Toxicological profile for

Acrylate styrene co-polymer

This ingredient has been assessed to determine potential human health effects for the consumer. It was considered not to increase the inherent toxicity of the product and thus is acceptable under conditions of intended use.

1. Name of substance and physico-chemical properties

1.1. IUPAC systematic name

Prop-2-enoic acid;styrene (PubChem).

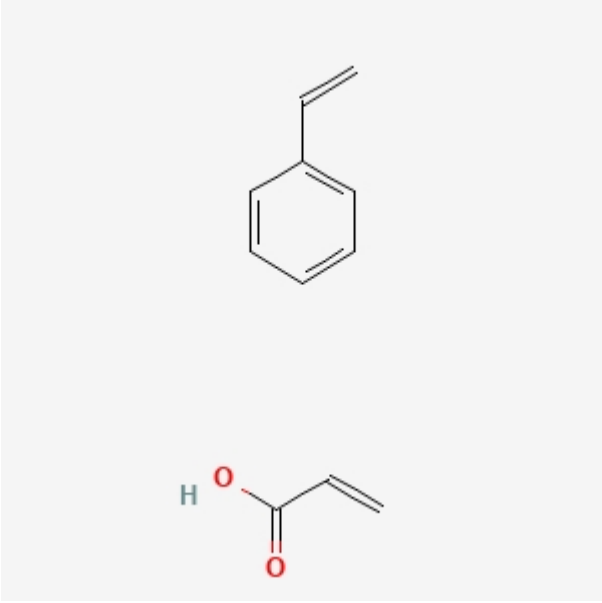
1.2. Synonyms

prop-2-enoic acid;styrene; Acrylic acid styrene polymer; 2-Propenoic acid, polymer with ethenylbenzene; Styrene-acrylic polymer; Acrylic acid-styrene copolymer; Styrene acrylic acid copolymer; Acrylic acid, polymer with styrene; styrene acrylic acid; Acrylic Acid Styrene; styrene acrylic acid resin; Benzene, ethenyl-, polymer with 2-propenoic acid; 2-Propenoic acid, polymer with ethenylbenzene and peroxydisulfonic acid, disodium salt (PubChem)

1.3. Molecular formula

C11H12O2 (PubChem)

1.4. Structural Formula



(PubChem)

1.5. Molecular weight (g/mol)

176.21 (monomeric weight) (PubChem).

1.6. CAS registration number

25085-34-1

1.7. Properties

1.7.1. Melting point

(°C): No data available to us at this time.

1.7.2. Boiling point

(°C): No data available to us at this time.

1.7.3. Solubility

No data available to us at this time.

1.7.4. pKa

No data available to us at this time.

1.7.5. Flashpoint

(°C): No data available to us at this time.

1.7.6. Flammability limits (vol/vol%)

No data available to us at this time.

1.7.7. (Auto)ignition temperature

(°C): No data available to us at this time.

1.7.8. Decomposition temperature

(°C): No data available to us at this time.

1.7.9. Stability

No data available to us at this time.

1.7.10. Vapor pressure

No data available to us at this time.

1.7.11. log Kow

No data available to us at this time.

2. General information

2.1. Exposure

Styrene-acrylic polymer (CAS RN 25085-34-1) is listed as an ingredient (at given concentrations, where specified) in commercial/institutional (<3%), home maintenance (>3-55%), inside the home (<1-20%, includes “old” products), pet care (<1%) and auto products by the CPID.

“Ingredients in the Acrylates Copolymer group all contain the monomers acrylic acid or methacrylic acid or one of their salts or esters. These ingredients are considered similar in that they are uniformly produced in chemical reactions that leave very little residual monomer. Although residual acrylic acid may be as high as 1500 ppm, typical levels are 10 to 1000 ppm. There is sufficient odor if residual monomers are present to cause producers to keep levels as low as possible. These ingredients function in cosmetics as binders, film formers, hair fixatives, suspending agents, viscosity-increasing agents, and emulsion stabilizers. Concentrations may be as high as 25% if

used as a binder, film former, or fixative; or as low as 0.5% if used as a viscosity-increasing agent, suspending agent, or emulsion stabilizer…"

Styrene/Acrylates Copolymer is used as a film former ingredient in cosmetics.

As taken from Zondlo Fiume M. 2002. International Journal of Toxicology 21(Suppl. 3), 1-50.

Styrene/Acrylates Copolymer, including CAS RN 25085-34-1, 25034-86-0 and 9010-92-8, is a polymer of styrene and a monomer consisting of acrylic acid, methacrylic acid or one of their simple esters, functioning as "Film formers; opacifying agents". "The highest maximum reported use concentrations for rinse-off and leave-on products… [was] 35% (styrene/acrylates copolymer)."

"These styrene and vinyl-type styrene copolymers function mostly as viscosity increasing agents, opacifying agents, and film formers in cosmetic products. ….. The absence of the potential for percutaneous absorption and the negative results of toxicity tests provided the Panel with a sufficient basis to assess the safety of these polymers as used in cosmetics. The Panel concluded that the 35 styrene and vinyl-type styrene copolymers are safe in the present practices of use and concentration in cosmetics, as described in this safety assessment."

As taken from CIR, 2014.

Styrene/acrylates copolymer (CAS RNs 27306-39-4; 25034-86-0; 25085-34-1; 9010-92-8) is used as a film forming and opacifying ingredient in cosmetics in the EU.

As taken from CosIng (Cosmetic substances and ingredients database).

2.2. Combustion products

No data available to us at this time.

2.3. Ingredient(s) from which it originates

No data available to us at this time.

3. Status in legislation and other official guidance

Included on the US FDA's Inventory of Food Contact Substances Listed in 21 CFR sections 175.105 (Adhesives), 175.320 (Resinous and polymeric coatings for polyolefin films), 176.170 (Components of paper and paperboard in contact with aqueous and fatty foods) and 176.180 (Components of paper and paperboard in contact with dry food) (FDA ,2025).

"Styrene, copolymers with acrylic acid and/or methacrylic acid, with none and/or one or more of the following monomers: acrylamidopropyl methyl sulfonic acid, methallyl sulfonic acid, 3-sulfopropyl acrylate, 3-sulfopropyl methacrylate, hydroxypropyl methacrylate, hydroxypropyl acrylate, hydroxyethyl methacrylate, hydroxyethyl acrylate, and/or lauryl methacrylate; and its sodium, potassium, ammonium, monoethanolamine, and triethanolamine salts; the resulting polymer having a minimum number average molecular weight (in amu), 1200" are covered under 40 CFR section 180.960 (Polymers; exemptions from the requirement of a tolerance). Residues resulting from the use of the above substances, "that meet the definition of a polymer and the criteria specified for defining a low-risk polymer in 40 CFR 723.250, as an inert ingredient in a pesticide chemical formulation, including antimicrobial pesticide chemical formulations, are exempted from the requirement of a tolerance under FFDCA section 408, if such use is in accordance with good agricultural or manufacturing practices" (US EPA, 2024).

Acrylic acid styrene polymer is listed in the US EPA Toxic Substances Control Act inventory, 2024 CDR TSCA Inv Active and is exempt from reporting under the US EPA CDR (Chemical Data Reporting Rule) (2024 CDR Full Exempt).

US EPA Substance Registry Services (SRS) – TSCA and CDR lists.

2-Propenoic acid, polymer with ethenylbenzene is not registered under REACH (ECHA).

Acrylic acid-styrene, copolymer is included in the inventory list of the Council of Europe Resolution AP (2004) on coatings intended to come into food contact.

As taken from European Commission, 2005.

2-Propenoic acid, polymer with ethenylbenzene (CAS RN 25085-34-1) is not classified for packaging and labelling under Regulation (EC) No. 1272/2008 (ECHA, 2025).

2-Propenoic acid, polymer with ethenylbenzene (CAS RN 25085-34-1) is a “low concern polymer under the NICNAS targeted tier I approach” and “poses no unreasonable risk to human health based on Tier I assessment under the NICNAS IMAP assessment framework” (AICIS, 2017).

Acrylate-Styrene Copolymer is listed in the US EPA Individual Inert Ingredient Database as approved for not specified use. (US EPA Individual Inert Ingredient Database, 2025)

4. Metabolism/Pharmacokinetics

4.1. Metabolism/metabolites

No data available to us at this time.

4.2. Absorption, distribution and excretion

“Male and female Han Wistar rats were exposed for 6 h/day, 5 days/week for 13 or 104 weeks (whole body) to a magnetite photocopying toner. The toner contained 45% to 50% magnetite, with 45% to 50% styrene acrylic resin and less than 5% external additives, including hydrophobic amorphous silica and proprietary surface functional modifiers. Exposure levels were 1, 5, and 25 mg/m(3) for the 13-week study and 1, 4, and 16 mg/m(3) for the 104-week study. Lung toner burdens averaged 36, 288, and 604 microg per lung after 104 weeks' exposure at 1, 4, and 16 mg/m(3). The lung burdens were lower than have been reported in a similar study with a carbon-based toner.” As taken from Slesinski RS & Turnbull D. 2008. Int. J. Toxicol. 27(6), 427-39. PubMed, 2013

“These styrene and vinyl-type styrene copolymers function mostly as viscosity increasing agents, opacifying agents, and film formers in cosmetic products. After considering the large sizes of these molecules, the Panel agreed that percutaneous absorption is not expected. ….”

As taken from CIR, 2014.

4.3. Interactions

No data available to us at this time.

5. Toxicity

5.1. Single dose toxicity

“Styrene/Acrylates Copolymer

OPULYNTM 302B Opacifier was evaluated in an acute oral toxicity study involving rats, and an LD50 of > 5 ml/kg was reported. The test protocol was not stated (32: Dow Chemical Company)”.

In an acute inhalation toxicity study on SunspheresTM Powder, an LC50 of > 5.3 mg/L was reported. The test protocol was not provided (28: Dow Chemical Company).

An acute inhalation LC50 (4 h) value of > 5.11 mg/L air was reported for ACUDYNETM Shine Polymer and ACUDYNETM Bold Polymer (29, 30: Dow Chemical Company). The test protocol was not described. The animal species was not stated, but it was noted that no clinical signs or mortalities were observed."

OPULYNTM 302B Opacifier was evaluated in an acute dermal toxicity study involving rats, and an LD50 of > 5 g/kg was reported. The test protocol was not stated (32: Dow Chemical Company)."

As taken from CIR, 2014.

5.2. Repeated dose toxicity

"Male and female Han Wistar rats were exposed for 6 h/day, 5 days/week for 13 or 104 weeks (whole body) to a magnetite photocopying toner. The toner contained 45% to 50% magnetite, with 45% to 50% styrene acrylic resin and less than 5% external additives, including hydrophobic amorphous silica and proprietary surface functional modifiers. Exposure levels were 1, 5, and 25 mg/m(3) for the 13-week study and 1, 4, and 16 mg/m(3) for the 104-week study. Lung toner burdens averaged 36, 288, and 604 microg per lung after 104 weeks' exposure at 1, 4, and 16 mg/m(3). The lung burdens were lower than have been reported in a similar study with a carbon-based toner. There were no significant effects on weight gain or food consumption in either study, or on clinical pathology parameters examined in the 13-week study. After 104 weeks' exposure at 16 mg/m(3), macroscopic examination revealed dark discoloration of the lungs and associated lymph nodes. Lung weights were significantly elevated by 21% and 14% for male and female rats, respectively. Microscopic findings indicative of a mild inflammatory response were similar in both studies, and included the presence of black-pigmented macrophages in the lungs and tracheobronchial and mediastinal lymph nodes; increased incidences of perivascular/peribronchiolar inflammatory cell infiltration; inflammation of the alveolar ducts (characterized by aggregations of black-pigmented alveolar macrophages and interstitial lymphocytic infiltration); increased cellularity of the bronchiole-associated lymphoid tissue; and a few instances of alveolar ciliated metaplasia. The 104-week study showed no increase in the incidence of pulmonary tumors." As taken from Slesinski RS & Turnbull D. 2008. Int. J. Toxicol. 27(6), 427-39. PubMed, 2013 available at "Styrene/Acrylates Copolymer

ACUDYNETM Shine Polymer and ACUDYNETM Bold Polymer were evaluated in a 2-week aerosol (nose only) exposure study involving rats (29, 30: Dow Chemical Company). The test protocol was not stated. There were no signs of clinical toxicity at any administered dose. The no-observed-effect-concentration (NOEC) was 10.8 mg polymer solids/m(3), based on slight irritant effects in the lungs at a concentration of 100 mg/m(3).

In a 13-week aerosol (nose only) study on ACUDYNETM Shine Polymer and ACUDYNETM Bold Polymer involving rats, the no-observable adverse-effect level (NOAEL) for changes in the lung (and related lymph nodes) was 8.3 mg/m(3) (29, 30: Dow Chemical Company)".

As taken from CIR, 2014.

5.3. Reproduction toxicity

No data available to us at this time.

5.4. Mutagenicity

"Styrene/Acrylates Copolymer

OPULYNTM 302B Opacifier was not genotoxic in the Ames test, with or without metabolic activation. The test protocol was not stated (32: Dow Chemical Company). This trade name

material also was not genotoxic in the in vitro cytogenetic assay, with or without metabolic activation (test protocol not stated).

In the Ames test, ACUDYNETM Shine Polymer and ACUDYNETM Bold Polymer were not genotoxic (29, 30: Dow Chemical Company). Negative results were also reported for these 2 trade name materials in the chromosomal aberrations test in vitro (test protocol not stated).

OPULYNTM 301 Opacifier was not genotoxic in the Ames test, with or without metabolic activation (50: Dow Chemical Company). This trade name material also was not genotoxic in the in vitro cytogenetic assay, with or without metabolic activation (test protocol was not stated.)."

As taken from CIR, 2014.

5.5. Cytotoxicity

No data available to us at this time.

5.6. Carcinogenicity

"Male and female Han Wistar rats were exposed for 6 h/day, 5 days/week for 13 or 104 weeks (whole body) to a magnetite photocopying toner. The toner contained 45% to 50% magnetite, with 45% to 50% styrene acrylic resin and less than 5% external additives, including hydrophobic amorphous silica and proprietary surface functional modifiers. Exposure levels were 1, 5, and 25 mg/m(3) for the 13-week study and 1, 4, and 16 mg/m(3) for the 104-week study. ..... The 104-week study showed no increase in the incidence of pulmonary tumors." As taken from Slesinski RS & Turnbull D. 2008. Int. J. Toxicol. 27(6), 427-39. PubMed, 2013

5.7. Irritation/immunotoxicity

"OBJECTIVES: Acrylate-styrene copolymer polish has been used to protect the surface of linoleum flooring since the 1960s. Problems with powdering of floor polish were observed at an early stage. In a secondary school in Linköping, Sweden, this phenomenon occurred in the winter of 1994-1995 and the pupils frequently reported irritative symptoms from the eyes and airways. This study was undertaken to assess the potential effect of powdering floor polish on the mucous membranes of the eyes and respiratory tract. METHODS: Repeated questionnaire-based surveys were conducted with identical questions in the spring of 1995 (during the powdering period) and in the autumn of 1995 (after the polish was removed). The questions dealt with irritative symptoms from the nose, eye, throat and lower respiratory tract. RESULTS: A preventive effect related to the removal of polish was found for irritative symptoms in all locations mentioned above, but was particularly clear for the lower respiratory tract (prevalence rate ratio = 0.37, 95% CI = 0.23-0.59). CONCLUSIONS: The results of this study indicate that the powdering of floor polish may cause irritative symptoms from the eyes and airways in school children." As taken from Malmberg B et al. 2000. Int. Arch. Occup. Environ. Health 73(7), 498-502. PubMed, 2013

"Ingredients in the Acrylates Copolymer group all contain the monomers acrylic acid or methacrylic acid or one of their salts or esters. These ingredients are considered similar in that they are uniformly produced in chemical reactions that leave very little residual monomer... These very large polymers exhibit little toxicity. In rabbits and guinea pigs, Acrylates Copolymer did produce irritation, but no evidence of sensitization was found. The principle concern regarding the use of these polymer ingredients is the presence of toxic residual monomers… Another concern regarding residual monomers was inhalation toxicity. Although the acrylic acid monomer is a nasal irritant, exposure to the monomer from use of these polymers in cosmetic formulations would always be less than the established occupational exposure limits for nasal irritation. Although there appears to be a huge variation in the mix of monomers used in the synthesis of these polymers, they are similar in that the polymers, except for dermal irritation, are not significantly toxic, and residual

monomer levels are kept as low as possible. Although the monomers may be toxic, the levels that would be found in cosmetic formulations are not considered to present a safety risk. Accordingly, these Acrylate Copolymers are considered safe for use in cosmetic formulations when formulated to avoid irritation." As taken from Zondlo Fiume M. 2002. International Journal of Toxicology 21(Suppl. 3), 1-50.

"Styrene/Acrylates Copolymer

SunspheresTM Powder was classified as minimally irritating to the eyes of rabbits (28: Dow Chemical Company). The test protocol was not stated.

In an ocular irritation study involving rabbits, OPULYNTM 302B Opacifier was classified as a non-irritant. The test protocol was not stated (32: Dow Chemical Company)."

"The ocular irritation potential of ACUDYNETM Shine Polymer was evaluated in the bovine corneal opacity and permeability test in vitro. The test protocol was not stated. Results were negative (29: Dow Chemical Company).

ACUDYNETM Bold Polymer was classified as a non-irritant in the bovine corneal opacity and permeability test in vitro (30: Dow Chemical Company). The test protocol was not stated."

"In a skin irritation study involving rabbits, OPULYNTM 302B Opacifier was classified as a non-irritant. The test protocol was not stated (32: Dow Chemical Company).

The skin irritation potential of ACUDYNETM Shine Polymer and ACUDYNETM Bold Polymer was evaluated in the EpiDermal in vitro assay (29, 30: Dow Chemical Company). The test protocol was not stated. Results were negative."

"In a 21-day [human] cumulative skin irritation study, OPULYNTM 302B Opacifier was classified as non-irritating and non-sensitizing. The test protocol was not stated (32: Dow Chemical Company).

OPULYNTM 301 Opacifier was also classified as non-irritating and non-sensitizing in a 21-day [human] cumulative irritation study. The test protocol was not stated (50: Dow Chemical Company)."

"ACUDYNETM Shine Polymer and ACUDYNETM Bold Polymer were classified as non-sensitizers in the mouse local lymph node assay (29,30: Dow Chemical Company). The test protocol was not stated."

As taken from CIR, 2014.

5.8. All other relevant types of toxicity

No data available to us at this time.

6. Functional effects on

6.1. Broncho/pulmonary system

"Male and female Han Wistar rats were exposed for 6 h/day, 5 days/week for 13 or 104 weeks (whole body) to a magnetite photocopying toner. The toner contained 45% to 50% magnetite, with 45% to 50% styrene acrylic resin and less than 5% external additives, including hydrophobic amorphous silica and proprietary surface functional modifiers. Exposure levels were 1, 5, and 25 mg/m(3) for the 13-week study and 1, 4, and 16 mg/m(3) for the 104-week study. Lung toner burdens averaged 36, 288, and 604 microg per lung after 104 weeks' exposure at 1, 4, and 16 mg/m(3). The lung burdens were lower than have been reported in a similar study with a carbon-based toner. There were no significant effects on weight gain or food consumption in either study, or on clinical pathology parameters examined in the 13-week study. After 104 weeks' exposure at 16 mg/m(3), macroscopic examination revealed dark discoloration of the lungs and associated

lymph nodes. Lung weights were significantly elevated by 21% and 14% for male and female rats, respectively. Microscopic findings indicative of a mild inflammatory response were similar in both studies, and included the presence of black-pigmented macrophages in the lungs and tracheobronchial and mediastinal lymph nodes; increased incidences of perivascular/peribronchiolar inflammatory cell infiltration; inflammation of the alveolar ducts (characterized by aggregations of black-pigmented alveolar macrophages and interstitial lymphocytic infiltration); increased cellularity of the bronchiole-associated lymphoid tissue; and a few instances of alveolar ciliated metaplasia. The 104-week study showed no increase in the incidence of pulmonary tumors." As taken from Slesinski RS & Turnbull D. 2008. Int. J. Toxicol. 27(6), 427-39. PubMed, 2013

6.2. Cardiovascular system

No data available to us at this time.

6.3. Nervous system

No data available to us at this time.

6.4. Other organ systems, dependent on the properties of the substance

No data available to us at this time.

7. Addiction

JTI is not aware of any information that demonstrates that this ingredient has any addictive effect.

8. Burnt ingredient toxicity

No data available to us at this time.

9. Heated/vapor emissions toxicity

No data available to us at this time.

10. Ecotoxicity

10.1. Environmental fate

The Ecological Categorization Results from the Canadian Domestic Substances List simply state that 2-propenoic acid, polymer with ethenylbenzene is persistent in the environment.

Data accessed January 2017 on the OECD website

"A number of environmental fate and effects studies on two distinctly different polycarboxylates were conducted as part of a product stewardship program. These studies led to the development of an environmental risk assessment for the two materials. Polymer emulsion (PE) is a typical anionic, styrene-acrylic polymer (MW 50,000–60,000) used in coating applications. Resin polymer (RP), insoluble at neutral pH but increasingly soluble at pH ≥8, is a neutral-charged, styrene-acrylic polymer (molecular weight 4,500–9,000) used primarily for graphic arts products. Some amount of both materials will enter the environment given their use and disposal patterns. Their environmental fate is driven by physical-chemical characteristics. Both polymers demonstrated low biodegradation and bioaccumulation potential and strong sorption to soils, sludge, and sediments in laboratory and/or field studies. .....These polymers are also compatible with wastewater and solid waste

treatment systems." As taken from Guiney PD et al. 1998. Environmental Toxiciology and Chemistry 17(10), 2122-2130.

10.2. Aquatic toxicity

Styrene acrylic acid polymer #1 and #2 were reported to have medium aquatic toxicity, which was described as more than 0.1 mg/liter and up to 10 mg/liter needed to cause a problem (US EPA, 2002).

The Ecological Categorization Results from the Canadian Domestic Substances List simply state that 2-propenoic acid, polymer with ethenylbenzene is not inherently toxic to aquatic organisms and is of low ecotoxicological concern.

Data accessed January 2017 on the OECD website

".....Ecotoxicity test results on a variety of plant and animal species indicated a very low order of acute and chronic toxicity. The environmental risk assessment included characterization of exposure in relevant environmental matrices, characterization of adverse effects or hazards to receptors for which there are complete exposure pathways, and characterization of risk by comparison of predicted exposure levels to adverse effect threshold levels. Based on conservative exposure assumptions, the safety margins established in this assessment indicate that the use of PE and RP, in both commercial and household applications, presents a very low risk to aquatic organisms in the water column and sediments, as well as to terrestrial plants, invertebrates, and wildlife....." As taken from Guiney PD et al. 1998. Environmental Toxiciology and Chemistry 17(10), 2122-2130.

10.3. Sediment toxicity

".....Ecotoxicity test results on a variety of plant and animal species indicated a very low order of acute and chronic toxicity. The environmental risk assessment included characterization of exposure in relevant environmental matrices, characterization of adverse effects or hazards to receptors for which there are complete exposure pathways, and characterization of risk by comparison of predicted exposure levels to adverse effect threshold levels. Based on conservative exposure assumptions, the safety margins established in this assessment indicate that the use of PE and RP, in both commercial and household applications, presents a very low risk to aquatic organisms in the water column and sediments, as well as to terrestrial plants, invertebrates, and wildlife....." As taken from Guiney PD et al. 1998. Environmental Toxiciology and Chemistry 17(10), 2122-2130.

10.4. Terrestrial toxicity

".....Ecotoxicity test results on a variety of plant and animal species indicated a very low order of acute and chronic toxicity. The environmental risk assessment included characterization of exposure in relevant environmental matrices, characterization of adverse effects or hazards to receptors for which there are complete exposure pathways, and characterization of risk by comparison of predicted exposure levels to adverse effect threshold levels. Based on conservative exposure assumptions, the safety margins established in this assessment indicate that the use of PE and RP, in both commercial and household applications, presents a very low risk to aquatic organisms in the water column and sediments, as well as to terrestrial plants, invertebrates, and wildlife....." As taken from Guiney PD et al. 1998. Environmental Toxiciology and Chemistry 17(10), 2122-2130.

10.5. All other relevant types of ecotoxicity

The Ecological Categorization Results from the Canadian Domestic Substances List simply state that 2-propenoic acid, polymer with ethenylbenzene is not bioaccumulative in the environment.

Data accessed January 2017 on the OECD website

11. References

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12. Other information

13. Last audited

February 2026

Safety Assessment of
Styrene and Vinyl-type Styrene Copolymers as Used in Cosmetics

Status:	Final Report
Release Date:	October 2, 2014
Panel Date:	September 8-9, 2014

The 2014 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 Wilbur Johnson, Jr., M.S., Senior Scientific Analyst and Bart Heldreth, Ph.D., Chemist.

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ABSTRACT: These styrene and vinyl-type styrene copolymers function mostly as viscosity increasing agents, opacifying agents, and film formers in cosmetic products. After considering the large sizes of these molecules, the Panel agreed that percutaneous absorption is not expected. The absence of the potential for percutaneous absorption and the negative results of toxicity tests provided the Panel with a sufficient basis to assess the safety of these polymers as used in cosmetics. The Panel concluded that the 35 styrene and vinyl-type styrene copolymers are safe in the present practices of use and concentration in cosmetics, as described in this safety assessment.

INTRODUCTION

This report presents information relevant to evaluating the safety of styrene and vinyl-type styrene copolymers as used in cosmetics. Film-former is the most frequent function reported for these ingredients. Other common functions include opacifying agent and viscosity increasing agent. Given the toxicity of two of the component monomers present in styrene and vinyl-type styrene copolymers, styrene and 1,3-butadiene, carcinogenicity data on these monomers are included. Styrene is a component of all of the copolymers reviewed in this safety assessment; however, butadiene monomer is a component of only three copolymers included in this review.

CHEMISTRY

Definition and Structure

Polystyrene is the polymerization product of vinylbenzene (a.k.a. styrene). The other ingredients in this report are all vinyl-type copolymers with vinylbenzene. The term "vinyl-type copolymers" means that all of the monomers, utilized to make these polymer ingredients, have in common an ethylene unit whose pi electrons are directly involved in the polymerization process. Typically, a catalyst is utilized to initiate the polymerization.[1] There is a large multitude of relevant initiating catalysts, ranging from UV light to Ziegler-Natta-type catalysts, which can result in a variety of differences in the characteristics (e.g. crystallinity and resultant hardness) of the copolymer formed. The synthesis of these ingredients is typically carried out in one or more organic solvents, with one or more catalysts.

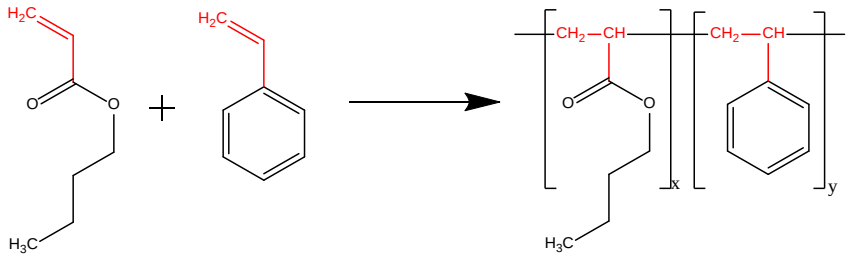


Figure 1. Butylacrylate/Styrene Copolymer

These ingredients are high molecular weight, large molecular volume, and inert polymers. While not truly soluble, these ingredients may be swellable in certain organic solvents.

The molecular structures and definitions of styrene and vinyl-type styrene copolymers are presented in Table 1.[2]

Physical and Chemical Properties

Polystyrene

Properties of polystyrene are presented in Table 2.[3,4,5] Some of the properties include physical state (colorless solid in various forms), molecular mass (10,000 to 300,000), relative density (1.04 to 1.13), melting point (240°C), flash point (345 to 360°C), and auto-ignition temperature (427°C).

The thermal degradation of high impact polystyrene to styrene and other thermal degradation products occurred at a temperature of 250°C.[6] Reportedly, the principal limitations of polystyrene in industry are brittleness, inability to withstand the temperature of boiling water, and poor oil resistance.[7] Thus, polystyrene is often modified, e.g., by copolymerization with acrylonitrile and/or butadiene. Regarding this process, the most common styrene polymers are poly(acrylonitrile-butadiene-styrene) and styrene-butadiene copolymer.

Styrene

Styrene is a component of each styrene and vinyl-type styrene copolymer reviewed in this safety assessment. The vinyl group of styrene is reactive, and styrene polymerizes at a significant rate at room temperature.[8] Polymerization proceeds more rapidly at elevated temperatures or in the presence of many commonly available reagents. Commercially available grades of styrene contain an inhibitor of styrene polymerization (e.g., 4-*t*-butylcatechol). Additionally, upon exposure to light and air, styrene undergoes polymerization and oxidation, with the formation of peroxides.[4] Additional properties of styrene are presented in Table 3.[4]

Styrene-Butadiene Copolymer

Properties of styrene-butadiene copolymer are presented in Table 4.[5]

1,3-Butadiene

Properties of 1,3-butadiene are presented in Table 5.[9]

Composition/Impurities

Polystyrene

Polystyrene is available in the United States in a variety of grades, and the following are considered major grades:[5] crystalline or straight polystyrene, (2) impact-modified grades, which typically contain approximately 5% polybutadiene elastomer, and (3) expandable beads, which contain a small amount of *n*-pentane entrapped in each globule.

During the early years of polystyrene production, the residual monomer content was as high as 2%, and, at the beginning of the 1960's, it was approximately 1%.[10] Compositon/impurities data from a 2013 safety dossier on a polystyrene trade name material summarized in Table 6 indicates that the residual monomer content of polystyrene is < 5 ppm. Furthermore, data summarized in Table 6 indicate that other styrene and vinyl-type styrene copolymer trade name materials contain styrene monomer at levels of < 100 ppm or less.

Styrene-Butadiene Copolymer

The following styrene-butadiene copolymers are available in the United States:[5] (1) styrene-butadiene elastomers (commonly called SBR, or styrene-butadiene rubber), (2) styrene block polymers with butadiene, and (3) styrene-butadiene copolymer latexes. Dry SBR (produced by emulsion polymerization) contains styrene units (23% to 25%) and butadiene units (75% to 77%) on a polymer basis. When produced via solution polymerization, the composition of dry SBR varies; however, typical grades contain styrene units (~ 10% to 25%) and butadiene units (75% to 90%). Styrene block polymers with butadiene are available with a styrene content of 25% to 50%, and the most widely used grades contain 30% styrene units.

Trade Name Materials

Composition/impurities data on styrene and vinyl-type styrene copolymer trade name materials included in this safety assessment are presented in Table 6. Data on properties of these trade name materials are also included.

Methods of Production

Ethylene/Propylene/Styrene Copolymer and Butylene/Ethylene/Styrene Copolymer

The ethylene/propylene/styrene copolymer and butylene/ethylene/styrene copolymer used as thickeners are made by anionic polymerization, which results in little or no residual monomer in the polymer.[11]

Polystyrene

Polystyrene is produced from styrene by mass, solution, suspension, or emulsion polymerization processes.[7] Polystyrene resins are typically produced by a modified mass polymerization process in a continuous manner.[5] The liquid styrene monomer is diluted with a relatively small amount of a diluent, e.g., 5% to 15% of ethylbenzene. In some cases, more diluent is used, and the process may then be called a solution process. The heated mixture of styrene, solvent, and initiator is reacted at 120°C to 160°C. Unreacted monomer and solvent are removed after polymerization is complete.

Styrene/Butadiene Copolymer

Dry SBR is produced via an emulsion polymerization (cold or hot) or solution polymerization process.[5] Composition data on styrene/butadiene copolymer resulting from either process are presented in the Composition/Impurities section.

The following components (in parts per 100 monomer) comprise a typical recipe for SBR produced by cold emulsion polymerization:[5] butadiene (70), styrene (30), water (180), fatty acid soap (2.25), disproportioned rosin soap (2.25), potassium chloride (0.3), potassium hydroxide (0.3), *t*-dodecyl mercaptan (0.23), sodium formaldehyde β-naphthalene sulfonate (0.04), sodium formaldehyde sulphoxylate (0.04), *p*-methane hydroperoxide (0.04), tetrasodium ethylenediaminetetraacetate (0.025), and ferrous sulfate heptahydrate.

A typical recipe (component data in parts per 100 monomer) for SBR produced by hot emulsion polymerization is as follows:[5] butadiene (75), styrene (25), water (180), fatty acid or rosin soap (5), *n*-dodecyl mercaptan (0.5), and potassium persulfate (0.3).

Recipes for SBR produced by solution polymerization are said to vary greatly, and depend upon the properties desired.[5] SBR is vulcanized (typically 1.5 to 2.0 parts sulfur per 100 parts of polymer are used). Furthermore, accelerators, antioxidants, activators, fillers (e.g., carbon black), and softeners may be used, depending on the properties of the finished rubber that are desired. SBR is also extended with aromatic and naphthenic oils to improve handling and processing.

Styrene block copolymers with butadiene are typically produced by anionic solution polymerization with *sec*-butyllithium or *n*-butyllithium in a solvent such as cyclohexane, isopentane, *n*-hexane, or mixtures.[5] The styrene is homopolymerized, followed by the addition of butadiene; more styrene is then added. The polymer is coagulated from the solution with water. Styrene block polymers are usually compounded with fillers, extenders oils, and, sometimes, other polymers (e.g., polyindene or polystyrene).

USE

Cosmetic

Styrene and vinyl-type styrene copolymers function mostly as viscosity increasing agents, opacifying agents, and film formers in cosmetic products.[2]

Information on the use of these ingredients as a function of product type was supplied to the Food and Drug Administration (FDA) by industry as part of the Voluntary Cosmetic Registration Program (VCRP).[12] The highest use frequency was reported for ethylene/propylene/styrene copolymer, followed by butylene/ethylene/styrene copolymer. The Personal Care Products Council conducted a survey of ingredient use concentrations in 2013-2014, and maximum use concentrations ranging from 0.000038% (styrene/VP copolymer, in skin care preparations) to 36.5% (polystyrene, in skin cleansing products) were reported.[13] The highest maximum reported use concentrations for rinse-off and leave on products were 36.5% (polystyrene) and 35% (styrene/acrylates copolymer, in basecoats and undercoats), respectively. Ingredient frequency of use and concentration data are presented in Table 7.

Cosmetic products containing styrene and vinyl-type styrene copolymers may be applied to the skin and hair or, incidentally, these products may come in contact with the eyes. Products containing these ingredients may be applied as frequently as several times per day and may come in contact with the skin or hair for variable periods following application. Daily or occasional use may extend over many years.

The following ingredients are used in products that are sprayed (maximum concentrations reported): hair sprays (styrene/acrylates copolymer [0.35%,]; styrene/VP copolymer [0.12%, in pump spray]), suntan sprays (styrene/acrylates copolymer [3.5%]), and body and hand sprays (ethylene/propylene/styrene copolymer [0.5%]). Additionally, isobutylene/styrene copolymer is used in face powders at a maximum concentration of 1%. Because styrene/acrylates copolymer, styrene/VP copolymer, and ethylene/propylene/styrene copolymer are used in products that are sprayed and isobutylene/styrene copolymer is used in face powders they could possibly be inhaled. 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 below 10 µm, compared with pump sprays.[14,15,14,16] Therefore, most droplets/particles incidentally inhaled from cosmetic sprays would be deposited in the nasopharyngeal and bronchial regions and would not be respirable (i.e., they would not enter the lungs) to any appreciable amount.[14,15]

Noncosmetic

Polystyrene

Polystyrene is used as a plasticizer in the bottled water industry, and studies have shown that styrene leaches continuously from polystyrene bottles.[17] The skin adhesive layer of a pressure ulcer preventive dressing may contain styrene block copolymer as an adhesive compound.[18] Polystyrene foam is widely used for thermal insulation.[7]

Additionally, polystyrene may be safely used as a component of articles intended for use in contact with food. For this purpose, polystyrene shall contain not more than 1 weight percent of total residual styrene monomer.[19] The exception to this limit relates to use in contact with fatty foods, whereas such polystyrene basic polymers shall contain not more than 0.5 weight percent of total residual styrene monomer.

Styrene

Styrene is listed among the synthetic flavoring substances and adjuvants that may be safely used in food.[20] It should be used in the minimum quantity required to produce the intended effect, and, otherwise, in accordance with all principles of good manufacturing practice.

Styrene/Butadiene Copolymer

Butadiene-styrene rubber (styrene/butadiene copolymer) is included on the list of FDA-approved direct food additives.[21]

TOXICOKINETICS

Styrene

Nine male volunteers were exposed for 10 to 30 minutes by dipping one hand in liquid styrene. Urine and breath were sampled periodically for metabolites (mandelic and phenylglyoxylic acids) and styrene analyses respectively. The results obtained show that the rate of absorption of styrene through the skin was very low, averaging 1 ± 0.5 µg/cm^2/minute.[22,23]

A field study comparing the urinary excretion of styrene metabolites in 4 groups of workers who performed the same task, but wore different protective equipment, was performed.[22] It was concluded that the percutaneous absorption of styrene was not an important contribution to the body burden.

Several studies have suggested that styrene accumulates in the subcutaneous fat.[22] However, based on the measurement of urinary metabolites, there was no styrene accumulation in workers exposed to 37 ppm (160 mg/m^3) styrene in air during the work week.

Styrene is primarily metabolized to styrene 7,8-oxide by cytochrome P450 (CYP) enzymes.[22] Epoxide hydrolase metabolizes the oxide to phenylethylene glycol, and then to mandelic, phenylglyoxylic, and benzoic acids. Additional routes of metabolism include ring hydroxylation, but this appears to be a minor pathway in humans. Another pathway is the conversion of styrene to 1- and 2-phenylethanol, which is further metabolized to phenylacetaldehyde, phenylacetic acid, phenylaceturic acid, and hippuric acid. Styrene 7,8-oxide may also be metabolized by conjugation with glutathione to form mercapturic acids. The conversion of styrene to mercapturic acids, considered a minor pathway in humans, is < 1% of the absorbed dose of styrene.[24]

Small amounts of styrene (0.7% to 4.4%) are exhaled unchanged.[22] This finding has been confirmed in additional studes in which 0.7% to 2.2% of the amount of inhaled styrene was found unchanged in the exhaled breath of 4 subjects exposed to 50 ppm [213 mg/m^3) styrene in air for 2 h. Small amounts of styrene are also excreted unmetabolized in the urine.

The pharmacokinetics of inhaled styrene (80 ppm [341 mg/m^3]) was studied using 4 volunteers.[22,25] Calculated half-life values of 0.6 h and 13.0 h for the 2 phases of elimination were reported. In a study of blood styrene concentrations in 76 exposed workers at the end of their work shift and in the morning thereafter, the half-life of blood styrene was 3.9 h at 16 h after the end of the workshift.

1,3-Butadiene and Styrene

Nine minutes after rabbits were exposed to 1,3-butadiene at concentrations of 250,000 ppm in air, the test chemical was found in the femoral artery at a concentration of 0.26 mg/ml and in the femoral vein at a concentration of 0.18 mg/ml.[26]

Mice and rats were exposed (dynamic flow exposure: 2 h [mice] and 4 h [rats]) to butadiene or styrene vapors at the following concentrations: 270 mg/liter (butadiene [mice]), 285 mg/liter (butadiene [rats]), 21 mg/liter (styrene [mice]), and 11.8 mg/liter (styrene [rats]).[26,27] The number, strain, and sex of the animals tested were not specified. Following exposure, the concentrations of butadiene and styrene in tissues were determined by gas liquid chromatography. Various tissues from rats were analyzed, but only brain tissue from mice was analyzed. Mean concentrations in tissues from rats are included below:

- 50.8 mg butadiene/100g brain (10 tests)
- 25 mg styrene/100g brain (7 tests)

- 51.4 mg butadiene/100g liver (10 tests)
- 20 mg styrene/100g liver (7 tests)
- 36.3 mg butadiene/100g kidney (7 tests)
- 14.7 mg styrene/100g kidney (7 tests)
- 45 mg butadiene/100g spleen (7 tests)
- 19.1 mg styrene/100 g spleen (7 tests)
- 152.1 mg butadiene/100g perinephric fat (7 tests)
- 132.8 mg styrene/100g perinephric fat (7 tests)

Mean concentrations in brain tissue from mice were 54.4 mg butadiene/100cc brain (10 tests) and 18.02 mg styrene/100cc brain (7 tests). In a subsequent experiment series (rats, same procedure), mean concentrations in the brain and liver were determined at various times for up to 90 minutes after removal from the chamber. By 90 minutes, mean tissue concentrations were:[26,27]

- 0 to traces of butadiene/100cc brain (4 tests)
- traces to 4.4 mg styrene/100 cc brain (4 tests)
- 0 to traces of butadiene/100cc liver (4 tests)
- 5.2 to 11 mg styrene/100cc liver (4 tests)

The first step in butadiene metabolism involves cytochrome P450 (CYP)-mediated oxidation to epoxybutene.[9] At low concentrations of butadiene, metabolism via CYP2E1 predominates. Epoxybutene may be metabolized by conjugation with glutathione (GSH), mediated by glutathione *S*-transferase (GST), or by hydrolysis, catalyzed by epoxide hydrolase (EH). Epoxybutene may also be oxidized to multiple diastereomers of diepoxybutane. Dihydroxybutene formed by hydrolysis of epoxybutene may be oxidized to epoxybutanediol. The latter epoxides are also detoxified by GST or EH. The partial hydrolysis of diepoxybutane also produces epoxybutanediol.

TOXICOLOGY

Composition data on copolymer trade name mixtures evaluated in toxicity tests are included in Table 6.

Acute Inhalation Toxicity

Styrene/Acrylates Copolymer

In an acute inhalation toxicity study on Sunspheres™ Powder, an LC_{50} of > 5.3 mg/L was reported. The test protocol was not provided.[28]

An acute inhalation LC_{50} (4 h) value of > 5.11 mg/L air was reported for ACUDYNE™ Shine Polymer and ACUDYNE™ Bold Polymer.[29,30] The test protocol was not described. The animal species was not stated, but it was noted that no clinical signs or mortalities were observed.

1,3-Butadiene and Styrene

Mice and rats were exposed (dynamic flow exposure: 2 h [mice] and 4 h [rats]) to butadiene or styrene vapors.[26,27] The number, strain, and sex of the animals tested were not specified. LC_{50} values were: 270 mg/liter (butadiene [mice]), 285 mg/liter (butadiene [rats]), 21 mg/liter (styrene [mice]), and 11.8 mg/liter (styrene [rats]).

Acute Oral Toxicity

Ethylene/Propylene/Styrene Copolymer and Butylene/Ethylene/Styrene Copolymer (mixture)

A trade name mixture containing ethylene/propylene/styrene copolymer (4 to 15%) and butylene/ethylene/styrene copolymer (0.1 to 2%) was evaluated in an acute oral toxicity study.[31] The mixture was fed in large doses to male and female rats (number of animals not stated). Details relating to the test protocol were not included. The estimated acute oral LD_{50} was > 5,050 mg/kg (nontoxic). It was noted that this finding was expected because the primary ingredient of the trade name mixture is white mineral oil.

Styrene/Acrylates Copolymer

OPULYN™ 302B Opacifier was evaluated in an acute oral toxicity study involving rats, and an LD_{50} of > 5 ml/kg was reported. The test protocol was not stated.[32]

An oral LD_{50} of > 2,000 mg/kg body weight (rats) for Syntran® 5903 was reported in a study performed according to OECD guideline n˚423.[33] There were no effects on body weight change, and no clinical and behavioral signs or mortalities were observed after dosing. In a toxicological assessment certificate on Syntran® 5907 (another styrene acrylates copolymer trade name material), it was noted that the acute oral toxicity data on Syntran® 5903 can be extrapolated to Syntran® 5907.[34] Similarly, in toxicological assessment reports on Syntran® 5904 and Syntran® 5905 it was determined that the acute oral toxicity study results for Syntran® 5903 are applicable to Syntran® 5904 and Syntran® 5905.[35,36]

Acute Dermal Toxicity

Styrene/Acrylates Copolymer

OPULYN™ 302B Opacifier was evaluated in an acute dermal toxicity study involving rats, and an LD_{50} of > 5 g/kg was reported. The test protocol was not stated.[32]

Repeated Dose Toxicity

Inhalation

Polyacrylate

Polyacrylate, a polymer of acrylic acid and sodium acrylate, was tested in a repeated dose toxicity study involving groups of Fischer 344 rats (ages and number per group not specified).[37] It was noted that the large particle size of polyacrylate used in manufacturing makes this material non-respirable, i.e., less than 1% of received material is < 40 microns. The particle size used in this study was reduced (by milling) to make it highly respirable in test animals (mass mean aerodynamic diameter [MMAD] = 1.95 to 2.07 microns). Four groups of animals were exposed to concentrations of 0.05, 0.2, 1, and 10 mg/m^3, respectively, 5 days per week (6 h/day) for up to 26 consecutive weeks. The control group was exposed to filtered room air. No adverse effects were observed at concentrations of 0.05 and 0.2 mg/m^3. Mild to moderate pulmonary inflammation, which resolved during the recovery period, was observed in the 1.0 mg/m^3 exposure group. Exposure to 10 mg/m^3 (at this concentration, threshold for clearing inhaled test material from the lungs was exceeded) caused adverse pulmonary effects (marked inflammation and benign alveolar/bronchiolar adenoma) that are not relevant to subthreshold exposure concentrations. Inflammation decreased during the recovery period. The authors stated that these results support the inhalation safety of the polyacrylate material under both occupational and consumer exposure conditions. The 0.05 and 0.2 mg/m^3 concentrations were considered no-adverse-effect levels.

Three groups of 120 F344 rats (60 males, 60 females/group) were exposed for 24 months to respirable polyacrylate particles (MMAD ≈ 2 to 3 microns) at concentrations of 0.05, 0.2, and 0.8 mg/m^3, respectively.[38]

Gross necropsy was performed at 6, 12, and 24 months. Gross necropsy results at 24 months indicated no visible effects in males or females exposed to 0.05 mg/m^3. Lung nodules were observed in 1 male and 3 females exposed to 0.2 mg/m^3. The numbers of pulmonary nodules were even higher in the 0.8 mg/m^3 exposure group (7 males and 23 females with nodules). Only one animal (1 female) in the air-exposed control group had a pulmonary nodule. Interim necropsy results at 6 and 12 months indicated the absence of nodule formation in all exposure groups. The authors noted that characterization of the nodules was not possible, and it was determined that conclusions regarding the lung nodule incidence and its significance (if any) in this study could not be made.

Styrene/Acrylates Copolymer

ACUDYNE™ Shine Polymer and ACUDYNE™ Bold Polymer were evaluated in a 2-week aerosol (nose only) exposure study involving rats.[29,30] The test protocol was not stated. There were no signs of clinical toxicity at any administered dose. The no-observed-effect-concentration (NOEC) was 10.8 mg polymer solids/m^3, based on slight irritant effects in the lungs at a concentration of 100 mg/m^3.

In a 13-week aerosol (nose only) study on ACUDYNE™ Shine Polymer and ACUDYNE™ Bold Polymer involving rats, the no-observable adverse-effect level (NOAEL) for changes in the lung (and related lymph nodes) was 8.3 mg/m^3.[29,30]

Oral

Styrene

The Environmental Protection Agency (EPA) has established a reference dose for chronic oral exposure (RfD) to styrene of 1 mg/kg/day, based on effects on red blood cells and the liver of dogs.[39] The RfD is based on the assumption that thresholds exist for certain toxic effects, such as cellular necrosis. In general, the RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The principal study that served as the basis for the oral RfD is summarized below.

Four beagle dogs/sex were gavaged with doses of 0, 200, 400, or 600 mg styrene/kg bw/day in peanut oil for 560 days.[40] No adverse effects were observed for dogs administered styrene at 200 mg/kg-day. In the higher dose groups, increased numbers of Heinz bodies in the RBCs, decreased packed cell volume, and sporadic decreases in hemoglobin and RBC counts were observed. Additionally, increased iron deposits and elevated numbers of Heinz bodies were found in the livers. Marked individual variations in blood cell parameters were noted for animals at the same dose. Other parameters examined were body weight, organ weights, urinalyses, and clinical chemistry. The NOAEL in this study was 200 mg/kg-day and the LOAEL was 400 mg/kg-day.

Ocular Irritation

Non-Human

Ethylene/Propylene/Styrene Copolymer and Butylene/Ethylene/Styrene Copolymer (mixture)

A mixture containing ethylene/propylene/styrene copolymer (4 to 15%) and butylene/ethylene/styrene copolymer (0.1 to 2%) was evaluated in an ocular irritation study involving albino rabbits (number of animals not stated).[41] Details relating to the test protocol were not included. The mixture was not a primary ocular irritant in this study. It was noted that, under EPA Guideline No. 81-4, this mixture was "minimally irritating" in rinsed and unrinsed eyes. Additionally, the minimal irritation observed was reversible and the material was assigned to Category IV, EPA's lowest toxicity category for ocular irritation.

Styrene/Acrylates Copolymer

In the embryonic hen's egg chorioallantoic membrane (HET-CAM) assay, a 5% dilution of Syntran® 5903 in distilled water was classified as a weak irritant.[42,33] In this test system, the hen's egg chorioallantoic membrane

was treated with the test material for 20 seconds and the following endpoints were evaluated: hyperemia, hemorrhage, and coagulation (including opacity and thrombosis).

Sunspheres™ Powder was classified as minimally irritating to the eyes of rabbits.[28] The test protocol was not stated.

In an ocular irritation study involving rabbits, OPULYN™ 302B Opacifier was classified as a non-iritant. The test protocol was not stated.[32]

Human

1,3-Butadiene

Workers exposed to 1,3-butadiene at concentrations of 8,000 ppm for 8 hours complained of eye irritation and blurred vision.[43]

In Vitro

Polyacrylate-15, Polyacrylate-18, Polyacrylate-19, and Polyacrylate-21

In the *in vitro* EpiOcular™ ocular irritation screening assay, the following copolymers were classified as non-irritating to the eye: polyacrylate-15 (Syntran® PC 5208),[44] polyacrylate-18 and polyacrylate-19 mixtures (Syntran® PC 5117 and Syntran® PC 5107),[45,46] and a product (100.58BM) closely related to polyacrylate-21 (Syntran® PC 5100CG).[47]

Styrene/Acrylates Copolymer

The ocular irritation potential of ACUDYNE™ Shine Polymer was evaluated in the bovine corneal opacity and permeability test *in vitro*. The test protocol was not stated. Results were negative.[29]

ACUDYNE™ Bold Polymer was classified as a non-irritant in the bovine corneal opacity and permeability test *in vitro*.[30] The test protocol was not stated.

Skin Irritation and Sensitization

Non-Human

Ethylene/Propylene/Styrene Copolymer and Butylene/Ethylene/Styrene Copolymer (mixture)

A mixture containing ethylene/propylene/styrene copolymer (4 to 15%) and butylene/ethylene/styrene copolymer (0.1 to 2%) was evaluated in a skin irritation study involving albino rabbits (number of animals not stated).[48] Details relating to the test protocol were not included. The material was not a primary skin irritant in this study. It was noted that the descriptive rating (under EPA Guideline No. 81-5) for this mixture was "slightly irritating", the lowest descriptive rating possible. Additionally, because this slight irritation was reversible, the trade name material was assigned to the EPA's lowest toxicity category (Categorty IV) for dermal irritation.

Styrene/Acrylates Copolymer

In a skin irritation study involving rabbits, OPULYN™ 302B Opacifier was classified as a non-iritant. The test protocol was not stated.[32]

The skin irritation potential of ACUDYNE™ Shine Polymer and ACUDYNE™ Bold Polymer was evaluated in the EpiDermal *in vitro* assay.[29,30] The test protocol was not stated. Results were negative.

Styrene/Acrylates Copolymer and Polystyrene

Syntran® 5903 (undiluted) was classified as a non-sensitizer in a guinea pig sensitization test, performed according to OECD guideline n˚406.[42,33] Based on these results for Syntran® 5903, Syntran® 5904 (another styrene/acrylates copolymer trade name material), Syntran® 5907 (another styrene/acrylates copolymer trade name material), Syntran® 5905 (another styrene/acrylates copolymer trade name material), and Syntran® 5900 (polystyrene trade name material) were classified as non-sensitizers.[42,35,34,36]

ACUDYNE™ Shine Polymer and ACUDYNE™ Bold Polymer were classified as non-sensitizers in the mouse local lymph node assay.[29,30] The test protocol was not stated.

Styrene and Methylstyrene

The skin sensitization potential of styrene was evaluated in the guinea pig maximization test (15 guinea pigs).[49] Details relating to the test protocol were not included. The test procedure involved intradermal injections of 10% (w/v) styrene, topical application of 20% (w/v) styrene, and challenge with 2% (w/v) styrene in acetone. Skin sensitization was not observed in any of the animals tested. Methylstyrene was also evaluated in a maximization test involving 15 guinea pigs, and the procedure involved intradermal injections of 2.5% (w/v) methylstyrene, topical application of 5% (w/v) methylstyrene, and challenge with 0.5% (w/v) methylstyrene in acetone. The results were also negative.

Human

Styrene/Acrylates Copolymer and Polystyrene

Syntran® 5903 (5% in distilled water) was classified as having good skin compatibility in 10 volunteers patch tested (single application patch test). Study details were not provided.[42,33] No signs of irritation were recorded, and observations throughout the test interval were within normal limits. Based on these results for Syntran® 5903, Syntran® 5904 (another styrene acrylates copolymer trade name material), Syntran® 5907 (another styrene/acrylates copolymer trade name material), Syntran® 5905 (another styrene/acrylates copolymer trade name material), and Syntran® 5900 (polystyrene trade name material) were classified as non-irritants.[42,35,34,36]

Styrene/Acrylates Copolymer

In a 21-day cumulative skin irritation study, OPULYN™ 302B Opacifier was classified as non-irritating and non-sensitizing. The test protocol was not stated.[32]

OPULYN™ 301 Opacifier was also classified as non-irritating and non-sensitizing in a 21-day cumulative irritation study. The test protocol was not stated.[50]

Styrene and Methylstyrene

Styrene (5% w/v in petrolatum) was evaluated in a skin sensitization study involving 303 patients (diagnoses not stated).[49] Details relating to the test procedure were not provided. Negative results were reported for all patients. Negative results for methylstyrene (1% w/v in ethanol) in these patients were also reported.

Ethylene/Propylene/Styrene Copolymer and Butylene/Ethylene/Styrene Copolymer (mixture)

A mixture containing ethylene/propylene/styrene copolymer (4 to 15%) and butylene/ethylene/styrene copolymer (0.1 to 2%) was evaluated in a human repeated insult patch test involving 117 subjects.[51] Details relating to the test protocol were not included. The subjects were evaluated for redness, swelling, “flares” and itching. The mixture did not induce allergic contact dermatitis in any of the subjects. It was noted that this conclusion was confirmed by a board-certified dermatologist.

In Vitro

Styrene/Acrylates Copolymer and Polystyrene

In the embryonic hen's egg chorioallantoic membrane (HET-CAM) assay, a 5% dilution of Syntran® 5903 in distilled water was classified as a weak irritant.[42,33] In this test system, the hen's egg chorioallantoic membrane was treated with the test material for 20 seconds and the following endpoints were evaluated: hyperemia, hemorrhage, and coagulation (including opacity and thrombosis). Based on these results for Syntran® 5903, Syntran® 5904 (another styrene/acrylates copolymer trade name material), Syntran® 5907 (another styrene/acrylates copolymer trade name material), Syntran® 5905 (another styrene/acrylates copolymer trade name material), and Syntran® 5900 (polystyrene trade name material) were also classified as weakly irritating to the chorioallantoic membrane.[42,35,34,36] Based on the minimal irritation potential of Syntran® 5903 in the HET-CAM assay (generally used to evaluate ocular irritation potential), it was concluded that it is not likely that this trade name material, or the other trade name materials, would produce dermal irritation.

Polyacrylate-15, Polyacrylate-18, Polyacrylate-19, and Polyacrylate-21

Based on negative results in the *in vitro* EpiOcular™ ocular irritation screening assay (see Ocular Irritation section), it is expected that the following copolymers would not produce dermal irritation: polyacrylate-15 (Syntran® PC 5208),[44] polyacrylate-18 and polyacrylate-19 mixtures (Syntran® PC 5117 and Syntran® PC 5107),[45,46] and a product (100.58BM) closely related to polyacrylate-21 (Syntran® PC 5100CG).[47]

Polyacrylate-15

In a cosmetic ingredient safety dossier on Syntran® PC 5208, skin irritation data on this trade name material were not included.[44] However, it was noted that the absence of ocular irritation potential in the EpiOcular™ assay on Syntran® PC 5208 indicates that this trade name material is not likely to produce skin sensitization, since skin is less susceptible to irritation than eye tissue.

Polyacrylate-18 and Polyacrylate-19 (mixture)

Skin irritation data were not included in a cosmetic ingredient safety dossier on polyacrylate-18 and polyacrylate-19 (Syntran® PC 5117).[45] However, it was noted that the absence of ocular irritation potential in the EpiOcular™ assay on a closely related product (Syntran® 5100, composition not stated) indicates that Syntran® PC 5117 is not likely to produce dermal sensitization, since skin is less susceptible to irritation than eye tissue. These statements are also applicable to Syntran® PC 5107 (polyacrylate-18 and polyacrylate-19).[46]

Polyacrylate-21

In a cosmetic ingredient safety dossier on polyacrylate-21 (Syntran® PC 5100CG), skin irritation data on this trade name material were not included.[47] However, it was noted that the absence of ocular irritation potential in the EpiOcular™ assay on a closely related product (100.58BM, composition data not provided) indicates that Syntran® PC 5100CG is not likely to produce dermal sensitization, since skin is less susceptible to irritation than eye tissue.

Case Reports

Styrene and Methylstyrene

A 40-year-old man with a history of bronchitis and contact allergy to styrene cross-reacted when patch-tested with 3- and 4-vinytoluene (also known as 3- and 4-methylstyrene, respectively).[49] The vinyltoluene compounds were patch-tested at concentrations equimolar to 0.1% w/v styrene. The patient also had a positive reaction to styrene (0.1% and 5% v/v in methy ethyl ketone).

In a subsequent case report, the same patient cross-reacted when patch tested with 2-, 3-, and 4-vinyltoluene (2-, 3-, and 4-methylstyrene, respectively) and to the metabolites styrene epoxide and 4-vinylphenol (4-hydroxystyrene).[52] It is assumed that styrene is a prohapten metabolized in the skin by aryl hydrocarbon hydroxylase (AHH) to styrene epoxide, which acts as a true hapten.

REPRODUCTIVE AND DEVELOPMENTAL TOXICITY

Styrene

The National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) Expert Panel concluded that styrene does not cause developmental or reproductive toxicity in experimental animals.[53] In developmental toxicity studies in rats and rabbits, the highest exposure concentration/dose on gestation days 6-15 (600 ppm by inhalation or 300 mg/kg body weight/day by oral dosing) did not have any observable adverse effects on fetuses. Rats and rabbits were used in inhalation studies, and rats only were involved in the oral dosing study. The effects of styrene exposure on reproduction and post-natal development were assessed in 2 multigeneration studies involving rats. Neither study produced results indicating a styrene-induced reproductive effect, even at the highest concentrations administered. However, in one of the studies, there was decreased birth weight and delays in the postnatal development of pups from parents exposed (by inhalation) to 500 ppm styrene from 70 days prior to mating through gestation day 20. This concentration of styrene also caused a significantly reduced body weight gain in the dams. Thus, the NTP-CERHR Expert Panel concluded that it was not possible to separate the observed effects in the offspring from the effects on maternal weight. Inhalation exposure to 500 ppm styrene did not cause developmental neurotoxicity.

In the second multigeneration study, a subset of animals (COBS (SD) BR rats) from a 2-year chronic toxicity study in which styrene was administered at concentrations up to 250 ppm in drinking water (estimated intake = 18 mg/kg body weight/day (for males) and 23 mg/kg body weight/day (for females) were used. The parental generations were cohabited after 90 days on study. Results indicated no treatment-related effects on maternal food consumption or weight gain, and no significant developmental effects on the pups. The NTP-CERHR Expert Panel considered these data to be relevant for the assessment of potential human hazard.

The NTP-CERHR Expert Panel determined that there was insufficient information available to arrive at conclusions about reproductive and developmental outcomes from studies of humans exposed to styrene. Studies performed in occupational settings suggest that the exposure of women to styrene is associated with slightly increased levels of prolactin in blood serum and possible depletion of peripheral blood dopamine metabolizing activities, when compared to levels in women not occupationally exposed to styrene. The Panel determined that the clinical relevance of these effects is uncertain for the following 2 reasons: (1) the average elevation in prolactin concentrations in blood serum was small and within the normal range of blood serum values and (2) menstrual function and other reproductive endpoints were not evaluated in these studies.[53]

1,3-Butadiene

The following reproductive toxicity study summaries are included in the 1984 NTP report on the toxicology and carcinogenesis of 1,3-butadiene.[26] The fertility of rats was not severely impaired when they were exposed (via inhalation) to 1,3-butadiene at concentrations of 600-6,700 ppm for 7.5 hours per day, 6 days per week, for 8 months; however, the decreased fecundity observed may have been related to exposure. No evidence of degenerative testicular changes in males was seen, and all embryos appeared normal at necropsy.

When female rats were exposed (via inhalation) to 1,3-butadiene for 4 months at 45 ppm, increased embryonic mortality and teratogenesis were reported.

Pregnant female Sprague-Dawley rats exposed (via inhalation) to 1,3-butadiene at concentrations of 0, 200, 1,000, or 8,000 ppm for 6 hours per day during days 6-15 of gestation showed embryonic growth retardation and slight embryo-mortality at all concentrations. At the highest exposure concentration, evidence of teratogenicity (major fetal defects such as cardiovascular, sternebral, and thoracic abnormalities) was seen.[26]

GENOTOXICITY

Styrene/Acrylates Copolymer and Polystyrene

In the Ames test (OECD guideline n˚471), Syntran® 5903 (doses up to 5,000 µg/plate) was non-genotoxic with and without metabolic activation in *Salmonella typhimurium* strains TA98, TA100, TA1535, and TA1537, and in *Escherichia coli* strains WP2, pKM101, and uvr A-.[42,33] Based on these results for Syntran® 5903, Syntran® 5904 (another styrene/acrylates copolymer trade name material), Syntran® 5907 (another styrene/acrylates copolymer trade name material), Syntran® 5905 (another styrene/acrylates copolymer trade name material), and Syntran® 5900 (polystyrene trade name material) were classified as non-genotoxic.[42,35,34,36]

The genotoxicity of polystyrene was evaluated in the Ames test using the following *Salmonella typhimurium* strains, with and without metabolic activation: TA97, TA98, TA100, and TA1535.[54] Concentrations of the test substance were not stated; however, at least 5 concentrations were tested. Methyl ethyl ketone served as the vehicle and the control. Polystyrene was not genotoxic with or without metabolic activation in any of the bacterial strains tested. The positive controls in experiments without metabolic activation were: 2-nitrofluorene, 4-nitro-o-phenylenediamine, sodium azide, 9-aminoacridine, mitomycin C, and methyl methanesulfonate. The positive control for the metabolic activation experiments was 2-aminoanthracene. Results for the vehicle control or positive controls were not stated.

Styrene/Acrylates Copolymer

OPULYN™ 302B Opacifier was not genotoxic in the Ames test, with or without metabolic activation. The test protocol was not stated.[32] This trade name material also was not genotoxic in the *in vitro* cytogenetic assay, with or without metabolic activation (test protocol not stated).

In the Ames test, ACUDYNE™ Shine Polymer and ACUDYNE™ Bold Polymer were not genotoxic.[29,30] Negative results were also reported for these 2 trade name materials in the chromosomal aberrations test *in vitro* (test protocol not stated).

OPULYN™ 301 Opacifier was not genotoxic in the Ames test, with or without metabolic activation.[50] This trade name material also was not genotoxic in the *in vitro* cytogenetic assay, with or without metabolic activation (test protocol was not stated.).

Polyacryate-18 and Polyacrylate-19 (mixture)

Syntran® PC 5117 (polyacrylate-18 and polyacrylate-19) was evaluated for genotoxicity in the Ames test at doses up to 5,000 µg/plate using the following bacterial strains: *Salmonella typhimurium* strains TA98, TA100, TA1535, and TA1537, and *E. coli* strain WP2 *uvr*A. Results were negative with and without metabolic activation.[45] These statements are also applicable to Syntran® PC 5107 (polyacrylate-18 and polyacrylate-19).[46]

Polyacrylate-21

Syntran® PC 5100 (mixture of polyacrylate-21 and acrylates/dimethylaminoethyl methacrylate copolymer)[2] was evaluated for genotoxicity in the Ames test at doses up to 5,000 µg/plate using the following bacterial strains: *Salmonella typhimurium* strains TA98, TA100, TA1535, and TA1537, and *E. coli* strain WP2 *uvr*A. Results were negative with and without metabolic activation.[47] Genotoxicity data on polyacrylate-21 (Syntran® 5100CG) were not provided, and data on a closely related product (Syntran® PC 5100) were used to evaluate the genotoxicity of Syntran® 5100CG. It was noted that negative results would be expected for Syntran® 5100CG.

Polyacrylate

The genotoxicity of polyacrylate (polymer of acrylic acid and sodium acrylate) was evaluated in the following assays:[37] unscheduled DNA synthesis assay (rat hepatocytes), the mouse lymphoma mammalian cell

assay, and the *in vivo* cytogenetics assay (rat bone marrow cells). Neither the test concentrations nor details relating to the test protocols were stated. However, it was stated that polyacrylate was not genotoxic in any of the assays.

CARCINOGENICITY

Information relating to the carcinogenicity of styrene and vinyl-type styrene copolymers and component monomers is presented in Table 8. Particularly, 1,3-butadiene and styrene monomer components have been classified as carcinogenic. In additon to the information presented in Table 8, a committee of the National Research Council (NRC) conducted a scientific peer review of the styrene assessment presented in the *12th Report on Carcinogens* (RoC). The committee found that the overall conclusion reached by the NTP in 2011, that styrene is "reasonably anticipated to be a human carcinogen", is appropriate.[55]

It should be noted that polyacrylates are included on the 2013 list of substances that have been nominated to the NTP's *Report on Carcinogens* (RoC), but have not yet been approved for formal review.[56]

OTHER EFFECTS

Hormonal Activity

Polystyrene

The estrogenic (uterotrophic) activity of low molecular weight polystyrene (identified as F2L5250) was studied in the Tiecco test using groups of 10 weanling female Wistar outbred rats (HsdCpb:WU strain).[57] The test substance was fed to 5 groups at the following dietary concentrations, respectively, during a 4-day period: 10 ppm, 20 ppm, 40 ppm, 80 ppm, and 160 ppm. The control group was fed standard diet only. Diethylstilbesterol (DES) served as the positive control. The mean absolute and relative uterine weights of the treatment groups were used for qualitative and quantitative assessment of possible uterotrophic activity. There were no significant differences in mean absolute and relative uterus weights between the control group and the 10 ppm, 20 ppm, 40 ppm, or 80 ppm group. However, significant and dose -related increases in mean absolute and relative uterus weights were observed in the 160 ppm group and in groups fed 5 ppb, 10 ppb, and 20 ppb DES, respectively. The results of this study indicated that the highest no-effect-level for estrogenic activity was 80 ppm polystyrene in the diet, which corresponded to a daily intake of 13.3 mg polystyrene/kg body weight. It was noted that 100 ppm polystyrene induced the same level of estrogenic activity as 5 ppb DES. It was concluded that the potentcy (estrogenic activity) of low molecular weight polystyrene (F2L5250) was a factor of 20,000 less than that of DES.

SUMMARY

The safety of 35 styrene and vinyl-type styrene copolymers as used in cosmetics is evaluated in this safety assessment. These ingredients function mostly as viscosity increasing agents, opacifying agents, and film formers in cosmetic products. Very limited safety test data on the styrene and vinyl-type styrene copolymers reviewed in this safety assessment were found in the published literature. However, data on monomers, styrene and 1,3-butadiene, are included.

Information on the use of these ingredients as a function of product type was obtained from FDA's VCRP in 2014. The highest use frequency was reported for ethylene/propylene/styrene copolymer, followed by butylene/ethylene/styrene copolymer. The Personal Care Products Council conducted a survey of ingredient use concentrations in 2013-2014, and maximum use concentrations ranging from 0.000038% (styrene/VP copolymer) to 36.5% (polystyrene) were reported. The highest maximum reported use concentrations for rinse-off and leave-on products were 36.5% (polystyrene) and 35% (styrene/acrylates copolymer), respectively.

Data provided by industry indicate that styrene and vinyl-type styrene copolymer trade name materials contain styrene monomer at levels of < 100 ppm or less.

The absorption of styrene was low (averaging 1 μg/cm^2/minute) in human volunteers exposed by placing one hand in liquid styrene for 10 to 30 minutes. The percutaneous absorption of styrene was not an important contribution to the body burden in a field study comparing the urinary excretion of styrene metabolites in 4 groups of workers, all performing the same task, but wearing different protective equipment. It was concluded that the percutaneous absorption of styrene was not an important contribution to the body burden. Styrene is primarily metabolized to styrene 7,8-oxide by cytochrome P450 enzymes.

Nine minutes after rabbits were exposed to 1,3-butadiene at concentrations of 250,000 ppm, the test chemical was found in the femoral artery at a concentration of 0.26 mg/ml and in the femoral vein at a concentration of 0.18 mg/ml. Following 1 h of exposure to 130,000 ppm 1,3-butadiene in rats, the chemical was detected in the brain and liver. At 2 h post-exposure to the same concentration (rats), 1,3-butadiene was detected in the perirenal fat, liver, brain, spleen, and kidneys. The first step in butadiene metabolism involves cytochrome P450-mediated oxidation to epoxybutene.

Polyacrylate, a polymer of acrylic acid and sodium acrylate, was tested in a repeated dose inhalation toxicity study involving groups of Fischer 344 rats. The particle size (MMAD) used in this study was 1.95 to 2.07 microns. The animals were exposed to polyacrylate at concentrations of 0.05, 0.2, 1, and 10 mg/m^3. Mild to moderate pulmonary inflammation and benign alveolar/bronchiolar adenomas were reported, and the 0.05 and 0.2 mg/m^3 concentrations were considered no-adverse-effect levels.

The EPA has estimated the safe dose of styrene for human oral exposure during a lifetime to be 1 mg/kg-day.

Workers exposed to 1,3-butadiene at concentrations of 8,000 ppm for 8 hours complained of eye irritation and blurred vision.

In the maximization test, sensitization was not observed in 15 guinea pigs challenged with 2% (w/v) styrene in acetone. Results were also negative for sensitization in 303 patients tested with 5% (w/v) styrene in petrolatum.

The National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) Expert Panel concluded that styrene does not cause developmental or reproductive toxicity in experimental animals. The highest doses/exposure concentrations in developmental toxicity studies (rats and rabbits) evaluated were 600 ppm (inhalation) or 300 mg/kg body weight/day by oral dosing. The NTP-CERHR Expert Panel determined that there was insufficient information available to arrive at conclusions on reproductive and developmental outcomes from studies of humans exposed (occupational exposure) to styrene.

The fertility of rats was not severely impaired when they were exposed to 1,3-butadiene at concentrations of 600-6,700 ppm for 8 months (6 days/week). However, it was noted that the decreased fecundity observed may have been exposure-related. There was no evidence of degenerative testicular changes in males. The results of other studies indicated increased embryonic mortality and teratogenesis at exposure concentrations as low as 45 ppm (4-month exposure) and embryonic growth retardation and embryo mortality at exposure concentrations ranging from 200 ppm to 8,000 ppm. Teratogenicity was observed only at the highest concentration of 8,000 ppm.

Polystyrene was not genotoxic with or without metabolic activation in the Ames test. Polyacrylates were not genotoxic in the following tests: Ames test, unscheduled DNA synthesis assay (rat hepatocytes), mouse lymphoma mammalian cell assay, and the *in vivo* cytogenetics assay (rat bone marrow cells).

The subcutaneous implantation of various physical forms of polystyrene produced sarcomas in rats. In an NTP oral carcinogenicity bioassay on styrene, it was concluded that there was no convincing evidence of carcinogencity in rats or mice receiving doses up to 2,000 mg/kg for 78 or 103 weeks (rats) or 78 weeks (mice). However, the NTP has concluded that styrene is reasonably anticipated to be a human carcinogen based on the results of occupational cohort studies. The EPA and IARC have also classified styrene as possibly carcinogenic to

humans. A committee of the NRC conducted a scientific peer review of the styrene assessment presented in the NTP 12th Report on Carcinogens, and concluded that the overall conclusion reached by the NTP is appropriate.

In NTP inhalation carcinogenicity studies, 1,3-butadiene was carcinogenic in $B6C3F_1$ mice at concentrations ≥ 20 ppm (male mice) and ≥ 6.25 ppm (female mice). Inhalation exposure was also associated with non-neoplastic lesions in the respiratory epithelium, liver necrosis, and testicular or ovarian atrophy. It should be noted that EPA and IARC have concluded that 1,3-butadiene is carcinogenic in humans by inhalation exposure.

The IARC has determined that epidemiological information on styrene-butadiene copolymer workers, which indicates lymphato-hematopoietic malignancies, clearly requires elucidation by further studies.

A cross-sectional respiratory survey of workers (164 workers: 153 men, 11 women; average age = 28.4 years) exposed to polyacrylate dust was performed to assess possible respiratory effects. There was no evidence of an excess risk of lung cancer or chest x-ray abnormalities in exposed workers. However, there were exposure-related decrements in lung function.

Polyacrylates are included on the 2013 list of substances that have been nominated to the NTP's *Report on Carcinogen*s, but have not yet been approved for formal review.

With certain exceptions, results were negative in the following toxicity tests on styrene and vinyl-type styrene copolymers reviewed in this safety assessment: acute inhalation, acute oral, acute dermal, ocular irritation, skin irritation, skin sensitization, and genotoxicity. The exceptions include: In an *in vitro* skin irritation test, styrene/ acrylates copolymer (Syntran® PC5903) was classified as a weak irritant. Styrene/acrylates copolymer (Sunspheres™ powder) was minimally irritating to the eyes of rabbits. In a 2-week aerosol (nose-only) study on 2 styrene/acrylates copolymer trade name materials (Acudyne™ Bold Polymer and Acudyne™ Shine Polymer), a slight irritant effect on the lungs was noted at a concentration of 100 mg/m^3. In light of these findings, it should be noted that a 13-week aerosol (nose-only) study on these 2 trade name materials yielded an NOAEL of 8.3 mg/m^3.

Low molecular weight polystyrene was found to have estrogenic (uterotrophic) activity in rats fed a dietary concentration of 160 ppm during a 4-day period.

DISCUSSION

After considering the large sizes of these molecules, the Panel agreed that percutaneous absorption is not expected. The absence of the potential for percutaneous absorption and the negative results of toxicity tests provided the Panel with a sufficient basis to assess the safety of these polymers as used in cosmetics. Styrene monomer, a component of all of the copolymers reviewed in this safety assessment, and 1,3-butadiene monomer are classified as carcinogenic in animals and in humans. Taking into consideration ingredient use concentrations and the data on residual monomer content, the Panel agreed that levels of residual styrene or 1,3-butadiene in cosmetic products would be substantially below levels of concern.

The Panel also discussed the potential for incidental inhalation exposures to these ingredients in products that are sprayed or in powder form and agreed that, based on likely airborne particle size distributions and concentrations in the breathing zone, ingredient use concentrations, and negative results in toxicity tests, incidental inhalation would not lead to local respiratory effects or systemic effects.

CONCLUSION

The CIR Expert Panel concluded that the following 35 ingredients are safe in the present practices of use and concentration in cosmetics, as described in this safety assessment.

Ethylene/Propylene/Styrene Copolymer
Butylene/Ethylene/Styrene Copolymer
Acrylates/Ethylhexyl Acrylate/Styrene Copolymer*
Butyl Acrylate/Styrene Copolymer
C4-6 Olefin/Styrene Copolymer*
C5-6 Olefin/Styrene Copolymer*
Hydrogenated Butadiene/Isoprene/Styrene Copolymer*
Hydrogenated Butylene/Ethylene/Styrene Copolymer
Hydrogenated Ethylene/ Propylene/Styrene Copolymer
Hydrogenated Styrene/Butadiene Copolymer
Hydrogenated Styrene/Isoprene Copolymer
Isobutylene/Styrene Copolymer
Methacrylic Acid/Styrene/VP Copolymer*
Methylstyrene/Vinyltoluene Copolymer
Polystyrene
Polystyrene/Hydrogenated Polyisopentene Copolymer
Sodium Methacrylate/Styrene Copolymer*
Sodium Styrene/Acrylates Copolymer
Sodium Styrene/Acrylates/Ethylhexyl Acrylate/Lauryl Acrylate Copolymer*
Styrene/Acrylates Copolymer
Styrene/Acrylates/Ethylhexyl Acrylate/Lauryl Acrylate Copolymer*
Styrene/Butadiene Copolymer
Styrene/Isoprene Copolymer*
Styrene/Methylstyrene Copolymer*
Styrene/Stearyl Methacrylate Crosspolymer*
Styrene/VA Copolymer*
Styrene/VP Copolymer
Polyacrylate-2*
Polyacrylate-5
Polyacrylate-12*
Polyacrylate-15
Polyacrylate-16
Polyacrylate-18*
Polyacrylate-21
Polyacrylate-30*

*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.

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.[2]

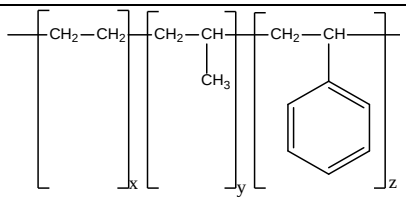
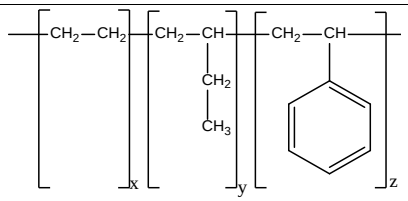
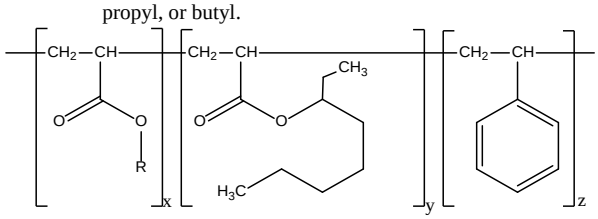
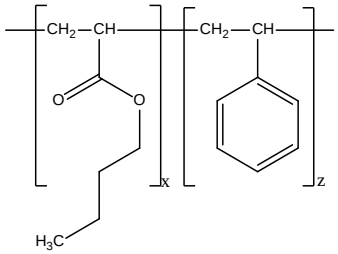
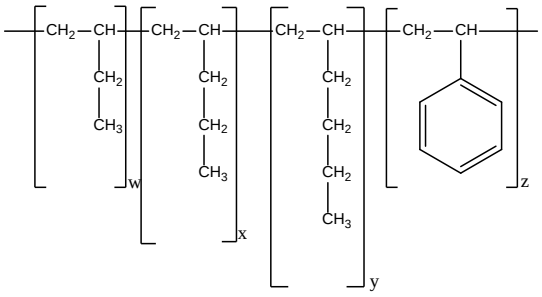
Ingredient CAS No.	Definition	Function(s)
Ethylene/Propylene/Styrene Copolymer 68648-89-5	Ethylene/Propylene/Styrene Copolymer is a polymer of ethylene, propylene and styrene monomers that has been terminated by hydrogenation. 	Viscosity increasing agent-nonaqueous
Butylene/Ethylene/Styrene Copolymer 66070-58-4	Butylene/Ethylene/Styrene Copolymer is a polymer of butylene, ethylene and styrene monomers terminated by hydrogenation. 	Viscosity increasing agent-nonaqueous
Acrylates/Ethylhexyl Acrylate/Styrene Copolymer	Acrylates/Ethylhexyl Acrylate/Styrene Copolymer is a copolymer of ethylhexyl acrylate, styrene and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters. wherein R is hydrogen, methyl, ethyl, propyl, or butyl. 	Film formers
Butyl Acrylate/Styrene Copolymer	Butyl Acrylate/Styrene Copolymer is a copolymer of butyl acrylate and styrene monomers. 	Film formers
C4-6 Olefin/Styrene Copolymer	C4-6 Olefin/Styrene Copolymer is a copolymer of C4-6 olefins and styrene monomers. 	Epilating agents

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.[2]

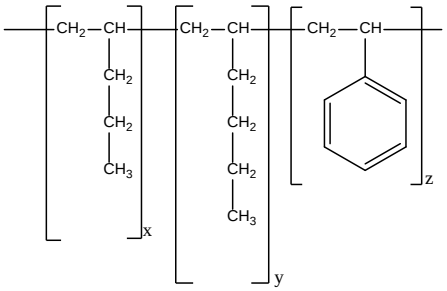
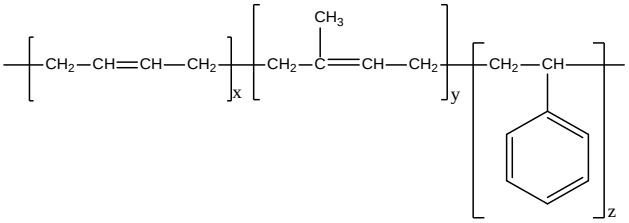
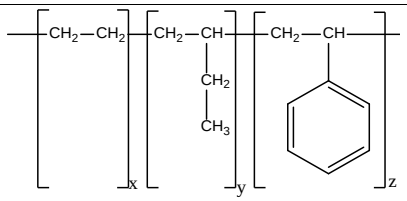
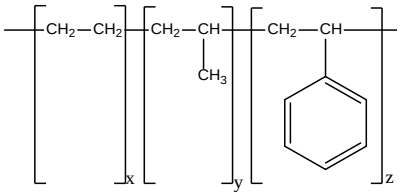
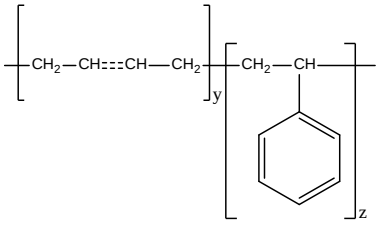
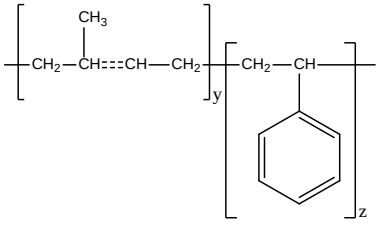
Ingredient CAS No.	Definition	Function(s)
C5-6 Olefin/Styrene Copolymer	C5-6 Olefin/Styrene Copolymer is the copolymer of C5-6 olefins and styrene monomers. 	Epilating agents
Hydrogenated Butadiene/ Isoprene/Styrene Copolymer 132778-07-5	Hydrogenated Butadiene/Isoprene/Styrene Copolymer is the end-product of the controlled hydrogenation of a block copolymer composed of 1,3-butadiene, isoprene and styrene monomers. 	Film formers
Hydrogenated Butylene/ Ethylene/Styrene Copolymer	Hydrogenated Butylene/Ethylene/Styrene Copolymer is a polymer of butylene, ethylene and styrene that has been hydrogenated. 	Viscosity increasing agents-nonaqueous
Hydrogenated Ethylene/ Propylene/Styrene Copolymer	Hydrogenated Ethylene/Propylene/Styrene Copolymer is a polymer of ethylene, propylene and styrene that has been hydrogenated. 	Viscosity increasing agents-nonaqueous
Hydrogenated Styrene/Butadiene Copolymer 66070-58-4	Hydrogenated Styrene/Butadiene Copolymer is the hydrogenated polymer of styrene and 1,4-butadiene. 	Film formers; viscosity increasing agents-nonaqueous
Hydrogenated Styrene/Isoprene Copolymer 68648-89-5	Hydrogenated Styrene/Isoprene Copolymer is the end product of the controlled hydrogenation of Styrene/Isoprene Copolymer. 	Viscosity increasing agents-nonaqueous

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.[2]

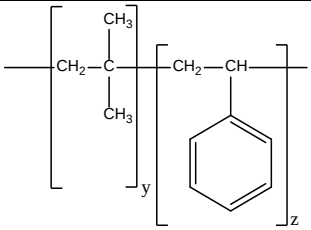
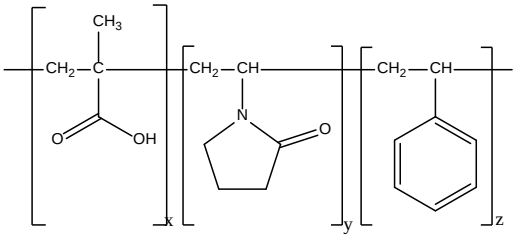
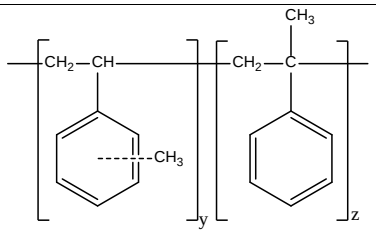
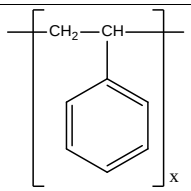
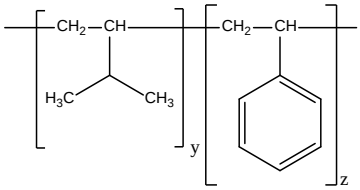
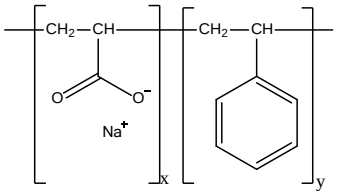
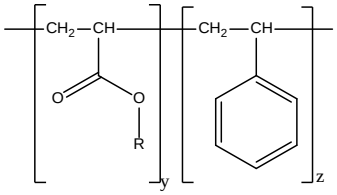
Ingredient CAS No.	Definition		Function(s)
Isobutylene/Styrene Copolymer 9011-12-5	Isobutylene/Styrene Copolymer is a copolymer of isobutylene and styrene monomers.		Film formers
Methacrylic Acid/Styrene/VP Copolymer 27554-92-3	Methacrylic Acid/Styrene/VP Copolymer is a copolymer of styrene, methacrylic acid and vinyl pyrrolidone.		Opacifying agents
Methylstyrene/Vinyltoluene Copolymer 9017-27-0	Methylstyrene/Vinyltoluene Copolymer is the polymer of methylstyrene and vinyltoluene monomers.		Viscosity increasing agents-nonaqueous
Polystyrene 9003-53-6	Polystyrene is the polymer that conforms to the formula. *Polystyrene is the homo-polymer formed from the polymerization of vinylbenzene.*		Film formers; viscosity increasing agents-nonaqueous
Polystyrene/Hydrogenated Polyisopentene Copolymer	Polystyrene/Hydrogenated Polyisopentene Copolymer is a copolymer of polystyrene and hydrogenated polyisopentene.		Not reported
Sodium Methacrylate/Styrene Copolymer 33970-45-5	Sodium Methacrylate/Styrene Copolymer is a copolymer of sodium methacrylate and styrene monomers.		Opacifying agents
Sodium Styrene/Acrylates Copolymer 9010-92-8	Sodium Styrene/Acrylates Copolymer is the sodium salt of a polymer of styrene and a monomer consisting of acrylic acid, methacrylic acid or one of their simple esters.	 wherein R is a lone pair of electrons with a sodium cation, methyl, ethyl, propyl, or butyl.	Film formers; viscosity increasing agents-aqueous

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.[2]

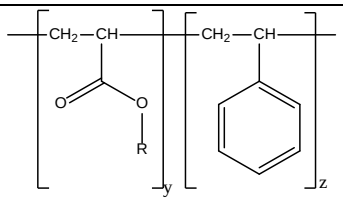
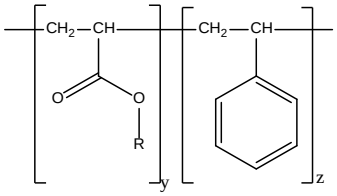
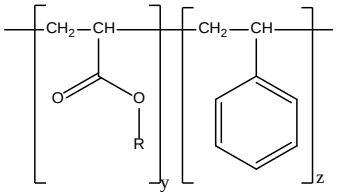
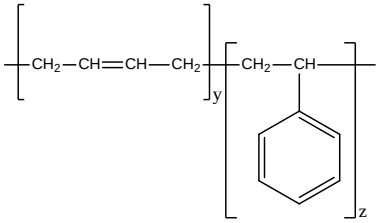
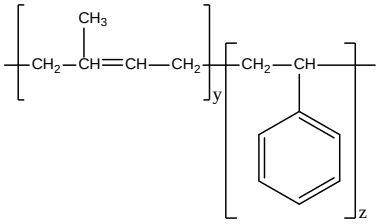
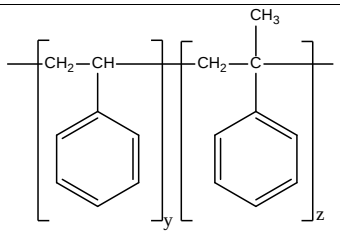
Ingredient CAS No.	Definition		Function(s)
Sodium Styrene/Acrylates/Ethylhexyl Acrylate/Lauryl Acrylate Copolymer	Sodium Styrene/Acrylates/Ethylhexyl Acrylate/Lauryl Acrylate Copolymer is the sodium salt of Styrene/Acrylates/Ethylhexyl Acrylate/Lauryl Acrylate Copolymer	 wherein R is a lone pair of electrons with a sodium cation, methyl, ethyl, propyl, butyl, lauryl, or ethylhexyl.	Film formers
Styrene/Acrylates Copolymer 25034-86-0 25085-34-1 9010-92-8	Styrene/Acrylates Copolymer is a polymer of styrene and a monomer consisting of acrylic acid, methacrylic acid or one of their simple esters.	 wherein R is hydrogen, methyl, ethyl, propyl, or butyl.	Film formers; opacifying agents
Styrene/Acrylates/Ethylhexyl Acrylate/Lauryl Acrylate Copolymer	Styrene/Acrylates/Ethylhexyl Acrylate/Lauryl Acrylate Copolymer is a coplymer of styrene, acrylates, ethylhexyl acrylate and lauryl acrylate.	 wherein R is a hydrogen, methyl, ethyl, propyl, butyl, lauryl, or ethylhexyl.	Film formers
Styrene/Butadiene Copolymer 9003-55-8	Styrene/Butadiene Copolymer is a copolymer of styrene and butadiene monomers.		Opacifying agents
Styrene/Isoprene Copolymer 25038-32-8	Styrene/Isoprene Copolymer is a copolymer of styrene and isoprene monomers.		Film formers; opacifying agents
Styrene/Methylstyrene Copolymer 37218-15-8 9011-11-4	Styrene/Methylstyrene Copolymer is a copolymer of styrene and methyl styrene monomers.		Binders; epilating agents

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.[2]

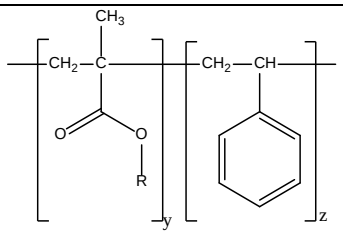
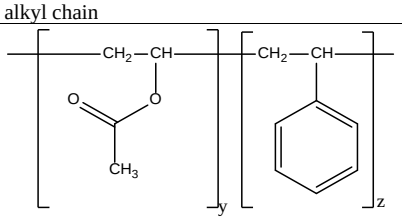
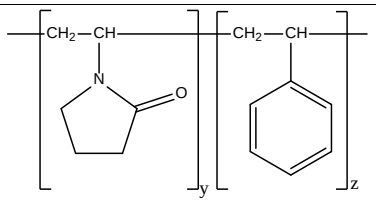
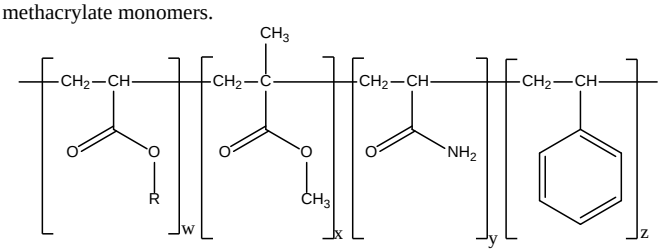
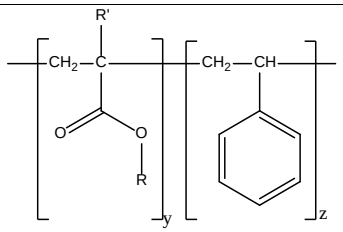
Ingredient CAS No.	Definition		Function(s)
Styrene/Stearyl Methacrylate Crosspolymer 91838-84-5	Styrene/Stearyl Methacrylate Crosspolymer is a copolymer of styrene and stearyl methacrylate monomers crosslinked with divinylbenzene.	 wherein R is an eighteen carbon, saturated alkyl chain	Absorbents; skin-conditioning agents-miscellaneous
Styrene/VA Copolymer	Styrene/VA Copolymer is a copolymer of styrene and vinyl acetate monomers.		Film formers;opacifying agents
Styrene/VP Copolymer 25086-29-7	Styrene/VP Copolymer is a copolymer prepared from vinylpyrrolidone and styrene monomers.		Film formers
Polyacrylate-2 31759-42-9	Polyacrylate-2 is a copolymer of styrene, acrylamide, octyl acrylate and methyl methacrylate monomers.		Film formers
Polyacrylate-5	Polyacrylate-5 is a copolymer of styrene, ethylhexyl acrylate, hydroxyethyl acrylate, and one or more monomers of acrylic acid, methacrylic acid, or one of their simple esters.	 wherein R is a hydrogen, methyl, ethyl, propyl, butyl, hydroxyethyl, or ethylhexyl. wherein R' is hydrogen, or in the cases where R is hydrogen, methyl, ethyl, propyl, or butyl, R' may also me methyl.	Film formers

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.[2]

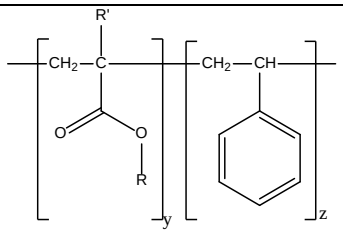
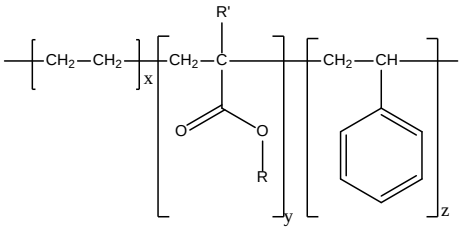
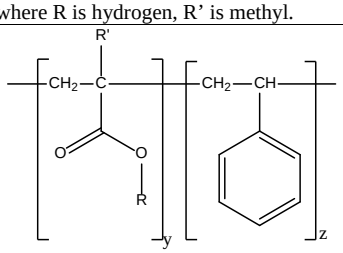
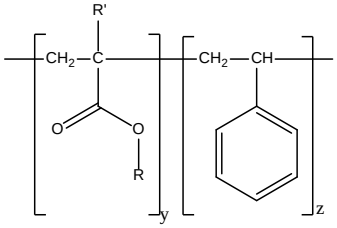
Ingredient CAS No.	Definition		Function(s)
Polyacrylate-12	Polyacrylate-12 is a copolymer of C3-11 acrylate, styrene, methacrylic Acid and acetoacetoxyethyl methacrylate monomers.	 wherein R is a hydrogen, methyl, an alkyl chain from 3 to 11 carbons in length methyl, or acetoacetoxyethyl wherein R' is hydrogen, or in the cases where R is methyl, or acetoacetoxyethyl, R' is methyl.	Film formers; nail conditioning agents
Polyacrylate-15 67892-91-5	Polyacrylate-15 is a copolymer of n-butyl acrylate, ethyl acrylate, methyl methacrylate, ethylene, methacrylic acid and styrene monomers	 wherein R is a hydrogen, methyl, ethyl , or butyl wherein R' is hydrogen, or in the case where R is hydrogen, R' is methyl.	Film formers; hair fixatives
Polyacrylate-16 67952-78-7	Polyacrylate-16 is a copolymer of n-butyl acrylate, diethylaminoethyl methacrylate, ethyl acrylate, methacrylic acid, hydroxypropyl methacrylate, methyl methacrylate and styrene monomers.	 wherein R is a hydrogen, methyl, diethylaminoethyl, or hydroxypropyl wherein R' is hydrogen, or in the cases where R is hydrogen, methyl, diethylaminoethyl, or hydroxypropyl, R' is methyl.	Film formers; hair fixatives
Polyacrylate-18	Polyacrylate-18 is a copolymer of n-butyl acrylate, ethyl acrylate, methacrylic acid, hydroxypropyl methacrylate and styrene monomers,	 wherein R is a hydrogen, ethyl, butyl, or hydroxypropyl wherein R' is hydrogen, or in the cases where R is hydrogen, butyl, or hydroxypropyl, R' is methyl.	Film formers; hair fixatives

Table 1. Definitions, idealized structures, and functions of the ingredients in this safety assessment.[2]

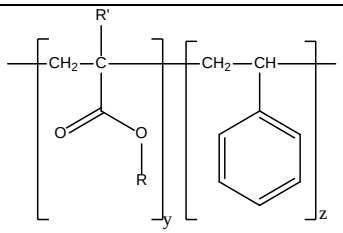
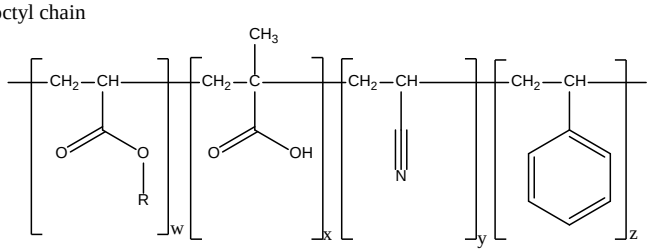
Ingredient CAS No.	Definition		Function(s)
Polyacrylate-21	Polyacrylate-21 is a copolymer of 2-ethylhexyl acrylate, butyl methacrylate, methacrylic acid, methyl methacrylate, hydroxypropyl methacrylate and styrene.		Binders; film formers; hair fixatives
Polyacrylate-30	Polyacrylate-30 is a copolymer of acrylonitrile, methacrylic acid, octyl acrylate, and styrene. wherein R is a hydrogen, methyl, butyl, ethylhexyl, or hydroxypropyl wherein R' is hydrogen, or in the cases where R is hydrogen, methyl, butyl, or hydroxypropyl, R' is methyl. wherein R is an octyl chain		Nail conditioning agents

Table 2. Properties of Polystyrene.[58,4,5]

Form	Transparent, hard solid; water-clear solid plastic
Molecular Mass	10,000 to 300,000
Density	1.04-1.065 (amorphous); 1.111 (crystalline)
Stability	Yellows on exposure to light
Solubility	Soluble in ethylbenzene, methyl isobutyl ketone, tetrahydrofuran, benzene, toluene, methylene chloride, and pyridine
Melting Point	240°C
Softening Temperature	Begins to soften at ≈ 85°C
Flash Point	345°C to 360°C
Auto-ignition Temperature	427°C
Refractive Index	1.591
Spectroscopy Data	λ_{max} at 260 nm, 215 nm, 194 nm and 80 nm

Table 3. Properties of Styrene.[4]

Form	Colorless to yellowish, very refractive oily liquid
Density	0.9059
Solubility	Soluble in alcohol, ether, methanol, acetone, and carbon disulfide; sparingly soluble in water
Melting Point	30.6°
Boiling Point	145° to 146°
Flash point (closed cup)	31°C
Refractive Index	1.5463

Table 4. Properties of Styrene/Butadiene Copolymer.[5]

Form	Amorphous solid
Density	0.933
Refractive Index	1.5345
Melting Point	-59 to -64°C

Table 5. Properties of 1,3-Butadiene.[9]

Form	Colorless gas
Relative Molecular Mass	54.09
Solubility	Sparingly soluble in water (1 g/L at 20°C); slightly soluble in ethanol and methanol; soluble in benzene, carbon tetrachloride, and diethyl ether

Table 6. Composition and Properties of Trade Name Materials

Ingredient Name and Trade Name	Composition/Impurities	Properties
Styrene/Acrylates Copolymer (Sunspheres™ LCG Polymer)	styrene/acrylates copolymer (up to 28%), individual residual monomers (< 100 ppm maximum; for styrene, butyl methacrylate, and methyl methacrylate), aqua ammonia (up to 0.1%), water (up to 74%), and mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (up to 23 ppm). Impurity: copper (0.7 ppm).[59]	pH: 6.50-7.5.[59]
Styrene/Acrylates Copolymer (Sunspheres™ Powder)	styrene/acrylates copolymer (up to 90%), individual residual monomers (≤ 100 ppm maximum; for styrene, butyl methacrylate, and methyl methacrylate), fatty acid ethoxylate (up to 11%), related reaction products (up to 2%), and water (up to 3%). Byproducts and impurities: 1,4-dioxane (1.23 ppm), toluene (< 0.05 ppm), 2-methyl-4-isothiazolin-3-one (5 ppm), and diethylene glycol (64 ppm), and iron (2 ppm).[28]	
Styrene/Acrylates Copolymer (OPULYN™ 302B Opacifier)	styrene/acrylic copolymers (up to 41%), individual residual monomers (< 500 ppm maximum), styrene (≤ 50 ppm), water (up to 61%), and benzoic acid (up to 0.5%). Impurities: iron (2,153 ppb) and magnesium (1,735 ppb).[32]	molecular weight: > 1,000,000.[32]
Styrene/Acrylates Copolymer (ACUDYNE™ Shine Polymer)	styrene/acrylates copolymer (up to 41%), individual residual monomers (< 100 ppm; for styrene, butyl acrylate, and 2-ethyl hexyl acrylate), water (up to 61%), and benzoic acid (up to 0.75%). Impurities: chromium (70 ppb), iron (333-1996 ppb), and nickel (92 ppb).[29]	pH: 3-5.[29]
Styrene/Acrylates Copolymer (SunSpheres™ PGL Polymer)	styrene/acrylates copolymer (up to 26%), residual monomers (< 100 ppm; for styrene, butyl methacrylate, and methyl methacrylate), aqua ammonia (up to 0.1%), pentylene glycol (up to 6%), and water (up to 69%). Impurity: iron (1 ppm).[60]	pH: 6.5-7.5.[60]
Styrene/Acrylates Copolymer (OPULYN™ 301 Opacifier)	styrene/acrylic copolymer (up to 41%), water (up to 61%), residual monomers (< 500 ppm), and styrene (≤ 20 ppm). Impurities: heavy metals not detected.[50]	molecular weight: > 1,000,000; pH: 2.05-2.50.[50]
Styrene/Acrylates Copolymer (ACUDYNE™ Bold Polymer)	styrene/acrylates copolymer (up to 41%), individual residual monomers (< 100 ppm; for styrene, butyl acrylate, 2-ethyl hexyl acrylate), water (up to 61%), and benzoic acid (up to 0.75%). Impurities: chromium (82 ppb), iron (2,270 ppb), and nickel (173 ppb).[30]	pH: 3-5.[30]
Styrene/Acrylates Copolymer (Syntran® 5903; corresponds to CAS Nos. 9011-14-7 and 9010-92-8)	dry extract of 35% styrene/acrylates copolymer + 65% water.[33]	white, milky dispersion (pH 7).[33]
Styrene/Acrylates Copolymer (Syntran® 5904; (corresponds to CAS Nos. 9011-14-7 and 9010-92-8)	dry extract of 40% styrene/acrylates copolymer + 60% water.[35]	white, milky dispersion (pH 2.5).[35]
Styrene/Acrylates Copolymer (Syntran® 5905; (corresponds to CAS Nos. 9011-14-7 and 9010-92-8)	dry extract of 40% styrene/acrylates copolymer + 60% water.[36]	white, milky dispersion (pH 2.5).[36]
Styrene/Acrylates Copolymer (Syntran® 5907; (corresponds to CAS Nos. 9003-63-8 and 9010-92-8)	dry extract of 40% styrene/acrylates copolymer + 60% water.[34]	white, milky dispersion (pH 2.5).[34]

Table 6. Composition and Properties of Trade Name Materials

Ingredient Name and Trade Name	Composition/Impurities	Properties
Ethylene/Propylene/Styrene Copolymer and Butylene/Ethylene/Styrene Copolymer	Both are used in ingredient mixtures in which the total polymer content is usually in the range of 5 to 20 weight % and the main component may be either of the following: mineral oil, isohexadecane, isododecane, hydrogenated polyisobutene, isopropyl palmitate, isononyl isononanoate, and residual monomer (below limit of detection [100 ppb])[11]	
Polyacrylate-15 (Syntran® PC 5208; corresponds to CAS No. 67892-91-5)	contains the following: olefin-acrylic graft polymer (37%), ethoxylated secondary alcohol (3%), 1,3-butanediol (2%), 0.20% methylparaben, 0.15% propylparaben, residual monomer (< 5 ppm), and water (58%).[44]	molecular weight reported as m + n > 100.[44]
Polyacrylate-18 and Polyacrylate-19 (Syntran® PC 5117; corresponds to CAS No. 848236-12-4)	contains the following: acrylate copolymer (35%), 1,3-butanediol (4%), methylparaben (0.20%), propylparaben (0.15%), residual monomer (< 5 ppm), and water (60%).[45]	molecular weight reported as n > 50.[45]
Polyacrylate-18 and Polyacrylate-19 (Syntran® PC 5107; corresponds to CAS No. 848236-12-4)	contains the following: acrylate copolymer (30%), 1,3-butanediol (4%), methylparaben (0.20%), propylparaben (0.15%), residual monomer (< 5 ppm), and water (65%).[46]	molecular weight reported as n > 50.[46]
Polyacrylate-21 (Syntran® PC 5100 CG (corresponds to CAS Nos. 68541-61-7 and 26316-50-7)	acrylate copolymers in an aqueous phase. dry extract of 25% non-volatiles.[47]	typical pH: 8.0.[47]
Polystyrene (Syntran® 5900)	contains the following: polystyrene (31% to 33%), surfactants (2% to 3%), residual monomer (< 5 ppm), and balance is water.[42]	molecular weight of ~ 50,000 daltons.[42]

Table 7. Frequency and Concentration of Use According to Duration and Type of Exposure.[12,13]

	Ethylene/Propylene/Styrene Copolymer		**Butylene/Ethylene/Styrene Copolymer**		**Butyl Acrylate/Styrene Copolymer**	
	# of Uses	Conc. (%)	# of Uses	Conc. (%)	# of Uses	Conc. (%)
Totals/Conc. Range	413	0.075-8.2	400	0.008-8.2	NR	0.25
Duration of Use						
Leave-On	408	0.075-8.2	395	0.008-8.2	NR	NR
Rinse off	5	0.18	5	0.11-0.95	NR	0.25
Diluted for (bath) Use	NR	NR	NR	0.95	NR	NR
Exposure Type						
Eye Area	16	0.075-2.3	19	0.01-0.25	NR	NR
Incidental Ingestion	324	6-8.2	314	1-8.2	NR	NR
Incidental Inhalation- Sprays	32	0.5	29	1.9**	NR	NR
Incidental Inhalation- Powders	27	0.5 -3.9*	25	0.008-0.84*	NR	NR
Dermal Contact	72	0.075-3.9	70	0.008-1.9	NR	NR
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	3	1-2	2	NR	NR	0.25
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	2	3-5.7	2	0.18-1.9	NR	NR
Mucous Membrane	328	6-8.2	318	0.11-8.2	NR	NR
Baby Products	NR	NR	NR	NR	NR	NR
	Hydrogenated Butylene/Ethylene/Styrene Copolymer		**Hydrogenated Ethylene/Propylene/Styrene Copolymer**		**Hydrogenated Styrene/Butadiene Copolymer**	
	# of Uses	Conc. (%)	# of Uses	Conc. (%)	# of Uses	Conc. (%)
Totals/Conc. Range	22	10	23	1.5-4.4	13	0.33-18.7
Duration of Use						
Leave-On	19	NR	20	1.5-4.4	13	0.33-18.7
Rinse off	3	10	3	NR	NR	2
Diluted for (bath) Use	NR	NR	NR	NR	NR	NR
Exposure Type						
Eye Area	NR	NR	1	2	NR	2.3
Incidental Ingestion	7	NR	7	NR	8	0.33-18.7
Incidental Inhalation- Sprays	4**	NR	4**	NR	2**	NR
Incidental Inhalation- Powders	4*	NR	4*	NR	1	4*
Dermal Contact	7	10	8	1.5-4.4	2	2.3-4
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	8	NR	8	NR	3	2
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	NR
Mucous Membrane	7	NR	7	NR	8	0.33-18.7
Baby Products	NR	NR	NR	NR	NR	NR
	Hydrogenated Styrene/Isoprene Copolymer		**Isobutylene/Styrene Copolymer**		**Methylstyrene/Vinyltoluene Copolymer**	
	# of Uses	Conc. (%)	# of Uses	Conc. (%)	# of Uses	Conc. (%)
Totals/Conc. Range	78	0.89-4.2	1	1	2	0.58
Duration of Use						
Leave-On	78	0.89-4	1	1	2	0.58
Rinse off	NR	4.2	NR	NR	NR	NR
Diluted for (bath) Use	NR	NR	NR	NR	NR	NR
Exposure Type						
Eye Area	25	NR	NR	NR	NR	NR
Incidental Ingestion	30	2.5-3	NR	NR	2	NR
Incidental Inhalation- Sprays	2	4**	NR	NR	NR	NR
Incidental Inhalation- Powders	5	3*	1	1	NR	NR
Dermal Contact	45	0.89-4	1	1	NR	0.58
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	2	4.2	NR	NR	NR	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	1	NR	NR	NR	NR	NR
Mucous Membrane	30	2.5-3	NR	NR	2	NR
Baby Products	3	NR	NR	NR	NR	NR

Table 7. Frequency and Concentration of Use According to Duration and Type of Exposure.[12,13]

	Polystyrene		**Polystyrene/Hydrogenated Polyisopentene Copolymer**		**Sodium Styrene/Acrylates Copolymer**	
	# of Uses	Conc. (%)	# of Uses	Conc. (%)	# of Uses	Conc. (%)
Totals/Conc. Range	19	0.08-36.5	16	0.0002-1.2	25	0.49
Duration of Use						
Leave-On	16	0.08-0.4	13	0.015-1.2	19	0.49
Rinse off	3	36.5	3	0.0002	4	NR
Diluted for (bath) Use	NR	NR	NR	NR	2	NR
Exposure Type						
Eye Area	2	NR	7	0.15-1.2	NR	NR
Incidental Ingestion	NR	NR	NR	0.05	NR	NR
Incidental Inhalation- Sprays	5	0.4**	2**	NR	4**	NR
Incidental Inhalation- Powders	4	0.2*	2**	NR	4*	NR
Dermal Contact	10	0.08-36.5	16	0.0002-1.2	22	NR
Deodorant (underarm)	NR	NR	NR	NR	13	NR
Hair - Non-Coloring	9	0.4	NR	NR	3	NR
Hair-Coloring	NR	NR	NR	NR	NR	NR
Nail	NR	NR	NR	NR	NR	0.49
Mucous Membrane	2	NR	NR	0.05	2	NR
Baby Products	NR	NR	NR	NR	NR	NR
	Styrene/Acrylates Copolymer		**Styrene/Butadiene Copolymer**		**Styrene/VP Copolymer**	
	# of Uses	Conc. (%)	# of Uses	Conc. (%)	# of Uses	Conc. (%)
Totals/Conc. Range	272	0.028-35	9	NR	82	0.000038-1
Duration of Use						
Leave-On	121	0.028-35	NR	NR	30	0.000038-0.4
Rinse off	135	0.04-12	9	NR	52	0.021-1
Diluted for (bath) Use	16	0.2-0.4	NR	NR	NR	NR
Exposure Type						
Eye Area	11	0.36-15	NR	NR	NR	0.2-0.4
Incidental Ingestion	3	0.13	NR	NR	1	NR
Incidental Inhalation- Sprays	34	0.35-3.5	NR	NR	22	0.12
Incidental Inhalation- Powders	21	0.028-2.7*	NR	NR	6	0.12-0.2*
Dermal Contact	201	0.028-17.7	8	NR	18	0.000038-0.4
Deodorant (underarm)	2	0.4	NR	NR	NR	NR
Hair - Non-Coloring	8	0.2-1	1	NR	36	0.032-1
Hair-Coloring	NR	0.04-12	NR	NR	25	0.04-0.7
Nail	57	0.52-35	NR	NR	2	NR
Mucous Membrane	133	0.04-7.7	8	NR	6	0.057
Baby Products	2	0.2	NR	NR	NR	NR
	Polyacrylate-5		**Polyacrylate-15**		**Polyacrylate-16**	
	# of Uses	Conc. (%)	# of Uses	Conc. (%)	# of Uses	Conc. (%)
Totals/Conc. Range	3	NR	22	0.38	4	1-11.3
Duration of Use						
Leave-On	3	NR	NR	0.38	4	1-11.3
Rinse off	NR	NR	22	NR	NR	NR
Diluted for (bath) Use	NR	NR	NR	NR	NR	NR
Exposure Type						
Eye Area	NR	NR	NR	NR	4	1-4.5
Incidental Ingestion	2	NR	NR	NR	NR	11.3
Incidental Inhalation- Sprays	NR	NR	NR	NR	NR	NR
Incidental Inhalation- Powders	NR	NR	NR	0.38*	NR	NR
Dermal Contact	NR	NR	NR	0.38	4	1-4.5
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair - Non-Coloring	NR	NR	NR	NR	NR	NR
Hair-Coloring	NR	NR	22	NR	NR	NR
Nail	1	NR	NR	NR	NR	NR
Mucous Membrane	2	NR	NR	NR	NR	11.3
Baby Products	NR	NR	NR	NR	NR	NR

Table 7. Frequency and Concentration of Use According to Duration and Type of Exposure.[12,13]

	Polyacrylate-21	
	# of Uses	Conc. (%)
Totals*/Conc. Range	NR	0.7-0.9
Duration of Use		
Leave-On	NR	0.7-0.9
Rinse off	NR	NR
Diluted for (bath) Use	NR	NR
Exposure Type		
Eye Area	NR	0.9
Incidental Ingestion	NR	NR
Incidental Inhalation-Sprays	NR	NR
Incidental Inhalation -Powders	NR	0.7
Dermal Contact	NR	0.7-0.9
Deodorant (underarm)	NR	NR
Hair - Non-Coloring	NR	NR
Hair-Coloring	NR	NR
Nail	NR	NR
Mucous Membrane	NR	NR
Baby Products	NR	NR

NR = Not Reported; Totals = Rinse-off + Leave-on Product Uses.
*It is possible that these products may be powders, but it is not specified whether the reported uses are powders.
**It is possible that this product may be a spray, but it is not specified whether the reported use is a spray.
***Not specified whether a powder or a spray, so this information is captured for both categories of incidental inhalation
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.

Table 8. Carcinogenicity Studies/Reviews of Carcinogenic Potential on Copolymers/Monomers

Copolymer/Monomer	Test Protocol/Basis for Conclusion	Results/Conclusion
Polystyrene	Groups of Wistar rats. Subcutaneous implantation of various forms of polystyrene: smooth discs (47 rats); perforated discs (51 rats); rods, sphweres, and fibers (40 rats); and powder (number of rats not stated).	Sarcoma incidences: 37 of 47 rats (78.7%), 25 of 51 rats (49%), and 15 of 40 rats (37.5%). Powder did not induce sarcomas.[5,61]
Polystyrene	Wistar rats (from 3 different laboratory sources; number not stated).	Differences in incidence of local sarcomas (8% to 40%) found, depending on the animal strain.[5,62]
Styrene	Groups of Fischer 344 rats and B6C3F$_1$ mice (50 males, 50 females/species) in NTP oral carcinogenicity bioassay. Styrene (in corn oil, by gavage) 5 days per week at doses up to 2,000 mg/kg/day (rats) and 300 mg/kg/day (mice). Dosing for 78 weeks (rats: 1,000 and 2,000 mg/kg/day dose groups; mice: 150 and 300 mg/kg/day dose groups) and 103 weeks (rats: 500 mg/kg/day dose group)	No convincing evidence for carcinogenicity of styrene found in rats or mice of either sex.[63]
1,3-Butadiene	Groups of 50 male and 50 female B6C3F$_1$ mice in NTP inhalation carcinogenicity study. Exposure to air containing 625 ppm or 1,250 ppm 1,3-butadiene 5 days per week (6 h/day) for 60 or 61 weeks.	Clear evidence of carcinogenicity in male and female mice.[26]
1,3-Butadiene	Groups of 70 male and 70 female B6C3F$_1$ mice in NTP inhalation carcinogenicity study. Exposure to air containing 6.25, 20, 62.5, or 200 ppm 1,3-butadiene 5 days/week (6 h/day) for up to 2 years	Clear evidence of carcinogenicity in male and female mice.[64]
1,3-Butadiene	Groups of 90 male and 90 female B6C3F$_1$ mice in NTP inhalation carcinogenicity study. Exposure to 625 ppm 1,3-butadiene 5 days/week (6 h/day) for up to 2 years	Clear evidence of carcinogenicity in male and female mice.[64]
Styrene	Sufficient evidence of carcinogenicity from studies involving experimental animals. Limited evidence of carcinogenicity of styrene in humans based on studies of workers exposed to styrene that showed: (1) increased mortality from or incidence of cancer of the lymphohematopoietic system and (2) increased levels of DNA adducts and genetic damage in lymphocytes from exposed workers	According to the NTP, styrene reasonably anticipated to be a human carcinogen.[65]
Styrene	Limited evidence of carcinogenicity of styrene in humans and in experimental animals	According to IARC, styrene possibly carcinogenic to humans.[22]
Styrene		According to the the United States EPA, styrene possibly carcinogenic to humans.[66]
1,3-Butadiene	Unit cancer risk estimate of 0.08/ppm, based on linear modeling and extrapolation of human data	According to the United States EPA, 1,3-butadiene carcinogenic to humans by inhalation exposure.[67]
1,3-Butadiene	1,3-Butadiene causes cancer of the hematolymphatic organs. There is strong evidence that carciniogenicity of 1,3-butadiene in humans operates by a genotoxic mechanism that involves formation of reactive epoxides, the interaction of these direct-acting mutagenic epoxides with DNA, and resultant mutagenicity.	According to IARC, sufficient evidence for carcinogenicity of 1,3-butadiene in humans and in experimental animals.[68]

Table 8. Carcinogenicity Studies/Reviews of Carcinogenic Potential on Copolymers/Monomers

Copolymer/Monomer	Test Protocol/Basis for Conclusion	Results/Conclusion
Styrene/Butadiene Copolymer	Multi-plant cohort studies of male styrene/butadiene rubber workers	Significantly increased cancer risks, including risks of non-Hodgkin's lymphoma (NHL), NHL-chronic lymphocytic leukemia, and leukemia.[69,70]
Styrene/Butadiene Copolymer	Epidemiological information on styrene/butadiene copolymer workers	According to IARC, this epidemiological information suggests elevated risk for lymphato-hematopoietic malignancies.[5]
Polyacrylate	Cross-sectional respiratory survey of 164 workers exposed to polyacrylate dust for average of 20.7 years	No evidence of excess risk of lung cancer.[71]

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Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name:	Acrylic acid-styrene copolymer
Compound ID:	AG00BJB9
CAS Number:	25085-34-1
Indentified uses:	Laboratory chemicals, manufacture of chemical compounds
Company:	Angene
Phone:	81777290

2. HAZARDS IDENTIFICATION

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)
Acute toxicity, oral,(Category 4), H302
Skin corrosion/irritation,(Category 2), H315
Serious eye damage/eye irritation,(Category 2A), H319
Specific target organ toxicity, single exposure; Respiratory tract irritation,(Category 3), H335
For the full text of the H-Statements mentioned in this Section, see Section 16.

Pictogram

Signal Word warning

Hazard statements

H302	Harmful if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation

Precautionary statements

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes.Remove contact lenses,if present and easy to do. Continue rinsing.

Hazards not otherwise classified (HNOC) or not covered by GHS - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name:	Acrylic acid-styrene copolymer	
CAS Number:	25085-34-1	
Molecular Formula:	C11H12O2	
Molecular Weight:	176.2118	g/mol

4. FIRST AID MEASURES

Description of first aid measures

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance.Move out of dangerous area.

If inhaled
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact
Wash off with soap and plenty of water. Consult a physician.

In case of eye contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Most important symptoms and effects, both acute and delayed
The most important known symptoms and effects are described in the labelling (see section 2 or section 11)

Indication of any immediate medical attention and special treatment needed
no data available

5. FIREFIGHTING MEASURES

Extinguishing media Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special hazards arising from the substance or mixture
Carbon oxides, nitrogen oxides (NOx), Hydrogen bromide gas

Advice for firefighters
Wear self contained breathing apparatus for fire fighting if necessary.

Further information
no data available

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures
Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. For personal protection see section 8.

Environmental precautions
Do not let product enter drains.

Methods and materials for containment and cleaning up
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Reference to other sections
For disposal see section 13.

7. HANDLING AND STORAGE

Precautions for safe handling
Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Provide appropriate exhaust ventilation at places where dust is formed.
Normal measures for preventive fire protection.
For precautions see section 2.

Conditions for safe storage, including any incompatibilities
Room Temperature.
Keep in dry area.

Specific end use(s)
Apart from the uses mentioned in section 1, no other specific uses are stipulated

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters
Contains no substances with occupational exposure limit values.

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment
Eye/face protection
Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Body Protection
Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection
For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator.For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure
Do not let product enter drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance / Form:	liquid
Odor:	no data available
Odor Threshold:	no data available
pH:	no data available
Melting point:	80-120℃
Boiling point/range:	no data available
Flash point:	no data available
Evapouration rate:	no data available
Flammability:	no data available
Upper/lower flammability:	no data available
explosive limits:	no data available
Vapor pressure:	no data available
Vapour density:	no data available
Relative density:	no data available
Water solubility:	no data available
Partition coefficient:	no data available
Auto-ignition temperature:	no data available
Decomposition Temp:	no data available
log Pow:	no data available
Viscosity:	no data available
Explosive properties:	no data available
Oxidizing properties:	no data available

Other safety information no data available

10. STABILITY AND REACTIVITY

Reactivity:	no data available
Chemical stability:	Stable under recommended storage conditions.
Possibility of hazardous reactions	no data available
Conditions to avoid	no data available
Incompatible materials	no data available
Hazardous decomposition products	no data available
Other decomposition products:	no data available
In the event of fire:	see section 5

11. TOXICOLOGICAL INFORMATION

Acute toxicity:	Classified based on available data. For more details, see section 2
Skin corrosion/irritation:	Classified based on available data. For more details, see section 2
Serious eye damage/irritation	Classified based on available data. For more details, see section 2
Respiratory or skin sensitisation	Classified based on available data. For more details, see section 2
Germ cell mutagenicity	Classified based on available data. For more details, see section 2
Carcinogenicity:	
IARC:	No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
ACGIH:	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP:	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
OSHA:	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
Reproductive toxicity	
Specific target organ toxicity - single exposure	no data available
Specific target organ toxicity - repeated exposure	no data available
Aspiration hazard	no data available
Additional Information	no data available

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

Toxicity	no data available
Persistence and degradability	no data available
Bioaccumulative potential	no data available
Mobility in soil	no data available
Results of PBT and vPvB assessment	PBT/vPvB assessment not available as chemical safety assessment not required/not conducted
Other adverse effects	no data available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods	Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.
Contaminated packaging	Dispose of as unused product.

14. TRANSPORT INFORMATION

14.1 UN number

ADR/RID:	IMDG:	IATA-DGR:

14.2 UN proper shipping name

ADR/RID:	Not dangerous goods
IMDG:	Not dangerous goods
IATA:	Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID:	IMDG:	IATA-DGR:

14.4 Packaging group

ADR/RID:	IMDG:	IATA-DGR:

14.5 Environmental hazards

ADR/RID: -	IMDG: -	IATA-DGR: -

14.6 Special precautions for user

Further information :	No data available

15. REGULATORY INFORMATION

SARA 302:	No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313:	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
SARA 311/312 Hazards	Acute Health Hazard
Massachusetts Right To Know Components	No components are subject to the Massachusetts Right to Know Act.
Pennsylvania Right To Know Components	
New Jersey Right To Know Components	

California Prop. 65 Components	This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.

Acute Tox.	Acute toxicity
Eye Irrit.	Eye irritation
Skin Irrit.	Skin irritation
H302	Harmful if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Angene shall not be held liable for any damage resulting from handling or from contact with the above product. See invoice or packing slip for additional terms and conditions of sale.