



MATERION



European Workplaces: Comparison of “Total” and Inhalable Particulate Measurements

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Background

Exposure values for beryllium developed based on epidemiology studies using CFC (total dust).

European countries generally use respirable sampling or inhalable sampling to assess compliance.

Some of those setting exposure limits ignore basic industrial hygiene and just look at the literature.

Background

- For Materion, the issue became of importance when Germany was proposing an OEL of $0.06 \mu\text{g}/\text{m}^3$
- A panel of experts in Germany determined the LOAEL was $0.2 \mu\text{g}/\text{m}^3$
- Panel divided by a safety factor of 3 and advanced an OEL of $0.06 \mu\text{g}/\text{m}^3$ as measured by the inhalable method.

Werner et al., *The Analyst*, 1996

“The results from the several hundred sample pairs taken so far show that the level of exposure based on inhalable aerosol consistently exceeds that for ‘total’ aerosol. The observed ratios between the inhalable and ‘total’ aerosol exposures range from 1.2 to >3, tending to be greater for workplaces where the aerosol is expected to be coarser.”

What to Do?

- Did not want to have bad science to prevail?
- Sought a reputable consultant in Europe
- Preferably German

What to do?

No studies have been conducted to correlate inhalable particulate method exposure data with chronic beryllium disease which is the critical health effect associated with exposure to Be.

Fraunhofer Item

Fraunhofer website:

“The Fraunhofer ITEM offers contract research in the area of human health. The institute has pooled its competences to form six business units: Pre-clinical Pharmacology; Toxicology Testing; Manufacturing of Biopharmaceuticals for Clinical Trials; Respiratory Clinical Trials; Environmental, Occupational and Consumer Protection; and Registration and Risk Assessment.”

Study Objective

The aim was to determine a conversion factor from 'total' particulate sampling (CFC) to inhalable sampling (GSP) specific to Be for use in the development of an OEL in Europe based specifically on USA Be research studies that utilized the CFC sampling method.

Area Sampling for Particle Size Information

GSP



CFC



Respicon

respirable,
thoracic
inhalable



- Microwave digestion, wet digestion with sulfuric and nitric acid
- Detection: ICP-MS (x-series II, Thermo)
- Limit of quantification:
 - 0.25 ng per 37 mm filter - 0.25 ng/m³ for 1 m³ air sample
- To be consistent with the epidemiology studies, Fraunhofer decided the cassette walls were not to be wiped in order to meet the objectives of the study.

- Typical analytical procedures with spiked filters were performed. The results revealed an average recovery of 99.5%.
- Spiked filters with Be content that was unknown to the analytical laboratory were provided by Materion. Analysis according to the procedure described above revealed Be masses (between 0 and 2000 ng), consistently matched the spiked masses.

- Sampling sites selected covered widely used processing operation of alloys containing Be.
- At most of the workplaces, the alloys were processed mechanically such as drilling, milling, stamping, turning, and sawing.
- Some involved high temperatures such as welding and annealing.

Sampling did not evaluate beryllium exposures in manufacturing sectors not associated with usage of beryllium metal or beryllium containing alloys e.g. construction, cement, glass, steel production, furniture making, and shipbuilding. (Vincent 2009).

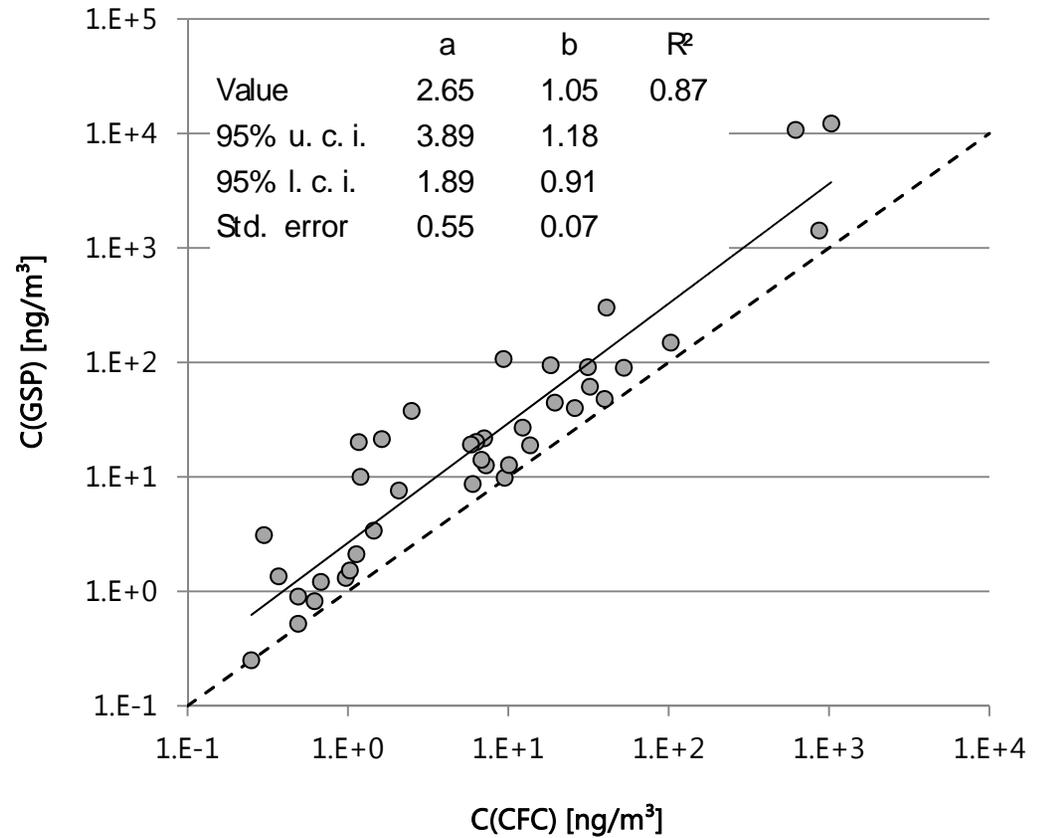
- Each person having a potential for exposure to airborne Be was monitored. (39)
- 21 area samples were collected where there was a likelihood of measuring process generated particles. (Always within 2 m proximity to the emission source.)

Results

40 personal side by side samples

$b=1.05$ -> linearity

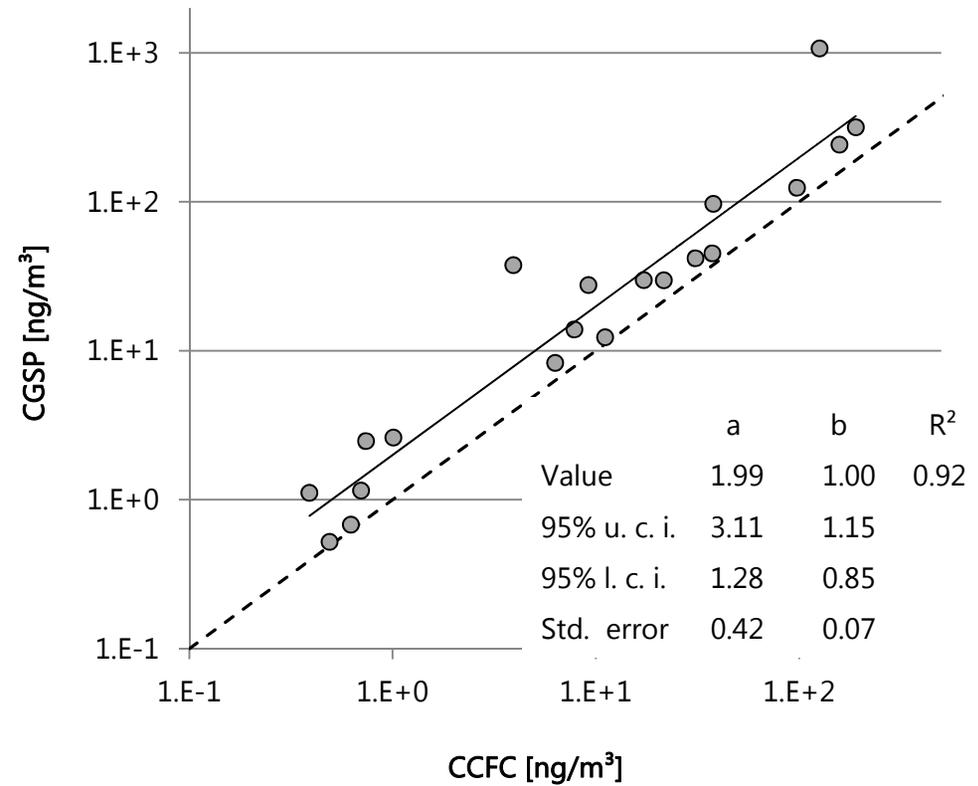
CF=2.88 (geom. mean)



20 area side by side samples

$b=1.00$ -> linearity

CF=1.99 (geom. mean)

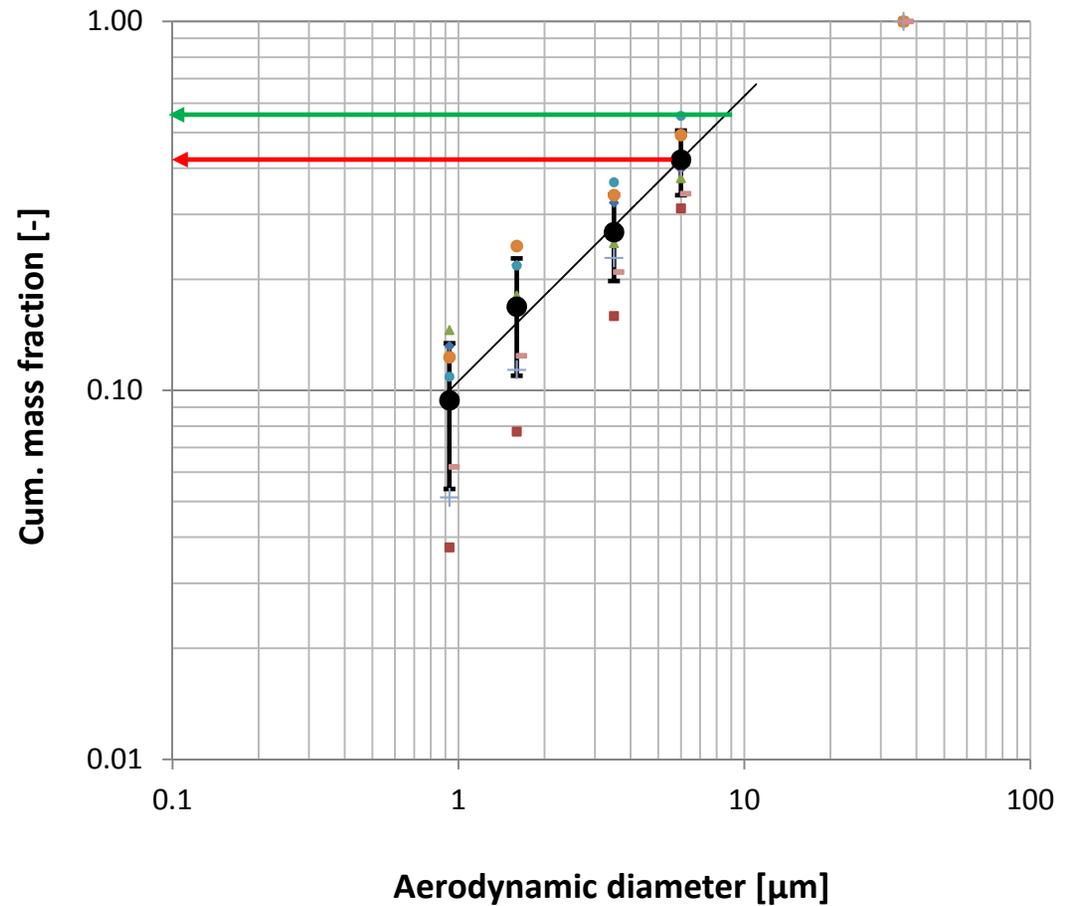


Respicon Results

40% respirable particles

55% thoracic particles

45% extra- thoracic fraction.



Geometric mean conversion factor to extrapolate from total to inhalable dust based on **all** personal samples: **2.9**

Conversion factors of other metal processing work environments

2.0	1.6 - 2.7	Ni processing
2.2	1.2 - 4.0	Ni mining and production
1.4		Al welding fumes
3.4		Al all workplaces in Norway
	1.4 – 2.6	Mn

- The Fraunhofer Study was presented to the German panel by the lead author Dr. Koch of the Fraunhofer on February 19.
- Since the German panel was using Schuler 2012 as a basis for deriving an OEL, Materion asked Dr. Schuler if she could provide the highest value in which CBD was not observed.

- Dr. Schuler responded in a letter to Marc Kolaniz with the following:

“For **average** total mass exposure, the lowest exposure at which CBD was observed (shown in Table 2b) was $0.200 \mu\text{g}/\text{m}^3$. The highest value at which CBD was not observed below the latter was $0.199 \mu\text{g}/\text{m}^3$. Table 2b also showed that 34.4% of the population had **average** exposures below $0.200 \mu\text{g}/\text{m}^3$, or 84 of 244 participants.”

- German Panel took the LOAEL of $0.2 \mu\text{g}/\text{m}^3$ - divided it by 3 and arrived at $0.07 \mu\text{g}/\text{m}^3$ which they multiplied by a factor of 2 to arrive at $0.14 \mu\text{g}/\text{m}^3$ inhalable.
- Applied the $0.06 \mu\text{g}/\text{m}^3$ to the respirable limit as the relationship was 1:1 @ respirable range (from Fraunhofer study).

- The Scientific Committee on Occupational Exposure Limits (SCOEL 2013) and the European Chemicals Agency (ECHA) recommend deriving OELs and DNELs from observed human exposure-response data using no observed adverse effect levels (NOAELs).
- Materion asked ToxStrategies to use ECHA guidelines to determine a Derived No Effect Level (DNEL).

- ToxStrategies also used the Schuler 2012 study to determine the appropriate DNEL.
- According to ToxStrategies “Schuler provides the best data available to assess the exposure-response relationship for CBD and occupational Be exposure to date.”
- “The exposure data and job exposure matrix of the worker cohort evaluated were robust, and the short time from initial exposure to assessment of BeS and CBD status allowed for greater certainty in the exposure assessment.”

- Based on the most conservative methodology, ToxStrategies proposed Occupational DNEs of:
 - 0.065 $\mu\text{g}/\text{m}^3$ respirable
 - 0.14 $\mu\text{g}/\text{m}^3$ total
 - 0.41 $\mu\text{g}/\text{m}^3$ inhalable Be (from Fraunhofer)
- Paper in pre-publication.