



Harco



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ENVIRONMENTAL ASSESSMENT (21 CFR 25.40(a))

FCN No.: 000071

1./ Date of Preparation: 26th April 2000

2./ Name of Sponsor: Harlow Chemical Company Ltd.

3./ Address: Central Road,
Templefields,
Harlow,
CM20 2BH,
UK.

4./ Description of the Proposed Action: Use of crotonic acid as a monomer in the preparation of polymeric stabilizers for use in the production of polyvinyl chloride.

Vinyl acetate monomer is copolymerized with crotonic acid, the latter at a maximum level of 2% on total monomer charge, weight on weight, which is then saponified using the standard industrial procedures to a partially hydrolysed polyvinyl alcohol, the stabilizer.

These stabilizers are typically present at no more than 0.05% by weight on the total polymerisation charge in the polyvinyl chloride reactor.

As these newly developed stabilizers are water-soluble they can be supplied as virtually methanol free solutions, where typically there was a need for aqueous methanol solutions with up to 5% methanol. Also, these stabilizers can now be supplied at the optimal hydrolysis level for easy removal of the unreacted vinyl chloride monomer in the final stripping stage in PVC production as well as improving its processability.

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a) Production of the Food Contact Substance: No extraordinary circumstances apply to the manufacture of the food contact substance

b) Use and Disposal of the Food Contact Substance: This action involves a food-contact substance that is a minor component of the finished food-packaging materials typically present at 22ppb by weight of the finished packaging material and remains with the packaging through its use by consumers. The principal routes of environmental introduction of the food contact substance will result from its disposal in municipal solid waste combustors or in landfills. These disposal routes are governed by Environmental Protection Agency (EPA) regulations in 40 CFR part 60 (for combustors) and part 258 (for landfills). Based on the low levels of the food contact substance in the packaging material, introduction of combustion products or introductions at landfill sites are not environmentally significant. Therefore, we do not expect that any limited increase in environmental introductions resulting from the proposed action will threaten a violation of the EPA regulations governing combustors and landfills or have any other adverse environmental effect.

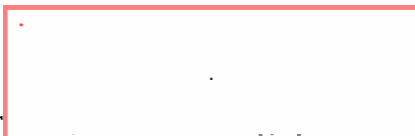
Alternatives to the proposed action need not be considered, because no potential adverse effects have been identified.

Preparer

Robert Jeremy Mallerman
Analytical Services Manager
BSc. (Hons) Chemistry, MSc. Management of Intellectual Property and Science.

The undersigned official certifies that the information presented is true, accurate, and complete to the best knowledge of Harlow Chemical Company Ltd.

2nd May 2000
Date



Signature



DR. S. ORMONDROYD
Name and title of responsible official

TECHNICAL MANAGER