

Classifications and Common Questions Regarding Polycrystalline Sol-gel Fibers as Potential RCF Substitute.

What is the European Council Directive?

The Directorate-General for Environment (DG-Environment), under European Council Directive 67/548/EEC (June 27, 1967), governs the classification, packaging and labeling of all dangerous substances. The directive was amended by Directive 97/69/EC on November 10, 1997 to incorporate *specific classification* decisions for Man-Made Vitreous Fibers (MMVF).

What was the impact of the amendment?

Under the DG-Environment Directive 97/69/EC, only fibers having a random orientation and length weighted geometric mean diameter (LWGMD) less than or equal to 6µm (microns) are classified. MMVF with a LWGMD greater than 6µm are *not* considered respirable and, therefore, do not fall under the classification.

How are MMVF with a LWGMD less than 6µm (microns) classified?

Classification and labeling regulations follow theories generally accepted within the scientific community that relate fiber toxicity to biodurability (biopersistence or solubility) within the lung. The underlying premise for Directive 97/69/EC being that fiber chemistry is used as a surrogate for biosolubility, which, in turn, is believed to be directly related to fiber toxicity. Fiber chemistry is therefore used as the primary determinant for fiber classification.

What are the classification categories?

Category 2: "Substances which should be regarded as if they are carcinogenic to man." MMVF with chemistries having less than 18% alkaline earth oxide by weight are classified as "Category 2 Carcinogens."

Category 3: "Substances which cause concern for man owing to possible carcinogenic effects but in respect to which the available information is not adequate for making a satisfactory assessment." MMVF with a fiber chemistry of greater than or equal to 18% alkaline earth oxides are initially classified as "Category 3 Possible Carcinogens." Provisions of the standard allow for exoneration of a Category 3 material from classification.

The Nota Q provision allows for exoneration from classification based on the successful completion of one of four (4) tests as defined under EU protocols. Possible exoneration under Nota Q is only applicable to Category 3 fibers.

How are refractory ceramic fibers (RCF) classified within the EU Directive?

Based on fiber chemistry, RCFs are classified as a Category 2 carcinogen.

How are polycrystalline Sol-gel fibers classified?

The EU Directive only encompasses man-made "vitreous" fibers. Other fibers such as man-made "crystalline" or "polycrystalline" fibers were not evaluated within the MMVF directive. Currently, no classification exists for polycrystalline Sol-gel fibers under European Council Directive 67/548/EEC.

Are Polycrystalline fibers a safe substitute for RCF because they are not classified?

Just because polycrystalline fibers were *not* evaluated under 97/69/EC does not mean they are safe. It simply means they have not yet been considered.

DG-XI *does not* describe polycrystalline fibers as a safe alternative to RCF.

- The underlying premise of the DG-XI classification in Directive 97/69/EC is that fiber chemistry can be used to determine its relative durability or biopersistence. Biopersistence is generally believed to be related to toxicity, with more durable fibers having the highest potential to cause disease.
- In vitro studies indicate that polycrystalline fibers are "durable" materials. In fact, much more so than RCFs.
- The International Agency for the Research on Cancer (IARC) currently classifies polycrystalline and RCF fibers both as Category 2(B) "Possible Human Carcinogen."
- In Germany, Polycrystalline Sol-gel fibers are currently under evaluation. The German government recently formalized the separation of polycrystalline (PC) fibers and alumina whiskers in a new version of the TRGS 905 Workplace Regulations. Alumina whiskers, which were found to be positive in animal testing, continue to be Category 2. Polycrystalline Sol-gel fibers, which have not yet been tested, are now considered to be Category 3 until such time as the proposed new animal testing is completed.
- Current German TRGS 619 workplace rules state polycrystalline fibers cannot be considered as a substitute for RCF.

For further information on the European MMVF classification or Unifrax products, please contact:

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