

Name: OECD_SIDS / SUBSTANCE : triallylamine / 102-70-5 / N,N-diallylprop-2-en-1-amine / 102-70-5 Fri, 16 Dec 2022, 15:59:22+0900 /

Legal entity owner: National Institute of Health Sciences

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Version core 7.0

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Dossier subject triallylamine / 102-70-5 / N,N-diallylprop-2-en-1-amine / 102-70-5

Public name

Submitting legal entity National Institute of Health Science

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General information -

Legal entity name

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triallylamine / 102-70-5

General information

Identification

Identification

SUBSTANCE: triallylamine / 102-70-5

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Substance name triallylamine / 102-70-5

Legal entity National Institute of Health Sciences / Kawasaki / Japan

Identification of substance

Reference substance

triallylamine / N,N-diallylprop-2-en-1-amine / 102-70-5 / 203-048-2

EC numberEC name203-048-2EC InventoryCAS numberCAS name102-70-5IUPAC name

N,N-diallylprop-2-en-1-amine

Role in the supply chain

Manufacturer false

Importer false

Only representative false

Downstream user false

Toxicological information

Repeated dose toxicity

Repeated dose toxicity: oral

ENDPOINT_STUDY_RECORD: Repeated dose toxicity: oral.001

UUID: 8d160a58-87f8-4a75-8eb0-4c61b2fa1891 Dossier UUID: Author: Date: 2022-12-16T15:51:30.064+09:00 Remarks:

Administrative data

Endpoint short-term repeated dose toxicity: oral

Type of information experimental study

Adequacy of study key study

Robust study summary false

Used for classification false

Used for SDS false

Reliability 1 (reliable without restriction)

Rationale for reliability incl. deficiencies guideline study Reliability 1

Data source -

Reference

A 28-day repeat dose oral toxicity test of triallylamine in rat with a recovery period of 2 weeks / Ministry of Health, Labour and Welfare(MHLW), Japan / publication

Data access data published

Materials and methods -

Test guideline

Qualifier according to guideline

Guideline

OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity Study in Rodents)

Deviations

no

Qualifier according to guideline

Guideline

other: Study Methods on New Chemical Substances, etc. (Chemical Substances Control Law of Japan)

Deviations

no

GLP compliance

yes

Test material

Specific details on test material used for the study triallylamine / 102-70-5

Test animals

Species

rat common rodent species

Strain other: Crl:CD(SD)

Sex male/female

Details on test animals or test system and environmental conditions

TEST ANIMALS

- Source: Charles River Laboratories Japan, Inc. Atsugi
- Age at study initiation: 6 weeks
- Weight at study initiation: Males: 191 213 g; Females: 150 181 g
- Housing: bracket-type metallic wire-mesh cages (W 250 × D 350 × H 200 mm)
- Diet: ad libitum
- Water: ad libitum
- Acclimation period: 9 days

ENVIRONMENTAL CONDITIONS

- Temperature (°C): 20-24 (acceptable range:23±3 °C)
- Humidity (%): 39-57 (acceptable range:50±20 %)
- Air changes: 10-15 times / hr
- Photoperiod: 12 hrs dark / 12 hrs light

Administration / exposure

Route of administration

oral: gavage

Vehicle corn oil

Details on oral exposure

PREPARATION OF DOSING SOLUTIONS: Test substance was dissolved in corn oil for injection.

Analytical verification of doses or concentrations

yes

Details on analytical verification of doses or concentrations

Test solutions were prepared at least once in 8 days and used within 7 days of preparation. The test solutions to be used for week 1 or week 4 of administration were analyzed for concentration by GC method at Gotemba Laboratory, Bozo Research Center Inc.

The results showed that the concentrations were 99.0 to 108.5% of the nominal concentrations (acceptable range: $100 \pm 10\%$ of the nominal value), which were all within the acceptable range.

Duration of treatment / exposure

28 days

Frequency of treatment

once a day

Doses / concentrations	
Dose / conc.	
0	mg/kg bw/day (actual dose received)
Dose / conc.	
6	mg/kg bw/day (actual dose received)
Dose / conc.	
25	mg/kg bw/day (actual dose received)
Dose / conc.	
100	mg/kg bw/day (actual dose received)

No. of animals per sex per dose

6 or 12/sex/dose

Control animals

yes, concurrent vehicle

Details on study design

As a result of administering triallylamine by oral gavage to groups of 5 rats per sex at 0 (corn oil), 100, 300 and 1000 mg/kg/day for 14 days, the main change observed was death in all males and females in 1000 mg/kg bw/day and in 1 male in the 300 mg/kg bw/day group.

Therefore, the high dose in this study was set at 100 mg/kg bw/day, with a middle dose of 25 mg/kg b w/day group and a low dose of 6 mg/kg bw/day, using the common ratio of approximately 4.

Examinations

Observations and examinations performed and frequency

CAGE SIDE OBSERVATIONS: Yes

Males and females: 3 times/day during the administration period (before and after dosing), once a day during the recovery period.

DETAILED CLINICAL OBSERVATIONS:Yes

The functional observational battery testing (FOB) was performed on all animals. Among the meas ures in the FOB, detailed clinical observations were made before the initiation of dosing. Thereafter, detailed clinical observations were made once a week in dosing and recovery periods. Sensory motor reflexes, forelimb and hindlimb grip strengths, and motor activity were measured on week 4 of administration period (main/recovery group animals) and week 2 of recovery period (r ecovery group animals).

BODY WEIGHT: Yes

All animals were weighed before administration on days 1, 4, 7, 10, 14, 17, 21, 24 and 28 of administration and on days 1, 3, 7, 10 and 14 of recovery.

FOOD CONSUMPTION AND COMPOUND INTAKE (if feeding study):yes

Food consumption of all animals was measured prior to administration on days 1, 7, 14, 21, and 28 of administration and on days 7 and 14 of recovery.

OPHTHALMOSCOPIC EXAMINATION: yes

HAEMATOLOGY:Yes

- Time schedule for collection of blood: the after completion of the administration and recovery periods

- Anaesthetic used for blood collection: ether
- Animals fasted: Yes (overnight)
- How many animals: all animals

[red blood cell count, hemoglobin, hematocrit, mean corpuscular volume, mean corpuscular hem oglobin, mean corpuscular hemoglobin concentration, reticulocyte percentage, platelet count, white b lood cell count, differential leukocyte counts, prothrombin time, activated partial thromboplastin time, fibrinogen]

CLINICAL CHEMISTRY: Yes

- Time schedule for collection of blood: the day after completion of the administration and recovery periods

- Anaesthetic used for blood collection: ether

- Animals fasted: Yes (overnight)

- How many animals: all animals

[ALP, total cholesterol, triglyceride, phospholipids (PL), total bilirubin (T-BIL), glucose (GLU), blood urea nitrogen (BUN), creatinine, Na, K, Cl, Ca, P, total protein, albumin, A/G ratio (A/G)]

URINALYSIS: Yes

- Time schedule for collection of urine: on weeks 4 of the administration period and weeks 2 of the recovery period.

- Metabolism cages used for collection of urine: Yes

- Animals fasted: 4-hour urine under fasting diet ad libitum

20- hour urine under diet and water ad libitum

Statistics

As for parametric data (grip strength, locomotor activity, body weight, body weight gain, food consu mption, water intake, quantitative items of urinalysis as well as data from hematology and blood che mistry, organ weight), the values of means and standard deviations were calculated per group. An analysis of variance was conducted by the Bartlett test (level of significance: 1%, two-tailed). Homogeneous data were analyzed by the Dunnett test while heterogeneous data were analyzed by a Dunnett-type mean rank test between the control and each dose group (levels of significance: 5 and 1 %, two-tailed).

or the recovery groups, homogeneity of variance was tested for each group by the F-test (level of significance: 5%, one-tailed). For homogeneous data, the difference in the mean values between the control and treatment groups was analyzed by Student's t-test (levels of significance: 5 and 1%, two-tailed) while heterogeneous data were analyzed by the Aspin-Welch t-test (levels of significance: 5 and 1%, two-tailed)

Results and discussion

Results of examinations

Clinical signs

effects observed, treatment-related

Description (incidence and severity)

Decreased spontaneous movement was observed in all males and all females in the 100 mg/kg bw/ day group and salivation was observed in 6/12 males and 4/12 females in the 100 mg/kg bw/day group on day 1 of administration. Further, decreased spontaneous movement was observed in 7/12 males and 7/12 females in the 100 mg/kg bw/day group on day 2 of administration.

Mortality no mortality observed

Body weight and weight changes

no effects observed

Food consumption and compound intake (if feeding study)

effects observed, treatment-related

Haematological findings

no effects observed

Organ weight findings including organ / body weight ratios effects observed, treatment-related

Description (incidence and severity)

Administration Period:

Significantly low values were observed in males from day 4 of administration, and in females on days 4, 7, 10, 14, 17, 21 and 28 of administration in the 100 mg/kg bw/day group. Additionally, a significantly low value of body weight gain during the administration period was observed in males and females in the 100 mg/kg bw/day group.

Recovery Period:

Significantly low values were observed throughout the recovery period in females in the 100 mg/kg bw/day group.

Gross pathological findings

effects observed, treatment-related

Description (incidence and severity)

End of Administration Period:

In the 25 mg/kg bw/day group(1/6 females), dark red focus of glandular stomach was observed. In the 100 mg/kg bw/day group(1/6 females), white focus of liver was observed. In the control group(1/6 males), enlargement testis was observed.

In the 25 mg/kg bw/day group(1/6 males), white focus of epididymis was observed. End of Recovery Period:

In the control group(1/6 females) and in the 100 mg/kg bw/day group(1/6 males), dark red focus of lung was observed.

In the control group(1/6 females), dark red focus of glandular stomach was observed.

Histopathological findings: non-neoplastic

effects observed, treatment-related

Description (incidence and severity)

End of Administration Period:

In the 25 mg/kg bw/day group(3/6 males and 3/6 females), in the 100 mg/kg bw/day group(in all males and all females), hypertrophy of centrilobular hepatocytes in the liver was observed .

In the control group(2/6 males), in the 6 mg/kg bw/day group(1/6 males), in the 25 mg/kg bw/day group(4/6 males), in the 100 mg/kg bw/day group(all males), minimal eosinophilic bodies in the kidney were observed. And their incidence and severity increased in males in the 25 mg/kg bw/day and above groups.

The following findings were judged to be incidental based on the incidence of their occurrence or their histopathological profiles.

[Eye boll, Pituitary, Thyroid, Spleen, Lung (including bronchus), Stomach, Liver, Kidney, Testis, Epid idymis, Prostate, Sternum (including bone marrow), Skeletal muscle femoral]

End of Recovery Period:

In the 100 mg/kg bw/day group(1/6 males), minimal hypertrophy of centrilobular hepatocytes in the l iver was observed.

In the control group(2/6 males), in the 100 mg/kg bw/day group(4/6 males), minimal eosinophilic bodies in the kidney were observed, and their incidence increased in males in the 100 mg/kg bw/day group.

Effect levels -

Key result false Dose descriptor NOAEL	
Effect level	
6	mg/kg bw/day (actual dose received)
Based on test mat.	

Sex male/female

Basis for effect level gross pathology pathological changes in the liver

Target system / organ toxicity

Key result false	
Critical effects observed yes	d
Lowest effective dose /	conc.
25	mg/kg bw/day (actual dose received)
System gastrointestinal tract	
Organ liver	
Treatment related yes	
Dose response relations yes	ship

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/PDF102-70-5b.pdf

Applicant's summary and conclusion

Conclusions

Based on the histopathological changes in the liver in the 25 mg/kg bw/day group, the NOAEL for repe ated-dose oftriallylamine was determined to be 6 mg/kg bw/day in rats.

Executive summary

The repeated-dose toxicity of triallylamine was evaluated in rats according to the OECD TG 407. Male and female rats (6 or 12 animals/sex/dose) were treated with triallylamine via oral gavage for 28 days at 0 (vehicle: corn oil), 6, 25, and 100 mg/kg bw/day. Six of the 12 animals/sex receiving 0 and 100 mg/ kg bw/day were assigned to a 14-day recovery group prior to sacrifice.

No deaths were observed in either sex. Salivation and decreased locomotor activity were observed at the beginning of the dosing period at the highest dose in both sexes. Hind limb grip strength decreased in males treated with 100 mg/kg bw/day. Body weight and body weight gain were decreased in both sexes treated with 100 mg/kg bw/day. Food consumption was decreased in both sexes treated with ≥

25 mg/kg bw/day. Water intake was increased in males receiving 25 and 100 mg/kg bw/day. Treatment with 100 mg/kg bw/day led to increased urine volume in males and decreased osmolality in both sexes, and positive results for calcium oxalate crystals tended to increase in the urine sediment examination in both sexes. Blood chemistry analysis showed decreased triglyceride levels in males receiving 25 and 100 mg/kg bw/day, but increased levels in females receiving 100 mg/kg bw/day. The relative weight of the kidney was increased, without histopathological changes, in males receiving 100 mg/kg bw/day. In females, the relative weight of the liver was increased at 25 and 100 mg/kg bw/day, while the absolute weight of the liver was increased in both sexes treated with 100 mg/kg bw/day. Histopathological examination of the liver showed centrilobular hepatocellular hypertrophy in both sexes receiving ≥ 25 mg/kg bw/day. Changes due to triallylamine treatment observed during or at the end of the 14-day recovery period recovered, with some exceptions. Body weight remained decreased during the recovery period in females treated with 100 mg/kg bw/day. Based on the histopathological changes in the liver in the 25 mg/kg bw/day group, the NOAEL for repeated-dose of triallylamine was determined to be 6 mg/kg bw/day in rats.

ENDPOINT_STUDY_RECORD: Repeated dose toxicity: oral.002

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Dossier UUID:

Author:

Date: 2022-12-16T15:54:11.334+09:00

Remarks:

Administrative data -

Endpoint

repeated dose toxicity: oral, other A reproduction/developmental toxicity screening test in rats treated orally of triallylamine

Type of information

experimental study

Adequacy of study key study

Robust study summary false

Used for classification false

Used for SDS false

Reliability 1 (reliable without restriction)

Rationale for reliability incl. deficiencies guideline study Reliability 1

Cross-reference

Reason / purpose for cross-reference reference to same study

Related information

OECD / Toxicity to reproduction / Toxicity to reproduction.001 / triallylamine / 102-70-5 / N,N-diallylprop-2-en-1-amine / 102-70-5

Remarks

Toxicity to reproduction.001

Data source

Reference

A reproduction/developmental toxicity screening test in rats treated orally of triallylamine / Ministry of Health, Labour and Welfare (MHLW), Japan / publication

Materials and methods -

Test guideline

Qualifier according to guideline

Guideline

other: Guideline for reproduction/developmental toxicity screening test in rats (Chemical Substances Control Law of Japan)

GLP compliance

yes

Test material

Specific details on test material used for the study triallylamine / 102-70-5

Test animals

Species rat common rodent species

Strain other: Crl:CD(SD)

Details on test animals or test system and environmental conditions

TEST ANIMALS

- Source: Charles River Laboratories Japan, Inc. Atsugi
- Age at study initiation: 10 weeks
- Weight at study initiation: Males: 402 455 g; Females: 239 283 g
- Housing: bracket-type metallic wire-mesh cages (W 254 × D 350 × H 170 mm)
- Diet: ad libitum
- Water: ad libitum
- Acclimation period: 20 days

ENVIRONMENTAL CONDITIONS

- Temperature (°C): 23-24 (acceptable range:23±3 °C)
- Humidity (%): 42-53 (acceptable range: 50±20 %)
- Air changes: 12-17 times / hr
- Photoperiod: 12 hrs dark / 12 hrs light

Administration / exposure

Route of administration oral: gavage

Vehicle corn oil

Details on oral exposure

PREPARATION OF DOSING SOLUTIONS: Test substance was dissolved in corn oil for injection.

Vehicle

- Name: Corn oil
- Lot Number: WEK6144, PDQ0071
- Manufacturer: Wako pure Chemical Industries, Ltd.

- Storage Conditions: Room temperature

Analytical verification of doses or concentrations

yes

Details on analytical verification of doses or concentrations

Test solutions were prepared at least once in 8 days and used within 7 days of preparation. The test solutions to be used for week 1 or week 6 of administration were analyzed for concentration by GC method at Gotemba Laboratory, Bozo Research Center Inc.

The results showed that the concentrations were 98.3 to 102.0% of the nominal concentrations (acceptable range: $100 \pm 10\%$ of the nominal value), which were all within the acceptable range.

Duration of treatment / exposure

Males were dosed for 30 days, including a 14-day pre-mating period and subsequent mating period. Females were dosed for 40–47 days, including 14-day pre-mating, mating, and gestation periods, and until lactation day 3.

Frequency of treatment

once a day

Doses / concentrations

Dose / conc.	
0	mg/kg bw/day (actual dose received)
Dose / conc.	
6	mg/kg bw/day (actual dose received)
Dose / conc.	
25	mg/kg bw/day (actual dose received)
Dose / conc.	
100	mg/kg bw/day (actual dose received)

No. of animals per sex per dose

12 animals/sex/dose

Control animals

yes, concurrent vehicle

Details on study design

The dose levels of this study were selected based on the results of the previously conducted study, "A 28-day repeat dose oral toxicity test of triallylamine in rat with a recovery period of 2 weeks".

In that study, there was decreased body weight gain at 100 mg/kg bw/day, but no effects were found for reproduction organs.

Based on these results, the high dose in this reproduction/developmental toxicity screening test was s et at 100 mg/kg bw/day, and the lower doses were set at 6 mg/kg bw/day.

- Rationale for animal assignment (if not random): Body weight-balanced randomization

Examinations -

Observations and examinations performed and frequency

CAGE SIDE OBSERVATIONS: Yes Males and females: 3 times/day during the administration period (before and after dosing)

DETAILED CLINICAL OBSERVATIONS: Yes

BODY WEIGHT: Yes male: on days 1, 8, 15, 22 of administration, and the day of necropsy. female: on days 1, 8, 15 before mating , gestation days 0, 7, 14, 20, lactation days 0, 4, and the day of necropsy.

FOOD CONSUMPTION AND COMPOUND INTAKE (if feeding study):yes male: on days2, 8, 15 of administration female: on days 2, 8, 15 before mating; gestation days 1, 7, 14, 20; lactation days 2, 4, and the day of necropsy.

OPHTHALMOSCOPIC EXAMINATION: yes Males and females: 3 times/day

HAEMATOLOGY: no CLINICAL CHEMISTRY: no URINALYSIS: no

Statistics

The data were analyzed for homogeneity of variance by the Bartlett test. If variances were homogeneous, data was analyzed by the Dunnett test, whereas heterogeneous data was analyzed by the Steel test (p<0.05, two-sided).

2 groups: The data were analyzed for homogeneity of variance by the F test. If variances were homo geneous, data was analyzed by the Student t test, whereas heterogeneous data was analyzed by the Aspin-Welch t test (p<0.05, two-sided).

Results and discussion -

Results of examinations -

Clinical signs no effects observed

Description (incidence and severity)

Reduced locomotor activity, salivation, or lacrimation were observed in males and females in the 25 mg/kg bw/day dose group 1-3 hours after the first dose in the pre-mating treatment period. This change was recovered by withdraw.

Mortality

no mortality observed

Body weight and weight changes effects observed, treatment-related

Description (incidence and severity)

In 6 mg/kg bw/day and 25 mg/kg bw/day groups in males, body weight gain were significantly decreased.

In 100 mg/kg bw/day groups in maels, body weight on Day 8 and 15 of administration were significan tly decreased and body weight, and weight gain were significantly decreased in administration period. In 25 mg/kg bw/day and 100 mg/kg bw/day groups in females, body weight gains were significantly decreased.

Food consumption and compound intake (if feeding study)

effects observed, treatment-related

Description (incidence and severity)

At 25 mg/kg bw/day and 100 mg/kg bw/day in males, low food consumption was observed in the administration period.

At 6 mg/kg bw/day in females, low food consumption was observed on day 2 of the administration. At 25 mg/kg bw/day in females, low food consumption was observed on days 2 and 8 of the ad ministration, on day 20 of gestation, and day 2 of lactation.

At 100 mg/kg bw/day in females, low food consumption was observed on days 2 and 8 of the administration, on days 7 and 20 of gestation, and on days 2 and 4 of lactation.

Haematological findings

not examined

Clinical biochemistry findings

not examined

Urinalysis findings

not examined

Organ weight findings including organ / body weight ratios

effects observed, treatment-related

Description (incidence and severity)

A significant increase in absolute and relative liver weights was observed in males at 100 mg/kg bw/ day.

The relative weights of the testes and epididymis were significantly higher, but the absolute weights did not change obviously, suggesting a change due to underweight.

At 6 mg/kg bw/day and 25 mg/kg bw/day, organ weights were not significantly different.

Higher relative weights of liver were significantly observed in females at 25 mg/kg bw/day and more. At 100 mg/kg bw/day, the relative weights of the ovaries were significantly higher.

At 6 mg/kg bw/day, no significant differences were observed in any organ weights.

Gross pathological findings

no effects observed

Description (incidence and severity)

At 6 mg/kg bw/day, dimpling foci of the liver were observed in one male and diaphragmatic herniated nodules in one male. However, it was judged to be an incidental based on the incidence of their occu rrence.

At 100 mg/kg bw/day, dark red foci and white foci of the liver were observed in one female. Histologi cally, extensive necrosis was seen consistent with gross abnormalities (dark red foci and white foci). This change was localized to a portion of multiple lobes, was accompanied by thrombus and hemorrhage, and was characterized by expression from the centrilobular zone to the intermediate z one.

These changes are frequent in dams from reproductive studies and are not seen with repeated dosing for 28 days and were therefore considered incidental.

Histopathological findings: non-neoplastic

effects observed, treatment-related

Description (incidence and severity)

At 25 mg/kg bw/day and 100 mg/kg bw/day both sexes, mild centrilobular hepatocellular hypertrophy in the liver was observed. This change was observed in most lobules, and the cytoplasm was slightly acidic ground-glass in the strong case.

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/PDF102-70-5c.pdf

Applicant's summary and conclusion

Executive summary

The reproductive and developmental toxicity of triallylamine was investigated in accordance with a reproduction/developmental toxicity screening test (OECD TG 421) in rats. Triallylamine was administered via oral gavage at doses of 0 (vehicle: corn oil), 6, 25, or 100 mg/kg bw/day. Males (12/ dose) were treated for 30 days, including a 14-day premating period and a subsequent mating period. Females (12/dose) were treated for 40–47 days, including 14-day premating, mating, and gestation periods, until lactation day 3.

There were no treatment-related deaths in either sex. Decreased locomotor activity, salivation, and lacrimation were observed at the beginning of the treatment period in both sexes treated with ≥ 25 mg/kg bw/day. Body weight gain was decreased in males treated with ≥ 6 mg/kg bw/day and females treated with ≥ 25 mg/kg bw/day. Food consumption decreased in both sexes treated with ≥ 25 mg/kg bw/day. Similar to the 28-day repeated-dose toxicity study described above, treatment with 25 mg/kg bw/day triallylamine showed effects in the liver and increased organ weights with histopathological changes.

Genetic toxicity

Genetic toxicity in vitro

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.001

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Dossier UUID:

Author:

Date: 2022-12-16T15:56:07.797+09:00

Remarks:

Administrative data -

Endpoint

in vitro gene mutation study in bacteria

Type of information experimental study

Adequacy of study key study

Robust study summary false

Used for classification false

Used for SDS false

Reliability 1 (reliable without restriction)

Rationale for reliability incl. deficiencies guideline study Reliability 1

Data source -

Reference

A reverse mutation test of triallylamine using bacteria / Ministry of Health, Labour and Welfare(MHLW), Japan / publication

Data access data published

Materials and methods

Test guideline

Qualifier according to guideline

Guideline OECD Guideline 471 (Bacterial Reverse Mutation Assay) in vitro gene mutation study in bacteria

Deviations

GLP compliance yes

Type of assay bacterial reverse mutation assay in vitro gene mutation study in bacteria

Test material -

Specific details on test material used for the study triallylamine / 102-70-5

Method

Species / strain

Species / strain / cell type S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and TA 102 bacteria

Species / strain / cell type E. coli WP2 uvr A

bacteria

Metabolic activation

with and without

Metabolic activation system

S9 mix, SD male rat liver, induced by phenobarbital (PB) and 5,6-benzoflavone (BF)

Test concentrations with justification for top dose

To set the dose levels for the main tests, the 50 mg/mL solution was diluted 4 times using a common ratio of 4 and a total of 5 dose levels were selected (19.5, 78.1, 313, 1250 and 5000 μ g/plate) in the dose-selection test.

In the dose-selection test, growth inhibition by the test substance was observed at 1250 μ g/plate and above for S. typhimurium TA strains without metabolic activation, at 5000 μ g/plate for E. coli WP2 uvrA without metabolic activation, and at 313 μ g/plate and above for all bacterial strains with metabolic activation. Neither precipitation of nor coloration by the test substance on the plate was observed at any dose level irrespective of the presence or absence of metabolic activation. Therefore, in the main tests, the lowest dose levels at which cell growth inhibition was observed in the dose-selection test were set as the highest dose levels 1250 μ g/plate for S. typhimurium TA strains without metabolic activation, 5000 μ g/plate for E. coli WP2 uvrA without metabolic activation, and 313 μ g/plate for all bacterial strains with metabolic activation , and a total of 6 dose levels were selected by 5-step dilution using a common ratio of 2.

Vehicle / solvent DMSO

Controls

Untreated negative controls no

Negative solvent / vehicle controls yes

True negative controls no

Positive controls yes

Positive control substance sodium azide benzo(a)pyrene other: 2-(2-Furyl)-3-(5-nitro-2-furyl)acrylamide (AF-2) 2-Methoxy-6-chloro-9-[3-(2-chloroethyl)aminopropylamino]acridine.2HCl (ICR-191) 2-Aminoanthracene (2AA)

Details on test system and experimental conditions

METHOD OF APPLICATION: Preincubation DURATION - Preincubation period: 20 min

Exposure duration: ca. 50 hours NUMBER OF REPLICATIONS: 3 DETERMINATION OF CYTOTOXICITY - Method: Cell growth

Evaluation criteria

If two-fold increase in the number of revertant colonies on the test plates or more was observed in comparison with the number of natural revertant colonies (the negative control) and dose response and reproducibility were noted, or if no clear dose response was observed but there was at least two-fold increase in comparison with the number of natural revertant colonies and reproducibility was observed in the two main tests, the test substance was judged to be positive. For the results of measu rement, mean with standard deviation was also indicated.

Statistics

not use

Any other information on materials and methods incl. tables -

Results and discussion

Test results

Key result false

Species / strain S. typhimurium TA 1535 bacteria

Metabolic activation without

Genotoxicity positive

Cytotoxicity / choice of top concentrations cytotoxicity 1250 ug/plate

Vehicle controls validity valid

Positive controls validity valid

Key result false

Species / strain S. typhimurium TA 100 bacteria

Metabolic activation without

Genotoxicity positive

Cytotoxicity / choice of top concentrations cytotoxicity 1250 ug/plate

Vehicle controls validity valid

Positive controls validity valid

Key result false

Species / strain S. typhimurium TA 98 bacteria

Metabolic activation with and without

Genotoxicity negative

Cytotoxicity / choice of top concentrations cytotoxicity 1250 ug/plate without activation, 313 ug/plate with activation

Vehicle controls validity valid

Positive controls validity valid

Key result false

Species / strain S. typhimurium TA 1537

bacteria

Metabolic activation with and without

Genotoxicity negative

Cytotoxicity / choice of top concentrations cytotoxicity 1250 ug/plate without activation, 313 ug/plate with activation

Vehicle controls validity valid

Positive controls validity valid

Key result false

Species / strain E. coli WP2 uvr A bacteria

Metabolic activation with and without

Genotoxicity negative

Cytotoxicity / choice of top concentrations cytotoxicity 5000 ug/plate without activation, 313 ug/plate with activation

Vehicle controls validity valid

Positive controls validity valid

Additional information on results

TEST-SPECIFIC CONFOUNDING FACTORS

- Precipitation: Precipitation was not observed on any plates with/without metabolic activation.

- Other effects: coloring was observed on plates with concentration of 1250 μ g/plate or more with/w ithout metabolic activation in range-finding studies.

RANGE-FINDING/SCREENING STUDIES:

In range-finding studies, growth inhibition was observed on plates with concentration of 1250 µg/ plate or more in all S. typhimurium strains with/without metabolic activation and on plates with concentrate on of 5000 µg/plate in all E.coli strains with/without metabolic activation. COMPARISON WITH HISTORICAL CONTROL DATA:

In all test conditions and in all tested strains, the number of revertant colonies of solvent controls and positive controls were within the range of historical control data.

Any other information on results incl. tables

Tables in English are attached.

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

http://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF 102-70-5d.pdf

Applicant's summary and conclusion

Executive summary

In a bacterial reverse mutation assay using S. typhimurium TA100, TA1535, TA98, and TA1537 and E.coli WP2uvrA (OECD TG 471), triallylamine was positive without metabolic activation for TA1535 and TA100.

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.002

UUID: 9b9a7c9e-94c5-453a-aa1f-ca9661a10c11

Dossier UUID:

Author:

Date: 2022-12-12T14:49:05.104+09:00

Remarks:

Administrative data -

Endpoint

in vitro cytogenicity / chromosome aberration study in mammalian cells

Type of information experimental study

Adequacy of study key study

Robust study summary false

Used for classification false

Used for SDS false

Reliability 1 (reliable without restriction)

Rationale for reliability incl. deficiencies guideline study Reliability 1

Data source -

Reference

Chromosome aberration test in cultured chinese hamster cells treated with triallylamine / Ministry of Health, Labour and Welfare(MHLW), Japan / publication

Data access data published

Materials and methods -

Test guideline

Qualifier according to guideline

Guideline

OECD Guideline 473 (In Vitro Mammalian Chromosomal Aberration Test) in vitro cytogenicity / chromosomal aberration study in mammalian cells (from 26 September 2014)

Deviations no

GLP compliance

yes

Type of assay

in vitro mammalian chromosome aberration test in vitro cytogenicity / chromosome aberration study in mammalian cells

Test material

Specific details on test material used for the study triallylamine / 102-70-5

Method -

Species / strain

Species / strain / cell type Chinese hamster lung (CHL/IU) mammalian cell line

Metabolic activation with and without

Metabolic activation system

S9 mix, SD male rat liver, induced by phenobarbital (PB) and 5,6-benzoflavone (BF)

Test concentrations with justification for top dose

-S9 mix(short-term treatment): 0, 10.9, 21.9, 43.8, 87.5, 175, 350, 700, 1400 μg/mL +S9 mix(short-term treatment): 0, 10.9, 21.9, 43.8, 87.5, 175, 350, 700, 1400 μg/mL -S9 mix(24hr-continuous treatment): 0, 10.9, 21.9, 43.8, 87.5, 175, 350, 700, 1400 μg/ μg/mL -S9 mix(48hr-continuous treatment): 0, 10.9, 21.9, 43.8, 87.5, 175, 350, 700, 1400 μg/ μg/mL

Cell-growth inhibition test was conducted up to the limited concentration of 1400 µg/mL (10 mM)

-Short term treatment, +S9 mix: concentration of 50% cell-growth inhibition was determined as 17. 9μ g/mL

-Short term treatment, -S9 mix: concentration of 50% cell-growth inhibition was determined as 1400 $\mu\text{g}/\text{mL}$

-Continous treatment (24 h): concentration of 50% cell-groth inhibition was determined as 1400 $\mu\text{g}/\text{mL}$

-Continous treatment (48 h): concentration of 50% cell-groth inhibition was determined as 1400 $\mu\text{g}/\text{mL}$

Vehicle / solvent DMSO

Controls

Untreated negative controls no

Negative solvent / vehicle controls yes True negative controls no

Positive controls yes

Positive control substance cyclophosphamide mitomycin C

Details on test system and experimental conditions

METHOD OF APPLICATION: Exposure duration: [continuous treatment]: 24, 48 hrs [short-term treatment]:6 hrs + 18 hr SPINDLE INHIBITOR: Colcemid NUMBER OF REPLICATIONS: 2 NUMBER OF CELLS EVALUATED: 200 cells / dose DETERMINATION OF CYTOTOXICITY - Method: relative total growth

Evaluation criteria

For the evaluation of the frequencies of structural aberrations and of polyploidy induced, the following criteria were employed. Appearance incidence of cells with chromosomal aberrations: Negative (-): < 5%; equivocal (±): 5 -10%; positive (+): > 10%.

Finally, the substance is positive when the incidence is considered to be dose-related and reproducible.

Statistics

not used

Results and discussion

Test results

Key result false

Species / strain Chinese hamster lung (CHL/IU) mammalian cell line

Metabolic activation with

Genotoxicity positive structural aberration

Cytotoxicity / choice of top concentrations cytotoxicity yes: 50% cell growth inhibition: 17.9μ g/mL (short , +S9) no: 50% cell growth inhibition: above 1400μ g/mL (short , -S9)

Vehicle controls validity valid

Positive controls validity valid

Key result false	
Species / strain Chinese hamster lung (CHL/IU) mammalian cell line	
Metabolic activation with and without	
Genotoxicity other: equivocal chromosome numerical aberrations	
Cytotoxicity / choice of top concentrations cytotoxicity yes : 50% cell growth inhibition: 17.9µg/mL (short , +S9) yes : 50% cell growth above 1400µg/mL (short , -S9)	inhibition:
Vehicle controls validity valid	
Positive controls validity valid	

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/PDF 102-70-5f.pdf

Applicant's summary and conclusion

Executive summary

It was concluded that triallylamine is equivocal (minimally positive) for chromosome numerical aberration with and without metabolic activation and poisitive for chromosome structural aberration with metabolic activation under the conditions of this study.

Toxicity to reproduction

Toxicity to reproduction

ENDPOINT_STUDY_RECORD: Toxicity to reproduction.001

UUID: 612b23e7-fd84-452f-b46f-492926d30d9c

Dossier UUID:

Author:

Date: 2022-12-16T15:58:56.087+09:00

Remarks:

Administrative data

Endpoint

screening for reproductive / developmental toxicity

Type of information experimental study

Adequacy of study key study

Robust study summary false

Used for classification false

Used for SDS false

Reliability 1 (reliable without restriction)

Rationale for reliability incl. deficiencies guideline study Reliability 1

Cross-reference

Reason / purpose for cross-reference reference to same study

Related information

OECD / Repeated dose toxicity: oral / Repeated dose toxicity: oral.002 / triallylamine / 102-70-5 / N,N-diallylprop-2-en-1-amine / 102-70-5

Remarks

Repeated dose toxicity: oral.002

Data source

Reference

A reproduction/developmental toxicity screening test in rats treated orally of triallylamine / Ministry of Health, Labour and Welfare (MHLW), Japan / publication

Data access data published

Materials and methods

Test guideline

Qualifier

according to guideline

Guideline

other: Guideline for reproduction/developmental toxicity screening test in rats (Chemical Substa nces Control Law of Japan)

Deviations

no

GLP compliance yes

Test material

Specific details on test material used for the study triallylamine / 102-70-5

Test animals -

Species rat

Strain other: Crl:CD(SD)

Sex male/female

Details on test animals or test system and environmental conditions

TEST ANIMALS

- Source: Charles River Laboratories Japan, Inc. Atsugi
- Age at study initiation: 10 weeks
- Weight at study initiation: Males: 402 455 g; Females: 239 283 g
- Housing: bracket-type metallic wire-mesh cages (W 254 × D 350 × H 170 mm)
- Diet: ad libitum
- Water: ad libitum
- Acclimation period: 20 days

ENVIRONMENTAL CONDITIONS

- Temperature (°C): 23-24 (acceptable range:23±3 °C)
- Humidity (%): 42-53 (acceptable range:50±20 %)
- Air changes: 12-17 times / hr
- Photoperiod: 12 hrs dark / 12 hrs light

Administration / exposure

Route of administration oral: gavage

Vehicle

corn oil

Details on mating procedure

Males and females in the same dose group were co-housed overnight on a one-to-one basis after the end of the pre-mating administration period. Copulation was considered successful if the formation of vaginal plugs or presence of sperm in vaginal smears was confirmed the following morning.

Details on analytical verification of doses or concentrations

Test solutions were prepared at least once in 8 days and used within 7 days of preparation. The test solutions to be used for week 1 or week 6 of administration were analyzed for concentration by GC method at Gotemba Laboratory, Bozo Research Center Inc.

The results showed that the concentrations were 98.3 to 102.0% of the nominal concentrations (acceptable range: $100 \pm 10\%$ of the nominal value), which were all within the acceptable range.

Duration of treatment / exposure

Males were dosed for 30 days, including a 14-day pre-mating period and subsequent mating period. Females were dosed for 40–47 days, including 14-day pre-mating, mating, and gestation periods, and until lactation day 3.

Frequency of treatment

once a day

Dose / conc. 0 mg/kg bw/day (actual dose received) Dose / conc. 6 mg/kg bw/day (actual dose received) Dose / conc. 25 mg/kg bw/day (actual dose received) Dose / conc. 100 mg/kg bw/day (actual dose received)

No. of animals per sex per dose

12 animals/sex/dose

Details on study design

The dose levels of this study were selected based on the results of the previously conducted study, "A 28-day repeat dose oral toxicity test of triallylamine in rat with a recovery period of 2 weeks".

In that study, there was decreased body weight gain at 100 mg/kg bw/day, but no effects were found for reproductive organs.

Based on these results, the high dose in this reproduction/developmental toxicity screening test was s et at 100 mg/kg bw/day, and the lower doses were set at 6 mg/kg bw/day.

Examinations -

Parental animals: Observations and examinations

CAGE SIDE OBSERVATIONS: Yes Males and females: 3 times/day during the administration period (before and after dosing)

DETAILED CLINICAL OBSERVATIONS: Yes

Oestrous cyclicity (parental animals)

yes

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)

no

Postmortem examinations (parental animals)

yes

Postmortem examinations (offspring)

yes

Statistics

The data were analyzed for homogeneity of variance by the Bartlett test. If variances were homogeneous, data was analyzed by the Dunnett test, whereas heterogeneous data was analyzed by the Steel test (p<0.05, two-sided).

2 groups: The data were analyzed for homogeneity of variance by the F test. If variances were homo geneous, data was analyzed by the Student t test, whereas heterogeneous data was analyzed by the Aspin-Welch t test (p<0.05, two-sided).

Especially, Implantation index, Stillborn index, Liveborn index, External abnormalities, Viability ind ex: the Steel test (p<0.05 and <0.01, two-sided) Copulation index, Fertility index, Insemination index, Delivery index: Fisher's exact test (p<0.05 and <0.01, two-sided)

Reproductive indices

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 Live birth index (%) = (No. of liveborn pups / No. of implantation sites) × 100 Sex ratio on day 0 after birth = No. of liveborn male pups/(No. of liveborn male pups + No. of liveborn female pups) Sex ratio on day 4 after birth = No. of liveborn male pups on day 4 after birth/(No. of liveborn male pups) ps + No. of liveborn female pups) on day 4 after birth

Offspring viability indices

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

Results	and	discu	ussion	
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Results: P0 (first parental generation) -

General toxicity (P0) -

Clinical signs no effects observed

Mortality no mortality observed

Body weight and weight changes

effects observed, treatment-related

Description (incidence and severity)

In 6 mg/kg bw/day and 25 mg/kg bw/day groups in males, body weight gains were significantly decreased.

In 100 mg/kg bw/day groups in males, body weights on Day 8 and 15 of administration were signific antly decreased, and body weight and weight gain were significantly decreased in the administration period.

In 25 mg/kg bw/day and 100 mg/kg bw/day groups in females, body weight gains were significantly decreased in the pregnancy period.

Food consumption and compound intake (if feeding study)

effects observed, treatment-related

Description (incidence and severity)

At 25 mg/kg bw/day in males and at 6 mg/kg bw/day in females, low food consumption was obs erved in the administration period.

At 25 mg/kg bw/day and 100 mg/kg bw/day in males, low food consumption was observed in the ad ministration period.

At 6 mg/kg bw/day in females, low food consumption was observed on day 2 of the administration. At 25 mg/kg bw/day in females, low food consumption was observed on days 2 and 8 of the admin istration, on day 20 of gestation, and on day 2 of lactation.

At 100 mg/kg bw/day in females, low food consumption was observed on days 2 and 8 of the administration, on days 7 and 20 of gestation, and on days 2 and 4 of lactation.

Organ weight findings including organ / body weight ratios

effects observed, treatment-related

Description (incidence and severity)

A significant increase in absolute and relative liver weights was observed in males at 100 mg/kg bw/ day.

The relative weights of the testes and epididymis were significantly higher, but the absolute weights did not change obviously, suggesting a change due to underweight.

At 6 mg/kg bw/day and 25 mg/kg bw/day, organ weights were not significantly different.

Higher relative weights of liver were significantly observed in females at 25 mg/kg bw/day and more.

At 100 mg/kg bw/day, the relative weights of the ovaries were significantly higher.

At 6 mg/kg bw/day, no significant differences were observed in any organ weights.

Reproductive function / performance (P0)

Reproductive function: oestrous cycle

no effects observed

Reproductive performance

no effects observed

Description (incidence and severity)

In the control group, mating was observed by day 4 of mating initiation, with the exception of one a nimal (mated on day 7 of mating initiation). At 25 mg/kg bw/day and 100 mg/kg bw/day, each one female was observed to be infertile. This was judged as an incidental change because there were no abnormalities in the pathological examination of the genital organs and accessory genital organs of male and female animals.

Results: P1 (second parental generation) —

Effect levels (P1)

Key result false

Results: F1 generation

General toxicity (F1)

Clinical signs no effects observed

Mortality / viability no mortality observed

Body weight and weight changes effects observed, treatment-related

Description (incidence and severity)

There was no significant difference in body weight between males and females on the day of birth bet ween the control group and each triallylamine administration group.

At 25 mg/kg bw/day, males and females, the lower body weight of at 4 days after birth were observed tendency, at 100 mg/kg bw/day, the lower body weight were observed significantly.

Effect levels (F1)

Key result false	
Dose descriptor NOAEL	
Effect level	
6	mg/kg bw/day (actual dose received)
Based on test mat.	
Sex male/female	
Basis for effect level body weight and weight gain At 25 mg/kg bw/day and 100 mg/kg bw/day, the lower bo females pups on PND 4.	dy weight were observed in males and

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/PDF102-70-5c.pdf

Applicant's summary and conclusion

Conclusions

Based on the effects in body weight of pups at 25 mg/kg bw/day group, the NOAEL of reproductive and developmental toxicity was considered to be 6 mg/kg bw/day.

Executive summary

The reproductive and developmental toxicity of triallylamine was investigated in accordance with a reproduction/developmental toxicity screening test (OECD TG 421) in rats. Triallylamine was administered via oral gavage at doses of 0 (vehicle: corn oil), 6, 25, or 100 mg/kg bw/day. Males (12/ dose) were treated for 30 days, including a 14-day premating period and a subsequent mating period. Females (12/dose) were treated for 40-47 days, including 14-day premating, mating, and gestation periods, until lactation day 3.

There were no treatment-related deaths in either sex. Decreased locomotor activity, salivation, and lacrimation were observed at the beginning of the treatment period in both sexes treated with $\ge 25 \text{ mg/kg}$ bw/day. Body weight gain was decreased in males treated with $\ge 6 \text{ mg/kg}$ bw/day and females treated with $\ge 25 \text{ mg/kg}$ bw/day. Food consumption decreased in both sexes treated with $\ge 25 \text{ mg/kg}$ bw/day. Similar to the 28-day repeated-dose toxicity study described above, treatment with25 mg/kg bw/day triallylamine showed effects in the liver and increased organ weights with histopathological changes. No effects on reproductive organs and fertility were observed following triallylamine treatment. Analysis of developmental toxicity showed decreased body weight in male pups in the 100 mg/kg bw/day group and a tendency to decrease in male pups at 25 mg/kg bw/day group and female pups at 25 md/kg bw/day group, the NOAEL of reproductive and developmental toxicity was considered to be 6 mg/kg bw/day.

References

Reference Substances

REFERENCE_SUBSTANCE: triallylamine

UUID: ECB5-d00ced4f-84ac-4ad4-95d6-505ef818c3f0

Dossier UUID:

Author:

Date: 2007-05-10T18:00:00.000+09:00

Remarks:

Reference substance name triallylamine

IUPAC name N,N-diallylprop-2-en-1-amine

Inventory

Inventory number

Inventory name triallylamine

Inventory EC Inventory

Inventory number 203-048-2

CAS number 102-70-5

Molecular formula C9H15N

Description

CAS number 102-70-5

Synonyms

Synonyms

Identity 2-Propen-1-amine, N,N-di-2-propenyl-

Identity

2-Propen-1-amine, N,N-di-2-propenyl-

Molecular and structural information

Molecular formula C9H15N

Molecular weight

137.2221

SMILES notation

C=CCN(CC=C)CC=C

InChl

InChI=1/C9H15N/c1-4-7-10(8-5-2)9-6-3/h4-6H,1-3,7-9H2

Structural formula



Related substances

Group / category information USEPA Category: Aliphatic Amines

Literatures

LITERATURE: A 28-day repeat dose oral toxicity test of triallylamine in rat with a recovery period of 2 weeks

UUID: f1185455-0792-41b2-9153-bfc87d93d278

Dossier UUID:

Author:

Date: 2019-05-21T16:59:04.000+09:00

Remarks:

General information

Reference Type

publication

Title

A 28-day repeat dose oral toxicity test of triallylamine in rat with a recovery period of 2 weeks

Author

Ministry of Health, Labour and Welfare(MHLW), Japan

Year 2011

2011

Testing facility

Gotemba Laboratory, Bozo Research Center Inc.

LITERATURE: A reproduction/developmental toxicity screening test in rats treated orally of triallylamine

UUID: 5f875192-46cc-41f8-b4f6-49dcdf76c1e4

Dossier UUID:

Author:

Date: 2019-03-26T17:01:02.000+09:00

Remarks:

General information

Reference Type

publication

Title

A reproduction/developmental toxicity screening test in rats treated orally of triallylamine

Author

Ministry of Health, Labour and Welfare (MHLW), Japan

Year 2014

LITERATURE: A reverse mutation test of triallylamine using bacteria

UUID: 42908206-fe83-49ad-a781-7e95ecb31d19

Dossier UUID:

Author:

Date: 2019-05-21T16:52:29.000+09:00

Remarks:

General information

Reference Type

publication

Title

A reverse mutation test of triallylamine using bacteria

Author

Ministry of Health, Labour and Welfare(MHLW), Japan

Year 2009

LITERATURE: Chromosome aberration test in cultured chinese hamster cells treated with triallylamine

UUID: 95039b29-0c90-477f-bedc-716d67064c4f

Dossier UUID:

Author:

Date: 2019-05-22T11:15:32.000+09:00

Remarks:

General information -

Reference Type

publication

Title

Chromosome aberration test in cultured chinese hamster cells treated with triallylamine

Author

Ministry of Health, Labour and Welfare(MHLW), Japan

Year 2010

Legal Entities

LEGAL_ENTITY: National Institute of Health Sciences

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

Dossier UUID:

Author:

Date: 2022-11-07T15:49:29.000+09:00

Remarks:

General information -

Legal entity name

National Institute of Health Sciences

Remarks

Disclaimer: The contents in this document were created based on the MHLW (Ministry of Health, Labour and Welfare) peer reviewed study reports (in Japanese) in JECDB (Japan Existing Chemical Database) at http://dra4.nihs.go.jp/mhlw_data/jsp/SearchPageENG.jsp. Authorship is in the Division of Risk Assessment, the National Institute of Health Sciences, and the contents do not reflect any o fficial MHLW opinions or any other regulatory policies.

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Region / State Kanagawa

Country Japan JP

Identifiers -

Other IT system identifiers

IT system LEO			
ID 10767			
IT system			