



## **HOODGARD 1 VALIDATION**

### **Validation**

- 1. Residuing properties of any cleaner considered for use in the IV admixtures process should be evaluated; any residues which may be inadvertently transmitted to the IV product during the compounding process should be eliminated.**

HOODGARD 1 has been tested and validated to leave no detectable worksurface residues of its active quaternary ammonium product<sup>1</sup>, and was shown to be more effective than both water and 70% isopropyl alcohol in recovering dried residues, using colormetric methods<sup>2</sup>.

- 2. OSHA guidelines recommend the use of a high-pH cleanser in the routine cleaning of areas used for the compounding and administration of antineoplastic drugs<sup>3</sup>.**

HOODGARD 1 has a pH of 12.5 as it is applied to the worksurface. In addition, HOODGARD 1 has demonstrated high-pH stability when challenged titrimetrically with standardized serial dilution aliquots of 0.1 N HCl, and standardized serial dilutions of three representative chemotherapeutic agents<sup>4</sup>.

- 3. Germicidal cleaners used in the decontamination of both critical and general environmental surfaces in the IV admixtures compounding areas require demonstrable, wide-range germicidal efficacy.**

HOODGARD 1 has been validated against more than thirty spore-form and vegetative hospital pathogenic agents, using A.O.A.C. methods. As such, HOODGARD 1 has the broadest demonstrated "kill-spectrum" of any non-residuing germicide available today.

In order to further insure actual product potency and reliability, each individual HOODGARD 1 PRODUCTION LOT is quality control tested for phenolic coefficient, and germicidal efficacy against *E. coli*, *S. aureus*, *A. niger*, and *P. aeruginosa*, utilizing A.O.A.C. methods.

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<sup>1</sup> HOODGARD 1 Validation Guide, Lab Safety Corporation, 1991.

<sup>2</sup> *ibid.*, item 1; Dried Residue Recovery Comparison.

<sup>3</sup> IV.A.3.b; Instruction Publication 8-1.1, Office of Occupational Medicine, OSHA, 1986.

<sup>4</sup> *op. cit.*, item 1, pH Stability Assay.

## User, Equipment, and Environmental Safety

4. **The use of aerosols in the BSC should be demonstrated to present no ignition or explosion hazard to the user<sup>5</sup>.**

HOODGARD 1 has been validated to constitute no ignition or explosion hazard whatsoever using standard flame propagation test methods<sup>6</sup>. HOODGARD 1 has demonstrated a flame extinguishing effect during intensified flame propagation testing.

5. **Caution in the use of quaternary ammonium compounds in the BSC should be exercised due to potential buildup of ammonia vapors which may be harmful to the user<sup>7</sup>.**

HOODGARD 1 has been validated to produce no exposure hazard from ammonia vapors when used in the manner recommended by the manufacturer<sup>8</sup>.

Three replicates of a monitoring procedure for the BSC interior and exterior were carried out during the recommended HOODGARD 1 cleaning process using a Miran 1B2 infrared spectrometer.

Initial introduction of HOODGARD 1 into an operating four-foot BSC in accordance with the manufacturer's recommendations (i.e., saturation of horizontal worksurface and vertical, user-accessible hood interior surfaces and undertray area with HOODGARD 1, which was recovered by "mopping-in" as de-foaming began to occur) demonstrated a peak ammonia vapor presence of 7.6 ppm\* (less than 17% of the OSHA 5 minute Permissible Exposure Limit (PEL) for this substance.

This BSC internal ammonia vapor concentration was observed to dissipate to exterior background levels (0.8 ppm) within three minutes of introduction of HOODGARD 1 into the hood interior, as facilitated by the normal BSC installation air change rate of five internal air changes per minute.

\*Parts per million parts of air

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<sup>5</sup> ASHP technical assistance bulletin on handling cytotoxic and hazardous drugs. Am. J. of Hosp. Pharm., Vol 47 May, 1990, Goal II; 5(g), P. 1040.

<sup>6</sup> op. cit., item 1, Flame Propagation Test.

<sup>7</sup> op. cit., item 5, Goal II; 5(g).

<sup>8</sup> op. cit., item 1, BSC Residual Vapor Testing.

**6. The use of aerosols within the BSC should be demonstrated to cause no interference with laminar flow patterns<sup>9</sup>.**

The application and use of HOODGARD 1 was validated to cause no interference with the laminar flow containment patterns of a BSC<sup>10</sup>.

HOODGARD 1 was applied and recovered in an operating BSC in the manner recommended, in the presence of four stationary smoke tracers, constituting a visualization of unit a) smoke induction, b) air intrusion, c) smoke split, and d) laminar downflow patterns. At no time was the procedure for application, manipulation, or recovery of HOODGARD 1 observed to defeat and of items a through d, which constitute the visual supply, inflow, and containment airflow tests of a BSC.

(While the routine application of any cleaning agent should be carried out as preparatory step, and at times when compounding procedures are not being carried out in the BSC, this precaution has somehow found its way into the current ASHP technical assistance bulletin. For this reason, we have performed the above validation).

**7. Aerosol cleaners used in the BSC should not cause or promote damage or degradation of the HEPA filters<sup>11</sup>.**

HOODGARD 1 was introduced in 1983, as an integral part of the comprehensive IV Admixtures Quality Assurance (Validation and Monitoring) program offered to Chicago area hospital pharmacies by Lab Safety Corporation since 1980.

Within the scope of the Validation and Monitoring program, Lab Safety has carefully monitored the effect of constant use of HOODGARD 1 in over 300 BSC's and LFCB's.

Through the use of detailed hood cleaning and disinfection logs establishing and documenting the daily patterns of use of HOODGARD 1 for all laminar flow equipment at three regional hospital pharmacies, it has been established that HOODGARD 1 has been used during an eight year period, in the manner recommended by the manufacturer, in more than 8,000 applications each to 10 BSC's, without any detectable degradation or damage to the functioning HEPA filters (the HEPA filters were unchanged during this period).

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<sup>9</sup> op. cit., item 5, Goal II; 5(g), p. 1040.

<sup>10</sup> op. cit., item 1, Pattern Integrity Test.

<sup>11</sup> op. cit., item 5, Goal II; 5(g), p. 1040.

Such HEPA filter serviceability and integrity has been positively established by the routine testing and recertification of this equipment at six-month intervals, involving a close examination and challenge of every HEPA filter through the use of DOP aerosol/photometer and optical particle counting procedures. In each case, the HEPA filter successfully passed the filter media and frame integrity test [50.1(a), Federal Standard 209b], static pressure/flow rating (manufacturer), supply and exhaust pattern velocity and laminarity test (NSF standard 49), and careful visual inspection of the HEPA media frame and condition.

### **Method of Use**

HOODGARD 1 should be used routinely in the decontamination and cleaning of laminar flow hoods and other equipment and worksurfaces used in your aseptic compounding processes.

This is especially true of equipment used in the antineoplastic compounding areas, where residues or buildup of these substances may be hazardous to pharmacy and nursing personnel.

HOODGARD 1 should be used to prepare the aseptic worksurface and all user-accessible surfaces of the hood interior (including the undertray area) at the beginning of each shift, and periodically thereafter during the shift as required to manage compounding residues.

HOODGARD 1 should be used in combination with 70% ethyl or isopropyl alcohol. First, the HOODGARD 1 should be applied and "mopped in" immediately as it is de-foaming and fully recovered with a clean, absorbent, non-linting towel, and the surface allowed to dry completely. Application of 70% ethyl or isopropyl alcohol should then follow in the normal manner, and the surface again allowed to dry completely. The hood interior and critical worksurface are then ready for compounding operations.

### **Additional Uses**

HOODGARD 1 may also be used to clean and maintain IV room countertops and other worksurfaces, and for removing dust accumulations and filth on admixture components prior to introducing them into the aseptic environment.

### **Residues and Streaking**

Initial use of HOODGARD 1 may cause some streaking, as latent drug and metallic oxide residues are liberated from worksurfaces. Multiple initial cleanings may be required to completely eliminate these residues, however, continued, routine use of HOODGARD 1 will prevent any recurrence of this type of buildup.