EN

Environmental Assessment

for a Premarket Notification for Polyvinylimidazole

1. **Date**: 15 December 2000

2. **Name of sponsor**: (1) Gordon Burns and (2) Robert Ellsworth

3. **Address**: (1) 899 Adams Street, Suite A, St. Helena, CA 94574
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4. **Description of the proposed action**

a) **Requested action**: Seeking FDA approval for use of the subject food-contact substance, polyvinylimidazole ("PVI"), in filter pads to be used for the reduction of metals and sulfides in alcoholic beverages.

b) **Need for action**: Elevated metal content in alcoholic beverages presents a difficult problem in their reduction to acceptable levels. Filter pads containing PVI accomplish this. Sulfide off characters in alcoholic beverages can also be reduced to acceptable levels with the use of specially prepared PVI filter pads.

c) **Locations of use**: PVI will be incorporated into filter pads that will be used at alcoholic beverage production facilities at various locations around the country.

d) **Locations of disposal**: We expect that used filter pads, containing minute quantities of PVI, will be disposed of along with municipal solid waste, i.e., deposited in municipal solid waste landfills or combusted along with municipal solid waste.

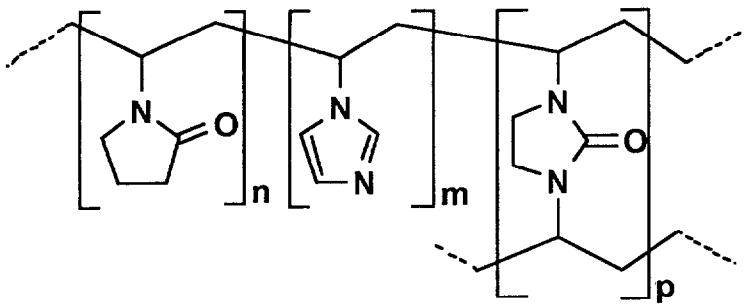
5. **Identification of substances that are the subject of the proposed action**

Described below are the polymer and its four ingredients.

Polyvinylimidazole

Empirical formula: $(C_6H_9NO)_n(C_5H_6N_2)_m(C_7H_{10}N_2O)_p$

Structural formula:



Molecular mass:	Cannot be determined due to the insolubility in all solvents.		
Appearance:	white to off-white powder		
Specifications:	Loss on drying (1h, 140°C, vacuum)	≤ 5 %	
		26.0 – 29.0	
		≤ 2.0 mg/kg	
		≤ 1.0 mg/kg	
		≤ 1.0 mg/kg	
		≤ 1.0 mg/kg	
		≤ 10.0 mg/kg	
		≤ 0.02 %	
		≤ 0.5 %	
		≤ 1.0 %	
	1-Vinylpyrrolidone (GC)	≤ 10.0 mg/kg	
	1-Vinylimidazole (HPLC)	≤ 10.0 mg/kg	
	1,3-Divinylimidazolidinone (GC)	≤ 2.0 mg/kg	
		≤ 50.0 mg/kg	
		≤ 50.0 mg/kg	

Chemical name:

- Crosslinked terpolymer of 1-vinylimidazole, 1-vinylpyrrolidone and 1,3-divinylimidazolidinone

List of ingredients / specifications:

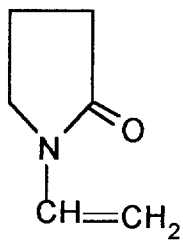
1-Vinylpyrrolidone

1-Vinylimidazole

1,3-Divinylimidazolidinone

1-Vinylpyrrolidone

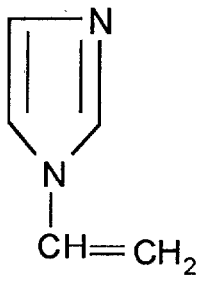
Formula: C_6H_9NO



Molecular weight:	111.14	
Description:	Colorless liquid	
Specification:	Assay	> 99.5 %
	Impurities	
	(= Pyrrolidone and others)	< 0.5 %
	Water	< 0.1 %
	Melting point	13.5-14.0 °C
	Polymer content	< 0.05 %

1-Vinylimidazole

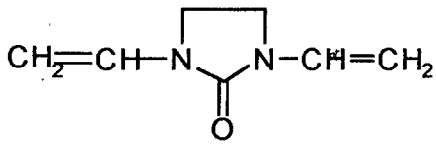
Formula: $C_5H_6N_2$



Molecular weight:	94.12	
Description:	Colorless to yellowish liquid	
Specification:	Assay	> 99.5 %
	Impurities:	
	Imidazole	< 0.3 %
	Pyrrolidone	< 0.2 %

1,3-Divinylimidazolidinone

Formula

$C_7H_{10}N_2O$ 

Molecular weight	138.2	
Appearance	white to yellowish powder	
Specification	Assay	≥ 99 %
	Melting point	66-68 °C

Formula

Molecular weight

Appearance

Specification

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

a) **Introduction of substances into the environment as a result of manufacture**: No extraordinary circumstances apply to the manufacture of the food-contact substance.

b) **Introduction of substances into the environment as a result of use**: Little or no introduction of PVI into the environment will result from its use because this food-contact substance is almost completely incorporated into food-contact filter pads and essentially all of it is expected to remain with these pads throughout their use.

c) **Introduction of substances into the environment as a result of disposals**: The filter pads containing the PVI are expected to be disposed of in municipal solid waste landfills and/or incinerators after use. With regard to landfilling, we expect insignificant levels of the substances to migrate from the filter pads in landfills because (1) migration studies previously submitted to FDA (our original petition dated April 9, 1999 and the attached Exhibit E.) show insignificant migration potential; (2) the concentration of the PVI substance in the filter pads is minimal; and (3) PVI is highly insoluble. In addition, the introduction of these substances into the environment will not threaten a violation of the Environment Protection Agency's regulations in 40 CFR Part 258 that pertain to landfills. With regard to combustion, PVI is composed of carbon, hydrogen and nitrogen, elements commonly found in municipal solid waste.[1] The complete combustion of this substance will produce carbon dioxide, water and oxides of nitrogen. Because the market volume [2] of the

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[1] *Municipal Waste Combustors - Background Information for Proposed Guidelines for Existing Facilities,* EPA-450/3-89-27e, United States Environment Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, NC 27711; August 1989; Table 2.2-1.

[2] Wine production in the USA is approximately 500,000,000 gallons per year. See Attached Key Facts Chart. Since wine production has remained static for the past several years, we make the assumption that this estimate is based on total fifth year production. It is estimated that approximately one percent of this volume may be treated for sulfide removal using the filter pads. Based on calculations in paragraph 9, scenario #3, approximately 6.9 pounds of PVI would treat 50,000 gallons, and thus annual PVI usage would be approximately 690 pounds. This volume is inconsequential when compared with the volume of solid waste generated and disposed of in the United States.

food-contact substance is a very small fraction of the municipal solid waste generated and disposed in the United States, adding this substance to waste that is combusted will not significantly alter the emissions from municipal waste combustors. Because of the low levels of the combustion products compared to the amounts currently generated by municipal waste combustors, we do not expect that the combustion of this substance will cause municipal waste combustors to threaten a violation of applicable federal and state emissions laws and regulations.

7. **Fate of substances released onto the environment**: No information need be provided on the fate of substances released into the environment as the result of use and/or disposal the filter sheets with PVI, because, as discussed above, only minute quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of the filter pads. Therefore, the use and disposal of the food-contact substance is not expected to threaten a violation of applicable laws and regulations, *e.g.*, the Environmental Protection Agency's regulations in 40 CFR Parts 60 and 258.

8. **Environmental effects of released substances**: No information need be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of the filter pads, because, as discussed under Item 6 above, only minute quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of the filter pads. Therefore, the use and disposal of the filter pads is not expected to threaten a violation of applicable laws and regulations, *e.g.*, the Environmental Protection Agency's regulations in 40 CRF Parts 60 and 258.

9. **Use of Resources**: The filter pads containing PVI are intended to replace current wine treatment activities (some of which use ferrocyanide) that are less protective of the environment. Thus, there is no anticipated effect on the use of natural resources and energy associated with proposed substitute.

Current wine treatment activities, based upon 50,000 gallon batches, are as shown below.

CURRENT FILTER PAD PRODUCTION METHODS

An aqueous slurry, composed of 40 to 60% diatomaceous earth (DE), 1 to 2 % resin binder, and the balance of cellulose fibers, is distributed across a moving vacuum belt, which dewaters the slurry forming a continuous sheet, often 48 to 50 inches wide, of moist material. The machine is usually a modified paper making machine. This continuous sheet is then dried in a forced air counterflow oven. After drying, a high pressure water jet, cuts to size individual sheets.

The grade or tightness of the filter pad is dependent upon the type and proportions of DE and type and proportions of cellulose fibers.

The Cellulo Company of Fresno, California uses about 640 tons of DE per year, and about

560 tons of cellulose per year. They estimate that they have between 20 to 30% of the filter pad market in the USA.

40 cm by 40 cm filter sheets weigh between 0.4 and 0.7 pounds each, depending on the composition, the higher the DE percentage the greater the weight.

ROUTINE WINE FILTRATION METHODS FOR CLARIFICATION AND MICROBIAL STABILITY

Scenario #1, a typical winery filtration of 50,000 gallons of wine from the fermenter to the bottle, using 40 cm by 40 cm filter pads:

1st filtration (coarse or clarifying). The expected flow rates are between 36 and 48 gallons per hour per pad and the expected run time would be 5 hours to exhaustion. This calculates to an average of 210 gallons per pad and a requirement of 238 filter pads.

2nd filtration (bright). The expected flow rates are between 24 and 36 gallons per hour per pad and an expected run time of 6 hours to exhaustion. This produces an average of 180 gallons per pad and a requirement of 278 pads.

3rd filtration (polish). The expected flow rates are between 13 and 19 gallons per hour per pad and an expected run time of 8 hours to exhaustion. This produces an average of 128 gallons per pad and a requirement of 391 pads.

For the life of this 50,000 gallon batch of wine, the filtrations will have consumed 906 filter pads. Each filter pad contained (on average) 0.27 pounds of DE and 0.27 pounds of cellulose fibers. Each batch of wine would consume 244 pounds of DE and 244 pounds of cellulose fibers.

In the production of 50,000 gallons of wine (approximately 400,000 pounds), the consumed filtering material amounts to about 0.12% by weight of the wine

While the above example is based on 50,000 gallons of wine, smaller or larger quantities would be roughly proportional in filtration requirements.

COMPARISON OF CURRENTLY APPROVED METHODS FOR REMOVAL OF SULFIDES AND METALS WITH THE PROPOSED PVI PAD METHOD

Scenario #2. The currently approved method for the removal of sulfides and metal from alcoholic beverages.

For the reduction of sulfides in alcoholic beverages, copper sulfate is added up to levels of 3.9 ppm, then the beverage is treated with a ferrocyanide compound, Cufex, in amounts of 1

to 10 pounds per 1000 gallons. The wine must then carefully filtered to remove any traces of ferrocyanide.

The first filtration to remove Cufex would be done with the same grade of filter pad as the 2nd filtration in Scenario #1 above. Both the flow rate would and the run time would be reduced considerably due to the high loading caused by the Cufex. We would expect to filter approximately 60 gallons per pad.

For the 50,000 gallon batch of wine, with an addition of 5 pounds per 1000 gallons of Cufex, 833 pads would be required for this filtration.

250 pounds of a ferrocyanide compound would be discarded along with about 226 pounds of DE and 226 pounds of cellulose fibers.

Scenario #3. Proposed use of PVI filter pads for the reduction of sulfides in wine.

The threshold of organoleptic detection is in the range of 1.0 to 1.5 ppb. A wine with 3.0 ppb of sulfide can be reduced to less than 1.0 ppb with PVI pads at about 900 gallons per pad to exhaustion. A 40% PVI filter pad eights 170 grams. The 56 pads required to process the 50,000 gallon batch of wine would use approximately 6.9 pounds of the PVI polymer and 10.4 pounds of cellulose fibers.

10. **Mitigation measures**: Based on a review of adequate data and information, no adverse environmental effects have been identified, so mitigation measures are inappropriate.

11. **Alternatives to the proposed action**: Based on a review of adequate data and information, no adverse environmental effects have been identified. Furthermore, as discussed in Item 9 above, the proposed use of PVI will minimize environmental impacts when compared to the current metal and sulfide reduction methods which employ a ferrocyanide compound.

12. **List of preparers**: Robert Ellsworth, Consulting Chemist, St. Helena, CA

Gordon Burns, Technical Director, E T S Laboratories, St. Helena, CA

13. **Certificate**: "The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the preparers"

8 March 01

(Signature of preparer)

Gordon Burns

(Name and title of preparer, printed)

(Signature of preparer)

Robert M. Ellsworth

(Name and title of preparer, printed)

14. **Attachments:** Key Facts Chart