



From: Wava Truscott, PhD, MBA.

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Comments to: The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) addressing the intent to list N,N-Dimethylformamide (DMF; CAS 68-12-2) as a chemical known to the state to cause cancer under the Safe Drinking Water and Toxic Environment Act of 1986 (California Proposition 65).

Listing DMF: The CA Office of Environmental Health Hazard Assessment (OEHHA) proposed the listing of N,N-Dimethylformamide (DMF; CAS 68-12-2) based on the International Agency for Research on Cancer's (IARC 2016, Grosse et al. 2016) rating of the chemical as a 2A carcinogen.

Current glove industry DMF use: Many advances have occurred over this last decade in the production of synthetic work gloves. New knitted materials of cotton, polyester or nylon are now polyurethane coated on the palm, or palm and contact areas of the fingers providing increased dexterity, flexibility, ergonomics and grip while reducing lint and particulate contamination of the items being handled or assembled. Similarly, the polyurethane coating on cut-resistant gloves provides surer grip and stability for added safety when performing hazardous tasks. Hand protection is important.

According to the Occupational Safety and Health Administration, there are over 1,000,000 hand injuries a year in the United States. Twenty percent (20%) of all disabling workplace injuries involve the hands.

Hand Injuries Types:

Lacerations:	63%
Crush:	13%
Avulsion	8%
Puncture	6%
Fracture	5%

Hand injuries occur as work items slip while being cut, hammered, trimmed, shaped, drilled, rotated, rapidly assembled, screwed together, etc. Rough edges, residual flash, sharp shavings, splinters can all cause injuries. Studies have shown that as many as 60% of hand injuries could be eliminated with appropriate hand protection. Preventing hand injuries is a priority in most US industries. Providing an abrasion resistant, durable glove with excellent grip is an important safety and productivity option for many employers and employees. The primary coating delivering these safety qualities is solvent-based polyurethane. The solvent used is DMF. Solvent-based polyurethane uniquely expands to encapsulate the fibers of the knitted "liner" support.

This quality of coating and secure adhesion is also critical for preventing shedding of the polyurethane into the workplace, and onto products made in those facilities. Adhesion, abrasion resistance, excellent aging characteristics, and a great grip without stickiness or shedding are the benefits of DMF

* Tear or rip apart

solvent-based polyurethane. At this time, a less hazardous but acceptable solvent for solvent based polyurethane coating has not yet been found. The search effort continues.

A possible alternative is the use of water-based polyurethane. The integrity of water-based polyurethane is dependent on, and limited by, the film forming-ability of the polyurethane particles that are dispersed in the water. Grip, strength, and glove durability using water-based polyurethane dispersions are often compromised. The use of co-solvents in water-based polyurethanes is common, and those co-solvents can have their own hazards.

Water-based polyurethane coatings have not been able to provide the same quality of fabric coating. Shedding of the polyurethane onto assembly parts, stickiness of the coating over time interferes with handling small or delicate assemblies, and reduced shelf-life continues to plague water-based textile coating attempts. However, here again, the effort continues.

The manufacturing process used to make polyurethane gloves is designed to remove much of the DMF solvent from the finished gloves, minimizing the residual amount of DMF on the gloves. This is done by washing and washing at elevated temperatures with agitation. However, methods used thus far have not resulted in zero leachable levels of DMF.

Testing: Currently, numerous sample preparation and test methods are being used by both industry and government agencies throughout the United States and the world. DMF testing results are widely variable making results (including zero DMF detection) unreliable. It is essential that a representative extraction method and appropriate test method is specified to standardize and legitimize assessments.

DMF health safety: Agreed, tight limits need to be imposed to limit DMF exposure for several potential adverse health concerns including cancer.

Glove industry: Efforts to develop alternative coatings that do not require DMF or methods to remove leachable DMF solvent to an acceptable inhalation and dermal exposure level must proceed.

Per the above information, the following requests are respectfully submitted:

- 1) Working with state laboratories and industry accessible contract test laboratories, establish standardized sample preparation and test methods to reliably quantify available DMF, and require assessments to be made using the approved method(s).
- 2) The development of successful alternative coatings or post-coating DMF reduction methods to reach acceptable inhalation and dermal exposure limits will take time. Requesting 2.5-year grace period.

Respectfully submitted,



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I submit this comment and request as a contract consultant and educator with over 35 years of medical device, patient and staff safety experience.

- Before my doctorate, I worked at MIDECO, an independent medical device contract-testing laboratory.
- I received my doctorate in Comparative Pathology (human and animal disease systems) with emphasis in microbiology, immunology and pathology from the University of California, School of Medicine, Davis campus.
- I worked at the bench with FDA's Office of Science and Technology (OST) to understand the potential for viral penetration in medical gloves during the emergence of HIV in 1987 through 1990. Then worked with standards committees to establish test methods and set glove requirements.
- I worked at the bench and in the field (Malaysia) with FDA, CDC, and international clinical researchers tracking down causes and solutions for Type I hypersensitivity to the *Hevea brasiliensis* (rubber tree) allergenic proteins found in medical gloves, dental dams, catheters, etc.
- As an AAMI/ANSI appointed delegate, I worked with regulatory and scientists on new ISO test methods and standards (ISO 10993) for medical device safety to be adopted by the then emerging European Union.
- I spent years working with others on an ASTM test method for quantifying glove powder, submitting case studies with scientific reasoning to the FDA, and authoring an extensive citizen's petition to the FDA in efforts to ban glove powder from all US healthcare facilities.
- My focus now is infection prevention in healthcare together with preventing medical staff, pharmaceutical staff and home caregiver safety from exposure to toxic and/or carcinogenic chemotherapy drugs.