



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

In Germany the Technical Rules for Hazardous Substances TRGS 905 Directory of carcinogenic, mutagenic or teratogenic substances provides guidance on worker protection and can be regarded as a national supplement to annex 1 of EU Directive 67/548 but is not limited to those substances listed in that annex. Whilst TRGS are not legally binding, they are technical rules / recommendations which have a quasi-legal status. They are referred to in national law requiring employers and employees to comply with their recommendations. TRGS 905 applies only to workplace atmospheric dust with a length of >5µm, a diameter of <3µm, and a length to diameter ratio of >3:1 (i.e. WHO fibres), and not to fibre products.

In Germany the Working Group "Fibres and Dusts" (AK Fasern und Staube or AK F&S) has been tasked with assessing the classification of polycrystalline fibre dust by the UAIH Committee who makes final recommendations for adoption by the Committee on Hazardous Substances (Ausschuss fur Gefahrstoffe or AGS).

TRGS 905 currently classifies 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 proven to be a very challenging task, however in November 2009 after discussions with Industry the UAIH Committee acting on the advice of AK Fasern und Staube 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 – a programme of work which it is expected will take a minimum of 4 years to complete.

In January 2010 a project manager was appointed by ECFIA and since this time discussions have been initiated with independent institutions to identify a suitable supplier to conduct the necessary fibre separation work.

In parallel, industry has paid for studies by BGIA to fully characterize work place dust diameter distributions and is continuing to develop test methods to assess respirable and non respirable dusts.

ECFIA are working with independent experts from several countries to define a size based exoneration basis for the new generation of high fibre diameter Polycrystalline Wools. The aim is to minimise respirable fibre content in dust – an approach that would mirror the principles applied to glass fibres under Nota R of European Directive 97/69 EC, but specific and appropriate to the density and characteristics of Polycrystalline Wools.