ENVIRONMENTAL ASSESSMENT

1. **Date:** May 30, 2006

2. **Name of Applicant:** DuPont Chemical Solutions Enterprise

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4. **Description of the Proposed Action**

The action requested in this submission is the notification of the use of copolymers produced by the polymerization of 2-(perfluoroalkyl)ethyl acrylate, 2-N,N-diethylaminoethyl methacrylate, glycidyl methacrylate, methacrylic acid, and acrylic acid. The developmental name of the water-based dispersed copolymer is [redacted], and this name is used in this Environmental Assessment (EA); the dry copolymer is referred to as the "[redacted] copolymer" or "copolymer" in this EA. The subject fluorinated copolymers are intended for use as additives in paper and paperboard that may contact all types of food under Conditions of Use B through H. The copolymers are intended to function as oil and grease resistant treatments. In such applications, the copolymers are intended for use at levels not to exceed 0.37 wt. % of fluorine based on paper; because the fluorine content of the copolymer is 53.6 +/- 3 wt. %, the intended use level is 0.69 +/- 0.01 wt. % of [redacted] copolymer based on paper.

DuPont does not manufacture the paper and paperboard that will use [redacted] as an oil and grease resistant treatment. Rather, DuPont plans to market [redacted] to manufacturers who will, in turn, use the product as an oil and grease resistant treatment in the manufacture of paper and paperboard.

[redacted] will be sold to manufacturers who will add the treatment in both the size press and wet end of the manufacturing process of food-contact paper and paperboard. With respect to the size press, no environmental effects are expected because [redacted] remains fully with the treated paper. Therefore, in keeping with guidance received from the FDA environmental review staff, this EA discusses the use of [redacted] in the wet-end of paper production only.

As discussed more fully below, it is expected that the great majority of the [redacted] copolymer will be incorporated into, and remain a component of, the finished paper and paperboard. To the extent that a fraction of the [redacted] copolymer does not become incorporated into the paper, it is expected that most of the remaining copolymer will be present as a component of the solid wastes generated in the waste water treatment process. These wastes are expected to be disposed of by either landfill or incineration. Only very low levels of the [redacted] copolymer are expected to be present in effluent from the on-site waste water treatment facility. Aquatic toxicity data provided herewith indicate a wide margin of safety relative to the estimated release concentrations.

Food-contact articles made with paper containing [redacted] will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide, with about 80% of the materials ultimately being deposited in land disposal sites, and about 20% incinerated.[1] The types of environments present at and adjacent to the disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared using [redacted]

5. **Identification of Chemical Substance that is the Subject of the Proposed Action**

Chemical Name:	Copolymer of 2-(perfluoroalkyl)ethyl acrylate, 2-N,N-diethylaminoethyl methacrylate, glycidyl methacrylate, methacrylic acid, and acrylic acid.
Common or Trade Name:	[redacted]
CAS Registry Number:	870465-08-0
CAS Registry Name:	2-Propenoic acid, 2-methyl-, polymer with 2-(diethylamino)ethyl 2-methyl-2-propenoate, .alpha.-fluoro-.omega.-[2-[(1-oxo-2-propenyl)oxy]ethyl]poly(difluoromethylene), oxiranylmethyl 2-methyl-2-propenoate and 2-propenoic acid

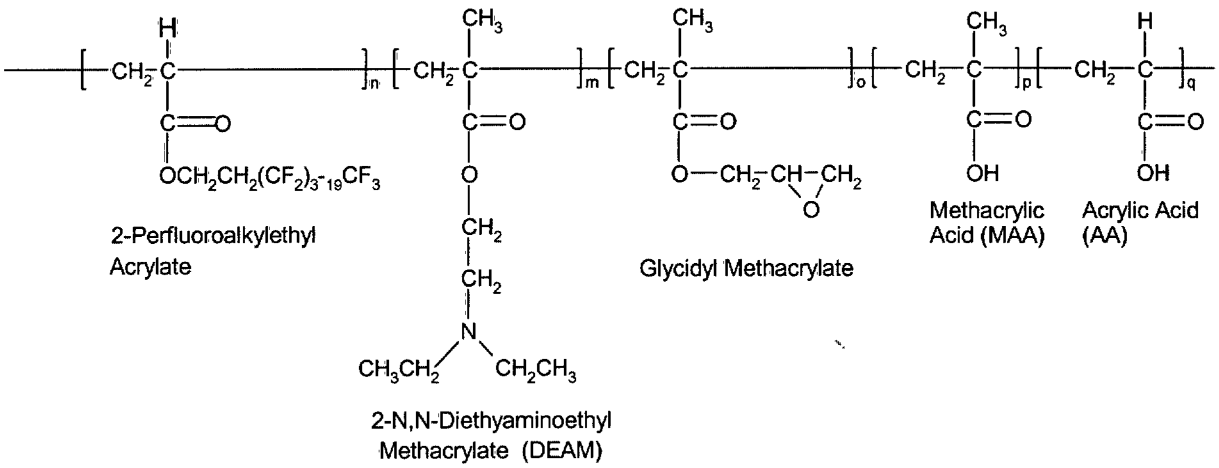
The starting monomers are identified in the following table:

CAS Registry Number	CAS Name
65605-70-1	2-(perfluoroalkyl)ethyl acrylate
105-16-8	2-propenoic acid, 2-methyl-, 2-(diethylamino)ethyl ester
106-91-2	glycidyl methacrylate
79-41-4	methacrylic acid
79-10-7	acrylic acid

1 "Characterization of Municipal Solid Waste in the United States, 1994 Update," EPA/530-S-94-042, U.S. Environmental Protection Agency, Washington, D.C. 20460.

The molecular formula for [redacted] copolymer is: $(C_{9\text{-}25}H_7O_2F_{9\text{-}41})_n$ $(C_{10}H_{19}O_2N)_m$ $(C_7H_{10}O_3)_o(C_5H_8O_2)_p(C_3H_4O_2)_r$.

The structural formula for [redacted] copolymer is given below:



The structural diagram set forth above depicts an intact epoxide ring on the GMA repeating unit. The epoxide ring is intended to react with the hydroxyl groups on the cellulose fibers making up the paper to provide substantivity of the copolymer to the paper fiber. It should be noted that due to the abundance of hydroxyl groups on the fibers, no epoxy moieties should be available to migrate to food since they will be reacted onto the cellulose fibers.

The weight average molecular weight (Mw) of [redacted] copolymer is >600,000 Daltons.

The following table (Table 1) describes the typical physical properties of [redacted]

Table 1
Physical Properties of Zonyl® 9594HP

Property	Typical Value or Range
Flash point (°F)	>200
Solids content (wt. %)	19.0 +/- 1.0
Viscosity (cP at 22.6°C)	<30
pH	4.0 – 5.0
Density (g/ml)	1.09 +/- 0.01 g/ml
Appearance	Amber liquid

6. **<u>Introduction of Substances into the Environment</u>**

1. Introduction of substances into the environment as a result of manufacture of the polymer

FDA has indicated that an EA ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA regulated articles. Moreover, information available to DuPont does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of [redacted] Consequently, information regarding the manufacturing site and compliance with the relevant emissions requirements is not provided here.

2. Introduction of substances into the environment as a result of use/disposal

As stated previously, based on available information, DuPont expects that the majority of the [redacted] copolymer will be incorporated into, and remain a component of, finished paper produced using the product. To address the potential environmental introductions as a result of use of the product, DuPont has obtained information on typical manufacturing and waste treatment practices at paper mills that will use [redacted] in the wet end. At this time, one manufacturer intending to use the product in the wet end has been identified. It is expected that the information obtained from this company will be reasonably representative of other mills that will apply the treatment in the wet end. The following discussion of environmental releases at the site of use is based upon the information supplied by this company.

Based on substantial experience with the use of fluorochemicals as oil and grease resistant treatments for paper and paperboard, it is estimated that at least 88% of the [redacted] copolymer introduced into the pulp slurry will become incorporated into the finished paper. This includes the amount of copolymer that becomes incorporated into the paper on the first pass, based on both laboratory and plant experiments, as well as that which is incorporated into the pulp in additional passes and copolymer that becomes adsorbed to fiber "fines" that initially do not become part of the paper. These fines typically are recovered from the white water via filtration and recycled back into the papermaking process. (The economics of the papermaking process demand such recycling of fines.) The total polymer retention level of 88% is equal to the retention rate achieved with competitive fluorochemicals; thus, substituting [redacted] in place of the currently used fluorochemical is not expected to result in a loss of retention of the treatment on the paper.

To the extent that the [redacted] copolymer is not incorporated into the finished paper, it will be present in the white water from the process. While the white water is typically recycled through the process, the water will ultimately be released to the waste water treatment facility. The frequency of such releases will vary from plant to plant. DuPont believes that all of the paper mills that will use the [redacted] product operate on-site treatment facilities. It is further estimated, again based on DuPont's knowledge of similar chemicals, that at least 90% of the fluoropolymer will be removed from the waste water as a component of the solid wastes, or sludge, from the waste water treatment process. This figure is based on several considerations.

First, the waste water treatment will begin with a filtration step that will remove fines containing adsorbed copolymer. Second, following the filtration, the aqueous stream is biotreated. Based on general experience in biotreatment, DuPont's knowledge indicates that acrylate polymers, such as the [redacted] copolymer, tend to go predominantly with the sludge. A third point is that once neutralized, the copolymer has extremely low solubility in water; this further implies that the copolymer will tend to stay with the solids.

Thus, at least 90% of the [redacted] copolymer going to the waste water is expected to be present in either the filtered solids or sludges recovered from the waste water. Based on DuPont's experience, these solid wastes are expected to be disposed of by means of either landfilling at suitable sites or by incineration, with the ash from the incinerator being disposed of via landfill.[2]

As for solid wastes from waste water treatment processes that are either directly disposed of by landfill or are incinerated followed by landfilling of the resultant ash, we expect that only very low levels of the subject food-contact substance will leach from the landfills containing these wastes. Moreover, even if a very small amount of the substance migrates from sludges disposed of in landfills, we expect extremely low quantities to actually enter the environment;

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2 The guidance document provided by FDA suggests that environmental releases resulting from soil application of sludges containing [redacted] should be considered. As noted here, the sole plant that currently intends to use the product in the wet end does not dispose of solid wastes by this means, so DuPont does not have information specifically dealing with this potential introduction. However, in the event that such sludges are used for soil amendment purposes, it is expected that the [redacted] copolymer will be present largely adhered to pulp fibers and thus will not be directly released to the surrounding environment.

this finding is based on the regulations of the Environmental Protection Agency (EPA) governing municipal solid waste landfills.[3]

The maximum level at which the [redacted] copolymer may be present in the waste water following treatment may be estimated based on the foregoing as follows. First, we will assume that all of the 12% of the polymer that may not be incorporated into the paper in either multiple passes or recycling of fines will be initially present in the waste water. Of the resulting amount, we will assume that 10% will remain in the waste water after removal via the filtered solids and sludge.

The calculations are based further on the following information regarding a typical large-scale paper production process, again supplied by DuPont's customer. Specifically, a total of 750 metric tons (750 x 10^3 kg) of treated paper is typically produced by the mill per day. As stated in the notification, the paper is intended to be treated with [redacted] at a level resulting in a fluorine content on the paper of 0.37%, corresponding to a copolymer content of 0.69%. If 88% of the copolymer is retained in finished paper, the actual level of [redacted] copolymer added to the pulp slurry will need to be adjusted for the retention rate; the adjusted amount may be estimated, relative to the dry paper weight, as (0.69% ÷ 0.88), or 0.78%. Thus, the total amount of [redacted] copolymer employed on a daily basis will be about 5.85 x 10^3 kg (0.78% of 750 x 10^3 kg). If 12% of this amount does not become incorporated into

[3] These regulations require (1) the use of composite liners and leachate collection systems with new municipal solid-waste landfill units and lateral expansions of existing units to prevent leachate from entering the ground and surface water, and (2) groundwater monitoring systems. *See* 40 C.F.R. Part 258. Although owners and operators of existing active municipal solid-waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

the finished paper, a total of 7×10^2 kg will remain with the white water. Further, if 10% of this amount remains in the waste water after treatment, this will amount to 70 kg of the copolymer.

In producing 750 metric tons of treated paper per day, the mill processes an estimated 18,000 gallons per minute (gpm) of waste water. This is equivalent to 26 million gallons per 24-hour day. (This includes both the release of white water from the papermaking process and other aqueous plant wastes.) This is equivalent to 99 million liters (or kg) of water per day (26×10^6 gal/day x 3.8 L/gal = 99×10^6 L/day). On this basis, if 70 kg of [redacted] copolymer is present in the post-treatment waste water, the resulting concentration will be 0.7 part per million (ppm) (70 kg ÷ 99×10^6 kg = 7×10^{-7} kg/kg = 0.7 ppm).

It should be noted that [redacted] is expected to be used in place of other oil and grease resistant treatments that are currently used in the production of food-contact paper and paperboard. Thus, the use of [redacted] in place of these materials will not result in any meaningful change in the nature or the amount of substances released into the environment upon the use of the product in the manufacture of food-contact paper and paperboard.

7. **Fate of Emitted Substances in the Environment**

As shown in Item 6 above, the primary means by which the [redacted] copolymer is expected to be released into the environment is as a component of effluents from waste water treatment facilities. The expected introduction concentration (EIC) is estimated to be 0.7 ppm.

This concentration, of course, will be greatly diluted once the effluent enters the receiving water. The resulting concentration of [redacted] copolymer is expected to be vanishingly low. For the sake of conservatism, we will estimate the expected environmental concentration (EEC) using a river dilution factor of 10; that is, we will assume just a 10-fold dilution in the concentration of [redacted] copolymer upon entering the receiving water. This will result in an EEC of 0.07 ppm, or 70 parts per billion (ppb).

We respectfully submit that the concentration at which the [redacted] copolymer may be released in effluent from waste water treatment facilities is so low as to warrant no substantive concern. The conclusion that there will be no significant adverse impact is further supported by the aquatic toxicity data discussed in Item 8 below.

8. **Environmental Effects of Released Substances**

The potential release of [redacted] at the worst-case level calculated above is not expected to result in any significant environmental effects. This expectation is based on the low levels at which the product may be introduced into the environment and on available data which indicate that the product is essentially non-toxic to aquatic organisms.

As documentation of this lack of toxicity, enclosed as Attachment 7 to the February 12, 2002 letter that accompanied the Environmental Assessment for FCN No. 206 are the reports of two acute toxicity studies conducted in aquatic organisms using a test substance that is closely related to [redacted][4] Specifically, the studies were conducted on a copolymer of 2-(perfluoroalkyl)ethyl acrylate, 2-N,N-diethylaminoethyl methacrylate, and glycidyl methacrylate. This product is known as [redacted] The only significant difference between this product and [redacted] is that, in addition to the levels of acrylic acid and methacrylic acid that were present on the [redacted] backbone as the result of hydrolysis, additional levels of acrylic acid and methacrylic acid are also used as starting materials to produce the [redacted] polymer; a different solvent and a different catalyst are also used in its production.

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[4] The reports are incorporated into this Environmental Assessment by reference. However, they contain confidential information that should not be disclosed.

The first of the two attached reports relates to a static, acute 96-hour screening test in fathead minnows. The 96-hour LC_{50} was found to be between 50 mg/L and 500 mg/L of the product. The second report relates to a static, acute 48-hour screening test in *Daphnia magna*. The LC_{50} was again found to be between 50 mg/L and 500 mg/L.

DuPont advises that these LC_{50} values are based on the concentration of the product as delivered, that is, on the wet basis. DuPont advises further that the tested product consists of 30% solids, whereas the subject product [redacted] contains approximately 19% solids. Thus, the LC_{50} values obtained on the tested formulation may be converted to the corresponding LC_{50} values for [redacted] by multiplying by a factor of 30%/19%, or about 1.5. This results in an estimated LC_{50} for [redacted] in fathead minnows and *Daphnia magna* of between 75 mg/L and 750 mg/L. On a polymer solids basis, this represents an LC_{50} for the [redacted] copolymer of 19% of these values, or between about 15 mg/L and 150 mg/L.

As discussed in Item 7 above, the maximum concentration at which the [redacted] copolymer is expected to be present in the environment, or the EEC, is 0.07 ppm, equivalent to 0.07 mg/L. The lower end of the estimated LC_{50} range, 15 mg/L, is more than 214 times the EEC. Thus, it may readily be concluded that the potential release of [redacted] copolymer will not lead to any significant adverse environmental impacts. Moreover, as noted previously, this release will not represent a new environmental introduction of fluorochemical but, rather, a substitution for the corresponding release of other fluorochemicals that would otherwise be used for the same purpose. We respectfully submit, therefore, that no adverse environmental effects are expected as a result of this release.

9. **Use of Resources and Energy**

The notified use of the [redacted] copolymer is expected to compete with, and to some degree replace, other fluorochemicals that are already used in the manufacture of paper and paperboard. Other fluorochemicals that are specifically listed in Section 176.170 of the food additive regulations for this purpose include, *e.g.*, perfluoroalkyl acrylate copolymer (CAS Reg. No. 92265-81-1). For this reason, the use of [redacted] in the production of food-contact paper and paperboard is not expected to result in a net increase in the use of energy and resources.

10. **Mitigation Measures**

As discussed above, no significant adverse environmental impacts are expected to result from the manufacture of food-contact paper and paperboard using [redacted]. This is largely due to the low levels at which the [redacted] copolymer may be introduced into the environment and the available data indicating an absence of toxicity to organisms in the environment. This conclusion is further supported by the close similarity of [redacted] to the fluorochemicals it is intended to replace. Thus, the use of [redacted] as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. **Alternatives to the Proposed Action**

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this request. Therefore, alternatives to the proposed action need not be considered.

12. **List of Preparers**

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13. **Certification**

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

Date: 05-31-06

George G. Misko
Counsel for DuPont Chemical Solutions Enterprise

14. **References**

None

15. **Attachments**

None