

US EPA ARCHIVE DOCUMENT



Non-Animal Approach To EPA Labeling for Eye Irritation for Antimicrobial Cleaning Products

Presented To:
Pesticide Program Dialogue Committee

Presented By:
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**On Behalf of the Alternative Testing Working
Group (ATWG)**

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ATWG Project History

- Fall, 2003: Diverse support within PPDC for project to identify non-animal assessment approach for acute toxicity endpoints.
- Spring, 2004: OPP Director Jones decision to pursue “informal workgroup” under PPDC focused on eye and skin alternatives for antimicrobial cleaning products (ACP).
- June, 2004: Jones letter to ICCVAM Director Stokes seeking “technical review” of “workshop” recommendations with Fall, 2005 goal of policy to accept non-animal test for ACP.
- Fall, 2004: ICCVAM indicates preference to conduct technical review of industry developed BRD. EPA and ATWG members agree.

ATWG Project History

- January-September, 2005: Animal and non-animal data submitted by ATWG to IIVS for compilation.
- Fall, 2005–Fall, 2006: Non-animal testing conducted by IIVS on formulations to complete database.
- 2005-2006: Several ATWG briefings of OPP staff on project progress.
- Summer, 2006: ATWG trip to RTP to brief Stokes/NICETM staff; check alignment.

ATWG Project History

- October, 2006: ATWG formal briefing for ICCVAM ODTWG (Tina Levine, John Redden, Amy Rispin, Karen Hamernik)
- Spring, 2007: Initial Draft of BRD circulated for ATWG review. Final decisions made on remaining issues.
- Fall, 2007: Submission of BRD to ICCVAM for expedited technical review of approach for EPA labeling of ACP only.

Participants

Seven Companies:

- Clorox
 - Colgate Palmolive
 - Dial
 - EcoLabs
 - JohnsonDiversey
 - P&G
 - SC Johnson
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- Institute of In Vitro Sciences (IIVS)

Overview

Anti-Microbial Cleaning Products,
e.g. Mr. Clean, Febreze, Scrubbing
Bubbles, Windex Anti-Microbial



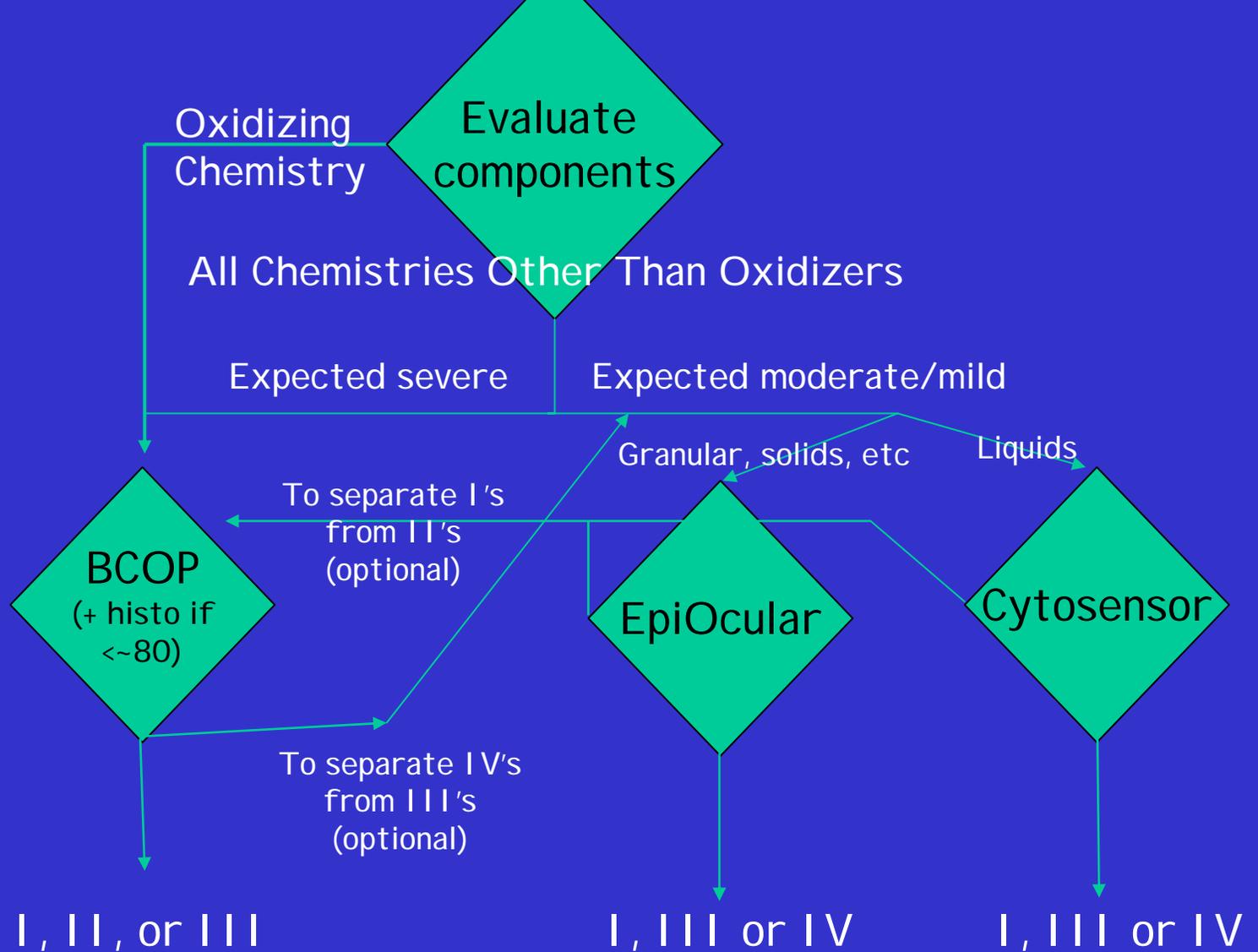
Non-Animal Hazard Evaluation,
e.g. formulation analysis, in vitro test
information

EPA Labeling Categories,
e.g. CAUTION (Toxicity Category
III eye irritant)

Anticipated Non-Animal Assays for Eye

- Cytosensor™ assay; Real time information on cytotoxicity to monolayer cells – Mild/Moderate irritation area
- EpiOcular™ assay; Engineered 3-D model (human tissue) of corneal epithelium – Mild/Moderate irritation area
- Bovine Cornea Opacity and Permeability (BCOP) Assay; Discarded bovine corneas from slaughter houses provide organotypic tissue – Moderate/Aggressive irritation area

Antimicrobial and Related Household Cleaning Chemistries



Experience With Validating Non-Animal Alternatives

- Parallel in vitro and in vivo data sets frequently incomplete.
- Though never validated, animal (i.e. Draize Eye) considered the “gold standard.”
- Animal tests generally very conservative and data mostly older.
- In vitro assays developed to be predictive of toxic endpoint.

P&G Non-FIFRA Cleaning Products

- \$80 billion in products sold in 140 countries annually.
- 4 billion consumers use company products each day; 50% U.S. market share.
- 95% of U.S. cleaning products are non-FIFRA; eye safety determined by in vitro/ex vivo methods.
- Eye safety closely monitored by U.S. “800” service, poison control centers, etc.

ICCVAM Pathway

- ATWG advised by diverse stakeholders not to bring this project to ICCVAM.
- ICCVAM enabling statute likely excludes alternative approaches for narrow group of products for a single Agency.
- Accepted ICCVAM pathway with understanding that precedent would be established for expedited technical review of “modular” approach with emphasis on the narrow product category.

Unconventional Issue for ICCVAM with a Narrow Regulatory Focus

- Does the BCOP/Cytosensor/EpiOcular-based approach assure EPA, with a reasonable degree of certainty, that there will be little to no under labeling of antimicrobial cleaning products?

Conclusion / Next Steps

- ATWG submission of project BRD to ICCVAM in October.
- Need for EPA to clarify:
 - Intended use of approach (i.e. for category labeling purposes only for ACP eye irritancy).
 - Intended scope and nature of ICCVAM assistance needed.
 - EPA plans – length of review; consideration of interim science policy, etc.
- Sound scientific basis for OPP to begin use of BCOP/Cytosensor/EpiOcular approach as Draize eye alternative in 2008.