

FILE NAME: Talc (TALC)

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U.S. Food and Drug Administration

Protecting and Promoting *Your* Health

Talc

Talc is an ingredient used in many cosmetics, from baby powder to blush. From time to time, FDA has received questions about its safety and whether talc contains harmful contaminants, such as asbestos.

FDA's authority over cosmetic safety

Under the Federal Food, Drug and Cosmetic Act (FD&C Act), cosmetic products and ingredients, with the exception of color additives, do not have to undergo FDA review or approval before they go on the market. Cosmetics must be properly labeled, and they must be safe for use by consumers under labeled or customary conditions of use. Cosmetic companies have a legal responsibility for the safety and labeling of their products and ingredients, but the law does not require them to share their safety information with FDA.

FDA monitors for potential safety problems with cosmetic products on the market and takes action when needed to protect public health. Before we can take such action against a cosmetic, we need sound scientific data to show that it is harmful under its intended use.

Talc: What it is and how it is used in cosmetics

Talc is a naturally occurring mineral, mined from the earth, composed of magnesium, silicon, oxygen, and hydrogen. Chemically, talc is a hydrous magnesium silicate with a chemical formula of $\text{Mg}_3\text{Si}_4\text{O}_{10}(\text{OH})_2$.

Talc has many uses in cosmetics and other personal care products; in food, such as rice and chewing gum; and in the manufacture of tablets. For example, it may be used to absorb moisture, to prevent caking, to make facial makeup opaque, or to improve the feel of a product.

Asbestos: What it is, why it's a concern, and how to prevent its occurrence in cosmetics

Asbestos is also a naturally occurring silicate mineral, but with a different crystal structure. Both talc and asbestos are naturally occurring minerals that may be found in close proximity in the earth. Unlike talc, however, asbestos is a known carcinogen. For this reason, FDA considers it unacceptable for cosmetic talc to be contaminated with asbestos.

Published scientific literature going back to the 1960s has suggested a possible association between the use of powders containing talc and the incidence of ovarian cancer. However, these studies have not conclusively demonstrated such a link, or if such a link existed, what risk factors might be involved. Nevertheless, questions about the potential contamination of talc with asbestos have been raised since the 1970s.

To prevent contamination of talc with asbestos, it is essential to select talc mining sites carefully and take steps to purify the ore sufficiently.

How FDA followed up on the latest reports

Because safety questions about the possible presence of asbestos in talc are raised periodically, FDA decided to conduct an exploratory survey of currently marketed cosmetic-grade raw material talc, as well as some cosmetic products containing talc.

Because FDA's cosmetic laboratories do not have the equipment needed to perform the analyses, we searched for a qualified outside laboratory to do the work. We contracted with AMA Analytical Services, Inc. (AMA) of Lanham, MD to conduct this laboratory survey, based on demonstrated experience with asbestos analysis in complex matrices, appropriate facilities, equipment, personnel, analytical strategy, and budget criteria. The study ran from September 28, 2009 to September 27, 2010.

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How the survey was conducted

The first step was to identify cosmetic talc suppliers and talc-containing cosmetic products. We found seven talc suppliers identified in the 2008 edition of the *International Cosmetic Ingredient Dictionary and Handbook* and two more by searching online. The contract laboratory contacted each supplier to request samples of its talc. Of the nine suppliers identified, four complied with the request.

We found talc-containing cosmetic products to analyze by visiting various retail outlets in the Washington, D.C. metropolitan area. The samples identified for testing included low, medium, and high priced products, along with some from "niche" markets, in order to cover as broad a product range as possible. A total of thirty-four cosmetic products containing talc were selected, including eye shadow, blush, foundation, face powder, and body powder. All cosmetic products were purchased from retail stores in the Washington, D.C. metropolitan area.

The contract laboratory analyzed the samples using polarized light microscopy (PLM) and transmission electron microscopy (TEM) methods published by the New York State Department of Health, Environmental Laboratory Approval Program. Each sample was analyzed three times using both methods.

The results of FDA's survey and what they mean

The survey found no asbestos fibers or structures in any of the samples of cosmetic-grade raw material talc or cosmetic products containing talc. The results were limited, however, by the fact that only four talc suppliers submitted samples and by the number of products tested. For these reasons, while FDA finds these results informative, they do not prove that most or all talc or talc-containing cosmetic products currently marketed in the United States are likely to be free of asbestos contamination. As always, when potential public health concerns are raised, we will continue to monitor for new information and take appropriate actions to protect the public health.

The tables below list details for each of the cosmetic-grade raw material talc samples and cosmetic products containing talc that were analyzed in this survey. Limits of detection are shown below the table for each group of samples. Note: "NAD" means "no asbestos detected."

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Cosmetic-grade raw material talc

Supplier	Product Identity	Lot #	% Asbestos by PLM	% Asbestos by TEM
Rio Tinto Minerals/Luzenac America	Imperial 200 USP	H10018	NAD	NAD
Rio Tinto Minerals/Luzenac America	Imperial 250 USP	H10018	NAD	NAD
Rio Tinto Minerals/Luzenac America	Imperial 400 USP	H06049-43	NAD	NAD

Rio Tinto Minerals/Luzenac America	Olympic H USP	H04018	NAD	NAD
Rio Tinto Minerals/Luzenac America	Supreme H USP Lot 2	H09219-79	NAD	NAD
Rio Tinto Minerals/Luzenac America	Supra H USP	H10018	NAD	NAD
Rio Tinto Minerals/Luzenac America	Suprafino H USP	H6309-78	NAD	NAD

PLM average limit of quantitation and limit of detection = 0.23% ± 0.01

TEM average limit of detection = 0.0000021% ± 1.26567E-09

TEM average limit of detection = 0.021 ppm ± 0.001

TEM average limit of quantitation = 0.46% ± 0.01

Supplier	Product Identity	Lot #	% Asbestos by PLM	% Asbestos by TEM
Presperse	Micro Ace P-2	33070516	NAD	NAD
Presperse	Micro Ace P-4	37080823	NAD	NAD
Presperse	Rose Talc	2008-09	NAD	NAD
Presperse	Talc NK-48	017 0306	NAD	NAD
Presperse	TalClear BH	070608	NAD	NAD
Presperse	TalClear LH	070529	NAD	NAD

PLM average limit of quantitation and limit of detection = 0.22% ± 0.01

TEM average limit of detection = 0.0000021% ± 3.0099E-09

TEM average limit of detection = 0.021 ppm ± 0.003

TEM average limit of quantitation = 0.43% ± 0.02

Supplier	Product Identity	Lot #	% Asbestos by PLM	% Asbestos by TEM
Sensient Cosmetic Technologies	28355 Talc PP	W249-06	NAD	NAD
Sensient Cosmetic Technologies	28368 Talc NBSB	W080720	NAD	NAD
Sensient Cosmetic Technologies	28460 Talc F-MS	W053-08	NAD	NAD
Sensient Cosmetic Technologies	61631 Talc LCW	26449	NAD	NAD
Sensient Cosmetic Technologies	R0175 Talc FHC	W041397	NAD	NAD

Sensient Cosmetic Technologies	R0255 Talc SI	W05630	NAD	NAD
Sensient Cosmetic Technologies	R0435 Talc AS	W061176	NAD	NAD

PLM average limit of quantitation and limit of detection = 0.22% ± 0.01

TEM average limit of detection = 0.0000022% ± 1.91529E-09

TEM average limit of detection = 0.022 ppm ± 0.002

TEM average limit of quantitation = 0.43% ± 0.01

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Supplier	Product Identity	Lot #	% Asbestos by PLM	% Asbestos by TEM
Brenntag Specialties, Inc.	Talc IMP BC IMP1886L	H01018	NAD	NAD
Brenntag Specialties, Inc.	Supra H USP BC (*1718)	H10016	NAD	NAD
Brenntag Specialties, Inc.	Imperial 400 USP BC (*1883)	H01017	NAD	NAD
Brenntag Specialties, Inc.	Talcron MP 60-30 USP (1745)	B8141N1	NAD	NAD
Brenntag Specialties, Inc.	Talc IMP BC IMP1820L	H07018	NAD	NAD
Brenntag Specialties, Inc.	Talc Imperial USP BC IMP1885L	H10017	NAD	NAD
Brenntag Specialties, Inc.	Lo-Micron USP BC 2755	B7375N2	NAD	NAD

PLM average limit of quantitation and limit of detection = 0.23% ± 0.01

TEM average limit of detection = 0.0000021% ± 2.10373E-09

TEM average limit of detection = 0.021 ppm ± 0.002

TEM average limit of quantitation = 0.46% ± 0.01

Cosmetic products containing talc

Blush:

Brand	Shade	% Asbestos by PLM	% Asbestos by TEM
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Maybelline New York Expert Wear Blush	Gentle Rose 109EWBR-30	NAD	NAD
N.Y.C. New York Color Cheek Glow Powder Blush	West Side Wine 652A	NAD	NAD
NARS Blush	Torrid 4017	NAD	NAD

Eye Shadow:

Brand	Shade	% Asbestos by PLM	% Asbestos by TEM
Physician's Formula Shimmer Strips Custom Eye Enhancing Shadow & Liner	Hazel Eyes 2222	NAD	NAD
Black Radiance Eyeshadow Quartet	Retro Chic 8805	NAD	NAD
Stilla Eye Shadow Trio	Venus S461-03	NAD	NAD
Dior 5-Colour Iridescent Eyeshadow	Petal Shine 809	NAD	NAD

Foundation:

Brand	Shade	% Asbestos by PLM	% Asbestos by TEM
Black Opal True Color Liquid Foundation	Heavenly Honey	NAD	NAD
Laura Mercier Foundation Powder	Number 2	NAD	NAD

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Brand	Shade	% Asbestos by PLM	% Asbestos by TEM
LA Colors Pressed Powder	Nude BPP320	NAD	NAD
Revlon Color Stay Pressed Powder	Fair 810	NAD	NAD
Cover Girl TruBlend Mineral Loose Mineral Powder	Translucent Fair 405	NAD	NAD
Physician's Formula Summer Eclipse Bronzing & Shimmery Face Powder	Moonlight/Light Bronzer 3104	NAD	NAD

Wet n Wild Bronzer	Light/Medium 701	NAD	NAD
Iman Luxury Pressed Powder	Clay Medium Dark	NAD	NAD
Coty Air Spun Loose Face Powder	Translucent 070-24	NAD	NAD
Black Opal Color Fusion Powder	Mosaic Raspberry Bronzer	NAD	NAD
Black Radiance Pressed Powder	Rich Mahogany Acajou riche 8607B	NAD	NAD
Posner Finishing Touch Pressed Powder	Honey Beige 53124	NAD	NAD
N.Y.C. New York Color Loose Face Powder	Translucent 741A	NAD	NAD
Almay Nearly Naked Loose Powder	Light/pale 100	NAD	NAD
Clinique Stay Matte Sheer Pressed Powder	Invisible Matte 101	NAD	NAD
BeneFit Hello Flawless Custom Powder Cover-Up for Face SPF 15	Me Vain? Champagne 1B168	NAD	NAD
Smashbox Fusion Soft Lights Intermix Pressed Powder	Baked Stardust DL 106	NAD	NAD
Guerlain Meteorites Poudre de Perles Illuminating Perfecting Pressed Powder	Mythic Parfait 01	NAD	NAD
Urban Decay Baked Bronzer	Gilded	NAD	NAD

Body Powder:

Brand	Shade	% Asbestos by PLM	% Asbestos by TEM
Johnson's Baby Powder	n/a	NAD	NAD
CVS Brand Baby Powder	n/a	NAD	NAD
Rite Aid Baby Powder	n/a	NAD	NAD
Anti Monkey Butt Powder	n/a	NAD	NAD
Assured Shower & Bath Absorbent Body Powder	n/a	NAD	NAD
Angel of Mine Baby Powder	n/a	NAD	NAD
Family Dollar Mild Baby Powder	n/a	NAD	NAD

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Shower to Shower Morning Fresh Absorbent Body Powder	n/a	NAD	NAD

PLM average limit of quantitation and limit of detection = 0.19% ± 0.04
TEM average limit of detection = 0.0000044% ± 1.76229E-08
TEM average limit of detection = 0.044 ppm ± 0.018
TEM average limit of quantitation = 0.39% ± 0.08

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