RAW MATERIAL MICROBIAL CONTENT

INTRODUCTION

In order to minimize the chance of contaminated finished product, it is necessary to control the microbial content of cosmetic raw materials along with other physical and chemical attributes. Cosmetic manufacturers should evaluate the microbiological quality of their raw materials and establish appropriate specifications based on the best available scientific information.

Water and water supplies are addressed in the CTFA "Microbiological Quality for Process Water" Guideline. Water systems should be properly validated and controlled. Quality specifications for water should be set, including alert and action levels.

GENERAL CONSIDERATIONS

When establishing acceptable levels for raw material microbial content, the following criteria should be considered:

- Chemical composition.
- Physical nature.
- Origin and availability.
- Lot uniformity.
- Intended use of the product.
- Concentration of raw material used in the product.
- Manufacturing process.
- Raw material history.
- Storage conditions.
- Water activity.

Many synthetic raw materials currently used by the industry contain low microbial counts, due to extremes in pH, low water content, or inherent antimicrobial properties. Others may be supplied as aqueous dispersions or solutions, and may be susceptible to microbial proliferation. Therefore, it is important to evaluate susceptible synthetic materials upon receipt to ensure that they have not been contaminated during the manufacturing process, packaging, transportation, and storage.

Naturally occurring raw materials are likely to contain a high level of microorganisms that may pose a contamination risk to the finished product if not reduced or eliminated during processing. The microbial content may vary depending upon the type and source of the raw material. It may be necessary to treat such materials to reduce microbial levels before use or to purchase already treated materials.

The criteria set by the manufacturer for the microbial content of a raw material should take into consideration the release criteria established for each finished product. For example, the absence of *Salmonella* is significant if a raw material is used in an oral product. A raw material microbial content specification is usually not greater than that

for the finished product, especially when it is used at greater than 1% in the formulation. A raw material with a microbial count greater than that set for the finished product may be acceptable if its use does not compromise the safety and stability of the formulation and its concentration in the finished product is low.

SPECIFIC CRITERIA

This guideline recognizes the importance of using raw materials of the highest quality in the manufacture of cosmetics. Special conditions may allow or necessitate acceptance criteria that vary from those recommended below. It is recommended that the minimum test portion be 1 g or 1 mL of sample.

The following are recommended guidelines:

- All Synthetic and Natural Raw Materials not more than 10^2 CFU per g or mL

  NOTE: Interpretation of results

  The inherent variability of a plate count should be taken into account, thus the interpretation may be as follows:

- 10^2 - may be interpreted as 5×10^2

In addition to these recommended numerical guidelines, no raw material should have a microbial content recognized as either harmful to the user or able to compromise integrity of the finished product as recovered by standard plate count, specific pathogen test, or an equivalent automated procedure.

GENERAL RECOMMENDATIONS

As cosmetics and toiletries need not be manufactured from sterile raw materials, it is important that raw materials are obtained from qualified suppliers and are handled, stored, and used under conditions designed to deter microbial proliferation or subsequent contamination. The CTFA Quality Assurance Guidelines are a useful guide for the storage and handling of raw materials[1] as well as microbiological sampling techniques.

Sampling techniques are located in “Microbiological Sampling” and in “Sampling: Part II-Sampling and Control Techniques for In-bound Receipts”[2]

Validated microbiological analytical methods should permit the detection of microorganisms and ensure the inactivation of the preservative.[3, 4] The presence of objectionable organisms can be determined by identification of isolates using procedures such as described in “M-2 Examination for *Staphylococcus aureus, Escherichia coli* and *Pseudomonas aeruginosa*”.

If raw materials are found to have a microbial content greater than specified, an investigation to identify and eliminate the source of the contamination can assist in implementing preventative measures. [5]

It is recommended[5] that a qualified microbiologist or independent microbiology laboratory be engaged to:

- Design procedures for the examination of specific raw materials,
- Examine the manufacturer's raw materials for microbial content on a continuing basis,
- Interpret assay data on a routine basis, and
- Periodically review and update procedures, when applicable.

REFERENCES

1. "Handling, Storage and Analysis of Raw Materials," CTFA Quality Assurance Guidelines, The Cosmetic, Toiletry, and Fragrance Association, Washington, D.C. 20036; December 1992.

2. "Sampling: Part II-Sampling and Control Techniques for In-bound Receipts," CTFA Quality Assurance Guidelines, The Cosmetic, Toiletry, and Fragrance Association, Washington, D.C. 20036; December 1992.

3. "M-1 Determination of the Microbial Content of Cosmetic Products," CTFA Microbiology Guidelines, The Cosmetic, Toiletry, and Fragrance Association, Washington, D.C.; November 2001.

4. ASTM E 1054-91, "Standard Practices for Evaluating Inactivators of Antimicrobial Agents Used in Disinfectant, Sanitizer, Antiseptic, or Preserved Products," Annual Book of ASTM Standards, Volume 11.05, ASTM, 1999.

5. "Vendor Quality Assurance", CTFA Quality Assurance Guidelines, The Cosmetic, Toiletry, and Fragrance Association, Washington, D.C. 20036; December 1992.