to be 99% pure.[12] (No other details were available.)

VA/Butyl Maleate/Isobornyl Acrylate Copolymer

A copolymer of vinyl acetate, butyl maleate and isobornyl acrylate in ethanol is reported to be at least 95.3% pure.[8] Impurities are reported as < 0.4% acetone dimethylformaldehyde; < 0.1% vinyl acetate; < 0.1% monobutyl maleate; and < 0.1% isobornyl acrylate. The maximum percentage of low molecular weight species (molecular weight < 1000) is < 2%.

USE

Cosmetic

The safety of the cosmetic ingredients addressed in this report is evaluated based on data received from the US FDA and the cosmetics industry on the expected use of these ingredients 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 information received from the VCRP and the Council survey, 66 of the 126 ingredients assessed in this report are in use.[19-25] Carbomer has the highest frequency of use; according to 2018 VCRP data, it is used in 6434 cosmetic formulations (with 6175 uses under the name Carbomer and 259 uses listed under various tradenames), and most of these uses (5336) are in leave-on products (Table 4).[25] Acrylates Copolymer and Acrylate/C10-30 Alkyl Acrylate Crosspolymer (solvent not specified) have the next highest frequencies of use, with 3177 and 3135 reported uses, respectively. Many of the other in-use acrylates copolymers have hundreds of use, although some have just a few.

The results of concentration of use surveys conducted by the Council in 2018 indicate that Acrylates Copolymer has the highest maximum use concentration; it is used at up to 98.6% in nail extenders; use in product categories other than nail products is not as high, but Acrylates Copolymer is used at up to 25% in products that result in dermal contact (face and neck products).[19] Ingredients with the next highest reported concentrations of use are Acrylates/VA Copolymer (at 50%, in "other" skin care formulations)[19] and Polymethyl Methacrylate (at up to 44.6%, in face powders).[23]

Numerous ingredients named in this report have been reviewed previously by the Panel. For many of the previously-reviewed ingredients, the frequency of use has increased since the time of the original review, with some increases being quite significant. For example, the frequency of use of Acrylates Copolymer increased from 227 uses in 1998[1] to 3177 uses in 2018,[25] and the frequency of use of Carbomer increased from 1504 uses in 2001[6] to 6434 uses in 2018.[25] Concentrations of use were not reported by the FDA at the time of the original assessment of Acrylates Copolymer and related ingredients, so it is not known if the concentrations of use have changed for those ingredients. For the other previously-reviewed ingredients, there were no notable increases in concentrations of use.

It should be noted that that the original report on Polymethyl Methacrylate stated this ingredient was used as beads in cosmetic products. However, based on environmental concerns, the use of microbeads in cosmetics is being phased out in many jurisdictions, including the US.[26] Microbeads include the Polymethyl Methacrylate beads described in the 2011 report.

In some cases, reports of uses were received from the FDA VCRP, but no concentration of use data were provided. For example, Potassium Carbomer is reported to be used in 73 formulations, but no use concentration data were submitted in response to the Council survey. In several other cases, no uses were reported to the VCRP, but a maximum use concentration was provided by industry. It should be presumed that for those ingredients, there is at least one use in each category for which a concentration was reported.

Many of the acrylates copolymers are used in products that can be used near the eye (e.g., 30% Acrylates/Ethylhexyl Acrylate Copolymer in mascara),[20] or are used in products that could result in incidental ingestion (e.g., 16.1% Polymethyl Methacrylate in lipstick formulations).[23] Additionally, some of these ingredients are used in cosmetic sprays and could possibly be inhaled; for example, VA/Butyl Maleate/Isobornyl Acrylate Copolymer is reported to be used at a maximum concentration of 10% in aerosol hair sprays). In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent

diameters > 10 µm, with propellant sprays yielding a greater fraction of droplets/particles < 10 µm compared with pump sprays.[27,28] Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and thoracic regions of the respiratory tract and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount.[29,30] Sodium Polyacrylate has reported use in an aerosol deodorant at a concentration of 2.9%.[19] There is some evidence indicating that deodorant spray products can release substantially larger fractions of particulates having aerodynamic equivalent diameters in the range considered to be respirable.[30] However, the information is not sufficient to determine whether significantly greater lung exposures result from the use of deodorant sprays, compared to other cosmetic sprays. Additionally, some of the acrylates copolymers are reportedly used in loose powders; for example, Polymethyl Methacrylate is used at concentrations up to 44.6% in face powders,[23] and could possibly be inhaled. 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.[31-33]

The acrylates copolymers that are not reported to be in use, according to 2018 FDA VCRP and 2018 Council survey data, are listed in Table 5.

With the exception of AMP-Acrylates Copolymer, the acrylates copolymers described in this safety assessment are not restricted from use in any way under the rules governing cosmetic products in the European Union (EU).[34] AMP-Acrylates Copolymer is restricted by a maximum secondary amine content of 5% in ready for use preparations.

Non-Cosmetic

From the Safety Assessment of PMMA and related ingredients[3]

Polymethyl methacrylate bone cement has been approved by the FDA as a class II (special controls) medical device that requires premarket notification and adherence to standards. Polymethyl methacrylate beads are incorporated into collagen as dermal fillers. Intraocular lenses are made of PMMA.

Several of the ingredients reviewed in this report are approved for use as secondary direct food additives or as indirect food additives. (See Table 6.) Additionally, Polymethyl Acrylate is a prior-sanctioned food ingredient as a substances used in the manufacture of paper and paperboard products used in food packaging. [21CFR181.30]

Acrylates Copolymer

Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate[15] and as a fully polymerized copolymer of methyl acrylate, methyl methacrylate, and methacrylic acid[16]) is used as an excipient in the preparations for oral tablets as a glazing/coating agent to permit the pH-independent delayed release of active ingredients.

TOXICOKINETIC STUDIES

Dermal Penetration

From the Safety Assessment of PMMA and related ingredients[3]

Polymethyl methacrylate-based cosmetic ingredients are large molecules and remain in particulate form (dispersed) in final preparations and thus will not likely cross the stratum corneum to induce systemic toxicity.

Absorption, Distribution, Metabolism, and Excretion (ADME)

Animal

Oral

Acrylates Copolymer

Five male rats were administered 55 - 75 mg/animal of Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate; supplied as a dried film labeled with ^{14}C with a specific activity of 0.17 µCi/mg) by gavage.[15] Urine and feces were collected for 5 days prior to dosing (to establish background radioactivity levels), and for 7 days following dosing. Animals were then killed, and tissue samples were collected and assessed for radioactivity. An additional 9 male rats were also given a single oral dose of the test article, and 3 animals were killed 1, 3, or 14 days after dosing, and tissue samples were collected. The mean total recovery of radioactivity over a period of 5 days following administration of the labeled substance was in excess of 90% of the administered dose. More than 97% of the radioactivity was recovered in the feces, primarily with 48 h of dosing. Little radioactivity (0.0092%) was excreted in the urine. Levels of radioactivity in the blood and tissues did not significantly differ between treated and control animals. The researchers concluded that less than 0.02% of the administered test article was absorbed from the gastrointestinal tract, and that any material that was absorbed was rapidly excreted.

Three groups of 4 male and 4 female Sprague-Dawley rats were dosed by gavage for 13 days with Acrylates Copolymer (as a fully polymerized copolymer of methyl acrylate, methyl methacrylate, and methacrylic acid; dose not stated), followed by a single dose of radiolabeled test material (10 µCi per animal; ^{14}C-labeled at the free carboxyl group of the methacrylic acid moiety).[16] One group was killed at 24 h, and one at 72 h, after the last dose. The last group was kept for 10 days, and urine and feces were collected. The majority of the dose was excreted in the feces; with 94% collected within 72 h of dosing. Little or no radioactivity (< 0.1%) was recovered in urine. Tissues and tissue contents accounted for < 0.01% of the total recovery, and levels of radioactivity in the carcass were below limits of detection.

TOXICOLOGICAL STUDIES

From the Safety Assessment of PMMA and related ingredients[3]

The Panel saw no need to review systemic toxicity data on PMMA and related polymers applied to the skin as the safety of this route of exposure can be extrapolated from data on use of these polymers as medical devices, which had already been reviewed and found safe by the FDA.

Acute Toxicity Studies

From the Original Safety Assessment of Acrylates Copolymers[1]

The following LD_{50} values were reported for Acrylates Copolymer: > 16 g/kg (dermal, rabbits), > 16 ml/kg (dermal), >9 g/kg (dermal), 9 g/kg (dermal, rats), > 5.2 mg/l (rats). Ethylene/Acrylic Acid Copolymer had a" low order of acute toxicity" following dermal and oral administration to rats; the oral LD_{50} was > 5 g/kg. The oral LD_{50} for rats of an ammonium salt of Ethylene/Acrylic Acid was 41.5 ml/kg. In an acute inhalation study, 0 of 6 rats exposed to an aqueous emulsion of the ammonium salt of Ethylene/Acrylic Acid polymer died. The dermal LD_{50} for rabbits and the oral LD_{50} for rats of Vinyl Acetate/Maleate/Acrylate Copolymer solution was > 5 g/kg. For rats, the oral LD_{50} values of Polyacrylic Acid and Sodium Polyacrylate were 2.5 and > 40 g/kg, respectively; and 0.34 and 2.59 ml/kg, respectively, for male rats.

From the Safety Assessment of Crosslinked Alkyl Acrylates[2]

Little toxicity data were available. Acute dermal toxicity data for Acrylates/C10-30 Alkyl Acrylate Crosspolymer and Acrylates/Vinyl Neodecanoate Crosspolymer in rabbits (LD_{50}s > 2.0 g/kg and > 5.0 g/kg, respectively) and oral LD_{50} values in rats for Acrylates/C10-30 Alkyl Acrylate Crosspolymer (>10 g/kg), Acrylates/ Vinyl Isodecanoate Crosspolymer (2 g/kg), Acrylates/Vinyl Neodecanoate Crosspolymer (> 5 g/kg), and Sodium Acrylates Crosspolymer-2(> 2 g/kg indicated that these ingredients are not very toxic. Additionally, the inhalation LC_{50} of Acrylates/Vinyl Neodecanoate Crosspolymer in rats is > 16.34 mg/l air (1 h).

From the Safety Assessment of [Carbomer][4]

Acute oral studies with rats, guinea pigs, mice, and dogs showed that Carbomer has low toxicity when ingested. The inhalation LC_{50} of Carbomer in albino rats was 1.71 mg/l. The dermal LD_{50} of rats exposed to Carbomer was > 3 g/kg.

The acute toxicity studies summarized here are described in Table 7. Dermal LD_{50}s of > 2 g/kg[13] and > 5 g/kg[14] were reported for Acrylates Copolymer in rats, and in rabbits, an LD_{50} of > 2 g/kg was reported for VA/Butyl Maleate/Isobornyl Acrylate Copolymer in ethanol.[8] The dermal LD_{50}s of Acrylates/Beheneth-25 Methacrylate Copolymer[10] and Acrylates/Hydroxyesters Acrylates Copolymer (product containing < 50%) in rats[14] were > 5 g/kg. Acute oral studies were conducted on Acrylates Copolymer; the LD_{50}s in rats and dogs were > 25.2 g dry copolymer/kg bw and > 7.95 g dry copolymer/kg bw, respectively.[15] In oral studies in rats, LD_{50}s of > 5 g/kg were reported for Acrylates/ Beheneth-25 Methacrylate Copolymer,[10] Acrylates/Hydroxyesters Acrylates Copolymer (product containing < 50%),[14] and VA/Butyl Maleate/Isobornyl Acrylate Copolymer in ethanol.[8] For Polyacrylate-1 Crosspolymer, the oral LD_{50} in rats was > 2 g/kg.[12] In an acute inhalation study in rats, a 4-h exposure resulted in an LC_{50} of > 3960 mg/l Acrylates Copolymer.[15]

Short-Term Toxicity Studies

From the Original Safety Assessment of Acrylates Copolymers[1]

Pulmonary lesions were observed in rats used in short-term inhalation studies of acrylic acid polymers.

From the Safety Assessment of [Carbomer][4]

Feeding of rats with doses up to 5.0 g/kg/day Carbomer (49 days) and of rats and dogs with up to 5.0% Carbomer in the diet (21 days) resulted in lower than normal body weights.

Oral

Acrylates Copolymer

Groups of 10 male and 10 female rats were dosed by gavage with 500, 1000, and 2000 mg/kg bw/day of dry Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate) for 35 days.[15] Two recovery groups of 5 males and 5 females were dosed with 0 or 2000 mg dry copolymer/kg bw/d and were used for a recovery period of 14 days without dosing. The control group received distilled water. No animals died during the study. Differences in hematology and clinical chemistry parameters and in organ weights that were observed between treated and control animals were not considered related to the test article because a dose-response was not observed. There were no changes in urinary parameters reported. The no-observed-adverse effect level (NOAEL) was 2000 mg/kg bw/day.

In a 28-day study, groups of 3 male and 3 female Göttingen minipigs were administered Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate) via coating on cellulose pellets containing 22.7% copolymer.[15] The animals received the coated cellulose pellets at dose levels of 500, 1000, and 2000 mg/kg bw/d, which corresponded to dose levels of 113, 227, and 454 mg/kg bw/d expressed as dry copolymer. Clinical signs were observed and feed consumption was measured daily, body weights were measured weekly, and hematology, clinical chemistry, urinalysis, and fecal parameters were evaluated. No treatment-related deaths were observed. There were no toxicologically relevant changes in body weight, food consump-

tion, clinical observations, ophthalmoscopy, clinical pathology, urinalysis, fecal analysis, or in organ weights. Microscopic examination revealed instances of mucosal/submucosal edema in the cecum and colon of one male receiving 454 mg dry copolymer/kg bw/d and in the caecum of one male dosed at 227 mg dry copolymer/kg bw/d; the researcher commented that the influence of the high doses is unclear, and the finding may be a physiological reaction of the intestine to the high amounts of non-soluble or non-degradable particles resulting in osmotic imbalance. No toxicological relevance was attributed to this change. Centrilobular yellow/brown pigmentation and mild fibrosis was apparent in the liver of a single female dosed at 454 mg dry copolymer/kg bw/d. The NOAEL was determined to be 227 mg dry copolymer/kg bw/d.

Subchronic Toxicity Studies

From the Original Safety Assessment of Acrylates Copolymers[1]

In a subchronic inhalation toxicity study of Acrylates Copolymer, alveolar histiocytosis was observed at a concentration of 30 mg/m^3. Pulmonary lesions were observed in rats used in subchronic inhalation studies of acrylic acid polymers.

From the Safety Assessment of [Carbomer][4]

Subchronic feeding of rats and dogs with up to 5.0% Carbomer in the diet (90 days) resulted in lower than normal body weights. In rats fed Carbomer at dietary levels of 5.0% for 90 days, absolute liver weights and liver to body and brain weight ratios were reduced, but no pathological changes were observed.

Chronic Toxicity Studies

From the Original Safety Assessment of Acrylates Copolymers[1]

In a chronic inhalation study of respirable polyacrylate particles, compound-related pulmonary lesions were not observed.

From the Safety Assessment of [Carbomer][4]

Rats fed Carbomer at dietary levels of 0.1%, 0.5%, or 5.0% for 6.5 months exhibited various organ weight changes. In dogs fed 0.5 or 1.0 g/kg/day Carbomer for 6.5 months, gastrointestinal irritation and marked pigment deposition within Kupffer cells of the liver were observed. In another study, there were no significant effects in dogs fed up to 1.0 g/kg/day Carbomer for 32 months.

Oral

Acrylates Copolymer

A 40% Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate) dispersion was sprayed onto powdered diet at a ratio of 1:10, and the coated diet was mixed with basal diet and administered to groups of 20 male and 20 female Sprague-Dawley rats for 26 wks.[15] Once mixed with basal diet, the dose levels were 500 and 2000 mg dry copolymer/kg bw/day. A control group of 20 males and 20 females received diet prepared by spraying with water and subsequent drying. The test was performed in accord with the Organisation for Economic Co-operation and Development (OECD) test guideline (TG) 408. Clinical signs were evaluated and feed consumption was measured daily, body weights were determined weekly, and clinical chemistry, hematology, and urinalysis parameters were evaluated at several intervals. All animals were killed at study termination. None of the animals died during the study, and no clinical signs of toxicity were observed. No treatment-related findings were observed. The NOAEL was ≥ 2000 mg dry copolymer/ kg bw/day.

A similar study was conducted using coated pellets containing approximately 22.7% Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate), and the pellets were placed into gelatin capsules and administered to groups of 4 male and 4 female Beagle dogs for 26 wks.[15] The dose levels used were 50, 125, and 250 mg dry copolymer/kg bw/d, which were equivalent to 200, 500, and 1000 mg test material/kg bw/d. A control group of 4 males and 4 females were given empty capsules. An additional 3 male and 3 female animals were included with both the control and high dose groups, and these animals were allowed to recover for 3 wks after the termination of dosing. Examinations were made as described above. High-dose animals had lower body weight gains as compared to controls, and the difference became statistically significant at wk 12. Males of the low- and mid-dose groups had slightly lower body weights compared to controls; no changes were observed in the body weights of females of these groups. Relative heart and right thyroid weights in treated females were increased, but these changes were not considered treatment-related because no differences were observed microscopically. Other observations were not considered toxicologically significant, and the NOAEL was determined to be 250 mg dry copolymer/kg bw/d.

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY STUDIES

From the Original Safety Assessment of Acrylates Copolymers[1]

Reproductive effects were not observed in a study in which rats were dosed orally with 4500- or 90,000-Da molecular weight (MW) Sodium Polyacrylate. In this study, groups of 30 gravid rats were dosed with up to 3000 mg/kg/day of the low MW test article in distilled water on days 6-15 of gestation, and the animals were killed on day 19 of gestation. Groups of 28-29 gravid rats were dosed with up to 1125 mg/kg/day of the high MW test article in distilled water; 8 animals/group were dosed on days 6-13 of gestation and killed on day 13, and the remaining animals in each high MW-test article group were dosed on days 6-15 of gestation, and killed on day 10 of gestation.

Oral

Acrylates Copolymer

Two studies were conducted in which an Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate) dispersion was sprayed onto powdered diet at a ratio of 1:10, and the coated diet was mixed with basal diet for testing.[15] In the first study, groups of 20 mated female Wistar rats were fed 0, 500, or 2000 mg dry copolymer/ kg bw/day on days 6 through 15 of gestation, and the gravid rats were killed on day 19 of gestation. In the second study, groups of 10 mated female New Zealand White rabbits were given the same dosages on days 6 to 18 of gestation, and killed on day 29 of gestation. There were no signs of maternal toxicity in rats or rabbits, and there were no reproductive or developmental effects observed for either species. The NOAELs for dams and fetuses were 2000 mg/kg bw/day in both rats and rabbits.

GENOTOXICITY STUDIES

From the Original Safety Assessment of Acrylates Copolymers[1]

Acrylates Copolymer was not mutagenic in Ames tests. A mixture containing 30% Ammonium Acrylates Copolymer was not mutagenic in a modified Ames test. Sodium Polyacrylate was not mutagenic in an Ames assay, a plate test, a mouse lymphoma assay, chromosomal aberration assays, an unscheduled DNA syntheses (UDS) assay, or an in vivo mouse micronucleus assay.

From the Safety Assessment of Crosslinked Alkyl Acrylates[2]

The little genotoxicity data that were available for the crosslinked alkyl acrylates reported negative results in Ames tests.

The genotoxicity studies summarized here are described in Table 8. Acrylates Copolymer (comprised of various monomer combinations) was not genotoxic in Ames tests (up to 5000 µg dry copolymer/plate), mouse lymphoma L5178Y cell mutation assays (up to 6250 µg dry copolymer/ml), or a chromosomal aberration assay (up to 9000 µg dry copolymer/ml in human lymphocytes), and it was not genotoxic in the mouse micronucleus test in which mice were dosed with up to 2000 mg dry copolymer/kg bw.[13,15,16] Acrylates/Hydroxyesters Acrylates Copolymer (in a product containing < 50%) was also not mutagenic in the Ames test.[14] Details were missing from many of these studies.

CARCINOGENICITY STUDIES

Published carcinogenicity studies on the acrylates copolymers were not discovered in the published literature, and unpublished data were not submitted.

DERMAL IRRITATION AND SENSITIZATION STUDIES

From the Original Safety Assessment of Acrylates Copolymers[1]

In dermal irritation studies using rabbits, Acrylates Copolymer was non- to mildly irritating. In one study, it produced signs of an irritant property. However, in a study in which the patches adhered to the skin, very slight to well-defined erythema, and severe erythema in one animal, were observed at 72 hours. A mixture containing 30% Ammonium Acrylates Copolymer was practically nonirritant, and an aqueous emulsion of the ammonium salt of an Ethylene/Acrylic Acid polymer produced minor irritation. Acrylates/VA Copolymer produced moderate to severe but reversible dermal irritation, Vinyl Acetate/ Maleate/Acrylate Copolymer solution had a primary irritation index of 4.4. Sodium Polyacrylate did not produce irritation. Acrylates Copolymer was not a sensitizer to guinea pigs in maximization studies or a Buehler sensitization test.

A 25% aq. dilution of Acrylates Copolymer was not an irritant or a sensitizer in a human repeated insult patch test (HRIPT; 47 subjects). In clinical testing, Acrylates Copolymer, 30% solids, was not an irritant or sensitizer, and neither was Acrylates Copolymer (100% solids) tested as a 15% solution in ammonia water or a 25% solution in acetone. Undiluted Sodium Polyacrylate did not produce irritation or sensitization in 50 subjects.

From the Safety Assessment of Crosslinked Alkyl Acrylates[2]

In an alternative method study, Acrylates/Vinyl Neodecanoate Crosspolymer was predicted to be a nonirritant. Studies in rabbits, guinea pigs, and humans reported no to slight irritation with undiluted and weak sensitization with 2% aq, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, no irritation with Acrylates Crosspolymer at 30% in olive oil, and no irritation or sensitization with Sodium Acrylates Crosspolymer 2 (concentration not specified). Mostly, human testing with undiluted Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates Crosspolymer, and Acrylates/Ethylhexyl Acrylate Crosspolymer, up to 2.5% aq. Acrylates/Vinyl Isodecanoate Crosspolymer, 1% aq. dilutions of formulations containing 2% Acrylates/Vinyl Neodecanoate Crosspolymer, and formulations containing up to 2.6% Lauryl Methacrylate/Glycol Dimethacrylate Crosspolymers do not indicate any dermal irritation or sensitization. The only exception was a weak irritant response noted during an intensified Shelanski HRIPT with undiluted Acrylates/C10-30 Alkyl Acrylate Crosspolymer.

While the residual monomer (MMA) has the potential to induce sensitization, the levels in these ingredients were reported to be well below the levels that would induce sensitization to MMA, thus resolving the Panel's concern about sensitization.

From the Safety Assessment of PMMA and related ingredients[3]

PMMA was not a dermal irritant to rabbits. PMMA was not irritating or sensitizing at 6.8% in an HRIPT test using 52 participants. The same result was obtained in another HRIPT test of PMMA at 2.0% (n = 106).

From the Safety Assessment of [Carbomer][4]

Rabbits showed minimal skin irritation when tested with 100% Carbomer. Clinical studies with Carbomer and its various salts showed low potential for skin irritation and sensitization at concentrations of 0.5%, 5%, 10%, and 100%. When tested on humans at 1.0% concentration, Carbomer and its various salts also demonstrated low potential for skin irritation and sensitization. Further, formulations containing up to 0.25% Carbomer demonstrated low potential for human skin irritation, sensitization, phototoxicity, and photo-contact allergenicity.

The dermal irritation and sensitization studies summarized here are described in Table 9; details were not available for many of the studies. In animal studies, Acrylates/Beheneth-25 Methacrylate Copolymer[10] and Acrylates/Hydroxyesters Acrylates Copolymer (in a product containing < 50%)[14] were classified as slightly irritating to rabbit skin. Acrylates Copolymer[13,15] and VA/Butyl Maleate/Isobornyl Acrylate Copolymer in ethanol[8] were not irritating to rabbit skin. Acrylates Copolymer was not classified as a sensitizer in a local lymph node assay (LLNA),[13] or in a Buehler test using guinea pigs.[15] VA/Butyl Maleate/Isobornyl Acrylate Copolymer in ethanol, tested neat, was not irritating or sensitizing in a Buehler test in guinea pigs [8] In clinical testing, VA/Butyl Maleate/Isobornyl Acrylate Copolymer (as a slurry in ethanol) produced slight erythema in 20% of the 25 subjects tested in a 48-h patch test.[8] In an HRIPT, Acrylates/Hydroxyesters Acrylates Copolymer (as a product containing < 50%) was not a sensitizer, and it was concluded that VA/Butyl Maleate/Isobornyl Acrylate Copolymer in 10% ethanol not likely to be a sensitizer (109 subjects); erythema was observed in a few subjects at both induction and challenge.[8]

Phototoxicity/Photosensitization

Human

VA/Butyl Maleate/Isobornyl Acrylate Copolymer

The phototoxicity of VA/Butyl Maleate/Isobornyl Acrylate Copolymer was evaluated in 10 fair-skinned subjects.[8] Patches with 0.2 ml of the copolymer in 10% ethanol were applied to both volar forearms of each subject for 24 h. One arm was irradiated with long-wave ultraviolet (UVA) for 15 minutes (total dose = 3.3 J); an untested site on this arm served as an irradiated control. The other arm was not irradiated and was protected from light, including sunlight, by either a mitten or a long sleeve. Immediately after irradiation and at 48 and 72 h, both arms were graded for reactions. Minimal erythema at the test site, which occurred immediately after irradiation, was observed in one subject; no other reactions were reported. It was concluded that the test article "is not likely to be phototoxic in humans" at the concentration tested.

In a photosensitization study, 24-h patches applied with 0.2 ml of VA/Butyl Maleate/Isobornyl Acrylate Copolymer in 10% ethanol were applied to both volar forearms of 28 fair-skinned subjects twice a week for 3 wks.[8] At 24 hours, the test sites of both arms were examined and graded. One arm was then irradiated with ultraviolet UVA for 15 minutes, followed by medium-wave ultraviolet (UVB) irradiation. The dose of UVB irradiation administered was determined separately for each subject and was based on skin type and the minimal erythema dose (MED), which was established on the control arm prior to the first irradiation. The MED used in the study was set at the lesser of either the time that was sufficient to achieve a 1.0 score, or 120 seconds. An untreated site on the irradiated arm served as the irradiated control. Each test site was graded immediately after irradiation. The other treated arm was not irradiated. After a 2–wk non-treatment period, challenge patches were applied to previously untreated sites for 24 h, and the irradiated arm was exposed to UVA only.

During induction, transient effects such as minimal erythema, slight edema, and tanning were observed; most of the responses reported were seen at the irradiated treated and non-treated sites. No responses were reported on the non-irradiated arm. Following challenge, 3 subjects exhibited positive responses on the treated and irradiated arm, including minimal erythema, slight edema, skin dryness, or a combination of these symptoms. Two of these subjects also showed similar symptoms on the treated but non-irradiated arm. No reactions were observed on the non-treated irradiated forearm. It was concluded that VA/Butyl Maleate/ Isobornyl Acrylate Copolymer in 10% ethanol was "not likely to be photoallergenic or photosensitizing."

OCULAR IRRITATION STUDIES

From the Original Safety Assessment of Acrylates Copolymers[1]

In two chorioallantoic membrane vascular assays (CAMVAs), Acrylates Copolymer was predicted to be non-irritating, and in two bovine corneal opacity and permeability (BCOP) test, it was predicted to be a mild irritant. In ocular irritation studies using rabbits, Acrylates Copolymer was generally non- to mildly irritating. In two other studies, Acrylates Copolymer (containing 1500 and 200 ppm stearyl acrylate and methacrylic acid, respectively) was an eye irritant but not corrosive according to OECD guidelines, by considered minimally irritating according to the methods of Kay and Calandra. A mixture containing 30% Ammonium Acrylates Copolymer was practically nonirritating. An aqueous emulsion of the ammonium salt of an Ethylene/Acrylic Acid polymer produced trace corneal injury. Acrylates/VA Copolymer produced severe but reversible ocular irritation, and Vinyl Acetate/Maleate/ Acrylate Copolymer solution produced moderate to severe but reversible ocular irritation. In a Draize eye test, the greatest tolerated concentration of Sodium Polyacrylate was 13% to 20% and 20% to 30% for unrinsed and rinsed eyes, respectively. In an irritant

threshold test, the greatest concentration of Sodium Polyacrylate that did not produce irritation in three or more of five rabbits was 2%.

From the Safety Assessment of Crosslinked Alkyl Acrylates[2]

Alternative test methods for ocular irritation indicated that Acrylates/Vinyl Isodecanoate Crosspolymer and a formulation containing 1% Lauryl Methacrylate/Glycol Dimethacrylate Crosspolymer are not likely ocular irritants. In studies using rabbits, undiluted Acrylates/C10-30 Alkyl Acrylate Crosspolymer produced minimal to moderate irritation, and it was considered a borderline irritant in unrinsed rabbit eyes. Acrylates Crosspolymer, at 50% in olive oil, and Sodium Acrylates Crosspolymer 2 did not appear to be ocular irritants in rabbit eyes.

From the Safety Assessment of PMMA and related ingredients[3]

In an EpiOcular test, PMMA had a Draize ocular irritation score of 0. PMMA was mildly irritating in rabbit eyes.

From the Safety Assessment of [Carbomer][4]

Rabbits showed zero to moderate eye irritation when tested with Carbomer and/or its various salts at concentrations of 0.20 - 100%.

The ocular irritation studies summarized here are described in Table 10. All of the studies were performed in rabbits; details were not available for several of the studies. Acrylates Copolymer was not an ocular irritant in one study,[15] and was slightly irritating in another.[13] Acrylates/Beheneth-25 Methacrylate Copolymer[10] and Acrylates/Hydroxyesters Acrylates Copolymer (as a product containing < 50%)[14] were slightly irritating to rabbit eyes, and VA/Butyl Maleate/Isobornyl Acrylate Copolymer in ethanol (tested undiluted) was a moderate to severe eye irritant.[8]

CLINICAL STUDIES

Occupational Exposure

From the Original Safety Assessment of Acrylates Copolymers[1]

In examining the effects of workplace exposures, employees exposed to a variety of acrylic polymer dusts (as well as other materials) did not have an excess of chest x-ray abnormalities, especially those suggestive of diffuse pulmonary fibrosis. Additionally, they did not have an excess of pulmonary function testing (PFT) abnormality.

SUMMARY

The Panel has previously issued a Final Report on Acrylates Copolymer and 33 Related Cosmetic Ingredients in 2002, concluding that the acrylates copolymers named in that report are safe for use in cosmetics when formulated to avoid irritation. The Panel also reviewed the safety of numerous similar ingredients in several other reports. The Panel determined that it is appropriate to include all the copolymers in one assessment, including crosslinked copolymers (i.e., crosspolymers) prepared from monomers that comprise, in part, acrylic acid and/or methacrylic acid; the methyl, ethyl, propyl, or butyl ester(s) of these acids; or the salts of one or both of these two acids. Additionally, the Panel determined that three acrylates copolymers that were included in the original report should be excluded here because these are already under review in a concurrent safety assessment. As a result, this is a safety assessment of 126 similar copolymers that are commonly reported to function as film formers and viscosity increasing agents.

According to FDA VCRP data and the results of the Council use survey, 66 of the 126 ingredients assessed in this report are in use. According to VCRP data, Carbomer has the highest frequency of use; it is reported to be used in 6434 cosmetic formulations, and most of these uses (5336) are in leave-on products. Acrylates Copolymer and Acrylate/C10-30 Alkyl Acrylate Crosspolymer (solvent not specified) also have very high frequency of use, with 3177 and 3135 reported uses, respectively.

The results of concentration of use surveys conducted by the Council in 2018 indicate that Acrylates Copolymer has the highest maximum use concentration; it is used at up to 98.6% in nail extenders; use in product categories other than nail products is not as high, but Acrylates Copolymer is used at up to 25% in products that result in dermal contact (face and neck products). Ingredients with the next highest reported concentrations of use are Acrylates/VA Copolymer (at 50%, in "other" skin care formulations) and Polymethyl Methacrylate (at up to 44.6%, in face powders).

In ADME studies of Acrylates Copolymer (either as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate or as a fully polymerized copolymer of methyl acrylate, methyl methacrylate, and methacrylic acid), most of the test substance was excreted in the feces. Very little radioactivity was recovered in the urine or in the carcass.

Dermal LD_{50}s of > 2 g/kg and > 5 g/kg were reported for Acrylates Copolymer in rats, and in rabbits, an LD_{50} of > 2 g/kg was reported for VA/Butyl Maleate/Isobornyl Acrylate Copolymer in ethanol. The dermal LD_{50}s of Acrylates/ Beheneth-25 Methacrylate Copolymer and Acrylates/Hydroxyesters Acrylates Copolymer (product containing < 50%) in rats were > 5 g/kg. Acute oral studies were conducted on Acrylates Copolymer; the LD_{50}s in rats and dogs were > 25.2 g dry copolymer/kg bw and > 7.95 g dry copolymer/kg bw, respectively. In oral studies in rats, LD_{50}s of > 5 g/kg were reported for Acrylates/Beheneth-25 Methacrylate Copolymer, Acrylates/Hydroxyesters Acrylates Copolymer (product containing < 50%), and VA/Butyl Maleate/Isobornyl Acrylate Copolymer in ethanol. For Polyacrylate-1 Crosspolymer, the oral LD_{50} in rats was > 2 g/kg. In an acute inhalation study of Acrylates Copolymer in rats, the LC_{50} was > 3960 mg/l.

In a gavage study, rats were dosed with 500, 1000, and 2000 mg/kg bw/day of dry Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate) for 35 days. There were no notable findings, and the NOAEL was 2000 mg/kg bw/day. In a 28-day dietary study in which rats were fed Acrylates Copolymer-coated cellulose pellets at a dose up to 2000 mg/kg bw/d. There were no toxicologically relevant changes in body weight, food consumption, clinical observations, ophthalmoscopy, clinical pathology, urinalysis, fecal analysis, or in organ weights. In this study, the NOAEL was determined to be 227 mg dry copolymer/kg bw/d. In similar studies in which rats and dogs were fed Acrylates Copolymer-coated pellets for 26 weeks, the NOAEL was ≥ 2000 mg dry copolymer/kg bw/day for rats, and it was determined to be 250 mg dry copolymer/kg bw/d for dogs. These were the highest doses tested in the 26 wk studies.

In two dietary studies in which an Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate) dispersion was sprayed onto powdered diet and administered at a dose up to 2000 mg dry copolymer/kg bw/day and fed to pregnant rats (on days 6 – 15 of gestation) and rabbits (on days 6 – 18 of gestation), there were no signs of maternal toxicity in rats or rabbits, and there were no reproductive or developmental effects observed for either species. The NOAELs for dams and fetuses were 2000 mg/kg bw/day in both rats and rabbits.

Acrylates Copolymer (comprised of various monomer combinations) was not genotoxic in Ames tests (up to 5000 µg dry copolymer/plate), mouse lymphoma L5178Y cell mutation assays (up to 6250 µg dry copolymer/ml), or a chromosomal aberration assay (up to 9000 µg dry copolymer/ml in human lymphocytes), and it was not genotoxic in the mouse micronucleus test in which mice were dosed with up to 2000 mg dry copolymer/kg bw. Acrylates/Hydroxyesters Acrylates Copolymer (in a product containing < 50%) also was not mutagenic in the Ames test.[14] Details were not available for many of these studies.

Carcinogenicity data were neither found in the published in the publically available literature, nor were unpublished studies submitted.

In animal studies, Acrylates/Beheneth-25 Methacrylate Copolymer and Acrylates/Hydroxyesters Acrylates Copolymer (in a product containing < 50%) were classified as slightly irritating to rabbit skin. Acrylates Copolymer and VA/Butyl Maleate/Isobornyl Acrylate Copolymer in ethanol were not irritating to rabbit skin. Acrylates Copolymer was not classified as a sensitizer in a LLNA, or in a Buehler test using guinea pigs. VA/Butyl Maleate/Isobornyl Acrylate Copolymer in ethanol, tested neat, was not irritating or sensitizing in a Buehler test in guinea pigs. In clinical testing, VA/Butyl Maleate/Isobornyl Acrylate Copolymer (as a slurry in ethanol) produced slight erythema in 20% of the 25 subjects tested in a 48-h patch test. In an HRIPT, Acrylates/Hydroxyesters Acrylates Copolymer (as a product containing < 50%) was not a sensitizer, and it was concluded that VA/Butyl Maleate/Isobornyl Acrylate Copolymer in 10% ethanol not likely to be a sensitizer (109 subjects); erythema was observed in a few subjects at both induction and challenge.

In study in which the phototoxicity of VA/Butyl Maleate/Isobornyl Acrylate Copolymer in 10% ethanol was evaluated in 10 fair-skinned subjects following 24 h patches, it was concluded that the test article "is not likely to be phototoxic in humans." In a similar test in which 24-h patches were applied to 28 fair-skinned subjects twice a week for 3 wks, VA/Butyl Maleate/Isobornyl Acrylate Copolymer in 10% ethanol was "not likely to be photoallergenic or photosensitizing."

Ocular irritation studies were performed in rabbits; details were not available for several of the studies. Acrylates Copolymer was not an ocular irritant in one study, and was slightly irritating in another. Acrylates/Beheneth-25 Methacrylate Copolymer and Acrylates/Hydroxyesters Acrylates Copolymer (as a product containing < 50%) were slightly irritating to rabbit eyes, and VA/Butyl Maleate/Isobornyl Acrylate Copolymer in ethanol (tested undiluted) was a moderate to severe eye irritant.

DISCUSSION

In accordance with its procedures, CIR evaluates the conclusions of previously-issued reports approximately every 15 years. In 2002, the Panel reviewed the safety of Acrylates Copolymer and 33 related cosmetic ingredients, and concluded that those ingredients were safe for use in cosmetics when formulated to avoid irritation. The Panel has issued three other reports on related copolymers and crosspolymers prepared from monomers that comprise, in part, acrylic acid or methacrylic acid (as well as appropriate salts and esters of these acids). In addition to those acrylates copolymers previously reviewed, the Panel determined that it was appropriate to include 70 acrylates copolymers that have not yet been reviewed. Subsequently, there are a few copolymers that fit the description for this family that are not included in this report because they were recently included in other reports, and there are some that will warrant a review of their own in in the near future because of frequency of use.

The Panel recognized the large number of ingredients in this safety assessment, and the fact that these polymers comprise many different monomeric building blocks. Nonetheless, these polymers are uniformly large molecules and are produced in chemical reactions that leave very little residual monomer. Despite differences in chemical composition, these ingredients have highly similar chemical and physical properties and similar cosmetic uses. For these reasons, the Panel concluded that it is reasonable to consider these ingredients as a group, and the collection of these 126 ingredients in one report enables the assembly of reinforcing and complementary test data.

Acrylates Copolymer is used at up to 98.6% in nail extenders; however, concentrations of use in products that result in dermal exposure are lower (i.e., 50% or less). Because these copolymers are generally large molecules, significant dermal absorption is not expected. Therefore, topical application of these ingredients is not expected to result in systemic toxicity. Additionally, the existing data support a lack of sensitization potential; consequently, the Panel was satisfied that the data included in this report (as well as those data described in the previous reports) supported the safety of the acrylates copolymers as used in cosmetics.

The Panel noted that in the original report on Polymethyl Methacrylate (2011), this ingredient was reported to be used in microbeads in cosmetic products. Environmental concerns fall outside of the Panel's purview of review of personal safety in the use of cosmetic formulations. However, based on environmental concerns, the use of microbeads in cosmetics is being phased out in many jurisdictions, including the US.

The Panel discussed the concern of residual monomer that might be present in these polymers. In most cases, taking into consideration the low amount of residual monomer in the polymers, the Panel was not concerned that the presence of residual monomer would result in adverse effects. However, the Panel did stress that manufacturers should continue to use good manufacturing processes to ensure the amount of residual monomer is kept to a minimum.

The Panel also discussed the issue of residual solvent that might be present. Again, the Panel stressed that the amount of residual solvent should be minimized. However, the Panel was particularly concerned with polymerization in benzene. It cannot be predicted with certainty what quantity of benzene would be volatilized/leached from a polymer during manufacture, formulation, or use; while some benzene is inevitably volatilized during manufacture, some benzene may be trapped in the polymer matrix and may leach out during formulation and use. Because of this uncertainty, the Panel stipulated that these ingredients should not be polymerized in benzene.

The Panel remarked that the potential exists for dermal irritation with the use of products formulated using the ingredients named in this assessment. Therefore, the Panel specified that products containing the acrylates copolymers named in this assessment must be formulated to be non-irritating.

Finally, because some of the acrylates copolymers are used in cosmetic sprays and powders (e.g., VA/Butyl Maleate/Isobornyl Acrylate Copolymer is reported to be used at a maximum concentration of 10% in aerosol hair sprays and Polymethyl Methacrylate is used at concentrations up to 44.6% in face powders) and could possibly be inhaled, the Panel discussed the issue of potential inhalation toxicity. As discussed in the initial assessment on Acrylates Copolymer, the acrylic acid monomer can be a nasal irritant; however, exposure to the monomer from use of these polymers in cosmetic formulations would be less than the established threshold limit value for nasal irritation. Also, the Panel noted that in aerosol products, 95% – 99% of droplets/particles would not be respirable to any appreciable amount. Furthermore, droplets/particles deposited in the nasopharyngeal or bronchial regions of the respiratory tract present no toxicological concerns based on the chemical and biological properties of these ingredients. Coupled with the small actual exposure in the breathing zone and the concentrations at which the ingredients are used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at https://www.cir-safety.org/cir-findings.

CONCLUSION

The CIR Expert Panel concluded that the following 126 acrylates copolymers are safe in cosmetics in the present practices of use and concentration described in the safety assessment when formulated to be non-irritating.

Acrylates Copolymer
Acrylates Crosspolymer
Acrylates Crosspolymer-3
Acrylates Crosspolymer-4
Acrylates Crosspolymer-5*
Acrylates/Ammonium Methacrylate Copolymer
Acrylates/Beheneth-25 Methacrylate Copolymer
Acrylates/Beheneth-25 Methacrylate/Steareth-30 Methacrylate Copolymer*
Acrylates/C10-30 Alkyl Methacrylate Copolymer
Acrylates/C10-30Alkyl Acrylate Crosspolymer
Acrylates/C12-13 Alkyl Methacrylates/Methoxyethyl Acrylate Crosspolymer*
Acrylates/C12-22 Alkyl Methacrylate Copolymer
Acrylates/C26-28 Olefin Copolymer*
Acrylates/C5-8 Alkyl Acrylate Copolymer*
Acrylates/Ceteareth-20 Methacrylate Crosspolymer*
Acrylates/Ceteareth-20 Methacrylate Crosspolymer-2*
Acrylates/Ceteth-20 Methacrylate Copolymer*
Acrylates/Ethylhexyl Acrylate Copolymer
Acrylates/Ethylhexyl Acrylate Crosspolymer
Acrylates/Ethylhexyl Acrylate/Glycidyl Methacrylate Crosspolymer*
Acrylates/Hydroxyesters Acrylates Copolymer
Acrylates/Hydroxyethyl Acrylate/Lauryl Acrylate Copolymer*
Acrylates/Hydroxyethyl Acrylate/Methoxyethyl Acrylate Copolymer*
Acrylates/Laureth-25 Methacrylate Copolymer*
Acrylates/Lauryl Methacrylate Copolymer*
Acrylates/Lauryl Methacrylate/Tridecyl Methacrylate Crosspolymer*
Acrylates/Methoxy PEG-4 Methacrylate Copolymer*
Acrylates/Methoxy PEG-15 Methacrylate Copolymer*
Acrylates/Methoxy PEG-23 Methacrylate Copolymer
Acrylates/Methoxy PEG-90 Methacrylate Crosspolymer*
Acrylates/Palmeth-25 Acrylate Copolymer
Acrylates/PEG-4 Dimethacrylate Crosspolymer*
Acrylates/Steareth-20 Methacrylate Copolymer
Acrylates/Steareth-20 Methacrylate Crosspolymer
Acrylates/Steareth-30 Methacrylate Copolymer
Acrylates/Steareth-50 Acrylate Copolymer*
Acrylates/Stearyl Methacrylate Copolymer
Acrylates/VA Copolymer
Acrylates/VA Crosspolymer
Acrylates/Vinyl Isodecanoate Crosspolymer
Acrylates/Vinyl Neodecanoate Crosspolymer
Acrylic Acid/C12-22 Alkyl Acrylate Copolymer*
Acrylic Acid/Stearyl Acrylate Copolymer

Allyl Methacrylate/Glycol Dimethacrylate Crosspolymer*
Allyl Methacrylates Crosspolymer
Ammonium Acrylates Copolymer
Ammonium Acrylates/Ethylhexyl Acrylate Copolymer*
Ammonium Acrylates/Methyl Styrene/Styrene Copolymer
Ammonium Polyacrylate
Ammonium Styrene/Acrylates Copolymer
Ammonium Styrene/Acrylates/Ethylhexyl Acrylate/Lauryl Acrylate Copolymer*
Ammonium VA/Acrylates Copolymer*
AMP-Acrylates Copolymer
Behenyl Methacrylate/t-Butyl Methacrylate Copolymer
Butyl Acrylate/Cyclohexyl Methacrylate Copolymer*
Butyl Acrylate/Ethylhexyl Methacrylate Copolymer*
Butyl Acrylate/Glycol Dimethacrylate Crosspolymer
Butyl Acrylate/Hydroxyethyl Methacrylate Copolymer*
Butyl Methacrylate/Acryoyloxy PG Methacrylate Copolymer*
C12-22 Alkyl Acrylate/Hydroxyethylacrylate Copolymer
C8-22 Alkyl Acrylates/Methacrylic Acid Crosspolymer*
Calcium Potassium Carbomer*
Carbomer
Cyclohexyl Methacrylate/Ethylhexyl Methacrylate Copolymer*
Ethylene/Acrylic Acid Copolymer
Ethylene/Acrylic Acid/VA Copolymer*
Ethylene/Calcium Acrylate Copolymer*
Ethylene/Magnesium Acrylate Copolymer*
Ethylene/Methacrylate Copolymer
Ethylene/Sodium Acrylate Copolymer
Ethylene/Zinc Acrylate Copolymer*
Ethylhexyl Acrylate/Methoxy PEG-23 Methacrylate/Vinyl Acetate Copolymer*
Ethylhexyl Acrylate/Methyl Methacrylate Copolymer
Glycol Dimethacrylate Crosspolymer*
Glycol Dimethacrylate/Vinyl Alcohol Crosspolymer*
Hydroxyethyl Acrylate/Methoxyethyl Acrylate Copolymer*
Lauryl Acrylate Crosspolymer
Lauryl Acrylate/VA Copolymer*
Lauryl Acrylate/VA Crosspolymer*
Lauryl Methacrylate/Glycol Dimethacrylate Crosspolymer
Lauryl Methacrylate/Sodium Methacrylate Crosspolymer
Methacrylic Acid/PEG-6 Methacrylate/PEG-6 Dimethacrylate Crosspolymer*
Methacryloyl Ethyl Betaine/Acrylates Copolymer
Methoxy PEG-23 Methacrylate/Glyceryl Diisostearate Methacrylate Copolymer
Methyl Methacrylate Crosspolymer
Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer
Methyl Methacrylate/PEG/PPG-4/3 Methacrylate Crosspolymer
PEG/PPG-5/2 Methacrylate/Methacrylic Acid Crosspolymer*
Poly C10-30 Alkyl Acrylate
Poly(Methoxy PEG-9 Methacrylate)*
Polyacrylate-14
Polyacrylate-29*
Polyacrylate-34*
Polyacrylate-1 Crosspolymer
Polyacrylic Acid
Polybutyl Acrylate*
Polybutyl Methacrylate*
Polyethylacrylate
Polyhydroxyethylmethacrylate*
Polyisobutyl Methacrylate*
Polymethyl Acrylate
Polymethyl Methacrylate
Polypropyl Methacrylate*
Polystearyl Methacrylate*
Potassium Acrylate Crosspolymer*
Potassium Acrylates Copolymer
Potassium Acrylates/C10-30 Alkyl Acrylate Crosspolymer
Potassium Acrylates/Ethylhexyl Acrylate Copolymer*
Potassium Aluminum Polyacrylate*
Potassium Carbomer
Potassium Polyacrylate*
Sodium Acrylate/Acrolein Copolymer*
Sodium Acrylate/Vinyl Alcohol Copolymer
Sodium Acrylates Copolymer
Sodium Acrylates Crosspolymer-2
Sodium Acrylates/Beheneth-25 Methacrylate Crosspolymer*
Sodium Acrylates/C10-30 Alkyl Acrylate Crosspolymer
Sodium Acrylates/Ethylhexyl Acrylate Copolymer*
Sodium Acrylates/Vinyl Isodecanoate Crosspolymer
Sodium Carbomer
Sodium Polyacrylate
Sodium Polymethacrylate
Steareth-10 Allyl Ether/Acrylates Copolymer
Stearyl/Lauryl Methacrylate Crosspolymer*
Styrene/Acrylates/Ammonium Methacrylate Copolymer
VA/Butyl Maleate/Isobornyl Acrylate Copolymer

**Not reported to be in current use. Were ingredients in this group not in current use to be used in the future, the expectation is that they would be used in product categories and at concentrations comparable to others in this group.*

TABLES

Table 1. List of 126 ingredients included in this re-review

Acrylates Copolymer
Acrylates Crosspolymer
Acrylates Crosspolymer-3
Acrylates Crosspolymer-4
Acrylates Crosspolymer-5
Acrylates/Ammonium Methacrylate Copolymer
Acrylates/Beheneth-25 Methacrylate Copolymer
Acrylates/Beheneth-25 Methacrylate/Steareth-30 Methacrylate Copolymer
Acrylates/C10-30 Alkyl Methacrylate Copolymer
Acrylates/C10-30Alkyl Acrylate Crosspolymer
Acrylates/C12-13 Alkyl Methacrylates/Methoxyethyl Acrylate Crosspolymer
Acrylates/C12-22 Alkyl Methacrylate Copolymer
Acrylates/C26-28 Olefin Copolymer
Acrylates/C5-8 Alkyl Acrylate Copolymer
Acrylates/Ceteareth-20 Methacrylate Crosspolymer
Acrylates/Ceteareth-20 Methacrylate Crosspolymer-2
Acrylates/Ceteth-20 Methacrylate Copolymer
Acrylates/Ethylhexyl Acrylate Copolymer
Acrylates/Ethylhexyl Acrylate Crosspolymer
Acrylates/Ethylhexyl Acrylate/Glycidyl Methacrylate Crosspolymer
Acrylates/Hydroxyesters Acrylates Copolymer
Acrylates/Hydroxyethyl Acrylate/Lauryl Acrylate Copolymer
Acrylates/Hydroxyethyl Acrylate/Methoxyethyl Acrylate Copolymer
Acrylates/Laureth-25 Methacrylate Copolymer
Acrylates/Lauryl Methacrylate Copolymer
Acrylates/Lauryl Methacrylate/Tridecyl Methacrylate Crosspolymer
Acrylates/Methoxy PEG-4 Methacrylate Copolymer
Acrylates/Methoxy PEG-15 Methacrylate Copolymer
Acrylates/Methoxy PEG-23 Methacrylate Copolymer
Acrylates/Methoxy PEG-90 Methacrylate Crosspolymer
Acrylates/Palmeth-25 Acrylate Copolymer
Acrylates/PEG-4 Dimethacrylate Crosspolymer
Acrylates/Steareth-20 Methacrylate Copolymer
Acrylates/Steareth-20 Methacrylate Crosspolymer
Acrylates/Steareth-30 Methacrylate Copolymer
Acrylates/Steareth-50 Acrylate Copolymer
Acrylates/Stearyl Methacrylate Copolymer
Acrylates/VA Copolymer
Acrylates/VA Crosspolymer
Acrylates/Vinyl Isodecanoate Crosspolymer
Acrylates/Vinyl Neodecanoate Crosspolymer
Acrylic Acid/C12-22 Alkyl Acrylate Copolymer
Acrylic Acid/Stearyl Acrylate Copolymer
Allyl Methacrylate/Glycol Dimethacrylate Crosspolymer
Allyl Methacrylates Crosspolymer
Ammonium Acrylates Copolymer
Ammonium Acrylates/Ethylhexyl Acrylate Copolymer
Ammonium Acrylates/Methyl Styrene/Styrene Copolymer
Ammonium Polyacrylate
Ammonium Styrene/Acrylates Copolymer
Ammonium Styrene/Acrylates/Ethylhexyl Acrylate/Lauryl Acrylate Copolymer
Ammonium VA/Acrylates Copolymer
AMP-Acrylates Copolymer
Behenyl Methacrylate/t-Butyl Methacrylate Copolymer
Butyl Acrylate/Cyclohexyl Methacrylate Copolymer
Butyl Acrylate/Ethylhexyl Methacrylate Copolymer
Butyl Acrylate/Glycol Dimethacrylate Crosspolymer
Butyl Acrylate/Hydroxyethyl Methacrylate Copolymer
Butyl Methacrylate/Acryoyloxy PG Methacrylate Copolymer
C12-22 Alkyl Acrylate/Hydroxyethylacrylate Copolymer
C8-22 Alkyl Acrylates/Methacrylic Acid Crosspolymer
Calcium Potassium Carbomer
Carbomer
Cyclohexyl Methacrylate/Ethylhexyl Methacrylate Copolymer
Ethylene/Acrylic Acid Copolymer
Ethylene/Acrylic Acid/VA Copolymer
Ethylene/Calcium Acrylate Copolymer
Ethylene/Magnesium Acrylate Copolymer
Ethylene/Methacrylate Copolymer
Ethylene/Sodium Acrylate Copolymer
Ethylene/Zinc Acrylate Copolymer
Ethylhexyl Acrylate/Methoxy PEG-23 Methacrylate/Vinyl Acetate Copolymer
Ethylhexyl Acrylate/Methyl Methacrylate Copolymer
Glycol Dimethacrylate Crosspolymer
Glycol Dimethacrylate/Vinyl Alcohol Crosspolymer
Hydroxyethyl Acrylate/Methoxyethyl Acrylate Copolymer
Lauryl Acrylate Crosspolymer
Lauryl Acrylate/VA Copolymer
Lauryl Acrylate/VA Crosspolymer
Lauryl Methacrylate/Glycol Dimethacrylate Crosspolymer
Lauryl Methacrylate/Sodium Methacrylate Crosspolymer
Methacrylic Acid/PEG-6 Methacrylate/PEG-6 Dimethacrylate Crosspolymer
Methacryloyl Ethyl Betaine/Acrylates Copolymer
Methoxy PEG-23 Methacrylate/Glyceryl Diisostearate Methacrylate Copolymer
Methyl Methacrylate Crosspolymer
Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer
Methyl Methacrylate/PEG/PPG-4/3 Methacrylate Crosspolymer
PEG/PPG-5/2 Methacrylate/Methacrylic Acid Crosspolymer
Poly C10-30 Alkyl Acrylate
Poly(Methoxy PEG-9 Methacrylate)
Polyacrylate-14
Polyacrylate-29
Polyacrylate-34
Polyacrylate-1 Crosspolymer
Polyacrylic Acid
Polybutyl Acrylate
Polybutyl Methacrylate
Polyethylacrylate
Polyhydroxyethylmethacrylate
Polyisobutyl Methacrylate
Polymethyl Acrylate
Polymethyl Methacrylate
Polypropyl Methacrylate
Polystearyl Methacrylate
Potassium Acrylate Crosspolymer
Potassium Acrylates Copolymer
Potassium Acrylates/C10-30 Alkyl Acrylate Crosspolymer
Potassium Acrylates/Ethylhexyl Acrylate Copolymer
Potassium Aluminum Polyacrylate
Potassium Carbomer
Potassium Polyacrylate
Sodium Acrylate/Acrolein Copolymer
Sodium Acrylate/Vinyl Alcohol Copolymer
Sodium Acrylates Copolymer
Sodium Acrylates Crosspolymer-2
Sodium Acrylates/Beheneth-25 Methacrylate Crosspolymer
Sodium Acrylates/C10-30 Alkyl Acrylate Crosspolymer
Sodium Acrylates/Ethylhexyl Acrylate Copolymer
Sodium Acrylates/Vinyl Isodecanoate Crosspolymer
Sodium Carbomer
Sodium Polyacrylate
Sodium Polymethacrylate
Steareth-10 Allyl Ether/Acrylates Copolymer
Stearyl/Lauryl Methacrylate Crosspolymer
Styrene/Acrylates/Ammonium Methacrylate Copolymer
VA/Butyl Maleate/Isobornyl Acrylate Copolymer

Ingredients in blue type were included in the original Safety Assessment of Acrylates Copolymer and 33 Related Cosmetic Ingredients[1]
Ingredients in green type were reviewed in the Safety Assessment of Cross-Linked Alkyl Acrylates[2]
Ingredients in pink type were reviewed in the safety assessment of Polymethyl Methacrylate and other ingredients[3]
The ingredient in gray type was reviewed in the safety assessment of Carbomers[4]
Prior to this assessment, the ingredients in black type had not yet been reviewed by CIR

Table 2. Definitions, Structures, and Functions of the ingredients reviewed in this report[5]

Ingredients (CAS Nos.)*	Definitions and Structures	Function(s)
Acrylates Copolymer 159666-35-0; 25035-69-2; 25212-88-8; 25685-29-4	a copolymer of two or more monomers consisting of acrylic acid, methacrylic acid or one of their simple esters	adhesives; artificial nail builders; binders; dispersing agents - nonsurfactant; film formers; hair fixatives; skin-conditioning agents - emollient; skin-conditioning agents - miscellaneous
Acrylates Crosspolymer 26794-61-6; 74464-10-1	a copolymer of acrylic acid, methacrylic acid or one of its simple esters, crosslinked with glycol dimethacrylate	absorbents
Acrylates Crosspolymer-3	a copolymer of acrylic acid, methacrylic acid or one of its simple esters, crosslinked with trimethylolpropane triacrylate and trimethylolpropane diallyl ether	film formers; hair fixatives; viscosity increasing agents - aqueous
Acrylates Crosspolymer-4	a copolymer of acrylic acid, methacrylic acid or one of its simple esters, crosslinked with trimethylolpropane triacrylate	emulsion stabilizers; film formers; surfactants - dispersing agents; viscosity increasing agents - aqueous
Acrylates Crosspolymer-5	a copolymer of acrylic acid, methacrylic acid or one of their simple esters, crosslinked with an allyl ether of pentaerythritol	viscosity increasing agents - aqueous
Acrylates/Ammonium Methacrylate Copolymer	a copolymer of ammonium methacrylate and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters	binders; film formers; hair fixatives
Acrylates/Beheneth-25 Methacrylate Copolymer	a copolymer of the ester of methacrylic acid and Beheneth-25 and one or more monomers of acrylic acid, methacrylic acid, or one of their simple esters	viscosity increasing agents - aqueous
Acrylates/Beheneth-25 Methacrylate/Steareth-30 Methacrylate Copolymer	a copolymer of beheneth-25 methacrylate, steareth-30 methacrylate and one or more monomers consisting of acrylic acid, methacrylic acid or one of their simple esters	film formers
Acrylates/C10-30 Alkyl Methacrylate Copolymer	the copolymer of C10-30 alkyl methacrylate and one or more monomers of acrylic acid, methacrylic acid, or one of their simple esters	viscosity increasing agents - aqueous
Acrylates/C10-30Alkyl Acrylate Crosspolymer	a copolymer of C10-30 alkyl acrylate and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters crosslinked with an allyl ether of sucrose or an allyl ether of pentaerythritol	emulsion stabilizers; viscosity increasing agents - aqueous; viscosity increasing agents - nonaqueous
Acrylates/C12-13 Alkyl Methacrylates/Methoxy-ethyl Acrylate Crosspolymer	a copolymer of C12-13 alkyl methacrylates, methoxyethyl acrylate, and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters, crosslinked with vinyloxazoline	hair fixatives
Acrylates/C12-22 Alkyl Methacrylate Copolymer	the copolymer of C12-22 alkyl methacrylate and one or more monomers of acrylic acid, methacrylic acid, or one of their simple esters	film formers
Acrylates/C26-28 Olefin Copolymer	a polymer of C26-28 olefins and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters	viscosity increasing agents - nonaqueous
Acrylates/C5-8 Alkyl Acrylate Copolymer	copolymer of C5-8 alkyl acrylate and one or more monomers of acrylic acid, methacrylic acid, or one of their simple esters	emulsion stabilizers; film formers; viscosity increasing agents - aqueous
Acrylates/Ceteareth-20 Methacrylate Crosspolymer	copolymer of the ester of methacrylic acid and Ceteareth-20 and one or more monomers of acrylic acid, methacrylic acid, or one of their simple esters, crosslinked with ethylene glycol dimethacrylate	viscosity increasing agents - aqueous
Acrylates/Ceteareth-20 Methacrylate Crosspolymer-2	a copolymer of the ester of methacrylic acid and ceteareth-20 and one or more monomers of acrylic acid, methacrylic acid, or one of their simple esters, crosslinked with diallyl maleate	bulking agents; chelating agents; emulsion stabilizers; opacifying agents; viscosity increasing agents - aqueous
Acrylates/Ceteth-20 Methacrylate Copolymer	a copolymer formed from the ester of methacrylic acid and ceteth-20 , and one or more monomers consisting of acrylic acid, methacrylic acid or one of their simple esters	viscosity increasing agents - aqueous
Acrylates/Ethylhexyl Acrylate Copolymer	a copolymer of ethylhexyl acrylate and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters	film formers
Acrylates/Ethylhexyl Acrylate Crosspolymer	a copolymer of 2-ethylhexylacrylate and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters, crosslinked with ethylene glycol dimethacrylate	binders
Acrylates/Ethylhexyl Acrylate/Glycidyl Methacrylate Crosspolymer	a copolymer of 2-ethylhexyl acrylate, glycidyl methacrylate and one or more monomers consisting of acrylic acid, methacrylic acid or one of their simple esters, crosslinked with triethylene glycol dimethacrylate	film formers

Table 2. Definitions, Structures, and Functions of the ingredients reviewed in this report[5]

Ingredients (CAS Nos.)*	Definitions and Structures	Function(s)
Acrylates/Hydroxyesters Acrylates Copolymer 25035-89-6	a copolymer of one or more monomers consisting of acrylic acid, methacrylic acid, or their simple esters, and one or more monomers of hydroxyacrylate esters	film formers
Acrylates/Hydroxyethyl Acrylate/Lauryl Acrylate Copolymer	a copolymer of hydroxyethyl acrylate, lauryl acrylate, and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters	film formers
Acrylates/Hydroxyethyl Acrylate/Methoxyethyl Acrylate Copolymer	a copolymer of hydroxyethyl acrylate, butyl acrylate and methoxyethyl acrylate	film formers
Acrylates/Laureth-25 Methacrylate Copolymer	the copolymer of laureth-25 methacrylate and one or more monomers of acrylic acid, methacrylic acid, or one of their simple esters	viscosity increasing agents - aqueous
Acrylates/Lauryl Methacrylate Copolymer	a copolymer of lauryl methacrylate and one or more monomers consisting of acrylic acid, methacrylic acid or one of their simple esters	film formers
Acrylates/Lauryl Methacrylate/Tridecyl Methacrylate Crosspolymer	a copolymer of lauryl methacrylate, tridecyl methacrylate and one or more monomers consisting of acrylic acid, methacrylic acid or one of their simple esters, crosslinked with vinyloxazoline	film formers
Acrylates/Methoxy PEG-4 Methacrylate Copolymer	a copolymer of methoxy PEG-4 methacrylate and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters	hair conditioning agents
Acrylates/Methoxy PEG-15 Methacrylate Copolymer	a copolymer of methoxy PEG-15 methacrylate and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters	dispersing agents - nonsurfactant
Acrylates/Methoxy PEG-23 Methacrylate Copolymer	a copolymer of methoxy PEG-23 methacrylate and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters	film formers
Acrylates/Methoxy PEG-90 Methacrylate Crosspolymer 957645-61-3	a copolymer of methoxy PEG-90 methacrylate and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters crosslinked by glycol dimethacrylate	skin protectants
Acrylates/Palmeth-25 Acrylate Copolymer	a copolymer of the ester of acrylic acid and ethoxylated palm alcohol with an average of 25 moles of ethylene oxide and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters	viscosity increasing agents - aqueous
Acrylates/PEG-4 Dimethacrylate Crosspolymer 50657-38-0	a copolymer of one or more monomers of acrylic acid, methacrylic acid or one of their simple esters crosslinked by PEG-4 dimethacrylate	film formers
Acrylates/Steareth-20 Methacrylate Copolymer	a copolymer of the ester of methacrylic acid and steareth-20 and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters	viscosity increasing agents - aqueous
Acrylates/Steareth-20 Methacrylate Crosspolymer	a copolymer of steareth-20 methacrylate and one or more monomers consisting of acrylic acid, methacrylic acid or one of their simple esters, crosslinked with an allyl ether of pentaerythritol or an allyl ether of trimethylolpropane	dispersing agents - nonsurfactant; film formers
Acrylates/Steareth-30 Methacrylate Copolymer 75760-37-1	a copolymer of the ester of methacrylic acid and steareth-30 and one or more monomers of acrylic acid, methacrylic acid, or one of their simple esters	viscosity increasing agents - aqueous
Acrylates/Steareth-50 Acrylate Copolymer	a copolymer of the ester of acrylic acid and steareth-50 and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters	viscosity increasing agents - aqueous
Acrylates/Stearyl Methacrylate Copolymer	a copolymer of stearyl methacrylate and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters	emulsion stabilizers; viscosity increasing agents - aqueous
Acrylates/VA Copolymer	a copolymer of vinyl acetate and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters	binders; film formers; hair fixatives
Acrylates/VA Crosspolymer	a copolymer of vinyl acetate and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters crosslinked with triallylisocyanurate	film formers
Acrylates/Vinyl Isodecanoate Crosspolymer	a copolymer of the ester of vinyl isodecanoate and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters crosslinked with polyalkenyl polyether	dispersing agents - nonsurfactant; emulsion stabilizers; viscosity increasing agents - aqueous
Acrylates/Vinyl Neodecanoate Crosspolymer	a copolymer of vinyl neodecanoate and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters crosslinked with an allyl ether of trimethylolpropane or pentaerythritol	emulsion stabilizers; film formers; viscosity increasing agents - aqueous
Acrylic Acid/C12-22 Alkyl Acrylate Copolymer	a copolymer of acrylic acid and C12-22 alkyl acrylate	binders; emulsion stabilizers; viscosity increasing agents - nonaqueous

Table 2. Definitions, Structures, and Functions of the ingredients reviewed in this report[5]

Ingredients (CAS Nos.)*	Definitions and Structures	Function(s)
Acrylic Acid/Stearyl Acrylate Copolymer 36120-03-3	a polymer of acrylic acid and stearyl acrylate monomers	emulsion stabilizers; film formers; surfactants - emulsifying agents
Allyl Methacrylate/Glycol Dimethacrylate Crosspolymer 779327-42-3	a highly crosslinked polymer of allyl methacrylate and ethylene glycol dimethacrylate	oral care agents; skin protectants; skin-conditioning agents - emollient; skin-conditioning agents - miscellaneous
Allyl Methacrylates Crosspolymer 182212-41-5	a copolymer of allyl methacrylates crosslinked with glycol dimethacrylate	emulsion stabilizers; opacifying agents; viscosity increasing agents - nonaqueous
Ammonium Acrylates Copolymer	the ammonium salt of a polymer of two or more monomers consisting of acrylic acid, methacrylic acid or one of their simple esters	binders; film formers; viscosity increasing agents - aqueous
Ammonium Acrylates/Ethylhexyl Acrylate Copolymer	a copolymer of ethylhexyl acrylate and the ammonium salt of one or more monomers consisting of acrylic acid, methacrylic acid, or one of their simple esters	film formers
Ammonium Acrylates/Methyl Styrene/Styrene Copolymer	a copolymer consisting of ammonium acrylate, methyl styrene and styrene monomers	film formers
Ammonium Polyacrylate 9003-03-6	the ammonium salt of Polyacrylic Acid	emulsion stabilizers; film formers
Ammonium Styrene/Acrylates Copolymer	the ammonium salt of a polymer of styrene and a monomer consisting of acrylic acid, methacrylic acid or one of their simple esters	dispersing agents - nonsurfactant; film formers
Ammonium Styrene/Acrylates/Ethylhexyl Acrylate/Lauryl Acrylate Copolymer	ammonium salt of Styrene/Acrylates/Ethylhexyl Acrylate/Lauryl Acrylate Copolymer	film formers
Ammonium VA/Acrylates Copolymer	the ammonium salt of a polymer of vinyl acetate and two or more monomers consisting of acrylic acid, methacrylic acid or their simple ester	binders; dispersing agents - nonsurfactant; film formers; hair fixatives
AMP-Acrylates Copolymer 1203962-19-9	the aminomethyl propanol salt of Acrylates Copolymer	film formers
Behenyl Methacrylate/t-Butyl Methacrylate Copolymer	a copolymer of behenyl methacrylate and t-butyl methacrylate monomers	film formers
Butyl Acrylate/Cyclohexyl Methacrylate Copolymer	a copolymer of butyl acrylate and cyclohexyl methacrylate	film formers
Butyl Acrylate/Ethylhexyl Methacrylate Copolymer	a copolymer of butyl acrylate and 2-ethylhexyl methacrylate monomers	film formers; hair fixatives
Butyl Acrylate/Glycol Dimethacrylate Crosspolymer	a homopolymer of butyl acrylate crosslinked with glycol dimethacrylate	absorbents; film formers
Butyl Acrylate/Hydroxyethyl Methacrylate Copolymer	a copolymer consisting of n-butyl acrylate and 2-hydroxyethyl methacrylate monomers	film formers
Butyl Methacrylate/Acryoyloxy PG Methacrylate Copolymer 1431551-12-0	a polymer of butyl methacrylate and acryloyloxy propylene glycol methacrylate monomers	film formers
C12-22 Alkyl Acrylate/Hydroxyethylacrylate Copolymer	a copolymer of C12-22 alkyl acrylate and hydroxyethylacrylate	binders; emulsion stabilizers; viscosity increasing agents - nonaqueous
C8-22 Alkyl Acrylates/Methacrylic Acid Crosspolymer	a copolymer of C8-22 alkyl acrylate and methacrylic acid crosslinked with hexanediol diacrylate	film formers; hair fixatives; hair-waving/straightening agents
Calcium Potassium Carbomer	the calcium potassium salt of Carbomer	emulsion stabilizers; film formers; viscosity increasing agents - aqueous
Carbomer 9003-01-4; 9007-16-3; 9007-17-4; 9062-04-8; 76050-42-5	a homopolymer of acrylic acid crosslinked with an allyl ether of pentaerythritol, an allyl ether of sucrose, or an allyl ether of propylene	emulsion stabilizers; viscosity increasing agents - aqueous
Cyclohexyl Methacrylate/Ethylhexyl Methacrylate Copolymer 82227-04-1	a copolymer of cyclohexyl methacrylate and ethylhexyl methacrylate	film formers
Ethylene/Acrylic Acid Copolymer 9010-77-9	a copolymer of ethylene and acrylic acid monomers	binders; film formers; viscosity increasing agents - nonaqueous
Ethylene/Acrylic Acid/VA Copolymer 26713-18-8	a copolymer of ethylene, acrylic acid and vinyl acetate monomers	binders; film formers; viscosity increasing agents - nonaqueous
Ethylene/Calcium Acrylate Copolymer 26445-96-5	a copolymer of ethylene and calcium acrylate monomers	binders; film formers
Ethylene/Magnesium Acrylate Copolymer 27515-37-3	a copolymer of ethylene and magnesium acrylate monomers	binders; film formers
Ethylene/Methacrylate Copolymer 25103-74-6	a copolymer of ethylene and methyl methacrylate monomers	film formers
Ethylene/Sodium Acrylate Copolymer 25749-98-8; 25750-82-7	a copolymer of ethylene and sodium acrylate monomers	binders; film formers; viscosity increasing agents - aqueous

Table 2. Definitions, Structures, and Functions of the ingredients reviewed in this report[5]

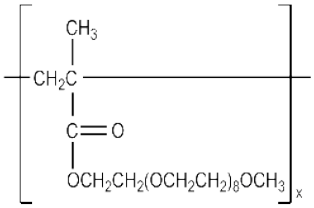
Ingredients (CAS Nos.)*	Definitions and Structures	Function(s)
Ethylene/Zinc Acrylate Copolymer 28208-80-2; 59650-68-9	a copolymer of ethylene and zinc acrylate monomers	film formers
Ethylhexyl Acrylate/Methoxy PEG-23 Methacrylate/Vinyl Acetate Copolymer 137455-77-7	a copolymer of methoxy PEG-23 methacrylate, vinyl acetate, and ethylhexyl acrylate	hair fixatives
Ethylhexyl Acrylate/Methyl Methacrylate Copolymer	a copolymer of ethylhexyl acrylate and methyl methacrylate	film formers
Glycol Dimethacrylate Crosspolymer	a crosslinked polymer of glycol dimethacrylate	slip modifier
Glycol Dimethacrylate/Vinyl Alcohol Crosspolymer	a crosslinked copolymer of vinyl alcohol and glycol dimethacrylate	film formers
Hydroxyethyl Acrylate/Methoxyethyl Acrylate Copolymer	the copolymer of hydroxyethyl acrylate and methoxyethyl acrylate	film formers
Lauryl Acrylate Crosspolymer	a polymer of lauryl acrylate crosslinked with divinylbenzene	hair fixatives
Lauryl Acrylate/VA Copolymer	a copolymer of lauryl acrylate and vinyl acetate monomers	film formers
Lauryl Acrylate/VA Crosspolymer	a copolymer of lauryl acrylate and vinyl acetate crosslinked with divinylbenzene	abrasives
Lauryl Methacrylate/Glycol Dimethacrylate Crosspolymer	a crosslinked copolymer of lauryl methacrylate and ethylene glycol dimethacrylate monomers	film formers; hair fixatives
Lauryl Methacrylate/Sodium Methacrylate Crosspolymer	a copolymer of lauryl methacrylate and sodium methacrylate crosslinked with ethylene glycol dimethacrylate	slip modifiers; surface modifiers
Methacrylic Acid/PEG-6 Methacrylate/PEG-6 Dimethacrylate Crosspolymer	a copolymer of methacrylic acid and PEG-6 methacrylate crosslinked with PEG-6 dimethacrylate	film formers
Methacryloyl Ethyl Betaine/Acrylates Copolymer	a polymer of methacryloyl ethyl betaine and two or more monomers of methacrylic acid or its simple esters	dispersing agents - nonsurfactant; film formers; hair fixatives
Methoxy PEG-23 Methacrylate/Glyceryl Diisostearate Methacrylate Copolymer	a copolymer of methoxy PEG-23 methacrylate and glyceryl diisostearate methacrylate monomers	skin protectants
Methyl Methacrylate Crosspolymer 25777-71-3	a copolymer of methyl methacrylate crosslinked with glycol dimethacrylate	bulking agent; film former; viscosity increasing agent - nonaqueous
Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer 25777-71-3	a crosslinked copolymer of methyl methacrylate and ethylene glycol dimethacrylate monomers	film formers
Methyl Methacrylate/PEG/PPG-4/3 Methacrylate Crosspolymer	a random copolymer of methyl methacrylate and PEG/PPG-4/3 methacrylate crosslinked with ethylene glycol dimethacrylate	film formers
PEG/PPG-5/2 Methacrylate/Methacrylic Acid Crosspolymer	copolymer of methacrylic acid and polyethylene glycol, polypropylene glycol methacrylate containing an average of 5 moles of ethylene oxide and 2 moles of propylene oxide, crosslinked with glycol dimethacrylate	film formers
Poly C10-30 Alkyl Acrylate	a polymer of the ester of acrylic acid and C10-30 alcohol	binders; emulsion stabilizers; viscosity increasing agents - nonaqueous
Poly(Methoxy PEG-9 Methacrylate)	the polymer that conforms generally to the formula: 	film formers; skin-conditioning agents - humectant; skin-conditioning agents - occlusive
Polyacrylate-14	a copolymer of PEG-25 C10-30 alkyl ether methacrylate, PEG-20 PPG-5 allyl ether and one or more monomers consisting of acrylic acid, methacrylic acid or one of their simple esters	film former
Polyacrylate-29	A copolymer of stearyl methacrylate, methoxy PEG-9 methacrylate and methacrylic acid	film formers; skin-conditioning agents - miscellaneous; surfactants - emulsifying agents
Polyacrylate-34	a copolymer of octoxy PEG-8 PPG-6 methacrylate, PPG-9 methacrylate, PPG-6 acrylate and 2-methoxyethylacrylate monomers	hair fixative
Polyacrylate-1 Crosspolymer	a copolymer of one or more simple esters of acrylic or methacrylic acid, C1-4 dialkylamino C1-6 alkyl methacrylate, PEG/PPG-30/5 allyl ether, PEG 20-25 C10-30 alkyl ether methacrylate, hydroxy C2-6 alkyl methacrylate crosslinked with ethylene glycol dimethacrylate	film formers; hair conditioning agents; hair fixatives; viscosity increasing agents - aqueous

Table 2. Definitions, Structures, and Functions of the ingredients reviewed in this report[5]

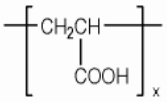
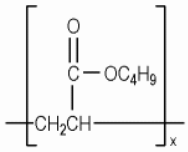
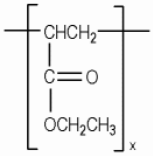
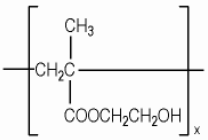
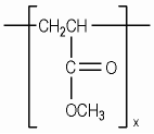
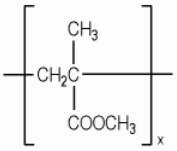
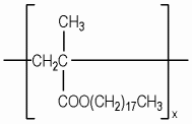
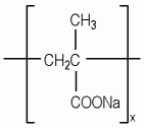
Ingredients (CAS Nos.)*	Definitions and Structures	Function(s)
Polyacrylic Acid 9003-01-4	the polymer of acrylic acid that conforms generally to the formula: 	binders; emulsion stabilizers; film formers; viscosity increasing agents - aqueous
Polybutyl Acrylate 9003-49-0	a polymer of n-butyl acrylate that conforms generally to the formula: 	binders; film formers
Polybutyl Methacrylate 9003-63-8	the homopolymer of butyl methacrylate	film formers
Polyethylacrylate 9003-32-1	the polymer of ethyl acrylate that conforms generally to the formula: 	binders; dispersing agents - nonsurfactant; film formers; hair fixatives
Polyhydroxyethylmethacrylate 25249-16-5	the organic compound that conforms to the formula: 	binders
Polyisobutyl Methacrylate 9011-15-8	the homopolymer of isobutyl methacrylate	film formers
Polymethyl Acrylate 9003-21-8	the polymer that conforms to the formula: 	film formers
Polymethyl Methacrylate 9011-14-7	the polymer of methyl methacrylate that conforms to the formula: 	bulking agents; film formers
Polypropyl Methacrylate	the homopolymer of propyl acrylate	film formers
Polystearyl Methacrylate	the polymer of stearyl methacrylate that conforms to the formula: 	film formers
Potassium Acrylate Crosspolymer 86416-97-9 (sodium salt)	the potassium salt of a polymer of acrylic acid crosslinked with *N*,*N*'-methylenebisacrylamide	absorbents; slip modifiers
Potassium Acrylates Copolymer	the potassium salt of a polymer consisting of acrylic acid, methacrylic acid or one of their simple esters	binders; film formers
Potassium Acrylates/C10-30 Alkyl Acrylate Crosspolymer	the potassium salt of Acrylates/C10-30 Alkyl Acrylate Crosspolymer	film formers
Potassium Acrylates/Ethylhexyl Acrylate Copolymer	the potassium salt of Acrylates/Ethylhexyl Acrylate Copolymer	film formers
Potassium Aluminum Polyacrylate	a mixture of the potassium and aluminum salts of Polyacrylic Acid	absorbents; binders; viscosity increasing agents - aqueous
Potassium Carbomer	the sodium salt of Carbomer	emulsion stabilizers; film formers; viscosity increasing agents - aqueous

Table 2. Definitions, Structures, and Functions of the ingredients reviewed in this report[5]

Ingredients (CAS Nos.)*	Definitions and Structures	Function(s)
Potassium Polyacrylate 25608-12-2	the potassium salt of Polyacrylic Acid	emulsion stabilizers; viscosity increasing agents - aqueous
Sodium Acrylate/Acrolein Copolymer	a polymer consisting of sodium acrylate and acrolein monomers	binders; film formers; viscosity increasing agents - aqueous
Sodium Acrylate/Vinyl Alcohol Copolymer 27599-56-0; 58374-38-2	a polymer of sodium acrylate and vinyl alcohol monomers	binders; emulsion stabilizers; film formers; viscosity increasing agents - aqueous
Sodium Acrylates Copolymer 25549-84-2	the sodium salt of a polymer consisting of acrylic acid, methacrylic acid or one of their simple esters	binders; film formers; viscosity increasing agents - aqueous
Sodium Acrylates Crosspolymer-2	the sodium salt of a copolymer of acrylic acid, methacrylic acid or one or more of its simple esters crosslinked with ethylene glycol diglycidyl ether	absorbents
Sodium Acrylates/Beheneth-25 Methacrylate Crosspolymer	the sodium salt of a copolymer of acrylic acid, methacrylic acid or one or more of its simple esters and beheneth-25 methacrylate, crosslinked with methylene bis-acrylamide	dispersing agents - nonsurfactant; skin-conditioning agents - miscellaneous; viscosity increasing agents - aqueous
Sodium Acrylates/C10-30 Alkyl Acrylate Crosspolymer	the sodium salt of Acrylates/C10-30 Alkyl Acrylate Crosspolymer	film formers
Sodium Acrylates/Ethylhexyl Acrylate Copolymer	a copolymer of ethylhexyl acrylate and the sodium salt of one or more monomers consisting of acrylic acid, methacrylic acid or one of their simple esters	film formers
Sodium Acrylates/Vinyl Isodecanoate Crosspolymer	the sodium salt of Acrylates/Vinyl Isodecanoate Crosspolymer	dispersing agents - nonsurfactant; emulsion stabilizers; viscosity increasing agents - aqueous
Sodium Carbomer 1401207-41-7; 73298-57-4	sodium salt of Carbomer	emulsion stabilizers; film formers; viscosity increasing agents - aqueous
Sodium Polyacrylate 25549-84-2; 9003-04-7	the sodium salt of Polyacrylic Acid	absorbent; emulsion stabilizer; film former; hair fixative; skin-conditioning agent - emollient; viscosity increasing agent - aqueous
Sodium Polymethacrylate 25086-62-8; 54193-36-1	the polymer that conforms generally to the formula: 	binders; emulsion stabilizers; film formers; viscosity increasing agents - aqueous
Steareth-10 Allyl Ether/Acrylates Copolymer 109292-17-3	a copolymer of the allyl ether of steareth-10 and one or more monomers consisting of acrylic acid, methacrylic acid or one of their simple esters	film formers; viscosity increasing agents - nonaqueous
Stearyl/Lauryl Methacrylate Crosspolymer	a copolymer of stearyl methacrylate and lauryl methacrylate crosslinked with ethylene glycol dimethacrylate	skin-conditioning agents - miscellaneous
Styrene/Acrylate/Ammonium Methacrylate Copolymer	a polymer of styrene, ammonium methacrylate and a monomer consisting of acrylic acid, methacrylic acid or one of their simple esters	dispersing agents - nonsurfactant; film formers
VA/Butyl Maleate/Isobornyl Acrylate Copolymer	a copolymer of vinyl acetate, butyl maleate and isobornyl acrylate monomers	film formers

***Ingredients in blue type were included in the original Safety Assessment of Acrylates Copolymer and 33 Related Cosmetic Ingredients[1]**
Ingredients in green type were reviewed in the Safety Assessment of Cross-Linked Alkyl Acrylates[2]
Ingredients in pink type were reviewed in the safety assessment of Polymethyl Methacrylate and other ingredients[3]
The ingredient in gray type was reviewed in the safety assessment of Carbomers[4]
Prior to this assessment, the ingredients in black type had not yet been reviewed by CIR

Table 3. Physical and Chemical Properties

Property	Value	Reference
Acrylates Copolymer		
Physical Form	white beads [as 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, ethyl 2-methyl-2-propenoate and ethyl 2-propenoate]	13
	liquid in commercial form; forms a film when dried	15,16
Color	milky white	15,16
Odor	"characteristic"	15,16
Molecular Weight (g/mol)	100,000 (wt avg) [as 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, ethyl 2-methyl-2-propenoate and ethyl 2-propenoate]	13
	600,000 (avg) [as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate]	15
	280,000 (avg) [as a fully polymerized copolymer of methyl acrylate, methyl methacrylate, and methacrylic acid]	16
Density/Specific Gravity (@ 20 ºC)	1.37 – 1.047 [as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate]	17
Water Solubility (g/L)	miscible in water	15,16
Acrylates/Beheneth-25 Methacrylate Copolymer		
Physical Form	opaque flowing dispersion	10
Color	white	10
Melting Point (ºC)	> 100	10
Water Solubility (@ pH 2 – 3)	insoluble	10
(@ pH 6 – 8)	soluble	
Acrylates/C12-22 Alkyl Methacrylate Copolymer		
Physical Form	aq. emulsion	9
Odor	acrylic	9
Water Solubility (g/L @ 20 ºC)	1000	9
Acrylates/Hydroxyesters Acrylates Copolymer		
Physical Form	emulsion	35
Color	white	14
Molecular Weight (g/mol)	~ 60,000	35
Acrylates/Palmeth-25 Acrylate Copolymer		
Physical Form	opaque emulsion	11
Color	white	11
Water Solubility (g/L @ 20 ºC)	1000	11
Acrylates/Steareth-20 Methacrylate Copolymer		
Physical Form	liquid	18
Color	milky white	18
Polyacrylate-1 Crosspolymer		
Physical Form	solid	12
Color	pale brown	12
Density (kg/m^3 @ 25 ºC)	1160	12
Melting Point (ºC)	47.35	12
VA/Butyl Maleate/Isobornyl Acrylate Copolymer in ethanol		
Physical Form	clear viscous liquid	8
Odor	ethanolic	8
Molecular Weight (g/mol)	79,000 – 154,000 (wt avg)	8
Vapor pressure (mmHg @ 20ºC)	44.48	8
Water Solubility (g/L)	< 1; if the ethanol is allowed to evaporate, the remaining polymer is stated to be water insoluble	8

Table 4. Current and historical (where applicable) frequency and concentration of use, according to duration and exposure

	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	Acrylates Copolymer				**Acrylates Crosspolymer**			
	2018[25]	**1998[1]**	**2018[19]**	**1998[1]**	**2018[25]**	**2011[2]**	**2018[21]**	**2011[2]**
Totals*	**3177**	**227**	**0.00025-98.6**	**	**5**	**2**	**0.15-4.5**	**0.1-4**
Duration of Use								
Leave-On	*2050*	*207*	*0.00025-98.6*	**	*5*	*2*	*1-4.5*	*0.1-4*
Rinse-Off	*1106*	*20*	*0.00052-4.2*	**	*NR*	*NR*	*0.15-2.7*	*0.3-0.8*
Diluted for (Bath) Use	*21*	*NR*	*0.9-2.4*	**	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	702	33	0.00025-18.4	**	1	NR	1	0.8
Incidental Ingestion	453	36	0.0003-3	**	NR	NR	NR	4
Incidental Inhalation-Spray	53; 107[a]; 58[b]	3; 5[a]; 3[b]	0.36-4.9; 0.12-2.6[a]	**	1[a]; 2[b]	NR	NR	NR
Incidental Inhalation-Powder	45; 58[b]	35; 3[b]	0.015-1.4; 0.045-25[c]	**	2[b]	NR	NR	2
Dermal Contact	1884	104	0.00025-25	**	4	2	1-4.5	0.1-4
Deodorant (underarm)	2[a]	3[a]	NR	**	NR	NR	NR	NR
Hair - Non-Coloring	184	3	0.00052-4.9	**	NR	NR	NR	NR
Hair-Coloring	17	14	0.36-3.6	**	NR	NR	0.15	NR
Nail	436	53	0.54-98.6	**	1	NR	NR	NR
Mucous Membrane	1297	36	0.0003-4.2	**	NR	NR	2.2-2.7	4
Baby Products	14	NR	0.26-1.4	**	NR	NR	NR	NR
	Acrylates Crosspolymer-3				**Acrylates Crosspolymer-4**			
	2018[25]		**2018[20]**		**2018[25]**		**2018[20]**	
Totals*	**4**		**1.6**		**16**		**3.1**	
Duration of Use								
Leave-On	*3*		*1.6*		*NR*		*3.1*	
Rinse-Off	*1*		*NR*		*16*		*NR*	
Diluted for (Bath) Use	*NR*		*NR*		*NR*		*NR*	
Exposure Type								
Eye Area	1		NR		NR		NR	
Incidental Ingestion	NR		NR		NR		NR	
Incidental Inhalation-Spray	2[a]		1.6[a]		NR		NR	
Incidental Inhalation-Powder	NR		NR		NR		3.1[c]	
Dermal Contact	NR		NR		16		NR	
Deodorant (underarm)	NR		NR		NR		NR	
Hair - Non-Coloring	3		1.6		NR		NR	
Hair-Coloring	NR		NR		NR		NR	
Nail	NR		NR		NR		NR	
Mucous Membrane	NR		NR		16		NR	
Baby Products	NR		NR		NR		NR	
	Acrylates/Ammonium Methacrylate Copolymer				**Acrylates/Beheneth-25 Methacrylate Copolymer**			
	2018[25]	**1998[1]**	**2018[19]**	**1998[1]**	**2018[25]**		**2018[20]**	
Totals*	**26**	**1**	**0.00063-10**	**	**91**		**0.05-1.7**	
Duration of Use								
Leave-On	*11*	*1*	*0.002-10*	**	*53*		*0.3-1.7*	
Rinse-Off	*15*	*NR*	*0.00063-0.0025*	**	*37*		*0.05-1*	
Diluted for (Bath) Use	*NR*	*NR*	*NR*	**	*1*		*NR*	
Exposure Type								
Eye Area	NR	1	NR	**	NR		NR	
Incidental Ingestion	1	NR	NR	**	NR		NR	
Incidental Inhalation-Spray	4[a]; 3[b]	NR	NR	**	48[a]		1.7; 0.95-1.1[a]	
Incidental Inhalation-Powder	3[b]	NR	0.002[c]	**	NR		0.3-0.8[c]	
Dermal Contact	25	NR	0.00063-0.005	**	34		0.3-8	
Deodorant (underarm)	NR	NR	NR	**	NR		NR	
Hair - Non-Coloring	NR	NR	NR	**	46		0.05-1.7	
Hair-Coloring	NR	NR	NR	**	11		0.2-1	
Nail	NR	NR	10	**	NR		NR	
Mucous Membrane	7	NR	0.00062	**	10		NR	
Baby Products	NR	NR	NR	**	NR		NR	

Table 4. Current and historical (where applicable) frequency and concentration of use, according to duration and exposure

	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	Acrylates/C10-30 Alkyl Methacrylate Copolymer				**Acrylates/C10-30Alkyl Acrylate Crosspolymer (†polymerized in solvents other than benzene)**			
	2018[25]		**2018[20]**		**2018[25]**	**2011[2] †**	**2018[21] †**	**2011[2] †**
Totals*	**NR**		**0.0001-1.1**		**3135**	**1696**	**0.000045-3**	**0.0002-5**
Duration of Use								
Leave-On	*NR*		*0.0001-1.1*		*2577*	*1365*	*0.000045-3*	*0.0002-5*
Rinse-Off	*NR*		*0.0005-0.001*		*546*	*313*	*0.1-1.8*	*0.002-5*
Diluted for (Bath) Use	*NR*		*NR*		*12*	*18*	*0.15*	*1*
Exposure Type								
Eye Area	NR		NR		215	132	0.12-0.9	0.003-2
Incidental Ingestion	NR		NR		1	3	0.6	0.5
Incidental Inhalation-Spray	NR		0.0001		176; 1167[a]; 770[b]	70[a]	0.08-2; 0.11-0.2[a]	0.03-2
Incidental Inhalation-Powder	NR		NR		77[b]; 4[c]	6	0.000045-0.6; 0.07-2[c]	0.0002-0.1
Dermal Contact	NR		0.15-0.3		2992	1591	0.000045-3	0.0002-5
Deodorant (underarm)	NR		NR		3[a]	1[a]	0.15-0.5 (not spray) 0.2 (spray)	0.001[a]
Hair - Non-Coloring	NR		0.0001-1.1		95	77	0.19-2	0.1-2
Hair-Coloring	NR		NR		35	11	0.19-1.8	0.4-5
Nail	NR		NR		8	9	0.05-1	0.1-1
Mucous Membrane	NR		NR		175	111	0.15-0.6	0.002-3
Baby Products			0.15		17	10	0.3	0.2
	Acrylates/C12-22 Alkyl Methacrylate Copolymer				**Acrylates/Ethylhexyl Acrylate Copolymer**			
	2018[25]		**2018[20]**		**2018[25]**		**2018[20]**	
Totals*	**9**		**0.23-1.4**		**60**		**0.25-30**	
Duration of Use								
Leave-On	*9*		*0.23-1.4*		*60*		*0.25-30*	
Rinse-Off	*NR*		*NR*		*NR*		*NR*	
Diluted for (Bath) Use	*NR*		*NR*		*NR*		*NR*	
Exposure Type								
Eye Area	1		0.23		53		0.9-30	
Incidental Ingestion	NR		NR		NR		NR	
Incidental Inhalation-Spray	5[a]; 1[b]		1; 0.9[a]		NR		NR	
Incidental Inhalation-Powder	1[b]		0.45-1.4[c]		NR		0.25[c]	
Dermal Contact	9		0.23-1.4		19		0.25-20.1	
Deodorant (underarm)	NR		NR		NR		NR	
Hair - Non-Coloring	NR		NR		NR		NR	
Hair-Coloring	NR		NR		NR		NR	
Nail	NR		NR		2		NR	
Mucous Membrane	NR		NR		NR		NR	
Baby Products	NR		NR		NR		NR	
	Acrylates/Ethylhexyl Acrylate Crosspolymer				**Acrylates/Hydroxyesters Acrylates Copolymer**			
	2018[25]	**2011[2]**	**2018[21]**	**2011[2]**	**2018[25]**	**1998[1]**	**2018[19]**	**1998[1]**
Totals*	**3**	**NR**	**1-5.4**	**4-6**	**35**	**NR**	**0.71-6**	******
Duration of Use								
Leave-On	*3*	*NR*	*1-5.4*	*4-6*	*30*	*NR*	*0.71-6*	**
Rinse-Off	*NR*	*NR*	*NR*	*NR*	*5*	*NR*	*NR*	**
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	**
Exposure Type								
Eye Area	NR	NR	NR	6	8	NR	0.8	**
Incidental Ingestion	1	NR	NR	NR	NR	NR	NR	**
Incidental Inhalation-Spray	NR	NR	NR	NR	15; 5[a]; 1[b]	NR	0.71-6	**
Incidental Inhalation-Powder	NR	NR	1-3.1; 4.5[c]	NR	NR	NR	NR	**
Dermal Contact	NR	NR	1-5.4	4-6	2	NR	NR	**
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	**
Hair - Non-Coloring	NR	NR	NR	NR	25	NR	0.71-6	**
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	**
Nail	2	NR	NR	NR	NR	NR	NR	**
Mucous Membrane	1	NR	NR	NR	NR	NR	NR	**
Baby Products	NR	NR	NR	NR	NR	NR	NR	**

Table 4. Current and historical (where applicable) frequency and concentration of use, according to duration and exposure

	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	Acrylates/Methoxy PEG-23 Methacrylate Copolymer				**Acrylates/Palmeth-25 Acrylate Copolymer**			
	2018[25]		**2018[20]**		**2018[25]**		**2018[20]**	
Totals*	**NR**		**0.4-1.4**		**9**		**0.53-1.3**	
Duration of Use								
Leave-On	*NR*		*0.4-1.4*		*2*		*NR*	
Rinse-Off	*NR*		*NR*		*7*		*0.53-1.3*	
Diluted for (Bath) Use	*NR*		*NR*		*NR*		*NR*	
Exposure Type								
Eye Area	NR		NR		NR		NR	
Incidental Ingestion	NR		NR		NR		NR	
Incidental Inhalation-Spray	NR		1.4; 0.4[a]		1[b]		NR	
Incidental Inhalation-Powder	NR		NR		1[b]		NR	
Dermal Contact	NR		NR		6		1.3	
Deodorant (underarm)	NR		NR		NR		NR	
Hair - Non-Coloring	NR		0.4-1.4		NR		NR	
Hair-Coloring	NR		NR		3		0.53	
Nail	NR		NR		NR		NR	
Mucous Membrane	NR		NR		2		NR	
Baby Products	NR		NR		NR		NR	
	Acrylates/Steareth-20 Methacrylate Copolymer				**Acrylates/Steareth-20 Methacrylate Crosspolymer**			
	2018[25]	**1998[1]**	**2018[19]**	**1998[1]**	**2018[25]**	**2011[2]**	**2018[21]**	**2011[2]**
Totals*	**65**	**35**	**0.06-2**	**	**4**	**NR**	**0.37-2.3**	**0.1-2**
Duration of Use								
Leave-On	*22*	*10*	*0.06-0.5*	**	*2*	*NR*	*2.3*	*0.1-2*
Rinse-Off	*43*	*24*	*0.3-2*	**	*2*	*NR*	*0.37-1.6*	*1*
Diluted for (Bath) Use	*NR*	*1*	*NR*	**	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	2	NR	0.11-0.21	**	NR	NR	NR	NR
Incidental Ingestion	1	NR	NR	**	NR	NR	NR	NR
Incidental Inhalation-Spray	2; 4[a]; 9[b]	2; 7[a]	0.06-0.5	**	1[a]; 1[b]	NR	2.3[a]	NR
Incidental Inhalation-Powder	9[b]	NR	0.09[c]	**	1[b]	NR	NR	NR
Dermal Contact	36	14	0.06-1.8	**	1	NR	1.6	0.1-1
Deodorant (underarm)	NR	NR	NR	**	NR	NR	NR	NR
Hair - Non-Coloring	19	15	0.45-0.5	**	1	NR	2.3	2
Hair-Coloring	9	5	0.54-2	**	2	NR	0.37	NR
Nail	NR	1	NR	**	NR	NR	NR	NR
Mucous Membrane	7	2	0.3	**	NR	NR	NR	1
Baby Products	1	2	NR	**	NR	NR	NR	NR
	Acrylates/Steareth-30 Methacrylate Copolymer				**Acrylates/Stearyl Methacrylate Copolymer**			
	2018[25]		**2018[20]**		**2018[25]**		**2018[20]**	
Totals*	**NR**		**0.03-2.1**		**NR**		**0.014-0.04**	
Duration of Use								
Leave-On	*NR*		*0.03-0.87*		*NR*		*0.014-0.04*	
Rinse-Off	*NR*		*1.8-2.1*		*NR*		*0.02-0.04*	
Diluted for (Bath) Use	*NR*		*NR*		*NR*		*NR*	
Exposure Type								
Eye Area	NR		0.03		NR		NR	
Incidental Ingestion	NR		NR		NR		NR	
Incidental Inhalation-Spray	NR		0.2-0.6; 0.87[a]		NR		0.014-0.04[a]	
Incidental Inhalation-Powder	NR		NR		NR		NR	
Dermal Contact	NR		0.15-2.1		NR		0.04	
Deodorant (underarm)	NR		NR		NR		NR	
Hair - Non-Coloring	NR		0.2-0.87		NR		0.014-0.04	
Hair-Coloring	NR		NR		NR		NR	
Nail	NR		NR		NR		NR	
Mucous Membrane	NR		2.1		NR		NR	
Baby Products	NR		NR		NR		NR	

Table 4. Current and historical (where applicable) frequency and concentration of use, according to duration and exposure

	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	Acrylates/VA Copolymer				**Acrylates/VA Crosspolymer**			
	2018[25]	**1998[1]**	**2018[19]**	**1998[1]**	**2018[25]**		**2018[20]**	
Totals*	**1**	**NR**	**2.5-50**	**	**1**		**25**	
Duration of Use								
Leave-On	*1*	*NR*	*2.5-50*	**	*1*		*25*	
Rinse-Off	*NR*	*NR*	*NR*	**	*NR*		*NR*	
Diluted for (Bath) Use	*NR*	*NR*	*NR*	**	*NR*		*NR*	
Exposure Type								
Eye Area	1	NR	2.5	**	NR		NR	
Incidental Ingestion	NR	NR	NR	**	NR		NR	
Incidental Inhalation-Spray	NR	NR	NR	**	NR		NR	
Incidental Inhalation-Powder	NR	NR	NR	**	NR		NR	
Dermal Contact	NR	NR	50	**	NR		NR	
Deodorant (underarm)	NR	NR	NR	**	NR		NR	
Hair - Non-Coloring	NR	NR	NR	**	NR		NR	
Hair-Coloring	NR	NR	NR	**	NR		NR	
Nail	NR	NR	NR	**	1		25	
Mucous Membrane	NR	NR	NR	**	NR		NR	
Baby Products	NR	NR	NR	**	NR		NR	
	Acrylates/Vinyl Isodecanoate Crosspolymer				**Acrylates/Vinyl Neodecanoate Crosspolymer**			
	2018[25]	**2011[2]**	**2018[21]**	**2011[2]**	**2018[25]**	**2011[2]**	**2018[21]**	**2011[2]**
Totals*	**30**	**33**	**0.2-0.4**	**0.2-0.5**	**14**	**10**	**NR**	**2**
Duration of Use								
Leave-On	*22*	*25*	*0.25-0.4*	*0.3-0.5*	*3*	*4*	*NR*	*2*
Rinse-Off	*8*	*8*	*0.2*	*0.2-0.5*	*5*	*4*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*6*	*2*	*NR*	*NR*
Exposure Type								
Eye Area	1	NR	NR	NR	1	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	8[a]; 10[b]	NR	0.34-0.4[a]	0.4	2[a]	NR	NR	NR
Incidental Inhalation-Powder	10[b]	NR	0.25[c]	NR	NR	NR	NR	NR
Dermal Contact	30	33	0.2-.0.4	0.2-0.5	14	10	NR	2
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	10	6	NR	2
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR
	Acrylic Acid/Stearyl Acrylate Copolymer				**Allyl Methacrylates Crosspolymer**			
	2018[25]		**2018[20]**		**2018[25]**	**2011[2]**	**2018[21]**	**2011[2]**
Totals*	**NR**		**0.1-2**		**31**	**48**	**0.0034-2**	**0.003-2**
Duration of Use								
Leave-On	*NR*		*0.1-2*		*27*	*44*	*0.0034-2*	*0.003-2*
Rinse-Off	*NR*		*0.25*		*4*	*4*	*0.075-1*	*0.1*
Diluted for (Bath) Use	*NR*		*NR*		*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	NR		NR		NR	4	0.0034	4
Incidental Ingestion	NR		NR		7	16	0.034	16
Incidental Inhalation-Spray	NR		0.1; 2[a]		7[a]; 4[b]	2[a]	1[a]	2[a]
Incidental Inhalation-Powder	NR		NR		4[b]	2	2; 0.4-2[c]	2
Dermal Contact	NR		NR		23	31	0.0034-2	31
Deodorant (underarm)	NR		NR		NR	NR	NR	NR
Hair - Non-Coloring	NR		0.1-2		1	NR	NR	NR
Hair-Coloring	NR		NR		NR	NR	NR	NR
Nail	NR		NR		NR	NR	NR	NR
Mucous Membrane	NR		NR		7	16	0.034	16
Baby Products	NR		NR		NR	NR	NR	NR

Table 4. Current and historical (where applicable) frequency and concentration of use, according to duration and exposure

	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	Ammonium Acrylates Copolymer				**Ammonium Acrylates/Methyl Styrene/Styrene Copolymer**			
	2018[25]	**1998[1]**	**2018[19]**	**1998[1]**	**2018[25]**		**2018[20]**	
Totals*	**60**	**21**	**0.0057-19.5**	**	**5**		**0.9**	
Duration of Use								
Leave-On	*60*	*21*	*0.3-19.5*	**	*5*		*0.9*	
Rinse-Off	*NR*	*NR*	*0.0057-0.046*	**	*NR*		*NR*	
Diluted for (Bath) Use	*NR*	*NR*	*NR*	**	*NR*		*NR*	
Exposure Type								
Eye Area	47	21	0.8-19.5	**	5		0.9	
Incidental Ingestion	NR	NR	NR	**	NR		NR	
Incidental Inhalation-Spray	1[b]	NR	NR	**	NR		NR	
Incidental Inhalation-Powder	1[b]	NR	NR	**	NR		NR	
Dermal Contact	20	3	0.0057-19.5	**	5		0.9	
Deodorant (underarm)	NR	NR	NR	**	NR		NR	
Hair - Non-Coloring	NR	NR	NR	**	NR		NR	
Hair-Coloring	NR	NR	NR	**	NR		NR	
Nail	10	NR	0.3-7.8	**	NR		NR	
Mucous Membrane	NR	NR	NR	**	NR		NR	
Baby Products	NR	NR	NR	**	NR		NR	
	Ammonium Polyacrylate				**Ammonium Styrene/Acrylates Copolymer**			
	2018[25]	**1998[1]**	**2018[19]**	**1998[1]**	**2018[25]**	**1998[1]**	**2018[19]**	**1998[1]**
Totals*	**15**	**NR**	**0.000001-1.8**	**	**2**	**NR**	**0.052-16.5**	**
Duration of Use								
Leave-On	*14*	*NR*	*0.00018-1.8*	**	*2*	*NR*	*0.052-16.5*	**
Rinse-Off	*1*	*NR*	*0.000001-0.0005*	**	*NR*	*NR*	*NR*	**
Diluted for (Bath) Use	*NR*	*NR*	*NR*	**	*NR*	*NR*	*NR*	**
Exposure Type								
Eye Area	2	NR	0.0022	**	1	NR	NR	**
Incidental Ingestion	NR	NR	NR	**	NR	NR	NR	**
Incidental Inhalation-Spray	3[a]; 6[b]	NR	NR	**	1[a]	NR	NR	**
Incidental Inhalation-Powder	6[b]	NR	0.00018[c]	**	NR	NR	0.052	**
Dermal Contact	14	NR	0.000001-1.8	**	2	NR	0.052	**
Deodorant (underarm)	NR	NR	NR	**	NR	NR	NR	**
Hair - Non-Coloring	NR	NR	NR	**	NR	NR	NR	**
Hair-Coloring	NR	NR	NR	**	NR	NR	NR	**
Nail	1	NR	NR	**	NR	NR	16.5	**
Mucous Membrane	1	NR	NR	**	NR	NR	NR	**
Baby Products	NR	NR	NR	**	NR	NR	NR	**
	AMP-Acrylates Copolymer				**Behenyl Methacrylate/t-Butyl Methacrylate Copolymer**			
	2018[25]	**1998[1]**	**2018[19]**	**1998[1]**	**2018[25]**		**2018[20]**	
Totals*	**31**	**NR**	**0.00084-8**	**	**5**		**NR**	
Duration of Use								
Leave-On	*28*	*NR*	*0.00084-8*	**	*5*		*NR*	
Rinse-Off	*3*	*NR*	*0.51*	**	*NR*		*NR*	
Diluted for (Bath) Use	*NR*	*NR*	*NR*	**	*NR*		*NR*	
Exposure Type								
Eye Area	1	NR	0.3	**	2		NR	
Incidental Ingestion	NR	NR	NR	**	3		NR	
Incidental Inhalation-Spray	12; 14[a]	NR	0.44-8; 0.00084-1.1[a]	**	NR		NR	
Incidental Inhalation-Powder	NR	NR	NR	**	NR		NR	
Dermal Contact	1	NR	0.035-0.64	**	2		NR	
Deodorant (underarm)	NR	NR	NR	**	NR		NR	
Hair - Non-Coloring	29	NR	0.00084-8	**	NR		NR	
Hair-Coloring	NR	NR	NR	**	NR		NR	
Nail	1	NR	NR	**	NR		NR	
Mucous Membrane	NR	NR	NR	**	3		NR	
Baby Products	NR	NR	NR	**	NR		NR	

Table 4. Current and historical (where applicable) frequency and concentration of use, according to duration and exposure

	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	Butyl Acrylate/Glycol Dimethacrylate Crosspolymer				**C12-22 Alkyl Acrylate/Hydroxyethylacrylate Copolymer**			
	2018[25]	**2011[2]**	**2018[21]**	**2011[2]**	**2018[25]**		**2018[20]**	
Totals*	**1**	**NR**	**4.2-10**	**NR**	**NR**		**3**	
Duration of Use								
Leave-On	*1*	*NR*	*4.2-10*	*NR*	*NR*		*3*	
Rinse-Off	*NR*	*NR*	*NR*	*NR*	*NR*		*NR*	
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*		*NR*	
Exposure Type								
Eye Area	NR	NR	8.3-8.5	NR	NR		NR	
Incidental Ingestion	NR	NR	NR	NR	NR		NR	
Incidental Inhalation-Spray	1[a]	NR	NR	NR	NR		NR	
Incidental Inhalation-Powder	NR	NR	4.2	NR	NR		NR	
Dermal Contact	1	NR	4.2-10	NR	NR		3	
Deodorant (underarm)	NR	NR	NR	NR	NR		NR	
Hair - Non-Coloring	NR	NR	NR	NR	NR		NR	
Hair-Coloring	NR	NR	NR	NR	NR		NR	
Nail	NR	NR	NR	NR	NR		NR	
Mucous Membrane	NR	NR	NR	NR	NR		NR	
Baby Products	NR	NR	NR	NR	NR		NR	
	C8-22 Alkyl Acrylates/Methacrylic Acid Crosspolymer				**Carbomer**			
	2018[25]	**2011[2]**	**2018[21]**	**2011[2]**	**2018[25] #**	**2001[6] ##**	**2018[22]**	**2001[6]**
Totals*	**2**	**NR**	**NR**	**NR**	**6434**	**1504**	**0.00001-15**	**0.001-2**
Duration of Use								
Leave-On	*2*	*NR*	*NR*	*NR*	*5336*	*1167*	*0.0012-15*	*0.001-2*
Rinse-Off	*NR*	*NR*	*NR*	*NR*	*1093*	*330*	*0.00001-2.5*	*0.003-2*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*5*	*7*	*0.18-0.3*	*0.1-1*
Exposure Type								
Eye Area	NR	NR	NR	NR	301	65	0.2-1.5	0.2-2
Incidental Ingestion	NR	NR	NR	NR	95	6	0.048-9	0.1-0.7
Incidental Inhalation-Spray	1[b]	NR	NR	NR	16; 2565[a]; 1870[b]	50; 347[a]; 412[b]	0.003-1; 0.048-2.5[a]	0.3-1; 0.003-2[a]; 0.05-1[b]
Incidental Inhalation-Powder	1[b]	NR	NR	NR	2; 1870[b]; 30[c]	1; 412[b]; 5[c]	0.0012-0.88 0.1-15[c]	0.3; 0.05-1[b]; 0.2-0.8[c]
Dermal Contact	1	NR	NR	NR	5601	1335	0.00001-15	0.001-2
Deodorant (underarm)	NR	NR	NR	NR	3[a]	NR	0.25 (not spray) 0.18 (spray)	NR
Hair - Non-Coloring	1	NR	NR	NR	490	96	0.0084-2.5	0.3-1.5
Hair-Coloring	NR	NR	NR	NR	222	57	0.2-2.5	0.7-2
Nail	NR	NR	NR	NR	12	7	0.003-0.87	0.2-2
Mucous Membrane	NR	NR	NR	NR	200	26	0.048-9	0.003-2
Baby Products	NR	NR	NR	NR	36	15	0.15-0.69	0.2-0.8
	Ethylene/Acrylic Acid Copolymer				**Ethylene/Methacrylate Copolymer**			
	2018[25]	**1998[1]**	**2018[19]**	**1998[1]**	**2018[25]**	**1998[1]**	**2018[19]**	**1998[1]**
Totals*	**316**	**6**	**0.001-16.5**	******	**60**	**5**	**0.0003-0.83**	******
Duration of Use								
Leave-On	*306*	*6*	*0.001-16.5*	**	*60*	*5*	*0.0003-0.83*	**
Rinse-Off	*NR*	*NR*	*0.001-0.5*	**	*NR*	*NR*	*NR*	**
Diluted for (Bath) Use	*NR*	*NR*	*NR*	**	*NR*	*NR*	*NR*	**
Exposure Type								
Eye Area	181	NR	0.001-16.5	**	29	NR	0.0003-0.74	**
Incidental Ingestion	3	NR	NR	**	NR	NR	0.3-0.59	**
Incidental Inhalation-Spray	18[a]; 7[b]	NR	0.25	**	2[a]; 1[b]	NR	NR	**
Incidental Inhalation-Powder	23; 7[b]	NR	0.5; 0.001-8[c]	**	9; 1[b]	NR	0.3;0.037-0.53[c]	**
Dermal Contact	298	6	0.001-16.5	**	42	5	0.037-0.83	**
Deodorant (underarm)	NR	NR	NR	**	NR	NR	NR	**
Hair - Non-Coloring	1	NR	NR	**	NR	NR	NR	**
Hair-Coloring	NR	NR	NR	**	NR	NR	NR	**
Nail	4	NR	4	**	NR	NR	NR	**
Mucous Membrane	3	NR	NR	**	NR	NR	0.3-0.59	**
Baby Products	NR	NR	NR	**	NR	NR	NR	**

Table 4. Current and historical (where applicable) frequency and concentration of use, according to duration and exposure

	# of Uses		Max Conc of Use (%)		# of Uses		Max Conc of Use (%)	
	Ethylene/Sodium Acrylate Copolymer				Ethylhexyl Acrylate/Methyl Methacrylate Copolymer			
	2018[25]	1998[1]	2018[19]	1998[1]	2018[25]		2018[20]	
Totals*	**1**	**1**	**NR**	**	**5**		**7**	
Duration of Use								
Leave-On	*NR*	*1*	*NR*	**	*5*		*7*	
Rinse-Off	*1*	*NR*	*NR*	**	*NR*		*NR*	
Diluted for (Bath) Use	*NR*	*NR*	*NR*	**	*NR*		*NR*	
Exposure Type								
Eye Area	NR	1	NR	**	5		NR	
Incidental Ingestion	NR	NR	NR	**	NR		NR	
Incidental Inhalation-Spray	NR	NR	NR	**	NR		NR	
Incidental Inhalation-Powder	NR	NR	NR	**	NR		NR	
Dermal Contact	1	1	NR	**	5		7	
Deodorant (underarm)	NR	NR	NR	**	NR		NR	
Hair - Non-Coloring	NR	NR	NR	**	NR		NR	
Hair-Coloring	NR	NR	NR	**	NR		NR	
Nail	NR	NR	NR	**	NR		NR	
Mucous Membrane	NR	NR	NR	**	NR		NR	
Baby Products	NR	NR	NR	**	NR		NR	
	Lauryl Acrylate Crosspolymer				Lauryl Methacrylate/Glycol Dimethacrylate Crosspolymer			
	2018[25]		2018[20]		2018[25]	2011[2]	2018[21]	2011[2]
Totals*	**NR**		**1.2**		**99**	**63**	**1.1-3.2**	**0.06-3**
Duration of Use								
Leave-On	*NR*		*1.2*		*90*	*56*	*1.1-3.2*	*0.06-3*
Rinse-Off	*NR*		*NR*		*9*	*7*	*NR*	*0.2-3*
Diluted for (Bath) Use	*NR*		*NR*		*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	NR		NR		25	9	NR	0.1-3
Incidental Ingestion	NR		NR		19	8	1.3	0.06-2
Incidental Inhalation-Spray	NR		1.2[a]		6; 2[b]	NR	NR	0.3
Incidental Inhalation-Powder	NR		NR		6; 2[b]	8	1.1; 3[c]	0.01-1
Dermal Contact	NR		NR		79	53	1.1-3.2	0.06-3
Deodorant (underarm)	NR		NR		NR	1[a]	NR	0.3[a]
Hair - Non-Coloring	NR		1.2		NR	NR	NR	NR
Hair-Coloring	NR		NR		NR	NR	NR	NR
Nail	NR		NR		1	1	NR	NR
Mucous Membrane	NR		NR		19	8	1.3	0.06-2
Baby Products	NR		NR		NR	NR	NR	NR
	Lauryl Methacrylate/Sodium Methacrylate Crosspolymer				Methacryloyl Ethyl Betaine/Acrylates Copolymer			
	2018[25]	2011[2]	2018[21]	2011[2]	2018[25]	1998[1]	2018[19]	1998[1]
Totals*	**4**	**1**	**0.081-7.7**	**0.004-4**	**12**	**NR**	**0.00015-11**	**
Duration of Use								
Leave-On	*3*	*1*	*1.3-7.7*	*0.1-4*	*3*	*NR*	*0.09-11*	**
Rinse-Off	*1*	*NR*	*0.081*	*0.004-0.1*	*9*	*NR*	*0.00015-2.7*	**
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	**
Exposure Type								
Eye Area	NR	NR	NR	NR	NR	NR	NR	**
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	**
Incidental Inhalation-Spray	NR	NR	1.3	NR	3[a]	NR	0.09-3.6; 5.1-11[a]	**
Incidental Inhalation-Powder	NR	NR	7.7[c]	NR	NR	NR	NR	**
Dermal Contact	4	1	0.081-7.7	0.004-4	NR	NR	NR	**
Deodorant (underarm)	NR	NR	4.6 (not spray)	NR	NR	NR	NR	**
Hair - Non-Coloring	NR	NR	NR	NR	4	NR	0.09-11	**
Hair-Coloring	NR	NR	NR	NR	8	NR	0.00015-2.7	**
Nail	NR	NR	NR	NR	NR	NR	NR	**
Mucous Membrane	1	NR	0.081	NR	NR	NR	NR	**
Baby Products	NR	NR	NR	NR	NR	NR	NR	**

Table 4. Current and historical (where applicable) frequency and concentration of use, according to duration and exposure

	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	Methyl Methacrylate Crosspolymer				**Methyl Methacrylate/Glycol Dimethacrylate Crosspolymer**			
	2018[25]	**2008[3]**	**2018[23]**	**2009[3]**	**2018[25]**	**2008[3]**	**2018[23]**	**2009[3]**
Totals*	**423**	**144**	**0.0001-13**	**0.1-14**	**38**	**7**	**0.39-1.6**	**0.1-3**
Duration of Use								
Leave-On	*417*	*142*	*0.0001-13*	*0.1-14*	*38*	*7*	*0.39-1.6*	*0.1-3*
Rinse-Off	*6*	*2*	*0.12*	*NR*	*N R*	*NR*	*NR*	*0.1*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	53	15	2-13	0.5-10	2	NR	1.4	NR
Incidental Ingestion	38	15	2	1-10	NR	NR	NR	NR
Incidental Inhalation-Spray	5; 46[a]; 39[b]	1; 24[a]; 16[b]	0.12-0.38; 0.0069[a]	0.1-0.6; 0.8-3[a]; 0.1-3[b]	5[a]; 11[b]	1[a]	NR	0.5[a]; 0.2[b]
Incidental Inhalation-Powder	36; 39[b]	17; 16[b]	7.6-12; 0.5-8[c]	0.8-8; 0.1-3[b]	1; 11[b]	NR	0.65; 1-1.5[c]	3; 0.2[b]
Dermal Contact	370	127	0.0069-13	0.1-14	38	7	0.39-1.6	3
Deodorant (underarm)	1[a]	NR	2 (not spray)	0.9[a]	NR	NR	NR	NR
Hair - Non-Coloring	1	NR	NR	0.1	NR	NR	NR	NR
Hair-Coloring	7	NR	0.12	NR	NR	NR	NR	NR
Nail	2	1	0.0001-4	1	NR	NR	NR	NR
Mucous Membrane	38	15	2	1-10	NR	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR

	Methyl Methacrylate/PEG/PPG-4/3 Methacrylate Crosspolymer		**Poly C10-30 Alkyl Acrylate**	
	2018[25]	**2018[20]**	**2018[25]**	**2018[20]**
Totals*	**1**	**NR**	**19**	**0.5-3.2**
Duration of Use				
Leave-On	*1*	*NR*	*19*	*0.5-3.2*
Rinse-Off	*NR*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*
Exposure Type				
Eye Area	NR	NR	2	3.2
Incidental Ingestion	NR	NR	3	0.52-1.2
Incidental Inhalation-Spray	NR	NR	9[a]; 3[b]	NR
Incidental Inhalation-Powder	NR	NR	3[b]	2[c]
Dermal Contact	1	NR	15	0.5-2
Deodorant (underarm)	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR
Nail	NR	NR	NR	NR
Mucous Membrane	NR	NR	3	0.5-1.2
Baby Products	NR	NR	NR	NR

	Polyacrylate-14		**Polyacrylate-1 Crosspolymer**	
	2018[25]	**2018[20]**	**2018[25]**	**2018[20]**
Totals*	**3**	**NS**	**14**	**0.2-2**
Duration of Use				
Leave-On	*2*	*NS*	*4*	*NR*
Rinse-Off	*1*	*NS*	*10*	*0.2-2*
Diluted for (Bath) Use	*NR*	*NS*	*NR*	*NR*
Exposure Type				
Eye Area	NR	NS	NR	NR
Incidental Ingestion	NR	NS	NR	NR
Incidental Inhalation-Spray	1[a]	NS	1[a]; 3[b]	NR
Incidental Inhalation-Powder	NR	NS	NR	NR
Dermal Contact	NR	NS	11	0.2-2
Deodorant (underarm)	NR	NS	NR	NR
Hair - Non-Coloring	3	NS	3	NR
Hair-Coloring	NR	NS	NR	NR
Nail	NR	NS	NR	NR
Mucous Membrane	NR	NS	6	1.5
Baby Products	NR	NS	NR	NR

Table 4. Current and historical (where applicable) frequency and concentration of use, according to duration and exposure

	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	Polyacrylic Acid				**Polyethylacrylate**			
	2018[25]	**1998[1]**	**2018[19]**	**1998[1]**	**2018[25]**		**2018[20]**	
Totals*	**111**	**31**	**0.0012-4**	**	**4**		**NR**	
Duration of Use								
Leave-On	*96*	*27*	*0.0012-4*	**	*4*		*NR*	
Rinse-Off	*15*	*7*	*0.0049-0.4*	**	*NR*		*NR*	
Diluted for (Bath) Use	*NR*	*NR*	*0.36*	**	*NR*		*NR*	
Exposure Type								
Eye Area	8	NR	0.5-2.1	**	2		NR	
Incidental Ingestion	2	NR	0.0049-0.048	**	NR		NR	
Incidental Inhalation-Spray	1; 34[a]; 29[b]	3[a]; 14[b]	0.0049-0.62[a]	**	NR		NR	
Incidental Inhalation-Powder	29[b]	14[b]	0.0012; 0.25-4[c]	**	NR		NR	
Dermal Contact	95	28	0.0012-4	**	1		NR	
Deodorant (underarm)	NR	NR	NR	**	NR		NR	
Hair - Non-Coloring	3	1	0.4-1.2	**	NR		NR	
Hair-Coloring	NR	NR	NR	**	NR		NR	
Nail	11	2	NR	**	1		NR	
Mucous Membrane	3	2	0.0049-0.4	**	NR		NR	
Baby Products	NR	NR	0.15	**	NR		NR	
	Polymethyl Acrylate				**Polymethyl Methacrylate**			
	2018[25]		**2018[20]**		**2018[25]**	**2008[3]**	**2018[23]**	**2009[3]**
Totals*	**1**		**0.0014-5.9**		**922**	**892**	**0.0036-44.6**	**0.01-45**
Duration of Use								
Leave-On	*1*		*0.0014-5.9*		*896*	*879*	*0.0036-44.6*	*0.01-45*
Rinse-Off	*NR*		*NR*		*26*	*13*	*0.009-15.6*	*0.3-6*
Diluted for (Bath) Use	*NR*		*NR*		*0*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	NR		4-5.9		293	304	1-9.8	0.1-45
Incidental Ingestion	NR		2		72	60	0.16-16.1	3-20
Incidental Inhalation-Spray	1[a]		NR		4; 97[a]; 88[b]	6; 74[a]; 79[b]	0.1; 4-14.9[a]	0.5-20; 0.01-15[a]; 0.3-16[b]
Incidental Inhalation-Powder	NR		5		76; 88[b]	93; 79[b]	0.27-44.6; 0.23-8.6[c]	2-30 0.3-16[b]
Dermal Contact	1		0.5-5.9		807	806	0.009-44.6	0.01-45
Deodorant (underarm)	NR		NR		NR	NR	NR	4[a]
Hair - Non-Coloring	NR		NR		4	2	0.1-14.9	0.3-1
Hair-Coloring	NR		NR		9	1	15.6	2
Nail	NR		0.0014-.44		19	14	0.0036-19	0.7-30
Mucous Membrane	NR		2		78	62	0.16-16.1	3-20
Baby Products	NR		NR		NR	NR	NR	NR
	Potassium Acrylates Copolymer				**Potassium Acrylates/C10-30 Alkyl Acrylate Crosspolymer**			
	2018[25]		**2018[20]**		**2018[25]**	**2011[2]**	**2018[21]**	**2011[2]**
Totals*	**16**		**0.00031-1.3**		**2**	**NR**	**0.3**	**NR**
Duration of Use								
Leave-On	*10*		*1.3*		*2*	*NR*	*NR*	*NR*
Rinse-Off	*6*		*0.00031-0.31*		*NR*	*NR*	*0.3*	*NR*
Diluted for (Bath) Use	*NR*		*NR*		*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	NR		NR		1	NR	NR	NR
Incidental Ingestion	NR		NR		NR	NR	NR	NR
Incidental Inhalation-Spray	NR		NR		1[b]	NR	NR	NR
Incidental Inhalation-Powder	NR		1.3[c]		1[b]	NR	NR	NR
Dermal Contact	14		NR		2	NR	0.3	NR
Deodorant (underarm)	NR		NR		NR	NR	NR	NR
Hair - Non-Coloring	2		0.00031		NR	NR	NR	NR
Hair-Coloring	NR		NR		NR	NR	NR	NR
Nail	NR		NR		NR	NR	NR	NR
Mucous Membrane	1		NR		NR	NR	NR	NR
Baby Products	12		0.00031		NR	NR	NR	NR

Table 4. Current and historical (where applicable) frequency and concentration of use, according to duration and exposure

	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	Potassium Carbomer				**Sodium Acrylate/Vinyl Alcohol Copolymer**			
	2018[25]		**2018[20]**		**2018[25]**		**2018[20]**	
Totals*	**73**		**NR**		**NR**		**1.5**	
Duration of Use								
Leave-On	*56*		*NR*		*NR*		*NR*	
Rinse-Off	*13*		*NR*		*NR*		*1.5*	
Diluted for (Bath) Use	*4*		*NR*		*NR*		*NR*	
Exposure Type								
Eye Area	3		NR		NR		NR	
Incidental Ingestion	NR		NR		NR		NR	
Incidental Inhalation-Spray	25[a]; 27[b]		NR		NR		NR	
Incidental Inhalation-Powder	27[b]		NR		NR		NR	
Dermal Contact	73		NR		NR		NR	
Deodorant (underarm)	NR		NR		NR		NR	
Hair - Non-Coloring	NR		NR		NR		1.5	
Hair-Coloring	NR		NR		NR		NR	
Nail	NR		NR		NR		NR	
Mucous Membrane	6		NR		NR		NR	
Baby Products	NR		NR		NR		NR	
	Sodium Acrylates Copolymer				**Sodium Acrylates Crosspolymer-2**			
	2018[25]	**1998[1]**	**2018[19]**	**1998[1]**	**2018[25]**	**2011[2]**	**2018[21]**	**2011[2]**
Totals*	**179**	**5**	**0.005-18**	**	**NR**	**NR**	**0.47-1.8**	**0.8**
Duration of Use								
Leave-On	*170*	*NR*	*0.005-18*	**	*NR*	*NR*	*0.47-1.8*	*0.8*
Rinse-Off	*9*	*5*	*NR*	**	*NR*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	**	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	20	NR	1.5	**	NR	NR	NR	NR
Incidental Ingestion	1	NR	NR	**	NR	NR	NR	NR
Incidental Inhalation-Spray	72[a]; 50[b]	NR	8[a]	**	NR	NR	NR	NR
Incidental Inhalation-Powder	50[b]; 2[c]	NR	0.5-1.2[b]	**	NR	NR	0.47-1.8[c]	NR
Dermal Contact	176	NR	0.005-18	**	NR	NR	0.47-1.8	0.8
Deodorant (underarm)	NR	NR	NR	**	NR	NR	NR	NR
Hair - Non-Coloring	1	NR	NR	**	NR	NR	NR	NR
Hair-Coloring	NR	5	NR	**	NR	NR	NR	NR
Nail	NR	NR	NR	**	NR	NR	NR	NR
Mucous Membrane	2	NR	NR	**	NR	NR	NR	NR
Baby Products	2	NR	NR	**	NR	NR	NR	NR
	Sodium Acrylates/C10-30 Alkyl Acrylate Crosspolymer				**Sodium Acrylates/Vinyl Isodecanoate Crosspolymer**			
	2018[25]	**2011[2]**	**2018[21]**	**2011[2]**	**2018[25]**	**2011[2]**	**2018[21]**	**2011[2]**
Totals*	**96**	**6**	**0.3**	**NR**	**NR**	**NR**	**0.55**	**NR**
Duration of Use								
Leave-On	*18*	*6*	*NR*	*NR*	*NR*	*NR*	*0.55*	*NR*
Rinse-Off	*78*	*NR*	*0.3*	*NR*	*NR*	*NR*	*NR*	*NR*
Diluted for (Bath) Use	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*	*NR*
Exposure Type								
Eye Area	2	NR	NR	NR	NR	NR	NR	NR
Incidental Ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Spray	5[a]; 5[b]	1	NR	NR	NR	NR	NR	NR
Incidental Inhalation-Powder	5[b]	NR	NR	NR	NR	NR	NR	NR
Dermal Contact	96	6	0.3	NR	NR	NR	0.55	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	NR	NR	NR	NR	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR	NR	NR

Table 4. Current and historical (where applicable) frequency and concentration of use, according to duration and exposure

	# of Uses		*Max Conc of Use (%)*		*# of Uses*		*Max Conc of Use (%)*	
	Sodium Carbomer				**Sodium Polyacrylate**			
	2018[25]		**2018[22]**		**2018[25]**	**1998[1]**	**2018[19]**	**1998[1]**
Totals*	**168**		**0.015-0.65**		**900**	**8**	**0.0001-29.7**	**
Duration of Use								
Leave-On	*146*		*0.015-0.65*		*782*	*5*	*0.0001-29.7*	**
Rinse-Off	*22*		*NR*		*118*	*3*	*0.0002-1.5*	**
Diluted for (Bath) Use	*NR*		*0.16*		*NR*	*NR*	*NR*	**
Exposure Type								
Eye Area	22		0.015		131	NR	0.9-29.7	**
Incidental Ingestion	NR		NR		3	NR	0.0095-0.09	**
Incidental Inhalation-Spray	76[a]; 39[b]		0.65[a]		1; 319[a]; 267[b]	1	0.0001-1.8 0.0005-0.0098[a]; 1.5[b]	**
Incidental Inhalation-Powder	39[b]		0.028-0.13[c]		7; 267[b]	NR	0.05; 1.5[b]; 0.0015-7[c]	**
Dermal Contact	166		0.015-0.16		774	5	0.0005-7	**
Deodorant (underarm)	NR		NR		NR	NR	1.5 (not spray) 2.9 (spray)	**
Hair - Non-Coloring	NR		0.65		83	NR	0.0001-1.8	**
Hair-Coloring	NR		NR		22	3	1.5	**
Nail	1		NR		1	NR	6	**
Mucous Membrane	1		0.16		16	2	0.0098-0.8	**
Baby Products	NR		NR		NR	NR	0.55	**
	Sodium Polymethacrylate				Steareth-10 Allyl Ether/Acrylates Copolymer			
	2018[25]		**2018[20]**		**2018[25]**	**1998[1]**	**2018[19]**	**1998[1]**
Totals*	**62**		**0.063-3.4**		**62**	**6**	**0.025-1.5**	**
Duration of Use								
Leave-On	*62*		*0.063-3.4*		*54*	*NR*	*0.025-1.5*	**
Rinse-Off	*NR*		*NR*		*8*	*6*	*1.5*	**
Diluted for (Bath) Use	*NR*		*NR*		*NR*	*NR*	*NR*	**
Exposure Type								
Eye Area	60		0.063-1.5		NR	NR	NR	**
Incidental Ingestion	NR		NR		NR	NR	NR	**
Incidental Inhalation-Spray	1[a]		NR		53[a]; 1[b]	NR	0.025-1.5[a]	**
Incidental Inhalation-Powder	NR		NR		1[b]	NR	NR	**
Dermal Contact	8		0.5-1.5		3	NR	NR	**
Deodorant (underarm)	NR		NR		NR	NR	NR	**
Hair - Non-Coloring	NR		3.4		53	NR	0.025-1.5	**
Hair-Coloring	NR		NR		6	6	NR	**
Nail	NR		NR		NR	NR	NR	**
Mucous Membrane	NR		NR		1	NR	NR	**
Baby Products	NR		NR		NR	NR	NR	**
	Styrene/Acrylates/Ammonium Methacrylate Copolymer				**VA/Butyl Maleate/Isobornyl Acrylate Copolymer**			
	2018[25]	**1998[1]**	**2018[19]**	**1998[1]**	**2018[25]**	**1998[1]**	**2018[19]**	**1998[1]**
Totals*	**106**	**1**	**1.2-38**	**	**2**	**5**	**1.3-10**	**
Duration of Use								
Leave-On	*102*	*1*	*1.2-38*	**	*2*	*5*	*1.3-10*	**
Rinse-Off	*4*	*NR*	*10*	**	*NR*	*NR*	*NR*	**
Diluted for (Bath) Use	*NR*	*NR*	*NR*	**	*NR*	*NR*	*NR*	**
Exposure Type								
Eye Area	99	1	1.2-22.6	**	NR	NR	NR	**
Incidental Ingestion	NR	NR	NR	**	NR	NR	NR	**
Incidental Inhalation-Spray	1[a]	NR	NR	**	1; 1[a]	NR	1.3-10	**
Incidental Inhalation-Powder	NR	NR	NR	**	NR	NR	NR	**
Dermal Contact	50	1	3.3-22.6	**	NR	NR	1.3-2	**
Deodorant (underarm)	NR	NR	NR	**	NR	NR	NR	**
Hair - Non-Coloring	NR	NR	NR	**	2	5	2.5-10	**
Hair-Coloring	4	NR	10	**	NR	NR	NR	**
Nail	1	NR	21-38	**	NR	NR	NR	**
Mucous Membrane	NR	NR	NR	**	NR	NR	NR	**
Baby Products	NR	NR	NR	**	NR	NR	NR	**

*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

** Concentration of use data were not provided at the time of the review.

[#] This ingredient is listed in the VCRP as Carbomer (6175 used under the INCI name) and several tradenames (259 used listed under the tradenames)

[##] At the time of the original assessment, this ingredient was reported under several names. The use frequencies of use were combined for the purposes of this table; this may overestimate the actual 2001 frequency of use

[a] It is possible these products are sprays, but it is not specified whether the reported uses are sprays.

[b] Not specified whether a spray or a powder, but it is possible the use can be as a spray or a powder, therefore the information is captured in both categories.

[c] It is possible these products are powders, but it is not specified whether the reported uses are powders

NR – no reported use

NS – not yet surveyed

Table 5. Acrylates copolymers not reported to be used in cosmetics, according to 2018 FDA VCRP[25] and 2018 Council survey[19-24] data

Acrylates Crosspolymer-5	Cyclohexyl Methacrylate/Ethylhexyl Methacrylate Copolymer
Acrylates/Beheneth-25 Methacrylate/Steareth-30 Methacrylate Copolymer	Ethylene/Acrylic Acid/VA Copolymer
Acrylates/C12-13 Alkyl Methacrylates/Methoxyethyl Acrylate Crosspolymer	Ethylene/Calcium Acrylate Copolymer
	Ethylene/Magnesium Acrylate Copolymer
Acrylates/C26-28 Olefin Copolymer	Ethylene/Zinc Acrylate Copolymer
Acrylates/C5-8 Alkyl Acrylate Copolymer	Ethylhexyl Acrylate/Methoxy PEG-23 Methacrylate/Vinyl Acetate Copolymer
Acrylates/Ceteareth-20 Methacrylate Crosspolymer	
Acrylates/Ceteareth-20 Methacrylate Crosspolymer-2	Glycol Dimethacrylate Crosspolymer*
Acrylates/Ceteth-20 Methacrylate Copolymer	Glycol Dimethacrylate/Vinyl Alcohol Crosspolymer
Acrylates/Ethylhexyl Acrylate/Glycidyl Methacrylate Crosspolymer	Hydroxyethyl Acrylate/Methoxyethyl Acrylate Copolymer
Acrylates/Hydroxyethyl Acrylate/Lauryl Acrylate Copolymer	Lauryl Acrylate/VA Copolymer
Acrylates/Hydroxyethyl Acrylate/Methoxyethyl Acrylate Copolymer	Lauryl Acrylate/VA Crosspolymer
Acrylates/Laureth-25 Methacrylate Copolymer	Methacrylic Acid/PEG-6 Methacrylate/PEG-6 Dimethacrylate Crosspolymer
Acrylates/Lauryl Methacrylate Copolymer	PEG/PPG-5/2 Methacrylate/Methacrylic Acid Crosspolymer
Acrylates/Lauryl Methacrylate/Tridecyl Methacrylate Crosspolymer	Poly(Methoxy PEG-9 Methacrylate)
Acrylates/Methoxy PEG-4 Methacrylate Copolymer	Polyacrylate-29*
Acrylates/Methoxy PEG-15 Methacrylate Copolymer	Polyacrylate-34*
Acrylates/Methoxy PEG-90 Methacrylate Crosspolymer	Polybutyl Acrylate
Acrylates/PEG-4 Dimethacrylate Crosspolymer	Polybutyl Methacrylate
Acrylates/Steareth-50 Acrylate Copolymer	Polyhydroxyethylmethacrylate
Acrylic Acid/C12-22 Alkyl Acrylate Copolymer	Polyisobutyl Methacrylate
Allyl Methacrylate/Glycol Dimethacrylate Crosspolymer	Polypropyl Methacrylate
Ammonium Acrylates/Ethylhexyl Acrylate Copolymer	Polystearyl Methacrylate
Ammonium Styrene/Acrylates/Ethylhexyl Acrylate/Lauryl Acrylate Copolymer	Potassium Acrylate Crosspolymer
	Potassium Acrylates/Ethylhexyl Acrylate Copolymer
Ammonium VA/Acrylates Copolymer	Potassium Aluminum Polyacrylate
Butyl Acrylate/Cyclohexyl Methacrylate Copolymer	Potassium Polyacrylate
Butyl Acrylate/Ethylhexyl Methacrylate Copolymer	Sodium Acrylate/Acrolein Copolymer
Butyl Acrylate/Hydroxyethyl Methacrylate Copolymer	Sodium Acrylates/Beheneth-25 Methacrylate Crosspolymer
Butyl Methacrylate/Acryoyloxy PG Methacrylate Copolymer	Sodium Acrylates/Ethylhexyl Acrylate Copolymer
C8-22 Alkyl Acrylates/Methacrylic Acid Crosspolymer	Stearyl/Lauryl Methacrylate Crosspolymer
Calcium Potassium Carbomer	

*not yet surveyed by the Council

Table 6. Acrylates Copolymers Approved for Use as Secondary Direct Food Additives and Indirect Food Additives

Secondary Direct Food Additives	
21CFR173.310 - boiler water additives	
Sodium Polyacrylate	
Sodium Polymethacrylate	
21CFR173.340 – defoaming agent	
Sodium Polyacrylate	
21CFR173.73 - polymer substances and polymer adjuvants for food treatment	
Sodium Polyacrylate	
Indirect Food Additives	
21CFR175.105 – adhesives	
Acrylates Copolymer	Polybutyl Acrylate
Ammonium Polyacrylate	Polybutyl Methacrylate
Ethylene/Calcium Acrylate Copolymer	Polyethylacrylate
Ethylene/Sodium Acrylate Copolymer	Sodium Polyacrylate
Ethylene/Zinc Acrylate Copolymer	Sodium Polymethacrylate
Polyacrylic Acid	
21CFR175.210 - acrylate ester copolymer coating	
Acrylates Copolymer	
21CFR175.300 - resinous and polymeric coatings	
Acrylates Copolymer	
Polyacrylic Acid	
Polyethylacrylate	
21CFR175.320 - resinous and polymeric coatings for polyolefin films	
Acrylates Copolymer	
Ethylhexyl Acrylate/Methyl Methacrylate Copolymer	
Polyacrylic Acid	
21CFR176.170 - components of paper and paperboard in contact with aqueous and fatty foods	
Acrylates Copolymer	Sodium Polyacrylate
Ethylene/Acrylic Acid Copolymer	Sodium Polymethacrylate
Polyacrylic Acid	
21CFR176.180 - components of paper and paperboard in contact with dry food	
Acrylates Copolymer	Polyethylacrylate
Acrylates VA Copolymer	Sodium Polyacrylate
Polyacrylic Acid	
21CFR176.200 - defoaming agents used in coatings	
Sodium Polyacrylate	
21CFR177.1010 acrylic and modified acrylic plastics, semi-rigid and rigid	
Ethylhexyl Acrylate/Methyl Methacrylate Copolymer	Polybutyl Methacrylate
Polybutyl Acrylate	Polyethylacrylate
21CFR177.1210 - closures with sealing gaskets for food containers	
Sodium Polyacrylate	
21CFR177.1310 – ethylene-acrylic acid copolymers	
Ethylene/Acrylic Acid Copolymer	
21CFR177.1520 - olefin polymers	
Polyethylacrylate	
21CFR178.3790 - polymer modifiers in semi-rigid and rigid vinyl chloride plastics	
Polybutyl Acrylate	
Polybutyl Methacrylate	
Polymethyl Methacrylate	

Table 7. **Acute toxicity studies**

Ingredient	Animals	No./Group	Vehicle	Concentration/Dose/Protocol	LD_{50}/LC_{50}/Results	Reference
			DERMAL			
Acrylates/Beheneth-25 Methacrylate Copolymer	rats	not stated	not stated	details not provided	> 5 g/kg	[10]
Acrylates Copolymer [as 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, ethyl 2-methyl-2-propenoate and ethyl 2-propenoate]	rats	not stated	not stated	in accord with OECD TG 423; details not provided	> 2 g/kg	[13]
Acrylates/Hydroxyesters Acrylates Copolymer (product containing < 50%)	rats	not stated	not stated	in accord with OECD TG 402; details were not provided	>5 g/kg bw	[14]
VA/Butyl Maleate/Isobornyl Acrylate Copolymer in ethanol	NZW rabbits	3/sex	applied neat	occlusive patch of 2 g/kg of the test material was applied to intact and abraded skin for 24 h	> 2 g/kg	[8]
			ORAL			
Acrylates/Beheneth-25 Methacrylate Copolymer	rats	not stated	not stated	details not provided	> 5 g/kg	[10]
Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate)	rats (strain not specified)	5/sex	copolymer dispersion was mixed with powdered diet	the copolymer dispersion was mixed with powdered diet to give a content of 20% of dry polymer substance; animals were given the treated feed for 24 h, and then observed for 4 wks	> 25.2 g dry copolymer/kg bw no mortality; no lesions observed at necropsy	[15]
Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate)	dogs (strain not specified)	2/sex	copolymer dispersion was mixed with powdered diet	the copolymer dispersion was mixed with powdered diet to give a content of 20% of dry polymer substance; fasted animals were fed 60 g formulated diet/kg bw, and then observed for clinical signs	> 7.95 g dry copolymer/kg bw no mortality; no lesions observed at necropsy	[15]
Acrylates/Hydroxyesters Acrylates Copolymer (product containing < 50%)	rats	not stated	not stated	in accord with OECD TG 425; details not provided	> 5 g/kg	[14]
Polyacrylate-1 Crosspolymer	rats	not stated	DMSO	in accord with OECD TG 423; details not provided	> 2 g/kg	[12]
VA/Butyl Maleate/Isobornyl Acrylate Copolymer in ethanol	Sprague-Dawley rats	5/sex	corn oil	5 g/kg by gavage	> 5 g/kg no mortality	[8]
			INHALATION			
Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate)	Wistar rats	5/sex	the copolymer was dispersed with dry matter	single 4-h exposure (nose-only) to an aerosol of the copolymer dispersion with a dry matter content of 30.2%; the test was performed in accord with OECD TG 403	> 3960 mg/l no mortality; no observations of toxicity	[15]

Abbreviations: DMSO – dimethyl sulfoxide; NZW – New Zealand White; OECD – Organisation for Economic Co-operation and Development; TG – test guideline

Table 8. Genotoxicity Studies

Test Article	Concentration/Dose	Vehicle	Test System	Procedure	Results	Reference
IN VITRO						
Acrylates Copolymer [as 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, ethyl 2-methyl-2-propenoate and ethyl 2-propenoate]	not provided	not provided	not provided	Ames test, in accord with OECD TG 471; details not provided	not mutagenic	[13]
Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate)	312.5 – 5000 µg dry copolymer/plate	acetone	*S. typhimurium* TA98, TA100, and TA1537	Ames test, with and without metabolic activation	not mutagenic	[15]
Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate)	40% dry substance 3 – 5000 µg dispersion/ plate (corresponds to 1.2 – 2000 µg dry copolymer/ plate	aq. dispersion	S. typhimurium TA98, TA100, TA102, TA1535, and TA1537	Ames test in accord with OECD TG 471, with and without metabolic activation	not mutagenic	[15]
Acrylates Copolymer (as a fully polymerized copolymer of methyl acrylate, methyl methacrylate, and methacrylic acid)	157 – 5000 µg dry copolymer/plate	DMSO	S. typhimurium TA98, TA100, TA1535, and TA1537; *E. coli* WP2uvrA	Ames test in accord with OECD TG 471 and 472, with and without metabolic activation	not mutagenic	[16]
Acrylates Copolymer [as 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, ethyl 2-methyl-2-propenoate and ethyl 2-propenoate]	not provided	not provided	not provided	mouse lymphoma cell assay; in accord with OECD TG 476; details not provided	not mutagenic	[13]
Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate)	195.3 – 6250 µg dry copolymer /ml	deionized water	mammalian L5178Y cells	mouse lymphoma L5178Y cell mutation assay in accord with OECD TG 476; cells were exposed to the test material for 4 h in the presence and absence of metabolic activation, or for 24 h without metabolic activation	not genotoxic	[15]
Acrylates Copolymer (as a fully polymerized copolymer of methyl acrylate, methyl methacrylate, and methacrylic acid)	14.5 - 5000 µg dry copolymer/ml	DMSO	mammalian L5178Y cells	mouse lymphoma L5178Y cell mutation assay in accord with OECD TG 476; cells were exposed to the test material for 4 h in the presence and absence of metabolic activation, or for 24 h without metabolic activation	not genotoxic	[16]
Acrylates Copolymer (as a fully polymerized copolymer of methyl acrylate, methyl methacrylate, and methacrylic acid)	≤ 1080 µg dry copolymer/ml (Exp. 1) ≤ 9000 µg dry copolymer/ml (Exp. 2)	DMSO	human lymphocytes	chromosomal aberration assay in accord with OECD TG 473 Exp 1: cells were exposed for 2 h with, and 3 h without, metabolic activation Exp. 2: cells were exposed for 24 h, with and without metabolic activation	not clastogenic	[16]
Acrylates/Hydroxyesters Acrylates Copolymer (product containing < 50%)	not provided	not provided	not provided	Ames test, in accord with OECD TG 471; details not provided	not mutagenic	[14]

Table 8. Genotoxicity Studies

Test Article	Concentration/Dose	Vehicle	Test System	Procedure	Results	Reference
IN VIVO						
Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate)	500, 1000, and 2000 mg dry copolymer/kg bw	sterile water	mice, 5/sex/group	mouse micronucleus test in accord with OECD TG 474; mice were dosed by gavage (10 ml/kg bw) and killed 24 h after dosing; a second high-dose group was killed 48 h after dosing	not genotoxic a minimal increase of MNPCE in male mice killed after 24 h was considered not biologically relevant, and was within historical range	15
Acrylates Copolymer (as a fully polymerized copolymer of methyl acrylate, methyl methacrylate, and methacrylic acid)	500, 1000, and 2000 mg dry copolymer/kg bw	1% aq CMC	mice, 5/sex/group	mouse micronucleus test in accord with OECD TG 474; mice were dosed by gavage (10 ml/kg bw) and killed 24 h after dosing; a second high-dose group was killed 48 h after dosing	not genotoxic	16

Abbreviations: CMC – carboxymethylcellulose; DMSO – dimethyl sulfoxide; MNPCE - micronucleated polychromatic erythrocytes; OECD – Organisation for Economic Co-operation and Development; TG – test guideline

Table 9. Dermal irritation and sensitization

Test Article	Dose/Concentration	Test Population	Procedure	Results	Reference
ANIMAL					
Acrylates/Beheneth-25 Methacrylate Copolymer	not stated	rabbits; # not stated	details not provided	classified as slightly irritating very slight to well-defined erythema and very slight edema were observed; erythema was resolved by day 7 and edema within 48 h	10
Acrylates Copolymer [as 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, ethyl 2-methyl-2-propenoate and ethyl 2-propenoate]	not stated	rabbits; # not stated	skin irritation test conducted in accord with OECD TG404; details not provided	not irritating	13
Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate)	0.5 ml	3 NZW rabbits	4-h semi-occlusive patch was applied to each animal, in accord with OECD TG 404; test sites were observed 1, 24, 48, and 72 h after patch removal	not an irritant	15
Acrylates Copolymer [as 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, ethyl 2-methyl-2-propenoate and ethyl 2-propenoate]	not stated	not stated; assumed to be mice	LLNA, in accord with OECD TG 429	not a sensitizer	13
Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate)	not stated; assumed neat	Dunkin-Hartley albino guinea pigs; 20 test and 10 control animals	Buehler test, performed in accord with OECD TG 406 induction: 6-h occlusive patches were applied 1 x/wk for 3 wks challenge: after a 2-wk non-treatment period, a 6-h occlusive patch was applied to an untreated site	not a sensitizer	15
Acrylates/Hydroxyesters Acrylates Copolymer (product containing < 50%)	not stated	rabbits; # not stated	skin irritation test conducted in accord with OECD TG404; details not provided	slightly irritating slight erythema observed at 1 and 24 h after patch removal; skin appeared normal after 48 h	14

Table 9. Dermal irritation and sensitization

Test Article	Dose/Concentration	Test Population	Procedure	Results	Reference
VA/Butyl Maleate/Isobornyl Acrylate Copolymer in ethanol	0.5 g	6 NZW rabbits	24 h occlusive patch of the test material moistened with 0.5 ml physiological saline applied to intact and abraded dorsal skin	not an irritant	[8]
VA/Butyl Maleate/Isobornyl Acrylate Copolymer in ethanol	Neat; 0.5 g	10 Hartley guinea pigs	Buehler test induction: 6-h occlusive patch applied 3x/wk for 3 wks challenge: after a 2-wk non-treatment period, patches were applied to the original test site, and to a previously untested site	not an irritant or a sensitizer	[8]
HUMAN					
Acrylates/Hydroxyesters Acrylates Copolymer (product containing < 50%)	not provided	# subjects not provided	HRIPT; details not provided	not a sensitizer	[14]
VA/Butyl Maleate/Isobornyl Acrylate Copolymer in ethanol	5 g; slurry in alcohol	25 subjects	48-h patch test	slight erythema observed in 20% of the subjects	[8]
VA/Butyl Maleate/Isobornyl Acrylate Copolymer	0.2 ml in 10% ethanol	109 subjects	HRIPT induction: 24-h patches 3x/wk for 3 wks challenge: after a 2-wk, non-treatment period, a 24-h patch was applied to a previously untreated site	not likely to be a sensitizer induction: minimal erythema in 3 subjects and hyperpigmentation in 1 subject; in 1 subject, edema and intense erythema with application 8 that did not recur when the patch was moved challenge: minimal erythema in the subject that had a reaction with the 8th induction patch; minimal erythema in 3 subjects that did not react during induction	[8]

Abbreviations: HRIPT – human repeated insult patch test; NZW – New Zealand White; OECD – Organisation for Economic Co-operation and Development; TG – test guideline

Table 10. Ocular irritation studies

Test Article	Concentration/Dose	Test Population	Procedure	Results	Reference
			ANIMAL		
Acrylates/Beheneth-25 Methacrylate Copolymer	not stated	rabbits; # not stated	details not provided	classified as slightly irritating transient conjunctival effects were observed; eyes were normal within 48 h	[10]
Acrylates Copolymer [as 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, ethyl 2-methyl-2-propenoate and ethyl 2-propenoate]	not stated	NZW rabbits; # not stated	in accord with OECD TG 405; details not provided	slightly irritating	[13]
Acrylates Copolymer (as a fully polymerized copolymer of methyl methacrylate and ethyl acrylate)	undiluted	3 NZW rabbits	0.1 ml was instilled into the conjunctival sac of one eye of each rabbits, in accord with OECD TG 405; test eyes were observed 1, 24, 48, and 72 h after patch removal	not an ocular irritant	[15]
Acrylates/Hydroxyesters Acrylates Copolymer (product containing < 50%)	not stated	rabbits; # not stated	details not provided	slightly irritating slight conjunctival irritation in treated eyes 1- and 24-h after instillation; irritation resolved within 48 h	[14]
VA/Butyl Maleate/Isobornyl Acrylate Copolymer in ethanol	undiluted	9 NZW rabbits	0.1 g was instilled into the conjunctival sac of one eye of each rabbits; the contralateral eye served as an untreated control. Following instillation, the eyes of 3 rabbits were immediately rinsed; the eyes of the remaining 6 rabbits were not rinsed.	moderate to severe eye irritant Slight corneal opacity, slight to moderate conjunctival redness, slight-to-severe conjunctival chemosis and slight to severe conjunctival discharge observed in the unwashed eyes; some degree of conjunctivitis observed in all unwashed eyes on day 7; within the first 3 days post-exposure, blistering of the conjunctiva was observed in 5 eyes that were not rinsed.	[8]

Abbreviations: NZW – New Zealand White; OECD – Organisation for Economic Co-operation and Development; TG – test guideline

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