Objectives
• Describe the purpose of preservatives in cosmetic products
• Describe the Dillarstone Effect for preservatives
• Discuss published North American preservatives data
• Discuss select preservatives

What is a preservative?
• Eliminate or inhibit the growth of unwanted microorganisms
• Slow the chemical degradation of products

What grows in cosmetic products?
• Contamination
• Body wash, shampoos
  • Gram negative bacteria, Enterobacteriaceae
• Creams
  • Same as above, Gram positive cocci, Aerobic spore formers
• Surface growth - molds

The ideal preservative...
• Is stable
• Is compatible with other ingredients
• Is active against most microorganisms at a low concentration and at a wide range of pH and temperature values
• Is nontoxic, nonirritating and nonsensitizing
• Low cost

Preservative Allergy Dillarstone Effect
• In 1997, Dillarstone proposed his observation of preservative trends

Estimates of Preservative Allergy Prevalence in North America
• North American Contact Dermatitis Group
  • NACDG Preservative Prevalence Rates 1994-2016 and 2015-2016 were discussed
• Mayo Clinic Contact Dermatitis Group 2011-2015 data were discussed

Methylisothiazolinone: Contact Allergen of the Year 2013
• #1 cause of NACDG preservative contact dermatitis 2015-16
• 13.4% of patients had positive patch test

Methylisothiazolinone Clinical Pattern
• Hand or facial dermatitis, Rinse-off or diffuse pattern, Airborne
Methylisothiazolinone (MI) Cosmetic Sources of Exposure
- Body wash, Hand soap, Shampoo, Conditioner, Makeup, Moisturizers, Sunscreens

Household Sources of Exposure
- Dishwashing liquid soap, Laundry detergent, Cleaning products, Laundry products

MI Regulation
- Europe
  - MCI/MI and MI are banned in leave-on products
  - MI 15ppm for rinse-off products
- United States - Cosmetic Ingredient Review Expert Panel
  - Rinse-off products safe at up to 100 ppm
  - Leave-on products should be <100ppm and non-sensitizing

Formaldehyde: Contact Allergen of the Year 2015
- Colorless gas with characteristic, pungent odor
- An allergen and an irritant
- #2 and 4 cause of NACDG preservative dermatitis 2015-16

Clinical Pattern
- Personal Care Products: Chronic hand, face or generalized dermatitis
- Occupational: Hand dermatitis
- Occult sources: May be present in cosmetics labeled as formaldehyde-free

Formaldehyde in FDA’s VCRP: use of formaldehyde in products decreasing over time

US Sources of Exposure in 2010: formaldehyde in <100 products

Formaldehyde Test Concentrations: test concentration of 2% aqueous is recommended

Formaldehyde Releasers:
- Quaternium-15, 2-bromo-2-nitropropane-1,3-diol (Bronopol), Imidazolidinyl Urea, Diazolidinyl Urea, DMDM Hydantoin
- Present in 24% of leave-on products registered with the FDA

Parabens: Contact (Non) Allergen of the Year 2019
- #12 (and LAST) cause of NACDG preservative contact dermatitis 2015-16
- 0.61% of patients had positive patch test
- Found in 15-20% of products in CAMP, EWG & SkinSAFE

Parabens:
- Methylparaben, Ethylparaben, Butylparaben, Propylparaben
- Rapidly metabolized to p-hydroxybenzoic acid, Excreted in the urine
Clinical Presentation

- Leave-on cosmetics: Makeups, moisturizers, hair care products, eye products
  - Face, neck, area of application
- Topical medicaments
  - Area of application
- Paraben Paradox: Allergy to paraben in topical medicaments is more common than allergy to cosmetic products. The theory is that this is because topical medicaments are typically applied to inflamed and/or eczematous skin and cosmetics are applied to normal skin.

Parabens in Personal Care Products (products with higher paraben content in CAMP):

- Makeup, Moisturizers, Antiaging/antiwrinkle/skin firming, Cuticle nail care products, Perianal products, Personal lubricants/fresheners

Parabens in Foods: can be present in both preserved and natural/fresh foods.

Parabens in Topical Medications: Acne medications, corticosteroids, hydroquinone, sertaconazole, urea, eflornithine, fluorouracil, imiquimod

References:

Unpublished Data, Amber Reck Atwater MD and the NACDG
Dermatitis 2013;24(1):2-6
Dermatitis 2015;26(1):3-6
Dermatitis 2017;28(4):284-287
Dermatitis 2018;29(6):297-309
Dermatitis 2018;29(6):310-315
Dermatitis 2019;30(1):3-31
Contact Dermatitis 1997;37(4):190
Contact Dermatitis 2011;65(3):176-179
Dermatologic Therapeutics 2004;17:251-263
Microbiology Australia 2010;31(4):195-197
International Journal of Toxicology 2013;32(6) 5S-32S
Acta Derm Vener 2010;90:480-484