

# "Safe" Beauty E-Summit

## Preservatives

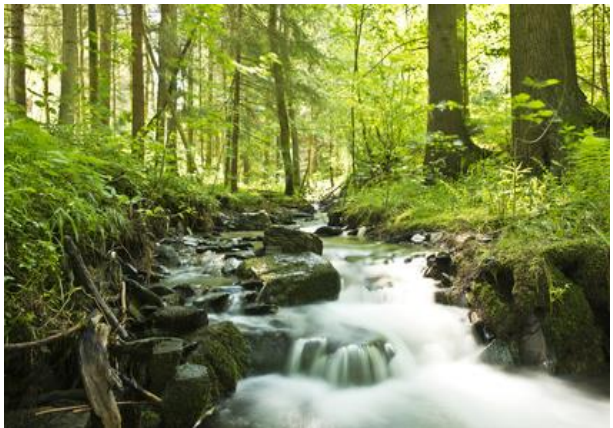
September 18<sup>th</sup>, 2022

Samir Sliman, Evonik

dr.straetmans ®



# Life is beautiful...



...and water is life!

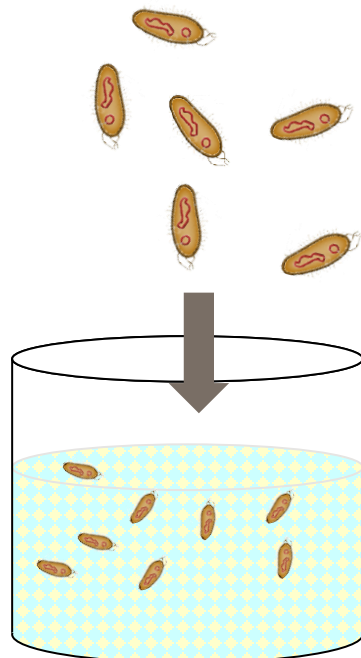
# Water supports life...



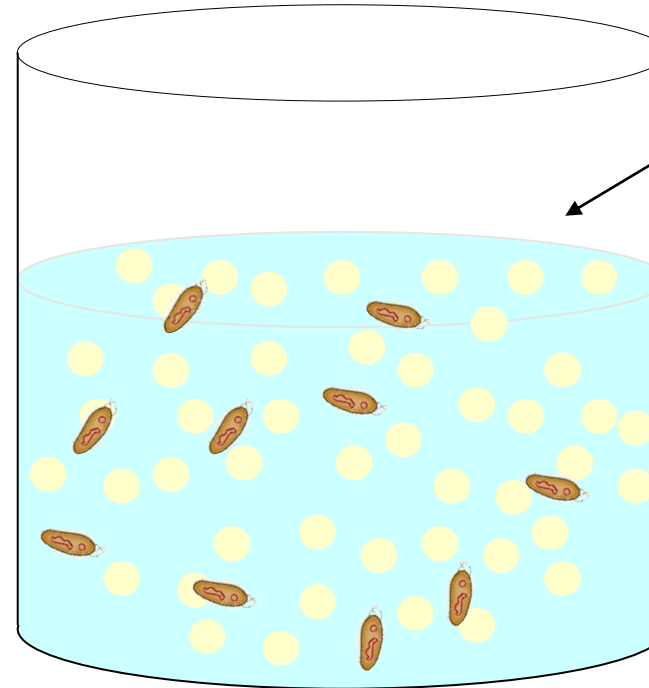
**...EVERYWHERE!**

# Why do we have to preserve cosmetic products?

## Oil in water emulsion



Rapid growth



Microorganisms live in the aqueous phase and feed on the oil phase

# Why do we have to preserve cosmetic products?

*Preservation of a cosmetic product is necessary, ...*

... to protect the esthetical aspect and the functionality of the product



... to protect the consumer of the product



Source: <http://healthy-lifestyle.most-effective-solution.com/2011/05/17/natural-antibiotics-for-staph-infections/>

# Why do we have to preserve cosmetic products?

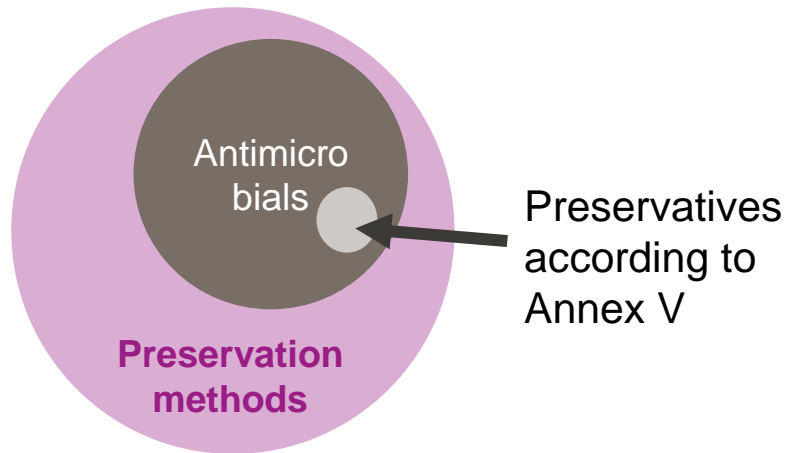
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- Unprotected or insufficiently protected cosmetic products can have a significant impact on the market image of a cosmetic product
- Unprotected or insufficiently protected cosmetic products can pose risk to the health of the user of the cosmetic product

*Better „wrong“  
then „none“*

# What is preservation?

## Technical definition



Antimicrobials: Substances impairing the conditions for microorganisms to survive in a given product matrix.

The mechanism of antimicrobial action can be physical or chemical and the efficacy of an individual substance depends on the given matrix itself and the target microorganism.

**Thousands of substances**

## Legal definition

### Article 14

#### Restrictions for substances listed in the Annexes

1. Without prejudice to Article 3, cosmetic products shall not contain any of the following:
  - (i) Preservatives other than those listed in Annex V and preservatives which are listed there but not in accordance with the conditions laid down in that Annex;

#### This directive defines the term „preservative“ as:

- (l) „preservative“ means substances which are exclusively or mainly **intended** to inhibit the development of microorganisms in the cosmetic Product;

**59 substances**

# Legal framework

## ... for the use of preservatives in cosmetic

	Europe	US
First common cosmetic regulation	Guideline 76/768/EC	Federal Food, Drug & Cosmetic Act 1938
First definition of a cosmetic preservative	Directive 82/369/CE	n.a.
Positive list for preservatives	yes	no
Current legal framework	Directive 1223-2009 EC	Federal Food, Drug & Cosmetic Act 1938
Expert Panels	SCCS	PCPC



# Legal framework EU

## ... for the use of preservatives in cosmetic

The legal basis for the production of cosmetic products is the EU-directive 1223/2009/CE. Article 14 refers to the annex V as a positive list of permitted preservatives.

### *Article 14*

#### **Restrictions for substances listed in the Annexes**

1. Without prejudice to Article 3, cosmetic products shall not contain any of the following:
  - (i) Preservatives other than those listed in Annex V and preservatives which are listed there but not in accordance with the conditions laid down in that Annex;

#### **This directive defines the term „preservative“ as:**

- (l) „preservative“ means substances which are exclusively or mainly intended to inhibit the development of micro-organisms in the cosmetic Product;

# Legal framework USA

## ... for the use of preservatives in cosmetic

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Federal Food, Drug, and Cosmetic Act (FD&C Act)

The Federal Food, Drug, and Cosmetic Act and subsequent amending statutes are codified into Title 21 Chapter 9 of the United States Code.

FDA doesn't have special rules that apply only to preservatives in cosmetics. The law treats preservatives in cosmetics the same as other cosmetic ingredients.

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), cosmetic products and ingredients, other than color additives, do not need FDA approval before they go on the market.

However, it is against the law to market a cosmetic in interstate commerce if it is adulterated or misbranded. This means, for example, that cosmetics must be safe for consumers when used according to directions on the label or in the customary way, and they must be properly labeled.

# Legal framework USA

## ... for the use of preservatives in cosmetic

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Federal Food, Drug, and Cosmetic Act (FD&C Act)

The Federal Food, Drug, and Cosmetic Act and subsequent amending statutes are codified into Title 21 Chapter 9 of the United States Code.

### **Prohibited & Restricted Ingredients in Cosmetics**

Although it's against the law to use any ingredient that makes a cosmetic harmful when used as intended, FDA has regulations that specifically prohibit or restrict the use of the following ingredients in cosmetics:

*Bithionol; Chlorofluorocarbon propellants; Chloroform; Halogenated salicylanilides (di-, tri-, metabromsalan and tetrachlorosalicylanilide; Hexachlorophene; Mercury compounds; Methylene chloride; Prohibited cattle materials; Sunscreens in cosmetics; Vinyl chloride; Zirconium-containing complexes.*

## How do we have to preserve cosmetic products?

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- Unprotected or insufficiently protected cosmetic products can have a significant impact on the market image of a cosmetic product
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*Better „wrong“  
then „none“ ?*

# How do we have to preserve cosmetic products?

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Microbiological and toxicological risks have to be balanced out

# How do we have to preserve cosmetic products?

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If the microbiological risks become smaller, we can reduce the amount of preservatives

# How do we have to preserve cosmetic products?

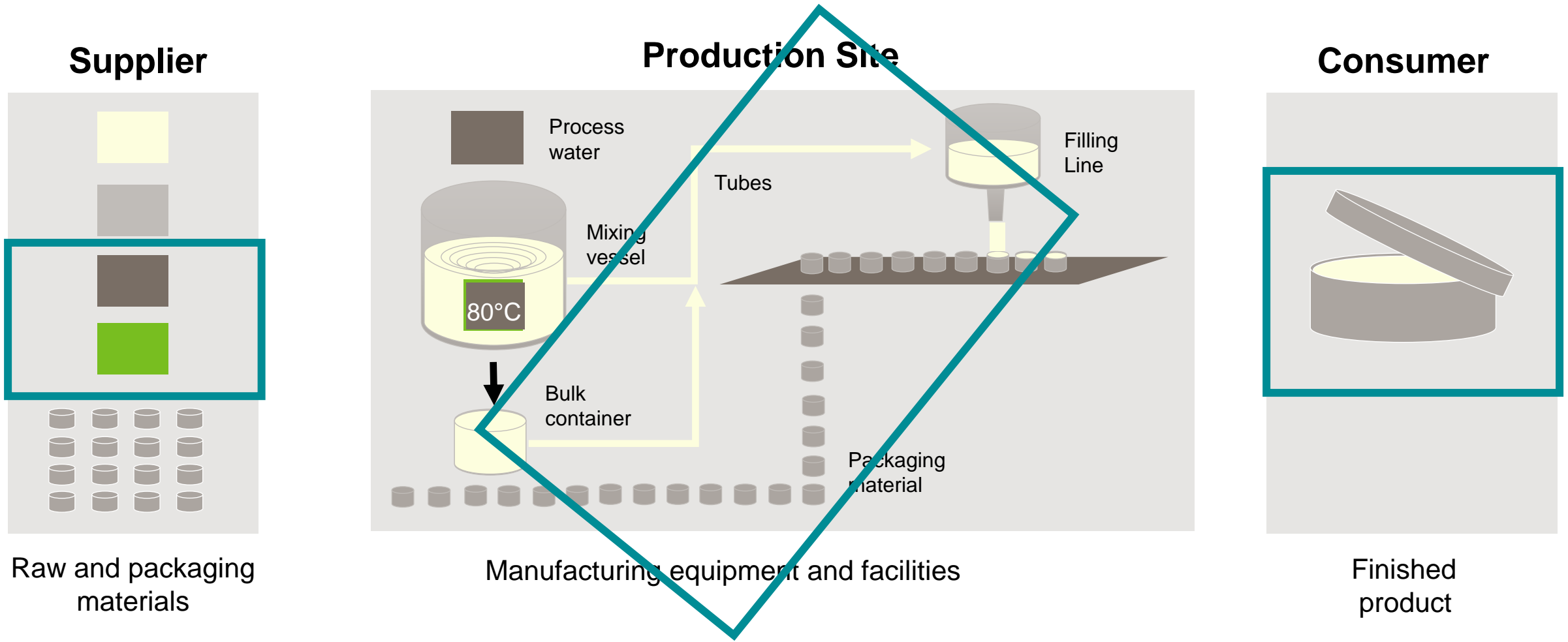
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Responsible preservation: Using as much preservatives as necessary but as little as possible

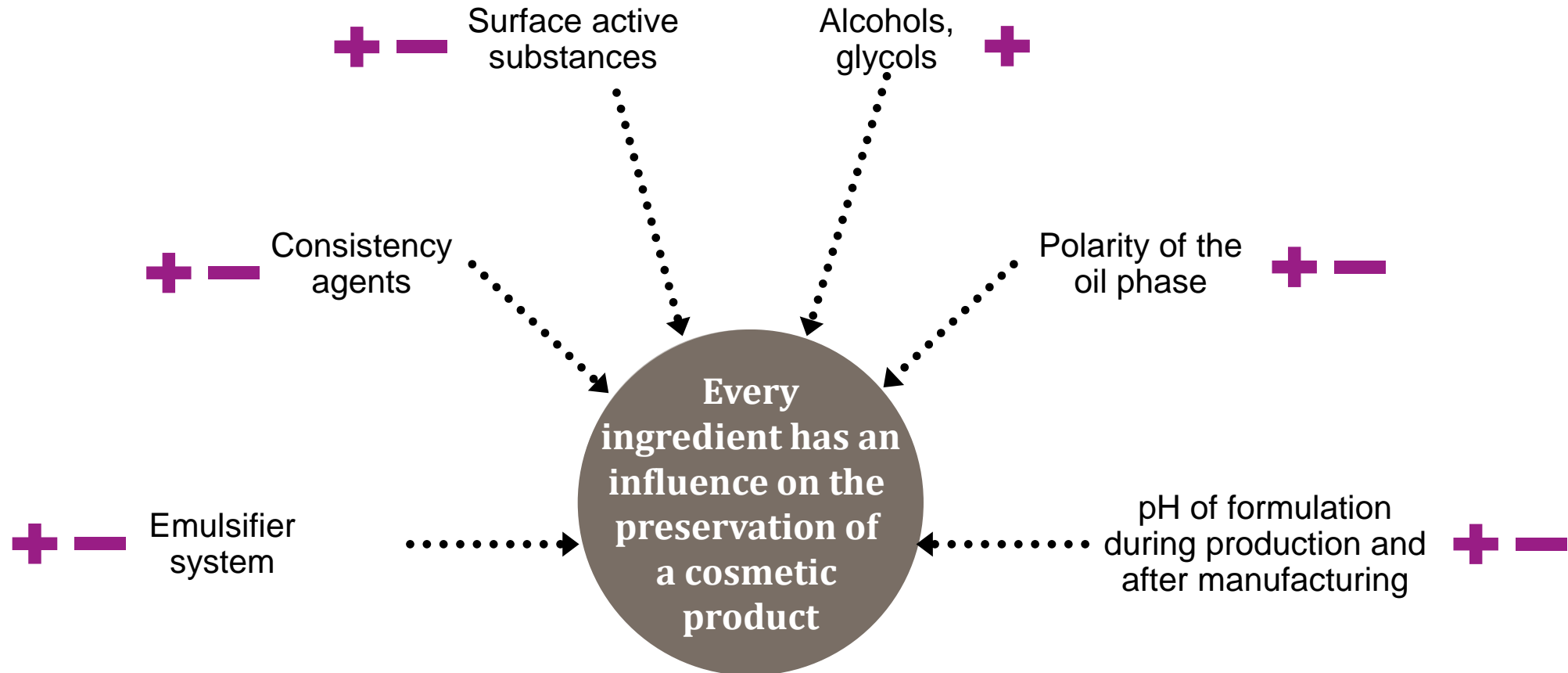
# Sources of microbiological contamination

## Risk assessment from raw material supplier to consumer

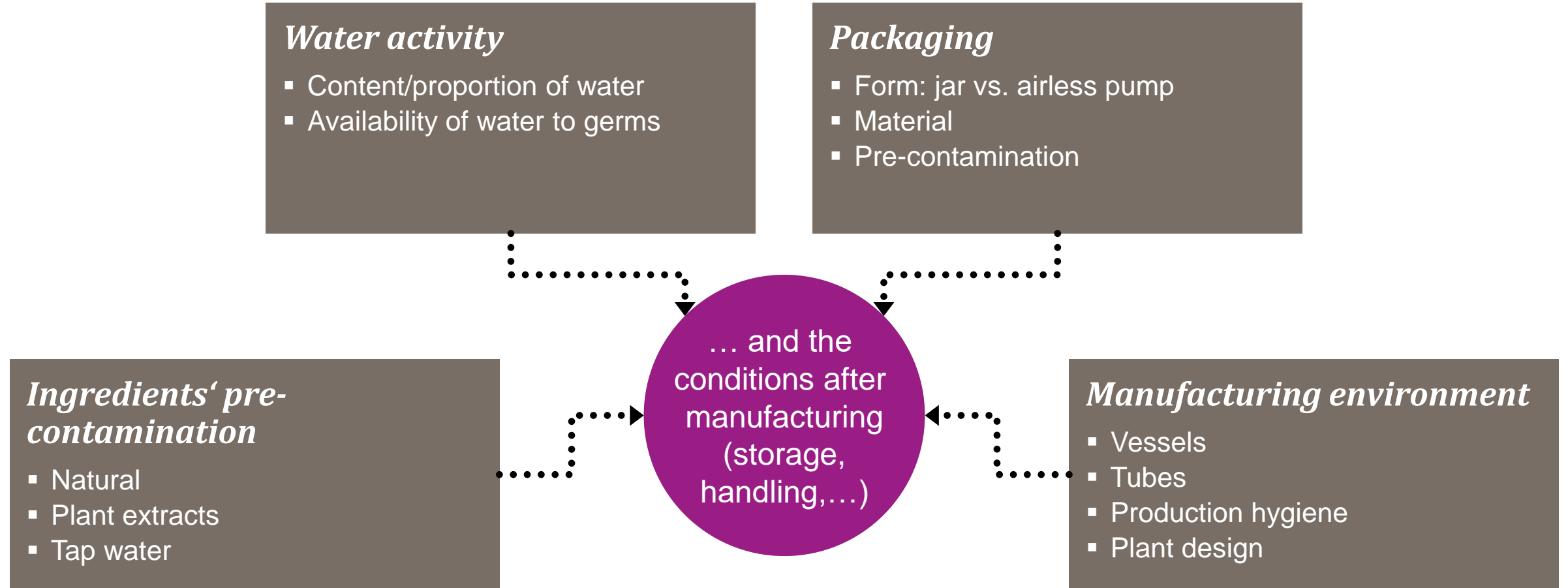




# Which factors may have an influence on the preservation of a cosmetic product?



# Which factors may influence the risk of contamination of a cosmetic product?



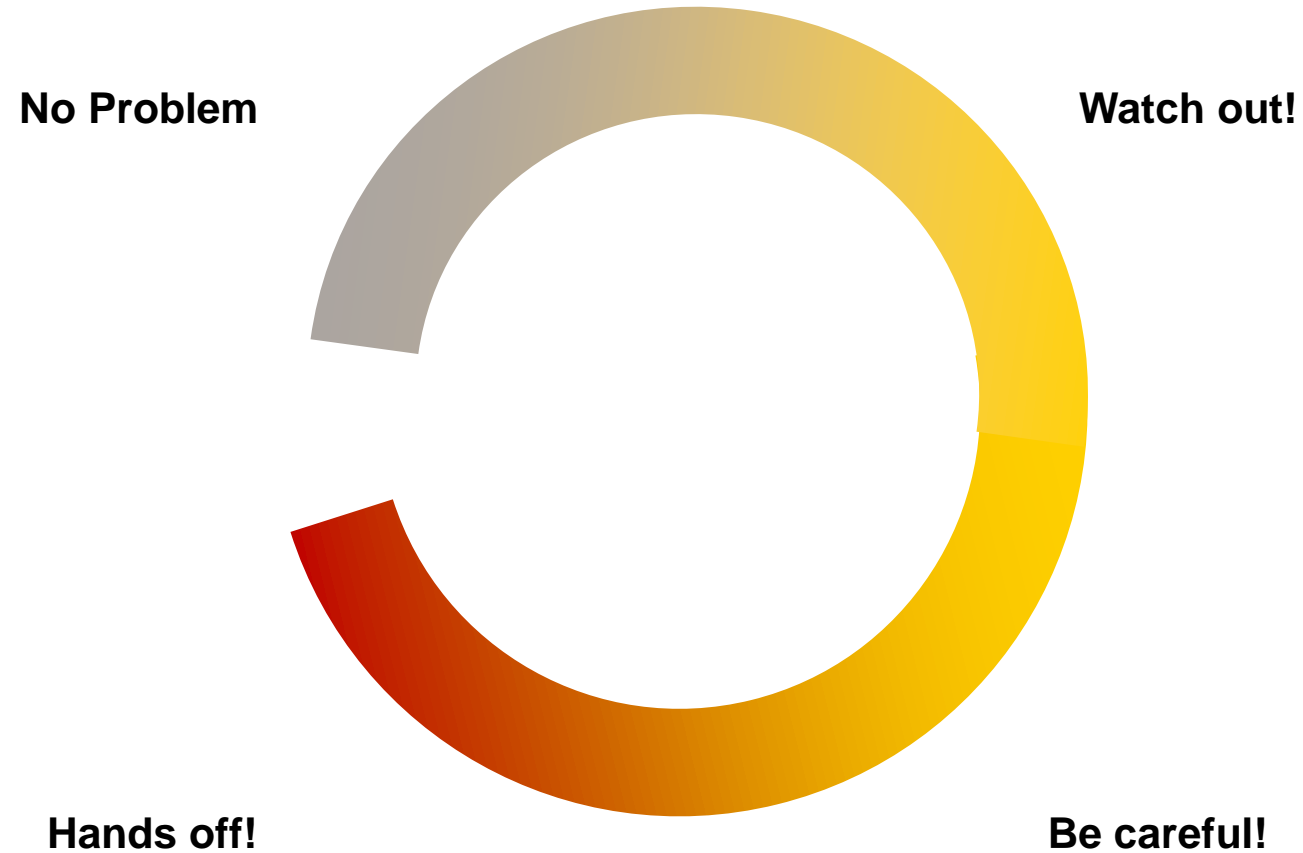
# Intermediate Summary

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- In the majority of cosmetic products preservation is mandatory to protect the product against microbiological deterioration in order to:
  - safeguard the consumer's health
  - to maintain the quality of the product within the specified limits
- Sources of microbiological contaminations can be:
  - raw materials or packaging
  - the production environment
  - the consumer or the use environment of the product
  - with being the consumer or the use environment the most important source of contamination.

# “Life-cycle“ of a preservative

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# “Life-cycle“ of a preservative

Cosmetic  
directive  
Annex V

Home / Skincare & Beauty / Skincare / Skin Care / What Are the Dangers of Parabens in Cosmetics?  
**WHAT ARE THE DANGERS OF PARABENS IN COSMETICS?**  
 Aug 11, 2011 | By Karen Eisenbraun | Related Searches: Cosmetics, Parabens, Skincare, Skin Care, What Are the Dangers of Parabens in Cosmetics?  
**The Secrets of Beauty Products**  
**What Are Parabens - About Them?**  
*These preservatives are common, but...*  
 By Eleni N. Gage  
 Facebook 316 | Pinterest 43 | Twitter 43 | Google+ 8  
 Parabens have been widely used in products to prevent bacteria growth since the 1950s. "About 85 percent of cosmetics have them," says Arthur Rich, Ph.D., a cosmetic chemist at Chestnut Ridge, New York. "They're inexpensive and effective." New York City dermatologist Fran E. Cook-Bolden explains, "Parabens have a long history of safe use and that's why they're commonplace. New preservatives have less of a proven track record." In fact, typically, more than one form of the ingredient is used in a product. The most common are butylparaben, methylparaben, and propylparaben. Over the last few years, however, in response to consumer concerns, many manufacturers have begun to phase out parabens from their products.



Adaption of entries/  
deletion of entries

SCCS/1348/10  
Revision 22 March 2011

Scientific Committee on Consumer Safety  
SCCS

**OPINION ON  
Parabens**

COLIPA n° P82

Scientific Committees

- on consumer safety
- on emerging and newly identified health risks
- on health and environmental risks

The SCCS adopted this opinion at its 9<sup>th</sup> plenary on 14 December 2010

Parabens, products is of ALL  
 in everyday  
 many of the  
 126 View comments

SCCS-Opinion

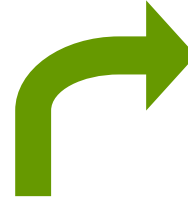
studies /  
press  
releases

# „Life-cycle“ of a preservative

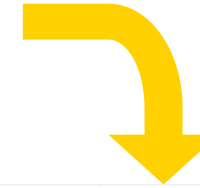
- Example:

Methylisothiazolinone /  
Chlormethylisothiazolinone  
(MIT / CMIT)

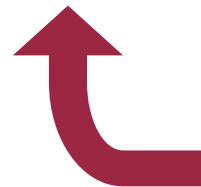
2009  
introduced as  
alternative for  
parabene



Studies on  
sensitization  
since 2011



Substance	Chemical Name	Chemical Structure	EC No.	EC Name	EC CAS No.	EC EC No.	EC EC Name	EC EC CAS No.	EC EC EC No.	EC EC EC Name	EC EC EC CAS No.
Methylisothiazolinone	Methylisothiazolinone	<chem>CN1C=CC(S1)=O</chem>	200-001-01	Methylisothiazolinone	100-001-01	200-001-01	Methylisothiazolinone	100-001-01	200-001-01	Methylisothiazolinone	100-001-01

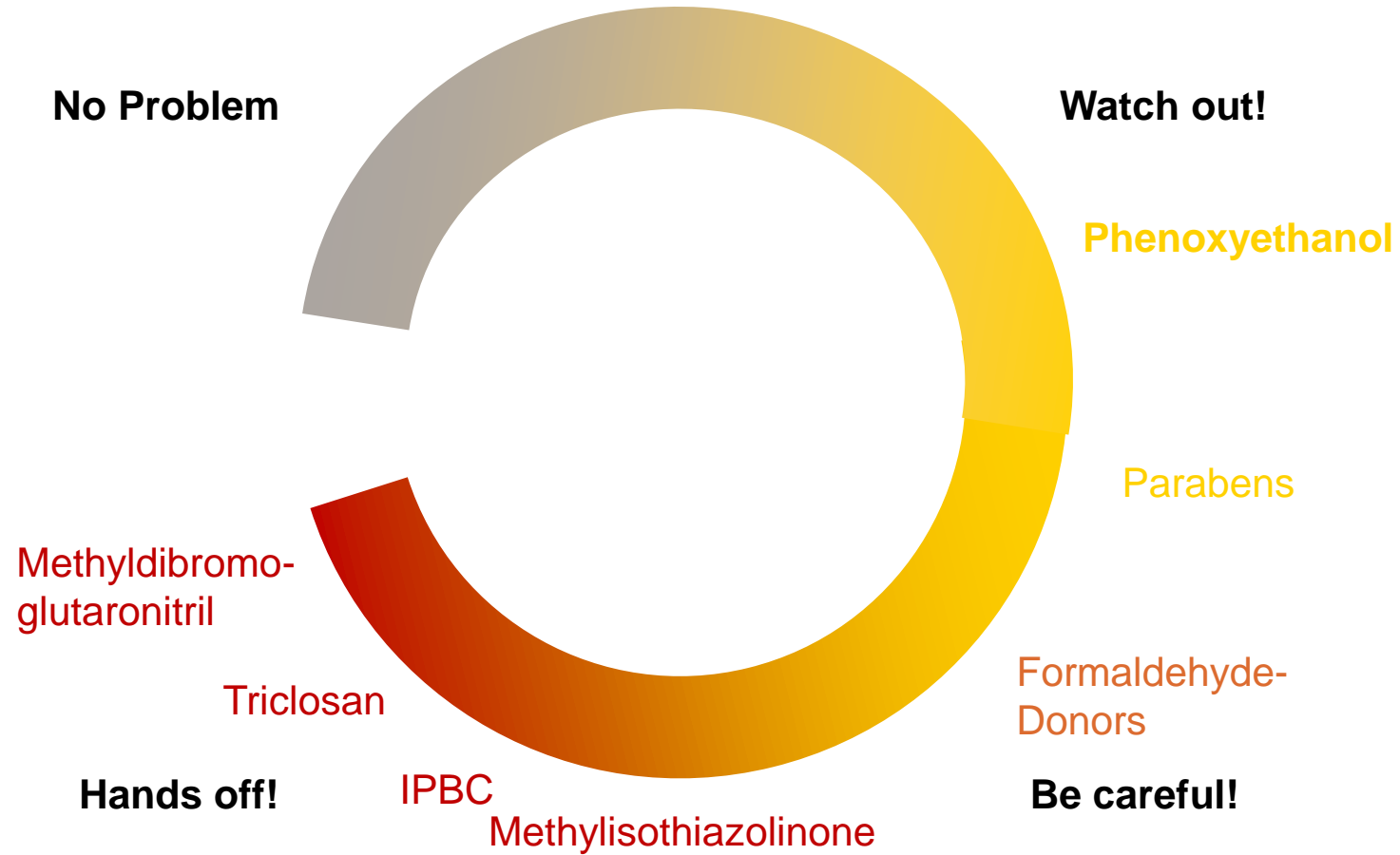


Limitation to rinse-off products  
max use level 0.0015 %  
as combination



SCCS-Opinion

# “Life-cycle“ of a preservative



# Preservation in conventional cosmetic market

Preservation of cosmetic products is of critical importance for consumer safety

Cosmetic ingredients image plays an increasing role on consumers product selection!

We discovered the challenges...

*...what about the solutions*

## Where does this image come from?

- Media (Press / social)
- Cosmetic manufacturer
- Scientific world
- Legal framework
- Competitors



# Choosing the right system

## A preservation guide

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*Do I have to follow a specific concept?*

Traditional cosmetics

Natural cosmetics



*What type of formulation do I want to preserve?*

O/W emulsion

W/O emulsion

Surfactant based

Aqueous system

*What is the desired pH of the formulation?*

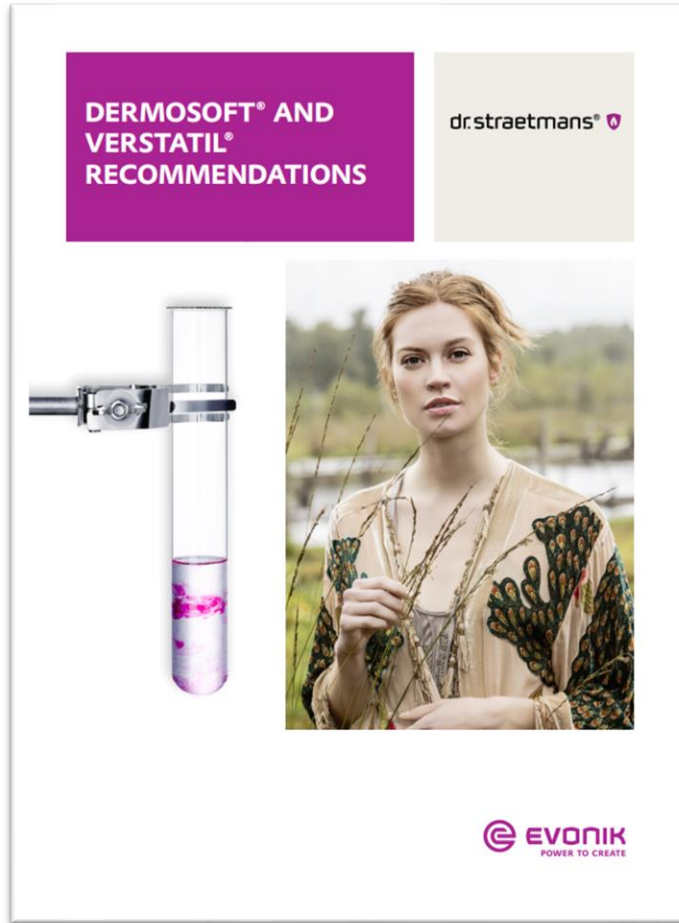
pH 4.5 – 5.5

pH 5.5 – 6.5

pH > 6.5

# Choosing the right system

## A preservation guide



3 questions about your individual product concept will lead you to our recommendations to ensure the antimicrobial safety of your formulation:

Evonik Dr. Straetmans **Personal Care Protection Guide**

*Available as  
brochure  
and digital  
tool*

Visit [intoBeauty.Evonik.com](https://intoBeauty.Evonik.com)





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**Leading Beyond Chemistry**