Press Release

Prevalidation study for testing toxic effects of inhalable substances (gases) using VITROCELL® cultivation and exposure system

Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA Berlin) presents study report

BAuA Press release dated August 22, 2011

Prevalidation study for testing toxic effects of inhalable substances (gases)

The aim of the study was the prevalidation of an inhalation toxicity test for gases using human lung cells exposed on the air liquid interface(ALI). Four test laboratories participated in the study:

Fraunhofer Institut für Toxikologie und Experimentelle Medizin
(ITEM Hanover, coordination),
Helmholtz-Zentrum für Umweltforschung (UFZ Leipzig)
Bundesinstitut für Risikobewertung (BfR/ZEBET Berlin) and
Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA Berlin).

Four gases, nitrogen dioxide (NO2), sulphur dioxide (SO2), formaldehyde, ozone as well as synthetic air for negative control were investigated. The human alveolar cell line A549, grown on microporous membranes was exposed on the air liquid interface to different concentrations of test gases and synthetic air. The test design comprised one hour gas exposure followed by direct determination of cytotoxicity (electrical current exclusion method, CASY, Innovatis) and genotoxicity (Comet assay).

Analyses of dose-response relationships for cytotoxicity showed a good repeatability within and reproducibility between the laboratories for all four gases. Comparison of the derived EC50 values with published LC50 values for mice and rats revealed a tight quantitative relationship between in vitro cytotoxicity and in vivo lethality.

Genotoxic endpoints demonstrated clear and reproducible dose-response relationships for SO2 and formaldehyde, indicating DNA strand-breaks (SO2) and DNA-protein crosslinks (formaldehyde). No such dose-dependent effects could be observed for NO2 and ozone by means of logistic regression analysis. The multivariate analysis of variance showed subtle hints for genotoxic effects of both gases.

Before entering a formal validation stage, extended prevalidation will be necessary to establish a set of data sufficiently large to allow for optimization of the prediction model.

Please download the complete report "Prevalidation study for testing toxic effects of inhalable substances (gases)" (in German only).

http://www.baua.de/de/Publikationen/Fachbeitraege/F1835.html

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