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Company Sanitized

APFN Work Group Presentation to EPA January 16, 2003



“COMPANY SANITIZED.
DOES NOT CONTAIN TSCA CBI”

Agenda

Background

- What is the APFN Work Group?
- Relationship with FMG
- What is APFN and what is it used for?

Analytical Methods Development

Toxicology and Environmental Program

- Current Knowledge of APFN
- Ongoing toxicology/ecotoxicology program

Summary

Fluoropolymer Manufacturers Group (FMG)

- The mission of the FMG is to promote the continued safe manufacture and use of fluoropolymers made using fluoropolymer polymerization aids (FPA) while establishing and supporting responsible use of fluoropolymer products and minimizing the impact on the environment

What is the APFN Work Group?

- Separate SPI Work Group
- Formed to evaluate APFN as compared to APFO
- Members are producers and users of APFN
 - Limited number of participants complicates the sharing of some information

APFN Work Group Members

➤ Asahi Glass Co. Ltd.

➤ Atofina Chemicals, Inc.

➤ Solvay Solexis, Inc. (Ausimont)

What is APFN?

- APFN is one of the FPAs used by the FMG member companies to produce fluoropolymers as reported in the FMG mass balance update in Sept. 2002
- FPA – Fluoropolymer polymerization aide
 - commercially available perfluoroalkyl carboxylate surfactant

Commercially Available APFN

↪ CAS number 72968-3-88

Use of Commercial APFN

PVDF Applications

- Handled only in industrial processes
 - Highly weatherable architectural coatings
 - Ultrapure water systems in semiconductor and pharmaceutical industries
 - Handling of corrosive chemicals – pipes, filter media, tanks, etc.
 - Fire resistant electrical insulation
 - Lithium ion batteries
- No direct consumer applications

Fluoropolymer Manufacturing Group

Point Source Emissions Include APFN

✓ Voluntary worldwide commitment to contain

- Global minimum emissions reduction of 50%
- Base year '99 or '00
- Goal years 2004 - 2006

✓ Emissions reduction forecast completed

- 49% Reduction by 2004
- 67% Reduction by 2006

Analytical Methods Development

Method development and validation underway at CRO

- Selected laboratory experienced with this family of chemistry
- Provide quantitation at ppb - ppt levels

Three matrices:

- Water (LC/MS/MS)
- Serum (LC/MS/MS)
- Air (LC/MS)

Analytical Methods Development

Methods developed

Validation in progress

Timing of validation

- Water: completed November 2002 to coincide with toxicology testing
- Serum: completed December 2002
- Air: January 2003

APFN Toxicology Data

- Acute Animal toxicity data in literature
 - LC50 4 hr. inhalation – rat: 820 mg/m³
 - ALD oral – rat: 187 mg/kg
- Repeated dose oral toxicity – mouse
 - Dietary exposure – 14 days
 - Increased liver weight –
 - males $\geq$ 1 ppm; females $\geq$ 3 ppm
 - Lethality > 300 ppm females; > 3000 ppm males
- Commercial APFN
 - LD50 oral – mouse: 500 – 2000 mg/kg (15% aq. soln)
 - Ames Test - Negative

Comparison of FPA Data

	Commercial and purified APFO	Commercial and purified APFN	PFDA
Acute oral, rat	LD50 540 mg/kg	ALD 187 mg/kg LD50: 500 – 2000 (mouse)(15% aq soln)	ALD 96 mg/kg
Acute dermal, rat	LD50 6959 mg/kg		
4 hr inhalation, rat	LC50 980 mg/m ³	LC50 820 mg/m ³	
Genotoxicity	Not mutagenic	Not mutagenic	Not mutagenic
Target organs	Liver, pancreas, testes	Liver (limited data)	Liver, testes, thymus
Peroxisome proliferator	Yes	Yes	Yes
Metabolized <i>in vivo</i>	No	Not expected	No
Biodegradation	No – very low	Not expected	Not expected
Water solubility	>10%	>10%	

APFN Testing Strategy

➤ Determine differences and similarities of commercial APFN and APFO

- Use screening approach to begin

➤ 3 Proposed studies

- Chemical/physical properties
- Health effects
- Environmental effects

APFN Studies Planned

☞ Physical/chemical properties

- Vapor pressure
- Water solubility
- Stability in water (hydrolysis as a function of pH)

☞ Health effects

- Acute oral toxicity in rats
- 28 day oral study with reproduction screen (rats)

☞ Environmental effects

- Acute studies in fish, daphnia, algae

APFN Testing Status

- ✓ Water method completed Nov. 2002
- ✓ 28 day oral study started at TNO in 4th Quarter 2002
 - Doses selected are 0.1, 0.5, and 2 mg/kg
 - Anticipate results 2nd quarter 2003
 - Preliminary range finding results were reported to TSCA 8(e) office Dec 20, 2002
- ✓ Environmental effects and phys/chem properties testing initiated

Summary

- APFN not widely used
 - Limited mostly to PVDF manufacturing
- Primarily industrial applications; No direct consumer applications
- Significant reduction in potential exposure sources planned
 - Emissions at fluoropolymer plants
- Toxicity and environmental effects work progressing on schedule