

# Risk Management in the Preservation of Personal Care Products

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# Drivers for the choice of preservative systems

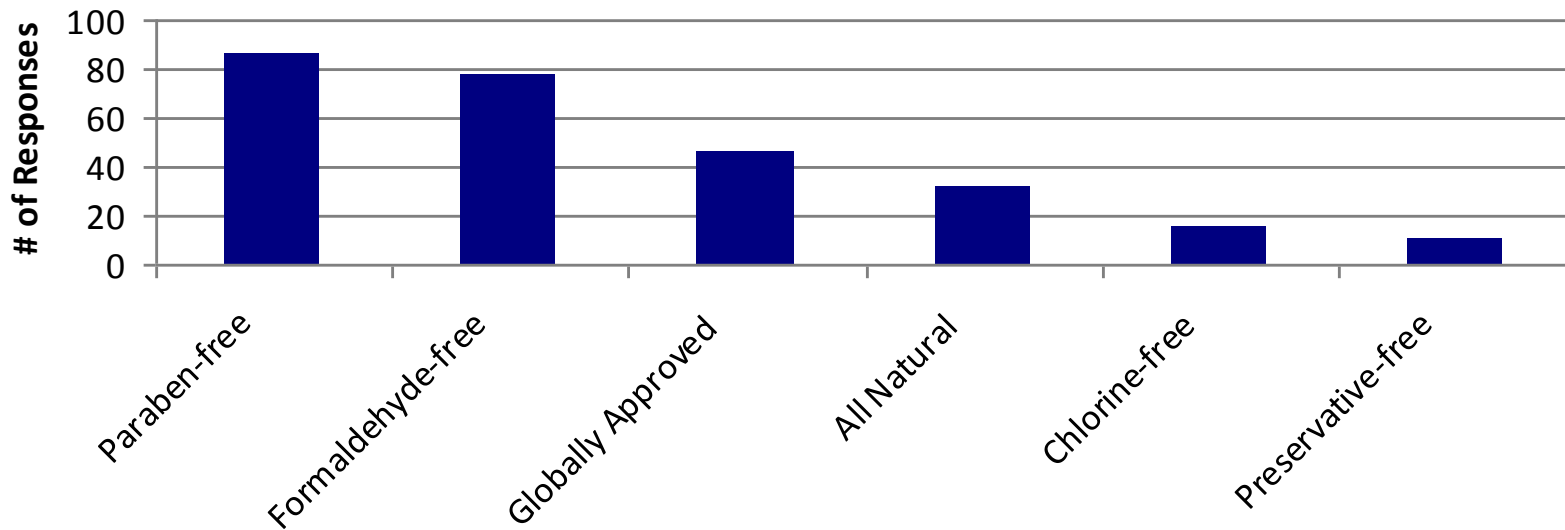
- **Regulatory Changes and Discussions**
- **Pressure on selected actives, influenced by press-releases with sometimes semi-scientific, questionable content**
- **Trend to launch natural and sustainable products**



# Personal Care Preservation – Trends



What preservative trends does your company participate in?



ChemPoint interviewed 117 small to mid-size customers in the US between October 2008 and July 2009. Customers gave multiple answers to each question (represented in the data above)

# Personal Care Preservation – Trends



## Negative consumer perception on “Chemicals” and “Preservatives” in special – why?

Growing body of consumers have limited trust in chemical industry and a mindset that chemically synthesized ingredients may pose a health risk.

**BUT:**

**Preservatives permitted for cosmetic use in the EU are:**

- **Listed in Annex VI of EU Cosmetics Directive**
- **Well defined chemically**
- **Extensively tested for toxicity**

(e.g. acute & reproductive toxicity, mutagenicity & genotoxicity, carcinogenicity, irritation & corrosivity, skin sensitization, human data etc.)

# Personal Care Preservation – Trends



**Positive consumer perception on “natural ingredients” – why?**

**The media coverage tells us that anything natural is safer and better for us than synthetic chemicals. Emerging markets, such as Asia tend to natural ingredients due to their own culture.**

**BUT:**

- **Natural preservatives are not listed in Annex VI of EU Cosmetics Directive.**
- **Mostly they are chemically not clearly defined. Unknown impurities and batch-dependent ingredient profile may influence the performance and compatibility of the actives.**
- **Limited toxicity testing on these ingredients**
- **Naturals like essential oils or plant extracts mostly need to be used at high dosages, which raises irritation and sensitization risk**
- **Natural products are not necessarily safer than synthetic ones**

# Sustainability



**Replacing a natural identical or synthetically produced preservative with a naturally derived one may pose several questions:**

- How large a harvest would be required?
- How much water, farmland and biocides will be used to produce a ton of natural preservative?
- Is this environmentally sustainable?



# Main risks in the preservation of PER products



- **Overdosage**
- **Unbalanced preservative system**
- **Inappropriate preservative system, due to:**
  - Deactivation
    - Parabens & Proteins
    - Anionic – cationic interactions
    - Wrong pH conditions
  - Destruction of actives
    - Nucleophilic interactions
    - Temperature instabilities
    - Too high or too low pH





# How to overcome those risks?

- **Define your preservative project**  
→ a list of questions might be helpful
- **Based on the answers, select the most appropriate preservative formulation for your product**
- **Define the Challenge Test Protocol and run micro and stability tests**
- **Evaluate the test result**
- **Optimise your packaging**



# Question list

- **What application?**
  - rinse off
  - leave on
  - baby
  - wet-wipe
- **What type?**
  - Surfactant based
  - W/O emulsion
  - O/W emulsion
- **Looking into the composition – what matrix effects can occur?**
  - Ionic deactivations
  - High load of natural ingredients
  - “strange pH values”



# Question list



- **What is your current preservation?**
- **Any need to improve the existing preservation?**
  - If improvement is asked for, what contamination occurs (Bacteria/Yeast/Fungi)?
- **Any internal negative list regarding preservation?**
- **Internal and/or customers' marketing demands?**
- **Any restrictions coming from regulatory issues?**
- **EU market or global product?**



# Question list



- **Is the plant hygiene robust or not?**
- **Any restrictions coming from the production process ?**
  - High temperature etc.?
- **When do you add the preservative?**
  - In Theory?
  - In Reality?
- **Do you produce and fill within short time-period?**
- **Is there any interim bulk storage, or final storage under hot climate?**
- **What packaging is planned?**
- ...



# Packaging concepts

- Try to avoid big pack sizes, as consumer will use those products much longer and increase contamination risk
- Prefer packaging where product does not come into direct contact with the consumer, like dispenser systems
- Packaging design should be seen as part of product development and not only as sales tool.



# Challenge test design



- **Consider if a single inoculation or a repetitive test should be performed**
  - **Single inoculation** provides results in optimised time-frame, aged samples should be used, to determine potential deactivation or destruction of the active ingredients. Result gives an estimation if product remains stable after production process.
  - **Repetitive inoculation** mirrors multiple contamination ways, that can occur during production, filling and use-up period at the customer.
- **Size of each challenged sample 50g to 100g**
  - to avoid dilution of the PER product by the inoculum
  - to minimise changes in pH or rheology, that will lead to false positive or negative challenge test results

# Challenge test design



- **What inoculum concentration should be used?**
  - $10^5 - 10^6$  cfu/g sample in line with the Pharm. Europe
  - $10^7 - 10^8$  cfu/g sample to reproduce higher contamination risks, that can occur when produced under lower hygiene level, or when packaging does not support low recontamination risk
- **Should so called “house bugs” be incorporated?**
  - **Yes** if you know already that your plant has certain microbes that occur quite often in the water or other raw materials

# Challenge test design

- **Choose at least 2 different preservative formulations**
  - To be able to figure out best system for your PER formulation
- **Test at min 2 different dosages**
  - To determine the minimal dosage to protect your PER formulation
- **Incorporate unpreserved product sample**
  - To provide information on susceptibility of your PER formulation





# Performance of selected preservative formulations



- **Rokonsal PB-5:** Methyl-, Ethyl-, Propyl-, Butyl-, Isobutylparaben + Phenoxyethanol
- **Rokonsal MEP:** Methyl-, Ethyl-, Propylparaben + Phenoxyethanol
- **LiquaPar ME:** Methyl-, Ethylparaben + Phenoxyethanol + Caprylyl Glycol
  
- **Rokonsal KS-4:** CIT/MIT + Benzyl Alcohol
- **Rokonsal S-1:** CIT/MIT
- **Optiphen MIT:** MIT
- **Optiphen MIT Plus:** MIT + booster Phenethyl alcohol
  
- **Rokonsal BJ:** Sodium benzoate, Potassium sorbate + IPBC
- **Rokonsal ND:** Benzoic acid, Dehydroacetic acid + Phenoxyethanol
- **Rokonsal BSB-N:** Benzoic acid, Sorbic acid + Benzyl alcohol
- **Rokonsal BS:** Sodium Benzoate, Potassium Sorbate

**RED = classic preservative**

**BLUE = modern preservative**

# Parameters of Challenge Test



- Repetitive Challenge Test of different preservative formulations
  - **different dosages of preservatives - as shown in the tables**
  - **4 inoculation cycles**
  - **two weeks in between**
  - **Inoculation 10E07-08 cfu/g with following microorganisms**

## Bacteria

DSM 1128 = *Pseudomonas aeruginosa*

DSM 799 = *Staphylococcus aureus*

DSM 1576 = *E. Coli*

DSM 788 = *Proteus mirabilis*

## Fungi

DSM 1988 = *Aspergillus niger*

DSM 1282 = *Penicillium expansum*

DSM 63064 = *Trichoderma viride*

## Yeast

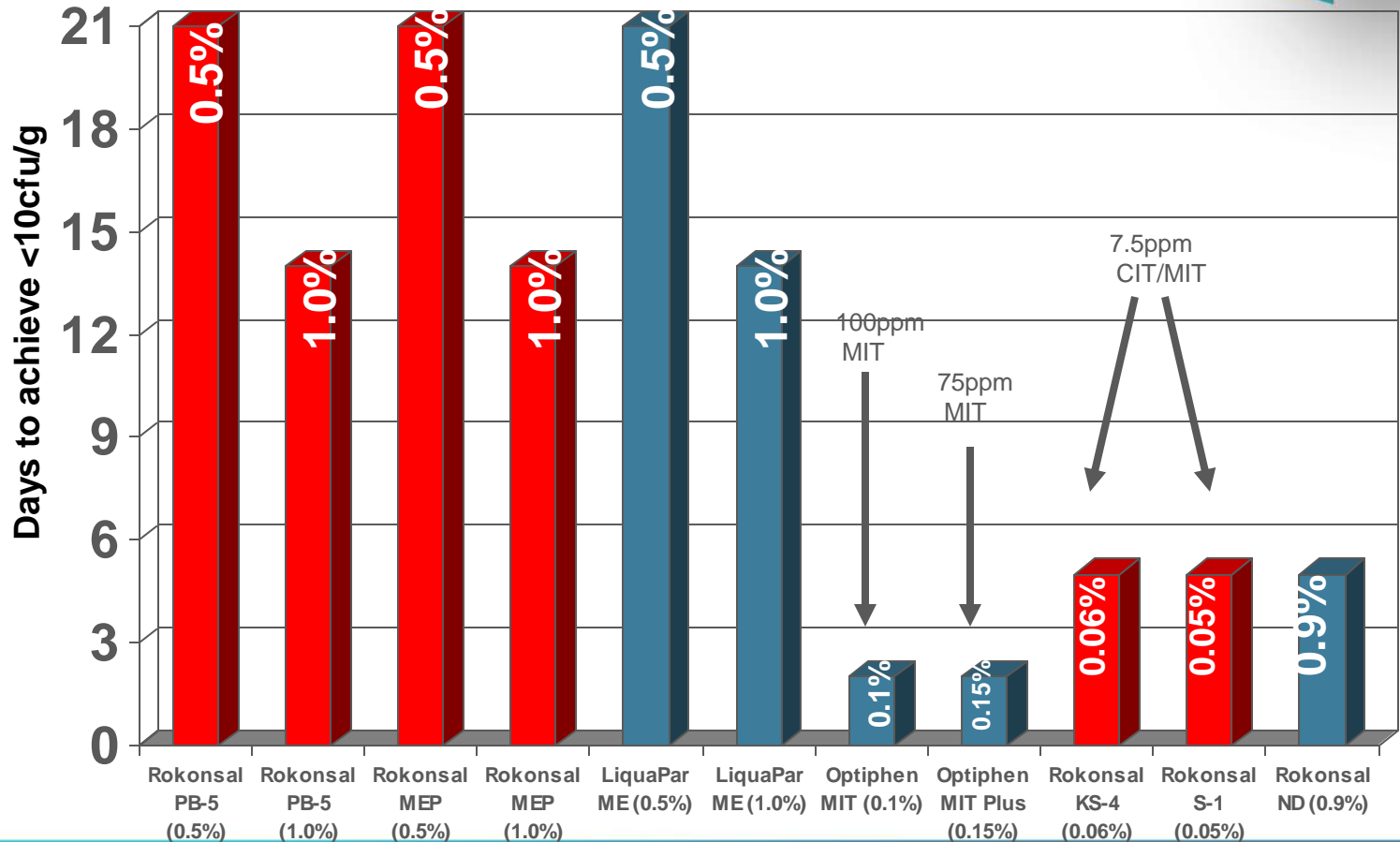
DSM 1386 = *Candida albicans*

- Macroscopic Control
  - **4 weeks after test start**
  - **when finished**

*Please note that every personal care formulation requires a preservative system that meets its specific needs. Therefore, every newly developed or modified product must be challenge tested to ensure adequate preservation.*

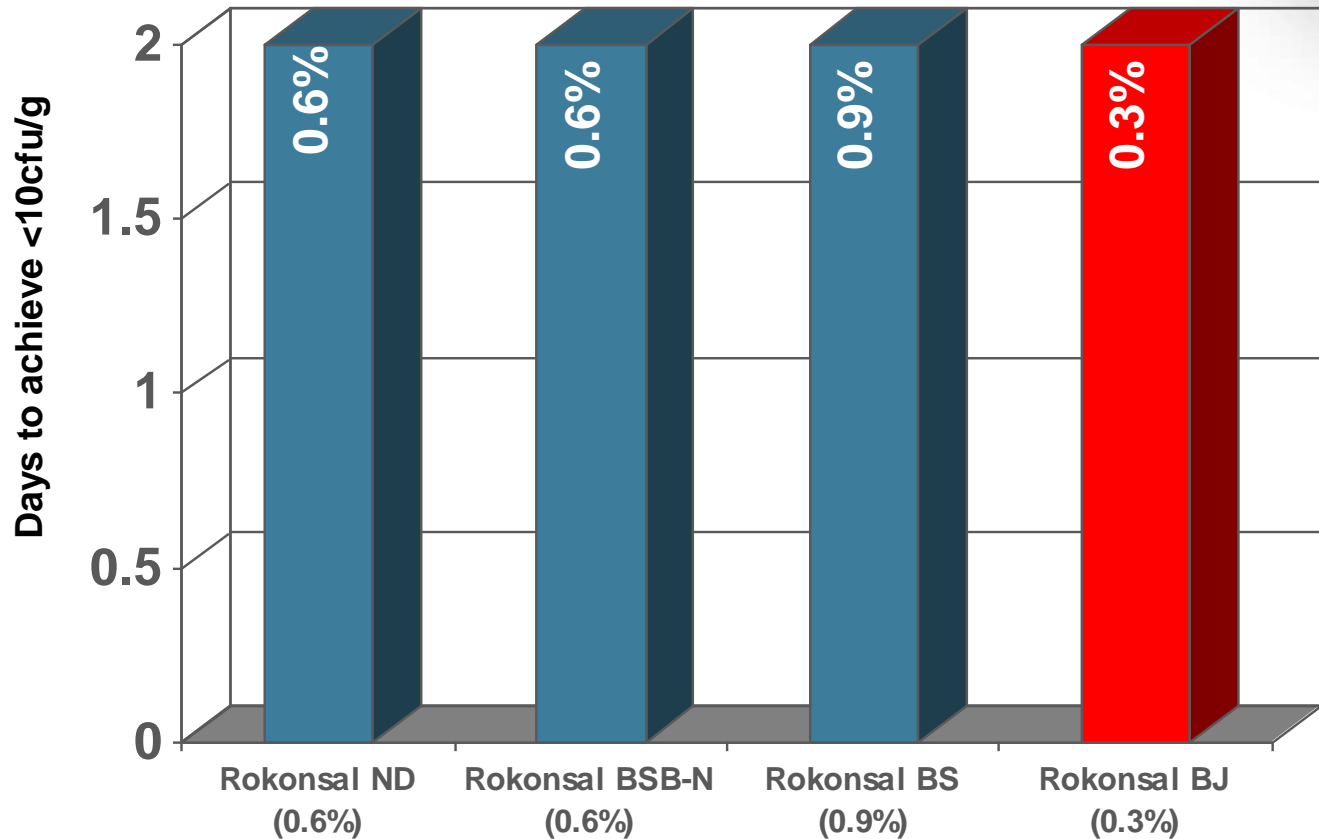
# Sunscreen with Prolipid141 and X-Tend 226

## Results after 4th inoculation at pH 6.3



# Sunscreen with Prolipid141 and X-Tend 226

## Results after 4th inoculation at pH 5.3

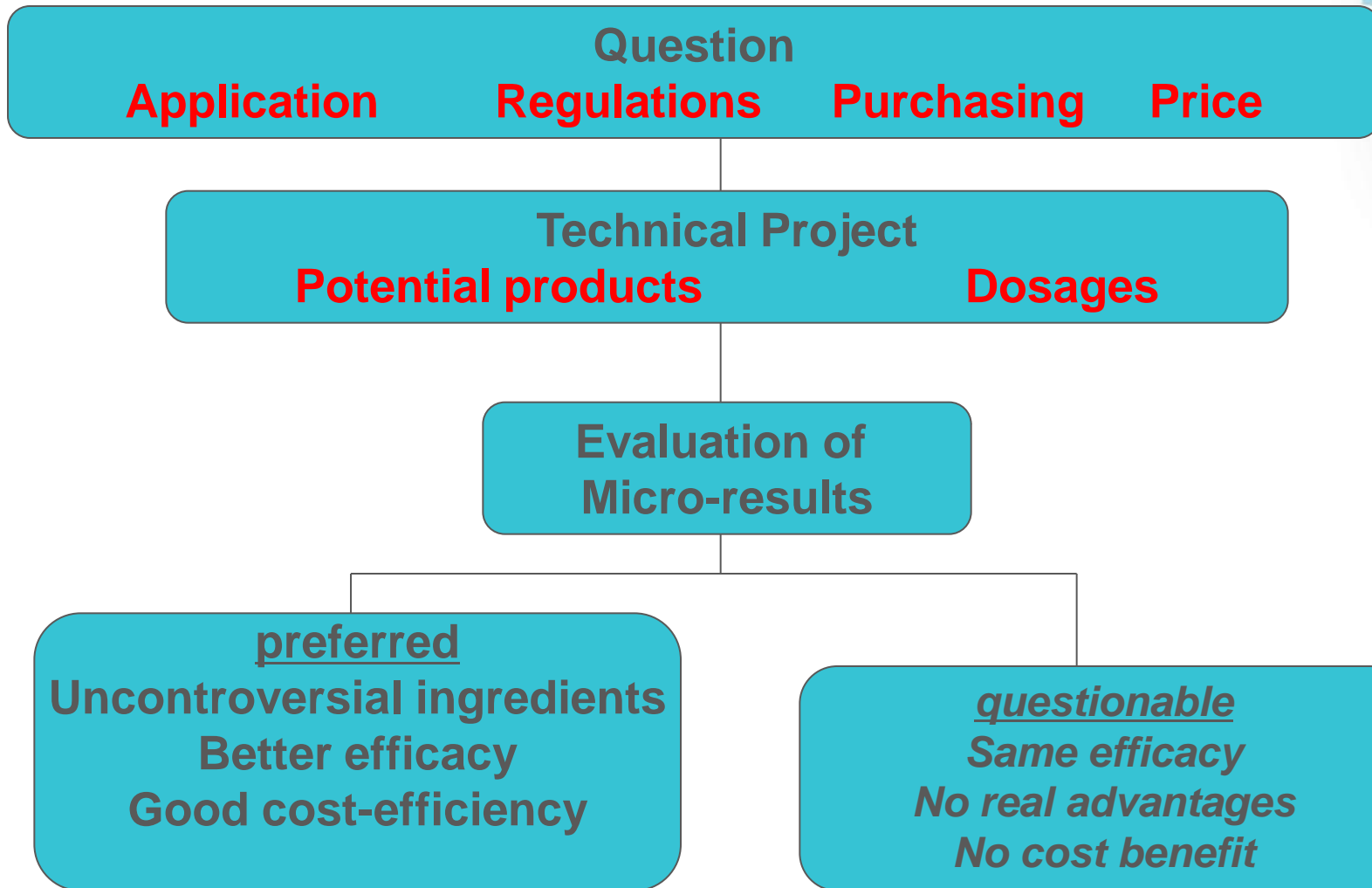


# Why use preservative formulations?



- 😊 **Intelligent and optimised combinations allow a reduction in the total amount of preservative in the finished products**
- 😊 **Formulation expertise ensures compliance with regulations**
- 😊 **Minimises the environmental impact**
- 😊 **Reduces risk of irritation or sensitisation at consumer**
- 😊 **Takes local consumer issues into account**
- 😊 **Provides durable preservation solutions**
  - long term stability
  - cost effective


# Preservative Project – Flow Chart



# Preservative Project – how to assist?



1. Explain your preservative project to your sales contact or technical specialist
2. Use the question list to find out details and to trace potential issues
3. Preselect applicable preservative formulations
4. Prepare samples
  - Unpreserved
  - Preserved with selected preservative(s) @ different dosages
5. Run challenge test, fitting to your requirements
6. Based on the challenge test result, the best fitting system at the lowest active dosage will be chosen
7. Do internal scale-up
8. Introduce into market

 **Appropriate plant hygiene and micro control of all raw materials including water is essential to keep good preservation properties**

# Preservatives – safety for the consumer



- The safety and toxicological profile of active ingredients is reviewed on international level
- All contained substances will be declared according INCI\* (important for allergic persons)
- New toxicological information or allergic trends in population lead to adaption of the cosmetics law (responsible care)
- Intelligent combination-products help avoiding overdosage of single actives,
- Drawback: sometimes „Ecotrend“ leads to higher dosages.
- Optimised packagings and good production hygiene help to reduce preservative dosages

 Optimised preservative systems are much safer compared to contaminated end-products



## **Risk Management in the Preservation of Personal Care Products**

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**Please contact me if you  
have further questions.**

