

## European Classification and Labeling of Man-Made Vitreous Fibers (MMVF)

On November 10, 1997, the European Union (EU), a commission of European countries (e.g., Belgium, Denmark, Greece, Spain, France, Ireland, Italy, the Netherlands, Portugal, Finland, Sweden, Austria, the United-Kingdom, Luxembourg and Germany), passed a classification and labeling standard pertaining to MMVF containing products. This action was published on December 13, 1997, within the Official Journal of the European Communities (L 343/19).

Within these provisions, the Directorate-General (DG-XI), under Commission Directive 97/69/EC, 23rd Adaptation to Technical Progress of Directive 67/548/EEC, added MMVF's to the laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances. Member states were given one year to adopt the Directive, with compliance being mandated no later than December 16, 1998.

This standard pertains to man-made (synthetic), vitreous (amorphous - glass) fibers. Other fiber types, such as crystalline and polycrystalline fibers, in addition to naturally occurring fibers, are not classified within this decision. Under the DG-XI MMVF Directive, only fibers having a random orientation and a length weighted geometric mean diameter (LWGMD) less than or equal to 6 µm (microns) are classified. MMVF's with a LWGMD greater than 6 µm (large fibers) are not considered to be potential carcinogens as they are not respirable. Most MMVF's are also classified as an "Irritant" (Xi).

In essence, the DG-XI MMVF 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 rule directly links fiber solubility (biopersistence) as a function of fiber chemistry. With fiber chemistry being relatively easy to determine between various fiber types, MMVF chemistry is relied upon as the primary determinant for fiber classification under this rule making.

All MMVF's covered by the EU Directive are subject to initial classification into one of two categories, based on fiber chemistry. The presence and concentration of alkaline earth oxides [i.e., sodium monoxide (Na<sub>2</sub>O), potassium monoxide (K<sub>2</sub>O), calcium oxide (CaO), magnesium oxide (MgO), and barium oxide (BaO)] provide the primary basis for MMVF classification.

### Category 2 Carcinogens

Those MMVF chemistries having an alkaline earth oxide concentration less than 18% by weight, are classified as "Category 2 carcinogens." MMVF's falling under the Category 2 classification must follow a product warning labeling criteria that requires a; (A) skull and crossbones symbol; (B) the identification of the hazard (Toxic) and (C) the risk phrases "May Cause Cancer by Inhalation" (R49) and "Irritating to Skin" (R38). Users of Category 2 MMVF's are also required under Directive 90/394/EC, to evaluate less toxic alternatives and use a substitute material when available.

The following is an example of a label proposed for use by the European Ceramic Fibers Industry Association (ECFIA) for RCF, a Category 2 substance.



(ECFIA recommended Category 2 Label)

### Category 3 Carcinogens

Those MMVF's having a fiber chemistry of greater than or equal to 18% alkaline earth oxides, are initially classified as "Category 3" carcinogens. MMVF's falling under Category 3 require a; (A) (R40) label depicting a St. Andrew's Cross; (B) the identification of the hazard (Harmful) and (C) the risk phrases "Possible Risk of Irreversible Effects" (R40) and "Irritating to Skin" (R38). However, unlike Category 2 fibers, there are provisions under the Category 3 standards that allow for fibers to be exempted (exonerated) from classification.

Commission Directive 97/69/EC, Note Q allows for derogation (exemption) from classification based on the successful completion of one of four (4) tests. As defined under EU protocols, derogation from Category 3 is permitted based on passing any one of the following four tests:

- 1) a short-term biopersistence test by inhalation showing fibers greater than 20 µm long to have a half life of less than 10 days;
- 2) a short-term biopersistence test by intratracheal injection (IT) showing fibers greater than 20 µm long to have a weighted half life of less than 40 days;
- 3) an appropriate intra-peritoneal injection (IP) test which demonstrates no evidence of excess carcinogenicity; and
- 4) the absence of relevant pathogenicity or neoplastic changes resulting from a suitable long-term inhalation study.

## German Workplace Standards

Passing one of the four (4) Note Q biopersistence tests permits product distribution within Europe without a cancer warning label. In addition to the DG-XI MMVF classification and labeling requirements, Germany has implemented a workplace standard (Hazardous Substances Ordinance) which requires fiber manufacturers to pass additional tests before a fiber product can be used in the workplace without special requirements. The workplace standard requires a successful IT or IP test or a KI>40 (a chemically based, mathematical approach to estimate relative solubility).

Unifrax has undertaken and passed animal testing of Isofrax™ under an IT testing protocol consistent with the requirements of the German workplace standard.

## Unifrax Insulating Fibers

### Fiberfrax® Refractory Ceramic Fiber (RCF) Products:

Fiberfrax® refractory ceramic fibers (RCF's) have a fiber chemistry of approximately equal proportions of alumina (Al<sub>2</sub>O<sub>3</sub>) and silica (SiO<sub>2</sub>). Hence, RCF's do not contain 18% alkaline earth oxides and therefore fall under the classification of "Category 2" carcinogens.

The European Ceramic Fibres Industry Association (ECFIA) has adapted product labeling guidelines that differentiate RCF products as being either an "Article" or a "Substance / Preparation." Under ECFIA's guidance, those RCF products designated as "Substances / Preparations (e.g., unlubricated bulk and blanket, unsized boards, dry cement, etc.) are subject to the labeling provisions of Directive 97/69/EC and must be labeled in a manner similar to that shown on the previous page. However, ECFIA also recommends that those RCF products designated as "Articles" (e.g., most value-added product forms such as wet cements, textiles, encapsulated furnace modules, pre-sized vacuum formed shapes and lubricated bulk and blanket, etc.) do not present end users with significant exposure potential. Therefore, ECFIA suggests that "Articles" are not subject to the Category 2 labeling requirements; instead ECFIA has adopted a voluntary labeling approach as shown in the next column.

## Article Label

ATTENTION ACHTUNG ATTENZIONE
<p>THIS PRODUCT CONTAINS REFRACTORY CERAMIC FIBRES            CE PRODUIT CONTIENT DES FIBRES            CERAMIQUES REFRACTAIRES            DIESES PRODUKT ENTHÄLT KERAMIKFASERN            QUESTO PRODOTTO CONTIENE FIBRA            CERAMICA REFRATTARIA</p> <p>BASED ON ANIMAL TESTS, RCF MAY CAUSE            CANCER BY INHALATION            SUR LA BASE D'EXPERIMENTATIONS ANIMALES, LES FCR            PEUVENT PROVOQUER LE CANCER PAR INHALATION            WIE TIERVERSUCHE ERGABEN, KANN KREBS DURCH            EINATMEN VON KERAMIKFASERN ENTSTEHEN            DA ESBERIMENTI SU ANIMALI RISULTA CHE LE FCR            POSSONO PROVOCARE IL CANCRO PER INALAZIONE</p> <p>MECHANICAL IRRITANT TO SKIN            IRRITATION POSSIBLE DE LA PEAU PAR FROTTEMENT            MÖGLICHE HAUTREIZUNG DURCH REIBUNG            POSSIBLE IRRITAZIONE DELLA PELLE IN            CASO DI SFREGAMENTO</p> <p>MINIMISE DUST            MINIMISER LA POUSSIERE            STAUBAUFWIRBELUNG VERMEIDEN            MINIMIZZARE LA POLVERE</p> <p>SEE ECFIA CODE OF PRACTICE AND            MATERIAL SAFETY DATA SHEET BEFORE USE            CONSULTER LE GUIDE D'UTILISATION D'ECFIA AINSI QUE            LA FICHE DE DONNEES DE SECURITE AVANT UTILISATION            VOR GEBRAUCH ECFIA HANDLUNGSANLEITUNG            UND SICHERHEITSDATENBLATT BEACHTEN            CONSULTARE IL CODICE DI COMPORTAMENTO            PRATICO ECFIA E LE SCHEDE DI SICUREZZA PRIMA            DELL'UTILIZZO</p>
<p><small>RCF have been classified as a category 2 carcinogen under EU Directive 67/548/EC.            Les fcr ont été classées catégorie 2 cancérogène d'après la            Directive européenne 67/548/EC.            Keramikfasern wurden durch die richtlinie 67/548/EC als krebszeugender            Stoff Kategorie 2 eingestuft.            Le FCR sono state classificate nella categoria cancerogene 2 secondo la            Direttiva Europea 67/548/EC.</small></p>

(ECFIA recommended label for Articles)

ECFIA's differentiation of product types as "Substance / Preparation" or "Article" has been embraced by many manufacturers throughout Europe; however, this approach was not specifically addressed within Directive 97/69/EC nor has it been explicitly endorsed by European regulators.

### Isofrax™ & Insulfrax™ Products:

Both Isofrax™ and Insulfrax™ insulating fibers contain greater than 18% alkaline earth oxides. Isofrax™ and Insulfrax™ have passed tests conducted by independent laboratories for exoneration prescribed under Commission Directive 97/69/EC, Note Q. Therefore, each are exempt from the classification requirements that pertain to many other high temperature insulating fibers.

Isofrax™ has also passed an IT test as prescribed by the German workplace standard. Isofrax™ passed an IT test with measured half life of "WHO fibers" of less than 40 days. Unlike most other high temperature insulating fibers, Isofrax™ qualifies under the German standard to be used within the workplace without special handling requirements.

**For further information on European MMVF classification or Unifrax products, please contact;**

Unifrax Product Stewardship  
 Health Hotline  
 1(800)332-2293

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