

Monte Carlo Analysis of Cumulative Asbestos Exposures Associated with the Consumer Use of Talcum Powders

AUTHORS

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INTRODUCTION

Concerns over the presence of asbestos and other elongate mineral particles (EMPs) as a naturally occurring contaminant in talc-containing cosmetics, including talcum body and baby powders, has reemerged as a concern (USFDA 2020). Due to the geological characteristics of talc and that it is ubiquitous in cosmetics and other consumer products, there is a possibility that amphibole minerals may be encountered by consumers in such products at levels below the sensitivity of many established analytical methods, including polarized light microscope (PLM) and x-ray diffraction (XRD). However, the presence of asbestos in cosmetics, if any, would be rare and intermittent due to modern methods of processing cosmetic talc and the rarity of asbestiform mineral from a geological perspective (Pierce et al. 2017; Wylie et al. 1985).

USEPA's risk model assumes risks diminishing to negligible levels at low cumulative exposures, consistent with conventional regulatory risk assessment models. USEPA action levels for non-occupational asbestos exposure associated with remediation sites correspond to cancer risks between 1×10^{-4} and 1×10^{-6} (1 per 10,000 to 1 per 1,000,000), which are considered de *minimis* (USEPA 2008).

In order to assist in risk characterization, a Monte Carlo analysis was used to predict the probability of cumulative exposures to asbestos based on distributions available in published literature.

METHODS

The exposure profiles are broken down into 3 components: talcum powder use during diapering as an infant (referred below as *infant* use), use in diaper changing as a parent (*parent* use), and personal cosmetic use after infancy (*adult* use).

$$\text{Cumulative lifetime exposure} = \frac{ED_i \cdot EF_i \cdot ET_i \cdot EPC_i + ED_p \cdot EF_p \cdot ET_p \cdot EPC_p + ED_a \cdot EF_a \cdot ET_a \cdot EPC_a}{AT}$$

ED_i , ED_p , and ED_a are exposure durations (in years)

EF_i , EF_p , and EF_a are exposure frequencies (in events/year)

ET_i , ET_p , and ET_a are exposure times (in minutes/event)

EPC_i , EPC_p , and EPC_a are exposure point concentrations (in fibers/cc) during the activity

AT is the averaging time (lifetime of 70 years)

Frequency of use information is available in average number of uses per day, so ET and EF are defined as time/event and events/year respectively, rather than time/day and day/year. Because EPC is measured over a specific timeframe (e.g., 5 minutes) during which concentration may remain in the air (which may be constant or variable between measurements), EPC distribution is bundled with the measurement time as EPC ET. The distributions of these variables are as follows.

Variable	Units	Probability distribution
ED_i	years	Uniform (1.5–3 years)
ED_p	years	1.5–3 years per child, number of children based on US Census (2010) family size data
ED_a	years	70 years - ED_i
EF_i	events/year	Normalized from percentiles in CFTA (1983)
EF_p	events/year	
EF_a	events/year	Normalized from percentiles in CFTA (1983)
$EPC_i \cdot ET_i$	fibers/cc · minutes/event	From empirical distribution for baby powder procedure in Russell et al. (1979)
$EPC_p \cdot ET_p$	fibers/cc · minutes/event	
$EPC_a \cdot ET_a$	fibers/cc · minutes/event	From empirical distribution for adult powder procedure in Russell et al. (1979)

The exposure duration for diaper changing ranges from 18–36 months, with adult exposure for the remainder of the lifetime, plus diaper changing as a parent for 18–36 months per child. The mean and 90th percentiles of frequency of baby and adult use were provided by USEPA's Exposure Factors Handbook (USEPA 2011), based on the Cosmetic, Toiletry, and Fragrance Association (CFTA 1983). The distributions of exposure frequency were estimated as normal distributions fitting those values, with a minimum of zero.

Information about EPC and ET were estimated using the respirable dust measurements (in mg/m³) from Russell et al. (1979) applying the conversion factor reported by Moon et al. (2011), based on the work of Mattenklott (2007) to transform dust measurements in mg/m³ to f/cc, assuming a bulk asbestos content of 0.1%:

$$\frac{\text{mg dust}}{\text{m}^3} = \frac{0.001 \text{ mg asbestos}}{\text{mg dust}} \cdot \frac{50,000 \text{ fibers}}{\text{mg asbestos}} \cdot \frac{1 \text{ m}^3}{1,000,000 \text{ cc}}$$

This was performed because an analysis of publications of asbestos exposures from cosmetic talc powder product usage – even in studies using the same product – have had vastly inconsistent results, raising questions on the reliability and utility of the findings for the purposes of this assessment. It should be noted that interstudy variability is likely a result of inclusion criteria (e.g., whether or not non-asbestos EMPs were included in exposure fiber counts) and a lack of precision and accuracy in analytical techniques and methodologies concerning trace asbestos in cosmetic talc (Anderson et al. 2017; Burns et al. 2019).

Russell et al. (1979) was determined to be best suited to transform air concentrations from mg/m³ to f/cc since it reported data for both baby diapering application and adult body powder use, and the results were more consistent with other published literature measuring respirable dust compared with Moon et al. (2019). In Russell et al. (1979), the authors conducted simulation studies on adult talcum body powder and talcum baby powder use to measure respirable dust exposures, as summarized below, using a relatively large data set.

Table 1. Data summary from Russell et al. (1979)

	# of subjects	Weight of talc used (g)	Exposure time (min)	Concentration (mg/m ³)
Adult powder procedure	44	8.84±8.32	1.23±0.55	2.03±1.49
Baby powder procedure	48	0.88±0.63	0.52±0.17	0.19±0.084

We performed a Monte Carlo analysis in the Wolfram Mathematica programming environment, modeling the distribution of cumulative lifetime exposure based on stochastic sampling from the distributions of the underlying variables (EF, ED, ET and EPC). The sampling was performed 1,000,000 times, a level giving the percentiles of cumulative lifetime exposure a precision within 0.5%.

RESULTS

When the distributions of the exposure factors are statistically analyzed via Monte Carlo analysis, the estimated median cumulative asbestos exposure is 0.0008 f-yrs/cc, and the 99th percentile cumulative asbestos exposure estimate is 0.0129 f-yrs/cc, as summarized below.

Percentile	Cumulative lifetime exposure (f-yrs/cc)
50 th (median)	0.000835
90 th	0.00392
95 th	0.00607
98 th	0.00973
99 th	0.0129
99.9 th	0.0231

Figure 1. Fraction of relevant population modeled to have each assigned cumulative exposure with the total equaling 100%

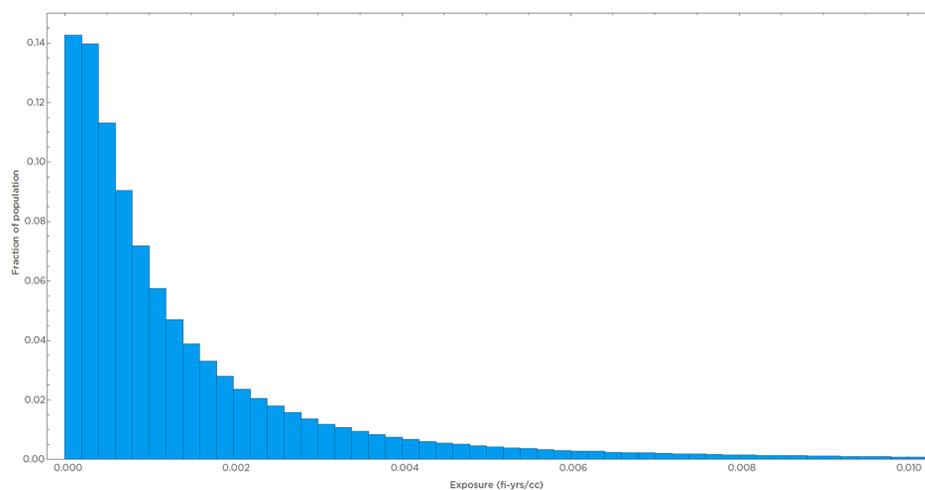
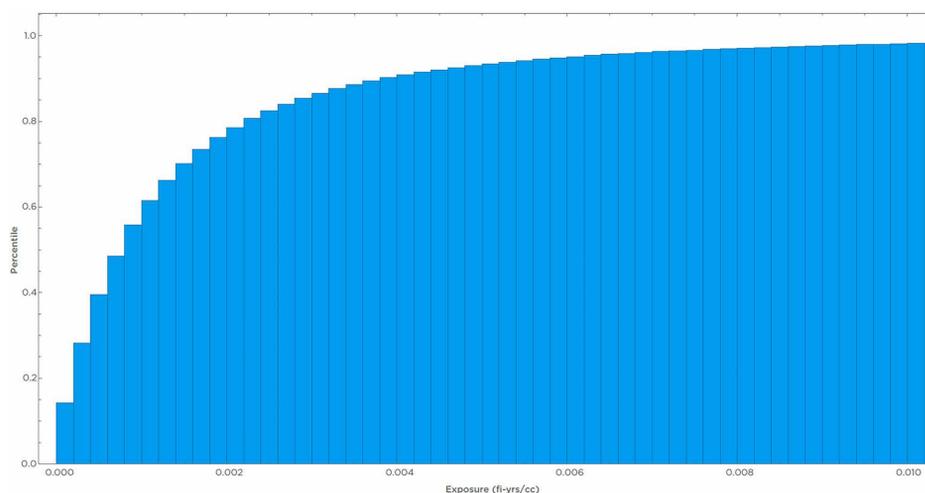


Figure 2. Cumulative exposure relative to the population percentile with the 50th percentile (i.e., 0.5) equalling the median estimate of 0.0008 f-yrs/cc



This analysis is midway between a population-wide characterization of the exposure and a conservative risk assessment based on reasonable maximum exposures. While it aims to be representative in the distribution of exposure duration and exposure point talcum dust concentrations, other assumptions are intended to result in conservative overestimates of the exposure distribution. These include the use of adult exposure frequencies based on a user-only study, the assumption that each parent does all of their baby's diaper changes, and, especially, the assumption that all cosmetic talc powder products used throughout an individual's life contained trace asbestos. The latter is an extremely conservative assumption that is not supported by the scientific literature as being plausible. This is buttressed by the epidemiological literature on cosmetic talc miners and miller cohorts, which has not demonstrated a risk of lung cancer and mesothelioma (Boffetta et al. 2018; Coggiola et al. 2003; Finley et al. 2017; Fordyce et al. 2019; IARC 2010; Marsh et al. 2019; Pira et al. 2017; Rubino et al. 1979; Rubino et al. 1976; Selevan et al. 1979; Wergeland 2017; Wild et al. 2002).

Background ambient airborne asbestos concentrations are well known to occur and have been reported using different sampling and analytical methods (HEI 1991; ATSDR 2001; Abelmann et al. 2015; Anderson et al. 2015; Burns et al. 2019), with asbestos concentrations appearing to decrease since the 1990s. More recent reported outdoor ambient asbestos concentrations, based on sampling performed in the 2000s in the US, are within the range of non-detectable to 0.0037 f/cc (Abelmann et al. 2015), which is generally consistent with ambient indoor air concentrations in buildings where asbestos-containing material are present but not being disturbed (i.e., ≤ 0.006 f/cc) (ATSDR 2001; HEI 1991; Burns et al. 2019). Estimates of retrospective cumulative background ambient asbestos concentrations are less than 0.4 f-yrs/cc (Burns et al. 2019).

CONCLUSION

By using the above statistical approach and assumptions, cumulative population-based lifetime asbestos exposures associated with the use of cosmetic talc powder products would be indistinguishable from background ambient asbestos concentrations.