# Skin & eye irritation studies performed on bentonite
# - Summary report, December 2005 -

## Introduction

Studies on the skin and eye irritation potential of bentonite have been performed to improve the knowledge of bentonite with regard to public health. These studies were performed in anticipation of impending legislation and in the absence of scientific data in the literature. The results of these studies are made available to the public so as to prevent the duplication of animal testing.

The studies were sponsored by the European Bentonite Producers AISBL, which supplied test materials. More information on European Bentonite Producers AISBL is available at the following link: http://www.ima-eu.org/en/eubaindex.htm

The studies described below were performed in compliance with UK GLP standards (Schedule 1, Good Laboratory Practice Regulations 1999 (SI 1999/3106 as amended by SI 2004/0994)). These Regulations are in accordance with GLP standards published as OECD Principles on Good Laboratory Practice (revised 1997, ENV/MC/CHEM(98)17); and are in accordance with, and implement, the requirements of Directives 2004/9/EC and 2004/10/EC.

## Description of the methods

The acute dermal irritation tests were performed to assess the irritancy potential of the test material to the skin of the New Zealand White rabbit. The method was designed to meet the requirements of the following:

- *OECD Guidelines for the Testing of Chemicals No. 404 "Acute Dermal Irritation/Corrosion" (adopted 24 April 2002);*
- *Commission Directive 92/69/EEC Method B4 Acute Toxicity (Skin Irritation)*

The acute eye irritation tests were performed to assess the irritancy potential of the test material to the eye of the New Zealand White rabbit. The method was designed to meet the requirements of the following:

- *OECD Guidelines for the Testing of Chemicals No. 405 "Acute Eye Irritation/Corrosion" (adopted 24 April 2002);*
- *Commission Directive 92/69/EEC Method B5 Acute Toxicity (Eye Irritation)*

## Test materials

Four different commercial bentonite products, selected for their representativeness of the bentonite products found on the EU market, were tested:

- *Sodium bentonite*
- *Calcium bentonite*
- *Sodium-activated bentonite*
- *Acid-activated bentonite*


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## Test results

A single 4-hour, semi-occluded application of the test material to the intact skin/eye of three rabbits produced the following results:

### *A. Skin irritation*

| | **Erythema and eschar formation**<br>*Mean value* | **Oedema formation**<br>*Mean value* | **Conclusion for classifcation**<br>*according to EU Directive 67/548/EEC as amended* |
|---|---|---|---|
| Criteria for classification according to EU Directive 67/548/EEC as amended | ≥ 2 | ≥ 2 | R38: irritating to skin |
| **Bentonite Type** | | | |
| Sodium bentonite | 0.0 | 0.0 | No classification |
| Calcium bentonite | 0.0 | 0.0 | No classification |
| Sodium-activated bentonite | 0.0 | 0.0 | No classification |
| Acid-activated bentonite | 0.0 | 0.0 | No classification |

### *B. Eye irritation*

| | **Cornea opacity**<br>*Mean value* | **Iris lesion**<br>*Mean value* | **Redness**<br>*Mean value* | **Chemosis**<br>*Mean value* | **Conclusion for classifcation**<br>*according to EU Directive 67/548/EEC as amended* |
|---|---|---|---|---|---|
| Criteria for classification according to Directive 67/548/EEC as amended | ≥ 2 | ≥ 1 | ≥ 2.5 | ≥ 2 | R36: irritating to eyes |
| **Bentonite type** | | | | | |
| Sodium bentonite | 0.0 | 0.2 | 0.9 | 0.9 | No classification |
| Calcium bentonite | 0.0 | 0.1 | 0.8 | 0.6 | No classification |
| Sodium-activated bentonite | 0.0 | 0.3 | 0.9 | 0.9 | No classification |
| Acid-activated bentonite | 0.0 | 0.0 | 0.7 | 0.3 | No classification |

## Conclusions

For the skin and eye irritation aspects, bentonite does not meet the criteria for classification as dangerous substances according to Directive 67/548/EEC as amended.

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