Detection of Ethylene Oxide (EO) Residue in Medical Protective Products

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Introduction

In 2019, Corona Virus or Covid-19, emerged worldwide with a major challenge for human health. Subsequently, the demand and production of medical protective products increased dramatically, including face masks and protective suits. Ethylene Oxide is commonly used during the sterilisation of protective equipment. Ethylene Oxide is a low temperature gas (volatile) which can efficiently penetrate protective equipment, and its packaging, when used at a low temperature and under vacuum. Although widely used as a sterilising agent, Ethylene Oxide possesses several physical and health hazards when an individual is exposed to high levels. Acute exposure can lead to respiratory irritation, shortness of breath, headaches and nausea. Long term effects include cancer, mutagenic changes and neurotoxicity.

Due to the long term health issues caused by exposure to Ethylene Oxide, it is critical that the amount of residue remaining on the protective equipment is measured and monitored. SCION Instruments developed a gas chromatography method with Headspace for the detection of Ethylene Oxide. The method developed was based on the standard Chinese test method GB/T 16886.7-2015.

Experimental

A SCION 456 GC with Flame Ionisation Detector (FID) coupled to a Tekmar HT3 Headspace Autosampler was used for the detection of Ethylene Oxide residues in medical protective products. Figure 1a and 1b shows the instrumentation used throughout this application.

Figure 1a. HT3 HS Autosampler

Figure 1b. SCION 456 GC-FID

Analytical conditions of the Headspace Autosampler and 456-GC can be found in Tables 1a and 1b, respectively.

Table 1a. HT3 HS Autosampler Conditions

Conditions	
Transfer Line	85°C
Equil. Temp	60°C
Sample Loop Temp	80°C
Sample Loop Time	0.1min
Sample Loop Pressure	7psi
Vibration Time	5 mins

Table 1b. SCION 456 GC Conditions

Conditions	
Injector	200°C
Carrier	Nitrogen, 2.5mL/min
Column	SCION Wax 30m x 0.25mm x0.25µm
Oven	50°C (1min), 10°C/min to 150°C (2mins)
FID	200°C

Analytical standards of Ethylene Oxide were prepared in concentrations of 0.4, 1, 2, 4 and 10µg/mL to form a calibration graph. Two different medical grade face mask samples were also analysed using the above parameters with the concentration of Ethylene Oxide residue determined.

Results

Figure 2 shows the chromatogram of the Ethylene Oxide standard at 0.4µg/mL.

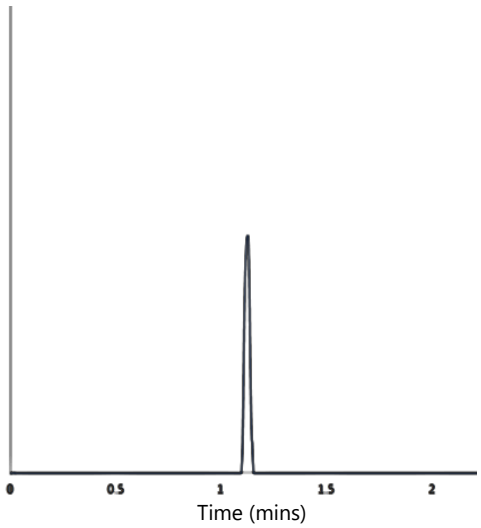

Figure 2. Chromatogram of 0.4µm Ethylene Oxide

Figure 3 details the calibration curve of Ethylene Oxide over five different concentrations.

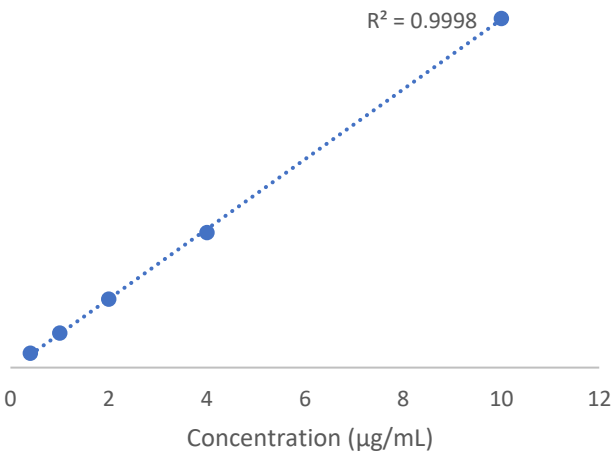

Figure 3. Ethylene Oxide calibration curve

Ethylene Oxide exhibited excellent linearity over a concentration range of 0.4µg/mL to 10µg/mL, with an R^2 value of 0.9998.

Figures 4 and 5 show the chromatograms obtained when two different protective face masks were analysed.

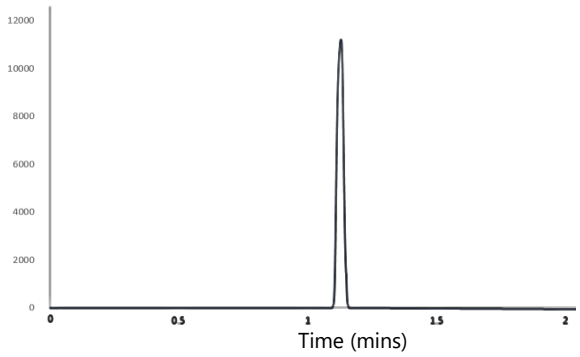

Figure 4. Chromatogram of Ethylene Oxide in Face Mask 1

Both face mask samples contained Ethylene Oxide. Table 2 details the calculated concentration of both samples, using the calibration curve and peak areas for concentration determination.

Table 2. Ethylene Oxide content in face mask samples

Sample	Peak Area (µV)	Concentration (µg/mL)
1	11097.5	2.2
2	14402.8	2.9

The two face masks contained 2.2µg/mL and 2.9µg/mL of Ethylene Oxide. The Scientific Committee on Occupational Exposure Limits (SCOEL), part of the European Commission, states that when wearing a medical face mask for eight hours a day, the exposure of Ethylene Oxide must not exceed 5µg/mL[1] whereas China's National Health Commission states that exposure must not exceed 1µg/mL during an eight hour period[2].

The face masks tested failed to meet the acceptable limits for use in China, even though they were manufactured and sterilised in the country.

Repeatability testing was also performed using three of the analytical standards at a concentration of 0.4µg/mL, 2µg/mL and 10µg/mL, respectively. Table 3 details the repeatability values.

Table 3. Repeatability values of Ethylene Oxide

Concentration (µg/mL)	RSD % (n=6)
0.4	2.7
2	2.4
10	1.8

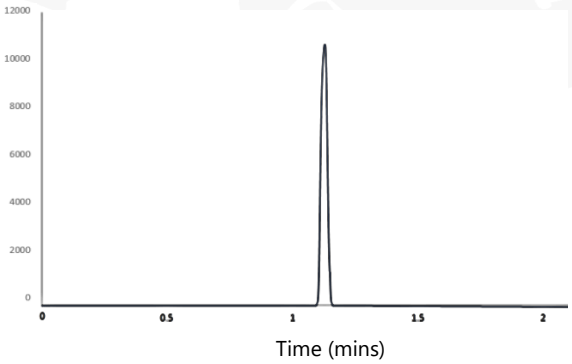

Figure 5. Chromatogram of Ethylene Oxide in Face Mask 1

Excellent repeatability was observed for the three different concentrations of Ethylene Oxide when analysed by Headspace Gas Chromatography, highlighting the robustness of the SCION 456 GC.

Conclusion

SCION Instruments developed a gas chromatography method with Tekmar headspace autosampler for the low level determination of Ethylene Oxide in medical protective products, in under two minutes. Ensuring low limits of residual Ethylene Oxide is critical for protecting the health and well being of users, especially during widespread use of such materials, due to the Corona Virus. The SCION 456 GC displayed excellent detection limits, linearity and repeatability highlighting the robustness and accuracy of the gas chromatography system.

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