

AR 226

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Cc: S. Korzeniowski - DuPont
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To Whom It May Concern:

Please find enclosed an updated copy of the DuPont presentation submitted to the Agency at the meeting held on December 17, 2001. The CBI claim for the information on pages 21 and 66 is withdrawn. These pages contain no CBI and should be included in the public record. Text has been added to pages 21 and 66 to clarify that the proposed timelines are subject to change and harmonize the study material names with those used throughout the balance of the document. Otherwise, these pages do not differ in any other way from the documents that were provided on December 17, 2001. The non-CBI version of this document is intended to replace the previous version (AR226-1042) in the public record.

Please contact me if you have any questions regarding this submission.

Best regards,

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DuPont Product Stewardship Update

United States Environmental Protection Agency

17 December 2001

R. C. Buck, G. L. Kennedy, S. H. Korzeniowski, J. C. Stadler



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Discussion Outline

- Reconnect to 21 Feb Discussion
- Work Plans & Chemistry, Radio-label
- Toxicology
 - Biopersistence
 - Repeated Dose, Reproduction & Developmental Studies
 - Structure - Activity Relationships
- Exposure Connection : What the data means
 - Human Exposure : Worker Data, Consumer
 - Environmental Exposure
- Environmental Fate & Effects
 - Physical - Chemical Properties
 - Environmental Fate
 - Environmental Effects
- Conclusions
- Discussion

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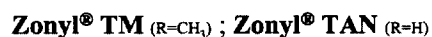
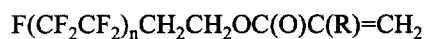
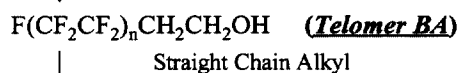
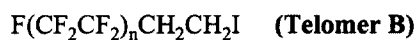
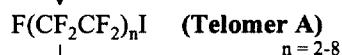
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DuPont Fluorotelomer Product Groups: Intermediates, Surfactants, Polymers

1) Intermediates



Sales Products

2) Surfactants / "Molecules"

- Anionic - Phosphate, Carboxylate, Sulfonate
- Nonionic - Ethoxylate
- Betaine

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3) Polymers

- Acrylic
- Ester
- Amide
- Urethane
- Urea



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Synthetic Strategies for Radiolabeled Fluorotelomers



November 2001

DCSE R&D



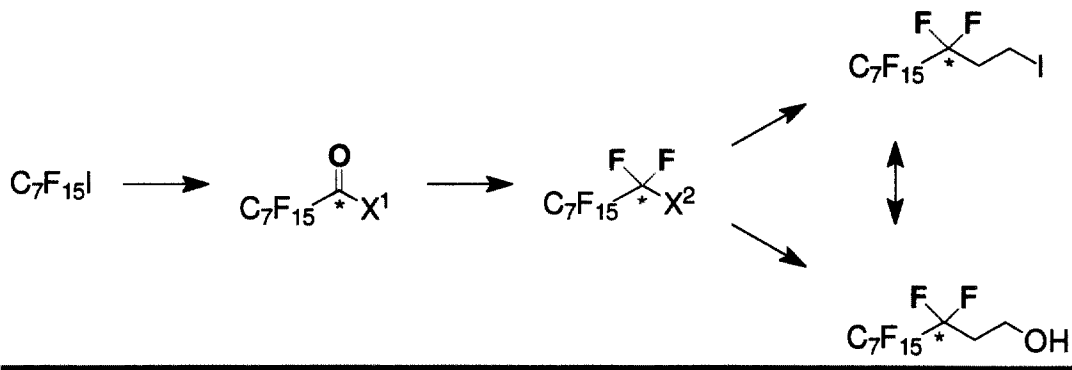
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General Synthetic Strategy



- **TFE not available as source of radiolabel**
 - practical synthesis not demonstrated; SHE issues
- **Must use readily available sources of ^{14}C**
 - e.g., CO_2 (ex. BaCO_3), NaCN , etc.
 - ample literature precedent for conversion of $\text{C}=\text{O}$ into CF_2
 - typical reagents: Et_2NSF_3 (DAST); $(\text{MeOCH}_2\text{CH}_2)_2\text{NSF}_3$ (DeoxoFluor®)



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Radio-label Synthetic Routes

- Multiple (5+) Deoxyfluorination routes explored using different starting synthons

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Successful Synthetic Route

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- Synthetic Route provides access to all the key Fluorotelomer Intermediates :
Telomer A, Telomer B and Telomer BA



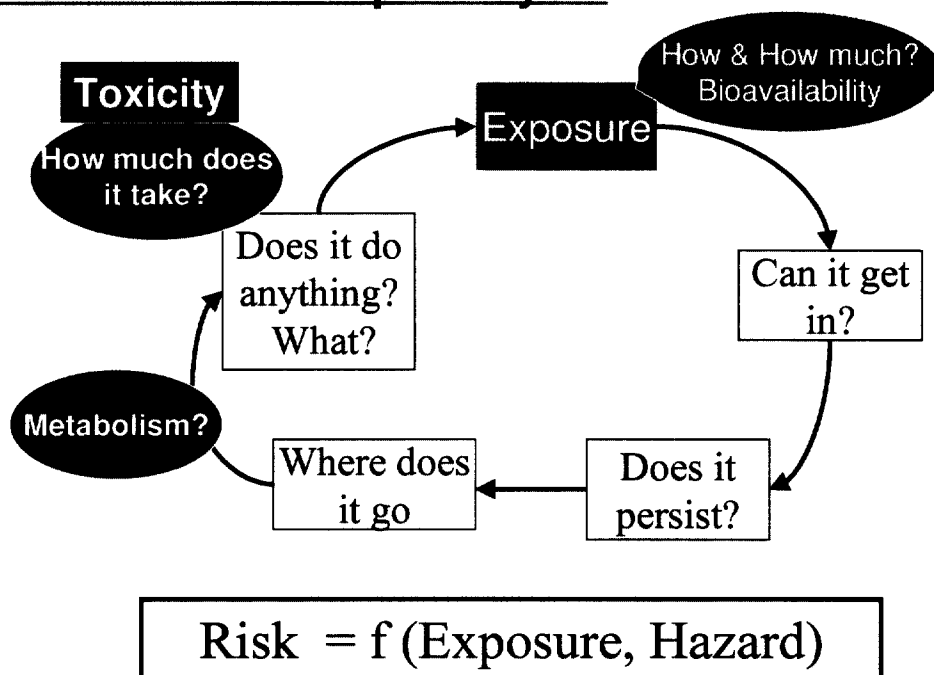
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Product Stewardship Analysis



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Toxicity Studies

Acute Toxicity

- Oral, Inhalation
- Eye, Skin Irritation
- Skin Sensitization

Repeat Dose Toxicity

Oral, Dermal
Inhalation (AEL)

Genetic Toxicity

Developmental Toxicity

Reproductive Toxicity

Pharmacokinetics

Basic evaluation set

Expanded evaluation



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Summary : *In Vivo* Biopersistence Screening of Fluoro-Organic Chemicals in Male Rats

- **Purpose** : To compare bio-uptake and bio-clearance in rat blood for a series of fluorotelomer intermediate, surfactant and polymeric products including PFOS as a positive control.
- **Study** : 10 consecutive days dosing via oral gavage, 84 day recovery period with analysis of total Blood, Liver & Fat fluorine on selected days (3 during dosing, 4 during recovery).
- **Analysis** : Use fluorine data to compare internal exposure of fluoro-organic materials on a dose normalized or μ molar basis.

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Biopersistence Studies -- Key Learnings

- Telomer-based materials do not act like PFOS in the blood or liver
 - Blood total fluorine AUC's much lower than PFOS
 - Liver total fluorine lower than PFOS

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Repeated-Dose Study Plans

90 Day Subchronic Study

Determine systemic effects from repeated oral gavage exposure

One-Generation Reproduction Study

Determine effects on parental capability to conceive, bear offspring and evaluate effects on offspring during pregnancy, early feeding and maturation to adulthood

Developmental Toxicity Study

Determine effects on fetal development (I.e. growth, maturation, abnormalities)



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90 Day Repeated Oral Dosing & One-Generation Reproduction Study

Dose Levels : three levels + control
Experimental Animal : Male & Female CD Rats

Study Evaluations :

90 Day Repeated Dose :

- appearance, behavior, weight, blood, organs and tissues, β -oxidation
- U.S. EPA Health Effects Test Guideline : OPPTS 870.3100 (1998)

Reproduction :

- Adult In life : body wt., clinical signs, limited histopathology, female reproductive cycle time, sperm assessment, reproductive organs, mating, fertility;
- Pups: physical development and maturation to adulthood, reproductive organs



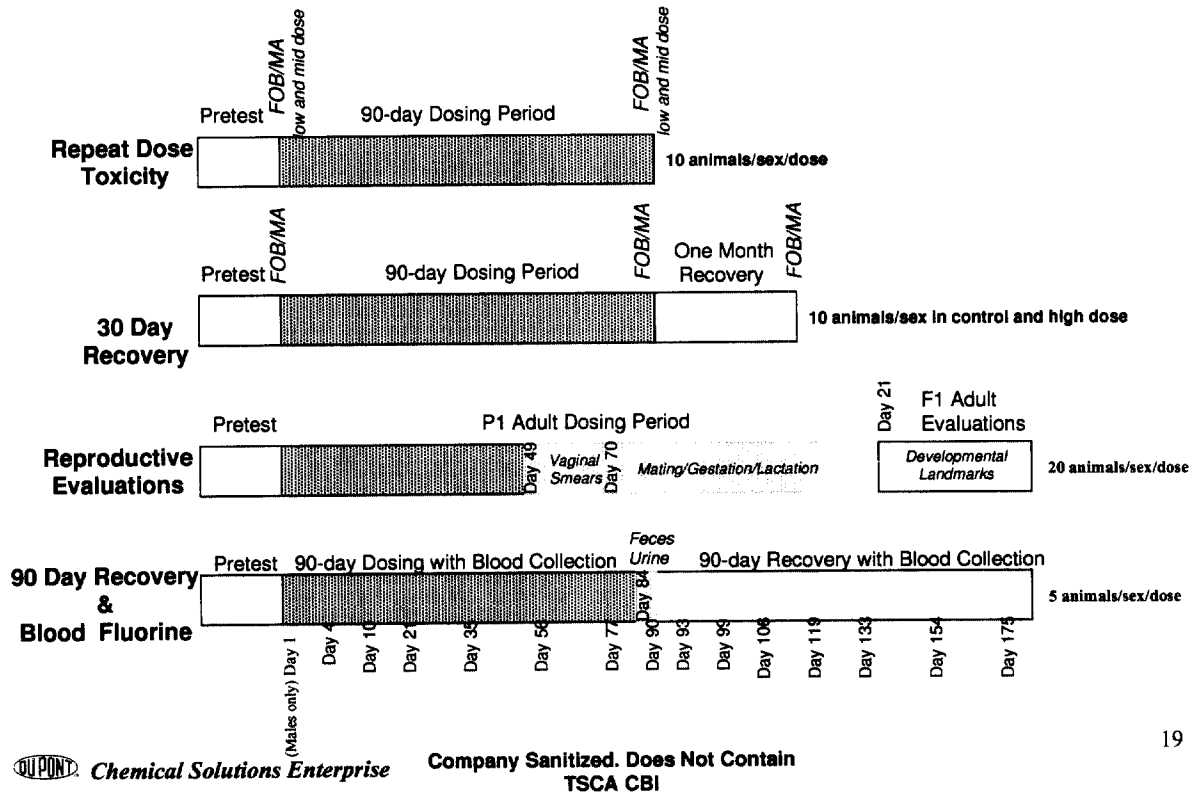
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90-day & One-Generation Reproduction Study Protocol

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Developmental Study

Dose Levels : Three Doses + Control

Experimental Animal : Male & Female CD Rats

U.S. EPA Test Guidelines : 870.3700; OECD Sect. 4, No. 414

Study Evaluations :

Determine effects on fetal development (I.e. growth, maturation, abnormalities)

Maternal : clinical signs, body weight, gross pathology

Pup: sex, body weight, external, skeletal and visceral examinations

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DuPont Toxicology Studies Timeline*

Test Material	Work	2000		2001		2002	
		3Q	4Q	1Q	2Q	3Q	4Q
Telomer Urethane Polymer	90 Day Oral Repeat Dose + 1 Gen Repro (Rat)						
	Developmental Study (F ₁)						
Telomer Alcohol Intermediate	90 Day Range-Finding Study						
	90 Day Oral Repeat Dose + 1 Gen Repro (Rat)						
	Developmental Study Rangefinder						
	Genetic Toxicity: <i>In Vitro</i> Chrom Ab						
	Developmental Study						
Telomer Ethoxylate	90 Day Range Finding						
	90 Day Oral Repeat Dose, 1 Gen Repro (Rat)						
	Developmental Study Rangefinder						
	Developmental Study						
Telomer Phosphate	Range Finding						
	90 Day Oral Chronic Repeat Dose (Rat)						
	1 Gen Reproduction Study (Rat)						
	Developmental Study						
Telomer Acrylate Polymer	Range Finding						
	Developmental Study						
	90 Day Oral Repeat Dose, 1 Gen Repro (Rat)						
Multiple Compounds Intermediate, Surfactant and Polymer	Biopersistence Gavage Screen #2						

* This is a proposed timeline and subject to change.

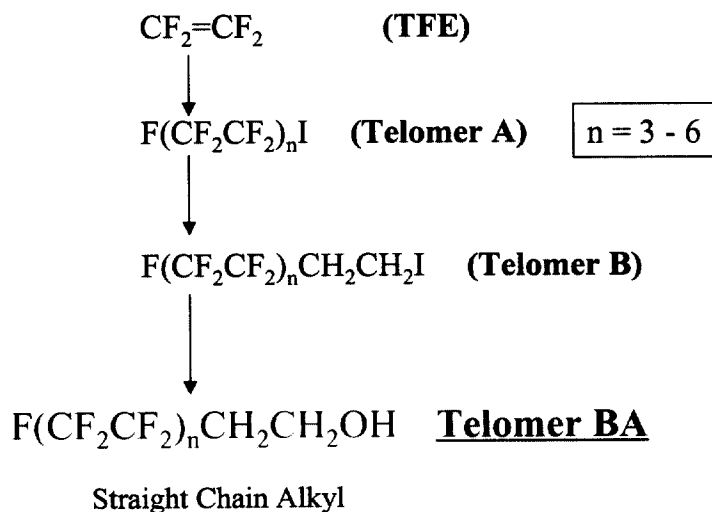
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Telomer BA Synthesis Chemistry



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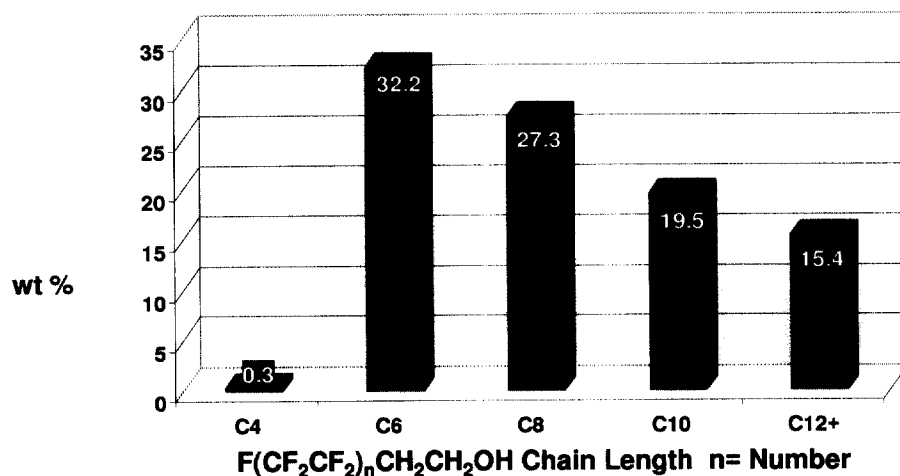


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Actual Telomer BA Study Material Composition



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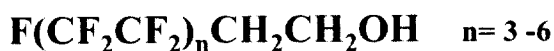
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Telomer BA : Repeated-Dose Toxicology Information



- Repeated Dose Toxicity : NOEL 25 mg/kg/day
- Reproductive Toxicity : NOEL 25 mg/kg/day
- Developmental Toxicity : NOEL 200 mg/kg/day
- Genetic Toxicity : Negative AMES, Chrom Ab



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Telomer BA : 90 Day Study Results

Study Conclusion: NOEL = 25 mg/kg/day

CBI Information has been redacted



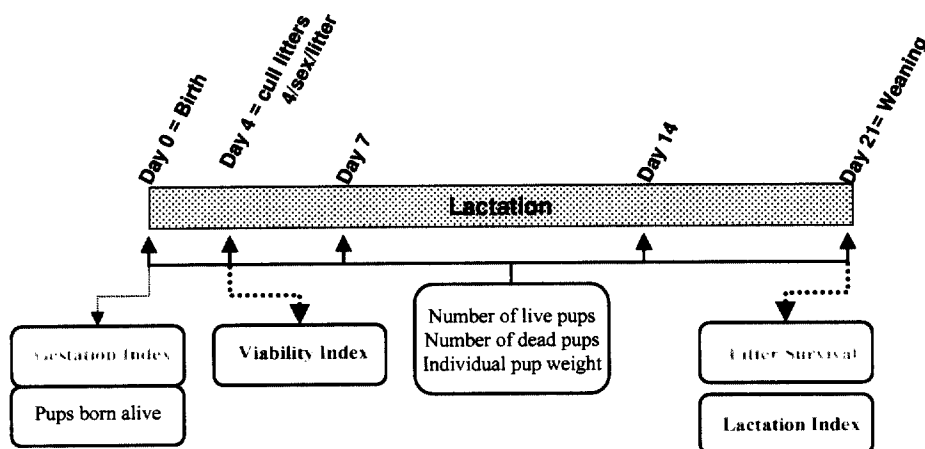
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One-Generation Reproduction Study : F1 Survival Indices



Litter indices

SURVIVAL INDICES

- *Gestation Index*: Percent litters delivered having at least one live pup
- *Litter Survival*: Percent litters born with at least one pup alive on day 21

Pup indices

- *Viability Index*: Percent pups surviving to day 4 of lactation
- *Lactation Index*: Percent pup survival from day 4 postculling to day 21



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Telomer BA : Reproduction Study Results

Study Conclusion: NOEL = 25 mg/kg/day

CBI Information has been redacted



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Telomer BA : Developmental Study Results

Study Conclusion: NOEL = 200 mg/kg/day

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Telomer BA : Study Conclusions

- Subchronic
 - *Primary adverse target is teeth (fluoride)*
 - *Other compound-related effects were non-adverse physiological responses : liver, kidney, thyroid*
- Reproduction
 - *not a selective reproductive toxin*
- Developmental
 - *not a selective developmental toxin*



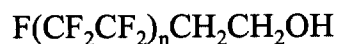
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Telomer Ethoxylate : Chemistry



EO

CBI Information has been redacted



- Product by Process
- Mixture of Mixtures : Fluorocarbon Chain and EO Chain are both gaussian distributions and tailored for specific end-uses



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Telomer Ethoxylate : Repeated Dose Toxicology Information

- Repeated Dose Toxicity: NOEL 50mg/kg/day
- Reproduction : P₁ NOEL = Not Established
F₁ NOEL = 25 mg/kg/day
- Developmental Toxicity: NOEL 50mg/kg/day
- Genetic Toxicity: negative AMES

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Telomer Ethoxylate : 90 Day Study Results

Study Conclusion: NOEL = 25 mg/kg/day

CBI Information has been redacted

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Telomer Ethoxylate : Reproduction Study Results

Study Conclusion: P₁ NOEL = Not Established

F₁ NOEL = 25 mg/kg/day

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One-Generation Reproduction Study - P1

Fertility Index (%) = $\frac{\text{\# Animals that Deliver Pups}}{\text{\# Animals that Mate}}$

- **Fertility Index accounts for any event from mating to birth.**
- **Reduction may be due to lack of fertilization, implantation or embryo viability**



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Telomer Ethoxylate : Developmental Study Results

Study Conclusion : NOEL 50 mg/kg/day

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Telomer Ethoxylate : Study Conclusions

- Subchronic
 - *Primary adverse targets are red blood cell mass & kidney*
 - *Other compound-related effects were non-adverse physiological responses : liver, thyroid, spleen*
- Reproduction
 - *pup (F1) effects occurred only at dose levels with systemic effects on blood and kidney*

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- Developmental
 - *not a selective developmental toxin*



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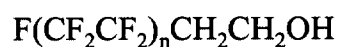
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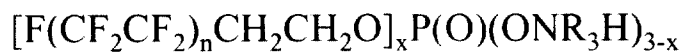
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Telomer Phosphate Chemistry



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- Products by Process
- BL, B Telomer Distributions tailored to end-use



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Telomer Phosphate : Study Update

- 90 Day Repeated Dose Oral Gavage Study
 - production material
 - *In-life* complete, histopathology evaluations ongoing
- Reproduction & Developmental
 - range-finder underway
 - studies to begin 1Q2002

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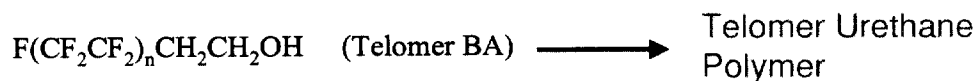


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Telomer Urethane Polymer : Chemistry



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Telomer Urethane Polymer : Repeated Dose Toxicology Information

- Repeated Dose Toxicity: LOEL 50mg/kg/day (nose only)
No Observed Adverse Effect at 50 mg/kg/day for all other parameters
- Reproductive Toxicity: No effects on reproduction at any dose level
- Developmental Toxicity: No abnormalities or birth defects
- Genetic Toxicity: Negative AMES and Chom Ab



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Telomer Urethane Polymer : 90 Day Study Results

Study Conclusions :

- NOEL Not Established
- No Observed Adverse Effect at 50 mg/kg/day for all other parameters

CBI Information has been redacted



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Telomer Urethane Polymer : Reproduction Study Results

Study Conclusion: NOEL = 50 mg/kg/day

No effects on functional reproductive parameters at any dose level

CBI Information has been redacted



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Telomer Urethane Polymer : Developmental Study Results

Study Conclusions:

- Developmental NOEL = 250 mg/kg/day
- Maternal NOEL = 50 mg/kg/day

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Telomer Urethane Polymer : Study Conclusions

- Subchronic
 - *Primary adverse effect is nasal lesions*
 - *Other compound-related effects were non-adverse physiological responses : liver, thyroid*
- Reproduction
 - *not a selective reproductive toxin*
- Developmental
 - *not a selective developmental toxin*



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Fluorotelomers Exposure Assessment

- **In-Use Exposure Assessment**
- **Environmental Release Assessment**
 - **Product Trails**
 - external focus : markets where used
 - distribution, use, disposal
 - **Mass Balance**
 - Environmental releases & media (Land, Air, Water)



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: In-Use Exposure Model

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: In-Use Exposure Model

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: In-Use Exposure Model

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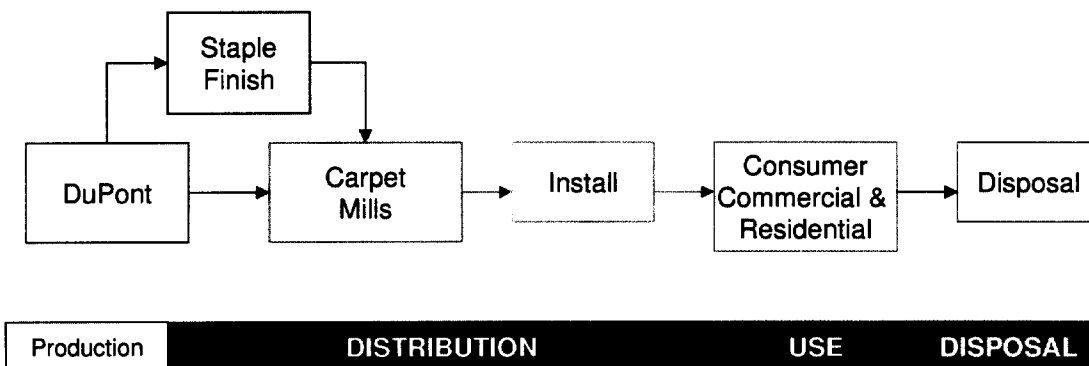
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Product Trails

- For each Market / End-Use by Product
- Used to determine product release points

Product Trail : Carpet



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Environmental Compartments

based on emissions assessment

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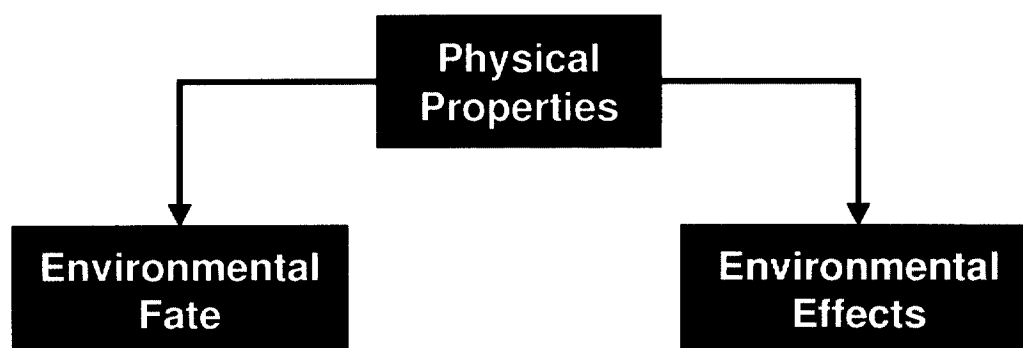
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DuPont Environmental Fate & Effects Studies

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Study Materials

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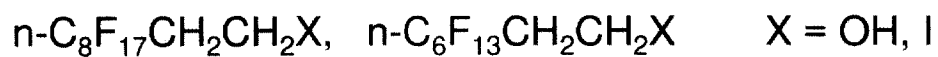


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Physical - Chemical Properties



- UV / Visible Absorption Spectrum
- Vapor Pressure
- Sorption
- Water Solubility
- Henry's Law Constant
- Log K_{ow} (Octanol - Water Partition)



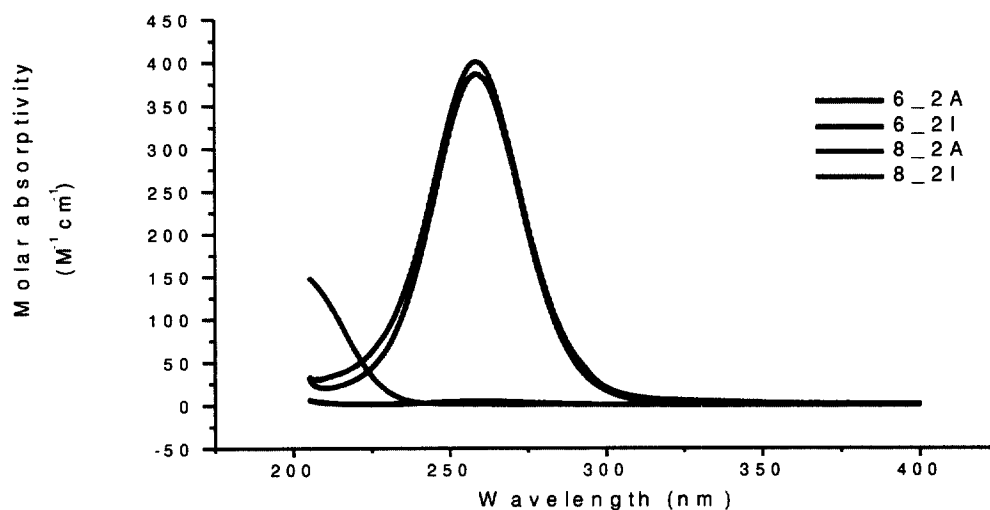
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UV-Visible Spectra : Telomer B Alcohols & Iodides



- No absorbance in visible light range, 350-800nm
- Direct photolytic degradation not expected
- Indirect Photolysis [OH Radical] work underway (8-2 Alcohol, TRP)



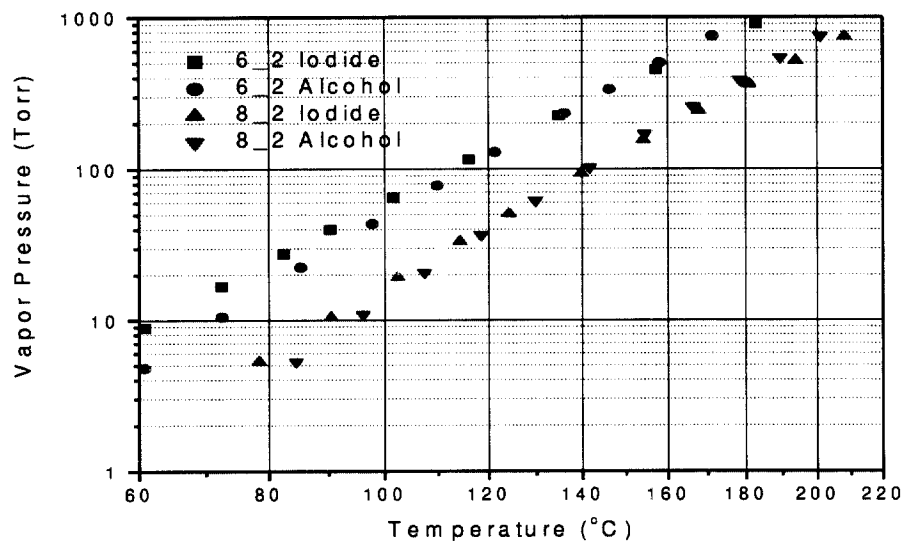
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Vapor Pressure : Telomer B Alcohols & Iodides



- Data fit to Antoine Equation extrapolated to ambient, 20°C
- No anomalies observed



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Physical - Chemical Properties : Sorption 6-2, 8-2 Telomer B Alcohols & Iodides

- rapid sorption from saturated aqueous solution
 - glass, silanized glass, plastic, PTFE, stainless steel
- *evidence of time-dependent adsorption with decreasing ability to recover material from surface(s)*
- specific recovery methods had to be developed and validated
 - weeks for each sample to reach equilibrium with continuous analysis
 - 8 to 20 samples replicated to establish method and analysis confidence
- *makes water solubility measurement much more complicated and mass balances difficult to achieve*



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Physical - Chemical Properties : Water Solubility 6-2, 8-2 Telomer B Alcohols & Iodides

- pH 3, 7, 9 ; T = 12, 25, 37, 60°C
- see no differences in solubility versus pH
- *material is adsorbed to the container, not in the water, when excess material is no longer present*
 - sorbed to the container surfaces

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Physical - Chemical Properties : Water Solubility 6-2, 8-2 Telomer B Alcohols & Iodides

	Solubility $\mu\text{g} / \text{mL}$ (ppm)			
	<u>12°C</u>	<u>25°C</u>	<u>37°C</u>	<u>60°C</u>
$\text{C}_6\text{F}_{13}\text{CH}_2\text{CH}_2\text{OH}$	preliminary data : 1 range			
$\text{C}_8\text{F}_{17}\text{CH}_2\text{CH}_2\text{OH}$	0.134 ± 0.029	0.150 ± 0.005	0.318 ± 0.176	
$\text{C}_6\text{F}_{13}\text{CH}_2\text{CH}_2\text{I}$	preliminary data : 0.1 range			
$\text{C}_8\text{F}_{17}\text{CH}_2\text{CH}_2\text{I}$	work ongoing			
PFOA	> wt 10 %			
PFOS	680			

- De-ionized water measurements



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Physical - Chemical Properties : Henry's Law Constant 6-2, 8-2 Telomer B Alcohols & Iodides

- Computed from Water Solubility and Vapor Pressure
- Non-linearity and Non-traditional behavior
- Surface Tension Driving Behavior?
- Plan to Measure utilizing Static Headspace Method

(ref. J. D. Stuart, et al., Analytical Chemistry, 1993, 65, 3113-3118)



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Physical - Chemical Properties : Conclusions 6-2, 8-2 Telomer B Alcohols & Iodides

- Water Solubility varies with T but not pH and is in the range of 0.1 - 1.0 ppm
- Highly sorptive onto many surfaces and may remain highly sorbed and difficult to remove
- Preliminary VP data do not exhibit anomalies
- No visible light absorbance

- These properties present significant method development and analysis challenges going forward and will require use of radiolabeled material for more studies than expected

63



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Analytical : Method Development Challenges

- Head-Space Analysis Method
 - Parent and potential degradation product(s)
- Extraction & Recovery Methods
 - Matrices: Soil, Sediment, Sludge, Labware Surfaces, Water
 - Materials : Parent & Degradation Product(s), including radiolabel
- Analysis Methods (GC/MS, LC/MS/MS)
 - Parent & Degradation Product(s) in relevant matrices
 - Radiolabeled Materials (stop-flow scintillation counter)

64



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Environmental Fate & Effects Work Plan

Physical Properties

- UV/Visible Spectrum
- Water Solubility
- Adsorption to Glass
- Air-Water Partition Coefficient

CBI Information has been redacted

Environmental Fate : Abiotic

- Hydrolysis
- Adsorption / Desorption *

Environmental Fate : Biotic

- Anaerobic Biodegradation*
 - Aerobic Biodegradation*
- (* Radiolabeled Material)

Environmental Effects

- Bioconcentration Screen

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DuPont Environmental Fate & Effects Timeline*

Test Materials	Work	2001				2002			
		1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
8-2& 6-2 B, BA	P Physical Properties								
Multiple Compounds Intermediate, Surfactant and Polymer	E Bioconcentration Factor (BCF) Screen (Minnow) I								
Multiple Compounds Intermediate, Surfactant and Polymer	E Bioconcentration Factor (BCF) Screen (Minnow) II								
8-2 Telomer Iodide C8F17CH2CH2I	F Hydrolysis								
	F Adsorption / Desorption (14C)					To be done in parallel with 8-2 Alcohol Work			
	F Aerobic Biodegradation (14C)								
	F Anaerobic Biodegradation (14C)								
"Model" Urethane Polymer	F Hydrolysis								
"Model" Urethane Polymer	F Anaerobic Biodegradation (14C)								
"Model" Acrylate Polymer	F Hydrolysis								
Work Underway					Proposed Timing				

* This is a proposed timeline and subject to change.

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66

34

Conclusions

- DuPont fluorotelomer-based products are safe for their intended uses.
 - DuPont's data and analysis support this conclusion
- DuPont fluorotelomer-based products *do not* have the same overall PBT properties as PFOS Chemicals



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DuPont Product Stewardship Summary

- We are *committed* to and *staying* in the business.
- We are *confident* that our products are safe for their intended uses.
- We have *programs in place* to learn more about our products:
Toxicology, Environmental Fate & Effect, Exposure
- We are *working together with industry members & groups*
- We will continue to have an *open & frequent dialogue* with
Regulators, Customers, and Employees



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35

- Reflections & Discussion
- Questions
- Path Forward



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