Natural Preservatives?/Preserving Natural Cosmetics?

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What is Natural?

Ask me no questions, I will tell you no lies

Or as Ken Klein used to say:

The only things that are natural are earth, wind, fire and rain

Or

Supreme Court Justice Potter in 1964 (on pornography)

I can’t define it but I know it when I see it

However

The Federal Trade Commission has taken action against cosmetics making these claims:

All natural

Or 100% natural

So What is a “Natural” Preservative?

- I would look at what the USDA Organic Certification says
- What REACH says
- What ANSI/NSF says

USDA Organic Certification

- See: https://www.ams.usda.gov/sites/default/files/media/OrganicCosmeticsFactSheet.pdf
- "100 percent organic"--Product must contain (excluding water and salt) only organically produced ingredients. Products may display the USDA Organic Seal and must display the certifying agent's name and address.
- "Organic"--Product must contain at least 95 percent organically produced ingredients (excluding water and salt). Remaining product ingredients must consist of nonagricultural substances approved on the National List or nonorganically produced agricultural products that are not commercially available in organic form, also on the National List. Products may display the USDA Organic Seal and must display the certifying agent's name and address.
- "Made with organic ingredients"-- Products contain at least 70 percent organic ingredients and product label can list up to three of the organic ingredients or "food" groups on the principal display panel. For example, body lotion made with at least 70 percent organic ingredients (excluding water and salt) and only organic herbs may be labeled either "body lotion made with organic lavender, rosemary, and chamomile," or "body lotion made with organic herbs." Products may not display the USDA Organic Seal and must display the certifying agent's name and address.
- Less than 70 percent organic ingredients- -Products cannot use the term "organic" anywhere on the principal display panel. However, they may identify the specific ingredients that are USDA-certified as being organically produced on the ingredients statement on the information panel. Products may not display the USDA Organic Seal and may not display a certifying agent's name and address. (Water and salt are also excluded here.)-Note-you cannot use the word or use asterisks in your IL. If you want to label this, you need a separate location

What Preservatives are Allowed?

- Benzoic acid
- Sorbic acid
- Benzyl alcohol

- But they must be from organically grown plants……

Benzoic Acid

- Found in Gum Benzoin at about 20% and obtained by dry distillation.
- Cost of gum benzoin is about $16/lb. so raw material cost is $80/lb. not counting processing and purification.
- Cost of synthetic material is about $1/lb.

Sorbic Acid

- Found in Rowanberry oil
- It is not commercially available
- Synthetic material is about $5/lb.

Benzyl Alcohol

- Found in essential oils (note-EO's are not natural!) with the highest level found is about 4.5% in Balsam of Peru.
- Price of Balsam of Peru is about $200/lb or for the Benzyl alcohol (no processing cost included) is over $4,000 per pound!
- Synthetic Benzyl alcohol cost about $1.25/lb.
- So try explaining to marketing why you can't use the USDA Organic seal!

What is the difference?

- A chemical is a chemical-it has no idea who its parents are or where it came from…
- But marketing wants “natural” or “organic”
- Be aware of your claims when using these preservatives

REACH Natural Product Registration Exemptions

- These apply to naturally occurring substances that are unprocessed-no treatment at all.
- Processed only by manual, mechanical or gravitational means.
- By dissolution in water only.
- By steam distillation, but not essential oils.

ANSI/NSF 305

- See: http://www.nsf.org/services/by-industry/food-safety-quality/organic-certification/personal-care-nsf-ansi-305

QAI, a leading organic certification organization that is part of the NSF International family of companies, can certify personal care products to the USDA National Organic Program (NOP) and to ANSI/NSF 305:

Personal Care Products Containing Organic Ingredients:

Products that contain at least 70 percent certified organic ingredients, but which do not meet the NOP food-focused requirements due to cosmetic industry chemical processes and production methods, can be certified to NSF/ANSI 305.

The Bomb Shell

- In late February 2016, the FDA issued its new guidelines for Cosmetic site inspections.
  - Collect samples of eye area cosmetics, tattoo inks or skin care preparations and lotions for microbiological analysis when adequate challenge test documentation cannot be produced, the adequacy of preservation is in doubt or non-traditional preservative systems are used.

FDA's Concern

Another change that the cosmetics industry is facing is consumer distaste for traditional preservatives. As an example, parabens, which are one of the most effective classes of preservatives, have been suspected of causing adverse effects to the endocrine system. In the European Union parabens are being phased out of all cosmetics because of this concern. As a result manufacturers are applying non-traditional preservative systems in order to assure the microbial safety of their products. FDA is concerned that cosmetic products that make a statement in labeling that the product is "green", "natural", "no parabens" and "no preservatives" may not be safe for consumers without appropriate safety testing. **Companies and products that make such label statements should be given priority over traditionally manufactured cosmetics during inspection and sampling.**

Preservative Compounds Commonly Used in Cosmetics

- Parabens (methyl, ethyl, propyl, and butyl)
- Quaternium 15
- Diazolidinyl Urea
- Imidazolidinyl Urea
- DMDM Hydantoin
- 2-Bromo-2-nitropropane-1,3-diol
- Sodium Hydroxyglycinate
- Phenoxyethanol
- Sorbic Acid / Potassium Sorbate
- Methylisothiazolinone
- Methylchloroisothiazolinone
- Sodium Benzoate
- Caprylyl Glycol
- Sodium Dehydroacetate
- Formaldehyde

Non-traditional Preservatives

Non-traditional preservatives are typically extracts of botanicals, organic acids, alcohols and glycerols. Fermentation products are also used as preservatives. The presence of these types of chemicals in a cosmetic, in the absence of traditional chemicals, indicates they may be used a part of a preservative system. This list is a small sample.

Examples

- Glyceryl Caprylate
- Levulinic Acid
- p-anisic acid
- Eucalyptus Globulus
- Glycyrrhiza Glabra (Licorice) Root Extract
- Salvia Officinalis
- Citrus Grandis (organic grapefruit) Extract
- Arnica Montana (organic arnica) extract
- Boraxitrus Seed Extracts
- Leuconostoc/Radish Root Ferment Filtrate
- Goldseal (Hydrastis Canadensis Root Extract)
- Citrus Medica Limonum (Lemon) Peel Extract
- Caprylhydroxamic Acid

Other “Natural” Preservatives

- Gluconolactone
- Lonicera Japonica (Honey Suckle) Flower Extract
- Lonicera Caprifolium (HS) Flower Extract
- Leuconostoc/Radish Root Ferment Filtrate
- Lactobacillus Ferment

Instructions to Inspectors

Since resistance to microbial contamination is especially important in the case of eye area products (especially those that are water-based), tattoo ink, skin lotions and no-alcohol mouthwash, collect samples of recently produced and retained products **when the manufacturer is unable to produce challenge test documentation** or the adequacy of preservation is otherwise in doubt or non-traditional preservative systems are used.

Marketeers of “Natural” Cosmetics

- They are the first to start claiming “free” of claims
- They should be promoting what their products contain and do, not what they are free of.

“Free” Claims

- Advertising Standards Canada considers these claims to be false and misleading.
- Example: Hydrogen Cyanide free
- They have issued conditions which must be met to make such a claim

Conditions for “free” Claims

- The product must have contained this ingredient and was on the Canadian market with established registrations and dates.
- The Government must be notified that you removed this ingredient.
- Outside analysis must show that **ZERO** amount of this ingredient can be detected.
- You are than allowed to make the claim…..free for 1 year.
- At the end of 1 year, all products must be removed from the shelf.

What You Can Say

- This product was never formulated with hydrogen cyanide
- This product naturally contains no hydrogen cyanide
- We do not have hydrogen cyanide in this product
- However all of these claims must be true and provable

In the US

- Each time someone makes a new ….”Free” claim, the press starts with these questions:
  - How many people did you kill or injure before you removed this horrible chemical?
  - What other toxic chemicals are in your product that you haven’t removed yet?
  - Shouldn’t the FDA pre-approve all cosmetics and all ingredients, as you clearly claim that self-regulation is not working?

So

- Marketers are quick to follow whatever they think will sell 1 more bottle without caring about the consequences.

- The British & French have now prohibited “free” claims. They have requested this be made part of the EU Regulations. This will happen soon.

But here in the US

- Paraben free
- Triclosan Free
- Formaldehyde Free
- Glycol Free
- Preservative Free
- Alcohol Free
- Everything but the price!

Preserving “Natural” Cosmetics

- What can we use?
- Am I confident it will work?
- Will I know if my “natural” preservative is always the same?
- Can I make products without using any preservative?

The Latest Disaster

- The “organic” and “natural” market subscribes to the theory that all preservatives are bad. The only ones they permit are weak and usually ineffective. Further they cannot be made from petrochemicals.
- But now, we find massive contamination of products usually coming from poor GMP’s, but especially coming from spores in raw materials.
- What do you expect when these are grown with “natural” fertilizers?

The Major Problems with “Natural” Preservatives

- What are they?
- If you do not know their exact chemical composition, how do you know it will work the same way each time?
- You will need to run a challenge test with each incoming lot, made into a small batch?
- Are they stable after opening the container?

FDA REGULATIONS-ADEQUACY OF PRESERVATION

- Cosmetics (and topical drugs) need not be sterile.
- They cannot be contaminated with pathogenic microorganisms and other organisms must be low.
- There must be sanitary storage and handling of raw materials and finished goods to prevent adulteration, including microbial contamination.

Recommendations

- Each batch of a cosmetic which is not self-preserving, should be tested for microbial contamination before it is released for interstate shipment, and

- Each cosmetic, particularly each eye area cosmetic, be tested during product development for adequacy of preservation against microbial contamination which may occur under reasonably foreseeable conditions of consumer use.

Reality

- **We add preservatives to correct cGMP failures in production.**
  - Why use pure strains in PET?
  - Why use “house” organisms?
  - How do you know if your preservative is working or you manufactured under cGMP’s ?
  - We call contamination of a finished product “a preservative failure”.
  - The FDA rejects post production sterilization for finished products.
    - Not applicable for ingredients

Common Test Method

- **USP <61> Microbial Limits Test**
  - A recovery analysis is performed to verify that microorganisms present in a sample can be adequately plated/recovered on the chosen agar medium.
  - An aliquot of test specimen is dissolved in phosphate buffer (additional media containing emulsifying agents and/or surfactants may also be used).
  - 1 mL of the suspension is plated over agar plates and incubated.
  - Microbial colonies are totaled and expressed as either CFU/g or CFU/mL of test specimen.
  - If positive (greater than 10 cfu/mL), you need to run USP<62> to see if they are pathogens

Why is this so Important?

- **All recalls of contaminated cosmetics occurred because companies shipped contaminated products.**
- Why didn't they test?
- I know my preservative system is working and all the bugs will die off

Or

- Marketing needed the product shipped…..
- Why waste time and money? We've never had a problem….

Developing a Challenge Test (PET)

- The same test might not give relevant results for different types of products.
- Many products are over preserved
  - You try one level and if it works, you should try it at a lower level
- Clearly atypical cosmetics cannot use classical methods.
  - “Teach to test”

Types of Products

- **Typical**
  - Water is the external phase (O/W emulsions) or solutions
    - Most PET tests give good results
- **Atypical**
  - All others including W/O emulsions
    - Difficult to test
    - Do they need to be preserved?
    - New guidelines from the PCPC's micro committee

In General

- Use Combinations
- Must be in the water phase
- Incorporate “active” chelating agents

Water Activity

- Freidel: The Application of Water Activity to Microbiological Attributes Testing Non-sterile OTC Drugs

- A_w The vapor pressure of the solution @°C divided by the vapor pressure of pure water at the same temperature

- Scale of 0 to 1.00
- Measured only by instrumentation !!!
- 0.60 to 0.99 is the range for growth

Applications of A_w

- Prevents growth
- Must have GMP's, HACCP
- Ingredients that lower available water include glycols, salt
- Not for amateurs!

HACCP

Hazardous

Analysis

Critical

Control

Points

Requirements for Growth

- Mold: 0.70 to 0.98
- Yeast: 0.88 to 0.91
- Gram +: 0.86 to 0.98
- Gram-: 0.91 to 0.98

What Can You Do if You Can't Use Preservatives That Work?

- Manufacture under strictly enforced cGMP's. (spend the big bucks!)
- Establish and use HACCP to find where contamination is taking place and eliminate it. (spend the bucks)
  - Hire a good consultant (this is a paid political announcement)
- Package your products so consumers cannot contaminate them. (spend big bucks)
- Insist that your company stop the self destructive behavior of claiming …."Free" (fire your marketeering department!)
- Do not use ingredients from suppliers who sell by being negative!
- If you are brave enough, tell marketing the costs of not using good, safe preservatives.

New Preservatives

- In 2008, I presented a talk on how every preservative that we use is under attack.
  - Even though the safety record has been reviewed time and again and they have been found to be safe.
- Will there be new preservatives?
  - NO!

What Does Marketing Want?

- Natural (what ever that means to them)
- 100% Safe
  - There is no 100% safety-the dose is what is important
- Works in all products
- Has never been tested on animals
- Protects against all possible contamination in your plant, ingredients and by consumers
- Be allowed world-wide
  - There are 206 recognized countries in the world. Could you narrow this down?
- Be cheap!

Why Is this Impossible?

- In the 1960's a new preservative was introduced with about $2,000 of safety testing-$LD_{50}$, Eye irritation-rabbits, Skin irritation-guinea pigs.

- In the 80's, the first preservative cocktail was introduced, based on existing preservatives and over $100,000 of safety testing was performed.

The Last Successful New Preservative

- Took over 5 years to obtain approvals in the EU, Japan, China.
- Costs were in the 7-8 figure range.
- Today a new chemical, besides the safety testing for cosmetic use, approvals by countries that require pre-approval for preservatives, we have environmental listings such as REACH, DSL, IESCS, NICNAS, etc.
- There will be no new preservatives!
  - The market is just not big enough.
  - The demand for cheap is impossible to meet.
  - Anything found in nature doesn't work and has major issues with what to do with all the by-products.
  - Someone will always attack it.
  - If it sounds too good to be true, it probably isn't!

Preservative “Boosters”

- Many suppliers are touting “boosters” as a way around the issues.
- They fall into two categories:
  - They really are preservatives-they have cidal activity, but the vendors will not spend the money to run the required safety testing for country approvals or the approvals require animal testing which are prohibited!
  - They are solvents which maybe preservatives at very high levels by lowering the water activity or dissolve the preservative better in the water phase.

Popular Solvents

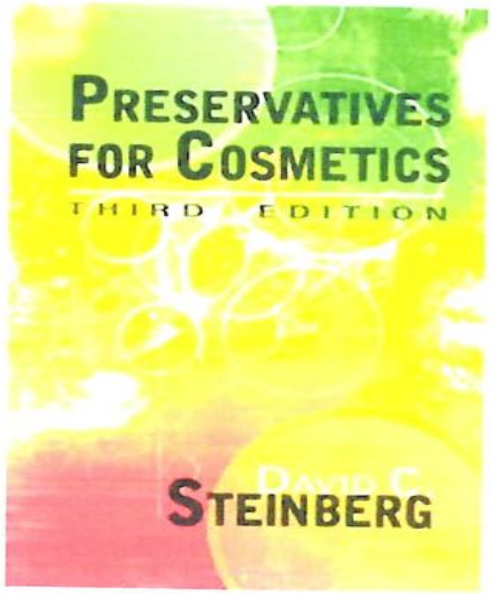
- For example- Caprylyl Glycol is not available except dissolved in a solvent such as:
- Phenoxyethanol
- Hexylene Glycol
- Propylene Glycol
- Butylene Glycol
- Pentylene Glycol
- Ethylhexylglycerin
- 1,3 Propanediol

The Future

- We continue to see new non-preservative preservatives offered. (It can't be a preservative-it is not on the approved EU list, so it must be a ……. which makes our product self-preserving.)

- We continue to see "natural" extracts which function as preservatives, just like dietary supplements work as real drugs.

- **Caveat Emptor!**



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