
Safety Assessment of Borosilicate Glasses as Used in Cosmetics

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The 2012 Cosmetic Ingredient Review Expert Panel members are: Chairman, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; Ronald A Hill, 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 F. Alan Andersen, Ph.D. This report was prepared by Lillian C. Becker, Scientific Analyst/Writer.

ABSTRACT

The Cosmetic Ingredient Review Expert Panel (the Panel) reviewed the safety of calcium sodium borosilicate, calcium aluminum borosilicate, calcium titanium borosilicate, silver borosilicate, and zinc borosilicate as used in cosmetics. These borosilicate glasses function mostly as bulking agents. Available animal and human data related to these ingredients were considered, along with data from a previous safety assessment of magnesium silicates. The similar structure, properties, functions and uses of these ingredients enabled grouping them and using the available toxicological data to assess the safety of the entire group. Data submitted on calcium borosilicate, which is not a cosmetic ingredient, are also included in this report as additional support for the safety of borosilicate glass ingredients. The Panel concluded that borosilicate glasses are safe as cosmetic ingredients in the practices of use and concentration as given in this safety assessment.

INTRODUCTION

The borosilicate glass ingredients used in cosmetics include:

- calcium sodium borosilicate,
- calcium aluminum borosilicate,
- calcium titanium borosilicate,
- silver borosilicate, and
- zinc borosilicate.

These ingredients function in cosmetics mostly as bulking agents, but also are used as abrasives, preservatives, and skin-conditioning agents-miscellaneous.

The Cosmetic Ingredient Review (CIR) Expert Panel previously reviewed the related ingredients silica, alumina magnesium metasilicate, aluminum calcium sodium silicate, aluminum iron silicates, hydrated silica, and sodium potassium aluminum silicate.¹ These ingredients were determined to be safe in the present practices of use and concentration. Data supporting the safety of silica and related silicate salts as used in cosmetics included single dose toxicity, where, for example, the acute dermal NOEL for silica was > 2 g/kg for rabbits, repeated-dose studies, genotoxicity studies, reproductive and developmental toxicity studies, and clinical and animal irritation and sensitization studies. Data were available regarding silicosis, but these data were not relevant to the amorphous silica ingredients under review.

The Panel also reviewed the safety of various silicates and silicate clays used in cosmetics.² These ingredients are not significantly toxic in single-dose or repeated-dose studies, except that inhalation toxicity is readily demonstrated. Skin irritation and sensitization studies supported the safety of these ingredients, as did ocular irritation studies. The risk of pulmonary damage was clearly affected by particle size, fiber length, and concentration. The Panel considered that any spray containing these solids should be formulated to minimize their inhalation. With this admonition to the cosmetics industry, the CIR Expert Panel concluded that these ingredients are safe as currently used in cosmetic formulations.

Data on the related compound calcium borosilicate, which is not an ingredient in the *International Cosmetic Ingredient Dictionary and Handbook*,³ are included since this chemical is similar to the ingredients under review and the data supplement the few toxicity data available on the ingredients covered in this report.

CHEMISTRY

Definition

The CAS numbers, definitions, and functions for the 5 ingredients in this literature review are provided in Table 1.

Borosilicate glass is frequently referred to as vitreous silica and consists of a network of SiO₄ tetrahedra and metal cations.⁴ Borosilicates display heterogeneity of structure, with submicroscopically small volumes of ordered structure, but a lack of long-range order.

Physical and Chemical Properties

Physical and chemical properties are provided in Table 2.

One manufacturer reported that calcium aluminum borosilicate, calcium sodium borosilicate or calcium titanium borosilicate all were sold under the same product names, further designated as low alkali or as extra corrosion resistant.⁵ The glass flakes were highly planar platelets with very smooth surfaces and were transparent. The “apparent” density of the “low-alkali” borosilicate glass was reported to be 0.09 g/cm³ and real density to be 2.6 g/cm³. The melt temperature for both types of borosilicates was reported to be 930 - 1020°C. The glass composition (Table 3) may vary from batch to batch. These products are reported to be stable.

The chemical composition of calcium sodium borosilicate was reported to be: SiO₂, 52%; Na₂O, 0.3%; CaO, 22.5%; MgO, 1.2%; Al₂O₃, 14.5%; Fe₂O₃, 0.2%; K₂O, 0.2%, and B₂O₃, 8.6% (Table 3).⁶

The borosilicate in a cosmetic was described in a patent document as comprising a cosmetic grade flaky glass constituted of components comprising, by weight, at least 52% alkali metal oxide.⁷ The flaky glass may be unmodified, surface-coated (silicone), or complexed (titania and rare metal, ultramarine, or other pigments).

One manufacturer reported that its calcium aluminum borosilicate product consists of microspheres instead of flakes.^{6,8}

The coordination of the boron network cations readily varied from 3 to 4 depending on composition and temperature, in turn varying the properties.⁴ There were also large differences caused by varying the size and charge of the "network modifier" cations (e.g., Na⁺ vs. Ca²⁺), B/Si ratio, and Al content.

Borosilicates generally are chemically unreactive and of high dielectric strength.⁴ Chemical analyses of samples of borosilicates of different compositions showed that B₂O₃ evaporation was practically negligible.

CALCIUM BOROSILICATE

The melting point of calcium borosilicate is >1540°C, its specific gravity is 2.65, and it has a water solubility of 0.035 g/L.⁹ It is reported to be 100% pure, chemically stable, and unreactive.

Particle Size

A manufacturer reported that their borosilicate glass particles are flakes that are 50 nm – 5 µm in thickness with a particle size of 15 – 350 µm.⁵ For the low-alkali borosilicate glass, the particle size distribution is stated as 1000 – 300 µm, 10% or less; 300 – 50 µm, 65% or more; and < 50 µm, 25% or less. The product may also be milled to have a specific size range of 4 – 65 µm. For the low corrosion resistant borosilicate glass, the particle size distribution is specified as being the same as the low alkali borosilicate.

In a product designed for cosmetic formulations, the calcium sodium borosilicate flakes had a geometric particle size of 9 – 13 µm.⁸ The size distribution is 3 – 6 µm 10%; 8 – 12 µm, 50%; and 16 – 23 µm, 90%.

In cosmetic applications, calcium aluminum borosilicate is used as a substrate for metal oxide colors.¹⁰ When coated with the colors, the particle size is reported to be 20 – 200 µm.

The borosilicate in a cosmetic was reported to have an average particle diameter of 1-100 µm, and an aspect ratio (average thickness dividing the average particle diameter) of ≥ 10 (in comparison to a value of 1 for a sphere).⁷

Manufacturers report supplying calcium aluminum borosilicate in sphere form with a mean diameter of 11.7 µm.^{6,8}

CALCIUM BOROSILICATE

Calcium borosilicate was reported to be a fine, white, odorless powder with a particle size range of the flakes of 3.4 – 4.2 µm.⁹

Method of Manufacture

Borosilicate powder is prepared by the rotary method where glass flake is produced from melting a batch of raw material by electricity in a furnace.⁵ Once molten, the glass is poured into a spinning cup. Centrifugal force causes the glass to leave the cup as a thin film. This film is broken into flakes. These flakes are then collected downstream if the product is classified as unmilled (large particle size). In further downstream processing, the flake is passed through a hammer mill if the product is to be classified as milled (smaller particle size). For micronized glass flake, an opposed jet mill is used.

Borosilicate glasses may also be prepared by the wet-chemical method.⁴ Reagent-grade metal salts (except for sodium and calcium) are introduced as nitrates, boron as boric acid and silicon as a colloidal solution of SiO₂.

The preparation of borosilicate glasses may also be by the sol-gel method, which results in reproducible properties.⁴ In this method HBO₃ is dissolved in the colloidal SiO₂ sol. A second solution of all the other glass constituents, such as nitrates, is then added. After partial evaporation, the sol sets to a gel, the gel is dried at 200°C for 16 h, which usually results in a friable product that is ball milled. This results in a fine powder in which all elements are intimately mixed. This powder is melted in a furnace to a bubble-free glass for 2 h at temperatures varying from 800 to 1400°C (depending on the composition of the glass).

Calcium aluminum borosilicate is manufactured by placing finely divided sodium tetrahydrate pentahydrate (80 g), quartz (100 g), kaolin (180 g) and wollastonite (40 g) as a dry mix into a small mixer then stirred at low speed.¹¹ Water is added slowly until the mixture forms a crumb. The crumb was heated at 1000°C until completely dry. The product is placed in a furnace and heated at a rate of 100°C/minute up to a maximum of 1500°C where the temperature is held for 90 min. The product is then allowed to cool to ambient temperature in the furnace, removed, and broken up with a hammer. The resulting composition is reportedly opaque with a creamy-white color and particulate form.

Silver borosilicate is prepared through introduction of Ag₂O during the melting process.¹²

Impurities

One manufacturer reported heavy metal impurities in calcium sodium borosilicate that included lead (<10ppm), arsenic (<2 ppm), and mercury (<1 ppm).⁸

A safety data sheet reports that calcium aluminum borosilicate has no free SiO₂; all components are amorphous/non-crystalline.⁶

Another manufacturer reported that a sample of calcium aluminum borosilicate contained lead (21.8 mg/kg) and barium (63.5 mg/kg).⁵ Arsenic, antimony, mercury, cadmium, chromium, or nickel were below the detection limit of 2 mg/kg.

USE **Cosmetic**

Data on ingredient usage are provided by industry to the Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) and a survey conducted by the Personal Care Products Council (Council) collected maximum use concentrations for ingredients in this group (Table 4).^{13,14} Calcium sodium borosilicate was reported to be used in 751 cosmetic products with a range of maximum concentrations of 0.0001% – 97%. Of these, 740 products were leave-on products (including 397 lipsticks with a maximum concentration of 2% - 10%; body sprays at 0.5% - 0.6%; and face powders at 4% - 97%). There were 11 rinse-off products with maximum concentrations of 0.05% - 11%. Calcium aluminum borosilicate was used in 717 cosmetic products with a maximum range of 0.001% - 33%. Of these 668 were leave-on products (including 320 lipsticks at 2% - 8%; eye shadow at 0.001% - 33%; body sprays at 0.1%; and aerosol hair color sprays at 0.08%), 48 rinse-off products with a maximum range of 0.03% - 6%; and 1 diluted for bath product (no concentration of use reported). Calcium titanium borosilicate was reported to be used in 1 eyeshadow at a maximum of 6%. There were no reported uses in the VCRP or use concentrations in the Council survey for silver borosilicate or zinc borosilicate.^{13,14}

Calcium sodium borosilicate and calcium aluminum borosilicate were reported to be used in body sprays and aerosol hair color sprays up to 0.8% and face powders up to 97%. In practice, 95% to 99% of the droplets/particles released from cosmetic sprays have aerodynamic equivalent diameters >10 µm. 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.^{15,16}

Non-Cosmetic

Borosilicates are used for laboratory glassware, household cooking ware, industrial piping, bulbs for hot lamps and electronic tubes of high wattage such as X-ray tubes.⁴ Multi-component borosilicate glasses have many applications, such as fiber reinforcements in composites, in flat-panel display screens for computers and cell phones, and in nuclear waste sequestration.¹⁷ Borosilicate glass impregnated with silver has antibacterial and anti-algal uses.^{18,19}

TOXICOKINETICS

There were no toxicokinetics data available for the cosmetic ingredients in this report.

TOXICOLOGICAL STUDIES

Acute Toxicity

Dermal – Non-Human

CALCIUM BOROSILICATE

The dermal LD₅₀ of calcium borosilicate (moistened with distilled water and applied to ~20% of the body under occlusion; clipped and intact or abraded skin) was reported to be > 2000 mg/kg (the highest amount tested) for New Zealand White rabbits (n = 5/sex).^{9,20} There were no deaths. Two animals showed decreased activity and 1 fecal staining of the anogenital area within 24 h. Some animals showed discharges from the nose or eyes in the second week after dosing. Examination at necropsy showed no changes considered related to the test substance.

Oral – Non-Human

CALCIUM BOROSILICATE

The oral LD₅₀ of calcium borosilicate (administered as a 30% solution in 1% carboxymethylcellulose) was reported to be > 5000 mg/kg for Sprague Dawley CD^R rats (n = 5/sex).^{9,21} One female rat showed slight weight loss at day 14 and 1 male had a soft stool 2 h after dosing.

REPRODUCTIVE AND DEVELOPMENTAL TOXICITY

There were no reproductive or developmental toxicity studies available for the cosmetic ingredients in this report.

GENOTOXICITY

In Vitro

CALCIUM BOROSILICATE

An Ames test using *Salmonella typhimurium* (TA100, TA98, TA1535 and TA1537) of the supernatant of calcium borosilicate in dimethyl sulfoxide (DMSO) was conducted. Calcium borosilicate (1 g/mL) was steeped in DMSO overnight and the supernatant was used for the assay. The supernatant was not mutagenic with or without metabolic activation. Controls were sodium azide, 2-nitrofluorene, and 9-aminoacridine which elicited the expected results.^{9,22}

CARCINOGENICITY

There were no carcinogenicity studies available for the cosmetic ingredients in this report.

IRRITATION AND SENSITIZATION

Irritation

Dermal – Non-Human

CALCIUM BOROSILICATE

Calcium borosilicate was moistened with distilled water and applied to ~20% of the body under occlusion to clipped skin (intact or abraded) of New Zealand White rabbits (n = 5/sex).²³ Mild erythema was observed in 2/5 animals in which the test material was applied to abraded skin and in 3/5 animals that received the test material applied to intact skin.

Calcium borosilicate (0.5 g in 0.5 ml saline) was administered to the abraded and non-abraded skin of New Zealand White Rabbits (n = 3/sex) under occlusion for 24 h.^{9,20} At 30 min and 48 h after removal, there was no difference between the response of intact and abraded skin. At removal, all treatment sites showed erythema ranging from very slight to moderate-to-severe. Edema was present at abraded and non-abraded sites in 2 animals, being barely perceptible in one and slight in the other. At 72 h, the irritation was much decreased. Calcium borosilicate was reported to be slightly irritating to rabbit skin.

Ocular

CALCIUM SODIUM BOROSILICATE

In a use test (n = 31), an eye shadow containing calcium sodium borosilicate (53%) was used daily for 4 weeks.²⁴ Ophthalmological examinations were conducted before and after the test period. Twenty-one of the subjects were self-perceived as “having sensitive eyes”. There were no adverse effects reported and all ophthalmologic examinations were normal.

In a use test, (n = 41), several eye shadows containing calcium sodium borosilicate (94% - 99%; 81% - 97%; 74% - 93%; 60% - 97%; 50% - 80%) were used daily for 4 weeks.²⁵ Ophthalmological examinations were conducted before and after the test period. No adverse effects were observed during treatment.

CALCIUM ALUMINUM BOROSILICATE

An Epiocular™ human cell assay was conducted on a powder eye shadow containing calcium aluminum borosilicate (31%).²⁶ Test results showed no expectation of ocular irritation.

Mucosal

CALCIUM SODIUM BOROSILICATE

In a use test (n = 41), several lipsticks containing calcium sodium borosilicate (94% - 99%; 81% - 97%; 92% - 97%; 74% - 93%; 60% - 97%; 50% - 80%) were used daily for 4 weeks.²⁷ No adverse effects were observed during treatment. There were no reports of irritation.

Sensitization

Human

CALCIUM SODIUM BOROSILICATE

In an human repeat insult patch test (HRIPT; n = 98) of a powder eye shadow containing calcium sodium borosilicate (53%; 0.2 g) under semi-occlusion, there were no signs of irritation or sensitization observed.²⁸

In an HRIPT (n = 104) of a cosmetic product containing calcium sodium borosilicate (60% - 97%; 0.2 g applied) under semi-occlusion, there were no signs of irritation or sensitization observed.²⁹

In an HRIPT (n = 103) of a cosmetic product containing calcium sodium borosilicate (53.5%; 0.2 g applied) under semi-occlusion, there were no signs of irritation or sensitization observed.³⁰

CALCIUM ALUMINUM BOROSILICATE

In an HRIPT (n = 105) of a powder eye shadow containing calcium aluminum borosilicate (31%; 0.2 g applied), there were no adverse effects observed and there was no evidence of sensitization.³¹

SUMMARY

Borosilicate glasses, including calcium sodium borosilicate, calcium aluminum borosilicate, calcium titanium borosilicate, silver borosilicate, and zinc borosilicate, are described as cosmetic ingredients although not all are reported to be in current use. These ingredients function mostly as bulking agents.

A previous safety assessment of silica and related silicate salts included single-dose toxicity, where, for example, the acute dermal NOEL for silica was > 2 g/kg for rabbits, repeated-dose studies, genotoxicity studies, reproductive and developmental toxicity studies, and clinical and animal irritation and sensitization studies. Data were available regarding silicosis, but these data were not relevant to the amorphous silica ingredients under review. A previous safety assessment of various silicates and silicate clays used in cosmetics noted that these ingredients are not significantly toxic in single-dose or repeated-dose studies, except that inhalation toxicity is readily demonstrated. Skin irritation and sensitization studies supported the safety of these ingredients, as did ocular irritation studies. The risk of pulmonary damage was clearly affected by particle size, fiber length, and concentration.

Potential heavy metal impurities of calcium sodium borosilicate are reported to be <10 ppm lead, <2 ppm arsenic and <1 ppm mercury. Calcium aluminum borosilicate has no free SiO₂; all components are amorphous/non-crystalline.

Calcium sodium borosilicate was reported to be used in 681 cosmetic products with a range of maximum concentrations of 0.0001% – 97%. Calcium aluminum borosilicate was used in 555 cosmetic products with a maximum range of 0.001% - 33%. Calcium titanium borosilicate was reported to be used at a maximum of 6% in eye shadows. There were no reported uses for silver borosilicate or zinc borosilicate.

No toxicokinetics data were available for the cosmetic ingredients in this report.

No acute or repeated dose toxicity data were found for the cosmetic ingredients in this report, but, calcium borosilicate, a related chemical, had a dermal LD₅₀ of > 2000 mg/kg for rabbits and an oral LD₅₀ of > 5000 mg/kg for rats.

No reproductive or developmental toxicity studies were available.

The supernatant of calcium borosilicate steeped in DMSO was not genotoxic in an Ames test.

No carcinogenicity studies were available.

An eye shadow containing calcium sodium borosilicate was not irritating or sensitizing, nor did it cause eye irritation when used daily for 4 weeks in clinical tests. Calcium aluminum borosilicate was not predicted to be an ocular irritant in an Epiocular™ assay. Calcium borosilicate was a slight to mild dermal irritating and a moderate ocular irritant to rabbits.

Lipsticks containing calcium sodium borosilicate up to 97% were not irritating in 4-week use studies.

Products containing calcium sodium borosilicate at ~53% and calcium aluminum borosilicate at 31% were not sensitizing in HRIPTs.

DISCUSSION

Although there were data gaps for borosilicate glasses, these ingredients have similar chemical structures, physicochemical properties, functions and concentrations in cosmetics compared to silicate salts and calcium borosilicate. These similarities allow grouping the ingredients together and extending the available toxicology data for the silicate salts and calcium borosilicate to support the safety of the entire group.

The Panel noted that these borosilicate ingredients are insoluble, inert, and will not significantly penetrate the skin. The zinc and silver are secure in the molecules and will not be bioavailable. Therefore, there would not be any systemic toxicity expected from dermal application. These ingredients are not dermal irritants or sensitizers.

The Panel discussed the issue of incidental inhalation exposure from body and hand sprays, hair color sprays, and fragrance preparations. There were no inhalation toxicity data available. However, the particle size of borosilicate glasses was reported to range from 50 nm – 1000 µm with the largest portion being in the 50 – 300 µm range. The Panel believes that the sizes of a substantial majority of the particles of these ingredients, as manufactured, are larger than the respirable range and/or aggregate and agglomerate to form much larger particles in formulation. These ingredients are reportedly used at concentrations up to 4% in cosmetic products that may be aerosolized and up to 97% in products that may become airborne. The Panel noted that 95% – 99% of droplets/particles would not be respirable to any appreciable amount. Coupled with the small actual exposure in the breathing zone and the short exposure time, this information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic toxic effects. The Panel considered other data available to characterize the potential for borosilicate glasses to cause irritation and sensitization. They noted the lack of irritation or sensitization in tests of dermal exposure, no systemic toxicity at 5000 mg/kg, and the absence of genotoxicity in an Ames test for a supernatant of the related chemical calcium borosilicate. Borosilicate glasses are chemically inert and thus not systemically toxic. A detailed discussion of the Panel's approach to evaluating incidental inhalation exposures to ingredients in cosmetic products is available at <http://www.cir-safety.org/cir-findings>.

CONCLUSION

The CIR Expert Panel concluded that borosilicate glasses are safe in the present practices of use and concentration as described in this assessment. The ingredients in this safety assessment include:

- calcium sodium borosilicate,
- calcium aluminum borosilicate,
- calcium titanium borosilicate,
- silver borosilicate*, and
- zinc borosilicate*.

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

TABLES

Table 1. Definitions and functions of borosilicate ingredients.³

Ingredient CAS No.	Definition	Function
Calcium Sodium Borosilicate 65997-17-3 (generic to all silicate glasses) [1204320-21-7] [308066-97-9]	Calcium Sodium Borosilicate is a glass consisting essentially of calcium and sodium borosilicates. [Essentially, Calcium Sodium Borosilicate is a synthetic product formed by the fusion of boron oxide, silica, sodium oxide, and calcium oxide, or combined sources thereof.]	Bulking agent
Calcium Aluminum Borosilicate 94891-31-3 65997-17-3 (generic to all silicate glasses) [155775-82-9]	Calcium Aluminum Borosilicate is a glass consisting essentially of calcium and aluminum borosilicates. [Essentially, Calcium Aluminum Borosilicate is a synthetic product formed by the fusion of boron oxide, silica, sodium oxide, aluminum oxide, and calcium oxide, or combined sources thereof.]	Bulking agent
Calcium Titanium Borosilicate	Calcium Titanium Borosilicate is a glass consisting essentially of calcium and titanium borosilicates. [Essentially, Calcium Titanium Borosilicate is a synthetic product formed by the fusion of boron oxide, silica, sodium oxide, titanium oxide, and calcium oxide, or combined sources thereof.]	Abrasive, bulking agent
Silver Borosilicate [308062-97-7]	Silver Borosilicate is a synthetic product formed by the fusion of boron oxide, silica, sodium oxide, and silver oxide.	Preservative, skin-conditioning agent-miscellaneous
Zinc Borosilicate 37341-47-2	Zinc Borosilicate is an amorphous glass composition consisting of boron oxide, silicon dioxide, sodium oxide and zinc oxide.	Bulking agent

Table 2. Chemical and physical properties.

Property	Value	Reference
Calcium sodium borosilicate		
Physical Form	Solid Spheres; white powder	6
Color	White	8
Density/Specific Gravity g/cm ³	1.1 0.390	8,32
Melting Point °C	~730	32
Water Solubility g/L @ °C & pH	Insoluble	32
Calcium aluminum borosilicate		
Physical Form	Hollow, non-porous spheres	8
Color	White	6
Odor	None	6
Density/Specific Gravity g/cm ²	1.1	6
Melting Point °C	~730	6
Calcium titanium borosilicate		
No data found		
Silver borosilicate		
No data found		
Zinc borosilicate		
No data found		

Table 3. Chemical analysis calcium sodium borosilicate glasses.⁵

Chemical	Annalysis (%)		
	Low-alkali	Corrosive-resistant	Calcium sodium borosilicate
SiO ₂	67-73	64-70	52
K ₂ O	0-3	0-3	0.2
B ₂ O ₃	7-12	2-5	8.6
ZnO	0-2	1-5	
Na ₂ O	8-13	8-13	0.3
MgO	1-4	1-4	1.2
CaO	1-4	3-7	22.5
Al ₂ O ₃	1-5	3-6	14.5
TiO ₂	0-3	0-3	
Fe ₂ O ₃			0.2

Table 4. Current frequency and concentration of use according to duration and type of exposure.^{13,33} There were no uses reported for silver borosilicate or zinc borosilicate.

Use type	Calcium sodium borosilicate		Calcium aluminum borosilicate		Calcium titanium borosilicate	
	# of Uses	Concentration (%)	# of Uses	Concentration (%)	# of Uses	Concentration (%)
Totals/conc. range	751	0.0001-97	717	0.001-33	1	6
<i>Duration of use</i>						
Leave-on	740	0.0001-97	668	0.001-33	1	6
Rinse-off	11	0.05-11	48	0.03-6	NR	NR
Diluted for (bath) use	NR	NR	1	NR	NR	NR
<i>Exposure Type</i>						
Eye	149	2-72	149	0.001-33	1	6
Incidental ingestion	397	2-10	320	2-8	NR	NR
Incidental inhalation-sprays	17	0.09-4 ¹	20	0.08-0.1 ²	NR	NR
Incidental inhalation-powders	29	0.08-97	24	0.009-15	NR	NR
Dermal contact	293	0.0001-97	352	0.001-33	1	6
Deodorant (underarm)	NR	NR	NR	NR	NR	NR
Hair – non coloring	6	0.3	3	NR	NR	NR
Hair - coloring	NR	NR	NR	0.08	NR	NR
Nail	41	0.3-6	29	0.6-5	NR	NR
Mucous Membrane	407	0.05-10	367	0.03-8	NR	NR
Baby products	NR	NR	NR	NR	NR	NR

NR = not reported. Totals = rinse-off + leave-on product + diluted for bath uses.

¹ Body sprays at 0.5% - 0.6%.

² Body sprays at 0.1%.

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.

REFERENCES

1. Becker LB, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Liebler DC, Marks Jr.JG, Shank RC, Slaga TJ, Snyder PW, and Andersen FA. Safety assessment of silica and related cosmetic ingredients. Washington, DC, Cosmetic Ingredient Review. 2009. pp. 1-81.
2. Andersen FA. Final report on the safety assessment of aluminum silicate, calcium silicate, magnesium aluminum silicate, magnesium silicate, magnesium trisilicate, sodium magnesium silicate, zirconium silicate, attapulgate, bentonite, Fuller's earth, hectorite, kaolin, lithium magnesium silicate, lithium magnesium sodium silicate, montmorillonite, pyrophyllite, and zeolite. *International Journal of Toxicology*. 2003;22(Suppl 1):37-102.
3. Gottschalck TE and Bailey JE eds. International Cosmetic Ingredient Dictionary and Handbook. 13th ed. Washington, D.C.: Personal Care Products Council; 2010.
4. Konijnendijk WL. The structure of borosilicate glasses. 1975. Eindhoven, Netherlands: Phillips Research Laboratories.
5. GlassFlake Limited. 2011. Information on the Glass flake and its use in cosmetics. Unpublished data submitted by Personal Care Products Council. 25 pages.
6. Potters Industries Inc. EC Material Safety Data Sheet; Luxsil® Cosmetic Microspheres [pamphlet]. Valley Forge, PA: Potters Industries Inc; 2004.
7. Ogami K; inventor. Pressed Powder Cosmetic Composition Comprising Flaky Glass. US 2010/0055140 A1. 3-4-2010.
8. Potters Europe. Luxil® Cosmetic microspheres [product sheet] [pamphlet]. Barnsley UK: Potters Europe; 2002.
9. National Industrial Chemicals Notification and Assessment Scheme. Full Public Report: Calcium Borosilicate. 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA, National Industrial Chemicals Notification and Assessment Scheme. 1992. <http://www.nicnas.gov.au/publications/car/new/na/nafullr/na0000fr/na10fr.pdf>. Report No. NA/10. Unpublished submitted by the Personal Care Products Council.
10. Schmidt CH and Petsitis X. Interference Effect Pigments -- New Technologies in Cosmetic Products. *SOFW Journal*. 2010;136(1-2):42-48.
11. Cook SG, Cercos G, and Joaquin M; inventor. Glaze Compositions. WO 2007/148101 A1. 12-27-2007.
12. Jinming H, Ping L, and Wentao L. Affecting factors on chemical stability of antibacterial borosilicate glass. *Huagong Xinxing Cailiao*. 2005;33(8):55-57.
13. Personal Care Products Council. 1-10-2012. Concentration of use by FDA Product Category: Borosilicate ingredients. Unpublished data submitted by Personal Care Products Council. 4 pages.
14. U.S.Food and Drug Administration. FDA database. Cosmetic production formulation and frequency of use data submitted to the Voluntary Cosmetic Registration Program (VCRP). 2010. Washington, DC: FDA.Data submitted in response to FOIA request.
15. Bremmer HJ, Prud'homme de Lodder LCH, and van Engelen JGM. Cosmetics Fact Sheet: To assess the risks for the consumer; Updated version for ConsExpo 4. 2006. <http://www.rivm.nl/bibliotheek/rapporten/320104001.pdf>. Date Accessed 8-24-2011. Report No. RIVM 320104001/2006. pp. 1-77.
16. Rothe H, Fautz R, Gerber E, Neumann L, Rettinger K, Schuh W, and Gronewold C. Special aspects of cosmetic spray safety evaluations: Principles on inhalation risk assessment. *Toxicol Lett*. 8-28-2011;205(2):97-104.
17. Stanford University School of Earth Sciences. Borosilicate Glass Structure. <http://geo-nmr.stanford.edu/research.area1.02.php>. Date Accessed 11-18-2011.
18. Jiao L-L, Chen K, Zhang F, and Zhou G-G. Antibacterial performance of silver-carrying glass with released control. *Water Purification Technology*. 2010;29(3):44-47.
19. Xu Y, Cheng J, Zheng W, and Gao D. Study on the preparation and properties of silver-doped borosilicate antibacterial glass. *Journal of Non-Crystalline Solids*. 2008;354:1341-1345.
20. Bio/dynamics Inc. Primary Dermal Irritation Study in Rabbits. Test material calcium borosilicate. Project No: 6427-80. Data on file Halox Pigments. No Date Given. 1992. <http://www.nicnas.gov.au/publications/car/new/na/nafullr/na0000fr/na10fr.pdf>.
21. Bio/dynamics Inc. Acute Oral Toxicity Study in Rats. Test Material Calcium Borosilicate: Project No. 6425-80. Data on file Halox Pigments. No Date Given. National Industrial Chemicals Notification and Assessment Scheme. In: *Full Public Report: Calcium Borosilicate*. 1992:
22. Hodgsons Dye Agencies Pty Ltd. Genetic Toxicology Report: Bacterial Mutagenicity test of sample labelled calcium borosilicate (CW 2230) employing a standard (Ames) salmonella plate incorporation as conducted according to OECD Guidelines for Testing of Chemicals. Data on file. No date given. 1992. <http://www.nicnas.gov.au/publications/car/new/na/nafullr/na0000fr/na10fr.pdf>.

23. Bio/dynamics Inc. Acute dermal toxicity study in rats. Test Material calcium borosilicate: Project No. 6425-80. Data on file Halox Pigments Pittsburgh, PA, U.S.A. No Date Given. In: *Full Public Report: Calcium Borosilicate*. National Industrial Chemicals Notification and Assessment Scheme: 2011:
24. Consumer Product Testing Co. 2011. Ophthalmological in-use safety evaluation of an eye shadow containing 53% Calcium Sodium Borosilicate. Experiment Reference Number C11-2693.01. Unpublished data submitted by the Personal Care Products Council. 13 pages.
25. BASF Beauty Care Solutions LLC. 2007. Safety in-use ocular/dermal irritation potential of eye shadows containing Calcium Sodium Borosilicate. Study #: IUS-OP/D-0207-001-005. Unpublished data submitted by Personal Care Products Council. 9 pages.
26. Institute for In Vitro Sciences Inc. 2007. Topical application ocular irritation screening assay using the Epiocular™ human cell construct: eye shadow containing 31% Calcium Aluminum Borosilicate. Study Number 07AE52-AE53.015001. Unpublished data submitted by Personal Care Products Council.
27. BASF Beauty Care Solutions LLC. 2007. Safety in-use/dermal irritation potential of lipstick containing Calcium Sodium Borosilicate. Study #: IUS-D-0207-001-004. Unpublished data submitted by Personal Care Products Council. 9 pages.
28. Consumer Product Testing Co. 2011. Repeated insult patch test of a powder eye shadow containing 53% Calcium Sodium Borosilicate. Experiment Reference Number C11-1390.03. Unpublished data submitted by the Personal Care Products Council. 13 pages.
29. Consumer Product Testing Co. 2006. Repeated insult patch test of Reflecks Diminision Shiny Bronze (contains 60-97% Calcium Sodium Borosilicate) Experiment Reference Number C06-0928.01. Unpublished data submitted by Personal Care Products Council. 13 pages.
30. Consumer Product Testing Co. 2008. Repeated insult patch test of an eye shadow containing 53.5% Calcium Sodium Borosilicate. Unpublished data submitted by Personal Care Products Council. 13 pages.
31. TKL Research Inc. 2007. Repeated insult patch test of an eye shadow containing 31% Calcium Aluminum Borosilicate. TKL Study No. DS105037-11. Unpublished data submitted by Personal Care Products Council.
32. TSI Inc. Spherical® Hollow Glass Spheres [product sheet] [pamphlet]. Shoreview MN: TSI Incorporated; 2006.
33. US Food and Drug Administration (FDA). Frequency of use of cosmetic ingredients. *FDA Database*. 2012. Washington, DC: FDA.