



## Focus on IFA's work

# Air to go? A new measuring method using sampling canisters for ethylene oxide

#### Problem

Some hazardous substances cannot be optimally adsorbed and stably stored by the active sampling methods commonly used in occupational safety and health (such as those utilising activated charcoal tubes). These include ethylene oxide and 1,3-butadiene. Both of these substances are produced, processed and used on an industrial scale in Germany. The measurement methods currently employed for these substances have limited potential for optimization. Consequently, there was a clear requirement for the development of an alternative method, in particular for ethylene oxide, given its use as a sterilizing agent for medical materials. An elevated risk of exposure exists for workers, particularly in workplaces situated in close proximity to the sterilization chamber, but also during the filling and cleaning of ethylene oxide gas cylinders, in largescale production and during the use of sterile materials.

#### **Activities**

In the course of a doctoral project, valid measurement methods for ethylene oxide and 1,3-butadiene were developed that satisfy the requirements of the TRGS 402 Technical Rules for Hazardous Substances and the EN 482 standard. The acceptable and tolerable concentrations, as defined by to the exposure-risk relationship concept of TRGS 910 were employed as assessment criteria. A sampling canister and a range of analytical methods were studied for their suitability for the detection and quantitative analysis of ethylene oxide and 1,3-butadiene. In these methods, the canister is evacuated in the laboratory by means of a vacuum pump prior to sampling. At the sampling site, the canister draws in a regulated flow of sample



Canister sampling during the cleaning of ethylene oxide gas cylinders.

air through a combination of fine-control valve and mechanical mass flow controller. The canister, and analysis and detection by means of gas chromatography-flame ionization detection (GC-FID), proved to be fully suitable. Validations were performed on the IFA's test gas stream. For trialling of the measurement method, over 100 ethylene oxide samples were taken at industrial workplaces and analysed in the laboratory.

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### **Results and use**

The new analysis methods for ethylene oxide and 1,3-butadiene satisfy the general requirements of EN 482 for the performance of measurement methods for determining the concentration of hazardous chemical agents in work areas.

Subsequently, the methods' suitability was tested by the performance of measurements on site in several companies in a number of different sectors and activities (production, filling, sterilization). The limit values for ethylene oxide (acceptable concentration 0.1ppm, tolerable concentration 1ppm) were exceeded at some workplaces, in some cases by several times the limit. The measurement results ranged from <10 ppb to > 10 ppm. The highest exposures occurred in the immediate vicinity of open sterilization chambers as they were being emptied, and during the re-flanging of gas cylinders. The measurement methods for ethylene oxide and 1,3-butadiene have been included as standard methods in the MGU measurement system for exposure assessment of the German Social Accident Insurance Institutions.

#### **User group**

Metrological services and OSH professionals in companies involved in sterilization, production and logistics of ethylene oxide; AGS Committee for Hazardous Substances

#### **Technical enquiries**

• IFA, Department "Chemical and Biological Hazards"

#### **Literature enquiries**

Published by:

• IFA, Department "Interdisciplinary Services"

#### **Further information**

- Thomas, B.; Breuer, D.: ☑ Messung von Ethylenoxid – Validierung eines neuen Messverfahrens und erste Feldmessungen. Gefahrstoffe – Reinhaltung der Luft 83 (2023) Nos 5/6, pp. 107-112
- Thomas, B.; Breuer, D.: ☑ Kanisterprobenahme für VOC und VVOC. Gefahrstoffe – Reinhaltung der Luft 82 (2022) Nos 11/12, pp. 285-293
- L<sup>2</sup> TRGS 402 Identification and assessment of the risks from activities involving hazardous substances: inhalation exposure. (GMBI 2011 p. 175 [No. 9], March 2011, not up-to-date and unofficial version; mandatory is the current German version: GMBI 2023, pp. 898-920 [No 42], 11 September 2023)
- DIN EN 482, Workplace exposure Procedures for the determination of the concentration of chemical agents – Basic performance requirements

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