

CTFA TECHNICAL GUIDELINES

CTFA Microbiology Guidelines



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2007

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* These guidelines and methods were newly written or substantively revised for the 2005 *CTFA Microbiology Guidelines*.

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* These guidelines and methods were newly written or substantively revised for the *2005 CTFA Microbiology Guidelines*.

** Method M-3 underwent substantive revisions and review for the *2007 CTFA Microbiology Guidelines*.

Acknowledgements

The *Guidelines* presented in this volume were developed by the CTFA Microbiology Committee, with assistance from many members of the CTFA Scientific Advisory Committee. As the development and updating effort has been a continuing one, listing all of the experts involved from CTFA member companies would be beyond the capabilities of the current editors. Therefore, to all who had a part, a very warm and sincere thank you. The editors also would like to thank Michelle Duellely at CTFA and Don English at Avon for their assistance.

Foreword

In 1969, CTFA began publishing its *Technical Guidelines* in the *CTFA Cosmetic Journal*. These guidelines were developed by the newly organized CTFA Microbiology Committee and were concerned with microbiological issues. The benefits of having the *Guidelines* available in a single volume, and presented in a standardized format, were recognized, and in 1974, the first independent compilation of the *Technical Guidelines* was published.

In 1993, after several major revisions and additions to the *Guidelines*, CTFA responded to requests made by the users and split the *Guidelines* into separate volumes so that individuals might purchase sets relating specifically to their areas of responsibility. The *Guidelines* are now published by CTFA in three volumes: Microbiology, Quality Assurance, and Safety Evaluation.

The *CTFA Technical Guidelines* are dynamic documents that undergo extensive development and review prior to publication by CTFA technical committees and staff, as well as public review by CTFA members and nonmember companies, federal government agencies, and scientific professional societies. Comments from individuals are welcome at any time.

While CTFA has sought to ensure that these *Guidelines* generally satisfy applicable U.S. federal statutory and regulatory requirements as of the date they were drafted, CTFA can assume no responsibility for their adequacy, nor does it purport to advise as to the necessity for their use in any particular situation. In those *Guidelines* that address regulatory requirements, decisions such as when a report must be filed and what information must be included in it can be made only by those individuals responsible for making such submissions. With regard to all of the areas covered by *CTFA Guidelines*, each company must independently assume responsibility to ensure that their conduct is consistent with all current, applicable federal, state and local laws and regulations.

It must be emphasized to the user that these *Guidelines* are intended only to aid manufacturers in developing programs that meet their individual needs. The *Guidelines* must not be considered either minimum or maximum requirements of effective programs. Alternative ways to reach the goals of the *Guidelines* may well exist and may be equally useful. *Guidelines* on any topic must, of course, be adapted to the particular operations of the manufacturer using them.

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Introduction

The production of quality personal care products requires a commitment from the manufacturer to establish and maintain a total quality program. The microbiological component of such a program is designed to ensure: (1) the product that reaches the consumer is free of microorganisms that could affect the product quality and consumer health, and (2) during normal product use, the quality of the product will not be affected by microbial activity.

The *CTFA Microbiology Guidelines* are intended to provide manufacturers with guidance regarding establishing and maintaining a microbiological quality program within their companies. The *Guidelines* are also recommended for contract packagers and suppliers of raw materials. Sections of the *Guidelines* will vary as to applicability for different sectors of the industry and for individual companies.

The *Guidelines* are organized into separate sections. The major provisions for an effective microbiological quality program are outlined in the basic guideline “Microbiological Quality Assurance for the Cosmetic Industry” (Section 1). More specific information on building and equipment design, personnel training, cleaning, sanitization and housekeeping immediately follows in a general section. The quality of raw materials used in cosmetic products is addressed in guidelines that cover handling, storage, analysis and sampling. Since process water is a major raw material in cosmetics and toiletries, a separate guideline focuses on process water systems and quality.

Because of the increasing dependency on microbiological laboratories to provide supportive data related to product safety and quality, guidelines are offered for evaluating laboratory practices both in-house and in contract laboratories. “Microbial Validation and Documentation” of methods under Section 9 offers guidance for use in the laboratory as well as the plant environment.

As an alternative to manufacturing sterile products, the consideration of rational limits to microbiological content based on the best available information is practical and proper. Microbiological limits for finished products as well as raw materials are covered in separate guidelines. “Establishing Microbial Quality of Cosmetic Products” (Section 12) is the result of the international harmonization efforts of Colipa, CTFA, and JCIA. “Microbiological Risk Factor Assessment of Atypical Cosmetic Products” (Section 16) offers advice on conducting risk assessment and testing of atypical and non-aqueous cosmetic formulations. An extensive glossary defines terms used in the *Guidelines*.

These *Guidelines* are not intended to establish minimum industry standards for all cosmetic, toiletry and fragrance products. Also, the *Guidelines* do not cover all areas that might be addressed under a specific category. CTFA intends to include additional topics in future updates to the *Guidelines*. In the interim, cosmetic companies are encouraged to refer to other microbiology resources. While these *Guidelines* can help ensure that products are microbiologically acceptable, they cannot substitute for day-to-day familiarity with the principles of microbial control. The *Guidelines* must never be taken to restrict additional activities when circumstances dictate.

Sections of these *Guidelines* that are new or substantively updated in 2005 or in this edition of the *CTFA Microbiology Guidelines* are indicated in the *Table of Contents*. References including website addresses for all sections have been updated for the 2007 edition. On November 28, 2007 the Cosmetic Toiletry and Fragrance Association changed its name to the **Personal Care Products Council**. The new, broader and more contemporary name for the association reflects our increasingly diverse membership. The *Microbiology Guidelines* will not be printed with the new name until the next edition.

SECTION 1

Microbiological Quality Assurance for the Cosmetic Industry

INTRODUCTION

Adequate control of the microbiological quality of finished cosmetic products depends upon the implementation of an effective microbiological quality assurance program. Although the applicability of some aspects of such a program will vary for different types of products, processes, and facilities, the major areas described below should be reviewed.

The reader is directed to review the “Glossary of Microbiological Terms” at the end of this document to ensure a proper understanding of the *Guidelines*.

Note that these guidelines do not apply to products that have been defined as drugs or pharmaceuticals by regulatory agencies. The Food and Drug Administration’s (FDA) Current Good Manufacturing Procedures (CGMPs) for Finished Pharmaceuticals should be consulted for the manufacture of drug products.¹

QUALITY ASSURANCE

Quality assurance is defined as “those planned and systematic activities necessary to provide confidence that a product satisfies given acceptance criteria.”² The goal of an effective microbiological quality assurance program is to assure that the finished product consistently meets established microbiological standards.

The microbiological quality assurance program can be viewed as having several major components:

- Personnel, including qualifications, functions, and training
- Physical environment, including plant, grounds, equipment and sanitary procedures
- Materials, including storage, raw materials, packaging, and finished goods
- Procedures, including sampling, testing, laboratory practices, and auditing

The *CTFA Quality Assurance Guidelines* provides information for establishing quality assurance programs within cosmetic manufacturing facilities, as well as establishing the control systems designed to assure product quality and consumer safety.³