REPLY

Reply to the Letters to the Editor Submitted by T. L. Ogden and K.T. Du Clos, and by R. Foster Regarding the Paper ‘SWeRF—A Method for Estimating the Relevant Fine Particle Fraction in Bulk Materials for Classification and Labelling Purposes’

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The authors respond to the points raised in the Letters to the Editor raised by Ogden and Du Clos and by Foster. Ad 1: The debate of the classification of respirable crystalline silica is outside the scope of the technical paper. Ad 2: A standard for the determination of SWeRF is under development, in which indeed the provision is made that for a correct determination all quartz within the fine fraction needs to be liberated. Ad 3: Dustiness tests provide useful information for occupational hygienists, but are not suitable for fulfilling classification and labelling requirements. Ad 4: Pipette effects are not discussed in the paper because the difference between calculating the SWeRF from the particle size distribution and the SWeRF from sedimentation is very small.

The authors are aware of the areas of caution and the controversial discussion concerning the classification and labelling of the fine fraction of crystalline silica, notably addressed by R. Foster. However, it was not the purpose of their article to address this debate. It is the authors’ opinion that a scientific journal like the *Annals of Occupational Hygiene* is not the right platform to debate regulatory but technical issues.

The SWeRF method aims to measure the fine fraction of crystalline silica in a bulk product, regardless of the substance’s hazard classification. Currently, the SWeRF method has been validated to meet the generic cut-off values of 1% which corresponds to a classification of the crystalline silica fine fraction as STOT RE 1. Whether the SWeRF method also allows reliable quantification of the fine fraction at a generic cut-off value of 0.1% cannot be answered yet and will be subject of future experimental work.

The STOT RE 1/2 classification is indeed not the only one submitted to the classification and labelling inventory of the European Chemicals Agency; it is however the one notified by the majority (690 STOT RE 1, 998 STOT RE 2, 180 Carcinogenic 1A, and 460 ‘not classified’ notifications for Quartz CAS 14808-60-7, EC number 238-878-4). The SWeRF method provides the EU suppliers who implement the STOT RE 1/2 classification with a tool to quantify the fine fraction of crystalline silica in their bulk products, for the purpose of their products’ classification.

Regarding point 2 of Ogden and Du Clos, it is indeed correct that when a mineral is denser than quartz and not all quartz is separated from this mineral, the SWeRF content will be underestimated. When the density is lower, the SWeRF will be overestimated. We are developing a standard for the determination of SWeRF, in which indeed the provision is made that for a correct determination all quartz within the fine fraction needs to be liberated.

The authors agree with the statement of Ogden and Du Clos in their third point that dustiness tests and the SWeRF sedimentation test are both dispersing techniques for particles used for hazard assessment. Dustiness tests in accordance with EN 15051 (CEN, 2006), however, do not quantify the amount of the relevant fine fraction in the bulk material, what is actually required by the European Regulation on Classification, Labelling and Packaging of substances and mixtures and the UN Globally Harmonized System of Classification and Labelling of Chemicals (United Nations, 2011), but they quantify the amount of the inhalable, thoracic, and respirable fraction that is generated upon agitation of the bulk material. This gives very useful information for occupational hygienists, too, but does not enable fulfilling classification and labelling requirements. Furthermore, studies have shown that the results of dustiness tests depend on the method applied, i.e. continuous drop method vs. rotating drum method (Lidén, 2006).

There is an essential difference between how much fine material actually is present in the bulk material and how much of the fine particles will be released upon agitation. Agitation (either rotating drum or continuous drop) can both lead to underestimation of the fine fraction due to agglomeration which again is influenced by humidity and overestimation when fine particles are formed in situ.

The authors did not claim that sedimentation is an endpoint under GHS and CLP. Sedimentation is one of two possibilities to quantify the relevant fine particle fraction in a bulk material for classification and labelling purposes.

The authors acknowledge the findings of Ogden and Du Clos in point 4 regarding their studies of fluid flow from a cylinder into a pipette, which has relevance to the
sedimentation method as presented in the SWeRF article (Pensis et al., 2014). The part of the fluid below the level of the pipette is always higher in density. When separation is not perfect this can only increase the SWeRF. This effect was not exactly quantified but according to the experimental results as presented in the paper, the difference between the SWeRF calculated from the particle size distribution and the SWeRF determined by sedimentation on pure substances, i.e. quartz flour, was relatively small. Since the error is always on the safe side, it was decided not to discuss this in the article.

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REFERENCES