



**Health and Safety**  
**Toxicology**



## **Ecoflex products fall outside European Directive 2000/53/EC End of Vehicle Life**

### **European Directive 2000/53/EC**

The end of life vehicle directive of 18 September 2000 addresses the 8-9 million tonnes waste generated every year as vehicles reach the end of their lives, providing a framework to influence the design of vehicles for recovery and recycling by setting requirements for collection and treatment facilities and targets for re-use, based on the principle of polluter-pays.

The directive requires manufacturers to seek alternatives where hazardous materials are being used affecting the recovery and recycling capability. The text of the directive refers to the application of preventive measures from the conception stage of the vehicle onwards and takes the form, in particular, of reduction and control of hazardous substances in vehicles, in order to prevent the release into the environment, to facilitate recycling and to avoid the disposal of hazardous waste.

Hazardous substance means any substance which is considered dangerous under Directive 67/548/EC (97/69/EC). There are a number of fibres, such as vitreous ceramic fibres, which are covered by this directive but polycrystalline alumina fibres such as Saffil (used in Ecoflex 200) and M-Fil (used in Ecoflex 200M) are not included and there are no special handling or disposal requirements for the products.

The Ecoflex products supplied by Saffil Ltd are not listed as a hazardous substances and do not contain the hazardous chemicals listed in the text of the directive in quantities we have been able to detect.

**In conclusion, Ecoflex products are not affected by directive 2000/53/EC.**

## **Ecoflex products fall outside European Directive 97/69/EC Classification, Packaging & Labelling of Dangerous Substances**

### **European Directive 97/69/EC**

The European Commission DGX1 Working Group reviewed the position of man-made mineral vitreous fibres (MMVFs) under Directive 67/548 concerning the classification, packaging and labelling of dangerous substances. The MMVFs affected included continuous glass filaments, slagwool, glasswool, rockwool and refractory ceramic fibres (RCFs).

In November 1997 the European Directive 97/69 was formally adopted with the following result:

- ❖ some mineral fibres were classified as category 3 carcinogens (substances which cause concern for man owing to possible carcinogenic effects). These products require a label showing the St Andrews Cross and the risk phrase: "possible risk of irreversible effects";
- ❖ certain fibres including RCFs were classified as category 2 carcinogens ("substances which should be regarded as if they are carcinogenic to man") on the basis of animal studies. These substances require a label showing a skull and crossbones and information (risk phrase R49) including "may cause cancer".

**However, it should be stressed that the European classification and labelling decisions on MMVFs do NOT affect Saffil alumina or M-Fil fibres, which fall outside the scope of Directive 97/69. This means that on a European basis Saffil and M-Fil fibre has not been categorised as a carcinogen and the health and safety position remains unchanged, with no special handling, labelling or disposal requirements for these products.**

## Regulatory Position in Germany

### TRGS 905

The provisions of TRGS 905 are applicable to man-made mineral fibre (MMMMF) dusts with WHO dimensions and cover both vitreous and crystalline fibres. However, it is important to note that:

- ❖ The decision to consider crystalline alumina fibres as being carcinogenic was based on single crystal "whiskers" of alumina which are very different to polycrystalline alumina fibre in terms of manufacture, properties and hazard. Saffil alumina fibres are polycrystalline not single crystal in nature.
- ❖ The responsibility for classification is with fibre manufacturers after reviewing the available scientific evidence, taking into account TRGS 905 guidelines. A series of toxicological studies have been carried out with Saffil alumina fibre, involving lifetime inhalation, intra-plural injection and feeding studies in rats which all gave negative results (ie no fibrogenic, carcinogenic nor other toxicological effects), whereas an asbestos control gave the expected positive results. The studies have been published in detail and copies are available on request.
- ❖ M-Fil fibres are also polycrystalline, manufactured using sol-gel technology and have a similar diameter distribution to Saffil alumina fibres. Thus we would expect similar toxicological results to Saffil fibres but no test data are available to date.

**We believe that Saffil alumina fibres do not fall under the criteria of TRGS 905 as carcinogenic dust.**

## BK Tox Committee of the AGS

The Bk-Tox Committee of the AGS considered the position of polycrystalline fibres. The results of the meeting were as follows:

1. A recommendation will be made to the AGS and the Ministry of Labour that a provisional classification 3 should be given to polycrystalline fibres (such as Saffil and M-Fil) for a limited period of time of up to 4 years.
2. A sub-committee would be formed to carry out an assessment, within a 6 month period, on a selected polycrystalline fibre to determine the feasibility of isolating a sample of fibre containing WHO fibres and then carrying out an animal injection test according to an agreed protocol.
3. If the sub-committee reaches agreement on the feasibility of conducting the injection tests then testing would be conducted over a 3 year period.
4. It is likely that a definition of the term "polycrystalline" and a fibre diameter specification will be required to support the eventual decision on the appropriate classification for this group of fibres.
5. This means that possibly until 2006 there may not be complete clarity on the classification of polycrystalline fibres since producers are still free to self-classify products, but the advice of the Bk-Tox Committee for a holding position of classification 3 should ease any concerns that users and potential users might have.

**The Saffil business therefore has the choice of continuing with its present zero self-classification or adopting the provisional classification 3 proposal for its Saffil alumina fibre products.**

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