

Aluminium silicate (Kaolin)

DOCUMENT M-CA, Section 10

CLASSIFICATION AND LABELLING OF THE ACTIVE SUBSTANCE

Version history¹

Date	Data points containing amendments or additions and brief description	Document identifier and version number
February 2018	None	M-CA S10 V1

¹ It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

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CA 10 CLASSIFICATION AND LABELLING OF THE ACTIVE SUBSTANCE

The proposed classification of kaolin under the provisions of Regulation (EC) 1272/2008 is the following:

Classification: No classification

Hazard statements: None

Pictograms: None

Signal word: None

Precautionary statements:

Although no classification under CLP Regulation is proposed several precautionary statements linked to the physical nature of kaolin (powder) that enables safe handling are advised:

P261 – Avoid breathing dust

P262 – Do not get in eyes, on skin, or on clothing.

P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P302+P350 – IF ON SKIN: Gently wash with plenty of soap and water.

P304+P341 – IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

Supplementary statements: None

Justification:

Physical hazards:

Kaolin is not flammable, nor explosive or oxidizing. The current data package does not warrant any classification on the basis of physico-chemical properties.

Health hazards:

Acute oral LD₅₀ of kaolin > 5000 mg/kg bw which gives no oral classification.

Acute dermal LD₅₀ of kaolin > 5000 mg/kg bw which gives no dermal classification.

Acute inhalation $LD_{50} > 2.18$ mg/l (highest concentration obtained) which gives no inhalation classification.

Skin irritation study showed no erythema or oedema, giving no skin irritation classification.

Eye irritation study performed on six rabbits showed grade-3 redness on two animals for less than 24 hours. Eye irritation study performed on three rabbits showed grade-1 redness that persisted for 24 hours on one animal. No eye irritation classification is required.

Sensitization study demonstrated the absence of sensitizing potential of kaolin. No sensitizing classification is required.

Environmental hazards:

Available acute aquatic toxicity data on fish, daphnia and algae indicate LC_{50} values are in excess of 100 mg/l, thus triggering no classification.

Available chronic aquatic toxicity data on fish provides a NOEC of 100 mg/l. This value can be extrapolated to other aquatic organisms since clay particles are ubiquitous in natural aquatic environments at levels higher than those expected from the use of aluminium silicate. No environmental classification is needed.