



“Getting More Information”

Because the following document was developed a number of years ago, the contact information is no longer accurate. If you wish to contact the agency with questions, please use the following:

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FDA SAFETY ALERT:
SODIUM AZIDE CONTAMINATION OF HEMODIALYSIS WATER SUPPLIES

TO: Hemodialysis personnel
Water service contractors

March 15, 1989

This is to alert you to a potentially hazardous contamination problem that can occur if dialysis water treatment filters preserved with sodium azide are not rinsed adequately before use, and to provide guidance on how to avert such hazards. Please share this alert with those in your organization who are responsible for selecting and installing filters and for maintaining dialysis water treatment systems.

In a recent incident investigated by the Food and Drug Administration, the Centers for Disease Control, and the New York State Department of Health, nine patients in a dialysis facility experienced life-threatening hypotension shortly after treatment began. Other symptoms included blurred vision, severe abdominal pain, headache, and loss of consciousness.

The problem has been attributed to contamination of the water treatment system with sodium azide, a potent hypotensive agent. This incident occurred after 4 new ultrafilters were put on line within the facility's water treatment system without pre-rinsing. These were packed by the manufacturer in a preservative solution containing 0.25% sodium azide to prevent bacterial contamination and 25% glycerine to prevent desiccation.

Ultrafilters preserved with sodium azide typically are intended industrial applications and are not labeled for medical use by their manufacturers. Nonetheless, these filters are used in some dialysis facilities, particularly in areas where the water contains a high silt concentration.

Users should also be aware that sodium azide has been identified as an explosive hazard when used with automatic cell counters in clinical laboratories.¹ It is not clear whether a similar hazard might exist in dialysis facilities where sodium azide-preserved filters are used.

If a dialysis facility chooses to use sodium azide-preserved filters, the filters should be installed according to the manufacturer's recommendations and care should be taken to rinse them thoroughly. This is particularly important because there is no readily available test to detect traces of sodium azide-preserved filters be rinsed with a minimum of 500 gallons of water.² All rinse fluid should be discarded before beginning the production of dialysis-quality water.

Other preservations used in manufacturing dialysis water treatment filters, such as formaldehyde and sodium bisulfite, are also toxic. Thus, **ALL** newly-installed filters in a dialysis facility's water treatment system must be adequately rinsed before use. If there is any questions about the presence of sodium azide or other preservatives in the filters to be used in the water treatment system, contact the filter manufacturer. When installing or changing any filter, facility personnel should closely follow the manufacturer's directions.

Thank you for your help in this important effort. If you have any comments or questions, please contact: Donald R. Hamilton (HFZ-240), Director of our Division of Technical Development at 5600 Fisher Lane, Rockville, MD 20857.

Sincerely yours,

John C. Villforth
Director
Center for Devices and Radiological Health

¹ Current Intelligence Bulletin: Explosive Azide Hazard, National Institute for Occupational Safety and Health, August 16, 1976.

² Centers for Diseases Control, Atlanta, Georgia.