

**CODING FORMS FOR SRC INDEXING**

<b>Microfiche No.</b>	OTS0001113		
<b>New Doc ID</b>	FYI-OTS-0794-1113		<b>Old Doc ID</b>
<b>Date Produced</b>	<b>Date Received</b>	<b>TSCA Section</b>	
01/07/93	07/26/94	FYI	
<b>Submitting Organization</b>	AKZO CHEMICALS INC		
<b>Contractor</b>			
<b>Document Title</b>	INITIAL SUBMISSION: AKZO CHEMICALS INC PRODUCT REGULATION AND TOXICOLOGY OF CHLOROALKYL PHOSPHATES DATED 01/07/93		
<b>Chemical Category</b>	CHLOROALKYL PHOSPHATES		

CODING FORM FOR GLOBAL INDEXING

Microfiche No. (7) e		1		No. of Pages		2	
Doc. I.D. <b>F42-0794-1113</b>		3		Old Doc. I.D.		4	
Case No. (a)						5	
Data Produced (6)		6		Data Bas'd (6)		7	
						8	
				Conf. Code e		N	
Check One: <input type="checkbox"/> Publications		<input type="checkbox"/> Internally Generated		<input type="checkbox"/> Externally Generated		9	
Pub/Journal Name						9	
						9	
Author(s)						10	
Organ. Name						11	
Bran/Div						12	
P.O. Box		13		Street No./Name		14	
CITY		15		STATE		16	
				ZIP		17	
COUNTRY						18	
NID No. (2)		19		P & B NO. (11)		20	
CONTRACTOR						21	
Doc Type						22	
				<b>F.Y.I.</b>			
Doc Title						23	
Client Name (300 char max)		25		CAS No. (10)		24	

*FYI-0794-00113*



FYI-94-001113  
INIT 87/26/94



64940000195



# AKZO

## CHEMICALS INC.

Product Regulation and Toxicology

### CHLOROALKYL PHOSPHATES

January 7, 1993

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07/26/93  
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# **CHLOROALKYL PHOSPHATES PRESENTATION AKZO CHEMICALS INC.**

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- **INTRODUCTION**
- **APPLICATIONS**
- **OECD/SIDS PROGRAM**
- **TOXICOLOGY**
- **ECOTOXICOLOGY**
- **HUMAN EXPOSURE**
- **PROPOSED TESTING**
- **CONCLUSIONS**

# INTRODUCTION

# **CHLOROALKYL PHOSPHATES**

## **23rd ITC Report (11/16/88)**

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- **TDCP Tris(1,3-dichloro-2-propyl) phosphate**
- **TCEP Tris(2-chloroethyl)phosphate**
- **TCIP Tris(1-chloro-2-propyl)phosphate**

# APPLICATIONS

## **TDCP/FYROL FR-2**

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- Additive flame retardant
- Flexible polyurethane foams
- Very good hydrolytic stability
- Very low volatility
- Stability to U.V. light
- **" Fyro! FR-2 is recommended only for foam application"**

## TCEP/FYROL CEF

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- Additive flame retardant
- Flexible polyurethane foams
- Low viscosity
- Hydrolytic stability
- Low volatility
- **"Fyrol CEF is not recommended either for direct applications to or for use in formulations which will be applied to fabrics intended for apparel use."**

## TCIP/FYROL PCF

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- Additive flame retardant
- Rigid polyurethane foams
- Low viscosity
- Hydrolytic stability
- Low volatility
- Reduced foam scorching
- **"Fyrol PCF is not recommended either for direct applications to or for use in formulations which will be applied to fabrics intended for apparel use."**

# **TCEP AND TDCP**

## **Polyurethane Foam Uses**

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- **AUTOMOTIVE FOAM USE**
  - U.S. DOT MVSS 302
  
- **UPHOLSTERED FURNITURE USE**
  - California Standard 117
  - California Standard 133
  - Other States

## **REDUCTION OF FIRE HAZARD**

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- Overall fire hazard reduced
- Fire escape time greatly increased
- Significantly less heat released
- Significantly less material consumed
- Significantly less toxic gas released
- No increase in smoke production

**OECD/SIDS PROGRAM**

# **TCIP**

## **Chemical/Physical Properties**

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- Vapor Pressure
- Water Solubility
- Flash Point
- Specific Gravity
- Decomposition Temperature
- Viscosity
- Pour Point
- Analytical Method
- Octanol/Water Partition Coefficient\*

\* Proposed Testing

# TCIP TOXICOLOGY

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- Acute oral toxicity
- Acute inhalation toxicity
- Acute dermal toxicity
- Dermal irritation
- Eye irritation
- 14-day repeated dose toxicity
- 13-week repeated dose toxicity
- Ames assay
- Mouse lymphoma assay
- Cell transformation assay
- UDS
- In vivo cytogenetics
- Acute delayed neurotoxicity
- Toxicokinetics
- 1-Generation reproduction study \*

\* Proposed Testing

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# TCIP

## ECOTOXICOLOGY DATA

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- Acute fish toxicity  
fathead minnow  
bluegill sunfish
- Acute invertebrate toxicity  
Daphnia magna
- Aquatic neurotoxicity \*
- Acute algal toxicity \*
- Aerobic biodegradation \*

\* Proposed Testing

# TOXICOLOGY

## **HISTORICAL INTRODUCTION TO THE FYROL FR-2 SAFETY ASSESSMENT PROGRAM**

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- "TRIS" (Tris[2,3-Dibromopropyl]phosphate) widely used
- 1975 Bruce Ames showed TRIS is a potent mutagen
- Some evidence that TRIS is a carcinogen
- 1977 TRIS banned for apparel and other uses
- Substitutes needed to meet fabric flammability standards
- 1977 Fyrol FR-2 introduced as substitute for TRIS
- Structural similarity raised concerns
- Toxicology information available in 1977 showed FYROL FR-2 has low toxicity

## **MANUFACTURER'S ACTIONS**

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- **Voluntarily withdrew FYROL FR-2 from apparel market**
- **Initiated voluntary toxicology testing program**
- **Maintained frequent communication with:**
  - Government Agencies**
  - Customers**
  - Government and University laboratories**
- **Informed regulators and customers of test results**
- **Responded to exposure-related safety concerns**

# ACUTE TOXICITY

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- **Acute Oral LD50**      **Rat: 2830 mg/kg**  
                                 **Mouse: 7500 mg/kg**  
                                 **Rabbit: 6800 mg/kg**
- **Acute Dermal LD50**    **Rabbit: >23900 mg/kg**
- **Acute Inhalation LC50**    **Rat: >9.8 mg/l**
- **Primary Eye Irritation:**      **Non-irritant**
- **Primary Skin Irritation:**      **Non-irritant**

**CONCLUSION: Fyrol FR-2 has low acute toxicity**

# FYROL FR-2 MUTAGENICITY TEST RESULTS

TEST	RESULTS	LABORATORY	YEAR
AMES TEST	NEGATIVE	COLUMBIA U.	1975
AMES TEST	WEAK POSITIVE	BRUCE AMES	1977
AMES TEST	NEGATIVE (35 TESTS)	LITTON	1977
AMES TEST	NEGATIVE	STAUFFER	1978
AMES TEST	WEAK POSITIVE	NORWAY NIH	1985
MOUSE LYMPH.	NEGATIVE - POINT	LITTON	1977
MOUSE LYMPH.	POSITIVE - CHROM AB	LITTON	1977
V79 CHL	NEGATIVE	NORWAY NIH	1985
DNA REPAIR	NEGATIVE	AMER. HEALTH	1982
DNA REPAIR	NEGATIVE	NORWAY NIH	1985
DROSOPHILA	NEGATIVE	LITTON	1978
BONE MARROW	NEGATIVE	LITTON	1979

CONCLUSION: FYROL FR-2 IS NOT GENOTOXIC OR MUTAGENIC

# EARLY COMMUNICATIONS

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DATE	FROM	TO	INFORMATION PROVIDED
AUG '77	STAUFFER	CPSC	All available toxicology data
SEPT '77	STAUFFER	CPSC	Preliminary Litton results
OCT '77	STAUFFER	CPSC	Presentations by Freudenthal, Ames, et. al at public hearing
OCT '77	STAUFFER	CPSC	Written copy of presentation
FEB '78	STAUFFER	CPSC	Litton final reports

**CONCLUSION:** The CPSC was promptly and continuously updated on results from manufacturer's testing program

# **FYROL FR-2 TOXICOLOGY SUMMARY**

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- **Neurotoxicity**
  - Acute Hen Study      No Neurotoxicity
  - Subchronic (90-day) study      No Neurotoxicity
- **Teratogenicity**
  - Maternal and fetal toxicity, MTD achieved
  - No teratogenic activity
- **Reproductive Toxicity**
  - CPSC study      No Reproductive Toxicity
  - Stauffer Study      No Reproductive Toxicity
- **Subchronic Toxicity**
  - CPSC Study, 90-Day Oral      No Target Organ Toxicity
  - CPSC Study, 90-Day Dermal      No Target Organ Toxicity

**COMMENT: No significant target organ toxicity**

## **FYROL FR-2 METABOLISM**

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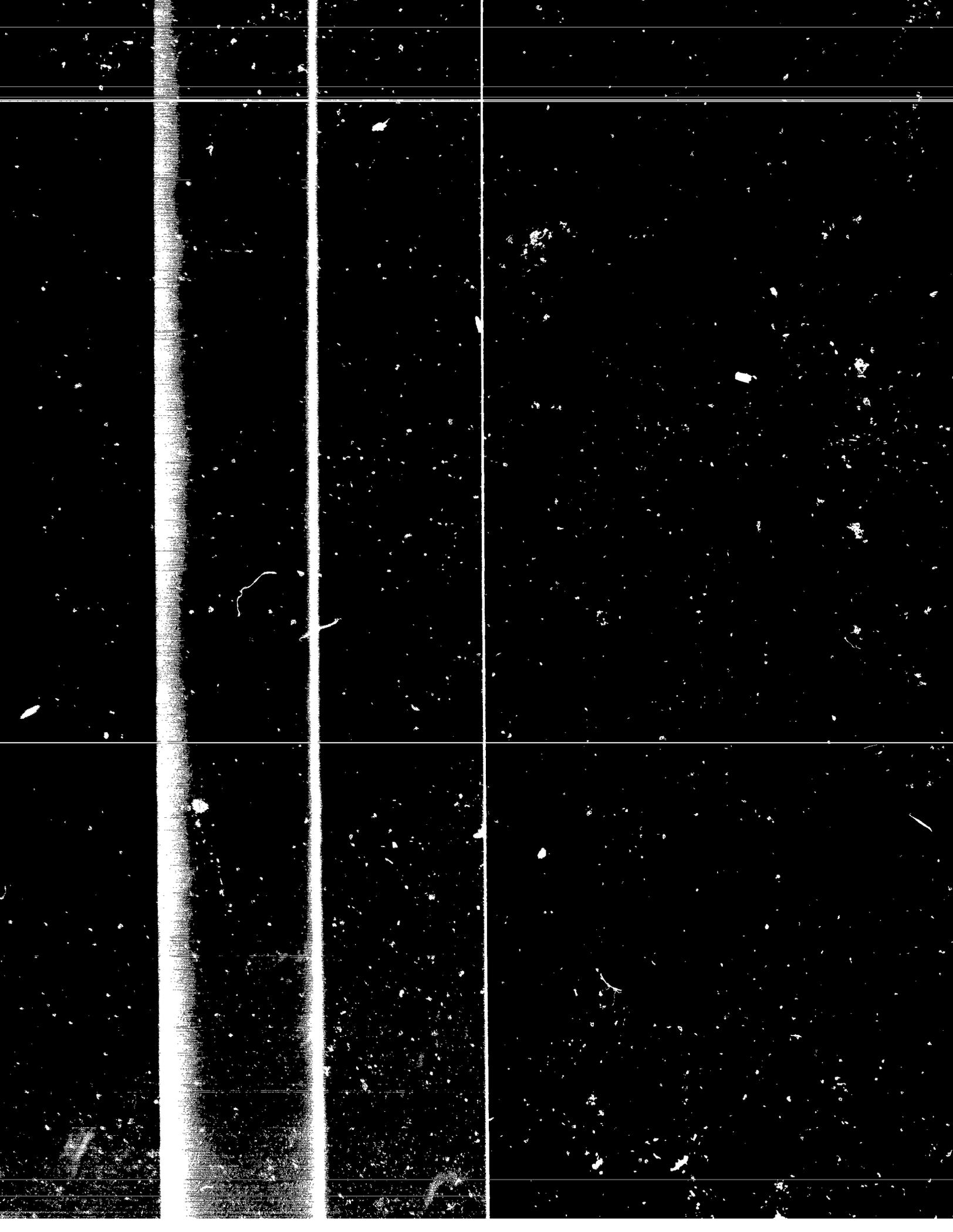
- **1980, NIEHS metabolism study in rats**
  - **Stauffer provided radioactive Fyrol FR-2**
  - **Absorbed through gut and skin**
  - **Metabolites identified**
  - **Rapidly excreted (>80% in 24 hours)**
  - **Results published in 1981**
  
- **1983, University of Oregon study in rats**
  - **Metabolites identified**
  - **Rapidly excreted (>92% in 5 days)**

**COMMENT: 1,3-Dichloro-2-propanone, postulated by Bruce Ames a mutagenic metabolite, was not identified as a metabolite in either study.**

# **FYROL FR-2 CARCINOGENICITY TEST**

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- **CHRONIC TOXICITY/CARCINOGENICITY TEST BY BIO/DYNAMICS**
- **TEST VOLUNTARILY INITIATED IN EARLY 1978**
- **RATS RECEIVED DIETARY FYROL FR-2 FOR 2 YEARS**
- **AUGUST, 1980, NOTICE OF POSSIBLE TESTICULAR TUMORS**
- **NOVEMBER, 1980, NOTICE OF LIVER CHANGES**
- **FINAL REPORT AVAILABLE IN SEPTEMBER, 1981**
- **FYROL FR-2 IS ONCOGENIC IN RATS**
- **AN NOEL WAS ESTABLISHED**



# COMMUNICATION BY STAUFFER OF TOXICOLOGY TEST RESULTS

DATE	TO	INFORMATION PROVIDED
AUG. '78	CPSC	TERATOLOGY, NEUROTOX. REPORTS
NOV. '79	GM, FORD, CPSC	12 MO. INTERIM BIOASSAY REPORT
DEC. '80	EPA, CPSC,	PRELIMINARY TUMOR DATA
DEC. '80	ALL CUSTOMERS	PRELIM. SUMMARY, IH, EXP. CONTROL
JAN. '81	GM, FORD, ETC.	SPECIAL PRESENTATIONS
FEB. '81	EPA	NOTIFICATION OF TUMOR DATA
SEPT. '81	EPA	FINAL REPORT OF BIOASSAY
SEPT. '81	ALL CUSTOMERS	SUMMARY, RISK ASSESSMENT
OCT. '81	GM, FORD, ETC.	FINAL REPORT OF BIOASSAY

**COMMENT: Regulatory agencies and customers were promptly informed of study results.**

# FYROL FR-2 CHRONIC TOXICITY/CARCINOGENICITY STUDY

ORGAN AND TUMOR TYPE	SEX	0	5	20	80 MG/KG
KIDNEYS					
RENAL CORTICAL TUMORS	M	1/60	3/60	9/60*	32/59*
	F	0/60	1/60	7/56*	29/60*
TESTES					
INTERSTITIAL CELL TUMORS	M	7/58	8/60	25/60*	34/56*
LIVER					
ADENOMA	M	2/60	7/60	1/60	16/60*
	F	1/60	1/60	4/55	9/60*
CARCINOMA	M	1/60	2/60	3/60	7/60
	F	0/60	2/60	2/55	4/60
ADRENAL GLANDS					
CORTICAL ADENOMA	M	5/59	3/14	5/16	5/57
	F	13/59	5/27	2/33	20/59*

\* Statistically significant

COMMENT: Possible exacerbation of normally occurring tumors

# FYROL FR-2 BIOASSAY TOTAL TUMOR INCIDENCE

	CONTROL	LOW	MID	HIGH
NON-MALIGNANT TUMORS	73/120	57/122	82/121	101/120
MALIGNANT TUMORS	32/120	30/122	34/121	41/120
ANIMALS WITH TUMORS	84/120	69/122	87/121	104/120

**COMMENT:** With age, rats develop spontaneously occurring tumors and, by the end of a 2-year bioassay, normally express a large number and variety of tumors in untreated populations.

## **ACTIONS TAKEN IN RESPONSE TO BIOASSAY RESULTS**

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- **EVALUATED EXISTING DATA TO ADDRESS TUMOR MECHANISM (GENOTOXIC VS. EPIGENETIC)**
- **EVALUATED WORKER EXPOSURE AT MANUFACTURING PLANT AND AT CUSTOMER FACILITIES**
- **REVIEWED EXISTING USES TO IDENTIFY EXPOSED POPULATIONS AND DISCONTINUE USES RESULTING IN SIGNIFICANT HUMAN EXPOSURE**
- **CONDUCTED EPIDEMIOLOGY STUDY AT MANUFACTURING PLANT**
- **CONDUCTED RISK ASSESSMENTS USING TUMOR INCIDENCE DATA FROM BIOASSAY**

# FYROL FR-2 RISK ASSESSMENTS

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1981 - ONE HIT MODEL (VERY CONSERVATIVE!)

- PREDICTS RISKS AT LOW EXPOSURE LEVELS
- ASSESSED RISK FROM USE IN AUTOMOTIVE FOAM
- ASSUMPTIONS MADE INCLUDE:
  - HUMAN SKIN ABSORPTION OF 14 PERCENT
  - 50% OF BODY SURFACE EXPOSED 8 HOURS/DAY (DRIVING WITH NO SHIRT, WEARING SHORTS)
  - DAILY EXPOSURE, 7 DAYS/WEEK, FOR 70 YEARS
  - HUMANS AND RATS ARE EQUALLY SENSITIVE

<u>TUMOR TYPE</u>	<u>ADDITIONAL CANCERS/MILLION</u>
RENAL ADENOMAS	0.7
HEPATIC CARCINOMAS	0.1
HEPATIC ADENOMAS	0.2
TESTICULAR INTERSTITIAL	1.0

**COMMENT: Exposure to treated foam in automobiles does not cause unreasonable human health risk**

# FYROL FR-2 RISK ASSESSMENTS, CONTINUED

## 1983 - RISK ASSESSMENT USING 3 MODELS

- "WORST CASE" ASSUMPTIONS USED, INCLUDING:

- SKIN ABSORPTION 100 PERCENT

- DAILY EXPOSURE, 7 DAYS/WEEK, 70 YEARS

<u>EXPOSURE</u>	<u>ONE-HIT</u>	<u>MULTI-STAGE</u>	<u>PROBIT</u>
AUTOMOBILE SEATS (DERMAL)	0.4	0.3	0.00001
OCCUPATIONAL (INHALATION)	0.1	0.1	0.0000003

**COMMENT: Models confirm no significant human health risk from major uses of Fyrol FR-2.**

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# FURTHER COMMUNICATION BY STAUFFER

DATE	TO	INFORMATION PROVIDED
MAY '82	EPA, CPSC	RESULTS OF RISK ASSESSMENTS
DEC '82	EPA, CPSC	REPORTS FOR DNA REPAIR AND FERTILITY
APRIL '83	CUSTOMERS	SUMMARY STATEMENT ON PRODUCT SAFETY
SEPT. '84	CPSC	MEETING ON USES/EXPOSURE/RISKS CPSC INDICATED NO FURTHER CONCERNS

COMMENT: Akzo continues to review potential new uses, provides toxicology/risk assessment information to government agencies and potential new users, and is pursuing the mechanism of tumor induction.

# FYROL CEF TOXICOLOGY TEST RESULTS

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- **Acute Toxicity**
  - Acute Oral LD50                      Rat: 550 mg/kg
  - Acute Dermal LD50                  Rabbit: >5000 mg/kg
  - Acute Inhalation LC50              Rat: >5 mg/l
  - Primary Eye Irritation              Rabbit: Non-irritant
  - Primary Skin Irritation              Rabbit: Mild irritant
  
- **Neurotoxicity**
  - Hen Neurotoxicity Test              No neurotoxicity
  - Rabbit Cholinesterase                No cholinesterase inhibition
  
- **Subchronic Toxicity**
  - 90-day Dietary Study in Rats
  - Achieved MTD (8000 ppm)
  - No Treatment-Related Tissue Changes

**COMMENT: Fyrol CEF has demonstrated low toxicity in all tests in which it has been evaluated**

# FYROL CEF MUTAGENICITY TEST RESULTS

TEST SYSTEM	WITH ACTIVATION	WITHOUT ACTIVATION
Ames Test (4 separate tests)	-	-
<u>Saccharomyces Cerevisiae</u>	-	-
Mouse Lymphoma - Gene Mutation	-	-
Mouse Lymphoma - Chromosomal Aberr.	-	-
Mouse Lymphoma - Sister Chromatid	+	-
Unscheduled DNA Synthesis - Human	-	-
CHO - Chromosomal Aberration	-	-
Rat Bone Marrow Cytogenetics	-	-

**COMMENT: Mutagenicity tests show Fyrol CEF does not adversely interact with DNA and provides strong evidence that it is not a genotoxic carcinogen**

# FYROL CEF NTP BIOASSAY

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- **NTP study entitled "Toxicology and Carcinogenesis Studies of TRIS(2-Chloroethyl) Phosphate in F344/N Rats and B6C3F1 Mice."**

# FYROL CEF NTP BIOASSAY

Oral gavage of Fyrol CEF for 2 years resulted in an increased incidence of benign renal tumors in rats:

	ADENOMAS	CARCINOMAS
0 44 88	0 44 88	0 44 88 mg/kg/day
MALE RAT	1/50 5/50 24/50	1/50 0/50 1/50
FEMALE RAT	0/50 2/50 5/50	0/50 0/50 0/50

# **FYROL CEF NTP BIOASSAY**

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- **NTP considers induction of both benign and malignant tumors a carcinogenic response**
- **Regulatory policy does not allow NTP to differentiate between benign and malignant tumors**
- **Therefore NTP must consider induction of benign tumors "Clear Evidence of Carcinogenic Activity"**

## **NTP BIOASSAY RESULTS SHOWED**

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- **Increased incidence of only benign tumors**
- **No evidence of transformation to malignancy**
- **Therefore mechanism appears to be epigenetic**
- **Mutagenicity tests support epigenetic mechanism**
- **Several chemicals induce benign renal tumors in rats**

## INDUCERS OF BENIGN RENAL TUMORS

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CHEMICAL	MECHANISM
Unleaded gasoline	Alpha-2U-Globulin
1,4-Dichlorobenzene	Alpha-2U-Globulin
2,2,4-Trimethylpentane	Alpha-2U-Globulin
4-Aminophenol	Active Metabolite
Hydroquinone	Active Metabolite
Severai Chloroalkenes	Active Metabolite

**COMMENT:** Benign renal tumor induction via cell proliferation appears to be common in the rat and may be species specific

## **FYROL CEF - RECENT AND ONGOING STUDIES**

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- **NIEHS Cell Proliferation Study**
  - Localized in outer margin of medulla (site of tumors)
  - Provides support of an epigenetic mechanism
  - Significantly increased cell proliferation
- **All genotoxicity tests conducted by NTP were negative**
- **According to Dr. H.B. Matthews, the NTP/NIEHS will do no further studies with Fyrol CEF.**
- **SRI validating state-of-the-art tests that may distinguish between genotoxic and epigenetic mechanisms**
  - May conduct studies to verify epigenetic mechanism
  - Would complement NIEHS cell proliferation study
- **Akzo considering multispecies metabolism study**

# ECOTOXICOLOGY

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# ECOTOXICOLOGY

	TCEP	TDCP	TCIP
Acute Fish	X	X	X
Neurotoxicity Fish	*	*	*
Acute Invertebrate	*	*	X
Acute Algal	*	*	*
Activated Sludge EC50	X	X	-
Biodegradation Tier I	X	X	-
Biodegradation Tier II	*	*	*

X = Test Completed

- = Not Tested

\* = Proposed Test

# HUMAN EXPOSURE

0 0 4 3

# **EXPOSURE SCENARIOS AND EPIDEMIOLOGY OF FR-2 IN THE PRODUCTION AND USE OF URETHANE FOAMS**

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- **CHLOROALKYL PHOSPHATE MANUFACTURING PROCESS**
- **FOAM MANUFACTURING/FABRICATION PROCESS**
- **FOAM PROCESSORS AND CONSUMER END-USE ISSUES**
- **ENVIRONMENTAL ISSUES**

## FR-2 EXPOSURE: THE MANUFACTURING PROCESS

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- Phosphorous oxychloride + epichlorohydrin ---> FR-2
  - Manufactured in a semi-closed batch process
  - Formulated in a semi-closed blending operation
  - CEF and FR-2 have very low vapor pressures
  - Control epichlorohydrin and one controls FR-2
- Limited number of workers potentially exposed
- In-place safeguards
  - Training program
  - Protective equipment and clothing
  - Engineering controls
- FR-2 monitoring program
  - Exposure to vapor ranged from non-detectable to 11 ppb
  - Increasing limit of detection (0.1 ppb)
  - Epidemiology studies

(cont'd)

## **FR-2 EXPOSURE: THE MANUFACTURING PROCESS**

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- **Chloroalkyl phosphate epidemiology studies**
  - **Retrospective cohort studies**
  - **N=289**
  - **1956 through 1980**
  - **1983 morbidity study: no causal relationships determined**
  - **1983 mortality study: no causal relationships determined**
  
- **CONCLUSIONS: IH surveys and retrospective epidemiology studies demonstrate the low potential for FR-2 exposure and adverse health risks during normal manufacturing operations.**

## FR-2 EXPOSURE: THE FOAM MANUFACTURING AND FABRICATION PROCESS

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- Approximately 90% of the urethane foam marketplace is for automotive interiors and furniture cushioning
- Foam efficiently fabricated to specifications limits downstream waste and exposure
- Fabricated foams contain only 5-10% FR-2
- Control isocyanates in foam production and exposure to FR-2 is automatically controlled; closed system
- FR-2 vapor pressure and basic industrial hygiene programs limit inhalation and dermal exposure potentials
- **CONCLUSION:** There is a limited potential for inhalation and dermal exposure to FR-2 during the manufacturing and fabrication of urethane foam.

# FR-2 EXPOSURE: FOAM PROCESSORS AND CONSUMER END-USE ISSUES

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- ACI controls the end-use applications -- "Fyrol FR-2 is recommended only for foam applications"
  - Sells only to foam industry
  - Excludes curtains, fabrics, apparel, etc.
- Major markets are those products with covered foams which limits dermal exposure
- FR-2 vapor pressure limits inhalation exposure
- Exposure of automakers to FR-2 in processing foam for use in automotive interiors was insignificant
- **CONCLUSION:** There is limited inhalation and dermal exposure potential to FR-2 in consumer end-use products as exemplified by insignificant exposure to FR-2 in automakers installing foam in automotive interiors -- the most significant end-use application for FR-2.

# FR-2 EXPOSURE: ENVIRONMENTAL ISSUES

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- **Biodegradation**
  - Screening test has been completed
  - Definitive assay planned
- **Significant risk reduction efforts through controlled stoichiometry and environmental controls have decreased FR-2 related emissions**
  - Air
  - Water
  - Landfill
- **CONCLUSION:** Exposure to FR-2 via its release in the environment at the manufacturing site is insignificant due to enhanced controls over the stoichiometry of the manufacturing process coupled with significant changes in other engineering processes.

## **FR-2 EXPOSURE SUMMARY: LACK OF SIGNIFICANT EXPOSURE**

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- **MANUFACTURING PROCESS --** Epidemiology studies demonstrated the lack of FR-2 exposure and related risk.
- **FOAM MANUFACTURING/FABRICATION PROCESS --** Controlled manufacturing practices and industrial hygiene standards along with the physical properties of FR-2 limit its dermal and inhalation exposure potential; exposure in the foam industry was deemed insignificant.
- **FOAM PROCESSORS AND CONSUMER END-USE ISSUES --** Controlled sales practices limit the end-use products and the potential exposure to the consumer; FR-2 inhalation exposure was shown to be insignificant in processing the end-use application in the automotive industry.
- **ENVIRONMENTAL ISSUES --** Exposure to FR-2 via its release in the environment at the manufacturing site is insignificant due to enhanced controls over the stoichiometry of the manufacturing process coupled with significant changes in other engineering processes.

## FR-2 EXPOSURE: CONCLUSION

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- THE POTENTIAL EXPOSURE TO FR-2 AT THE MANUFACTURING SITE; DURING FOAM MANUFACTURING, FABRICATION AND PROCESSING; AND IN END-USE PRODUCTS WAS DEMONSTRATED TO BE INSIGNIFICANT.

# **PROPOSED TESTING**

# PROPOSED TESTING

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## TCIP

Biodegradation

Acute Algae

Octanol-Water  
Partition  
coefficient

Reproduction study

## TDCP

Biodegradation

Acute Algae

Acute Daphnia

## TCEP

Biodegradation

Acute Algae

Acute Daphnia

# CONCLUSIONS

## **CHLOROALKYL PHOSPHATES CONCLUSIONS**

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- **FUNCTION:** Reduction of Fire Hazards
- **AVAILABLE DATA BASE:** Extensive
- **DOSE-RESPONSE DATA:** Available
- **HUMAN EXPOSURE DATA:** Available
- **HUMAN RISK:** Minimal
- **RISK REDUCTION PROGRAM:** Yes