The Role of the Preservative

- The prevention or retardation of product deterioration caused by microorganisms from the time of production until the product is used up by the consumer

- The prevention of microbial contamination caused by typical consumer use of the product

- **The preservative system is NOT a replacement for good hygiene/cleanliness during manufacturing**

- **The preservative system is a NOT intended to replace microbial control of raw materials or water used in the formulation**
**Preservation - Regulations**

- Each production batch of a cosmetic product which is not self-preserving, must be tested for contamination, before it is released for shipment.

- Each cosmetic must be tested for adequacy of preservation, during product development, for preservation against microbial contamination under foreseeable conditions of customer use.

**Preservative Realities**

- If water is present in any formulation a preservative system is recommended.
- Anhydrous formulations should also contain a preservative in case of contact with water.
- “Self Preserving” - The use of multifunctional cosmetic ingredients to provide “preserving” properties.
- It is always better to use combinations of preservatives for broad spectrum protection.
- The safety of a preservative is dependent on the concentration being used - *Paracelsus said it in the 16th century, “Poison is in everything and no thing is without poison. The dosage makes it either a poison or a remedy.”*
Product Optimization to achieve “Self Preserving” Formulations*

Manufacturing Control-i.e. GMP, ISO
Packaging-i.e. airless packaging, unit dose
Emulsion Form- W/O vs. O/W
Water Activity
pH Control
Choice of Multifunctional ingredients


Non-Formulation factors that impact selection of preservative

How will product be used-leave on, rinse off
Consumer potential to contaminate the product
Regulatory requirements/global formulations
“Preservative Free”????
NGO requirements(i.e. “Natural”, NPA, Ecocert, “Whole Foods”)
Misinformation and junk science-i.e. EWG
Safety of the preservatives being considered
Cost
All preservatives need to be in the water phase of the formulation.

pH of the formulation (water phase)

The chemistry of the formulation and the compatibility with the preservatives that can be used

Efficacy of Preservative system in formulations being developed-Challenge Testing

Susceptibility of the product to microbial growth (i.e. water activity, anhydrous)

Partition Coefficient of the preservative

Temperature of Incorporation

Percentage of Active Ingredients/proteins in Formula

Type of Surfactant System-i.e. high ethoxylates

Presence of particulates i.e.: talc, metallic oxides, clays

Presence of a chelating agent
Questions to ask suppliers

- Safety testing
- Any regulatory issues- i.e. max conc., use restrictions, etc.
- What is the form/composition-powder, solution, emulsion?
- Recommended use concentration
- How and when do I add it to the formulation-temperature, solubility?
- What type of formulations to use it in?
- Preservative challenge data-not MIC data
- Any stability/compatibility issues- i.e. color, odor, viscosity, emulsion stability, etc.
- Global availability (if required)
- Shelf life/expiration date
- Packaging sizes
- Has Steve Schnittger seen it yet??

Preservatives being used

Preservatives for Leave-on formulations

- Alcohol (ethanol or Isopropanol)
- Benzalkonium chloride
- Benzyl Alcohol
- Chlorphenesin
- Dehydroacetic acid
- Iodopropynyl Butylcarbamate (IPBC)
- Phenoxyethanol
- Polyaminopropyl Biguanide
- Sorbic Acid and Benzoic acid (and their salts)
- Parabens
- ε-Polylysine
- PolyLysine

- A small homopolymer (25-30 units) of the amino acid L-Lysine
- Soluble water
- History of use as a preservative in foods
- Cationic
- Use level 0.01-0.05%

Formulating with Preservatives
Current commonly used Preservative systems

Preservatives primarily used in Rinse Off formulations

- Methylchloroisothiazolinones (MCIT) + Methylisothiazolinones (MIT)
- DMDM Hydantoin
"Multifunctional" Cosmetic Ingredients used for Preservative efficacy
These are not Preservatives, but.......

- Cosmetic ingredients
  - 1,2 Hexanediol
  - Caprylyl Glycol
  - Ethylhexylglycerin
  - Glyceryl Monolaurate (i.e. Lauricidin)
  - Pentylene Glycol
  - Propanediol
  - EDTA and its salts
  - Phenyl Ethyl Alcohol (Phenethyl Alcohol)
  - Caprylydroxamic Acid

Phenethyl Alcohol

- Phenethyl Alcohol = Phenyl Ethyl Alcohol
- Fragrance Ingredient
- Occurs widely in Nature in various essential oils
- Contributes a “rose” odor
- Similar in structure to Phenoxyethanol
- Commonly referred to as “Rose Ether”
An effective chelating agent for Fe$^{++}$ and Fe$^{+++}$
Most effective at neutral pH
Use level 0.05-0.15%
Frequently used with other ingredients to provide "broad spectrum" protection
Appears to be very effective against mold & yeast
Can have compatibility issue with clay type materials containing iron, causing color formation

"Preservative Free" Blends:
- Caprylhydroxamic Acid (and) Propanediol
- Caprylhydroxamic Acid (and) Caprylyl Glycol (and) Glycerin
- 1,2-Hexanediol (and) Caprylyl Glycol
- Caprylyl glycol and Ethylhexylglycerin
- Phenethyl Alcohol (and) Glycerine (and) Citrus Reticulata Fruit Extract (and) Citrus Aurantium Amara Fruit Extract (and) Citrus Sinensis Peel Extract (and) Ascorbic acid (and) Citric acid (and) Lactic acid (and) Aqua

Preservative containing Blends
- Polylysine (and) Propanediol (and) Benzyl Alcohol
- Polylysine (and) Propanediol (and) Caprylyl Glycol
- Phenethyl alcohol (and) Benzoic Acid (and) Sorbic Acid
- Phenoxyethanol (and) Capryl Glycol (and) Ethylhexylglycerin (and) Hexylene Glycol
Preservative + Multifunctional ingredient Blends

- Phenoxyethanol, Glycerin, Citrus Rusticulata Fruit extract, Citrus Sinensis Fruit extract, Ascorbic acid, Lactic acid, Aqua **
- Benzyl Alcohol, Glycerin, Citrus Rusticulata Fruit extract, Citrus Sinensis Fruit extract, Tocopherol, Ascorbic acid, Lactic acid, Aqua **

**According to supplier - A cream containing 0.8% of either blend at a pH of 6.7 passed USP challenge test

Natural Blends

Phenethyl Alcohol, Glycerin, Citrus Reticulata Fruit Extract, Citrus Aurantium Amara Fruit extract, Citrus Sinensis Peel Extract, Ascorbic Acid, Lactic Acid, Aqua

- Clear yellow viscous liquid with characteristic odor
- pH 10% sol’n: 2.2-4.0
- Data shows efficacy in USP 30 Challenge Test for Category 1 products vs. E. coli, S. aureus, P. aeruginosa, C. albicans, A. niger
- Tested at 0.8% in a cream at pH 6.7
The New generation of Blends

- **Essential Oil/Botanical combinations**
  - Cinnamon Leaf oil, Curry Leaf oil, Lemon Grass oil, Orange oil
  - Extract combinations of Oregano Leaf, Thyme, Cinnamon Bark, Olive Leaf, Rosemary Leaf, Peppermint Leaf, Lavender Flower, Goldenseal Root, Lemon Peel
  - Parfum [Fragrance]

### Natural Blends

**Natural Liquid Preservative based on Cinnamon Leaf, Curry Leaf and Sesame Oils**

**Linatural** is the new line of all natural ingredients that bring value added to personal care, pharmaceutical and household products.

**Linatural NLPS** is a patent pending natural preservative of Curry leaf and Cinnamon leaf and Sesame oils that are cultivated from exclusive fields and prepared by GMP steam distillation process using sugar alcohol from molasses.

**Linatural NLPS** has excellent broad spectrum activity against gram positive and gram negative bacteria and mold and yeast. Curry and Cinnamon leaf and Sesame oils are globally acceptance and have excellent toxicity profiles.

**Typical Properties**

- **Appearance** @ 25°C: Clear liquid
- **Color**: Pale Yellow
- **Specific Gravity**: 0.92 ± 0.01
- **INCI Name**: 
  - Murraya Koenigii (Curry Leaf Oil)
  - Cinnamomum Zeylanicum (Cinnamon Leaf Oil)
  - Sesamum Indicum (Sesame Oil)
  - Alcohol (Ethyl) – Sugar alcohol from Molasses

**Typical Use Levels/PH range**

- 0.3% - 1.2%
- Formulation pH range 3 – 9
Based on Organic Orange, Lemongrass, Sunflower Oils

A patent pending natural preservative consisting of certified organic oils.
Broad spectrum activity against gram positive and gram negative bacteria and mold and yeast.

Typical Properties
Appearance @ 25°C: Clear Liquid
Color: Pale Yellow to Orange
Specific Gravity: 0.88 ± 0.01
Typical Use Levels: 0.75-2.00%
Formulation pH range: 3-7

INCI Name:
- Citrus Aurantium (Orange Oil)
- Cymbopogon Citratus (Lemon Grass Oil)
- Helianthus Annuus (Sunflower Oil)
- Processing Aid - Organic Ethyl Alcohol Denatured with Organic Lavender Oil

USDA Certified Organic Natural Liquid Preservative
**Lets look at some formulation successes**

(Formulations that passed either a PCPC or USP Challenge test)

**Successfully tested formulations**

SPF 30 O/W sunscreen emulsion; pH 6.2
- Non-ionic emulsifier system
- Organic sunscreens (No TiO2 or ZnO)

- Preservative efficacy system
  - 0.2% Chlorphenesin
  - 0.8% Ethylhexylglycerin
  - 2.0% Pentylene Glycol
  - 0.1% Disodium EDTA

Formulation passed USP micro challenge test
Successfully tested formulations

O/W treatment cream
- pH 6.0-6.5
- Non-Ionic Emulsifier system
- Emollients-natural oils, butters, silicones
- Mixture of bioactive ant-aging ingredients
- Preservative efficacy system
  - 0.27% chlorophenesin
  - 0.67% solution of 1,2 Hexanediol/Caprylyl Glycol
  - 0.10% Disodium EDTA

Formulation passed PCPC micro challenge test

Successfully tested formulations

Hair + Scalp cleanser - OTC drug formulation
- Opaque/Pearlescent Liquid
- Anionic/non-ionic/amphoteric surfactants
- pH 6.0-6.5
- Cationic polymeric conditioner
- Preservative efficacy system
  - 0.55% sol’n of Phenoxethanol/Methylisothiazolione (1.65%MIT,83.5% PE)
  - 0.1% Disodium EDTA

Formulation passed USP challenge test
Oil-in-Water emulsion
- Non-ionic emulsifier system
- Emollient system a mixture of natural & synthetic esters + petrolatum; no silicones
- Mixture of skin barrier protecting agents
- pH 5.0-5.5
- Preservative efficacy system
  - 1.0% of a solution of 1,2 Hexanediol/Caprylyl Glycol
  - 0.1% Disodium EDTA

Formulation passed PCPC challenge test

Rinse off Cationic Hair & Scalp Treatment
- Contains cationic emulsifiers and conditioning agents
- Contains OTC drug Ingredient
- pH 4.5-5.0
- Preservative efficacy system
  - 0.55% sol’n of Phenoxyethanol/Methylisothiazolinone
    (1.65%MIT, 83.5% PE)
  - 0.1% Disodium EDTA

Formulation passed USP Challenge Test
Now let's see what systems are currently being used in the marketplace.........
Active Ingredients: Avobenzone 2% (Sunscreen), Homosalate 4% (Sunscreen), Octisalate 4% (Sunscreen), Octocrylene 2% (Sunscreen)

Inactive Ingredients: Water, Dimethicone, Isononyl Isononanoate, Glycerin, Cetyl Alcohol, Styrene/Acrylates Copolymer, Steareth-21, Trisiloxane, Nylon 12, Dimethicone/Vinyl Dimethicone Crosspolymer, Retinol, BHT, Ascorbic Acid, Hydrolyzed Myrtus Communis Leaf Extract, Silica, Caprylyl Glycol, Polysorbate 20, Stearyl Alcohol, Glycerlyl Stearate, PEG-100 Stearate, Sodium Hyaluronate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Xanthan Gum, Disodium EDTA, Sodium Hydroxide, Chlorenesin, Phenoxyethanol, Fragrance
**Active Ingredients:** Octylmethoxycinnamate, Phenylbenzimidazole Sulfonic Acid

**Inactive Ingredients:** Water, Cyclomethicone, Glycerin, Polyglyceryl 3 Methylglucose Distearate, Shea Butter (Butyrospermum Parkii), Triethanolamine, Apricot (Prunus Armeniaca) Kernel Oil, Phenoxyethanol, Cetearyl Alcohol, Panthenol [pro-Vitamin B5], Stearic Acid, Acrylates /C10-30 Alkyl Acrylate Crosspolymer, Fragrance, Xanthan Gum, Disodium EDTA, Balm Mint (Melissa Officinalis) Extract, FD&C Yellow 5 Aluminum Lake

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**Active Ingredients:** Octylmethoxycinnamate, Phenylbenzimidazole Sulfonic Acid

**Inactive Ingredients:** Water, Dimethicone, Glycerin, Isopropyl Isostearate, Pentaerythrityl Tetraethyhexanoate, Octyldodecanol, Cetyl Alcohol, Silica, Behenyl Alcohol, Talc, PTFE, Polyethylene, Eperua Falcata Bark Extract, PBG 100 Stearate, Stearic Acid, Stearyl Alcohol, Carbomer, Arachidyl Alcohol, Dimethicone/Vinyl Dimethicone Crosspolymer, Cetearyl Alcohol, Cetearyl Glucoside, Sodium Hyaluronate, Sodium Hydroxide, Palmitic Acid, Adenosine, Poloxamer 334, Ammonium Polyacryldimethyltauramide/Ammonium Polyacryloyldimethyl Taurate, Disodium EDTA, Capryloyl Salicylic Acid, Caprylyl Glycol, Lens Esculenta (Lentil) Seed Extract, Dextrin, Phenoxyethanol, Red 40 (CI 16035), Red 33 (CI 17200), Linalool, Alpha Isomethyl Ionone, Limonene, Citral, Citronellol, Fragrance
Water, Glycerin, Panthenol, Isohexadecane, Niacinamide, Dimethicone, Isopropyl Isostearate, Stearyl Alcohol, Acrylamide/Sodium Acryloyldimethyltaurate Copolymer, Camellia Sinensis Leaf Extract, Allantoin, Tocopheryl Acetate, Polyethylene, Titanium Dioxide, Cetyl Alcohol, Aluminum Starch Octenylsuccinate, Behenyl Alcohol, C13 14 Isoparaffin, Benzyl Alcohol, Nylon 12, Dimethiconol, Ethylparaben, Laureth-7, Stearic Acid, Propylparaben, PEG 100 Stearate, Methylparaben, Disodium EDTA, Triethanolamine, Cetearyl Glucoside, Cetearyl Alcohol
Water, Glycerin, Cetearyl Alcohol, Cetyl Esters, Ceteareth 20, Cetyl Alcohol, Glyceryl Dilaureate, Mineral Oil, CI2 15 Alkyl Benzoyl, Dimethicone, Stearic Acid, DMDM Hydantoin, Methylisothiazolinone, Isopropyl Myristate, Propylparaben, Carbomer Sodium Hydroxide, Hydrolyzed Silk

Water, Glycerin, Mineral Oil (Paraffinum Liquidum), Caprylic (Capric Triglycerides), Cetyl Alcohol, Dimethicone, Glycerol Stearate, Cyclopentasiloxane, Cyclohexasiloxane, PEG 40 Stearate, Ginkgo Biloba Leaf Extract, Tocopheryl Acetate, Butyrospermum Parkii (Shea Butter) (Shea Butter), Phenoxethanol, Fragrance Carbomer, Sodium Hydroxide, EDTA, Methylparaben, Propylparaben
- water (aqua), lauryl lactate, behenic acid, behenoxy dimethicone, glycerin, glyceryl stearate se, behenyl alcohol, pentaerythrityl tetraacrylate/tetraacrate, cyclopentasiloxane, tocopheryl acetate, benzyl alcohol, cyclohexasiloxane, retinyl palmitate, arginine, stearic acid, panthenol, beta-glucan, lavandula angustifolia (lavender) oil, xanthan gum, triethanolamine, propylene glycol, methylparaben, propylparaben, diazolidinyl urea.

- Water, Mineral Oil, Glycerin, Petrolatum, Stearic Acid, Glyceryl Stearate, Sesamum Indicum (Sesame) Oil, Urea, Lanolin Alcohol, Triethanolamine, Hordeum Vulgare (Barley) Extract/Extrait D’Orage, Cucumis Savitus (Cucumber) Fruit Extract, Helanthus Annuus (Sunflower) Seedcake, Propylene Glycol Dicaprate, Sodium Hyaluronate, Butylene Glycol, Pentylene Glycol, Trisodium EDTA, Phenoxethanol, Yellow 6 (CI 15985), Yellow 5 (CI 19140), Red 33 (CI 17200)
Water, Isodecyl Neopentanoate, Squalane, Cetearyl Alcohol, Mineral Oil, Solanum Tuberosum Extract, Shea Butter, Prunus Domestica Seed Extract, Sorbitol, Propylene Glycol, Cetearyl Glucoside, Butylene Glycol, Tilia Platyphyllos Extract, Mallow Extract, Phenoxyethanol, Panthenol, Ceteareth-33, Bisabolol, Arginine, Allantoin, Butylene Glycol, Polyacrylamide, Butylphenyl, Sage Oil, Xanthan Gum, Thymus Masticina Herb Oil, Potassium Cetyl Phosphate, C13-14 Isoparaffin, Retinyl Palmitate, Anthemis Nobilis Flower Oil, Oryza Sativa Bran Oil, Tocopherol, Laureth-7, Propylene glycol, Chlorphenesin, Propyl Gallate, Citric Acid

Water, Glycerin, Sodium Lauroyl Glutamate, Zea Mays (Corn) Starch, Ricinus Communis (Castor) Seed Oil, Fragrance, Citrus Aurantium Dulcis (Orange) Oil, Salvia Sclarea (Clary) Extract, Lactobacillus, Theobroma Grandiflorum Seed Butter, Cera Alba (Beeswax), Cocos Nucifera (Coconut) Oil, Olea Europaea (Olive) Fruit Oil, Jojoba Esters, Hydrolyzed Jojoba Esters, Citrus Medica Limonum (Lemon) Peel Oil, Citrus Aurantium Amara (Bitter Orange) Peel Oil, Polymnia Sonchifolia Root Juice, Zinc Oxide, Alpha Glucan Oligosaccharide, Propanediol, Maltodextrin, Tocopherol, Xanthan Gum, Glycine Soja (Soybean) Oil, Arginine, Sodium Lauroyl Lactylate, Lactic Acid, Hydroxyisobutyl Propionic Acid, Amyl Cinnamal, Citral, Eugenol, Hydroxycitronellal, Limonene, Linalool
Final Comments and Thoughts

- The reduction in the arsenal of safe and effective preservatives has been a leading cause for the increased use of multifunctional, "preservative free" ingredients.

- The multifunctional blends being developed and used are as effective, in most cases, as traditional preservative systems.

- The use of multifunctional ingredients should not be a replacement for the use of safe & effective preservatives but instead should be an addition to the arsenal of choices available to the formulator.
Having a well preserved product is never going to win you any awards or help insure success in the marketplace.

Having an inadequately preserved product (whether it be for safety or efficacy reasons) can result in potential safety & health issues for consumers, and result in a disastrous recall from the marketplace.

We have a responsibility to provide safe, well preserved products to consumers and to continually look for and evaluate new, safe and effective preservative systems.

The Industry has a responsibility to educate consumers regarding the safety of the preservatives that are being used and counter the misinformation and junk science being disseminated.

Thank You... and now if you have any questions!