Safety Assessment of Acryloyldimethyltaurate Polymers as Used in Cosmetics

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date to comment on this safety assessment and to identify additional published data that should be included or provide unpublished data which can be made public and included.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 All unpublished data submitted to CIR will be discussed in open meetings, will be available at the CIR office for review by any interested party and may be cited in a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

The 2016 Cosmetic Ingredient Review Expert Panel members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Ronald A. Hill, Ph.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D.; Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Director is Lillian J. Gill, D.P.A. This report was prepared by Lillian C. Becker, Scientific Analyst/Writer.

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ABSTRACT

The Cosmetic Ingredient Review (CIR) Expert Panel (Panel) assessed the safety of 21 acryloyldimethyltaurate polymers as used in cosmetics. The reported functions of these ingredients include dispersing agent – nonsurfactant, emulsion stabilizers, opacifying agent, and viscosity increasing agent – aqueous. The Panel expressed concern about residual monomers and impurities including acrylamide, vinyl formamide, and methacrylamidolauric acid monomers. They stressed that the cosmetics industry should continue to use current good manufacturing practices (cGMPs) to limit impurities. The Panel concluded that acryloyldimethyltaurate polymers are safe in cosmetics in the present practices of use and concentration described in this safety assessment.

INTRODUCTION

This is a review of the published scientific literature and unpublished data provided by Industry relevant to assessing the safety of 21 acryloyldimethyltaurate polymers as used in cosmetics. This group of ingredients comprises homopolymers, copolymers, and crosslinked polymers, the monomers of which are at least partially composed of acryloyldimethyltaurate. According to the *International Cosmetic Ingredient Dictionary and Handbook*, the functions of these ingredients include dispersing agent – nonsurfactant, emulsion stabilizer, opacifying agent, and viscosity increasing agent – aqueous (Table 1).[1] The ingredients in this safety assessment are:

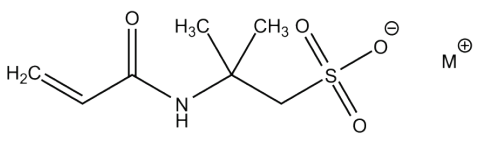
Acrylamide/Sodium Acryloyldimethyltaurate Copolymer
Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer
Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer
Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer
Ammonium Acryloyldimethyltaurate/Laureth-7 Methacrylate Copolymer
Ammonium Acryloyldimethyltaurate/Steareth-25 Methacrylate Crosspolymer
Ammonium Acryloyldimethyltaurate/Steareth-8 Methacrylate Copolymer
Ammonium Acryloyldimethyltaurate/Vinyl Formamide Copolymer
Ammonium Acryloyldimethyltaurate/VP Copolymer
Ammonium Polyacryloyldimethyl Taurate
Dimethylacrylamide/Sodium Acryloyldimethyltaurate Crosspolymer
HEA/Sodium Acryloyldimethyltaurate/Steareth-20 Methacrylate Copolymer
Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer
Sodium Acrylate/Acryloyldimethyltaurate/ Dimethylacrylamide Crosspolymer
Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer
Sodium Acrylate/Sodium Acryloyldimethyl Taurate/Acrylamide Copolymer
Sodium Acryloyl Dimethyl Taurate/PEG-8 Diacrylate Crosspolymer
Sodium Acryloyldimethyl Taurate/Acrylamide/VP Copolymer
Sodium Acryloyldimethyltaurate/Methacrylamidolauric Acid Copolymer
Sodium Acryloyldimethyltaurate/VP Crosspolymer
Sodium Polyacryloyldimethyl Taurate

The Panel has previously reviewed polymers that are similar to the acryloyldimethyltaurate polymers (Table 2). Some of the ingredients in this report are copolymers with acrylate monomers; the Panel has reviewed the polyacrylates, and other acrylate copolymers, and concluded that they are safe as used when formulated to be non-irritating.[2] Some other ingredients in this report are copolymers with acrylamide monomers; polyacrylamides were found to be safe as used if the concentration of residual acrylamide monomers in formulation is not greater than 5 ppm, and Polyvinylpryrrolidone (PVP; another polymer with vinyl-type amide monomers) was found to be safe as used.[3,4] The Panel has also previously reviewed components/monomers of the acryloyldimethyltaurate polymers. The alkyl taurate amides and taurate salts were found to be safe when formulated to be non-irritating.[5]

CHEMISTRY

Definition and Structure

The acryloyldimethyltaurate polymers are composed of homopolymers, copolymers and crosslinked polymers, the monomers of which are at least partially composed of acryloyldimethyltaurate.



acryloyldimethyltaurate

Figure 1. This monomer is common to all acryloyldimethyltaurate polymers, where M is a sodium cation or ammonium.

The definitions and structures of these acryloyldimethyltaurate polymers ingredients are presented in Table 1.

Physical and Chemical Properties

The characteristics of acryloyldimethyltaurate polymers may vary greatly with manufacturing methods. For instance, the fluidity, solubility, and swelling capacity of these polymers can be determined by the degree of polymerization and crosslinking. In other words, altering manufacturing conditions, such as temperature, reaction time, and/or stoichiometric ratios, may result in significantly different physical forms even when the same monomers are used (i.e., even included under one ingredient name). It is also possible that these polymers are manufactured *in situ* to produce hydrogels. Accordingly, only cosmetic ingredient-specific data on the chemical and physical properties (including the molecular weight) of these ingredients are useful and cannot be assumed.

Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer and Ammonium Acryloyldimethyltaurate/VP Copolymer are reported to be white powders (Table 3).[6,7]

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer is reported to be provided in water, at up to 27%.[8]

These ingredients are large (2000 μm; >1000 to >1,000,000 g/mol) molecules. None of the particle diameters of Ammonium Acryloyldimethyltaurate/VP Copolymer were >2000 μm, 97.2% were <2000 μm, 81.3% were <1000 μm, 11.8% were <200 μm, and 0.5% were <100 μm.[6] For Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer, 90.8% of the particles were <100 μm and 84.5% were <10 μm, and had an overall median diameter of 2.8 μm.[7] Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer is reported have a molecular weight of approximately 250,000 g/mol.[8] The molecular weight of Sodium Polyacryloyldimethyl Taurate was reported to be >1,000,000 g/mol.[9]

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, and a Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer mixture were reported to be stable under normal environmental conditions.[10-12] Under normal conditions of use in personal care products, Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer is not expected to degrade; however, it does have functional groups that can be hydrolyzed in the pH range of 4-9.[10] Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer and Ammonium Acryloyldimethyltaurate/VP Copolymer were also reported to be stable under normal conditions, but may release ammonia under alkaline conditions.[6,7]

Method of Manufacture

Information on the methods of manufacture of these ingredients was not found in the published literature and no unpublished data were submitted. However, it is likely that radical type polymerization is commonly used, as it is for polyacrylamide and other vinyl-type polymers. This type of synthesis begins with formaldehyde and acetylene, and proceeds through 2-butyne-1,4-diol and γ-butyrolactone to α-pyrrolidone and *N*-vinyl-2-pyrrolidone (the monomer), which is then polymerized to form the polymer. Usually, the monomer is polymerized in water; however, commercial polymerization may be carried out in isopropyl alcohol. The alcoholic solution is subsequently wetted to an aqueous solution by steam distillation and then either spray or drum dried.[4,13,14]

Composition/Impurities

One supplier reported that Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer is supplied as an aqueous solution containing 25% to 27% of the polymer and the preservative sodium methylparaben (0.2%).[8] This polymer is also reported to be supplied as an aqueous solution at 24%.[12]

Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer is reported to be supplied in a trade name mixture at <60%; the lowest concentration is not specified.[11]

Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer is reported to be supplied in a trade name mixture at <45%; the lowest concentration is not specified.[10]

Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer was reported to be >90% pure; data on the remaining <10% was not provided.[7]

Sodium Polyacryloyldimethyl Taurate is reported to contain <2000 ppm 2-acrylamido-2-methylpropane sulfonic acid (AMPS) and <10 ppm (detection limit) acrylamide.[9]

USE

Cosmetic

The safety of the cosmetic ingredients included in this safety assessment is evaluated based on the data the Panel receives from the U.S. Food and Drug Administration (FDA) and the cosmetics Industry on the expected cosmetic use of ingredients. The FDA collects data from manufacturers on the use of individual ingredients in cosmetics by cosmetic product category in its Voluntary Cosmetic Registration Program (VCRP). Those data received from the cosmetic Industry are submitted in response to a survey conducted by the Personal Care Products Council (Council) of the maximum reported use concentrations by category.

According to VCRP data received from the FDA in 2016, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate

Copolymer was reported to be used in 474 formulations, including use in 451 leave-on products, 21 rinse-off products, and 2 products used in the bath (Table 4).[15] Ingredients with the next highest reported frequency of use are Ammonium Acryloyldimethyltaurate/VP Copolymer with 456 uses (428 leave-on and 28 rinse-off products), Acrylamide/Sodium Acryloyldimethyltaurate Copolymer, with 236 uses (229 leave-on and 7 rinse-off products), Ammonium Polyacryloyldimethyl Taurate, with 197 uses (185 leave-on and 12 rinse-off products), and Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer with 165 uses (159 leave-on and 6 rinse-off products). All other ingredients are reported to be used in 49 or fewer products.

The results of a concentration of use survey conducted by the Council in 2015 indicate Hydroxyethyl Acrylate/ Sodium Acryloyldimethyl Taurate Copolymer has the highest reported maximum concentration of use; it is reported to be used at up to 4.3% in depilatories (rinse-off products) and up to 3.6% in eyeliner and eye shadow (leave-on products).[16] The reported maximum concentrations of use for the other ingredients range from 0.015%-3% in leave-on products and 0.078%-3.2% in rinse-off products.

In some cases, reports of uses were received from the VCRP, but concentration of use data were not reported in the use concentration survey.[15,17] For example, Sodium Acryloyldimethyltaurate/VP Crosspolymer is reported to be used in 8 cosmetic formulations, but no use concentrations were reported. In other cases, no uses were reported to the VCRP, but concentration of use data were reported by Industry; for example, Sodium Acryloyldimethyl Taurate/Acrylamide/VP Copolymer had no reported uses in the VCRP, but a use concentration (0.65%) in the category of other suntan preparations was provided in the Industry survey. Therefore, it is assumed that there is at least one use in every cosmetic product category for which a concentration was reported.

The ingredients not in use, based on the data from both the VCRP and the Industry survey, are listed in Table 5.

Several of these ingredients were reported to be used in products that are used around the eye (the highest maximum reported concentration is 3.6% for Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer in eyeliners and eye shadow) and in products that come in contact with mucus membranes (the highest maximum reported concentration 2.4% Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer in the use category of other personal cleanliness products). Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer was reported to be used in 1 baby product (no concentration of use was reported).

Acrylamide/Sodium Acryloyldimethyltaurate Copolymer, Ammonium Polyacryloyldimethyl Taurate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, and Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer are reported to be used in powder products, in which the highest reported concentration of use was 0.7% Acrylamide/Sodium Acryloyldimethyltaurate Copolymer in face powders. 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.[18,19] Additionally, some of the acryloyldimethyltaurate polymers are used in cosmetic sprays and could possibly be inhaled; for example, Dimethylacrylamide/Sodium Acryloyldimethyltaurate Crosspolymer is reported to be used at up to 3% in perfume and Ammonium Acryloyldimethyltaurate/VP Copolymer at up to 0.4% in spray tonics, dressings and other hair grooming aids. 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.[20,21] 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.[22,23]

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) of Australia concluded that there is low concern to public health when Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer is used in rinse-off cosmetics at ≤2% and when Ammonium Acryloyldimethyltaurate/VP Copolymer is used in cosmetics at 0.5% to 1.2% (the concentrations requested to be reviewed by the suppliers) based on toxicity and environmental data.[6,7] NICNAS also concluded that Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer is safe in cosmetics at <3% and that Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer is safe in cosmetics when used as a component of hair styling products for salon and home use at 1% to 2% (the concentrations requested by the suppliers) based on toxicity and environmental data.[11,12]

Acrylamide/Sodium Acryloyldimethyltaurate Copolymer, Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer, Sodium Acrylate/Sodium Acryloyldimethyl Taurate/Acrylamide Copolymer, and Sodium Acryloyldimethyl Taurate/Acrylamide/VP Copolymer are restricted in Europe according to the European Union (EU) Annex III/66.[24] The amount of residual acrylamide content is limited to 0.1 mg/kg in leave-on cosmetics used on the body and 0.5 mg/kg in other cosmetic products that are used on specific body parts (e.g., eye, face, and hand).

According to the EU regulations on labelling and packaging of substances and mixtures, if Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer is present in a product in a non-stabilized form, the name of the substance is to be followed by the words "non-stabilized" on the label.[25] According to the Commission directive, certain substances, which are susceptible to spontaneous polymerization or decomposition, are generally placed on the market in a stabilized form. It is in this form that they are listed in Annex I. However, such substances are sometimes placed on the market in a non-stabilized form.

Non-Cosmetic

Acrylamide/Sodium Acryloyldimethyltaurate Copolymer may be used as a component of the uncoated or coated

food-contact surface of paper and paperboard intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding dry food not to exceed 0.015 weight percent of dry fiber. [21CFR176.180]

TOXICOKINETICS

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

TOXICOLOGICAL STUDIES

Acute Toxicity

Acute dermal and oral toxicity studies are summarized in Table 6.

Dermal

The acute dermal LD_{50} for a solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (24% in water) was reported to be >5000 mg/kg (1200 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/ Acrylic Acid Copolymer) in rats.[12] The acute dermal LD_{50} for Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27% solids in water) was reported to be >5000 mg/kg (1250 to 1350 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer) in rats.[26]

Oral

The acute oral LD_{50} for a solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (24% in water) was reported to be >5000 mg/kg (>1200 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer) in rats.[12] The acute oral LD_{50} for Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer and Ammonium Acryloyldimethyltaurate/VP Copolymer was reported to be >2000 mg/kg in rats; the oral LD_{50} for Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (<60%) in a trade name mixture was reported to be >1200 mg/kg.[6,7,11] The acute oral LD_{50} of Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27% solids in water) was reported to be >5000 mg/kg (>1250 to >1350 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer) in rats.[26]

Short-Term to Chronic Toxicity

Short-term, subchronic, and chronic toxicity data were not found in the published literature and no unpublished data were submitted.

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY (DART) STUDIES

Developmental and reproductive toxicity data were not found in the published literature and no unpublished data were submitted.

GENOTOXICITY STUDIES

In Vitro

In vitro genotoxicity studies are summarized in Table 7.

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer, Ammonium Acryloyldimethyltaurate/ Carboxyethyl Acrylate Crosspolymer, Ammonium Acryloyldimethyltaurate/VP Copolymer, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, and Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer were not mutagenic in bacterial reverse mutation assays using *Salmonella typhimurium* and *Escherichia coli*.[6,7,10-12] Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27% solids in water) was not mutagenic in an Ames test at up to 5000 µg/plate (1250 to 1350 µg/plate).[26]

CARCINOGENICITY STUDIES

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

DERMAL IRRITATION AND SENSITIZATION STUDIES

Irritation

Animal

Dermal irritation studies in rabbits are summarized in Table 8.

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (24%), Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer (100%), and Ammonium Acryloyldimethyltaurate/VP Copolymer (assumed applied at neat not specified) were slightly or not irritating to rabbit skin.[6,7,12] A solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27% in water; assumed applied neat, not specified) was not irritating to rabbit skin.[26] An solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27% in water; assumed applied neat, not specified) was not irritating to rat skin after 24 h of exposure.[26]

Human

Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer was not irritating in a human irritation assay.[11] No further details were provided.

Sensitization

Animal and human sensitization studies are summarized in Table 9.

Animal

Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer (25%) and Ammonium Acryloyldimethyltaurate/VP Copolymer (assumed applied neat, not specified) were not sensitizing to guinea pigs.[6,7]

Human

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (24%), Sodium Acrylate/ Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer (<2.25%), and Sodium Polyacryloyldimethyl Taurate (30% to 40%) were not sensitizing in human repeated insult patch tests (HRIPT). [9,10,12] An aqueous solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27% solids in water; assumed applied neat, not specified) was not sensitizing in an HRIPT.[26]

A trade name mixture containing Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (<60%; assumed administered neat, not specified) was not sensitizing in a human sensitization assay.[11]

OCULAR IRRITATION STUDIES

In vitro and animal ocular irritation studies are summarized in Table 10.

In Vitro

Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer was not an ocular irritant in an unspecified *in vitro* assay.[11] Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer (<2.25%) was not considered an eye irritant in a Hens Eggs Test-Chorioallantoic Membrane (HET-CAM) assay.[10]

Animal

In ocular irritation assays, Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer, Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer, and Ammonium Acryloyldimethyltaurate/VP Copolymer were not irritating or slightly irritating in rabbit eyes.[6,7,12] A solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27% in water; assumed tested neat, not specified) was not irritating, according to Organization for Economic Co-operation and Development Test Guideline (OECD TG) criteria, or minimally irritating, according to US EPA criteria, to rabbit eyes.[26]

SUMMARY

This is a review of the published scientific literature and unpublished data provided by Industry for assessing the safety of 21 acryloyldimethyltaurate polymers as used in cosmetics. This group of ingredients is composed of homopolymers, copolymers, and crosslinked polymers, the monomers of which are at least partially composed of acryloyldimethyltaurate. The reported functions of these ingredients include dispersing agent – nonsurfactant, emulsion stabilizer, opacifying agent, and viscosity increasing agent – aqueous.

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer is reported have a molecular weight of approximately 250,000 Da. None of the particles of Ammonium Acryloyldimethyltaurate/VP Copolymer were >2000 µm, 97.2% were <2000 µm, 81.3% were <1000 µm, 11.8% were <200 µm, and 0.5% were <100 µm. For Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer, 90.8% of the particles of were <100 µm and 84.5% were <10 µm, and had a median diameter of 2.8 µm. The molecular weight of Sodium Polyacryloyldimethyl Taurate was reported to be >1,000,000.

Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer was reported to be >90% pure. Sodium Polyacryloyldimethyl Taurate is reported to contain <2000 ppm AMPS and <10 ppm acrylamide.

According to VCRP data received in 2016, Hydroxyethyl Acrylate/Sodium Acryloyldimethyltaurate Copolymer was reported to be used in 474 formulations, including 451 leave-on products, 21 rinse-off products, and 2 products used in the bath. The ingredients with next highest reported number of uses are Ammonium Acryloyldimethyltaurate/VP Copolymer with 456 uses, Acrylamide/Sodium Acryloyldimethyltaurate Copolymer, with 236 uses, Ammonium Polyacryloyldimethyl Taurate, with 197 uses, and Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer with 165 uses. All other in-use ingredients are reported to be used in 49 or fewer products.

The results of a concentration of use survey conducted by the Council in 2015 indicate Hydroxyethyl Acrylate/ Sodium Acryloyldimethyl Taurate Copolymer has the highest reported maximum concentration of use; it is reported to be used at up to 4.3% in depilatories (a rinse-off product) and up to 3.6% in eyeliner and eye shadow (leave-on products). The

reported maximum concentrations of use for the remaining ingredients range from 0.015% to 3% for leave-on products and 0.078% to 3.2% in rinse-off products.

The acute dermal LD_{50} for Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer was reported to be >5000 mg/kg in rats. The acute dermal LD_{50} for a product containing Acrylamide/Sodium Acryloyldimethyltaurate/ Acrylic Acid Copolymer (25% to 27%) was >5000 mg/kg (>1250 to >1350 mg/kg) in rats.

The acute dermal LD_{50} for a solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (24% in water) was reported to be >5000 mg/kg (>1200 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/ Acrylic Acid Copolymer) in rats. The acute oral LD_{50} for a solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27%) was reported to be >5000 mg/kg (>1250 to >1350 mg/kg) in rats.

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Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer, Ammonium Acryloyldimethyltaurate/ Carboxyethyl Acrylate Crosspolymer, Ammonium Acryloyldimethyltaurate/VP Copolymer, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, and Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer were not mutagenic in bacterial reverse mutation assays. A product containing Acrylamide/Sodium Acryloyldimethyltaurate/ Acrylic Acid Copolymer (25% to 27%) was not mutagenic in an Ames test.

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (up to 27%), Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer (100%), and Ammonium Acryloyldimethyltaurate/VP Copolymer (assumed applied neat, not specified) were slightly or not irritating to rabbit skin. A solution containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27% in water; assumed applied neat, not specified) was not irritating to rat skin.

Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer was not irritating in a human assay.

In a Buehler test, Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer was not sensitizing to guinea pigs at 25%. Ammonium Acryloyldimethyltaurate/VP Copolymer was not sensitizing to guinea pigs at 100%.

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (assumed neat), Sodium Acrylate/ Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer (<2.25%), and Sodium Polyacryloyldimethyl Taurate (30% to 40%) were not sensitizing in human repeated insult patch tests HRIPTs. Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer was not sensitizing in a human sensitization assay. A product containing Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (25% to 27%) was not sensitizing in an HRIPT.

Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (up to 27%), Sodium Acrylate/ Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer (<2.25%), and Sodium Polyacryloyldimethyl Taurate (30% to 40%) were not sensitizing in HRIPTs. A trade name mixture containing Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (<60%; assumed administered neat, not specified) was not sensitizing in a human sensitization assay.

Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer was not an ocular irritant in an unspecified *in vitro* assay. Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer (<2.25%) was not considered an eye irritant in a HET-CAM assay.

In ocular irritation assays Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer, Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer, and Ammonium Acryloyldimethyltaurate/VP Copolymer were not irritating or slightly irritating to rabbit eyes. A solution containing Acrylamide/Sodium Acryloyldimethyltaurate/ Acrylic Acid Copolymer (25% to 27% in water; assumed tested neat, not specified) was not irritating, according to OECD TG criteria, or minimally irritating, according to US EPA criteria, to rabbit eyes.

DISCUSSION

The Panel examined data on dermal and oral acute toxicity, genotoxicity, dermal and ocular irritation, and sensitization for the acryloyldimethyltaurate polymers. There were no studies that elicited concern.

These ingredients are large (2000 μm; >1000 to >1,000,000 g/mol) molecules and should not be absorbed through the skin. This is consistent with the favorable safety profile in dermal and oral toxicity studies.

The Panel expressed concern about impurities, including residual monomers because of potential sensitization or other deleterious effects that may occur due to exposure. Monomers of concern include acrylamide, vinyl formamide (in Ammonium Acryloyldimethyltaurate/Vinyl Formamide Copolymer), and methacrylamidolauric acid (in Sodium Acryloyldimethyltaurate/Methacrylamidolauric Acid Copolymer). It is appropriate to apply the limit of 5 ppm acrylamide imposed by the Panel in the safety assessment of Polyacrylamide to the ingredients in this safety assessment. It was stressed that the cosmetics industry should continue to use cGMPs to limit impurities.

The Panel discussed the issue of incidental inhalation exposure from perfumes; tonics, dressings and other hair

grooming aids; body and hand products; and face powders. There were no inhalation toxicity data available. These ingredients are reportedly used at concentrations up to 3% in cosmetic products that may be aerosolized and up to 0.7% in loose powder products that may become airborne. The Panel noted that droplets/particles from cosmetic products would not be respirable to any appreciable amount. Furthermore, these ingredients are not likely to cause any direct toxic effects in the upper respiratory tract, based on the properties of the acryloyldimethyltaurate polymers and on data that shows that these ingredients are not irritants. 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. They noted the lack of irritation or sensitization in tests of dermal exposure, no systemic toxicity at 5000 mg/kg, the absence of genotoxicity in Ames tests, and the fact that these ingredients are large molecules, which supports the view that they are unlikely to be absorbed or cause local effects in the respiratory tract. A detailed discussion and summary of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at http://www.cir-safety.org/cir-findings.

CONCLUSION

The CIR Expert Panel concluded that the following ingredients are safe in cosmetics in the present practices of use and concentration described in this safety assessment:

Acrylamide/Sodium Acryloyldimethyltaurate Copolymer
Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer*
Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer
Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer
Ammonium Acryloyldimethyltaurate/Laureth-7 Methacrylate Copolymer*
Ammonium Acryloyldimethyltaurate/Steareth-25 Methacrylate Crosspolymer
Ammonium Acryloyldimethyltaurate/Steareth-8 Methacrylate Copolymer
Ammonium Acryloyldimethyltaurate/Vinyl Formamide Copolymer*
Ammonium Acryloyldimethyltaurate/VP Copolymer
Ammonium Polyacryloyldimethyl Taurate
Dimethylacrylamide/Sodium Acryloyldimethyltaurate Crosspolymer
HEA/Sodium Acryloyldimethyltaurate/Steareth-20 Methacrylate Copolymer
Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer
Sodium Acrylate/Acryloyldimethyltaurate/ Dimethylacrylamide Crosspolymer
Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer
Sodium Acrylate/Sodium Acryloyldimethyl Taurate/Acrylamide Copolymer
Sodium Acryloyl Dimethyl Taurate/PEG-8 Diacrylate Crosspolymer*
Sodium Acryloyldimethyl Taurate/Acrylamide/VP Copolymer
Sodium Acryloyldimethyltaurate/Methacrylamidolauric Acid Copolymer
Sodium Acryloyldimethyltaurate/VP Crosspolymer
Sodium Polyacryloyldimethyl Taurate

* 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 the group.

TABLES AND FIGURES

Table 1. Definitions, idealized structures, and functions of acryloyldimethyltaurate polymers in this safety assessment.[1; CIR Staff]

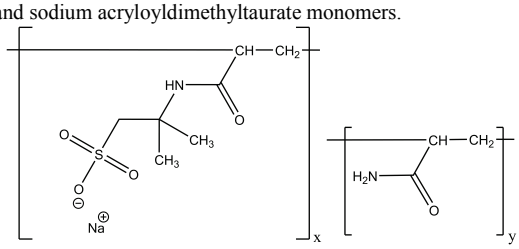
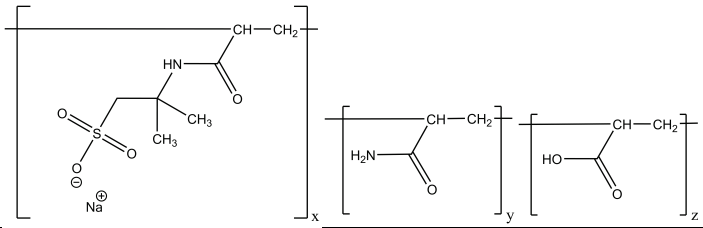
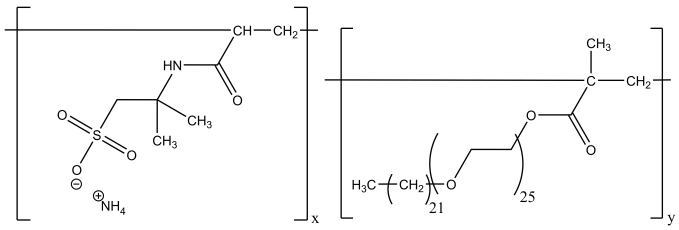
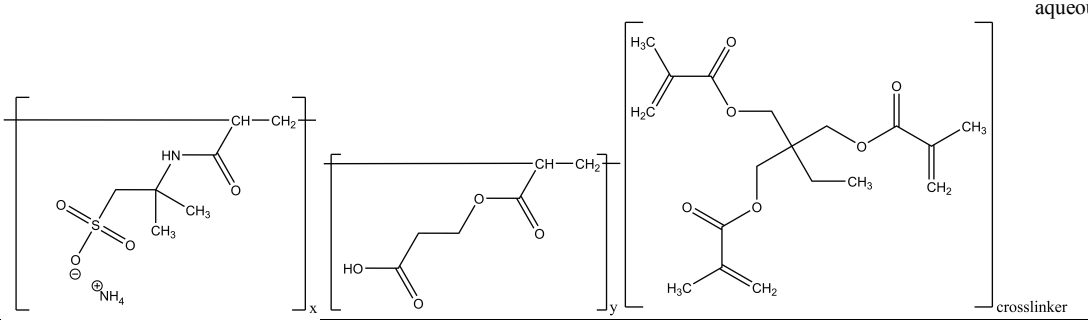
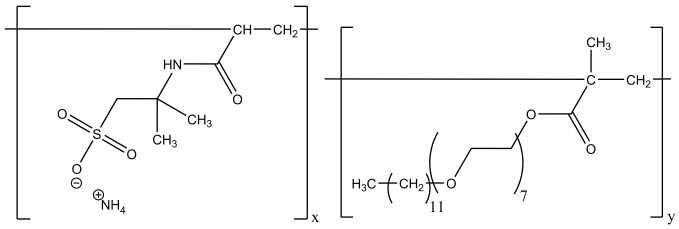
Ingredient CAS No.	Definition & Monomer Residue Structures	Function(s)
Acrylamide/Sodium Acryloyldimethyltaurate Copolymer 38193-60-1 [1258874-55-3; 159157-50-3]	Acrylamide/Sodium Acryloyldimethyltaurate Copolymer is a copolymer of acrylamide and sodium acryloyldimethyltaurate monomers. 	Emulsion stabilizer; viscosity increasing agent - aqueous
Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer [1453194-38-1; 1417986-34-5]	Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer is a copolymer of acrylamide, sodium acryloyldimethyltaurate and acrylic acid monomers. 	Film former; hair fixative
Ammonium Acryloyldimethyltaurate/ Beheneth-25 Methacrylate Crosspolymer	Ammonium Acryloyldimethyltaurate/Beheneth-25 Methacrylate Crosspolymer is a copolymer of ammonium acryloyldimethyltaurate and beheneth-25 methacrylate monomers. 	Emulsion stabilizer
Ammonium Acryloyldimethyltaurate/ Carboxyethyl Acrylate Crosspolymer	Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer is a copolymer of ammonium acryloyl dimethyltaurate and carboxyethyl acrylate crosslinked with trimethylolpropane trimethacrylate. 	Dispersing agent – nonsurfactant; viscosity increasing agent - aqueous
Ammonium Acryloyldimethyltaurate/ Laureth-7 Methacrylate Copolymer 683748-07-4	Ammonium Acryloyldimethyltaurate/Laureth-7 Methacrylate Copolymer is a copolymer of ammonium acryloyldimethyltaurate and laureth-7 methacrylate monomers. 	Abrasive

Table 1. Definitions, idealized structures, and functions of acryloyldimethyltaurate polymers in this safety assessment.[1; CIR Staff]

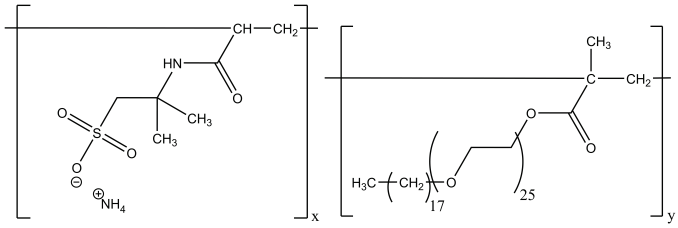
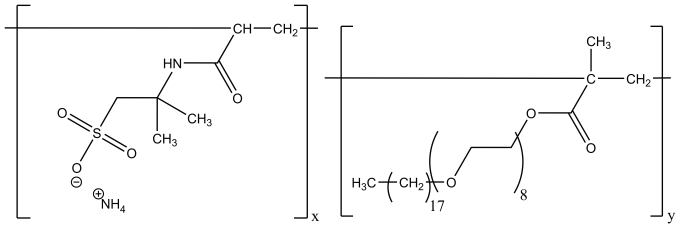
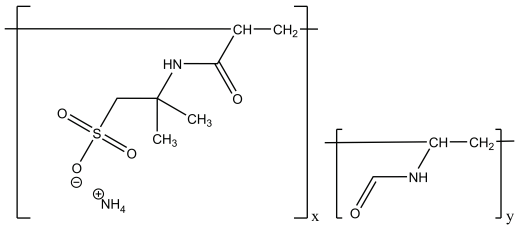
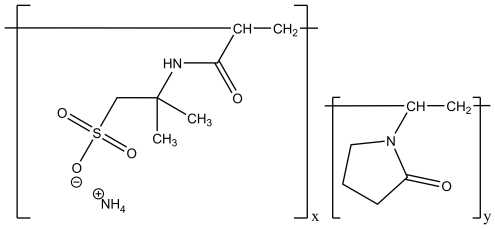
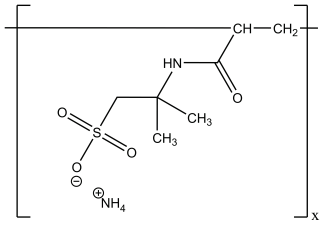
Ingredient CAS No.	Definition & Monomer Residue Structures	Function(s)
Ammonium Acryloyldimethyltaurate/ Steareth-25 Methacrylate Crosspolymer	Ammonium Acryloyldimethyltaurate/Steareth-25 Methacrylate Crosspolymer is a copolymer of ammonium acryloyldimethyltaurate and steareth-25 methacrylate monomers. 	Emulsion stabilizer
Ammonium Acryloyldimethyltaurate/ Steareth-8 Methacrylate Copolymer	Ammonium Acryloyldimethyltaurate/Steareth-8 Methacrylate Copolymer is a copolymer of ammonium acryloyldimethyltaurate and steareth-8 methacrylate monomers. 	Emulsion stabilizer; viscosity increasing agent - aqueous
Ammonium Acryloyldimethyltaurate/ Vinyl Formamide Copolymer [600172-76-7]	Ammonium Acryloyldimethyltaurate/Vinyl Formamide Copolymer is a copolymer of ammonium acryloyldimethyltaurate and vinyl formamide monomers. 	Emulsion stabilizer; viscosity increasing agent – aqueous
Ammonium Acryloyldimethyltaurate/ VP Copolymer [1509895-12-8; 53845-64-0]	Ammonium Acryloyldimethyltaurate/VP Copolymer is a copolymer of ammonium acryloyldimethyltaurate and vinylpyrrolidone monomers. 	Viscosity increasing agent – aqueous
Ammonium Polyacryloyldimethyl Taurate [62152-14-1]	Ammonium Polyacryloyldimethyl Taurate is the polymer that conforms generally to the formula. [Ammonium Polyacryloyldimethyl Taurate is the homopolymer of ammonium acryloyldimethyltaurate.] 	Emulsion stabilizer; viscosity increasing agent - aqueous

Table 1. Definitions, idealized structures, and functions of acryloyldimethyltaurate polymers in this safety assessment.[1; CIR Staff]

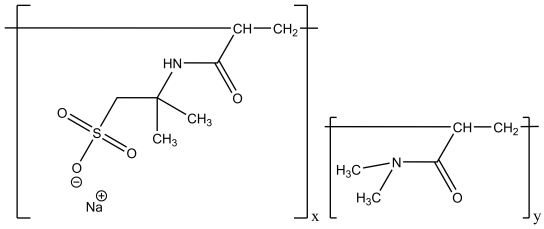
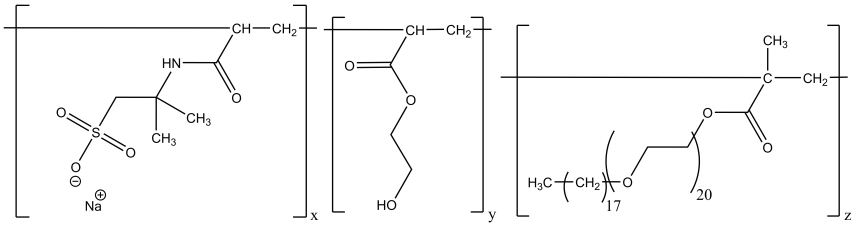
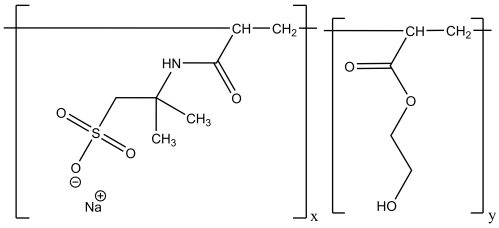
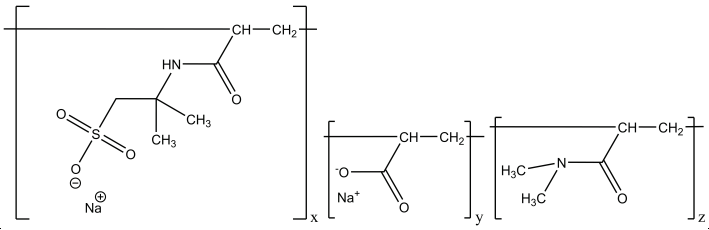
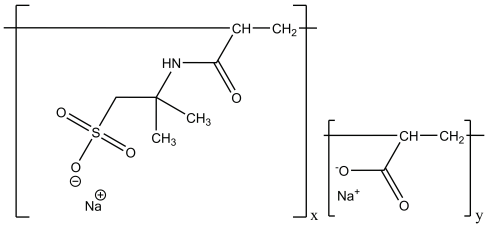
Ingredient CAS No.	Definition & Monomer Residue Structures	Function(s)
Dimethylacrylamide/Sodium Acryloyldimethyltaurate Crosspolymer [869772-40-7; 92815-96-8]	Dimethylacrylamide/Sodium Acryloyldimethyltaurate Crosspolymer is a copolymer of dimethylacrylamide and sodium acryloyldimethyltaurate crosslinked with methylene bis-acrylamide. 	Viscosity increasing agent – aqueous
HEA/Sodium Acryloyldimethyltaurate/ Steareth-20 Methacrylate Copolymer 1562414-82-7	HEA/Sodium Acryloyldimethyltaurate/Steareth-20 Methacrylate Copolymer is a copolymer of 2-hydroxyethylacrylate (HEA), sodium acryloyldimethyltaurate and steareth-20 methacrylate monomers. 	Dispersing agent – nonsurfactant; emulsion stabilizer; viscosity increasing agent – aqueous
Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer 111286-86-3	Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer is a copolymer of sodium hydroxyethyl acrylate and acryloyldimethyl taurate monomers. 	Dispersing agent – nonsurfactant; emulsion stabilizer; opacifying agent; viscosity increasing agent – aqueous
Sodium Acrylate/Acryloyldimethyltaurate/ Dimethylacrylamide Crosspolymer 187725-30-0	Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer is a crosslinked copolymer of sodium acrylate, acryloyldimethyltaurate and dimethylacrylamide. 	Dispersing agent – nonsurfactant; emulsion stabilizer; film former; viscosity increasing agent – aqueous
Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer 77019-71-7	Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer is a copolymer of sodium acrylate and sodium acryloyldimethyl taurate monomers. 	Dispersing agent – nonsurfactant; emulsion stabilizer; opacifying agent; viscosity increasing agent – aqueous

Table 1. Definitions, idealized structures, and functions of acryloyldimethyltaurate polymers in this safety assessment.[1; CIR Staff]

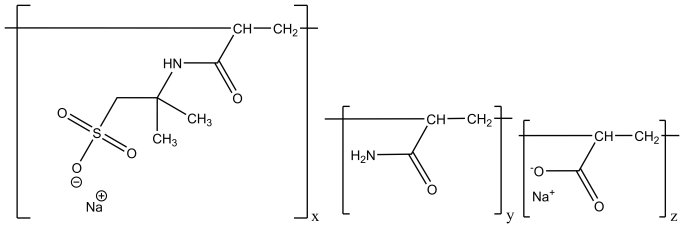
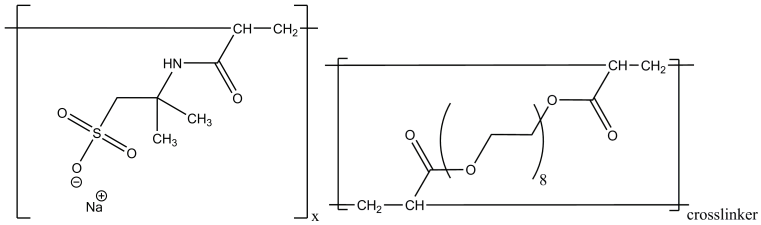
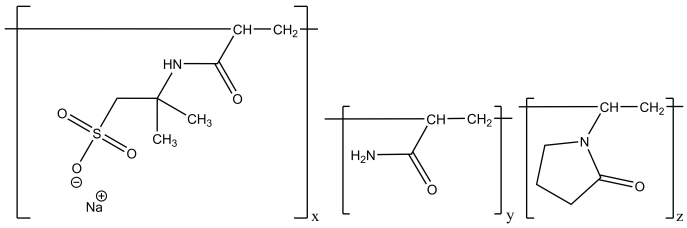
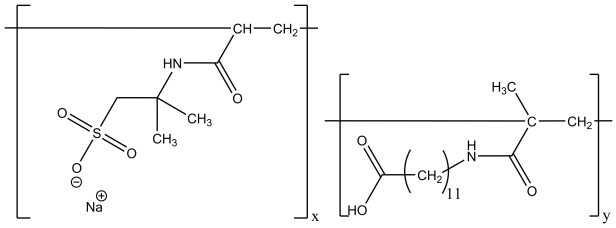
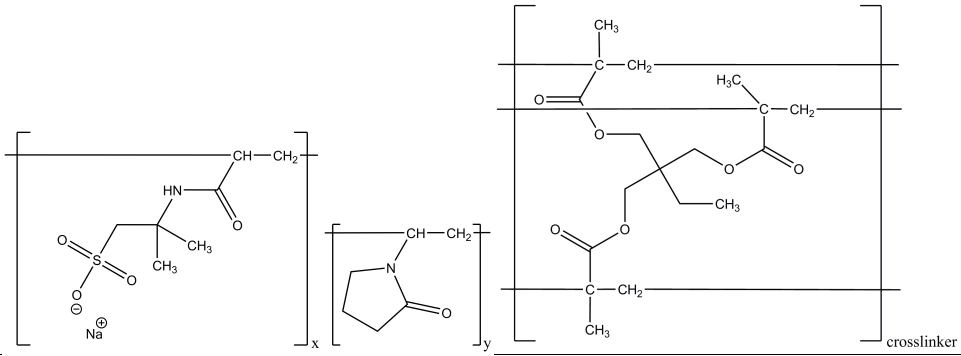
Ingredient CAS No.	Definition & Monomer Residue Structures	Function(s)
Sodium Acrylate/Sodium Acryloyldimethyl Taurate/Acrylamide Copolymer [1453194-38-1; 1417986-34-5]	Sodium Acrylate/Sodium Acryloyldimethyl Taurate/Acrylamide Copolymer is a copolymer of sodium acrylate, sodium acryloyldimethyltaurate and acrylamide monomers. 	Dispersing agent – nonsurfactant; emulsion stabilizer; opacifying agent; viscosity increasing agent – aqueous
Sodium Acryloyl Dimethyl Taurate/ PEG-8 Diacrylate Crosspolymer	Sodium Acryloyl Dimethyl Taurate/PEG-8 Diacrylate Crosspolymer is a polymer of sodium acryloyl dimethyl taurate crosslinked by PEG-8 diacrylate. 	Skin-conditioning agent – miscellaneous
Sodium Acryloyldimethyl Taurate/ Acrylamide/VP Copolymer [92815-97-9]	Sodium Acryloyldimethyl Taurate/Acrylamide/VP Copolymer is a copolymer of sodium acryloyldimethyltaurate, acrylamide and vinylpyrrolidone monomers. 	Dispersing agent – nonsurfactant; emulsion stabilizer; opacifying agent; viscosity increasing agent – aqueous
Sodium Acryloyldimethyltaurate/ Methacrylamidolauric Acid Copolymer [882176-38-7]	Sodium Acryloyldimethyltaurate/Methacrylamidolauric Acid Copolymer is a copolymer of sodium acryloyldimethyltaurate and methacrylamidolauric acid monomers. 	Opacifying agent
Sodium Acryloyldimethyltaurate/ VP Crosspolymer	Sodium Acryloyldimethyltaurate/VP Crosspolymer is a copolymer of sodium acryloyldimethyltaurate and vinylpyrrolidone crosslinked by 1,1,1-trimethylolpropane triacrylate. 	Emulsion stabilizer

Table 1. Definitions, idealized structures, and functions of acryloyldimethyltaurate polymers in this safety assessment.[1; CIR Staff]

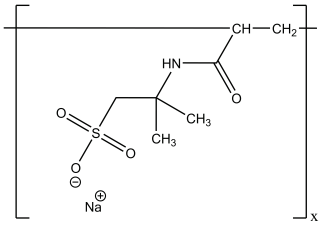
Ingredient CAS No.	Definition & Monomer Residue Structures	Function(s)
Sodium Polyacryloyldimethyl Taurate [35641-59-9]	Sodium Polyacryloyldimethyl Taurate is the polymer that conforms generally to the formula. [Sodium Polyacryloyldimethyl Taurate is the homopolymer of sodium acryloyldimethyltaurate.] 	Emulsion stabilizer; viscosity increasing agent-aqueous

Table 2. Previous safety assessments of similar ingredients and components/monomers of acryloyldimethyltaurate polymers in this safety assessment.

Constituent and ingredient group report	Conclusion	Maximum reported concentration of use reported for ingredients in the safety assessment	Reference
Alkyl Taurate Amides And Taurate Salts	Safe when formulated to be non-irritating	28% Sodium Methyl Oleoyl Taurate in bath products; 11% Calcium Lauroyl Taurate in leave-on products; 13% Sodium Methyl Cocoyl Taurate in rinse-off products	5
Acrylates Copolymers	Safe when formulated to be non-irritating	40% Acrylates Copolymer[a]	2
Polyacrylamide And Acrylamide Residues	Safe as used if the level of acrylamide monomer in formulation is not greater than 5 ppm	2.8% Polyacrylamide in leave-on formulations	3
Polyvinylpryrrolidone (PVP)	Safe as used	>5%-10% in leave-on eye products	4

[a] Not known if leave-on or rinse-off product(s)

Table 3. Chemical and physical properties of acryloyldimethyltaurate polymers.

Property	Value	Reference
Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer		
Molecular Weight g/mol	~250,000	8
Water Solubility	Forms an aqueous clear colorless liquid at 25% to 27%	8
Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer		
Physical Form	Powder	7
Color	White	7
Molecular Weight g/mol	>10,000	7
Bulk Density kg/m^3 @ 25 ^{o}C	237	7
Melting Point ^{o}C	>250 (decomposition)	7
Water Solubility g/L @ 20^{o}C	200	7
Ammonium Acryloyldimethyltaurate/VP Copolymer		
Physical Form	Powder	6
Color	White	6
Molecular Weight g/mol	>1000	6
Bulk Density kg/m^3	230	6
Water Solubility g/L @ 20^{o}C	>5	6

Table 3. Chemical and physical properties of acryloyldimethyltaurate polymers.

Property	Value	Reference
Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer		
Physical Form	Viscous liquid	11
Color	White	11
Odor	Characteristic	11
Molecular Weight g/mol	>10,000	11
Bulk Density g/kg @ 25˚C	1100	11
Melting Point ºC	6	
Water Solubility	Dispersible	11
Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer		
Molecular Weight g/mol	>10,000	10
Density/Specific Gravity kg/m^3 @ 25ºC	1100	10
Melting Point ºC	>200	10
Sodium Polyacryloyldimethyl Taurate		
Molecular Weight g/mol	>1,000,000	9

Table 4. Frequency of use according to duration and exposure of acryloyldimethyltaurate polymers.[16,27]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	Acrylamide/Sodium Acryloyldimethyltaurate Copolymer		**Ammonium Acryloyldimethyltaurate /Beheneth-25 Methacrylate Crosspolymer**		**Ammonium Acryloyldimethyltaurate /Carboxyethyl Acrylate Crosspolymer**		**Ammonium Acryloyldimethyltaurate/ Steareth-25 Methacrylate Crosspolymer**	
Total/range	**236**	**0.34-3.2**	**49**	**0.1-2.5**	**1**	**NR**	**3**	**0.6-1.3**
Duration of use								
Leave-on	229	0.34-3.2	47	0.1-2.5	NR	NR	3	0.6-1.3
Rinse-off	7	0.38-1.6	2	0.2-0.75	1	NR	NR	1
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type[a]								
Eye area	44	0.71-1.8	13	0.4-0.66	NR	NR	1	0.8-0.94
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-sprays	1; 114[b]; 38[c]	0.47-1.5[b]	13[b]; 16[c]	0.2; 0.1-0.5[b]	NR	NR	1[b]; 1[c]	NR
Incidental inhalation-powders	4; 38[c]	0.7; 0.54-1.8[d]	16[c]	0.3-2.5[d]	NR	NR	1[c]	0.6[d]
Dermal contact	230	0.34-3.2	43	0.1-2.5	1	NR	3	0.6-1.3
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	4	0.47-1.7	NR	0.5-0.8	NR	NR	NR	NR
Hair-coloring	NR	NR	NR	0.2	NR	NR	NR	1
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	1	NR	NR	NR	NR	NR	NR	NR
Baby	NR	NR	NR	NR	NR	NR	NR	NR

Table 4. Frequency of use according to duration and exposure of acryloyldimethyltaurate polymers.[16,27]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	Ammonium Acryloyldimethyltaurate/ Steareth-8 Methacrylate Copolymer		Ammonium Acryloyldimethyltaurate /VP Copolymer		Ammonium Polyacryloyldimethyl Taurate		Dimethylacrylamide/ Sodium Acryloyldimethyltaurate Crosspolymer	
Total/range	**1**	**0.42-0.65**	**456**	**0.016-3**	**197**	**0.015-2.3**	**7**	**0.06-3**
Duration of use								
Leave-on	1	0.42-0.65	428	0.016-3	185	0.015-2.3	6	0.06-3
Rinse-off	NR	NR	28	0.3-1.8	12	0.078-1.5	1	3
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	0.42	58	1.4-3	26	0.025-2	4	1-2
Incidental ingestion	NR	NR	2	1.5	NR	NR	NR	NR
Incidental Inhalation-sprays	1[b]	NR	1; 168[b]; 153[c]	0.096-1	63[b]; 57[c]	1.2[b]	2[c]	0.35-3; 0.72[b]
Incidental inhalation-powders	NR	0.65[d]	1; 1[d]; 153[c]	0.18-2[d]	1; 57[c]	0.024-2[d]	2[c]	0.65-3[d]
Dermal contact	1	0.42-0.65	451	0.016-3	197	0.015-2.3	7	0.06-3
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	0.6[e]
Hair-noncoloring	NR	NR	NR	0.4	NR	1.2	NR	0.72
Hair-coloring	NR	NR	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	4	1.5	2	1.2	NR	NR
Baby	NR	NR	1	NR	NR	NR	NR	NR

	HEA/Sodium Acryloyldimethyltaurate/ Steareth-20 Methacrylate Copolymer		Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer		Sodium Acrylate/ Acryloyldimethyltaurate /Dimethylacrylamide Crosspolymer		Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer	
Total/range	**NR**	**0.18**	**474**	**0.15-4.3**	**1**	**1.6**	**165**	**0.023-3.2**
Duration of use								
Leave-on	NR	0.18	451	0.15-3.6	1	1.6	159	0.023-2.4
Rinse-off	NR	NR	21	0.2-4.3	NR	NR	6	0.6-3.2
Diluted for (bath) use	NR	NR	2	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	NR	33	0.15-3.6	NR	NR	18	0.18-1.2
Incidental ingestion	NR	NR	11	1.4	NR	NR	1	NR
Incidental Inhalation-sprays	NR	NR	216[b]; 124[c]	0.38-1[b]	1[b]	NR	33[b]; 76[c]	0.45-0.6[b]
Incidental inhalation-powders	NR	NR	2; 124[c]	0.19-2.9[d]	NR	NR	5; 1[d]; 76[c]	0.088-1.1[d]
Dermal contact	NR	NR	448	0.15-4.3	NR	NR	157	0.023-2.4
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	NR	0.18	11	0.74	1	1.6	5	0.6-3.2
Hair-coloring	NR	NR	NR	0.94-1.4	NR	NR	NR	2.3
Nail	NR	NR	3	NR	NR	NR	NR	NR
Mucous Membrane	NR	NR	17	0.2-1.4	NR	NR	1	2.4
Baby	NR	NR	NR	NR	NR	NR	1	NR

Table 4. Frequency of use according to duration and exposure of acryloyldimethyltaurate polymers.[16,27]

Use type	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)	Uses	Maximum Concentration (%)
	Sodium Acrylate/Sodium Acryloyldimethyl Taurate/Acrylamide Copolymer		Sodium Acryloydimethyl Taurate/Acrylamide/VP Copolymer		Sodium Acryloyldimethyltaurate /Methacrylamidolauric Acid Copolymer		Sodium Acryloyldimethyltaurate/ VP Crosspolymer	
Total/range	**6**	**0.3-1.5**	**NR**	**0.65**	**NR**	**0.28-0.35**	**8**	**NR**
Duration of use								
Leave-on	6	0.3-1.5	NR	0.65	NR	0.28-0.35	8	NR
Rinse-off	NR	0.3	NR	NR	NR	NR	NR	NR
Diluted for (bath) use	NR	NR	NR	NR	NR	NR	NR	NR
Exposure type								
Eye area	NR	0.58-0.75	NR	NR	NR	NR	1	NR
Incidental ingestion	NR	NR	NR	NR	NR	NR	NR	NR
Incidental Inhalation-sprays	1[b]; 1[c]	NR	NR	0.65[b]	NR	NR	4[b]; 3[c]	NR
Incidental inhalation-powders	1[c]	0.3-1.5[d]	NR	NR	NR	0.28-0.35[d]	3[c]	NR
Dermal contact	6	0.3-1.5	NR	0.65	NR	0.28-0.35	7	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR	NR	NR
Hair-noncoloring	NR	1.2	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	NR	NR	NR	NR	NR	NR	NR	NR

	Sodium Polyacryloyldimethyl Taurate	
Total/range	**38**	**1.4**
Duration of use		
Leave-on	37	1.4
Rinse-off	1	NR
Diluted for (bath) use	NR	NR
Exposure type		
Eye area	NR	NR
Incidental ingestion	NR	NR
Incidental Inhalation-sprays	31[b]; 3[c]	NR
Incidental inhalation-powders	3[c]	1.4[d]
Dermal contact	38	1.4
Deodorant (underarm)	NR	NR
Hair-noncoloring	NR	NR
Hair-coloring	NR	NR
Nail	NR	NR
Mucous Membrane	NR	NR
Baby	NR	NR

NR = Not Reported; Totals = Rinse-off + Leave-on + Diluted for Use Product Uses.
Note: Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure type uses may not equal the sum total uses.
[a] Because each ingredient may be used in cosmetics with multiple exposure types, the sum of all exposure types may not equal the sum of total uses.
[b] It is possible these products may be sprays, but it is not specified whether the reported uses are sprays.
[c] Not specified whether a powder or a spray, so this information is captured for both categories of incidental inhalation.
[d] It is possible these products may be powders, but it is not specified whether the reported uses are powders.
[e] Not sprays.

Table 5. Acryloyldimethyltaurate polymers with no reported uses.[15,16]

Acrylamide/Sodium Acryloyldimethyltaurate/ Acrylic Acid Copolymer	Ammonium Acryloyldimethyltaurate/Laureth-7 Methacrylate Copolymer
Ammonium Acryloyldimethyltaurate/Vinyl Formamide Copolymer	Sodium Acryloyl Dimethyl Taurate/PEG-8 Diacrylate Crosspolymer

Table 6. Acute toxicity data on acryloyldimethyltaurate polymers.

Ingredient	Animal; Methods	Results	Reference
Dermal			
Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (aqueous solution containing ingredient at 24%)	Rats (strain and n not specified); OECD TG 402	LD_{50} >5000 mg/kg (>1200 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer)	12
Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (aqueous solution containing ingredient at 25% to 27%; assumed applied neat, not specified).	Rats (strain and n not specified); 24 h exposure under patch.)	No deaths. All rats gained weight and there were no clinical signs (gross toxicity, dermal irritation, adverse pharmacologic effects, or abnormal behavior). Necropsy was unremarkable. LD_{50} >5000 mg/kg (>1250 to >1350 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer)	26
Oral			
Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (aqueous solution containing ingredient at 24%)	Rats (strain and n not specified); OECD TG 425	LD_{50} >5000 mg/kg (>1200 mg/kg polymer)	12
Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (aqueous solution containing ingredient at 25% to 27%; assumed administered neat, not specified)	Rats (strain and n not specified); method not specified	LD_{50} >5000 mg/kg (>1250 to >1350 mg/kg Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer)	26
Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer	HanRcc:WIST (SPF) Rats (n=3); OECD TG 423	LD_{50} >2000 mg/kg; 5 h after treatment, 3 rats showed slight ruffled fur; no other clinical signs were observed and no macroscopic findings were observed at necropsy. Body weight of the rats was within range commonly recorded for this strain and age.	7
Ammonium Acryloyldimethyltaurate/VP Copolymer	Rats; OECD TG 401	LD_{50} >2000 mg/kg	6
Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (trade name mixture containing ingredient at <60%)	Rats (strain and n not specified); method not specified	LD_{50} >2000 mg/kg (>1200 mg/kg)	11

OECD TG = Organization for Economic Co-operation and Development Test Guideline

Table 7. In vitro genotoxicity assays of acryloyldimethyltaurate polymers.

Ingredient	Assay/Method	Results	Reference
Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (aqueous solution containing ingredient at 24%; assumed applied neat, not specified)	Bacterial reverse mutation assay (OECD TG 471)	Not mutagenic	12
Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer (aqueous solution containing ingredient at 25% to 27%; applied at 2.5, 7.5, 25, 75, 200, 600, 1800, and 5000 µg/plate and at 75, 200, 600, 1800, and 5000 µg/plate)	Ames test. *S. typhimurium* (TA98, TA100, TA1535, and TA1537) and *E. coli* (WP2uvrA)	Not mutagenic up to 5000 µg/plate (1250 to 1350 µg/plate Acrylamide/Sodium Acryloyldimethyltaurate/Acrylic Acid Copolymer) with and without metabolic activation	26
Ammonium Acryloyldimethyltaurate/ Carboxyethyl Acrylate Crosspolymer (concentration not provided)	Bacterial reverse mutation assay (OECD TG 471) *S. typhimurium* (TA98, TA100, TA1535, and TA1537) and *E. coli* (WP2uvrA)	Not mutagenic up to 2000 µg/plate with and without metabolic activation	7
Ammonium Acryloyldimethyltaurate/VP Copolymer (concentration not provided)	Bacterial reverse mutation assay (OECD TG 471)	Not mutagenic	6
Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (trade name mixture at <60%; concentration not provided)	Bacterial reverse mutation assay;	Not mutagenic	11
Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer (trade name mixture at <45%; assumed applied neat, not specified)	Bacterial reverse mutation assay (OECD TG 471) in a trade name mixture at <45%; assumed applied neat, not specified	Not mutagenic or cytotoxic up to 5000 µg/plate (<2250 µg/plate Sodium Acrylate/Acryloyldimethyltaurate /Dimethylacrylamide Crosspolymer)	10

OECD TG = Organization for Economic Co-operation and Development Test Guideline

Table 8. Dermal irritation studies of acryloyldimethyltaurate polymers in rabbits.

Ingredient (concentration)	Animal; method	Results	Reference
Acrylamide/Sodium Acryloyldimethyltaurate/ Acrylic Acid Copolymer (aqueous solution containing ingredient at 24%; assumed applied neat, not specified)	Rabbits (n and strain not specified); primary skin irritation test	Exhibited very slight to well-defined erythema and very slight edema 1 h after patch removal. All signs of dermal irritation were resolved at 48 h after patch removal. The PII according to Draize score was 1.2.	12
Acrylamide/Sodium Acryloyldimethyltaurate/ Acrylic Acid Copolymer (aqueous solution at 25% to 27%; assumed administered neat, not specified)	Rabbits (n and strain not specified); method not specified	US EPA: minimal irritant; OECD TG: Nonirritant	26
Ammonium Acryloyldimethyltaurate/ Carboxyethyl Acrylate Crosspolymer (100% moistened with water when administered)	New Zealand White rabbit (n=3); OECD TG 404	Mild signs of irritation (erythema formation) observed in all rabbits; no longer evident at day 7 after treatment.	7
Ammonium Acryloyldimethyltaurate/VP Copolymer (assumed neat, not specified)	Rabbit (n and strain not specified); OECD TG 404	Not irritating	6

OECD TG = Organization for Economic Co-operation and Development Test Guideline
PII = Primary Irritation Index

Table 9. Sensitization studies of acryloyldimethyltaurate polymers.

Ingredient (concentration)	Assay; n	Results	Reference
Animal			
Ammonium Acryloyldimethyltaurate/Carboxyethyl Acrylate Crosspolymer (25% in petrolatum)	Buehler Test OECD TG 406 in Pirbright-White guinea pigs/HsdPoc:DH; n=19; control=10	Not sensitizing	7
Ammonium Acryloyldimethyltaurate/VP Copolymer (assumed neat, not specified)	OECD TG 406 in guinea pigs; n and strain not specified	No signs of irritation or sensitization	6
Human			
Acrylamide/Sodium Acryloyldimethyltaurate/ Acrylic Acid Copolymer (aqueous solution containing ingredient at 24%; assumed applied neat, not specified)	HRIPT; n not specified	No evidence of sensitization.	12
Acrylamide/Sodium Acryloyldimethyltaurate/ Acrylic Acid Copolymer (25% to 27% in water; assumed administered neat, not specified)	HRIPT; n=102	Not sensitizing	26
Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (in a trade name mixture at <60%; assumed administered neat, not specified)	Not specified; not specified	Not sensitizing	11
Sodium Acrylate/Acryloyldimethyltaurate/ Dimethylacrylamide Crosspolymer (<2.25%; in a trade name mixture at <45%; tested at 5% in water)	HRIPT; n=50	One reaction of erythema/edema was observed in 1 subject on Day 40.	10
Sodium Polyacryloyldimethyl Taurate (30% to 40%)	HRIPT; n=100	No adverse reactions were observed during the study. Not irritating or sensitizing.	9

HRIPT = Human repeated insult patch test.

Table 10. *In vitro* and animal ocular irritation assays.

Ingredient (concentration)	Animal; method	Results	Reference
	In vitro		
Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (trade name mixture <60%; assumed applied neat, not specified)	Not specified	Not an ocular irritant	11
Sodium Acrylate/Acryloyldimethyltaurate/ Dimethylacrylamide Crosspolymer (<2.25%; in a trade name mixture at <45%; tested at 5% in water)	HET-CAM	No signs of hyperemia, hemorrhage, or coagulation were observed in any of the membranes tested. The test substance was not considered an eye irritant.	10
	Animal		
Acrylamide/Sodium Acryloyldimethyltaurate/ Acrylic Acid Copolymer (aqueous solution containing ingredient at 24%; assumed tested neat, not specified)	Rabbit eyes (n and strain not specified); OECD TG 405	Not irritating	12
Acrylamide/Sodium Acryloyldimethyltaurate/ Acrylic Acid Copolymer (solution containing 25% to 27% in water; assumed tested neat, not specified)	Rabbit eyes (n and strain not specified); primary eye irritation test	After a single instillation, no corneal opacity or iritis was noted for any treated eye during the study. ~1 h after instillation, conjunctivitis was observed in all treated eyes. All signs of ocular irritation were resolved by 48 h. US EPA scoring: Minimal irritant; OECD TG scoring: nonirritant.	26
Ammonium Acryloyldimethyltaurate/ Carboxyethyl Acrylate Crosspolymer (assumed tested neat, not specified)	New Zealand White rabbit eyes (n=3); OECD TG 405	Slight to moderate reddening and slight swelling of the conjunctivae in all rabbits at 1 h; resolved 72 h after treatment. It was concluded that this polymer is slightly irritating to the eye.	7
Ammonium Acryloyldimethyltaurate/VP Copolymer (assumed tested neat, not specified)	Rabbit eyes (n and strain not specified); OECD TG 405	Not irritating	6

HET-CAM = Hens Eggs test-Chorio-Allantoic Membrane
OECD TG = Organization for Economic Co-operation and Development Test Guideline

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