NOVEMBER 2016

ECFIA UPDATE FOR POLYCRYSTALLINE WOOLS

POSITION IN EUROPE

European Directive 97/69/EC – Classification, Packaging & Labelling of Dangerous Substances

In November 1997 the directive 97/69/EC was published as a result of the considerations of a Working Group of the European commission DG Environment (then DGXI) which reviewed the position of man-made mineral vitreous [silicate] fibres (MMVFs) as a consequence of the need for all Member states of the EU to implement a common framework for hazardous substance classification and labelling, based on Directive 67/548/EC.

Polycrystalline wools are not vitreous and so were not assessed under this directive.

It should be noted that all animal testing conducted to date on Polycrystalline Wools has yielded no significant adverse effects and has included a wide array of test methodologies including inhalation studies, feeding studies and direct instillation in test animals. Information on these peer-reviewed studies is available on request.

POSITION IN GERMANY - UPDATE 2016

In Germany the Working Group "Fibres and Dusts" (AK Fasern und Stäube or AK F&S) was tasked with assessing the classification of polycrystalline fibre dust by the UAIII Committee who makes final recommendations for adoption by the Committee on Hazardous Substances (Ausschuss für Gefahrstoffe or AGS).

TRGS 905 classified polycrystalline fibrous dusts as K3 based on a proposal of the former Advisory Group on Toxicology that regarded this as an interim assessment pending the preparation of a suitable sample for intraperitoneal (IP) injection testing of rats.

To separate a sample suitable for IP testing resembling work place dust from commercially available Polycrystalline Wools has remained a very challenging task. In 2009 after discussions with Industry the UAIII Committee acting on the advice of AK Fasern und Stäube working group requested ECFIA to proceed with a project to isolate a suitable test sample in sufficient quantity to carry out an IP test and then to proceed to IP testing of a suitable sample.

In January 2010 a project manager was appointed by ECFIA and work was commenced with the IGF (Institut für Gefahrstoff-Forschung der Berufsgenossenschaft Rohstoffe und chemische Industrie; Ruhr-Universität Bochum) who had previous experience in separating fibrous and dust sample fractions for further study.

After several attempts, using blanket, bulk and milled fiber, IGF concluded they were unable to separate a suitable fraction from standard PCW material that met the morphology requirements for IP testing. This finding is consistent with previous work carried out by the Fraunhofer Institute, in which, via a different separation method they were also unable to separate a suitable test fraction.

As a result, currently dust from PCW remains classified by TRGS 905 as K3.