

# NATIONAL MASTITIS COUNCIL

## GUIDELINES FOR DEVELOPING TEAT SANITIZER CONCENTRATES

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The National Mastitis Council (NMC) Teat Dip Committee recognizes the benefits of teat sanitizer concentrates, including decreased transportation and distribution costs, decreased plastic container waste, and decreased product cost to the dairy producer. However, due to the variables associated with on-farm dilution, it is the committee's opinion that teat sanitizer concentrates should be tested by the manufacturer in such a way to assure effectiveness and safety following on-farm preparation. Such testing could be documented in an appropriate manner to instill confidence in the dairy producer and the farm milk quality consultants regarding efficacy and safety.

### **I. General Testing as Compared to Manufactured Ready-To-Use (RTU) Products**

Teat sanitizer concentrates should be tested to meet the same criteria as manufactured ready-to-use (RTU) teat sanitizer products in terms of safety, efficacy, and stability. Irritation and toxicity studies should be conducted on both the concentrate and reconstituted product, as both will likely contact human skin, and in case the concentrate is accidentally applied to the teats without being diluted. Tests should include skin and eye irritation, sensitization and oral toxicity. Germicidal activity of the reconstituted product should be determined using appropriate *in-vitro* tests such as the AOAC Germicidal and Detergent Sanitizer Test Method, or the Excised Teat Germicidal Activity Assay against mastitis pathogens, including *Staphylococcus aureus*, *Streptococcus uberis* and *Escherichia coli* and other organisms deemed relevant. It is also recommended that products be tested for efficacy in preventing new intramammary infections (IMI) using the NMC Recommended Experimental Challenge Protocol and/or the Natural Exposure Protocol.

Additional testing on concentrate products becomes necessary since a significant portion of the reconstituted product is water that is added at the farm. Considerations different from those required in the development of manufactured RTU products include: 1) stability testing to determine shelf life of reconstituted teat sanitizer; 2) the quality of water used to dilute the product; and 3) how to assure proper mixing of concentrate and water to create a homogeneous dilution.

### **II. Stability and Shelf Life**

The chemical and physical stability of both the concentrate and reconstituted teat sanitizer should be tested in the laboratory to determine shelf life of both under the range of expected use, storage, and transportation temperatures. Suggested testing includes: aging at 4<sup>o</sup> and 40<sup>o</sup> and/or 50<sup>o</sup> C for at least three months; aging at 22<sup>o</sup> C until product failure (test mandated by the U.S. Food and Drug Administration to determine expiration dates for both concentrate and reconstituted products); freeze-thaw cycling for three cycles. Additional stability testing of

reconstituted teat sanitizer made from aged concentrate should be done to determine the difference in shelf life of reconstituted product if diluted near the end of the shelf life of the concentrate. All stability tests for reconstituted teat sanitizers should be performed on dilutions that were made utilizing the same equipment and methodology as will be specified on the product label for the dairy producer to use.

Stability testing at the various temperatures could consist of chemical assays on active ingredients, viscosity, pH, visual appraisal of the solution for precipitation, gel formation, separation, color change, etc., as well as biological assays to assess continued acceptable germicidal activity against *Staphylococcus aureus*, *Streptococcus uberis* and *Escherichia coli*. The manufacturer would determine appropriate tests, depending on the chemical formulation of the product, to demonstrate that the concentrate and the reconstituted teat sanitizer were stable under the labeled storage conditions and to determine length of stability. Under such testing, the shelf life of most concentrate should be specified to be between one and three years.

### **III. Suitability of On-Farm Water For Dilution of Teat Sanitizer Concentrates**

Because the water used for dilution of teat sanitizer concentrates equals up to 90% of the final reconstituted product, considerable emphasis should be placed on determining how various components of on-farm water will interact with the components of the concentrate and what affect that will have on the stability, efficacy, and safety of the reconstituted teat sanitizer.

The presence of minerals, ions, disinfectants, etc., in the dilution water can have significant effects on the stability and efficacy of the reconstituted product. For example, with **iodine**-based concentrates, alkalinity appears to be the primary variable affecting stability and germicidal activity and is more important than hardness. For some manufacturers, iron does not seem to cause a problem at the levels found in most waters tested. **Chlorhexidine** products have a tendency to form precipitates in water with elevated levels of carbonate, sulfate, phosphate, or chloride. Products containing **chlorine dioxide** or **peroxide**, or other active ingredients, may be affected by these or others as well.

During the development stage and prior to marketing, manufacturers should evaluate the teat sanitizer concentrate in the presence of varying concentrations of a large variety of minerals and ions, as well as disinfectants that may be present in on-farm water supplies, to determine whether the product will be compatible with the water supplies of the majority of dairy farms in the U.S. Standardized formulations, such as the official hard water formulations may be used (see U.S. government publication *Standard Methods for Water Testing*, 1980 ed.). For iodine-based products, a recommendation would be to document the titratable iodine and pH of reconstituted teat sanitizer made with a range of water alkalinity. From this data, water alkalinity limits and shelf life limits could be determined. Other water components (such as iron, sulfur, chlorine, fluorine, etc.) should be evaluated depending on the chemical formulation of the teat sanitizer concentrate. To assess interactions between components, combinations of the extremes of the ranges of the various components can be tested with the teat sanitizer concentrate, and statistical models used to determine if there would be compatibility problems. From the results of the compatibility testing, the manufacturer should

document acceptable properties of dilution water and supply a table listing those properties, such as this example:

<u>Product Q</u>	
alkalinity	0 - 400 ppm as CaCO <sub>3</sub>
water hardness	0 - 800 ppm as CaCO <sub>3</sub>
iron	0 - 20 ppm
shelf life	30 days

Prior to marketing, it is recommended that the germicidal activity of reconstituted products be demonstrated with concentrate diluted with water that is near the limits of acceptability with an acceptable germicidal activity assay.

In the marketing phase, the suitability of the water on each farm should be determined prior to implementation of the teat sanitizer concentrate on that farm. First, the on-farm water supply to be used for concentrate dilution should be potable and tested for bacteria. Second, the water should fall within the manufacturer's established ranges of acceptability for all the various components (minerals, ions, alkalinity, etc.). These ranges of should be printed on the concentrate label or in the product literature. *The responsibility to determine suitability of the farm's water supply should be left with the dairy producer.* The producer should have the water tested periodically, advisably seasonally, either at the manufacturer's laboratory or by a local certified laboratory for the properties listed in the table of acceptability.

#### **IV. Methods For On-Farm Dilution and Mixing**

Simply pouring teat sanitizer concentrate into a container and adding water may not lead to a properly mixed reconstituted product. Differences in specific gravity and density between the concentrate and water, solubility differences of components in concentrate and dilution, different mixing container configurations and sizes, and temperatures of the water or concentrate can all lead to problems with obtaining a homogeneous reconstituted product.

Manufacturers should perform laboratory tests to devise on-farm dilution and mixing methods and frequencies and the corresponding label instructions that result in homogeneous product for the various sizes and types of containers to be used from a one-gallon jug to a 250-gallon tote. Proper dilution and mixing may be most effectively accomplished by utilizing a metered pump dilution system that thoroughly mixes water and concentrate in specific ratios into a container or spray system. The system could be provided and maintained by the manufacturer's trained sales and service field representatives, and be required in order for the teat sanitizer concentrate to be used on the farm. This would eliminate much of the human error involved with diluting and mixing, especially where large-volume containers are used.

Equipment or manual dilution and mixing methods should consistently yield a product with the active ingredient concentration within +/-10% of the label-stated concentration (ex. A 1% iodine sanitizer should be between 0.9% and 1.1% iodine in the reconstituted product) throughout the labeled shelf life of that product. Manufacturers should strive to develop tests

that can be used in the field by trained sales and service personnel and/or milk quality consultants to determine if a batch of reconstituted product is properly diluted and mixed and meets these concentration specifications. Alternatively, the manufacturer could provide this service at its own (or other specified) laboratory for a reasonable fee.

The container used on-farm to dilute the concentrate should also meet certain specifications, which should be included on the teat sanitizer concentrate label or product literature. Recommendations for such specifications are listed below.

- A. Use only dedicated, clean, non-reactive containers. Never mix teat sanitizer in containers that have been used for pesticides, herbicides, motor oil, etc.
- B. Triple rinse container with three doses of water equal to 25% of the container volume prior to mixing every batch.
- C. Never add a new batch of teat sanitizer to any volume of an old batch.
- D. Mix the contents of teat sanitizer container thoroughly.
- E. Label the teat sanitizer container with the product name, dilution date, and expiration date.
- F. Dilute only in accordance with directions provided. Do not over-dilute or under-dilute in an attempt to make weaker or stronger products. The stability, efficacy, and safety of such blends have not been demonstrated.
- G. Never add extraneous ingredients, such as glycerin, sorbitol or aloe vera, to the teat sanitizer, unless specified on the label. The effects on stability, efficacy, and safety are not known.

## **V. Labeling of Teat Sanitizer Concentrates and Reconstituted Product**

In addition to the labeling requirements for manufactured RTU teat sanitizer products, it is recommended that concentrate products also have the following information on the container label or at least in the product literature: 1) specific directions for diluting and mixing product, both method and frequency, to obtain and maintain a uniform reconstituted product in various sizes of containers; 2) storage temperatures for concentrate and reconstituted product; 3) expiration date of concentrate and shelf life of reconstituted product after dilution; 4) specific criteria for dilution container. In addition, there should be a statement *strongly suggesting* that the farm water source to be used for diluting the concentrate should be tested by either a local certified laboratory or by the manufacturer to determine compatibility with the concentrate product. The manufacturer should provide a label for the container that will hold the reconstituted product with the following information: 1) product name and type (reconstituted dilution of a concentrate); 2) concentration of active ingredient; 3) directions for use. An additional label/sticker with spaces to write in dilution date and expiration date of each batch would provide necessary expiration information on the container. These labels could be affixed to the container by the manufacturer's sales and service field representative.