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Alkyl Amine Hydrochloride Final Work Plan
Registration Review
June 2008

Approved by:

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Introduction:

This is EPA's ***Final Work Plan*** for the registration review of alkyl amine hydrochloride. The work plan includes the expected registration review time line. The work plan also addresses public comments received concerning the ***Preliminary Work Plan*** in the ***Summary Document*** which was posted in the alkyl amine hydrochloride registration review docket, or any other comments concerning initial docket postings. The ***Summary Document*** provided information on what EPA knows about the pesticide and what additional risk analyses and data or information the Agency believes are needed to make a registration review decision.

The Agency is implementing the new Registration Review program and plans to review each registered pesticide every 15 years to determine whether it continues to meet the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) standard for registration. Changes in science, public policy, and pesticide use practices will occur over time. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet that statutory standard. The public phase of registration review begins when the initial docket is opened for each case. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

Comments Received on Preliminary Work Plan:

EPA received one comment during the public comment period on the initial docket. This comment is regarding the data needs identified in the Preliminary Work Plan (PWP) and is addressed in this document. This comment has not resulted in any changes to the data needed for completing the Registration Review of alkyl amine hydrochloride. The data needs, work plan and timeline described in the Preliminary Work Plan remain as they were presented initially. Further, this document makes final the work plan for the alkyl amine hydrochloride registration review process.

Risk Assessment and Data Needs:

The Agency will conduct a human health assessment for alkyl amine hydrochloride. Additional human health data will be needed to complete this registration review. Based on the review of the four basic ecotoxicology studies for alkyl amine hydrochloride, indoor use patterns, low exposure levels, and low toxicity potential, no additional data or assessment of the ecological risks are needed for alkyl amine hydrochloride.

Human Health Risk

A Reregistration Eligibility Decision (RED) document for alkyl amine hydrochloride was issued in 1992. Occupational uses of this chemical were qualitatively assessed and residential uses were not assessed. Because of the limited nature of this risk assessment, a new human health risk assessment will need to be conducted. Based on the registered uses of alkyl amine hydrochloride as a materials preservative there is potential

for residential and occupational exposure and risk. Therefore, the Agency anticipates conducting a complete occupational and residential human health exposure risk assessment for all alkyl amine hydrochloride uses. For a detailed discussion of the anticipated human health exposure and risk assessment needs please refer to the *Summary of Human Health Effects Data for Alkyl Amine Hydrochloride (Coco Alkyl Amine Registration Review Case) Decision Document*, dated October 25, 2007.

In addition, no human health toxicity endpoints for the active ingredient alkyl amine hydrochloride have been selected. Consequently, toxicity endpoints need to be established.

Dietary Exposure

A dietary risk assessment is not needed for alkyl amine hydrochloride because it has no registered uses where it will come in direct or indirect contact with food. In addition, alkyl amine hydrochloride has no tolerances or exemptions from tolerance in raw agricultural commodities or processed food and feed products under the Federal Food, Drug and Cosmetic Act (FFDCA). The Preliminary Work Plan indicated that there may be potential for indirect food contact because there is an adhesive use for alkyl amine hydrochloride and there are no use limitations stated on either of the labels. However, the registrant indicated that alkyl amine hydrochloride is not used in this manner. As a result, product labels will be revised to prohibit alkyl amine hydrochloride use in adhesives where it will come in direct contact with food. Therefore, the dietary risk assessment is not needed.

Occupational and Residential Exposure

The alkyl amine hydrochloride RED was completed prior to the advent of the Food Quality Protection Act (FQPA) in 1996. As a result, a residential assessment was not conducted. However, a qualitative occupational assessment for alkyl amine hydrochloride was conducted and the Agency concluded that when the chemical was used with Personal Protective Equipment (PPE) as directed by the label that the occupational risks to alkyl amine hydrochloride would be minimal. Since that time the Agency has developed new exposure databases that can more accurately characterize specific antimicrobial exposures to paint, wallboard, grout, and similar products used in occupational and residential settings. For certain antimicrobial chemicals, exposures to products such as paint may lead to risk concerns for occupational and residential handlers even when PPE label restrictions are imposed and often for residential handlers as well. It is for these reasons that the Agency will now quantitatively assess risk for alkyl amine hydrochloride.

At this time the Agency anticipates that short- and intermediate-term dermal occupational assessments as well as an inhalation assessment will be needed to evaluate exposure for open situations in manufacturing settings for all material preservative uses of alkyl amine hydrochloride. In addition, short-term dermal and inhalation assessments will be needed for the residential paint use of alkyl amine hydrochloride. Because occupational and residential post-application dermal and inhalation exposures are expected to be minimal, the Agency does not anticipate performing those assessments.

Aggregate and Cumulative Exposure

Alkyl amine hydrochloride has no direct food or feed uses; therefore, aggregate exposures are not being evaluated. Because the Agency has not yet determined whether alkyl amine hydrochloride has a common mechanism with other compounds, a cumulative assessment will not be performed at this time.

Anticipated Human Health Data Needs

The Agency anticipates that the following data are needed to conduct a complete human health exposure and risk assessment for all alkyl amine hydrochloride uses. Please refer to Appendix A of the *Summary of Human Health Effects Data for Alkyl Amine Hydrochloride (Coco Alkyl Amine Registration Review Case) Decision Document* for a detailed description of the anticipated toxicity database needs and Appendix B of the same document for a detailed description of the anticipated occupational and residential applicator data needs.

Human Health Toxicity Data Needs for the AI:

- (GLN 870.3465) 90-Day Inhalation Toxicity-rat

The Agency received a comment from the American Chemistry Council questioning the need for the 90-Day Inhalation Toxicity study in the rat. This study is necessary in order to assess the risks of the short- and intermediate-term inhalation exposure routes for the paint uses. For a detailed discussion regarding the anticipated toxicological data needs, refer to the *Summary of Human Health Effects Data for Alkyl Amine Hydrochloride (Coco Alkyl Amine Registration Review Case) Decision Document, dated November 29, 2007.*

Residential Applicator Exposure Data Needs

- (GLN 875.1100) Dermal Outdoor Exposure
- (GLN 875.1200) Dermal Indoor Exposure
- (GLN 875.1300) Inhalation Outdoor Exposure
- (GLN 875.1400) Inhalation Indoor Exposure
- (GLN 875.1600) Data Reporting and Calculations
- (GLN 875.1700) Product Use Information

Occupational Applicator Exposure Data Needs

- (GLN 875.1100) Dermal Outdoor Exposure
- (GLN 875.1200) Dermal Indoor Exposure
- (GLN 875.1300) Inhalation Outdoor Exposure
- (GLN 875.1400) Inhalation Indoor Exposure
- (GLN 875.1600) Data Reporting and Calculations
- (GLN 875.1700) Product Use Information

Anticipated Physical/ Chemical Property Data Needs

All product chemistry data requirements have been fulfilled for alkyl amine hydrochloride. Therefore, no additional physical/chemical property data are needed.

Anticipated Environmental Fate Data Needs

All uses of alkyl amine hydrochloride are considered indoor uses and are not expected to result in environmental exposure. Therefore, no environmental fate data are needed.

Ecological Assessment Status and Anticipated Data Needs

Ecological risk assessments have not been conducted for alkyl amine hydrochloride since there is no exterior exposure from its indoor use. However, the Agency has reviewed four basic ecotoxicology studies for alkyl amine hydrochloride and, although some of the studies were deficient in their conduct, they were adequate to provide the Agency with sufficient information to determine appropriate label precautions. Based on its review, the Agency believes that no additional data or assessment of the ecological risks are needed for alkyl amine hydrochloride.

Based on indoor use patterns, low exposure levels, and low toxicity potential of alkyl amine hydrochloride, the Agency expects that the registered uses of alkyl amine hydrochloride will have "no effect" (NE) on endangered or threatened terrestrial or aquatic species, or their designated critical habitats as listed by the U.S. Fish and Wildlife Service (USFWS) and the National Oceanic and Atmospheric Administration (NOAA).

Timeline:

EPA has created the following estimated timeline for the completion of the alkyl amine hydrochloride registration review.

Registration Review for Alkyl Amine Hydrochloride Projected Registration Review Timeline	
Activities	**Time**
Opening Docket	
Open Docket	December 2007
Public Comment Period	March 2008
Case Development	
Final Work Plan	June 2008
Issue DCI	March 2009
Data Submission	April 2011[1]
Preliminary Risk Assessment	October 2012
Public Comment Period	January 2013
Registration Review Decision	
Proposed Registration Review Decision	April 2013
Public Comment Period	July 2013
Final Registration Review Decision & Begin Post-Decision Follow-up	2013
Total (years)	6

[1] Time-frames may change depending on the studies needed and the development and approval of the Human Studies Review Board protocols for the following studies: residential and occupational applicator dermal outdoor exposure (GLN 875.1100), dermal indoor exposure (GLN 875.1200), inhalation outdoor exposure (GLN 875.1300) and inhalation indoor exposure (GLN 875.1400).

Summary of Comments Received During Docket Opening:

The alkyl amine hydrochloride review docket was open for a 90-day comment period beginning on December 12, 2007. During that time, one comment was received from the American Chemistry Council. The comment is related to the data needs listed in the Preliminary Work Plan. For additional information, please see the comment response document titled, "EPA Response to Public Comments on Preliminary Work Plan (PWP)," dated June 17, 2008. EPA Response to Public Comments on Preliminary Work Plan (PWP)

Next Steps:

A DCI will be developed regarding the data gaps listed under the "Risk Assessment and Data Needs" section. Also, human health assessments will be conducted for all uses.