Containment performance assessment of Chemfort™ (Onguard®2) closed system transfer device according to 2016 draft NIOSH protocol at first & tenth activations end of shelf life – 3PC-007.

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1. Introduction

The National Institute of Occupational Safety and Health (NIOSH) defines a CSTD as a device that mechanically prohibits the transfer of environmental contaminants into and escape of hazardous drug or vapor outside of the system. In 2016, the NIOSH submitted a draft "Performance Test Protocol for Closed System Transfer Devices" capable of assessment of CSTDs. [1] Wilkinson *et al* published data using the 2016 draft NIOSH protocol in combination with challenge agents 2-phenoxyethanol (2-POE) and 1,1,3,3-tetraethylurea (TEU). After several connection/disconnection cycles (activations) & extended storage the containment performance of a CSTD may deteriorate risking exposure. The Chemfort® CSTD is approved for 10 activations. [4]

Figure 1. BSTL CSTD test NIOSH chamber.

2. Aim and objectives

The study aim was to evaluate the containment performance of Chemfort® at: (1) 1st, 10th activations & (2) end of 3-year shelf-life in accordance with the 2016 draft NIOSH protocol and instructions for use (IFU). [4]

3. Materials and methods

NIOSH Tasks 1 (reconstitution) and 2 (administration) were performed using 3-year aged Chemfort® following the 2016 NIOSH protocol, using 2.5% v/v 2-POE as surrogate. Devices were assessed in replicate (n=4), on first & tenth activation. Release was quantified using a qualified thermal desorption-GC/ MS method using a Griffin G510 (FLIR, USA), a close to real time portable instrument. 2-POE retention was 4.6 minutes on column DB-5 (15m x 0.18mm x 0.18micron). Positive control tasks were performed with needle and syringe. Limits of detection (LOD) and quantitation (LOQ) were determined based on chamber blank measurement (n=33). Griffin system software (GSS) was used for quantification.

Figure 2. The Griffin G510 real time TDGCMS.

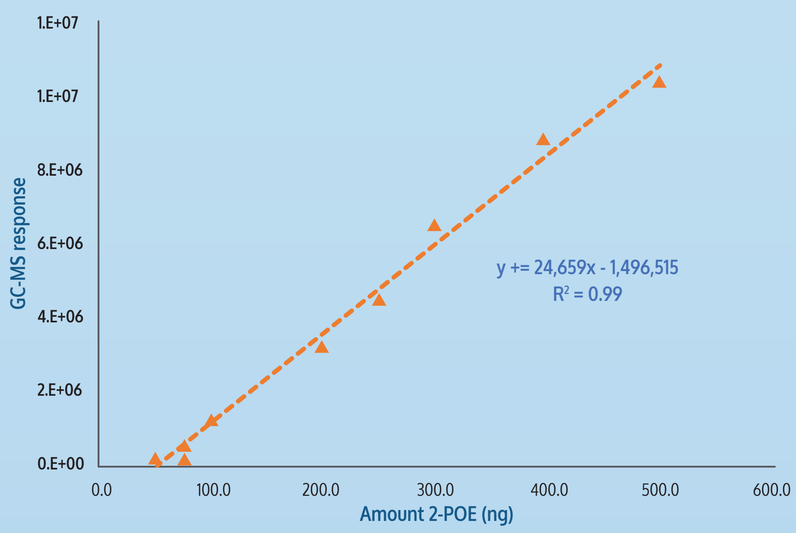

Figure 3. Showing system response of Griffin G510 versus amount of 2-POE (ng) in NIOSH chamber.

Results

The experimental limit of detection (LOD) and lower limit of quantitation (LLOQ) were 0.36±0.013 ppb & 0.62±0.013 ppb (n=33 Blank measurements). Chemfort® containment performance was <LOD (<LLOQ) at end of 3-year shelf-life at 1st & 10th activations. Positive controls: Needle and syringe gave releases of 2-POE of 7.79 ppb and 1.82 ppb (NIOSH tasks 1 & 2). Data shown in Table 1.

Griffin G510 TD-GC-MS is a real time portable parts per billion (ppb) detector of small footprint capable of use with the 2016 draft NIOSH test protocol.

DATA GROUP (A OR B)	NIOSH TASK	MEAN CONCENTRATION OF 2-POE ± 95% CI PPBV
GROUP A: (FIRST ACTIVATION)	1	≤LLOQ (0.62)
	2	≤LLOQ (0.62)
GROUP B: (TENTH ACTIVATION)	1	≤LLOQ (0.62)
	2	≤LLOQ (0.62)
NEEDLE AND SYRINGE (OPEN)	1	7.79
	2	1.82
BLANK (N=33)	n/a	≤LLOQ (0.25 ± 0.01)

Table 1. Containment performance for 3-year aged Chemfort® products at 1st (group A) and 10th (group B) activation(s), using 2.5% v/v 2-POE, according to 2016 draft NIOSH protocol: task 1 (n=4) & task 2 (n=4), according to IFU.

Conclusions

No difference in containment performance was observed for Chemfort® components used at 1st activation vs. 10th activation end of 3-year shelf-life according to 2016 draft NIOSH protocol. Chemfort® demonstrated containment of 2-POE. Positive controls gave >LOQ (7.79 ppb & 1.82 ppb) releases for (tasks 1 and 2). This is the first time CSTD performance has been evaluated at the end of its shelf-life and at 10th activation for Chemfort® according to (IFU). [4] Other CSTDs may exhibit deterioration in containment performance with increasing number of activations and at end of shelf-life which could result in exposure of healthcare workers to hazardous drug vapour, aerosols or liquid droplets.

References

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