EN

ENVIRONMENTAL ASSESSMENT FOR FCN 359

1. *Date*: August 2003 Revised October 2003

2. *Name of Applicant*: 3V Inc.

3. *Address*: Mail: PO Box 2810 Georgetown, SC 29442
Physical: 888 Woodstock Street Georgetown, SC 29440

4. *Description of the proposed action*:

a. Requested action: Food contact notification FCN 359 – Everclean 104NS. The FCS is a spray on antifouling agent for PVC autoclaves

b. Need for action: Everclean 104 NS is intended for use as a coating of the walls of reactors used in the polymerization of vinyl chloride, or other vinyl monomers. The coating acts as an anti-foulant, and is classified as a phenolic resin. Antifouling is achieved as the FCS adheres to the reactor wall surfaces and functions as a local radical inhibitor.

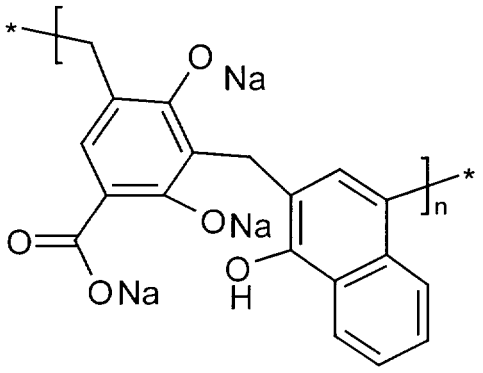
c. Locations of use disposal: The FCS will be produced in Italy. It will be imported by 3V Inc. and distributed to US customers from the Georgetown facility. The product will be used by PVC manufacturers throughout the United States the majority of which are located on the Gulf Coast. The FCS will also be disposed of as a component of food packaging material in landfills and municipal incinerators or waste to energy facilities throughout the United States However, the concentration of the FCS in food packaging materials will not exceed 6 ppm.

5. *Identification of the chemical substance that is the subject of the EA*:

a. Complete nomenclature: Benzoic acid, 2,4-dihydroxy-, polymer with formaldehyde and 1-naphthalenol, sodium salt (CAS); Benzoic acid, 3-[[[[[5-carboxy-3-[[[[[5-carboxy-2,4-dihydroxy-3-[(1-naphthalenyloxy)methyl]phenyl]methoxy]naphthalenyl]oxy]methyl]-2,4-dihydroxyphenyl] methoxy] naphthalenyl]oxy]methyl]-5-[[[[[3-carboxy-2,6-dihydroxy-5-[(1-naphthalenyloxy)methyl]phenyl] methoxy]naphthaleneyl]oxy]methyl/]-2,4-dihydroxy- (IUPAC)

b. Molecular weight (Mw): 1074 Daltons

c. Structural formula:



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d. Physical description: Clear brown liquid

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***6. Introduction of substances into the environment*:**

a. Introduction of substances into the environment as a result of manufacture: To the best of our knowledge, no extraordinary circumstances pertain to the manufacture of the food contact substance.

b. Introduction of substances into the environment as a result of use/disposal: The predominant mode of introduction of the FCS into the environment is from the treatment of waste water from PVC production facilities.

1. The amount of FCS that is expected to be used by PVC manufacturing facilities in the US is considered confidential. This information has been provided in Attachment 9 of the FCN.
2. The percentage of that which is expected to be released into waste water streams is considered confidential. This information has been provided in Attachment 9 of the FCN.
3. PVC manufacturing is conducted in batch processes. Given that multiple batch reactor systems are located at PVC manufacturing facilities and that waste equalization is used prior to waste water treatment processes, releases to the environment are expected to be on a continuous basis.
4. The concentration of the FCS in waste water discharged to the treatment facility (EIC) is expected to be 2 mg/L.
5. Attached in Attachment A is an MSDS for the FCS formulated product Everclean 104NS.

7. Fate of emitted substances in the environment: An analysis based upon PVC production capacity, FCS use rates, waste water discharge rates and receiving stream dilution was completed for all known potential US customers to determine in-stream concentrations of the FCS Attached in Attachment 9 of the FCN is a spread sheet which lists each facility considered in the analysis and the resulting in stream concentration for the corresponding receiving stream. Based on this information the range of the expected environmental concentration is 0 01 to 40 ppb depending on the location of the treatment facilities discharge.

8. Environmental effects of released substances: Attached in Attachment B is a copy of an Algal toxicity study for the FCS. This study demonstrated a NOEC of 8 mg/L for the FCS. The expected concentration in effluent containing the FCS is 2.0 mg/L. The in-stream concentrations as seen in the spread sheet attached in Attachment 9 of the FCN are considerably less ranging from less than 0.01 ppb to 40 ppb. The US Environmental Protection Agency reviewed the fate and effects data during a Pre-Manufacture Notification review process and concluded that no adverse effects would result from this use.

9. Use of resources and energy: The FCS will be used as a substitute for an existing, FDA approved release agent which is identified in 21 CFR 178.3860 as Formaldehyde, polymer with 1-naphthalenol. Wastes associated with the use of the product include waste water discharges as described above as well as empty container management. The number of containers expected to be generated on annual basis is 55 - 55 gallon containers. These will likely be sent to a drum recycler and reused as recycled drums for other products.

10. Mitigation measures: No potential adverse environmental impacts have been identified for the proposed action therefore; mitigation measures need not be discussed.

11. Alternatives to proposed action: No potential adverse environmental impacts have been identified for the proposed action therefore; alternatives to the proposed action need not be discussed.

12. *List of preparers:* John Schroer, 3V Inc., MS, PE Chemical Engineer, 20 years experience in the chemical industry involved in environmental permitting and compliance issues.

13. Certification: The undersigned official certifies that the information presented is true, accurate and complete to the best of the knowledge of 3V Inc.

Date: 10/08/03

Signatu[redacted]

John Centioni - Executive Vice President Technical Affairs

14. References: NA

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15. Attachments: A. Material safety data sheet for Everclean 104NS
B. Effect of the active ingredient of Everclean 104NS on the growth of green alga

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