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	RE EVALUATION AND SHELF LIFE POLICY	Version : 03
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History of Modifications :

Update of marketing contact §III.2.c

§ IV Change on residual shel-life committment for cosmetic products from 4 to 6 months

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INTRODUCTION
QUALITY SYSTEM AND GMP

GATTEFOSSE is an independent international group, with headquarters based in France, which creates, manufactures and markets specialty products used as ingredients in the pharmaceutical, dietary and personal care industries.

GATTEFOSSE strives to be a strategic supplier of raw materials for cosmetics and pharmaceutical industries world-wide. The company aims to maintain this strategic position through the supply of high-quality, high-performance products and services expected by its clients. In order to do this, we have implemented quality systems and processes that are continually being improved to satisfy our customers' evolving needs.

I. INTRODUCTION

GATTEFOSSE SAS meets the internationally recognised ISO 9001 quality standard, the assurance that we maintain consistently high standards (Certification ISO 9001 since 2003).

Our products are manufactured according to applicable Good Manufacturing Practices (GMP). GATTEFOSSE SAS is an active member of the International Excipient Council (IPEC)[1] and has aligned its quality system with joint "IPEC/PQG (Pharmaceutical Quality Group), GMP Guide for Pharmaceutical Excipients"[2]. Since 2010, Gattefosse is also certified GMP for the manufacturing of Cosmetic Ingredients following the EFfCi[3] guide.

[1] IPEC Europe, the International Pharmaceutical Excipients Council Europe, serves the interests of producers, distributors and users of pharmaceutical excipients.
[2] This document can be freely downloaded from the IPEC Europe website.
[3] EFfCi : European Federation for Cosmetic Ingredients

GATTEFFOSSE RE EVALUATION AND SHELF LIFE POLICY

According to GMP requirements of the IPEC/PQG GMP , IPEC Excipient Stability Program and EFfCi guides, Gattefossé has established Expiry dates for the excipients for pharmaceutical use and a re-evaluation date for the ingredients for personal care use.

Definitions

Expiry date or Expiration date
This refers to the date after which the excipients should no longer be used due to quality or safety reasons.

Re-evaluation Date
The date when the ingredient should be re-examined to ensure that material is still suitable for use.

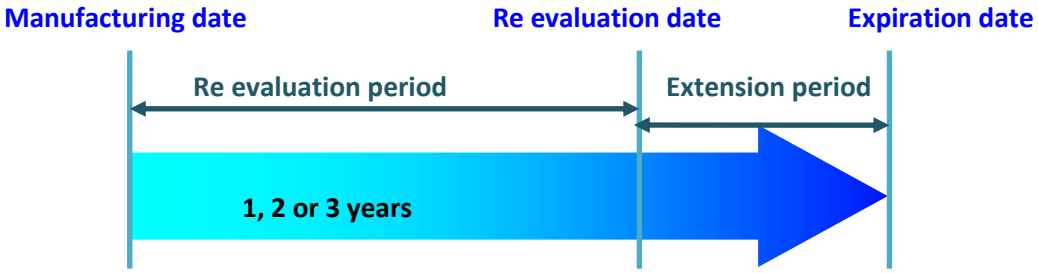
Re-evaluation Period
The period of time during which the ingredient can be considered to remain within the specification and therefore acceptable for use in the manufacture of a given product, provided that it has been stored under the manufacturers recommended conditions. After this period, the batch should be retested for compliance with specification.

Extension period
Added period from the re evaluation date during which the ingredient can be used.

Shelf-life
The period between the date of manufacture and expiry date is known as the shelf-life.

An Expiry date is assigned to each Gattefossé excipient for pharmaceutical use. A re-evaluation period is assigned to each Gattefosse ingredient for personal care use. Those dates are communicated to the customer through the CoA and the label**.**

For Cosmetic Ingredients:



For Pharmaceutical Excipients:

II. DETERMINATION OF THE RE-EVALUATION / EXPIRY PERIOD

Adequate stability evaluation is performed in order to support the intended period of use of the excipient/ingredient. An appropriate recommended Re-evaluation or Expiry date for each excipient/ingredient is established from the results of a documented stability-testing program, from historical data or from applicable "product model" studies.

Historical data

For excipients/ingredients that have been on the market for a long time, historical data can be used to indicate stability (e.g. results or previous re-evaluation tests…).

Stability-testing program

Where historical data do not exist, a documented testing program designed to assess the stability characteristics of the excipient/ ingredient is undertaken. The results of such stability testing are used in determining appropriate storage conditions and the expiry/ re-evaluation period.

"Product model" studies (e.g. Suppocire® or Vegetol®)

Some excipients/ingredients from a same "product family" are highly comparable in terms of composition. Minor quantitative differences of some of the components are the only variations from one product to another. For these types of excipients/ingredients, a "product model" approach is appropriate to assess the stability of similar excipients.

Stability studies of this type involve selection of several "product models" that would be expected to simulate the stability of the product family being assessed. This selection is scientifically sound and documented. Data from stability studies of these "product models" are used to determine theoretical shelf life for similar products.

III. GENERAL RULES FOR THE SHELF LIVES EXTENSION

1. Pharmaceutical Excipients

A shelf life for a pharmaceutical excipient will never be extended unless new stability data can support the shelf-life extension and only if the product has been stored in Gattefosse main Logistic Platform.
([3])

2. Cosmetic Ingredients

A cosmetic ingredient can be extended only once at the re-evaluation date. After re-evaluation, an expiry date will be set on the CoA and the product will not be extended anymore after expiry date.

a. Product stored in a customer's warehouse

GATTEFOSSE WILL NOT RE- EVALUATE PRODUCTS STORED IN CUSTOMERS' WAREHOUSES.
Gattefosse may re-evaluate a product on request of a customer only if the batch has been delivered less than 3 months before.

In the other case, Gattefosse can advise which parameters the customer has to retest to extend the re-evaluation period of the product. Such decision will remain under the customer's responsibility.

b. Product stored at affiliates logistic platforms

The shelf life can be extended provided that:

- The ingredient has been stored according to GATTEFOSSE recommended storage conditions in the premises of a Logistic partner who has signed a Quality Agreement with Gattefosse and is committed to the application of the Good Distribution Practices described in the IPEC GDP Guide.
- The Logistic Platform is regularly visited and evaluated in terms of its quality performances by Gattefosse employees.
- The product is still in its original package tightly closed with the original seal.

Under here above conditions, a batch of a cosmetic ingredient can be re tested and its shelf life extended.
In that case, a new CoA (Certificate of Analysis) will be issued with the new results and an expiry date and the packages will be re-labeled according to Gattefosse relabeling SOP, with the new expiry date.

(3) Pharmaceutical Excipients recently developed may have a re-evaluation date until the stability studies are completed and a definitive shelf life is settled .

c. Product stored in a distributor's warehouse

Derogations can be decided case by case by Operational Marketing Department conjointly with the Quality Department to extend the shelf life of a cosmetic product stored in a distributor's logistic platform. In that case, the distributor will have to send the request form (see Annex I) to the Operational Marketing Service, (lschubnel@gattefosse.com) with the following information:

- Delivery date
- Initial delivered quantity
- Quantity remaining in stock
- Sales forecasts for the next 6 months

Besides those data, the distributor will have to demonstrate through records sent to the Quality Department that storage conditions have been respected along the storage period.

If the decision is taken to re-evaluate the product, the Distributor will send back at its expenses a full package of the Ingredient to Gattefosse Laboratory for sampling and retesting.
If the product does not meet the specification anymore, the shelf-life is not extended and the product must be disposed.
Gattefosse will not accept any complaint or payback request due to a batch which cannot be extended.
An investigation will be led to determine whether the product has degraded due to storage or handling conditions. In that case the disposal will be at the expenses of the stock owner.

d. Invoicing

Depending on the situation, Gattefosse SAS may decide to invoice the cost of the re evaluation to the Distributor or Affiliate, provided the goods are still in their stock. The minimum cost is 500€.

IV. GENERAL RULES FOR RESIDUAL SHELF LIFE

GATTEFOSSE SAS take the commitment to deliver to its customers, including affiliates and distributors, products with following residual shelf lives:

- Pharmaceutical excipients : 12 months
- Cosmetic ingredients : 6 months

V. INVENTORY RETURNS

In corollary of this Policy, the product take-back at the customers by commercial gesture will not be accepted.