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STERILIZING COMPOSITION

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This invention relates to improvements in solutions to be used for sterilization by immersion therein of the articles to be sterilized, and more particularly to solutions intended for the sterilizing of metal surfaces, most commonly used in the manufacture of surgical instruments.

The means most commonly employed at the present time for the sterilization of surgical instruments involves either the action of heat (immersion in hot water or subjection to steam at varying pressures) or immersion in any various chemical germicidal agents. Under the present methods, sterilization is usually effected only after prolonged exposure to the sterilizing agent, and, moreover, the chemical agents commonly employed cause corrosion of the instruments and in particular roughen the keen cutting edge of the instrument blades, rendering them unfit for further use. Moreover, the degree of sterilization attained is often incomplete particularly in view of the necessity of safeguarding the instrument from corrosion and the cutting edge from the effects aforementioned. On the other hand, when heat is relied on to accomplish sterilization, its action is apt to dull the cutting edge of the blade and to destroy the finely balanced structure of the metal produced by proper tempering methods.

Our invention provides a method which insures complete sterilization of the metal surfaces exposed in a relatively short period of time, even with the most resistant forms of micro-organisms likely to be present under the most severe conditions. At the same time, our improved method protects the metal instruments from corrosive influences, and the keen cutting edge of the blade from any undesirable changes. The use of solutions made in accordance with the principles of our invention involves merely immersion of the instruments therein for short periods of time at ordinary room temperature and does not involve, therefore, the application of heat. For this reason no deleterious effect on the cutting edge results by reason of the action of heat.

In general our invention involves three distinct phases which may be discussed separately.

The first phase relates to the germicidal agent. While in our preferred solution we use formaldehyde, the concentration of which in the final product may run between 3% and 4%, it is to be understood that we do not limit ourselves either as to the strength of formaldehyde employed or as to the choice of germicidal agents, since we may employ any germicidal agent of sufficient germicidal strength to satisfy our requirements,

provided that it is sufficiently volatile or usable in sufficiently low concentration to leave no appreciable residue on the instruments sterilized, and provided further that it does not interfere with the essential elements of our invention described below that deal with the factors inhibiting the corrosive effects of the solution on the metal instruments. Thus one may use stabilized solutions of acrylic aldehyde, low concentrations of phenolic germicides.

The second phase has to do with the vehicle used as the solvent for the active germicidal and corrosion-inhibiting agents. An important feature of our invention is to provide a substantially non-aqueous solvent or vehicle for the active germicidal agent which solvent shall be of the proper volatility and in which is tolerated preferably only the water resulting from the incorporation therein of the amount of formaldehyde used in the form of formalin, U. S. P. which contains approximately 40% of formaldehyde. In our preferred final solution, the amount of formaldehyde is such as to bring the water content to about 10% by volume. We do not, however, wish to limit ourselves to this precise quantity as under certain circumstances a greater per cent of water may be tolerated or by using formaldehyde in specially prepared form the amount of water may be decreased or substantially eliminated. However, if the amount of water is substantially greater than about 10 or 15 per cent, the efficiency of the solution in preventing corrosion is apt to be impaired. In accordance with these principles, we prefer ethyl alcohol as the preferred major solvent ingredient although other and neutral and suitably volatile compounds may be substituted therefor either in whole or in any part. We find, for example, that equally satisfactory results may be obtained by using isopropyl alcohol, butyl alcohol, amyl alcohol, and the like, by themselves or in admixture with each other and/or ethyl alcohol.

The third phase of our invention relates to the provision of an agent which, when used with a germicidal solution of the above type, effectively inhibits any corrosive action thereof upon metal instruments. We have found, for example, that very small concentrations of a nitrite i. e., a salt of nitrous acid, as for example, potassium or sodium nitrite, in a very slightly alkaline solution have remarkable corrosion-inhibiting properties. Thus, its presence in a germicidal solution of the above type under the conditions mentioned enables surgical instruments to be immersed in the solution for an in-

definite period of time without producing any apparent corrosion on the metal surfaces. We have determined that our improved solution is non-corrosive even in the presence of dissimilar metals and in fact have maintained without corrosion various surgical instruments in the solution in a Monel metal container for long periods of time. Without the presence of inhibiting agents, these conditions would quickly corrode metals of the type used in surgical instruments. Ordinarily, such solutions produce visible evidences of corrosion even without the presence of dissimilar metals but when such metals are present the corrosion is greatly increased because of the electrolytic action which is thereby set up.

Without intending to limit ourselves to specific ingredients and quantities thereof, we give the following as a specific example of our invention in its preferred form:

20	U. S. P. formalin solution (40%) -----	8 cc.
	Ethyl alcohol special denatured in accordance with Prohibition Bureau regulations such that to each 100 gal. of ethyl alcohol there is added ten gallons of normal butyl alcohol (specially denatured alcohol formula #44) -----	92 cc.
	Potassium nitrite in 1 cc. water -----	.10 grams
30	Sodium hydroxide in 0.2 cc. water -----	.02 grams

It will be evident from this formula that we have provided a sterilizing solution which contains a germicidal agent of high power and as a vehicle therefor a solution of relatively high volatility containing but a slight amount of water. To this absence of substantial quantities of water we contribute in large part the freedom from electrolysis which we have mentioned above. By virtue of the corrosion-inhibiting agent or agents, surgical instruments may be immersed in the solution for indefinite periods of time without corrosion, a circumstance which allows the surgeon to keep the instruments used in the course of his daily practice immersed in the solution between times of use. When the instrument is to be used, he need only remove it from the solution and allow the entrained liquid to evaporate. Because of the nature of the vehicle used,

this evaporation is rapid and for practical purposes causes no delay in the use of the instrument and avoids the necessity of wiping it and the consequent liability of recontamination.

A further advantageous property of our solution resides in the fact that in spite of the volatility of the active agent, the solution remains stable and involves no loss of formaldehyde strength. This is important since no loss in activity may be feared by reason of storage on dealers' shelves or by any storage prior to or in the course of its use. Actually, the relative volatilities of the active agents and the vehicle are such that the vehicle evaporates slightly more rapidly than the formaldehyde whereby the solution tends to increase in germicidal strength upon standing rather than the contrary. Particularly, where aqueous solutions are employed, the germicidal agent, if formaldehyde, tends upon standing to evaporate at a more rapid rate than the solvent and/or to polymerize, resulting in loss of sterilizing efficiency. For this reason, our solution has the added advantage that it may be kept for considerable lengths of time in a surgeon's sterilizing tray, without fear of loss of germicidal activity through evaporation and/or polymerization during continued use.

We claim:

1. A germicidal preparation for sterilizing at room temperature surgical instruments and other articles subject to impairment by heat or corrosion, said preparation containing approximately 4% formaldehyde, an alcohol, a small quantity of a corrosion inhibiting agent comprising a nitrite and water, the water content of the solution being not substantially greater than 15%.

2. A germicidal preparation for sterilizing at room temperature surgical instruments and other articles subject to impairment by heat or corrosion, said preparation containing approximately 4% formaldehyde, approximately 85% of an alcohol, water, and a small quantity of a corrosion inhibiting agent comprising a nitrite and an alkali.

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