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Proposal to Conduct a General Human Health and Environmental Effects Risk Analysis on C-8

Purpose: The purpose of this project is to evaluate the risks to human health and the environment from exposure to C-8 during manufacture, transport, product use; and disposal of C-8. The analysis will be conducted in a fashion that will provide semi-quantitative estimates of risks so that exposures yielding the highest risks can be identified and recommendations on reducing these risks can be developed. Risks from manufacture, transport and product use will developed in a way that will facilitate future comparisons of risks estimated for potential C-8 alternatives. The project will be conducted in three parts. The first two will be conducted in parallel, in which human health and ecological risks will be characterized. The final part will develop conclusions on exposures that contribute the highest risks so that recommendations for risk management strategies and alternatives can be developed. The project is estimated to take 12 months to complete from the time of initiation. The Exposure analyses listed below will require collaboration with appropriate plant personnel. *(The dates presented assume a Feb. 1, 1997 SBU approval date.)*

Scope:

I. Human Health Risk

A. Hazard Identification — Time Line: 4/18/97 — Est. Cost($): 8000

Hazards to human health will be reviewed and summarized in this section. The critical toxicity endpoints of relevance to human health risk will be identified and potential dosimeters to be used for interspecies extrapolation of risk will be discussed. The Haskell toxicity summary will be updated as part of this task.

B. Dose-Response Analysis — 9/30/97 — 43,200

The dose-response characteristics of C-8 will be evaluated. This may include conducting benchmark dose analyses to identify no-observed adverse effect levels where necessary. Appropriate dosimeters for interspecies extrapolation will also be developed based on the likely mode of action. The pharmacokinetics of C-8 will also be reviewed. If possible, rudimentary physiologically-based pharmacokinetics approaches will be developed to facilitate interspecies extrapolation of risk. Risks vs. dose relationships will be developed in this phase

C. Exposure Analysis — 9/30/97 — 16,000

Reasonable exposure scenarios for C-8 will be developed. This are likely to include airborne, drinking water, dermal, and other oral ingestion pathways. Intake rates and durations of exposure will be developed. Haskell will work with an assigned person(s) from the plant site to help characterize these exposure pathways for manufacturing, transport, product use, and waste disposal operations. The business will provide Haskell with data on concentrations of C-8 in the affected media (air, water, soil). These data will be tabulated. Monte Carlo techniques may be used to calculate expected upper confidence limits for these exposures, depending the availability of data. The cost associated with this task includes only Haskell personnel time.

D. Risk Characterization — 12/15/97 — 16,000

Risks will be summarized according to the major routes of exposure (air, water, dermal, other oral) for each C-8 application (manufacture, transport, product use, disposal). The risks will be characterized by comparing the likely exposure concentrations to the dose-response relationship. This method is generally referred to as a Margin of Exposure. The characterization will provide the risk manager with

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information that will help identify the operations and exposure pathways that present the highest risk. The characterizations will also enable future comparisons to be made of potential risks posed by C-8 alternatives.

II Ecological Effects

A. Hazard Identification — Time Line — Est. Cost($)

Hazards to key environmental health indicator species will be reviewed and summarized in this section. The critical toxicity endpoints will be identified. Based on the current literature search, chronic studies in aquatic species will need to be undertaken. Avian reproduction and avian food-chain accumulation will need assessment; however this may be extrapolated using mammalian toxicology and PB-PK data and E Fate information. The Haskell toxicity summary will be updated as part of this task.

	Time Line	Est. Cost($)
1.) Hazard Assessment	9/15/97	$10,000
2.) Testing (Fish ELS and Daphnid Chronic) (This is with static renewal and analytical)	8/15/97	$80,000
3.) Avian (if needed)	8/15/97	$80,000

B. Exposure Analysis

Reasonable exposure scenarios for C-8 will be developed for the higher environmental exposure areas at the three manufacturing sites, including their respective disposal sites and a customer site. Intake rates and durations of exposure will be developed. Haskell will work with an assigned person(s) from the plant site to help characterize these exposure pathways for manufacturing, transport, product use, and waste disposal operations. The business will provide Haskell with data on concentrations of C-8 in the affected media (air, water, soil). These data will be tabulated. Monte Carlo techniques may be used to calculate expected upper confidence limits for these exposures, depending on the availability of data. The cost associated with this task includes only Haskell personnel time.

1.) Exposure Assessment - Washington Works	6/15/97	8,000
2.) Exposure Assessment - Dordrecht	8/15/97	8,000
3.) Exposure Assessment - Shimizu	9/15/97	2,000
4.) Exposure Assessment - Customer	10/15/97	2,000

D. Risk Characterization

Risks will be summarized according to the major media of environmental exposure (water, soil, air) for each C-8 application (manufacture, transport, product use, disposal). The risks will be characterized by comparing the likely Predicted Environmental Concentrations (PEC) to the Predicted No Effect Concentrations (PNEC). This method is generally referred to as Hazard Quotient. The characterization will provide the risk manager with information that will help identify the operations and exposure pathways that present the highest risk. The characterizations will also enable future comparisons to be made of potential risks posed by C-8 alternatives.

12/15/97 16,000

III. Recommendations on Risk Management Strategies and Alternatives

12/15/97 4800

This section will evaluate collectively the risks identified to human health and ecological receptors. Based on these analyses, recommendations will be made as to which operations could be targeted to ensure risks are appropriately managed in the most cost effective manner. This will be a very subjective exercise (narrative) and will require some intereaction with the appropriate people from the business.

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