Part IV – Environmental Impact of Food Contact Substance (21 CFR part 25)

B. Environmental Assessment

1. **Date:** July 24, 2007

2. **Name of Notifier:** Alco Chemical, A National Starch & Chemical Company

3. **Address:** 909 Mueller Avenue, Chattanooga, TN 37406

4. **Description of the proposed action:**

Requested Action:
It is proposed that the use of 2-Propenoic acid, homopolymer, sodium salt (with a weight average molecular weight of 2300 to 5700 Daltons and a weight average molecular weight to number average molecular weight ratio of not more that 6.3), be allowed

Need for Action:
The food contact substance (FCS) will be used to control the mineral scale formed during the evaporation of beet or cane sugar juice liquor, at an addition rate not to exceed 3.6 µg/g (ppm) of active sodium polyacrylate to the sugar juice liquor, in compliance with 21 CFR 173 73 (with the exceptions of subparagraphs (a)(1) and (a)(2)

Location of Use:
This product would be manufactured in the United States The polymer used by Alco Chemical customers will be used in the processing of beet and cane sugar at production sites located throughout the United States The resultant sugar and sugar by-products are expected to be distributed widely across the country in patterns corresponding to national population density.

Location of Disposal:
Disposal of the food contact substance (FCS) would be part of the waste material that is typically generated by the sugar processing industry It is expected to occur nationwide with the FCS ultimately being deposited in municipal solid waste landfills or combusted as a result of the disposal of sugar processing waste

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

CAS Name: 2-Propenoic acid, homopolymer, sodium salt

CAS Registry Number: 9003-04-7

Physical Description:
The neat FCS is a clear, colorless liquid with a faint acrylic odor It is non-flammable and stable to light and heat

Impurities:
This information is contained on page 5 of the FDA form 3480 form Only very low amounts of the impurities are present Typical analysis of the food contact substance shows the levels for these impurities to be around 0.07% These impurities are completely soluble in water and will steam-distill during sugar evaporation and become incorporated into the condensate water which is recycled to extract the maximum amount of sugar

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

a Introduction of the substances into the environment as a result of manufacture

This product shall be manufactured in the United States All components used to manufacture the product are incorporated into the final product as sold. The manufacturing site where the product is produced is in compliance will all Federal, State and local emission and discharge requirements

b. Introduction of the substances into the environment as a result of use:

There will be little or no introduction of the food contact substance (FCS) as a result of its use in sugar processing This is based on the FDA's environmental decisions for FAP 3A 3699 which is based on the experimental data provided in FAP 3A 1019 This FCS would behave in a similar way with the substances found in the two Food Additive Petitions listed above. Based on this information, we believe that the FCS will become a component of the aqueous phase of the molasses produced during sugar processing and refining This molasses, commonly referred to as "blackstrap molasses" is primarily used as a supplement in cattle feed Much of the molasses produced in the world is used in this fashion and is an important part of feed providing up 2,000 Kcals/kg of metabolisable energy When molasses is used in animal feed, it may be included in amounts up to 20% but normally averages around 15% (Tate & Lyle Website) According to an article titled "Molasses – General Considerations" by Dr. Leo V Curtain, see attachment A to this document, 81% of the molasses used in the U S was consumed in the mixed feeds and direct feeding industry Therefore, we conclude that after the 0 2% of the FCS contained in the final sugar is accounted for, the remaining 99 8% (3 6 ppm) of the FCS that remains in the aqueous phase of the molasses shall be concentrated 8 times (per reference to FAP 3A 3699, Dr Joseph Polack) resulting in a 28 8 ppm residual of the FCS in the molasses. According to the information found in FAP 3A 3699, the maximum amount of FCS that could be found in animal feed would be 3 5 ppm (28 8 ppm x 12%) or assuming the worst case, 5 76 ppm (28.8 ppm x 20%). Data found in the FONSI for FAP 3A 3699 showed that the maximum concentration of the FCS found in the excrement of beef cattle was estimated to be 14 4 ppm, the concentration of the FCS found in run-off from the feedlot was estimated to be 2.4 ppm and the concentration of the FCS found in agricultural soil was estimated to be 68 ppb, all relatively low numbers for a substance with a low toxicity Since the FCS in question here is chemically identical to FCN 554 and FAP 3A 3699, there will be no net gain in the release of this substance to the environment

c Introduction of the substances into the environment as a result of disposal

i Landfills:
The process used in the refining of sugar generates very little waste that would find its way to a landfill, therefore, only low levels of the FCS are expected to be present in landfills Even if a very small amount of the FCS is present in landfills, we expect extremely low levels will ever enter the environment. This finding is based on the Environmental Protection Agency's regulations governing municipal solid waste landfills Additionally, introduction of the FCS into the environment will not threaten a violation of the Environmental Protection Agency's regulations found at 40 CFR 258 (Criteria for municipal solid waste landfills)

ii Combustion
The FCS is composed of carbon, hydrogen, sodium and oxygen, which are elements commonly found in municipal solid waste The complete combustion of the FCS in a properly functioning incinerator will only produce carbon dioxide and water Since the market volume of the FCS is a minute fraction of the municipal solid waste generated and disposed of in the United States, adding the FCS to the waste that is combusted will not significantly alter the emissions from municipal waste combustion The nature of the combustion products and their low levels when compared to the amount currently generated by municipal waste combustors leads us to believe that the combustion products from the incineration of the FCS will not cause a violation of applicable emission laws and regulations

7. **Fate of substances released into the environment:**

Since the FCS in question here is chemically identical to FCN 554 and FAP 3A 3699, there will be no net gain in the release of this substance to the environment Additionally, the fate of this substance is well documented in FCN 554 and FAP 3A 3699 Therefore, the use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, i e 40 CFR 60 (Standards of performance for new stationary sources) and 258 (Criteria for municipal solid waste landfills)

8. **Environmental effects of released substances:**

Since the FCS in question here is chemically identical to FCN 554 and FAP 3A 3699, there will be no net gain in the release of this substance to the environment Additionally, the environmental effects of this substance is well documented in FCN 554 and FAP 3A 3699. Therefore, the use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, i e 40 CFR 60 (Standards of performance for new stationary sources) and 258 (Criteria for municipal solid waste landfills).

9. **Use of resources and energy:**

This item does not ordinarily require documentation because the FCS is intended for the use as other commercial grades of sodium polyacrylates already in use made by manufacturers such as

Ciba Specialty Chemicals Corporation
Cytec Industries Inc
Houghton Chemical Corporation
Arkema Inc

In response to the claims found in US Patent 6506258 that this FCS shall interfere with the use of the molasses as a feedstock for the production of secondary products (alcohol, citric acid), we claim that there are mechanisms already in place that have negated this effect It is known that by-products produced during the fermentation process can effect the rate of fermentation, but as discussed in article titled "By-product inhibition effects on ethanolic fermentation by *Saccharomyces cerevisiae,*" found in Volume 25, Issue 1 of the Journal "Biotechnology and Bioengineering", mechanisms have been discussed and implemented to prevent this inhibition Furthermore, the total amount of molasses used in these types of industries only accounts for 15% of the U.S molasses supply according to the article titled "Molasses – General Considerations" by Dr Leo V. Curtain. The substance proposed in US Patent 6506258 has been around since 2000 and has not made a significant impact on the ant-scalent market, which could be due to the cost of the substance or other reasons. This FCS does not require any more use of energy or resources than FCN 554 or FAP 3A 3699, nor does it impose any new uses of energy or resources that have not been accounted for in the two submissions listed above

10. **Mitigation measures:**

Based upon our review of adequate and complete data and information we have identified no adverse environmental effects

11. **Alternatives to the proposed action:**

Based upon our review of adequate and complete data and information we have identified no adverse environmental effects

12. **Preparer:**

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13. Certification:

The undersigned certifies that the information presented is true, accurate and complete to the best of my knowledge.

Allen Carrier, Ph D

21 July 2007
Date