

Mr. G. Heinze
bcc: Mr. G. Lee ✓
Dr. D. R. Petters
Dr. B. Semple

Johnson & Johnson

See warning for

BABY PRODUCTS COMPANY

RARITAN, N. J. 08869

August 26, 1977

Mr. Gordon K. Wurster
United States Pharmacopeial
Convention, Inc.
12601 Twinbrook Parkway
Rockville, Maryland 20852

Dear Mr. Wurster:

Thank you for the information on the USP XIX Talc Monograph. We understand that the statement, "Do not inhale", under dispensing information for talc was placed there only as a suggested precaution in case the talc contained asbestos.

Current information does not indicate that the warning is needed for talc, and we feel strongly that the statement should be removed. However, we do support a standard for cosmetic talc (CTFA Cosmetic Talc Specification, Rev. 10/7/76), which specifies no detectable fibrous asbestos minerals and a typical purity level of 90% mineral talc. We encourage that this attached standard be perpetuated because the data certainly indicates that normal exposure to cosmetic talc presents no inhalation hazard.

Appended for your review is a talc safety summary and supporting literature.

Thank you for your consideration.

Respectfully yours,

Wm. C. Waggoner

Wm. C. Waggoner, PhD
Manager
Medical and Regulatory Affairs

clj
Attachments

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SAFETY OF TALC

Rubino, et al.,¹ conducted a retrospective epidemiological study of talc mine employees to determine whether the causes of death were different compared with a control population of agricultural workers not involved in dusty industries. Respiratory deaths in the talc miners exposed to mixed mineral dusts were significantly higher than controls, although the incidence of pulmonary cancer, all cancers and cardiovascular disease was statistically significantly lower for the miners than the control group. However, the millers who were exposed only to the high grade cosmetic talc had a similar incidence of deaths from respiratory disease, lung cancer and all cancers, but a statistically lower incidence of cardiovascular deaths. The data indicates that prolonged exposure to cosmetic grade talc at the current threshold limit value (TLV) for talc (20 million particles per cubic foot) did not increase deaths from pulmonary disease compared with the control group.

Wehner, et al.,² studied the effect of inhalation of a commercially available cosmetic talc baby powder in Syrian golden hamsters for as long as 300 days. The talc dust consisted of 97% mineral talc in platy form free of detectable asbestos and silica. The highest dose corresponded to 1700 times the dose to which an infant is exposed when it is dusted with it. From the data there was no difference in viability or body weight between treated hamsters and the untreated control animals. In addition, histological examination and the incidence of tumors of lungs, heart stomach, liver, kidney, testes, and ovaries showed no difference between treated and control animals.

To determine pulmonary deposition, translocation, and clearance of inhaled talc, 10-week-old hamsters received a single 2-hour nose-only large exposure to neutron-activated talc.³ An estimated 6% to 8% of the inhaled talc was deposited in the alveoli. The biological half-life of the alveolar deposited talc was 7 to 10 days. Alveolar clearance was essentially complete 4 months post-exposure. No translocation of talc to liver, kidneys, ovaries, or other parts of the body was found.

The Food and Drug Administration commissioned teratologic⁴ and mutagenic⁵ studies on talc. In the teratologic study "the number of abnormalities seen in soft or skeletal tissues of the test groups did not differ from the number occurring spontaneously in the sham-treated controls." Mutagenic testing in 3 systems, (1) host mediated assay, (2) cytogenetics, and (3) dominant lethal, produced no adverse results. Subsequent evaluation⁶ of the talc used in these studies showed that it conformed to USP requirements and was free from asbestos minerals.

Finally, a recent editorial⁷ from Lancet reviewed the subject of talc inhalation and concluded "there is no reason to believe that normal consumer exposure to cosmetic talc has in the past led either to cancer at any site or to measurable loss of lung function. It seems unlikely that future exposure to cosmetic talc of the specifications now agreed to by major manufacturers will present a health hazard."

REFERENCES

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4. Teratologic Evaluation of FDA 71-43 (Talc), PB-221 804, Food and Drug Research Labs., Inc., January, 1973.
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