



Introduction

Products made from Alumino-Silicate Wools (ASW), often also referred to as Refractory Ceramic Fibres (RCF) are indispensable for the efficient thermal management of modern industrial high temperature processes in various key industry sectors across Europe.



Based on the results of animal studies, ASW/RCF has, since 1997, been classified in the EU as a carcinogen. As a consequence of this hazard classification ASW/RCF has been included in various national rules as well as in EU Directives under the framework of the Occupational Safety and Health (OSH) regulation. This document and the associated references are intended to inform regulatory decision-makers about our industry's approach to workplace risk management for ASW/RCF products. We specifically highlight some of the important considerations and scientific findings related to the definition of an adequately protective workplace limit value for ASW/RCF fibrous dust. We

would emphasize that a recently completed 30-year longitudinal respiratory morbidity and mortality study of RCF workers found no increase in lung fibrosis or lung cancers; no mesotheliomas occurred and there was no increase in respiratory deaths.

We conclude that the application of OSH regulation based on the STOP principle (Substitution where feasible, otherwise Technical, Organizational and Personal exposure protection as needed), including compliance with a scientifically justified exposure limit adequately manages the potential risk associated with the handling and use of ASW/RCF products. In the following sections we provide detailed information via links to additional documents and scientific publications to support this conclusion. This is indicated by a 'globe' symbol (clicking on the symbol will open the link).

ASW/RCF products can be used safely

Certain precautions have to be taken during handling and use of ASW/RCF products to avoid potential health effects associated with the exposure to respirable fibrous dust in the workplace.

No human disease associated with ASW/RCF exposure has been reported after more than 60 years of industrial use and 30 years of epidemiological research.

Over the last three decades our industry has actively advocated the control and reduction of workplace exposures, leading to substantial improvements in

exposure controls at manufacturers and users alike. Our joint efforts have demonstrated that ASW/RCF products can be used safely – in fact, no human disease associated with ASW/RCF exposure has been reported after more than 60 years of industrial use and 30 years of epidemiological research.

Risk management of ASW/RCF: risk models and exposure limits

Our industry, along with industrial user sectors, has been advocating for some while the implementation of a EU-wide binding occupational exposure limit value (BOELV) instead of the inclusion of ASW/RCF on REACH Annex XIV. The concept of a stronger acknowledgement and implementation of occupational safety and health (OSH) Directives along with appropriate EU limit values has also been promoted as an alternative to REACH authorisation by a wider industry group (CII: cross industry initiative for better chemicals regulation).  

The HTIW industry has developed a comprehensive and multi-faceted product stewardship program to manage and reduce the potential health risks associated with production and use of ASW/RCF. Among its many features, this program includes substitute evaluation, the development of effective engineering controls, workplace practices (such as publishing multi-lingual outreach, guidance, and training materials), efficient exposure monitoring protocols, and recommendations on use and types of personal protective equipment. We will focus here on the importance of a valid occupational exposure limit (OEL). In the specific case of ASW/RCF, the derivation of an adequately 



protective exposure limit should be based on the following considerations:

- ASW/RCF products are designed for industrial high temperature applications – the potential health concern is limited to the release of fibrous dust in workplace situations.
- Because of limitations in the methodology of the original animal studies¹, the cancer risk associated with the current CLP 1B classification is probably overstated and ASW/RCF products can be handled safely. The following points are especially pertinent:
 - ASW/RCF shares many relevant intrinsic properties with rock/slag wools.² Various epidemiology studies have concluded that neither the ASW/RCF worker cohort nor the much larger cohorts exposed to rock/slag wools show an increase in lung cancer (incl. mesothelioma)  above background rates.
 - Read across from amphibole asbestos, a known human carcinogen, is not scientifically justified. The only studies potentially supporting this approach are intraperitoneal injection experiments carried out in the laboratories of Dr. F. Pott. The injection of high doses of foreign particles into the abdomen of study animals has been rejected as a meaningful method to evaluate a human risk for inhaled parti-

¹ Brown, R. C., et al., 2005. Survey of the biological effects of refractory ceramic fibres: overload and its possible consequences. *Ann. Occup. Hyg.* 49: 295-307.

² Greim, H., et al., 2014. Perspectives on refractory ceramic fibre (RCF) carcinogenicity: comparisons with other fibers. *Inhal. Toxicol.* 26, 789-810

cles and, moreover, the published study reports do not satisfy various important quality criteria.³ 

- ASW/RCF is not a primary genotoxic carcinogen. This means that a safe exposure level (threshold) can be defined. If workplace exposures are kept below this level, ASW/RCF products are safe to use.⁴
- Risk assessments and the resulting occupational exposure limit values vary significantly between regulatory bodies. A robust risk assessment should take account of the total weight of scientific evidence, including the results of human epidemiology studies.⁵ Risk models solely based on injection studies or linear dose-response extrapolations based on 'worst case' non-threshold scenarios are inappropriate and do not reflect  current scientific knowledge.
- The key study used for the purpose of REACH registration (a chronic, multi-dose rat inhalation study carried out by RCC Geneva) allows the calculation of a DNEL of 2.17 f/ml following the applicable REACH guidance, using conservative assessment factors.

³ Umweltbundesamt Austria, 2011. Reliability assessment of selected references used for carcinogenic potency comparison of Zirconia Aluminosilicate Refractory Ceramic Fibres and Aluminosilicate Refractory Ceramic Fibres with Crocidolite, Vienna 2011

⁴ SCOEL-EU: Recommendation from the Scientific Committee on Occupational Exposure Limits for Refractory Ceramic Fibres, SCOEL/SUM/165, September 2011 and DECOS. Refractory Ceramic Fibres; Evaluation of the Carcinogenicity and Genotoxicity. Dutch Expert Committee on Occupational Safety. Health Council of the Netherlands, The Hague. Publication no. 2011/29.

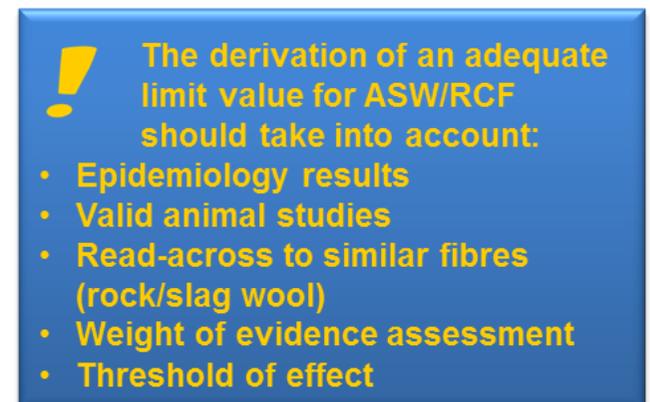
⁵ Harrison, P.T.C., et al., 2015. Regulatory risk assessment approaches for synthetic mineral fibers. *Reg Toxicol Pharmacol* 73, 425-441

- The current recommended exposure guideline supported by our industry is 0.5 f/ml. This is much lower than the calculated DNEL; it is based on prudence and demonstrated feasibility and provides an additional 4-fold safety margin.

Conclusion

The application of OSH regulation based on the STOP principle (Substitute evaluation, Technical, Organizational and Personal exposure protection as needed), including compliance with a scientifically justified exposure limit adequately manages the potential risk associated with the handling and use of ASW/RCF products.

The derivation of an exposure limit must follow a robust scientific procedure, including consideration of all relevant information in a 'weight of evidence' approach. Human data are of utmost importance in this process. In the case of ASW/RCF, the available epidemiological evidence supports the implementation of a safe exposure level, as no human disease has been associated with ASW/RCF or other fibres with a similar toxicological profile after many years of research and follow-up.



The derivation of an adequate limit value for ASW/RCF should take into account:

- Epidemiology results
- Valid animal studies
- Read-across to similar fibres (rock/slag wool)
- Weight of evidence assessment
- Threshold of effect