

## Cytotoxic versus Noncytotoxic in Long-Term Care/Skilled Nursing Facilities

From The Centers for Medicare and Medicaid Services (CMS) State Operations Manual Appendix PP: Guidance to Surveyors for Nursing Facilities:



### ***GUIDANCE §483.21(b)(3)(i)***

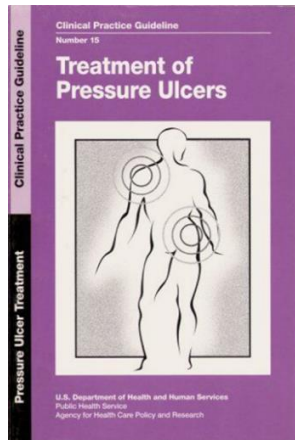
*“Professional standards of quality” means that care and services are provided according to accepted standards of clinical practice. Standards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting. Standards regarding quality care practices may be published by a professional organization, licensing board, accreditation body or other regulatory agency. Recommended practices to achieve desired resident outcomes may also be found in clinical literature. Possible reference sources for standards of practice include:*

- Clinical practice guidelines published by the Agency for Healthcare Research and Quality.*

In 1994, the Agency for Health Care Policy and Research (AHCPR), now called the Agency for Healthcare Research and Quality (AHRQ), wrote clinical practice guidelines published by the Department of Health and Human Services (also known as CMS). The guidelines state that betadine, Dakin’s Solution, Acetic Acid, and Peroxide should not be used because they are cytotoxic and not beneficial for wound healing.

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Screenshot from the AHRQ (AHRQ) guidelines:

Antiseptic agents are reactive chemicals that are cytotoxic to normal tissue. Betadine®, Hibiclens®, pHisoHex®, benzalkonium chloride, and Granulex® have been found to be toxic to human fibroblasts ([Custer, Edlich, Prusak, et al., 1971](#); [Johnson, White, and McAnalley, 1989](#); [Rodeheaver, Kurtz, Kircher, et al., 1980](#); [Rydberg and Zederfeldt, 1968](#)).

Skin cleansers contain chemicals that are cytotoxic to wound tissue and should not be used as wound cleansers. Studies have shown that most wound cleansers need to be diluted to maintain cell viability ([Burkey, Weinberg, and Brenden, 1993](#); [Foresman, Payne, Becker, et al., 1993](#)). [Foresman, Payne, Becker, et al. \(1993\)](#) studied the required amounts of dilution needed for various skin and wound cleansers to maintain white blood cell viability and phagocytic function. They found a wide range of toxicities among available skin and wound-cleansing agents (see [Table 2](#)).



Use normal saline for cleansing most pressure ulcers. (Strength of Evidence = C.)

Normal saline is the preferred cleansing agent because it is physiologic, will not harm tissue, and adequately cleanses most wounds. Wounds with adherent materials may benefit from the use of those commercial wound cleansers that do not contain harmful chemicals. Available wound cleansers range widely from safe to toxic. Commercial wound cleansers contain surfactants and other chemicals intended to enhance their efficacy, and some of these chemicals may have deleterious effects on wound cells ([Bryant, Rodeheaver, Reem, et al., 1984](#); [Foresman, Payne, Becker, et al., 1993](#)). Commercial wound cleansers do not require FDA approval for distribution.

**\*SHOULD NOT BE CLEANED WITH SKIN CLEANSERS OR ANTISEPTIC AGENTS (e.g. POVIDONE IODINE, IODOPHOR, SODIUM HYPOCHLORITE (DAKINS SOLUTION® HYDROGEN PEROXIDE, OR ACETIC ACID) AS THEY ARE TOXIC TO HUMAN FIBROBLAST, DECREASE WHITE BLOOD CELL VIABILITY AND PHAGOCYtic EFFICIENCY. (Clinical practice guideline number 15, pressure ulcer treatment, AHCPR Pub 95-0652, Pg 50, Dec 1994)**

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In addition, the National Pressure Injury Advisory Panel also states:



**Warning: Hydrogen peroxide is highly toxic to tissues even at low concentrations<sup>38, 39</sup> and should not be used as a preferred topical antiseptic. Its use should be totally avoided in cavity wounds due to the risk of surgical emphysema and gas embolus.<sup>39-41</sup>**

**Caution: Iodine products should be avoided in patients with impaired renal failure, history of thyroid disorders or known iodine sensitivity.<sup>42, 43</sup> Sodium hypochlorite (Dakin's solution) is cytotoxic at all concentrations and should be used with caution, at concentrations no greater than 0.025%, for short periods only when no other appropriate option is available.<sup>44-46</sup> There is a risk of acidosis when acetic acid is used for extended periods over large wound surface areas.<sup>47</sup>**

The typical strength of Dakin's solution ordered is ¼ strength Dakin's, which is 0.125%. This is well above the 0.025% concentration that is considered safe for human tissue.

### Dakin's Solution® Quarter Strength (0.125%)



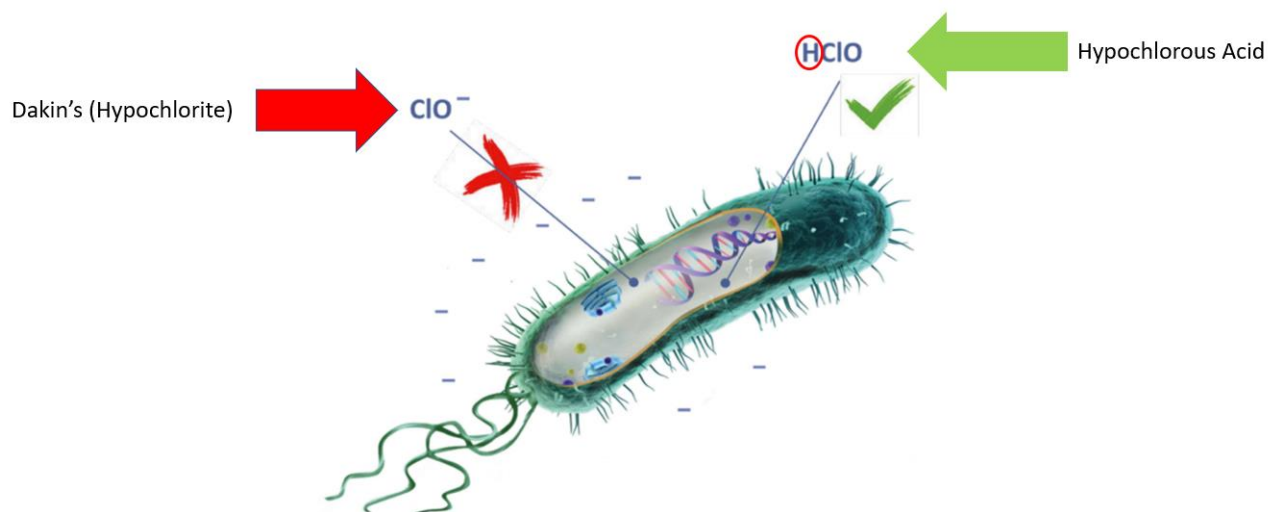
Dakin's Solution® Quarter Strength is a broad-spectrum antimicrobial cleanser that is gentle to the skin. Effective against MRSA, VRE, other bacteria, viruses, molds, fungi, and yeast. Also used for odor control.

Povidone-iodine (betadine) is contraindicated for use in patients with impaired renal failure, thyroid disorders, or a known sensitivity or allergy to iodine. Many elderly patients have issues with impaired renal function, thyroid function or disorder, and/or allergies or sensitivities to iodine. In addition, this product is also cytotoxic.

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Hypochlorous acid has the same chemical makeup as Dakin's solution (hypochlorite) EXCEPT for the addition of ONE molecule. That additional molecule ensures stability, makes the solution non-cytotoxic, and is safe for human cells.



For a full list of Time Kill Assay and organisms, please email Wound Care Plus, LLC

The antimicrobial preservative effectiveness of hypochlorous acid has been demonstrated against the organisms in the table below with in vitro testing (Time Kill Assay):

Pathogenic Bacteria	Log Reduction / Exposure Time
<i>Staphylococcus aureus</i>	99.9992% (5.11 Log <sub>10</sub> ) after 15 sec
<i>Staphylococcus pyogenes</i>	99.9958% (4.38 Log <sub>10</sub> ) after 15 sec
<i>Staphylococcus epidermidis</i>	99.9499% (3.30 Log <sub>10</sub> ) after 15 sec
<i>Pseudomonas aeruginosa</i>	>99.9999% (> 6.11 Log <sub>10</sub> ) after 15 sec
<i>Escherichia coli</i>	>99.999% (> 5.55 Log <sub>10</sub> ) after 15 sec
Multi-drug resistant (MDR) <i>Staphylococcus aureus</i>	>99.999% (> 5.44 Log <sub>10</sub> ) after 15 sec
Extended-spectrum beta-lactamase (ESBL) producing <i>Enterobacteriaceae</i>	>99.9999% (> 6.23 Log <sub>10</sub> ) after 15 sec
Vancomycin intermediate resistant <i>Staphylococcus aureus</i> (VISA)	>99.999% (>5.84 Log <sub>10</sub> ) after 15 sec
Multi-drug resistant (MDR) and OXA-48 producing <i>Klebsiella pneumoniae</i>	>99.999% (> 5.32 Log <sub>10</sub> ) after 15 sec
Extended-spectrum beta-lactamase (ESBL) producing <i>Proteus mirabilis</i>	>99.999% (>5.99 Log <sub>10</sub> ) after 15 sec
Multi-drug resistant (MDR) <i>Escherichia coli</i>	>99.999% (>5.92 Log <sub>10</sub> ) after 15 sec
<i>Candida albicans</i>	>99.999% (>5.01 Log <sub>10</sub> ) after 15 sec

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