

FC-143 AND APME

TOXICOLOGY RELATED ISSUES FROM 1995 TO PRESENT

01/13/1997

Roger G. Perkins

**Exhibit
2551**

State of Minnesota v. 3M Co.,
Court File No. 27-CV-10-28862

APME TOXICOLOGY COMMITTEE

- DUPONT - GERRY
KENNEDY
- ICI-UK - DAVID FARRAR
- AUSIMONT - GIUSEPPE
MALINVERNO
- HOECHST AG - REINHARD
JUNG
- MITENI - MARIO
MISTRORIGO
- 3M as invited guest - ROGER
PERKINS

01/13/1997

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APME TOXICOLOGY COMMITTEE MEETINGS

- IN BALTIMORE, MD
MARCH 1995
- IN GENEVA AND BRUSSELS
IN JUNE & OCTOBER 1995
- IN ANAHEIM, CA MARCH
1996
- PROPOSED 1997 MEETING

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APME TOX. COMMITTEE INTEREST IN FC-143

■ COMPILE TOXICITY DATA FOR Scientific Committee for Food

■ LIST OF ADDITIVES FOR PLASTICS AND COATINGS

- INCLUDES AMMONIUM
PERFLUOROOCTANOATE
- INCLUDES SODIUM
PERFLUOROOCTANOATE

» LIST 8 FOR SCF = substances for which
no or only scanty and inadequate data were
available

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APME TOX. COMMITTEE INTEREST IN FC-143

- OUTLINE OF 3M DATA PER PTSS
- IDENTIFICATION OF DATA NEEDED
- 3M SCD COMMITS TO DOING STUDIES
- STUDIES COMPLETED AND ADDED TO PTSS
- STUDY NEEDS APPLIED TO FC-1090

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APME TOX. COMMITTEE INTEREST IN FC-143

■ SCF GUIDELINES RE TOXICITY TESTS

– IF $5 < M < 60$ MG/KG “FULL
DOSSIER”

» 90-DAY ORAL

» 3 MUTAGENICITY STUDIES

■ GENE MUTATION IN BACTERIA

■ CHROMOSOMAL ABERRATION

■ GENE MUTATION IN
MAMMALIAN CELLS

» STUDIES ON ABSORPTION,
DISTRIBUTION, METABOLISM
AND EXCRETION

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APME TOX. COMMITTEE INTEREST IN FC-143

■ SCF GUIDELINES RE TOXICITY TESTS

– IF $5 < M < 60$ MG/KG
CONTINUED

- » DATA FOR REPRODUCTION
- » DATA FOR TERATOGENICITY
- » DATA ON LONG-TERM
TOXICITY / CARCINOGENICITY

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APME TOX. COMMITTEE INTEREST IN FC-143

■ SCF GUIDELINES RE TOXICITY TESTS

- IF $0.05 < M < 5$ MG/KG
 - » REDUCED EXCLUDES LAST THREE

■ SCF GUIDELINES RE TOXICITY TESTS

- IF $M < 0.05$ MG/KG
 - » THREE MUTAGENICITY TESTS LISTED FOR “FULL DOSSIER”

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3M SCD ACTIONS

■ FURTHER MUTAGENICITY TESTING

- MOUSE MICRONUCLEUS
14 MAY 96 REPORT DATE
- CHROMOSOMAL
ABERRATION
25 APR 96 REPORT DATE

■ MEETING ON SCF TECHNICAL DOSSIER

- NEED FOR EXTRACTION
DATA

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APME TOX. COMMITTEE ISSUES RE LONG-TERM DATA

■ MEMBER TOXICOLOGISTS DISCUSS

- 3M TWO YEAR FEEDING
STUDY RESULTS
- DuPont TWO YEAR FEEDING
STUDY RESULTS

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APME TOX. COMMITTEE ISSUES RE LONG-TERM DATA

■ IDENTIFY OPEN ISSUES ON MECHANISM OF TUMOR FORMATION

- CONSENSUS THAT LEYDIG
CELL MECHANISM IS
EXPLAINED
- CONSENSUS THAT LIVER
TUMOR MECHANISM IS
EXPLAINED
- CONCERN THAT ACINAR
PANCREATIC TUMORS
MECHANISM NOT CLEAR

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APME TOX. COMMITTEE ISSUES RE LONG-TERM DATA

■ PROPOSAL FROM ICI- ZENECA

– PREPARE PROTOCOL

- » TO OUTLINE METHODS FOR
RESEARCH ON PANCREAS
ACINAR CELL TUMORS
- » CONDUCT STUDIES OF
EFFECTS OF FC-143 IN ACINAR
CELLS

■ PROPOSAL PRESENTED MARCH 1996

– NO CONSENSUS , REQUESTED REVIEW

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3M RESPONSE TO APME TOX. COM ISSUES RE LONG-TERM DATA

- 3M SCD ASKED FOR MORE TIME
 - FALL 1996
- DUPONT DRAFT ARTICLE ON WYETH
 - 3M TOX. SUGGESTS AS METHOD FOR STUDYING MECHANISM OF PANCREATIC TUMOR FORMATION
- DUPONT PROPOSES MONKEY STUDY
 - DECEMBER 1996 MEETING WITH CHW

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R. JUNG QUESTIONS 17 JUNE 1996

- CAS NUMBERS ON 3M FC-143
MSDS
- ANALYTICAL METHOD FOR
SUBSTANCE IN BLOOD
- REVIEW OF EU R-40 LABEL
CRITERIA
- CHROMOSOMAL ABERRATION
ASSAY IN HUMAN VERSUS
ANIMAL CELLS

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Tuesday, August 20, 1996

- **1a.** Discuss and resolve if the MSDSs for FC-143, 118, 1006, etc. should list cas numbers found in EINECS for the branched isomers.
- **1b.** Determine which structures cas number 3825-26-1 includes.
- **1c.** Which structures are listed on TSCA, EINECS, etc

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Tuesday, August 20, 1996

- **2. Provide Reinhard Jung the analytical method for determining level of perfluorooctanoic acid in employee blood. They want to start monitoring of their employees; R. Jung would pass information to their physicians. Discussion between J. Mandel and their physicians is also desirable.**

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Tuesday, August 20, 1996

- **3. Review the criteria for use of R-40 EU label statement and determine if FC-143 and related products need such warning for irreversible damage.**

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Tuesday, August 20, 1996

- 4. Get chromosomal aberration assay in human lymphocytes started for FC-1090 which is the sodium salt of perfluorooctanoic acid and also get okay for the same study for FX-1006.

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3M ACTION ON R. JUNG QUESTIONS

■ AUGUST MEETING CALLED BY SCD ST. PAUL

- DECISION THAT CAS NUMBERS
ARE COMPLETE
- SCD SEEKS CONFIDENTIALITY
AGREEMENT FOR BLOOD
ANALYSIS METHODS
- REVIEW INDICATES R-40
“POSSIBLE RISK OF
IRREVERSIBLE DAMAGE” IS NOT
WARRANTED
- STUDY ON FC-1090 IN HUMAN
LYMPHOCYTES DONE

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PENDING ISSUES RE FC-143

■ APME RELATED

- STUDY OF MECHANISM OF PANCREATIC TUMORS
- COMPLETE TOXICITY SUMMARY STARTED JOINTLY BY 3M AND DUPONT
- COMPLETION OF SCF DOSSIER

■ 3M DUPONT RELATED

- MONKEY STUDY
- RISK ASSESSMENT

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DYNEON INTEREST IN APME

■ DYNEON PERSON NOW IN APME

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