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Representing the personal care products industry

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MEMORANDUM

DATE: February 5, 1993
TO: Talc Interested Party Task Force
FROM: Stephen D. Gettings, Ph.D., D.A.B.T.
Director - Toxicology
SUBJ: Talc Exposure Assessment



I re-checked my file on Talc Exposure Assessment. In the latter part of 1992 the Task Force expressed no interest in Procter & Gamble's proposal to conduct exposure assessments. CTFA was, however, able to provide Procter & Gamble with the information attached.

This information may now be of use to the rest of the Task Force re preparation of the document on human exposure we propose to send to FDA.

Attachment

H:\sdg\talc\mailing\1993-1

APPENDIX 2

EXPOSURE FACTORS: NTP 2-YEAR TALC STUDY VERSUS HUMAN DATA FROM AYLOTT ET AL (attached)

1. Rat exposure data (very similar for mice)

6 hrs/day, 5 days/week. Exposure levels 0, 6, 18mg/m³ (actual very similar). Assume 100% respirable for rats.

So respirable exposures (respirable mass x time) were:

Exposure level (mg/m ³)	: 0	6	18
Exposure/day (mg.hrs/m ³)	: 0	36	108
Exposure/week (mg.hrs/m ³)	: 0	180	540

2. Man

Concentrations measured as respirable dust. Averaged values taken from table on p184 and rounded up. Representative times taken from Table 2 and rounded up. Assume 7 days/week.

	<u>Concentration (mg/m³)</u>	<u>Duration (secs)</u>
1. <u>Adult face dusting</u>	0.48 (say 0.5)	18 (say 30)
2. <u>Adult dusting</u>	1.13 (say 1.5)	45 (say 60)
3. <u>Baby dusting</u>	0.21 (say 0.3)	20 (say 30)
	<u>per day</u>	<u>per week</u>
Exposure (mg.hrs/m ³)(1)	0.0042	0.029
(2)	0.025	0.175
(3)	0.0025	0.0175
(4)*		0.058
(5)*		0.105

* see next para.

Other data for infant dusting are in the literature (Wehner et al, 1977). These authors derived a median infant exposure of 0.058mg.hr/m³ per week with an upper 95th percentile of 0.105mg.hr/m³ per week; these values are included in the table as (4) and (5) respectively. Wehner et al's median figure is three times and the upper 95th percentile six times the baby dusting figures given above but both are lower than the adult dusting figure.

Therefore the adult dusting figures will be taken as worst case.

3. Ratios: exposure rat/man

	<u>Animal exposure concentration</u>	
	6	18
Adult dusting exposure/rat exposure: per day	1440	4320
: per week	1029	3086

EXPOSURE FACTORS BY COMPARISON WITH OCCUPATIONAL EXPOSURE LIMITS

1. Animals 6hrs/day, man 8hrs/day

ACGIH 2mg/m³ as respirable dust
UK EH40/92 1mg/m³ as respirable dust, (10mg/m³ as total dust).

2. Ratios: exposure rat/man

	<u>Animal exposures</u>	
Concentrations (mg/m ³)	6	18
Exposure/day (mg.hrs/m ³)	36	108
	<u>Exposures and ratios:</u>	
ACGIH: exposure (mg.hrs/m ³): 16	2.25	6.75
UK EH40/92 : exposure (mg.hrs/m ³): 8	4.5	13.5
