Name: 2,3,4,4'-Tetrahydroxybenzophenone / 31127-54-5

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

Printing date: 2019-09-03T14:18:42.947+09:00

Table of Contents

2,3,4,4'-Tetrahydroxybenzophenone

CORE

General information

Identification

SUBSTANCE: 2,3,4,4'-Tetrahydroxybenzophenone

UUID: IUC5-240cac4f-f27d-4ed7-ab4d-9fde7ed35f68
Dossier UUID:
Author: SuperUser
Date: 2016-12-21T15:06:08.000+09:00
Remarks:

Substance name
2,3,4,4'-Tetrahydroxybenzophenone

Legal entity
National Institute of Health Sciences / Kawasaki / Japan

Identification of substance

Reference substance
2,3,4,4'-Tetrahydroxybenzophenone / 31127-54-5

EC number	EC name
CAS number	**CAS name**
31127-54-5	
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: IUC5-81f8cc24-0026-4622-bd2a-06850fde77f0
Dossier UUID:
Author: SuperUser
Date: 2017-02-15T16:02:42.000+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 2,3,4,4'-Tetrahydroxybenzophenone in Rats / MHLW / publication

Data access
data published

Materials and methods

Test guideline

Qualifier
according to

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

Test material

Test material information
31127-54-5

Test animals

Species
rat
common species

Strain
other: Crl:CD(SD)

Sex
female

Details on test animals and environmental conditions
TEST ANIMALS
- Source :Charles River Japan Inc.
- Age at study initiation: 6 weeks old
- Weight at study initiation: Females, 123-135 g
- Fasting period before study: Approximately 16 hrs
- Housing:1/cage
- Diet (e.g. ad libitum): Ad libitum except fasting period for 16 hrs before administration to 6 hrs after administration
- Water (e.g. ad libitum):Ad libitum
- Acclimation period:7 days
ENVIRONMENTAL CONDITIONS
- Temperature (°C): 23±3 ℃(actual temperature: 21-25℃)
- Humidity (%):50 ± 20% (actual humidity: 40-59%)
- Air changes (per hr): Approximately 10-15 times/hr
- Photoperiod (hrs dark / hrs light):12 hrs light / 12 hrs dark

Administration / exposure

Route of administration
oral: gavage

Vehicle
corn oil

Details on oral exposure
- Amount of vehicle (if gavage):10 ml/kg bw

Doses
2000 mg/kg bw

No. of animals per sex per dose
3 (1st step group) and 3 (2nd step group)

Control animals
no

Details on study design
- Duration of observation period following administration: 14 days

- Frequency of observations: nearly successive observation (from time just to 1 hr after adminis tration) and observation of every 2 hr (from 2 hr – 6 hr after administration) (day 0); once a day (from day 1-day14)
- Frequency of weighing : just before administration (day 0), and 1,3,7 and 14 day after administration
- Necropsy of survivors performed: yes

Results and discussion

Effect levels

Key result
false

Sex
female

Dose descriptor
LD50

Effect level

>	2000	mg/kg bw

Mortality
No deaths were observed in any group.

Clinical signs
No changes related to the test substance were observed in any group.

Body weight
No changes related to the test substance were observed in any group.

Gross pathology
No changes related to the test substance were observed in any group.

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/PDF31127 -54 -5a.pdf

Applicant's summary and conclusion

Executive summary

The acute oral median lethal dose (LD50) for 2,3,4,4'-tetrahydroxybenzophenone was established at > 2,000 mg/kg bw in female rats on the basis of a study conducted according to the Organisation for Economic Co-operation and Development Test Guideline (OECD TG) 423. The substance caused no deaths or clinical signs of toxicity at 2,000 mg/kg bw.

Repeated dose toxicity: oral

ENDPOINT_STUDY_RECORD: Repeated dose toxicity: oral.001

UUID: IUC5-b49d0715-b5a9-4ebc-bed0-1f609412fd9f
Dossier UUID:
Author: SuperUser
Date: 2017-02-15T16:04:12.000+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: GLP guideline study

Cross-reference

Reason / purpose
reference to same study

Remarks
7.8.1 Reproductive/developmental toxicity.001

Data source

Reference

Combined repeat dose and reproductive/developmental toxicity screening test of 2,3,4,4'-Tetrahydroxy... / MHLW Japan / study report

Data access
data published

Materials and methods

Test guideline

Qualifier
according to

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

Deviations
no

GLP compliance
yes

Limit test
no

Test material

Test material information
31127-54-5

Test animals

Species
rat
common rodent species

Strain
other: Crl: CD(SD)

Sex
male/female

Details on test animals and environmental conditions
TEST ANIMALS
- Source: Charles River Laboratories Japan, Inc. Atsugi
- Age at study initiation: 10 weeks
- Weight at study initiation: Males: 335-391 g; Females: 202-249 g
- Housing: Steel wire-mesh cage (250 mm x 350 mm x 200 mm)
- Diet: ad libitum
- Water: ad libitum
- Acclimation period: 14 days

ENVIRONMENTAL CONDITIONS
- Temperature (°C): 21-23
- Humidity (%): 46-61
- Air changes: 10-15 times / hr
- Photoperiod: 12 hrs dark / 12 hrs light

Administration / exposure

Route of administration
oral: gavage

Vehicle
corn oil

Details on oral exposure
PREPARATION OF DOSING SOLUTIONS:
VEHICLE
- Amount of vehicle (if gavage): 5 mL/kg bw
- Lot/batch no. (if required): SDE2487

Duration of treatment / exposure
(P) Males: 42 days including 14 days pre-mating and mating periods, and thereafter 14 days (P) Females: 42-55 days including 14 days pre-mating, mating and gestation periods, and the days until day 4 of lactation; satellite animals: 42 days.

Frequency of treatment
Once/day, 7days/week

Doses / concentrations

Remarks
Doses / Concentrations:
0 (vehicle), 100, 300, and 1000 mg/kg bw/day
Basis:
actual ingested

No. of animals per sex per dose
12 animals/sex/dose as a main dose group,
5 males and 5 females at 0 and 1000 mg/kg bw/day as a satellite group (without mating)

Control animals
yes, concurrent vehicle

Details on study design
- Dose selection rationale: Doses in this test were set based on the results of the following study: 14-day repeated dose oral toxicity test (doses: 100, 300, and 1000 mg/kg bw/day). In the 14-day repeated dose oral toxicity test, abnormalities were observed in animals in the 1000 mg/kg bw/day group, such as low values of body weight and food consumption an increase in liver weight. No effects were observed at 300 mg/kg bw/day. On the basis of these effects, a dose level of 1000 mg/kg was selected as the maximum dose expecting to induce the toxic changes, and then dose levels of 300 and 100 mg/kg bw/day were selected as a middle dose and a minimum dose levels, respectively, in accordance with a common ratio of approximately 3.
- Rationale for animal assignment (if not random): Body weight-balanced randomization
- Post-exposure recovery period in satellite groups: 14 days

Examinations

Observations and examinations performed and frequency
CAGE SIDE OBSERVATIONS: Yes
- Time schedule:
Males and females: once before the start of administration, 3 times/day during the administration period, and once during the recovery period

DETAILED CLINICAL OBSERVATIONS: Yes
The functional observational battery testing (FOB) was performed on all animals. Among the measures in the FOB, detailed clinical observations were made before the initiation of dosing. Thereafter, in males of the main groups, detailed clinical observations were made once a week. Also in females of the main groups, detailed clinical observations were made once a week in pre-mating and mating periods thereafter, and then those were made on days 1,7,14 and 20 of gestation, and on day

4 of lactation. For the satellite group, detailed clinical observations were made once a week in dosing and recovery periods.
Sensory motor reflexes, forelimb and hindlimb grip strengths, and motor activity were measured on week 6 of administration period (main/recovery group animals) and week 2 of recovery period (recove ry group animals).

BODY WEIGHT: Yes
- Time schedule for examinations: Males (main) & males and females (recovery group): Days 1, 4, 8, 11, 15, 22, 25, 29, 32, 36, 39, 42, and the day of necropsy (after ca. 16h-fasting) in dosing period
Males and females (recovery group): Days 1, 4, 8, 11, 14, and the day of necropsy (after ca. 16h-fasting) in recovery period
Females (main group): Twice a week during the precopulation period (days 1, 4, 8, 11, and 15); ge station days 0, 4, 7, 11, 14, 17, and 20; lactation days 0 and 4; and the day of necropsy (after ca. 16 h-fasting)

FOOD CONSUMPTION AND COMPOUND INTAKE (if feeding study):
- Food consumption: Yes
Males (main) & males and females (recovery group): Days 1, 4, 8, 11, 15, 32, 36, and 39 in dosing pe riod
Males and females (recovery group): Days 1, 4, 8, 11, and 14 in recovery period
Females (main group): Days 1, 4, 8, 11, and 15; gestation days 1, 4, 7, 11, 14, 17, and 20; lactation days 2 and 4

OPHTHALMOSCOPIC EXAMINATION: No

HAEMATOLOGY: Yes
- Time schedule for collection of blood: Blood was collected on the day of necropsy
- Anaesthetic used for blood collection: Yes (ether)
- Animals fasted: Yes, 16-20h
- How many animals: 5 sex/dose/group
- Parameters checked in table were examined.

CLINICAL CHEMISTRY: Yes
- Time schedule for collection of blood: Same as hematology
- Animals fasted: Same as hematology
- How many animals: Same as hematology
- Parameters checked in table were examined.

URINALYSIS: Yes (males only)
- Time schedule for collection of urine: Day 36-37 in dosing period, day 8-9 in recovery period
- Metabolism cages used for collection of urine: No data
- Animals fasted: fasting and only water at libitum (4h-urine), no fasting (20h-urine)

Sacrifice and pathology
GROSS PATHOLOGY: Yes, whole organs and tissues (see tables)
HISTOPATHOLOGY: Yes (see tables)

Other examinations
Organ weight: Brian, thyroids (including parathyroids), thymus, heart, liver, spleen, kidneys, adrenals, testes, epididymis

Statistics
The data were analyzed for homogeneity of variance by the Bartlett test. If variances were homogeneous, data was analyzed by the Dunnett test, whereas heterogeneous data was analyzed by the Dunnett type mean rank test ($p<0.05$, two-sided).
In the recovery test, these values of two groups were analyzed by F test. If variances were ho mogeneous, data was analyzed by the Student t-test, whereas heterogeneous data was analyzed by the Aspin-Welch t-test ($p<0.05$, two-sided).

Results and discussion

Results of examinations

Clinical signs
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)
effects observed, treatment-related

Food efficiency
not examined

Water consumption and compound intake (if drinking water study)
not examined

Ophthalmological findings
not examined

Haematological findings
effects observed, treatment-related

Clinical biochemistry findings
effects observed, treatment-related

Urinalysis findings
effects observed, treatment-related

Behaviour (functional findings)
effects observed, treatment-related

Description (incidence and severity)
see clinical signs.

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 examined

Details on results
CLINICAL SIGNS AND MORTALITY
Males: No dead or moribund animals were observed. Salivation was observed at 1000 mg/kg bw/day.
Females: After delivery (day 0 of lactation), one animal died at 1000 mg/kg bw/day.
Home cage observation: No effects.
In-the-hand observation: No effects.
Open field observation: No effects.
-Sensory motor reflexes:

Auditory response, approach response, touch response, tail pinch response, pupillary reflex, aerial righting reflex: No effects. Landing foot splay: High value in females at 1000 mg/kg bw/day (main group, day 4 of lactation)
-Forelimb and hindlimb grip strengths: Low value of hindlimb grip strength in males at 1000 mg/kg bw/day in the 6-week of dosing
-Motor activity: High value in females at 300 mg/kg bw/day (main group, day 4 of lactation) without dose-response relationship. In females, high value at 1000 mg/kg bw/day in the 6-week of dosing in the recovery group, but not in the main group at the same dose. (No toxicological effects)

BODY WEIGHT AND WEIGHT GAIN
Males: Low values of body weight gain was observed at 1000 mg/kg bw/day in main group.
Females: Low value of body weight gain was observed at 1000 mg/kg bw/day at the ends of pre-mating and gestation periods. Low value of body weight was observed at 300 mg/kg bw/day on day 4 of lactation.
At the end of recovery period, high value of body weight gain was observed in both sexes at 1000 mg/kg bw/day.

FOOD CONSUMPTION
Males: Low value of food consumption was observed at 1000 mg/kg bw/day on day 4 of dosing, and significant increase was observed on days 36-42.
Females: Low value of food consumption was observed at 1000 mg/kg bw/day on day 4 of dosing, high value on day 15 of dosing, and then low value on day 20 of gestation and day 2 of lactation. Low value of food consumption was observed at 300 mg/kg bw/day on day 4 of dosing and day 2 of lactation.

HAEMATOLOGY
Low values of RBC, Hb, Ht and MCHC, and high values of platelet, neutrophilic count and monocyte count were observed at 1000 mg/kg bw/day at the end of dosing. At the end of recovery period, low values of RBC and Hb, and high value of reticulocyte were observed in males at 1000 mg/kg bw/day. Other significant findings in the table were within the normal ranges of physiological variability.

CLINICAL CHEMISTRY
High value of inorganic phosphorus was observed at 300 mg/kg bw/day and more at the end of dosing. Other significant findings in the table were within the normal ranges of physiological variability.

URINALYSIS (only males; statistical analysis was not performed on qualitative items.)
Occult blood was observed in all administered males, and the degree of occult blood was enhanced in a dose-dependent manner. Dark yarrow color was observed in each 2-3 males at 100 mg/kg bw/day and more.

ORGAN WEIGHTS
Low values of absolute and relative thymus weights were observed in females at 300 mg/kg bw/day and more at the end of dosing. High value of relative liver weight was observed in both sexes at 1000 mg/kg bw/day at the end of dosing, and in females at the end of recovery period. Other significant findings in the table were within the normal ranges of physiological variability.

GROSS PATHOLOGY
In the dead female at 1000 mg/kg bw/day, small sizes of spleen and thymus were observed.
Undernourishment of general descriptions was observed in one female at 1000 mg/kg bw/day. Dark discoloration of liver was observed in six males at 1000 mg/kg bw/day. Small size of thymus was observed in one female at 300 mg/kg bw/day, and in three females at 1000 mg/kg bw/day. Other findings in the table were considered to be incidental due to low frequency of appearance and/or pathological properties.

HISTOPATHOLOGY: NON-NEOPLASTIC
In the dead female at 1000 mg/kg bw/day, atrophy of white pup in the spleen and atrophy of thymus were observed.

[At the end of dosing]
Cecum: Single cell necrosis of mucosal epithelial cells was observed in 4 males and 2 females at 100 mg/kg bw/day, in 3 males and 3 females at 300 mg/kg bw/day, and in 8 males and 7 females at 1000 mg/kg bw/day. Diffuse hyperplasia of mucosa was observed in 1 male and 1 female at 100 mg/kg bw/day, in 3 males and 4 females at 300 mg/kg bw/day, and in 7 males and 6 females at 1000 mg/kg bw/day.
Liver: Vacuolation of peripheral hepatocytes was dose-dependently decreased in males and females at 300 mg/kg bw/day and more.
Thymus: Atrophy was dose-dependently increased in females at 300 mg/kg bw/day and more.
[At the end of recovery period]
Cecum: Diffuse hyperplasia of mucosa was observed in one male at 1000 mg/kg bw/day.
Other findings in the tables were considered to be incidental due to low frequency of appearance and/or pathological properties.

Effect levels

Dose descriptor
LOAEL

Effect level

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

Based on
test mat.

Sex
male/female

Basis for effect level
other: effects on the cecum

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/PDF31127 -54 -5d.pdf

Applicant's summary and conclusion

Conclusions
Based on the effects on the cecum, the low observed adverse effect level (LOAEL) for repeated oral dosing was determined to be 100 mg/kg bw/day in male and female rats.

Executive summary

A combined repeated oral dose toxicity study with the reproduction/developmental toxicity screening test was performed according to OECD TG 422. Male and female rats (12 animals/sex/dose) were

administered 2,3,4,4'-tetrahydroxybenzophenone at 0, 100, 300, and 1,000 mg/kg bw/day. Males were dosed for 42 days, including a 14-day pre-mating and mating periods; females were dosed for 41–45 days, including a 14-day pre-mating, mating, and gestation periods and the time until day 4 of lactation. In addition, male and female rats (five animals/sex/dose) were administered 0 and 1,000 mg/kg bw/day for 42 days without mating and examined after a 14-day recovery period. At 1,000 mg/kg bw/day, one female died on day 0 of lactation, salivation was observed in males and a decreased body weight gain was observed in both sexes. Regarding hematology parameters, anemia was observed at the same dose in males. Clinical chemistry studies demonstrated increased inorganic phosphorus at 300 mg/kg bw/day and higher in males. In the thymus, decreased organ weight and atrophy were observed at 300 mg/kg bw/day and higher in females. In the cecum, single cell necrosis of mucosal epithelial cells and diffuse mucosal hyperplasia were observed at 100 mg/kg bw/day and higher in both sexes. In the liver, in both sexes, increased organ weight at 1,000 mg/kg bw/day and decreased vacuolation of the perilobular hepatocytes in a dose-dependent manner at 300 mg/kg bw/day and higher was observed. These changes tended to resolve after the recovery period. On the basis of the findings in the cecum, the LOAEL for repeated-dose toxicity of 2,3,4,4'-tetrahydroxybenzophenone was determined to be 100 mg/kg bw/day in male and female rats.

Genetic toxicity in vitro

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.001

UUID: IUC5-9c9461e4-d1ec-4fcd-aa97-faf2ecde802a
Dossier UUID:
Author: SuperUser
Date: 2019-09-03T14:18:02.598+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
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 2,3,4,4'-Tetrahydroxybenzophenone on Bacteria. / MHLW, Japan / study report

Data access
data published

Materials and methods

Test guideline

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
31127-54-5

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
rat liver, induced by phenobarbital and 5,6-benzoflavone

Species / strain
E. coli WP2 uvr A
bacteria

Metabolic activation
with and without

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

Test concentrations with justification for top dose
-S9 mix: 1.56, 3.13, 6.25, 12.5, 25, 50 µg/plate (TA1537, TA98 strains),
62.5, 125, 250, 500, 1000, 2000 µg/plate (WP2uvrA strain),
and 31.3, 62.5, 125, 250, 500, 1000 µg/plate (TA100, TA1535 strains)
+S9 mix: 15.6, 31.3, 62.5, 125, 250, 500, 1000 µg/plate (all strains)

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

Controls

Negative controls
no

Solvent 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), sodium azide (TA1535) and 9-aminoacridine hydrochloride (TA1537). +S9 mix: 2-aminoanthracene (all strains)

Details on test system and conditions
RANGE-FINDING/SCREENING STUDIES:Concentration: 20-5000 µg/plate
Cytotoxic conc.: [-S9mix] Yes; >50 µg/plate (TA 98, TA1537), >1000 µg/plate (TA100, TA1535), >2000 µg/plate (WP2uvrA), [+S9mix] No.

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
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-related 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 and TA 100
bacteria

Metabolic activation
with and without

Genotoxicity
negative

Vehicle controls valid
yes

Negative controls valid
not examined

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
bacteria

Metabolic activation
with and without

Genotoxicity
negative

Vehicle controls valid
yes

Negative controls valid
not examined

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/
PDF31127 -54 -5e.pdf

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

Applicant's summary and conclusion

Conclusions
Interpretation of results (migrated information):
negative

Executive summary

In a bacterial reverse mutation assay using Salmonella typhimurium TA100, TA1535, TA98, and TA1537 and Escherichia coli WP2uvrA (similar to OECD TG 471), 2,3,4,4'-tetrahydroxybenzophenone was negative with or without metabolic activation.

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.002

UUID: IUC5-22ba9be0-7295-4c58-9fdd-5b2112f052bb
Dossier UUID:
Author: SuperUser
Date: 2017-02-15T16:04:52.000+09:00
Remarks:

Administrative data

Endpoint
in vitro cytogenicity / chromosome aberration study in mammalian cells Type of genotoxicity: chromos ome 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 2,3,4,4'-Tetrahydroxybenzophenone on Cultured Chinese Hamste... / MHLW, Japan / study report

Data access
data published

Materials and methods

Test guideline

Qualifier
according to

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

Deviations
no

Qualifier
according to

Guideline
JAPAN: Guidelines for Screening Mutagenicity Testing Of Chemicals

Deviations
no

GLP compliance
yes

Type of assay
in vitro mammalian chromosome aberration test
chromosome aberration

Test material

Test material information
31127-54-5

Method

Target gene
Chromosome

Species / strain

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

Metabolic activation
with and without

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

Test concentrations with justification for top dose
-S9 mix (short-term treatment): 0, 19.5, 39.1, 78.1, 156, 313 ug/mL
+S9 mix (short-term treatment): 0, 39.1, 78.1, 156, 313, 625 ug/mL
-S9 mix (continuous treatment, 24 h): 0, 19.5, 39.1, 78.1, 156, 313 ug/mL
-S9 mix (continuous treatment, 48 h): 0, 2.44, 4.88, 9.77, 19.5, 39.1 ug/mL

[Confirmation test]
-S9 mix (short-term treatment): 0, 6.58, 9.88, 14.8, 22.2, 33.3, 50 ug/mL
+S9 mix (short-term treatment): 0, 205, 256, 320, 400, 500 ug/mL

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

Controls

Negative controls
no

Solvent controls
yes

True negative controls
no

Positive controls
yes

Positive control substance
cyclophosphamide
mitomycin C

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

Evaluation criteria
For the evaluation of the frequencies of structural aberrations and of polyploidy induced, the following criteria were employed.
Appearance incidence of cells with chromosomal aberrations: Negative (-): < 5%; equivocal (±): 5-10%; positive (+): > 10%.
Finally, the substance is positive when the incidence is considered to be dose-related and reproducible.

Statistics
not used.

Results and discussion

Test results

Key result
false

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

Metabolic activation
with

Genotoxicity
positive weakly

Cytotoxicity
yes 625 ug/mL

Vehicle controls valid
yes

Negative controls valid
not examined

Positive controls valid
yes

Key result
false

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

Metabolic activation
without

Genotoxicity
negative

Cytotoxicity
yes 313 ug/mL (short), 78.1 ug/mL and more (continuous)

Vehicle controls valid
yes

Negative controls valid
not examined

Positive controls valid
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/PDF31127 -54 -5f.pdf

Applicant's summary and conclusion

Executive summary

An in vitro chromosomal aberration test using CHL/IU cells (OECD TG 473) showed positive.

Genetic toxicity in vivo

ENDPOINT_STUDY_RECORD: Genetic toxicity in vivo.001

UUID: IUC5-9f1cf02c-892b-4385-87b1-b9308a1b4173
Dossier UUID:
Author: SuperUser
Date: 2017-02-15T16:06:01.000+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
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: GLP guideline study

Data source

Reference

Micronucleous test of 2,3,4,4'-Tetrahydroxybenzophenone on rat / MHLW Japan / study report

Data access
data published

Materials and methods

Test guideline

Qualifier
according to

Guideline
other: Japan (Iyakushin No.1604): Genetic toxicity test guideline of drugs

Deviations
not specified

Qualifier
according to

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

Deviations
not specified

GLP compliance
yes

Type of assay
micronucleus assay
chromosome aberration

Test material

Test material information
31127-54-5

Test animals

Species
mouse

Strain
other: CRLj:CD1(ICR)SPF

Sex
male

Details on test animals and environmental conditions
TEST ANIMALS
- Source: Charles River Laboratories Japan, Inc. Hino Farm
- Age at study initiation: 7 weeks old
- Weight at study initiation: 29.6-34.4 g (avg. 31.9 g)
- Assigned to test groups randomly: yes
- Housing: polycarbonate cag (225 mm × 338 mm × 140 mm)
- Diet: ad libitum
- Water: ad libitum
- Acclimation period: 6 days

ENVIRONMENTAL CONDITIONS
- Temperature (°C): 22.8-24.1
- Humidity (%):52.1-61.5
- Air changes: 10-15/h
- Photoperiod: 12 h dark/ 12 h light (light time: 7:00 to 19:00)

Administration / exposure

Route of administration
oral: gavage

Vehicle
- Vehicle(s)/solvent(s) used: corn oil
- Lot/batch no. (if required): 6G2122

Details on exposure
PREPARATION OF DOSING SOLUTIONS:
Dosing solutions were prepared on the day of administration by dissolving the test substance in corn oil.

Frequency of treatment
Twice, 24 h interval

Doses / concentrations

Remarks
Doses / Concentrations:
0 (vehicle), 125, 250, 500, 1000, 2000 mg/kg bw/day
Basis:
actual ingested

No. of animals per sex per dose
6 animals/sex/dose

Control animals
yes, concurrent vehicle

Positive control(s)
mitomycin C
- Route of administration: single intraperitoneal injection
- Doses / concentrations: 2 mg/kg/day

Examinations

Tissues and cell types examined
Polychromatic erythrocytes from the femur bone marrow

Details of tissue and slide preparation
TREATMENT AND SAMPLING TIMES (in addition to information in specific fields): Cells for spe cimen were collected 24 h after the last administration.

DETAILS OF SLIDE PREPARATION: Cell suspensions were expanded on the slides, fixed with methanol, and stained with Giemsa.
METHOD OF ANALYSIS: microscopy, blind method

Evaluation criteria
Criterion for determining a positive result: A dose-related increase in the number of micronucleated cells.

Statistics
The number of micronucleated polychromatic erythrocytes was determined by the Kastenbaum and Bowman method, and Cochran Armitage test;
Ratio of polychromatic erythrocytes to whole erythrocytes by F-test, and t-test.

Results and discussion

Test results

Key result
false

Sex
male

Genotoxicity
negative

Vehicle controls valid
yes

Negative controls valid
not examined

Positive controls valid
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/
PDF31127 -54 -5g.pdf

Applicant's summary and conclusion

Conclusions
Interpretation of results (migrated information): negative
The test substance did not produce micronuclei in the immature erythrocytes of the test species.

Executive summary

An in vivo micronucleus study (OECD TG 474) showed negative up to the limit dose (2,000 mg/kg bw/day for 2 days) in mice.

Toxicity to reproduction

ENDPOINT_STUDY_RECORD: Reproductive/developmental toxicity.001

UUID: IUC5-bae76ab8-3928-4002-9f8e-b2f2b22173cc
Dossier UUID:
Author: SuperUser
Date: 2017-02-15T16:07:17.000+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
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
reference to same study

Remarks
7.5.1 Repeated dose toxicity: oral.001

Data source

Reference

Combined repeat dose and reproductive/developmental toxicity screening test of 2,3,4,4'-Tetrahydroxy... / MHLW, Japan / study report

Data access
data published

Materials and methods

Test guideline

Qualifier
according to

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

Deviations
no

GLP compliance
yes

Limit test
no

Test material

Test material information
31127-54-5

Test animals

Species
rat

Strain
other: Crl:CD(SD)

Sex
male/female

Details on test animals and environmental conditions
TEST ANIMALS
- Source: Charles River Laboratories Japan, Inc. Atsugi
- Age at study initiation: 10 weeks
- Weight at study initiation: Males: 335-391 g; Females: 202-249 g
- Housing: Steel wire-mesh cage (250 mm x 350 mm x 200 mm)
- Diet: ad libitum
- Water: ad libitum
- Acclimation period: 14 days

ENVIRONMENTAL CONDITIONS
- Temperature (°C): 21-23
- Humidity (%): 46-61
- Air changes: 10-15 times / hr
- Photoperiod: 12 hrs dark / 12 hrs light

Administration / exposure

Route of administration
oral: gavage

Vehicle
corn oil

Details on exposure
PREPARATION OF DOSING SOLUTIONS:
VEHICLE
- Amount of vehicle (if gavage): 5 mL/kg bw
- Lot/batch no. (if required): SDE2487

Details on mating procedure
- M/F ratio per cage:1:1
- Length of cohabitation:up to 14 days
- 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 to be used for males in week 1 and six week of admin istration were analyzed by the HPLC method at Bozo Research Center Inc. Results showed that the concentration of the test article in each suspension was 95.7 to 104.5% of the nominal concen tration and both values were within the acceptable range (concentration: percentage of the nominal concentration, 100 ± 10%; C.V.: 10% or below)

Duration of treatment / exposure
(P) Males: 42 days including 14 days pre-mating and mating periods, and thereafter 14 days
(P) Females: 42-55 days including 14 days pre-mating, mating and gestation periods, and the days u ntil day 4 of lactation; satellite animals: 42 days.

Frequency of treatment
Once/day, 7days/week

Doses / concentrations

Remarks
Doses / Concentrations:
0 (vehicle), 100, 300, and 1000 mg/kg bw/day
Basis:
actual ingested

No. of animals per sex per dose
12 animals/sex/dose (main dose group), 5 males and 5 females at 0 and 1000 mg/kg bw/day as a satellite group (without mating).

Control animals
yes, concurrent vehicle

Examinations

Parental animals: Observations and examinations
CAGE SIDE OBSERVATIONS: Yes
- Time schedule:
Males and females: once before the start of administration, 3 times/day during the administration p eriod, and once during the recovery period

DETAILED CLINICAL OBSERVATIONS: Yes
The functional observational battery testing (FOB) was performed on all animals. Among the measures in the FOB, detailed clinical observations were made before the initiation of dosing. The

reafter, in males of the main groups, detailed clinical observations were made once a week. Also in females of the main groups, detailed clinical observations were made once a week in pre-mating and mating periods thereafter, and then those were made on days 1,7,14 and 20 of gestation, and on day 4 of lactation. For the satellite group, detailed clinical observations were made once a week in dosing and recovery periods.
Sensory motor reflexes, forelimb and hindlimb grip strengths, and motor activity were measured on week 6 of administration period (main/recovery group animals) and week 2 of recovery period (recove ry group animals).

BODY WEIGHT: Yes
- Time schedule for examinations: Males (main/recovery group): Days 1, 4, 8, 11, 15, 22, 25, 29, 32, 36, 39, 42, and the day of necropsy (after ca. 16h-fasting) in dosing period
Males and females (recovery group): Days 1, 4, 8, 11, 14, and the day of necropsy (after ca. 16h-fas ting) in recovery period
Females (main group): Twice a week during the precopulation period (days 1, 4, 8, 11, and 15); gestat ion days 0, 4, 7, 11, 14, 17, and 20; lactation days 0 and 4; and the day of necropsy (after ca. 16 h-fasting)

FOOD CONSUMPTION AND COMPOUND INTAKE (if feeding study):
- Food consumption: Yes
Males (main/recovery group): Days 1, 4, 8, 11, 15, 32, 36, and 39 in dosing period
Males and females (recovery group): Days 1, 4, 8, 11, and 14 in recovery period
Females (main group): Days 1, 4, 8, 11, and 15; gestation days 1, 4, 7, 11, 14, 17, and 20; lactation d ays 2 and 4

OPHTHALMOSCOPIC EXAMINATION: No
HAEMATOLOGY: Yes
- Time schedule for collection of blood: Blood was collected on the day of necropsy
- Anaesthetic used for blood collection: Yes (ether)
- Animals fasted: Yes, 16-20h
- How many animals: 5 sex/dose/group
- Parameters checked in table were examined.

CLINICAL CHEMISTRY: Yes
- Time schedule for collection of blood: Same as hematology
- Animals fasted: Same as hematology
- How many animals: Same as hematology
- Parameters checked in table were examined.

URINALYSIS: Yes (males only)
- Time schedule for collection of urine: Day 36-37 in dosing period, day 8-9 in recovery period
- Metabolism cages used for collection of urine: No data
- Animals fasted: fasting and only water at libitum (4h-urine), no fasting (20h-urine)

NEUROBEHAVIOURAL EXAMINATION: No

Estrous cyclicity (parental animals)
Vaginal smears were collected from all females in the main groups and microscopically examined every day from the day after the start of administration until the day copulation was confirmed. During the pre-mating administration period, vaginal smear pictures were classified as proestrus, estrus, metestrus or diestrus and examined for the frequency of estrus and interval between estruses (estrous cycle). During the mating period, vaginal smears were examined for the presence of sperm.

Sperm parameters (parental animals)
Parameters examined in P male parental generations: testes weight, epididymis 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.

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

Postmortem examinations (parental animals)
SACRIFICE:
Male animals: Rats were euthanized by exsanguination under ether anesthesia on the day after the last administration.
Maternal animals: Rats were euthanized by exsanguination under ether anesthesia on day 4 of lac tation.

GROSS PATHOLOGY, Yes: whole organs and tissues

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

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

Postmortem examinations (offspring)
GROSS NECROPSY
- Gross necropsy consisted of external and internal examinations including the cervical, thoracic, and abdominal viscera.

Statistics
The data were analyzed for homogeneity of variance by the Bartlett test. If variances were homogeneous, data was analyzed by the Dunnett test, whereas heterogeneous data was analyzed by the Dunnett type mean rank test ($p<0.05$, two-sided).
In the recovery test, these values of two groups were analyzed by F test. If variances were ho mogeneous, data was analyzed by the Student t-test, whereas heterogeneous data was analyzed by the Aspin-Welch t-test ($p<0.05$, two-sided).

Reproductive indices
Each parameter was determined by the following equations:
Copulation index (%) = (No. of copulated animals/No. of co-housed animals) × 100
Fertility index (%) = (No. of pregnant females/No. of copulated females) × 100
Insemination index (%) = (No. of pregnant females/No. of copulated males) × 100
Duration of gestation (days) = day 0 of lactation – day 0 of gestation
Delivery index (%) = (No. of females delivered liveborn pups/No. of pregnant females) × 100
Implantation index (%) = (No. of implantation sites/No. of corpora lutea) × 100
Stillborn index (%) = (No. of stillborn pups/Total No. of pups born) × 100
Liveborn index (%) = (No. of liveborn pups/Total No. of pups born) × 100
External abnormalities (%) = (No. of pups with external abnormalities/No. of liveborn pups) × 100
Sex ratio = No. of liveborn male pups/(No. of liveborn male pups + No. of liveborn female pups)

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

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 Repeated dose toxicity: oral.001

Body weight and weight changes
effects observed, treatment-related

Description (incidence and severity)
see 7.5.1 Repeated dose toxicity: oral.001

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

Description (incidence and severity)
see 7.5.1 Repeated dose toxicity: oral.001

Organ weight findings including organ / body weight ratios
no effects observed

Description (incidence and severity)
on reproductive organs

Gross pathological findings
no effects observed

Description (incidence and severity)
on reproductive organs

Histopathological findings: non-neoplastic
no effects observed

Description (incidence and severity)
on reproductive organs

Reproductive function / performance (P0)

Reproductive function: estrous cycle
no effects observed

Reproductive function: sperm measures
not examined

Reproductive performance
no effects observed

Description (incidence and severity)
on reproductive organs

Effect levels (P0)

Dose descriptor
NOAEL

Effect level

1000	mg/kg bw/day (actual dose received)

Sex
male/female

Basis for effect level
other: no effects on reproduction

Dose descriptor
LOAEL

Effect level

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

Sex
male/female

Basis for effect level
other: (See repeated dose toxicity)

Results: F1 generation

General toxicity (F1)

Clinical signs
no effects observed

Mortality / viability
no mortality observed

Body weight and weight changes
effects observed, treatment-related

Description (incidence and severity)
Low values of body weights of male and female pups were observed on postnatal day (PND) 4 at 300 mg/kg bw/day, and on PND 0 and PND 4 at 1000 mg/kg bw/day.

Sexual maturation
not examined

Organ weight findings including organ / body weight ratios
not examined

Gross pathological findings
no effects observed

Histopathological findings
not examined

Effect levels (F1)

Dose descriptor
NOAEL

Generation
F1

Effect level

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

Sex
male/female

Basis for effect level
other: Low body weight of pups at 300 mg/kg bw/day

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/PDF31127 -54 -5d.pdf

Applicant's summary and conclusion

Conclusions
The NOAELs for rat reproductive toxicity and developmental toxicity were determined to be 1000 mg/kg bw/day and 100 mg/kg bw/day, respectively.

Executive summary

In the combined repeated oral dose toxicity study (0, 100, 300, and 1,000 mg/kg bw/day) with the reproduction/developmental toxicity screening test (OECD TG 422), no effects were found on reproductive parameters up to 1,000 mg/kg bw/day. The body weights of male and female pups decreased on postnatal day (PND) 4 at 300 mg/kg bw/day and higher, with decreased body weights observed for both sexes on PND 0 at 1,000 mg/kg bw/day. The no observed adverse effect levels (NOAELs) for rat reproductive toxicity and developmental toxicity were determined to be 1,000 mg/kg bw/day and 100 mg/kg bw/day, respectively.

References

REFERENCE_SUBSTANCE: 2,3,4,4'-Tetrahydroxybenzophenone

UUID: IUC5-9a63fecd-2bcb-4b40-abf4-b43e1c6090c7
Dossier UUID:
Author: SuperUser
Date: 2017-10-30T11:33:45.000+09:00
Remarks:

General information

Reference substance name
2,3,4,4'-Tetrahydroxybenzophenone

Reference substance information

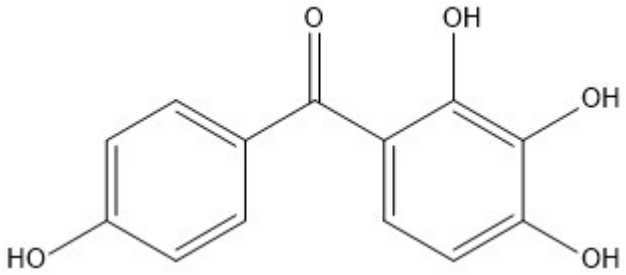
CAS information

CAS number
31127-54-5

Molecular and structural information

Molecular formula
31127-54-5

Structural formula



TEST_MATERIAL_INFORMATION: 3 1127-54-5

UUID: 3ea7b465-3454-38a8-ad75-f19cc02fdb16
Dossier UUID:
Author: SuperUser
Date: 2017-02-15T16:02:42.000+09:00
Remarks:

Name
31127-54-5

Composition

Type
Constituent

Reference substance
2,3,4,4'-Tetrahydroxybenzophenone / 31127-54-5

EC number	EC name
CAS number	CAS name
31127-54-5	
IUPAC name	

Other characteristics

Details on test material
- Name of test material (as cited in study report): 2,3,4,4'-Tetrahydroxybenzophenone
- Analytical purity: 99.86%
- Lot/batch No.: GL01
- Stability under test conditions: The stability of test material was identified by analysis of the remainde r.
- Storage condition of test material: At a cold place (temperature 2~8℃) in a light resistant container

TEST_MATERIAL_INFORMATION: 3 1127-54-5

UUID: 93a10ff0-382e-3a77-a723-13aa1b58d75c
Dossier UUID:
Author: SuperUser
Date: 2017-02-15T16:04:12.000+09:00
Remarks:

Name
31127-54-5

Composition

Type
Constituent

Reference substance
2,3,4,4'-Tetrahydroxybenzophenone / 31127-54-5

EC number	EC name
CAS number	CAS name
31127-54-5	

IUPAC name

Other characteristics

Details on test material
- Name of test material (as cited in study report): 2,3,4,4'-Tetrahydroxybenzophenone
- Purity: 99.91%
- Impurities (identity and concentrations): Unknown
- Lot/batch No.: JSCXB
- Stability under test conditions: Stable
- Storage condition of test material: Refrigeration
- Dosing solution storage condition: Room temperature and protected from light
- Other: The dosing solution was used within 7 days of preparation.

TEST_MATERIAL_INFORMATION: 3 1127-54-5

UUID: 4c2d18df-3eef-3b53-b47a-180f8b7bb73d
Dossier UUID:
Author: SuperUser
Date: 2016-12-21T14:50:21.000+09:00
Remarks:

Name
31127-54-5

Composition

Type
Constituent

Reference substance
2,3,4,4'-Tetrahydroxybenzophenone / 31127-54-5

EC number	EC name
CAS number	CAS name
31127-54-5	

IUPAC name

Other characteristics

Details on test material
- Name of test material (as cited in study report): 2,3,4,4'-Tetrahydroxybenzophenone
- Purity: 100%
- Lot/batch No.: GL01
- Storage condition of test material: Refrigeration
- Stability under test conditions: The stability of test material was identified by analysis of the remainder.

TEST_MATERIAL_INFORMATION: 3 1127-54-5

UUID: 6beb221b-5dbc-3b58-8350-9527480efbca
Dossier UUID:
Author: SuperUser
Date: 2017-02-15T16:04:52.000+09:00
Remarks:

Name
31127-54-5

Composition

Type
Constituent

Reference substance
2,3,4,4'-Tetrahydroxybenzophenone / 31127-54-5

EC number	EC name
CAS number	CAS name
31127-54-5	

IUPAC name

Other characteristics

Details on test material
- Name of test material (as cited in study report): 2,3,4,4'-Tetrahydroxybenzophenone
- Analytical purity: 99.86% (GL01), 99.91% (JSCXB)
- Supplier: Tokyo Chemical Industry Co., Ltd
- Lot/batch No.: GL01 and JSCXB
- Storage condition of test material: cool and dark place

TEST_MATERIAL_INFORMATION: 3 1127-54-5

UUID: bbbd9567-0515-3f86-b1a3-3e3d9795e741
Dossier UUID:
Author: SuperUser
Date: 2017-02-15T16:06:01.000+09:00
Remarks:

Name
31127-54-5

Composition

Type
Constituent

Reference substance
2,3,4,4'-Tetrahydroxybenzophenone / 31127-54-5

EC number	EC name
CAS number	CAS name
31127-54-5	

IUPAC name

Other characteristics

Details on test material
- Name of test material (as cited in study report): 2,3,4,4'-Tetrahydroxybenzophenone
- Analytical purity:99.9%
- Lot/batch No.: EPF0296
- Stability under test conditions: stable
- Storage condition of test material: room temperature (17.6-20.8°C) in an airtight container.

TEST_MATERIAL_INFORMATION: 3 1127-54-5

UUID: 465c97b2-bdb1-31f4-9ecd-14cf6ccceeb6
Dossier UUID:
Author: SuperUser
Date: 2017-02-15T16:07:17.000+09:00
Remarks:

Name
31127-54-5

Composition

Type
Constituent

Reference substance
2,3,4,4'-Tetrahydroxybenzophenone / 31127-54-5

EC number	EC name
CAS number	CAS name
31127-54-5	

IUPAC name

Other characteristics

Details on test material
- Name of test material (as cited in study report): 2,3,4,4'-Tetrahydroxybenzophenone
- Purity: 99.91%
- Impurities (identity and concentrations): Unknown
- Lot/batch No.: JSCXB
- Stability under test conditions: Stable
- Storage condition of test material: Refrigeration
- Dosing solution storage condition: Room temperature and protected from light
- Other: The dosing solution was used within 7 days of preparation.

LITERATURE: Combined repeat dose and reproductive/developmental toxicity screening test of 2,3,4,4'-Tetrahydr oxybenzophenone by oral administration in rats

UUID:	693bb7a7-c435-3dfb-bd05-d9d66ea298ec
Dossier UUID:	
Author:	SuperUser
Date:	2017-02-15T16:04:12.000+09:00
Remarks:	

General information

Reference Type
study report

Title
Combined repeat dose and reproductive/developmental toxicity screening test of 2,3,4,4'-Tet rahydroxybenzophenone by oral administration in rats

Author
MHLW Japan

Year
2009

Bibliographic source
available in the web of Japan Existing Chemical Data Base (JECDB) at http://dra4.nihs.go.jp/mhlw_data/jsp/SearchPageENG.jsp

Testing facility
BoZo Research Center

LITERATURE: Combined repeat dose and reproductive/developmental toxicity screening test of 2,3,4,4'-Tetrahydr oxybenzophenone by oral administration in rats

UUID:	7c3f72b1-27ef-3a47-99bc-11e3711427e3
Dossier UUID:	
Author:	SuperUser
Date:	2017-02-15T16:07:17.000+09:00
Remarks:	

General information

Reference Type
study report

Title
Combined repeat dose and reproductive/developmental toxicity screening test of 2,3,4,4'-Tet rahydroxybenzophenone by oral administration in rats

Author
MHLW, Japan

Year
2009

Bibliographic source
available in the web of Japan Existing Chemical Data Base (JECDB) at http://dra4.nihs.go.jp/mhlw_data/jsp/SearchPageENG.jsp

Testing facility
BoZo Research Center

LITERATURE: In Vitro Chromosomal Aberration Test of 2,3,4,4'-Tetrahydroxy benzophenone on Cultured Chinese Hamster Cells.

UUID: 4a1c80b0-857a-3d37-8c79-0685b9624cbf
Dossier UUID:
Author: SuperUser
Date: 2017-02-15T16:04:52.000+09:00
Remarks:

General information

Reference Type
study report

Title
In Vitro Chromosomal Aberration Test of 2,3,4,4'-Tetrahydroxybenzophenone on Cultured Chinese Hamster Cells.

Author
MHLW, Japan

Year
2007

Bibliographic source
Japan Existing Chemical Data Base (JECDB)

Testing facility
BoZo Research Center

LITERATURE: Micronucleous test of 2,3,4,4'-Tetrahydroxybenzophenone on rat

UUID: fec3c0ae-8118-3436-a32f-6c1913b31327
Dossier UUID:
Author: SuperUser
Date: 2017-02-15T16:06:01.000+09:00
Remarks:

General information

Reference Type
study report

Title
Micronucleous test of 2,3,4,4'-Tetrahydroxybenzophenone on rat

Author
MHLW Japan

Bibliographic source
data unpublished

Testing facility
Chemicals Evaluation and Research Institute, Japan

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
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Identifiers

Other IT system identifiers

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10767

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16558402024DIV750

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LITERATURE: Reverse Mutation Test of 2,3,4,4'-Tetrahydroxybenzophenone on Bacteria.

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Author: SuperUser
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Reference Type
study report

Title
Reverse Mutation Test of 2,3,4,4'-Tetrahydroxybenzophenone on Bacteria.

Author
MHLW, Japan

Year
2006

Bibliographic source
Japan Existing Chemical Data Base (JECDB)

Testing facility
Research Institute for Animal Science in Biochemistry & Toxicology (RIAS)

LITERATURE: Single Dose Oral Toxicity Test of 2,3,4,4'-Tetrahydroxybenzophenone in Rats

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Single Dose Oral Toxicity Test of 2,3,4,4'-Tetrahydroxybenzophenone in Rats

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Testing facility
BoZo Research Center