Set a Course for

TROY

Preservative Selection In A Changing Environment

Dr. Gary Horacek
Director, Troy Technical Support

Who Is…… Dr. Gary Horacek

- Director, Microbiology Technical Support - Americas
- Technical Interface Between Customers
  - Troy Laboratories,
  - Troy R&D, Product Development,
  - Troy Product Registration,
  - Sales & Marketing, AND
  - Agents & Distributors

Problems Caused By Wet-State (In-Can) Microbial Growth Are Several..

- Viscosity loss
- Gassing
- Malodors
- pH changes
- Visible growth

Microbial growth must be controlled to provide a saleable and usable product

INTRODUCTION

- Preservatives Are Necessary
- Preservatives Are Toxic To Target Organisms
- Non-Target Organisms Safety
- Regulations Often Do Not Follow Science
- #Of 'Approved' Preservatives Decreasing
- Future-Proofing Preservation Not Feasible
- Preservative Selection Requires Flexibility
- Robust And Quick Testing Essential

OUTLINE

- Politics Aside
- How Are Preservatives Selected?
- Can We Improve
- Factors
  - What factors that limit options
  - Impact of these factors on choices
  - How to deal with those factors
  - Testing for real world conditions

WHERE DO YOU START?

No, Really: Where Do You Start?

- First: Answer Some Basic Questions
  - What matrix is to be protected?
  - pH of the system (and it's range during life span)?
  - Temperature where preservative is added?
  - Redox at preservative addition?
  - Longevity of protection required?
  - Are there constraints on active chemistry used?
    - VOC Limits?
    - Formaldehyde (HCHO) sensitivity?
    - Color reactions?
    - Regulatory constraints

WHAT'S IN THE TOOLBOX?

- Formaldehdye Adducts (FA)
  - Many choices and alternatives
- Isothiazolines
  - CMIT/MIT, BIT, MIT
- Bronopol
- Pyrithiones (Zn, Na)
- Combinations of the above
- Each Active Has Strong and Weak Points
- The Skill/Art Is In Balancing These
  - Within cost, regulatory, performance needs

EXAMPLE: LATEX COATINGS

- Selecting a preservative package
  - pH Is A Primary Consideration
  - There Are Critical pH 'Break Points'
    - Neutral to Acidic pH
    - Alkaline pH but < 8.5
    - Alkaline pH > 8.5

Neutral or Acidic pH

- Many Options Available In The Toolkit
  - CMIT/MIT, Bronopol, Combinations
  - BIT and FA not generally useful
- Ladder Studies Determine Dose Rates
- Dose Rates Factored By $/Lb Yields Ranking of Cost Effective Choices
- Very High Confidence For Success
- Relatively Low Cost-In-Use Expected

Alkaline pH <8.5

- All Options Available
  - FA, CMIT/MIT, BIT, Bronopol, Combinations
- Next Question: Do You Accept Formaldehyde?
  - Yes: select most cost effective; all on table
  - No: select from the other pool of actives
- Ladder Studies Determine Dose Rates
- Factored By $/Lbs Yields Cost Effective Choices
- High Probability of Success
- Low to Moderate Cost-in-Use

Alkaline pH >8.5

- All options are NOT available @ elevated pH
- Next Question: Do You Accept Formaldehyde?
  - Yes = many viable options
  - No
    - BIT and BIT combinations are preferred
    - CMIT/MIT, Bronopol, & Combinations maybe but definitely limited efficacy should be suspected
- BUT: BIT is not available globally
- Without BIT, we have a problem

Global BIT Shortage

- Sudden Loss of BIT Was Devastating
- Illustrates The Need For Flexibility And Nimbleness In Preservative Programs
- Early Movers Understood The 'Landscape' of Preservation, Preservative & Formulation Properties, and Regulatory Constraints
- Others Shoot From Hip With Many Misses

Why BIT Unavailability Hurt

- BIT Positive Attributes
  - Zero VOC, Zero HCHO
  - Thermal stability
  - Alkaline pH stability
- BIT Weakness
  - Seldom A Complete Preservative
    - Pseudomonas Gap
    - Bacteriostatic = Slow Activity (days)

Easiest Option w/out BIT

- When Alkaline pH And Is HCHO Acceptable?
  - "Yes" = easy substitution usually
    - Use traditional formaldehyde adducts (FA)
    - Determine preservative/dose rate via lab study
- "Yes, but would like to limit formaldehyde"
    - Low-release formaldehyde adducts
    - Use alone or in combination with CMIT/MIT
    - Explore 'costs' of HCHO and VOC additions
      - Trade-offs in market place/performance

Options to BIT (continued)

- Given: pH is below 8.4
  - Why use BIT at all?
    - Demand from exporting market? FDA considerations? Compatability? Safety?
  - Use CMIT/MIT w/ or w/out Bronopol
  - This switch requires little effort – probably pound for pound substitution
  - May or may not be 'issues' to work around (i.e., the ones that led to the use of BIT)

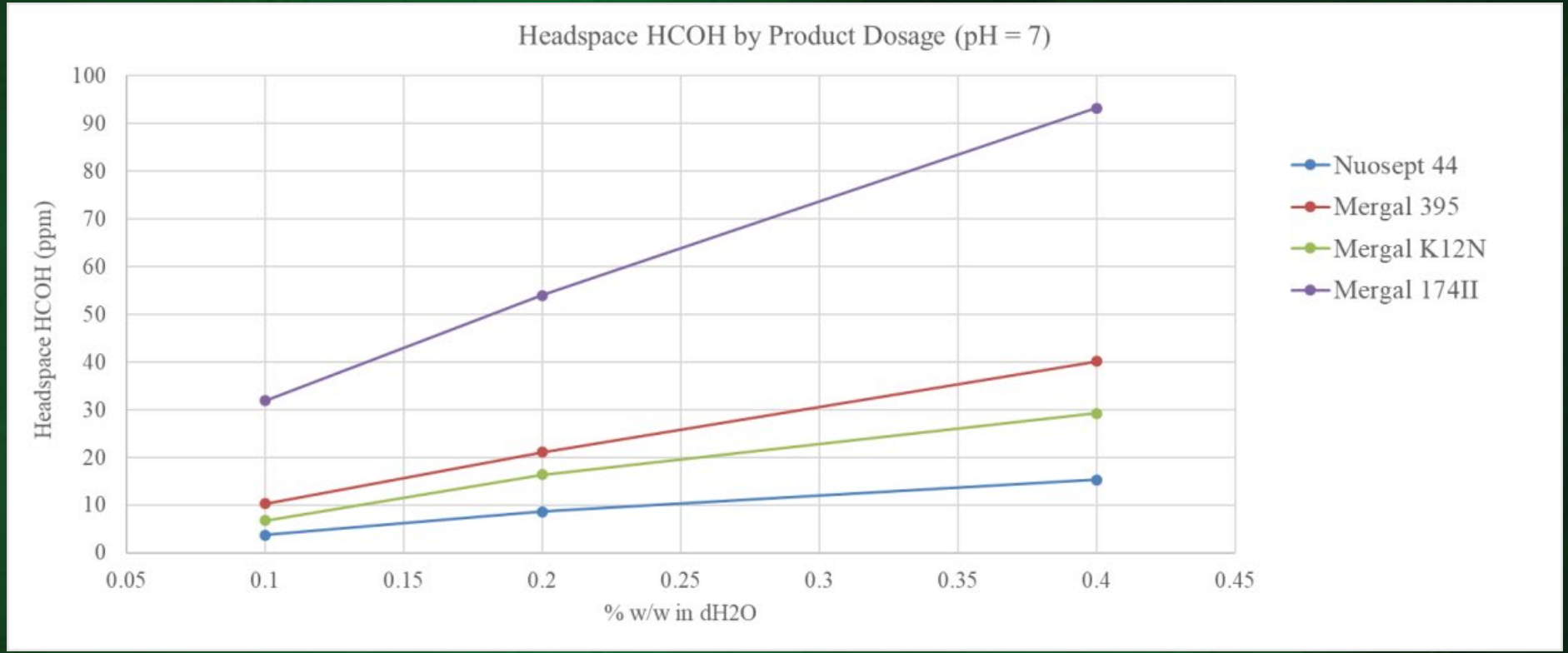
pH > 8.5 Considerations

- CMIT/MIT And Bronopol Are Not Stable
  - Half-life is weeks (depends on specific matrix)
  - Both are still effective as short term biocides
  - Can use high dose rates to extend half-life
    - Recontamination can occur
    - End customer misuse/abuse = a major issue
    - Plant hygiene is critical
- Can Achieve Initial Success, But Give Up Security About Long-term Preservation

Additional Alkaline Considerations

- Given CMIT/MIT and Bronopol Instability, Can You Accept Some Formaldehyde?
- "Not desirable, but maybe just a little"
  - Supplement with low yield FAs
    - Will extend protection, but yield some VOC/HCHO
    - Laboratory work to determine what this means in extended time vs amount of HCHO/VOC added

Headspace HCHO Contribution



'NO', I Cannot Accept Formaldehyde

- Best Starting Strategy Becomes
  - Apply CMIT/MIT at near label limit
  - Lab test rigorously
  - If long term preservation is still too weak, investigate OIT supplement to extend protection
- 2nd, Investigate NaPT and ZnPT Instead
  - Investigate color stability issues
  - CMIT/MIT are not compatible -- ouch
  - OIT supplementation does not help

Strategies Are Often One-Off

- Matrix Being Treated Matters
- Often Choosing Among Sub-Optimal Paths
- 80+% Success Rate Over Past Year
- Your Supplier Should Offer:
  - Guidance, experience, and products
  - Lab support
  - On-site technical support including hygiene audits

Laboratory Back-up To Theory

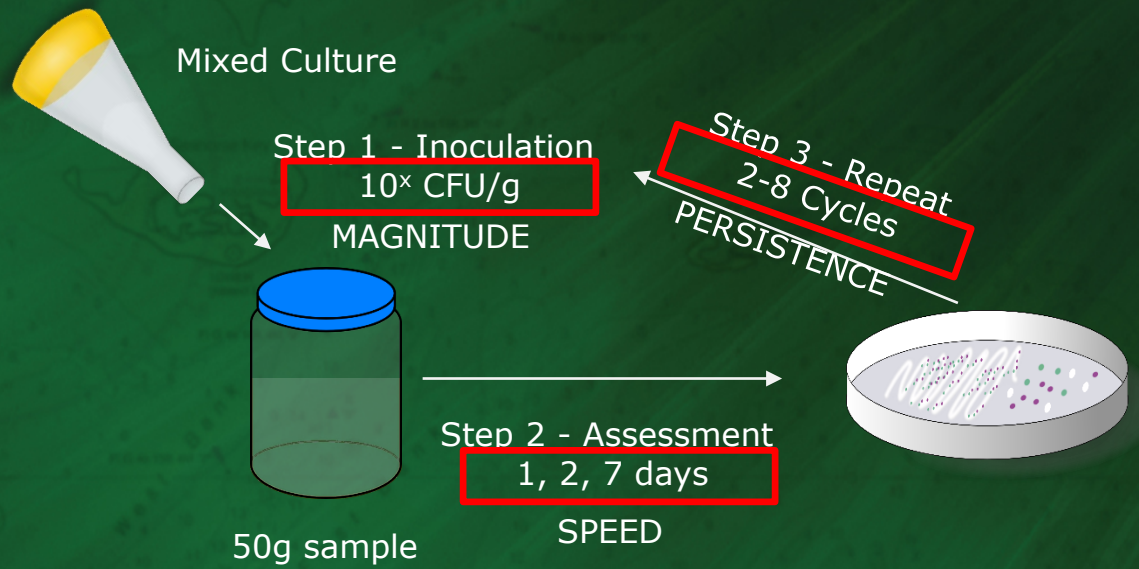
- Standard Laboratory Methods Are Adept At Proving Efficacy Except:
- Predicting Duration Of Performance When Using Sub-Optimum Preservatives
- Requires Rigorous Test Procedures To Properly Stress Preservation
- Will Be Increased Risk

Laboratory Challenge Testing

- Laboratory Must Consider Three Variables
  - Magnitude of the challenge to use
  - Assessing the speed of activity
  - Assessing the robustness of activity

Assessing Preservative Performance

- Challenge testing predicts the speed, magnitude, and persistence
- General Procedure:



Summary

- Preservative 'Landscape' Is Constantly Changing
  - From sourcing issues to regulatory changes
- Must Truly Understand Interactions Of Customer Matrixes And The Actives In Our Shrinking Toolbox
- Test Methods Must Be Flexible and Powerful
- There Will Be Increased Risk/Trade-Offs

Thank You….

Questions?