

How to Preserve a Product in
an Ever Changing Marketplace:

The Shift from Conventional to
Natural!

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Overview

- ❖ The number of **preservatives** that are acceptable for use in today's market place is becoming **smaller**. The shift into the natural and **organic** market has reduced acceptable number of chemicals used for preservation **even smaller**.
- ❖ The process of manufacturing natural or organic products requires stronger adherence to quality and consistent processes than conventional products. The risk of microbial contamination in natural types products is higher based on the source of the raw materials and the way in which they are harvested.
- ❖ To properly ensure that all products are **properly tested** and evaluated a **risk factor analysis** should be performed on all products being manufactured
- ❖ **Packaging and storage containers** can play an important role in ensuring the integrity of your products.
- ❖ To properly manufacture these types of products requires cooperation and communication between the chemists, raw material vendors, quality assurance and manufacturing.

Consumable Products

- We can now buy Organic **cotton clothes**
- We eat Organic **vegetables**
- We drink Organic **milk**
- And now apply Organic **cosmetics**

The Transformation to Organic

People are making the switch to organic products because:

- The customer is concerned about the *risk* of synthetic chemicals
- Health Benefits
- Healthy Lifestyle
- Environmental Concerns
- Good Marketing
- Trendy

Risk Potential

When you talk about microbiology you always have to talk about risk potential:

- Risk from sensitization
- Risk of contamination in manufacturing
- Risk of consumer contamination
- Overall product risk

Contamination Risk ?

- If you are going to develop an organic product and comply with all of the guidelines how do you reduce the Risk of Contamination?
- Cannot use any chemical preservatives
- Cannot use any form of chemical remediation
- Cannot use any form of chemical extraction.

So Lets Talk about Organic and Natural Products!

How do you Reduce those Microbiological Risk Factors while trying to Comply with the Organic Guidelines?

Processing and Preserving Natural Extracts

The major backbone of organic products is the use of **natural extracts** which have been known in the past to support bacterial growth.

How are you going to make sure they are clean if you cannot **sterilize** them via conventional methods?

How are you going to **preserve** your products if you cannot use chemical preservatives?

Organic Processing – Raw Materials

- So let's first talk about processing and making sure that your raw materials are free from bacteria.
- Since you are using natural extracts you can only use steam, ozone, hot water, filtration, or heat (pasteurization) to ensure that you are free from bacteria.
 - *Try to reduce the bio-burden with your RM to as low as possible!*
- You need to work with the supplier to review their process to ensure that it is clean. *Take samples at each step of their process to determine source of contamination and ensure the process is in control*
 - *Treatments such as ethylene oxide and gamma sterilization are not acceptable for natural and organic.*

Organic Processing - Water

Water is the major source of contamination!

- Make sure that the manufacturing plant has sterile water and tests it weekly at every point of use.
- Heat the water phase before using to ensure sterility.
- Ozone and chlorine dioxide is allowed in an organic mfg. site for process water

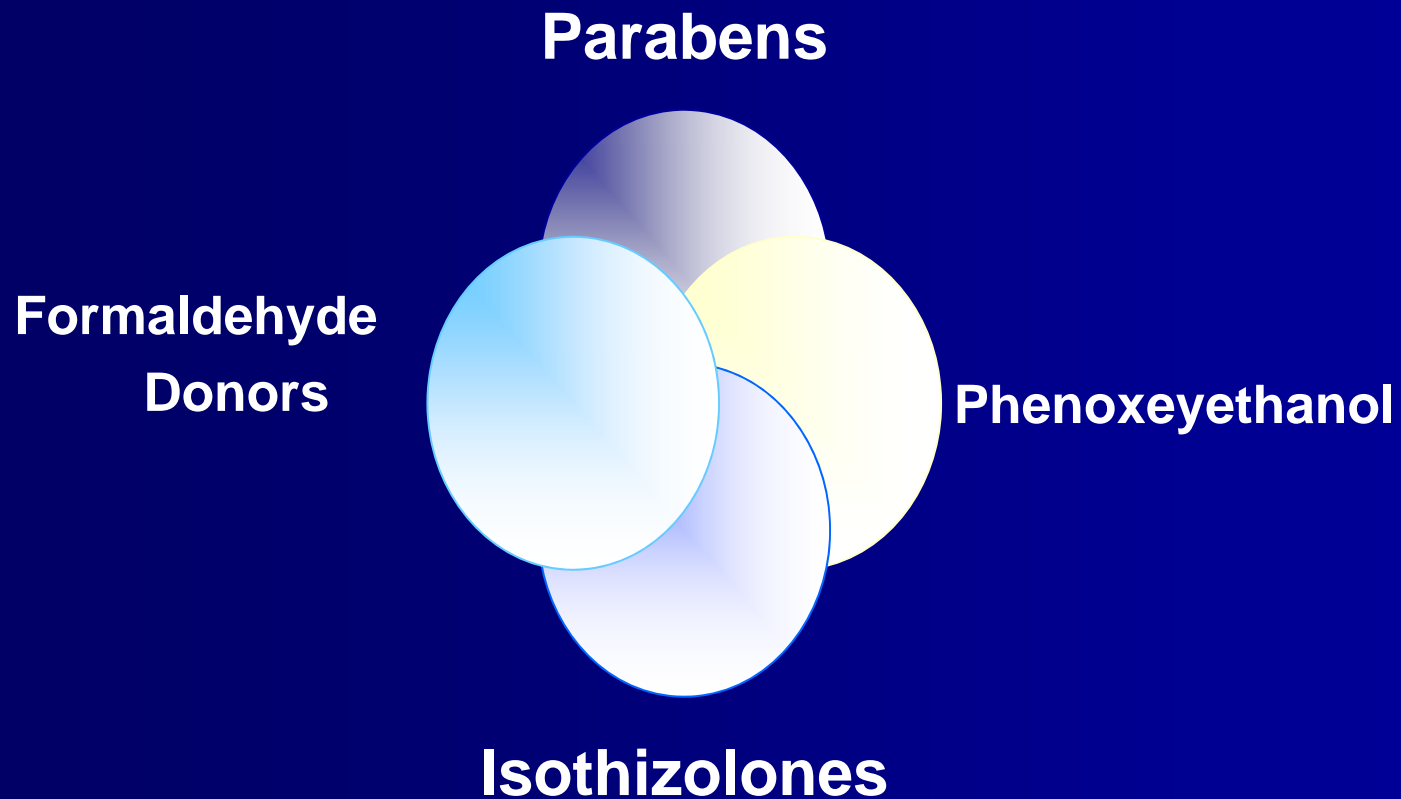
Manufacturing of Organic Products

Is there is place in their process where you can reduce the bio-burden through heat or some other form of engineering process ?

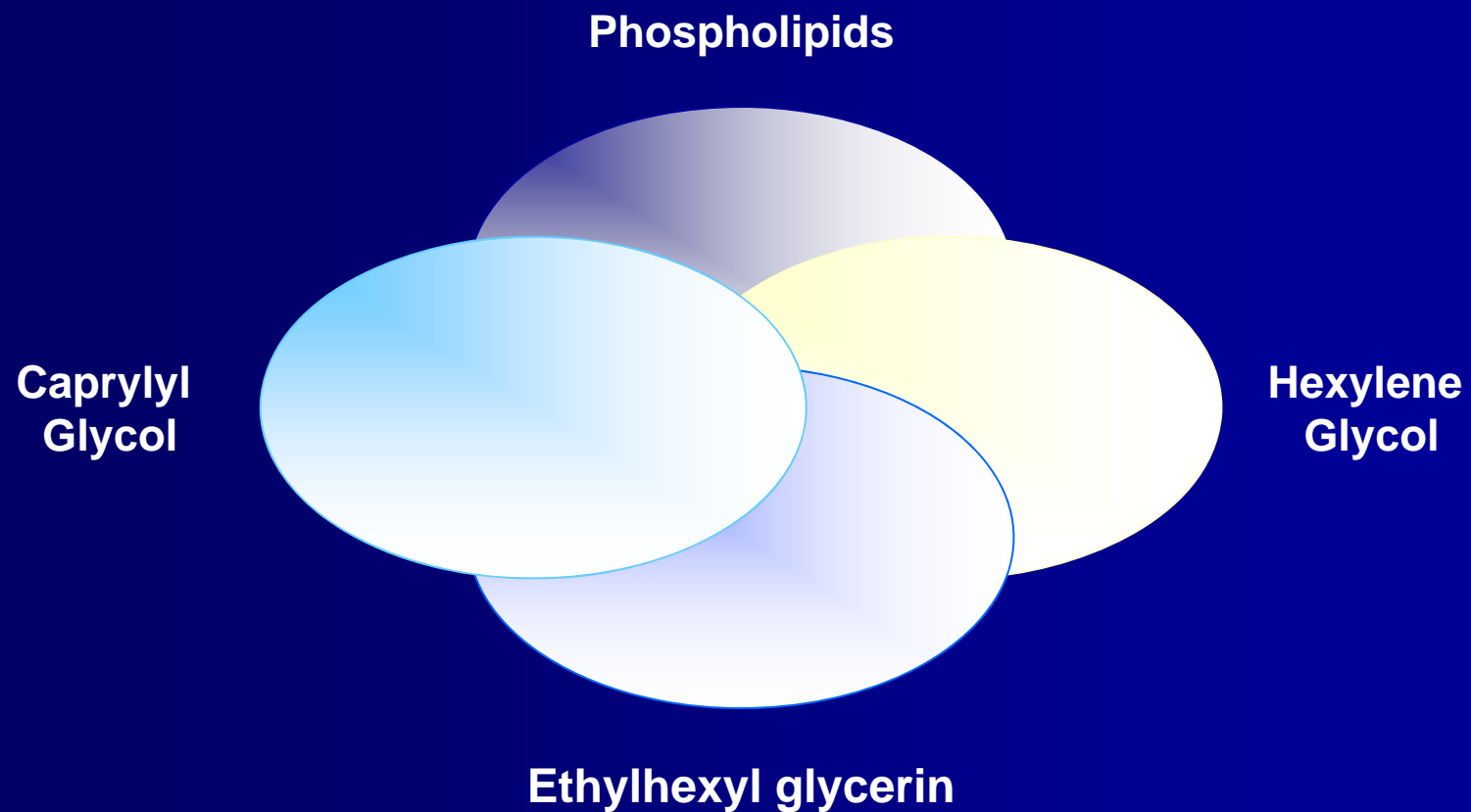
- Since you are limited on the use of preservatives you need to make sure that your manufacturing process and raw materials are in control.
- You need to look hard at the process to see where there may be sources of contamination, or where there could be a way to reduce the bio-burden.

Formulation
&
Preservation

Conventional Preservative Systems



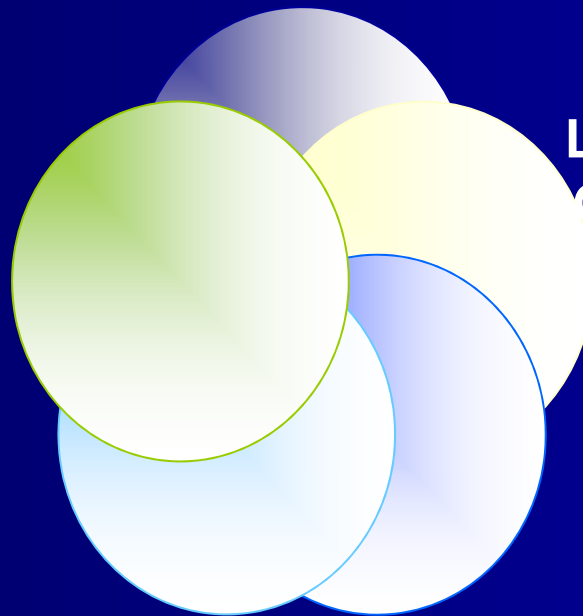
Non-conventional Preservative Systems



Organic Systems

Glucono – delta - lactone

Essential oils



Lactoperoxidase/
Glucose oxidase

Benzoic / Sorbic Acid
DHA
Eco-cert Approved

Isopropyl alcohol

Non – Conventional Preservative Systems (Multi-functional ingredients)

- Caprylyl glycol
- Ethyl Lauroyl Arginate HCl
- Glyceryl Caprylate
- Citrus aurantium amara flower extract
- p-Anisic Acid
- Polylysine
- Gluconolactone / sodium benzoate / calcium gluconate
- Levulinic acid / sodium levulinate / phenylpropanol
- Sodium coco pg-dimonium chloride phosphate
- Ethyl-Hexyl-glycerin

Cosmetic Microbiology Today

- **If you are the microbiologist you are asked the following:**
 - Is it paraben free?
 - Is it formaldehyde free?
 - Is it atypical or typical formulation?
 - Does it contain a conventional or non-conventional preservative system?
 - Should I use full inoculum or half inoculum?
 - How did it do on RIPT, sting and safety testing?
 - Does it need to be micro tested?
 - Does it require a PAO?
- **All of these factors now play a role in how you develop, preserve, test, and market your products**

Formulation Rules

- Even though Label Claim is Different:
 - Type of formulation has not changed

We are still making cosmetics!

- Rules stay the same...
 - Do not overheat preservative
 - Stay with in pH range of preservative activity
 - Try to add post - emulsification
 - Watch out for preservative neutralizers

Factors which Impact on Preservative Effectiveness

- **pH of emulsion (water phase)**
- **Temperature of Incorporation**
- **Water Activity**
- **Order of addition of your preservative system**
- **Partition Coefficient (HLB) of the Preservative**
- **Percentage of Active Ingredients in Formula**
- **Type of Surfactant System**

Water Activity / pH Values

	Min. Aw	Min. – Max pH
<u>Most Bacteria</u>	0.91	4.4 – 9.0
Pseudomonas	0.97	5.6 – 8.0
Enterics	0.95	4.4 – 9.0
Staph	0.86	4.0 – 9.8
Yeast	0.88	2.0 – 8.8
Mold	0.80	2.0 – 11.0

* with organic products these factors play a major role in preservation!

Factors to Ensure Micro Stability

- **pH of the product**
 - Acid pH is more effective in minimizing growth
- **Water Activity of the product**
 - $<.90$ Aw bacteria will not grow. By reducing water activity you can preserve for yeast and mold.
- **Use of Potentiators to enhance activity**
 - Glycols, glycerin, humectants, chelators if possible

Storage and Package Protection

Packaging: A Major Role in Preservation

Package can be the 1st Line of Defense.

- Prevent entry of bacteria, moisture, air, and product buildup
- Applies to both storage and finished product.
- Use sanitary or sterile procedures when possible!
- Comply with all cGMP standards

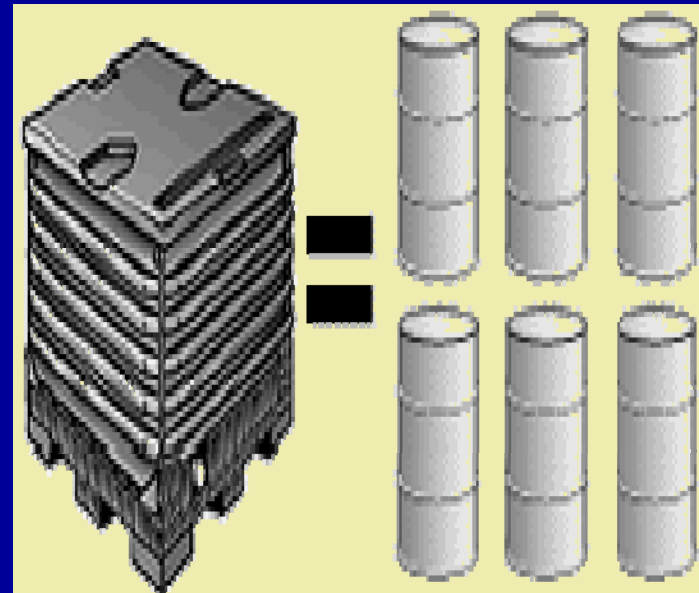
Final Packaging

- **Low Risk** - Pumps, Sprays, ophthalmic tip tubes, tubes with one way valves.
- **Moderate Risk** – Tubes, bottles, flow through pens.
- **High Risk** – Wide orifice jars, sponge applicators.

Storage Containers

Bag in the Box Sterile Containers

- 1-330 gallon container = 6 drums
 - Reduce handling
 - Sanitary connections
 - Sterile containers
 - No partial containers
 - Minimal headspace



Highest Risk Potential

Mascara Products

- Standard Challenge Test Required
- Standard Protocol
- Clinical Testing Required

Lowest Risk Potential

Lipsticks

- Anhydrous Hot Pour
- No Potential of Microbial growth
- No Testing Required

Highest Risk Potential

Flow Through Pen

- **Atypical Product**
- Challenge Test Not Required on mass
- Clinical Testing Required to test product – component interaction

Lowest Risk Potential Powder Products

- Proper Preservation of all formulations
- Pass Challenge test at all phases of development - **Lower inoculum**
- Clinical-in-Use Testing and micro evaluation

Highest Risk Potential

Atypical Product

Proper Preservation of all formulations

Pass Challenge test at all phases of development -

Lower inoculum

Plate Count before safety testing can proceed.

Safety-in-Use Testing and micro evaluation

Clinical-in-use testing of all applicators

All sponge applicators should be preserved

Words of Wisdom

- With Natural and Organic - **all the old rules go out the window**
- You cant just think that it is going to be the same from batch to batch
- If it is labeled “**Organic**” – **Test It..!**
- Since you are so limited with preservation focus on other factors such as in process control, sterile raw materials, aseptic containers, protective packaging to help with preservation.

Conclusion

- ❖ The number of preservatives are limited in the natural organic market.
- ❖ The process of manufacturing natural or organic products requires almost sterile conditions.
- ❖ Risk factor analysis should be performed on all products being manufactured
- ❖ Packaging and storage containers play an important role in ensuring the integrity of your products.
- ❖ To properly manufacture these types of products requires cooperation and communication between the chemists, raw material vendors, quality assurance and manufacturing.



Wise man once said:

**What would you rather
have with your Cheerios?**

**“A little Pseudomonas
infection or a teaspoon of
Phenoxyethanol !”**

Thank you!

Any questions?

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