



Name: 1,3-cyclohexanedimethanamine / 2579-20-6

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

Printing date: 2019-09-03T11:46:19.687+09:00

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1,3-cyclohexanedimethanamine

CORE

General information

Identification

SUBSTANCE: 1,3-cyclohexanedimethanamine

UUID: IUC5-851687c2-464b-449c-86f2-ad7eb2a7b895

Dossier UUID:

Author: SuperUser

Date: 2017-01-06T16:18:15.000+09:00

Remarks:

Substance name

1,3-cyclohexanedimethanamine

Legal entity

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

Identification of substance

Reference substance

[1,3-cyclohexanedimethanamine / 2579-20-6 / 219-941-5](#)

EC number

219-941-5

EC name

EC Inventory

CAS number

2579-20-6

CAS name

IUPAC name

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-def78f2c-745c-45f4-9a6b-add50aad930e

Dossier UUID:

Author: SuperUser

Date: 2017-01-05T11:10:20.000+09:00

Remarks:

Administrative data

Endpoint

acute toxicity: oral

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 1,3-Bis \(aminomethyl\) cyclohexane in Rats / MHW \(Ministry of Health and Welfare\), Japan / study report](#)

Data access

data published

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

[2579-20-6](#) / [219-941-5](#)

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: 8-9 weeks old
- Weight at dosing: Females, 179 - 199 g (Third from first dosing)
- Used animal number: A total of 16 females - Fasting period before study: Approximately 17 hrs
- Housing: Three animal/cage- Diet (e.g. ad libitum): Ad libitum except fasting period for 17 hrs before administration to 3 hrs after administration
- Water (e.g. ad libitum): Ad libitum
- Acclimation period: 5 days. ENVIRONMENTAL CONDITIONS
- Temperature (°C): 21.0 – 22.6
- Humidity (%): 51.5 – 66.5
- Ventilation (per hr): Approximately 6 - 20 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: 30 and 200 mg/ml.
MAXIMUM DOSE VOLUME APPLIED: 10 ml/kg b.w.

Applicant's summary and conclusion

Conclusions

The acute oral LD50 of 1,3-cyclohexanedimethanamine was >300–2000 mg/kg bw in female rats based on the study conducted according to the OECD TG 423

Repeated dose toxicity: oral

ENDPOINT_STUDY_RECORD: Repeated dose toxicity: oral.001

UUID: IUC5-2c83f3d8-ebc6-474e-a65b-bdfd8e22d558

Dossier UUID:

Author: SuperUser

Date: 2017-01-06T11:59:01.000+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 1,3-Bis \(aminomethyl\) cyclohex...](#) / MHW (Ministry of Health and Welfare), 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

[2579-20-6](#) / [219-941-5](#)

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: 9 weeks of age
- Weight at study initiation: 307-370 g for males and 197-239 g for females
- Housing: bracket-type metallic wire-mesh cages (W 195 × D 235 × H 180 mm)
- Diet (e.g. ad libitum): ad libitum
- Water (e.g. ad libitum): ad libitum
- Acclimation period: 5 days

ENVIRONMENTAL CONDITIONS

- Temperature (°C): 21.6 to 22.4°C
- Humidity (%): 52.9 to 64.9%
- Air changes (per hr): 6 to 20 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 olive oil 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
- Stability (test solutions): For 8 days
- Storage condition of test solution: Stored in a refrigerator (2.8 – 8.4°C).

Analytical verification of doses or concentrations

yes

Details on analytical verification of doses or concentrations

Test suspensions at each concentration of initial and final preparations were analyzed by the GC method at Mitsubishi Safety Institute Ltd. Results showed that the concentration of the test article in each concentration was 92.0 to 108.5% of the nominal concentration and both values were within the acceptable range (concentration: percentage of the nominal concentration, 100 ± 10%)

Duration of treatment / exposure

(P) Males: 42 days including 14 days pre-mating (P) Females: Days including 14 days pre-mating, mating and gestation periods and the days until day 4 of lactation Female (no mating, satellite group): for 42 days

Frequency of treatment

Daily: 7 times / week

Doses / concentrations

Remarks

Doses / Concentrations:

0 (vehicle), 10, 60 and 300 mg/kg bw/day

Basis:

actual ingested

No. of animals per sex per dose

Main group: 12 females/dose (0, 10, 60, and 300 mg/kg bw/day), 7, 12, 12, and 7 males/dose (0, 10, 60, and 300 mg/kg bw/day)

Satellite group: 5 females/dose (0 and 300 mg/kg bw/day)

Recovery group: 5 males/dose and 5 females (satellite group)/dose (0 and 300 mg/kg bw/day)

Control animals

yes, concurrent vehicle

Details on study design

- Dose selection rationale: A preliminary study was conducted to determine the doses to be employed. Three males and three female SD rats were administered 0, 30, 100, 300, and 1000 mg/kg bw/day of the substance for 14 days. As a result, death or dying was observed in all males and females receiving 1000 mg/kg bw/day. Edema of the forestomach was observed in all dead animals receiving 300 mg/kg bw/day. No changes attributable to the test substance were observed on both sexes receiving 30 and 100 mg/kg bw/day. Therefore, the high dose was set at 300 mg/kg bw/day, and the middle and low dose were set at 60 and 10 mg/kg bw/day by using common ratio 5.

Positive control

no

Examinations

Observations and examinations performed and frequency

CAGE SIDE OBSERVATIONS: Yes

- Time schedule:

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

DETAILED CLINICAL OBSERVATIONS: Yes

- Time schedule:

All animals; once before the start of administration, once every week until Week 6 of the administration period.

BODY WEIGHT: Yes

- Time schedule for examinations:

Males in the main and recovery groups were weighed on Day 1, 8, 15, 22, 29, 36, 42, and 43 of administration, and males of recovery groups were weighed on Day 50 and 56. Female satellite groups were weighed same frequencies to male recovery groups. Females in the main groups were weighed on Day 1, 8 and 15 of administration and copulated females were weighed on Day 0, 7, 14 and 20 of gestation, and days 0 and 4 of lactation.

FOOD CONSUMPTION : Yes

- Food consumption (g/day/rat) for each animal determined from the difference of the of the previous day's feeding amount: Yes

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

Males in the main and recovery groups; on Day 1-8, 8-15, 15-22, 22-29, 29-36, 36-38, 43-50, and 50-52. Females in the satellite group; on Day 1-8, 8-15, 15-22, 22-29, 29-36, 36-42, 43-50, and 50-56. Females in the main group; on Day 1, 8 and 15 of administration, on Day 0, 7, 14 and 20 of gestation, and on Day 0 and 4 of lactation.

FOOD INTAKE: No

HAEMATOLOGY: Yes

- Time schedule for collection of blood: On Day 42 and 56 in males and satellite group females. On Day 4 of the lactation period in main group females.

- Anaesthetic used for blood collection: Yes

- 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 count, platelet count, white blood cell count, differential white blood cell count, prothrombin time, activated partial thromboplastin time

CLINICAL CHEMISTRY: Yes

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

- Animals fasted: Yes

- How many animals: 5 animals/sex/group

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

URINALYSIS OF MALES: Yes

- Time schedule for collection of urine (males only): Day 38 of administration

- Metabolism cages used for collection of urine: Yes

- Animals fasted: Yes

- How many animals: 5 animals/males/group

- Parameters checked: pH, protein, glucose, ketones, bilirubin, occult blood, urobilinogen

BLOOD HORMONE: No

NEUROBEHAVIOURAL EXAMINATION: Yes

Functional observation: Five males/dose at Week 6, and five females/dose during the lactation period. No tests conducted during the recovery period because no changes were observed during the administration period.

- Battery of functions tested:

- 1) Open field observation. Aerial righting reaction, arousal, urination, defecation, posture and body position, breathing, co-ordination movement, gait, tremor, clonic convulsion, tonic convulsion, stereotypy, and bizarre behavior.
- 2) Manipulative Test. Approach response, touch response, auditory response, tail pinch response, and aerial righting reflex
- 3) Measurement of Grip Strength. Following manipulative test, grip strength of forelimb and hind limb was measured by Digital force gauge MODEL-DPS-5 (IMADA CO., LTD.).
- 4) Measurement of Motor Activity. Motor activity was measured by a motor activity sensor for experimental animals SUPERMEX (Muromachi Kikai Co., Ltd.). The measurement was conducted for 1 hour, and measured values at 10-minute intervals and from 0 to 60 minutes was collected.

Sacrifice and pathology

GROSS PATHOLOGY AND ORGAN WEIGHTS : Yes, brain, heart, liver, kidneys, adrenals, thymus, spleen, testes, and epididymis.

HISTOPATHOLOGY: Yes, cerebrum, pituitary, thymus, lymph nodes (including mesenteric and mandibular lymph nodes), trachea, lung, stomach, intestinal tract (duodenum, jejunum, ileum, cecum, colon, rectum), thyroids, parathyroid, heart, liver, spleen, kidneys, adrenals, urinary bladder, testes, epididymis, seminal vesicles (including the coagulating gland), prostate (ventral lobe), ovaries, uterus, vagina, bone marrow (one side femur), Sciatic nerve (one side femur), spinal cord, and gross abnormalities site.

Statistics

Parametric data such as grip strength, motor activity, body weight and gain, food consumption, urine volume, specific gravity, hematology, blood biochemistry, and absolute and relative organ weights were analyzed by Bartlett's test for homogeneity of distribution. When homogeneity was recognized, one-way analysis of variance was performed. When a significant difference was observed, Dunnett's multiple comparison test was conducted for comparison between control and treated groups. If not homogenous, analysis was performed using the Kruskal-Wallis ranking test. In consequence, if not homogenous, Dunnett's type mean rank sum test was conducted to compare to control and individual treatment groups. Qualitative value as the pathological findings was analyzed by Wilcoxon test and Fisher's exact test. Urinalyses data were analyzed by Kruskal-Wallis and Dunnett's type mean rank test. Significance level was set at 0.05 compared with the control group and among the groups.

Results and discussion

Results of examinations

Clinical signs

effects observed, treatment-related

Mortality

mortality observed, treatment-related

Body weight and weight changes

effects observed, treatment-related

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

effects observed, treatment-related

Gross pathological findings

effects observed, treatment-related

Histopathological findings: non-neoplastic

effects observed, treatment-related

Details on results

CLINICAL SIGNS AND MORTALITY: Mortality: One male animal died in the 300 mg/kg bw/day group. Clinical signs: Transient salivation was observed in all males and 16 females receiving 300 mg/kg bw/day, sporadically.

DETAILED CLINICAL OBSERVATIONS, MANIPULATIVE TEST, GRIP STRENGTH TEST AND Locomotor Activity Measurement: There were no changes related to the test substance in any group during the dosing.

BODY WEIGHT: Depression of body weight gains was observed in males receiving 300 mg/kg bw/day on Day 8 to 42. This change was recovered by withdraw. No changes in body weights were observed in both sexes receiving 10 and 30 mg/kg bw/day compared with the control groups.

FOOD CONSUMPTION: There were no changes related to the test substance in any groups during the dosing and recovery periods.

URINALYSIS: There were no changes related to the test substance in any groups at the end of the dosing period.

HAEMATOLOGY: Increases in reticulocyte count and increase tendencies in white blood cell count were observed in males receiving 300 mg/kg bw/day at end of the administration. No changes were observed in females receiving 300 mg/kg bw/day at end of the dosing and recovery periods compared with the control group.

CLINICAL CHEMISTRY: At the end of the dosing period, decreases in total protein level and increases in ALAT activity were observed in males and females receiving 300 mg/kg bw/day, respectively. ALP activity tended to increase at the end of the dosing period and significantly increased at the end of the recovery period in females at 300 mg/kg bw/day.

URINALYSES OF MALES: There were no changes related to the test substance.

ORGAN WEIGHTS: At the end of the dosing period, increases in absolute and relative adrenal weights were observed in males receiving 300 mg/kg bw/day and increases in relative kidney and adrenal weights were observed in females receiving 300 mg/kg bw/day. At the end of the recovery period, an increase in relative adrenal weight was observed in males receiving 300 mg/kg bw/day. No changes in absolute and relative organ weights were observed in both sexes receiving 10 and 60 mg/kg bw/day compared with the control group.

GROSS PATHOLOGY: At the end of the dosing period, thickening forestomach wall was observed in all males and females receiving 300 mg/kg bw/day and ulcer in the forestomach mucosa and adhesion to the liver were observed in each female receiving 300 mg/kg bw/day. For the genital system, small sized testes and epididymis were observed in two males receiving 300 mg/kg bw/day. These lesions were recovered at the end of the recovery period. Dark reddish changes in mucosa of the glandular stomach, abnormal contents (tar) in the duodenum, jejunum, and ileum, and dilatation in the cecum and ileum were observed in dead animals receiving 300 mg/kg bw/day.

HISTOPATHOLOGY: NON-NEOPLASTIC:

Stomach: Focal hyperplasia of squamous, focal hyperkeratosis, ulcer and focal inflammatory cell infiltration were observed in the forestomach of all males and females receiving 300 mg/kg bw/day. These lesions trended to recover at the end of the recovery period.

Testes: Atrophy of seminiferous tubule was observed in four males receiving 300 mg/kg bw/day and two males receiving 10 mg/kg bw/day. Diffuse hyperplasia of interstitial cell was observed in one male out of four males receiving 300 mg/kg bw/day. Atrophy of seminiferous tubule in the 10 mg/kg bw/day group was slight, and this lesion was not observed in the 60 mg/kg bw/day group. Therefore, this

lesion was considered to be spontaneous. Atrophy of seminiferous tubule was observed in one male receiving 300 mg/kg bw/day at the end of the recovery period.

Epididymis: Cell debris in duct in two males, decreases in sperm of duct in two males, and atrophy in duct in one male were observed at 300 mg/kg bw/day.

In dead animals, there were focal hyperplasia of squamous and focal inflammatory cell infiltration in the forestomach, hemorrhage in the glandular stomach, atrophy in the spleen and thymus, and congestion and edema in the lungs.

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: see 'Remark'

One male died in the 300 mg/kg bw/day group. At this dose, salivation was observed in both sexes, and decreased body weight gain was observed in males. The relative and absolute weights of the adrenal gland in males and relative weights of the kidneys and adrenal gland in females increased in the 300 mg/kg bw/day groups. Upon histopathological examination, inflammatory cell infiltration, focal hyperkeratosis, focal squamous cell hyperplasia, and ulceration in the forestomach in both sexes, and atrophy of seminiferous tubules of the testis in males were observed 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/PDF2579-20-6d.pdf

Applicant's summary and conclusion

Conclusions

Based on the decreased body weight gain and histopathological changes in the forestomach, the NOAEL for the male and female rat repeated dose toxicity of 1,3-cyclohexanedimethanamine was determined to be 60 mg/kg bw/day.

Genetic toxicity in vitro

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.001

UUID: IUC5-cacf676c-1e5b-4a70-a9b9-477ceacbff28

Dossier UUID:

Author: SuperUser

Date: 2019-09-03T11:45:31.831+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 1,3-Bis \(aminomethyl\) cyclohexane on Bacteria. / MHW \(Ministry of Health and Welfare\), 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

Deviations

no

GLP compliance

yes

Type of assay

bacterial reverse mutation assay

in vitro gene mutation study in bacteria

Test material**Test material information**[2579-20-6 / 219-941-5](#)**Method****Species / strain****Species / strain**S. typhimurium TA 1535, TA 1537, TA 98 and TA 100
bacteria**Metabolic activation**

with and without

Metabolic activation system

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

Species / strainE. coli WP2 uvr A pKM 101
bacteria**Metabolic activation**

with and without

Metabolic activation system

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

Test concentrations with justification for top dose

-S9 mix: 39.1, 78.1, 156, 313, 625, 1250 µg/plate (TA100, TA 98, TA 1537, TA1535 strains),

156, 313, 625, 1250, 2500, 5000 µg/plate (P2uvrA/pKM101 strains)

+S9 mix: 39.1, 78.1, 156, 313, 1250 µg/plate (TA100, TA98, TA1537 strains), 9.77, 19.5, 39.1, 78.1,
156, 313, 625, 1250 µg/plate (TA 1535)

39.1, 78.1, 156, 313, 625, 1250 µg/plate (WP2uvrA/pKM101 strain)

Vehicle

- Vehicle(s)/solvent(s) used: Distilled 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/pKM101), 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- Method: other: growth inhibition

Evaluation criteria

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

Statistics

no

Results and discussion

Test results

Key result

false

Species / strain

S. typhimurium TA 1535, TA 1537, TA 98 and TA 100
bacteria

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'.

Key result

false

Species / strain

E. coli WP2 uvr A pKM 101
bacteria

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'.

Any other information on results incl. tables

Figures and Tables (in Japanese) are available in the following full report of the study. http://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF2579-20-6e.pdf

Tables (in English) are attached to this document. Please download the export file to see the Tables.

Applicant's summary and conclusion

Conclusions

Interpretation of results (migrated information):

negative

In a bacterial reverse mutation assay using Salmonella typhimurium TA100, TA1535, TA98, and TA 1537, and Escherichia coli WP2uvrA/pKM101 (OECD TG 471), 1,3-cyclohexanedimethanamine was negative with or without metabolic activation.

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.002

UUID: IUC5-8e0b8c68-92bf-413e-a1a0-975e363142bb

Dossier UUID:

Author: SuperUser

Date: 2017-01-06T16:17:10.000+09:00

Remarks:

Administrative data

Endpoint

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

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 1,3-Bis \(aminomethyl\) cyclohexane on Cultured Chinese Hamste... / MHW \(Ministry of Health and Welfare\), 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

[2579-20-6](#) / [219-941-5](#)

Method

Species / strain

Species / strain

other: Chinese hamster lung(CHL/IU) cells

Metabolic activation

with and without

Metabolic activation system

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

Test concentrations with justification for top dose

Cell growth inhibition study

-S9 mix: 125, 250, 500, 750, 1000, 1250, 1500 ug/mL (IC50=297 ug/mL)

+S9 mix: 125, 250, 500, 750, 1000, 1250, 1500 ug/mL (IC50=353 ug/mL)

continuous treatment 1: 12.5, 25, 50, 75, 100, 125, 150, 200 ug/mL

continuous treatment 2: 100, 150, 200, 250, 300, 350, 400, 450, 500 ug/mL (IC50=320 ug/mL)

Main study

-S9: 200, 250, 300, 350, 400, 450, 500 ug/mL

+S9: 250, 300, 350, 400, 500 ug/mL

Vehicle

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

Controls

Negative controls

no

Solvent controls

yes

True negative controls

no

Positive controls

yes

Positive control substance

other:

Remarks

[-S9]: mitomycin C; [+S9]: Benzo[a]pyrene

Details on test system and conditions

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

SPINDLE INHIBITOR: Colcemid

STAIN: Giemsa stain for 20 min.

NUMBER OF REPLICATIONS: 2

NUMBER OF CELLS EVALUATED: 500 cells /concentration

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 cell with chromosomal aberrations: Negative(-): less than 5%, Equivocal(±): 5% or more and less than 10%, Positive(+): 10% or more

Statistics

no

Results and discussion

Test results

Key result

false

Species / strain

other: Chinese hamster lung (CHL/IU) cells

Metabolic activation

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'.

Key result

false

Species / strain

other: Chinese hamster lung (CHL/IU) cells

Metabolic activation

with

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

Figures and Tables (in Japanese) are available in the following full report of the study.
http://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF2579-20-6f.pdf

Applicant's summary and conclusion

Conclusions

Interpretation of results (migrated information):

positive without metabolic activation

negative with metabolic activation

The in vitro chromosomal aberration test using CHL/IU cells (OECD TG 473) was positive without metabolic activation.

Genetic toxicity in vivo

ENDPOINT_STUDY_RECORD: Genetic toxicity in vivo.001

UUID: IUC5-0e5723ed-e003-4aba-a6dc-8f7e0401ba4a

Dossier UUID:

Author: SuperUser

Date: 2017-01-10T11:56:31.000+09:00

Remarks:

Administrative data

Endpoint

in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus Type of genotoxicity: chromosome aberration

Type of information

experimental study

Adequacy of study

other information

Robust study summary

false

Used for classification

false

Used for SDS

false

Study period

11/10/2009-3/26/2010

Reliability

1 (reliable without restriction)

Rationale for reliability incl. deficiencies

other: GLP guideline study

Data source

Reference

[Micronucleus test of 1,3-Bis \(aminomethyl\) cyclohexane on mouse / MHLW / study report](#)

Data access

data published

Materials and methods

Test guideline

Qualifier

according to

Guideline

OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)
in vivo mammalian somatic cell study: cytogenicity / erythrocyte micronucleus

Deviations

no

Qualifier

according to

Guideline

JAPAN: Guidelines for Screening Mutagenicity Testing Of Chemicals

Deviations

no

GLP compliance

yes (incl. certificate)

Type of assay

micronucleus assay
chromosome aberration

Test material**Test material information**

[2579-20-6](#) / [219-941-5](#)

Test animals**Species**

mouse

Strain

other: Crlj:CD1(ICR)

Sex

male

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

- ICR, [CD1 (ICR), SPF
- Source: Charles River Laboratories Japan, Inc.
- Age at study initiation: 9 weeks
- Weight at study initiation: range finding study, males: 32.5-37.4 g, females: 23.7-29.5 g; main study: males: 31.3-37.8 g
- Assigned to test groups randomly: yes

- Housing: bracket type TPX resin cage, (143W×293D×148Hmm)
- Diet: ad libitum
- Water: ad libitum
- Acclimation period: 7 days

ENVIRONMENTAL CONDITIONS

- Temperature (°C): 22.5-24.0
- Humidity (%): 49.0-69.0
- Air changes (per hr): 10-15/h

- Photoperiod : 12 h dark/12 h light (light time: 7:00 AM to 7:00 PM)

Administration / exposure

Route of administration

oral: gavage

Vehicle

- Vehicle(s)/solvent(s) used: Water for Injection
- Concentration of test material in vehicle: 12.5, 25, and 50 mg/mL
- Amount of vehicle: 10 mL/kg bw

Details on exposure

PREPARATION OF DOSING SOLUTIONS: It was administered within three days after the p reparation

Duration of treatment / exposure

2 dyas

Frequency of treatment

Twice, 24 h interval

Post exposure period

24 h

Doses / concentrations

Remarks

Doses / Concentrations:
125, 250, and 500 mg/kg bw/day
Basis:
actual ingested

No. of animals per sex per dose

5 males/dose

Control animals

yes, concurrent vehicle

Positive control(s)

- Cyclophosphamide monohydrate (CP)
- Route of administration: oral gavage
 - Doses / concentrations: 50 mg/kg bw/day, single dose

Examinations

Tissues and cell types examined

polychromatic erythrocytes from the femur bone marrow

Details of tissue and slide preparation

TREATMENT AND SAMPLING TIMES: Cells for specimen were collected 24 h after the last adminis tration.

DETAILS OF SLIDE PREPARATION: Cell suspensions were spread on a slide glass, dried, and fixed with methanol for five min. Each specimen was stained with acridine orange.

METHOD OF ANALYSIS: fluorescence microscopy, blind method.

Evaluation criteria

The test substance was determined to be positive if the micronucleated cells were statistically incr eased in the dosing groups compared with the negative control group

Statistics

Appearance frequency of micronuclei: Fisher's test (one-sided test) was conducted between the negative or positive control and treatment groups. The Bonferroni correction was used for consideration of multiplicity. Significant level was set as 5 and 1% levels. Trend test of Cochran-Armitage (one-sided test) was used for frequency of micronuclei appearance.

Polychromatic erythrocytes in erythrocytes: These rates were analyzed using Bartlett's test for homogeneity of distribution excluding positive control, and homogeneity was observed. Difference between negative control group and each treatment groups was analysed by Dunnett's multiple comparison test (two-sided test). Difference between negative and positive controls was analysed by F-test and Student's t-test. Significant levels were set as 5% for Bartlett's test and F-test, and as 1 and 5% for Dunnett's test and Student t-test.

Results and discussion**Test results****Key result**

false

Sex

male

Genotoxicity

negative

Toxicity

yes Decrease in locomotor activity and piloerection were observed at 500 mg/kg bw/day

Vehicle controls valid

yes

Negative controls valid

not examined

Positive controls valid

yes

Additional information on results**RESULTS OF RANGE-FINDING STUDY**

- Dose range: 0, 250, 500, 1000, and 2000 mg/kg bw/day (two times)
- Clinical signs of toxicity in test animals: Decreases in locomotor activity and piloerection with salivation were observed in all males and one male receiving 500 mg/kg bw/day, respectively. Decreases in locomotor activity, piloerection, lacrimation, staggering gait, subnormal temperature, prone position, and death (all males and one female) were observed in 1000 mg/kg bw/day groups. Decreases in locomotor activity, prone position, and decrease in respiration, death, and moribund condition were observed in 2000 mg/kg bw/day groups.

RESULTS OF DEFINITIVE STUDY

- Induction of micronuclei: appearance frequency of micronucleated cells (%MNPCE) for dose levels, 0, 125, 250, and 500 mg/kg bw/day were 0.13%, 0.10%, 0.05%, and 0.08%, respectively.
- Frequency of PCEs for dose levels, 0, 125, 250, and 500 mg/kg bw/day were 54.5%, 59.6%, 55.7%, and 51.2%, respectively.
- Body weight: not examined
- Statistical evaluation: yes

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/PDF2579-20-6g.pdf

Applicant's summary and conclusion

Conclusions

Interpretation of results (migrated information): negative

The test substance did not increase the frequency of micronucleated polychromatic erythrocytes or induce chromosomal aberrations in vivo.

Toxicity to reproduction

ENDPOINT_STUDY_RECORD: Toxicity to reproduction.001

UUID: IUC5-f5198f4a-19fa-4670-81e6-7283a5ca8d96

Dossier UUID:

Author: SuperUser

Date: 2017-01-10T12:21:07.000+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 1,3-Bis \(aminomethyl\) cyclohex... / MHW \(Ministry of Health and Welfare\), 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

[2579-20-6](#) / [219-941-5](#)

Test animals

Species

rat

Strain

other: Crj: CD(SD), SPF

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: 9 weeks of age
- Weight at study initiation: 307-370 g for males and 197-239 g for females
- Housing: bracket-type metallic wire-mesh cages (W 195 × D 235 × H 180 mm)- Diet (e.g. ad libitum):ad libitum
- Water (e.g. ad libitum):ad libitum
- Acclimation period: 5 days

ENVIRONMENTAL CONDITIONS

- Temperature (°C): 21.6 to 22.4°C
- Humidity (%): 52.9 to 64.9%
- Air changes (per hr): 6 to 20 times per hour
- Photoperiod (hrs dark / hrs light):12-hour lighting per day

Administration / exposure

Route of administration

oral: gavage

Vehicle

water

Details on mating procedure

- M/F ratio per cage: 1/1
- Length of cohabitation: up to 2 weeks

- Proof of pregnancy: vaginal plug / sperm in vaginal smear referred to as day 0 of pregnancy

Analytical verification of doses or concentrations

yes

Details on analytical verification of doses or concentrations

Test suspensions at each concentration of initial and final preparations were analyzed by the GC method at Mitsubishi Safety Institute Ltd. Results showed that the concentration of the test article in each concentration was 92.0 to 108.5% of the nominal concentration and both values were within the acceptable range (concentration: percentage of the nominal concentration, 100 ± 10%)

Duration of treatment / exposure

(P) Males: 42 days including 14 days pre-mating, mating, and thereafter 14 periods (subsequent 28 days)

(P) Females: Days including 14 days pre-mating, mating and gestation periods and the days until day 4 of lactation

Frequency of treatment

Daily: 7 times / week

Doses / concentrations

Remarks

Doses / Concentrations:

0 (vehicle), 10, 60 and 300 mg/kg bw/day

Basis:

actual ingested

No. of animals per sex per dose

12 females/dose (0, 10, 60, 300 mg/kg bw/day), 7, 12, 12, and 7 males of 0, 10, 60, and 300 mg/kg bw/day, respectively, 5 males (recovery group) and 5 females (satellite group) at 0 and at 0 and 300 mg/kg bw/day

Control animals

yes, concurrent vehicle

Examinations

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. Mean estrous cycle (day) and abnormal estrous cycle animals (not 4 to 6 day in estrous cycle) were examined by dams.

Sperm parameters (parental animals)

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

Litter observations

PARAMETERS EXAMINED: The following parameters were examined in F1 offspring: Number and sex of pups, stillbirths, live births, postnatal mortality, presence of gross anomalies, and weight gain.

Postmortem examinations (parental animals)

METHOD OF SACRIFICED: All animals were sacrificed by exsanguination under pentobarbital sodium anesthesia, intraperitoneally.

SACRIFICE: Male animals: On Day 42, Maternal animals: on Day 4 of lactation, and Male recovery and female satellite animals: on Day 56.

GROSS PATHOLOGY AND ORGAN WEIGHTS : Yes Brain, heart, liver, kidneys, adrenals, thymus, spleen, testes, and epididymis.

HISTOPATHOLOGY: Yes Cerebrum, pituitary, thymus, lymph nodes (including mesenteric and mandibular lymph nodes), trachea, lung, stomach, intestinal tract (duodenum, jejunum, ileum, cecum,

colon, rectum), thyroids, parathyroid, heart, liver, spleen, kidneys, adrenals, urinary bladder, testes, epididymis, seminal vesicles (including the coagulating gland), prostate (ventral lobe), ovaries, uterus, vagina, bone marrow (one side femur), Sciatic nerve (one side femur), spinal cord, and gross abnormalities site.

Postmortem examinations (offspring)

SACRIFICE: The F1 pups were euthanized on PND 4 by exsanguination pentobarbital sodium anesthesia, intraperitoneally.

GROSS NECROPSY: Yes

Statistics

Parametric data such as grip strength, motor activity, body weight and gain, food consumption, urine volume, specific gravity, hematology, blood biochemistry, and absolute and relative organ weights were analyzed by Bartlett's test for homogeneity of distribution. When homogeneity was recognized, one-way analysis of variance was performed. When a significant difference was observed, Dunnett's multiple comparison test was conducted for comparison between control and treated groups. If not homogenous, analysis was performed using the Kruskal-Wallis ranking test. In consequence, if not homogenous, Dunnett's type mean rank sum test was conducted to compare to control and individual treatment groups. Qualitative value as the pathological findings was analyzed by Wilcoxon test and Fisher's exact test. Urinalyses data were analyzed by Kruskal-Wallis and Dunnett's type mean rank test. Significance level was set at 0.05 compared with the control group and among the groups.

Reproductive indices

1) Each parameter was determined by the following equations:

Mean estrus cycle, incidence of females with irregular estrus cycle, mating periods,

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

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

Gestation length, number of corpora lutea, number of implantation sites, total number of offspring,

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

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

Gestation index (%) = (No. of pregnant animals delivered live offspring/number of pregnant animals) × 100

Offspring viability indices

Total number of offspring at birth, number of live offspring at birth,

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

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

External examination of offspring, necropsy finding

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

Results and discussion

Results: P0 (first parental animals)

General toxicity (P0)

Clinical signs

effects observed, treatment-related

Description (incidence and severity)

see 7.5.1

Body weight and weight changes

effects observed, treatment-related

Description (incidence and severity)

see 7.5.1

Food consumption and compound intake (if feeding study)

effects observed, treatment-related

Description (incidence and severity)

see 7.5.1

Other effects

no effects observed

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 incidence of females with irregular estrus cycle, mating period with the number of estrus and day of conceiving, copulation index, and fertility index between the control group and any treatment groups.

3) Delivery Data and Delivery

There were no significant differences in the gestation length, number of corpora lutea, number of implantation sites, implantation index, and delivery index between the control group and any treatment groups.

GROSS PATHOLOGY

See 7.5.1 Repeated dose toxicity: oral

HISTOPATHOLOGY

See 7.5.1 Repeated dose toxicity: oral

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: No effects 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/PDF2579-20-6d.pdf

Applicant's summary and conclusion

Conclusions

In the combined repeated oral dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422) described above, there were no effects on reproductive and developmental

parameters at 300 mg/kg bw/day. The NOAEL for the rat reproductive/developmental toxicity of 1,3-cyclohexanedimethanamine was regarded as 300 mg/kg bw/day, the highest dose tested.

References

REFERENCE_SUBSTANCE: 1,3-cyclohexanedimethanamine

UUID: IUC5-c6161afa-424f-4a3a-9f14-f5aab542828b

Dossier UUID:

Author: SuperUser

Date: 2017-01-04T16:53:27.000+09:00

Remarks:

General information

Reference substance name

1,3-cyclohexanedimethanamine

Inventory

Inventory name

1,3-Cyclohexanedimethanamine

Inventory

EC

Inventory number

219-941-5

CAS number

2579-20-6

Molecular formula

C₈H₁₈N₂

Description

Reference substance information

CAS information

CAS number

2579-20-6

Molecular and structural information

Molecular formula

C₈H₁₈N₂

TEST_MATERIAL_INFORMATION: 2579-20-6 / 219-941-5

UUID: ee9eafa9-55bf-32ff-a298-e32c81563440

Dossier UUID:

Author: SuperUser

Date: 2017-01-05T11:10:20.000+09:00

Remarks:

Name

2579-20-6 / 219-941-5

Composition

Type

Constituent

Reference substance

1,3-cyclohexanedimethanamine / 2579-20-6 / 219-941-5

EC number

219-941-5

EC name

EC Inventory

CAS number

2579-20-6

CAS name

IUPAC name

Other characteristics

Details on test material

- Name of test material (as cited in study report): 1,3-Bis (aminomethyl) cyclohexane or 1,3-Cyclohexanedimethanamine
- CAS No.: 2579-20-6
- Lot No.: 50303
- Purity: 99.98%
- Supplier: MITSUBISHI GAS CHEMICAL COMPANY, INC.
- Boiling point : 244°C
- Melting point/Freezing point: <-70°C
- Flash point: 113°C
- Specific gravity: 0.940-0.950 (20°C)
- Solubility: Soluble in water, alcohol, n-hexane et al.
- Odor: Amine odor
- Physical state: Colorless liquid
- Storage condition of test material: in a refrigerator with nitrogen gas replacement

TEST_MATERIAL_INFORMATION: 2579-20-6 / 219-941-5

UUID: 1edf6b5f-321a-3630-aa97-6515a1fa6206

Dossier UUID:

Author: SuperUser

Date: 2017-01-06T11:59:01.000+09:00

Remarks:

Name

2579-20-6 / 219-941-5

Composition

Type

Constituent

Reference substance

1,3-cyclohexanedimethanamine / 2579-20-6 / 219-941-5

EC number

219-941-5

EC name

EC Inventory

CAS number

2579-20-6

CAS name

IUPAC name

Other characteristics

Details on test material

- Name of test material (as cited in study report): 1,3-Bis (aminomethyl) cyclohexane or 1,3-Cyclohexanedimethanmine
- CAS No.: 2579-20-6
- Lot No.: 50303
- Purity: 99.98%
- Supplier: MITSUBISHI GAS CHEMICAL COMPANY, INC.
- Boiling point : 244°C
- Melting point/Freezing point: <-70°C
- Flash point: 113°C
- Specific gravity: 0.940-0.950 (20°C)
- Solubility: Soluble in water, alcohol, and n-hexane.
- Odor: Amine odor
- Physical state: Colorless liquid
- Storage condition of test material: Stored in a refrigerator (2.8 – 8.4°C).

TEST_MATERIAL_INFORMATION: 2579-20-6 / 219-941-5

UUID: 3cf05eca-a8ef-3c79-b1d4-a65400828533

Dossier UUID:

Author: SuperUser

Date: 2017-01-06T16:17:10.000+09:00

Remarks:

Name

2579-20-6 / 219-941-5

Composition

Type

Constituent

Reference substance

1,3-cyclohexanedimethanamine / 2579-20-6 / 219-941-5

EC number

219-941-5

EC name

EC Inventory

CAS number

2579-20-6

CAS name

IUPAC name

Other characteristics

Details on test material

- Name of test material (as cited in study report): 1,3-Bis (aminomethyl) cyclohexane or 1,3-Cyclohexanedimethanamine
- CAS No.: 2579-20-6
- Lot No.: 50303
- Purity: 99.98%
- Supplier: MITSUBISHI GAS CHEMICAL COMPANY, INC.
- Boiling point : 244°C
- Melting point/Freezing point: <-70°C
- Flash point: 113°C
- Specific gravity: 0.940-0.950 (120°C)
- Vapor pressure: 1866 Pa, 14 mmHg (120°C)
- Solubility: Soluble in water, alcohol, n-hexane et al.
- Odor: Amine odor
- Physical state: Colorless liquid
- Storage condition of test material: stored in a refrigerator

TEST_MATERIAL_INFORMATION: 2579-20-6 / 219-941-5

UUID: e8451f0b-499f-3741-bd73-3b0d233b4969

Dossier UUID:

Author: SuperUser

Date: 2017-01-10T11:56:31.000+09:00

Remarks:

Name

2579-20-6 / 219-941-5

Composition

Type

Constituent

Reference substance

1,3-cyclohexanedimethanamine / 2579-20-6 / 219-941-5

EC number

219-941-5

EC name

EC Inventory

CAS number

2579-20-6

CAS name

IUPAC name

Other characteristics

Details on test material

- Name of test material (as cited in study report): 1,3-Bis (aminomethyl) cyclohexane or 1,3-Cyclohexanedimethanmine
- CAS No.: 2579-20-6
- Molecular formula: C₈H₁₈N₂
- Lot No.: CDH5467
- Purity: 100.1%
- Supplier: Wako Pure Chemical Industries, Ltd..
- Physical state: Colorless liquid
- Storage condition of test material: Stored in a refrigerator

TEST_MATERIAL_INFORMATION: 2579-20-6 / 219-941-5

UUID: a9d37dae-c813-3e10-a23b-96eb4f47595a

Dossier UUID:

Author: SuperUser

Date: 2017-01-10T12:21:07.000+09:00

Remarks:

Name

2579-20-6 / 219-941-5

Composition

Type

Constituent

Reference substance

1,3-cyclohexanedimethanamine / 2579-20-6 / 219-941-5

EC number

219-941-5

EC name

EC Inventory

CAS number

2579-20-6

CAS name

IUPAC name

Other characteristics

Details on test material

- Name of test material (as cited in study report): 1,3-Bis (aminomethyl) cyclohexane or 1,3-Cyclohexanedimethanmine

See 7.5.1 Repeated dose toxicity: oral Endpoint study record: Repeated dose toxicity: oral.001 for further information

LITERATURE: A combined repeated-dose/ reproductive-developmental toxicity study of 1,3-Bis (aminomethyl) cyclohexane by oral administration in rats.

UUID: 2ffaa0b9-3cf3-3eb0-ac98-28f5a754c7af

Dossier UUID:

Author: SuperUser

Date: 2017-01-10T12:21:07.000+09:00

Remarks:

General information

Reference Type

study report

Title

A combined repeated-dose/reproductive-developmental toxicity study of 1,3-Bis (aminomethyl) cyclohexane by oral administration in rats.

Author

MHW (Ministry of Health and Welfare), Japan

Year

2007

Bibliographic source

Japan Existing Chemical Data Base (JECDB)

Testing facility

Mitsubishi Safety Institute Ltd.

Study no.

B041794

Report Date

2007-01-23

LITERATURE: A combined repeated-dose/ reproductive-developmental toxicity study of 1,3-Bis (aminomethyl) cyclohexane by oral administration in rats.

UUID: 9c85df8c-a37d-33d0-90d8-cce94ed30246

Dossier UUID:

Author: SuperUser

Date: 2017-01-06T11:59:01.000+09:00

Remarks:

General information

Reference Type

study report

Title

A combined repeated-dose/reproductive-developmental toxicity study of 1,3-Bis (aminomethyl) cyclohexane by oral administration in rats.

Author

MHW (Ministry of Health and Welfare), Japan

Bibliographic source

Japan Existing Chemical Data Base (JECDB)

Testing facility

Mitsubishi Safety Institute Ltd.

Study no.

B041798

LITERATURE: In Vitro Chromosomal Aberration Test of 1,3-Bis (aminomethyl) cyclohexane on Cultured Chinese Hamster Cells

UUID: c80664bd-5492-3747-ad3c-992a01f8196d

Dossier UUID:

Author: SuperUser

Date: 2017-01-06T16:17:10.000+09:00

Remarks:

General information

Reference Type

study report

Title

In Vitro Chromosomal Aberration Test of 1,3-Bis (aminomethyl) cyclohexane on Cultured Chinese Hamster Cells

Author

MHW (Ministry of Health and Welfare), Japan

Year

2006

Bibliographic source

Japan Existing Chemical Data Base (JECDB)

Testing facility

Mitsubishi Safety Institute Ltd.

Study no.

B041800

Report Date

2006-09-15

LITERATURE: Micronucleus test of 1,3-Bis (aminomethyl) cyclohexane on mouse

UUID: 35b125e8-c778-35b0-8540-5fef7fa7633c

Dossier UUID:

Author: SuperUser

Date: 2017-01-10T11:56:31.000+09:00

Remarks:

General information

Reference Type

study report

Title

Micronucleus test of 1,3-Bis (aminomethyl) cyclohexane on mouse

Author

MHLW

Year

2010

Bibliographic source

Japan Existing Chemical Data Base (JECDB)

Testing facility

Food and Drug Safety Center

Study no.

G-09-02-023

Report Date

2010-03-30

LEGAL_ENTITY: National Institute of Health Sciences

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

Dossier UUID:

Author: SuperUser

Date: 2019-09-03T10:05:28.255+09:00

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 official MHLW opinions or any other regulatory policies.

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 official MHLW opinions or any other regulatory policies.

Identifiers

Other IT system identifiers

IT system LEO
ID 10767
IT system IUCLID4
ID 16558402024DIV750

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LITERATURE: Reverse Mutation Test of 1,3-Bis (aminomethyl) cyclohexane on Bacteria.

UUID: cd1215ac-345f-345f-a6ba-51ce0ed44575

Dossier UUID:

Author: SuperUser

Date: 2017-01-06T15:59:51.000+09:00

Remarks:

General information

Reference Type

study report

Title

Reverse Mutation Test of 1,3-Bis (aminomethyl) cyclohexane on Bacteria.

Author

MHW (Ministry of Health and Welfare), Japan

Year

2006

Bibliographic source

Japan Existing Chemical Data Base (JECDB)

Testing facility

Mitsubishi Safety Institute Ltd.

Report no.

B041799

Report Date

2006-09-14

LITERATURE: Single Dose Oral Toxicity Test of 1,3-Bis (aminomethyl) cyclohexane in Rats

UUID: fd4818f3-11a2-3e3f-980d-1fc3fd5c56da

Dossier UUID:

Author: SuperUser

Date: 2017-01-05T11:10:20.000+09:00

Remarks:

General information

Reference Type

study report

Title

Single Dose Oral Toxicity Test of 1,3-Bis (aminomethyl) cyclohexane in Rats

Author

MHW (Ministry of Health and Welfare), Japan

Year

2007

Bibliographic source

Japan Existing Chemical Data Base (JECDB)

Testing facility

Mitsubishi Safety Institute Ltd.

Study no.

B041797