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OTC Topical Antiseptics: Opportunity To Bring Innovative Decolonization Products To Market

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American Cleaning Institute

- Trade association representing the $57B cleaning products industry including suppliers, formulators and packaging companies
- ACI also represents the topical antiseptics industry and was awarded FDA deferrals from final regulation of 5 OTC antiseptic ingredients

ACI Members Active in the Topical Antiseptics Coalition

- Arxada
- Ashland Specialty Ingredients
- BODE Chemie GmbH
- Colgate-Palmolive Company
- Diversey
- Eastman Chemical Company
- Ecolab Inc.
- Edgewell Personal Care
- Georgia-Pacific Professional
- GOJO Industries, Inc.
- Henkel Corporation
- Kao Specialties America LLC
- Novo Nordisk
- Pilot Chemical Company
- Procter & Gamble
- Purdue Pharma
- Reckitt
- safeHands
- SC Johnson Professional
- Stepan Company
- Thomas Swan & Company

Background & Key Context

- Topical Skin Antiseptics:
  - Decades of safe use in professional and consumer settings
  - Critical for preventing infections in many settings: Healthcare, food processing and preparation, workplace and public spaces
- Topical Skin Antiseptics Regulation
  - FDA OTC Monographs and recent Monograph Reform
    - ACI is currently completing extensive studies to support GRASE determinations for 5 active ingredients
    - Allowable OTC indications include: antimicrobial handwash / handrub, preoperative skin prep, presurgical handwash / handrub
  - New Drug Approval for new skin antiseptics is long, costly and commercially risky
- Decolonization is not an OTC skin antiseptic indication today, nor is it approved labeling for skin antiseptic New Drugs.
- **This significantly constrains development and use of products for reducing infections due to skin colonization**

Active Ingredients Supported by ACI

Active Ingredient	Consumer Hand Washes	Healthcare					Consumer Hand Rubs
		Patient Preoperative Skin Prep / Pre-Injection Skin Preparation	Health Care Personnel Hand Washes	Health Care Personnel Hand Rubs	Surgical Hand Scrubs	Surgical Hand Rubs	
Ethyl Alcohol		✓		✓		✓	✓
Benzalkonium chloride (BAC)	✓	✓	✓	✓	✓		✓
Benzethonium chloride (BZT)	✓	✓	✓		✓		
Chloroxylenol (PCMX)	✓	✓	✓		✓		
Povidone-iodine (PVP-I)		✓	✓		✓		

FDA Assessment of Safety Data Gaps

Active Ingredient	Human Pharmacokinetic (MUsT)	Animal Pharmacokinetic	Oral Carcinogenicity	Dermal Carcinogenicity	Reproductive Toxicity (DART)	Potential Hormonal Effects	Resistance Potential
Ethyl Alcohol	○	●	●	●	●	●	●
BAC			○				○
BZT		○		●	○		○
PCMX	○	○			○		○
PVP-I	○	●	●		●	●	●

○ = incomplete data

● = available data sufficient to make a GRAS/GRAE determination

Empty cell = no data available.

Current Status of ACI Research

- Completed
  - Antimicrobial Resistance Study final report submitted to FDA July 2021 (BAC, BZT, PCMX)
  - Pilot Healthcare Personnel Hand Wash Efficacy Study – final report (BAC, PCMX, PVP-I)
  - Pilot Ethyl Alcohol Surgical Hand Rub Efficacy Study – final report
  - Pre-Pilot BAC Hand Rub Efficacy Study – final report
  - Pilot BAC Consumer MUsT - completed
  - Additional Time Kill Study – PVP-I
- Near Completion
  - Childcare Observational Study manuscript for publication
  - Antimicrobial Resistance Study manuscript for publication
  - MIC-MBC Study manuscript for publication
  - Additional Time Kill Study – BAC, EtOH, PCMX
  - Pilot BAC Hand Rub Efficacy Study
  - Consumer Clinical Outcome Study Design Development – BAC, BZT, PCMX
- Ongoing
  - Pilot PCMX MUsT Study
  - Pilot BZT MUsT Study
  - Pilot EtOH MUsT Study
  - Pilot 90% EtOH Hand Rub Efficacy Study
  - Pivotal BAC Consumer MUsT
  - Additional Laboratory Qualifications for Hand Rub Efficacy Testing

Future Directions

- Background – Searching for decades to execute infection prevention studies with reasonable, manageable designs
- Consumer Clinical Efficacy
  - Pursuing a study design using US Marine Corp trainees as enriched population – barracks to serve as control (bland soap) and treatment (antibacterial soaps) groups
  - Propose to FDA to use skin colonization as one of the clinical endpoints
  - Contracted Trauma Insight to assist in study design and implementation (http://traumainsight.com/)

Summary

- Current Regulatory Structure is a significant barrier to development of innovative topical skin antiseptics
- New Drug Approval process for new skin antiseptics is long, costly and challenged with uncertainty
- Monograph Reform is potential mechanism to facilitate new skin antiseptic products/technologies to reduce infections and pathogen transmission
- For either Regulatory pathway, establishment of skin decolonization and pathogen reduction as a determinant of clinical outcomes would greatly facilitate new skin antiseptic development
- We look forward to working with FDA to clarify the requirements for new products, enabling innovation to benefit Public Heath