National Mastitis Council

Guidelines For On-Farm Transfer of Teat Disinfectants

Teat disinfectants are to be manufactured in accordance with the code of Good Manufacturing Practices (cGMP) established by the United States Food and Drug Administration (FDA). To ensure product integrity, it is safest for teat disinfectants to be purchased in the manufacturers' original unopened, labeled container directly from manufacturers or their authorized distributors or agents. If bulk teat disinfectants are delivered to, and used on farms, the following precautions should be taken to ensure the safety and efficacy of the product.

- The agent performing the transfer must be registered and have a drug establishment number.
- Use only dedicated, clean, non-reactive containers. Never store teat disinfectant in containers that have been used for pesticides, herbicides, motor oil, etc.
- Do not add a new batch of teat disinfectant to any volume of an old batch.
- Triple rinse the container with three doses of potable water equal to 25% of the container volume and drain completely prior to every filling.
- The on-farm container should have the following information on the label:
 - 1) name of manufacturer, repacker, and distributor
 - 2) net weight or volume of product delivered
 - 3) product name and type
 - 4) statement of active ingredient(s)
 - 5) directions for use
 - 6) batch code number
 - 7) expiration date
 - 8) relevant safety information.
- The accompanying label needs to be replaced or updated at each filling.
- The equipment used for the transfer must be maintained to prevent contamination. Wash and cap ends of transfer lines after each transfer. The rest of the equipment must be cleaned following the plant's cGMP.
- Each lot manufactured or repackaged is to be sampled by the agent delivering the product and samples retained by them as per FDA requirements.
- Routine product testing should be done as part of the agent's cGMP validation.
- All teat disinfectants should be stored in a clean, cool, and dry area and not be exposed to freezing conditions.

Teat disinfectants are considered to be drugs by the FDA. For more information on teat disinfectant regulations refer to the Code of Federal Regulations (CFR) 21, Part 210. For more information on the use of teat disinfectants refer to *NMC Teat Disinfection Facts* and other related articles at *www.nmconline.org*.

The information in this factsheet is based on United States regulations. Regulations vary worldwide so check with your local sanitarian for the appropriate practices in your country.