An Evaluation of Four Personal Monitoring Methods for Glutaraldehyde in Ambient Air

Glutaraldehyde-based sterilants have been in use for over 30 years as high level disinfectants of semi-critical and critical instruments and other devices in hospitals, doctors' offices and dental offices. Glutaraldehyde is also used as a general industrial antimicrobial, in X-ray film processing, embalming fluid and as a biological tissue fixative.

Glutaraldehyde vapor is a strong irritant of the lungs, throat, nose, eyes and skin and has an irritation threshold of approximately 0.3 ppmv.[1-4] According to the American Conference of Governmental Industrial Hygienists (ACGIH), the Threshold Limit Value (TLV) ceiling for glutaraldehyde in workplace atmospheres is 0.05 ppmv.[5] The TLV ceiling means that personnel exposure to airborne concentration of glutaraldehyde should not exceed 0.05 ppmv at any time during the work period. Human panel testing has indicated that glutaraldehyde vapor odors may be detected at concentrations below a part per billion,[1-4] a level 100 times below the TLV ceiling exposure limit. Because the ACGIH TLV may exceed the analytical capability of some sampling and analysis methods, an evaluation of these methods is particularly important at this time.

Personal monitoring can be used to determine compliance with established occupational exposure limits. For ceiling limit determinations in the absence of instantaneous monitors, personal monitoring is conducted by collecting a sample over a 15-minute period. A variety of different personal air monitoring methods are available that can be used to quantify glutaraldehyde vapor concentrations.[6-11] These methods include sorbent tubes or pre-treated filters through which air is drawn with a personal air sampling pump, passive diffusion badges, and a glutaraldehyde direct reading meter.[12] The accuracy of each of the four different sampling methods for monitoring glutaraldehyde vapor concentrations was investigated both under controlled laboratory conditions and in a hospital setting. The sampling devices evaluated were: (1) silica gel tube,[8] (2) DNPH-impregnated filter,[9] (3) DNPH-impregnated passive badge,[10] and (4) direct reading glutaraldehyde meter.[11]

Silica Gel Tube/GC-FID

This method measures glutaraldehyde directly. The sampler (SKC, Inc. Model 226-10)[14] consists of a glass tube packed with a front section of 150 mg and a back section of 75 mg of silica gel. High volume personal sample pumps (Gilian Instrument Corp Model HFS-513[15]) were used to draw air through the samplers at 1 L/min for 15 minutes. The collected glutaraldehyde was desorbed from the tubes with 1 mL of acetone (HPLC grade) and quantified using gas chromatography (GC) with a flame ionization detector (FID).

This method has a lower limit of quantitation (LLQ) of 0.29 µg sample or 0.005 ppmv for a 15 L sample.

DNPH-impregnated Filter Cassette/HPLC-UV

This method is based on OSHA method 64[9] and measures the glutaraldehyde as its DNPH derivative. The sampler consists of a 37-mm filter cassette with DNPH pre-coated type AE glass fiber filters, (SKC, Model 225-9003) or (Supelco, Model 827M[16]). Again, Gilian Model HFS-513 high volume personal sample pumps were used to collect 15-minute air samples at 1 L/min. Each section was desorbed using 2 mL acetonitrile (HPLC grade). The desorption efficiency of this method is reported to be near 100%.[9] The desorbed solutions were analyzed using high performance liquid chromatography (HPLC) with a UV detector set at a wavelength of 355 nm.

OSHA Method 64 has a LLQ of 0.27 mg per sample, which is equivalent to 0.004 ppmv glutaraldehyde for a 15 minute sample.[9]

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Passive Badge/HPLC-UV

The passive badge sampler contains a filter impregnated with DNPH (AT Model X568,[17] 1070 East Meadow Circle, Palo Alto, CA 94303). The badge required no additional sampling equipment and is reported by AT to have a sampling rate of 5.88 mL/min. Badges were exposed to the air for 15 minutes. At the completion of the sampling period the badges were capped and returned to our laboratory for analysis. The derivatized glutaraldehyde was desorbed from the badges with 1 mL of acetonitrile (HPLC grade) and quantified using the same HPLC conditions used for the DNPH-impregnated filter cassettes. The badge has a second or backup pad located behind the primary pad. This second and smaller pad is protected from exposure and is used as an analytical blank.

This method has a LLQ of 0.006 mg per sample or 0.016 ppmv for the 15 minute exposure. The HPLC method's analytical range was validated from 0.006 to 0.55 mg/mL.[10] The masses reported in this paper are calculated as un-reacted glutaraldehyde, not as the DNPH derivative.

Glutaraldehyde Meter

The Model Glutaraldemeter® 3 hand-held meter contains an electrochemical fuel cell and is available from PPM Limited.[11] The meter has a self-contained sample pump which draws in a sample (approximately 10 mL) for analysis. The response time is reported to be approximately 60 seconds, with a manufacturer's reported detection range of 0.03 to 4 ppmv glutaraldehyde.

Glutaraldehyde Test Protocol in the Laboratory

The four sampling methods were evaluated using glutaraldehyde atmospheres over the range of 0.05 ppmv to 0.4 ppmv. For tests conducted using the silica gel tube, filter cassette, and badge, six replicate samplers were evaluated for each type of sampling device. The samplers were operated or exposed at the same time for each glutaraldehyde air concentration. Readings at 1-5 minute intervals were taken over the 15-minute sampling period with the hand-held Glutaraldemeter®. The results of the evaluation are summarized in Table I.

Table I
Summary of Laboratory Evaluation of Glutaraldehyde Methods

Method	Theoretical Air Concentration, ppmv	Concentration Found, ppmv[a]	Standard Deviation, ppmv[a]	Percent Recovery[b]
Silica Gel	0.415	0.390	0.011	94%
Filter Cassette	0.415	0.410	0.016	99%
Badge	0.415	0.400	0.036	96%
Meter	0.415	not detected [c]		0%
Silica Gel	0.208	0.190	0.010	91%
Filter Cassette	0.208	0.190	0.010	91%
Badge	0.208	0.210	0.014	101%
Meter	0.208	not detected [c]		0%
Silica Gel	0.104	0.099	0.002	95%
Filter Cassette	0.104	0.090	0.002	86%
Badge	0.104	0.080	0.009	77%
Meter	0.104	not detected [c]		0%
Silica Gel	0.052	0.050	0.001	96%
Filter Cassette	0.052	0.050	0.001	96%
Badge	0.052	0.060	0.009	115%
Meter	0.052	not detected [c]		0%

(a) Reported as the mean and standard deviation for 6 replicates.
(b) Percent recovery is based on the monitored concentration versus the theoretically calculated concentration of the glutaraldehyde test atmosphere. The air concentrations were rounded after the recoveries were calculated.
(c) The meter did not give any readings greater than 0.03 ppmv, its reported lower limit of detection.

Hospital Evaluation Protocol

Facility

The four sampling methods were evaluated at a hospital during routine use of glutaraldehyde-based sterilants in a cysto operating room, physical therapy room, and an ultrasound room. The sterilants used during the sampling period were Cidex™ and Cidex Plus™ solutions. Both personal and area samples were collected. Samples were collected during operations where maximum potential glutaraldehyde exposures were assumed to exist.

Samples were collected and properly sealed and returned to a Dow Chemical Company laboratory for analysis. Analysis of the samplers was completed either on the same day or the next day to minimize any potential effects of storage.

During sampling, individuals participating in the test wore four samplers in close proximity to one another – silica gel tube, filter cassette and two badges. All four samplers were placed as close as practical to the breathing zone of the participant. The hand-held glutaraldehyde meter is not designed to be worn in the breathing zone.

Results and Discussion

Laboratory Evaluation

The silica gel tubes, DNPH-impregnated filter cassettes and DNPH-impregnated passive badges all gave satisfactory performance in the laboratory study. The three methods correlate well with each other, especially considering that the silica gel tube device uses a direct measurement of the trapped glutaraldehyde and the latter two measure it as a derivative. The standard deviations estimated for the tube and cassette methods are significantly better than that for the passive badge method. Nevertheless, based on the laboratory evaluation, these three sampling devices are suitable for monitoring workplace atmospheres and employee exposures at these concentrations.

The hand-held glutaraldehyde meter provides an almost instantaneous reading. The meter collects a 10 mL sample in approximately 3 seconds. The collected sample is analyzed by the internal electrochemical fuel cell detector, and the results of the analysis are displayed in approximately 60 seconds. However, the meter that was being evaluated did not respond to the generated test atmospheres (0.05 - 0.4 ppmv) in the laboratory study, even after a new calibration tube was obtained from the manufacturer.

The glutaraldehyde concentrations found in the hospital comparison for the badge, silica gel tube and filter cassette methods are statistically equivalent.

Hospital Evaluation

In the hospital study, because the true air concentrations are unknown, it can not be determined which device gave the most accurate results. However, because the differences between the sampling devices are small compared with the ACGIH TLV ceiling for glutaraldehyde of 0.05 ppmv, the results of this evaluation show that the silica gel and filter cassette methods can both be used to monitor glutaraldehyde air concentrations with a reasonable assurance of accuracy (see Table II). Considering the presence of uncontrolled variables in the hospital study, such as differences in location and air flow, the practical agreement between the two devices is quite good. The OSHA acceptable criteria for industrial hygiene monitoring at exposure TLV limits is ± 25%[13].

Table II
Summary of Hospital Evaluation of Glutaraldehyde Methods

Set No.	Sample Type	Location	Air Concentration Found, ppmv				
			Silica Gel	Filter	Badge[a]	Meter Readings[b]	Average Above 0.03
1	Personal	Cysto Room[c]	< 0.005	0.004	< 0.016	2 of 6	0.055
2	Personal	Cysto Room[c]	0.006	0.007	0.018	1 of 5	0.080
3	Personal	Cysto Room[c]	0.015	0.007	0.024	4 of 9	0.052
4	Personal	Cysto Room[c]	0.030	0.014	0.045	4 of 9	0.062
5	Personal	Ultrasound[c]	< 0.005	0.009	< 0.016	3 of 5	0.060
6	Personal	Physical Therapy[d]	0.041	0.028	0.085	2 of 3	0.060
7	Area	Physical Therapy[e]	0.020	0.015	0.032	9 of 15	0.054
8	Personal	Physical Therapy[e]	0.093	0.060	0.095	4 of 4	0.060
9	Personal	Physical Therapy[e]	0.094	0.065	0.128	3 of 4	0.047
10	Personal	Physical Therapy[e]	0.067	0.043	0.111	0 of 4	< 0.03
11	Area	Physical Therapy[e]	0.018	[f]	[f]	9 of 15	0.054
12	Personal	Physical Therapy[e]	0.008	0.009	< 0.016	3 of 5	0.053
13	Personal	Physical Therapy[e]	0.050	0.028	0.100	5 of 5	0.055
14	Personal	Physical Therapy[e]	0.039	0.033	< 0.016	0 of 2	< 0.03

(a) Average of two badges.
(b) The number of individual meter readings observed above the stated detection limit of 0.03 ppmv out of the total number of readings. The adjacent column has the average of the readings that were above 0.03 ppmv.
(c) Cidex™ 2.4% glutaraldehyde solutions were used per standard operating procedures.
(d) Cidex™ Plus 3.4% glutaraldehyde solutions were agitated with impellers for 7 minutes in a partially closed container per standard operating procedures.
(e) Cidex™ Plus 3.4% glutaraldehyde solution was used.
(f) No samples were taken with the respective sampler.

For the hand-held meter in the hospital study many of the readings were at or below the stated detection limit of the meter (0.03 ppmv). However, if the meter was used to monitor the air a few inches above the surface of Cidex™ soaking solutions, the meter readings were a factor of three to ten times higher than those in the employee's breathing zone. Thus, at apparently higher concentrations the meter did appear to respond to the glutaraldehyde in the air.

However, at levels employees might be exposed to in the workplace air, the meter's accuracy and precision could not be validated or compared to the other methods studied. Further studies or others' experience with the glutaraldehyde meter will be needed to determine its effectiveness for use in monitoring ambient air concentrations of glutaraldehyde.

Conclusion

The silica gel tube and the DNPH-impregnated cassette are suitable for the ACGIH TLV ceiling of 0.05 ppmv. The passive badge, with a 0.02 ppmv limit of detection, is expected to be only marginal at best at the 0.05 ppmv ceiling.

Although the hand-held meter did appear to respond to the glutaraldehyde in the air in a qualitative way during the hospital study, the meter's accuracy could not be validated either in the laboratory or the hospital, and the new ceiling limit is probably too close to the meter's 0.03 ppmv limit of detection to give the user much confidence in its readings.

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Printed in U.S.A.

Form No. 253-01438-02/01/02