INTERNATIONAL SOCIETY OF REGULATORY TOXICOLOGY AND PHARMACOLOGY

FAX COVER SHEET

FAX #: 410/740-9181

DATE: September 12, 1994

FROM: C. Jelleff Carr, Ph.D.

SUBJECT: Talc Meeting - Boorman's MS

TO FAX #: 202/331-1969

COMPANY: The Cosmetic, Toiletry and Fragrance Assn.

ATTN: Stephen D. Gettings, Ph.D.

 # OF PAGES INCLUDING COVER PAGE: 4

MESSAGE: Steve:

Boorman came through with the promised report attached. I will try to incorporate it in our draft of the Executive Summary I am holding awaiting Jay Goodman's reply re: his correct identification reference to the NTP Board of Scientific Councillors. Give me your suggestions.

The lack of an ovarian effect of lifetime talc exposure in F344/N rats and B6C3F1 mice.

Gary A Boorman DVM, Ph.D. and John C Seely, DVM,

There has been some concern reported about the perineal exposure to talc and the occurrence of ovarian cancer in women (1,2) although other studies have failed to find such an association (5). Talc particles have also been reported to be present in the ovary of women regardless of history of talc exposure (3). An NTP study of lifetime whole body exposure talc exposure (4) offered the opportunity to determine whether rodents would have ovarian talc particles after inhalation, oral and dermal exposure for more than two years.

Male and female Fisher 344/N rats and B6C3F1 mice were exposed to aerosol concentrations of 0, 6, or 18 mg/m^3 of talc for lifetime (rats) or 2 years (mice). There were no exposure related lesions in the ovaries of rats (Table I) or mice (Table II) however, because of the concern of potential effects of talc on the ovary, additional studies were performed.

Ten female rats were selected randomly from the control, 6 and 18 mg/m^3 exposure groups and the histological slides containing the lungs and ovaries were examined under polarized light for the presence of anisotropic material consistent with talc fibers. The lungs from the controls were negative for anisotropic materials but talc fibers were easily identified from the lungs of the exposed animals. The fibers were present in the alveolar macrophages and in areas associated with chronic inflammation in the lungs. There was no material consistent with talc found in the ovaries or ovarian bursa from any rats from any group.

This would suggest extensive lifetime exposure to talc for (a does) not result in the deposition of talc in the ovary. Since the animals were exposed for six hours per day with talc covering the fur and the cage bars, there was ample opportunity for perineal as well as oral and respiratory exposure. In the extrapolation of this data one should consider limitations relative to the marked anatomical and physiological differences between rodents and humans. ?

Table I. Incidence of Ovarian Lesions in Female Rats

Diagnoses	0 mg/m³	6 mg/m³	18 mg/m³
Ovarian Cyst	5	0	1
Granulosa Cell tumor, Malig.	1	0	0
Granulosa Cell tumor, Benign	0	2	0
Granulosa-theca Tumor, Malig.	0	1	0
Granulosa-theca Tumor, Malig.	0	0	1

Table II. Incidence of Ovarian Lesions in Female Mice

Diagnoses	0 mg/m³	6 mg/m³	18 mg/m³
Ovarian Cyst	6	11	10
Abscess	4	10	7
Thrombosis	1	2	0
Adenoma	1	1	0
Cystadenoma	0	1	0
Luteoma	2	0	0

References

1) Cramer, D. W., Welch, W. R., Scully, R. E., Wojciechowski, C. A. (1982). Ovarian cancer and talc: a case control study. Cancer 50, 372-376.

2) Henderson. W. J. Joslin, C. A., Turnbull, A. C., Griffeths, K. (1971) Talc and carcinoma of the ovary and cervix. J. Obst.. Gynaecol. Br. Commonw. 78, 266-272.

3) Heller, D., Westhall, C., Katz, N. Gordon, R. The relationship between perineal cosmetic talc usage and ovarian talc particle burden. (1994) Am. J. Clin. Pathol., 101, 382-383 (abstract).

4) National Toxicology Program. Toxicology and carcinogenesis studies of talc (CAS No. 14807-96-6) in F344/N rats and B6C3F1 mice (Inhalation studies). (1993) NTP Technical Report 421, U. S. Dept. of Health and Human Services, PHS, NIH Publication no. 93-3152, NIEHS, Research Triangle Park, NC 27709

5) Whittemore, A. S., Wu, M. L., Paffenbarger, R. S. Jr., Sarles, D. L., Kampert, J. B., Grosser, S., Jung, D. L., Ballon, S., Hendrickson, M. (1988). Personal and environmental characteristics related to epithelial ovarian cancer. II. Exposures to talcum powder, tobacco, alcohol , and coffee. Am. J. Epidem. 128, 1228-1240.

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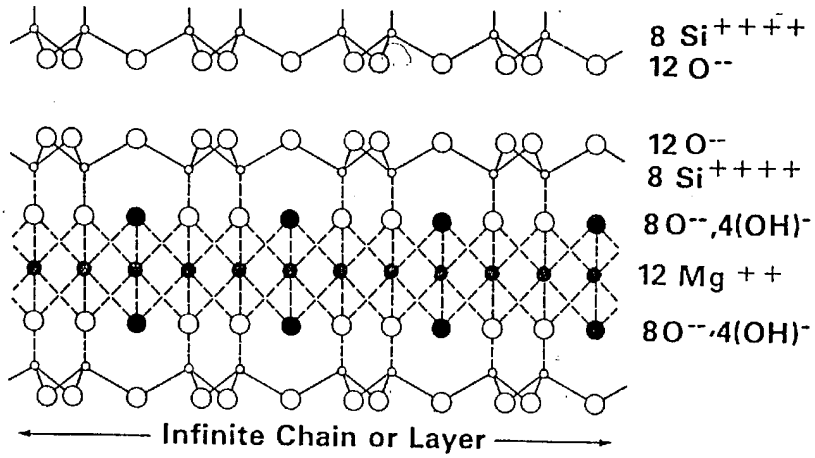

TALC - A NATURAL HYDROUS MAGNESIUM SILICATE