PRODUCT STEWARDSHIP PROGRAMME

HEALTH EFFECTS RESEARCH

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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

Health effects research is a fundamental aspect of ECFIA's PSP. This document explains the rationale for such research and details some of the studies that have been recenty conducted or are ongoing. It should be read in conjunction with the 'Product research' and 'Special studies' documents.

HEALTH EFFECTS RESEARCH

ECFIA is active in the design and sponsorship of health effects research programmes. These studies investigate the potential health effects of inhalation exposure to HTIW fibrous dust and include both experimental and epidemiological studies. They constitute part of the ongoing risk assessment process for HTIW. Their focus is on a better understanding the potential health impacts of HTIW products, at all stages of the life-cycle, to enable early identification of any health risks and the mitigation of any ensuing health impacts, hence ensuring continued protection of the workforce.

ECFIA´s members are major sponsors of several studies designed to determine the potential long-term health effects of inhalation exposure to HTIW fibrous dust. Past studies sponsored by the industry include inhalation bioassays in rodents, short-term inhalation studies to measure biopersistence of fibres in vivo, durability measurements of new fibres in vitro, and risk analysis of occupational exposure. Results of these historical studies are detailed elsewhere (see www.ecfia.eu) and are also the focus of a number of published papers and reports - listed in the 'References' section below.

Current studies include the continued detailed surveillance of workers in the RCF/ASW manufacturing industry. This longitudinal epidemiological study has been running since 1987 and involves male and female current workers at three RCF production sites, and current and former workers at two additional sites. Results of this research are critical in determining the health consequences of workplace exposure to RCF fibres, particulary in relation to pulmonary disease - lung fibrosis, lung cancer and mesohelioma. Data from this important study have been published in several peer reviewed scientific papers (see References). Results so far indicate that there is no increased risk of lung cancer or of mesothelioma in the workforce. As fibre exposure levels in the industry continue to decrease, it is extremely unlikely that any significant health effects will be detected. Results from such studies are essential for the proper risk assessment of RCF/ASW and the establishment of appropriate regulation and risk management measures.

MAJOR INSTITUTES WHO HAVE ORGANISED AND PUBLISHED STUDIES

University of Cincinnati: various epidemiological studies on the health of ASW production workers

University of Birmingham: cross-sectional morbidity study

Institute of Occupational Medicine in collaboration with INRS and University of Cologne: cross-sectional morbidity study

More recently, concern has been expressed about the possible health impacts of cristobolite (crystalline silica, CS) present in HTIW and other synthetic vitreous fibres that have been exposed to heat. Such materials include so-called 'after-service' fibres that have been removed from furnace linings. To answer questions regarding the potential toxicity of such fibres, ECFIA members commissioned a series of in vitro studies looking at cytotoxic and genotoxic end points in rat pulmonary macrophages for a range of heated HTIW fibres. Results from these studies, recently publshed in a peer reviewed scientific journal (Ziemann et al., 2014), clearly indicate that the presence of CS does not enhance the toxicity of the heated fibres. Based on these findings, it is assumed that the CS present in the fibre is not bioavailable, either because the effects are somehow neutralised or the CS present is not physically available to the cells. Additional research is underway on this topic.

ECFIA has also commissioned desk-based research on regulatory risk assessment approaches to synthetic vitreous fibres (including RCF), fibre toxicology tests and the relevance of intraperitoneal assays, and the importance for regulation of appropriate differentiation between threshold and non-threshold carcinogens (see References).

All these studies constitute part of the ongoing risk assessment process for HTIW initiated by industry.

SUMMARY

This document details ECFIA's involvement in 'Health Effects Research' and explains what studies have been undertaken or are underway to better understand the potential health impacts of exposure to HTIW both during manufacture and after commercial use. Results so far indicate no significant health effects in workers and no effects of the CS that is present in after-service fibres. Results of these studies, and of several desk-based projects sponsored by ECFIA, are critical for the continued safe use and appropriate regulation of HTIW.

FOR FURTHER INFORMATION PLEASE VISIT

www.ecfia.eu
www.guidance.ecfia.eu

OR CONTACT US

Mail: info@ecfia.eu
Phone: + 33 6 31 48 74 26

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