

## **Skin & eye irritation studies performed on Kaolin and Clay - Summary report, December 2005 -**

### **Introduction**

Studies on the skin and eye irritation potential of kaolin and clay have been performed to improve the knowledge of kaolin and clay 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 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.

The studies were sponsored by the European Kaolin and Plastic Clay AISBL, which supplied test materials. More information on European Kaolin and Plastic Clay AISBL is available at the following link: <http://www.ima-eu.org/en/kpcindex.htm>

### **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 samples of kaolin and clay, selected for their representativeness of the kaolin and clay products found on the EU market, were tested:

- *Kaolin*
- *Calcined kaolin*
- *Plastic clay*
- *Calcined clay (Chamotte)*

## 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

	<b>Erythema and eschar formation</b> <i>Mean value</i>	<b>Oedema formation</b> <i>Mean value</i>	<b>Conclusion for classification</b> <i>according to EU Directive 67/548/EEC as amended</i>
Criteria for classification according to EU Directive 67/548/EEC as amended	≥ 2	≥ 2	R38: irritating to skin
<b>Kaolin &amp; clay type</b>			
Kaolin	0.3	0.0	No classification
Calcined kaolin	0.0	0.0	No classification
Plastic clay	0.0	0.0	No classification
Calcined clay (Chamotte)	0.0	0.0	No classification

### B. Eye irritation

	<b>Cornea opacity</b> <i>Mean value</i>	<b>Iris lesion</b> <i>Mean value</i>	<b>Redness</b> <i>Mean value</i>	<b>Chemosis</b> <i>Mean value</i>	<b>EU classification</b> <i>according to Directive 67/548/EEC as amended</i>
Criteria for classification according to Directive 67/548/EEC as amended	≥ 2	≥ 1	≥ 2.5	≥ 2	R36: irritating to eyes
<b>Kaolin &amp; clay type</b>					
Kaolin	0.0	0.0	0.3	0.0	No classification
Calcined kaolin	0.0	0.0	0.4	0.0	No classification
Plastic clay	0.0	0.0	0.7	0.3	No classification
Calcined clay (Chamotte)	0.0	0.0	0.3	0.1	No classification

## Conclusions

For the irritation aspects, the kaolin and clay products tested do not meet the criteria for classification as dangerous substances according to Directive 67/548/EEC as amended.

## Contacts:

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