



Name: Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt

Legal entity owner: National Institute of Health Sciences / Tokyo / Japan

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Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt

CORE

General information

Identification

SUBSTANCE: Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt

UUID: IUC5-45e7d1b9-a09e-4bc1-bcc0-0ef3107af152

Dossier UUID:

Author: SuperUser

Date: 2017-01-18T17:06:20.000+09:00

Remarks:

Substance name

Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt

Legal entity

[National Institute of Health Sciences / Tokyo / Japan](#)

Role in the supply chain

Manufacturer

false

Importer

false

Only representative

false

Downstream user

false

OECD

Health Effects

Acute toxicity: oral

ENDPOINT_STUDY_RECORD: Acute toxicity: oral.001

UUID: IUC5-f949fdfb-b2fe-45c3-84d5-ecf2977221e1

Dossier UUID:

Author: SuperUser

Date: 2017-01-18T15:00:11.000+09:00

Remarks:

Administrative data

Endpoint

acute toxicity: oral

Type of information

experimental study

Adequacy of study

other information

Robust study summary

false

Used for classification

false

Used for SDS

false

Reliability

1 (reliable without restriction)

Rationale for reliability incl. deficiencies

other: OECD Test Guideline study under GLP condition

Data source

Reference

[Single Dose Oral Toxicity Test of Benzenesulfonic acid, 4-hydroxy-, tin\(2+\)salt in Rats / MHLW, Japan / study report](#)

Data protection claimed

yes

Materials and methods

Test guideline

Qualifier

according to

Guideline

OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method)

Deviations

no

GLP compliance

yes

Test type

acute toxic class method

Limit test

yes

Test material

Test material information

[70974-33-3](#) / [70974-33-3](#)

Test animals

Species

rat

common species

Strain

Crj: CD(SD)

rat

Sex

female

Details on test animals and environmental conditions**TEST ANIMALS**

- Source: Charles River Japan Inc.
- Age at the time of purchase: 7 weeks old
- Weight at dosing: Females, 191 - 205 g- Fasting period before study: Approximately 16 hrs
- Housing: One animal/cage- Diet (e.g. ad libitum): Ad libitum except fasting period for 16 hrs before administration to 3 hrs after administration
- Water (e.g. ad libitum): Ad libitum
- Acclimation period: 7 - 14 days

. ENVIRONMENTAL CONDITIONS

- Temperature (°C): 22.6 - 23.6
- Humidity (%): 45.6 - 62.2- Ventilation (per hr): Approximately > 12 times
- Photoperiod (hrs light / hrs dark): 12/12

Administration / exposure

Route of administration

oral: gavage

Vehicle

water

Details on oral exposure

VEHICLE

- Concentration in vehicle: 3 and 20 w/v%
 - Lot no.: 5K91 produced by Otsuka Pharmaceutical Factory, Inc.
- MAXIMUM DOSE VOLUME APPLIED: 10 ml/kg bw.

Doses

300 and 2000 mg/kg bw

No. of animals per sex per dose

First time of administration: 300 mg/kg bw, 3 females (animal ID No. 8, 9, 12), 2000 mg/kg bw, 3 females (animal ID No. 5, 6, 11)

Second time of administration: 300 mg/kg, 3 females (animal ID No. 1, 4, 7), 2000 mg/kg bw, 3 females (animal ID No. 2, 3, 10)

Control animals

no

Details on study design

- Duration of observation period following administration: 14 days- Frequency of observations: Day 1 (day of administration): within 30 minutes and 1, 2, 3, 4, 5 and 6 hrs after administration. After Day 2: once a day
- Frequency of weighing: Days 1 (before administration), 7, 14
- Necropsy of survivors performed: Yes

Statistics

No

Results and discussion

Effect levels

Key result

false

Sex

female

Dose descriptor

LD50

Effect level

> 2000 mg/kg bw

Based on

act. ingr.

Mortality

No deaths were observed at 300 and 2000 mg/kg bw

Clinical signs

Salivation was observed in one rat receiving 300 mg/kg bw just after administration. Loose stool was observed on the day of administration, and dirty nose and no-feces were observed on the 1-2 days after administration in rats receiving 2000 mg/kg bw.

Body weight

No effects.

Gross pathology

No effects.

Applicant's summary and conclusion

Conclusions

The LD50 value was more than 2000 mg/kg bw for female rats.

Executive summary

The acute oral LD50 of benzenesulfonic acid, 4-hydroxy-, tin (2+) salt was >2000 mg/kg bw in female rats based on a study conducted according to the OECD TG 423. No deaths were observed at 2000 mg/kg bw. The substance caused transient salivation at 300 mg/kg bw, and the transient effects of dirty nose, loose stool, and no feces at 2000 mg/kg bw.

Repeated dose toxicity: oral

ENDPOINT_STUDY_RECORD: Repeated dose toxicity: oral.001

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Dossier UUID:

Author: SuperUser

Date: 2017-01-18T15:46:34.000+09:00

Remarks:

Administrative data

Endpoint

short-term repeated dose toxicity: oral

Type of information

experimental study

Adequacy of study

other information

Robust study summary

false

Used for classification

false

Used for SDS

false

Reliability

1 (reliable without restriction)

Rationale for reliability incl. deficiencies

other: OECD Test Guideline study under GLP condition

Cross-reference

Reason / purpose

reference to same study

Remarks

7.8.1 Toxicity to reproduction: Toxicity to reproduction.001

Data source

Reference

[A combined repeated-dose/reproductive-developmental toxicity study of Benzenesulfonic acid, 4-hydrox... / MHLW, Japan / study report](#)

Data access

data published

Materials and methods

Test guideline

Qualifier

according to

Guideline

OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)

Deviations

no

GLP compliance

yes

Limit test

no

Test material

Test material information

[70974-33-3](#) / [70974-33-3](#)

Test animals

Species

rat

common rodent species

Strain

Crj: CD(SD)

rat

Sex

male/female

Details on test animals and environmental conditions**TEST ANIMALS**

- Source: Atsugi Breeding Center, Charles River Laboratories Japan, Inc.
 - Age at study initiation: 10 weeks of age
 - Weight at study initiation: 340-409 g for males and 205-257 g for females
 - Housing: bracket-type metallic wire-mesh cages (W 250 × D 350 × H 200 mm)
 - Diet (e.g. ad libitum): ad libitum
 - Water (e.g. ad libitum): ad libitum
 - Acclimation period: 15 days
- ENVIRONMENTAL CONDITIONS**
- Temperature (°C): 21 to 26°C
 - Humidity (%): 38 to 63%
 - Air changes (per hr): 10 to 15 times per hour
 - Photoperiod (hrs dark / hrs light): 12-hour lighting per day

Administration / exposure

Route of administration

oral: gavage

Vehicle

water

Details on oral exposure

PREPARATION OF DOSING SOLUTIONS: Test substance was dissolved in distilled water for injection.

VEHICLE

- Justification for use and choice of vehicle: No data
- Amount of vehicle (if gavage): 5 mL/kg bw
- Lot/batch no. (if required): No data
- Dosing volume: 5 mL/kg
- Storage condition of test solution: Stored in a refrigerator

Analytical verification of doses or concentrations

yes

Details on analytical verification of doses or concentrations

Test suspensions at each concentration to be used for males in week 1 and 6 of administration were analyzed by the HPLC method at Bozo Research Center Inc. Results showed that the concentration of the test article in each suspension was 94.5 to 107.5% of the nominal concentration, and both values were within the acceptable range (concentration: percentage of the nominal concentration, $100 \pm 10\%$; C.V.: 10% or below)

Duration of treatment / exposure

All males and females without mating: 42 days

Females with mating: up to 51 days including 14 days pre-mating, mating and gestation periods and until day 4 of lactation

Frequency of treatment

Daily: 7 times / week

Doses / concentrations

Remarks

Doses / Concentrations:

0 (vehicle), 12, 60 and 300 mg/kg bw/day

Basis:

actual ingested

No. of animals per sex per dose

12 animals/sex/dose with mating (main dose group), 5 animals/sex/dose at 0 and 300 mg/kg bw/day without mating (recovery group)

Control animals

yes, concurrent vehicle

Details on study design

- Dose selection rationale: A preliminary study was conducted to determine the doses to be employed. Male and female rats were receiving 0, 100, 300, and 1000 mg/kg bw/day (5 animals/sex/dose) of the substance was administered for 14 days. As the results, thickening in limiting ridge of the stomach was observed in 2 males and 2 females receiving 100 mg/kg bw/day. Thickening in limiting ridge of the stomach and dilatation in the cecum were observed in almost all animals receiving 300 mg/kg bw/day or more. Decreases in body weights in males and food consumption in both sexes, and increases in AST and ALT activities were observed in an early administration period at 1000 mg/kg bw/day. Therefore, the high dose was set at 300 mg/kg/day, and the middle and low dose were set at 60 and 12 mg/kg/day using common ratio 5.

Examinations

Observations and examinations performed and frequency

CAGE SIDE OBSERVATIONS: Yes

- Time schedule:

Males and females: once a day before the start of administration, 3 times/day during the administration period, and once a day during the recovery period

DETAILED CLINICAL OBSERVATIONS: Yes

- Time schedule:

Males: once before the start of administration, once a week during the administration and recovery periods

Females: once before the start of administration, days 1, 7, 14 and 20 of gestation, and day 4 of lactation

BODY WEIGHT: Yes

- Time schedule for examinations:

Males in the main groups were weighed on days 1, 4, 8, 11, 15, 18, 22, 25, 29, 32, 36, 39 and 42 of administration and on the day of necropsy, and males and females in the recovery groups were weighed on days 1, 4, 8, 11 and 14 of recovery and on the day of necropsy.

Females in the main groups were weighed on days 1, 4, 8, 11 and 15 of administration (uncopulated animals were weighed on day 18 and 22 of administration as well), days 0, 4, 7, 11, 14, 17 and 20 of gestation, days 0 and 4 of lactation and the day of necropsy.

FOOD CONSUMPTION : Yes

Measurement of food consumption was conducted on all animals at the following frequencies:

males in the main groups: on days 1, 4, 8, 11, 15, 32, 36, 39 and 42 of administration; males and females in the recovery groups on days 1, 4, 8, 11 and 14 of recovery in addition to the measurement days for males in the main groups; and females in the main groups on days 1, 4, 8, 11 and 15 of administration, days 1, 4, 7, 11, 14, 17 and 20 of gestation and days 2 and 4 of lactation.

FOOD INTAKE: No

HAEMATOLOGY: Yes

- Time schedule for collection of blood: On the next day of the last administration and on the last day of the recovery period

- Anaesthetic used for blood collection: Yes (identity)

- Animals fasted: Yes

- How many animals: 5 animals/sex/group

- Parameters examined: red blood cell count, hemoglobin, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, reticulocyte percentage, platelet count, white blood cell count, differential white blood cell count, absolute number of each white blood cell, prothrombin time, activated partial thromboplastin time, fibrinogen volume

CLINICAL CHEMISTRY: Yes

- Time schedule for collection of blood: On the next day of the last administration and on the last day of the recovery period

- Animals fasted: Yes

- How many animals: 5 animals/sex/group

- Parameters checked: ALP, total cholesterol, triglyceride, phospholipids, total bilirubin, glucose, blood urea nitrogen, creatinine, sodium, potassium, chloride, calcium, inorganic phosphorus, total protein, albumin, A/G ratio, AST (GOT), ALT (GPT), LDH, γ -GTP

URINALYSIS: Yes

- Time schedule for collection of urine (males): final week of administration period (days 37 to 38 of administration) and in the final week of recovery period (days 9 to 10 of recovery)

- Metabolism cages used for collection of urine: Yes

- Animals fasted: Yes

Collection of four-hour urine samples under fasting but ad libitum drinking conditions, followed by collection of 20-hour urine samples under ad libitum feeding and drinking conditions.

- Parameters checked: pH, protein, ketones, glucose, occult blood, bilirubin, urobilinogen, color, sediment, urine volume (4-hour sample), osmotic pressure, urine volume (20-hour sample), water intake (4-hour+20-hour volume)

BLOOD HORMONE: No

- Time schedule for collection of serum: No

- Parameters checked: No

NEUROBEHAVIOURAL EXAMINATION: Yes

- Time schedule for examinations: Manipulative test and measurements of grip strength and motor activity were conducted on 5 animals per group with the following frequencies: males in the main groups were examined in the final week of administration (day 36 of administration), females in the main

groups on day 4 of lactation (day 42 and 43 of administration) after necropsy of F1 pups, and males and females in the recovery groups in the final week of administration (day 36 of administration) and in the final week of recovery (day 8 of recovery).

- Dose groups that were examined: All animals were examined for detailed clinical signs once before the start of administration. Thereafter, males in the main groups were examined once weekly during the administration period, whereas females were observed once weekly during the pre-mating administration period and mating period as well as on designated days during the gestation and lactation periods (days 1, 7, 14 and 20 of gestation, and day 4 of lactation). Animals in the recovery groups were examined once weekly during the administration and recovery periods.

- Battery of functions tested:

- 1) Open field observation. Arousal, gait, posture, tremor, convulsion, rearing count, defecation (defecation count, urination), stereotypy (grooming, circling, etc.), abnormal behavior (self-biting, backward walking, etc.)
- 2) Manipulative Test. Auditory response, approach response, touch response, tail pinch response, pupillary reflex, aerial righting reflex, landing foot splay
- 3) Measurement of Grip Strength. Following manipulative test, grip strength of forelimb and hind limb was measured by CPU gauge MODEL-9502A (AIKOH Engineering Co., Ltd.).
- 4) Measurement of Motor Activity. Following measurement of grip strength, motor activity was measured by a motor activity sensor for experimental animals NS-AS01 (NeuroScience, Inc). The measurement was conducted for 1 hour, and measured values at 10-minute intervals and from 0 to 60 minutes were recorded.

Sacrifice and pathology

GROSS PATHOLOGY AND ORGAN WEIGHTS : Yes Brain, thyroids(including parathyroids), thymus, heart, liver, spleen, kidneys, adrenals, testes, and epididymis

HISTOPATHOLOGY: Yes Cerebrum, cerebellum, pituitary, spinal cord (thoracic), thyroid, parathyroid, adrenal glands, thymus, spleen, submandibular lymph nodes, mesenteric lymph nodes, heart, lung (including bronchial), stomach, duodenum, jejunum, ileum, cecum, colon, rectum, liver, kidney, bladder, testis, epididymis, ovary, uterus, seminal vesicles, sternum and femur (including bone marrow), macroscopic lesions, and parts for identification (auricles)

Statistics

The data were analyzed for homogeneity of variance by the Bartlett test (level of significance: 0.01, two-tailed). If variances were homogeneous, data were analyzed by the Dunnett test, whereas heterogeneous data were analyzed by the Steel test. In the recovery test, these values of two groups were analyzed by F test and Student or Aspin-Welch t-test. Frequency data were analysed by Fisher test. Statistical significance was set at < 5% by two-sided

Results and discussion

Results of examinations

Clinical signs

effects observed, treatment-related

Mortality

mortality observed, treatment-related

Body weight and weight changes

no effects observed

Food consumption and compound intake (if feeding study)

no effects observed

Food efficiency

not examined

Haematological findings

effects observed, treatment-related

Clinical biochemistry findings

effects observed, treatment-related

Urinalysis findings

no effects observed

Behaviour (functional findings)

no effects observed

Organ weight findings including organ / body weight ratios

no effects observed

Gross pathological findings

effects observed, treatment-related

Histopathological findings: non-neoplastic

effects observed, treatment-related

Histopathological findings: neoplastic

not specified

Details on results

CLINICAL SIGNS AND MORTALITY: Mortality: No animal died in any group. Clinical signs: Salivation was observed in six males (main group) receiving 300 mg/kg bw/day on week 4 of the dosing period. This effect was considered to be due to irritating property of the test substance.

DETAILED CLINICAL OBSERVATIONS, MANIPULATIVE TEST, GRIP STRENGTH TEST AND Locomotor Activity Measurement:

Home cage observation: No effects

In-the-hand observation: No effects

Open field observation: No effects

Manipulative test: A significant decrease in landing foot splay was observed in females receiving 300 mg/kg bw/day on Day 4 of the lactation period, but it was considered to be spontaneous.

Measurement of grip strength: No effects

Measurement of Motor Activity: No effects

BODY WEIGHT: No effects

FOOD CONSUMPTION: No effects

URINALYSIS: No effects

HAEMATOLOGY: Significant decreases in hemoglobin and hematocrit levels were observed in females receiving 300 mg/kg bw/day at the end of the dosing period. Significant increases in hemoglobin and hematocrit levels and a significant decrease in reticulocyte counts were observed in females receiving 300 mg/kg bw/day at the end of the recovery period.

CLINICAL CHEMISTRY: A significant increase in ALT and a decrease in total protein level were observed in males receiving 300 mg/kg bw/day at the end of the dosing period.

ORGAN WEIGHTS: There were no changes related to the test substance in any group during the dosing and recovery periods.

GROSS PATHOLOGY:

At the End of the Administration Period

Cecum: Dilatation was observed in eight males and two females receiving 300 mg/kg bw/day.

Stomach: Thickening in limiting ridge was observed in four males and two females receiving 300 mg/kg bw/day.

At the End of the Recovery Period

There were no lesions related to the test substance in any group.

HISTOPATHOLOGY: NON-NEOPLASTIC:

At the End of the Administration Period

Both sexes had minimal hypertrophy of the duodenal mucosal epithelia at 300 mg/kg bw/day

Intestine: Diverticulum in ileum was observed in one control male.

Kidney: Cyst was observed in one control male.

Spleen: Focus in raised was observed in one control male.

At the End of the Recovery Period

There were no lesions related to the test substance in any group.

Effect levels

Dose descriptor

NOAEL

Effect level

60

mg/kg bw/day (actual dose received)

Based on

act. ingr.

Sex

male/female

Basis for effect level

other: Decreases in hemoglobin and hematocrit levels(females), increases in ALT (males), and lesions in the caecum, stomach and duodenum at 300 mg/kg bw/day.

Target system / organ toxicity

Key result

false

Critical effects observed

not specified

Any other information on results incl. tables

Figures and Tables (in English) are available in the following full report of the study.

http://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF70974-33-3d.pdf

Applicant's summary and conclusion

Conclusions

Based on the changes in the blood and gastrointestinal organs, the NOAEL of repeated dose toxicity was determined to be 60 mg/kg bw/day in male and female rats.

Executive summary

A combined repeated oral dose toxicity study with the reproduction/developmental toxicity screening test was performed according to the OECD TG 422. Male and female rats (12 animals/sex/dose) were administered benzenesulfonic acid, 4-hydroxy-, tin (2+) salt at 0, 12, 60, and 300 mg/kg bw/day. Males were dosed for 42 days, including a 14-day pre-mating period and subsequent mating period. Females were dosed for 41–51 days, including 14 day pre-mating, mating, and gestation periods, and the time until lactation day 4. Five animals/sex/dose administered 0 and 300 mg/kg bw/day were treated as a recovery group and examined after a 14 day recovery period. Salivation was observed after 4 weeks of administration in males at 300 mg/kg bw/day. After the administration period, rats administered 300 mg/kg bw/day showed decreased hemoglobin and hematocrit levels in females and increased serum alanine transaminase levels in males. By gross pathology, both sexes exhibited thickening of the limiting ridge of the stomach and dilatation of the cecum at 300 mg/kg bw/day. Upon histopathological examination, both

sexes had minimal hypertrophy of the duodenal mucosal epithelia at 300 mg/kg bw/day. These changes resolved after the recovery period. Based on the changes in the blood and gastrointestinal organs, the NOAEL of repeated dose toxicity was determined to be 60 mg/kg bw/day in male and female rats.

Genetic toxicity in vitro

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.001

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Dossier UUID:

Author: SuperUser

Date: 2017-01-18T16:47:14.000+09:00

Remarks:

Administrative data

Endpoint

in vitro gene mutation study in bacteria Type of genotoxicity: gene mutation

Type of information

experimental study

Adequacy of study

other information

Robust study summary

false

Used for classification

false

Used for SDS

false

Reliability

1 (reliable without restriction)

Rationale for reliability incl. deficiencies

other: OECD Test Guideline study under GLP condition

Data source

Reference

[Reverse Mutation Test of Benzenesulfonic acid, 4-hydroxy-, tin\(2+\)salt on Bacteria. / MHLW, Japan / study report](#)

Data access

data published

Materials and methods

Test guideline

Qualifier

according to

Guideline

OECD Guideline 471 (Bacterial Reverse Mutation Assay)

in vitro gene mutation study in bacteria

Deviations

no

Qualifier

according to

Guideline

JAPAN: Guidelines for Screening Mutagenicity Testing Of Chemicals

GLP compliance

yes

Type of assay

bacterial reverse mutation assay
in vitro gene mutation study in bacteria

Test material

Test material information

[70974-33-3](#) / [70974-33-3](#)

Method

Species / strain

Species / strain

other: Salmonella typhimurium TA1535, TA1537, TA98, TA100 and Escherichia coli WP2 uvrA

Metabolic activation

with and without

Metabolic activation system

S9 mix; rat liver, induced by phenobarbital and 5,6-benzoflavone

Test concentrations with justification for top dose

-S9 mix: 156, 313, 625, 1250, 2500, 5000 µg/plate (TA100, TA1535, TA98, TA1537, WP2uvrA strains)

+S9 mix: 156, 313, 625, 1250, 2500, 5000 µg/plate (TA100, TA1535, TA98, TA1537, WP2uvrA strains)

Vehicle

- Vehicle(s)/solvent(s) used: water

Controls

Negative controls

no

Solvent controls

yes

True negative controls

no

Positive controls

yes

Positive control substance

other:

Remarks

S9 mix: 2-(2-Furyl)-3-(5-nitro-2-furyl) acrylamide (TA 100, TA98 and WP2 uvrA), sodium azide (TA1535) and 9-aminoacridine hydrochloride (TA1537). +S9 mix: 2-aminoanthracene (all strains)

Details on test system and conditions

METHOD OF APPLICATION: Preincubation

DURATION- Preincubation period: 20 min at 37 °C - Exposure duration:48 hrs

NUMBER OF PLATES: 3

NUMBER OF REPLICATIONS: 2

DETERMINATION OF CYTOTOXICITY- growth inhibition

Evaluation criteria

When the mean number of revertant colonies per plate increased twice more than that of the negative control and when a dose-related and reproducible increase was observed, the chemical was judged to be mutagenic.

Statistics

No

Results and discussion

Test results

Key result

false

Species / strain

other: Salmonella typhimurium TA1535, TA1537, TA98, TA100 and Escherichia coli WP2 uvrA

Metabolic activation

with and without

Genotoxicity

negative

Cytotoxicity

yes

Vehicle controls valid

yes

Positive controls valid

yes

Remarks on result

other: all strains/cell types tested Migrated from field 'Test system'.

Additional information on results

RANGE-FINDING/SCREENING STUDIES:Concentration: 8.19, 20.5, 51.2, 128, 320, 800, 2000, 5000 µg/plate

Cytotoxic conc.: Yes TA1537 at 5000 ug/plate with S9 mix.

Any other information on results incl. tables

Figures and Tables (in English) are available in the following full report of the study.

http://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF70974-33-3e.pdf

Applicant's summary and conclusion

Conclusions

Interpretation of results (migrated information):

negative with and without S9mix

Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt did not induce gene mutations in the in vitro bacteria test.

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.002

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Dossier UUID:

Author: SuperUser

Date: 2017-01-18T17:06:07.000+09:00

Remarks:

Administrative data

Endpoint

in vitro cytogenicity / chromosome aberration study in mammalian cells Type of genotoxicity: gene mutation

Type of information

experimental study

Adequacy of study

other information

Robust study summary

false

Used for classification

false

Used for SDS

false

Reliability

1 (reliable without restriction)

Rationale for reliability incl. deficiencies

other: OECD Test Guideline study under GLP condition

Data source

Reference

[In Vitro Chromosomal Aberration Test of Benzenesulfonic acid, 4-hydroxy-, tin\(2+\)salt on Cultured Ch... / MHLW, Japan / study report](#)

Data access

data published

Materials and methods

Test guideline

Qualifier

according to

Guideline

OECD Guideline 473 (In Vitro Mammalian Chromosome Aberration Test)
in vitro cytogenicity / chromosome aberration study in mammalian cells

Deviations

no

Qualifier

according to

Guideline

JAPAN: Guidelines for Screening Mutagenicity Testing Of Chemicals

Deviations

no

GLP compliance

yes

Type of assay

in vitro mammalian chromosome aberration test
chromosome aberration

Test material**Test material information**

[70974-33-3](#) / [70974-33-3](#)

Method**Species / strain****Species / strain**

mammalian cell line, other: Chinese hamster lung(CHL/IU) cells
mammalian cell line

Metabolic activation

with and without

Metabolic activation system

S9 mix; rat liver, induced by phenobarbital and 5,6-benzoflavone

Test concentrations with justification for top dose

-S9 mix (continuous treatment): 0, 181, 259, 370, 528, 755, 1078 ug/mL

-S9 mix (short-term treatment): 0, 370, 528, 755, 1078, 1540 ug/mL

+S9 mix (short-term treatment): 0, 370, 528, 755, 1078, 1540, 2200 ug/mL

Vehicle

- Vehicle(s)/solvent(s) used: water

Controls**Negative controls**

no

Solvent controls

yes

True negative controls

no

Positive controls

yes

Positive control substance

other:

Remarks

[continuous treatment and short time treatment, -S9]: mitomycin C; [short-term treatment, +S9]: cyclophosphamide

Details on test system and conditions

METHOD OF APPLICATION: Exposure duration: [continuous treatment]: 24 hrs [short-term treatment]: 6 hrs + 18 hr

SPINDLE INHIBITOR: Colcemid

STAIN: Giemsa stain for 12 min.

NUMBER OF REPLICATIONS: 2

NUMBER OF CELLS EVALUATED: 200 cells / dose

DETERMINATION OF CYTOTOXICITY

- Method: relative total growth

RANGE-FINDING/SCREENING STUDIES:

1st test; Concentration: 9.08, 18.2, 36.3, 72.7, 145, 291, 581, 1163, 2325, and 4650 µg/mL (10 mM)

Visible precipitation was observed at 1163 µg/mL and higher

2nd test to confirm cytotoxicity; Concentration: 581, 1163, 2325, and 4650 µg/mL (10 mM)

50% growth inhibitions were observed at 1086 µg/mL for -S9, 1796 µg/mL for +S9, 510 µg/mL for continuous treatment

Evaluation criteria

For the evaluation of the frequencies of structural aberrations and of polyploidy induced, the following criteria, which are usually used for chromosomal aberration testing with CHL, were employed. Appearance incidence of cell with chromosomal aberrations: Negative(-): less than 5% Equivocal(±): 5% or more, less than 10% Positive(+): 10% or more

Statistics

Fisher and Cochran-Armitage trend tests (one-sided test, P = 2.5%)

Results and discussion

Test results

Key result

false

Species / strain

mammalian cell line, other: Chinese hamster lung (CHL/IU) cells
mammalian cell line

Metabolic activation

with and without

Genotoxicity

positive

Cytotoxicity

yes

Vehicle controls valid

yes

Positive controls valid

yes

Remarks on result

other: all strains/cell types tested Migrated from field 'Test system'.

Any other information on results incl. tables

Figures and Tables (in English) are available in the following full report of the study.

http://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF70974-33-3f.pdf

Applicant's summary and conclusion

Conclusions

Interpretation of results (migrated information):

positive

Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt induce chromosomal aberrations in cultured cells with and without S9 mix under the conditions of this study. The positive control showed expected results.

Toxicity to reproduction

ENDPOINT_STUDY_RECORD: Toxicity to reproduction.001

UUID: IUC5-c6d5ef64-4719-4fbb-8394-78905f3abbe7

Dossier UUID:

Author: SuperUser

Date: 2017-01-19T11:43:43.000+09:00

Remarks:

Administrative data

Endpoint

screening for reproductive / developmental toxicity based on test type (migrated information)

Type of information

experimental study

Adequacy of study

other information

Robust study summary

false

Used for classification

false

Used for SDS

false

Reliability

1 (reliable without restriction)

Rationale for reliability incl. deficiencies

other: OECD Test Guideline study under GLP condition

Cross-reference

Reason / purpose

reference to same study

Remarks

7.5.Repeated dose toxicity: oral: Repeated dose toxicity: oral.001

Data source

Reference

[A combined repeated-dose/reproductive-developmental toxicity study of Benzenesulfonic acid, 4-hydrox... / MHLW, Japan / study report](#)

Data access

data published

Materials and methods

Test guideline

Qualifier

according to

Guideline

OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)

Deviations

no

GLP compliance

yes

Limit test

no

Test material

Test material information

[70974-33-3](#) / [70974-33-3](#)

Test animals

Species

rat

Strain

Crj: CD(SD)

rat

Sex

male/female

Details on test animals and environmental conditions**TEST ANIMALS**

- Source: Atsugi Breeding Center, Charles River Laboratories Japan, Inc.
 - Age at study initiation: 10 weeks of age
 - Weight at study initiation: 340-409 g for males and 205-257 g for females
 - Housing: bracket-type metallic wire-mesh cages (W 250 × D 350 × H 200 mm)- Diet (e.g. ad libitum): ad libitum
 - Water (e.g. ad libitum): ad libitum
 - Acclimation period: 15 days
- ENVIRONMENTAL CONDITIONS**
- Temperature (°C): 21 to 26°C
 - Humidity (%): 38 to 63%
 - Air changes (per hr): 10 to 15 times per hour
 - Photoperiod (hrs dark / hrs light): 12-hour lighting per day

Administration / exposure

Route of administration

oral: gavage

Vehicle

water

Details on exposure

PREPARATION OF DOSING SOLUTIONS: Test substance was dissolved in distilled water for injection.

VEHICLE

- Justification for use and choice of vehicle: No data
- Amount of vehicle (if gavage): 5 ml/kg bw
- Lot/batch no. (if required): No data
- Dosing volume: 5 mL/kg
- Storage condition of test solution: Stored in a refrigerator

Analytical verification of doses or concentrations

yes

Details on analytical verification of doses or concentrations

Test suspensions at each concentration to be used for males in week 1 and 6 of administration were analyzed by the HPLC method at Bozo Research Center Inc. Results showed that the concentration of the test article in each suspension was 94.5 to 107.5% of the nominal concentration, and both values were within the acceptable range (concentration: percentage of the nominal concentration, $100 \pm 10\%$; C.V.: 10% or below)

Duration of treatment / exposure

All males and females without mating: 42 days

Females with mating: up to 51 days including 14 days pre-mating, mating and gestation periods and until day 4 of lactation

Frequency of treatment

Daily: 7 times / week

Doses / concentrations

Remarks

Doses / Concentrations:

0 (vehicle), 12, 60 and 300 mg/kg bw/day

Basis:

actual ingested

No. of animals per sex per dose

12 animals/sex/dose with mating (main dose group), 5 animals/sex/dose at 0 and 300 mg/kg bw/day without mating (recovery group)

Control animals

yes, concurrent vehicle

Details on study design

- Dose selection rationale: A preliminary study was conducted to determine the doses to be employed. Male and female rats were receiving 0, 100, 300, and 1000 mg/kg bw/day (5 animals/sex/dose) of the substance was administered for 14 days. As the results, thickening in limiting ridge of the stomach was observed in 2 males and 2 females receiving 100 mg/kg bw/day. Thickening in limiting ridge of the stomach and dilatation in the cecum were observed in almost all animals receiving 300 mg/kg bw/day or more. Decreases in body weights in males and food consumption in both sexes, and increases in AST and ALT activities were observed in an early administration period at 1000 mg/kg bw/day. Therefore, the high dose was set at 300 mg/kg/day, and the middle and low dose were set at 60 and 12 mg/kg/day using common ratio 5.

Examinations

Parental animals: Observations and examinations

See 7.5.1 Repeated dose toxicity: oral Endpoint study record: Repeated dose toxicity: oral.001 for observations and examinations for general toxicity

Estrous cyclicity (parental animals)

Vaginal smears were collected from all females in the main groups and microscopically examined every day from the day after the start of administration until the day copulation was confirmed.

During the pre-mating administration period, vaginal smear pictures were classified as proestrus, estrus, metestrus or diestrus and examined for the frequency of estrus and interval between estruses (estrous cycle). During the mating period, vaginal smears were examined for the presence of sperm.

Sperm parameters (parental animals)

Parameters examined in P male parental generations: testes weight, epididymides weight

Litter observations

PARAMETERS EXAMINED: Number and sex of pups, stillbirths, live births, postnatal mortality, presence of gross anomalies, and weight gain.

GROSS EXAMINATION OF DEAD PUPS: Yes, for external and internal abnormalities.

Postmortem examinations (parental animals)

SACRIFICE: Male animals: Rats were euthanized by exsanguination under ether anesthesia on the day after the last administration. Maternal animals: Rats were euthanized by exsanguination under ether anesthesia on day 4 of lactation.

GROSS PATHOLOGY AND ORGAN WEIGHTS : Yes Brain, thyroids(including parathyroids), thymus, heart, liver, spleen, kidneys, adrenals, testes, and epididymis

HISTOPATHOLOGY: Yes Cerebrum, cerebellum, pituitary, spinal cord (thoracic), thyroid, parathyroid, adrenal glands, thymus, spleen, submandibular lymph nodes, mesenteric lymph nodes, heart, lung (including bronchial), stomach, duodenum, jejunum, ileum, cecum, colon, rectum, liver, kidney, bladder, testis, epididymis, ovary, uterus, seminal vesicles, sternum and femur (including bone marrows), macroscopic lesions, and parts for identification (auricles)

Postmortem examinations (offspring)

SACRIFICE: The F1 pups were euthanized on PND 4 by exsanguination under ether anesthesia.

GROSS NECROPSY: Yes

Statistics

The data were analyzed for homogeneity of variance by the Bartlett test (level of significance: 0.01, two-tailed). If variances were homogeneous, data was analyzed by the Dunnett test, whereas heterogeneous data was analyzed by a Steel test. In the recovery test, these values of two groups were analyzed by F test and Student or Aspin-Welch t-test. Frequency data were analysed by Fisher test. Statistical significance was set at < 5% by two-sided

Reproductive indices

Each parameter was determined by the following equations:

Copulation index (%) = (No. of copulated animals/No. of co-housed animals) × 100

Fertility index (%) = (No. of pregnant females/No. of copulated females) × 100

Insemination index (%) = (No. of pregnant females/No. of copulated males) × 100

Duration of gestation (days) = day 0 of lactation – day 0 of gestation

Delivery index (%) = (No. of females delivered liveborn pups/No. of pregnant females) × 100

Implantation index (%) = (No. of implantation sites/No. of corpora lutea) × 100

Stillborn index (%) = (No. of stillborn pups/Total No. of pups born) × 100

Liveborn index (%) = (No. of liveborn pups/Total No. of pups born) × 100

External abnormalities (%) = (No. of pups with external abnormalities/No. of liveborn pups) × 100

Sex ratio = No. of males/(No. of males + No. of females)

Viability index (%) = (No. of surviving pups on day 4 after birth/No. of liveborn pups on day 0 after birth) × 100

Offspring viability indices

Number of live pups on day 0 of lactation
Birth index (%) = (Number of live pups on day 0/Number of implantation sites) × 100

Live birth index (%) = (Number of live pups on day 0/Number of pups born) × 100

Pups weight on day 0 of lactation
Sex ratio on day 0 of lactation

Number of live pups on day 4 of lactation

Pups weight on day 4 of lactation

Sex ratio on day 4 of lactation

Viability index = (Number of live pups on day 4 after birth/Number of live pups born) × 100

Results and discussion

Results: P0 (first parental animals)

General toxicity (P0)

Clinical signs

effects observed, treatment-related

Body weight and weight changes

effects observed, treatment-related

Food consumption and compound intake (if feeding study)

effects observed, treatment-related

Organ weight findings including organ / body weight ratios

no effects observed

Description (incidence and severity)

on reproductive organ

Gross pathological findings

no effects observed

Description (incidence and severity)

on reproductive organ

Histopathological findings: non-neoplastic

no effects observed

Description (incidence and severity)

on reproductive organs

Other effects

not examined

Reproductive function / performance (P0)

Reproductive function: estrous cycle

no effects observed

Reproductive performance

no effects observed

Details on results (P0)

1) Estrous Cycle

There were no animals showing abnormal estrous cycles, and there were no significant differences in the average length of the estrous cycle between the control group and any treatment group.

2) Results of Mating

There were no significant differences in the number of elapsed days until copulation, copulation index, insemination index or fertility index between the control group and any treatment groups.

3) Delivery Data and Delivery

There were no significant differences in the delivery index, duration of gestation, number of corpora lutea, number of implantation sites, implantation index, stillborn index, number of liveborn pups or liveborn index between the control group and any treatment groups. No changes in nesting, gather the pups, and breast-feeding behavior were observed in all dams during the lactation period.

Effect levels (P0)

Dose descriptor

NOAEL

Effect level

300

mg/kg bw/day (actual dose received)

Based on

act. ingr.

Sex

male/female

Basis for effect level

other: Noeffects on reproduction

Results: F1 generation

General toxicity (F1)

Clinical signs

no effects observed

Mortality / viability

no mortality observed

Body weight and weight changes

no effects observed

Gross pathological findings

no effects observed

Effect levels (F1)

Dose descriptor

NOAEL

Generation

F1

Effect level

300

mg/kg bw/day (actual dose received)

Based on

act. ingr.

Sex

male/female

Basis for effect level

other: No effects on development

Overall reproductive toxicity

Key result

false

Reproductive effects observed

not specified

Any other information on results incl. tables _____

Figures and Tables (in English) are available in the following full report of the study.

http://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF70974-33-3d.pdf

Applicant's summary and conclusion _____

Executive summary

In the combined repeated oral dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) , there were no effects on reproductive and developmental parameters at 300 mg/kg bw/day. The NOAEL for the rat reproductive/developmental toxicity of benzenesulfonic acid, 4-hydroxy-, tin(2+) salt was determined to be 300 mg/kg bw/day, the highest dose tested.

References

TEST_MATERIAL_INFORMATION: 7 0974-33-3 / 70974-33-3

UUID: 4fe9d66e-438c-3ab2-b743-a623fc4ee0a9

Dossier UUID:

Author: SuperUser

Date: 2017-01-18T15:00:11.000+09:00

Remarks:

Name

70974-33-3 / 70974-33-3

Composition

Type

Constituent

Reference substance

70974-33-3 / 70974-33-3 / 70974-33-3

EC number

EC name

CAS number

CAS name

70974-33-3

IUPAC name

70974-33-3

Other characteristics

Details on test material

- Name of test material (as cited in study report): Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt
- Chemical structure: [C6H4(OH)SO3]2Sn
- Chemical formula: C₁₂H₁₀O₈S₂Sn
- Molecular weight: 465.05
- Purity: >95%
- Impurities: Benzenesulfonic acid, 2-hydroxy-, tin(2+)salt; <2% ; Benzenesulfonic acid, 2,4-hydroxy-, tin(2+)salt; <2%
- Solubility: 420 mg/mL in water
- Supplier: Daiwakasei Industry Co., Ltd
- Physical state: White crystalline solid
- Stability: Stability during the test period was confirmed by the Daiwakasei Industry Co., Ltd (May 19, 2006).
- Storage condition of test material: Room temperature

TEST_MATERIAL_INFORMATION: 7 0974-33-3 / 70974-33-3

UUID: 05f3eab6-95b2-3c4b-bf9b-5fa68788234c

Dossier UUID:

Author: SuperUser

Date: 2017-01-19T11:43:43.000+09:00

Remarks:

Name

70974-33-3 / 70974-33-3

Composition

Type

Constituent

Reference substance

70974-33-3 / 70974-33-3 / 70974-33-3

EC number

EC name

CAS number

CAS name

70974-33-3

IUPAC name

70974-33-3

Other characteristics

Details on test material

- Name of test material (as cited in study report): Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt
- Lot No.: 060501
- Supplier: Daiwakasei Industry Co., Ltd
- Chemical structure: [C6H4(OH)SO3]2Sn
- Chemical formula: C₁₂H₁₀O₈S₂Sn
- Molecular weight: 465.05
- Purity: 96.0%
- Impurities: Benzenesulfonic acid, 2-hydroxy-, tin(2+)salt; <2% ; Benzenesulfonic acid, 2,4-hydroxy-, tin(2+)salt; <2%
- Boiling point: 300°C or more
- Solubility: White turbidity in 2% ethanol
- Storage condition of test material: Cold dark place at 2 - 8°C

TEST_MATERIAL_INFORMATION: 7

0974-33-3 / 70974-33-3

UUID: d37c9e1d-58d5-3318-8e79-a7acca16d160

Dossier UUID:

Author: SuperUser

Date: 2017-01-18T16:47:14.000+09:00

Remarks:

Name

70974-33-3 / 70974-33-3

Composition

Type

Constituent

Reference substance

70974-33-3 / 70974-33-3 / 70974-33-3

EC number

EC name

CAS number

CAS name

70974-33-3

IUPAC name

70974-33-3

Other characteristics

Details on test material

- Name of test material (as cited in study report): Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt
- Chemical structure: [C6H4(OH)SO3]2Sn
- Chemical formula: C₁₂H₁₀O₈S₂Sn
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- Physical state: White crystalline solid
- Stability: Stability during the test period was confirmed by the Daiwakasei Industry Co., Ltd (May 19, 2006).
- Storage condition of test material: Room temperature

LITERATURE: A combined repeated-dose/ reproductive-developmental toxicity study of Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt by oral administration in rats.

UUID: e04fcd9b-5edc-34b4-95e1-a71c4e81b070

Dossier UUID:

Author: SuperUser

Date: 2017-01-18T15:46:34.000+09:00

Remarks:

General information

Reference Type

study report

Title

A combined repeated-dose/reproductive-developmental toxicity study of Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt by oral administration in rats.

Author

MHLW, Japan

Year

2009

Bibliographic source

Japan Existing Chemical Data Base (JECDB)

Testing facility

BoZo Research Center Inc

Report no.

R-945

Report Date

2009-04-10

LITERATURE: A combined repeated-dose/ reproductive-developmental toxicity study of Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt by oral administration in rats.

UUID: bcb11bbe-0392-39a5-a634-7c715cd59b47

Dossier UUID:

Author: SuperUser

Date: 2017-01-19T11:43:43.000+09:00

Remarks:

General information

Reference Type

study report

Title

A combined repeated-dose/reproductive-developmental toxicity study of Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt by oral administration in rats.

Author

MHLW, Japan

Year

2009

Bibliographic source

Japan Existing Chemical Data Base (JECDB)

Testing facility

BoZo Research Center Inc.

Report no.

R-945

Report Date

2009-04-10

LITERATURE: In Vitro Chromosomal Aberration Test of Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt on Cultured Chinese Hamster Cells.

UUID: 8d0fc545-3aee-3f58-b439-4febb72e2944

Dossier UUID:

Author: SuperUser

Date: 2017-01-18T17:06:07.000+09:00

Remarks:

General information

Reference Type

study report

Title

In Vitro Chromosomal Aberration Test of Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt on Cultured Chinese Hamster Cells.

Author

MHLW, Japan

Year

2006

Bibliographic source

Japan Existing Chemical Data Base (JECDB)

Testing facility

Biosafety Research Center, Foods, Drugs and Pesticides (Anpyo Center)

Report no.

9053 (115-204)

Report Date

2006-09-19

LEGAL_ENTITY: National Institute of Health Sciences

UUID: IUC4-b036ff75-0f3c-323b-b200-ed5f46cf5101

Dossier UUID:

Author: SuperUser

Date: 2011-06-23T11:55:01.000+09:00

Remarks:

General information

Legal entity name

National Institute of Health Sciences

Identifiers

Other IT system identifiers

IT system

LEO

ID

10767

IT system

IUCLID4

ID

16558402024DIV750

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Contact persons

Person

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Last name

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Organisation

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Division of Risk Assessment

Title

Dr.

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158-8501

Town

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Country

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LITERATURE: Reverse Mutation Test of Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt on Bacteria.

UUID: 7c3c1ace-5565-39db-9bf7-705153fd0090

Dossier UUID:

Author: SuperUser

Date: 2017-01-18T16:47:14.000+09:00

Remarks:

General information

Reference Type

study report

Title

Reverse Mutation Test of Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt on Bacteria.

Author

MHLW, Japan

Year

2006

Bibliographic source

Japan Existing Chemical Data Base (JECDB)

Testing facility

Biosafety Research Center, Foods, Drugs and Pesticides (Anpyo Center)

Report no.

9052 (115-203)

Report Date

2006-09-19

LITERATURE: Single Dose Oral Toxicity Test of Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt in Rats

UUID: a2820de3-8cd5-3360-b920-e24bbb2bf4a4

Dossier UUID:

Author: SuperUser

Date: 2017-01-18T15:00:11.000+09:00

Remarks:

General information

Reference Type

study report

Title

Single Dose Oral Toxicity Test of Benzenesulfonic acid, 4-hydroxy-, tin(2+)salt in Rats

Author

MHLW, Japan

Year

2007

Bibliographic source

Japan Existing Chemical Data Base (JECDB)

Testing facility

Biosafety Research Center, Foods, Drugs and Pesticides (An-Pyo Center)

Report no.

9079 (115-206)

Report Date

2007-01-26