Name: OECD_SIDS / SUBSTANCE : chlorocyclohexane / chlorocyclohexane / 542-18-7 Fri, 16 Dec 2022, 15:39:03+0900 /

Legal entity owner: National Institute of Health Sciences

Printing date: 2022-12-16T15:39:03.352+09:00

Table of Contents

DOSSIER:

UUID: 0
Dossier UUID:
Author:
Date: 2022-12-16T15:39:03.199+09:00
Remarks:

Dossier header

Dossier submission type

Name
OECD SIDS

Version
core 7.0

Name (given by user)

Dossier subject

Dossier subject
chlorocyclohexane / chlorocyclohexane / 542-18-7

Public name

Submitting legal entity
National Institute of Health Science

Dossier creation date/time
Fri, 16 Dec 2022, 15:39:03+0900

Used in category

LEGAL_ENTITY: National Institute of Health Science

UUID:	f51e7b54-9211-4863-90ce-fcf8a155d647
Dossier UUID:	
Author:	
Date:	2022-11-07T16:24:02.822+09:00
Remarks:	

General information

Legal entity name
National Institute of Health Science

chlorocyclohexane

General information

Identification

Identification

SUBSTANCE: chlorocyclohexane

UUID:	IUC5-cd10453c-72f2-45d4-a87e-fc2882f22d3b
Dossier UUID:	
Author:	
Date:	2022-12-16T15:38:53.673+09:00
Remarks:	

Substance name
chlorocyclohexane

Legal entity
National Institute of Health Sciences / Kawasaki / Japan

Identification of substance

Reference substance
chlorocyclohexane / chlorocyclohexane / 542-18-7 / 208-806-6

EC number	EC name
208-806-6	EC Inventory
CAS number	**CAS name**
542-18-7	
IUPAC name	
chlorocyclohexane	

Role in the supply chain

Manufacturer
false

Importer
false

Only representative
false

Downstream user
false

Assessment approach (assessment entities)

FIXED_RECORD: Assessment approach

UUID:	0e786433-e052-36ba-9957-1546f3cee548
Dossier UUID:	
Author:	
Date:	2017-01-04T16:41:51.000+09:00
Remarks:	

Toxicological information

Acute Toxicity

Acute toxicity: oral

ENDPOINT_STUDY_RECORD: Acute toxicity: oral.001

UUID:	IUC5-6f52b438-c5b8-41b0-b587-ae524ef28122
Dossier UUID:	
Author:	
Date:	2022-12-12T14:33:55.039+09:00
Remarks:	

Administrative data

Endpoint
acute 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
other: OECD Test Guideline study under GLP condition

Data source

Reference

Single Dose Oral Toxicity Test of Chlorocyclohexane in Rats / MHLW (Ministry of Health, Labour and Welfare), Japan / study report

Data access
data published

Materials and methods

Test guideline

Qualifier
according to guideline

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

Deviations
no

GLP compliance
yes

Test type
standard acute method

Limit test
yes

Test material

Test material information
chlorocyclohexane / 542-18-7 / 208-806-6

Specific details on test material used for the study
- Name of test material (as cited in study report): Chlorocyclohexane
- CAS No.: 542-18-7
- Molecular weight: 118.61
- Lot No.: 5C1114
- Purity: 99.7%
- Supplier: Junsei Chemical Co., Ltd.
- Vapor pressure: 6.73 mmHg (25°C)
- Vapor density : 4.12 (air = 1)
- Boiling point : 142°C
- Melting point: -44°C
- Flash point: °C
- Specific gravity: 1.004 (20/4°C)
- Solubility: Insoluble in water and miscible by organic solvents as the alcohol and ether et al.
- Odor: Characteristic odor
- Physical state: Slightly pale yellow from colorless liquid
- Storage condition of test material: Dark and sealed in refrigerator (2.8 – 8.4°C)

Test animals

Species
rat
common species

Strain
Crj: CD(SD)
rat

Sex
female

Administration / exposure

Route of administration
oral: gavage

Vehicle
olive oil

Details on oral exposure
VEHICLE- Concentration in vehicle: 60 and 400 mg/ml.MAXIMUM DOSE VOLUME APPLIED: 5 ml/kg b .w.

Doses
300 mg/kg bw (first and second administration)
2000 mg/kg bw (third and fourth administration)

No. of animals per sex per dose
First and second administration (first purchase): 3 animals and 3 animals (animal ID No. 50101 – 501 03 and 60101 - 60103) /female/300 mg/kg dose
Third and fourth administration (second purchase): 3 animals and 3 animals (animal ID No. 70101 – 70103 and 80101 - 80103) /female/2000 mg/kg dose

Control animals
no

Details on study design
- Duration of observation period following administration: 14 days
- Frequency of observations: Before dosing, Day 1 (day of administration):10, and 30 minutes and 1, 3, and 6 hrs after administration. After day 2: once a day
- Frequency of weighing: Days 1 (before administration), 4, 8 and 15
- Necropsy of survivors performed: Yes

Statistics
No

Results and discussion

Preliminary study
Dose levels were determined by the Globally Harmonized Classification System (GHS) (mg/kg b.w.). Mortality was not observed in each first and second administrations of 300 mg/kg groups and in each third and fourth administrations of 2000 mg/kg groups.

Effect levels

Key result
false

Sex
female

Dose descriptor
LD50

Effect level

> 2000

Mortality
No deaths were observed from first to fourth administration.

Clinical signs
other: No changes related to the test substance were observed from first to forth administration.

Gross pathology
No changes related to the test substance were observed from first to fourth administration.

Other findings
- Organ weights: No data- Histopathology: No data- Potential target organs: Not identified- Other ob servations: No data

Applicant's summary and conclusion

Conclusions
The LD50 value was more than 2000 mg/kg bw for females.
GHS classification was classified in Category 5 (>2000 – 5000 mg/kg b.w.).

Repeated dose toxicity

Repeated dose toxicity: oral

ENDPOINT_STUDY_RECORD: Repeated dose toxicity: oral.001

UUID:	IUC5-32931199-101f-41ea-aa8c-9e2425253f75
Dossier UUID:	
Author:	
Date:	2022-12-16T15:36:32.251+09:00
Remarks:	

Administrative data

Endpoint
short-term repeated dose toxicity: oral combined repeated dose and reproduction / developmental screening

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
other: OECD Test Guideline study under GLP condition

Cross-reference

Reason / purpose for cross-reference
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 chlorocyclohexane by oral admi / MHLW (Ministry of Health, Labour and Welfare), Japan / study report

Data access
data published

Materials and methods

Test guideline

Qualifier
according to guideline

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
chlorocyclohexane / 542-18-7 / 208-806-6

Specific details on test material used for the study
- Name of test material (as cited in study report): Chlorocyclohexane
- CAS No.: 542-18-7
- Molecular weight: 118.60
- Lot No.: 5C1114
- Purity: 99.7%
- Supplier: Junsei Chemical Co., Ltd.
- Vapor pressure: 6.73 mmHg (25°C)
- Vapor density : 4.12 (air = 1)
- Boiling point : 142°C
- Melting point: -44°C
- Flash point: 29°C
- Specific gravity: 1.004 (20/4°C)
- Solubility: Insoluble in water and miscible with organic solvents such as alcohol and ether etc.
- Odor: Peculiar odor
- Physical state: Colorless liquid to slightly pale yellow
- Storage condition of test material: Dark and sealed in refrigerator (2.8 – 8.4°C)

Test animals

Species
rat
common rodent species

Strain
Crj: CD(SD)
rat

Sex
male/female

Details on test animals or test system 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: 325-386 g for males and 193-231 g for females
- Housing: bracket-type metallic wire-mesh cages/males and females excluding gestation and lacta tion periods (W 195 × D 325 × H 180 mm),
and polycarbonate cage during gestation and lactation periods/females (W 265 × D 426 × H 200 mm)
- Water (e.g. ad libitum):ad libitum
- Acclimation period: 5 days
ENVIRONMENTAL CONDITIONS
- Temperature (°C): 21.4 to 23.7°C
- Humidity (%): 48.8 to 65.0%
- 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
olive oil

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 dark place at room temperature

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 met hod at Mitsubishi Safety Institute Ltd. Results showed that the concentration of the test article in each suspension was 95.0 to 106.2% of the nominal concentration and both values were within the acc eptable range (concentration: percentage of the nominal concentration, 100 ± 10%)

Duration of treatment / exposure
(P) Males: 42 days including 14 days pre-mating and mating periods
(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), 7, 12, 12, 7 males of 0, 10, 60, 300 mg/kg, respectively, 5 males and 5 females at 0 and 300 mg/kg bw/day (recovery group)

Control animals
yes, concurrent vehicle

Details on study design
- Dose selection rationale: A preliminary study was conducted to determine the doses to be employed. Three males and three female SD rats receiving 0, 30, 100, 300, and 1000 mg/kg groups of the substance were administered for 14 days. As a result, death or moribundity was observed in all males and females receiving 1000 mg/kg groups. Salivation and increases in absolute and relative adrenal weights were observed in females receiving 300 mg/kg group. No clear changes related to the test substance were observed in males receiving 300 mg/kg group. Therefore, the high dose was set at 300 mg/kg/day, and the middle and low dose were set at 60 and 10 mg/kg/day using common ratio 5. Vehicle control groups were set using olive oil only.

Examinations

Observations and examinations performed and frequency
CAGE SIDE OBSERVATIONS: Yes
- Time schedule:
Males and females: once before the start of administration, during the administration period, and during the recovery period
DETAILED CLINICAL OBSERVATIONS: Yes
- Time schedule:
Males: once before the start of administration, once every week until Week 6 during the administration
Females: once before the start of administration, once every week until Week 6 during the administration and once during the lactation period.
No observation performed during the recovery period because no observed clinical changes during 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 weighted 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. Female satellite groups 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, 8-15, 22-29, 29-36, 36-38, 43-50, and 50-52.
FOOD INTAKE: No
HAEMATOLOGY: Yes
- Time schedule for collection of blood: On the day after the final day of administration and on the final day of the recovery period
- 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 day after the final day of administration and on the en ding 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: Yes
- Time schedule for collection of urine: final week of administration (Day 38 of administration) in males
- 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
- 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: Grip strength of forelimb and hind limb
4) Measurement of Motor Activity.Motor activity: 10-minute intervals from 0 to 60 minutes

Sacrifice and pathology
GROSS PATHOLOGY AND ORGAN WEIGHTS：Brain, heart, liver, kidneys, adrenals, thymus, spleen, testes, and epididymis.
HISTOPATHOLOGY: 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 abnormal sites.

Statistics
The data were analyzed for homogeneity of variance by the Bartlett test. If variances were homogeneous, data was analyzed by one-way analysis of variance, whereas heterogenous data was analyzed by Kruskal-Wallis ranking test. When a significant difference was observed, Dunnett's multiple comparison test was conducted between control and treated groups. If not homogenous, analysis was performed using the Kruskal-Wallis ranking test. Qualitative value as the pathological findings was analyzed by Wilcoxon test and Fisher's exact test. Urinalyses data were analyzed by Kruskal-Wallis and Dunnet's type mean rank test. Statistical significance was set at < 5% by two-sided.

Results and discussion

Results of examinations

Clinical signs
effects observed, treatment-related

Mortality
mortality observed, treatment-related

Body weight and weight changes
effects observed, treatment-related

Food consumption and compound intake (if feeding study)
no effects observed

Food efficiency
not examined

Haematological findings
no effects observed

Description (incidence and severity)
Significant increase in reticulocyte counts was observed in males receiving 300 mg/kg bw/day, but it was not considered to be toxicological effects.

Clinical biochemistry findings
effects observed, treatment-related

Description (incidence and severity)
Significant decrease in inorganic phosphorus concentration was observed in females receiving 300 mg/kg bw/day, but it was not considered to be toxicological effects.

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

Histopathological findings: neoplastic
not specified

Details on results
CLINICAL SIGNS AND MORTALITY: No animal died in any group. Salivation was observed in males and females receiving 300 mg/kg from Day 9 to the end of dosing. No abnormal changes were observed in both sexes with recovery animals during the recovery period.
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 and females receiving 300 mg/kg from Day 8 to 42.
ORGAN WEIGHTS: A significant increase in relative kidney weight was observed in males receiving 300 mg/kg bw/day at the end of both administration and recovery periods. HISTOPATHOLOGY: Hyaline droplet of proximal tubular epithelium in kidneys was observed in all males receiving 300 mg/kg. Minimal hyperplasia of mucosal epithelium in urinary bladder was observed in males receiving 60 mg/kg and males and females receiving 300 mg/kg at the end of the administration. This pathological change was found in females receiving 300 mg/kg after the recovery period. Minimal cell infiltration was present in one male and one female receiving 300 mg/kg at the end of administration and recovery periods.

Effect levels

Key result
false

Dose descriptor
NOAEL

Effect level

10 mg/kg bw/day (actual dose received)

Sex
male

Basis for effect level
other: Effects of lesions in the hyperplasia of mucosal epithelium of urinary bladder in males re ceiving 60 mg/kg .

Key result
false

Dose descriptor
NOAEL

Effect level

60 mg/kg bw/day (actual dose received)

Sex
female

Basis for effect level
other: Effects of lesions in the hyperplasia of mucosal epithelium of urinary bladder in females receiving 300 mg/kg.

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/PDF542-18-7d.pdf

Applicant's summary and conclusion

Conclusions
Based on the effects of chlorocyclohexane on the urinary bladder, the no observed adverse effect lev el (NOAEL) for repeated oral dosing was determined to be 10 mg/kg bw/day in male rats and 60 mg/ kg bw/day in female rats.

Executive summary

A combined repeated oral dose toxicity study and reproduction/developmental toxicity screening test was performed according to the OECD TG 422. Male and female rats (12 animals/sex/dose) were administered chlorocyclohexane at 0, 10, 60, and 300 mg/kg bw/day. Males were dosed for 42 days, including a 14 day pre-mating period and subsequent mating period. Females were dosed for up to 55 days, including 14 day pre-mating, mating, and gestation periods, and the time until lactation day 4. Five out of 12 males dosed at 0 and 300 mg/kg bw/day were treated as a recovery group. In addition, 5 females/dose 0 and 300 mg/kg bw/day groups were dosed for 42 days without mating and examined after the recovery period. At 300 mg/kg bw/day, increased salivation and decreased body weight gain were observed in both sexes. Absolute and relative kidney weights increased and hyaline droplet formation in the proximal tubular epithelium increased in males administered 300 mg/kg bw/day. Hyperplasia of the urinary bladder mucosal epithelium was observed in males administered 60 and 300 mg/kg bw/day and in females administered 300 mg/kg bw/day. Among these changes, increased relative kidney weight in males and hyperplasia of the urinary bladder mucosal epithelium in females persisted after the recovery period. Based on these effects in the kidney and urinary bladder, the NOAELs for repeated dose toxicity were determined to be 10 mg/kg bw/day and 60 mg/kg bw/day in male and female rats, respectively.

Genetic toxicity

Genetic toxicity in vitro

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.001

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Dossier UUID:	
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Remarks:	

Administrative data

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

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
other: OECD Test Guideline study under GLP condition

Data source

Reference

Reverse Mutation Test of chlorocyclohexane on Bacteria. / MHLW (Ministry of Health, Labour and Welfare), Japan / study report

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
no

Qualifier
according to guideline

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
chlorocyclohexane / 542-18-7 / 208-806-6

Specific details on test material used for the study
- Name of test material (as cited in study report): Chlorocyclohexane
- CAS No.: 542-18-7
- Molecular weight: 118.61
- Lot No.: 5C1114
- Purity: 99.7%
- Supplier: Junsei Chemical Co., Ltd.
- Vapor pressure: 6.73 mmHg (25°C)
- Vapor density : 4.12 (air = 1)
- Boiling point : 142°C
- Melting point: -44°C
- Flash point: °C
- Specific gravity: 1.004 (20/4°C)
- Solubility: Insoluble in water and miscible by organic solvents as the alcohol and ether et al.
- Odor: Characteristic odor
- Physical state: Slightly pale yellow from colorless liquid
- Storage condition of test material: Dark and sealed in refrigerator (2.8 - 8.4°C)

Method

Species / strain

Species / strain / cell type
S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and E. coli WP2
bacteria

Metabolic activation
with and without

Metabolic activation system
SD male rat liver, induced by phenobarbital and 5,6-benzoflavone

Test concentrations with justification for top dose
-S9 mix: 2.44, 4.88, 9.77, 19.5, 39.1, 78.1, 156 µg/plate (TA100, TA1535 strains),

9.77, 19.5, 39.1, 78.1, 156, 313 µg/plate (TA98, TA1537, WP2uvrA/pKM101 strains)
+S9 mix: 9.77, 19.5, 39.1, 78.1, 156, 313 µg/plate (TA100, TA1535, TA98, TA1537 strains),
9.77, 19.5, 39.1, 78.1, 156, 313, 625 µg/plate (WP2uvrA/pKM101 strain)

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

Controls

Untreated negative controls
no

Negative solvent / vehicle controls
yes

True negative controls
no

Positive controls
yes

Positive control substance
other: -S9 mix: 2-(2-Furyl)-3-(5-nitro-2-furyl) acrylamide (TA 100, TA98 and WP2 uvrA/pKM101), so dium azide (TA1535) and 9-aminoacridine hydrochloride (TA1537). +S9 mix: 2-aminoanthracene (all strains)

Details on test system and experimental conditions
METHOD OF APPLICATION: Preincubation DURATION- Preincubation period: 20 min at 37°C - Expo sure duration:48 hrs NUMBER OF PLATES: 3 NUMBER OF REPLICATIONS: 1 DETERMINATION OF CYTOTOXICITY- Method: other: growth inhibition

Evaluation criteria
In any strain(s) tested with or without S9 mix, when the mean number of revertant colonies per plate increased twice more than that of the negative control and when the increase was shown to be dose-r elated and reproducible, the chemical was judged mutagenic.

Statistics
No

Results and discussion

Test results

Key result
false

Species / strain
S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and E. coli WP2
bacteria

Metabolic activation
with and without

Genotoxicity
negative

Cytotoxicity / choice of top concentrations
cytotoxicity

Vehicle controls validity
valid

Untreated negative controls validity
not examined

Positive controls validity
valid

Additional information on results
RANGE-FINDING/SCREENING STUDIES: Concentration: 1.22, 4.88, 19.5, 78.1, 313, 1250, 5000 µg/plate with and without S9 mix
Cytotoxic conc.: -S9 at 78.1µg/plate and higher, +S9 at 313 µg/plate and higher

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/PDF542-18-7e.pdf

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

Overall remarks, attachments

Overall remarks

No increase in revertant colonies was observed in the test with either the non-activation method (-S9) or activation (+S9) method. Reverse mutation assays using microorganisms (Salmonella typhimurium, Escherichia coli) were conducted to assess the potential of chlorocyclohexane to induce gene mutations. Chlorocyclohexane did not induce gene mutations in the bacteria under the conditions of this study. The positive control showed expected results.

Applicant's summary and conclusion

Conclusions
Chlorocyclohexane did not induce gene mutations in the in vitro bacteria test.

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.002

UUID: IUC5-5c6ddd27-d102-4a29-91ea-e87ededc3b69
Dossier UUID:
Author:
Date: 2022-12-16T15:38:04.901+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
key study

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 Chlorocyclohexane on Cultured Chinese Hamster Cells / MHLW (Ministry of Health, Labour and Welfare), Japan / study report

Data access
data published

Materials and methods

Test guideline

Qualifier
according to guideline

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

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
chlorocyclohexane / 542-18-7 / 208-806-6

Specific details on test material used for the study
- Name of test material (as cited in study report): Chlorocyclohexane
- CAS No.: 542-18-7
- Molecular weight: 118.61
- Lot No.: 5C1114
- Purity: 99.7%
- Supplier: Junsei Chemical Co., Ltd.
- Vapor pressure: 6.73 mmHg (25°C)
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- Boiling point : 142°C
- Melting point: -44°C
- Flash point: °C
- Specific gravity: 1.004 (20/4°C)
- Solubility: Insoluble in water and miscible by organic solvents as the alcohol and ether et al.
- Odor: Characteristic odor
- Physical state: Slightly pale yellow from colorless liquid
- Storage condition of test material: Dark and sealed in refrigerator (2.8 - 8.4°C)

Method

Target gene
Chromosome

Species / strain

Species / strain / cell type
other: Chinese hamster lung(CHL/IU) cells

Metabolic activation
with and without

Metabolic activation system
SD male rat liver, induced by phenobarbital and 5,6-benzoflavone

Test concentrations with justification for top dose
-S9 mix (short term treatment): 100, 150, 200, 250, 300, 350 ug/mL
+S9 mix (short term treatment): 200, 300, 400, 450, 500 ug/mL
Continuous treatment: 150, 175, 200, 225, 275 ug/mL

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

Controls

Untreated negative controls
no

Negative solvent / vehicle controls
yes

True negative controls
no

Positive controls
yes

Positive control substance
other: [continuous treatment -S9]: mitomycin C; [continuous treatment +S9]: Benzo[a]pyrene

Details on test system and experimental conditions
METHOD OF APPLICATION: Exposure duration: [continuous treatment]: 24 hrs [short-term treat ment]:6 hrs + 18 hr
SPINDLE INHIBITOR: Colcemid
STAIN: Giemsa stain for 20 min.
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, which are usually used for chromosomal aberration testing with CHL, were employed. Ap pearance incidence of cell with chromosomal aberrations:Negative(-): less than 5%Equivocal(±): 5% or more, less than 10%Positive(+): 10% or more

Statistics
No analyses

Any other information on materials and methods 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/PDF542-18-7f.pdf

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

Results and discussion

Test results

Key result
false

Species / strain
other: Chinese hamster lung (CHL/IU) cells

Metabolic activation
with and without

Genotoxicity
negative

Cytotoxicity / choice of top concentrations
no cytotoxicity

Vehicle controls validity
valid

Untreated negative controls validity
not examined

Positive controls validity
valid

Remarks on result
other: strain/cell type: Chinese hamster lung (CHL/IU) cells Migrated from field 'Test system'.

Applicant's summary and conclusion

Conclusions
Interpretation of results (migrated information):
negative

Chlorocyclohexane did not induce chromosomal aberrations in cultured cells.

Executive summary

An in vitro chromosomal aberration test using CHL/IU cells (OECD TG 473) was negative with or without metabolic activation.

Toxicity to reproduction

Toxicity to reproduction

ENDPOINT_STUDY_RECORD: Toxicity to reproduction.001

UUID: IUC5-d811110c-8c27-46af-af04-96e78a861e27
Dossier UUID:
Author:
Date: 2022-12-16T15:38:43.716+09:00
Remarks:

Administrative data

Endpoint
one-generation reproductive toxicity based on generations indicated in Effect levels (migrated in formation)

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
other: OECD Test Guideline study under GLP condition

Cross-reference

Reason / purpose for cross-reference
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 chlorocyclohexane by oral admi / MHLW (Ministry of Health, Labour and Welfare), Japan / study report

Data access
data published

Materials and methods

Test guideline

Qualifier
according to guideline

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
chlorocyclohexane / 542-18-7 / 208-806-6

Specific details on test material used for the study
- Name of test material (as cited in study report): Chlorocyclohexane
- CAS No.: 542-18-7
- Molecular weight: 118.61
- Lot No.: 5C1114
- Purity: 99.7%
- Supplier: Junsei Chemical Co., Ltd.
- Vapor pressure: 6.73 mmHg (25°C)
- Vapor density : 4.12 (air = 1)
- Boiling point : 142°C
- Melting point: -44°C
- Flash point: 29°C
- Specific gravity: 1.004 (20/4°C)
- Solubility: Insoluble in water and miscible with organic solvents such as the alcohol and ether etc.
- Odor: Peculiar odor
- Physical state: Slightly pale yellow from colorless liquid
- Storage condition of test material: Dark and sealed in refrigerator (2.8 - 8.4°C)

Test animals

Species
rat

Strain
Crj: CD(SD)
rat

Sex
male/female

Details on test animals or test system 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: 325-386 g for males and 193-231 g for females
- Housing: bracket-type metallic wire-mesh cages/males and females excluding gestation and lactat ion periods (W 195 × D 325 × H 180 mm),

and polycarbonate cage during gestation and lactation periods/females (W 265 × D 426 × H 200 mm)
- Diet (e.g. ad libitum): ad libitum
- Water (e.g. ad libitum): ad libitum excluding collected fresh urine
- Acclimation period:8 days
ENVIRONMENTAL CONDITIONS
- Temperature (°C):21.4 to 23.7°C
- Humidity (%): 48.8 to 65.0%
- Air changes (per hr): 9 to 20 times per hour
- Photoperiod (hrs dark / hrs light):12-hour lighting per day

Administration / exposure

Route of administration
oral: gavage

Vehicle
olive oil

Details on 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): At least 7 days
- Storage condition of test solution: Stored in a refrigerator

Analytical verification of doses or concentrations
yes

Details on analytical verification of doses or concentrations
Test suspensions at each concentration of initial and final preparations were analyzed by the GC met hod at Mitsubishi Safety Institute Ltd. Results showed that the concentration of the test article in each suspension was 95.0 to 106.2% of the nominal concentration and both values were within the acc eptable range (concentration: percentage of the nominal concentration, 100 ± 10%)

Duration of treatment / exposure
(P) Males: 42 days including 14 days pre-mating and mating periods (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), 7, 12, 12, 7 males of 0, 10, 60, 300 mg/kg, respectively, 5 males and 5 females at 0 and 300 mg/kg bw/day (recovery group)

Control animals
yes, concurrent vehicle

Details on study design
- Dose selection rationale: A preliminary study was conducted to determine the doses to be employed. Three males and three female SD rats were receiving 0, 30, 100, 300, and 1000 mg/kg groups of the substance were administered for 14 days. As a result, death or dying was observed in all males and females receiving 1000 mg/kg groups. Salivation and increases in absolute and relative adrenal weights were observed in females receiving 300 mg/kg group. No clear changes related to the test substance were observed in males receiving 300 mg/kg group. Therefore, the high dose was set at 300 mg/kg/day, and the middle and low dose were set at 60 and 10 mg/kg/day using common ratio 5. Vehicle control groups were set using olive oil only.

Examinations

Parental animals: Observations and examinations
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:
Males: once before the start of administration, during the administration and recovery periods
Females: once before the start of administration, days 1, 7, 14 and 20 of gestation, and day 4 of lacta tion
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 weighted 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 were measured on Day 1-8, 8-15, 15-22, 22-29, 29-36, 36-38, 43-50, and 50-52. Female satellite groups were measured on Day 1-8, 8-15, 15-22, 22-29, 29-36, 36-42, 43-50, and 50-56. Main females were measured same frequencies to body weighted days. It is not measured during the mating.
FOOD INTAKE: No
COMPOUND INTAKE: No
FOOD EFFICIENCY: No
WATER CONSUMPTION: No

Oestrous 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)
SACRIFICE: The F1 pups were euthanized on PND 4 by exsanguination pentobarbital sodium ane sthesia, 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 Dunnet's type mean rank test. Reproductive incidences of estrous cycle, fertility index, copulation index, delivery index, sex rati o, and external abnormalities were analysed by Fisher's exact 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 lactationBirth 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 generation)

General toxicity (P0)

Clinical signs
effects observed, treatment-related

Body weight and weight changes
effects observed, treatment-related

Food consumption and compound intake (if feeding study)
effects observed, treatment-related

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

Gross pathological findings
effects observed, treatment-related

Histopathological findings: non-neoplastic
effects observed, treatment-related

Other effects
no effects observed

Reproductive function / performance (P0)

Reproductive function: oestrous cycle
no effects observed

Reproductive function: sperm measures
not examined

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)

Key result
false

Dose descriptor
NOAEL

Effect level

300	mg/kg bw/day

Sex
male/female

Basis for effect level
other: No reproductive effects up to highest dose tested

Results: F1 generation

General toxicity (F1)

Clinical signs
no effects observed

Mortality / viability
no mortality observed

Body weight and weight changes
no effects observed

Sexual maturation
no effects observed

Organ weight findings including organ / body weight ratios
not specified

Gross pathological findings
no effects observed

Histopathological findings
not specified

Effect levels (F1)

Key result
false

Dose descriptor
NOAEL

Generation
F1

Effect level

300	mg/kg bw/day

Sex
male/female

Basis for effect level
other: No developmental effects up to highest dose tested

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/PDF542-18-7d.pdf

Applicant's summary and conclusion

Conclusions
The NOAEL for rat reproductive and developmental toxicity was determined to be 300 mg/kg bw/day.

Executive summary

A combined repeated oral dose toxicity study and reproduction/developmental toxicity screening test was performed according to the OECD TG 422. Male and female rats (12 animals/sex/dose) were administered chlorocyclohexane at 0, 10, 60, and 300 mg/kg bw/day. Males were dosed for 42 days, including a 14 day pre-mating period and subsequent mating period. Females were dosed for up to 55 days, including 14 day pre-mating, mating, and gestation periods, and the time until lactation day 4. Five out of 12 males dosed at 0 and 300 mg/kg bw/day were treated as a recovery group. In addition, 5 females/dose 0 and 300 mg/kg bw/day groups were dosed for 42 days without mating and examined after the recovery period. There were no effects on reproductive and developmental parameters at 300 mg/kg bw/day. The NOAEL for the rat reproductive/developmental toxicity of chlorocyclohexane was determined to be 300 mg/kg bw/day, the highest dose tested.

References

Reference Substances

REFERENCE_SUBSTANCE: chlorocyclohexane

UUID: ECB5-9483ca56-6e33-4ec9-a0f4-545b621d4c14
Dossier UUID:
Author:
Date: 2007-05-10T18:00:00.000+09:00
Remarks:

Reference substance name
chlorocyclohexane

IUPAC name
chlorocyclohexane

Inventory

Inventory number

Inventory name
chlorocyclohexane

Inventory
EC Inventory

Inventory number
208-806-6

CAS number
542-18-7

Molecular formula
C6H11Cl

Description

CAS number
542-18-7

Synonyms

Synonyms

Identity
chlorocyclohexane

Identity
Cyclohexane, chloro-

Identity
Cyclohexane, chloro-

Molecular and structural information

Molecular formula
C6H11Cl

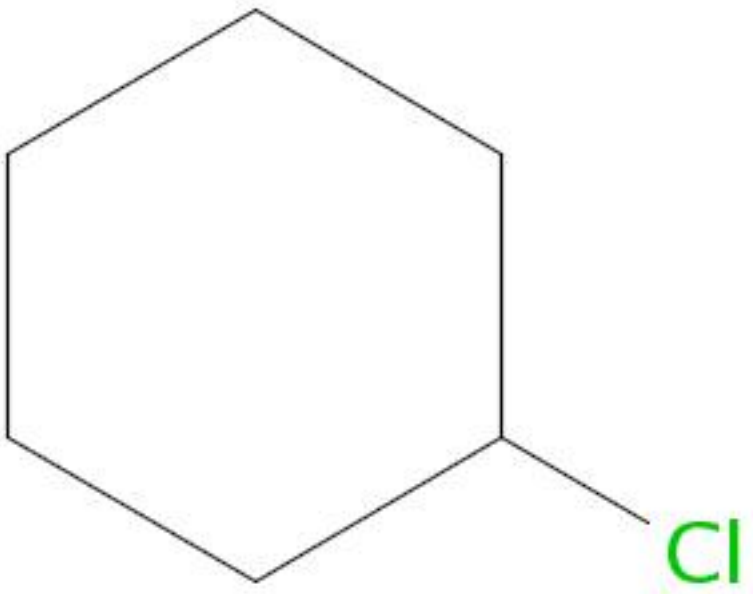
Molecular weight

118.6045

SMILES notation
ClC1CCCCC1

InChI
InChI=1/C6H11Cl/c7-6-4-2-1-3-5-6/h6H,1-5H2

Structural formula



Related substances

Group / category information
DSL Category: Organics

Test Materials

TEST_MATERIAL_INFORMATION: chlorocyclohexane / 542-18-7 / 208-806-6

UUID: 12489c5c-655c-3e0c-b6cf-5f492c38624a
Dossier UUID:
Author:
Date: 2022-12-12T14:33:50.898+09:00
Remarks:

Name
chlorocyclohexane / 542-18-7 / 208-806-6

Composition

Composition

Type
Constituent

Reference substance
chlorocyclohexane / chlorocyclohexane / 542-18-7 / 208-806-6

EC number	EC name
208-806-6	EC Inventory
CAS number	**CAS name**
542-18-7	
IUPAC name	
chlorocyclohexane	

Literatures

LITERATURE: A combined repeated-dose/reproductive-developmental toxicity study of chlorocyclohexane by oral administration in rats.

UUID: 830ba0b0-26d5-37a9-8ef7-84c4a85199b0
Dossier UUID:
Author:
Date: 2017-01-04T16:42:46.000+09:00
Remarks:

General information

Reference Type
study report

Title
A combined repeated-dose/reproductive-developmental toxicity study of chlorocyclohexane by oral administration in rats.

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

Year
2007

Bibliographic source
Japan Existing Chemical Data Base (JECDB)

Testing facility
Mitsubishi Safety Institute Ltd.

Report date
2007-01-23

Study number
B041794

LITERATURE: In Vitro Chromosomal Aberration Test of Chlorocyclohexane on Cultured Chinese Hamster Cells

UUID: 9d974c31-5cd8-3cff-a6ab-0ee04becc208
Dossier UUID:
Author:
Date: 2017-01-04T16:43:02.000+09:00
Remarks:

General information

Reference Type
study report

Title
In Vitro Chromosomal Aberration Test of Chlorocyclohexane on Cultured Chinese Hamster Cells

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

Year
2006

Bibliographic source
Japan Existing Chemical Data Base (JECDB)

Testing facility
Mitsubishi Safety Institute Ltd.

Report date
2016-09-15

Study number
B041796

LITERATURE: Reverse Mutation Test of chlorocyclohexane on Bacteria.

UUID: 04ba63b5-4aaf-38de-a757-3593a38ec717
Dossier UUID:
Author:
Date: 2017-01-04T16:42:56.000+09:00
Remarks:

General information

Reference Type
study report

Title
Reverse Mutation Test of chlorocyclohexane on Bacteria.

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

Year
2006

Bibliographic source
Japan Existing Chemical Data Base (JECDB)

Testing facility
Mitsubishi Safety Institute Ltd.

Report date
2006-09-14

Study number
B041795

LITERATURE: Single Dose Oral Toxicity Test of Chlorocyclohexane in Rats

UUID:	5eb44718-fca3-3d6a-ba1f-2cc869f878f5
Dossier UUID:	
Author:	
Date:	2017-01-04T16:42:38.000+09:00
Remarks:	

General information

Reference Type
study report

Title
Single Dose Oral Toxicity Test of Chlorocyclohexane in Rats

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

Year
2007

Bibliographic source
Japan Existing Chemical Data Base (JECDB)

Testing facility
Mitsubishi Safety Institute Ltd.

Report date
2007-01-23

Study number
B041793

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.

Address

Address 1
Tonomachi 3-25-26

Address 2
Kawasaki-ku

Postal code
210-9501

Town
Kawasaki

Region / State
Kanagawa

Country
Japan
JP

Identifiers

Other IT system identifiers

IT system LEO **ID** 10767
IT system IUCLID4

ID
16558402024DIV750