PRODUCT STEWARDSHIP PROGRAMME

PRODUCT RESEARCH

ECFIA´S PRODUCT STEWARDSHIP PROGRAMME

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INTRODUCTION

This is a document in the ECFIA Product Stewardship Programme (PSP) series. Documents in this series provide detailed information on key PSP elements. The purpose of this document is to provide a brief description of the health effects research being undertaken by ECFIA and its member companies. A general overview of the PSP is provided in the ECFIA Action document "ECFIA´s Product Stewardship Programme".

WHAT IS THE PRODUCT STEWARDSHIP PROGRAMME?

In the 1990s ECFIA, the European association of the manufacturers of High Temperature Insulation Wools (HTIW), proactively developed a comprehensive Product Stewardship Programme (PSP). Its purpose is to enable full understanding of the way that HTIW may impact workers and the environment, and to mitigate any such possible impacts. It is designed to give manufacturers, end-users and regulators knowledge about the manufacture, use, levels and health effects of HTIW in industrial settings, and to provide analysis and recommendations on the proper storage, handling, use and disposal of HTIW products.

BACKGROUND

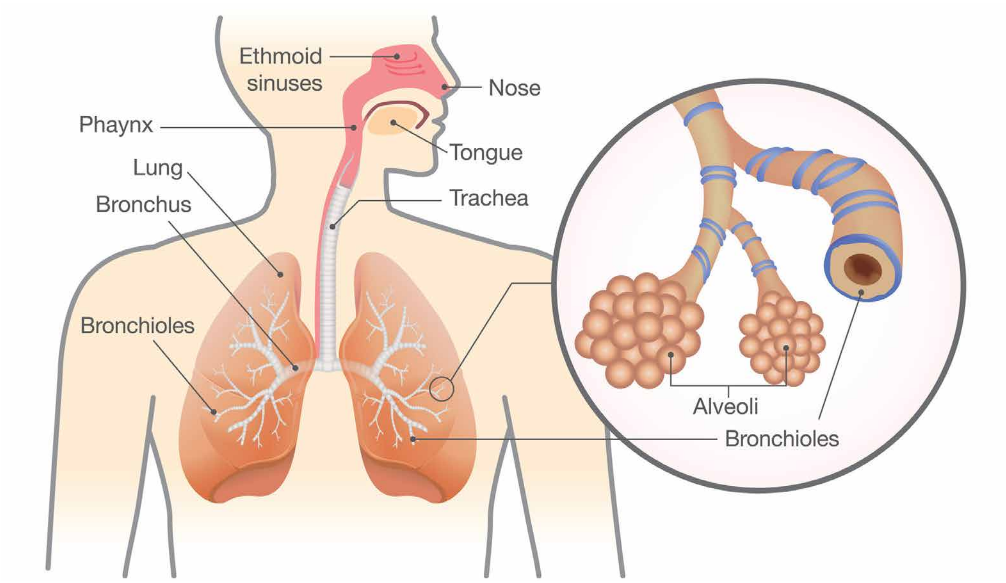
ECFIA's members are committed to programmes that develop products and systems for the effective reduction of the risk of disease. In this context 'product research' describes activities predominantly aiming at developing HTIW materials with a reduced hazard or risk profile. Activities in this area are obviously of a competitive nature, hence product research and development activities are not carried out jointly, but rather by individual ECFIA member companies.

PRODUCT RESEARCH AND HEALTH EFFECTS RESEARCH

The findings of the health effects research activities carried out under the PSP have provided invaluable scientific information. The "3D paradigm of fibre toxicity" is of particular relevance for product research:

- Dose: the fibre concentration at the workplace (external dose) or the number of fibres deposited in the lungs (internal dose or chronic lung burden)
- Dimension: fibre diameter defines respirability and probability of alveolar deposition (with fibres around 1 µm being most likely to be deposited). Fibre length influences macrophage clearance (macrophages cannot fully engulf particles longer than 15 … 20 µm).
- Durability: aka biopersistence – the capability of fibres to resist clearance mechanisms.

The potential health concern is related to fibres deposited in the alveolar region of the lungs. The respiratory tract acts as a filter, using different mechanisms to either avoid foreign particles to be inhaled or to remove them once deposited. Very fine fibres (about 1 µm in diameter) have the highest probability to reach the alveoli, whereas bigger fibres are blocked or cleared in the upper regions of the respiratory system. Once a fibre is deposited in the alveoli it can be cleared via macrophage cells, provided it is short enough (< 15 … 20 µm) to be fully engulfed by the cell. This is why particularly fibres longer than 20 µm have a higher toxic potency, unless they break into shorter fragments as a result of (local) dissolution effects. These shorter fragments can then be cleared by macrophage cells.



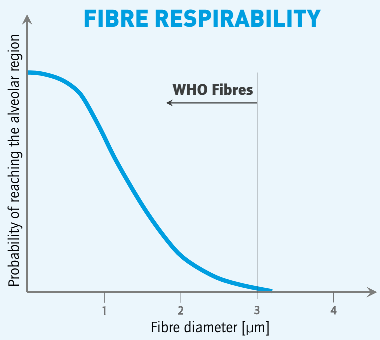
Product research aims at reducing the hazard profile of fibres, hence the 3D paradigm results in two guiding principles for the development of fibres:

- Reducing biopersistence will reduce the toxic potency of a fibre. A fibre rapidly cleared from the lungs has less potential to cause a chronic effect.
- Reducing respirability will reduce the amount of fibres becoming airborne (external dose) and the amount of fibres deposited in the target organ (internal dose - i.e. alveolar region of the lungs).

FIBRE DEPOSITION

The number of fibres reaching the deep (alveolar) region of the lung depends on:

- The number of airborne fibres to which the lung is exposed
- The physical characteristics (dimensions) of the fibres, especially diameter, which determines their respirability



'WHO' fibres are not all equally respirable.

Prof. Dr. Paul Harrison, Toxicologist - BOHS conference April 2017 - Harrogate UK

FIBRE DEVELOPMENT

The concept of reduced biopersistence has been the leading design parameter in the development of AES (alkaline earth silicate) wools. These fibres are typically based on a Mg-Ca-Si chemistry, providing sufficient high temperature capabilities for a range of applications while the biopersistence half life of these fibres is typically < 10 days following short term inhalation experiments in rats (one of the tests established under Note Q in European regulation). Chronic inhalation experiments with these fibres have demonstrated the absence of carcinogenic potency. Hence, when used under controlled conditions based on appropriate industrial hygiene practices, AES fibres are considered an alternative to other, more durable fibres. It has, however, been a major challenge to develop a fibre durable enough to withstand the chemical and physical conditions of the most demanding industrial applications which at the same time breaks down rapidly in the lung milieu under macrophage attack.

Another approach has been used in the development of PCW (polycrystalline wools). The "sol gel" manufacturing process allows a tighter control of fibre diameters compared to the conventional melt-blown or melt-spun process used to manufacture other synthetic mineral fibres. PCW products contain practically no sub-micron fibres and several products also contain a significantly reduced content of fibres falling under the WHO definition[1] (i.e. fibres ≤ 3 µm). Animal experiments using maximum achievable doses of PCW fibres did not result in any indication of chronic health impacts. The increase in fibre diameter affects safety in two ways. Fewer fibres have the potential to be deposited in the lungs because of the shift towards larger diameters. In addition, larger diameter

1 The World Health Organisation defined fibres for the purpose of workplace exposure measurements as follows: elongated particles with a diameter ≤ 3 µm, a length ≥ 5 µm and an aspect ratio greater than 3:1

fibres show a reduced potential to become or stay airborne, hence controlling workplace exposure levels is usually much easier. The advantage of larger and better controlled fibre diameters has, however, some technical and economical drawbacks. The manufacturing process is inherently slow, leading to reduced output quantities at a much higher cost profile compared to conventional HTIW products.

APPLICATION DEVELOPMENT

In addition to the development of new fibers described in the previous section, another approach to reduce the risk of fiber release into the workplace air is followed in the design of product forms suitable for specific applications. Fibers or wools are typically not placed on the market in their initial "bulk" form, but rather converted into products (articles) suitable for a range of applications. One design feature of these products is the reduction of exposure risk via different design features such as "ready to install" geometries which do not require further manipulation before installation or the addition of binder systems which can act as a dust suppressant. The objective from a health standpoint is to reduce the required amount of handling and/or the inherent "dustiness" of the products as this can help to significantly reduce the amount of fibrous dust released at the workplace.

Shaped products "ready to install"

Paper and Felt incl. organic binder

SUMMARY

Fibre toxicology research resulted in the 3D paradigm of fibre toxicity, which in turn provided invaluable directions for the development of fibres with a low risk profile. ECFIA members have individually developed products which demonstrated the absence of severe chronic health effects in toxicology tests. Products based on AES and PCW can be used as alternatives to ASW/RCF in a range of applications (technical and economic suitability has to be evaluated case by case) and are subject to less stringent regulatory requirements. If used under adequately controlled conditions, these products can provide an additional "safety margin" for workers' health.

The development of new fibers is complemented by the design of products that are easy to install and less dusty – design features which can significantly reduce the exposure potential.

FOR FURTHER INFORMATION PLEASE VISIT

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REFERENCES

Robert C. Brown; Paul T.C. Harrison, Alkaline earth silicate wools - a new generation of high temperature insulation (Regulatory Toxicology and Pharmacology 64 (2): 296-304) Sept 2012