Dustiness testing of high aspect ratio nanomaterials and its use for exposure assessment – towards an OECD Test Guideline

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1. Introduction

High aspect ratio nanomaterials (HARNs) possess exceptional properties that makes them advantageous in different application fields. However, there are concerns regarding their potential harmful effects e.g., carcinogenicity, due to their elongated shape especially when linked to biopersistence and rigidity (Madl and O'Neill 2022, Nagai et al., 2011). WHO (1997) defined a counting rule for fibres which may reach the human lung and even the alveoli with following dimensions: equal or longer than 5 µm, diameter equal or smaller than 3 µm and an aspect ratio equal to or greater than 3. For exposure assessment, the ability of materials to release dust with nanofibers may be determined quantitatively using dustiness test methods, which are already well-established for determination of the respirable mass-fraction and total number-based-dustiness of granular nanomaterials (EN17199).

2. Objectives

The aim of this work was to harmonize and test two dustiness methods for their use on HARNs by means of an inter- and intra-laboratory comparison (ILC) with the final objective to develop an OECD Test Guideline (TG), for both HARN and granular nanomaterials.

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3. Methodology

An ILC was conducted with the participation of 7 international partners, which covered two dustiness methods, small rotating drum (EN17199-4) and fluidizer (Broßell et al., 2019). Harmonized SOPs were developed for each method as well as for the analysis of the generated aerosol using scanning electron microscopy (SEM). The two methods were tested by two laboratories with 5 different HARNs. The total number-based dustiness index (DI) was calculated based on real-time measurement instruments ($I_{n\text{-}CPC}$) (i.e., condensation particle counter – CPC) as well as on microscopy analysis of collected aerosol samples. In addition, HARN-specific dustiness measurands that take into account the complexity of HARNs and their potential harmful effects were defined and determined based on the microscopy analysis. Outcomes of this analysis include the assessment of the DI in terms of 1) the total number of high aspect ratio objects ($I_{HAR\text{-}object}$) and 2) the WHO criteria-fulfilling objects (I_{WHO}) (L ≥5 µm; D ≥ 3 µm; L:D ≥3).

The agreement of the ILC generated data was assessed by determining the coefficient of variation within and between laboratories. Further assessment of the generated data will include, among others, linear regression and the calculation of the z-score (ISO 13528), which assess the consistency of the data.

4. Results

The coefficient of variation of the calculated number-based DI within each laboratory was <35%. In general, DI calculated with CPC and microscopy analysis were in agreement, which indicates a potential use of CPC data for screening purposes. The coefficient of variation of the CPC number-based DI between different laboratories was <40 and 30% for small rotating drum and fluidizer, respectively. Overall, the DI number-based ranking of the tested materials was similar for all laboratories and methods (Figure 1), with the small rotating drum showing consistently lower DI than the fluidizer. However, some differences were found between the two methods related to the type of objects released by each one with the small rotating drum showing a higher proportion of agglomerates.

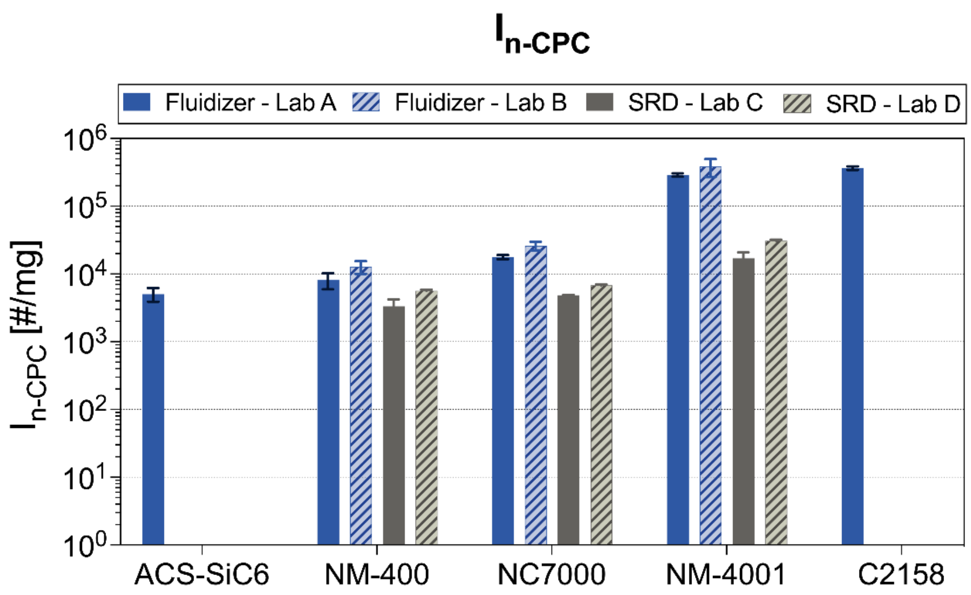

Figure 1: Average and standard deviation of CPC particle number-based dustiness index ($I_{n\text{-}CPC}$) for material, method (Fluidizer and Small Rotating Drum; SRD) and laboratory. Note: logarithmic scale used.

5. Conclusions

With the development of this OECD TG on dustiness of HARN, a harmonized framework for testing and risk assessment of airborne fibrous dust will be built. The long-term goal is to establish a ranking scheme that enables the comparison of different test methods with the potential to be used for regulatory exposure assessment of HARNs. Reliable test methods for quantifying the potential of HARN release from powders is pivotal to allow informed Safe and Sustainable by Design (SSbD) assessments and decisions.

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7. References

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