

Ca Calcium Silicate

1 Nonproprietary Names

USP–NF: Calcium Silicate

2 Synonyms

Calcium hydrosilicate; calcium metasilicate; calcium monosilicate; calcium polysilicate; *Micro-Cel*; okenite; silicic acid, calcium salt; tobermorite.

3 Chemical Name and CAS Registry Number

Calcium silicate [1344-95-2]

4 Empirical Formula and Molecular Weight

CaSiO₃ 116.2

5 Structural Formula

See Section 4.

6 Functional Category

Adsorbent; anticaking agent; opacifier; tablet and capsule diluent.

7 Applications in Pharmaceutical Formulation or Technology

Calcium silicate is used as a filler aid for oral pharmaceuticals. It has also been used in pharmaceutical preparations as an antacid.

The main applications of calcium silicate relate to its anticaking properties, and it has therefore been used in dusting powders and a range of different cosmetic products (e.g. face powders, eye shadow).⁽¹⁾

8 Description

Calcium silicate occurs as a crystalline or amorphous white or off-white material, and often exists in different hydrate forms.

9 Pharmacopeial Specifications

The USP 40–NF 35 S1 describes the material as containing not less than 4% of calcium oxide and not less than 35% of silicon dioxide.

See Table I.

Table I: Pharmacopeial specifications for calcium silicate.

Test	USP 40–NF 35 S1
Identification	+
pH	8.4–11.2
Loss on ignition	≤20%
Heavy metals	≤20 ppm
Fluoride	≤50 ppm
Lead	≤10 ppm
Assay for silicon dioxide	90–110%
Assay for calcium oxide	90–110%
Ratio of silicon dioxide to calcium oxide	0.5 : 20
Sum of calcium oxide, silicon dioxide and loss on ignition	≥90%

10 Typical Properties

Acidity/alkalinity pH = 8.4–10.2 (5% w/v aqueous solution)

Density 2.10 g/cm³

Melting point 1540°C

Solubility Practically insoluble in water; forms a gel with mineral acids. It can absorb up to 2.5 times its weight of liquids and still remain a free-flowing powder.

11 Stability and Storage Conditions

Calcium silicate is chemically stable and nonflammable, but it should be protected from moisture. Store in airtight containers in a cool, dry place.

12 Incompatibilities

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13 Method of Manufacture

Calcium silicate is a naturally occurring mineral, but for commercial applications it is usually prepared from lime and diatomaceous earth under carefully controlled conditions.

14 Safety

When used in oral formulations, calcium silicate is practically nontoxic. Inhalation of the dust particles may cause respiratory tract irritation.

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of the material handled. In large quantities, calcium silicate is irritating to eyes, the respiratory system, and skin. Gloves, eye protection, a respirator, and other protective clothing should be worn. In the UK, the long-term (8-hour TWA) workplace exposure standards for calcium silicate are 10 mg/m³ for total inhalable dust and 4 mg/m³ for respirable dust.⁽²⁾

16 Regulatory Status

GRAS listed. Included in the FDA Inactive Ingredients Database (oral dosage forms). Included in nonparenteral (oral, orodispersible, effervescent and enteric-coated tablets) formulations licensed in the UK.

17 Related Substances

Calcium diorthosilicate; calcium trisilicate.

Calcium diorthosilicate

Empirical formula Ca₂SiO₄

Molecular weight 172.2

CAS number [10034-77-2]

Synonyms Belite; dicalcium silicate

Comments The EINECS number for calcium diorthosilicate is 233-107-8.

Calcium trisilicate

Empirical formula Ca₃SiO₅

Molecular weight 228.3

CAS number [12168-85-3]

Synonyms Tricalcium silicon pentaoxide

Comments The EINECS number for calcium trisilicate is 235-336-9.