

FILE NAME: Talc (TALC)

DATE: 2020 Aug 18

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DOCUMENT DESCRIPTION: Email to Barry Castleman from USP

From: **NF Monographs** <nfmonographs@usp.org>
Date: Tue, Aug 18, 2020 at 9:23 AM
Subject: Talc; Asbestos; History (30) [Case Number: 00061446] [ref:_00D4164Hr._5002M19bGfv:ref]
To: barry.castleman@gmail.com <barry.castleman@gmail.com>

Mr. Castleman,

Thank you for your question. Your email was forwarded to me at the NF monographs account to answer queries relating to the USP-NF Excipient monographs and general chapters.

As you may already be aware, this USP-NF monograph is part of the Pharmacopeial Discussion Group (PDG). The PDG (EP, JP and USP) works to harmonize excipient monographs and general chapters which will reduce manufacturers' burden of performing analytical procedures in different ways, using different acceptance criteria.

Here is what I can tell you about the Talc monograph and its history. According to the historical file, it indicates Talc was first introduced into the USP in 1900 in USP VIII (8). In PF 28(3) May/Jun 2002, there was a proposal to add the labeling statement and tests in the monograph for the absence of asbestos.

The monograph was then re-proposed in 29(1) Jan/Feb 2003 with the same labeling statement and tests for the absence of asbestos. A Stage 6 (this indicates harmonization with the EP and JP) was posted in PF 30(5) Sep/Oct 2004 (official) and the following were added:

1. Labeling - A requirement that the labeling indicate its suitability for oral or topical administration is added. A requirement that the labeling indicate the absence of asbestos is also added.
2. Absence of asbestos - This section is added to ensure that the article does not contain asbestos. Talc derived from deposits that are known to contain associated asbestos is not suitable for pharmaceutical use.

The monograph was then published in the 2nd Supplement of USP 28/NF 23 which was Aug 1, 2005 as part of the harmonization process. Please keep in mind, it became official Sep/Oct 2004 as part of the Stage 6 publication.

Now, what is considered the official version is in USP42-NF37 on page 4165. Since 2004, the information stated above regarding the absence of asbestos has not changed.

Please be aware, just because this information was added to the monograph in 2004 does not mean mining companies who handle Talc were not already testing for it.

For background information, USP currently has an Expert Panel who are working on the Talc monograph and this expert panel is made up of the FDA, industry experts and manufacturers of

talc and they have been working to improve the monograph to reflect what is needed to make sure asbestos is not present as well as improve the overall monograph to reflect the testing needed for its use in pharmaceutical product(s). Once they get a draft, it will be published in the Pharmacopeial Forum (PF). Please go to: <http://www.usp.org/USPNF/pf/> to register for free. The PF gives access to new proposed monographs and general chapters along with proposed changes to all current monographs and chapters in the USP-NF with background info for these changes.

Additionally, please go to: <https://www.usp.org/frequently-asked-questions/talc-monograph> to see the FAQ's which should give you more information including links to stimuli articles and where the Talc panel is in their process. Another link is: <https://www.uspnf.com/notices/talc-nitr-20200731>. This is a notice for the intent to revise the monograph based on the expert panel and is mentioned in the FAQ's

Finally, as a scientist, I believe stating Talc is asbestos free could be misleading. One needs to know the limit of quantitation, limit of detection for the assay being utilized which is why this expert panel has been working on the monograph as stated in the notice.

Please let me know if you have any further questions. You are also encouraged to follow the link in my signature below to take an anonymous survey.
Thank you.

Robert Lafaver
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This response has been provided for informational purposes only, and should not be construed as an official interpretation of USP text or relied on to demonstrate compliance with USP standards or requirements.

Please do not remove this ref Id [ref:_00D4164Hr._5002M19bGfv:ref]

----- Original Message -----

From: Barry Castleman [barry.castleman@gmail.com]

Sent: 8/14/2020 9:30 PM

To: rstech@usp.org

Subject: Asbestos Contamination in Talc

Dear Sir or Madam,

From what I can tell, USP talc did not include any reference to asbestos until 2008. Can you confirm this or correct me?

There is concern about asbestos in talcum powders all over the world, and some manufacturers' claims that they used USP talc, or pharmaceutical grade talc, seem unmoored to any specifications that support the derivative assertion that this meant the USP talc was asbestos-free before 2008.

Thanks for your trouble in answering my inquiry.

Barry

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Barry Castleman, ScD