Data Supplement

Methicones

MI

Priorities

CIR EXPERT PANEL MEETING
JUNE 8-9, 2020

Commitment & Credibility since 1976

Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Preethi S. Raj, Senior Scientific Writer/Analyst, CIR
Date: March 6th, 2020
Subject: Draft Amended Report on Dimethicone, Methicone, and Substituted-Methicone Polymers – Wave 2

Enclosed are three publicly-accessible materials presented by the Council which may further inform the CIR Working Group's upcoming decision regarding the addition of Simethicone as an ingredient to this Draft Amended Report. Furthermore, the information summarized below may elucidate whether inhalation toxicity is of concern for Simethicone, as it partially comprises Silica.

Two US Pharmacopeia monographs on silicon dioxide (*methic062020wave2_data1*) and colloidal silicon dioxide (*methic062020_data2*) describe the nature of synthethic amorphous silica, which the Council surmises is the variety of silica found in Simethicone. The first monograph describes the silica in silicon dioxide to be insoluble dissolved silica in a sodium silicate solution, which is either considered a silica gel or precipitated silica, based on how it is produced. The second monograph describes the silica in colloidal silicon dioxide to be a submicroscopic, fumed silica, produced during the vapor-phase hydrolysis of a silicon compound.

A recent guidance document from the Silicones Environmental, Health, and Safety Center (SEHSC; 2018) recommends that any aerosol formulation of a silicone-based material should have an aerodynamic particle size distribution ≥ 30 µm with no more than 1% of the particle mass being ≤ 10 µm (*methic062020wave2_data3*). The rationale provided for this recommendation is that inhaled particles 10 µm ≥ x ≤ 100 µm are not expected to pass beyond the nasopharyngeal region into the mucus-covered, ciliated, bronchial epithelium. Soluble particles, such as silicone in silicate gel, are expected to dissolve, while insoluble particles are either swallowed or expectorated.

Silicon Dioxide
SiO_2xH_2O

Anhydrous 60.08

» Silicon Dioxide is obtained by insolubilizing the dissolved silica in sodium silicate solution. Where obtained by the addition of sodium silicate to a mineral acid, the product is termed silica gel; where obtained by the destabilization of a solution of sodium silicate in such manner as to yield very fine particles, the product is termed precipitated silica. After ignition at 1000° for not less than 1 hour, it contains not less than 99.0 percent of SiO_2.

Packaging and storage— Preserve in tight containers, protected from moisture.

Labeling— Label it to state whether it is silica gel or precipitated silica.

Identification— Transfer about 5 mg to a platinum crucible, mix with about 200 mg of anhydrous potassium carbonate, ignite at a red heat over a burner for 10 minutes, and cool. Dissolve the melt in 2 mL of recently distilled water, warming if necessary, and slowly add 2 mL of ammonium molybdate TS: a deep yellow color is produced.

pH ⟨ 791 ⟩: between 4 and 8, in a slurry (1 in 20).

Loss on drying ⟨ 731 ⟩ **—** Dry it at 145° for 4 hours: it loses not more than 5.0% of its weight.

Loss on ignition ⟨ 733 ⟩ **—** Ignite about 1 g of it, previously dried and accurately weighed, at 1000° for not less than 1 hour: it loses not more than 8.5% of its weight.

Chloride ⟨ 221 ⟩ **—** Boil 5 g in 50 mL of water under a reflux condenser for 2 hours, cool, and filter. A 7-mL portion of the filtrate shows no more chloride than corresponds to 1.0 mL of 0.020 N hydrochloric acid (0.1%).

Sulfate ⟨ 221 ⟩ **—** A 10-mL portion of the filtrate obtained in the test for *Chloride* shows no more sulfate than corresponds to 5.0 mL of 0.020 N sulfuric acid (0.5%).

Arsenic, *Method I* ⟨ 211 ⟩ **—** Prepare the *Test Preparation* as follows. Transfer 4.0 g to a platinum dish, add 5 mL of nitric acid and 35 mL of hydrofluoric acid, and evaporate on a steam bath. Cool, add 5 mL of perchloric acid, 10 mL of hydrofluoric acid, and 10 mL of sulfuric acid, and evaporate on a hot plate to the production of heavy fumes. Cool, cautiously transfer to a 100-mL beaker with the aid of a few mL of hydrochloric acid, and evaporate to dryness. Cool, add 5 mL of hydrochloric acid, dilute with water to about 40 mL, and heat to dissolve any residue. Cool, transfer to a 100-mL volumetric flask, dilute with water to volume, and mix. A 25.0-mL portion of this solution meets the requirements of the test. The limit is 3 ppm.

Heavy metals, *Method I* ⟨ 231 ⟩ **—** Transfer 16.7 mL of the solution prepared for the test for *Arsenic* into a 100-mL beaker, and neutralize with ammonium hydroxide to litmus paper. Adjust with 6 N acetic acid to a pH of between 3 and 4. Filter, using medium-speed filter paper, wash with water until the filtrate and washings measure 40 mL, and mix. The limit is 0.003%.

Organic volatile impurities, *Method IV* ⟨ 467 ⟩: meets the requirements.

Residual solvents ⟨ 467 ⟩**:** meets the requirements.
(Official January 1, 2007)

Assay— Transfer about 1 g of Silica Gel to a tared platinum dish, ignite at 1000° for 1 hour, cool in a desiccator, and weigh. Carefully wet with water, and add about 10 mL of hydrofluoric acid, in small increments. Evaporate on a steam bath to dryness, and cool. Add about 10 mL of hydrofluoric acid and about 0.5 mL of sulfuric acid, and evaporate to dryness. Slowly increase the temperature until all of the acids have been volatilized, and ignite at 1000°. Cool in a desiccator, and weigh. The difference between the final weight and the weight of the initially ignited portion represents the weight of SiO_2.

Auxiliary Information— *Staff Liaison* : Catherine Sheehan, B.Sc., Scientist
Expert Committee : (EM105) Excipient Monographs 1
USP29–NF24 Page 3418
Pharmacopeial Forum : Volume No. 31(4) Page 1229
Phone Number : 1-301-816-8262

P

Colloidal Silicon Dioxide
SiO_2 60.08

Silica.
Silica [*7631-86-9*].

» Colloidal Silicon Dioxide is a submicroscopic fumed silica prepared by the vapor-phase hydrolysis of a silicon compound. When ignited at 1000° for 2 hours, it contains not less than 99.0 percent and not more than 100.5 percent of SiO_2.

Packaging and storage— Preserve in well-closed containers.

Identification—

A: Transfer about 5 mg to a platinum crucible, and mix with about 200 mg of anhydrous potassium carbonate. Ignite at a red heat over a burner for about 10 minutes, and cool. Dissolve the melt in 2 mL of freshly distilled water, warming if necessary, and slowly add 2 mL of ammonium molybdate TS to the solution: a deep yellow color is produced.

B: [*Caution—Avoid contact with o-tolidine when performing this test, and conduct the test in a well-ventilated hood.*] Place 1 drop of the yellow silicomolybdate solution obtained in *Identification* test *A* on a filter paper, and evaporate the solvent. Add 1 drop of a saturated solution of *o*-tolidine in glacial acetic acid to reduce the silicomolybdate to molybdenum blue, and place the paper over ammonium hydroxide: a greenish blue spot is produced.

pH ⟨ 791 ⟩ : between 3.5 and 5.5, in a 1 in 25 dispersion.

Loss on drying ⟨ 731 ⟩ **—** Dry it in a tared platinum crucible at 105° for 2 hours: it loses not more than 2.5% of its weight. Retain the dried specimen, in the crucible, for the test for *Loss on ignition*.

Loss on ignition ⟨ 733 ⟩ **—** Ignite the portion of Colloidal Silicon Dioxide, retained from the test for *Loss on drying*, at 1000 ± 25° to constant weight: the previously dried Colloidal Silicon Dioxide loses not more than 2.0% of its weight.

Arsenic, *Method I* ⟨ 211 ⟩ **—** Prepare the *Test Preparation* as follows. Transfer 2.5 g to a flask, add 50 mL of 3 N hydrochloric acid, and reflux for 30 minutes using a water condenser. Cool, filter with the aid of suction, and transfer the filtrate to a 100-mL volumetric flask. Wash the filter and flask with several portions of hot water, and add the washings to the flask. Cool, dilute with water to volume, and mix: a 15.0-mL portion of this solution, to which 3 mL of hydrochloric acid has been added, meets the requirements of the test, the addition of the 7 N sulfuric acid being omitted. The limit is 8 µg per g.

Organic volatile impurities, *Method IV* ⟨ 467 ⟩ : meets the requirements.

Residual solvents ⟨ 467 ⟩ **:** meets the requirements.
(Official January 1, 2007)

Assay— Transfer about 500 mg of Colloidal Silicon Dioxide to a tared platinum crucible, ignite at 1000 ± 25° for 2 hours, cool in a desiccator, and weigh. Add 3 drops of sulfuric acid, and add enough alcohol to just moisten the sample completely. Add 15 mL of hydrofluoric acid, and in a well-ventilated hood evaporate on a hot plate to dryness, using medium heat (95° to 105°) and taking care that the sample does not spatter as dryness is approached. Heat the crucible to a red color with the aid of a Bunsen burner. Ignite the residue at 1000 ± 25° for 30 minutes, cool in a desiccator, and weigh. If a residue remains, repeat the procedure, beginning with “add 15 mL of hydrofluoric acid.” The weight lost by the assay specimen, previously ignited at 1000 ± 25°, represents the weight of SiO_2 in the portion taken.

Auxiliary Information— *Staff Liaison* : Catherine Sheehan, B.Sc., Scientist
Expert Committee : (EM105) Excipient Monographs 1
USP29–NF24 Page 3419
Pharmacopeial Forum : Volume No. 31(4) Page 1232
Phone Number : 1-301-816-8262

American Chemistry Council | SEHSC Silicones Environmental, Health, and Safety Center

Recommendations for Aerosol Applications of Silicone-Based Materials

September 2001
Revised March 2018

This document provides information and recommendations relevant to formulating aerosol products containing silicone-based materials and explains the impact of aerodynamic particle size in aerosol product applications containing these silicone-based materials (ISO, 1995). Silicone-based materials may be safely used in industrial spray applications where exposure to aerosols can be minimized through appropriate industrial hygiene practices including engineering controls and use of personal protective equipment. The considerations and recommendations set forth in this document should be followed for aerosol applications, such as consumer spray applications, in which industrial hygiene practices are not available. It is recommended that if a silicone-based material or emulsion is being developed for an aerosol application, the developer should pay particular attention to the aerodynamic particle size distribution (MMAD) that will be generated and consider the potential for enhanced toxicity resulting from the presence of other components in the aerosol formulation.

General Recommendations

When considering a consumer aerosol application using any silicone-based material, regardless of the method of aerosol generation, the aerodynamic particle size distribution (expressed as the Mass Median Aerodynamic Diameter; MMAD) should be 30 μm or greater with no more than 1% of the particle mass having an aerodynamic diameter of 10 μm or less. By following this recommendation, virtually all aerosol particles will be deposited in the nasopharyngeal region with substantially less deposited in the tracheobronchial (conducting airways) or alveolar (gas exchange) regions. If an aerosol application results in a particle size distribution with more than 1% of the aerosol mass with a MMAD of 10 μm, or less, further evaluation of the inhalation toxicity potential (*e.g.* acute inhalation toxicity test) should be considered.

Potential Effects

The physical properties of an oil or fat aerosol may lead to a number of potentially serious health effects following inhalation exposure. Chemical pneumonitis, lipoid pneumonia, and petroleum distillate pneumonitis are all terms that describe pulmonary (deep lung) tissue damage, edema, fibrosis, or other inflammatory changes in the lungs. These changes can be induced by inhalation of an oil or fat aerosol such as a silicone-based material into the alveolar region of the lung. Regional release of endogenous lipid (fatty) or oil within the lung, as occurs in certain disease

700 2nd Street, NE, Washington, DC 20002

states, also can produce a pneumonitis reaction. Ostensibly, this damage is not due to a specific mechanism of chemical toxicity but rather is driven by a physical disturbance of the alveolar lining and subsequent attempts by inflammatory cells within the lung to resolve the lesion.

Considerations

Physical characteristics, such as surface tension/activity and spreadability, contribute to the similarity between silicone-based materials and other oils or fats, and the potential for pulmonary effects for aerosols of MMAD <30 μm. Silicone-based materials have a wide variety of uses including applications for consumer use. It is recommended that if a silicone-based material is being developed for an aerosol application, the developer should pay particular attention to the aerodynamic particle size distribution (MMAD) that will be generated and also consider the potential for respiratory effects resulting from the presence of other components in the aerosol formulation.

APPENDIX

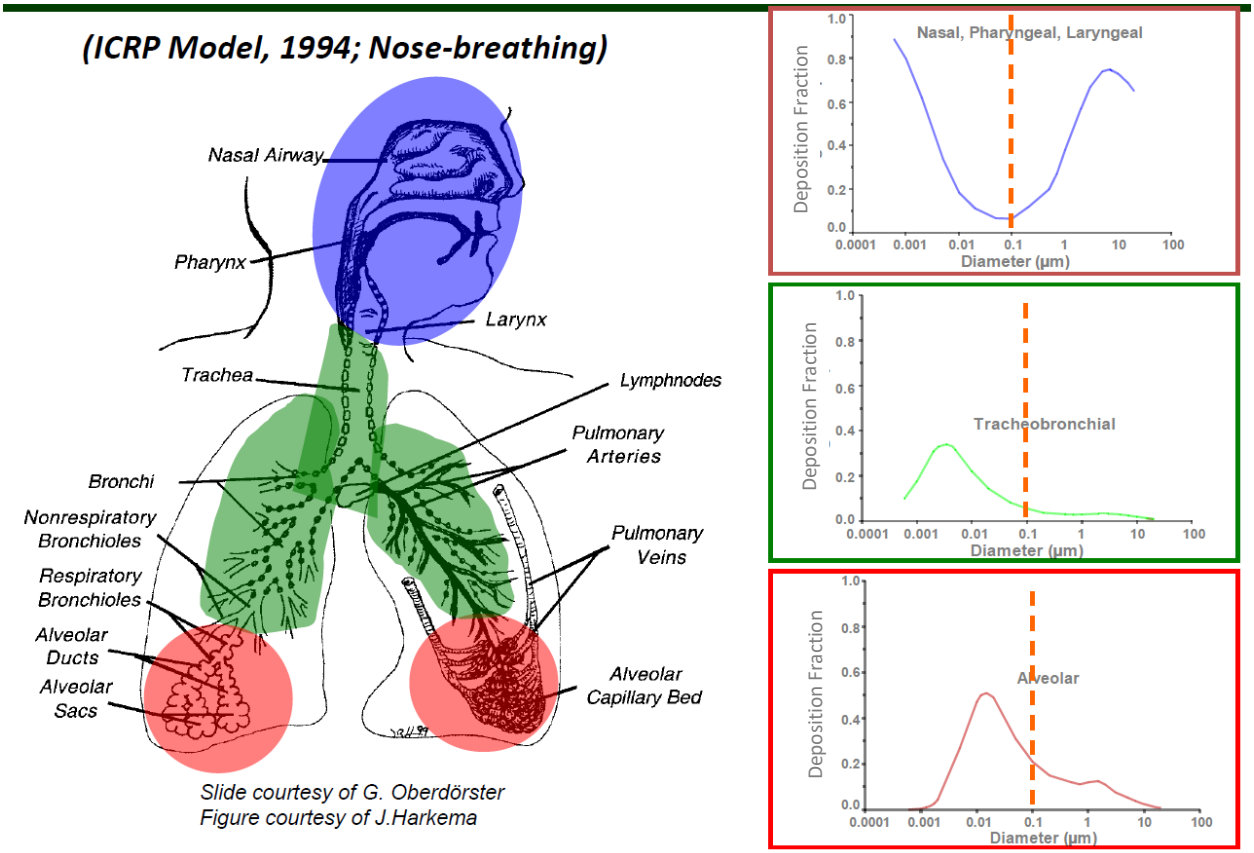
What Are Aerosols?

Aerosols are often described as multiphase systems of solid (fumes or dusts) or liquid (mists) particulates suspended in air or other gases (Rothe, *et al.* 2011). The particles remain suspended because they are small and, therefore, do not fall (or sediment) rapidly under the force (or pull) of gravity. Many chemicals can be inhaled as aerosols. Just as liquid and solid aerosol particles can sediment in air, they can also be deposited in the upper and lower respiratory tract, if inhaled. The aerodynamic diameter of a particle determines the location and efficiency of deposition within the upper and lower respiratory tract (Fig. 1). Any aerosol can be described based on its particle size distribution and penetration of these particles in the various regions of the respiratory tract (Nieboer et al. 2005). The Inhalable Aerosol Fraction is that fraction of aerosol particles that can enter the body through the nose and/or mouth during breathing. This fraction corresponds to particles with aerodynamic diameter (d_{ae}) $\leq$ 100 µm. This aerosol fraction may be relevant to health effects anywhere in the respiratory tract. The Thoracic Aerosol Fraction (d_{ae} < 30 µm) is a sub-fraction of the Inhalable Fraction composed of particles that can penetrate into the tracheo-bronchial/alveolar region of the lung. The Respirable Aerosol Fraction (or alveolar fraction) is the sub-fraction of inhaled particles (d_{ae} < 10 µm) that penetrates into the alveolar (gas exchange) region of the lung.

The regional deposition, clearance, and absorption of aerosols in the respiratory tract depend on many factors including solubility, reactivity, and aerodynamic diameter (MMAD). (Rothe, *et al*., 2011, Bakand, *et al.*, 2005, WHO, 1999). The aerodynamic diameter of an aerosol particle is defined as the diameter of a hypothetical, smooth sphere of unit density (1 g/cm^3) that has the same gravitational settling velocity as the droplet in calm air, regardless of its actual geometric size, shape and density (WHO, 1999, Phalen and Oldem, 2006). The following are just a few references that can be consulted for information on methods for determining the particle size distribution for an aerosol: Vincent, 1995; Hinds, 1982; FEA European Aerosol Federation, 2009; Kulkarni and Willeke, 2011.

Brown *et al.* (2013) have determined the size of respirable particle fractions for both adults and children. They estimated the fraction of inhaled particles penetrating beyond the larynx (0.5-20 µm aerodynamic diameter, based on experimental data) and ciliated airways (based on a mathematical model) for an adult male, adult female, and a 10-year old child during typical daily activities and breathing patterns and found that the aerodynamic diameter needed to be <3 µm for adults and <5 µm for children in order to pass beyond the larynx. Similarly, the US National Institutes of Environmental Health Sciences, citing Johnson and Vincent (2003), has stated, "Particles in the size of range of 10 to 100 µm are unable to make the turns and impact on the nasal hairs, nasal mucosa, or mucus-covered ciliated epithelium in the bronchi and bronchioles. Soluble particles simply dissolve, while insoluble particles are transported up the conducting airways by the ciliated epithelium and swallowed or expectorated." The Cosmetic Ingredient Review Precedent on Aerosols (2012) concludes the same in that "there is broad scientific consensus that the probability of penetration of droplets/particles with d_{ae} >10 µm into the alveolar region is essentially zero."

Figure 1. Impact of aerodynamic particle size on regional deposition in humans



References

Bakand, S, Winder C, Khalil C, and Hayes A. 12-1-2005. Toxicity assessment of industrial chemicals and airborne contaminants: transition from in vivo to in vitro test methods: a review. *Inhal.Toxicol*. 17(13):775-787.

Brown, J.S., Gordon, T., Price, O., Asgharian, B. (2013). Thoracic and respirable particle definitions for human health risk assessment. Particle and Fibre Toxicology, 10:12.

Cosmetic Ingredient Review - Precedents, Aerosols. 9/2012. http://www.cir-safety.org/sites/default/files/aeroso092012rep_0.pdf

FEA European Aerosol Federation. 2009. Guide on Particle Size Measurement from Aerosol Products.

Hinds, William C. 1982. *Aerosol Technology*. New York: John Wiley and Sons.

International Commission on Radiological Protection (ICRP). 1994. *Human Respiratory Tract Model for Radiological Protection,* International Commission on Radiological Protection Publication 66, Pergamon Press, New York.

International Organization for Standardization (ISO): Air Quality – Particle Size Fraction Definitions for Health-Health Related Sampling, ISO 7708:1995. ISO, Geneva (1995)

Johnson, D., & Vincent, J. (2003). Sampling and Sizing of Airborne Particles. In The occupational Environment: Its Evaluation, Control and Management, by Salvatore R DiNardi, 202-223. Virginia: American Industrial Hygiene Association

Kulkarni, P. Baron, PA, Willeke, K., 2011. *Aerosol Measurement: Principles, Techniques, and Applications, 3rd Edition.* Wiley

Nieboer, E., Thomassen, Y., Chashchin, V., Odland, J.O. 2005. Occupational exposure assessment of metals. JEM 7: 411-415.Phalen, RF and Oldham MJ. Aerosol dosimetry considerations. *Clin Occup Environ Med*. 2006;5(4):773-784.

Rothe, H, Fautz R, Gerber E, Neumann L, Rettinger K, Schuh W, and Gronewold C. 8-28-2011. Special aspects of cosmetic spray safety evaluations: Principles on inhalation risk assessment. *Toxicol Lett*. 205(2):97-104.

Vincent, James, H. 1995. *Aerosol Science for Industrial Hygienists.* New York: Elsevier Science.

World Health Organization (WHO). 1999. Hazard Prevention and Control in the Work Environment: Airborne Dust. Geneva, Switzerland. Report No. WHO/SDE/OEH/99.14. pp. 1-246.

Cosmetic Ingredient Review

Commitment & Credibility since 1976

Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Christina L. Burnett, Senior Scientific Writer/Analyst, CIR
Date: March 6th, 2020
Subject: Draft Amended Safety Assessment on Methylisothiazolinone – Wave 2

Enclosed is the concentration of use survey results for Methylisothiazolinone as a stand-alone ingredient (*MI062020wave2_data*). The updated Use Table is below. The maximum concentration of use range for Methylisothiazolinone in 2020 is 0.000002% - 0.00975%. The concentration of use for products containing Methylisothiazolinone that may be incidentally inhaled is 0.00095% in hairsprays.

Table 1. Frequency and concentration of use according to duration and type of exposure for methylisothiazolinone.

	# of Uses	*Max Conc of Use (%)*	*# of Uses*	*Max Conc of Use (%)*
	2019[1]	**2020[2]**	**2014[3]**	
Totals†	**915**	**0.000002-0.00975**	**745**	**0.000000035-0.01**
Duration of Use				
Leave-On	559	0.00019-0.009	478	0.000000035-0.01
Rinse Off	345	0.000002-0.00975	260	0.00000025-0.01
Diluted for (Bath) Use	11	0.00023-0.009	7	0.0002-0.01
Exposure Type				
Eye Area	28	NR	22	0.00019-0.01
Incidental Ingestion	1	NR	1	0.0048
Incidental Inhalation-Spray	3; 278[a]; 168[b]	0.00095	3; 268[a]; 114[b]	0.00018-0.01; 0.0002-0.01[a]
Incidental Inhalation-Powder	168[b]	NR	114[b]	NR
Dermal Contact	679	0.000002-0.009	544	0.000000035-0.01
Deodorant (underarm)	NR	NR	NR	0.0095
Hair - Non-Coloring	224	0.0001-0.00975	190	0.000004-0.01
Hair-Coloring	NR	0.00001-0.008	NR	0.000056-0.0095
Nail	3	NR	5	0.0002-0.006
Mucous Membrane	124	0.000051-0.009	103	0.0000009-0.01
Baby Products	5	0.0003	6	0.0002-0.0075

NR = Not reported

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

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

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

References

1. US Food and Drug Administration (FDA) Center for Food Safety & Applied Nutrition (CFSAN). 2019. Voluntary Cosmetic Registration Program (VCRP) - Frequency of Use of Cosmetic Ingredients. College Park, MD Obtained under the Freedom of Information Act from CFSAN; requested as "Use Data Methylisothiazolinone When Used in Cosmetics Without Methylchloroisothiazolinone" October 11, 2019; received November 11, 2019.

2. Personal Care Products Council. 2020. Concentration of Use by FDA Product Category: Methylisothiazolinone (used without Methylchloroisothiazolinone). Unpublished data submitted by Personal Care Products Council

3. Burnett CL, Boyer I, Bergfeld WF, et al. Amended Safety Assessment of Methylisothiazolinone as Used in Cosmetics. *Int J Toxicol.* 2019;38(Suppl 1):70S-84S.

Concentration of Use by FDA Product Category – Methylisothiazolinone (used without Methylchloroisothiazolinone)

Product Category	Maximum Concentration of Use
Baby shampoos	3 ppm
Bath oils, tablets and salts	90 ppm
Bubble baths	2.3 ppm
Other bath preparations	3.2 ppm
Hair conditioners	2.6-97.5 ppm
Hair sprays Aerosol	 9.5 ppm
Rinses (non-coloring)	2.6-40 ppm
Shampoos (non-coloring)	1-90 ppm
Other hair preparations (noncoloring)	1.9-90 ppm
Hair dyes and colors	0.1-80 ppm
Hair rinses (coloring)	2.6 ppm
Hair shampoos (coloring)	2.2-3.8 ppm
Hair lighteners with color	0.2 ppm
Bath soaps and detergents	0.51-75.5 ppm
Shaving cream	73.4 ppm
Skin cleansing (cold creams, cleansing lotions, liquids and pads)	0.02-82.8 ppm
Other skin care preparations	1.9 ppm

Information collected in 2019-2020

Table prepared: February 21, 2020

Cosmetic Ingredient Review

Commitment & Credibility since 1976

Memorandum

Date: March 6th, 2020

From: Bart Heldreth, Ph.D., Executive Director, Cosmetic Ingredient Review

To: All Stakeholders

Re: 2021 Draft Priority List – Update – Wave 2

For organic chemicals, the list of lead ingredients (presented in the initial meeting materials) was forwarded to the newly convened CIR Grouping/Clustering Working Group for consideration. The Working Group has since provided input on such review groupings. Herein, in highlighting, please find my representation of their input.

1620 L Street, NW Suite 1200, Washington, DC 20036
(Main) 202-331-0651 (Fax) 202-331-0088
(Email) cirinfo@cir-safety.org (Website) www.cir-safety.org

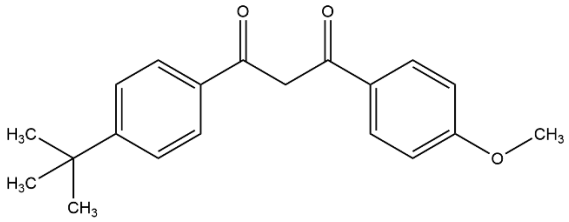
2021 Draft Priorities Groupings for New Reports

Proposed 2021 Reports – per FOU

Butyl Methoxydibenzoylmethane

FOU = 5128

Definition: Butyl Methoxydibenzoylmethane is the substituted aromatic compound that conforms to the structure:



Reported **Functions**: Light Stabilizers; Sunscreen Agents

Notes: *CAS No. 70356-09-1. While this ingredient is used as an OTC active ingredient (as a sunscreen; drug name = Avobenzone), only 49 uses are reported in the VCRP under its drug name (compared to 5128 uses reported under its cosmetic ingredient name). The Expert Panel has previously assessed the safety of a number of ingredients as light stabilizers (which are also reported as sunscreen agents; e.g., cosmetic ingredient, Benzophenone-3 = OTC sunscreen (drug), oxybenzone).*

Grouping proposal/clustering:

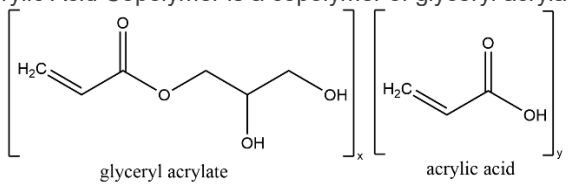
1. ***Pongamol (CAS No. 484-33-3) – fragrance only – but structurally related*** **1**
2. ***Isopropyl Dibenzoylmethane (CAS No. 63250-25-9) – light stabilizer*** **-**

Glyceryl Acrylate/Acrylic Acid Copolymer & Glyceryl Polymethacrylate

FOU = 519

FOU = 364

Definition: Glyceryl Acrylate/Acrylic Acid Copolymer is a copolymer of glyceryl acrylate and Acrylic Acid.



Reported **Functions**: Humectant; Viscosity Increasing Agents – Aqueous; Film Formers

Notes: *The Panel recently (2018) concluded that 126 acrylates copolymers are safe (e.g., Acrylates Copolymer or Ethylene/Acrylic Acid Copolymer).*

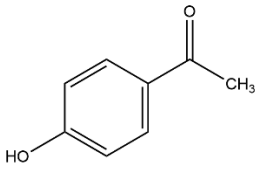
Grouping/clustering proposal (in addition to the 2 above):

1. ***Caprylyl Glycol/Glycerin/Polyacrylic Acid Copolymer – humectant*** **-**

Hydroxyacetophenone

FOU = 409

Definition: Hydroxyacetophenone is the organic compound that conforms to the formula:



Reported **Functions**: Antioxidants; Skin-Conditioning Agents - Miscellaneous

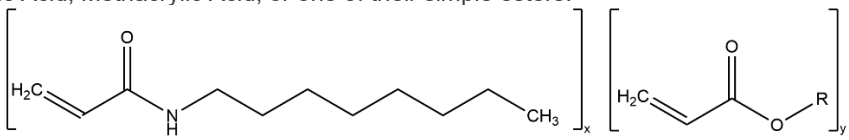
Notes: CAS No. *99-93-4*

Grouping/clustering proposal: None

Acrylates/Octylacrylamide Copolymer

FOU = 361

Definition: Acrylates/Octylacrylamide Copolymer is a copolymer of octylacrylamide and one or more monomers consisting of Acrylic Acid, Methacrylic Acid, or one of their simple esters.



Octylacrylamide "Acrylates"

wherein "R" is hydrogen, methyl, ethyl, propyl, or butyl

Reported **Functions**: Film Formers; Hair Fixatives

Notes: *CAS No. 129702-02-9. The Panel has previously assessed the safety of some acrylamide copolymers and found them to be safe or safe with qualifications.*

Grouping/clustering proposal:

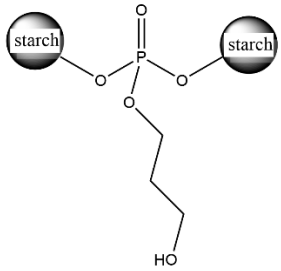
1.	*Acrylamide/Sodium Acrylate Copolymer (25085-02-3; 25987-30-8)*	**36**
2.	*Acrylates/Acrylamide Copolymer (9003-06-9)*	**3**
3.	*Acrylates/t-Butylacrylamide Copolymer*	**11**
4.	*Acrylates/Methacrylamide Copolymer*	**1**
5.	*AMP-Acrylates/C1-18 Alkyl Acrylate/C1-8 Alkyl Acrylamide Copolymer*	**2**
6.	*AMP-Acrylates/C1-18 Alkyl Acrylate/C1-8 Alkyl Acrylamide/ Hydroxyethylacrylate Copolymer*	**-**
7.	*t-Butylacrylamide/Dimethylacrylamide/PEG-14 Diacrylate Crosspolymer*	**-**
8.	*Butyl Acrylate/Isopropylacrylamide/PEG-18 Dimethacrylate Crosspolymer*	**-**
9.	*Corn Starch/Acrylamide/Sodium Acrylate Copolymer*	**8**
10.	*Dimethyl Acrylamide/Hydroxyethyl Acrylate/Methoxyethyl Acrylate Copolymer*	**6**
11.	*Dimethyl Acrylamide/Lauryl Methacrylate Copolymer (103479-14-7)*	**-**
12.	*Potassium Acrylates/Acrylamide Copolymer*	**-**
13.	*Sodium Acrylate/Hydroxyethyl Acrylamide Copolymer*	**-**
14.	*Starch/Acrylates/Acrylamide Copolymer*	**-**
15.	*Acrylamide/Ammonium Acrylate Copolymer (26100-47-0)*	**14**

Other polyacrylamides previously assessed by the Panel include*: Polyacrylate-2 (31759-42-9), Polyacrylamide (9003-05-8), and Acrylamide/Sodium Acryloyldimethyltaurate Copolymer (38193-60-1).*

Hydroxypropyl Starch Phosphate

FOU = 353

Definition: Hydroxypropyl Starch Phosphate is the hydroxypropyl ether of Distarch Phosphate.



Reported **Functions**: Antiacne Agents; Chelating Agents; Skin-Conditioning Agents - Miscellaneous

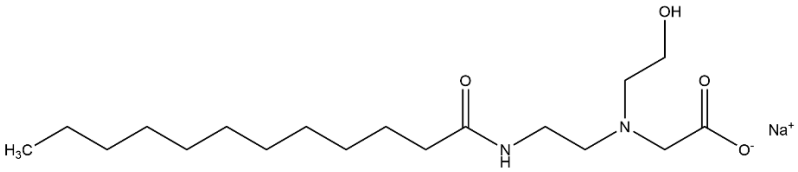
Notes: *CAS Nos. 113894-92-1, 39346-84-4, 53124-00-8. The Panel has previously assessed modified starches (e.g. Starch Hydroxypropyl Trimethylammonium Chloride), but not with phosphate groups.*

Grouping/clustering proposal: *Sodium Hydroxypropyl Starch Phosphate (221355-22-2; FOU=33), Distarch Phosphate (55963-33-2; FOU=125), Distarch Phosphate Acetate (68130-14-3; FOU not reported), and Sodium Dimaltodextrin Phosphate (no CAS No.; FOU not reported)*

Sodium Lauroamphoacetate

FOU = 344

Definition: Sodium Lauroamphoacetate is the amphoteric organic compound that conforms generally to the structure:



Reported **Functions**: Hair Conditioning Agents; Surfactants - Cleansing Agents; Surfactants - Foam Boosters

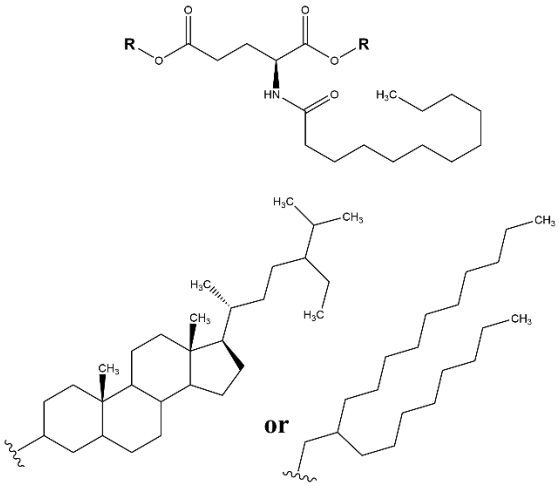
Notes: *CAS Nos. 68608-66-2, 156028-14-7, 66161-62-4. The Panel previously assessed the safety of the sodium salts of Cocoamphoacetate, Cocoamphopropionate, Cocoamphodiacetate, and Cocoamphodipropionate, and, found these to be safe as used. The only structural difference between Sodium Cocoamphoacetate and Sodium Lauroamphoacetate is the length(s) of the amide chain. The amide chain-lengths in Sodium Cocoamphoacetate are the results of derivation from coconut fats (i.e. a mixture of lengths, 6 – 18 carbons long (only the even numbers)), while the amide chain for Sodium Lauroamphoacetate is lauramide (12 carbons).*

Grouping/clustering proposal: None, unless rereviewed with previously reviewed amphoacetate(s).

Phytosteryl/Octyldodecyl Lauroyl Glutamate

FOU = 313

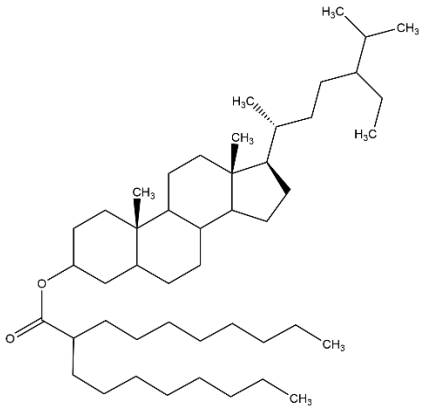
Definition: Phytosteryl/Octyldodecyl Lauroyl Glutamate is the mixed ester of phytosterol and Octyldodecanol with Lauroyl Glutamic Acid.



Reported **Functions**: Skin-Conditioning Agents - Occlusive

Notes: *CAS No. 220465-88-3. The Panel has previously assessed the safety of phytosterols (e.g., Dihydrophytosteryl Octyldecanoate) and found such ingredients to be safe as used. The Panel has also previously assessed the safety of sodium lauroyl glutamate, and found it to be safe when formulated to be non-irritating.*

Dihydrophytosteryl Octodecanoate:



Dihydrophytosteryl Octyldecanoate

Grouping/clustering proposal: *Phytosteryl/Behenyl/ Octyldodecyl/Isostearyl Lauroyl Glutamate (no CAS No.; FOU=5) and Phytosteryl/Behenyl/Octyldodecyl Lauroyl Glutamate (no CAS No.; FOU=77).*