

THE ROLE OF PRESERVATIVES IN CONTROLLING MICROBIAL CONTAMINATION INTRODUCED IN THE MANUFACTURE OF COSMETICS

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Synopsis

The use of a preservative or a preservative mixture cannot be the only means by which cosmetics and toiletries are protected from microbial contamination introduced during the manufacturing process. The use of a preservative must be coupled with laboratory tests which demonstrate that the preservative system is effective and stable in the product. In addition, manufacturing practices must strictly control the levels of microorganisms which are introduced to products via routes such as raw materials and improper storage and handling practices. A microbial quality assurance program is essential in manufacturing cosmetics and toiletries. Such a program will ensure that use levels of preservatives are not consumed eradicating high levels of contaminants introduced during manufacturing so that an adequate level of the preservative will be present to protect the product throughout its life.

Riassunto

L'uso di un conservante o di una miscela di conservanti non può essere il solo mezzo per eliminare i contaminanti introdotti durante i processi di lavorazione. L'uso del conservante deve essere convalidato dai test di laboratorio che ne dimostrino l'efficacia e la stabilità nel prodotto finito. Inoltre tutto il processo di lavorazione deve essere eseguito in modo da ridurre il livello dei microrganismi introdotti sia attraverso le materie prime che attraverso l'ambiente. È, quindi, di fondamentale importanza seguire le norme di buona fabbricazione affinché i preservanti introdotti nel cosmetico servano a conservarlo bene durante tutto l'arco della sua vita.

Preservatives are designed to protect clean products from occasional microbial challenges encountered through use. The addition of a preservative or preservative mixture to a product cannot be the only means by which cosmetics and toiletries are protected from microbial contamination in a manufacturing environment. To prevent contamination of cosmetics and toiletries, it is essential that each of the following items are addressed in developing and manufacturing such products:

- An adequate level of a preservative must be added to the product.
- The preservative must be stable in and compatible with the product for the timeframe over which protection is required.
- Precautions must be taken as to how the product is manufactured, stored and handled (i.e., good hygiene practices must be followed in manufacturing).

Why do contamination problems occur in preserved products ?

On-going emphasis on safety, regulatory and environmental issues continue to impact on the preservation of cosmetics and toiletries. As a result, preservative use is being driven towards lower use levels, lower toxicity active ingredients (including “natural” and even “preservative free” products), and less volatile active ingredients.

Unlike the forgiving high levels of preservatives such as formaldehyde used in the past, typical use levels of many of today’s preservative systems are not able to withstand continual repeated challenges of high levels of microorganisms which occur in improperly maintained manufacturing facilities. In such situations, the preserva-

tive(s) can be consumed or overwhelmed, and the product will no longer be protected from subsequent microbial challenges. This can result in consumer exposure to contaminated or inadequately preserved products. In addition, on-going focus on water conservation and waste minimization and detoxification is forcing manufacturers to recycle process and wash water, and to treat wastes prior to discharge. When recycled water is not effectively monitored and treated with biocides, microbial contamination problems will arise and will provide yet another source of challenges to the preservative systems used in products which come into contact with recycled water. Tightening regulations on waste water discharges can also lead to greater reluctance to clean and sanitize equipment since it is more difficult to discharge large volumes of water containing cleaners and sanitizers such as bleach or quaternary ammonium salts. If cleaning and sanitization frequency is reduced to avoid discharge regulations, microbial contamination problems can occur more frequently.

Unlike older preservatives such as formaldehyde, the preservatives used today have very low vapour pressures. The use of low vapour pressure actives results in little or no preservative presence in the headspace and condensation in storage tanks. As a result, microorganisms introduced into the headspace of a storage tank by poor storage and handling practices will often proliferate in the condensate water on the product surface, on the walls and ceiling of the tank and on the agitator shaft. When new material is added to the tank, the microorganisms on the walls and surface of the product are introduced to the bulk preserved product. Over time, this process initiated by poor storage and handling practices can lead to microbial contamination in a preserved product because:

- Some or all of the preservatives in the product can be consumed each time large numbers of microorganisms introduced to the product are

eradicated. Eventually, the preservative can be depleted.

- Biofilms can form on unprotected surfaces in storage tanks. Biofilms provide protection for microorganisms making it more difficult for the preservative in a product to eradicate the microorganisms.
- As a greater number of microorganisms come into contact with a preservative system there is a greater likelihood of encountering microorganisms which are less susceptible to the preservative. Continued poor storage and handling conditions can lead to the development of a microbial population which is not controlled by the preservative system, particularly when an inadequate level of preservative is being used.
- The more often large microbial populations are exposed to inadequate levels of preservatives, the greater the chance that some microorganisms may respond to the preservatives and after their susceptibility to it. This can lead to the development of a microbial population which is resistant to the preservative system being used.

How do you prevent contamination problems?

The first step in preventing microbial contamination in products is a thorough laboratory evaluation of candidate preservative systems during product development. Such an evaluation should include rigorous multiple challenge testing and accelerated aging studies. It is critical to include accelerated aging studies in evaluating preservative systems to ensure that the preservative system chosen will be stable in and compatible with the formulation from the time the product is manufactured until it is used by the consumer. Accelerated aging can be in-

corporated into the challenge test by performing additional challenges after various periods of aging. In addition, following the preservative levels remaining in the product after various aging intervals provides valuable information for assessing the ability of the preservative to protect a product over an extended time period.

The next step in preventing microbial contamination in products is to ensure that the facilities manufacturing the product are following good hygiene practices. Good hygiene practices must encompass the following:

- Raw materials
- Process water
- Cleaning and sanitization practices
- Storage and handling practices.

Raw materials can be a troublesome source of microbial contaminants in manufacturing facilities. Aqueous raw materials often support microbial growth, and many non-aqueous raw materials can harbour bacterial and fungal spores. Natural raw materials are usually very susceptible to microbial contamination. Raw materials which are susceptible to contamination must be treated and/or preserved prior to entering the manufacturing area. Microbial limit specifications and preservative specifications should be put in place for these raw materials to ensure that contaminated materials do not enter the facility, and that raw materials which are readily contaminated are protected with a preservative. Specifications must also include formulations or dilutions of raw materials such as aqueous solution of dyes which are made in the facility and which are often more susceptible to contamination than the raw materials as received.

Water is probably the most common source of microbial contamination in manufacturing facilities. Mains water often contain low levels of microorganisms such as the ubiquitous *Pseudomonas* species as water authority standards do

not demand the absence of all microorganisms. Given that water supplies will bring this low level of microorganisms into a manufacturing facility, care must be taken to ensure that the microorganisms are not exposed to environments which will allow them to multiply.

Treatment units such as de-ionizing resin beds and reverse osmosis purifiers offer ideal sites for bacteria to collect and multiply. Such units must be cleaned and disinfected regularly to prevent accumulation of microorganisms. Stagnant water must be avoided in pipes, and, if present, must always be flushed to waste with copious quantities of microbially clean water prior to using the pipe. If water is stored in tanks prior to use it should be treated with a biocide or stored at $>75^{\circ}\text{C}$ to control microbial growth.

Cleaning and sanitization procedures are also important tools which will help prevent microbial contamination problems if they are used correctly. It is crucial that such procedures are validated first to ensure they are effective. In addition it is equally important that the procedures are documented so that the desired results (eradication of contaminants) are achieved by all workers every time they are used. It is not enough to state that equipment be sanitized with steam after each use. An effective procedure would specify in detail when it needs to be done, how to clean product residues out to the system prior to steaming, how and where to steam, how long to steam, and how to validate that the procedure was effective.

Storage and handling practices in manufacturing can have a tremendous impact on the microbial quality of products. From the start, a manufacturing facility needs to be designed with hygiene issues in mind. Design should include details such as:

- High quality, non-porous materials of construction
- Short pipe runs

- Minimum number of joints, valves, manifolds, gauges
- No dead end lines
- Sloped pipes for good drainage
- Storage tanks with hatches that seal and air vents which are protected with microbiological filters.

In addition, **worker training** which emphasizes the importance of good plant hygiene and how to practice good plant hygiene is invaluable. Workers need to gain a basic understanding and appreciation of the facts: microorganisms are very small, microorganisms are everywhere, microorganisms grow rapidly, and microorganisms cause raw materials and products to go bad. Worker training should also raise the level of awareness of the ways in which they might introduce microorganisms into raw materials and products if specified practices and procedures are not followed. Examples of actions workers who receive appropriate training can and will control include:

- Leaving tank hatches open
- Pumping air into storage tanks with new deliveries
- Leaving hoses and pipes filled with product or water
- Improper use of protective clothing in packaging areas
- Improper cleaning and sanitization practices.

Finally, **microbiological** monitoring programs are a very important component in any program designed to ensure that contamination problems in manufacturing are controlled and minimized. Raw materials, water, products and equipment must be sampled for microbiological analysis on a regular basis. The frequency for sampling should depend on issues such as:

- Susceptibility of raw materials or products to contamination
- How water is treated, stored and used in the

facility

- How often equipment is shut down or changed over

For microbiological monitoring programs to be effective, in addition to sampling and analysis, one needs to develop responses to the detection of contamination whether the level is low or high. For example, if a low level of contamination is detected in a raw material should it be treated, returned to the supplier, used in the next

production run, etc.? If a piece of equipment is found to be harbouring a contaminant how should it be cleaned and sanitized, and how should you verify that the contaminant has been eradicated before you use the equipment again?

In conclusion, if the above practices are incorporated into the product development and manufacturing of cosmetics and toiletries, the incidence of microbial contamination problems should be greatly reduced.

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