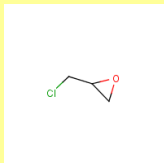
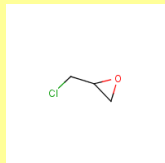


項目名	和訳結果(SIDS Dossier)	原文(SIDS Dossier)
1. 一般情報 GENERAL INFORMATION		
1.01 物質情報 SUBSTANCE INFORMATION		
CAS番号	106-89-8	106-89-8
物質名(日本語名)	エピクロロヒドリン	
物質名(英名)		1-chloro-2,3-epoxypropane
別名等		
国内適用法令の番号		
国内適用法令物質名		
OECD/HPV名称		
分子式	C3H5ClO	C3H5ClO
構造式		
備考	分子量 : 92.53	Molecular weight : 92.53

#### 1.02 安全性情報収集計画書／報告書作成者に関する情報

##### SPONSOR INFORMATION

機関名	OECD/HPVプログラム(SIAM22)により収集された情報 ( <a href="http://cs3-hq.oecd.org/scripts/hpv/">http://cs3-hq.oecd.org/scripts/hpv/</a> )	OECD/HPV Program, SIDS Dossier, assessed at SIAM 22- APR-2006 <a href="http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=hpv">http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=hpv</a>
代表者名		-
所在地及び連絡先		-
担当者氏名		-
担当者連絡先(住所)		-
担当者連絡先(電話番号)		-
担当者連絡先(メールアドレス)		-
報告書作成日		-
備考	スポンサー国: 米国	Sponsor Country: United States

#### 1.03 カテゴリー評価

##### DETAILS ON CHEMICAL CATEGORY

#### 1.1 一般的な物質情報

##### GENERAL SUBSTANCE INFORMATION

物質のタイプ	有機物	organic
物質の色・におい・形状等の情報	色 : 無色 臭い : 甘い, 刺激臭	Colour : Colorless Odour : Sweet, pungent odor
物理的状態(20°C、1013hPa)	液体	liquid
純度(重量／重量%)	> 99.8 % w/w	> 99.8 % w/w
出典	(2)	(2)
備考		

#### 1.2 不純物

##### IMPURITIES

#### 1.3 添加物

##### ADDITIVES

#### 1.4 別名

##### SYNONYMS

#### 1.5 製造・輸入量

##### QUANTITY

#### 1.6 用途情報

##### USE PATTERN

#### 1.7 環境および人への暴露情報

##### SOURCES OF EXPOSURE

#### 1.8 追加情報

##### ADDITIONAL INFORMATION

#### 2. 物理化学的性状

##### PHYSICAL CHEMICAL DATA

#### 2.1 融点

##### MELTING POINT

試験物質名		
CAS番号		
純度等		
注釈		
方法		
GLP	データなし	no data
試験を行った年		
試験条件		
結果		
融点: °C	-57 °C	-57 °C

分解: °C		
昇華: °C		
結論		
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(50)	(50)
引用文献		
備考	フラグ: SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	データなし	no data
CAS番号		
純度等		
注釈		
方法		
GLP	いいえ	no
試験を行った年		
試験条件		
結果		
融点: °C	-57.1 ° C	-57.1 ° C
分解: °C		
昇華: °C		
結論		
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(52) (53) (54)	(52) (53) (54)
引用文献		
備考		

## 2.2 沸点

### BOILING POINT

試験物質名		
CAS番号		
純度等		
注釈		
方法		
GLP	いいえ	no
試験を行った年		
試験条件		
結果		
沸点: °C	116 – 117 ° C	116 – 117 ° C
圧力	1013 hPa	at 1013 hPa
分解: °C		
結論		
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(60)	(60)
引用文献		
備考	フラグ: SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

## 2.3 密度(比重)

### DENSITY (RELATIVE DENSITY)

試験物質名		
CAS番号		
純度等		
注釈		
方法		
GLP	データなし	no data
試験を行った年		
試験条件		
結果	1.181 g/cm <sup>3</sup>	1.181 g/cm <sup>3</sup>
タイプ	密度	density
温度(°C)	20 ° C	at 20 ° C
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(59) (62)	(59) (62)
引用文献		
備考		

## 2.4 蒸気圧

### VAPOUR PRESSURE

試験物質名		
CAS番号		
純度等		
注釈		
方法		
GLP		
試験を行った年		
試験条件		

結果		
蒸気圧	22.7 hPa	22.7 hPa
温度: °C	25 ° C	at 25 ° C
分解: °C		
結論		
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(64) (54)	(64) (54)
引用文献		
備考	フラグ: SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	その他の試験物質	other TS																					
CAS番号																							
純度等	>99%	>99% purity																					
注釈																							
方法	(測定): ASTM E1719-95に相当	(measured): Equivalent to ASTM E1719-95																					
GLP	いいえ	no																					
試験を行った年																							
試験条件	2つのebulliometric method	Twin ebulliometric method																					
結果																							
蒸気圧	22.8 hPa	22.8 hPa																					
温度: °C	25 ° C	at 25 ° C																					
分解: °C																							
結論																							
注釈	※英文参照	<p>Temperature (C) P (mmHg) P (hPa)</p> <table> <tr><td>34.247</td><td>27.657</td><td>36.876</td></tr> <tr><td>40.033</td><td>38.378</td><td>51.171</td></tr> <tr><td>48.392</td><td>59.023</td><td>78.697</td></tr> <tr><td>54.693</td><td>79.247</td><td>105.663</td></tr> <tr><td>59.744</td><td>99.175</td><td>132.223</td></tr> <tr><td>76.734</td><td>195.374</td><td>260.499</td></tr> <tr><td>87.649</td><td>291.198</td><td>388.264</td></tr> </table> <p>Based on these data the coefficients for the Antoine Equation of <math>\log P = A - B/(T+C)</math> are <math>A = 7.27619</math>, <math>B = 1468.20</math>, <math>C = 217.943</math> (DEG C, MMHG).</p> <p>Using the Antoine equation and these coefficients, the vapor pressure at 25 deg C was calculated to be 17.1 mmHg (22.8 hPa).</p>	34.247	27.657	36.876	40.033	38.378	51.171	48.392	59.023	78.697	54.693	79.247	105.663	59.744	99.175	132.223	76.734	195.374	260.499	87.649	291.198	388.264
34.247	27.657	36.876																					
40.033	38.378	51.171																					
48.392	59.023	78.697																					
54.693	79.247	105.663																					
59.744	99.175	132.223																					
76.734	195.374	260.499																					
87.649	291.198	388.264																					
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions																					
信頼性の判断根拠																							
出典	(65)	(65)																					
引用文献																							
備考																							

## 2.5 分配係数(log Kow)

### PARTITION COEFFICIENT

試験物質名	データなし	no data
CAS番号		
純度等		
注釈	オクタノール/水分配係数	Partition coefficient : octanol-water
方法	(測定): Slow stirring method (Brooke et al., 1986)	(measured): Slow stirring method (Brooke et al., 1986)
GLP	データなし	no data
試験を行った年		
試験条件	試験開始温度は「室温」であった	Temperature was stated as "room temperature".
結果		
Log Kow	0.45	0.45
温度: °C	25 ° C	at 25 ° C
結論		
注釈	※英文参照	<p>Brooke, D.N., Dobbs, J.J. and Williams, N. (1986) Octanol:water partition coefficients (P): measurement, estimation and interpretation; particularly for chemicals with <math>P &gt; 10^{exp5}</math>. Ecotoxicol. Environ. Saf. 11: 251-260. Method was similar to the OECD Shake Flask method, but because of the tendency of the material to form emulsions, a modification of the method was done: the water and octanol phases were allowed to equilibrate under conditions of slow stirring for 2-3 days.</p>
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(67)	(67)
引用文献		
備考	フラグ: SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

## 2.6.1 水溶解性(解離定数を含む)

### WATER SOLUBILITY & DISSOCIATION CONSTANT

試験物質名		
CAS番号		
純度等		
注釈		
方法		
GLP		
試験を行った年		
試験条件		
結果		
水溶解度	66 g/l	66 g/l

温度: °C	25 ° C	at 25 ° C
pH		
pH測定時の物質濃度		
結論		
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(69)	(69)
引用文献		
備考	フラグ: SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint
解離定数		
試験物質		
同一性		
方法		
温度: °C		
GLP		
試験条件		
試験を行った年		
結果		
結論		
注釈		
信頼性スコア		
信頼性の判断根拠		
出典		
引用文献		
備考		

試験物質名		
CAS番号		
純度等		
注釈		
方法		
GLP		
試験を行った年		
試験条件		
結果		
水溶解度	60 g/l	60 g/l
温度: °C	20 ° C	at 20 ° C
pH		
pH測定時の物質濃度		
結論		
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(60)	(60)
引用文献		
備考		
解離定数		
試験物質		
同一性		
方法		
温度: °C		
GLP		
試験条件		
試験を行った年		
結果		
結論		
注釈		
信頼性スコア		
信頼性の判断根拠		
出典		
引用文献		
備考		

## 2.6.2 表面張力 SURFACE TENSION

## 2.7 引火点(液体) FLASH POINT (LIQUIDS)

試験物質名		
CAS番号		
純度等		
注釈		
方法	ASTM D 56 TCC	ASTM D 56 TCC
GLP	データなし	no data
試験を行った年		
試験条件		
結果		
引火点: °C	31 ° C	31 ° C
試験のタイプ	密閉式	closed cup
結論		
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(71)	(71)

引用文献		
備考		

2.8 自己燃焼性（固体／気体）  
AUTO FLAMMABILITY (SOLIDS/GASES)

試験物質名		
CAS番号		
純度等		
注釈		
方法		
GLP		
試験を行った年		
試験条件		
結果		
自動発火点: °C	371 °C	371 °C
圧力		
結論		
注釈		
信頼性スコア	(4) 信頼性を評価できない	(4) not assignable
信頼性の判断根拠		
出典	(48)	(48)
引用文献		
備考		

2.9 引火性  
FLAMMABILITY

試験物質名		
CAS番号		
純度等		
注釈		
方法		
GLP	データなし	no data
試験を行った年		
試験条件		
結果		
固体の場合		
引火性が高い		
気体の場合		
水との接触		
結論	引火性である	flammable
注釈	下限界 = 3.8% v/v 上限界 = 21% v/v	Lower limit = 3.8% v/v Upper limit = 21% v/v
信頼性スコア	(4) 信頼性を評価できない	(4) not assignable
信頼性の判断根拠		
出典	(47) (58) (4) (48) (9) (11)	(47) (58) (4) (48) (9) (11)
引用文献		
備考		

2.10 爆発性  
EXPLOSIVE PROPERTIES

試験物質名		
CAS番号		
純度等		
注釈		
方法		
GLP	データなし	no data
試験を行った年		
試験条件		
結果		
火により爆発		
m-ジニトロベンゼンより摩擦に敏感		
m-ジニトロベンゼンより衝撃に敏感		
爆発性ない		
その他		
結論	爆発性なし	not explosive
注釈	20°C、1 hPaの大気中における爆発限界: -下限: 3.8 vol% = 142 g/m3 -上限: 21 vol% = 785 g/m3	Explosion limits in air at 20 degrees C and 1 hPa: -lower: 3.8 vol% = 142 g/m3 -upper: 21 vol% = 785 g/m3
信頼性スコア	(4) 信頼性を評価できない	(4) not assignable
信頼性の判断根拠		
出典	(59) (51)	(59) (51)
引用文献		
備考		

2.11 酸化性  
OXIDISING PROPERTIES

2.12 酸化還元ポテンシャル  
OXIDATION/REDUCTION POTENTIAL

2.13 その他の物理化学的性状に関する情報  
ADDITIONAL INFORMATION

3. 環境運命と経路  
ENVIRONMENTAL FATE AND PATHWAYS  
3.1 安定性  
STABILITY  
3.1.1. 光分解  
PHOTODEGRADATION

試験物質名		
CAS番号		
純度等		
注釈		
方法		
タイプ	大気	air
GLP		
試験を行った年		
光源と波長(nm)		
太陽光強度に基づいた相対強度	太陽光強度に基づく	based on intensity of sunlight
物質のスペクトル		
試験条件		
結果		
物質濃度		
温度(°C)		
直接光分解		
半減期t <sub>1/2</sub>		
分解度(%)と時間		
量子収率 (%)		
間接光分解		
増感剤(タイプ)	OH	OH
増感剤濃度	1500000 molecule/cm <sup>3</sup>	1500000 molecule/cm <sup>3</sup>
速度定数	.00000000000044 cm <sup>3</sup> /(molecule*sec)	.00000000000044 cm <sup>3</sup> /(molecule*sec)
半減期t <sub>1/2</sub>	292 時間:実験データに基づく	50 % after 292 hour(s); value based on experimental data
分解生成物		
結論		
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(72)	(72)
引用文献		
備考	フラグ: SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

試験物質名		
CAS番号		
純度等		
注釈		
方法		
タイプ	大気	air
GLP		
試験を行った年		
光源と波長(nm)	太陽光、> 290 nm	Sun light、> 290 nm
太陽光強度に基づいた相対強度	約2.6 太陽光強度に基づく	ca. 2.6 based on intensity of sunlight
物質のスペクトル		
試験条件		
結果		
物質濃度	.0378 mg/l	.0378 mg/l
温度(°C)	at 27 ° C	at 27 ° C
直接光分解		
半減期t <sub>1/2</sub>	16時間後、測定データに基づく	16 hour(s) based on measured data
分解度(%)と時間		
量子収率 (%)		
間接光分解		
増感剤(タイプ)		
増感剤濃度		
速度定数		
半減期t <sub>1/2</sub>		
分解生成物		
結論		
注釈		
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(73)	(73)
引用文献		
備考		

試験物質名		
CAS番号		
純度等		
注釈	※英文参照	ECH does not strongly absorb solar ultraviolet radiation, so that direct photochemical degradation would seem unlikely [Santodonato et al. (1980); Krijgsheld & van der Gen (1986)].
方法	EPIWIN v3.05 AOPWINによる計算	(calculated): EPIWIN v3.05 AOPWIN
タイプ	大気	air
GLP		
試験を行った年	2000	2000
光源と波長(nm)		
太陽光強度に基づいた相対強度	太陽光強度に基づく	based on intensity of sunlight

物質のスペクトル	$\lambda$ (max, >295nm) : 204 nm $\epsilon$ (max) : 27 $\epsilon$ (295) :	lambda (max, >295nm) : 204 nm epsilon (max) : 27 epsilon (295) :
試験条件		
結果		
物質濃度	24.1 mmol/l	24.1 mmol/l
温度(°C)		
直接光分解		
半減期t1/2		
分解度(%)と時間		
量子収率(%)		
間接光分解		
増感剤(タイプ)	OH	OH
増感剤濃度	500000 molecule/cm <sup>3</sup>	500000 molecule/cm <sup>3</sup>
速度定数	.00000000000066 cm <sup>3</sup> /(molecule*sec)	.00000000000066 cm <sup>3</sup> /(molecule*sec)
半減期t1/2	約 24 日間	ca. 50 % after 24 day(s)
分解生成物		
結論		
注釈	※英文参照	UV/VIS absorption spectrum for 0.25 % ECH in methanol (21.4 mmol/l) gives the following parameters: - lambda max: 204 nm - epsilon max: 27 l/mol.cm
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(75) (76) (68) (77)	(75) (76) (68) (77)
引用文献		
備考		

### 3.1.2. 水中安定性(加水分解性)

#### STABILITY IN WATER

試験物質名	1.1 – 1.4で規定	as prescribed by 1.1 – 1.4
CAS番号		
純度等		
注釈	タイプ: 非生物学的	Type : abiotic
方法	OECDガイドライン 111 “pHの機能としての加水分解”	OECD Guide-line 111 “Hydrolysis as a Function of pH”
GLP	はい	yes
試験を行った年	2001	2001
試験条件		
結果		
設定濃度		
実測濃度		
所定時間後の分解度(%)、pH、温度		
半減期	t1/2 pH4 : = 7.3 日間、20 ° C t1/2 pH7 : = 3.9 日間、20 ° C t1/2 pH9 : = 6.8 日間、20 ° C	t1/2 pH4 : = 7.3 day(s) at 20 ° C t1/2 pH7 : = 3.9 day(s) at 20 ° C t1/2 pH9 : = 6.8 day(s) at 20 ° C
分解生成物		
結論		
注釈	※英文参照	Breakdown products are not discussed in the report. However, it is known that hydrolysis of epichlorohydrin results in the formation of 1-chloro-2,3-dihydroxypropane also known as alpha-monochlorohydrin.
信頼性スコア	(1) 制限なく信頼性あり	(1) valid without restriction
信頼性の判断根拠		
出典	(81)	(81)
引用文献		
備考	フラグ: SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	1.1 – 1.4で規定	as prescribed by 1.1 – 1.4
CAS番号		
純度等		
注釈	タイプ: 非生物学的	Type : abiotic
方法	OECDガイドライン 111 “pHの機能としての加水分解”	OECD Guide-line 111 “Hydrolysis as a Function of pH”
GLP	はい	yes
試験を行った年	2001	2001
試験条件		
結果		
設定濃度		
実測濃度		
所定時間後の分解度(%)、pH、温度		
半減期	t1/2 pH4 : = 1.3 日間、35 ° C t1/2 pH7 : = .8 日間、35 ° C t1/2 pH9 : = 1.4 日間、35 ° C	t1/2 pH4 : = 1.3 day(s) at 35 ° C t1/2 pH7 : = .8 day(s) at 35 ° C t1/2 pH9 : = 1.4 day(s) at 35 ° C
分解生成物	いいえ	no
結論		
注釈	※英文参照	Breakdown products are not discussed in the report. However, it is known that hydrolysis of epichlorohydrin results in the formation of 1-chloro-2,3-dihydroxypropane also known as alpha-monochlorohydrin.
信頼性スコア	(1) 制限なく信頼性あり	(1) valid without restriction
信頼性の判断根拠		
出典	(81)	(81)
引用文献		
備考		

試験物質名	1.1 - 1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等		
注釈	タイプ: 非生物学的	Type : abiotic
方法	その他	other
GLP	いいえ	no
試験を行った年	1977	1977
試験条件		
結果		
設定濃度		
実測濃度		
所定時間後の分解度(%), pH, 温度		
半減期	t1/2 pH4 : = 6.3 日間、20 ° C t1/2 pH7 : = 6.5 日間、20 ° C t1/2 pH9 : = 6.5 日間、20 ° C t1/2 pH 10 : = 6.5 日間、20 ° C	t1/2 pH4 : = 6.3 day(s) at 20 ° C t1/2 pH7 : = 6.5 day(s) at 20 ° C t1/2 pH9 : = 6.5 day(s) at 20 ° C t1/2 pH 10 : = 6.5 day(s) at 20 ° C
分解生成物		
結論		
注釈	計算による半減期 推奨値: t1/2 = 6.5 日間	Calculated half-life values. Recommended value : t1/2 = 6.5 days.
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(82)	(82)
引用文献		
備考		

### 3.1.3. 土壌中安定性 STABILITY IN SOIL

### 3.2. モニタリングデータ(環境) MONITORING DATA(ENVIRONMENT)

試験物質名		
CAS番号		
純度等		
注釈		
方法		
測定タイプ(地点)	バックグラウンド濃度	background concentration
媒体	表層水	surface water
結果	< 10 µg/l	< 10 µg/l
結論		
注釈	エピクロロヒドリンは、10 µg/Lの検出下限では検出されなかった。	Epichlorohydrin was not detected, detection limit of 10 micrograms/L
信頼性スコア		
信頼性の判断根拠		
出典		
引用文献	(84)	(84)
備考		

試験物質名		
CAS番号		
純度等		
注釈		
方法		
測定タイプ(地点)	バックグラウンド濃度	background concentration
媒体	底質	sediment
結果	< 60 mg/kg soil 乾燥重量	< 60 mg/kg soil dw
結論	濃度 < 60 µg/kg (日本, 1977).	Concentration < 60 microg/kg (Japan 1977).
注釈	エピクロロヒドリンは、60 µg/kgの検出下限では検出されなかった。	Epichlorohydrin was not detected, detection limit was 60 micrograms/kg
信頼性スコア		
信頼性の判断根拠		
出典		
引用文献	(85)	(85)
備考		

試験物質名		
CAS番号		
純度等		
注釈		
方法		
測定タイプ(地点)	汚染地域の濃度	concentration at contaminated site
媒体	大気	air
結果		
結論		
注釈	EPA (1987) の SAIC (Science Applications International Corporation)による推定では、製造及び加工工場周辺のエピクロロヒドリン 濃度は > 0.05 mg/m3 であった。	According to an EPA (1987) estimation cited by the SAIC (Science Applications International Corporation), ECH concentrations > 0.05 mg/m3 can be detected in the vicinity of production and processing plants.
信頼性スコア		
信頼性の判断根拠		



出典		
引用文献	(44)	(44)
備考		

### 3.3. 移動と分配

#### TRANSPORT AND DISTRIBUTION

##### 3.3.1 環境区分間の移動

#### TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

試験物質名																																																																										
CAS番号																																																																										
純度等																																																																										
注釈	タイプ : フガシティモデル level III	Type : fugacity model level III																																																																								
方法	Mackay, D., 2001. 多媒体環境モデル. :Fugacityアプローチ. Lewis Publishers, CRC Press, Boca Raton, FL. Models available at: <a href="http://www.trentu.ca/cemc/models.html">http://www.trentu.ca/cemc/models.html</a>	other: Mackay, D., 2001. Multimedia Environmental Models: The Fugacity Approach. Lewis Publishers, CRC Press, Boca Raton, FL. Models available at: <a href="http://www.trentu.ca/cemc/models.html">http://www.trentu.ca/cemc/models.html</a>																																																																								
	実施年: 2001	Year : 2001																																																																								
結果																																																																										
媒体	大気-水-土壌-底質	air-water-soil-sedimen																																																																								
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環境分布予測と媒体中濃度 (level III/III)	Air : % (Fugacity Model Level I) Water : % (Fugacity Model Level I) Soil : % (Fugacity Model Level I) Biota : % (Fugacity Model Level II/III) Soil : % (Fugacity Model Level II/III)	Air : % (Fugacity Model Level I) Water : % (Fugacity Model Level I) Soil : % (Fugacity Model Level I) Biota : % (Fugacity Model Level II/III) Soil : % (Fugacity Model Level II/III)																																																																								
結論	<p>この化合物は中程度の溶解度、蒸気圧をもち、Kowは低い。これらの特性はこの物質が水中から大気中への揮発や、土壌及び底質への吸着の可能性が低いことを示す。</p> <p>大気中へ放出された場合、この物質は移流及び光分解による消失を伴うが、大気中に残存する。</p> <p>水中に放出された場合、この物質は水中に溶解してとどまり、生分解及び加水分解を受ける。</p> <p>土壌中に放出された場合、この物質は最初は土壌孔げき水(地下水)に溶解し、迅速な生分解及び加水分解による分解を受ける。</p> <p>この物質は、間接光分解、生分解、及び加水分解のように分解される可能性があるため、環境中での残存時間は見時間と推測される。</p>																																																																									
注釈	添付資料 : EPI 3.3.1.doc EPI fugacity1.doc	Attached document : EPI 3.3.1.doc EPI_fugacity1.doc																																																																								
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions																																																																								
信頼性の判断根拠	土壌への推定平衡分配 = 3.4 x 10exp-3%	Predicted equilibrium distribution to sediment = 3.4 x 10exp-3%																																																																								
出典	認められた計算法	Accepted calculation method																																																																								
引用文献	(89)	(89)																																																																								
備考	フラグ: SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint																																																																								

### 3.3.2 分配

#### DISTRIBUTION

試験物質名		
CAS番号		
純度等		
注釈		
媒体	大気 - 水 - 土壌 - 底質	air-water-soil-sediment
	実施年: 2001	Year : 2001
方法	Mackay, Level IIによる計算	Calculation according Mackay, Level I
試験条件		
結果		
結論		
注釈	添付資料 : EPI 3.3.2.doc EPI fugacity1.doc	Attached document : EPI 3.3.2.doc EPI_fugacity1.doc
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(90)	(90)
引用文献		
備考	フラグ: SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

試験物質名		
CAS番号		
純度等		
注釈	添付資料 : EPI fugacity3.doc	Attached document : EPI_fugacity3.doc
媒体	大気 - 生物相 - 底質 - 土壌 - 水	air - biota - sediment(s) - soil - water - aerosol
	実施年: 2001	Year : 2001
方法	Mackay, Level IIIによる計算	Calculation according Mackay, Level III

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Soil	720*	Modified MITI Test [7]																																																																																																																		
Sediment	720*	Modified MITI Test [7]																																																																																																																		
Suspended Sediment	**1.0 x 10 <sup>3</sup>	Not expected to adsorb to susp. sediment																																																																																																																		
Soil	**1.0 x 10 <sup>3</sup>	No adsorption/accumulation is expected																																																																																																																		
Aquatic	**1.0 x 10 <sup>3</sup>	Aquatic emissions not expected																																																																																																																		
Property	Value	Source																																																																																																																		
Data Temperature (°C)	25	Default environmental temperature																																																																																																																		
Chemical Type	1	Type 1 indicates chemical case partition into all environmental compartments																																																																																																																		
Molecular Mass (g/mol)	92.52	Calculated from molecular structure																																																																																																																		
Water Solubility (g/m³)	6.6 x 10 <sup>4</sup>	Measured value [1]																																																																																																																		
Vapor Pressure @ 25°C (Pa)	2.276	Measured value [2]																																																																																																																		
Melting Point (°C)	-93	Measured value [3]																																																																																																																		
Estimated Henry's Law Constant (H)	3.18	Calculated by Level I Fugacity Model [4]																																																																																																																		
(Pa·m³/mol)																																																																																																																				
Log K <sub>ow</sub>	0.45	Measured value [5]																																																																																																																		
Octanol:Water Partition Coefficient																																																																																																																				
Reaction Half-lives (hr.) Input to Level III Model																																																																																																																				
Air (vapor phase)	227	Estimated half-life for indirect photolysis [6]																																																																																																																		
Water (no susp. solids)	360*	Half-lives in water, soil, and sediment extrapolated from measured ready biodegradability in the																																																																																																																		
Soil	720*	Modified MITI Test [7]																																																																																																																		
Sediment	720*	Modified MITI Test [7]																																																																																																																		
Suspended Sediment	**1.0 x 10 <sup>3</sup>	Not expected to adsorb to susp. sediment																																																																																																																		
Soil	**1.0 x 10 <sup>3</sup>	No adsorption/accumulation is expected																																																																																																																		
Aquatic	**1.0 x 10 <sup>3</sup>	Aquatic emissions not expected																																																																																																																		
結果	この化合物は中程度の溶解度、蒸気圧をもち、Kowは低い。これらの特性はこの物質が水中から大気中への揮発や、土壌及び底質への吸着の可能性が低いことを示す。 大気中へ放出された場合、この物質は移流及び光分解による消失を伴うが、大気中に残存する。 水中に放出された場合、この物質は水中に溶解してとどまり、生分解及び加水分解を受ける。 土壌中に放出された場合、この物質は最初は土壌孔げき水（地下水）に溶解し、迅速な生分解及び加水分解による分解を受ける。 この物質は、間接光分解、生分解、及び加水分解のように分解される可能性があるため、環境中での残存時間は見時間と推測される。	This material has moderate water solubility, moderate vapor pressure, and a low log Kow. These properties dictate that the material has low potential to volatilize from water to air, or adsorb to soil and sediments. When released to air, the material will remain in air, with rapid dissipation occurring through advection and photochemical reaction. When released to water, the material will remain dissolved in water and will be rapidly degraded through biodegradation and hydrolysis reactions. When released to soil, the material will be primarily dissolved in soil pore water (groundwater), and will be rapidly degraded through biodegradation and hydrolysis reactions. Since the material is susceptible to destructive reactions such as indirect photolysis, biodegradation, and hydrolysis, this material is expected to be short-lived in the environment.																																																																																																																		
結論																																																																																																																				
注釈																																																																																																																				
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions																																																																																																																		
信頼性の判断根拠																																																																																																																				
出典	(90)	(90)																																																																																																																		
引用文献																																																																																																																				
備考	フラグ：SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint																																																																																																																		

### 3.4 好気性生分解性

#### AEROBIC BIODEGRADATION

試験物質名	データなし	no data
CAS番号		
純度等		
注釈	タイプ：好気性	Type : aerobic
方法	OECD ガイドライン 301 C “易分解性：修正 MITI試験 (I)”	OECD Guide-line 301 C “Ready Biodegradability: Modified MITI Test (I)”
培養期間	14日間	14 day(s)
植種源	活性汚泥	activated sludge
GLP	データなし	no data
試験を行った年		
試験条件		
試験物質濃度	100 mg/l 試験物質として	100 mg/l related to Test substance
汚泥濃度		
培養温度 °C		
対照物質および濃度(mg/L)		
分解度測定方法		
分解度算出方法		
結果		
最終分解度(%) 日目	14日後で18 (±) %	18 (±) % after 14 day(s)
分解速度-1		
分解速度-2		
分解速度-3		
分解速度-4		
分解生成物		
上記結果以外の分解度測定方法及びその結果		
対象物質の7, 14日目の分解度その他		
結論		
注釈	低い生分解性は速い加水分解によって説明される。20° C、p H7におけるエピクロロヒドリンの半減期は 3.9 日間である。	The low biodegradation could be explained by the rapid hydrolysis. The half-life of epichlorohydrin at 20° C is 3.9 days
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(91)	(91)
引用文献		
備考	フラグ：SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

試験物質名		
CAS番号		
純度等		
注釈	タイプ：好気性	Type : aerobic
方法	OECD ガイドライン 301 A (旧バージョン) “易分解性：修正 AFNOR 試験”	OECD Guide-line 301 A (old version) “Ready Biodegradability: Modified AFNOR Test”
培養期間		
植種源	活性汚泥、順化あり	activated sludge, adapted
GLP		
試験を行った年		
試験条件		
試験物質濃度	20 mg/l 試験物質として	20 mg/l related to Test substance
汚泥濃度		
培養温度 °C		

対照物質および濃度(mg/L)		
分解度測定方法		
分解度算出方法		
結果		
最終分解度(%) 日目	48時間後で 75 (±) %	75 (±) % after 48 hour(s)
分解速度-1		
分解速度-2		
分解速度-3		
分解速度-4		
分解生成物		
上記結果以外の分解度測定方法及びその結果	※英文参照	The incubations were done under denitrifying conditions to avoid loss by aeration, hence the results (35% in 24 hr and 75% in 48 hours) were given without a stripping effect. When the incubations were continued for 96 hours total, 91% biodegradation occurred. BOD30 was estimated as 97% of Theoretical Oxygen Demand (ThOD).
対象物質の7, 14日目の分解度その他		
結論		
注釈	標準試験法ではないが、この試験は良く記載され、エピクロロヒドリンが生分解されやすいという評価に値する結果を示している。	Although not a standardized test, this study was well documented and demonstrated that epichlorohydrin is highly biodegradable with the results acceptable for assessment.
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(92)	(92)
引用文献		
備考	フラグ: SIDSエンドポイントに重要な試験	Flag : Critical study for SIDS endpoint

試験物質名		
CAS番号		
純度等		
注釈	タイプ: 好気性	Type : aerobic
方法	単純迅速法、河川水及び海水	simple and rapid method, river and sea water
培養期間	3 日間	3 day(s)
植種源	河川水	river water
GLP		
試験を行った年		
試験条件		
試験物質濃度	100 mg/l 試験物質として	100 mg/l related to Test substance
汚泥濃度		
培養温度 °C		
対照物質および濃度(mg/L)		
分解度測定方法		
分解度算出方法		
結果		
最終分解度(%) 日目	3日後で60 (±) %	60 (±) % after 3 day(s)
分解速度-1		
分解速度-2		
分解速度-3		
分解速度-4		
分解生成物		
上記結果以外の分解度測定方法及びその結果		
対象物質の7, 14日目の分解度その他		
結論		
注釈	※英文参照	The simple and rapid screening method for biodegradation in river water was used and showed 60% degradation within three days. Biodegradation in sea water was also studied and was 8 % within three days. The authors concluded that epichlorohydrin was easily biodegraded in fresh water, but that biodegradation in sea water was more difficult. The authors also compare the results to a MITI test (no data available in publication) which was reported as showing that epichlorohydrin is easily biodegradable.
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(93)	(93)
引用文献		
備考		

### 3.5. BOD-5、CODまたはBOD-5／COD比

BOD-5、COD OR RATIO BOD-5/COD

試験物質名		
CAS番号		
純度等		
注釈		
BOD5の算出方法	APHA 標準法 No. 219	APHA standard method No. 219
GLP	いいえ	no
試験を行った年	1979	1979
試験条件	植種源: 家庭排水処理施設のろ過放流水(順化なし)	Inoculum: filtered effluent from domestic waste water treatment plant (non-adapted).
結果		
濃度		
結果 mgO <sub>2</sub> /L	BOD5 = 0.03 g O <sub>2</sub> / g substance = 3 % ThOD (ThOD = 1.21 g O <sub>2</sub> / g substance) COD = 1.16 g O <sub>2</sub> / g substance = 96 % ThOD	BOD5 = 0.03 g O <sub>2</sub> / g substance = 3 % ThOD (ThOD = 1.21 g O <sub>2</sub> / g substance) COD = 1.16 g O <sub>2</sub> / g substance = 96 % ThOD
BOD/COD比	0.026	0.026

その他	COD 方法: ASTM 標準法 No. D 1252-67 実施年: 1974	COD Method: ASTM Standards No. D 1252-67 Year : 1974
結論		
注釈	COD : = 1160 mg/g 物質 GLP : いいえ	COD : = 1160 mg/g substance GLP : no
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(96)	(96)
引用文献		
備考		

試験物質名		
CAS番号		
純度等		
注釈		
BOD5の算出方法	APHA s標準法 No. 219	APHA standard method No. 219
GLP	いいえ	no
試験を行った年	1979	1979
試験条件	植種源: 家庭排水処理施設のろ過放流水 (順化なし)	Inoculum: filtered effluent from domestic waste water treatment plant (non-adapted).
結果		
濃度		
結果 mgO <sub>2</sub> /L	BOD5 = 0.16 g O <sub>2</sub> / g substance = 14 % ThOD (ThOD = 1.21 g O <sub>2</sub> / g substance) inherently biodegradable  COD = 1.16 g O <sub>2</sub> / g substance = 96 % ThOD	BOD5 = 0.16 g O <sub>2</sub> / g substance = 14 % ThOD (ThOD = 1.21 g O <sub>2</sub> / g substance) inherently biodegradable  COD = 1.16 g O <sub>2</sub> / g substance = 96 % ThOD
BOD/COD比	0.12	0.12
その他	COD 方法: ASTM 標準法 No. D 1252-67 実施年: 1974	COD Method: ASTM Standards No. D 1252-67 Year : 1974
結論		
注釈	COD : = 1160 mg/g 物質 GLP : いいえ	COD : = 1160 mg/g substance GLP : no
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(96)	(96)
引用文献		
備考		

### 3.6 生物濃縮性

#### BIOACCUMULATION

試験物質名		
CAS番号		
純度等		
注釈		
方法	推定	estimation
生物種	BCFの推定 (Neelyら (1974)による)	estimation of BCF (acc. to method of Neely et al. (1974))
暴露期間 (日)		
曝露濃度		
排泄期間		
GLP		
試験を行った年	1974	1974
分析方法		
試験条件		
被験物質溶液		
対照物質		
対照物質名及び分析方法		
試験方式/実施		
結果		
死亡率/行動		
脂質含有量 (%)		
試験中の被験物質濃度		
濃縮係数 (BCF)	約 4.6	ca. 4.6
取込/排泄定数		
排泄時間		
代謝物		
その他の観察		
結論		
注釈	※英文参照	The bioconcentration factor (BCF) was calculated by the method of Neely et al., (1974) Environ. Sci. Technol. 8: 1113-1115 using the formula $\log BCF = 0.542 \log K + 0.124$ , where $\log K$ is the n-octanol:water partition coefficient. A partition coefficient of about 10 for epichlorohydrin was extrapolated from a graphed relationship between K and water solubility. The calculated BCF was approximately 4.6 ( $\log BCF = 0.666$ ). This is a relatively low value indicating that bioaccumulation in the environment is not likely.
信頼性スコア	(2) 制限つきで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典	(77)	(77)
引用文献		
備考		

項目名	和訳結果(SIDS Dossier)	原文(SIDS Dossier)
4-1 魚への急性毒性 ACUTE TOXICITY TO FISH		
試験物質	入手源: Eastman Kodak 純度: 分析用試薬 不純物: 記載無し	SOURCE: Eastman Kodak PURITY: reagent-grade quality IMPURITIES: not described
同一性		
方法	その他: ASTM	other: ASTM
方法	※英文参照	DEVIATIONS FROM GUIDELINE: The dissolved oxygen concentration fell below the recommended limit of 40% saturation. However, the low oxygen concentration did not appear to influence fish mortality.
GLP	はい	yes
試験を行った年	1980	1980
魚種、系統、供給者	<i>Pimephales promelas</i> (魚類、淡水)	<i>Pimephales promelas</i> (Fish, fresh water)
エンドポイント	試験生物の死亡率	mortality of test organisms
試験物質の分析の有無	なし	no
試験物質の分析方法		
結果の統計解析手法	※英文参照	STATISTICAL METHODS: LC50 and 95% confidence intervals were determined using nominal concentrations by Thompson's method of moving averages. The LC50 values of the three age groups were combined by calculating the geometric mean.
試験条件		
試験魚の月齢、体長、体重	※英文参照	TEST ORGANISMS - Strain: <i>Pimephales promelas</i> Rafinesque - Source/supplier: not described - Age/size/weight/loading: age (days)      size (mm)      weight (mg) fry                    10-15            9.5            11.6 juvenile            30-35           14.9           76.8 subadult           65-94           28.0           391 - Feeding: Newly hatched fry were fed with <i>Artemia salina</i> (2 times per hour), older fish were fed daily with a synthetic diet - Pretreatment: All fish were held in 57 liter aquaria with a constant water flow of 0.2 l/minute at a temperature of 25 ± 1° C, illumination of 430-645 lux and a light-dark cycle of 8h:16h. Fish were acclimated to the test temperature of 22 ± 1° C at least 48 hours prior to the start of the test - Feeding during test: no
試験用水量あたりの魚体重		
参照物質での感受性試験結果		
じゅん化条件		
希釈水源		
希釈水の化学的性質	※英文参照	DILUTION WATER - Source: Lake Huron water, carbon filtered and UV irradiated - Alkalinity: not described - Hardness: 96-125 mg/l as CaCO3 - pH: 7.9-8.3 - Conductance: 135-215 µmhos/cm
試験溶液(及び保存溶液)とその調製法	※英文参照	STOCK AND TEST SOLUTION AND THEIR PREPARATION - Vehicle/solvent: not described
試験物質の溶液中での安定性		
溶解助剤/溶剤の種類とその濃度		
暴露容器		
暴露期間	96時間	96 hour(s)
試験方式	止水	static
換水率/換水頻度		
連数、1連当たりの魚数		
影響が観察された少なくとも1濃度区及び対照区における水質		
試験温度範囲		
照明の状態		
平均測定濃度の計算方法		
結果		
設定濃度		
実測濃度		
生物学的影響観察		
累積死亡率の表		
統計的結果		
注釈	結果 下記の96時間LC50 (95% 信頼区間) が得られた: - 稚魚 (10-15日間): 12.7 mg/l (11.5-14.2 mg/l) - 幼魚 (30-35日間): 10.6 mg/l (9.1-12.3 mg/l) - 成魚 (65-94日間): 13.2 mg/l (9.6-18.6 mg/l)	RESULTS The following LC50 (96h) with 95% Confidence Intervals were found: - fry (10-15 day): 12.7 mg/l (11.5-14.2 mg/l) - juvenile (30-35 day): 10.6 mg/l (9.1-12.3 mg/l) - subadult (65-94 day): 13.2 mg/l (9.6-18.6 mg/l)
対照区における死亡率		
異常反応		
その他の観察結果		
結論		
結果 (96h-LC50)	LC50 := 12.7 mg/l 計算値	LC50 := 12.7 mg/l calculated
信頼性スコア	(2) 制限付で信頼性あり	(2) valid with restrictions
キースタディ		

信頼性の判断根拠	※英文参照	GLP guideline study. Although chemical analyses were absent the data of section 3.1.2 (Stability in water) indicate sufficient exposure.  Reliability of 2 given because of dissolved oxygen concentration in test system fell below 60%. However, mortality of the fish did not appear to be affected, and the species tested is more tolerant of low oxygen levels than other species. No reason was documented for the reduced oxygen levels, but postulated reasons include (but are not limited to) respiration of fish in a static system and degradation of fish waste.
出典		
引用文献	(97) (98)	(97) (98)
備考	※英文参照	TEST SYSTEM - Test type: static with aeration and without renewal of test solution - Concentrations: six exposure concentrations and one control - Exposure vessel type: round glass vessels measuring 22 cm deep and 24.5 cm in diameter containing 10 liters (juvenile and subadult test) or 3.5 liters (fry test) - Number of replicates, fish per replicate: Number of replicates is not described, 10 subadults, 10 juveniles or 20 fry - Test temperature: 21-23° C - Dissolved oxygen: 2.2-8.7 mg/l - pH: 7.2-8.4 - Intensity of irradiation: not described - Photoperiod: 16h:8h light-dark cycle
備考	フラグ: SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

#### 4-2 水生無脊椎動物への急性毒性(例えばミジンコ)

##### ACUTE TOXICITY TO AQUATIC INVERTEBRATES (DAPHNIA)

試験物質	入手源: Eastman Kodak 純度: 分析用試薬 不純物: 記載無し	SOURCE: Eastman Kodak PURITY: Reagent grade IMPURITIES: not reported
同一性		
方法	その他: ASTMガイドライン	other: ASTM Guidelines
GLP	はい	yes
試験を行った年	1980	1980
生物種、系統、供給者	<i>Daphnia magna</i> (甲殻類)	<i>Daphnia magna</i> (Crustacea)
エンドポイント	試験生物の遊泳阻害	immobility of test organisms
試験物質の分析の有無	なし	no
試験物質の分析方法		
結果の統計解析手法	※英文参照	STATISTICAL METHODS: The LC50 value and 95% confidence interval were estimated using nominal concentrations by Thompson's method of moving averages. EC50 data declared as LC50.
試験条件		
試験生物の起源、前処理、繁殖方法	※英文参照	TEST ORGANISMS - Strain: <i>Daphnia magna</i> Straus 1820 - Source/supplier: not described - Breeding method: the brood stock was maintained at 20 ± 1° C and a light-dark cycle of 16h:8h - Feeding: <i>Selenastrum capricornutum</i> three times a week (1.25 mg dry wt/L of dilution water) - Pretreatment: 24 h before testing, multiparous females were isolated and the neonates were used for testing - Feeding during test: no - Control group: yes
参照物質での感受性試験結果		
試験開始時の時間齢		
希釈水源		
希釈水の化学的性質	※英文参照	DILUTION WATER - Source: Lake Huron water - Alkalinity: 65 ± 4 mg/l as CaCO3 - Hardness: 157 ± 4 mg/l as CaCO3 - pH: 8.0 ± 0.2 - Conductance: 311 ± 11 µmhos/cm
試験溶液(及び保存溶液)とその調製法	※英文参照	STOCK AND TEST SOLUTION AND THEIR PREPARATION - Vehicle/solvent: no data
試験物質の溶液中での安定性		
溶解助剤/溶剤の種類とその濃度		
暴露容器		
暴露期間	48時間	48 hour(s)
試験方式	止水	static
連数、1連当たりの試験生物数		
対照区と影響が観察された少なくとも1濃度区における水質		
試験温度範囲		
照明の状態		
平均測定濃度の計算方法		
結果		
設定濃度		
実測濃度		
遊泳阻害数		
累積遊泳阻害数の表		
注釈	結果 48時間LC50値は23.9 mg/l(95%信頼区間 19.4-32.9 mg/l)であった。対照群の死亡率は妥当性基準以下であった。	RESULTS A 48h LC50 value of 23.9 mg/l with 95% confidence intervals of 19.4-32.9 mg/l was found. The control mortality was below the validity criterion.
対照区における反応は妥当か		



対照区における反応の妥当性の考察		
結論		
結果(48h-EC50)	EC50 := 23.9 mg/l	EC50 := 23.9 mg/l
信頼性スコア	(2) 制限付で信頼性あり	(2) valid with restrictions
キースタディ		
信頼性の判断根拠	※英文参照	GLP guideline study. Although chemical analyses were absent the data of section 3.1.2 (Stability in water) indicate sufficient exposure.
出典		
引用文献	(107) (108)	(107) (108)
備考	※英文参照	TEST SYSTEM - Test type: static without renewal of test solution and without aeration - Concentrations: not described - Exposure vessel type: 200 ml test solution in a 250 ml glass beaker - Number of replicates, individuals per replicate: 3/10 - Test temperature: 19.8–20.9° C - Dissolved oxygen: > 90% saturation - pH: 7.7–8.3 - Intensity of irradiation: 970–1250 lumens per m2 - Photoperiod: 16h:8h light-dark cycle
備考	フラグ: SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

#### 4-3 水生植物への毒性(例えば藻類)

##### TOXICITY TO AQUATIC PLANTS e. g. ALGAE

試験物質	入手源: Solvay Elektrolysespezialitäten, Rheinberg, ドイツ 純度: 99.9% 不純物: 記載無し	SOURCE: Solvay Elektrolysespezialitäten, Rheinberg, Germany PURITY: 99.9% IMPURITIES: not reported																																																
同一性																																																		
方法	OECDガイドライン201“藻類、生長阻害試験”	OECD Guide-line 201 “Algae, Growth Inhibition Test”																																																
GLP	はい	yes																																																
試験を行った年	1984	1984																																																
生物種、系統、供給者	<i>Selenastrum capricornutum</i> (藻類) 代替名: <i>Pseudokirchneriella subcapitata</i> .	<i>Selenastrum capricornutum</i> (Algae) Alternate species name: <i>Pseudokirchneriella subcapitata</i> .																																																
エンドポイント	バイオマス 細胞増殖阻害	biomass inhibition of cell multiplication																																																
毒性値算出に用いたデータの種別																																																		
試験物質の分析の有無	あり	yes																																																
試験物質の分析方法	ガスクロマトグラフィー	Gas chromatography																																																
結果の統計解析手法	※英文参照	STATISTICAL METHODS: Endpoints of the test were based on mean measured test concentrations. The EC50 (0–72 hour) was calculated by linear interpolation. The NOEC, based on biomass integral at test termination, was calculated by Williams' Test.																																																
試験条件																																																		
試験施設での藻類継代培養方法																																																		
藻類の前培養の方法及び状況	※英文参照	TEST ORGANISMS - Strain: ATCC 22662 - Source/Supplier: Culture Collection of Algae and Protozoa, Ambleside, Cumbria, UK - Laboratory culture: yes - Method of cultivation: algae were incubated at 23° C with continuous illumination and weekly transferred into fresh medium - Controls: yes (six replicates) - Initial cell concentration: 1x10E+04																																																
参照物質での感受性試験結果																																																		
希釈水源																																																		
培地の化学的性質	使用培地: OECD201に従う	Medium used: according to OECD 201																																																
試験溶液(及び保存溶液)とその調製法																																																		
試験物質の溶液中での安定性																																																		
溶解助剤/溶剤の種類とその濃度	溶媒は使用せず	no solvent used																																																
暴露容器	100mlの培地を250ml通気性蓋付き三角フラスコに入れた。	100 ml medium in a 250 ml Erlenmeyer flask with a cap that allowed ventilation																																																
暴露期間	72時間	72 hour(s)																																																
試験方式	止水、試験液の換水なし	static without renewal of test solution																																																
連数	3/濃度	three/concentration																																																
各濃度区の少なくとも1連における試験開始時と終了時の水質																																																		
試験温度範囲	22.3–23.4° C	22.3–23.4° C																																																
照明の状態	照射強度: 約 4400 lx 照射期間: 連続	Intensity of irradiation: about 4400 lx Photoperiod: continuous																																																
平均測定濃度の計算方法																																																		
結果																																																		
設定濃度	0, 1.0, 2.2, 5.0, 11, 25 及び 55 mg/l	0, 1.0, 2.2, 5.0, 11, 25 and 55 mg/l																																																
実測濃度																																																		
細胞密度	<table> <tr> <th>設定濃度</th><th>平均測定濃度</th><th>平均細胞密度(3日目)</th></tr> <tr> <td>0</td><td>不検出</td><td>110 x 10E+4</td></tr> <tr> <td>1.0</td><td>0.87</td><td>103 x 10E+4</td></tr> <tr> <td>2.2</td><td>1.7</td><td>110 x 10E+4</td></tr> <tr> <td>5.0</td><td>3.9</td><td>91.6 x 10E+4</td></tr> <tr> <td>11</td><td>8.4</td><td>44.8 x 10E+4</td></tr> <tr> <td>25</td><td>19</td><td>5.86 x 10E+4</td></tr> <tr> <td>55</td><td>40</td><td>1.90 x 10E+4</td></tr> </table>	設定濃度	平均測定濃度	平均細胞密度(3日目)	0	不検出	110 x 10E+4	1.0	0.87	103 x 10E+4	2.2	1.7	110 x 10E+4	5.0	3.9	91.6 x 10E+4	11	8.4	44.8 x 10E+4	25	19	5.86 x 10E+4	55	40	1.90 x 10E+4	<table> <tr> <th>Nominal conc.</th><th>mean measured conc.</th><th>mean cell density (day 3)</th></tr> <tr> <td>0</td><td>not detected</td><td>110 x 10E+4</td></tr> <tr> <td>1.0</td><td>0.87</td><td>103 x 10E+4</td></tr> <tr> <td>2.2</td><td>1.7</td><td>110 x 10E+4</td></tr> <tr> <td>5.0</td><td>3.9</td><td>91.6 x 10E+4</td></tr> <tr> <td>11</td><td>8.4</td><td>44.8 x 10E+4</td></tr> <tr> <td>25</td><td>19</td><td>5.86 x 10E+4</td></tr> <tr> <td>55</td><td>40</td><td>1.90 x 10E+4</td></tr> </table>	Nominal conc.	mean measured conc.	mean cell density (day 3)	0	not detected	110 x 10E+4	1.0	0.87	103 x 10E+4	2.2	1.7	110 x 10E+4	5.0	3.9	91.6 x 10E+4	11	8.4	44.8 x 10E+4	25	19	5.86 x 10E+4	55	40	1.90 x 10E+4
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生長阻害率(%)		
各濃度区における生長曲線	生長曲線: 試験終了時(72時間)まで対数増殖	Growth curves: Logarithmic growth until end of the test (72 h)
その他観察結果		
注釈		
対照区での生長は妥当か		
対照区における反応の妥当性の考察		
結論		
結果(ErC50)	EC50 := 7.1 mg/l	EC50 := 7.1 mg/l
結果(NOEC)	NOEC := 1.7 mg/l	NOEC := 1.7 mg/l
信頼性スコア	(1) 制限なく信頼性あり	(1) valid without restriction
キースタディ		
信頼性の判断根拠	GLPガイドライン試験	GLP guideline study
出典		
引用文献	(111)	(111)
備考	※英文参照	pH: 8.0 at start and 8.4 at end of the test Shaking: about 100 rpm MONITORING OF TEST SUBSTANCE CONCENTRATION: after 0, 24, 48 and 72 hours of exposure
備考	フラグ: SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

#### 4-4 微生物への毒性(例えばバクテリア)

TOXICITY TO MICROORGANISMS e. g. BACTERIA

#### 4-5 水生生物への慢性毒性

CHRONIC TOXICITY TO AQUATIC ORGANISMS

##### A. 魚への慢性毒性

CHRONIC TOXICITY TO FISH

##### B. 水生無脊椎動物への慢性毒性

CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

#### 4-6 陸生生物への毒性

TOXICITY TO TERRESTRIAL ORGANISMS

##### A. 陸生植物への毒性

TOXICITY TO TERRESTRIAL PLANTS

##### B. 土壌生物への毒性

TOXICITY TO SOIL DWELLING ORGANISMS

##### C. 他の非哺乳類陸生種(鳥類を含む)への毒性

TOXICITY TO OTHER NON-MAMMALIAN TERRESTRIAL SPECIES (INCLUDING AVIAN)

#### 4-6-1底生生物への毒性

TOXICITY TO SEDIMENT DWELLING ORGANISMS

#### 4-7 生物学的影響モニタリング(食物連鎖による蓄積を含む)

BIOLOGICAL EFFECTS MONITORING (INCLUDING BIOMAGNIFICATION)

#### 4-8 生体内物質変換と動態

BIOTRANSFORMATION AND KINETICS

#### 4-9 追加情報

ADDITIONAL INFORMATION



項目名	和訳結果 (SIDS Dossier)	原文 (SIDS Dossier)
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5-1 トキシコキネティクス、代謝、分布  
TOXICOKINETICS, METABOLISM, and DISTRIBUTION

試験物質名	他のTS	other TS
CAS番号		
純度等		
注釈	非放射性標識のエピクロヒドリン (ECH)はShell Chemical Co., Deer Park, TXから入手し、最終比放射能は約16.4 microCi/mg (1.52 mCi/mmol)となるように、Amersham Internationalから入手した (2-14C-ECH)と混ぜた。GC/MS分析ではこの混合物は化学的に99%以上の純度を有し、ラジオGLCにより99%以上の放射化学純度であることが示された。	Non-radiolabeled epichlorohydrin (ECH) was obtained from Shell Chemical Co., Deer Park, TX was mixed with (2-14C-ECH) obtained from Amersham International to give a final specific activity of approximately 16.4 microCi/mg (1.52 mCi/mmol). GC/MS analysis showed this mixture to be greater than 99% chemically pure and greater than 99% radiochemically pure by radio-GLC.
方法		
方法/ガイドライン		
試験形態	In vivo トキシコキネティクス	In vivo Toxicokinetics
GLP適合	データなし	no data
試験をおこなった年		
方法の概略	暴露時間 : 3日間  ※英文参照	Exposure time : 3 day(s)  (2-14C-Epichlorohydrin) was administered as a single dose to male Fischer 344 rats by gavage. Animals were fasted overnight prior to dosing; then after dosing they were allowed to feed. Doses were 6 mg/kg (3 ml/kg of dosing solutions) by gavage of the 98% radiochemically pure material in an aqueous solution. Prior to dosing, control samples for separation and collection of excreta including expired air were collected for a 24-hour period. Following dosing the rats were placed in glass metabolism cages for 72 hours post-dosing for the separation and collection of excreta including expired air. Animals were sacrificed three days post-dosing. Tissues were collected and analyzed for radioactivity. Excreta was also analyzed for radioactivity.
動物種	ラット	rat
試験動物:系統		
性別	雄	Males
細胞株		
年齢		
体重		
試験動物数	5匹	5
曝露経路	強制経口	gavage
溶媒 (賦剤)	水	water
投与量	6 mg/kg	6 mg/kg
統計手法		
実際に投与された量		
排泄経路		
採取体液		
採取組織		
代謝産物		
代謝産物 CAS No.		
結果		
試験結果	投与放射能量の約38%が <sup>14</sup> CO <sub>2</sub> として排出され、50%が尿中にエピクロヒドリン (ECH)の代謝物として排泄され、3%が糞中に存在した。組織の放射能は投与量の残りを占めた。組織1g当たりで表した場合、放射能は肝臓、腎臓及び前胃で最高値を示した。尿中の主代謝物はN-アセチル-S-(3-クロル-2-ヒドロキシプロピル)-L-ジステイン及びα-クロロヒドリンと同定され、それぞれ投与量の約36及び4%であった。これらの代謝物は2つの最初の(しかし異なる)ECHに対する代謝反応、グルタチオンとの抱合、及びその後のN-アセチル-S-(3-クロル-2-ヒドロキシプロピル)-L-ジステインへの更なる代謝及びα-クロロヒドリンを産生するエポキシドの加水分解と一致している。	Approximately 38% of the radioactive dose was exhaled as <sup>14</sup> CO <sub>2</sub> , 50% was excreted as metabolites of epichlorohydrin (ECH) in the urine, and 3% was present in the feces. Radioactivity in tissues accounted for the remainder of the administered dose. When expressed per gram of tissue, radioactivity was highest in the liver, kidney, and forestomach. The major metabolites in the urine were identified a N-acetyl-S-(3-chloro-2-hydroxypropyl)-L-cysteine and alpha-chlorohydrin, about 36 and 4% of the administered dose, respectively. These metabolites are consistent with two initial (but different) metabolic reactions for ECH, the conjugation with glutathione and subsequent further metabolism to the N-acetyl-S-(3-chloro-2-hydroxypropyl)-L-cysteine and hydrolysis of the epoxide to produce alpha-chlorohydrin.
	半減期: 1次: 2.16時間 2次: 17.02時間	Half-lives : 1st: 2.16 hours 2nd: 17.02 hours
結論		
結論		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献 (元文献)	(128)	(128)
備考	フラグ: SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

試験物質名		
CAS番号		
純度等		
注釈		
方法		
方法/ガイドライン		
試験形態	In vivo トキシコキネティクス	In vivo Toxicokinetics
GLP適合		
試験をおこなった年		

方法の概略	暴露時間 : 3日間 ※英文参照	Exposure time : 3 day(s)  (1,3-14C-Epichlorohydrin) was administered as a single dose or exposure to 4 male rats per group by gavage or inhalation. Doses were 1 or 100 mg/kg by gavage and 1 or 100 ppm for six hours by inhalation. Following dosing or exposure the rats were placed in glass metabolism cages for 72 hours post-dosing for the separation and collection of excreta including expired air. Animals were sacrificed at 72 hours post-dosing or the end of exposure, tissues collected and analyzed for radioactivity. Excreta was also analyzed for radioactivity.
動物種	ラット	rat
試験動物: 系統		
性別	雄	Males
細胞株		
年齢		
体重		
試験動物数		16
曝露経路	強制経口	gavage
溶媒(賦剤)	水	water
投与量	強制経口では1又は100 mg/kg; 6時間吸入では100 ppm又は1 ppm	1 or 100 mg/kg, by gavage; 100 ppm or 1 ppm by inhalation for six hours
統計手法		
実際に投与された量		
排泄経路		
採取体液		
採取組織		
代謝産物		
代謝産物 CAS No.		
結果		
試験結果	<p>吸収: 6時間の暴露中又は暴露後に回収された全放射能の合計により算出した0次の取込み速度は1 ppm及び100 ppmの暴露でそれぞれ15.5 micrograms/時間及び1394 micrograms/時間であった。1及び100 ppmの暴露での吸入により吸収された総量はそれぞれ0.37及び33 mg/kgであった。</p> <p>分布: 投与後72時間で投与レベル又は投与経路にかかわらず、放射標識の投与量の46-54%が尿中に排泄され、25-42%が二酸化炭素として呼気に排出された。強制経口投与後には胃、小腸、腎臓及び大腸で最高の組織濃度が検出された。吸入暴露後には鼻甲介、涙腺、腎臓、大腸及び肝臓で最高濃度が検出された。</p> <p>代謝: 吸入暴露後には6つの代謝物のピークが尿中にみられ、経口投与後には7つがみられた。代謝物の同定については報告されていなかった。</p>	<p>ABSORPTION: The zero-order uptake rate calculated by the summing of all the recovered radiolabel during and after the 6 hour exposure was 15.5 micrograms/hr and 1394 micrograms/hr for the 1 ppm and 100 ppm exposures, respectively. The total doses absorbed by inhalation for the 1 and 100 ppm exposures were 0.37 and 33 mg/kg, respectively.</p> <p>DISPOSITION: At 72 hours post-dosing, regardless of the dose level or route of administration 46-54% of the administered dose of radiolabel was excreted in the urine and 25-42% was exhaled as carbon dioxide. After the gavage dose, the highest tissue concentrations were found in the stomach, small intestine, kidneys and large intestine. After inhalation, the highest levels were found in the nasal turbinates, lacrimal glands, kidneys, large intestine and liver.</p> <p>METABOLISM: Six metabolite peaks observed in the urine after inhalation exposure, seven observed following oral dosing. No identities of the metabolites were reported.</p>
試験結果	<p>半減期: 1次: 1.5時間 2次: 26.4時間</p> <p>注釈: 報告された半減期は吸入経路の暴露に対しては総放射能に対してである。</p>	<p>Half-lives : 1st: 1.5 hours 2nd: 26.4 hours</p> <p>Remark : Halfives reported are for the inhalation route of exposure for total radioactivity.</p>
結論		
結論		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	(129)	(129)
備考		

5-2 急性毒性  
ACUTE TOXICITY  
A. 急性経口毒性  
ACUTE ORAL TOXICITY

試験物質名	他のTS	other TS
CAS番号		
純度等	99.8% エピクロロヒドリン 0.11% 2,3-ジクロロプロペン 0.01% beta-クロロアリルアルコール	99.8% epichlorohydrin 0.11% 2,3-dichloropropene 0.01% beta-chloroallyl alcohol
注釈		
方法		
方法/ガイドライン	EPA OPP 81-1	EPA OPP 81-1
GLP適合	いいえ	no
試験を行った年	1970	1970
試験系(種/系統)	ラット	rat
	その他: Fischer 344, Sprague-Dawley	other: Fischer 344, Sprague-Dawley
性別(雄:M、雌:F)	雌雄	male/female
投与量	25, 50, 100, 200, 210, 225, 252, 398, 795 mg/kg	25, 50, 100, 200, 210, 225, 252, 398, 795 mg/kg
各用量群(性別)の動物数	動物数: 5匹	Number of animals : 5
溶媒(担体)	その他: 原液	other: undiluted
投与経路		
観察期間(日)		

その他の試験条件	英文参照	TEST ORGANISM: Source: Fischer 344 rats: Charles River Breeding Laboratories, Portage, MI; Sprague-Dawley rats: Spartan Research Animals, Inc., Haslett, MI Age: 7-8 weeks Mean Weight at Study Initiation: male Fischer 344 rats: 103-185 g female Fischer 344 rats: 80-132 g; male Sprague-Dawley rats: 262-325 g; female Sprague-Dawley rats: 192-208 g Controls: None  ADMINISTRATION: Doses: 25, 50, 100, 200, 210, 225, 252, 398, 795 mg/kg Doses per time period: Single-dose oral gavage Maximum volume administered: Fischer 344 rats: 2.8 ml; Sprague-Dawley rats: 4.7 ml Post-Dose Observation Period: 2 weeks Examinations: Clinical observations, gross pathological examination Statistics: The acute oral median lethal dose and approximate slope of the dose-response curve for both strains were calculated by the moving average method of Thompson and Weil (Biometrics 8: 51-54, 1952).
統計学的処理		
結果		
各用量群での死亡数	死亡率:  # 死亡動物/# 投与動物 用量 雄 雌 雄 雌 (mg/kg) S-D S-D CDF CDF 25 0/5 0/5 0/5 0/5 50 0/5 0/5 0/5 0/5 100 0/5 0/5 0/5 0/5 200 1/5 2/5 0/5 0/5 210 --- --- 0/5 3/5 225 --- --- 5/5 5/5 252 --- --- 5/5 5/5 398 4/5 5/5 5/5 5/5 795 5/5 5/5 5/5 5/5  ---: 試験されず 死亡までの時間は利用できない。	MORTALITY:  # Dead/# Treated Dose Male Female Male Female (mg/kg) S-D S-D CDF CDF 25 0/5 0/5 0/5 0/5 50 0/5 0/5 0/5 0/5 100 0/5 0/5 0/5 0/5 200 1/5 2/5 0/5 0/5 210 --- --- 0/5 3/5 225 --- --- 5/5 5/5 252 --- --- 5/5 5/5 398 4/5 5/5 5/5 5/5 795 5/5 5/5 5/5 5/5  ---: not tested Time to death not available.
臨床所見	臨床症状:  # 有所見動物/# 投与動物 用量 症状 雄 雌 雄 雌 (mg/kg) S-D S-D CDF CDF 25 0/5 0/5 0/5 0/5 50 0/5 0/5 0/5 0/5 100 0/5 0/5 0/5 0/5 200 軽度 嗜眠 5/5 5/5 5/5 0/5 210 軽度 嗜眠 --- --- 5/5 5/5 立毛 --- --- 5/5 5/5 225 嗜眠 --- --- 5/5 5/5 立毛 --- --- 5/5 5/5 252 重度の 嗜眠 --- --- 5/5 5/5 立毛 --- --- 5/5 0/5 浅い 呼吸 --- --- 5/5 5/5 黒ずんだ 四肢末端 --- --- 5/5 0/5 398 嗜眠 5/5 5/5 5/5 5/5 過剰 活動性 1/5 0/5 0/5 0/5 潤んだ眼 0/5 0/5 0/5 5/5 下痢 0/5 0/5 0/5 5/5 795 嗜眠 5/5 5/5 5/5 5/5 重度の 下痢 0/5 0/5 0/5 5/5  ---: 試験されず	CLINICAL SIGNS:  # Affected/# Treated Dose Sign Male Female Male Female (mg/kg) S-D S-D CDF CDF 25 0/5 0/5 0/5 0/5 50 0/5 0/5 0/5 0/5 100 0/5 0/5 0/5 0/5 200 Slight Lethargy 5/5 5/5 5/5 0/5 210 Slight Lethargy --- --- 5/5 5/5 Piloerection --- --- 5/5 5/5 225 Lethargy --- --- 5/5 5/5 Piloerection --- --- 5/5 5/5 252 Extreme Lethargy --- --- 5/5 5/5 Piloerection --- --- 5/5 0/5 Shallow Breathing --- --- 5/5 5/5 Darkened Extremities --- --- 5/5 0/5 398 Lethargy 5/5 5/5 5/5 5/5 Hyper-activity 1/5 0/5 0/5 0/5 Watery eyes 0/5 0/5 0/5 5/5 Diarrhea 0/5 0/5 0/5 5/5 795 Lethargy 5/5 5/5 5/5 5/5 Severe Diarrhea 0/5 0/5 0/5 5/5  ---: not tested
剖検所見	肉眼病理所見: 前胃の扁平上皮の荒れ及び肥厚が100-210 mg/kgを投与したラットで観察された。他の所見は非特異的で投与に関連した所見と考えられなかった。	GROSS PATHOLOGY: Roughening and thickening of the squamous epithelium of the non-glandular stomach was observed in rats given 100-210 mg/kg. Other findings were non-specific and not considered treatment-related.
その他	潜在的な標的器官: 特定されなかった。  性特異的な差異: 有意な差はみられなかった。	POTENTIAL TARGET ORGANS: None identified.  SEX-SPECIFIC DIFFERENCES: No significant differences observed.
結論		
LD50値又はLC50値	LD50= 175 - 282 mg/kg bw	LD50= 175 - 282 mg/kg bw
雌雄のLD50値又はLC50値の違い等		
注釈		
信頼性	(1) 制限なく信頼性あり	(1) valid without restriction
信頼性の判断根拠	GLP施行前に実施された	Conducted prior to advent of GLP.
出典		
引用文献(元文献)	(130)	(130)
備考	フラグ : SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	データなし	no data
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	その他	other
GLP適合	データなし	no data
試験を行った年	1963	1963
試験系(種／系統)	ラット	rat
	その他: Carworth-Wistar	other: Carworth-Wistar
性別(雄:M、雌:F)	雄	male
投与量		
各用量群(性別)の動物数	動物数 : 5匹	Number of animals : 5
溶媒(担体)	その他: 原液、希釈せず	other: neat, undiluted
投与経路		
観察期間(日)		
その他の試験条件	英文参照	Groups of five non-fasted male rats were given the undiluted chemical, then observed for signs of toxicity for 14 days.
統計学的処理		
結果		
各用量群での死亡数		
臨床所見		
剖検所見		
その他		
結論		
LD50値又はLC50値	LD50= 246 mg/kg bw	LD50= 246 mg/kg bw
雌雄のLD50値又はLC50値の違い等		
注釈	経口LD50は0.21 ml/kgと報告されている。246 mg/kgに換算される。	Oral LD50 reported as 0.21 ml/kg; converted to 246 mg/kg.
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	(131)	(131)
備考		

試験物質名	その他:ガスクロマトグラフィにより、～99%の純度	other: ～99% purity by gas chromatography
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	その他: 有姿の物質を用量を变化させて1群4ないし5匹の動物に強制経口投与した。動物は7日間死亡の有無を観察した。	Other: graded doses of neat material administered intragastrically to groups of 4 or 5 animals; animals observed for mortality for 7 days
GLP適合	データなし	no data
試験を行った年	1972	1972
試験系(種／系統)	ラット	rat
	Sprague-Dawley	Sprague-Dawley
性別(雄:M、雌:F)	雄	Male
投与量		
各用量群(性別)の動物数	動物数 : 4ないし5匹	Number of animals : 4 or 5
溶媒(担体)	その他: 綿実油	other: cottonseed oil
投与経路		
観察期間(日)		
その他の試験条件		
統計学的処理		
結果		
各用量群での死亡数		
臨床所見		
剖検所見		
その他	LD50値の95%信頼限界値: 147～461 mg/kg	95% Confidence Limits for LD50 value: 147 to 461 mg/kg.
結論		
LD50値又はLC50値	LD50= 260 mg/kg bw	LD50= 260 mg/kg bw
雌雄のLD50値又はLC50値の違い等		
注釈		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	(132)	(132)
備考		

試験物質名	その他:ガスクロマトグラフィにより、～99%の純度	other: ～99% purity by gas chromatography
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	その他: 有姿の物質を用量を变化させて1群4ないし5匹の動物に強制経口投与した。動物は7日間死亡の有無を観察した。	other: graded doses of neat material administered intragastrically to groups of 4 or 5 animals; animals observed for mortality for 7 days
GLP適合	データなし	no data
試験を行った年	1972	1972

試験系(種/系統)	マウス	mouse
性別(雄:M、雌:F)	雄	male
投与量		
各用量群(性別)の動物数		
溶媒(担体)	その他:綿実油	other: cottonseed oil
投与経路		
観察期間(日)		
その他の試験条件		
統計学的処理		
結果		
各用量群での死亡数		
臨床所見		
剖検所見		
その他	LD50値の95%信頼限界値: 191~294 mg/kg	95% Confidence Limits for LD50 Value: 191 to 294 mg/kg.
結論		
LD50値又はLC50値	LD50= 236 mg/kg bw	LD50= 236 mg/kg bw
雌雄のLD50値又はLC50値の違い等		
注釈		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	(132)	(132)
備考		

試験物質名	データなし	no data
CAS番号		
純度等		
注釈		
方法		
方法/ガイドライン	その他:各動物に0.1 ml/10 g体重の量を投与するように懸濁液を調製した。胃管を介して投与。	Other: suspension was prepared such that each animal received a volume of 0.1 ml /10 g body weight; administered via stomach tube
GLP適合	いいえ	no
試験を行った年	1941	1941
試験系(種/系統)	マウス	mouse
性別(雄:M、雌:F)	系統:その他:white	Strain : other: white
投与量	データなし	no data
投与量	0.23, 0.50 ml/kg	0.23, 0.50 ml/kg
各用量群(性別)の動物数	動物数 :30匹	Number of animals : 30
溶媒(担体)	その他: 25%アラビアゴム水溶液	other: 25% aqueous gum arabic solution
投与経路		
観察期間(日)		
その他の試験条件		
統計学的処理		
結果		
各用量群での死亡数		
臨床所見		
剖検所見		
その他		
結論		
LD50値又はLC50値	LD50= 271 - 590 mg/kg bw	LD50= 271 - 590 mg/kg bw
雌雄のLD50値又はLC50値の違い等		
注釈	LD50値は引用された2つの値の間にある。100%死亡率は0.5 ml/kgでみられ、0%死亡は0.23 ml/kgでみられた。	LD50 value is between the two values cited; 100% lethality was observed at 0.5 ml/kg, while 0% lethality was observed at 0.23 ml/kg.
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	(133)	(133)
備考		

B. 急性吸入毒性  
ACUTE INHALATION TOXICITY

試験物質名	他のTS	other TS
CAS番号		
純度等	純度 >99%	>99% purity
注釈		
方法		
方法/ガイドライン	その他	other
GLP適合	はい	yes
試験を行った年	1985	1985
試験系(種/系統)	ラット	rat
性別(雄:M、雌:F)	Fischer 344	Fischer 344
投与量	雌雄	male/female
各用量群(性別)の動物数		6
溶媒(担体)	その他: 空気	other: air
投与経路		

観察期間(日)		
その他の試験条件	暴露時間：1時間	Exposure time：1 hour(s)
その他の試験条件	英文参照	TEST ORGANISMS: Source: Charles River Breeding Laboratories, Kingston, NY Age: 6-8 weeks Weight at study initiation: males: 177-266 g; females: 126-148 g Number of animals: 6/sex/exposure concentration Contols: None  ADMINISTRATION: Type of Exposure: whole-body vapor exposures Concentrations: Target 500 1000 2000 2800 3350 4000 Nominal 599 1133 2329 3306 3866 4609 Analyt. 552 1008 1970 2865 3275 3995  Exposures occurred in 2.6 cubic meter Rochester-type inhalation chambers. Atmospheres were generated by passing heated compressed air through a J-tube assembly. Chamber concentrations were monitored 7 times/hour using gas chromatography.
その他の試験条件	英文参照	EXAMINATIONS:  Animals were observed for signs of toxicity during exposure and for 14 days post-exposure. Animals were weighed at study initiation, and surviving rats were weighed on study days 2, 4, 8, 11, and 15. All animals were submitted for pathological examination of major organ systems either at death or at study termination. In addition, nasal cavities were split longitudinally for examination of the turbinate area.
統計学的処理	英文参照	STATISTICS The LC50 for females was calculated as a function of the time-weighted average analytical exposure concentrations by the moving-average method (Thompson and Weil, 1952). The LC50 for males was estimated by calculating the geometric man between exposure levels that resulted in 0 and 100% mortality among males, as implemented in a computer program furnished by Dr. Charles E. Stephan, USEPA Environmental Research Laboratory, Duluth, MN.
結果		
各用量群での死亡数	死亡率:  # 死亡動物/# 投与動物 死亡までの時間 用量 雄 雌 雄 雌 (PPM) CDF CDF CDF CDF 552 0/6 0/6 --- --- 1008 0/6 0/6 --- --- 1970 0/6 2/6 --- 1匹@2日 1匹@3日 2865 0/6 --- --- --- 3275 0/6 --- --- --- 3995 6/6 6/6 3匹@1日 6匹@1日 1匹@2日 1匹@3日 1匹@4日  ---: 試験されず	MORTALITY:  # Dead/# Treated Time to Death Dose Male Female Male Female (PPM) CDF CDF CDF CDF 552 0/6 0/6 --- --- 1008 0/6 0/6 --- --- 1970 0/6 2/6 --- 1@2 days 1@3 days 2865 0/6 --- --- --- 3275 0/6 --- --- --- 3995 6/6 6/6 3@1 day 6@1 day 1@2 days 1@3 days 1@4 days  ---: not tested
臨床所見	臨床症状: 1008又は552 ppmに暴露された全ラットが暴露時間中の殆どを眼を完全に閉じてケージ内でうずくまっていたが、毒性症状は主に1970 ppm以上で認められた。眼及び鼻の刺激症状、呼吸困難、顔面上に赤色のポルフィリン様物質の分泌物が1970 ppm以上のレベルに暴露したラットで認められた。3275及び3995 ppm(雄)、及び3995 ppm(雌)の濃度では暴露中の過剰活動性が観察された。この後に暴露後の嗜眠が生じた。最高濃度の3995 ppmでは雌雄の全てのラットが暴露終了直前にチアノーゼ様の外観を呈した。	CLINICAL SIGNS: Signs of toxicity were predominantly noted at exposure concentrations of 1970 ppm and above, although all rats exposed to 1008 or 552 ppm spent most of their exposure time huddled in their cages with eyes completely shut. Signs of eye and nasal irritation, respiratory difficulty, and secretion of a reddish, porphyrin-like material on the facial area were noted among rats exposed to levels greater than or equal to 1970 ppm. At concentrations of 3275 and 3995 ppm (males) and 3995 ppm (females), hyperactivity during exposure was also observed. This was followed by post-exposure lethargy. At the top exposure level of 3995 ppm, all male and female rats were also cyanotic in appearance immediately prior to the end of exposure.
剖検所見	肉眼的病理所見: 2週間の観察期間生存した雄ラットで剖検時に最も頻繁に認められた所見は1970 ppm (1/6), 2865 (5/6)または3275 (6/6)での両側性の角膜の混濁であった。他に認められた所見は投与物質に関連したものではないと考えられた。	GROSS PATHOLOGY: The most frequent observation noted at necropsy among male rats surviving the 2-week observation period was bilateral corneal cloudiness at 1970 ppm (1/6), 2865 (5/6), or 3275 (6/6). No other observations noted were considered to be treatment-related.
その他	潜在的な標的器官: 眼  性特異的な差異: LD50の違い以外なし	POTENTIAL TARGET ORGANS: Eye.  SEX-SPECIFIC DIFFERENCES: None other than differing LC50's.
結論		
LD50値又はLC50値	LC50= 2165 - 3617 ppm	LC50= 2165 - 3617 ppm
雌雄のLD50値又はLC50値の違い等		
注釈	ppmから換算したLC50= 8227 - 13,746 mg/m3	LC 50 values converted from ppm = 8227 - 13,746 mg/m3
信頼性	(1) 制限なく信頼性あり	(1) valid without restriction
信頼性の判断根拠		
出典		
引用文献(元文献)	(137)	(137)
備考	フラグ：SIDSエンドポイントにとって重要な試験	Flag：Critical study for SIDS endpoint

試験物質名	他のTS	other TS
CAS番号		
純度等	純度 >99%	>99% purity
注釈		
方法		
方法／ガイドライン	その他	other
GLP適合	データなし	no data
試験を行った年	1980	1980
試験系(種／系統)	ラット Sprague-Dawley	rat Sprague-Dawley
性別(雄:M、雌:F)	雄	male
投与量		
各用量群(性別)の動物数	動物数 : 120匹	Number of animals : 120
溶媒(担体)	その他: 空気	other: air
投与経路		
観察期間(日)		
その他の試験条件	暴露時間 : 6時間	Exposure time : 6 hour(s)
その他の試験条件	英文参照	<p>TEST ORGANISMS:</p> <ul style="list-style-type: none"> <li>- Source: Blue Spruce Farms, Inc. Altamont, N. Y.</li> <li>- Age: 8 weeks</li> <li>- Weight at study initiation: Not presented</li> <li>- Number of animals: Groups of 20 rats per 6 exposure groups</li> <li>- Controls: Yes</li> </ul> <p>ADMINISTRATION:</p> <ul style="list-style-type: none"> <li>- Type of exposure: Single 6-hour period</li> <li>- Concentrations: 283-445 ppm range</li> </ul> <p>Test atmospheres containing ECH were generated by passing an air stream over the liquid in a generating flask and then diluting the effluent vapor with a second air stream prior to introduction into the exposure chambers. Exposures were done either in 128-liter or 1.3-m<sup>3</sup> exposure chambers. Chamber concentrations were analyzed at ½ hour intervals during exposures.</p>
その他の試験条件	英文参照	<p>EXAMINATIONS:</p> <p>All animals were carefully observed daily and weighed. Complete necropsies were conducted with particular attention given to the respiratory tract. Histologic sections were prepared from the each side of the head to display the entire nasal cavity. Histologic sections were also prepared from each pulmonary lobe, the larynx, trachea, stem bronchi, liver, bladder, kidneys, spleen, and other organs with gross pathologic alterations.</p>
統計学的処理		
結果		
各用量群での死亡数		
臨床所見		
剖検所見		
その他	339 ppmでは観察された死亡率は僅か5%であったが、369 ppmでは75%に増加した。ECHの14日間LC50は約360 ppmと算出された。24匹(6暴露群のそれぞれから4匹ずつ)の病理検査では肺に出血と重度の浮腫を伴う急性呼吸器刺激が示された。これらの動物では肺重量の体重比は顕著に上昇した。	At 339 ppm, the observed mortality was only 5%, but it increased to 75% at 369 ppm. The 14-day LC50 for ECH was calculated to be approximately 360 ppm. Pathologic examination of 24 rats (4 from each of the 6 exposed groups) revealed acute respiratory irritation with hemorrhage and severe edema in the lung. The lung-to-body weight ratios in these animals were markedly elevated.
結論		
LD50値又はLC50値	LC50= 360 ppm	LC50= 360 ppm
雌雄のLD50値又はLC50値の違い等		
注釈		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	(138)	(138)
備考		

試験物質名	データなし	no data
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	その他	other
GLP適合	いいえ	no
試験を行った年	1941	1941
試験系(種／系統)	マウス 系統 : データなし	mouse Strain : no data
性別(雄:M、雌:F)	データなし	no data
投与量	16,600, 8,300 及び 2,370 ppm	16,600, 8,300 and 2,370 ppm
各用量群(性別)の動物数	動物数 : 90匹	Number of animals : 90
溶媒(担体)	その他: 空気	other: air
投与経路		
観察期間(日)		
その他の試験条件	暴露時間 : 60分間	Exposure time : 60 minute(s)
その他の試験条件	暴露時間は30-60分に変化した。	Exposure time varied from 30-60 minutes.



その他の試験条件	英文参照	<p>TEST ORGANISMS:</p> <ul style="list-style-type: none"> <li>- Source: No data</li> <li>- Age: No data</li> <li>- Weight at study initiation: No data</li> <li>- Number of animals: 80</li> <li>- Controls: No data</li> </ul> <p>ADMINISTRATION:</p> <ul style="list-style-type: none"> <li>- Type of exposure: 30 or 60 minutes</li> <li>- Concentrations: 2,370, 8,300 and 16,600 ppm range</li> </ul> <p>Test atmospheres in a glass chamber containing ECH were constantly renewed containing the desired concentrations of vapors as estimated by a flowmeter.</p>																								
統計学的処理																										
結果																										
各用量群での死亡数	<p>死亡率</p> <table> <tr> <th>濃度 (ppm)</th><th>暴露 時間</th><th>暴露後24時間以内の 死亡率</th></tr> <tr> <td>16,600</td><td>30</td><td>30/30</td></tr> <tr> <td>8,300</td><td>30</td><td>20/20</td></tr> <tr> <td>2,370</td><td>60</td><td>0/30</td></tr> </table>	濃度 (ppm)	暴露 時間	暴露後24時間以内の 死亡率	16,600	30	30/30	8,300	30	20/20	2,370	60	0/30	<p>MORTALITY</p> <table> <tr> <th>Concentration (ppm)</th><th>Time of exposure</th><th>Mortality within 24 hours after exposure</th></tr> <tr> <td>16,600</td><td>30</td><td>30/30</td></tr> <tr> <td>8,300</td><td>30</td><td>20/20</td></tr> <tr> <td>2,370</td><td>60</td><td>0/30</td></tr> </table>	Concentration (ppm)	Time of exposure	Mortality within 24 hours after exposure	16,600	30	30/30	8,300	30	20/20	2,370	60	0/30
濃度 (ppm)	暴露 時間	暴露後24時間以内の 死亡率																								
16,600	30	30/30																								
8,300	30	20/20																								
2,370	60	0/30																								
Concentration (ppm)	Time of exposure	Mortality within 24 hours after exposure																								
16,600	30	30/30																								
8,300	30	20/20																								
2,370	60	0/30																								
臨床所見	<p>臨床症状</p> <p>全濃度で鼻及び眼の刺激が認められた。8300及び16100 ppm投与群は次第に進展するチアノーゼに続き、四肢末端の筋肉の弛緩を示した。尾が堅くなり、体の細かい振戦が生じた。強直性痙攣が始まり、死亡する数時間前には呼吸は顕著に抑制された。</p>	<p>CLINICAL SIGNS</p> <p>Irritation of the nose and eyes were noted at all concentrations. The 8,300 and 16,100 ppm dose groups exhibited a gradual developing cyanosis followed by muscular relaxation of the extremities. The tail stiffens followed by a fine tremor of the body. Respiration becomes markedly depressed several hours before death which may initiate clonic convulsions.</p>																								
剖検所見																										
その他	<p>組織検査</p> <p>肺、心臓、腎臓、脾臓及び腸の顕微鏡検査では特徴的な病理変化は示されなかった。</p>	<p>HISTOLOGY</p> <p>Microscopic examination of the lungs, heart, kidney, spleen, and bowels did not reveal any characteristic pathological changes.</p>																								
結論																										
LD50値又はLC50値	LC50= 2370 – 8300 ppm	LC50= 2370 – 8300 ppm																								
雌雄のLD50値又はLC50値の違い等																										
注釈																										
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions																								
信頼性の判断根拠																										
出典																										
引用文献(元文献)	(139)	(139)																								
備考																										

### C. 急性経皮毒性

#### ACUTE DERMAL TOXICITY

試験物質名	他のTS	other TS
CAS番号		
純度等	純度 >99%	>99% purity
注釈		
方法		
方法／ガイドライン	その他	other
GLP適合	いいえ	no
試験を行った年	1976	1976
試験系(種／系統)	ウサギ	rabbit
	ニュージーランド白色	New Zealand white
性別(雄:M、雌:F)	雌雄	male/female
投与量		
各用量群(性別)の動物数	動物数 : 16匹	Number of animals : 16
溶媒(担体)	その他: 希釈せず	other: undiluted
投与経路		
観察期間(日)		
その他の試験条件	英文参照	<p>Approximately 24 hours prior to dosing, the hair was removed from the trunk of 2 laboratory white rabbits/dose level with electric clippers. The test material was applied at 100, 200, 465, or 795 mg/kg body weight under an impervious cuff held in place with a cloth bandage taped to the hair. Following application the animals were returned to holding cages and allowed to eat and drink ad libitum. Following a 24-hour exposure period, the cuffs were removed and the skins washed with soap and water. The animals were observed during and after exposure and weighed at intervals up to two weeks post-application. The animals were then submitted for necropsy examination at death or at scheduled study termination.</p>



その他の試験条件	英文参照	TEST ORGANISM:  Source, Age, Strain: Unknown  Weight at Study Initiation: 2.43–3.50 kg  Controls: None  ADMINISTRATION:  Area Covered: Unknown  Occlusion: Impervious cuff held in place with cloth bandage taped to hair  Doses: 100, 200, 465, 795 mg/kg; single 24-hour dose  Vehicle: None, administered undiluted  Removal of Test Material: Washing with soap and water 24 hours post-dosing  Maximum Volume Administered: 2.38 ml																														
その他の試験条件	英文参照	Post-Dose Observation Period: 2 weeks  Examinations: Clinical observations, body weights  Statistics: LD50 calculation method not specified.																														
統計学的処理																																
結果																																
各用量群での死亡数	死亡率: <table><thead><tr><th>用量 (mg/kg)</th><th colspan="2"># 死亡動物/# 投与動物 雄 雌</th></tr></thead><tbody><tr><td>100</td><td>0/2</td><td>0/2</td></tr><tr><td>200</td><td>0/2</td><td>0/2</td></tr><tr><td>465</td><td>1/2</td><td>0/2 投与後24時間で死亡発見</td></tr><tr><td>795</td><td>2/2</td><td>2/2 投与後24時間で死亡発見</td></tr></tbody></table>	用量 (mg/kg)	# 死亡動物/# 投与動物 雄 雌		100	0/2	0/2	200	0/2	0/2	465	1/2	0/2 投与後24時間で死亡発見	795	2/2	2/2 投与後24時間で死亡発見	MORTALITY: <table><thead><tr><th>Dose (mg/kg)</th><th colspan="2"># Dead/# Treated Male Female</th></tr></thead><tbody><tr><td>100</td><td>0/2</td><td>0/2</td></tr><tr><td>200</td><td>0/2</td><td>0/2</td></tr><tr><td>465</td><td>1/2</td><td>0/2 Found dead 24 hours post-dosing</td></tr><tr><td>795</td><td>2/2</td><td>2/2 Found dead 24 hours post-dosing</td></tr></tbody></table>	Dose (mg/kg)	# Dead/# Treated Male Female		100	0/2	0/2	200	0/2	0/2	465	1/2	0/2 Found dead 24 hours post-dosing	795	2/2	2/2 Found dead 24 hours post-dosing
用量 (mg/kg)	# 死亡動物/# 投与動物 雄 雌																															
100	0/2	0/2																														
200	0/2	0/2																														
465	1/2	0/2 投与後24時間で死亡発見																														
795	2/2	2/2 投与後24時間で死亡発見																														
Dose (mg/kg)	# Dead/# Treated Male Female																															
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465	1/2	0/2 Found dead 24 hours post-dosing																														
795	2/2	2/2 Found dead 24 hours post-dosing																														
臨床所見																																
剖検所見																																
その他																																
結論																																
LD50値又はLC50値	LD50= 515 mg/kg bw	LD50= 515 mg/kg bw																														
雌雄のLD50値又はLC50値の違い等																																
注釈																																
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions																														
信頼性の判断根拠	GLP要求前胃に実施された。用量水準当たりの最小限の動物数のガイドライン要求を満たしていない。	Conducted prior to GLP requirements, does not meet guideline requirements for minimum number of animals/dose level.																														
出典																																
引用文献(元文献)	(145)	(145)																														
備考	フラグ : SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint																														

試験物質名	データなし	no data
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	その他	other
GLP適合	データなし	no data
試験を行った年	1972	1972
試験系(種／系統)	ウサギ	rabbit
性別(雄:M、雌:F)	データなし	Strain : no data
投与量	データなし	no data
各用量群(性別)の動物数		
溶媒(担体)	その他: 希釈せず	other: undiluted
投与経路		
観察期間(日)		
その他の試験条件	英文参照	<p>Dermal toxicity was determined by applying measured quantities of the material to a Webril patch, applying the patch to shaved rabbit backs with an occlusive bandage, and allowing it to remain in contact for 24 hrs, after which the bandage was removed. The animals were observed an additional six days for mortality.</p>
統計学的処理		
結果		
各用量群での死亡数		
臨床所見		
剖検所見		
その他	ウサギへの経皮適用は0.64 ml/kg (754 mg/kg bw)のLD50を生じたが、95%信頼限界値は経口及び腹腔内経路の値と重なった。	Dermal application to rabbits produced an LD50 value of 0.64 ml/kg (754 mg/kg bw), but the 95% confidence limits overlapped values for the oral and intraperitoneal routes.
結論		
LD50値又はLC50値	LD50= 754 mg/kg bw	LD50= 754 mg/kg bw
雌雄のLD50値又はLC50値の違い等		

注釈		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	(132)	(132)
備考		

試験物質名	データなし	no data
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	その他	other
GLP適合	データなし	no data
試験を行った年	1941	1941
試験系(種／系統)	ラット	rat
	系統：その他:white	Strain : other: white
性別(雄:M、雌:F)	データなし	no data
投与量	590, 1180, 2360 mg/kg bw	590, 1180, 2360 mg/kg bw
各用量群(性別)の動物数	動物数：10匹	Number of animals : 10
溶媒(担体)	その他：希釈せず	other: undiluted
投与経路		
観察期間(日)		
その他の試験条件	英文参照	Number of animals/dose group: Dose # Animals (mg/kg) 590 10 1180 10 2360 20 Compound was applied under occluded conditions
統計学的処理		
結果		
各用量群での死亡数		
臨床所見		
剖検所見		
その他		
結論		
LD50値又はLC50値	LD50= 1180 – 2360 mg/kg bw	LD50= 1180 – 2360 mg/kg bw
雌雄のLD50値又はLC50値の違い等		
注釈	LD50値は引用した2つの値の間にある。1180 mg/kgで2/10が死亡したのに対し、2360 mg/kgでは18/20が死亡した。	LD50 value lies between two values cited; 2/10 died at 1180 mg/kg, while 18/20 died at 2360 mg/kg.
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	(133)	(133)
備考		

試験物質名	データなし	no data
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	その他	other
GLP適合	いいえ	no
試験を行った年	1963	1963
試験系(種／系統)	ウサギ	rabbit
		New Zealand white
性別(雄:M、雌:F)	雄	male
投与量	1.0, 1.58 ml/kg bw (1181, 1865 mg/kg bw)	1.0, 1.58 ml/kg bw (1181, 1865 mg/kg bw)
各用量群(性別)の動物数	動物数：3匹	Number of animals : 3
溶媒(担体)	その他：希釈せず	other: undiluted
投与経路		
観察期間(日)		
その他の試験条件	英文参照	Three rabbits per dose level (weighing approximately 2–3 kg each) were exposed to the test material. Material was placed on the clipped back of the rabbit, then held in place for 24 hrs with an occlusive ("Vinylite") dam. After 24 hrs, the dam was removed and the animals were observed for mortality according to "FDA procedures" personally communicated to the investigators, inferred to be those in force at the time of the test (1946). Animals were observed until time of death, or for at least 14 days for surviving animals.
統計学的処理		
結果		
各用量群での死亡数		
臨床所見		
剖検所見		
その他	1.58 ml/kg bw (1865 mg/kg bw) を投与した全てのウサギが投与の1–2日以内に死亡した。1.0 ml/kg bw (1181 mg/kg bw)を投与したウサギは全例とも体重は20–140 g減少したが、少なくとも14日間は生存した。	All rabbits given 1.58 ml/kg bw (1865 mg/kg bw) died within 1–2 days of treatment. All rabbits given 1.0 ml/kg bw (1181 mg/kg bw) survived for at least 14 days with weight losses of 20–140 g.
結論		

LD50値又はLC50値	LD50= 1534 mg/kg bw	LD50= 1534 mg/kg bw
雌雄のLD50値又はLC50値の違い等		
注釈		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	(146)	(146)
備考		

試験物質名	データなし	no data
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	その他	other
GLP適合	いいえ	no
試験を行った年	1948	1948
試験系(種／系統)	ウサギ 系統：データなし	rabbit Strain : no data
性別(雄:M、雌:F)	データなし	no data
投与量	1.0, 1.58 ml/kg bw (1181, 1865 mg/kg bw)	1.0, 1.58 ml/kg bw (1181, 1865 mg/kg bw)
各用量群(性別)の動物数	動物数：3匹	Number of animals : 3
溶媒(担体)		other: undiluted
投与経路		
観察期間(日)		
その他の試験条件	英文参照	Three rabbits per dose level (weighing approximately 2-3 kg each) were exposed to the test material. Material was placed on the clipped back of the rabbit, then held in place for 24 hrs with an occlusive ("Vinylite") dam. After 24 hrs, the dam was removed and the animals were observed for mortality according to "FDA procedures" personally communicated to the investigators, inferred to be those in force at the time of the test (1946). Animals were observed until time of death, or for at least 14 days for surviving animals.
統計学的処理		
結果		
各用量群での死亡数		
臨床所見		
剖検所見		
その他	1.58 ml/kg bw (1865 mg/kg bw) を投与したウサギ全例が投与の1-2日以内に死亡した。1.0 ml/kg bw (1181 mg/kg bw) を投与したウサギ全例は体重が20-140 g減少したが、少なくとも14日間は生存した。	All rabbits given 1.58 ml/kg bw (1865 mg/kg bw) died within 1-2 days of treatment. All rabbits given 1.0 ml/kg bw (1181 mg/kg bw) survived for at least 14 days with weight losses of 20-140 g.
結論		
LD50値又はLC50値	LD50= 1534 mg/kg bw	LD50= 1534 mg/kg bw
雌雄のLD50値又はLC50値の違い等		
注釈	これは文献139(Study Order Number 4)で記述したのと同じの試験である。	This is the same study as that documented in reference 139 (Study Order Number 4).
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	(147)	(147)
備考		

D. 急性毒性(その他の投与経路)  
ACUTE TOXICITY, OTHER ROUTES

5-3 腐食性／刺激性  
CORROSIVENESS/IRRITATION

A. 皮膚刺激／腐食  
SKIN IRRITATION/CORROSION

試験物質名	他のTS	other TS
CAS番号		
純度等	純度は明記されていない。	Purity not specified.
注釈		
pH		
方法		
方法／ガイドライン	その他:エピクロロヒドリン原液を2-24時間適用	other: 2-24 h application of undiluted epichlorohydrin
GLP適合	データなし	no data
試験を行った年	1967	1967
試験系(種／系統)	ウサギ	rabbit
性別(雄:M、雌:F)		
投与量	濃度：原液 暴露：閉塞 暴露時間：24時間	Concentration : undiluted Exposure : Occlusive Exposure time : 24 hour(s)
各用量群(性別)の動物数		
溶媒(担体)		
投与経路		
観察期間(日)		

その他の試験条件	英文参照	TEST CONDITIONS Test Animals: Rabbits, number tested, strain, sex, age, source and weight at study initiation, unknown Administration/Exposure: Draize and Woodard, 1949; Preparation of Test Substance: undiluted; Area of Exposure: unknown; Occlusion: Yes; Total volume applied: 0.5 ml for 24 hours or 0.1 to 0.2 ml for 2 hours Examinations : Draize and Woodard, 1949
統計学的処理		
結果		
一次刺激スコア		
皮膚反応等		
その他	結果 0.5 mlの量を24時間皮膚に適用したエピクロロヒドリンは硬い腫脹に囲まれた凝固壊死の中心帯として現され、かつ皮膚の表層にも影響を及ぼしている損傷の外観を示した。損傷部の周辺には様々な程度の紅斑の領域がみられ、適用部位を被って多くの皮下出血を伴っていた。0.1-0.2 mlのより少量の適用では2時間というより短時間の適用では強さと次元はより低いものの同様の傷害が認められた。2-3日後には全例とも壊死及び紅斑の領域は痂皮で被われ、徐々に(0.5 mlの適用30日後)治癒した。回復後には皮膚の肉眼的な外観は正常であった。	RESULTS Epichlorohydrin applied on the skin in quantities of 0.5 ml for 24 hours caused appearance of a lesion presenting as a central zone of coagulation necrosis surrounded by hard swelling also affecting the superficial layers of the dermis. At the periphery of the lesion was a zone of erythema of various intensities with numerous petechial hemorrhages covering the application area. The application of smaller quantities, 0.1 to 0.2 ml, for a shorter period, 2 hours, resulted in the appearance of a similar lesion but of less intensity and reduced dimensions. In all cases after two to three days the zones of necrosis and erythema were covered by eschar which healed slowly (after 30 days for the 0.5 ml application). Following recovery the macroscopic appearance of the skin was normal.
結論		
皮膚刺激性		
皮膚腐食性	腐食性あり	corrosive
注釈	分類：腐食性あり(火傷を生じる)	Classification : corrosive (causes burns)
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	GLPの施行前に実施された試験。試験条件及び結果の詳細な情報(個別動物のPDIIのスコアなど)は発行物には記述されていない。	Study conducted prior to the advent of GLPs, detailed information on test conditions and results (i.e., individual animal scores for PDII) were not given in the publication.
出典		
引用文献(元文献)	(151)	(151)
備考	フラグ：SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	データなし	no data
CAS番号		
純度等		
注釈		
pH		
方法		
方法ノガイドライン	その他：非閉塞下のウサギの皮膚に0.01 mlを24時間適用した。使用した毒性学的方法はSmyth et al. (1962)により述べられている。Range Finding Toxicity Data, List VI. Amer. Ind. Hyg. Ass. J. 23:95.	other: 0.01 ml applied to unoccluded rabbit skin for 24 hours. The toxicological method used is discussed in Smyth et al. (1962). Range Finding Toxicity Data, List VI. Amer. Ind. Hyg. Ass. J. 23:95.
GLP適合	いいえ	no
試験を行った年	1963	1963
試験系(種ノ系統)	ウサギ	rabbit
性別(雄:M、雌:F)		
投与量	濃度：原液 暴露：開放 暴露時間：24時間	Concentration : undiluted Exposure : Open Exposure time : 24 hour(s)
各用量群(性別)の動物数	動物数：5匹	Number of animals : 5
溶媒(担体)		
投与経路		
観察期間(日)		
その他の試験条件	英文参照	Test Animals: Rabbits, number tested, strain, sex, age, source and weight at study initiation, not indicated Administration/Exposure: Preparation of Test Substance: undiluted; Amount of Substance Applied: 0.01 ml;
統計学的処理		
結果		
一次刺激スコア		
皮膚反応等		
その他		
結論		
皮膚刺激性	軽度の刺激性あり	slightly irritating
皮膚腐食性		
注釈		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	(146)	(146)
備考		

B. 眼刺激／腐食  
EYE IRRITATION/CORROSION

試験物質名	データなし	no data
CAS番号		
純度等		
注釈		
方法		
方法ノガイドライン	その他:ECHの原液0.001 mlを点眼	other: instillation of 0.001 ml of undiluted ECH
試験のタイプ		
GLP適合	データなし	no data
試験を行った年	1963	1963

試験系(種／系統)	ウサギ	rabbit
性別(雄:M、雌:F)		
投与量	濃度 : 原液 暴露時間 : 24時間	Concentration : undiluted Exposure time : 24 hour(s)
各用量群(性別)の動物数		
溶媒(担体)		
投与経路		
観察期間(日)		
その他の試験条件	英文参照	TEST CONDITIONS Test Animals: Rabbits, number tested, strain, sex, age, source and weight at study initiation, unknown Administration/Exposure: Preparation of Test Substance: undiluted; Amount of Substance Instilled: 0.001 ml; Post-Exposure Period: Scored at 24 hours post-dosing Examinations : Ophthalmoscopic examination: No; Scoring system: as cited in Carpenter and Smyth, 1946; Tool Used to Assess Score: fluorescein
統計学的処理		
結果		
腐食		
刺激点数: 角膜		
刺激点数: 虹彩		
刺激点数: 結膜		
その他	ウサギの眼において、0.001 mlは重度の壊死を生じた。0.1%水溶液の過剰量でも壊死を生じたが、0.01%の水溶液では生じなかった(原著の試験報告書8-28に記述されている)。原著の試験報告書8-28では個体別及び総合のスコアはりようできなかった。回復性に関してのデータは得られていない。 Weil et al. (1963) は恐らく10のうちの4の傷害等級を発表した(定義: 原液0.02 mlは20点の最大スケールの上で5点までの傷害を示す)。これは元の報告書で引用されている結果と一致しない。	In the rabbit eye, 0.001 ml produced severe necrosis. An excess of 0.1% solution in water also caused necrosis, but a 0.01% aqueous solution did not (as documented in original study report 8-28). Individual and total scores were not available in original study report 8-28. No data given as to reversibility. Weil et al. (1963) published an injury grade of 4 out of a possible 10 (defined as: 0.02 ml undiluted gives injury of up to 5 points on a maximum scale of 20 points). This is inconsistent with the results cited in the original report.
結論		
眼刺激性		
眼腐食性	腐食性あり	corrosive
注釈	分類 : 眼に重大な損傷を及ぼすリスクがある 重度の角膜の火傷	Classification : risk of serious damage to eyes Severe corneal burns.
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	(152)	(152)
備考	フラグ : SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	データなし	no data
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	その他: 綿実油中80%ECH0.1 mlの点眼	other: instillation of 0.1 ml of 80% ECH in cottonseed oil
試験のタイプ		
GLP適合	データなし	no data
試験を行った年	1972	1972
試験系(種／系統)	ウサギ	rabbit
性別(雄:M、雌:F)		
投与量	濃度 : 80% 用量 : 1 ml 暴露時間 : 3時間	Concentration : 80 % Dose : 1 ml Exposure time : 3 hour(s)
各用量群(性別)の動物数		
溶媒(担体)		
投与経路		
観察期間(日)		
その他の試験条件		
統計学的処理		
結果		
腐食		
刺激点数: 角膜		
刺激点数: 虹彩		
刺激点数: 結膜		
その他		
結論		
眼刺激性	高度の刺激性あり	highly irritating
眼腐食性		
注釈	3時間以内に角膜の損傷	Corneal damage within 3 hours.
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	GLPの施行前に実施された試験。原液ではなく媒体として綿実油を用いた。	Study conducted prior to advent of GLP; cottonseed oil vehicle used rather than undiluted.
出典		
引用文献(元文献)	(132)	(132)
備考		

試験物質名	データなし	no data
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	その他: 綿実油中20%ECH0.1 mlの点眼	other: instillation of 0.1 ml of 20% ECH in cottonseed oil

試験のタイプ		
GLP適合	データなし	no data
試験を行った年	1972	1972
試験系(種/系統)	ウサギ	rabbit
性別(雄:M、雌:F)		
投与量	濃度 : 20% 用量 : 1 ml 暴露時間 : 3時間	Concentration : 20 % Dose : .1 ml Exposure time : 3 hour(s)
各用量群(性別)の動物数		
溶媒(担体)		
投与経路		
観察期間(日)		
その他の試験条件		
統計学的処理		
結果		
腐食		
刺激点数: 角膜		
刺激点数: 虹彩		
刺激点数: 結膜		
その他		
結論		
眼刺激性	軽度の刺激性あり	slightly irritating
眼腐食性		
注釈	結膜の刺激及び浮腫	Conjunctival irritation and edema.
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	GLPの施行前に実施された試験。原液ではなく媒体として綿実油を用いた。	Study conducted prior to advent of GLP; cottonseed oil vehicle used rather than undiluted.
出典		
引用文献(元文献)	(132)	(132)
備考		

試験物質名	データなし	no data
CAS番号		
純度等		
注釈		
方法		
方法/ガイドライン	その他	other
試験のタイプ		
GLP適合	いいえ	no
試験を行った年	1972	1972
試験系(種/系統)	ウサギ	rabbit
性別(雄:M、雌:F)		
投与量	濃度 : 5% 用量 : 0.1 ml 暴露時間 : 3時間	Concentration : 5 % Dose : .1 ml Exposure time : 3 hour(s)
各用量群(性別)の動物数		
溶媒(担体)		
投与経路		
観察期間(日)		
その他の試験条件		
統計学的処理		
結果		
腐食		
刺激点数: 角膜		
刺激点数: 虹彩		
刺激点数: 結膜		
その他		
結論		
眼刺激性	刺激性なし	not irritating
眼腐食性		
注釈		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	GLPの施行前に実施された試験。原液ではなく媒体として綿実油を用いた。	Study conducted prior to advent of GLP; cottonseed oil vehicle used rather than undiluted.
出典		
引用文献(元文献)	(132)	(132)
備考		

#### 5-4 皮膚感作

##### SKIN SENSITISATION

試験物質名	他のTS	other TS
CAS番号		
純度等	純度の明記なし	Purity not specified.
注釈		
方法		
方法/ガイドライン	OECDガイドライン406 "皮膚感作性"	OECD Guide-line 406 "Skin Sensitization"
試験のタイプ	モルモットマキシマイゼーション試験	Guinea pig maximization test
GLP適合	いいえ	no
試験を行った年	1977	1977
試験系(種/系統)	モルモット	guinea pig
性別(雄:M、雌:F)		
投与量	1回目: 誘導 5%皮内 2回目: 誘導 5%閉塞塗布 3回目: 惹起 1%閉塞塗布	1st: Induction 5 % intracutaneous 2nd: Induction 5 % occlusive epicutaneous 3rd: Challenge 1 % occlusive epicutaneous
各用量群(性別)の動物数	動物数 : 15匹	Number of animals : 15

溶媒(担体)	その他: エタノール	other: ethanol
投与経路		
観察期間(日)		
その他の試験条件		
統計学的処理		
結果		
試験結果	15日いいのモルモットのうち9匹が感作性影響を示した。	9 of 15 guinea pigs showed a sensitizing effect.
その他		
結論		
感作性	感作性あり	sensitizing
注釈	分類: 感作性あり	Classification : sensitizing
信頼性	(1) 制限なく信頼性あり	(1) valid without restriction
信頼性の判断根拠	GLPの施行前に実施された試験	Study conducted prior to advent of GLP.
出典		
引用文献(元文献)	(153)	(153)
備考	フラグ: SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	1.1～1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等		
注釈		
方法		
方法/ガイドライン	その他: Maguire法	other: Maguire method
試験のタイプ	その他: Maguire法	other: Maguire Test
GLP適合	いいえ	no
試験を行った年	1986	1986
試験系(種/系統)	モルモット	guinea pig
性別(雄:M、雌:F)		
投与量	濃度: 1回目: 誘導 10%閉塞塗布 2回目: 惹起 10%開放塗布	Concentration : 1st: Induction 10 % occlusive epicutaneous 2nd: Challenge 10 % open epicutaneous
各用量群(性別)の動物数	動物数: 10匹	Number of animals : 10
溶媒(担体)	その他: ジプロピレングリコールメチルエーテル:Tween 80, 9:1	other: dipropylene glycol methyl ether: Tween 80, 9:1
投与経路		
観察期間(日)		
その他の試験条件		
統計学的処理		
結果		
試験結果	10匹の動物のうち5匹が感作された。	Five out of ten animals sensitized.
その他		
結論		
感作性	感作性あり	sensitizing
注釈		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	GLPに準じて実施された試験かどうかは不明。全体的に示されたガイドラインには合致していないが、試験は科学的に許容できる。	Unknown whether study was conducted according to GLP. Does not totally comply with suggested guideline, but study is scientifically acceptable.
出典		
引用文献(元文献)	(154)	(154)
備考		

試験物質名	データなし	no data
CAS番号		
純度等		
注釈		
方法		
方法/ガイドライン	その他: 明記なし (Maguire 又は Landsteiner & Jacobsのいずれかの方法)	other: unspecified (either Maguire or Landsteiner & Jacobs)
試験のタイプ	その他: Maguire 又は Landsteiner & Jacobsのいずれか	other: either Maguire or Landsteiner & Jacobs
GLP適合	いいえ	no
試験を行った年	1981	1981
試験系(種/系統)	モルモット	guinea pig
性別(雄:M、雌:F)		
投与量	濃度: 1回目: 誘導 5%開放塗布 2回目: 惹起 5%開放塗布	Concentration : 1st: Induction .5 % open epicutaneous 2nd: Challenge .5 % open epicutaneous
各用量群(性別)の動物数	動物数: 10匹	Number of animals : 10
溶媒(担体)	その他: ジプロピレングリコールメチルエーテル:Tween 80混合物、9:1	other: dipropylene glycol methyl ether: Tween 80 mixture, 9:1
投与経路		
観察期間(日)		
その他の試験条件		
統計学的処理		
結果		
試験結果		
その他	10匹の実験動物の全例で陽性反応が得られた。濃度のデータは与えられていない。濃度のデータはオリジナルのDow Chemical Companyの未公表報告書から得た。	Positive reaction in all 10 experimental animals obtained. No concentration data given. Concentration data obtained from original unpublished report of The Dow Chemical Company.
結論		
感作性	感作性あり	sensitizing
注釈	分類: 感作性あり	Classification : sensitizing
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		

出典		
引用文献(元文献)	(155)	(155)
備考		

# 5-5 反復投与毒性

## REPEATED DOSE TOXICITY

試験物質名	その他TS	other TS
CAS番号		
純度等	純度 >99%	>99% purity
注釈		
方法		
方法／ガイドライン	その他	other
GLP適合	いいえ	no
試験を行った年	1979	
試験系(種／系統)	その他: マウス、ラット、ラット	other: mice, rats, rats
性別(雄:M、雌:F)	雌/雄	male/female
投与量	0, 5, 25, 50 ppm (0, 18.9, 94.5, 189 mg/m3)	0, 5, 25, 50 ppm (0, 18.9, 94.5, 189 mg/m3)
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	吸入	inhalation
対照群に対する処理		
投与期間(日)(OECD422等で、投与期間のデータ等がある場合、最長投与期間)	雄: 87 日間 雌: 88 日間	
投与頻度	6 時間/日、5 日間/週	6 h/d, 5 d/week
回復期間(日)	なし	None
試験条件	*英文参照	<p>TEST ORGANISMS:</p> <p>Fischer 344 rat: 9–11 weeks old, males 205–219 g, females 125–139 g.</p> <p>Sprague–Dawley rat: 9–11 weeks old, males 357–376 g, females 236–245 g.</p> <p>B6C3F1 mouse: 7–9 weeks old, males 20–27 g, females 20–22 g.</p> <p>ADMINISTRATION/EXPOSURE:</p> <p>Groups of 20 animals per sex per dose level were exposed to 0, 5, 25, or 50 ppm six hours daily, five days per week, for approximately 12 weeks (87 days, males; 88 days, females).</p> <p>Whole-body vapor exposures were carried out in 14.5 cubic meter chambers. Atmospheres were generated by metering liquid through a pump into a warmed vaporization flask, then sweeping the vapors into the chamber with compressed air. Chamber air was assayed for vapor concentration at least 3 times during each 6-hour exposure period.</p>
試験条件	*英文参照	<p>CLINICAL OBSERVATIONS AND FREQUENCY:</p> <p>Animals were observed daily for signs of toxicity and morbidity/mortality. Body weights were collected twice weekly for the first two weeks of exposure, weekly for weeks three and four, and every two weeks thereafter.</p> <p>One to two weeks prior to necropsy (rats) or at necropsy (mice), blood samples were collected for hematologic analysis. Parameters examined were packed cell volume, red blood cell count, hemoglobin concentration, and white blood cell count. Urinalysis samples from rats were collected when blood samples were collected; parameters examined were specific gravity, pH, sugar, protein, ketones, bilirubin, occult blood, urobilinogen.</p> <p>Feed/water consumption were not monitored during the study. Ophthalmoscopic examinations were not performed during the study.</p>



試験条件	*英文参照	<p>ORGANS EXAMINED AT NECROPSY:</p> <p>At necropsy, blood samples were collected for analysis of clinical chemistry parameters: blood urea nitrogen, glutamic pyruvic transaminase activity, alkaline phosphatase activity, glutamic oxaloacetic transaminase activity, and glucose concentration.</p> <p>A complete necropsy examination was conducted on each animal, during which organ weights for brain, heart, liver, kidneys, testes, spleen, and thymus were recorded. Approximately 40 organs/tissues (esophagus, stomach, small intestine, pancreas, mediastinal lymphoid tissue (thymus, mediastinal lymph nodes), urinary bladder, heart, testes, ovaries, uterus, gall bladder, pituitary gland, salivary glands, lungs, vertebral bone and bone marrow, spinal cord, spleen, kidneys, prostate, epididymides, skeletal tissue, oviducts, parathyroid gland, brain, skin, eyes, trachea, nasal turbinates, large intestine, liver, lymph nodes, seminal vesicles, aorta, adrenal gland, thyroid gland, mammary gland, adipose tissue, peripheral nerve) from each animal were examined histologically for the control and high dose groups; possible target organs were examined for low and middle dose groups.</p> <p>After thirty days on test, an interim sacrifice was conducted on 10 animals per sex per dose level. Parameters evaluated were hematology, urinalysis (rats only), clinical chemistry, gross pathology, organ weights, and histopathology. Histopathology was conducted on five animals per sex per dose level from the control and high dose groups.</p>
統計学的処理	*英文参照	<p>STATISTICAL METHODS:</p> <p>Body weights, hematology, urinalysis, clinical chemistries, and organ weights were analyzed via ANOVA with a Dunnetts Test.</p>
結果		
体重、体重増加量	<p>[Fischer 344 rats]</p> <p>[SPRAGUE-DAWLEY RATS]</p> <p>[B6C3F1 MICE]</p>	<p>[Fischer 344 rats]</p> <p>Body Weights: Female Fischer 344 rats exposed to 50 ppm showed statistically decreased body weights on day zero which tended to remain lower throughout the study. Female Fischer 344 rats exposed to 25 ppm occasionally showed decreased body weights during the first month of exposure, but not at study termination.</p> <p>[SPRAGUE-DAWLEY RATS]</p> <p>Body Weight: Male Sprague-Dawley rats exposed to 50 ppm showed statistically decreased body weights during the first month which tended to remain lower throughout the study. There were no treatment-related changes in body weights for female rats.</p> <p>[B6C3F1 MICE]</p> <p>Body Weight: Male and female B6C3F1 mice exposed to 50 ppm showed a trend toward decreased weight during the last few weeks of the study, occasionally identified as statistically significant.</p>
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)	<p>暴露時間中、ラットでは眼の病変のその後の証拠のない、一過性とも割れる結膜の発赤、眼瞼閉鎖がみられた。暴露の最初の10日間に主に25及び50 ppm群でケージの中の動きの低下が観察された。マウスでは観察されなかった。</p>	<p>Clinical Observations (Fischer 344 and Sprague-Dawley rats, B6C3F1 mice): During the hours of exposure, the rats appeared to show conjunctival redness and palpebral closure without subsequent evidence of ocular involvement. These effects appeared to be transient, with recovery occurring overnight. Slight decreases in cage movements were observed in rats exposed to 25 or 50 ppm primarily during the first ten days of exposure and intermittently thereafter. These effects were not observed in mice.</p>
眼科学的所見(発生率、重篤度)		
血液学的所見(発生率、重篤度)	<p>[Fischer 344 rats]</p> <p>投与と関連する変化なし</p> <p>[SPRAGUE-DAWLEY RATS]</p> <p>投与と関連する変化なし</p> <p>[B6C3F1 MICE]</p> <p>投与と関連する変化なし</p>	<p>[Fischer 344 rats]</p> <p>Hematology: No treatment-related changes in hematology were found in Fischer 344 rats.</p> <p>[SPRAGUE-DAWLEY RATS]</p> <p>Hematology: No treatment-related changes in hematology were found in Sprague-Dawley rats.</p> <p>[B6C3F1 MICE]</p> <p>Hematology: No treatment-related changes in hematology were found in B6C3F1 mice.</p>
血液生化学的所見(発生率、重篤度)	<p>[Fischer 344 rats]</p> <p>投与と関連する変化なし</p> <p>[SPRAGUE-DAWLEY RATS]</p> <p>投与と関連する変化なし</p> <p>[B6C3F1 MICE]</p> <p>投与と関連する変化なし</p>	<p>[Fischer 344 rats]</p> <p>Clinical Chemistry: No treatment-related changes in clinical chemistries were found in Fischer 344 rats.</p> <p>[SPRAGUE-DAWLEY RATS]</p> <p>Clinical Chemistry: No treatment-related changes in clinical chemistries were found in Sprague-Dawley rats.</p> <p>[B6C3F1 MICE]</p> <p>Clinical Chemistry: No treatment-related changes in clinical chemistries were found in B6C3F1 mice.</p>

尿検査所見(発生率、重篤度)	<p>[Fischer 344 rats] 投与と関連する変化なし</p> <p>[SPRAGUE-DAWLEY RATS] 投与と関連する変化なし</p>	<p>[Fischer 344 rats] Urinalysis: No treatment-related changes in urinalysis parameters were found in Fischer 344 rats.</p> <p>[SPRAGUE-DAWLEY RATS] Urinalysis: No treatment-related changes in urinalysis parameters were found in Sprague-Dawley rats.</p> <p>[B6C3F1 MICE]</p>
死亡数(率)、死亡時間 剖検所見(発生率、重篤度)	<p>[Fischer 344 rats] 投与と関連すると考えられる病変なし</p> <p>[SPRAGUE-DAWLEY RATS] 25及び50 ppmの雄で腎臓の軽度蒼白化、サイズの増加がみられた。50ppmの雄で肝臓の蒼白化を伴った葉の文様の明瞭化がみられた。</p> <p>[B6C3F1 MICE] 50 ppmの雄(及び雌の1例)で体重の減少と一致した腹腔内脂肪の減少がみられた。</p>	<p>[Fischer 344 rats] Gross Pathology: No lesions were observed which were considered treatment-related.</p> <p>[SPRAGUE-DAWLEY RATS] Gross Pathology: Kidneys in male Sprague-Dawley rats exposed to 25 or 50 ppm were slightly pale in color and increased in size at study termination. Livers in male Sprague-Dawley rats exposed to 50 ppm a slight accentuated lobular pattern with a pale color at study termination. No other lesions were observed which were considered treatment-related in either male or female Sprague-Dawley rats.</p> <p>[B6C3F1 MICE] Gross Pathology: At study termination, male mice (and one female mouse) at 50 ppm had decreased intraabdominal fat, consistent with decreased body weight. No other lesions were observed which were considered treatment-related in either male or female mice.</p>
臓器重量	<p>[Fischer 344 rats] 25及び50 ppmの雌雄で中間時、終了時に腎臓の絶対・相対重量増加がみられた。</p> <p>[SPRAGUE-DAWLEY RATS] 25及び50 ppm雌雄で中間時、終了時に腎臓の絶対・相対重量増加がみられた。</p> <p>[B6C3F1 MICE] 5及び50 ppmの雄で、中間(30日)で肝臓の絶対・相対重量減少がみられたが、終了時にはみられなかった。 50 ppmの雄で終了時に脳の相対重量増加がみられた。</p> <p>5、25、50 ppmの雌で中間時(30日)に肝臓の絶対・相対重量減少がみられたが終了時にはみられなかった。</p>	<p>[Fischer 344 rats] Organ Weights: Absolute and/or relative kidney weights were increased in male and female Fischer 344 rats at 25 and 50 ppm at interim and terminal examinations. Various other changes in organ weights were judged to be unrelated to treatment.</p> <p>[SPRAGUE-DAWLEY RATS] Organ Weights: Absolute and/or relative kidney weights were increased in male and female Sprague-Dawley rats at either 25 or 50 ppm at interim and terminal examinations. Various other changes in organ weights were judged to be unrelated to treatment.</p> <p>[B6C3F1 MICE] Organ Weights: Interim (day 30) absolute and relative liver weights in male mice at 5 and 50 ppm were statistically decreased; this effect was not seen at study termination. Male mice at 50 ppm had statistically significantly increased relative brain weights at study termination. Interim (day 30) absolute and/or relative liver weights in female mice at 5, 25, and 50 ppm were statistically decreased; this effect was not seen at study termination. Absolute heart weight was also decreased in female mice at 50 ppm; this effect was not seen at study termination.</p>
病理組織学的所見(発生率、重篤度)	<p>高濃度で、鼻甲骨で過形成、化生と炎症を起こした細胞浸潤がみられた。25及び50 ppmでラットでは、腎臓の絶対・相対重量増加で示される腎臓の非進行性影響がみられた、この変化はマウスではみられなかった。</p> <p>50 ppmのラット(両方の系統)とマウスで軽度の非退行性の肝臓の影響がみられた。両方の系統の雄ラットでは50ppmで経度の副腎に対する影響が、みられたが、ストレスによる可能性がある。雄のSprague-Dawley ラットでは 50 ppmで、精巣上体の内容物にわずかな変化があった。</p>	<p>Histopathology (Fischer 344 and Sprague-Dawley rats, B6C3F1 mice): Histopathological examinations showed that the nose was the most sensitive organ to exposure. At the higher concentrations microscopic examination revealed hyperplasia, metaplasia and inflamed cell infiltration in the nasal turbinates. In addition, exposure at 25 or 50 ppm caused slight non-progressive kidney effects in rats but not mice, as evidenced by increased kidney weights (relative and/or absolute). Slight non-degenerative liver effects were noted in rats of both strains as well as the mice exposed to 50 ppm. Male rats of both strains at 50 ppm had slight effects on the adrenal glands, possibly mediated by stress. In male Sprague-Dawley rats at 50 ppm, there were minimal changes in the contents of the epididymides.</p>
実際に摂取された量		
用量反応性		
注釈		
結論		
NOAEL (NOEL)	18.9 mg/m <sup>3</sup>	18.9 mg/m <sup>3</sup>
LOAEL (LOEL)	94.5 mg/m <sup>3</sup>	94.5 mg/m <sup>3</sup>
NOAEL/LOAELの推定根拠		
雌雄のNOAEL(LOAEL)の違い等		
注釈		
信頼性	(1) 制限なく信頼性あり	(1) valid without restriction
信頼性の判断根拠	GLPの施行前に実施された試験	Study conducted prior to advent of GLP.
出典		
引用文献(元文献)	(156) (157)	(156) (157)
備考	フラグ: SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

試験物質名		
CAS番号		
純度等	純度の明記なし	Purity not specified.
注釈		
方法		
方法／ガイドライン	その他	other
GLP適合	データなし	no data
試験を行った年	1996	1996
試験系(種／系統)	ラット	rat
	Sprague-Dawley	Sprague-Dawley
性別(雄:M、雌:F)	雌雄	male/female

投与量	1, 5, 25 mg/kg/日	1, 5, 25 mg/kg/day
各用量群(性別)の動物数		
溶媒(担体)		
投与経路		
対照群に対する処理	媒体対照群	yes, concurrent vehicle
投与期間(日)(OECD422等で、投与期間のデータ等がある場合、最長投与期間)	90日間	90 day
投与頻度	1日1回	Once daily
回復期間(日)		
試験条件		
統計学的処理		
結果		
体重、体重増加量	高用量で体重増加抑制(29-90%)	Epichlorohydrin did not adversely affect mortality, but toxicity, at the higher doses, was evident by: 1) losses in body weight gain (29-90%) and increases in organ weights (15% absolute kidney weight, 23% relative kidney weight, 13% relative liver weight), 2) reduction in food consumption (19%) , and
摂餌量、飲水量	高用量で摂餌量減少(19%)	Epichlorohydrin did not adversely affect mortality, but toxicity, at the higher doses, was evident by: 1) losses in body weight gain (29-90%) and increases in organ weights (15% absolute kidney weight, 23% relative kidney weight, 13% relative liver weight), 2) reduction in food consumption (19%) , and
臨床所見(重篤度、所見の発現時期と持続時間)		
眼科学的所見(発生率、重篤度)		
血液学的所見(発生率、重篤度)	90日後の中用量、高用量の雄で赤血球数、ヘモグロビン量、ヘマトクリット値の有意な減少がみられた。	3) in the hematological and microscopic examinations. Significant decreases in erythrocyte count, hemoglobin, and hematocrit levels were found in the middle and high dose level in males after 90 days.
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間	死亡なし	Epichlorohydrin did not adversely affect mortality, but toxicity, at the higher doses, was evident by: 1) losses in body weight gain (29-90%) and increases in organ weights (15% absolute kidney weight, 23% relative kidney weight, 13% relative liver weight), 2) reduction in food consumption (19%) , and
剖検所見(発生率、重篤度)		
臓器重量	高用量で腎臓の絶対重量増加(15%)、腎臓の相対重量増加(23%)、肝臓の相対重量増加(13%)  90日試験の25 mg/kg群の雌雄で用量依存的な腎臓、肝臓重量増加がみられた。	Epichlorohydrin did not adversely affect mortality, but toxicity, at the higher doses, was evident by: 1) losses in body weight gain (29-90%) and increases in organ weights (15% absolute kidney weight, 23% relative kidney weight, 13% relative liver weight), 2) reduction in food consumption (19%) , and ... Dose-related increases in kidney and liver weights were observed in both sexes at 25 mg/kg-day in the 90-day study.
病理組織学的所見(発生率、重篤度)	前胃の粘膜過形成(アークアトシス)、過角化の用量依存的な増加がみられ、一次標的器官と特定された。	Histopathological examination identified the forestomach as the primary target organ for both sexes with significant dose-related increases in mucosal hyperplasia (acanthosis) and hyperkeratosis.
実際に摂取された量		
用量反応性		
注釈	*英文参照	Based on the data presented, for oral exposure of Sprague-Dawley rats to epichlorohydrin 1 mg/kg/day is suggested as the no observed adverse effect level (NOAEL) for a 90 day oral exposure. These conclusions were the same whether the lesions were analyzed for each sex individually or whether the data was pooled.
結論		
NOEL (NOEL)	1mg/kg bw	1mg/kg bw
LOEL (LOEL)	5mg/kg bw	1mg/kg bw
NOEL/LOELの推定根拠		
雌雄のNOEL(LOEL)の違い等		
注釈		
信頼性		
信頼性の判断根拠	(2) 制限付きで信頼性あり	(2) valid with restrictions
出典		
引用文献(元文献)	-158	-158
備考		

試験物質名	EHC	ECH in cottonseed oil as vehicle.
CAS番号		
純度等		
注釈		
方法		
方法/ガイドライン		
GLP適合		
試験を行った年	1972	1972
試験系(種/系統)	ラット	rat
	Sprague-Dawley	Sprague-Dawley
性別(雄:M、雌:F)	雄	male
投与量	11, 22, 56 mg/kg 体重	11, 22, 56 mg/kg body weight
各用量群(性別)の動物数		

溶媒(担体)	綿実油	ECH in cottonseed oil as vehicle.
投与経路	腹腔内	i.p.
対照群に対する処理	媒体対照群	yes, concurrent vehicle
投与期間(日)(OECD422等で、投与期間のデータ等がある場合、最長投与期間)	12週間	12 weeks
投与頻度	3回/週	3 times a week
回復期間(日)	なし	none
試験条件		
統計学的処理		
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
眼科学的所見(発生率、重篤度)		
血液学的所見(発生率、重篤度)	統計的に有意で用量依存性のあるヘモグロビンの減少がみられた。 上2つの用量でリンパ球の割合の有意な減少がみられ、全ての用量で好酸球の有意な増加がみられた。	A statistically significant, dose-dependent reduction in haemoglobin was found. In the two highest dosage groups the proportion of lymphocytes was significantly reduced, while the proportion of eosinophils was increased in all of the dosage groups.
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)		
臓器重量	最高用量で心臓、肝臓、腎臓重量の増加がみられた。	In the highest dosage group a marked increase in the weight of the heart, liver and kidneys was observed.
病理組織学的所見(発生率、重篤度)		
実際に摂取された量		
用量反応性		
注釈		
結論		
NOAEL (NOEL)		
LOAEL (LOEL)	11mg/kg bw	11mg/kg bw
NOAEL/LOAELの推定根拠		
雌雄のNOAEL(LOAEL)の違い等		
注釈		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	科学的には有効な試験であるが、投与経路は工業的暴露とは無関係である。	Scientifically valid study, but route is irrelevant to potential industrial exposure.
出典		
引用文献(元文献)	132	132
備考		

試験物質名	1.1～1.4で規定	as prescribed by 1.1 – 1.4
CAS番号		
純度等	純度 >99%	> 99% purity
注釈		
方法		
方法/ガイドライン	その他	other
GLP適合	データなし	no data
試験を行った年	1980	1980
試験系(種/系統)	ラット Sprague-Dawley	rat Sprague-Dawley
性別(雄:M、雌:F)	雄	male
投与量	100 ppm	100 ppm
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	吸入	inhalation
対照群に対する処理	あり	yes
投与期間(日)(OECD422等で、投与期間のデータ等がある場合、最長投与期間)	30日間	30 days
投与頻度	6時間	6-hour
回復期間(日)		

試験条件	*英文参照	<p>TEST ORGANISMS:</p> <ul style="list-style-type: none"> <li>- Source: Blue Spruce Farms, Inc. Altamont, N. Y.</li> <li>- Age: 8 weeks</li> <li>- Weight at study initiation: Not presented</li> <li>- Number of animals: 100 rats</li> <li>- Controls: Yes</li> </ul> <p>ADMINISTRATION:</p> <ul style="list-style-type: none"> <li>- Type of exposure: Thirty 6-hour period</li> <li>- Concentrations: 100 ppm</li> </ul> <p>Test atmospheres containing ECH were generated by passing an air stream over the liquid in a generating flask and then diluting the effluent vapor with a second air stream prior to introduction into the exposure chambers. Exposures were done either in 128-liter or 1.3-m<sup>3</sup> exposure chambers. Chamber concentrations were analyzed at ½ hour intervals during exposures.</p> <p>EXAMINATIONS:</p> <p>All animals were carefully observed daily and weighed monthly. Complete necropsies were conducted with particular attention given to the respiratory tract. Histologic sections were prepared from the each side of the head to display the entire nasal cavity. Histologic sections were also prepared from each pulmonary lobe, the larynx, trachea, stem bronchi, liver, bladder, kidneys, spleen, and other organs with gross pathologic alterations.</p>
統計学的処理		
結果		
体重、体重増加量		A mortality rate of 9% was seen among the exposed animals within the first 8 weeks of the initial exposure to ECH. However, the subsequent survival of the treated animals was actually better than that of the controls. Similarly, overall weight gain shown by ECH-treated rats equaled or exceeded that of the controls. The increased mortality in sham controls was attributed to respiratory infection.
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
眼科学的所見(発生率、重篤度)		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)	<p>ほとんど全ての暴露されたラットで、刺激に伴う重篤な甲介骨の粘膜の破壊による化膿がみられた。喉頭と気管の変性は、最も近くから末梢部まで頻度は減少するが、重篤な刺激性の変化を含みました。肺疾患としては、主に浮腫、うっ血と肺炎がみられた。腫瘍性変化はみられなかった。腎臓の障害はラットの63%にみられた。皮質と髄質の硝子円柱で満たされた尿細管の拡張がみられた。</p>	<p>Gross Pathology</p> <p>Almost all the exposed rats showed a severe inflammatory accompanied by suppuration with destruction of the mucous membrane of the turbinates. Alterations in the larynx and trachea included severe inflammatory changes with decreasing frequency from proximal to distal zones. Lung disorders were mainly edema, congestion, and pneumonia. No neoplastic changes were observed. Renal damage was noted in 63% of the rats and included dilatation of cortical and medullary tubules, which were filled with hyaline casts. The controls showed congestion, edema, bronchiectasis, and pneumonia in the lungs, and lesions in the kidney were significantly reduced and found mostly in the older animals.</p> <p>Of the 140 animals, 18 (13%) developed tumors, either benign or malignant of the nasal cavity, which occurred 330-933 days from onset of the exposure. Of these 15 were squamous cell carcinomas, and their presence was denoted by nasal swelling. Clinically, affected rats displayed dyspnea and wheezing. Clinical examination revealed a solid mass filled the nasal cavity. Histologically, almost all the tumors were well-differentiated squamous cell carcinomas with keratin pearls.</p>
臓器重量		
病理組織学的所見(発生率、重篤度)		
実際に摂取された量		
用量反応性		
注釈	*英文参照	<p>Because of LC50 response, a group of only 40 Sprague-Dawley rats was first tested at the 100-ppm level. After 100 ppm ECH was discovered to be tolerable over a course of 30 6-hour exposures, this experiment was begun with the group of 100 animals.</p>
結論		
NOEL (NOEL)		
LOEL (LOEL)		
NOEL/LOELの推定根拠		
雌雄のNOEL(LOEL)の違い等		
注釈		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	138	138
備考		
試験物質名	1.1～1.4で規定	as prescribed by 1.1 - 1.4
CAS番号		
純度等	純度 >99%	> 99% purity
注釈		
方法		

方法／ガイドライン	その他	other
GLP適合	データなし	no data
試験を行った年	1980	1980
試験系(種／系統)	ラット Sprague-Dawley	rat Sprague-Dawley
性別(雄:M、雌:F)	雄	male
投与量	10、30 ppm	10 and 30 ppm
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	吸入	inhalation
対照群に対する処理	その他: 平行シャム及び無処置対照群	other: parallel sham and untreated controls
投与期間(日)(OECD422等で、投与期間のデータ等がある場合、最長投与期間)	6時間/日	6 hours/day
投与頻度	5日間/週	5 days/week
回復期間(日)		
試験条件	*英文参照	<p>ITEST ORGANISMS:</p> <ul style="list-style-type: none"> <li>- Source: Blue Spruce Farms, Inc. Altamont, N. Y.</li> <li>- Age: 8 weeks</li> <li>- Weight at study initiation: Not presented</li> <li>- Number of animals: 200 rats</li> <li>- Controls: Parallel sham and untreated controls</li> </ul> <p>ADMINISTRATION:</p> <ul style="list-style-type: none"> <li>- Type of exposure: 5 days/week, 6 hours/day over their lifetime</li> <li>- Concentrations: 10 and 30 ppm</li> </ul> <p>Test atmospheres containing ECH were generated by passing an air stream over the liquid in a generating flask and then diluting the effluent vapor with a second air stream prior to introduction into the exposure chambers. Exposures were done either in 128-liter or 1.3-m<sup>3</sup> exposure chambers. Chamber concentrations were analyzed at ½ hour intervals during exposures.</p>
試験条件	*英文参照	<p>EXAMINATIONS:</p> <p>All animals were carefully observed daily and weighed monthly. Complete necropsies were conducted with particular attention given to the respiratory tract. Histologic sections were prepared from the each side of the head to display the entire nasal cavity. Histologic sections were also prepared from each pulmonary lobe, the larynx, trachea, stem bronchi, liver, bladder, kidneys, spleen, and other organs with gross pathologic alterations.</p>
統計学的処理		
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
眼科学的所見(発生率、重篤度)		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間	<p>エビクロロヒドリンの両暴露群は暴露開始後16週間まで有意な死亡率を示さなかった。10 ppmで48週、30 ppmで60週までに死亡率は両暴露条件で45/100匹となった。いずれの場合も重度の肺のうっ血及び肺炎がみられた。2年間の生存率は対照群を含む全群で約5-10%であった。最初の暴露から136週までに死亡率は100%に達した。</p>	<p>In two chronic inhalation studies, weight gain for animals exposed to 10 ppm ECH were comparable to controls. The 30 ppm group showed a significant weight loss after 40 weeks. By 48 weeks, 45% of the 10 ppm ECH animals had died and a similar degree of mortality was shown by 60 weeks in the 30 ppm group. In all cases, severe lung congestion and pneumonia were observed. By week 136, mortality reached 100% in the 30 ppm group.</p>
剖検所見(発生率、重篤度)		
臓器重量		
病理組織学的所見(発生率、重篤度)	<p>10ppm 群で、非腫瘍性病変がみられた。両群で肺のうっ血、細気管支拡張、肺炎を示した。肺の腫瘍性変化を示す動物はなかった。</p> <p>10及び30 ppm群で鼻粘膜の扁平上皮化生がみられ、それぞれ2%と1%であった。</p> <p>腎臓の障害は30ppm、10ppm、シャム、無処置で65、37、24、14%であった。病変は、主に尿管拡張を伴う尿管の退行性的変化であった。腎臓の病変は質的には対照群と同じであった。</p>	<p>Animals in the 10 ppm group showed no neoplastic lesions. Both of the groups showed pulmonary congestions, bronchiolectasis, and pneumonia, but none of the animals had any neoplastic changes in the lungs.</p> <p>Squamous metaplasia of the nasal mucosa was only observed in the 10 and 30 ppm group at 2% and 1%, respectively. Renal damage was 65, 37, 24, and 14% for the 30-ppm, 10-ppm, sham, and untreated groups, respectively. The lesions seen were predominately tubular degenerative changes, with tubules undergoing dilatation. The kidney lesions were qualitatively the same in the ECH group as in the controls.</p>
実際に摂取された量		
用量反応性		
注釈	*英文参照	<p>Because 90% of the control rats showed severe inflammatory changes in the nasal cavity, no effects of ECH were observable in terms either of incidence or severity in the dose groups.</p>
結論		
NOEL (NOEL)		
LOEL (LOEL)		
NOEL/LOELの推定根拠		
雌雄のNOEL(LOEL)の違い等		
注釈		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		



出典		
引用文献(元文献)	138	138
備考		

5-6 *in vitro* 遺伝毒性  
GENETIC TOXICITY IN VITRO  
A. 遺伝子突然変異  
GENE MUTATION

試験物質名		
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	エームス試験 OECDガイドライン471	Ames test OECD Guide-line 471
GLP適合	情報無し	no data
試験を行った年		
細胞株又は検定菌	ネズミチフス菌 <i>Salmonella typhimurium</i> TA 98,100,1535,1537,1538	<i>Salmonella typhimurium</i> TA 98,100,1535,1537,1538
代謝活性化(S9)の有無	有及び無	with and without
試験条件		
結果		
細胞毒性		
代謝活性ありの場合		
代謝活性なしの場合		
変異原性		
代謝活性ありの場合	陽性	positive
代謝活性なしの場合	陽性	positive
注釈	原文参照	This summary references the results of a number of different studies conducted from 1978 to 1989, across a wide range of concentrations, all generally following OECD guidelines for the standard Ames assay. For individual test conditions, see individual references. In standard assays, ECH has been shown to increase the yield of revertant in strains of <i>Salmonella typhimurium</i> (TA 100, TA 1535) and <i>E. Coli</i> (WP3uvrA), <i>Klebsiella pneumoniae</i> . Other <i>S. typhimurium</i> strains were negative or marginally positive (TA 98, TA 1537, TA 1538). In the presence of metabolic activation, reduction of the genotoxic potential was seen. Exposure of bacteria in vapour phase or sealed systems also resulted in a positive response.
結論		
遺伝子突然変異	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠		
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	<ul style="list-style-type: none"> <li>Anderson M., Kiel P., Larsen H., Maxild J. (1978), "Mutagenic action of aromatic epoxy resins", <i>Nature</i>, 276, 391-92.</li> <li>Bridges B.A. (1978), "On the detection of volatile liquid mutagens with bacteria : experiments with dichlorvos and epichlorohydrin", <i>Mutat. Res.</i>, 54, 367-71.</li> <li>De Flora S., BenNICELLI C., Zanacchi P., Camoirane A., Petruzzelli S., Giuntini C. (1984), "Metabolic activation and deactivation of mutagens by preparations of human lung parenchyma and bronchial tree", <i>Mutat. Res.</i>, 139, 9-14.</li> <li>De Serres F.J., Ashby J. (1981), "Evaluation of Short-Term Tests for Carcinogens", <i>Progress in mutation research</i>, Vol. I, Elsevier, ISBN 0 444 20570 6.</li> <li>Eder E., Neudecker T., Lutz D., Henschler D. (1980), "Mutagenic potential of allyl and allylic compounds. Structure-activity relationship as determined by alkylating and directing vitromutagenic properties", <i>Biochem. Pharmacol.</i>, 29, 993-98.</li> <li>Elmore J.D., Wong J.L., Streips U.N. (1976), "Vinyl chloride, mutagenicity via the metabolites chloroxirane and chloroacetaldehyde monomer hydrate", <i>Biochim. Biophys. Acta</i>, 442, 405-19.</li> <li>McGregor D.B., Reynolds D.M., Zeiger E. (1989), "Conditions affecting the mutagenicity of trichloroethylene in <i>Salmonella</i>", <i>Environ. Mol. Mutagen.</i>, 13, 197-202.</li> <li>McMahon R.E., Cline J.E., Thompson C.Z. (1979), "Assay on 855 test chemicals in ten tester strains using a new modification of the Ames test for bacterial mutagens", <i>Cancer Res.</i>, 39, 682-93.</li> <li>Ohtani H., Nishioka H. (1981), "Mutagenic activity of epoxide compounds as constituents of resins in bacterial test systems", <i>Sci. Eng. Rev. Doshiha Univ.</i>, 21, 247-55.</li> <li>Probst G.S., McMahon R.E., Hill L.E., Thompson C.Z., Epp J.K., Neal S.B. (1981), "Chemically-induced unscheduled DNA synthesis in primary rat hepatocyte cultures : a comparison with bacterial mutagenicity using 218 compounds", <i>Environ. Mutagen.</i>, 3, 11-32.</li> <li>Stolzenberg S.J., Hine C.H. (1979), "Mutagenicity of halogenated and oxygenated three-carbon compounds", <i>J. Toxicol. Environ. Health</i>, 5, 1149-58.</li> <li>Wade D.R., Airy S.C., Sinsheimer J.E. (1978), "Mutagenicity of aliphatic epoxides", <i>Mutat. Res.</i>, 58, 217-23.</li> </ul>	<ul style="list-style-type: none"> <li>Anderson M., Kiel P., Larsen H., Maxild J. (1978), "Mutagenic action of aromatic epoxy resins", <i>Nature</i>, 276, 391-92.</li> <li>Bridges B.A. (1978), "On the detection of volatile liquid mutagens with bacteria : experiments with dichlorvos and epichlorohydrin", <i>Mutat. Res.</i>, 54, 367-71.</li> <li>De Flora S., BenNICELLI C., Zanacchi P., Camoirane A., Petruzzelli S., Giuntini C. (1984), "Metabolic activation and deactivation of mutagens by preparations of human lung parenchyma and bronchial tree", <i>Mutat. Res.</i>, 139, 9-14.</li> <li>De Serres F.J., Ashby J. (1981), "Evaluation of Short-Term Tests for Carcinogens", <i>Progress in mutation research</i>, Vol. I, Elsevier, ISBN 0 444 20570 6.</li> <li>Eder E., Neudecker T., Lutz D., Henschler D. (1980), "Mutagenic potential of allyl and allylic compounds. Structure-activity relationship as determined by alkylating and directing vitromutagenic properties", <i>Biochem. Pharmacol.</i>, 29, 993-98.</li> <li>Elmore J.D., Wong J.L., Streips U.N. (1976), "Vinyl chloride, mutagenicity via the metabolites chloroxirane and chloroacetaldehyde monomer hydrate", <i>Biochim. Biophys. Acta</i>, 442, 405-19.</li> <li>McGregor D.B., Reynolds D.M., Zeiger E. (1989), "Conditions affecting the mutagenicity of trichloroethylene in <i>Salmonella</i>", <i>Environ. Mol. Mutagen.</i>, 13, 197-202.</li> <li>McMahon R.E., Cline J.E., Thompson C.Z. (1979), "Assay on 855 test chemicals in ten tester strains using a new modification of the Ames test for bacterial mutagens", <i>Cancer Res.</i>, 39, 682-93.</li> <li>Ohtani H., Nishioka H. (1981), "Mutagenic activity of epoxide compounds as constituents of resins in bacterial test systems", <i>Sci. Eng. Rev. Doshiha Univ.</i>, 21, 247-55.</li> <li>Probst G.S., McMahon R.E., Hill L.E., Thompson C.Z., Epp J.K., Neal S.B. (1981), "Chemically-induced unscheduled DNA synthesis in primary rat hepatocyte cultures : a comparison with bacterial mutagenicity using 218 compounds", <i>Environ. Mutagen.</i>, 3, 11-32.</li> <li>Stolzenberg S.J., Hine C.H. (1979), "Mutagenicity of halogenated and oxygenated three-carbon compounds", <i>J. Toxicol. Environ. Health</i>, 5, 1149-58.</li> <li>Wade D.R., Airy S.C., Sinsheimer J.E. (1978), "Mutagenicity of aliphatic epoxides", <i>Mutat. Res.</i>, 58, 217-23.</li> </ul>
備考		

試験物質名	他の物質	other TS
CAS番号		
純度等		
注釈	被験物質はチェコスロバキアで製造と記載されている。	Test substance was noted as having been manufactured in Czechoslovakia.
方法		
方法／ガイドライン	他法:細菌を用いる宿主經由試験	other: Bacterial host-mediated assay
GLP適合	非適合	no
試験を行った年	1976年	1976
細胞株又は検定菌	ネズミチフス菌 S. typhimurium (G48, TA100, TA1950)	S. typhimurium (G48, TA100, TA1950)
代謝活性化(S9)の有無	有	with
試験条件	原文参照	Strains of S. typhimurium sensitive to base-pair substitution were inoculated into the peritoneal cavities of mice, which were subsequently exposed either i.m. or s.c. to ECH. In the same experiment, no increase in revertants was observed in strains (TA1957 and TA1952) sensitive to frameshift mutations. Test concentration : 0, 50, 100 mg/kg bw. Host animals were female ICR mice 10-12 weeks old, weighing ~35 g, in dose groups of 5 mice each. Tester strains were injected intraperitoneally into mice according to the method of Bochkov et al. (1976). ECH (dose dissolved in 0.2 ml DMSO) was then injected intramuscularly or subcutaneously at dose levels of 50 or 100 mg/kg bw. Mice were killed three hours after administration of ECH and their peritoneal fluid was cultivated on Spizizen minimal medium. Results were calculated according to the characteristic C, which is a relative mutagenicity expressed as the ratio between the mutant frequency in an experimental group and the mutant frequency in the control group. C values greater than 2 were considered as being a significant increase.
結果		
細胞毒性		
代謝活性ありの場合	適用しない	Not applicable
代謝活性なしの場合		
変異原性		
代謝活性ありの場合	陽性	positive
代謝活性なしの場合		
注釈		
結論		
遺伝子突然変異	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	原文参照	The method is an older one used prior to the advent of in vitro metabolic activation, but valid for the time conducted. No information about test material purity was available. Study conducted prior to the advent of GLP.
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	<p>•Bochkov, N.P., Sram, R.J., Kuleshov, N.P., and Zhurhov, V.S. (1976). System for the evaluation of the risk from chemical mutagens to man: basic principles and practical recommendations. Muta. Res. 38: 191-201.</p> <p>•Sram R.J., Cerna M., Kucerova M. (1976), "The genetic risk of epichlorohydrin as related to the occupational exposure", Biol. Zbl., 95, 451-62.</p>	<p>•Bochkov, N.P., Sram, R.J., Kuleshov, N.P., and Zhurhov, V.S. (1976). System for the evaluation of the risk from chemical mutagens to man: basic principles and practical recommendations. Muta. Res. 38: 191-201.</p> <p>•Sram R.J., Cerna M., Kucerova M. (1976), "The genetic risk of epichlorohydrin as related to the occupational exposure", Biol. Zbl., 95, 451-62.</p>
備考		

試験物質名		
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	酵母の遺伝子突然変異試験	Yeast gene mutation assay
GLP適合		
試験を行った年		
細胞株又は検定菌		
代謝活性化(S9)の有無	有及び無	with and without
試験条件		
結果		
細胞毒性		
代謝活性ありの場合		
代謝活性なしの場合		
変異原性		
代謝活性ありの場合	陽性	positive
代謝活性なしの場合	陽性	positive
注釈	原文参照	This summary references the results of a number of different studies conducted from 1981 to 1989 (one in 1955), across a wide range of concentrations, all assaying gene mutation in yeast cell lines via generally accepted scientific methods. For individual test conditions, see individual references. The induction of both forward and reverse mutations by epichlorohydrin in strains of Neurospora crassa, Schizosaccharomyces pombe and cerevisiae have been reported. Also reported were inter- and intra-chromosomal recombination, gene conversion, mitotic cross-overs and mitotic aneuploidy in S. cerevisiae as well as reduced survival in repair-deficient strains. The addition of metabolic activation generally results in a reduction of the genotoxic activity.



結論		
遺伝子突然変異	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠		
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	<p>•De Serres F.J., Ashby J. (1981), "Evaluation of Short-Term Tests for Carcinogens", Progress in mutation research, Vol. I, Elsevier, ISBN 0 444 20570 6.</p> <p>•De Serres F.J., Mallng H.V., Brockman H.E., Hung C.Y. (1982), "Mutagenicity of epichlorohydrin and 1,2-dibromomethane in heterokaryon 12 of <i>Neurospora crassa</i>", Environ. Mutagen., 4, 398-99.</p> <p>•Kolmark G., Gilles N.H. (1955), "Comparative studies of monoepoxides as inducers of reverse mutations in <i>Neurospora</i>", Genetics, 40, 890-92.</p> <p>•Migliore L., Rossi A.M., Loprieno N., (1982), "Mutagenic action of structurally related alkyl oxides on <i>Schizosaccharomyces pombe</i> : the influence, in vitro, of mouse-liver metabolizing system", Mutat. Res., 102, 425-37.</p> <p>•Migliore L., Rossi A.M., Loprieno N., Romano M., Salmona M. (1983), "Mutagenic relevance of rat hepatocyte nuclei in the activation and inactivation of xenobiotics : cyclophosphamide and epichlorohydrin activity on the yeasts <i>S. pombe</i> and <i>S. cerevisiae</i>", Mutat. Res., 111, 313-23.</p> <p>•Rossi A.M., Migliore L., Lascialfari D., Sbrana I., Loprieno N., Tortoreto M., Bidoli F., Pantarotto, C. (1984), "Genotoxicity, metabolism and blood kinetics of epichlorohydrin in mice", Mutat. Res., 118, 213-26.</p> <p>•Rossi A.M., Migliore L., Loprieno N., Romano M., Salmona M. (1983), "Evaluation of epichlorohydrin (ECH) genotoxicity. Microsomal epoxide hydrolase-dependent deactivation of ECH mutagenicity in <i>Schizosaccharomyces pombe</i> in vitro", Mutat. Res., 109, 41-52.</p> <p>•Schiestl R.H., Gretz R.D., Mehta R.D., Hastings J. (1989), "Carcinogens induce intrachromosomal recombination in yeast", Carcinogen, 10, 1445-55.</p> <p>•Vashishat R.K., Vasudeva M., Kaka S.N. (1980), "Induction of mitotic crossing over, mitotic gene conversion and reverse mutation by epichlorohydrin in <i>Saccharomyces cerevisiae</i>", Indian J. Exp. Biol., 18, 1337-38.</p>	<p>•De Serres F.J., Ashby J. (1981), "Evaluation of Short-Term Tests for Carcinogens", Progress in mutation research, Vol. I, Elsevier, ISBN 0 444 20570 6.</p> <p>•De Serres F.J., Mallng H.V., Brockman H.E., Hung C.Y. (1982), "Mutagenicity of epichlorohydrin and 1,2-dibromomethane in heterokaryon 12 of <i>Neurospora crassa</i>", Environ. Mutagen., 4, 398-99.</p> <p>•Kolmark G., Gilles N.H. (1955), "Comparative studies of monoepoxides as inducers of reverse mutations in <i>Neurospora</i>", Genetics, 40, 890-92.</p> <p>•Migliore L., Rossi A.M., Loprieno N., (1982), "Mutagenic action of structurally related alkyl oxides on <i>Schizosaccharomyces pombe</i> : the influence, in vitro, of mouse-liver metabolizing system", Mutat. Res., 102, 425-37.</p> <p>•Migliore L., Rossi A.M., Loprieno N., Romano M., Salmona M. (1983), "Mutagenic relevance of rat hepatocyte nuclei in the activation and inactivation of xenobiotics : cyclophosphamide and epichlorohydrin activity on the yeasts <i>S. pombe</i> and <i>S. cerevisiae</i>", Mutat. Res., 111, 313-23.</p> <p>•Rossi A.M., Migliore L., Lascialfari D., Sbrana I., Loprieno N., Tortoreto M., Bidoli F., Pantarotto, C. (1984), "Genotoxicity, metabolism and blood kinetics of epichlorohydrin in mice", Mutat. Res., 118, 213-26.</p> <p>•Rossi A.M., Migliore L., Loprieno N., Romano M., Salmona M. (1983), "Evaluation of epichlorohydrin (ECH) genotoxicity. Microsomal epoxide hydrolase-dependent deactivation of ECH mutagenicity in <i>Schizosaccharomyces pombe</i> in vitro", Mutat. Res., 109, 41-52.</p> <p>•Schiestl R.H., Gretz R.D., Mehta R.D., Hastings J. (1989), "Carcinogens induce intrachromosomal recombination in yeast", Carcinogen, 10, 1445-55.</p> <p>•Vashishat R.K., Vasudeva M., Kaka S.N. (1980), "Induction of mitotic crossing over, mitotic gene conversion and reverse mutation by epichlorohydrin in <i>Saccharomyces cerevisiae</i>", Indian J. Exp. Biol., 18, 1337-38.</p>
備考		

試験物質名	他の物質	other TS
CAS番号		
純度等		
注釈	被験物質はチェコスロバキアで製造と記載されている。	Test substance was noted as having been manufactured in Czechoslovakia.
方法		
方法／ガイドライン	エームス試験	Ames test
	他法	other
GLP適合	非適合	no
試験を行った年	1976年	1976
細胞株又は検定菌	ネズミチフス菌 <i>Salmonella typhimurium</i> TA 100, 1535; G 46	<i>Salmonella typhimurium</i> TA 100, 1535; G 46
代謝活性化(S9)の有無	無	without
試験条件		
結果		
細胞毒性		
代謝活性ありの場合		
代謝活性なしの場合		
変異原性		
代謝活性ありの場合		
代謝活性なしの場合	陽性	positive
注釈	原文参照	<p>In a preliminary test, tester strains G46, TA100, TA1950, TA1951, TA1952, TA1534, TA1537, and TA1538 were subjected to spot testing with 50 microliters of ECH solutions at concentrations of 1, 10, 50, or 100% according to the methods described in Bochkov et al. (1976), in five replicates. Dose response relationships were then tested on G46 and TA100, as they were the only strains demonstrating positive results. The other strains either demonstrated a negative result or an equivocal result at 10% with no dose response at higher concentrations. After 60 min exposures to ECH, tester strain suspensions were cultivated on Spizizen minimal medium at dose volumes of 0.3 ml for each of 6-9 replicates at each concentration:</p> <p>G46:</p> <p>5.40E-1 M 1.08E-1 M 5.40E-2 M 2.70E-2 M 1.08E-2 M 5.40E-3 M 1.08E-3 M 1.08E-4 M</p> <p>TA100:</p> <p>1.08E-1 M 5.40E-2 M 1.08E-2 M 5.40E-3 M 1.08E-3 M</p> <p>Concurrent controls were also run.</p>

結論		
遺伝子突然変異	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	原文参照	The method is an older one used prior to the advent of in vitro metabolic activation, but valid for the time conducted. No information about test material purity was available. Study conducted prior to the advent of GLP.
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	・Bochkov, N.P., Sram, R.J., Kuleshov, N.P., and Zhurhov, V.S. (1976). System for the evaluation of the risk from chemical mutagens to man: basic principles and practical recommendations. Muta. Res. 38: 191-201. ・Sram R.J., Cerna M., Kucerova M. (1976), "The genetic risk of epichlorohydrin as related to the occupational exposure", Biol. Zbl., 95, 451-62.	・Bochkov, N.P., Sram, R.J., Kuleshov, N.P., and Zhurhov, V.S. (1976). System for the evaluation of the risk from chemical mutagens to man: basic principles and practical recommendations. Muta. Res. 38: 191-201. ・Sram R.J., Cerna M., Kucerova M. (1976), "The genetic risk of epichlorohydrin as related to the occupational exposure", Biol. Zbl., 95, 451-62.
備考		

試験物質名		
CAS番号		
純度等		
注釈		
方法		
方法ノガイドライン	哺乳動物細胞の遺伝子突然変異試験	Mammalian cell gene mutation assay
GLP適合	情報無し	no data
試験を行った年		
細胞株又は検定菌		
代謝活性化(S9)の有無	有及び無	with and without
試験条件		
結果		
細胞毒性		
代謝活性ありの場合		
代謝活性なしの場合		
変異原性		
代謝活性ありの場合	陽性	positive
代謝活性なしの場合	陽性	positive
注釈	原文参照	This summary references the results of a number of different studies conducted from 1981 to 1985, across a wide range of concentrations, all assaying gene mutation in mammalian cell lines via generally accepted scientific methods. For individual test conditions, see individual references. In various mammalian cell lines including mouse lymphoma and human embryonic, ECH in the liquid phase induced an increase in the frequency of forward mutations (e.g. at the HGPRT and TK loci).
結論		
遺伝子突然変異	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠		
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	・Amacher D.E., Dunn E.A. (1985), "Mutagenesis at the ouabain-resistance locus of 3.7 ZO L5178Y cells by chromosomal mutagens", Environ. Mutagen., 7, 523-33. ・De Serres F.J., Ashby J. (1981), "Evaluation of Short-Term Tests for Carcinogens", Progress in mutation research, Vol. I, Elsevier, ISBN 0 444 20570 6. ・Knapp A.G.A., Voogd C.E., Kramers P.G.N. (1982), "Comparison of the mutagenic potency of 2-chloroethanol, 2-bromoethanol, 1,2-epoxybutane, epichlorohydrine and glycidaldehyde in Klebsiella pneumoniae, Drosophila melanogaster and L5178Y mouse lymphoma cells", Mutat. Res., 101, 199-208. ・Perocco P., Rocchi P., Ferreri A.M., Capucci A. (1983), "Toxic DNA-damaging and mutagenic activity of epichlorohydrin on human cells cultured in vitro", Tumori, 69, 191-94.	・Amacher D.E., Dunn E.A. (1985), "Mutagenesis at the ouabain-resistance locus of 3.7 ZO L5178Y cells by chromosomal mutagens", Environ. Mutagen., 7, 523-33. ・De Serres F.J., Ashby J. (1981), "Evaluation of Short-Term Tests for Carcinogens", Progress in mutation research, Vol. I, Elsevier, ISBN 0 444 20570 6. ・Knapp A.G.A., Voogd C.E., Kramers P.G.N. (1982), "Comparison of the mutagenic potency of 2-chloroethanol, 2-bromoethanol, 1,2-epoxybutane, epichlorohydrine and glycidaldehyde in Klebsiella pneumoniae, Drosophila melanogaster and L5178Y mouse lymphoma cells", Mutat. Res., 101, 199-208. ・Perocco P., Rocchi P., Ferreri A.M., Capucci A. (1983), "Toxic DNA-damaging and mutagenic activity of epichlorohydrin on human cells cultured in vitro", Tumori, 69, 191-94.
備考		

#### B. 染色体異常

#### CHROMOSOMAL ABBERATION

試験物質名	情報無し	no data
CAS番号		
純度等		
注釈		
方法		
方法ノガイドライン	姉妹染色分体交換試験	Sister chromatid exchange assay
GLP適合	非適合	no
試験を行った年	1980年	1980
細胞株	ヒトリンパ球	human lymphocytes
代謝活性化(S9)の有無	有及び無	with and without

試験条件	原文参照	<p>Microcultures were set up containing 0.3 ml whole heparinized blood obtained from 1 male and 2 female healthy adult donors, 0.4 ml Eagles MEM (Wellcome) containing 5 BrdU (Aldrich) at a final concentration of 7.2 micromolar, 0.5 ml bovine serum (Difco) and 0.1 ml PHA (Wellcome). Culturing took place in the dark at 37 C for 73 hours with Colcemid (2.5 microg/culture) present for the final 3 hours.</p> <p>Slides were Harlequin-stained by an FPG technique. The yield of SCE expressed as SCE/cell was obtained from scoring 20-30 clear complete metaphases by direct observation of slides prepared from at least 2 replicate cultures.</p> <p>Rat-liver microsomal extract was prepared according to the method of Ames et al. (1975). S9 mix was freshly prepared for each experiment. Activity was assessed using cyclophosphamide.</p> <p>ECH was dissolved in equal volumes of DMSO and 0.9% normal saline immediately prior to use. A 1% dilution of ECH in DMSO/saline in either Eagles MEM alone or Eagles MEM with bovine serum was then prepared.</p> <p>Lymphocytes from 1 donor were then exposed to ECH as follows:</p> <ol style="list-style-type: none"> <li>1. 73 hours without activation. Final culture concentrations ranged 1E-3 to 1E-5 M.</li> <li>2. Final 25 hours of incubation without activation. Centrifuged and pelleted cultures were resuspended in Eagles MEM with ECH and bovine serum. No further PHA was added.</li> <li>3. 2 hour period from 48-50 hours of incubation both with and without activation for each dose level.</li> </ol> <p>Appropriate control cultures were set up for each exposure scenario.</p>
結果		
細胞毒性		
代謝活性ありの場合	73 hrs: 2E-4 M; 25 hrs: 4E-4	2E-4 M for 73 hrs; 4E-4 for 25 hrs
代謝活性なしの場合	73 hrs: 2E-4 M; 25 hrs: 4E-4	2E-4 M for 73 hrs; 4E-4 for 25 hrs
姉妹染色分体交換		
代謝活性ありの場合	陽性	positive
代謝活性なしの場合	陽性	positive
注釈	原文参照	<p>Test concentration : 4E-5 to 1E-3 M</p> <p>Human lymphocytes were cultivated for 73 h in the presence of 5-bromo-2-deoxyuridine and exposed to ECH with/without S-9. At an ECH concentration of 0.0004 M, without activation a 3-fold increase in the SCE rate was observed compared to the control, while with activation with S-9 the same increase was produced by an ECH concentration of 0.001 M.</p>
結論		
姉妹染色分体交換	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠		
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	White D. (1980), "In vitro induction of SCE in human lymphocytes by epichlorohydrin with and without metabolic activation", Mutat. Res., 78, 171-76.	White D. (1980), "In vitro induction of SCE in human lymphocytes by epichlorohydrin with and without metabolic activation", Mutat. Res., 78, 171-76.
備考		

試験物質名	情報無し	no data
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	姉妹染色分体交換試験	Sister chromatid exchange assay
GLP適合	情報無し	no data
試験を行った年	2000年	2000
細胞株	ヒトリンパ球	human lymphocytes
代謝活性化(S9)の有無	無	without

試験条件	原文参照	Test concentration: Four concentrations (molar) = $10 \times 10^{-10}$ , $10 \times 10^{-8}$ , $10 \times 10^{-6}$ , $10 \times 10^{-4}$ of epichlorohydrin in dimethylsulfoxide. Four concentrations ( $1 \times 10^{-10}$ , $1 \times 10^{-8}$ , $1 \times 10^{-6}$ , or $1 \times 10^{-4}$ M) of ECH in DMSO were prepared one day before use. All test cultures received a total of 25 microliters of solution to obtain the desired final concentration. Cultures were set up a few hours after blood donation from four healthy, non-smoking, 31–33 year old male donors (all with similar lifestyles). For smokers, blood from three healthy male smokers with the same characteristics as the other four subjects was used. Five duplicate cultures per subject were established for the assay. 350 microliters of whole heparinized blood from each subject were incubated in 5 ml of RPMI 1640 with 10% fetal calf serum (FCS), 5 microg/l of phytohemagglutinin (PHA), 100 units/ml of penicillin, 100 microg/l of streptomycin, and 2mM of L-glutamine. 24 hours later, a total of 25 microl of ECH was added to treated cultures, while other cultures were set up as controls (nothing added) or solvent controls (25 microl of DMSO added). 5-BrdU was added to the culture as well. All cultures were set up in duplicate and incubated at 37 C. Treatment lasted 72 hours. Cell division was stopped by adding 0.2 microg/ml Colcemid during the last 2 hours. Slides were then made and stained with the FPG staining technique. At least 50 sec division metaphases were scored for SCE per culture on coded slides by a single observer and at least 200 mitoses were calculated for the Proliferative Rate Index for each treatment group culture from each donor. The PRI = $(1 \times M1\% + 2 \times M2\% + 3 \times M3\%) / 100$ , where M1%, M2%, and M3% represent the ratio of the first, second, and third metaphases, respectively, expressed as a percentage of the total mitoses.
結果		
細胞毒性		
代謝活性ありの場合		
代謝活性なしの場合	なし	no evidence of cytotoxicity at the four concentrations tested.
姉妹染色分体交換		
代謝活性ありの場合		
代謝活性なしの場合	陽性	positive
注釈	原文参照	Test concentration : $4 \times 10^{-5}$ to $1 \times 10^{-3}$ M Human lymphocytes were cultivated for 73 h in the presence of 5-bromo-2-deoxyuridine and exposed to ECH with/without S-9. At an ECH concentration of 0.0004 M, without activation a 3-fold increase in the SCE rate was observed compared to the control, while with activation with S-9 the same increase was produced by an ECH concentration of 0.001 M.
結論		
姉妹染色分体交換	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	被験物質の純度は示されていないが、一般に受容される科学的方法に基づく試験である。	No purity of test substance given, but study otherwise follows generally accepted scientific methods.
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	Bukvic, N., Bavaro, P., Soleo, L., Fanelli, M., Stipani, I., Elia, G., Susca, F. and Guanti, G. (2000) Increment of sister chromatid exchange frequencies (SCE) due to epichlorohydrin (ECH) in vitro treatment in human lymphocytes. Teratog. Mutag. Carcinog. 20: 313–320.	Bukvic, N., Bavaro, P., Soleo, L., Fanelli, M., Stipani, I., Elia, G., Susca, F. and Guanti, G. (2000) Increment of sister chromatid exchange frequencies (SCE) due to epichlorohydrin (ECH) in vitro treatment in human lymphocytes. Teratog. Mutag. Carcinog. 20: 313–320.
備考		

試験物質名	情報無し	no data
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	染色体異常試験	Cytogenetic assay
GLP適合	非適合	no
試験を行った年	1981年	1981
細胞株	チャイニーズハムスター卵巣細胞	Chinese hamster ovary cells
代謝活性化(S9)の有無	有及び無	with and without
試験条件	原文参照	Test concentration : 0.017–0.1 microg/ml. CHO cells were grown in the dark for 12 hours at 37 C in F10 medium with 10 microM BrdU. The cells were then washed with phosphate buffered saline and treated for 1 hour with ECH at the specified concentrations in the presence or absence of S9 fraction. Cells were then treated with colcemid, trypsinized, and prepared via air-drying. Slides were stained with Giemsa stain for assessment of chromosomal aberrations, while for sister chromatid exchange assessment slides were stained with Hoechst 33258 and exposed to visible light prior to treatment with Giemsa stain. Twenty-five to fifty cells were scored for SCE. Fifty to one hundred cells were scored for aberrations for each point. Doubling of the frequencies of SCEs was considered a positive result. A concentration-dependent increase in aberrations was considered a positive result. Concurrent controls (negative and positive) were run for comparison.
結果		
細胞毒性		
代謝活性ありの場合	情報無し	No data.
代謝活性なしの場合	情報無し	No data.
染色体異常		
代謝活性ありの場合	陽性	positive
代謝活性なしの場合	陽性	positive

注釈	ECHは代謝活性化の有無に関わらずSCE及び染色体異常で陽性であった。	ECH was positive both with and without activation, for both SCEs and chromosomal aberrations.
結論		
染色体異常	陽性	positive
注釈	姉妹染色分体交換及び染色体異常試験	Sister chromatid exchange and chromosome aberration test.
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠		
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	Natarajan A.T., van Kesteren-van Leeuwen A.C. (1981), "Mutagenic activity of 20 coded compounds in chromosome aberrations/sister chromatid exchanges assay using chinese hamster ovary (CHO) cells" in de Serres F.J., Ashby J., Progress in mutation research, Vol. 1 : Evaluation of short-term tests for carcinogens, Elsevier/North-Holland, New York, Amsterdam, Oxford, 551-59.	Natarajan A.T., van Kesteren-van Leeuwen A.C. (1981), "Mutagenic activity of 20 coded compounds in chromosome aberrations/sister chromatid exchanges assay using chinese hamster ovary (CHO) cells" in de Serres F.J., Ashby J., Progress in mutation research, Vol. 1 : Evaluation of short-term tests for carcinogens, Elsevier/North-Holland, New York, Amsterdam, Oxford, 551-59.
備考		

試験物質名	情報無し	no data
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	染色体異常試験	Cytogenetic assay
GLP適合	非適合	no
試験を行った年	1981年	1981
細胞株	ヒトリンパ球	human lymphocytes
代謝活性化(S9)の有無	有及び無	with and without
試験条件	原文参照	Test concentration : 0.017-0.1 microI/ml. CHO cells were grown in the dark for 12 hours at 37 C in F10 medium with 10 microM BrdU. The cells were then washed with phosphate buffered saline and treated for 1 hour with ECH at the specified concentrations in the presence or absence of S9 fraction. Cells were then treated with colcemid, trypsinized, and prepared via air-drying. Slides were stained with Giemsa stain for assessment of chromosomal aberrations, while for sister chromatid exchange assessment slides were stained with Hoechst 33258 and exposed to visible light prior to treatment with Giemsa stain. Twenty-five to fifty cells were scored for SCE. Fifty to one hundred cells were scored for aberrations for each point. Doubling of the frequencies of SCEs was considered a positive result. A concentration-dependent increase in aberrations was considered a positive result. Concurrent controls (negative and positive) were run for comparison.
結果		
細胞毒性		
代謝活性ありの場合	情報無し	No data.
代謝活性なしの場合	情報無し	No data.
染色体異常		
代謝活性ありの場合	陽性	positive
代謝活性なしの場合	陽性	positive
注釈	ECHは代謝活性化の有無に関わらずSCE及び染色体異常で陽性であった。	ECH was positive both with and without activation, for both SCEs and chromosomal aberrations.
結論		
染色体異常	陽性	positive
注釈	原文参照	This summary references the results of three different studies, two conducted in 1976 and one in 1981, across a range of concentrations. For individual test conditions, see individual references. Increases in chromosome breaks and exchanges were observed in PHA-stimulated human peripheral lymphocytes. No effect when ECH was used before stimulation.
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠		
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	<ul style="list-style-type: none"> <li>•Kucerova M., Polivkova Z., Sram R., Matousek V. (1976), "Mutagenic effect of epichlorohydrin. I. Testing on human lymphocytes in vitro in comparison with TEPA", Mutat. Res., 34, 271-78.</li> <li>•Norppa H et al (1981) Mutat. Res. 91, 243-250</li> <li>•Sram R.J., Cerna M., Kucerova M. (1976), "The genetic risk of epichlorohydrin as related to the occupational exposure", Biol. Zbl., 95, 451-62.</li> </ul>	<ul style="list-style-type: none"> <li>•Kucerova M., Polivkova Z., Sram R., Matousek V. (1976), "Mutagenic effect of epichlorohydrin. I. Testing on human lymphocytes in vitro in comparison with TEPA", Mutat. Res., 34, 271-78.</li> <li>•Norppa H et al (1981) Mutat. Res. 91, 243-250</li> <li>•Sram R.J., Cerna M., Kucerova M. (1976), "The genetic risk of epichlorohydrin as related to the occupational exposure", Biol. Zbl., 95, 451-62.</li> </ul>
備考		

#### 5-7 in vivo遺伝毒性

#### GENETIC TOXICITY IN VIVO

試験物質名	1-クロロ-2,3-エポキシプロパン	1-chloro-2,3-epoxypropane
CAS番号	106-89-8	106-89-8
純度等		
注釈		
方法		
方法／ガイドライン	他法	other
試験のタイプ	染色体異常試験	Cytogenetic assay
GLP適合	情報無し	no data
試験を行った年	1983年	1983
試験系(種／系統)	マウス	mouse
	CD-1	CD-1
性別(雄:M、雌:F)	雄	male

投与量	用量: 50, 200 mg ECH/kg b.w.	Doses : 50, 200 mg ECH/kg b.w.
投与経路	他:水で経口投与	other: oral administration in water
試験期間	単回投与	single treatment
試験条件	原文参照	Mice were given single oral doses of either 50 or 200 mg/kg bw. At intervals of 6, 24, 48 h following treatment, mice were killed by decapitation and samples of bone marrow were taken from the animals' femur for chromosome aberration examination. One hour prior to death, animals were injected intraperitoneally with colcemid at 3.2 mg/kg bw. 100 cells per mouse were analyzed for gaps, breaks, and exchanges. Abnormal cells were considered, both including and excluding only with gaps. Cyclophosphamide at 10, 20, or 40 mg/kg bw given intraperitoneally was evaluated as a positive control.
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陰性	negative
NOEL (NOEL)		
LOEL (LOEL)		
統計的結果		
注釈	設定した2用量のいずれも染色体異常の増加は認められなかった。また、毒性影響も報告されていない。	For neither of the two dose levels was an increased chromosome aberration rate found. No toxic effects are reported.
結論		
<i>in vivo</i> 遺伝毒性	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠		
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	Rossi A.M., Migliore L., Lascialfari D., Sbrana I., Loprieno N., Tortoreto M., Bidoli F., Pantarotto, C. (1984), "Genotoxicity, metabolism and blood kinetics of epichlorohydrin in mice", Mutat. Res., 118, 213-26.	Rossi A.M., Migliore L., Lascialfari D., Sbrana I., Loprieno N., Tortoreto M., Bidoli F., Pantarotto, C. (1984), "Genotoxicity, metabolism and blood kinetics of epichlorohydrin in mice", Mutat. Res., 118, 213-26.
備考		

試験物質名	1-クロロ-2,3-エポキシプロパン	1-chloro-2,3-epoxypropane
CAS番号	106-89-8	106-89-8
純度等		
注釈		
方法		
方法／ガイドライン	他法	other
試験のタイプ	染色体異常試験	Cytogenetic assay
GLP適合	非適合	no
試験を行った年	1979年	1979
試験系(種／系統)	ラット Fischer 344	rat Fischer 344
性別(雄:M、雌:F)	雌雄	male/female
投与量	用量: 0, 5, 25, 50 ppm 6 時間/日, 週5日	Doses : 0, 5, 25, 50 ppm 6 h/d, 5 d a week.
投与経路	吸入	inhalation
試験期間	4週間	4 weeks
試験条件	原文参照	The authors estimated that the amount of absorbable ECH at the 3 administered concentrations was 0.6, 12, 24mg/animal/day. Groups of 10 male and female Fischer 344 rats were exposed via inhalation to 0, 5, 25, or 50 ppm ECH for 6 hours/day, 5 days/week, for 4 weeks. Rats were individually housed in wire mesh cages with exposure chambers. Food was available ad libitum except during exposure periods. Water was available ad libitum. On the day following the last exposure, rats were injected intraperitoneally with colchicine 4 hours prior to sacrifice. Bone marrow samples were prepared in a balanced salt solution and fixed using a methanol/acetic acid solution. Slides were prepared by dropping 5 drops cell suspension onto a slide, then passing the slide through a flame and drying on a warming plate. The slides were then stained with Giemsa stain, dehydrated, and coverslipped with xylol. Slides were coded, randomized, and evaluated by accredited medical technologists according the methods of the WHO. The mitotic phase was determined as the percentage of cells in metaphase, based on observation of 500 cells. Mitotic index was analyzed using a one-way ANOVA.
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陽性	positive
NOEL (NOEL)		
LOEL (LOEL)		
統計的結果		
注釈	原文参照	Although not all of the administered ECH was absorbed and a part of that which was absorbed was metabolized before reaching the bone marrow, no significant increase in the number of chromosome aberrations was observed.
結論		
<i>in vivo</i> 遺伝毒性	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions

信頼性の判断根拠		
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	Dabney B.J., Johnston R.V., Quast J.F., Park C.N. (1979), "Epichlorohydrin – subchronic studies. III. Cytogenetic evaluation of bone marrow cells from rats exposed by inhalation to epichlorohydrin for four weeks", Final report of Texas Bio-Medical Res. Lab., Dow Chem. USA, Freeport, Texas 77541 and Toxicol. Res. Lab., Dow Chem. USA, Midland, Michigan 48640.	Dabney B.J., Johnston R.V., Quast J.F., Park C.N. (1979), "Epichlorohydrin – subchronic studies. III. Cytogenetic evaluation of bone marrow cells from rats exposed by inhalation to epichlorohydrin for four weeks", Final report of Texas Bio-Medical Res. Lab., Dow Chem. USA, Freeport, Texas 77541 and Toxicol. Res. Lab., Dow Chem. USA, Midland, Michigan 48640.
備考		

試験物質名	1-クロロ-2,3-エポキシプロパン	1-chloro-2,3-epoxypropane
CAS番号	106-89-8	106-89-8
純度等		
注釈		
方法		
方法／ガイドライン	他法	other
試験のタイプ	染色体異常試験	Cytogenetic assay
GLP適合	非適合	no
試験を行った年	1981年	1981
試験系(種／系統)	ラット	rat
性別(雄:M、雌:F)	情報無し	no data
投与量	用量:1.3 ~ 33 ppm.	Doses: 1.3 ~ 33 ppm.
投与経路	吸入	inhalation
試験期間	120時間	120 hours
試験条件		
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陰性	negative
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		
注釈	原文参照	Analysis of bone marrow and peripheral lymphocytes indicates that, although increases occurred in lymphocytes, no statistically significant increases in the frequency of chromosome aberrations occurred.
結論		
<i>in vivo</i> 遺伝毒性	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠	本試験は要約のみの記載であり不十分な試験内容が利用可能であるが、この試験で使用された標準法に従って行われた他の試験において科学的に制限付きで有効と評価している。	Although this study is summarized only in abstract and insufficient study details are available, other studies conducted by this investigator following his standard methodology have proved scientifically valid with restrictions.
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	Sram R.J. et al (1981), Mutat. Res., 85, 287-88 (abstract).	Sram R.J. et al (1981), Mutat. Res., 85, 287-88 (abstract).
備考		

試験物質名	他の物質	other TS
CAS番号		
純度等		
注釈	ECHはチェコスロバキアで製造されたと報告されている。	ECH was reported to have been manufactured in Czechoslovakia.
方法		
方法／ガイドライン	他法	other
試験のタイプ	染色体異常試験	Cytogenetic assay
GLP適合	非適合	no
試験を行った年	1976年	1976
試験系(種／系統)	マウス	mouse
性別(雄:M、雌:F)	雌	female
投与量	1 x 100 mg/kg or 5 x 20 mg/kg	1 x 100 mg/kg or 5 x 20 mg/kg
投与経路	強制経口	gavage
試験期間	単回ないし数回の暴露	single or multiple exposure



試験条件	原文参照	Female ICR mice 8–10 weeks old weighing ~ 32–35 g were treated as follows with ECH: Single dose: 1, 3, 5, 10, 20, or 50 mg/kg bw administered intraperitoneally; bone marrow examined 24 hours post-treatment. 5, 20, 40, or 100 mg/kg bw administered orally; bone marrow examined 24 hours post-treatment. Single dose: 50 mg/kg bw administered intraperitoneally; bone marrow examined 6 and 48 hours post-treatment. 100 mg/kg bw administered orally; bone marrow examined 6 and 48 hours post-treatment. Repeated dose (24 hr interval between doses): 10 doses of 5 mg/kg bw administered intraperitoneally; bone marrow examined 6 hours post-treatment. 20 doses of 5 mg/kg bw administered orally; bone marrow examined 6 hours post-treatment. Repeated dose (5 doses per 7 days): 5 doses of 5 mg/kg bw administered intraperitoneally; bone marrow examined 6 hours post-treatment. 10 doses of 5 mg/kg bw administered intraperitoneally; bone marrow examined 6 hours post-treatment. 20 doses of 5 mg/kg bw administered intraperitoneally; bone marrow examined 6 hours post-treatment. 20 doses of 5 mg/kg bw administered orally; bone marrow examined 6 hours post-treatment. Bone marrow was prepared after a modification of the method of Tjio and Wang (Goetz et al., 1975). 250 metaphases were analyzed in each group. Gaps, breaks and exchanges were evaluated. Cells bearing some of these changes were considered abnormal. Cells with more than 10 aberrations were counted separately.
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陽性	positive
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		
注釈	原文参照	Dose-dependant increase in frequency of chromosome breaks as compared to DMSO-treated controls was observed in treated mice.
結論		
<i>in vivo</i> 遺伝毒性	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠		
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	Sram R.J., Cerna M., Kucerova M. (1976), "The genetic risk of epichlorohydrin as related to the occupational exposure", Biol. Zbl., 95, 451-62.	Sram R.J., Cerna M., Kucerova M. (1976), "The genetic risk of epichlorohydrin as related to the occupational exposure", Biol. Zbl., 95, 451-62.
備考		

試験物質名	他の物質	other TS
CAS番号		
純度等		
注釈	ECHはチェコスロバキアで製造されたと報告されている。	ECH was reported to have been manufactured in Czechoslovakia.
方法		
方法／ガイドライン	他法	other
試験のタイプ	染色体異常試験	Cytogenetic assay
GLP適合	非適合	no
試験を行った年	1976年	1976
試験系(種／系統)	マウス	mouse
	ICR	ICR
性別(雄:M、雌:F)	雌	female
投与量	1 x 100 mg/kg or 5 x 20 mg/kg	1 x 100 mg/kg or 5 x 20 mg/kg
投与経路	腹腔内	i.p.
試験期間	単回ないし数回の暴露	single or multiple exposure
試験条件	原文参照	Bone marrow was examined at 6, 24, 48 hour post treatment. Note that this is the same study as the previous entry. I.P . dosing regimen details are included in that entry.
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陽性	positive
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		
注釈	原文参照	Dose-dependant increase in frequency of chromosome breaks as compared to DMSO-treated controls. Effects more pronounced than with oral administration.
結論		
<i>in vivo</i> 遺伝毒性	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠		
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006



引用文献(元文献)	Sram R.J., Cerna M., Kuceroval M. (1976), "The genetic risk of epichlorohydrin as related to the occupational exposure", Biol. Zbl., 95, 451-62.	Sram R.J., Cerna M., Kuceroval M. (1976), "The genetic risk of epichlorohydrin as related to the occupational exposure", Biol. Zbl., 95, 451-62.
備考		

試験物質名	1-クロロ-2,3-エポキシプロパン	1-chloro-2,3-epoxypropane
CAS番号	106-89-8	106-89-8
純度等		
注釈		
方法		
方法／ガイドライン	他法	other
試験のタイプ	優性致死試験	Dominant lethal assay
GLP適合	非適合	no
試験を行った年	1972年	1972
試験系(種／系統)	マウス	mouse
性別(雄:M、雌:F)	雌雄	male/female
投与量	150 mg ECH/kg b.w.	150 mg ECH/kg b.w.
投与経路	腹腔内	i.p.
試験期間	単回投与	single treatment
試験条件	原文参照	Male ICR mice 8-10 weeks of age were treated with single intraperitoneal injections of 150 mg ECH/kg bw. Males were then caged with 3 virgin female ICR mice 8-10 weeks of age. Females were replaced weekly for 8 consecutive weeks, and were sacrificed 13 days after midweek of their caging and presumptive mating. At necropsy, females were scored for pregnancy and for numbers of total implants, as comprised by live implants, early fetal deaths and late fetal deaths. Reductions in number of implants were determined by comparison with concurrent controls.
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陰性	negative
NOEL (NOEL)		
LOEL (LOEL)		
統計的結果		
注釈	原文参照	During the 8-week mating period the male animals showed no effects from the treatment.
結論		
<i>in vivo</i> 遺伝毒性	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠		
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	Epstein S.S., Arnold E., Andrea J., Bass W., Bishop Y. (1972), "Detection of chemical mutagens by dominant lethal assay in the mouse", Toxicol. Appl. Pharmacol., 23, 288-325.	Epstein S.S., Arnold E., Andrea J., Bass W., Bishop Y. (1972), "Detection of chemical mutagens by dominant lethal assay in the mouse", Toxicol. Appl. Pharmacol., 23, 288-325.
備考		

試験物質名	他の物質	other TS
CAS番号		
純度等		
注釈	ECHはチェコスロバキアで製造されたと示されている。	Article indicates the ECH was manufactured in Czechoslovakia.
方法		
方法／ガイドライン	他法	other
試験のタイプ	優性致死試験	Dominant lethal assay
GLP適合	非適合	no
試験を行った年	1976年	1976
試験系(種／系統)	マウス	mouse
性別(雄:M、雌:F)	雌雄	male/female
投与量	5, 10, 20 mg ECH/kg b.w.	5, 10, 20 mg ECH/kg b.w.
投与経路	腹腔内	i.p.
試験期間	単回投与	single treatment
試験条件	原文参照	Male ICR mice ~10 weeks old weighing 34-38 g were given ECH intraperitoneally or orally in a single dose or 5 repeated doses over 5 days. Each dose was dissolved in 0.17-0.19 ml DMSO. A concurrent control group received 0.2 ml DMSO. Each male was mated weekly with 2 virgin ICR female mice for either 3 or 8 subsequent weeks. Dose groups were as follows: 1. Single dose: intraperitoneal: 5, 10, or 20 mg/kg bw oral: 20 or 40 mg/kg bw 2. Repeated dose: intraperitoneal: 1 or 4 mg/kg bw, 5 doses; 1 or 5 mg/kg, 5 doses oral: 4 or 16 mg/kg bw, 5 doses; 4 or 20 mg/kg bw, 5 doses
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陰性	negative
NOEL (NOEL)		

LOAEL (LOEL)		
統計的結果		
注釈	原文参照	No induction of dominant lethal mutations was observed. Some instances of reduced fertility were observed, but no dose response relationship could be established.
結論		
<i>in vivo</i> 遺伝毒性	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠		
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	Sram R.J., Cerna M., Kucerovala M. (1976), "The genetic risk of epichlorohydrin as related to the occupational exposure", Biol. Zbl., 95, 451-62.	Sram R.J., Cerna M., Kucerovala M. (1976), "The genetic risk of epichlorohydrin as related to the occupational exposure", Biol. Zbl., 95, 451-62.
備考		

試験物質名	他の物質	other TS
CAS番号		
純度等		
注釈	ECHはチェコスロバキアで製造されたと示されている。	Article indicates the ECH was manufactured in Czechoslovakia.
方法		
方法／ガイドライン	他法	other
試験のタイプ	優性致死試験	Dominant lethal assay
GLP適合	非適合	no
試験を行った年	1976年	1976
試験系(種／系統)	マウス	mouse
	ICR	ICR
性別(雄:M、雌:F)	雌雄	male/female
投与量	20, 40 mg ECH/kg b.w.	20, 40 mg ECH/kg b.w.
投与経路	経口(特定されていない)	oral unspecified
試験期間	単回投与	single treatment
試験条件	原文参照	Note that this is the same study referenced in the previous entry – originally, the oral dose regimen was summarized separately from the intraperitoneal dose regimen. See the previous summary for details of test conditions and results.
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陰性	negative
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		
注釈	優性致死の誘発は観察されなかった。	No induction of dominant lethal mutations were observed.
結論		
<i>in vivo</i> 遺伝毒性	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠		
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	Sram R.J., Cerna M., Kucerovala M. (1976), "The genetic risk of epichlorohydrin as related to the occupational exposure", Biol. Zbl., 95, 451-62.	Sram R.J., Cerna M., Kucerovala M. (1976), "The genetic risk of epichlorohydrin as related to the occupational exposure", Biol. Zbl., 95, 451-62.
備考		

試験物質名	情報無し	no data
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン	他法	other
試験のタイプ	小核試験	Micronucleus assay
GLP適合	情報無し	no data
試験を行った年	1986年	1986
試験系(種／系統)	マウス	mouse
	Swiss Webster	Swiss Webster
性別(雄:M、雌:F)	雄	male
投与量	12 doses of 10 mg ECH/kg b.w.	12 doses of 10 mg ECH/kg b.w.
投与経路	他:経口、コーン油でのECH	other: oral, ECH in corn oil
試験期間	16 days, 19 days post-treatment	16 days, 19 days post-treatment
試験条件	原文参照	During the 19-day post-treatment observation period, from the 8th day following treatment the number of micronuclei observed in normochromatic erythrocytes of the animals' peripheral blood increased continually.
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陽性	positive
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		
注釈		
結論		

<i>in vivo</i> 遺伝毒性	陽性	positive
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠		
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	Wang Y.F., Hine C.H. (1986), "Evaluation of epichlorhydrin on mice by micronucleus test", Chin. Med. J. Engl., 99, 461-64.	Wang Y.F., Hine C.H. (1986), "Evaluation of epichlorhydrin on mice by micronucleus test", Chin. Med. J. Engl., 99, 461-64.
備考	情報源: Epichlorohydrin Task Force, The Society of the Plastics Industry, Inc., Washington, D.C.	Source: Epichlorohydrin Task Force, The Society of the Plastics Industry, Inc., Washington, D.C.

試験物質名	1-クロロ-2,3-エポキシプロパン	1-chloro-2,3-epoxypropane
CAS番号	106-89-8	106-89-8
純度等		
注釈		
方法		
方法／ガイドライン	他法	other
試験のタイプ	他: 精子頭部形態	other: sperm head morphology
GLP適合	情報無し	no data
試験を行った年	1980年	1980
試験系(種／系統)	マウス	mouse
性別(雄:M、雌:F)	他: CBA x BALB/c	other: CBA x BALB/c
投与量	雄	male
投与経路	0.2 mg/kg以下の用量	up to 0.2 mg/kg
投与経路	腹腔内	i.p.
試験期間	5 日間	5 days
試験条件	原文参照	During the 19-day post-treatment observation period, from the 8th day following treatment the number of micronuclei observed in normochromatic erythrocytes of the animals' peripheral blood increased continually.
統計学的処理		
結果		
性別及び投与量別の結果		
遺伝毒性効果	陰性	negative
NOAEL (NOEL)		
LOAEL (LOEL)		
統計的結果		
注釈		
結論		
<i>in vivo</i> 遺伝毒性	陰性	negative
注釈		
信頼性	(2)制限付きで有効	(2) valid with restrictions
信頼性の判断根拠		
出典	OECD SIDS Dossier, 2006	OECD SIDS Dossier, 2006
引用文献(元文献)	Topham J.C. (1980), Mutat. Res., 74, 379-87.	Topham J.C. (1980), Mutat. Res., 74, 379-87.
備考		

5-8 発がん性  
CARCINOGENICITY

試験物質名	他のTS	other TS
CAS番号		
純度等	純度: 99.5%	Purity: 99.5%
注釈		
方法		
方法／ガイドライン	その他	other
試験のタイプ		
GLP適合	データなし	no data
試験を行った年	1985	1985
試験系(種／系統)	ラット	rat
性別(雄:M、雌:F)	Wistar	Wistar
投与量	雌雄	male/female
投与量	0、2 及び 10 mg/kg.日	0, 2 and 10 mg/kg.d
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	強制経口	gavage
処理頻度	5日/週	5 days/week
対照群と処理	あり、溶媒対照	yes, concurrent vehicle
試験条件	暴露期間: 2年間 暴露後の観察期間: 該当せず	Exposure period : 2 years Post exposure period : Not applicable

試験条件	※英文参照	<p>TEST ORGANISMS: Male and female Wistar rats: age at study initiation unknown, initial body weight ~60 g (male) and ~50 g (female), 50 per sex per dose group</p> <p>ADMINISTRATION/EXPOSURE: Groups of animals were dosed via gavage at 0 (distilled water), 2, or 10 mg/kg/day five days per week, for lifetime. Experiment was terminated after 2 years.</p> <p>ECH in water solutions was given at a rate of 0.5 ml/100 g body weight.</p> <p>CLINICAL OBSERVATIONS AND FREQUENCY: Animals were observed weekly for the first year and daily thereafter for health, behavior, and mortality. Body weights were collected weekly during the first 12 weeks and every 4 weeks thereafter.</p>
試験条件	※英文参照	<p>Feed/water consumption were not monitored during the study. Ophthalmoscopic examinations were not performed during the study.</p> <p>Hematology was conducted on 10 animals per sex per dose group. The following parameters were evaluated: hemoglobin concentration, hematocrit value, erythrocyte and total and differential leukocyte counts, mean corpuscular volume, mean corpuscular hemoglobin, and mean corpuscular hemoglobin concentration (calculated).</p> <p>Clinical chemistry and urinalysis evaluations were not performed.</p>
試験条件	※英文参照	<p>ORGANS EXAMINED AT NECROPSY: A complete necropsy examination was conducted on each animal, including: brain, heart, lungs (inflated with fixative), liver, spleen, kidneys, pituitary, thyroid, thymus, pancreas, adrenals, ovaries, testes, uterus, prostate, mesenteric lymph nodes, submandibular salivary glands, esophagus, stomach, small and large intestine, urinary bladder (inflated with fixative), nasal cavity with turbinates. In addition, tumors and lesions suspected of being tumors were collected and examined. Histopathologic examination was conducted on all tissues from all animals.</p>
統計学的処理	※英文参照	<p>STATISTICAL METHODS: Except for pathology, experimental data were analyzed by the Student's t-test. Pathology data were analyzed by the prevalence method described by Peto et al.</p>
<b>結果</b>		
体重、体重増加量	雄ラットは100週後には用量に相関した有意な体重の減少を示した。	Male rats showed a significant dose-related reduction in body weight after 100 weeks. A tendency for reduced body weight gain was present in females.
摂餌量、飲水量	報告なし。	None reported.
臨床所見(重篤度、所見の発現時期と持続時間)	報告なし。	None reported.
眼科学的所見(発生率、重篤度)	報告なし。	None reported.
血液学的所見(発生率、重篤度)	赤血球パラメータにも白血球百分比にも差はなかった。	There were no differences either in red blood cell parameters or differential leukocyte counts.
血液生化学的所見(発生率、重篤度)	報告なし。	None reported.
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間	試験の最初の4ヶ月の間に胃石虫による腸閉塞のために途中死亡例が生じた。この状態は飼料の変更により軽減した。1年後の生存率は雄及び雌でそれぞれ、80%及び98%(対照群)、62%及び94%(低用量)、及び62%及び90%(高用量)であった。2年後にはこれらの%はそれぞれ62%及び76、40%及び62、及び44%及び58%になった。	During the initial 4 months of the study, intercurrent mortality occurred due to intestinal obstruction by trichobezors (hair-balls). This condition was relieved by a change of diet. Survival after 1 year was 80% and 98% (control), 62% and 94% (low dose), and 62% and 90% (high dose), for males and females, respectively; after 2 years these percentages were 62 and 76, 40 and 62, and 44 and 58, respectively.
剖検所見(発生率、重篤度)		
臓器重量		
病理組織学的所見(発生率、重篤度)	20ヵ月後に剖検された高用量群の動物(1例を除き全例)は粗い表面又は極めて小さい突起から潰瘍及び壊死を伴う大きな塊まで変動する前胃粘膜の増殖性変化を示した。より早い時点で、また低用量において粘膜の増殖性変化の頻度及び程度の低値がみられ、範囲は試験の終わり近くには高用量群ではさらに小さくなった。剖検時にみられた他の腫瘍は部位と頻度に関してラットのこの系統ではまれなものではなかった。	High dose group animals (all but 1) necropsied after 20 months showed proliferative alterations of the forestomach mucosa varying from a rough surface or very small protrusions to extensive masses with ulceration and necrosis. At earlier time points and in the low dose group, lower incidence and severity of proliferative changes of the mucosa were observed, and the extension was far less than in the high dose group near the end of the study. Other tumors observed at gross inspection were not uncommon for the strain of rats with respect to site and incidence.
病理組織学的所見(発生率、重篤度)	組織的な検査で前胃の傷害は主に扁平上皮の基礎細胞の過形成からなっているように思われた。傷害は低用量レベルでの軽度の局所の過形成から高用量での極めて高頻度の癌(雌では100%、雄では81%のリスク(> 18ヶ月))までの範囲であった。高用量の雌では最初の癌は22ヶ月後に、雄では20ヶ月後に生じた。これらの癌では分化及び未分化の成分の両方が存在し、分裂指数は一般に低かった。侵襲はしばしば増殖性の炎症性反応を伴ったが、上皮の障害の近傍で炎症が性質としてより滲出性を示した。前胃の増殖性粘膜傷害は以下の分類に従って表1に掲載されている。	At histologic examination, lesions of the forestomach appeared to be composed principally of hyperplasia of basal cells of the squamous epithelium. The lesions ranged from slight local hyperplasia at low dose level to a very high incidence of carcinomas at high dose level (100% in females, 81% in males at risk (>18 months)). The first carcinoma in the high dose females occurred after 22 months and in males 20 months. In these carcinomas, both differentiated and undifferentiated components were present, and the mitotic index was generally low. Invasion was often accompanied by proliferative inflammatory reaction but in the vicinity of epithelial defects inflammation was more exudative in character. Proliferative mucosa lesions in the forestomach are listed in Table I according to the following classification:

病理組織学的所見（発生率、重篤度）	<p>過形成：限局性で、しばしば多中心性で鋭く境界を仕切られた規則的、典型的な基礎細胞の増加</p> <p>乳頭腫：局所的な有茎又は無柄(菌性)の上皮の塊；上皮は変化する分化の程度を示すが、規則的、典型的及び非侵襲性である。</p> <p>癌：境界がはっきりせず、胃壁の基底層あるいはリンパ節への浸潤を示す上皮の増殖；また、非侵襲性の癌はこの項目の下で分類される。このような癌は細胞質-核形態学（高充実性、明瞭な仁、高い分裂指数、異型性、多型）では悪性の特徴を示し、しばしば明瞭な侵襲性成長を伴わない顕著な異常構造（異形成）を示す上皮の増殖により特徴づけられる。</p>	<p>Hyperplasia: local, often multicentric, sharply demarcated increase of regular typical basal cells</p> <p>Papilloma: localized pedunculated or sessile (fungoid) epithelial mass; epithelium may exhibit varying degrees of differentiation, but remains regular, typical, and non-invasive</p> <p>Carcinoma: proliferation of epithelium, exhibiting poor demarcation and invasion in underlying layers of the stomach wall or lymphatics; also, non-invasive carcinomas are classified under this heading. Such carcinomas are characterized by proliferation of the epithelium exhibiting malignant features in cyto-nuclear morphology (high cellularity, prominent nucleoli, high mitotic index, atypia, polymorphism), often in a marked abnormal architectural conformation (dysplasia), but without clear invasive growth.</p>																																																																																																																																																																																																																																												
実際に摂取された量 腫瘍発生までの時間	<p>腫瘍発生頻度の年表</p> <p>腫瘍の頻度（腫瘍を有するラット/検査したラット） 各期間の間（ヶ月）</p> <p>0-12 12-14 14-16 16-18 18-20 20-22 22-24 最終</p> <p>雌</p> <table><tr><td>対照</td><td>0/10</td><td>0/0</td><td>0/0</td><td>0/0</td><td>2/2</td><td>2/3</td><td>2/4</td><td>27/31</td></tr><tr><td>10 mg</td><td>2/19</td><td>1/2</td><td>0/2</td><td>1/2</td><td>0/0</td><td>0/0</td><td>2/2</td><td>22/22</td></tr></table> <p>雄</p> <table><tr><td>対照</td><td>0/1</td><td>0/0</td><td>0/0</td><td>0/0</td><td>1/1</td><td>2/3</td><td>5/7</td><td>38/38</td></tr><tr><td>10 mg</td><td>0/5</td><td>0/1</td><td>0/0</td><td>1/1</td><td>1/2</td><td>7/7</td><td>6/6</td><td>29/29</td></tr></table>	対照	0/10	0/0	0/0	0/0	2/2	2/3	2/4	27/31	10 mg	2/19	1/2	0/2	1/2	0/0	0/0	2/2	22/22	対照	0/1	0/0	0/0	0/0	1/1	2/3	5/7	38/38	10 mg	0/5	0/1	0/0	1/1	1/2	7/7	6/6	29/29	<p>Tumor Incidence Chronology</p> <p>Tumor incidence (rats with tumors/rats examined) during the periods (months)</p> <p>0-12 12-14 14-16 16-18 18-20 20-22 22-24 Terminal</p> <p>Females</p> <table><tr><td>Control</td><td>0/10</td><td>0/0</td><td>0/0</td><td>0/0</td><td>2/2</td><td>2/3</td><td>2/4</td><td>27/31</td></tr><tr><td>10 mg</td><td>2/19</td><td>1/2</td><td>0/2</td><td>1/2</td><td>0/0</td><td>0/0</td><td>2/2</td><td>22/22</td></tr></table> <p>Males</p> <table><tr><td>Control</td><td>0/1</td><td>0/0</td><td>0/0</td><td>0/0</td><td>1/1</td><td>2/3</td><td>5/7</td><td>38/38</td></tr><tr><td>10 mg</td><td>0/5</td><td>0/1</td><td>0/0</td><td>1/1</td><td>1/2</td><td>7/7</td><td>6/6</td><td>29/29</td></tr></table>	Control	0/10	0/0	0/0	0/0	2/2	2/3	2/4	27/31	10 mg	2/19	1/2	0/2	1/2	0/0	0/0	2/2	22/22	Control	0/1	0/0	0/0	0/0	1/1	2/3	5/7	38/38	10 mg	0/5	0/1	0/0	1/1	1/2	7/7	6/6	29/29																																																																																																																																																																				
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用量反応性 統計的結果 注釈	<p>TABLE 1 INCIDENCE OF PRENEOPLASTIC AND NEOPLASTIC CHANGES IN THE FORESTOMACH OF RATS AFTER EXPOSURE TO CEP BY GAVAGE (NO. OF LESIONS/NO. OF RATS EXAMINED)</p> <table><tr><th rowspan="2">Conc. CEP (mg/kg)</th><th colspan="3">Females</th><th colspan="3">Males</th></tr><tr><th>0</th><th>2</th><th>10</th><th>0</th><th>2</th><th>10</th></tr><tr><td>0-12 months</td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Hyperplasia</td><td>0/9</td><td>1/14</td><td>5/13</td><td>0/1</td><td>2/3</td><td>1/4</td></tr><tr><td>Papilloma</td><td></td><td>1/14</td><td></td><td></td><td></td><td></td></tr><tr><td>12-18 months</td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Hyperplasia</td><td>0/0</td><td>0/3</td><td>2/2</td><td>0/0</td><td>2/3</td><td>1/2</td></tr><tr><td>Papilloma</td><td></td><td></td><td></td><td></td><td></td><td>1/2</td></tr><tr><td>18-24 months</td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Hyperplasia</td><td>3/38</td><td>11/27</td><td></td><td>5/49</td><td>20/43</td><td>4/43</td></tr><tr><td>Papilloma</td><td>2/38</td><td>2/27</td><td></td><td>1/49</td><td>6/43</td><td>3/43</td></tr><tr><td>Squamous cell carcinoma</td><td></td><td>2/27</td><td>24/24</td><td></td><td>6/43</td><td>35/43</td></tr><tr><td>Cumulative</td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Lost (autolysis)</td><td>3</td><td>6</td><td>10</td><td>1</td><td>2</td><td></td></tr><tr><td>Hyperplasia</td><td>3/47</td><td>12/44</td><td>7/39</td><td>5/50</td><td>24/49</td><td>6/49</td></tr><tr><td>Papilloma</td><td>2/47</td><td>3/44</td><td>1/50</td><td>5/49</td><td>4/49</td><td></td></tr><tr><td>Squamous cell carcinoma</td><td></td><td>2/44</td><td>24/39</td><td></td><td>6/49</td><td>35/49</td></tr></table>	Conc. CEP (mg/kg)	Females			Males			0	2	10	0	2	10	0-12 months							Hyperplasia	0/9	1/14	5/13	0/1	2/3	1/4	Papilloma		1/14					12-18 months							Hyperplasia	0/0	0/3	2/2	0/0	2/3	1/2	Papilloma						1/2	18-24 months							Hyperplasia	3/38	11/27		5/49	20/43	4/43	Papilloma	2/38	2/27		1/49	6/43	3/43	Squamous cell carcinoma		2/27	24/24		6/43	35/43	Cumulative							Lost (autolysis)	3	6	10	1	2		Hyperplasia	3/47	12/44	7/39	5/50	24/49	6/49	Papilloma	2/47	3/44	1/50	5/49	4/49		Squamous cell carcinoma		2/44	24/39		6/49	35/49	<p>TABLE 1 INCIDENCE OF PRENEOPLASTIC AND NEOPLASTIC CHANGES IN THE FORESTOMACH OF RATS AFTER EXPOSURE TO CEP BY GAVAGE (NO. OF LESIONS/NO. OF RATS EXAMINED)</p> <table><tr><th rowspan="2">Conc. CEP (mg/kg)</th><th colspan="3">Females</th><th colspan="3">Males</th></tr><tr><th>0</th><th>2</th><th>10</th><th>0</th><th>2</th><th>10</th></tr><tr><td>0-12 months</td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Hyperplasia</td><td>0/9</td><td>1/14</td><td>5/13</td><td>0/1</td><td>2/3</td><td>1/4</td></tr><tr><td>Papilloma</td><td></td><td>1/14</td><td></td><td></td><td></td><td></td></tr><tr><td>12-18 months</td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Hyperplasia</td><td>0/0</td><td>0/3</td><td>2/2</td><td>0/0</td><td>2/3</td><td>1/2</td></tr><tr><td>Papilloma</td><td></td><td></td><td></td><td></td><td></td><td>1/2</td></tr><tr><td>18-24 months</td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Hyperplasia</td><td>3/38</td><td>11/27</td><td></td><td>5/49</td><td>20/43</td><td>4/43</td></tr><tr><td>Papilloma</td><td>2/38</td><td>2/27</td><td></td><td>1/49</td><td>6/43</td><td>3/43</td></tr><tr><td>Squamous cell carcinoma</td><td></td><td>2/27</td><td>24/24</td><td></td><td>6/43</td><td>35/43</td></tr><tr><td>Cumulative</td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Lost (autolysis)</td><td>3</td><td>6</td><td>10</td><td>1</td><td>2</td><td></td></tr><tr><td>Hyperplasia</td><td>3/47</td><td>12/44</td><td>7/39</td><td>5/50</td><td>24/49</td><td>6/49</td></tr><tr><td>Papilloma</td><td>2/47</td><td>3/44</td><td>1/50</td><td>5/49</td><td>4/49</td><td></td></tr><tr><td>Squamous cell carcinoma</td><td></td><td>2/44</td><td>24/39</td><td></td><td>6/49</td><td>35/49</td></tr></table>	Conc. CEP (mg/kg)	Females			Males			0	2	10	0	2	10	0-12 months							Hyperplasia	0/9	1/14	5/13	0/1	2/3	1/4	Papilloma		1/14					12-18 months							Hyperplasia	0/0	0/3	2/2	0/0	2/3	1/2	Papilloma						1/2	18-24 months							Hyperplasia	3/38	11/27		5/49	20/43	4/43	Papilloma	2/38	2/27		1/49	6/43	3/43	Squamous cell carcinoma		2/27	24/24		6/43	35/43	Cumulative							Lost (autolysis)	3	6	10	1	2		Hyperplasia	3/47	12/44	7/39	5/50	24/49	6/49	Papilloma	2/47	3/44	1/50	5/49	4/49		Squamous cell carcinoma		2/44	24/39		6/49	35/49
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信頼性の判断根拠	ガイドライン又はGLP適合性に関して利用可能なデータはないが、本試験は信頼性のある試験ガイドラインのもとで組み込まれる形で行われた。	Although no data are available as to guideline or GLP compliance, this study was carried out in a manner which can be subsumed under valid testing guidelines.																																																																																																																																																																																																																																												
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試験物質名	他のTS	other TS
CAS番号		
純度等	純度：99%	Purity: 99%
注釈		
方法		
方法／ガイドライン	その他	other
試験のタイプ		
GLP適合	データなし	no data
試験を行った年	1980	1980
試験系(種／系統)	ラット Sprague-Dawley	rat Sprague-Dawley
性別(雄:M、雌:F)	雄	male
投与量	30 ppm (113 mg/m3) 及び 10 ppm (38 mg/m3)	30 ppm (113 mg/m3) and 10 ppm (38 mg/m3)
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	吸入	inhalation
処理頻度	6時間/日、5日/週	6 hours/day, 5 days/week
対照群と処理	あり、溶媒対照	yes, concurrent vehicle
試験条件	暴露期間：生涯 暴露後の観察期間：該当せず	Exposure period：lifetime Post exposure period：Not applicable
試験条件	※英文参照	Groups of 40 and 100 rats were exposed to ECH vapour and observed for their remaining lives. Control groups consisted of 100 each of a (sham)-treated and unexposed rats. The rates of mortality and weight gain were combined for the 2 treated groups because there was no significant difference between these parameters.

試験条件	※英文参照	<p>TEST ORGANISMS: Male Sprague-Dawley rats: 8 weeks old, initial body weight unknown, 100 per dose group</p> <p>ADMINISTRATION/EXPOSURE: Groups of 100 animals were exposed to 10 or 30 ppm six hours daily, five days per week, for lifetime. Groups of 100 animals, either sham-exposed or untreated, were used as controls.</p> <p>Whole-body vapor exposures were carried out in 1.3 cubic meter chambers. Atmospheres were generated by passing an air stream over the liquid in a generating flask, then diluting the effluent vapor with a second air stream prior to introduction to the exposure chambers. Chamber air was assayed for vapor concentration every half-hour during each 6-hour exposure period.</p>
試験条件	※英文参照	<p>CLINICAL OBSERVATIONS AND FREQUENCY: Animals were observed daily for signs of toxicity and morbidity/mortality. Body weights were collected monthly.</p> <p>Feed/water consumption were not monitored during the study. Ophthalmoscopic examinations were not performed during the study. Hematology, clinical chemistry, and urinalysis evaluations were not performed.</p> <p>ORGANS EXAMINED AT NECROPSY: A complete necropsy examination was conducted on each animal, with particular attention given to the respiratory tract. Histologic sections were prepared from each pulmonary lobe, the larynx, trachea, stem bronchi, liver, bladder, kidneys, spleen and other organs with gross pathologic alterations.</p>
統計学的処理	データの統計解析は行われなかった。	Statistical analysis of the data was not carried out.
結果		
体重、体重増加量	10 ppmに暴露した動物の体重増加は対照群と平行したが、30 ppmに暴露した群は40週以降は有意な体重減少を示し始めた。	Weight gain for animals exposed to 10 ppm paralleled that of controls, but the group exposed to 30 ppm began to show significant weight loss after 40 weeks.
摂餌量、飲水量	報告なし	None reported.
臨床所見(重篤度、所見の発現時期と持続時間)	報告なし	None reported
眼科学的所見(発生率、重篤度)	報告なし	None reported.
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)	報告なし	None reported.
尿検査所見(発生率、重篤度)	報告なし	None reported.
死亡数(率)、死亡時間	エピクロロヒドリンの両暴露群は暴露開始後16週間まで有意な死亡率を示さなかった。10 ppmで48週、30 ppmで60週までに死亡率は両暴露条件で45/100匹となった。いずれの場合も重度の肺のうっ血及び肺炎がみられた。2年間の生存率は対照群を含む全群で約5-10%であった。最初の暴露から136週までに死亡率は100%に達した。	Both epichlorohydrin-exposed groups showed no significant mortality up to 16 weeks after the start of exposure. By week 48 at 10 ppm and week 60 at 30 ppm, the mortality rate was 45/100 rats for both exposure conditions. In all cases severe lung congestion and pneumonia were observed. The 2-year survival was about 5-10% in all groups including controls. By 136 weeks from the first exposure, mortality reached 100%.
剖検所見(発生率、重篤度)		
臓器重量	報告なし	None reported.
病理組織学的所見(発生率、重篤度)	10及び30 ppm群は肺のうっ血、細気管支拡張、肺の腫瘍性変化を伴わない肺炎を示した。非呼吸器の腫瘍も報告されたが、投与に関連した腫瘍の頻度増加は認められなかった。	Both the 10 and 30 ppm group showed pulmonary congestion, bronchiolectasis, and pneumonia without neoplastic changes in the lungs. Tumors in non-respiratory organs were also reported, but no treatment-related increases in incidence of tumors was noted.
病理組織学的所見(発生率、重篤度)	10 ppmでは鼻の腫瘍はみられなかった。30 ppmで2例が腫瘍を、1例が鼻の乳頭腫(暴露開始後402日で発見)、1例が鼻の扁平細胞癌(暴露開始後752日で発見)を生じた。繰り返し、対照群には鼻の腫瘍はみられなかった。生涯暴露試験において、ECH両暴露群は暴露開始後16週間まで有意な死亡率を示さなかった。10 ppmで48週、30 ppmで60週までに死亡率は両暴露条件で45/100匹となった。いずれの場合も重度の肺のうっ血及び肺炎がみられた。2年間の生存率は対照群を含む全群で約5-10%であった。10 ppmでは鼻の腫瘍は認められなかった。30 ppmで2例が腫瘍を、1例が鼻の乳頭腫(暴露開始後402日で発見)、1例が鼻の扁平細胞癌(暴露開始後752日で発見)を生じた。繰り返すが、対照群には鼻の腫瘍はみられなかった。これらの試験の両方において、対照群と比べて他のタイプの腫瘍の頻度に差は認められなかった。	No nasal tumors were observed at 10 ppm. At 30 ppm, 2 animals developed tumors, 1 nasal papilloma (detected at 402 days after the start of exposure) and 1 nasal squamous cell carcinoma (detected at 752 days from the start of exposure). No nasal tumors were found in control In the lifetime exposure study, both ECH-exposed groups showed no significant mortality up to 16 weeks after the start of exposure. By week 48 at 10 ppm and week 60 at 30 ppm, the mortality rate was 45/100 rats for both exposure conditions. The 2-year survival was about 5-10% in all groups including controls. No nasal tumors were observed at 10 ppm. After 30 ppm, 2 animals developed tumours, 1 nasal papilloma (detected at 402 days after the start of exposure) and 1 nasal squamous cell carcinoma (detected at 752 days from the start of exposure). Again, no nasal tumours were found in controls. In both of these studies, no difference was noted in the incidence of other types of tumour compared to controls.
実際に摂取された量		
腫瘍発生までの時間		
用量反応性		
統計的結果		
注釈		
結論		
実験動物における発がん性の有無	陽性	positive
注釈		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	試験はGLPに従って行われたわけではないが、動物数、暴露期間及び病理組織検査は十分に記述され、科学的に許容できる	Study not performed according to GLP, but animal numbers, exposure duration and histopathology sufficiently documented and scientifically acceptable.
出典		
引用文献(元文献)	(138)	(138)
備考	フラグ: SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint



試験物質名	他のTS	other TS
CAS番号		
純度等	純度：99%	Purity: 99%
注釈		
方法		
方法／ガイドライン	その他	other
試験のタイプ		
GLP適合	データなし	no data
試験を行った年	1980	1980
試験系(種／系統)	ラット	rat
	Sprague-Dawley	Sprague-Dawley
性別(雄:M、雌:F)	雄	male
投与量	100 ppm (378 mg/m3)	100 ppm (378 mg/m3)
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	吸入	inhalation
処理頻度	6時間/日、5日/週	6 hours/day, 5 days/week
対照群と処理	あり、溶媒対照	yes, concurrent vehicle
試験条件	暴露期間：30日間 暴露後の期間：暴露後に生涯にわたり観察	Exposure period : 30 days Post exposure period : Exposures followed by lifetime observation.
試験条件	※英文参照	Groups of 40 and 100 male rats were exposed to epichlorohydrin vapour and observed for their remaining lives. Control groups consisted of 100 each of a (sham)-treated and unexposed rats. The rates of mortality and weight gain were combined for the 2 treated groups because there was no significant difference between these parameters.
統計学的処理		
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
眼科学的所見(発生率、重篤度)		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)		
臓器重量		
病理組織学的所見(発生率、重篤度)		
実際に摂取された量		
腫瘍発生までの時間		
用量反応性		
統計的結果		
注釈	暴露の最初の8週間に対照群の0%と比べて、投与群では9%の死亡率がみられた。暴露開始後330～933日の間に投与群の13%が鼻の腫瘍を生じ、うち83%は扁平細胞癌であった。全ての癌及び1つの乳頭腫は鼻腔の前半部の粘膜から生じたように思われた。このような腫瘍は同じ期間にわたり偽暴露群にも未処置対照群にもみられなかった。	A mortality rate of 9% was seen among the treated animals within the first 8 weeks of the initial exposure, compared to 0% in the controls. Between 330 and 933 days after the onset of exposure, 13% of the treated rats developed nasal tumours, of which 83% were squamous cell carcinomas. All of the carcinomas and 1 papilloma appeared to have developed from the mucosa of the anterior half of the nasal cavity. No such tumors were observed in either sham-exposed or untreated controls over the same time period.
結論		
実験動物における発がん性の有無	陽性	positive
注釈		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	試験はGLPに従って行われたわけではなく、特定の試験ガイドラインに合致していたわけでもない。片性のみ、1用量レベルのみ試験された。しかし、用いた動物数および試験の長さは発がん性を検出するには十分であった。	Study not performed according to GLP nor does it comply with a specific testing guideline. Only one sex and one dose level tested. However, sufficient number of animals was used and study length was sufficient to detect a carcinogenic effect.
出典		
引用文献(元文献)	(138)	(138)
備考		

試験物質名	他のTS	other TS
CAS番号		
純度等		
注釈	ECH (Nakarai Chem. Ltd., Kyoto) は毎日新しく飲料水に溶解し、遮光するために黒いテープで覆った瓶の中に入れた。	ECH (Nakarai Chem. Ltd., Kyoto) was dissolved in drinking water freshly every day and placed in a bottle covered with black tape to protect it from the light.
方法		
方法／ガイドライン	その他	other
試験のタイプ		
GLP適合	いいえ	no
試験を行った年	1981	1981
試験系(種／系統)	ラット	rat
	Wistar	Wistar
性別(雄:M、雌:F)	雄	male
投与量	0、375、750、1500 mg/l	0, 375, 750, 1500 mg/l
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	飲料水	drinking water

処理頻度	毎日	daily
対照群と処理	あり、溶媒対照	yes, concurrent vehicle
試験条件	暴露期間：81週間 暴露後の期間：なし	Exposure period : 81 weeks Post exposure period : none
試験条件	※英文参照	<p>In a briefly reported study, groups of 18 rats received ECH in drinking water continuously for up to 81 weeks. After week 60, ECH administration had to be stopped intermittently due to the poor condition of the rats. ECH intake was determined by daily measurements of water consumption.</p> <p>Although average daily water consumption was not reported, the total intake of ECH per rat throughout the experimental period was reported as follows:</p> <p>0 mg/l = 0 g 375 mg/l = 5.0 g 750 mg/l = 8.9 g 1500 mg/l = 15.1 g</p> <p>Averaging this amount over the treatment period (560 days), an average daily intake was calculated to be:</p> <p>0 mg/l = 0 mg/day 375 mg/l = 8.9 mg/day 750 mg/l = 15.9 mg/day 1500 mg/l = 27.0 mg/day</p> <p>When the average final body weight of the rats in each dose group was used, the estimated dose levels were calculated to be:</p> <p>0 mg/l = 0 mg/kg bw/day 375 mg/l = 18 mg/kg bw/day 750 mg/l = 40 mg/kg bw/day 1500 mg/l = 93 mg/kg bw/day</p>
統計学的処理		
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
眼科学的所見(発生率、重篤度)		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)		
臓器重量		
病理組織学的所見(発生率、重篤度)		
実際に摂取された量		
腫瘍発生までの時間		
用量反応性		
統計的結果		
注釈	<p>結果：</p> <p>試験終了時に最終体重は対照群に比べて用量依存的な減少(7-45%)を示した。投与ラットにおける前胃の扁平上皮細胞の過形成の頻度には用量依存的な増加がみられた。2つの高用量でも前胃の乳頭腫及び癌の頻度に用量依存的な増加がみられた。このような変化は対照群のラットにはみられなかった。</p>	<p>Result :</p> <p>At the end of the study, the final body weights showed a dose-dependent reduction (7-45%) compared to controls. A dose-dependent increase was observed in the incidence of squamous epithelial-cell hyperplasia of the forestomach of the treated rats. At the 2 higher doses, there was also a dose-related increase in the incidence of forestomach papillomas and carcinomas.</p> <p>No such changes were observed in the control rats.</p>
結論		
実験動物における発がん性の有無	陽性	positive
注釈	<p>注釈：</p> <p>mg/Lの用量レベルは参照した試験では摂水量のデータが利用できなかったため、摂水量の推定値を用いてmg/kg/日の単位に換算した。未公表データ(The Dow Chemical Company)及び米国EPA(Publication PB88179874)により公表された参考値が換算に用いられた。600 gのラットに対して1日摂水量60mlと推定された。</p> <p>0 mg/L = 0 mg/kg 体重/日 375 mg/L = 37.5 mg/kg 体重/日 750 mg/L = 75.0 mg/kg 体重/日 1500 mg/L = 150.0 mg/kg 体重/日</p>	<p>Remark :</p> <p>Dose levels in mg/L were converted to units of mg/kg bw/day through the use of water consumption estimations, since the water consumption data for the referenced study was unavailable. Unpublished data (The Dow Chemical Company) and reference values published by the US EPA (Publication PB88179874) were used in the conversion; a daily water consumption of 60 ml was assumed for a 600 g rat.</p> <p>0 mg/L = 0 mg/kg bw/day 375 mg/L = 37.5 mg/kg bw/day 750 mg/L = 75.0 mg/kg bw/day 1500 mg/L = 150.0 mg/kg bw/day</p>
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	本試験はGLPで実施されず、片性的のみ試験されたが、報告書の記述されたパラメータはデータを許容するのに十分であった。(2e)	Although this study was not performed under GLP and only 1 sex was tested, test parameters documented were sufficient to accept the data. (2e)
出典		
引用文献(元文献)	(207) (208)	(207) (208)
備考		

#### 5-9 生殖・発生毒性(受胎能と発生毒性を含む)

#### REPRODUCTIVE TOXICITY(Including Fertility and Development Toxicity)

#### A. 受胎能

#### FERTILITY

試験物質名	他のTS	other TS
CAS番号		
純度等	製造グレード、純度98.8%	Production grade, 98.8% purity



注釈		
方法		
方法／ガイドライン	その他	other
試験のタイプ	受胎能	Fertility
GLP適合	いいえ	no
試験を行った年	1979	1979
試験系(種／系統)	ラット	rat
	Sprague-Dawley	Sprague-Dawley
性別(雄:M、雌:F)	雌雄	male/female
投与量	0、5、25、50 ppm	0, 5, 25, 50 ppm
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	吸入	inhalation
試験期間	20週間	20 weeks
交配前暴露期間	雄: 10週間 雌: 10週間	Male : 10 weeks Female : 10 weeks
試験条件	暴露期間: 10週間 処置頻度: 6時間/日 対照群: あり、媒体対照群	Exposure period : 10 weeks Frequency of treatm. : 6 hours/day Control group : yes, concurrent vehicle
試験条件	※英文参照	<p>TEST ORGANISMS/EXPOSURE</p> <p>Groups of 30 rats per sex per dose level were exposed (whole-body) to 0 (chambered control), 5, 25, or 50 ppm epichlorohydrin vapor six hours daily, five days per week, for 10 weeks, then held for a 10-week recovery period. Means of daily analytical concentrations were 5.2+/-0.4, 24.7+/-1.4, 50.0+/-1.8 ppm for the 50 days of exposure.</p> <p>Exposures were carried out in 14.5 cubic meter chambers. Atmospheres were generated by metering liquid through a pump into a warmed vaporization flask, then sweeping the vapors into the chamber with compressed air. Chamber air was assayed for vapor concentration 3-4 times during each 6-hour exposure period.</p>
試験条件	※英文参照	<p>MATING PROCEDURES/PARAMETERS ASSESSED DURING STUDY (P AND F1)</p> <p>Groups of 25 exposed female rats were mated to unexposed male rats at the end of the 10-week exposure period. The females were cohoused with the males for 2 consecutive 5-day periods, until the presence of sperm was detected in a vaginal smear. These females were then allowed to carry and deliver their litters in nesting boxes. The day of delivery was noted, and the number of live and dead pups recorded on day 0 (delivery) and days 1 and 2 post-delivery. The pups were examined on day 1 for morphologic alterations and presence of milk in the stomach as an indication of nursing.</p> <p>Groups of 25 exposed male rats were mated to unexposed female rats during the 2nd, 4th, 7th, and 10th 12th, 15 and 20th weeks of exposure. Males were cohoused for 7 days with 2 females each during the time when exposure was not in progress. All of the males used for the experiment were able to sire at least one litter in a pre-exposure mating. The area beneath each males cage was examined for evidence of copulatory plugs as evidence of mating. Twelve days after the last day of cohabitation, the females were sacrificed and their uterine contents examined for number of corpora lutea, implantation sites, and resorption sites.</p> <p>Animals were observed daily for signs of toxicity. Body weights were collected weekly.</p>
試験条件	※英文参照	<p>One week prior to exposure and one week after the last exposure, blood samples were collected for hematologic analysis from 5 rats/sex/dose. Parameters examined were packed cell volume, red blood cell count, hemoglobin concentration, and white blood cell count, and clinical chemistry parameters: blood urea nitrogen, glutamic pyruvic transaminase activity, alkaline phosphatase activity, glutamic oxaloacetic transaminase activity, and glucose concentration. Urinalysis samples from rats were collected when blood samples were collected; parameters examined were specific gravity, pH, sugar, protein, ketones, bilirubin, occult blood, urobilinogen. The animals on whom these determinations were made were sacrificed at the end of the exposure period.</p> <p>A complete necropsy examination was conducted on each remaining animal at the end of the 10-week recovery period, during which organ weights for brain, heart, liver, kidneys, testes, and epididymides were recorded. Approximately 40 organs/tissues from five rats/sex/dose level were examined histologically.</p>
統計学的処理		
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
妊娠率(妊娠個体数/交配数)		

交尾前期間(交配までの日数及び交配までの性周期回数)		
妊娠期間(妊娠0日から起算)		
妊娠指数(生存胎仔数/着床痕数)		
哺乳所見		
性周期変動		
精子所見		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)		
着床数		
黄体数		
未熟卵胞数		
臓器重量		
病理組織学的所見(発生率、重篤度)		
実際に摂取された量		
用量反応性		
同腹仔数及び体重		
性比		
生存率(生後4日目生存仔数/総分娩仔数)		
離乳までの分娩後生存率		
新生仔所見(肉眼的な異常)		
生後発育及び発育率		
陰開口又は精巣下降(包皮分離)		
生殖器-肛門間距離などその他の観察事項		
臓器重量		
統計的結果		
注釈	親動物、受胎能 NOAEL/LOAEL  50 ppm 群では雄ラットの受胎指数は有意に低下した。25又は50 ppm群の雄は未処置の雌動物を受胎させることができなかったが、対照群と比べて着床数は有意に低下した。この影響は処置終了後2週間後には消失した。雄での生殖/受胎能のNOAELは5 ppmであった。	NOAEL/LOAEL Parental, FERTILITY  In the 50 ppm group, the fertility index for male rats was significantly reduced. Males from the 25 or 50 ppm group were able to fertilize untreated female animals, but there was a significantly reduced number of implantations compared with the controls. This effect disappeared 2 weeks following termination of treatment. The NOAEL for reproduction/fertility in males was 5 ppm.
注釈	雌ラットの生殖能は有害影響を受けなかった。雌は暴露終了後の2週間の交配期間中、正常な性周期を示し、妊娠し、生存児を分娩できるようになった。いずれの暴露群においても妊娠雌の割合、妊娠期間の長さ、同腹児数、又は分娩後2日間の児の生存率には有害影響はなかった。雌での生殖/受胎能のNOAELは50 ppmであった。  雌雄ラットにおいて、25及び50 ppmの暴露レベルでは鼻甲介に投与に関連した病理組織学的な変化がみられた。顕微鏡的な変化は性質的には変性であり、鼻甲介粘膜の扁平な外観を伴った炎症、限局性の糜爛、過形成及び化生により特徴づけられた。50 ppm 群では中間屠殺時の雌雄の腎臓で尿細管の拡張が示された。また、25及び50 ppmの雄では限局的な尿細管の変化の頻度に軽度の増加が示された。これらの変化は対照群のラットの腎臓でも生じたが、25及び50 ppm群でのみより高頻度に見られた。検査した他のいずれの組織においてもその他の投与に関連した変化は検出されなかった。雌雄において他の全ての影響に対するNOAELは5 ppmであった。	The reproductive capacity of female rats was not adversely affected. The females showed normal estrus patterns during the 2-week mating period following termination of exposures and were able to become pregnant and deliver viable young. There were no adverse effects on the percentage of pregnant females, length of gestation period, litter size, or pup survival through 2 days postpartum in any exposure group. The NOAEL for reproduction/fertility in females was 50 ppm.  In male and female rats there were treatment-related histopathologic changes in the nasal turbinates at the 25 and 50 ppm exposure levels. The microscopic changes were degenerative in nature and characterized by inflammation, focal erosions, hyperplasia, and metaplasia with a squamous appearance to the turbinate mucosa. The kidneys of males and females from the interim sacrifice showed dilated tubules in the 50 ppm group. In addition, males in the 25 and 50 ppm groups showed a slightly increased incidence of focal tubular change. These changes occurred in the control rat kidneys; however, they were observed with a greater frequency in the 25 and 50 ppm groups only. There were no other treatment-related changes detected in any other tissues examined. The NOAEL for all other effects in both sexes was 5 ppm.
注釈	生殖パラメーター 吸入によりエピクロロヒドリンに暴露された雄ラットの受胎能指標  暴露レベル、ppm (a) 試験の 0                      5                      25                      50 週 2    100(25/25) <sup>b</sup> 100(25/25)    100(25/25)    16(4/25) <sup>c</sup> 4    100(25/25)    96(24/25)    88(22/25)    8(2/25) <sup>c</sup> 7    100(25/25)    100(25/25)    92(23/25)    8(2/25) <sup>c</sup> 10   100(25/25)    100(25/25)    96(24/25)    12(3/25) <sup>c</sup> 12   100(25/25)    100(25/25)    100(25/25)    96(24/25) 15   100(25/25)    100(25/25)    100(25/25)    100(25/25) 20   100(25/25)    100(25/25)    100(25/25)    100(25/25)  (a) 雄ラットはエピクロロヒドリン蒸気 0、5、25、又は 50 ppm に6時間/日、5日/週で10週間暴露された。2、4、7及び10週間の暴露の間に、暴露レベル当たり25匹の雄ラットを7日間の暴露の間、2匹づつの非暴露雌と同居させた。交配は回復期間の12、15及び20週にも行われた。  b 雄の受胎指数 = # 受胎能のある雄/# 雌と同居させた雄 x 100  c Fischerの正確確率検定により対照群と有意差あり、p<0.05.	Reproductive Parameters – Fertility Index of Male Rats Exposed to Epichlorohydrin by Inhalation  Exposure Level, ppm (a) Week of    0                      5                      25                      50 Study 2    100(25/25) <sup>b</sup> 100(25/25)    100(25/25)    16(4/25) <sup>c</sup> 4    100(25/25)    96(24/25)    88(22/25)    8(2/25) <sup>c</sup> 7    100(25/25)    100(25/25)    92(23/25)    8(2/25) <sup>c</sup> 10   100(25/25)    100(25/25)    96(24/25)    12(3/25) <sup>c</sup> 12   100(25/25)    100(25/25)    100(25/25)    96(24/25) 15   100(25/25)    100(25/25)    100(25/25)    100(25/25) 20   100(25/25)    100(25/25)    100(25/25)    100(25/25)  (a) Male rats were exposed to 0, 5, 25, or 50 ppm of epichlorohydrin vapor for 6 hrs/day; 5 days/week for 10 weeks. During the 2nd, 4th, 7th, and 10th weeks of exposure, 25 male rats per exposure level were housed with 2 unexposed female rats each during the period between exposures for 7 days. Matings were also conducted during weeks 12, 15, and 20 of the recovery period.  b Male fertility index = # fertile males/# males housed with females x 100  c Significantly different from the control value by the Fisher's exact probability test, p<0.05.

注釈	生殖パラメーター 吸入によりエピクロロヒドリンに暴露された雄と交配した非暴露の雌における平均着床数、黄体数及び吸収胚数	Reproductive Parameters – Average Number of Implantations, Corpora Lutea, and Resorptions in Unexposed Female Rats Bred to Male Rats Exposed to Epichlorohydrin by Inhalation			
	暴露レベル、ppm (a)	Exposure Level, ppm (a)			
	試験の週	0	5	25	50
	Week of Study				
	Week 2 –				
	平均値 #	13.7+/-	14.0+/-	7.8+/-	1.0+/-
	着床数	1.8b	1.5	3.3c	0.0 c
	平均値 #	14.4+/-	14.6+/-	12.4+/-	8.8+/-
	黄体数	1.9	1.6	2.4d	3.3 d
	平均値 #	0.8+/-	0.8+/-	0.4+/-	0.5+/-
吸収胚	1.0	0.9	0.5	0.6	
Week 4 –					
平均値 #	13.1+/-	13.7+/-	8.4+/-	2.0+/-	
着床数	1.7	1.6	3.6 c	1.4 c	
平均値 #	13.6+/-	13.8+/-	13.4+/-	8.5+/-	
黄体数	1.4	1.3	2.0	4.9 d	
平均値 #	0.7+/-	1.1+/-	0.9+/-	0.5+/-	
吸収胚	0.8	1.8	0.9	0.7	
注釈	第7週 –	Week 7 –			
	平均値 #	13.0+/-	13.6+/-	7.1+/-	1.0+/-
	着床数	1.5	2.3	3.8 c	0.0 c
	平均値 #	13.9+/-	14.5+/-	13.2+/-	10.5+/-
	黄体数	1.0	1.7	1.5	0.7 d
	平均値 #	0.6+/-	0.9+/-	0.5+/-	0.5+/-
	吸収胚	0.5	1.9	0.6	0.7
	第10週 –	Week 10 –			
	平均値 #	14.2+/-	13.8+/-	9.1+/-	4.0+/-
	着床数	1.1	1.8	4.7c	4.4 c
	平均値 #	14.4+/-	15.0+/-	13.4+/-	11.7+/-
	黄体数	1.4	1.7	2.3	0.6 d
	平均値 #	0.9+/-	1.0+/-	0.6+/-	2.0+/-
	吸収胚	0.8	1.0	0.7	1.0
	第12週 12 –	Week 12 –			
	平均値 #	13.7+/-	13.3+/-	12.6+/-	13.8+/-
	着床数	2.6	1.7	3.1	1.2
	平均値 #	14.2+/-	13.9+/-	14.0+/-	14.3+/-
	黄体数	1.4	1.5	1.2	1.6 e
	平均値 #	1.0+/-	0.9+/-	1.1+/-	0.4+/-
	吸収胚	1.2	1.8	1.0	0.5
	第15週 –	Week 15 –			
	平均値 #	14.2+/-	14.1+/-	14.5+/-	13.7+/-
	着床数	1.9	1.5	1.2	2.2
	平均値 #	14.0+/-	14.3+/-	14.5+/-	14.5+/-
	黄体数	1.5	1.0	1.3	1.5
	平均値 #	0.7+/-	1.2+/-	0.9+/-	1.2+/-
	吸収胚	0.7	1.7	0.8	1.0
	第20週 –	Week 20 –			
	平均値 #	14.2+/-	14.4+/-	13.9+/-	15.2+/-
着床数	2.0	1.6	1.6	1.4 d	
平均値 #	13.1+/-	14.1+/-	13.6+/-	14.5+/-	
黄体数	2.2	1.6	2.1	1.1	
平均値 #	0.8+/-	0.9+/-	0.7+/-	0.5+/-	
吸収胚	1.0	0.9	1.2	0.4	
a 雄ラットをエピクロロヒドリン蒸気の 0、5、25、又は 50 ppm に6時間/日、5日/週で10週間暴露した。2、4、7及び10週間の暴露の間、暴露レベル当たり25匹の雄ラットをそれぞれ2匹の非暴露雌ラットと暴露の間の期間中同居させた。交配は回復期間の12、15、及び20週に間にも行われた。					
a Male rats were exposed to 0, 5, 25, or 50 ppm of epichlorohydrin vapor for 6 hrs/day; 5 days/week for 10 weeks. During the 2nd, 4th, 7th, and 10th weeks of exposure, 25 male rats per exposure level were housed during the period between exposures with 2 unexposed female rats each. Matings were also conducted during weeks 12, 15, and 20 of the recovery period.					
b 平均値 +/- 標準偏差。各々の雄に対して交配された2匹の雌に対して、着床数、黄体数又は吸収胚数の平均値を算出した。群の平均値をこれらの平均値から算出した。					
b Mean +/- S.D. The average number of implantations, corpora lutea, or resorptions for the two female rats bred to each male was calculated. Group means were then calculated from these averaged values.					
c Wilcoxon検定を用いてランクによるノンパラメトリックな分散分析をにより対照群の値と有意差あり。					
c Significantly different from the control value by a non-parametric analysis of variance by ranks, using Wilcoxon's test.					
d 分散分析及びDunnnett法により対照群の値と有意差あり。p<0.05.					
d Significantly different from the control value by an analysis of variance and Dunnnett's test, p<0.05.					
e Wilcoxon変法により対照群の値と有意差あり。p<0.05.					
e Significantly different from the control value by a modified Wilcoxon test, p<0.05.					

注釈	<p>生殖パラメーター 吸入によりエピクロロヒドリンに暴露した雄ラットと交配した非暴露雌における平均着床前胚損失及び平均胚吸収率</p> <table><tr><th>試験の週</th><th colspan="4">暴露レベル、ppm (a)</th></tr><tr><th></th><th>0</th><th>5</th><th>25</th><th>50</th></tr></table> <p>平均着床前胚損失、パーセント b</p> <table><tr><td>第2</td><td>8</td><td>5</td><td>42 c</td><td>84 c</td></tr><tr><td>第4</td><td>6</td><td>4</td><td>38</td><td>78</td></tr><tr><td>第7</td><td>6</td><td>8</td><td>48 c</td><td>90 c</td></tr><tr><td>第10</td><td>4</td><td>9 c</td><td>36 c</td><td>66 c</td></tr><tr><td>第12</td><td>7</td><td>6</td><td>12</td><td>5</td></tr><tr><td>第15</td><td>5</td><td>4</td><td>3</td><td>8 c</td></tr><tr><td>第20</td><td>9</td><td>4 c</td><td>6 c</td><td>6 d</td></tr></table> <p>平均胚吸収率、パーセント e</p> <table><tr><td>第2</td><td>6</td><td>6</td><td>4</td><td>50 f</td></tr><tr><td>第4</td><td>5</td><td>8</td><td>13</td><td>50 g</td></tr><tr><td>第7</td><td>4</td><td>7</td><td>6</td><td>50 g</td></tr><tr><td>第10</td><td>6</td><td>9</td><td>14</td><td>78 c,h</td></tr><tr><td>第12</td><td>8</td><td>8</td><td>10</td><td>3 c</td></tr><tr><td>第15</td><td>7</td><td>8</td><td>6</td><td>11</td></tr><tr><td>第20</td><td>8</td><td>7</td><td>5</td><td>4</td></tr></table>	試験の週	暴露レベル、ppm (a)					0	5	25	50	第2	8	5	42 c	84 c	第4	6	4	38	78	第7	6	8	48 c	90 c	第10	4	9 c	36 c	66 c	第12	7	6	12	5	第15	5	4	3	8 c	第20	9	4 c	6 c	6 d	第2	6	6	4	50 f	第4	5	8	13	50 g	第7	4	7	6	50 g	第10	6	9	14	78 c,h	第12	8	8	10	3 c	第15	7	8	6	11	第20	8	7	5	4	<p>Reproductive Parameters – Average Preimplantation Loss and Average Resorption Rate in Unexposed Female Rats Bred to Male Rats Exposed to Epichlorohydrin by Inhalation</p> <table><tr><th>Week on Study</th><th colspan="4">Exposure Level, ppm (a)</th></tr><tr><th></th><th>0</th><th>5</th><th>25</th><th>50</th></tr></table> <p>Average preim-plantation loss, percent b</p> <table><tr><td>2nd</td><td>8</td><td>5</td><td>42 c</td><td>84 c</td></tr><tr><td>4th</td><td>6</td><td>4</td><td>38</td><td>78</td></tr><tr><td>7th</td><td>6</td><td>8</td><td>48 c</td><td>90 c</td></tr><tr><td>10th</td><td>4</td><td>9 c</td><td>36 c</td><td>66 c</td></tr><tr><td>12th</td><td>7</td><td>6</td><td>12</td><td>5</td></tr><tr><td>15th</td><td>5</td><td>4</td><td>3</td><td>8 c</td></tr><tr><td>20th</td><td>9</td><td>4 c</td><td>6 c</td><td>6 d</td></tr></table> <p>Average resorp-tion rate, percent e</p> <table><tr><td>2nd</td><td>6</td><td>6</td><td>4</td><td>50 f</td></tr><tr><td>4th</td><td>5</td><td>8</td><td>13</td><td>50 g</td></tr><tr><td>7th</td><td>4</td><td>7</td><td>6</td><td>50 g</td></tr><tr><td>10th</td><td>6</td><td>9</td><td>14</td><td>78 c,h</td></tr><tr><td>12th</td><td>8</td><td>8</td><td>10</td><td>3 c</td></tr><tr><td>15th</td><td>7</td><td>8</td><td>6</td><td>11</td></tr><tr><td>20th</td><td>8</td><td>7</td><td>5</td><td>4</td></tr></table>	Week on Study	Exposure Level, ppm (a)					0	5	25	50	2nd	8	5	42 c	84 c	4th	6	4	38	78	7th	6	8	48 c	90 c	10th	4	9 c	36 c	66 c	12th	7	6	12	5	15th	5	4	3	8 c	20th	9	4 c	6 c	6 d	2nd	6	6	4	50 f	4th	5	8	13	50 g	7th	4	7	6	50 g	10th	6	9	14	78 c,h	12th	8	8	10	3 c	15th	7	8	6	11	20th	8	7	5	4
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注釈	<p>生殖パラメーター 吸入によりエピクロロヒドリンに暴露した雌ラットにおける受胎指数、生存率</p> <table><tr><th></th><th colspan="4">暴露レベル、ppm a</th></tr><tr><th></th><th>0</th><th>5</th><th>25</th><th>50</th></tr></table> <p>雌の例数 25 25 25 25</p> <p>分娩中の母動物の死亡数 0 1 0 1</p> <p>受胎しう b</p> <table><tr><td>84%(21/25)</td><td>92%(23/25)</td><td>92%(23/25)</td><td>92%(23/25)</td></tr></table> <p>妊娠期間、日 c</p> <table><tr><td>22+/-0.6</td><td>22+/-0.6</td><td>23+/-2.0</td><td>22+/-1.0</td></tr></table> <p>生時の同腹児数 c</p> <table><tr><td>12+/-4</td><td>12+/-5</td><td>12+/-4</td><td>12+/-3</td></tr></table> <p>妊娠期の生存</p> <table><tr><td>97%</td><td>97%</td><td>96%</td><td>98%</td></tr></table> <p>指数 (243/250) (261/269) (268/278) (265/270)</p> <p>24時間の生存 99% 100% 99% 98%</p> <p>指数 e (240/243) (261/261) (265/268) (259/265)</p> <p>2日間の生存 98% 100% 98% 97%</p> <p>指数 f (238/243) (261/261)g (262/268) (258/265)</p> <p>1日目の性比、雄:雌 52:48 55:45 49:51 49:51</p>		暴露レベル、ppm a					0	5	25	50	84%(21/25)	92%(23/25)	92%(23/25)	92%(23/25)	22+/-0.6	22+/-0.6	23+/-2.0	22+/-1.0	12+/-4	12+/-5	12+/-4	12+/-3	97%	97%	96%	98%	<p>Reproductive Parameters – Fertility Index Survival Indices in Female Rats Exposed to Epichlorohydrin by Inhalation</p> <table><tr><th></th><th colspan="4">Exposure Level, ppm a</th></tr><tr><th></th><th>0</th><th>5</th><th>25</th><th>50</th></tr></table> <p>No. Females 25 25 25 25</p> <p>No. maternal deaths during delivery 0 1 0 1</p> <p>Fertility index b</p> <table><tr><td>84%(21/25)</td><td>92%(23/25)</td><td>92%(23/25)</td><td>92%(23/25)</td></tr></table> <p>Gestation period, days c</p> <table><tr><td>22+/-0.6</td><td>22+/-0.6</td><td>23+/-2.0</td><td>22+/-1.0</td></tr></table> <p>Litter size at birth c</p> <table><tr><td>12+/-4</td><td>12+/-5</td><td>12+/-4</td><td>12+/-3</td></tr></table> <p>Gestation survival</p> <table><tr><td>97%</td><td>97%</td><td>96%</td><td>98%</td></tr></table> <p>index (243/250) (261/269) (268/278) (265/270)</p> <p>24-Hr survival 99% 100% 99% 98%</p> <p>index e (240/243) (261/261) (265/268) (259/265)</p> <p>2-Day survival 98% 100% 98% 97%</p> <p>index f (238/243) (261/261)g (262/268) (258/265)</p> <p>Sex ratio on day 1, M:F 52:48 55:45 49:51 49:51</p>		Exposure Level, ppm a					0	5	25	50	84%(21/25)	92%(23/25)	92%(23/25)	92%(23/25)	22+/-0.6	22+/-0.6	23+/-2.0	22+/-1.0	12+/-4	12+/-5	12+/-4	12+/-3	97%	97%	96%	98%																																																																																																												
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結論		
Pに対するNOAEL (NOEL)又はLOAEL (LOEL)	NOAEL 親動物 : = 5 ppm その他: 繁殖のNOAEL : = 5 ppm	NOAEL parental : = 5 ppm other: fertility NOAEL : = 5 ppm
F1に対するNOAEL (NOEL)又はLOAEL (LOEL)		
F2に対するNOAEL (NOEL)又はLOAEL (LOEL)		
注釈		
信頼性	(1) 制限なく信頼性あり 1d	(1) valid without restriction 1d
信頼性の判断根拠		
出典		
引用文献(元文献)	(212)	(212)
備考	フラグ: SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	他のTS	other TS
CAS番号		
純度等	製造グレード、純度98.8%	Production grade, 98.8% purity
注釈		
方法		
方法/ガイドライン	その他	other
試験のタイプ	受胎能	Fertility
GLP適合	いいえ	no
試験を行った年	1979	1979
試験系(種/系統)	ウサギ ニュージーランド白色種	rabbit New Zealand white
性別(雄:M、雌:F)	雄	male
投与量	0、5、25 及び 50 ppm	0, 5, 25 and 50 ppm
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	吸入	inhalation
試験期間	20週間	20 weeks
交配前暴露期間	雄: 10週間 雌: 10週間	Male : 10 weeks Female : none
試験条件	暴露期間: 10週間 処置頻度: 6時間/日、5日/週 対照群: あり、媒体対照	Exposure period : 10 weeks Frequency of treatm. : 6 hours/day, 5 days/week Control group : yes, concurrent vehicle
試験条件	※英文参照	<p>TEST ORGANISMS/EXPOSURE</p> <p>Groups of 10 male rabbits per dose level were exposed (whole-body) to 0 (chambered control), 5, 25, or 50 ppm epichlorohydrin vapor six hours daily, five days per week, for 10 weeks, then held for a 10-week recovery period. Means of daily analytical concentrations were 5.2+/-0.4, 24.7+/-1.4, 50.0+/-1.8 ppm for the 50 days of exposure.</p> <p>Exposures were carried out in 14.5 cubic meter chambers. Atmospheres were generated by metering liquid through a pump into a warmed vaporization flask, then sweeping the vapors into the chamber with compressed air. Chamber air was assayed for vapor concentration 3-4 times during each 6-hour exposure period.</p>
試験条件	※英文参照	<p>MATING PROCEDURES/PARAMETERS ASSESSED DURING STUDY (P AND F1)</p> <p>Semen evaluation was conducted on all males on a weekly basis during the 10-week exposure period, which included sperm count, motility, morphology, and ratio of live to dead sperm.</p> <p>Groups of 10 exposed male rabbits were allowed to mate with unexposed female rabbits during the 10th week of exposure. Females were injected with human chorionic gonadotropin to induce ovulation. On day 28 of gestation, the females were sacrificed and their uterine contents examined for number of corpora lutea, implantation sites, and resorption sites.</p> <p>Animals were observed daily for signs of toxicity. Body weights were collected weekly.</p>

試験条件	※英文参照	<p>One week prior to exposure and one week after the last exposure, blood samples were collected for hematologic analysis from 4 rabbits/dose. Parameters examined were packed cell volume, red blood cell count, hemoglobin concentration, and white blood cell count, and clinical chemistry parameters: blood urea nitrogen, glutamic pyruvic transaminase activity, alkaline phosphatase activity, glutamic oxaloacetic transaminase activity, and glucose concentration.</p> <p>A complete necropsy examination was conducted on each remaining animal at the end of the 10-week recovery period, during which organ weights for brain, heart, liver, kidneys, testes, and epididymides were recorded. Approximately 40 organs/tissues from 4 rabbits/dose level were examined histologically.</p>
統計学的処理	※英文参照	<p>Statistics: Body weights, organ weights, clinical chemistry determinations, specific gravity of urine, hematological parameters, number of corpora lutea and implants, and parameters concerning semen evaluations were evaluated by a on-way analysis of variance; differences between experimental means and the controls were examined by Dunnett's test (Steel and Torrie, 1960, Principals and Procedures of Statistics, McGraw-Hill, NY). Where appropriate after evaluation by Barlett's test for equality of variances (Winer, 1971, Statistical Principals in Experimental Design, 2nd Ed., McGraw-Hill, NY), nonparametric analysis of variance and Wilcoxon's test were used to evaluate these parameters. The number of resorptions and resorption rate were analyzed by the Wilcoxon test as modified by Haseman and Hoel (J. Statist. Comput. Simul. 3: 117-135, 1974). The fertility indexes were analyzed by the Fischer's exact probability test (Siegel, Non-Parametric Statistics for the Behavioral Sciences, McGraw-Hill, NY, 1956). The nominal alpha level used for statistical analysis of all experimental parameters was 0.05.</p>
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
妊娠率(妊娠個体数/交配数)		
交尾前期間(交配までの日数及び交配までの性周期回数)		
妊娠期間(妊娠0日から起算)		
妊娠指数(生存胎仔数/着床痕数)		
哺乳所見		
性周期変動		
精子所見		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)		
着床数		
黄体数		
未熟卵胞数		
臓器重量		
病理組織学的所見(発生率、重篤度)		
実際に摂取された量		
用量反応性		
同腹仔数及び体重		
性比		
生存率(生後4日目生存仔数/総分婉仔数)		
離乳までの分娩後生存率		
新生仔所見(肉眼的な異常)		
生後発育及び発育率		
陰開口又は精巣下降(包皮分離)		
生殖器-肛門間距離などその他の観察事項		
臓器重量		
統計的結果		
注釈	<p>NOAEL/LOAEL 親</p> <p>50 ppmに暴露したウサギは対照群と比べて統計的に有意な体重の減少を示した。25又は50 ppmに暴露したウサギの大部分は剖検で鼻甲介の炎症の証拠を示した。25又は50 ppmに暴露したウサギは両側性の膿瘍性鼻炎、副鼻腔炎、限局性糜爛又は鼻の上皮の化生をより高頻度に生じた。5 ppmでは投与に関連したと考えられる病理組織学的な変化はみられなかった。</p>	<p>NOAEL/LOAEL P</p> <p>Rabbits exposed to 50 ppm showed a statistically significant decrease in body weight as compared to controls. The majority of rabbits exposed to 25 or 50 ppm showed evidence of nasal turbinate inflammation at gross necropsy. Rabbits exposed to 25 or 50 ppm showed a greater incidence of bilateral suppurative rhinitis, sinusitis, focal erosion, or metaplasia of the nasal epithelium. There were no histopathological changes at 5 ppm considered treatment-related. Therefore, the NOAEL for parental toxicity was 5 ppm.</p>



注釈	吸入によりエピクロロヒドリンに暴露した雄ウサギの体重 暴露レベル, ppma 試験の週 0 5 25 50 暴露前、 -2 3.94±0.34b 3.77±0.40 3.77±0.24 3.74±0.31 暴露前、 -1 3.91±0.37 3.71±0.32 3.83±0.22 3.81±0.34 週 1 4.00±0.35 3.73±0.34 3.84±0.24 3.84±0.39 2 3.95±0.34 3.78±0.35 3.85±0.24 3.68±0.27 3 4.00±0.33 3.84±0.37 3.96±0.39 3.68±0.30 4 3.99±0.34 3.84±0.32 3.89±0.26 3.58±0.28c 5 4.01±0.31 3.81±0.26 3.90±0.33 3.56±0.35c 6 4.04±0.34 3.88±0.34 3.92±0.28 3.52±0.42c 7 3.98±0.39 3.91±0.34 3.93±0.30 3.67±0.23 8 4.11±0.44 3.91±0.38 3.93±0.28 3.67±0.23 9 4.04±0.34 3.95±0.38 3.90±0.30 3.69±0.23 10 4.06±0.35 3.98±0.38 3.86±0.44 3.70±0.22				Body Weights of Male Rabbits Exposed to Epichlorohydrin by Inhalation Exposure Level, ppma Week of Study 0 5 25 50 Pre-exposure, -2 3.94±0.34b 3.77±0.40 3.77±0.24 3.74±0.31 Pre-exposure, -1 3.91±0.37 3.71±0.32 3.83±0.22 3.81±0.34 Week 1 4.00±0.35 3.73±0.34 3.84±0.24 3.84±0.39 2 3.95±0.34 3.78±0.35 3.85±0.24 3.68±0.27 3 4.00±0.33 3.84±0.37 3.96±0.39 3.68±0.30 4 3.99±0.34 3.84±0.32 3.89±0.26 3.58±0.28c 5 4.01±0.31 3.81±0.26 3.90±0.33 3.56±0.35c 6 4.04±0.34 3.88±0.34 3.92±0.28 3.52±0.42c 7 3.98±0.39 3.91±0.34 3.93±0.30 3.67±0.23 8 4.11±0.44 3.91±0.38 3.93±0.28 3.67±0.23 9 4.04±0.34 3.95±0.38 3.90±0.30 3.69±0.23 10 4.06±0.35 3.98±0.38 3.86±0.44 3.70±0.22
注釈	体重増加量 週 1-10 0.15±0.20 0.27±0.15 0.03±0.34 -0.13±0.21c 暴露後、 11日 4.17±0.39 4.01±0.36 4.10±0.46 3.77±0.28 12 4.20±0.38 3.98±0.35 4.14±0.46 3.84±0.28 13 4.14±0.40 4.08±0.38 4.20±0.49 3.98±0.26 14 4.05±0.42 4.02±0.38 4.11±0.36 3.91±0.24 15 4.13±0.40 3.97±0.41 3.99±0.39 3.94±0.32 16 4.12±0.38 3.86±0.45 4.15±0.22 3.94±0.35 17 4.12±0.36 3.85±0.52 4.26±0.22 4.05±0.31 18 4.09±0.40 3.83±0.58 4.29±0.25 4.09±0.29 19 4.14±0.42 4.05±0.38 4.33±0.25 4.16±0.32 20 4.15±0.47 4.05±0.36 4.38±0.29 4.20±0.32				Body weight gain Weeks 1-10 0.15±0.20 0.27±0.15 0.03±0.34 -0.13±0.21c Post-exposure, 11d 4.17±0.39 4.01±0.36 4.10±0.46 3.77±0.28 12 4.20±0.38 3.98±0.35 4.14±0.46 3.84±0.28 13 4.14±0.40 4.08±0.38 4.20±0.49 3.98±0.26 14 4.05±0.42 4.02±0.38 4.11±0.36 3.91±0.24 15 4.13±0.40 3.97±0.41 3.99±0.39 3.94±0.32 16 4.12±0.38 3.86±0.45 4.15±0.22 3.94±0.35 17 4.12±0.36 3.85±0.52 4.26±0.22 4.05±0.31 18 4.09±0.40 3.83±0.58 4.29±0.25 4.09±0.29 19 4.14±0.42 4.05±0.38 4.33±0.25 4.16±0.32 20 4.15±0.47 4.05±0.36 4.38±0.29 4.20±0.32
	a 雄ウサギ10匹の群にエピクロロヒドリン蒸気の 0、5、25、又は 50 ppm を6時間/日、5日/週、10週間暴露した。 b データはキログラム当たりで表されている。平均値 + S.D. c 分散分析及びDunnett法により対照群の値と有意差あり、 p<0.05。 d 0、5、及び 25 ppm の暴露レベルで4匹のウサギを10週間の暴露中に屠殺した。50 ppmで3匹のウサギを屠殺した。この用量レベルでは暴露期間中に追加の2匹が死亡した。 暴露10週後に行われた精液の検査では精子の形態、運動性、生存率又は濃度に有害な影響はみられなかった。				a Groups of 10 male rabbits were exposed to 0, 5, 25, or 50 ppm of epichlorohydrin vapor for 6 hrs/day; 5 days/week for 10 weeks. b Data are expressed in kilograms, means + S.D. c Significantly different from the control value by an analysis of variance and Dunnett's test, p<0.05. d Four rabbits at the 0, 5, and 25 ppm exposure levels were sacrificed during the 10th week of exposure. Three rabbits were sacrificed at the 50 ppm level; 2 additional rabbits died during the exposure period at this dose level. Measurements of semen samples made after 10 weeks of exposure indicated no adverse effects on sperm morphology, motility, viability or concentration.
注釈	生殖パラメータ - 吸入によりエピクロロヒドリンに暴露した雄ウサギの精子の運動性 暴露レベル, ppm a 試験の週 PMb 0 5 25 50 NM NP NM NP NM NP NM NP NM NP NM % 運動性 c 暴露前、-2 58±27 33±30 10±5 48±22 40±26 12±11 46±23 42±26 13±10 56±8 31±11 13±8 暴露前、-1 45±29 47±31 8±6 52±25 31±22 17±30 56±21 34±23 10±10 50±24 42±27 8±4 週 1 64±15 26±16 10±6 58±21 34±25 9±10 48±32 37±27 15±17 50±35 38±28 12±14 2 55±24 31±21 14±9 40±36 37±33 23±12 43±27 36±26 21±11 55±25 32±15 12±12 3 49±29 33±30 18±14 36±25 39±32 25±31 25±22 64±30 12±11 38±36 28±28 34±37 4 36±28 42±28 23±29 28±27 50±23 22±18 32±32 44±2 23±26 26±23 60±92 14±14 5 33±16 60±20 10±13 29±32 55±25 16±16 26±34 43±35 30±39 39±28 43±27 18±32 6 50±25 26±17 24±28 24±24 44±25 32±33 37±26 38±18 25±20 34±10 51±30 14±25 7 36±31 35±23 28±22 32±21 35±26 34±30 21±20 38±30 40±31 20±30 38±15 41±39 8 34±30 48±24 21±21 33±32 48±32 19±32 44±37 30±22 25±33 38±33 34±28 29±33 9 27±19 52±29 21±15 31±25 52±25 17±14 19±24 64±21 16±12 35±32 47±30 18±17 10 33±24 55±24 13±12 23±17 61±14 15±10 34±36 22±17d 44±36d 28±24 49±31 23±25				Reproductive Parameters - Motility of Sperm from Male Rabbits Exposed to Epichlorohydrin by Inhalation Exposure Level, ppm a Week of Study PMb 0 5 25 50 % Motility c Pre-exp-2 58±27 33±30 10±5 48±22 40±26 12±11 46±23 42±26 13±10 56±8 31±11 13±8 Pre-exp-1 45±29 47±31 8±6 52±25 31±22 17±30 56±21 34±23 10±10 50±24 42±27 8±4 Week 1 64±15 26±16 10±6 58±21 34±25 9±10 48±32 37±27 15±17 50±35 38±28 12±14 2 55±24 31±21 14±9 40±36 37±33 23±12 43±27 36±26 21±11 55±25 32±15 12±12 3 49±29 33±30 18±14 36±25 39±32 25±31 25±22 64±30 12±11 38±36 28±28 34±37 4 36±28 42±28 23±29 28±27 50±23 22±18 32±32 44±2 23±26 26±23 60±92 14±14 5 33±16 60±20 10±13 29±32 55±25 16±16 26±34 43±35 30±39 39±28 43±27 18±32 6 50±25 26±17 24±28 24±24 44±25 32±33 37±26 38±18 25±20 34±10 51±30 14±25 7 36±31 35±23 28±22 32±21 35±26 34±30 21±20 38±30 40±31 20±30 38±15 41±39 8 34±30 48±24 21±21 33±32 48±32 19±32 44±37 30±22 25±33 38±33 34±28 29±33 9 27±19 52±29 21±15 31±25 52±25 17±14 19±24 64±21 16±12 35±32 47±30 18±17 10 33±24 55±24 13±12 23±17 61±14 15±10 34±36 22±17d 44±36d 28±24 49±31 23±25
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注釈	平均の着床部位数、黄体数又は吸収胚数への有意な影響は暴露した雄と交配した雌の間にはみられなかった。雄の繁殖指数は暴露により影響を受けなかった。雄全例が非暴露の雌を妊娠させることができた。暴露した雄と交配した非暴露の雌では対照群 (8%)よりも高い頻度の着床前胚損失を示し、5 ppm群では22%、50 ppm群では27%であった。しかし、これらの値は両方とも試験ラバにおいて歴史的にみられた着床前胚損失割合の範囲、9-27%の範囲内であった。25 ppmでの平均着床前胚損失は僅かに12%であった。従って、生殖/受胎能に対するNOAELは50 ppmであった。				No significant effects on the average number of implantations, corpora lutea, or resorptions were observed among females bred to exposed males. The fertility index of males was not affected by exposure; all males were able to impregnate an unexposed female. The unexposed females bred to exposed males showed a higher incidence of preimplantation loss than the control group (8%), 22% for the 5 ppm group and 27% for the 50 ppm group. However, both of these values were within the range of pre-implantation loss percentage observed historically among rabbits within the testing laboratory, a range of 9-27%. The average preimplantation loss at 25 ppm was only 12%. Therefore, the NOAEL for reproduction/fertility effects was 50 ppm.

注釈	<p>生殖パラメータ－吸入によりエピクロロヒドリンに暴露した雄ウサギと交配した非暴露の雌ウサギにおける平均着床数、黄体数、及び胚吸収数</p> <table><thead><tr><th></th><th colspan="4">暴露レベル、ppma</th></tr><tr><th>試験の週</th><th>0</th><th>5</th><th>25</th><th>50</th></tr></thead><tbody><tr><td>第10週－</td><td></td><td></td><td></td><td></td></tr><tr><td>平均着床数</td><td>9±4</td><td>7±3b</td><td>8±2</td><td>7±3</td></tr><tr><td>平均黄体数</td><td>8±3</td><td>9±1</td><td>8±2</td><td>9±3</td></tr><tr><td>平均吸収胚数</td><td>1±1</td><td>0.8±1</td><td>1±2</td><td>0.6±1</td></tr><tr><td>雄の繁殖指数、%</td><td></td><td></td><td></td><td></td></tr><tr><td>雌を妊娠させた雄の例数/ 雌と交配した雄の例数</td><td>80(8/10)</td><td>90(9/10)</td><td>100(10/10)</td><td>100(8/8)</td></tr></tbody></table> <p>Reproductive Parameters – Average Number of Implantations, Corpora Lutea, and Resorptions in Unexposed Female Rabbits Bred to Male Rabbits Exposed to Epichlorohydrin by Inhalation</p> <table><thead><tr><th></th><th colspan="4">Exposure Level, ppma</th></tr><tr><th>Week of Study</th><th>0</th><th>5</th><th>25</th><th>50</th></tr></thead><tbody><tr><td>Week 10－</td><td></td><td></td><td></td><td></td></tr><tr><td>Average implantations</td><td>9±4</td><td>7±3b</td><td>8±2</td><td>7±3</td></tr><tr><td>Average corpora lutea</td><td>8±3</td><td>9±1</td><td>8±2</td><td>9±3</td></tr><tr><td>Average resorptions</td><td>1±1</td><td>0.8±1</td><td>1±2</td><td>0.6±1</td></tr><tr><td>Male Fertility Index, %</td><td></td><td></td><td></td><td></td></tr><tr><td>No. Fertile Males/ No. Males Bred to Females:</td><td>80(8/10)</td><td>90(9/10)</td><td>100(10/10)</td><td>100(8/8)</td></tr></tbody></table>		暴露レベル、ppma				試験の週	0	5	25	50	第10週－					平均着床数	9±4	7±3b	8±2	7±3	平均黄体数	8±3	9±1	8±2	9±3	平均吸収胚数	1±1	0.8±1	1±2	0.6±1	雄の繁殖指数、%					雌を妊娠させた雄の例数/ 雌と交配した雄の例数	80(8/10)	90(9/10)	100(10/10)	100(8/8)		Exposure Level, ppma				Week of Study	0	5	25	50	Week 10－					Average implantations	9±4	7±3b	8±2	7±3	Average corpora lutea	8±3	9±1	8±2	9±3	Average resorptions	1±1	0.8±1	1±2	0.6±1	Male Fertility Index, %					No. Fertile Males/ No. Males Bred to Females:	80(8/10)	90(9/10)	100(10/10)	100(8/8)	
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Average pre-implantation loss, % b	8	22c	12	27c																																																																														
Average resorption rate, % d	12	11	15	8																																																																														
注釈	<p>a 雄ウサギ10匹の群をエピクロロヒドリン蒸気に 0、5、25、又は 50 ppm で6時間/日、5日/週、10週間暴露した。暴露の10週目に各雄ウサギを1匹の非暴露雌ウサギと交配させた。</p> <p>b 着床前胚損失 = (# 黄体 – # 着床) / # 黄体 X 100</p> <p>c Wilcoxon変法により対照群値と有意差あり、p &lt; 0.05</p> <p>d 胚吸収率 = # 吸収胚数 / # 着床数 X 100</p> <p>a Groups of 10 male rabbits were exposed to 0, 5, 25, or 50 ppm of epichlorohydrin vapor for 6 hrs/day; 5 days/week for 10 weeks. During the 10th week of exposure; each male rabbit was allowed to breed one unexposed female rabbit.</p> <p>b Pre-implantation loss = (# corpora lutea – # implantations) / # corpora lutea X 100</p> <p>c Significantly different from the control value by a modified Wilcoxon test, p &lt; 0.05</p> <p>d Resorption rate = # resorptions / # implantations X 100</p>																																																																																	
結論																																																																																		
Pに対するNOAEL (NOEL)又はLOAEL (LOEL)	NOAEL 母動物 : = 5 ppm その他: NOAEL 受胎能 : = 50 ppm	NOAEL parental : = 5 ppm other: NOAEL fertility : = 50 ppm																																																																																
F1に対するNOAEL (NOEL)又はLOAEL (LOEL)																																																																																		
F2に対するNOAEL (NOEL)又はLOAEL (LOEL)																																																																																		
注釈																																																																																		
信頼性	(1) 制限なく信頼性あり 1d	(1) valid without restriction 1d																																																																																
信頼性の判断根拠																																																																																		
出典																																																																																		
引用文献(元文献)	(212)	(212)																																																																																
備考	フラグ: SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint																																																																																

試験物質名	他のTS	other TS
CAS番号		
純度等	純度 99+%, Aldrich Chemical コーン油で希釈したECH	99+% purity, Aldrich Chemical ECH diluted in corn oil
注釈		
方法		
方法/ガイドライン	その他	other
試験のタイプ	受胎能	Fertility
GLP適合	データなし	no data
試験を行った年	1989	1989
試験系(種/系統)	ラット Long-Evans	rat Long-Evans
性別(雄:M、雌:F)	雄	male
投与量	0、12.5、25、50 mg/kg/日	0, 12.5, 25, 50 mg/kg/day.
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	強制経口	gavage



試験期間	21日間	21 days
交配前暴露期間	雄：21日間 雌：該当せず	Male : 21 days Female : not applicable
試験条件	暴露期間：21日間 処置頻度：1日1回、5日/週 対照群：あり、溶媒対照	Exposure period : 21 days Frequency of treatm. : once a day, 5 days/week Control group : yes, concurrent vehicle
試験条件	※英文参照	Remark : In a well-conducted and well-reported study, groups of 20 (m) and 10 (f) rats received ECH by oral gavage. Males received ECH daily prior to mating to evaluate effects on late-stage spermatids and epididymal spermatozoa only. At the end of the treatment, ejaculatory sperm was assessed by mating each (m) with hormonally primed untreated (f). Two days later, (m) in the 0 and 50 mg/kg groups only were allowed to mate for up to 5 days with a different prooestrus (f) each day until each (m) had copulated successfully with one female. The (f) were sacrificed on day 15 of pregnancy and corpora lutea, implantations and resorptions were counted. (m) were sacrificed 48 h. after successful mating to access testicular and epididymal sperm. For the measurement of cauda epididymal motion, an additional group of animals was used at each dose level and treated with ECH using an identical protocol to the one described above. These groups were mated 2 days after the last day of dosing (day 23) corresponding to the matings used for ejaculatory sperm assessment described above.
統計学的処理		
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
妊娠率(妊娠個体数/交配数)		
交尾前期間(交配までの日数及び交配までの性周期回数)		
妊娠期間(妊娠0日から起算)		
妊娠指数(生存胎仔数/着床痕数)		
哺乳所見		
性周期変動		
精子所見		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)		
着床数		
黄体数		
未熟卵胞数		
臓器重量		
病理組織学的所見(発生率、重篤度)		
実際に摂取された量		
用量反応性		
同腹仔数及び体重		
性比		
生存率(生後4日目生存仔数/総分娩仔数)		
離乳までの分娩後生存率		
新生仔所見(肉眼的な異常)		
生後発育及び発育率		
陰開口又は精巣下降(包皮分離)		
生殖器-肛門間距離などその他の観察事項		
臓器重量		
統計的結果		
注釈	交配試験で最高用量群では完全不妊(同腹の生存児は産生されず)が示されたが、交配成績又は選択した精子検査(精子の形態、運動能のある精子の割合)への影響はなかった。精子の速度/パラメータは全ての投与レベルで低下した。同じ試験において25及び50 mg/kg体重/日で交配前に14日間投与した雌は生殖あるいは受胎能への影響を示さなかった(100 mg/kg体重/日の高用量群は毒性過剰のために途中で終了した)。本試験の生殖/受胎能に対するNOAELは雄では25 mg/kg体重/日、及び雌では50 mg/kg体重/日であった。	Complete sterility (no viable litters produced) in the highest dose group in the mating trials but there no effects on mating performance, or selected sperm measurements (sperm morphology and percentage mobile sperm). Sperm velocity parameters were decreased at all treatment levels. In the same study, females dosed by gavage with 25 and 50 mg/kg body weight/day for 14 days prior to mating showed no effects on reproduction or fertility (a high dose group of 100 mg/kg body weight/day was terminated due to excessive toxicity). In the same study, females dosed by gavage with 25 and 50 mg/kg body weight/day for 14 days prior to mating showed no effects on reproduction or fertility (a high dose group of 100 mg/kg body weight/day was terminated due to excessive toxicity). The NOAELs for reproduction/fertility in this study were 25 mg/kg body weight/day for males and 50 mg/kg body weight/day for females.
結論		
P1に対するNOAEL (NOEL)又はLOAEL (LOEL)	NOAEL 親動物 : = 25 mg/kg 体重	NOAEL parental : = 25 mg/kg bw
F1に対するNOAEL (NOEL)又はLOAEL (LOEL)		
F2に対するNOAEL (NOEL)又はLOAEL (LOEL)		
注釈		
信頼性	(1) 制限なく信頼性あり 1d	(1) valid without restriction 1d
信頼性の判断根拠		

出典		
引用文献(元文献)	(213)	(213)
備考	フラグ： SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint
試験物質名	他のTS	other TS
CAS番号		
純度等	純度 99+%, Aldrich Chemical コーン油で希釈したECH	99+% purity, Aldrich Chemical ECH diluted in corn oil
注釈		
方法		
方法／ガイドライン	その他	other
試験のタイプ	受胎能	Fertility
GLP適合	データなし	no data
試験を行った年	1989	1989
試験系(種／系統)	ラット Long-Evans	rat Long-Evans
性別(雄:M、雌:F)	雌	female
投与量	0、25、50、100 mg/kg 体重	0, 25, 50, 100 mg/kg b.w
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	強制経口	gavage
試験期間	8週間	8 weeks
交配前暴露期間	雄：該当せず 雌：2週間	Male : not applicable Female : 2 weeks
試験条件	暴露期間：5週間 処置頻度：1日1回、5日/週 対照群：あり、溶媒対照	Exposure period : 5 weeks Frequency of treatm. : once a day, 5 days/week Control group : yes, concurrent vehicle
試験条件	※英文参照	Remark : In a well-conducted and well-reported study, groups of 20 (m) and 10 (f) rats received ECH by oral gavage. Females received ECH prior to mating with an untreated (m) and then treatment continued through pregnancy until parturition. If delivery of a litter had not occurred by day 23 of pregnancy, (f) were killed and examined for signs of pregnancy. Litters were sexed on day one culled to eight pups [4 (m) + 4 (f)] on post-natal day 8 followed through until day 42.
統計学的処理		
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
妊娠率(妊娠個体数/交配数)		
交尾前期間(交配までの日数及び交配までの性周期回数)		
妊娠期間(妊娠0日から起算)		
妊娠指数(生存胎仔数/着床痕数)		
哺乳所見		
性周期変動		
精子所見		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)		
着床数		
黄体数		
未熟卵胞数		
臓器重量		
病理組織学的所見(発生率、重篤度)		
実際に摂取された量		
用量反応性		
同腹仔数及び体重		
性比		
生存率(生後4日目生存仔数/総分娩仔数)		
離乳までの分娩後生存率		
新生仔所見(肉眼的な異常)		
生後発育及び発育率		
陰開口又は精巣下降(包皮分離)		
生殖器-肛門間距離などその他の観察事項		
臓器重量		
統計的結果		
注釈	投与第1週に100 mg/kg体重/日群ではラット全例が死亡した、又は瀕死のため切迫屠殺された。剖検時に胃の出血及び皮質の蒼白化及び髄質の出血を伴った腎臓の出血がみられた。残りの動物には投与に関連した有意な影響は示されなかった。  雌の受胎能又は児動物の平均数及び生存率又は離乳時の体重には影響はみられなかった。	Within the first week of treatment, all rats in the 100 mg/kg/day group died or were so moribund as to warrant sacrifice. On autopsy, findings included hemorrhagic stomachs and kidneys with pale cortices and hemorrhagic medullae. The remaining animals showed no significant treatment-related effects.  No effect was seen on female fertility or on mean number and survival of the offspring or weaning weight.
結論		
PIに対するNOAEL (NOEL)又はLOAEL (LOEL)	NOAEL 親動物 : = 50 mg/kg 体重 その他: NOEL 受胎能 : = 50 mg/kg 体重	NOAEL parental : = 50 mg/kg bw other: NOEL fertility : = 50 mg/kg bw

F1に対するNOAEL (NOEL)又は LOAEL (LOEL)	NOAEL F1 児動物 : = 50 mg/kg 体重	NOAEL F1 offspring : = 50 mg/kg bw
F2に対するNOAEL (NOEL)又は LOAEL (LOEL)		
注釈		
信頼性	(1) 制限なく信頼性あり 1d	(1) valid without restriction 1d
信頼性の判断根拠		
出典		
引用文献(元文献)	(213)	(213)
備考		

試験物質名	他のTS	other TS
CAS番号		
純度等	B.D.H. Chemicals Ltd から入手したECH (純度不明)を蒸留して精製した。	ECH obtained from B.D.H. Chemicals Ltd. (purity unspecified) were purified by distillation.
注釈		
方法		
方法／ガイドライン	その他	other
試験のタイプ	受胎能	Fertility
GLP適合	いいえ	no
試験を行った年	1974	1974
試験系(種／系統)	ラット Wistar	rat Wistar
性別(雄:M、雌:F)	雄	male
投与量	20、50、又は 100 mg/kg	20, 50, or 100 mg/kg
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	強制経口	gavage
試験期間	10週間又は20週間	10 weeks or 20 weeks
交配前暴露期間	雄: 5日又は1日 雌: 無処置	Male : 5 days or 1 day Female : untreated
試験条件	暴露期間: 5日間 (20又は50 mg/kg/日)又は1日間 (100 mg/kg) 処置頻度: 毎日 対照群:あり	Exposure period : 5 days (20 or 50 mg/kg/day) or 1 day (100 mg/kg) Frequency of treatm. : daily
試験条件	※英文参照	Groups of 5 male rats were treated either for 5 consecutive days with 20 or 50 mg/kg or given a single dose of 100 mg/kg of ECH by oral gavage and then mated with untreated females during a 10 week period post-exposure. Other groups (size unspecified) of males were treated with a single oral dose of 100 mg/kg and sacrificed up to 20 weeks post-treatment. Reproductive tissues for these animals were examined histologically.
統計学的処理		
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
妊娠率(妊娠個体数/交配数)		
交尾前期間(交配までの日数及び交配までの性周期回数)		
妊娠期間(妊娠0日から起算)		
妊娠指数(生存胎仔数/着床痕数)		
哺乳所見		
性周期変動		
精子所見		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)		
着床数		
黄体数		
未熟卵胞数		
臓器重量		
病理組織学的所見(発生率、重篤度)		
実際に摂取された量		
用量反応性		
同腹仔数及び体重		
性比		
生存率(生後4日目生存仔数/総分娩仔数)		
離乳までの分娩後生存率		
新生仔所見(肉眼的な異常)		
生後発育及び発育率		
陰開口又は精巣下降(包皮分離)		
生殖器-肛門間距離などその他の観察事項		
臓器重量		
統計的結果		

注釈	ECHによる反復投与は無処置雌との交配により評価したように雄の不妊を生じた。 単回投与後の繁殖試験は歴史的対照と比較して腹当たりの児動物の過ごとの平均数の低下を生じた。 ECHの単回投与を受けた雄での病理組織学的な試験では投与後8週まで明らかな影響は示されなかったが、12週までに貯留した精子の大きな嚢胞が4/5のラットで精巢の輸出小管及び近位精巢上体尾部にみられた。	Multiple treatments with ECH resulted in male infertility as assessed by mating with untreated female. Fertility studies following a single dose resulted in a reduction in the weekly average numbers of offspring per litter compared to historical controls. Histopathological studies on males receiving a single dose of ECH indicated no apparent effects up to 8 weeks post-treatment, but by week 12 large cysts of retained sperm were observed in the ductuli efferentes of the testis and the proximal caput epididymis in 4/5 rats.
結論		
PIに対するNOAEL (NOEL)又はLOAEL (LOEL)	LOEL 親動物 : = 20 mg/kg 体重	LOEL parental : = 20 mg/kg bw
F1Iに対するNOAEL (NOEL)又はLOAEL (LOEL)		
F2Iに対するNOAEL (NOEL)又はLOAEL (LOEL)		
注釈		
信頼性	(2) 制限付きで信頼性あり 2e	(2) valid with restrictions 2e
信頼性の判断根拠		
出典		
引用文献(元文献)	(214)	(214)
備考		

試験物質名		
CAS番号		
純度等		
注釈		
方法		
方法／ガイドライン		
試験のタイプ	その他: 精巣毒性	other: testicular toxicity
GLP適合		
試験を行った年		
試験系(種／系統)	ラット	rat
性別(雄:M、雌:F)	雄	male
投与量	25、50 mg ECH/kg 体重	25, 50 mg ECH/kg b.w.
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	経口、非特定	oral unspecified
試験期間		
交配前暴露期間		
試験条件	暴露期間 : 単回投与 処置頻度 : 1回	Exposure period : single treatment Frequency of treatm. : once
統計学的処理		
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
妊娠率(妊娠個体数/交配数)		
交尾前期間(交配までの日数及び交配までの性周期回数)		
妊娠期間(妊娠0日から起算)		
妊娠指数(生存胎仔数/着床痕数)		
哺乳所見		
性周期変動		
精子所見		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)		
着床数		
黄体数		
未熟卵胞数		
臓器重量		
病理組織学的所見(発生率、重篤度)		
実際に摂取された量		
用量反応性		
同腹仔数及び体重		
性比		
生存率(生後4日目生存仔数/総分娩仔数)		
離乳までの分娩後生存率		
新生仔所見(肉眼的な異常)		
生後発育及び発育率		
陰開口又は精巣下降(包皮分離)		
生殖器-肛門間距離などその他の観察事項		
臓器重量		
統計的結果		

注釈	50 mg/kg群では形態的に異常な精子の数が有意に増加したが、25 mg/kg群では精子の総数の有意な低下が観察されたに過ぎなかった。それ以上の解釈は提供できない。 動物は処置後11日に屠殺された。精巣重量の有意な減少はみられなかった。	The number of morphologically abnormal sperm was significantly increased in the 50 mg/kg group, while a significant reduction in the total number of sperm was only observed in the 25 mg/kg group. No further interpretation offered. The animals were sacrificed 11 days after treatment. There was no significant decrease in weight of the testes.
結論		
Pに対するNOAEL (NOEL)又はLOAEL (LOEL)		
F1に対するNOAEL (NOEL)又はLOAEL (LOEL)		
F2に対するNOAEL (NOEL)又はLOAEL (LOEL)		
注釈		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	(215)	(215)
備考		

試験物質名	他のTS	other TS
CAS番号		
純度等	純度 >99%	>99% purity
注釈		
方法		
方法／ガイドライン	その他	other
試験のタイプ	その他: 精巣毒性	other: testicular toxicity
GLP適合	データなし	no data
試験を行った年	1983	1983
試験系(種／系統)	ラット	rat
	Fischer 344	Fischer 344
性別(雄:M、雌:F)	雄	male
投与量	75 mg/kg	75 mg/kg
各用量群(性別)の動物数		
溶媒(担体)		
投与経路	皮下投与	s.c.
試験期間	75日間	75 days
交配前暴露期間	雄: 該当せず 雌: 該当せず	Male : not applicable Female : not applicable
試験条件	暴露期間: 1日 対照群: あり、溶媒対照	Exposure period : 1 day Control group : yes, concurrent vehicle
試験条件	※英文参照	Remark : Groups of 40 males were treated once and then serially sacrificed (8 each time) up to 75 days after treatment. Route of administration not relevant to potential human exposure.
統計学的処理		
結果		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
妊娠率(妊娠個体数/交配数)		
交尾前期間(交配までの日数及び交配までの性周期回数)		
妊娠期間(妊娠0日から起算)		
妊娠指数(生存胎仔数/着床痕数)		
哺乳所見		
性周期変動		
精子所見		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
尿検査所見(発生率、重篤度)		
死亡数(率)、死亡時間		
剖検所見(発生率、重篤度)		
着床数		
黄体数		
未熟卵胞数		
臓器重量		
病理組織学的所見(発生率、重篤度)		
実際に摂取された量		
用量反応性		
同腹仔数及び体重		
性比		
生存率(生後4日目生存仔数/総分娩仔数)		
離乳までの分娩後生存率		
新生仔所見(肉眼的な異常)		
生後発育及び発育率		
陰開口又は精巣下降(包皮分離)		
生殖器-肛門間距離などその他の観察事項		
臓器重量		
統計的結果		

注釈	処置後25及び50日に処置群では精子濃度は低下し、精巢上体尾部の異常な精子の割合は増加した。組織学的検査の結果、75日までに試験したラットの90%で精細管の萎縮を導く進行性の変性が示された。精子顆粒膜の形成 (3/8匹)及び精液瘤 (2/8匹)も精巢上体尾部でみられた。	Sperm concentration was reduced in the treated group and the percent of abnormal sperm in the cauda epididymis increased at 25 and 75 days after treatment. Histological examination revealed progressive degeneration leading to atrophy of the seminiferous tubules in 90 % of the tested rats by day 75. Formation of sperm granuloma (3/8 rats) and spermatocoeles (2/8 rats) were also found in the caput region of the epididymis.
結論		
PIに対するNOAEL (NOEL)又はLOAEL (LOEL)		
F1に対するNOAEL (NOEL)又はLOAEL (LOEL)		
F2に対するNOAEL (NOEL)又はLOAEL (LOEL)		
注釈		
信頼性	(2) 制限付きで信頼性あり	(2) Valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	(217)	(217)
備考		

## B. 発生毒性

### DEVELOPMENTAL TOXICITY

試験物質名	他のTS	other TS
CAS番号		
純度等	純度 = 99.8%	Purity = 99.8%
注釈		
方法		
方法／ガイドライン	その他	other
GLP適合	いいえ	no
試験を行った年	1979	1979
試験系(種／系統)	ラット Sprague-Dawley	rat Sprague-Dawley
性別(雄:M、雌:F)	雌	female
投与量	2.5、25 ppm	2.5, 25 ppm
各用量群(性別)の動物数		
投与経路	吸入	inhalation
試験期間	21日間	21 d
交配前暴露期間		
試験条件	暴露期間: 妊娠6-15日 処置頻度: 7時間/日 対照群: あり	Exposure period : day 6-15 Frequency of treatm. : 7 h/d Control group : yes
試験条件	※英文参照	TEST ORGANISMS: Groups of 43-46 pregnant Sprague-Dawley rats (~250 g) per dose level were exposed to 0, 2.5, or 25 ppm seven hours per day on days 6 through 15 of gestation.  ADMINISTRATION/EXPOSURE Whole-body exposures were carried out in 4.3 cubic meter Rochester-type chambers. Atmospheres were generated by metering liquid through a pump into a warmed vaporization flask, then sweeping the vapors into the chamber with compressed air. Chamber air was assayed for vapor concentration 2-7 times during each 7-hour exposure period.  Chamber Concentrations (ppm): Target 0 2.5 25 Nominal 0 2.43+/-0.32 24.4+/-1.1 Analytical 0 2.46+/-0.32 24.6+/-1.0
試験条件	※英文参照	PARAMETERS ASSESSED DURING STUDY Animals were observed daily during the exposure period for signs of toxicity. Body weights were recorded on gestation days 6-10, 12, and 16. Food and water consumption were also recorded at 3-day intervals beginning on gestation day 6.  Cesarean-sections were performed on all animals on gestation day 21. Liver weights were recorded at that time, and samples of nasal turbinates, trachea, and lungs were preserved for possible histologic examination. Examination of these tissues was not deemed necessary.  At cesarean-section, developmental parameters were recorded: the number and position of live, dead, and resorbed fetuses, the number of corpora lutea, and the weight of the gravid uterus with ovaries attached. After being weighed and measured for crown-rump length, all fetuses were examined for external alterations and cleft palate. One-third of each litter, randomly selected, was examined for evidence of soft-tissue alterations by fresh dissection. Heads of fetuses undergoing soft-tissue examination were preserved in Bouin's fixative and examined by free-hand serial sectioning. All fetuses were then eviscerated and processed for skeletal examination.
統計学的処理		
結果		
死亡数(率)、死亡時間		
用量あたり妊娠数		
流産数		
早期/後期吸収数		
着床数		

黄体数																										
妊娠期間(妊娠0日から起算)																										
体重、体重増加量																										
摂餌量、飲水量																										
臨床所見(重篤度、所見の発現時期と持続時間)																										
血液学的所見(発生率、重篤度)																										
血液生化学的所見(発生率、重篤度)																										
剖検所見(発生率、重篤度)																										
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統計的結果																										
注釈	NOAEL/LOAEL  母動物のLOAELでは母動物の体重及び摂餌量の減少を含む影響が25 ppmの暴露レベルで観察された。母動物毒性のNOELは2.5 ppmであった。  処置に関連した影響は胚又は胎児にはいずれの暴露レベルでもみられなかった。従って、胎児のNOELは25 ppmであった。	NOAEL/LOAEL  At the maternal LOAEL, effects including reduced body weight and food intake for the dams were observed at the 25 ppm exposure level. The NOEL for maternal toxicity was 2.5 ppm.  No adverse effects related to treatment were observed in the embryos or fetuses at any exposure level. Therefore, the fetal NOEL was 25 ppm.																								
注釈	吸入によりエピクロロヒドリンに暴露された妊娠ラットの体重及び肝臓重量 <table><tr><td></td><td colspan="3">ppm エピクロロヒドリン (a)</td></tr><tr><td></td><td>0</td><td>2.5</td><td>25</td></tr><tr><td>母動物数(b)</td><td>36</td><td>33</td><td>32</td></tr></table> 各妊娠日の母動物 (g) 体重 6 277+/-26(c) 263+/-27(d) 262+/-20(d) 8 284+/-26 272+/-23 263+/-20(d) 10 294+/-27 280+/-24(d) 271+/-20(d) 12 305+/-28 294+/-23 283+/-21(d) 16 334+/-31 324+/-23 311+/-21(d) 21 413+/-41 402+/-43 394+/-31  各妊娠日の母動物 (g) 体重増加量 6-7 6+/-3 8+/-6 1+/-7(d) 8-9 10+/-5 8+/-9 8+/-9 10-11 1+/-5 14+/-8 12+/-8 12-15 30+/-9 31+/-7 29+/-9 16-20 79+/-17 77+/-21 82+/-19 6-21計 136+/-27 138+/-34 131+/-28  21日の母動物肝臓重量 絶対重量(e) 15.97+/-1.77 16.12+/-1.72 15.83+/-1.76 相対重量(f) 38.82+/-3.87 40.25+/-2.90 40.30+/-4.08  21日の妊娠子宮重量 絶対重量(d) 97+/-29 89+/-34 93+/-24 体重による 補正值 (g) 316+/-25 313+/-22 297+/-22(d)		ppm エピクロロヒドリン (a)				0	2.5	25	母動物数(b)	36	33	32	BODY AND LIVER WEIGHTS OF PREGNANT RATS EXPOSED TO EPICHLOROHYDRIN BY INHALATION <table><tr><td></td><td colspan="3">ppm Epichlorohydrin (a)</td></tr><tr><td></td><td>0</td><td>2.5</td><td>25</td></tr><tr><td>Number of Dams(b)</td><td>36</td><td>33</td><td>32</td></tr></table> Maternal body weight (g) on gestation day 6 277+/-26(c) 263+/-27(d) 262+/-20(d) 8 284+/-26 272+/-23 263+/-20(d) 10 294+/-27 280+/-24(d) 271+/-20(d) 12 305+/-28 294+/-23 283+/-21(d) 16 334+/-31 324+/-23 311+/-21(d) 21 413+/-41 402+/-43 394+/-31  Maternal body weight gain (g) on gestation days 6-7 6+/-3 8+/-6 1+/-7(d) 8-9 10+/-5 8+/-9 8+/-9 10-11 1+/-5 14+/-8 12+/-8 12-15 30+/-9 31+/-7 29+/-9 16-20 79+/-17 77+/-21 82+/-19 Total 6-21 136+/-27 138+/-34 131+/-28  Maternal Liver weight on day 21 Absolute(e) 15.97+/-1.77 16.12+/-1.72 15.83+/-1.76 Relative(f) 38.82+/-3.87 40.25+/-2.90 40.30+/-4.08  Gravid Uterus Weight on day 21 Absolute(d) 97+/-29 89+/-34 93+/-24 Adjusted body weight (g) 316+/-25 313+/-22 297+/-22(d)		ppm Epichlorohydrin (a)				0	2.5	25	Number of Dams(b)	36	33	32
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エピクロロヒドリン(a)				0	2.5	25	妊娠雌数	46	44	43	母動物死亡数/妊娠動物数	0/46	0/44	0/43	みかけの妊娠率、%(b)	85(39/46)	86(38/44)	77(33/43)	染色法のみによる妊娠、%(c)	29(2/7)	0(0/6)	10(1/10)	妊娠率、計(d)	89(41/46)	86(38/44)	79(34/43)	腹数	36	33	32	黄体/母動物(e)	14+/-2	14+/-3	15+/-2	着床部位/母動物(e)	13+/-3	12+/-4	13+/-3	着床前損失(e)	2+/-2	3+/-0	2+/-0	胎児/腹(e)	12+/-4	11+/-4	12+/-3	吸収胚/腹 (e,f)	1+/-1	1+/-1	1+/-2	吸収された着床胚のパーセント(f)	5(25/460)	4(17/386)	7(30/408)	吸収胚を示した腹のパーセント(f)	44(16/36)	36(12/33)	44(14/32)	全胚吸収された腹(f)	0	0	0	吸収胚数/吸収胚を示した腹(f)	1.6(25/16)	1.4(17/12)	2.1(30/14)	死亡胎児のパーセント	0.2(1/435)	0(0/369)	0(0/378)	性比、雄:雌、%	47:53	47:53	52:48	胎児体重、(grams)g	5.60+/-0.36	5.59+/-0.44	5.49+/-0.45	胎児の頭尾長、(mm)g	42.7+/-1.8	42.3+/-1.4	42.4+/-1.5	<div>OBSERVATIONS AT CESAREAN SECTION OF RATS EXPOSED TO EPICHLOROHYDRIN BY INHALATION</div> <table><thead><tr><th></th><th colspan="3">ppm Epichlorohydrin(a)</th></tr><tr><th></th><th>0</th><th>2.5</th><th>25</th></tr></thead><tbody><tr><td>Number of bred females</td><td>46</td><td>44</td><td>43</td></tr><tr><td>Number 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注釈	<div>(a) 妊娠ラットに 0、2.5 又は 25 ppm のエピクロロヒドリンを7時間/日で妊娠6-15日に吸入暴露した。</div> <div>(b) 帝王切開又は剖検時に視認可能な着床を示した雌の数/妊娠動物総数。2.5 ppm のエピクロロヒドリンに暴露したラットでは、妊娠21日の前に5匹が分娩した。25 ppm のレベルでは1匹の雌が早期に分娩し、対照群では3匹が妊娠21日の前に分娩した。</div> <div>(c) 硫化ナトリウムで子宮の染色後にもみ妊娠が検出された雌の数/染色した総数</div> <div>(d) 子宮の肉眼検査又は硫化ナトリウム染色による妊娠雌の数/総妊娠数</div> <div>(e) 平均値 +/- 標準偏差。</div> <div>(f) 硫化ナトリウム染色により検出された吸収はこれらの計算からは除外した。</div> <div>(g) 同腹児数平均値 平均値 +/- 標準偏差</div> <div>数値は適切な統計検定によっても対照群と有意差を示さなかった、p&lt;0.05.</div>	<div>(a) Bred rats were exposed to 0, 2.5 or 25 ppm epichlorohydrin by inhalation for 7 hrs/day on days 6 through 15 of gestation.</div> <div>(b) Number of females with visible implantations at the time of C-section or necropsy/total bred. Among rats exposed to 2.5 ppm epichlorohydrin, 5 animals delivered a litter prior to day 21 of gestation. At the 25 ppm level, a single female delivered early, and 3 control rats delivered prior to gestation day 21.</div> <div>(c) Number of females detected as being pregnant only after staining uterus with sodium sulfide stain/total stained.</div> <div>(d) Number of females pregnant by visual inspection of the uterus or by sodium sulfide stain/total bred.</div> <div>(e) Mean +/- S.D.</div> <div>(f) Resorptions detected by sodium sulfide staining were not included in these calculations.</div> <div>(g) Mean of litter means +/- S.D.</div> <div>No values were significantly different from the control values by the appropriate statistical test, p&lt;0.05.</div>																																																																																																																																																																								



注釈	エピクロロヒドリンに吸入暴露したラットの同腹児における胎児の異常頻度(a)					INCIDENCE OF FETAL ALTERATIONS AMONG LITTERS OF RATS EXPOSED TO EPICHLOROHYDRIN BY INHALATION(a)				
	ppm エピクロロヒドリン 0 2.5 25					ppm Epichlorohydrin 0 2.5 25				
	胎児数 (腹数)					Number Fetuses (Number Litters)				
	外表検査		435(36)	369(33)	378(32)	EXTERNAL EXAMINATION		435(36)	369(33)	378(32)
	軟組織検査		147(36)	127(33)	130(32)	SOFT TISSUE EXAMINATION		147(36)	127(33)	130(32)
	骨格検査		435(36)	369(33)	378(32)	SKELETAL EXAMINATION		435(36)	369(33)	378(32)
	頭蓋骨(b)		288(33)	242(29)	248(31)	BONES OF THE SKULL(b)		288(33)	242(29)	248(31)
	影響のあったパーセント (影響があった例数)					Percent Affected (Number Affected)				
	主な奇形の合計数	F(e) L	1(5) 11(4)	1(3) 9(3)	1(3) 9(3)	Total Major Malformations	F(e) L	1(5) 11(4)	1(3) 9(3)	1(3) 9(3)
	外表検査					External Examination				
	短い躯体、尾の形成不全*	F L	0.5(2) 6(2)	0.3(l) 3(l)	0(0) 0(0)	Short Trunk, Hypoplastic Tail*	F L	0.5(2) 6(2)	0.3(l) 3(l)	0(0) 0(0)
	無尾*	F L	0(0) 0(0)	0(0) 0(0)	0.3(l) 3(l)	Acaudia*	F L	0(0) 0(0)	0(0) 0(0)	0.3(l) 3(l)
	複数の顔面異常(d)*	F L	0.2(l) 3(l)	0(0) 0(0)	0(0) 0(0)	Multiple Facial Anomalies(d)*	F L	0.2(l) 3(l)	0(0) 0(0)	0(0) 0(0)
	右後肢の内側への曲がり*	F L	0(0) 0(0)	0.3(l) 3(l)	0(0) 0(0)	Inward rotation of right hind paw*	F L	0(0) 0(0)	0.3(l) 3(l)	0(0) 0(0)
	両後肢の内側への曲がり*	F L	0(0) 0(0)	0(0) 0(0)	0.3(l) 3(l)	Inward rotation of both hind limbs*	F L	0(0) 0(0)	0(0) 0(0)	0.3(l) 3(l)
	皮下の浮腫	F L	0.2(l) 3(l)	0(0) 0(0)	0(0) 0(0)	Subcutaneous Edema	F L	0.2(l) 3(l)	0(0) 0(0)	0(0) 0(0)
	軟組織検査					Soft Tissue Examination				
	尿管拡張 (片側性又は両側性)	F L	3(4) 6(2)	2(3) 6(2)	1(1) 3(l)	Dilated Ureter (Unilateral or Bilateral)	F L	3(4) 6(2)	2(3) 6(2)	1(1) 3(l)
	腎盂拡張 (片側性又は両側性)	F L	l(l) 3(l)	0(0) 0(0)	2(2) 6(2)	Dilated Renal Pelvis (Unilateral or Bilateral)	F L	l(l) 3(l)	0(0) 0(0)	2(2) 6(2)
	脳髄膜瘤*	F L	l(l) 3(l)	0(0) 0(0)	l(l) 3(l)	Encephalomeningocele*	F L	l(l) 3(l)	0(0) 0(0)	l(l) 3(l)
	片側性の外部の水頭症*	F L	0(0) 0(0)	l(l) 3(l)	0(0) 0(0)	Unilateral External Hydrocephalus*	F L	0(0) 0(0)	l(l) 3(l)	0(0) 0(0)
	軽度に拡張した脳室 (脳)	F L	0(0) 0(0)	l(l) 3(l)	0(0) 0(0)	Slightly Dilated Ventricle (brain)	F L	0(0) 0(0)	l(l) 3(l)	0(0) 0(0)
	短くなった左側脳室 (脳)*	F L	0(0) 0(0)	0(0) 0(0)	l(l) 3(l)	Shortened Left Lateral Ventricle (brain)*	F L	0(0) 0(0)	0(0) 0(0)	l(l) 3(l)
	皮下出血 (頭部-鼻 の領域)	F L	0(0) 0(0)	0(0) 0(0)	l(l) 3(1)	Subcutaneous Hemorrhage (head-nasal area)	F L	0(0) 0(0)	0(0) 0(0)	l(l) 3(1)
	骨格検査					Skeletal Examination				
	頭蓋骨 - 骨化遅延	F L	15(44) 48(16)	14(35) 41(12)	12(30) 58(18)	Skull - delayed ossification	F L	15(44) 48(16)	14(35) 41(12)	12(30) 58(18)
	- 骨島	F L	1(2) 6(2)	2(4) 14(4)	1(2) 7(2)	- bone island	F L	1(2) 6(2)	2(4) 14(4)	1(2) 7(2)
	- 骨化の過剰部位	F L	3(9) 15(5)	2(6) 14(4)	1(3) 6(2)	- extra site of ossification	F L	3(9) 15(5)	2(6) 14(4)	1(3) 6(2)
	- 後頭骨の非癒合及び奇形*	F L	0(0) 0(0)	0.4(l) 3(l)	0(0) 0(0)	- occipital unfused and misshapen*	F L	0(0) 0(0)	0.4(l) 3(l)	0(0) 0(0)
	胸骨分節 - 骨化遅延	F L	4(18) 31(11)	5(18) 39(13)	6(24) 34(11)	Sternebrae - delayed ossification	F L	4(18) 31(11)	5(18) 39(13)	6(24) 34(11)
	- 非癒合	F L	0.2(l) 3(l)	0.3(l) 3(l)	0.3(l) 3(l)	- unfused	F L	0.2(l) 3(l)	0.3(l) 3(l)	0.3(l) 3(l)
	肋骨- 過剰肋骨	F L	1(4) 11(4)	0.3(l) 3(l)	0.5(2) 6(2)	Ribs- extra ribs	F L	1(4) 11(4)	0.3(l) 3(l)	0.5(2) 6(2)
	- 欠損*	F L	0.2(l) 3(l)	0(0) 0(0)	0.3(l) 3(l)	- missing*	F L	0.2(l) 3(l)	0(0) 0(0)	0.3(l) 3(l)
	- 波状肋骨	F L	1(4) 11(4)	0.3(l) 3(l)	0.3(l) 3(l)	- wavy ribs	F L	1(4) 11(4)	0.3(l) 3(l)	0.3(l) 3(l)

注釈	脊椎 - 欠損*	F L	1(3) 8(3)	0.3(1) 3(1)	0.3(1) 3(1)	Vertebrae - missing*	F L	1(3) 8(3)	0.3(1) 3(1)	0.3(1) 3(1)
	- 奇形*	F L	0.2(1) 3(1)	0(0) 0(0)	0(0) 0(0)	- misshapen*	F L	0.2(1) 3(1)	0(0) 0(0)	0(0) 0(0)
	- 頸椎中心の骨化遅延	F L	25(107) 72(26)	23(84) 76(25)	28(105) 78(25)	- delayed ossification of cervical centra	F L	25(107) 72(26)	23(84) 76(25)	28(105) 78(25)
	- 二裂になった中心胸椎	F L	5(22) 39(14)	7(25) 52(17)	5(18) 28(9)	- bilobed thoracic centra	F L	5(22) 39(14)	7(25) 52(17)	5(18) 28(9)
	- 中心胸椎の非癒合	F L	0.2(1) 3(1)	1(3) 6(2)	1(4) 13(4)	- unfused thoracic centra	F L	0.2(1) 3(1)	1(3) 6(2)	1(4) 13(4)
	- 小突起	F L	18(76) 75(27)	14(50) 70(23)	13(48) 59(19)	- spurs	F L	18(76) 75(27)	14(50) 70(23)	13(48) 59(19)
	その他					Other				
	- 非対称の骨盤	F L	0(0) 0(0)	0(0) 0(0)	0.3(1) 3(1)	- Asymmetric pelvis	F L	0(0) 0(0)	0(0) 0(0)	0.3(1) 3(1)
	複数の骨格障害(e)*	F L	0.2(1) 3(1)	0(0) 0(0)	0(0) 0(0)	Multiple Skeletal Defects(e)*	F L	0.2(1) 3(1)	0(0) 0(0)	0(0) 0(0)
	(a) 妊娠ラットにエピクロロヒドリンの 0、2.5 又は 25 ppm を7時間/日で妊娠6-15日に吸入暴露した。					(a) Bred rats were exposed to 0, 2.5 or 25 ppm of epichlorohydrin by inhalation for 7 hrs/day on days 6 through 15 of gestation.				
	(b) 4匹以下の胎児を含む腹では、全ての胎児を軟組織の検査中に断頭したため、頭蓋骨の検査には用いられなかった。					(b) In litters containing less than 4 fetuses, all fetuses were decapitated during the soft tissue examination and were therefore not available for examination of bones of the skull.				
	(c) F = 胎児      L = 腹					(c) F = Fetuses      L = Litters				
	(d) 対照群の胎児1匹は鼻の象鼻症の形成、上顎及び下顎の小顎症、小さい頭部及び顔面領域、正常な位置よりも後部についた耳介、及び小眼球を示した。					(d) One fetus in the control group exhibited multiple facial anomalies including the formation of a nasal proboscis, micrognathia of both upper and lower jaws, a small head and facial area, pinnae attached posterior to the normal position, and microphthalmia.				
	(e) 対照群の胎児1匹は脛骨及びひ骨の奇形、右大腿骨の奇形、とう骨及び尺骨の奇形、全頭蓋骨の骨化遅延及び中心非骨化を含む複数の骨格障害を示した。					(e) One control fetus exhibited multiple skeletal defects, including misshapen tibias and fibulas; misshapen right femur; misshapen radii and ulnas; unossified centra and delayed ossification of all skull bones.				
	* 主要な奇形と考えられる。					* Considered to be a major malformation.				
	いずれの値もWilcoxon変法により対照群と有意差なし、P<0.05。					No value differed significantly from the control value by a modified Wilcoxon Test, P<0.05.				
結論										
Pに対するNOAEL (NOEL)又はLOAEL (LOEL)		NOAEL 母動物毒性 : = 2.5 ppm LOAEL 母動物毒性 : = 25 ppm				NOAEL maternal tox. : = 2.5 ppm LOAEL Maternal Toxicity : = 25 ppm				
F1に対するNOAEL (NOEL)又はLOAEL (LOEL)		NOAEL 催奇形性 : > 25 ppm				NOAEL teratogen. : > 25 ppm				
F2に対するNOAEL (NOEL)又はLOAEL (LOEL)										
注釈										
信頼性		(1) 制限なく信頼性あり 1B				(1) valid without restriction 1B				
信頼性の判断根拠										
出典										
引用文献(元文献)		(218) (219)				(218) (219)				
備考		フラグ: SIDSエンドポイントにとって重要な試験				Flag : Critical study for SIDS endpoint				
試験物質名		他のTS				other TS				
CAS番号										
純度等		純度 = 99.8%				Purity = 99.8%				
注釈										
方法										
方法／ガイドライン		その他				other				
GLP適合		いいえ				no				
試験を行った年		1979				1979				
試験系(種／系統)		ウサギ				rabbit				
		ニュージーランド白色				New Zealand white				
性別(雄:M、雌:F)		雌				female				
投与量		2.5、25 ppm				2.5, 25 ppm				
各用量群(性別)の動物数										
投与経路		吸入				inhalation				
試験期間		29日間				29 days				
交配前暴露期間										
試験条件		暴露期間: 妊娠6-18日 処置頻度: 7時間/日 対照群: あり				Exposure period : days 6-18 Frequency of treatm. : 7 hours/day Control group : yes				

試験条件	※英文参照	<p>TEST ORGANISMS: Groups of 16–23 pregnant New Zealand White rabbits (~4 kg) per dose level were exposed to 0, 2.5, or 25 ppm seven hours per day on days 6 through 18 of gestation.</p> <p>ADMINISTRATION/EXPOSURE Whole-body exposures were carried out in 4.3 cubic meter Rochester-type chambers. Atmospheres were generated by metering liquid through a pump into a warmed vaporization flask, then sweeping the vapors into the chamber with compressed air. Chamber air was assayed for vapor concentration 2–7 times during each 7-hour exposure period.</p> <p>Chamber Concentrations (ppm): Target 0 2.5 25 Nominal 0 2.43+/-0.32 24.4+/-1.1 Analytical 0 2.46+/-0.32 24.6+/-1.0</p>
試験条件	※英文参照	<p>PARAMETERS ASSESSED DURING STUDY Animals were observed daily during the exposure period for signs of toxicity. Body weights were recorded on gestation days 6–10, 12, 16, and 19. No food and water consumption data were recorded.</p> <p>Cesarean-sections were performed on all animals on gestation day 29. Liver weights were recorded at that time, and samples of nasal turbinates, trachea, and lungs were preserved for possible histologic examination. Examination of these tissues was not deemed necessary.</p> <p>At cesarean-section, developmental parameters were recorded: the number and position of live, dead, and resorbed fetuses, the number of corpora lutea, and the weight of the gravid uterus with ovaries attached. After being weighed and measured for crown-rump length, all fetuses were examined for external alterations and cleft palate. One-third of each litter, randomly selected, was examined for evidence of soft-tissue alterations by fresh dissection. All fetuses were then eviscerated and processed for skeletal examination.</p>
統計学的処理		
結果		
死亡数(率)、死亡時間		
用量あたり妊娠数		
流産数		
早期/後期吸収数		
着床数		
黄体数		
妊娠期間(妊娠0日から起算)		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
剖検所見(発生率、重篤度)		
臓器重量(総子宮量への影響)		
病理組織学的所見(発生率、重篤度)		
同腹仔数及び体重		
生存数(生存胎仔数及び胎仔数)		
性比		
生存率(生後4日目生存仔数/総分娩仔数)		
生後発育		
分娩後生存率		
肉眼的異常(外表観察、内臓標本、骨格標本)		
実際に投与された量		
用量反応性		
注釈	<p>NOAEL/LOAEL</p> <p>体重、臓器重量、又は臨床観察にはいずれの暴露レベルでも母動物毒性の証拠は明らかでなかった。従って、母動物毒性のNOELは25 ppmであった。</p> <p>胚又は胎児にはいずれの暴露レベルでも処置に関連した有害影響はみられなかった。従って、胎児のNOELは25 ppm であった。</p>	<p>NOAEL/LOAEL</p> <p>No evidence of maternal toxicity was evident in body weights, organ weights, or clinical observations at any exposure level. Therefore, the NOEL for maternal toxicity was 25 ppm.</p> <p>No adverse effects related to treatment were observed in the embryos or fetuses at any exposure level. Therefore, the fetal NOEL was 25 ppm.</p>

注釈	エピクロロヒドリンに吸入暴露した妊娠ウサギの体重及び肝臓重量 ppm エピクロロヒドリン (a)				BODY AND LIVER WEIGHTS OF PREGNANT RABBITS EXPOSED TO EPICHLOROHYDRIN BY INHALATION ppm Epichlorohydrin (a)											
	0		2.5		25		0		2.5		25					
	母動物数(b)				Number of Dams(b)											
	23		18		16		23		18		16					
	各妊娠日の母動物の体重 (kg)				Maternal body weight (kg) on gestation day											
	6		3.94+/-0.50(c)		3.96+/-0.38		3.87+/-0.26		6		3.94+/-0.50(c)		3.96+/-0.38		3.87+/-0.26	
	8		3.95+/-0.44		3.93+/-0.36		3.83+/-0.25		8		3.95+/-0.44		3.93+/-0.36		3.83+/-0.25	
	10		3.97+/-0.43		3.96+/-0.34		3.82+/-0.23		10		3.97+/-0.43		3.96+/-0.34		3.82+/-0.23	
	12		3.99+/-0.45		3.96+/-0.36		3.84+/-0.26		12		3.99+/-0.45		3.96+/-0.36		3.84+/-0.26	
	16		4.06+/-0.44		4.05+/-0.36		3.91+/-0.28		16		4.06+/-0.44		4.05+/-0.36		3.91+/-0.28	
	19		4.04+/-0.46		4.07+/-0.36		3.91+/-0.29		19		4.04+/-0.46		4.07+/-0.36		3.91+/-0.29	
	29		4.10+/-0.42		4.18+/-0.34		4.00+/-0.23		29		4.10+/-0.42		4.18+/-0.34		4.00+/-0.23	
	各妊娠日の母動物体重増加量 (kg)				Maternal body weight gain (kg) on gestation days											
	6-7		-0.01+/-0.15		-0.03+/-0.08		-0.04+/-0.04		6-7		-0.01+/-0.15		-0.03+/-0.08		-0.04+/-0.04	
	8-9		0.02+/-0.06		0.03+/-0.12		-0.01+/-0.07		8-9		0.02+/-0.06		0.03+/-0.12		-0.01+/-0.07	
10-11		0.02+/-0.06		0.00+/-0.12		0.02+/-0.05		10-11		0.02+/-0.06		0.00+/-0.12		0.02+/-0.05		
12-15		0.07+/-0.09		0.08+/-0.07		0.07+/-0.05		12-15		0.07+/-0.09		0.08+/-0.07		0.07+/-0.05		
16-18		-0.02+/-0.11		0.03+/-0.08		0.00+/-0.09		16-18		-0.02+/-0.11		0.03+/-0.08		0.00+/-0.09		
19-28		0.06+/-0.19		0.11+/-0.14		0.09+/-0.18		19-28		0.06+/-0.19		0.11+/-0.14		0.09+/-0.18		
計				Total												
6-29		0.14+/-0.31		0.22+/-0.21		0.13+/-0.20		6-29		0.14+/-0.31		0.22+/-0.21		0.13+/-0.20		
29日の母動物の肝臓重量				Maternal Liver weight on day 29												
絶対重量(d)		111+/-21		112+/-14		117+/-21		Absolute(d)		111+/-21		112+/-14		117+/-21		
相対重量(e)		27.2+/-4.3		26.7+/-2.8		29.3+/-5.1		Relative(e)		27.2+/-4.3		26.7+/-2.8		29.3+/-5.1		
29日の妊娠子宮重量				Gravid Uterus Weight on day 29												
絶対値(d)		366+/-103		390+/-139		360+/-100		Absolute(d)		366+/-103		390+/-139		360+/-100		
体重での補正值								Adjusted body weight (f)								
(f)		373+/-0.39		3.79+/-0.30		3.64+/-0.25		weight (f)		3.73+/-0.39		3.79+/-0.30		3.64+/-0.25		
注釈	(a) 妊娠ウサギにエピクロロヒドリンの 0、2.5 又は 25 ppm を7時間/日で妊娠6-18日に吸入暴露した。				(a) Bred rabbits were exposed to 0, 2.5 or 25 ppm of epichlorohydrin by inhalation for 7 hrs/day on days 6 through 18 of gestation.											
	(b) 非妊娠ウサギのデータはこれらの解析から除外した。				(b) Data from non-pregnant rabbits were not included in these analyses.											
	(c) 平均値 +/- 標準偏差				(c) Mean +/- S.D.											
	(d) g、平均値 +/- 標準偏差				(d) g, Mean +/- S.D.											
	(e) g、肝臓/kg 体重、平均値 +/- 標準偏差。				(e) g, liver/kg body weight, mean +/- S.D.											
	(f) 母動物の体重 - 妊娠子宮重量 (g)、平均値 +/- 標準偏差				(f) Maternal body weight minus the gravid uterus weight (g), mean +/- S.D.											
	いずれの値もDunnett法で対照群の値と有意差なし、P<0.05.				No values were significantly different from the control values by Dunnett's test, P<0.05.											
注釈	エピクロロヒドリンに吸入暴露したウサギの帝王切開時の観察 ppm エピクロロヒドリン(a)				OBSERVATIONS AT CESAREAN SECTION OF RABBITS EXPOSED TO EPICHLOROHYDRIN BY INHALATION ppm Epichlorohydrin(a)											
	0		2.5		25		0		2.5		25					
	妊娠した雌の数				Number of bred females											
	25		20		20		25		20		20					
	死亡動物数/				Number of maternal deaths/											
	妊娠動物数		0/25		0/20		1/20		Number of maternal deaths/		0/25		0/20		1/20	
	みかけの妊娠率、%(b)		92(23/25)		95(19/20)		80(16/20)		number bred		0/25		0/20		1/20	
	染色法のみでの妊娠率、%(c)		50(1/2)		0(0/1)		33(1/3)		Apparent pregnancy rate, %(b)		92(23/25)		95(19/20)		80(16/20)	
	妊娠率、計(d)		96(24/25)		95(19/20)		85(17/20)		Pregnant with stain only, %(c)		50(1/2)		0(0/1)		33(1/3)	
	腹の数		23		18		16		Percent pregnant, total(d)		96(24/25)		95(19/20)		85(17/20)	
	黄体/母動物(e)		9+/-3		10+/-3		9+/-2		Number of Litters		23		18		16	
	着床部位/母動物(e)		7+/-2		8+/-3		7+/-2		Corpora lutea/dam(e)		9+/-3		10+/-3		9+/-2	
	着床前損失(e)		2+/-2		2+/-3		2+/-2		Implantation sites/dam(e)		7+/-2		8+/-3		7+/-2	
	胎児/腹(e)		7+/-2		7+/-3		7+/-2		Preimplantation loss(e)		2+/-2		2+/-3		2+/-2	
	吸収胚/腹 (e,f)		0+/-1		1+/-1		0+/-1		Fetuses/Litter(e)		7+/-2		7+/-3		7+/-2	
	吸収された着床パーセント(f)		6(9/165)		9(13/140)		4(4/110)		Resorptions/Litter (e,f)		0+/-1		1+/-1		0+/-1	
	吸収胚を有する腹のパーセント(f)		26(6/23)		33(6/18)		19(3/16)		Percent Implantations resorbed(f)		6(9/165)		9(13/140)		4(4/110)	
	全胚吸収された腹(f)		0		0		0		Percent litters with resorptions(f)		26(6/23)		33(6/18)		19(3/16)	
	吸収胚/吸収胚を有する								Litters totally resorbed(f)		0		0		0	
	腹(f)		1.5(9/6)		2.2(13/6)		1.3(4/3)		Resorptions/litters							
	死亡胎児パーセント		1(1/156)		0(0/127)		0(0/106)		with resorptions(f)		1.5(9/6)		2.2(13/6)		1.3(4/3)	
	性比、雄:雌、%		54:46		57:43		58:42		Percent dead fetuses		1(1/156)		0(0/127)		0(0/106)	
	胎児体重 (grams)g		37.0+/-6.6		36.3+/-4.6		37.9+/-5.3		Sex ratio, M:F, %		54:46		57:43		58:42	
	胎児の頭尾長、(mm)g		92.4+/-5.6		92.2+/-4.3		93.9+/-5.9		Fetal body weight, (grams)g		37.0+/-6.6		36.3+/-4.6		37.9+/-5.3	
									Fetal crown-rump length, (mm)g							
										92.4+/-5.6		92.2+/-4.3		93.9+/-5.9		

	<p>(a) 妊娠ウサギにエピクロロヒドリンの 0、2.5 又は 25 ppm を7時間/日で妊娠6-18日に吸入暴露した。</p> <p>(b) 帝王切開又は剖検時に視認可能な着床胚を有した動物数/妊娠総数。2.5 ppm 暴露レベルの雌1匹は妊娠29日の前に分娩した。</p> <p>(c) 硫化ナトリウム染色による子宮の染色後のみにより妊娠を判定した雌の数/染色した総数</p> <p>(d) 子宮の肉眼検査又は硫化ナトリウム染色により妊娠を判定した雌の数/妊娠総数。</p> <p>(e) 平均値 +/- 標準偏差</p> <p>(f) 硫化ナトリウム染色により検出した吸収はこの計算からは除外した。</p> <p>(g) 腹の平均値 +/- 標準偏差。</p> <p>いずれの数値も適切な統計検定により対照群の値と有意差を示さなかった、p&lt;0.05。</p>	<p>(a) Bred rabbits were exposed to 0, 2.5 or 25 ppm epichlorohydrin by inhalation for 7 hrs/day on days 6 through 18 of gestation.</p> <p>(b) Number of females with visible implantations at the time of C-section or necropsy/total bred. One female from the 2.5 ppm exposure level delivered a litter prior to day 29 of gestation.</p> <p>(c) Number of females detected as being pregnant only after staining uterus with sodium sulfide stain/total stained.</p> <p>(d) Number of females pregnant by visual inspection of the uterus or by sodium sulfide stain/total bred.</p> <p>(e) Mean +/- S.D.</p> <p>(f) Resorptions detected by sodium sulfide staining were not included in these calculations.</p> <p>(g) Mean of litter means +/- S.D.</p> <p>No values were significantly different from the control values by the appropriate statistical test, p&lt;0.05.</p>																																																																																
注釈	<p>エピクロロヒドリンに吸入暴露したウサギの同腹児における胎児異常の頻度(a)</p> <table><tr><td>ppm エピクロロヒドリン</td><td>0</td><td>2.5</td><td>25</td></tr><tr><td>胎児数 (腹数)</td><td></td><td></td><td></td></tr><tr><td>外表検査</td><td>156(23)</td><td>127(18)</td><td>106(16)</td></tr><tr><td>軟組織検査</td><td>67(23)</td><td>53(18)</td><td>47(16)</td></tr><tr><td>骨格検査</td><td>156(23)</td><td>127(18)</td><td>106(16)</td></tr></table> <p>影響を受けたパーセント(影響のあった例数)</p> <p>主要な奇形の総数</p> <table><tr><td>F(e)</td><td>I(l)</td><td>5(6)</td><td>I(l)</td></tr><tr><td>L</td><td>4(1)</td><td>17(3)</td><td>6(1)</td></tr></table> <p>外表検査</p> <p>外表異常は観察されなかった。</p>	ppm エピクロロヒドリン	0	2.5	25	胎児数 (腹数)				外表検査	156(23)	127(18)	106(16)	軟組織検査	67(23)	53(18)	47(16)	骨格検査	156(23)	127(18)	106(16)	F(e)	I(l)	5(6)	I(l)	L	4(1)	17(3)	6(1)	<p>INCIDENCE OF FETAL ALTERATIONS AMONG LITTERS OF RABBITS EXPOSED TO EPICHLOROHYDRIN BY INHALATION(a)</p> <table><tr><td>ppm Epichlorohydrin</td><td>0</td><td>2.5</td><td>25</td></tr><tr><td>Number Fetuses (Number Litters)</td><td></td><td></td><td></td></tr><tr><td>EXTERNAL EXAMINATION</td><td>156(23)</td><td>127(18)</td><td>106(16)</td></tr><tr><td>SOFT TISSUE EXAMINATION</td><td>67(23)</td><td>53(18)</td><td>47(16)</td></tr><tr><td>SKELETAL EXAMINATION</td><td>156(23)</td><td>127(18)</td><td>106(16)</td></tr></table> <p>Percent Affected (Number Affected)</p> <p>Total Major Malformations</p> <table><tr><td>F(e)</td><td>I(l)</td><td>5(6)</td><td>I(l)</td></tr><tr><td>L</td><td>4(1)</td><td>17(3)</td><td>6(1)</td></tr></table> <p>External Examination</p> <p>No external alterations observed.</p>	ppm Epichlorohydrin	0	2.5	25	Number Fetuses (Number Litters)				EXTERNAL EXAMINATION	156(23)	127(18)	106(16)	SOFT TISSUE EXAMINATION	67(23)	53(18)	47(16)	SKELETAL EXAMINATION	156(23)	127(18)	106(16)	F(e)	I(l)	5(6)	I(l)	L	4(1)	17(3)	6(1)																								
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注釈	<p>軟組織検査</p> <p>無名動脈と左頸動脈の癒合</p> <table><tr><td>F</td><td>79(53)</td><td>72(38)</td><td>72(34)</td></tr><tr><td>L</td><td>100(23)</td><td>94(17)</td><td>94(15)</td></tr></table> <p>主要な動脈からの衛星血管の分離</p> <table><tr><td>F</td><td>33(22)</td><td>36(19)</td><td>30(14)</td></tr><tr><td>L</td><td>70(16)</td><td>67(12)</td><td>63(10)</td></tr></table> <p>主要な動脈からの過剰な血管の分離</p> <table><tr><td>F</td><td>6(4)</td><td>8(4)</td><td>4(2)</td></tr><tr><td>L</td><td>17(4)</td><td>22(4)</td><td>13(2)</td></tr></table> <p>複数の心臓障害(c)*</p> <table><tr><td>F</td><td>1(1)</td><td>0(0)</td><td>0(0)</td></tr><tr><td>L</td><td>4(l)</td><td>0(0)</td><td>0(0)</td></tr></table> <p>腎盂拡張*</p> <table><tr><td>F</td><td>0(0)</td><td>0(0)</td><td>2(l)</td></tr><tr><td>L</td><td>0(0)</td><td>0(0)</td><td>6(l)</td></tr></table>	F	79(53)	72(38)	72(34)	L	100(23)	94(17)	94(15)	F	33(22)	36(19)	30(14)	L	70(16)	67(12)	63(10)	F	6(4)	8(4)	4(2)	L	17(4)	22(4)	13(2)	F	1(1)	0(0)	0(0)	L	4(l)	0(0)	0(0)	F	0(0)	0(0)	2(l)	L	0(0)	0(0)	6(l)	<p>Soft Tissue Examination</p> <p>Fused Innominate and Left Carotid Arteries</p> <table><tr><td>F</td><td>79(53)</td><td>72(38)</td><td>72(34)</td></tr><tr><td>L</td><td>100(23)</td><td>94(17)</td><td>94(15)</td></tr></table> <p>Satellite Vessels Off of Major Arteries</p> <table><tr><td>F</td><td>33(22)</td><td>36(19)</td><td>30(14)</td></tr><tr><td>L</td><td>70(16)</td><td>67(12)</td><td>63(10)</td></tr></table> <p>Extra Vessels Off of Major Arteries</p> <table><tr><td>F</td><td>6(4)</td><td>8(4)</td><td>4(2)</td></tr><tr><td>L</td><td>17(4)</td><td>22(4)</td><td>13(2)</td></tr></table> <p>Multiple Heart Defects(c)*</p> <table><tr><td>F</td><td>1(1)</td><td>0(0)</td><td>0(0)</td></tr><tr><td>L</td><td>4(l)</td><td>0(0)</td><td>0(0)</td></tr></table> <p>Dilated Renal Pelvis*</p> <table><tr><td>F</td><td>0(0)</td><td>0(0)</td><td>2(l)</td></tr><tr><td>L</td><td>0(0)</td><td>0(0)</td><td>6(l)</td></tr></table>	F	79(53)	72(38)	72(34)	L	100(23)	94(17)	94(15)	F	33(22)	36(19)	30(14)	L	70(16)	67(12)	63(10)	F	6(4)	8(4)	4(2)	L	17(4)	22(4)	13(2)	F	1(1)	0(0)	0(0)	L	4(l)	0(0)	0(0)	F	0(0)	0(0)	2(l)	L	0(0)	0(0)	6(l)
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注釈	<p>骨格検査</p> <p>頭蓋骨</p> <p>－ 頭蓋内の根尖孔 F 5(8) 2(3) I(I)(d) L 22(5) 11(2) 6(I)</p> <p>－ 骨島 F 5(7) 2(2) I(I) L 22(5) 11(2) 6(1)</p> <p>胸骨分節</p> <p>－ 骨化遅延 F 83(130) 87(110) 86(91) L 100(23) 100(18) 100(16)</p> <p>－ 癒合 F 1(1) 1(1) 0(0) L 4(1) 6(1) 0(0)</p> <p>肋骨</p> <p>－ 過剰肋骨 F 63(98) 52(66) 39(41)(e) L 96(22) 94(17) 75(12)</p> <p>－ 腰部の小突起 F 6(9) 9(11) 4(4) L 30(7) 44(8) 19(3)</p> <p>脊椎</p> <p>－ 中心非癒合 F 0(0) 2(2) 0(0) L 0(0) 11(2) 0(0)</p> <p>－ 半椎* F 0(0) 3(4) 0(0) L 0(0) 17(3) 0(0)</p> <p>－ 奇形* F 0(0) 2(3) 0(0) L 0(0) 11(2) 0(0)</p> <p>その他</p> <p>複数の骨格異常(f)* F 0(0) 1(1) 0(0) L 0(0) 6(1) 0(0)</p>	<p>Skeletal Examination</p> <p>Skull</p> <p>－ foramen in skull F 5(8) 2(3) I(I)(d) L 22(5) 11(2) 6(I)</p> <p>－ bone island F 5(7) 2(2) I(I) L 22(5) 11(2) 6(1)</p> <p>Sternebrae</p> <p>－ delayed ossification F 83(130) 87(110) 86(91) L 100(23) 100(18) 100(16)</p> <p>－ fused F 1(1) 1(1) 0(0) L 4(1) 6(1) 0(0)</p> <p>Ribs</p> <p>－ extra ribs F 63(98) 52(66) 39(41)(e) L 96(22) 94(17) 75(12)</p> <p>－ lumbar spurs F 6(9) 9(11) 4(4) L 30(7) 44(8) 19(3)</p> <p>Vertebrae</p> <p>－ unfused centrum F 0(0) 2(2) 0(0) L 0(0) 11(2) 0(0)</p> <p>－ hemivertebrae* F 0(0) 3(4) 0(0) L 0(0) 17(3) 0(0)</p> <p>－ misshapen* F 0(0) 2(3) 0(0) L 0(0) 11(2) 0(0)</p> <p>Other</p> <p>Multiple Skeletal Defects(f)* F 0(0) 1(1) 0(0) L 0(0) 6(1) 0(0)</p>
注釈	<p>(a) 妊娠ウサギにエピクロロヒドリンの 0、2.5、又は 25 ppm を7時間/日で妊娠6-18日に吸入暴露した。</p> <p>(b) F = 胎児、L = 腹。</p> <p>(c) 0 ppm の胎児1匹は肺動脈と大動脈の癒合、心臓の弁の欠損、及び心室中隔の開口を含む複数の異常を示した。</p> <p>(d) p = .059</p> <p>(e) Wilcoxon 変法で対照群の値と有意差あり、p&lt;0.05.</p> <p>(f) エピクロロヒドリン2.5 ppm の胎児1匹は分岐した肋骨、中心の非癒合、脊椎の奇形及び癒合、肋骨の欠損、脊柱側彎症及び半椎からなる多数の骨格異常を示した。</p> <p>*主要な奇形と考えられる</p>	<p>(a)Bred rabbits were exposed to 0, 2.5, or 25 ppm of epichlorohydrin by inhalation 7 hrs/day on days 6 through 18 of gestation.</p> <p>(b) F = fetuses; L = litters.</p> <p>(c)One fetus at 0 ppm exhibited multiple defects, including fused pulmonary artery and aorta, missing valves of the heart and an opening in the interventricular septum.</p> <p>(d) p = .059</p> <p>(e)Significantly different from control value by a modified Wilcoxon test, p&lt;0.05.</p> <p>(f)One fetus at 2.5 ppm of epichlorohydrin exhibited multiple skeletal defects, including a forked rib, an unfused centrum, a misshapen and an unfused vertebrae, a missing rib, scoliosis and a hemivertebra.</p>
注釈		
結論		
Pに対するNOAEL (NOEL)又はLOAEL (LOEL)	NOAEL 母動物毒性 : > 25 ppm	NOAEL maternal tox. : > 25 ppm
F1に対するNOAEL (NOEL)又はLOAEL (LOEL)	NOAEL 催奇形性 : > 25 ppm	NOAEL teratogen. : > 25 ppm
F2に対するNOAEL (NOEL)又はLOAEL (LOEL)		
注釈		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	2C 試験は母動物毒性の証拠を示さなかったが、胎児のパラメータの検査では堅牢であった。	2C Study did not produce evidence of maternal toxicity, but was robust in the examination of fetal parameters.
出典		
引用文献(元文献)	(220) (219)	(220) (219)
備考	フラグ: SIDSエンドポイントにとって重要な試験	Flag : Critical study for SIDS endpoint

試験物質名	他のTS	other TS
CAS番号		
純度等	Fisher Scientific, Fair Lawn, NJ. から入手した試薬等級の材料	Reagent grade material from Fisher Scientific, Fair Lawn, NJ.
注釈		
方法		
方法/ガイドライン	その他	other
GLP適合	いいえ	no
試験を行った年	1982	1982
試験系(種/系統)	ラット	rat
性別(雄:M、雌:F)	雌	other: CD
投与量	40、80、160 mg/kg	female
各用量群(性別)の動物数		40, 80, 160 mg/kg
投与経路	強制経口	
試験期間	21日間	gavage
		21 days

交配前暴露期間		
試験条件	暴露期間：妊娠6-15日 処置頻度：1日1回 対照群：あり、溶媒対照	Exposure period : 6th – 15th day of pregnancy Frequency of treatm. : once a day Control group : yes, concurrent vehicle
試験条件	※英文参照	Male and female nulliparous female rats (176–200 g) were acclimated to laboratory conditions for 1 week. Mating was accomplished by placing 2 females into each male's cage. The day spermatozoa were found in vaginal lavage fluid was considered Day 0 of gestation. Sperm-positive females were then randomly divided into treatment groups.  On Days 6–15 of gestation, ECH (0.1% in solution in cottonseed oil) was administered via gastric intubation at dose levels of 0, 40, 80, or 160 mg/kg bw/day; all dose levels were studied in five replicates.
試験条件	※英文参照	On Day 21 of gestation, rats were anesthetized with carbon dioxide and killed via cervical dislocation, and their reproductive status determined. Implantation sites in each uterine horn and the general condition of each conceptus was recorded. Live fetuses were weighed individually, sexed internally, and examined for external anomalies. Live fetuses weighing <1.0 g or weighing <2/3 the mean of their larger littermates were designated as "stunted". At least 1/3 of the fetuses of each litter, as well as all stunted fetuses and those having external malformations, were examined for visceral alterations via the Staples method. The bodies of all fetuses were then processed for skeletal examination (Staples and Schnell method). The heads of fetuses subjected to visceral examination (with the exception of any fetuses that had external head malformations) were cut off at the base and prepared for freehand examination (Wilson method).
統計学的処理		
結果		
死亡数(率)、死亡時間		
用量あたり妊娠数		
流産数		
早期/後期吸収数		
着床数		
黄体数		
妊娠期間(妊娠0日から起算)		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
血液学的所見(発生率、重篤度)		
血液生化学的所見(発生率、重篤度)		
剖検所見(発生率、重篤度)		
臓器重量(総子宮量への影響)		
病理組織学的所見(発生率、重篤度)		
同腹仔数及び体重		
生存数(生存胎仔数及び胎仔数)		
性比		
生存率(生後4日目生存仔数/総分娩仔数)		
生後発育		
分娩後生存率		
肉眼的異常(外表観察、内臓標本、骨格標本)		
実際に投与された量		
用量反応性		
統計的結果		
注釈	発生中の胎児には胎児毒性も催奇形性影響もみられなかった。160 mg/kg/日では母動物に致死的な影響(3/27例)。80 mg/kg/日では妊娠中に平均体重増加量の10%以上の減少。	No teratogenic or fetotoxic effects on the developing embryos were observed. Lethal effects in dams (3/27) at 160 mg/kg/day. Greater than 10% reduction in average body weight gain during pregnancy at 80 mg/kg/day.
結論		
P1に対するNOAEL (NOEL)又はLOAEL (LOEL)	NOAEL 母動物毒性 : = 40 mg/kg 体重	NOAEL maternal tox. : = 40 mg/kg bw
F1に対するNOAEL (NOEL)又はLOAEL (LOEL)	NOAEL 催奇形性 : > 160 mg/kg 体重	NOAEL teratogen. : > 160 mg/kg bw
F2に対するNOAEL (NOEL)又はLOAEL (LOEL)		
注釈	結果：催奇形性又は胎児毒性はなし	Result : Not teratogenic or fetotoxic
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠	2b 許容できる制限のあるガイドライン試験	2b Guideline study with acceptable restrictions
出典		
引用文献(元文献)	(221)	(221)
備考		

試験物質名	他のTS	other TS
CAS番号		
純度等	Fisher Scientific, Fair Lawn, NJ. から入手した試薬等級の材料	Reagent grade material from Fisher Scientific, Fair Lawn, NJ.
注釈		
方法		
方法／ガイドライン	その他	other
GLP適合	いいえ	no
試験を行った年	1982	1982
試験系(種／系統)	マウス	mouse
	CD-1	CD-1
性別(雄:M、雌:F)	雌	female



投与量	80、120、160 mg/kg	80, 120, 160 mg/kg
各用量群(性別)の動物数		
投与経路	強制経口	gavage
試験期間	18日間	18 d
交配前暴露期間		
試験条件	暴露期間：妊娠6～15日 処置頻度：1日1回 対照群：あり、溶媒対照	Exposure period : Days 6-15 Frequency of treatm. : once a day Control group : yes, concurrent vehicle
統計学的処理		
結果		
死亡数(率)、死亡時間		
用量あたり妊娠数		
流産数		
早期/後期吸収数		
着床数		
黄体数		
妊娠期間(妊娠0日から起算)		
体重、体重増加量		
摂餌量、飲水量		
臨床所見(重篤度、所見の発現時期と持続時間)		
血液学的所見(発生率、重篤度)		
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剖検所見(発生率、重篤度)		
臓器重量(総子宮量への影響)		
病理組織学的所見(発生率、重篤度)		
同腹仔数及び体重		
生存数(生存胎仔数及び胎仔数)		
性比		
生存率(生後4日目生存仔数/総分娩仔数)		
生後発育		
分娩後生存率		
肉眼的異常(外表観察、内臓標本、骨格標本)		
実際に投与された量		
用量反応性		
統計的結果		
注釈	母動物毒性は120 mg/kg/日では肝臓重量の統計的に有意な増加及び160 mg/kg/日では母動物の死亡として認められた。胎児の奇形の平均的な割合には増加はみられなかった。 120 mg/kg/日(対照群の値の93%)及び160 mg/kg/日(対照群の値の91%)では平均胎児重量の統計的に有意な減少がみられた。しかしながら、18ないし46 mg/kg/日で強制経口により10日間投与したげっ歯類は肝臓及び腎臓重量の用量に相関した増加を示した(Daniel, 1996)。従って、胎児体重への観察された影響は検査されなかった母親の臓器への毒性影響による二次的なものであった可能性がある。	Maternal toxicity was evident as statistically significant increases in liver weight at 120 and maternal deaths at 160 mg/kg/day. No increase in the average percent of fetal malformations. There were statistically significant decreases in mean fetal weight at 120 mg/kg (93 % of control value) and 160 mg/kg (91 % of control value). However, rodents dosed with 18 or 46 mg/kg/day via oral gavage for 10 days (Daniel, 1996) exhibited dose-related increases in liver and kidney weights. Hence, the observed effects on fetal body weight may have been secondary to toxic effects on maternal organs which were not examined.
結論		
Pに対するNOAEL (NOEL)又はLOAEL (LOEL)	NOAEL 母動物毒性 : = 80 mg/kg 体重	NOAEL maternal tox. : = 80 mg/kg bw
F1に対するNOAEL (NOEL)又はLOAEL (LOEL)	NOAEL 催奇形性 : = 160 mg/kg 体重	NOAEL teratogen. : = 160 mg/kg bw
F2に対するNOAEL (NOEL)又はLOAEL (LOEL)		
注釈		
信頼性	(2) 制限付きで信頼性あり	(2) valid with restrictions
信頼性の判断根拠		
出典		
引用文献(元文献)	(221)	(221)
備考		

# 5-10その他関連情報

## OTHER RELEVANT INFORMATION

試験物質名	他のTS	other TS
CAS番号		
純度等	3H-ECHの放射化学純度は98%以上であった。 非放射標識体のECHの純度は99.5%超であった。	Radiochemical purity of 3H-ECH was greater than or equal to 98%. Purity of the non-radiolabeled ECH was greater than 99.5%.
注釈		
方法		
方法/ガイドライン	エンドポイント: その他: ヘモグロビン及びDNA付加体形成 タイプ: その他: ヘモグロビン及びDNA付加体形成	Endpoint : other: Haemoglobin and DNA adduct formation Type : other: Haemoglobin and DNA adduct formation
GLP適合		
試験を行った年		
試験条件	※英文参照	Species : rat Sex : female Strain : Wistar Route of admin. : intraperitoneal injection No. of animals : 20 Vehicle : other: corn oil Exposure period : 1 day(s) Frequency of treatm. : single dose Doses : Four rats per dose of tritiated epichlorohydrin: 0.11 mmol/kg (~10 mg/kg), 0.22 mmol/kg (~20 mg/kg), 0.43 mmol/kg (~40 mg/kg), 0.97 mmol/kg (~80 mg/kg) with 5 mCi/kg of radioactivity per rat. Control group : yes, concurrent vehicle
結果		



結果	ラットにおいて、ヘモグロビンへの総結合量は0.43 mmol/kgまでの用量で直線的な相関性を示した。最高用量での結合量はより低用量からの外挿による予測値よりも高く、代謝の飽和を示唆した。	The total binding of radioactivity to haemoglobin in rats was linearly related to the dose up to 0.43 mmol/kg. The binding at the highest dose was higher than predicted by extrapolation from lower doses suggesting saturation of metabolism.
信頼性		
信頼性の判断根拠		
出典		
引用文献(元文献)	Landin, H.H., Segerback, D., Damberg, C., Osterman-Golkar, S. (199) Adducts with haemoglobin and with DNA in epichlorohydrin exposed rats. Chemico-Biol. Interac. 117: 49-64.	Landin, H.H., Segerback, D., Damberg, C., Osterman-Golkar, S. (199) Adducts with haemoglobin and with DNA in epichlorohydrin exposed rats. Chemico-Biol. Interac. 117: 49-64.
備考		

5-11 ヒト暴露の経験  
EXPEIENCE WITH HUMAN EXPOSURE

試験物質名		
CAS番号		
純度等		
注釈		
製造／加工／使用情報		
研究デザイン		
仮説検証		
データ収集方法		
被験者の説明		
暴露期間		
測定又は評価曝露データ		
結果		
統計的結果		
発病頻度		
相関		
分布		
研究提供者等		
注釈		
結論		
結論		
注釈	注釈：刺激性 ----- 皮膚、眼及び呼吸器の刺激が事故で暴露されたヒトで報告されてきた。	Remark : Irritation ----- Skin, eye and respiratory irritation have been reported in man exposed accidentally.
信頼性		
信頼性の判断根拠		
出典		
引用文献(元文献)	(222) (223) (224)	(222) (223) (224)
備考		

試験物質名		
CAS番号		
純度等		
注釈	暴露の経験：直接観察、臨床例	Type of experience : Direct observation, clinical cases
製造／加工／使用情報		
研究デザイン		
仮説検証		
データ収集方法		
被験者の説明		
暴露期間		
測定又は評価曝露データ		
結果		
統計的結果		
発病頻度		
相関		
分布		
研究提供者等		
注釈		
結論		
結論		
注釈	注釈：感作性： エポキシ樹脂を製造又は加工する工場の従業員の間には作業に関連した接触性皮膚炎が知られている (Jolanki et al., 1987; Prens et al., 1986; van Joost, 1988; van Joost et al., 1990)。 オランダのエポキシ樹脂製造工場の228名の作業員の間で接触性皮膚炎26症例の評価が1974年から1984年の間に行われた。作業員全員が特殊な業務の結果、加工品の化学物質と接触した。接触性皮膚炎を有した26名の従業員のうち19名が自発的に経皮パッチテストを受けた。8症例でエピクロロヒドリンに対して陽性反応が示された。ビスフェノールA/エピクロロヒドリンオリゴマー（平均分子量385）は10症例で陽性反応を生じ、液体樹脂は8症例で、硬化樹脂は7症例で陽性反応を示したが、ビスフェノールAはいずれの症例に対しても陽性反応を示さなかった。著者らの意見として樹脂中の遊離エピクロロヒドリンの残渣がその揮発性と空気中に不可避の濃度で存在するために感作性がみられた症例の原因になっている可能性が示された(Prens et al., 1986)。	Remark : Sensitization: Work-related contact dermatitis is known to occur among employees at plants producing or processing epoxy resins (Jolanki et al., 1987; Prens et al., 1986; van Joost, 1988; van Joost et al., 1990). There was an evaluation between 1974 and 1984 of 26 cases of contact dermatitis among the 228 workers of a Dutch epoxy resin production plant. All of the workers had contact with process chemicals as a result of their particular jobs. 19 of 26 employees with contact dermatitis submitted themselves to a voluntary, epicutaneous patch test. In 8 cases there was a positive reaction to epichlorohydrin. The bisphenol A/epichlorohydrin oligomer (mean molecular weight 385) elicited a positive reaction in 10 cases, liquid resin in 8 cases, hardened resin in 7 cases and bisphenol A in none of the cases. In the opinion of the authors, residues of free epichlorohydrin in the resins and, due to its volatility, unavoidable concentrations in the air were responsible for the observed cases of sensitization (Prens et al., 1986)

注釈	フィンランドで1974年から1983年の間にエポキシ樹脂（塗料、ニス、接着剤、電気絶縁材料など）によって生じた職業性皮膚炎の症例74/542(13 %)が集められた。これらの患者の標準的なエポキシ樹脂のシリーズ及びその成分のエピクロロヒドリン及びビスフェノールAを用いて皮膚への塗布試験が行われた。全例で標準品の結果は陽性であったが、それらの成分に対する結果は陰性であった。陽性の結果を導いた樹脂調製品は全て分子量340のエピクロロヒドリン-ビスフェノールAオリゴマーを0.2-15%の濃度で含んでいることが判明した。このオリゴマーは強力なアレルゲンであることが知られている。このアレルゲンが皮膚炎の調査症例を生じた原因であり、それにより樹脂を溶解している溶媒が皮膚への浸透に都合よく影響を及ぼしたと著者らは結論している (Jolanki et al., 1987)。	There was in Finland 74/542 (13 %) cases of occupational dermatitis registered between 1974 and 1983 which were caused by epoxy resins (paints, varnishes, adhesives, electrical insulation materials etc.). On these patients epicutaneous tests were carried out with standard series of epoxy resins and the component materials epichlorohydrin and bisphenol A. In all instances the results for the standard were positive, while those for the component materials were negative. All of the resin preparations which led to positive effects were found to contain an epichlorohydrin-Bisphenol A oligomer with a molecular weight of 340 at concentrations of 0.2-15 %. This oligomer is known to be a strong allergen. The authors conclude that this allergen was responsible for causing the investigated cases of dermatitis, whereby the solvent in which the resins were dissolved favourably influenced skin penetration (Jolanki et al., 1987).
注釈	Van Joost は Prens et al. (1986)の中で述べられているエポキシ樹脂製造工場の228名の作業者の間で合計11症例の接触性皮膚炎がみられたと報告している。パッチテストでは全症例がエピクロロヒドリンに対し陽性反応を示した。11症例中6例が他の樹脂成分に対し試験された。6例全例がビスフェノールAに対しては陰性に反応したが、4症例では液体樹脂及びエピクロロヒドリン/ビスフェノールAオリゴマー（分子量385）が陽性反応を引き起こした。エピクロロヒドリンに対し最も顕著な感作性反応を示した2症例はエポキシ樹脂及びエピクロロヒドリン/ビスフェノールAオリゴマーに対しては陰性に反応した。	Van Joost reports a total of 11 cases of contact dermatitis among the 228 workers of the epoxy resin producing plant mentioned in Prens et al. (1986). In the patch test all of the cases reacted positively towards epichlorohydrin. 6 of the 11 cases were tested against other resin components. All 6 reacted negatively towards bisphenol A, while in 4 cases liquid resin and the epichlorohydrin/ bisphenol A oligomer (molecular weight 385) elicited a positive reaction. Two cases, which showed the most marked sensitization reaction towards epichlorohydrin, reacted negatively towards the epoxy resins and the epichlorohydrin/bisphenol A oligomer.
信頼性		
信頼性の判断根拠		
出典		
引用文献(元文献)	(225) (226) (227) (228)	(225) (226) (227) (228)
備考		

試験物質名		
CAS番号		
純度等		
注釈	暴露の経験 : ヒト-医学データ	Type of experience : Human - Medical Data
製造／加工／使用情報		
研究デザイン		
仮説検証		
データ収集方法		
被験者の説明		
暴露期間		
測定又は評価曝露データ		
結果		
統計的結果		
発病頻度		
相関		
分布		
研究提供者等		
注釈	<p>注釈 : 受胎能</p> <p>Milby &amp; Whorton (1980; 1981) はECHの製造に関連した男性作業者の2つのコホートについて研究を行った。ECH暴露の平均レベルは0.1-1ppm (0.38-3.8 mg/m3)の範囲であった。作業者の健康の一般状態及び血液データは正常であることが判明していた。2つの群はそれぞれ44人及び84人の男性からなり、他の化学工場の男性90人の対照群と精巣機能に関して比較が行われた。男性の授精能が健康の一般状態、ホルモン状況 (FSH、LH、テストステロン)及び精子の分析 (精子数)から推定された。有害な影響はみられなかった。</p> <p>Venable et al (1980)は研究前5年間の間、全て推定濃度&lt; 1 ppm (8時間TWA) で、様々なECH混合物、塩化アリル及び1,3ジクロロプロパンに暴露された作業者を研究した。精巣の大きさ、精液量及び精子数、生存率、運動能及び形態の測定ではいずれも暴露群と対照群との間に差はなかった。また、血清ホルモンにも差は認められなかった。</p>	<p>Remark : Fertility</p> <p>Milby &amp; Whorton (1980; 1981) carried out studies on 2 cohorts of male workers involved with the manufacture of ECH. The average level of ECH exposure ranged from 0.1-1 ppm (0.38-3.8 mg/m3). The general state of health and the blood data of the workers were found to be normal. The 2 groups consisted of 44 and 84 men, respectively, and were compared in respect to testicular function with a control group of 90 men from another chemical factory. The fertility of the men was deduced from their general state of health, their hormonal status (FSH, LH, testosterone) and analyses of their sperm (sperm count). No adverse effects were found.</p> <p>Venable et al (1980) studied workers exposed to various mixture of ECH, allyl chloride and 1,3 dichloropropane, all at estimated conc of &lt; 1 ppm (8 hour TWA) during the 5 years preceeding the study. Measurement of testicular size, semen volume and sperm count, viability, motility and morphology all indicated no difference between the exposed and control groups. Also no difference was noted concerning serum hormones</p>
結論		
結論		
注釈		
信頼性		
信頼性の判断根拠		
出典		
引用文献(元文献)	(229)(230)(231)	(229)(230)(231)
備考		

## 6 参考文献(以下に欄を追加の上、一文献について一行にて一覧を記載)

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