

Study demonstrates worker safety at Synthetic Amorphous Silica (SAS) Production Plants

A cross sectional study on respiratory morbidity in workers after exposure to Synthetic Amorphous Silica (SAS) at five German production plants has been published in 2016.¹ The study published in the Journal of Occupational and Environmental Medicine covered 462 workers and shows no indication of a specific toxicological effect of SAS at the workplace.

Silica is the common name for silicon dioxide (SiO₂) and exists in two major polymorphs; crystalline and amorphous. They differ substantially in their toxicological profile. The International Agency for Research on Cancer (IARC) has classified amorphous silica as a Group 3 substance which is “not classifiable as to its carcinogenicity to humans”.²

Synthetic Amorphous Silica (SAS) is a fully amorphous form of silicon dioxide (SiO₂) that is intentionally manufactured. It is produced by thermal (pyrogenic) or wet (precipitated, gel, colloidal) processes.

SAS has been produced for more than 50 years without significant changes to its physico-chemical properties or production processes. A comprehensive data set concerning various toxicological endpoints exists for SAS. In animal studies, no relevant toxicity after oral or dermal exposures has been observed. After inhalation, laboratory animals develop an inflammatory reaction, followed by fast elimination of SAS from the lung/lymph nodes. There is no long term formation of SAS deposits and no progressive lung reaction has been observed.^{3,4}

SAS is considered a nanomaterial under the current EU Commission Recommendation 2011/696/EU definition. In this context epidemiological data are of significant importance to evaluating health effects of SAS. Previously published human health data associated with exposures to SAS do not identify specific hazard, however, these data were limited.

To improve the existing database, a cross-sectional study of workers with long-term exposure to SAS dust at five German production plants has been performed.^{1,5} These manufacturing plants produce the full range of SAS powders including pyrogenic, precipitated, and surface treated.

This cross-sectional study investigated the effects of cumulative exposure to inhalable SAS dust on lung function parameters. This included the Forced vital capacity (FVC), Forced expiratory volume at 1 second intervals (FEV1), FEV1/FVC ratio, respiratory symptoms such as chronic bronchitis, and chronic obstructive pulmonary disease including pneumoconiosis by chest radiographs in 462 exposed male workers. This epidemiological study is the first in SAS exposed workers to investigate pulmonary effects based on quantitative exposure assessments based on measured data and experts assessments of historical exposure levels.

The authors of the study have concluded, “the most important finding of this study is the absence of pneumoconiosis in the SAS exposed study group”.¹ The study provides limited evidence of minor dose-related effects of chronic exposure to SAS on lung function and supports the concept that physiological soluble and non-biopersistent particles like SAS cause only minor lung function impairment.

These results are entirely consistent with former published epidemiological studies.³ These data show no indication of a specific toxicological effect of SAS in humans under former and current exposure situations at the workplace.

ASASP recommends the results of these epidemiology studies be considered in any hazard evaluation of new *in vitro* or animal data of SAS.

References:

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