Synthetic Amorphous Silica
and Silicate Industry Association

Cosmetic Ingredient Review
1620 L St. N. W. Suite 1200
Washington D. C. 20036

September 12, 2019

Dr. Bart Heldreth, Ph.D., Executive Director, CIR

Comments from the
Synthetic Amorphous Silica and Silicate Industry Association
To
Cosmetic Ingredient Review
Dr. Bart Heldreth, Director and the Expert Panel
on
Post Meeting Announcement
Cosmetic Ingredient Review Expert Panel 151st Meeting (June 6-7, 2019) - Findings
June 12, 2019
and
Amended Safety Assessment of Silica and Synthetically-Manufactured Silicates
as Used in Cosmetics: June 19, 2019 Tentative Amended Report for Public Comment

Dear Dr. Heldreth,

As we noted in our August 15, 2019 letter, we committed to providing additional information on several silicates that are manufactured by one of our member companies. Attached are documents covering two products from Evonik Corporation (ZEOFREE 5133 (EU) and ZEOFREE 600, both calcium silicate) and a description of the calcium silicate production process.

As in the past, we are open to discussing any opportunity to assist CIR in completing a comprehensive and accurate review of synthetic amorphous silica and silicate ingredients. Please contact me to determine how we can support the efforts of your organization. We look forward to your response.

Sincerely yours,

David A. Pavlich

David A. Pavlich
Association Manager
Synthetic Amorphous Silica and Silicate Industry
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South Russell, OH 44022
440-897-8780

ZEOFREE®

Product information

ZEOFREE® 600

Precipitated Calcium Silicate

Characteristic physico-chemical data*

Properties and test methods	Unit	Value
Median particle size	µm	8
Linseed oil absorption	ml/100g	475
Carrying Capacity	%	71
Loss on drying	%	6
pH value, 5 % in water	-	10
Bulk density	kg/m^3	96
BET Surface Area	m^2/g	250

*) The given data are typical values. Specifications on request.

Certifications and Classifications

ZEOFREE® 600

CAS-No.	1344-95-2

- Quality excellence achieved through GMPs and ISO:9001 certifications
- FDA compliance 21CFR 172.410, 182.2227, 178.3297
- Conformity with COSMOS standard
- Certified as Kosher, Pareve, Kosher for Passover, and Halal

Evonik provides solutions to improve the flow behavior and storage stability of powders with specialty engineered anti-caking & free-flow agents and carriers. Moisture, pressure, temperature, static charge, fat and oil content all adversely affect your powdered and granulated products during production, processing, storage and customer use. They can make your products cake, lump, bridge, clog equipment and give you packaging and performance issues. Through advanced controlled structure technology and custom application development, Evonik can provide the optimal solution for your application. Our proven conditioning agents and carriers are non-deleterious, odorless and tasteless powders that can be used in a wide variety of applications.

Benefits

- Improved flow properties
- Offers faster production rates and increased capacity
- Reduced production downtime and maintenance
- Improved product quality and consistency
- Improved package weight accuracy

Safety and Handling

Information concerning the safety of this product is listed in the corresponding Safety Data Sheet. We recommend to read carefully the Safety Data Sheet prior to the use of our product.

Packaging and storage

For details regarding our packaging options for this product, please contact your local sales representative.
Our silica products are inert and extremely stable chemically. However, due to their high specific surface area, they can absorb moisture and volatile organic compounds from the surrounding atmosphere. Therefore, we recommend storing the products in sealed containers in a dry, cool place, and removed from volatile organic substances. Even if a product is stored under these conditions, after a longer period it can still pick up ambient moisture over time, which could lead to its exceeding the specified moisture content.

EVONIK INDUSTRIES

Product specification

Material ZEOFREE® 600
Spec.Code K00

Evonik Resource Efficiency GmbH

Business Line Silica

www.evonik.com

Contact: specification-silica@evonik.com

Inspection Characteristics	Method	Limits	Units	Z
Appearance	SOP SI_Y157	White, light, fine, amorph pwd., no grit		C
Loss on drying, 2h at 105°C	following ISO 787-2	<=10.0	%	X
pH value, 5% in water	following ISO 787-9	9.5-10.2		X
Linseed oil abs., dried subst.	following ISO 787-5	>=450	ml/100 g	X
Sieve residue 45 µm, spray	following ISO 3262-19	<=2.0	%	X
Loss on ignition	acc. to USP/NF Calcium Silicate	<=20.0	%	C
CaO content	acc. to USP/NF Calcium Silicate	18.0-33.0	%	C
SiO2 content	acc. to USP/NF Calcium Silicate	45.0-60.0	%	C
Sum of CaO, SiO2 and LOI	acc. to USP/NF Calcium Silicate	>=90.0	%	C
Ratio of SiO2 - CaO	acc. to USP/NF Calcium Silicate	0.5-20.0		C
Fluoride	acc. to USP/NF Calcium Silicate	<=50	ppm	C
Pb content	acc. to USP/NF Calcium Silicate	<=2.0	ppm	C
Total aerobic microbial count	accord. to USP & EP	<=1000	CFU/g	C
Total yeasts and molds count	accord. to USP & EP	<=300	CFU/g	C
Pathogenic bact. (P.a; Salm; E	accord. to USP & EP	Absence		C
Requirements	accord. to USP/NF "Calcium Silicate"	conforms		C
Requirements	acc. to FCC "Calcium Silicate"	conforms		C

Report on inspection certificate: X = specific/actual value, C = unspecific value/conformity, T = not reported

This document is computer printed and therefore valid without signature.
All warranty claims in respect of the conformity of our product are subject to our General Terms and Conditions of Sale and Delivery. The data listed above reflects the criteria for our internal quality tests. We do not hereby make any express or implied warranty, whether for specific properties or for fitness for any particular application or purpose. All values are valid for the product when despatched from the works.

The Standard Test Methods can be obtained from specialized publishers. Evonik's test methods are available on request.

ZEOFREE®

Product information

ZEOFREE® 5133 (EU)

Precipitated Calcium Silicate

Characteristic physico-chemical data*

Properties and test methods	Unit	Value
Median particle size	µm	11
Linseed oil absorption	ml/100g	130
Loss on drying	%	6
pH value, 5 % in water	-	10
Bulk density	kg/m³	200

*) The given data are typical values. Specifications on request.

Certifications and Classifications

ZEOFREE® 5133 (EU)

CAS-No.	1344-95-2

- EC 215-710-8
- Quality excellence achieved through GMPs and ISO:9001 certifications
- FDA compliance: 21 CFR 169.179, 172.410, 175.105, 176.170, 177.2355, 178.3297, 182.2227
- Compliance with the purity criteria in Regulation (EU) 231/2012 (E552) as amended
- Conformity with COSMOS standard
- Certified as Kosher, Pareve, Kosher for Passover, and Halal

ZEOFREE® 5133 Calcium Silicate provides low dusting, anti-caking and free-flow properties for a broad variety of food products and processes. Moisture, pressure and temperature all adversely affect powdered and granulated products. These conditions can make products cake, lump, bridge, clog equipment and cause packaging and performance problems. This low dusting product is particularly effective in promoting flow in process, preventing buildup on spray dryer walls and in finished products such as salt and non-dairy creamers as well as other food powders. ZEOFREE® 5133 Calcium Silicate is specifically engineered to provide improved handling, metering ability and function as a spray drying productivity aid.

Benefits

- Prevents caking and eliminates lumps
- Improves flow and increases packaging rates
- Reduces or eliminates build up in spray drying operations
- Decreases clogging and bridging during production
- Provides a low dusting and non-aluminum option when regulations require

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Product specification

Material **ZEOFREE® 5133**
Spec.Code **K00**

Evonik Resource Efficiency GmbH

Business Line Silica

www.evonik.com

Contact: specification-silica@evonik.com

Inspection Characteristics	Method	Limits	Units	Z
Appearance	SOP SI_Y158	White to off-white, free-flowing powder		C
Loss on drying, 2h at 105°C	following ISO 787-2	<=7.0	%	X
pH value, 5% in water	following ISO 787-9	9.5-11.0		X
Na2SO4 content, sol. in water	following ISO 787-8	<=2.0	%	X
Linseed oil abs., dried subst.	following ISO 787-5	110-150	ml/100 g	X
Requirements	accord. to USP/NF "Calcium Silicate"	conforms		C
Requirements	acc. to FCC "Calcium Silicate"	conforms		C

Report on inspection certificate: X = specific/actual value, C = unspecific value/conformity, T = not reported

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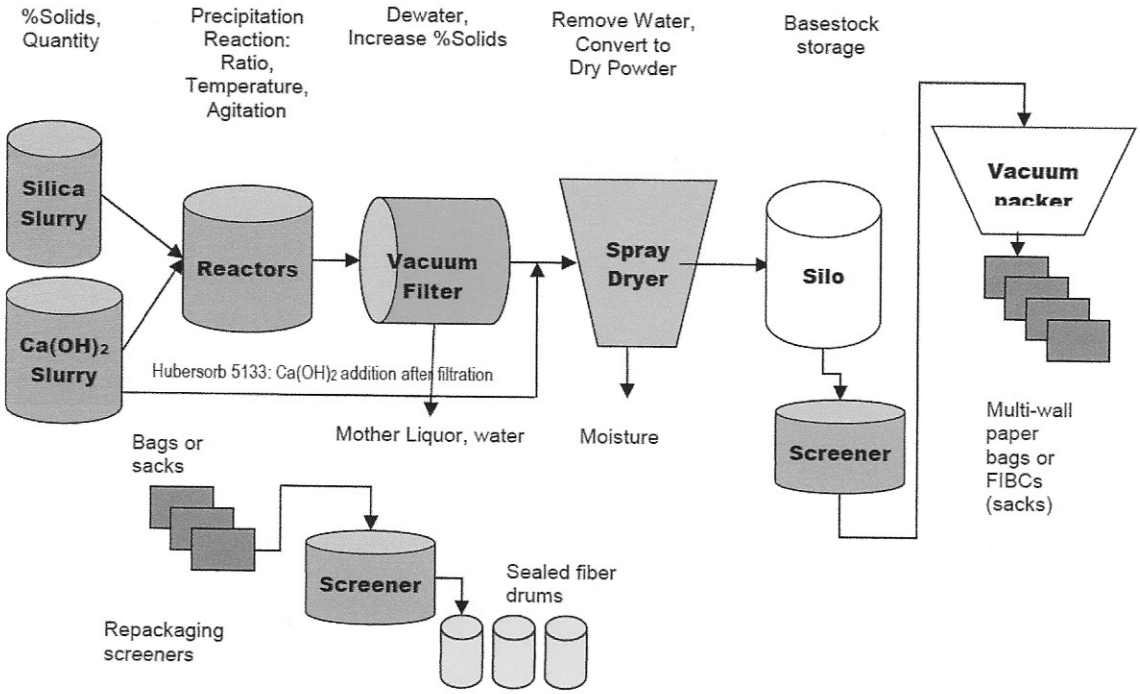
The Standard Test Methods can be obtained from specialized publishers. Evonik's test methods are available on request.

CALCIUM SILICATE

8. Production Process

Amorphous silicon dioxide slurry is precipitated from reaction of sodium silicate solution with sulfuric acid under controlled conditions and reacted with $Ca(OH)_2$ slurry. A by-product of the precipitation is sodium sulfate. The slurry is filtered and washed, and then spray dried. The dry product may then be milled or compacted, depending on the particle size requirements, prior to packaging or bulk loading.



17. Heavy metals and other metal traces

We do not intentionally use or add during the manufacturing process any heavy metals or other metals. **Calcium silicate** is formed in the reaction of $Ca(OH)_2$ slurry with synthetic amorphous silica slurry, which is made from mineral, alkalized sand (sodium silicate) and precipitated with mineral acid. Elemental impurities in calcium silicate originate from the mined sand and have variation due to natural variation in sand with specified max content controlled. There may be also some non-intentionally added elemental residues derived from the manufacturing pipes and valves.

Annual testing for trace elements indicates the following to be representative or typical for precipitated calcium silicate products[1] (as total content, based on original material). This should not be interpreted to be a specification.

Heavy metals:

Cadmium (Cd)	Mercury (Hg)	Chromium (Cr)	Lead (Pb)
< 1 ppm	< 1 ppm	< 10 ppm	< 2 ppm

Other metal traces:

Antimony (Sb)	Arsenic (As)	Barium (Ba)	Zinc (Zn)	Iron (Fe)	Copper (Cu)	Nickel (Ni)
< 5 ppm	< 3 ppm	< 50 ppm	< 10 ppm	< 450 ppm	< 6 ppm	< 3 ppm