

Amendment 1 – Limited Study Evaluating UVGI-Treated FFR Odor

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ARA is a private research and development (R&D) company and we are not providing guidance or direction on the decontamination of FFRs. ARA was asked by United States Food and Drug Administration (FDA) to make publically available this report relating to the FFR decontamination work performed for the FDA under contract number HHSF223201400158C.

As of this writing: (i) no regulatory agency that we are aware of has approved or cleared decontaminated FFRs for use in the US; and (ii) manufacturers of FFRs have not provided approval to use the decontamination techniques discussed on their products. ARA in no way represents or warrants the effectiveness on these decontamination techniques for any purpose whatsoever.

This article is for informational purposes only. We do not recommend any particular course of action. A decision as to whether or not to decontaminate and reuse FFRs should be made in careful consideration with your legal, medical and public health advisors after considering all available information sources

FDA Disclaimer

The data provided to you was generated by an FDA contractor. The FDA does not endorse or guarantee the efficacy of any method and/or data or potential applications described in the report. Additionally, the views expressed in this report are those of the authors and do not necessarily represent those of the U.S. Food and Drug Administration nor should they be interpreted as official Agency policy or guidance.

Overview

During the study, it was noted that the respirators contained a singed smell following treatment with UVGI. This was unexpected and to better understand the issue, ARA performed a limited study outside of the initial scope of work to evaluate the odor.

Study Description

To further investigate a singed odor on FFRs following UVGI treatment, off-gassing samples were collected from one respirator model (Moldex 1512) that provided the most intense odor. Triplicate samples of the respirator were treated with UVGI treatment at 1 J/cm² for one minute. The treated respirators were then placed in Tedlar bags, sealed and allowed to set for 1 hour. The total air volume was then sampled into a metal sample canister and sent for evaluation using EPA TO-15 test method. Untreated control samples and room-air samples were also collected. The EPA test method evaluates the presence of 62 volatile organic compounds (Table 1).

Table 1. Volatile organic compounds screened for by Eurofins Air Toxics using TO-15 method.

Compounds Tested Using Eurofins TO-15 Method		
Freon 12	cis-1,2-Dichloroethene	Dibromochloromethane

Freon 114	Tetrahydrofuran	1,2-Dibromoethane
Chloromethane	Chloroform	Chlorobenzene
Vinyl chloride	1,1,1-Trichloroethane	Ethyl benzene
1,3-Butadiene	Cyclohexane	m,p-Xylene
Bromomethane	Carbon tetrachloride	o-Xylene
Chloroethane	2,2,4-Trimethylpentane	Styrene
Freon 11	Benzene	Bromoform
Ethanol	1,2-Dichloroethane	Cumene
Freon 113	Heptane	1,1,2,2-Tetrachloroethane
1,1-Dichloroethene	Trichloroethene	Propylbenzene
Acetone	1,2-Dichloropropane	4-Ethyltoluene
2-Propanol	1,4-Dioxane	1,3,5-Trimethylbenzene
Carbon disulfide	Bromodichloromethane	1,2,4-Trimethylbenzene
3-Chloropropene	cis-1,3-Dichloropropene	1,3-Dichlorobenzene
Methylene chloride	4-Methyl-2-Pentanone	1,4-Dichlorobenzene
Methyl tert-butyl ether	Toluene	α -Chlorotoluene
trans-1,2-dichloroethene	trans-1,3-dichloropropene	1,2-dichlorobenzene
Hexane	1,1,2-trichloroethane	1,2,4-trichlorobenzene
1,1-Dichloroethane	Tetrachloroethene	Hexachlorobutadiene
2-Butanone	2-Hexanone	

Results

The results detected eight compounds, but all well below the permissible exposure limits (PEL) provided by OSHA (Table 2). Some compounds were found that could not be traced to the compounds identified in Table 1. The top 10 tentatively identified compounds (TICs) were compared to a compound library. Based on the TIC analysis, four compounds were found in the UVGI-treated samples. However, the concentrations of the compounds are well below the OSHA PELs (Table 3).

Table 2. Volatile organic compounds detected from untreated and UV-treated Moldex 1512 FFRs (1 J/cm²)

Volatile Organic Compound	Treated FFR (ppbv)	Permissible Exposure Limit (ppbv)
Ethanol	19.7 ± 1.2	1,000,000 ^a
Isopropanol	11.3 ± 1.2	400,000 ^a
cis-1,2-Dichloroethene	1.1 ± 1.8	200,000 ^a
2,2,4-Trimethylpentane	0.3 ± 0.5	300,000 ^b
Benzene	4.0 ± 0.6	1,000 ^c
4-Methyl-2-Pentanone	0.3 ± 0.6	100,000 ^c
4-Ethyltoluene	0.4 ± 0.6	NLE ^d

1,2,4-Trimethylbenzene	0.3 ± 0.6	25,000 ^c
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ND = not detected

NLE = No limit established

^ahttps://www.osha.gov/dts/chemicalsampling/toc/toc_chemsamp.html

^b<https://www.cdc.gov/niosh/ipcs/default.html>

^c<https://www.cdc.gov/niosh/npg/default.html>

^d<http://www.emsl.com/PDFDocuments/Marketing/NIOSH%20and%20OSHA%20Exposure%20Levels.pdf>

Table 3. Tentatively identified compounds detected from UV-treated Moldex 1512 FFRs (~1 J/cm²)

Compound	CAS #	Treated FFR A		Treated FFR B		Treated FFR C		PELs (ppbv)
		ppbv	% match	ppbv	% match	ppbv	% match	
2-Methylpropene	115-11-7	8	90	6	90	10	90	250,000 ¹
2,3-Dimethyl-2-pentene	10574-37-5	-	-	-	-	4	52	NLE ²
Acetaldehyde	75-07-0	7	83	7	9	12	74	200,000 ³
Limonene	138-86-3	6	91	6	94	-	-	30,000 ⁴

PEL = Permissible exposure limit

NLE = No limit established

Conclusion

Based on the results of this off-gassing analysis, VOCs were not detected above their established exposure limit. However, it is not possible to account for all chemicals that are potentially off-gassing. The compounds identified are orders of magnitude below the PELs. The presence of an odor does not necessarily indicate toxicity. However, the odor is not ideal, but was found to dissipate < 4 hours, depending on the FFR model.

¹ <http://www.advgas.com/msds/isobutylene.pdf>

² [http://www.fluorochem.co.uk/\(S\(n44zatyqnyuqxf2wmdacr244\)\)/System/DownloadSDS?fileName=\(en-GB\)342254_3.00.pdf](http://www.fluorochem.co.uk/(S(n44zatyqnyuqxf2wmdacr244))/System/DownloadSDS?fileName=(en-GB)342254_3.00.pdf)

³ https://www.osha.gov/dts/chemicalsampling/data/CH_216300.html

⁴ <http://www.sigmaaldrich.com>