

# Registration Review Docket



## **1-Methyl-3,5,7-Triaza-1-Azoniatricyclodecane Chloride (BUSAN 1024)**

PPDC Registration Review Workgroup Meeting

July 24, 2007

# PPDC Registration Review Workgroup Meeting

## BUSAN 1024

Tuesday, July 24, 2007

Potomac Yard South, 1st Floor Conference Center

- I. Background-** Avivah Jakob
- II. Human Health Risk Discussion-** Tim Leighton
- III. Ecological Risk Discussion-** Rick Petrie
- IV. Preliminary Work Plan Timeline-** Avivah Jakob
- v. Questions/Comments**

# OPP Regulatory History Timeline

- ❑ **1987- Busan 1024 is registered**
  
- ❑ **1988- FIFRA Amendments**
  - Amendments to FIFRA authorize the EPA to review human health & ecological assessments for pesticides registered prior to 1984 (establishes reregistration).
  
- ❑ **1996- FQPA Amends FIFRA & FFDCA**
  - FQPA amendments change the way the EPA regulates pesticides.
  - Enforces stricter safety standards (e.g., infants & children).
  
- ❑ **1996- The Antimicrobials Division (AD) is formed**

# Busan 1024 Background

- ❑ First Registered: 1987
- ❑ Technical Registrant: Buckman Laboratories
- ❑ There is one registered product containing Busan 1024.
- ❑ Busan 1024 is a bacteriostat & microbiocide/  
microbiostat.
- ❑ Pests controlled include deterioration/spoilage bacteria  
and fungi.

# Busan 1024 Background

## Use Information

- Formulated as a ready-to-use solution.
- Uses:
  - Materials Preservative
    - Emulsion paints, detergents, laundry starch, caulks, textiles, inks, polishes, papermaking chemicals, papermaking coatings and metalworking fluids (MWF), and more.
  - Industrial Processes & Water Systems- petroleum production & recovery, oil drilling muds & waters, and fountain wash systems.

# Human Health Effects

## Overview

- Status
- Assessments Needed:
  - Toxicity
  - Dietary
  - Occupational & Residential Exposure (ORE)

# Human Health Effects

## Risk Assessment Status & Regulatory History

- ❑ Toxicity, dietary, occupational, and residential assessments have not been conducted for Busan 1024.
- ❑ Limited data have been submitted to the Agency on this active ingredient (AI).
- ❑ There is the potential for residential & occupational exposure based on the materials preservative & industrial processes and water system uses.

# Human Health Effects Assessments that are Needed

- ❑ Toxicity endpoints need to be selected.
- ❑ Dietary, occupational and residential risk assessments for labeled uses are needed.



# Human Health Effects

## Anticipated Data Needs

- ❑ The Agency has reviewed the available toxicity data and the current use patterns for Busan 1024 to determine what additional data the Agency anticipates needing to conduct the necessary risk assessments.
  
- ❑ The Agency anticipates that the following studies are needed to establish toxicity endpoints for the risk assessment:
  - 90-Day Oral Toxicity, rodent
  - 90-Day Oral Toxicity, non-rodent
  - 90-Day Inhalation Toxicity, rat
  - Chronic Toxicity, rodent
  - Carcinogenicity, preferably rat
  - Carcinogenicity, preferably mouse
  - Developmental Toxicity, rabbit preferred
  - Reproductive Toxicity, rodent

# Human Health Effects

## Dietary Assessment

### Indirect Food Contact Surfaces

- ❑ Busan 1024 is a preservative used to treat paper-making chemicals. These treated chemicals may have the potential of contacting food, resulting in indirect food contact with Busan 1024.
- ❑ Busan 1024 is a preservative in detergents (e.g., dishwashing).
- ❑ A screening-level dietary exposure and risk assessment is needed for Busan 1024 when used as a materials preservative in paper making chemicals and detergents.

# Occupational & Residential Exposure Risk Assessment Status

- ❑ There are no existing risk assessments for Busan 1024.
- ❑ A dermal assessment is not required. The 90-day dermal toxicity study indicates no dermal and systemic effects at the limit dose (1000 mg/kg bw/day).
- ❑ Busan 1024 is classified as toxicity category IV for skin irritation, not a sensitizer.

# Occupational & Residential Exposure Assessments that are Needed

- Residential exposure assessments that will need to be assessed:
  - inhalation handler (e.g., painting), and
  - incidental post-application oral exposures (e.g., textiles).

# Occupational & Residential Exposure Assessments that are Needed (cont.)

- ❑ Occupational inhalation handler exposure assessments will be needed to assess:
  - liquid pour activities in manufacturing settings,
  - spraying applications for commercial painters, and
  - machinists working with metal working fluids (MWF).
  
- ❑ Most of the inhalation exposures are expected to be short- and intermediate-term in duration. However, MWF exposures are expected to be long-term.
  
- ❑ Occupational post-application bystander exposures are expected to be minimal and an assessment is not required.

# Occupational & Residential Exposure

## Anticipated Exposure Data Needs

- ❑ Mixing/loader inhalation exposure studies for material preservation at the manufacture (i.e., liquid pour for MWF, paint, textiles, and paper making chemicals).
- ❑ Mixing/loading data are not needed if closed systems are required on labels.
- ❑ Applicator inhalation exposure studies for MWF and painters.
- ❑ Post-application study for textiles (leaching study) **if** screening level assessments using 100% leaching indicate incidental oral risks of concern.

# Ecological Effects & Environmental Fate Assessment Status

- ❑ No ecological risk or environmental fate assessments have been conducted for Busan 1024.
  
- ❑ It is anticipated that ecological risk and environmental fate assessments are needed to evaluate:
  - Impacts of industrial waste water on aquatic life in surface waters, on waste water treatment plant (WWTP) digestion organisms, and on terrestrial and aquatic organisms after passing through the WWTP; and
  
  - Impacts of oil drilling waste water on terrestrial and aquatic organisms.

# Ecological Effects & Environmental Fate

## Industrial Waste Water Discharges

- ❑ Industrial process water discharges (material preservatives, starches, and detergents) may be released into surface waters; impact waste water treatment plant (WWTP) processes; and, if persistent may pass through WWTPs into the aquatic environment in effluent or into the terrestrial environment by way of sludge disposal.
- ❑ A screening level model will be used to screen antimicrobials that have high volume usage or are persistent. Acute toxicity and environmental fate studies are needed to run the screening model.
- ❑ In the past, the Agency has used Epi-suite to predict concentrations in surface waters. However, the Agency must now refine modeling estimates to better characterize exposure for non-target and endangered species risk assessments.



# Ecological Effects & Environmental Fate

## Oil Drilling Muds and Waters

- ❑ Oil drilling muds and waters treated with Busan 1024 may expose terrestrial and aquatic species to residues at the time of drilling or when disposing of wastes.
- ❑ On land, settling ponds are used to evaporate wastes. In marine areas, direct contamination can occur during off-shore drilling.
- ❑ The Agency anticipates possibly needing a risk assessment for non-target and endangered species. However, the Agency is still in the information gathering stage to better characterize these on-shore and off-shore use patterns.
- ❑ The Department of the Interior, Minerals Management Service has addressed environmental impacts of synthetic based drilling fluids in a 2000 study for the Gulf of Mexico region. This study may be useful in evaluating these uses.

# Acute Ecological Toxicity

## Anticipated Screening Level Data Needs

- It is anticipated that one acute green algae study is needed to determine if Busan 1024 is toxic to plants. Many antimicrobial pesticides are registered to kill aquatic plants and mosses.
- It is anticipated that three acute studies (one shrimp, one oyster, and one fish) are needed to determine if Busan 1024 is toxic to these estuarine/marine aquatic animals based on the off-shore drilling use.

# Environmental Fate

## Anticipated Screening Level Data Needs

- ❑ The Agency anticipates that the following fate study is needed for all registered uses of busan 1024:
  - Hydrolysis Study- needed to understand degradation of Busan 1024 in water at various pH levels.
  
- ❑ The Agency anticipates that the following fate studies are needed for modeling industrial waste water discharges:
  - Modified Activated Sludge Respiration Inhibition- needed to determine impacts of Busan 1024 on beneficial microbes.
  
  - Activated Sludge Sorption Isotherm- needed to understand the distribution of Busan 1024 among solid, aqueous, and vapor phases; and to determine if Busan 1024 sorbs to sludge biomass.
  
  - Ready Biodegradability- needed to determine if Busan 1024 will biodegrade in aquatic environments under aerobic conditions.

# Preliminary Work Plan Timeline

Activities	Estimated Quarter/Year
<b>Phase 1: Opening the docket</b>	
Open Public Comment Period for Busan 1024 Docket	July 6, 2007
Close Public Comment Period	October 4, 2007
<b>Phase 2: Case Development</b>	
Develop Final Work Plan (FWP)	4 <sup>th</sup> Quarter 2007
Issue DCI	3 <sup>rd</sup> Quarter 2008
Data Submission	3 <sup>rd</sup> Quarter 2012
Open Public Comment Period for Preliminary Risk Assessments	4 <sup>th</sup> Quarter 2013
Close Public Comment Period	1 <sup>st</sup> Quarter 2014
<b>Phase 3: Registration Review Decision</b>	
Open Public Comment Period for Proposed Reg. Review Decision	2014
Close Public Comment Period	2014
Final Decision and Begin Post-Decision Follow-up	2014
<b>Total (years)</b>	<b>8*</b>

\*The length of time needed to complete this case is largely due to the need for chronic toxicity data.

# Question and Answer Session