

- (c) Species/strain: Mice/B6C3F1
 Sex: Female []; Male []; Male/Female [X]; No data []
 Route of Administration: Oral (in drinking water)
 Exposure period: 90 days
 Frequency of treatment: Daily
 Post exposure observation period:
 Dose: 896, 1,792, 5,375 ppm
 Control group: Yes [X]; No []; No data [];
 Concurrent no treatment[X]; Concurrent vehicle[X]; Historical[]
 NOAEL: 5,375 ppm (male: 1,994 mg/kg/day, female:
 2,200mg/kg/day)
 LOAEL:
 Results: Although increase in water consumption in both sexes and
 absolute and relative weights of ovaries in females were
 observed, these changes were considered due to the high sodium
 content. No adverse effect was observed.
 Method: Other
 GLP: Yes [X] No [] ? []
 Test substance: Sodium isocyanurate, purity: unknown
 Remarks: Sodium hippurate was used as a second control in order to have
 the sodium burden as the top concentration.
 Reference: Hazleton U.S.: 1982
- (d) Species/strain: Dogs/Beagle
 Sex: Female []; Male []; Male/Female [X]; No data []
 Route of Administration: Oral (in diet)
 Exposure period: 6 months
 Frequency of treatment: Daily
 Post exposure observation period:
 Dose: 0 (vehicle), 0.8 % (calculated daily dose: 291 mg/kg)
 Control group: Yes []; No [X]; No data [];
 Concurrent no treatment[]; Concurrent vehicle[]; Historical[]
 NOAEL: 0.8 % (291 mg/kg/day)
 LOAEL:
 Results: There were no changes in body weight gain, organ weight, and
 sugar and protein in urine. In addition, hematological and
 histological changes were not observed.
 Method: Other
 GLP: Yes [] No [X] ? []
 Test substance: Sodium isocyanurate, purity: unknown
 Reference: Hodge *et al.*: 1965
- (e) Species/strain: Dogs/Beagle
 Sex: Female []; Male []; Male/Female [X]; No data []
 Route of Administration: Oral (in diet)
 Exposure period: 2 years
 Frequency of treatment: Daily
 Post exposure observation period:
 Dose: 8 % (calculated daily dose: 2,912 mg/kg)
 Control group: Yes []; No [X]; No data []

- Concurrent no treatment[]; Concurrent vehicle[]; Historical[]
 NOAEL:
 LOAEL: 8 % (2912 mg/kg/day)
 Results: Two of three dogs died after 16 and 21 months on the regimen, respectively. No change or slight increase in body weights was observed. Periodic urinalyses gave normal trace values for sugar and protein. In hematologic study, only a survival dog showed changes, which are low red blood cell counts, hemoglobin values, and hematocrits. There was no change in organ weights (thyroid, liver, brain, lungs, heart, etc.), expect for decrease in kidney weight of two dogs surviving more than 20 months. In these dogs, there was gross evidence of kidney fibrosis. Sections revealed numerous linear streaks of gray fibrous tissue extending from the papillary tip to the cortical surface. Microscopically, similar changes were observed in the kidneys of all three dogs. The collecting tubules were more uniformly and severely involved, but all portions of the nephron were compressed by fibrosis. There were slight focal dilatation and epithelial proliferation in the ducts of Bellini. In survival dog, focal areas of thyroid atrophy were found with lymphocytic infiltration, but without evidence of hyperplasia.
- Method: Other
 GLP: Yes [] No [X] ? []
 Test substance: Sodium isocyanurate, purity: unknown
 Reference: Hodge *et al.*: 1965
- (f) Species/strain: Rabbits/Albino
 Sex: Female []; Male []; Male/Female [X]; No data []
 Route of Administration: Dermal
 Exposure period: Approx. 3 months
 Frequency of treatment: 5 days/week
 Post exposure observation period:
 Dose: 5 ml of 0.8 % or 8 % aqueous suspension
 Control group: Yes []; No [X]; No data []
 Concurrent no treatment[]; Concurrent vehicle[]; Historical[]
 NOAEL: 0.8 %
 LOAEL: 8 %
 Results: Urinalyses (sugar and protein) and hematological study showed no change. There were no irritation or other adverse effects on the skin. In histological findings of liver and skin from treated and untreated area, no change was observed at the termination of the study. In the kidneys of the rabbits treated with the 8 % isocyanurate suspension, slight dilatation of the ducts of Bellini and mild tubular changes were found.
- Method: Other
 GLP: Yes [] No [X] ? []
 Test substance: Sodium isocyanurate, purity: unknown
 Reference: Hodge *et al.*: 1965
- (g) Species/strain: Rabbits/Albino
 Sex: Female []; Male []; Male/Female [X]; No data []

Route of Administration: Eye application
 Exposure period: Approx. 3 months
 Frequency of treatment: 5 days/week
 Post exposure observation period:
 Dose: 0.1 ml of 0.8 % or 8 % aqueous suspension
 Control group: Yes [X]; No []; No data [];
 Concurrent no treatment[X]; Concurrent vehicle[]; Historical[]
 NOAEL: 0.8 %
 LOAEL: 8 %
 Results: Increase in body weight was observed during the period of the study in all treated groups. No eye injury was caused and no eye irritation was observed in rabbits treated with an 8 % aqueous suspension of the sodium salt.
 Method: Other
 GLP: Yes [] No [X] ? []
 Test substance: Sodium isocyanurate, purity: unknown
 Reference: Hodge *et al.*: 1965

*5.5 GENETIC TOXICITY IN VITRO

A. BACTERIAL TEST

Type: Ames test
 System of testing: *Salmonella typhimurium* TA1535, TA1537, TA98, TA100
 Concentration: 100 to 1000 µg/plate
 Metabolic activation: With []; Without []; With and Without [X]; No data []
 S9: Hamster liver - Arochlor 1254
 Results:

Cytotoxicity conc: With metabolic activation:
 Without metabolic activation:

Precipitation conc:

Genotoxic effects: + ? -

With metabolic activation: [] [] [X]

Without metabolic activation: [] [] [X]

Method: Other
 GLP: Yes [] No [X] ? []
 Test substance: purity: unknown
 Remarks:
 Reference: Hayworth *et al.*: 1983

Type: Other: Inductest Pasteur
 System of testing: Induction of bacteriophage Lambda in *Escherichia Coli* K12 en VA UVRB
 Concentration: 0.2 to 2000 µg/plate
 Metabolic activation: With []; Without []; With and Without [X]; No data []
 Results:

Cytotoxicity conc: With metabolic activation:
 Without metabolic activation:

Precipitation conc:

Genotoxic effects: + ? -

With metabolic activation: [] [] [X]

Without metabolic activation:
 Method: Other
 GLP: Yes No ?
 Test substance: purity: unknown
 Remarks:
 Reference: NORSOLOR/APC: 1977

B. NON-BACTERIAL IN VITRO TEST

Type: Chromosomal aberration test
 System of testing: Chinese hamster lung (CHL/IU) cells
 Concentration: +S9 (short-term treatment): 0, 0.33, 0.65, 1.3 mg/ml
 -S9 (continuous treatment): 0, 0.33, 0.65, 1.3 mg/ml
 -S9 (short-term treatment): 0, 0.33, 0.65, 1.3 mg/ml
 Metabolic activation: With ; Without ; With and Without ; No data
 S9: Rat liver, induced with phenobarbital and 5,6-benzoflavone
 Results:
 Cytotoxicity conc: Not observed
 Precipitation conc:
 Genotoxic effects: clastogenicity polyploidy
 + ? - + ? -
 With metabolic activation:
 Without metabolic activation:
 Method: Guidelines for Screening Mutagenicity Testing of Chemicals
 (Japan), and OECD TG (473).
 GLP: Yes No ?
 Test substance: purity: 99.5 %
 Remarks: Exposure period: short-term treatment: 6 hr
 continuous treatment: 24, or 48 hr
 Positive control: -S9: Mitomycin, +S9: Cyclophosphamide
 Reference: MHW, Japan: 1997

Type: Mouse lymphoma assay
 System of testing: L 5178 TK +/-
 Concentration: 50 to 2000 µg/plate
 Metabolic activation: With ; Without ; With and Without ; No data
 Results:
 Cytotoxicity conc: With metabolic activation:
 Without metabolic activation:
 Precipitation conc:
 Genotoxic effects: + ? -
 With metabolic activation:
 Without metabolic activation:
 Method: Other
 GLP: Yes No ?
 Test substance: purity: unknown
 Remarks:
 Reference: Industry ad hoc Committee for Isocyanurates: 1981a

Type: Sister chromatid exchange assay
 System of testing: CHO cells

Concentration: 93 to 1500 µg/plate
 Metabolic activation: With []; Without []; With and Without [X]; No data []
 Results:
 Cytotoxicity conc: With metabolic activation:
 Without metabolic activation:
 Precipitation conc:
 Genotoxic effects: + ? -
 With metabolic activation: [] [] [X]
 Without metabolic activation: [] [] [X]
 Method: Other
 GLP: Yes [X] No [] ? []
 Test substance: purity: unknown
 Remarks:
 Reference: Industry ad hoc committee for Isocyanurates: 1981b

* 5.6 GENETIC TOXICITY IN VIVO

Type: Chromosomal aberration test
 Species/strain: Rats
 Sex: Female []; Male []; Male/Female []; No data [X]
 Route of Administration: Oral (single gavage administration)
 Exposure period:
 Doses: Up to 5000 mg/kg
 Results:
 Effect on mitotic
 index or P/N ratio:
 Genotoxic effects: + ? -
 [] [] [X]
 Method: Other
 GLP: Yes [] No [X] ? []
 Test substance: Sodium isocyanurate, purity: unknown
 Remarks: Rats were killed 24 and 48 hr after dosing, and bone
 marrow cells were collected and examined for
 chromosomal aberrations.
 Reference: Hammond *et al.*: 1985

5.7 CARCINOGENICITY

- (a) Species/strain: Rats/CD
 Sex: Female []; Male []; Male/Female [X]; No data []
 Route of Administration: Oral (in drinking water)
 Exposure period: 2 years
 Frequency of treatment: Daily
 Postexposure observation period:
 Doses: 0 (vehicle), 400, 1,200, 2,400, 5,375 ppm
 (Estimated daily doses were indicated only for 2,400 and 5,375
 ppm (male: 154 and 371 mg/kg/day, female: 266 and 634
 mg/kg/day))
 Control group: Yes [X]; No []; No data []; tap water
 Concurrent no treatment []; Concurrent vehicle [X]; Historical []
 Results: No test article related carcinogenesis.

- Method: Other
 GLP: Yes [] No [X] ? []
 Test substance: Sodium isocyanurate, purity: unknown
 Remarks: Sodium hippurate was administered at the equivalent amount of sodium to the highest dose group as a second control. Treatment-related mortality was observed in some males of highest dose group, which died during the first 12 months of the study. This mortality was due to the development of calculi in the urinary tract. In some males that died on test and in some that were sacrificed at 12 months, there were pathologic changes, including hyperplasia, bleeding, and inflamed ureters, and renal tubular nephrosis. Although slight tubular nephrosis was also observed in a few females of highest dose group during the first 12 months, these animals did not exhibit bladder calculi. Inflammatory lesions in the heart were also apparent in some of the highest dose males that died early.
 Reference: Cascieri *et al.*: 1985
- (b) Species/strain: Mice/B6C3F1
 Sex: Female []; Male []; Male/Female [X]; No data []
 Route of Administration: Oral (in drinking water)
 Exposure period: 2 years
 Frequency of treatment: Daily
 Postexposure observation period:
 Doses: 0 (vehicle), 100, 400, 1,200, 5,375 ppm
 Control group: Yes [X]; No []; No data [];
 Concurrent no treatment[]; Concurrent vehicle[X]; Historical[]
 Results: There was no evidence of test article related carcinogenesis.
 Method: Other
 GLP: Yes [X] No [] ? []
 Test substance: Sodium isocyanurate, purity: unknown
 Remarks: Sodium hippurate was administered at the equivalent amount of sodium to the highest dose group as a second control. Apparent swollen enlarged abdomen was observed at the highest dose groups (both isocyanurate and hippurate). There were no effects on survival, clinical pathology (except for urinary sodium), organ weight, gross and histopathology.
 Reference: Industry Ad hoc Committee for Isocyanurates, Hazleton laboratories, Report 2169-100 (1986)
- (c) Species/strain: Rats
 Sex: Female []; Male []; Male/Female []; No data [X]
 Route of Administration: Subcutaneous
 Exposure period: 2 years
 Frequency of treatment: Once a week
 Postexposure observation period:
 Doses: Total dose: 6.06 g (approx. daily dose: 8.3 mg/day)
 Control group: Yes []; No []; No data [X];
 Concurrent no treatment[]; Concurrent vehicle[]; Historical[]

Results: A lymphosarcoma in lungs has been observed in 1 of the 5 surviving rats after 28 months, and a subdermal lipoma in 1 of the other rats after 30.5 months.

Method: Other

GLP: Yes [] No [X] ? []

Test substance: purity: unknown

Remarks:

Reference: Toxikologische Bewertung.: 1993

(d) Species/strain: Mice

Sex: Female []; Male []; Male/Female []; No data [X]

Route of Administration: Subcutaneous

Exposure period: 2 years

Frequency of treatment: Once a week

Postexposure observation period:

Doses: Total dose: 0.6 g (estimated daily dose: 0.82 mg/day)

Control group: Yes []; No []; No data [X];
Concurrent no treatment[]; Concurrent vehicle[]; Historical []

Results: No tumours were observed.

Method: Other

GLP: Yes [] No [X] ? []

Test substance: purity: unknown

Remarks:

Reference: Toxikologische Bewertung.: 1993

*5.8 TOXICITY TO REPRODUCTION

(a) Type: Fertility []; One-generation study []; Two-generation study []; Other [X]

Species/strain: Rats/Crj: CD (SD)

Sex: Female []; Male []; Male/Female [X]; No data []

Route of Administration: Oral (by gavage)

Exposure period: Male: 14 days before mating
Female: 14 days before mating to day 3 of lactation

Frequency of treatment: Daily

Post exposure observation period:

Premating exposure period: 14 days

Duration of the test:

Dose: 0, 10, 40, 150, 600 mg/kg/day

Control group: Yes [X]; No []; No data []; Sesame oil
Concurrent no treatment[]; Concurrent vehicle[X]; Historical[]

NOEL Parental: Male: 600 mg/kg/day, Female: 600 mg/kg/day

NOEL F1 Offspring: 600 mg/kg/day

NOEL F2 Offspring:

Results: General parental toxicity:
Isocyanuric acid indicated no alteration in reproductive parameters including the copulation index, fertility index, gestation length, numbers of corpora lutea or implantations, implantation index, gestation index, delivery index, and behavior at delivery and lactation.

Toxicity to offspring:
 There were no significant differences in offspring parameters including number of offspring or live offspring, the sex ratio, live birth and viability indices, and body weight. No external or visceral abnormalities related to the test substance were detected in any of the offspring.

Method: OECD Combined Repeat Dose and Reproductive/Developmental Toxicity Screening Test

GLP: Yes [X] No [] ? []

Test substance: purity: 99.8 %

Remarks:

Reference: MHW, Japan: 1997

(b) Type: Fertility []; One-generation study []; Two-generation study []; Other [X] *Three generation study

Species/strain: Rats/CD

Sex: Female []; Male []; Male/Female [X]; No data []

Route of Administration: Oral (in drinking water)

Exposure period: P0: A minimum of 100 days from 36 days of age to mating
 F1 and F2: 120 days after weaning
 F3: 4 weeks

Frequency of treatment: Daily

Post exposure observation period:

Premating exposure period: A minimum of 100 days

Duration of the test:

Dose: 0 (vehicle), 400, 1,200, 5,375 ppm

Control group: Yes [X]; No []; No data []; tap water
 Concurrent no treatment[]; Concurrent vehicle[X]; Historical[]

NOAEL Parental: 5,375 ppm (Approx. 370 mg/kg/day for male, 634 mg/kg/day for female)

NOAEL F1 Offspring: 5,375 ppm

NOAEL F2 Offspring: 5,375 ppm

NOAEL F3 Offspring: 5,375 ppm

Results:

General parental toxicity:
 No compound related changes were observed in mortality, body weight, food consumption, and gestation length. In pathological and histological findings, there were also no changes.

Toxicity to offspring:
 No compound-related changes were observed in mortality, body weights, food consumption litter size, pup survival to weaning, sex ratio, and pup weight. In pathological and histological findings, epithelial hyperplasia with chronic cystitis was observed in a few of high-dose treated males in F2 offsprings, which were attributed to chronic irritation by the calculi in the urinary bladder. In other treated groups, there were no changes.

Method: Other

GLP: Yes [X] No [] ? []

Test substance: Sodium isocyanurate, purity: unknown

- Remarks: Sodium hippurate was provided an equivalent amount of sodium administered to high-dose sodium isocyanurate animals as second control.
Weanlings from the F1 and F2 litters were randomly selected as parents for the next generation and continued on treatment. Related litters and F3 offsprings were sacrificed 4 weeks after weaning and organ weight measurements and microscopic examination of tissues were carried out.
- Reference: Wheeler *et al.*: 1985
- (c) Type: Fertility []; One-generation study []; Two-generation study []; Other [X]
- Species/strain: Mice/CD-1
- Sex: Female []; Male [X]; Male/Female []; No data []
- Route of Administration: i.p.
- Exposure period: 6 weeks
- Frequency of treatment:
- Post exposure observation period:
- Premating exposure period:
- Duration of the test: 6 weeks
- Doses: 0 (vehicle), 125 and 250 mg/kg/day
- Control group: Yes [X]; No []; No data [];
Concurrent no treatment[]; Concurrent vehicle[X]; Historical[]
- NOAEL Parental: 250 mg/kg/day
- NOAEL Foetal: 250 mg/kg/day
- Results:
- General parental toxicity:
Any treatment related effects were not observed in females, mated with sodium isocyanurate treated males.
- Toxicity to fetus:
Any toxicity was not observed.
- Method: Other
- GLP: Yes [] No [X] ? []
- Test substance: Sodium isocyanurate, purity: unknown
- Remarks: As positive control, methyl methane sulfonate was used at dose of 50 mg/kg/day.
Non-treated females are mated with the treated males every week.
As a result, early resorptions were observed in females mated with males treated with methyl methane sulfonate.
- Reference: FMC Corporation: 1972

*5.9 DEVELOPMENTAL TOXICITY/ TERATOGENICITY

- Species/strain: Rabbits/Dutch belted
- Sex: Female [X]; Male []; Male/Female []; No data []
- Route of Administration: Oral (by gavage)
- Duration of the test: 22 days
- Exposure period: Days 6-18 of gestation
- Frequency of treatment: Daily
- Doses: 0 (vehicle), 50, 200, 500 mg/kg/day

Control group:	Yes [X]; No []; No data []; 20 mL/kg water Concurrent no treatment[]; Concurrent vehicle[X]; Historical[]
NOAEL Maternal Toxicity:	50 mg/kg/day
NOAEL teratogenicity:	200 mg/kg/day
Results:	
Maternal general toxicity:	Although slight decrease in body weight were observed in mid- and high-dose groups during the treatment period, compensatory weight gains occurred after termination of treatment on day 18. There were no compound related mortality or other adverse reactions.
Pregnancy/litter data:	
Foetal data:	The mean number of live fetus/dam and the sex ratio were essentially comparable for all groups. Body weights and crown/rump lengths were reduced slightly in high-dose groups, compared to control. There was no evidence of external or internal malformations or skeletal anomalies.
Method:	Other
GLP:	Yes [] No [X] ? []
Test substance:	Sodium isocyanurate, purity: unknown
Remarks:	
Reference:	FMC Corporation, unpublished observations
Species/strain:	Rats/Sprague-Dawley
Sex:	Female [X]; Male []; Male/Female []; No data []
Route of Administration:	Oral (by gavage)
Duration of the test:	20 days
Exposure period:	Days 6-15 of gestation
Frequency of treatment:	Daily
Doses:	0 (vehicle), 200, 1,000, 5,000 mg/kg/day
Control group:	Yes [X]; No []; No data []; Concurrent no treatment[]; Concurrent vehicle[X]; Historical[]
NOAEL Maternal Toxicity:	5,000 mg/kg/day
NOAEL teratogenicity:	5,000 mg/kg/day
Results:	
Maternal general toxicity:	There were no treatment-related effects on maternal appearance, behavior and body weight gain in all groups treated with sodium isocyanurate.
Pregnancy/litter data:	
Foetal data:	No teratogenic effects were observed in all groups treated with sodium isocyanurate.
Method:	Other
GLP:	Yes [X] No [] ? []
Test substance:	Sodium isocyanurate, purity: unknown
Remarks:	Sodium control groups received sodium hippurate at doses of 1,118 and 5,590 mg/kg/day.

In sodium control group, decrease in body weight and crown/rum length, and increase in post-implantation loss and incidence of incomplete ossification were observed.

Reference:

Industry ad hoc Committee for Isocyanurates: 1982

5.10 OTHER RELEVANT INFORMATION

A. Specific toxicities

There is no available data.

B. Toxicodynamics, toxicokinetics

Type:

Toxicokinetics

Results:

Toxicokinetics study of sodium isocyanurate was performed in rats, using [¹⁴C] sodium isocyanurate. The elimination half-life was 30 to 60 min after oral or intravenous administration at 5 mg/kg and 2.5 hr after oral administration at 500 mg/kg. At 5 mg/kg, this chemical was completely absorbed and largely eliminated in urine, while at 500 mg/kg, this chemical was incompletely absorbed and largely eliminated in feces. The remainder of radioactivity in most tissues was below the level of detection (0.1-1.0 µg/g) 7 days after treatment. In second study, rats were administered unlabeled sodium isocyanurate orally at 5 mg/kg/day for 14 days followed by the single exposure on day 15. As results of second study, no bioaccumulation and no significant changes in disposition or metabolism were observed, compared to the single exposure. In excreta, only unchanged isocyanurate was found.

Remarks:

References:

Barbee *et al.*: 1983

Type:

Toxicokinetics

Results:

Toxicokinetics study of sodium isocyanurate was conducted in dogs, using [¹⁴C] sodium isocyanurate. Administration was performed at 5 mg/kg by oral or intravenous route and at 500 mg/kg by oral route. At 5 mg/kg, this chemical was completely absorbed and largely eliminated in urine, while at 500 mg/kg, this chemical was only partially absorbed and largely eliminated in feces. Sodium isocyanurate distributed into an apparent volume of distribution of 0.7 L/kg, which is somewhat greater than total body water volume. The elimination half-life was from 1.5 to 2 hr after administration. Dogs were also administered unlabeled sodium isocyanurate orally at 5 mg/kg/day followed by the single exposure of 5 mg/kg radiolabeled sodium isocyanurate on day 15. The remainder of radioactivity in most tissues was below the level of detection (0.1-3.3 µg/g) for all sampling times for both single and repeated dose administration. In excreta, only unchanged isocyanurate was found.

Remarks:

References:	Barbee <i>et al.</i> : 1984
Type:	Toxicokinetics
Results:	Toxicokinetics study by dermal route was performed, in which species was not indicated. After dermal application, the ¹⁴ C-labelled substance is not detectable in the blood and < 0.01% of the administered dose is found in the urine.
Remarks:	
References:	Toxikologische Bewertung: 1993

* 5.11 EXPERIENCE WITH HUMAN EXPOSURE

Results:	Toxicokinetics of isocyanuric acid was investigated in 5 volunteers, who soaked in a swimming pool for 120 minutes. As a result, the cumulative excretion of isocyanuric acid was 0.03-2.8 mg, equivalent to 3.0-3.6 ml of pool water and the elimination half-life is calculated as 3 hr. On the other hand, recovery of ingested isocyanuric acid is 98 % in urine. No correlation observed between toxicokinetics and gamma glutamyl transpeptidase activity. Distribution 1 compartment open model.
Remarks:	
Reference:	Allen <i>et al.</i> : 1982

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