

disinfectants. FDA has not cleared any liquid chemical sterilant or high-level disinfectants with iodophors as the main active ingredient. An iodophor is a combination of iodine and a solubilizing agent or carrier; the resulting complex provides a sustained-release reservoir of iodine and releases small amounts of free iodine in aqueous solution. The best-known and most widely used iodophor is povidone-iodine, a compound of polyvinylpyrrolidone with iodine. This product and other iodophors retain the germicidal efficacy of iodine but unlike iodine generally are nonstaining and relatively free of toxicity and irritancy^{677, 678}.

Several reports that documented intrinsic microbial contamination of antiseptic formulations of povidone-iodine and poloxamer-iodine⁶⁷⁹⁻⁶⁸¹ caused a reappraisal of the chemistry and use of iodophors⁶⁸². "Free" iodine (I₂) contributes to the bactericidal activity of iodophors and dilutions of iodophors demonstrate more rapid bactericidal action than does a full-strength povidone-iodine solution. The reason for the observation that dilution increases bactericidal activity is unclear, but dilution of povidone-iodine might weaken the iodine linkage to the carrier polymer with an accompanying increase of free iodine in solution⁶⁸⁰. Therefore, iodophors must be diluted according to the manufacturers' directions to achieve antimicrobial activity.

Mode of Action. Iodine can penetrate the cell wall of microorganisms quickly, and the lethal effects are believed to result from disruption of protein and nucleic acid structure and synthesis.

Microbicidal Activity. Published reports on the in vitro antimicrobial efficacy of iodophors demonstrate that iodophors are bactericidal, mycobactericidal, and virucidal but can require prolonged contact times to kill certain fungi and bacterial spores^{14, 71-73, 290, 683-686}. Three brands of povidone-iodine solution have demonstrated more rapid kill (seconds to minutes) of *S. aureus* and *M. chelonae* at a 1:100 dilution than did the stock solution⁶⁸³. The virucidal activity of 75–150 ppm available iodine was demonstrated against seven viruses⁷². Other investigators have questioned the efficacy of iodophors against poliovirus in the presence of organic matter⁶⁸⁵ and rotavirus SA-11 in distilled or tapwater²⁹⁰. Manufacturers' data demonstrate that commercial iodophors are not sporicidal, but they are tuberculocidal, fungicidal, virucidal, and bactericidal at their recommended use-dilution.

Uses. Besides their use as an antiseptic, iodophors have been used for disinfecting blood culture bottles and medical equipment, such as hydrotherapy tanks, thermometers, and endoscopes. Antiseptic iodophors are not suitable for use as hard-surface disinfectants because of concentration differences. Iodophors formulated as antiseptics contain less free iodine than do those formulated as disinfectants³⁷⁶. Iodine or iodine-based antiseptics should not be used on silicone catheters because they can adversely affect the silicone tubing⁶⁸⁷.

Ortho-phthalaldehyde (OPA)

Overview. Ortho-phthalaldehyde is a high-level disinfectant that received FDA clearance in October 1999. It contains 0.55% 1,2-benzenedicarboxaldehyde (OPA). OPA solution is a clear, pale-blue liquid with a pH of 7.5. (Tables 4 and 5)

Mode of Action. Preliminary studies on the mode of action of OPA suggest that both OPA and glutaraldehyde interact with amino acids, proteins, and microorganisms. However, OPA is a less potent cross-linking agent. This is compensated for by the lipophilic aromatic nature of OPA that is likely to assist its uptake through the outer layers of mycobacteria and gram-negative bacteria⁶⁸⁸⁻⁶⁹⁰. OPA appears to kill spores by blocking the spore germination process⁶⁹¹.

Microbicidal Activity. Studies have demonstrated excellent microbicidal activity in vitro^{69, 100, 271, 400, 692-703}. For example, OPA has superior mycobactericidal activity (5-log₁₀ reduction in 5 minutes) to glutaraldehyde. The mean times required to produce a 6-log₁₀ reduction for *M. bovis* using 0.21% OPA was 6 minutes, compared with 32 minutes using 1.5% glutaraldehyde⁶⁹³. OPA showed good activity against the mycobacteria tested, including the glutaraldehyde-resistant strains, but 0.5% OPA was not sporicidal with 270 minutes of exposure. Increasing the pH from its unadjusted level (about 6.5) to pH 8