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

B. Environmental Assessment

This environmental assessment has been prepared in accordance with 21 CFR 25.40

- 1) Date: May 21, 2003
- 2) Name of notifier: **Technical Absorbents, Ltd.**
- 3) Address: PO Box 34
Great Coates
Grimsby, UK
DN31 2SS

4) Description of the proposed action:

Requested action:

It is proposed that the use of 2-propenoic acid, 2-methyl,-monoester with 1,2-propanediol, polymer with methyl 2-propenoate, 2-propenoic acid and sodium 2-propenoate, as a fluid absorbent in food-contact materials used with produce (fruit and vegetables), be allowed.

Need for action:

The absorbent pads would be used in the packaging of produce, which is either refrigerated or frozen until used. This product, marketed commercially as Oasis Fiber Superabsorbent, is a highly effective at retaining fluid, leading to better food hygiene in transport, and retail display.

Location of use:

This product will not be manufactured in the United States. The superabsorbent fiber will be incorporated into food contact materials at food-packaging production sites located throughout the United States. The FCS is 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) 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 the absorbent pads.

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

CAS Name:

000030

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2-Propenoic acid, 2-methyl-,monoester with 1,2-propanediol, polymer with methyl 2-propenoate, 2-propenoic acid and sodium 2-propenoate

CAS Registry Number:
117675-55-5

Molecular weight distribution:

Mw = 376,000 (RSD = 0.4%)
Mn = 50,200 (RSD = 12.8%)

Structural formula:

This information can be found on page 12 of the FCN 000098, in a confidential section.

Physical description:

This product has the appearance and handling characteristics of a textile fiber. It is white, odorless and has a chemistry similar to widely used granular superabsorbents. It is non-flammable and stable to light and heat.

Impurities:

This information is contained on page 17 in a confidential section of FCN 000098. Only very low amounts of these chemicals will be expected to enter the environment as a result of this action.

6) Introduction of substances into the environment:

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

This product will not be manufactured in the United States. No extraordinary circumstances apply to the manufacture of the FCS.

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

Little or no introduction of superabsorbent fiber will result from its use because this substance is almost completely incorporated into the absorbent pads and essentially all of it is expected to remain with these materials throughout the use of the pads.

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

i) Landfills:

Based on the migration studies on meat soaker pads containing the superabsorbent fiber that were performed to demonstrate its safety, only very low levels of the FCS are expected to leach from these materials in landfills. Moreover, even if a very small amount of the FCS migrates from the food packaging in landfills, we expect extremely low quantities to actually enter the environment; this finding is based on the

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Environmental Protection Agency's (EPA's) regulations governing municipal solid waste landfills. In addition, introducing these substances into the environment will not threaten a violation of the Environmental Protection Agency's (EPA) regulations in 40 CFR part 258 that pertain to landfills.

ii) Combustion:

The superabsorbent fiber is composed of carbon, hydrogen and oxygen, elements commonly found in municipal solid waste. The complete combustion of this FCS in a properly functioning incinerator will produce only carbon dioxide and water. Because the market volume of the FCS is a small fraction of the municipal solid waste generated and disposed in the United States, adding the FCS to waste that is combusted will not alter significantly the emissions from municipal waste combustors. Because of the nature of the combustion products and their low levels compared to the amounts currently generated by municipal waste combustors, we do not expect that the combustion products from incineration of the soaker pads containing the superabsorbent fiber will cause a violation of applicable emissions laws and regulations.

7) Fate of substances released into the environment:

No information need be provided on the fate of substances released into the environment as the result of use and disposal of superabsorbent fiber, because only small quantities of substances, if any, will be introduced into the environment from its use and disposal. Therefore, the use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, e.g., EPA'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 superabsorbent fiber, because only small quantities, if any, of substances will be introduced into the environment as a result of the use and disposal of this product. Therefore, the use and disposal of the FCS is not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR parts 60 and 258.

9) Use of resources and energy

This item does not ordinarily require documentation because the proposed superabsorbent polymers is intended for the same use as other superabsorbent polymers already in use, primarily:

- 2-propenoic acid, polymers with N,N-di-2-propenyl-2-propen-1-amine and hydrolyzed polyvinyl acetate, sodium salts, graft
- Trade Name: FAVOR PAC 100
Manufactured by Stockhausen

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- 2-propenoic acid, polymer with 2-ethyl-2-(((1-oxo-2-propenyl)oxy)methyl)-1,3-propanediyl di-2-propenoate and sodium 2-propenoate
Manufactured by Japan Vilene Co., Inc

This fiber will not materially change the potential uses of the absorbent pads to which it is added.

10) Mitigation measures:

We identify no adverse environmental effects, based upon our review of adequate and complete data and information.

11) Alternatives to the proposed action:

We identify no adverse environmental effects, based upon our review of adequate and complete data and information.

12) List of Preparer : Naeem Mady
 Head, Regulatory Affairs
 Additives Division
 Ciba Specialty Chemicals Corporation

Mr. Mady has over twenty years experience in the preparation and prosecution of food-contact submissions. He has prepared, compiled and reviewed this petition on behalf of the petitioner, Ciba Specialty Chemicals Corporation.

13) Certification:

The undersigned certifies that the information presented is true, accurate and complete to the best of the knowledge of Ciba Specialty Chemicals Corporation.

May 21, 2003



Naeem Mady
Ciba Specialty Chemicals Corporation