

# Data Supplement Wave 2

Clays

EXPERT PANEL MEETING  
September 26-27, 2022

**Memorandum**

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons  
From: Christina L. Burnett, Senior Scientific Analyst/Writer, CIR  
Date: September 16, 2022  
Subject: Wave 2 - Amended Safety Assessment of Naturally-Sourced Clays as Used in Cosmetics

In communications from the Council earlier this year, data were submitted (from one supplier) for the ingredient, clay. According to this supplier, this ingredient comprises 75% Illite, 19% Kaolin, and 6% Montmorillonite. These data were provided to the Panel in the September Clays report package as *data1\_Clays\_092022*. In comments and communications on the draft Tentative Amended Report (*PCPCcomments\_Clays\_Wave2\_092022*), the Council informed CIR staff that this material has been assigned the INCI name Clay, and is not named as a mixture (i.e., not labeled as Illite, Kaolin, and Montmorillonite).

In light of the composition of these test materials and the similarity of Illite to the other ingredients in this report, the Panel is being asked if it should be included as an ingredient in this report. ***The Panel should discuss Illite and provide guidance to CIR staff.***

The data that this change pertains to (highlighted in the current draft Tentative Amended Report under Kaolin and Montmorillonite) are as follows:

- Raw material specifications (as described in Table 3 of the report)
- Method of manufacturing
- Composition/impurities
- Ex vitro bioavailability
- Acute dermal, oral, and inhalation toxicity
- In vitro genotoxicity
- Dermal irritation and sensitization in animals
- Ocular irritation in rabbits

An updated data profile reflecting where the new data aligns accompanies this transmittal memo (*UpdatedDataProfile\_Clays\_Wave2\_092022*). Please note that this material comprises Illite, Kaolin, and Montmorillonite, and was indicated as such a mixture in the original data profile. However, the updated data profile presented herein this Wave 2 data supplement, instead, designates these endpoints for the ingredient, Clay (as indicated by highlighting.)



## Memorandum

**TO:** Bart Heldreth, Ph.D.  
Executive Director - Cosmetic Ingredient Review

**FROM:** Alexandra Kowcz, MS, MBA  
Industry Liaison to the CIR Expert Panel

**DATE:** September 15, 2022

**SUBJECT:** Draft Tentative Amended Report: Safety Assessment of Naturally-Sourced Clays as Used in Cosmetics (September 26-27, 2022 meeting draft)

The Personal Care Products Council respectfully submits the following comments on the draft tentative amended report, Safety Assessment of Naturally-Sourced Clays as Used in Cosmetics.

### Key Issue

It should be made clear that the clay product containing 75% Illite, 19% Kaolin and 6% Montmorillonite is being sold under the INCI name Clay. The information on this material should be presented under the heading "Clay" rather than "Kaolin and Montmorillonite".

Discussion – There is no evidence in the report that metals bound to clay are "readily separable". There is a study that indicates that vanadium, lead, arsenic, barium, nickel, chromium, and aluminum were not available when skin was exposed to a clay *in vitro*. This study should be mentioned in the Discussion to indicate that trace metals in clays will not be absorbed through the skin.

### Additional Considerations

Non-Cosmetic Use – When materials (such as Attapulgit and Hectorite) are listed in 21CFR 310.545, they are not permitted for use in drugs. The CIR report should not say that Attapulgit and Hectorite are used as drugs.

ADME, Kaolin, old report summary – Please correct: "72 h late" (to "72 h later")

ADME, Montmorillonite, old report summary – The inhalation exposure study was a short-term exposure with long-term follow-up. Saying: "Rats and mice were counted on exposure days 2, 4, 8, 16,.....and 850" is misleading as this was time after exposure. The original CIR report also had this error. Please go back to the original study and correct the information in this report.

Acute, Oral, Kaolin, old report summary – Please correct: “These were a pathological reaction...” (should be “These were pathological reactions...” or “This was a pathological reaction...”)

Subchronic, Oral, Montmorillonite – Please indicate that the “modifier” was hexadecyltrimethylammonium bromide.

Dermal Irritation and Sensitization – Please include the number of subjects used in the HRIPTs in the text.

Occupational Exposure, Kaolin, old report summary – Since this information came from the 2003 CIR report, stating “current employees in the industry” is not appropriate.

Occupational Exposure – The OSHA PEL should be cited to OSHA not NIOSH (reference 52).

Discussion – Please clarify that the clay ingredients were some of the ingredients included in the 2003 CIR report. The draft Discussion states that there are 8 ingredients in this report. In this draft, there are only 7 ingredients. If Illite is added to the report, there will be 8 ingredients as stated in the first paragraph of the Discussion.

**UPDATED - Clays Data Profile – September 2022, Christina Burnett**

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	Use				Toxico-kinetic		Acute Tox			Repeated Dose Tox			DART		Genotox		Carci			Dermal Irritation			Dermal Sensitization				Ocular Irritation		Clinical Studies		
	New Rpt	Old Rpt	Method of Mfg	Composition/ Impurities	Dermal Pen.	ADME	Dermal	Oral	Inhalation	Dermal	Oral	Inhalation	Dermal	Oral	In Vitro	In Vivo	Dermal	Oral	Inhalation	In Vitro	Animal	Human	In Vitro	Animal	Human	Phototoxicity	In Vitro	Animal	Retrospective/ Multicenter	Case Reports	
Attapulgit	X	O	O	O											O				O												
Bentonite	X	O	XO	XO											X						X				X	X					O
Clay*†	X		X	X		X	X	X	X						X						X			X					X		
Fuller's Earth	X	O		O																											O
Hectorite	X	O		XO				O							O						O			X					O		
Kaolin	X	O	O	XO		O		O						O					O			X		X	X		X				O
Montmorillonite	X			O		O				X					X	X				X			X	X							O

Updates to the previous version are highlighted in yellow.

\*Not previously reviewed

†With exception of the Use data, the data are reported to be on a clay material containing 75% illite, 19% Kaolin, and 6% Montmorillonite.

“X” indicates that new data were available in this category for the ingredient; “O” indicates that data from the original assessment were available