Name: OECD_SIDS / SUBSTANCE : Undecanal / undecanal / 112-44-7 Wed, 26 Nov 2025, 09:24:29+0900 /

Printing date: 2025-11-26T09:24:29.919+09:00

Table of Contents

DOSSIER:

UUID: 0
Dossier UUID:
Author:
Date: 2025-11-26T09:24:29.669+09:00
Remarks:

Dossier header

Dossier submission type

Name
OECD SIDS

Version
core 9.0

Name (given by user)

Dossier subject

Dossier subject
Undecanal / undecanal / 112-44-7

Public name

Submitting legal entity
National Institute of Health Sciences

Dossier creation date/time
Wed, 26 Nov 2025, 09:24:29+0900

Used in category

LEGAL_ENTITY: National Institute of Health Sciences

UUID:	71368d76-19ad-4a2e-bc26-6c8ef515e6e3
Dossier UUID:	
Author:	
Date:	2024-05-29T16:58:20.759+09:00
Remarks:	

General information

Legal entity name
National Institute of Health Sciences

Undecanal

General information

Identification

SUBSTANCE: Undecanal

UUID: 9362b790-1ef3-40d7-b749-f29201768408
Dossier UUID:
Author:
Date: 2024-02-19T11:38:37.000+09:00
Remarks:

Substance name
Undecanal

Identification of substance

Reference substance
undecanal / undecanal / 112-44-7 / 203-972-6

EC number	EC name
203-972-6	EC Inventory

CAS number **CAS name**
112-44-7

IUPAC name
undecanal

Role in the supply chain

Manufacturer
false

Importer
false

Only representative
false

Downstream user
false

Toxicological information

Repeated dose toxicity

Repeated dose toxicity: oral

ENDPOINT_STUDY_RECORD: Repeated dose toxicity: oral.001.

UUID:	61553bf1-b296-49a8-8335-8a7d77c2bcda
Dossier UUID:	
Author:	
Date:	2024-02-20T14:33:02.000+09:00
Remarks:	

Administrative data

Endpoint
short-term repeated dose toxicity: oral

Type of information
experimental study

Adequacy of study
key study

Robust study summary
false

Used for classification
false

Used for SDS
false

Study period: start date
2013-09-18

End date
2014-03-25

Reliability
1 (reliable without restriction)

Rationale for reliability incl. deficiencies
guideline study
Reliability 1

Cross-reference

Reason / purpose for cross-reference
reference to same study

Related information
OECD / Toxicity to reproduction / Toxicity to reproduction.001. / Undecanal / undecanal / 112-44-7

Data source

Reference

Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test of / Ministry of Health, Labour and Welfare (MHLW), Japan / study report

Data access
data published

Materials and methods

Test guideline

Qualifier
according to guideline

Guideline
other: Guideline for Combined Repeated Dose Study with the Reproduction /Developmental Toxicity Screening Test in Mammalian Species (Chemical Substances Control Law of Japan)

Version / remarks
similar to OECD TG422

GLP compliance
yes (incl. QA statement)

Limit test
no

Test material

Test material information
Undecanal

Specific details on test material used for the study
- Name of test material (as cited in study report): Undecanal
- Analytical purity: 98.8% (GC)
- Storage condition of test material: Sealed, nitrogen-filled after opening, dark, refrigerated (actual te mperature: 3-6°C)
- Stability under test conditions: The stability of test material was identified by analysis of the re mainder

Test animals

Species
rat
common rodent species

Strain
other: Crl: CD(SD)

Sex
male/female

Details on test animals or test system and environmental conditions
TEST ANIMALS
- Source: Charles River Japan, Inc., Atsugi Breeding Center.

- Age at study initiation: 10 weeks old
- Weight at study initiation: Male: 374.2-428.4 g, Female: 230.4-267.6 g
- Housing: Animals were individually housed in bracket-type metallic wire-mesh cages (220W × 270D×190H mm), from gestation day 18 to lactation day 4, Dams were bred individually or with individ ual
- littermates in plastic cages (350W × 400D × 180H mm) and bedding.
- Diet: Solid feed (CE-2: CLEA Japan Inc.) was given ad libitum.
- Water: Tap water was given ad libitum.
- Acclimation period: 13 days

ENVIRONMENTAL CONDITIONS
- Temperature (°C): 21.0-25.0 (actual temperature: 22.0-25.5°C)
- Humidity (%): 40.0-75.0% (actual humidity: 49.0-72.0%)
- Air changes (per hr): 15
- Photoperiod (hrs dark / hrs light): 12 hr dark/12 hr light (light: 7:00-19:00)

Administration / exposure

Route of administration
oral: gavage

Vehicle
corn oil

Details on oral exposure
- Amount of vehicle (if gavage): 4 mL/kg
- Dosing volume: 4 mL/kg

Analytical verification of doses or concentrations
yes

Details on analytical verification of doses or concentrations
The concentrations of each test suspension used at day1 of administration were analyzed by HPLC. The results showed that the concentration of each test suspension was 101.5 to 104.5% of the nominal concentration.

Duration of treatment / exposure
Males: 42 days including 14 days pre-mating
Females (mating group): 41-55 days including 14 days pre-mating, mating and gestation periods and the days until day 4 of lactation (non-mated females: 52 days including 14 days pre-mating, and non-parturient females: until equivalent day 25 of gestation)
Female (non-mating group: satellite group): 42 days

Frequency of treatment
Once/day, 7 days/week

Doses / concentrations

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

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

Dose / conc.	
300	mg/kg bw/day (actual dose received)

Dose / conc.	
1000	mg/kg bw/day (actual dose received)

No. of animals per sex per dose
Mating group: 12 animals/sex /dose (0, 100, 300, and 1000 mg/kg bw/day)
Non-mating group (satellite group): 10 females/dose (0 and 1000 mg/kg bw/day)
Recovery group: 5 males/dose in the mating group (0 and 1000 mg/kg bw/day) and 5 females/dose in the non-mating groups (0 and 1000 mg/kg bw/day)

Control animals
yes, concurrent vehicle

Details on study design
- Dose selection rationale: Based on the results of a 14-day preliminary study, the highest dose was 1000 mg/kg, which is the amount limit, and the intermediate and low doses were divided by a common ratio of 3, to 300 and 100 mg/kg respectively.

[14-day preliminary study]
A 14-day repeated dose oral toxicity test (Crl:CD(SD) rats, males and females, doses: 0, 250, 500 or 1000 mg/kg bw/ day. A transient decrease in locomotor activity was observed in one male and on e female in the 1000 mg/kg bw/day group. No obvious toxicological changes were observed in the body weights, hematology, blood biochemistry, and pathology.

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

Examinations

Observations and examinations performed and frequency
CAGE SIDE OBSERVATIONS: Yes
- Time schedule: 2 or more times/day (before administration, after administration) during the administ ration period. At least once a day during the recovery period.

DETAILED CLINICAL OBSERVATIONS: Yes
- Time schedule:
Males: At the end of acclimation period, Days 8, 15, 24, 30, 36, and 42 of administration and Days 7 an d 14 of recovery period.
Females in the mating groups: At the end of acclimation period and Days 8, 15, 24, 30, 36, and 42* of administration period. (*Note: For delivered females, once during lactation period (lactation day 0 to day 4).)
Females in the non-mating groups (satellite group): At the end of acclimation period, Days 8, 15, 24, 30, 36, and 42 of administration and Days 7 and 14 of recovery period.

BODY WEIGHT: Yes
- Time schedule for examinations:
Males: Days 1, 4, 7, 14, 21, 28, 35, and 42 of administration period and on the day of necropsy, and Days 1, 7 and 14 of recovery period and on the day of necropsy.
Females in the mating groups: Days 1, 4, 7, and 14 of administration period, Days 0, 7, 14, and 20 of gestation, Days 0 and 4 of lactation, and on the day of necropsy. For unmated females, Days 21, 28, 35, 42 and 49 of administration period and on the day of necropsy.
Females in the non-mating groups (satellite group): Days 1, 4, 7, 14, 21, 28, 35, and 42 of administra tion period and on the day of necropsy, and Days 1, 7 and 14 of recovery period and on the day of ne cropsy.

FOOD CONSUMPTION AND COMPOUND INTAKE (if feeding study):
- Food consumption: Yes
Measurement of food consumption was conducted on all animals at the following frequencies:
Males: Days 1-2, 7-8, 14-15, 29-30, 35-36 and 41-42 of administration period. Days 6-7 and 12-13 of recovery period.
Females in the mating groups: Days 1-2, 7-8 and 14-15 of administration period. Days 0-1, 7-8, 14-15, and 20-21 of gestation period. Days 3-4 of lactation period. For unmated females, Days 29-30, 35-36, 41-42 and 48-49 of administration period.
Females in the non-mating groups (satellite group): Days 1-2, 7-8, 14-15, 21-22, 29-30, 35-36 and 41-42 of administration period. Days 6-7 and 12-13 of recovery period.

OPHTHALMOSCOPIC EXAMINATION: No

HAEMATOLOGY: Yes
- Time schedule for collection of blood: At the end of administration period, or at the end of recovery period in both sexes
- Anaesthetic used for blood collection: Pentbarbital sodium
- Animals fasted: Yes
- How many animals:
5 animals/sex/group
- Parameters examined: red blood cell count (RBC), white blood cell count (WBC), differential white blood cell count, reticulocyte ratio, hemoglobin (HGB), mean corpuscular volume (MCV), platelet co unt, hematocrit, mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), activated partial thromboplastin time (APTT), prothrombin time (PT)
CLINICAL CHEMISTRY: Yes
- Time schedule for collection of blood: At the end of administration period, or at the end of recovery p eriod in both sexes
- Animals fasted: Yes
- How many animals:
5 animals/sex/group
- Parameters checked: total protein, albumin, A/G ratio, glucose, total cholesterol, triglyceride, phospholipids, AST, ALT, γ-GTP, LDH, bile acid, blood urea nitrogen, creatinine, total bilirubin, ALP, inorganic phosphorus, calcium, sodium, potassium, chloride

BLOOD HORMONE: No

URINALYSIS: Yes
- Time schedule for collection of urine: : On the final week of administration (Day 37 of administration) and on the final week of recovery (Day 13 of recovery) in males and females in the non-mating groups (satellite group).
- Metabolism cages used for collection of urine: Yes
- How many animals: 5 animals/group
- Parameters checked:
4-hour urine sample: color, turbidity, pH, occult blood, protein, glucose, ketone, urobilinogen, bilirubin, urinary sediments
24-hour urine sample: urine volume, specific gravity, sodium, potassium, chloride

NEUROBEHAVIOURAL (FUNCTIONAL) EXAMINATION: Yes
- Time schedule for examinations:
Males: On the final week of administration (Manipulative Test: Day 42, Measurement of Grip Strength and Motor Activity: Day 39). No examinations were performed during the recovery period.
Females in the mating group: On the final week of administration
Females in the non-mating groups (satellite group): On the final week of administration (Manipulativ e Test: Day 42, Measurement of Grip Strength and Motor Activity: Day 39). On day 14 of recovery peri od, Mesurement of Motor Activity were performed.
- Dose groups that were examined: All dose groups (5 animals/sex/group)
- Battery of functions tested:

1) Manipulative Test. Prayer's reaction, pupillary reflex, visual placing, startle reaction, withdrawal ref lex, eyelid reflex, and righting reflex.
2) Measurement of Grip Strength. Grip strength of forelimb and hindlimb were measured by grip stren gth meter, Chatillon (Columbus Instruments, LLC).
3) Measurement of Motor Activity. Motor activity was measured by a motor activity sensor for experi mental animals, SUPER-MEX (Muromachi Kikai. Co., Ltd.). The measurement was conducted for 20 min.

Sacrifice and pathology
METHOD OF SACRIFICED: All animals were sacrificed by exsanguination under pentobarbital sodium anesthesia.

SACRIFICE:
Males of mating groups and females of non-mating groups (satellite group):
On day 43 (next day after the last administration).
Females of mating groups:
Delivered case: On day 5 of lactation period.
Undelivered case: On equivalent to day 26 of gestation period.
Unmated case: On day 53 (next day after the last administration).
Males and females of recovery groups:
On day 15 of recovery period.
GROSS PATHOLOGY: Yes
ORGAN WEIGHT: Yes [brain, thyroid gland (including parathyroid gland), thymus, heart, liver, kidney, spleen, adrenal gland, testis, epididymis, prostate (ventral), seminal vesicles (including coagulating gland), ovary, uterus]
Note: The organ weights of the dams those unmated females and non-delivered females were ex cluded from the evaluation.
HISTOPATHOLOGY: Yes [brain, spinal cord, pituitary gland, eyeball (Harderian gland), submandibular gland, sublingual gland, trachea, thyroid gland, parathyroid gland, thymus, heart, lung, bronchus, liver, kidney, spleen, pancreas, adrenal gland, stomach, duodenum, jejunum, ileum, cecum, colon, rectum, submandibular lymph node, mesenteric lymph node, testis, epididymis, prostate, seminal vesicle and coagulating gland, ovary, uterus, vagina, urinary bladder, femur and femur marrow, skeletal muscle, sciatic nerve, and gross abnormalities site]

Statistics
Changes in estrous cyclicity, copulation index and fertility index were analyzed by Fisher’s test (s ignificance level = 0.05).
Graded pathological data was analyzed by Mann-Whitney’s U test and pathological data with number of positive and negative animals was analyzed by one-sided Fisher’s test (significance level = 0.05).
In females, the tests were only performed on the animals necropsied on day 5 of lactation.
These data were analyzed using F-test for homogeneity of variance. The Student’s t-test and t he Aspin-Welch’s t-test were conducted for homogenous and non-homogenous distribution, res pectively to compare the control and individual treatment groups. Three or more groups setting, thes e data were analyzed using Bartlett’s test for homogeneity of distribution. The Dunnett’s multiple c omparison test after the ANOVA and the Dunnett’s-type mean rank sum test after Kruskal-Wallis’s H test were conducted for homogenous and non-homogenous distribution, respectively to compare the control and individual treatment groups. Significance level was set at 0.05 compared with the control group and among the groups.

Results and discussion

Results of examinations

Clinical signs
effects observed, treatment-related

Description (incidence and severity)
[At the dosing period]:
In males, at the 1000 mg/kg bw/day group, transient salivation was observed.
In mating females, at the 1000 mg/kg bw/day group, transient salivation was observed.
In non-mating females (satellite group), at the 1000 mg/kg bw/day group, transient salivation was observed.

[At the recovery period]:
There were no findings related to the test substance in any of the groups.

Mortality
mortality observed, non-treatment-related

Description (incidence)
[At the dosing period]:
In males, at the 300 mg/kg bw/day group, one male died on day 15 of dosing period.

Body weight and weight changes
no effects observed

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

Food efficiency
not examined

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

Ophthalmological findings
not examined

Haematological findings
no effects observed

Clinical biochemistry findings
effects observed, treatment-related

Description (incidence and severity)
[At the end of dosing period]:
In non-mating females (satellite group), significant increase in AST was observed at 1000 mg/kg bw/day.

[At the end of recovery period]:
There were no findings related to the test substance in any of the groups.

Endocrine findings
not examined

Urinalysis findings
no effects observed

Behaviour (functional findings)
no effects observed

Immunological findings
not examined

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

Gross pathological findings
no effects observed

Neuropathological findings
not examined

Histopathological findings: non-neoplastic
no effects observed

Histopathological findings: neoplastic
not examined

Effect levels

Key result
true

Dose descriptor
NOAEL

Effect level

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

Based on
test mat.

Sex
male

Basis for effect level
other:
No effects were observed in males up to 1000 mg/kg bw/day.

Key result
true

Dose descriptor
NOAEL

Effect level

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

Based on
test mat.

Sex
female

Basis for effect level
clinical biochemistry
A significant increase in AST was observed in non-mating females at 1000 mg/kg bw/day.

Any other information on results incl. tables

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

https://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF112-44-7d.pdf

Applicant's summary and conclusion

Conclusions
The NOAEL for repeated dose toxicity in this study was determined to be 1000 mg/kg bw/day for males and 300 mg/kg bw/day for females.

Executive summary

A combined repeated oral dose toxicity study with the reproduction/developmental toxicity screening test was performed according to a Japanese guideline (similar to OECD TG 422). Male and female rats (12 animals/sex/dose) were administered undecanal by gavage at 0 (vehicle: corn oil), 100, 300, and 1000 mg/kg bw/day.

Males were administered for 42 days, including a 14-day premating period and subsequent mating period, whereas females in the mating group were administered for 41–55 days, including the 14-day premating, mating, and gestation periods, and until lactation day 4. Five males at the 0 and 1000 mg/kg bw/day were allocated to a recovery group and maintained for 14 days after the administration period. Ten additional females were administered at 0 and 1000 mg/kg bw/day as a satellite group. These females were administered for 42 days without mating, and five females at 0 and 1000 mg/kg bw/day were allocated to a recovery group and maintained for 14 days after the administration period.

In the clinical signs, transient salivation was observed in males and females at 1000 mg/kg bw/day during the dosing period. The salivation was considered to be induced by the irritation of the test substance, because the no neurotoxic effects were observed during detailed clinical observations or functional examination.

In the clinical chemistry results, a significant increase in AST was observed in non-mating females at 1000 mg/kg bw/day.

There were no effects on the body weights, food consumptions, hematology results, organ weights and histopathological examinations.

In the recovery study, there was no salivation, and no increase in AST in satellite females at 1000 mg/kg bw/day.

Genetic toxicity

Genetic toxicity in vitro

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.001.

UUID:	cce486f9-383d-4fa3-a2e3-99ac6f47badb
Dossier UUID:	
Author:	
Date:	2024-02-19T10:52:55.000+09:00
Remarks:	

Administrative data

Endpoint
in vitro gene mutation study in bacteria

Type of information
experimental study

Robust study summary
false

Used for classification
false

Used for SDS
false

Study period: start date
2013-08-27

End date
2014-03-26

Reliability
1 (reliable without restriction)

Rationale for reliability incl. deficiencies
guideline study
Reliability 1

Data source

Reference

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

Data access
data published

Materials and methods

Test guideline

Qualifier
according to guideline

Guideline
JAPAN: Guidelines for Screening Mutagenicity Testing Of Chemicals
genetic toxicity in vitro, other

Deviations
no

GLP compliance
yes (incl. QA statement)

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

Test material

Test material information
Undecanal

Specific details on test material used for the study
Specific details on test material used for the study
-Name of test material (as cited in study report): Undecanal
- Analytical purity: 98.8% (GC)
- Storage condition of test material: Sealed, nitrogen-filled after opening, dark, refrigerated (actual temperature: 4-7°C)
- Stability under test conditions: The stability of test material was identified by analysis of the remainder.

Method

Species / strain

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

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

Metabolic activation
with and without

Metabolic activation system
S9 mix: SD male rat liver, induced by phenobarbital and 5,6-benzoflavone

Test concentrations
-S9 mix:
0.147, 0.293, 0.586, 1.17, 2.34, 4.69, 9.38 µg/plate (TA100 and TA1535 strains)

0.586, 1.17, 2.34, 4.69, 9.38, 18.8 µg/plate (WP2uvrA, TA98 and TA537 strains)
+S9 mix:
1.17, 2.34, 4.69, 9.38, 18.8, 37.5, 75.0 µg/plate (TA100 strain)
4.69, 9.38, 18.8, 37.5, 75.0, 150 µg/plate (TA1535, WP2uvrA, TA98 and TA1537 strains)

High dose level used
no

Justification for deviation from the high dose level
Maximum concentration was established based on the result of the range-finding study at co ncentration up to 5000 ug/plate. In this study, growth inhibition and precipitation were observed. (See Additional information on results)

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

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 (AF-2) (TA100, WP2uvrA, TA98), Sodium azide (SAZ) (TA1535) and 9-Aminoacridine (9 AA) (TA1537)
+S9 mix: 2-Aminoanthracene (2AA) (TA1535, WP2uvrA), Benzo[a]pyrene (B[a]P) (TA100, TA98, TA1537)

Details on test system and experimental conditions
METHOD OF APPLICATION: Preincubation
DURATION
- Preincubation period: 20 min at 37°C
- Exposure duration:48 hrs
NUMBER OF PLATES: 2
NUMBER OF REPLICATIONS: 2
DETERMINATION OF CYTOTOXICITY
- Method: other: growth inhibition

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

Statistics
no

Results and discussion

Test results

Key result
true

Species / strain
S. typhimurium TA 1535
bacteria

Metabolic activation
with and without

Genotoxicity
negative

Cytotoxicity / choice of top concentrations
cytotoxicity -S9 mix: 4.69 µg/plate and above, +S9 mix: 150 µg/plate

Vehicle controls validity
valid

Untreated negative controls validity
not examined

True negative controls validity
not examined

Positive controls validity
valid

Key result
true

Species / strain
S. typhimurium TA 1537
bacteria

Metabolic activation
with and without

Genotoxicity
negative

Cytotoxicity / choice of top concentrations
cytotoxicity -S9 mix: 9.38 µg/plate and above, +S9 mix: 150 µg/plate

Vehicle controls validity
valid

Untreated negative controls validity
not examined

True negative controls validity
not examined

Positive controls validity
valid

Key result
true

Species / strain
S. typhimurium TA 98
bacteria

Metabolic activation
with and without

Genotoxicity
negative

Cytotoxicity / choice of top concentrations
cytotoxicity -S9 mix: 9.38 µg/plate and above, +S9 mix: 150 µg/plate

Vehicle controls validity
valid

Untreated negative controls validity
not examined

True negative controls validity
not examined

Positive controls validity
valid

Key result
true

Species / strain
S. typhimurium TA 100
bacteria

Metabolic activation
with and without

Genotoxicity
negative

Cytotoxicity / choice of top concentrations
cytotoxicity -S9 mix: 4.69 µg/plate and above, +S9 mix: 75.0 µg/plate

Vehicle controls validity
valid

Untreated negative controls validity
not examined

True negative controls validity
not examined

Positive controls validity
valid

Key result
true

Species / strain
E. coli WP2 uvr A
bacteria

Metabolic activation
with and without

Genotoxicity
negative

Cytotoxicity / choice of top concentrations
cytotoxicity -S9 mix: 9.38 µg/plate and above, +S9 mix: 150 µg/plate

Vehicle controls validity
valid

Untreated negative controls validity
not examined

True negative controls validity
not examined

Positive controls validity
valid

Additional information on results
RANGE-FINDING/SCREENING STUDIES (if applicable):
Concentration: 1.50, 5.00, 15.0, 50.0, 150, 500, 1500, 5000 ug/plate with and without S9mix

Growth inhibition:
-S9 mix:
TA 100 and TA1535: 5.00 µg/plate and above
WP2uvrA, TA98 and TA1537: 15 µg/plate and above
+S9 mix:
TA 100: 50 µg/plate and above
TA1535, WP2uvrA, TA98, and TA1537: 150 µg/plate and above

Precipitation:
- S9 mix: 1500 µg/plate and above
+S9 mix: 5000 µg/plate.

Any other information on results incl. tables

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

https://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF112-44-7e.pdf

please also see the attached files (Tables in English)

Overall remarks, attachments

Attachments

Attached (sanitised) documents for publication
R5_112-44-7_Ames Tables.xlsx / 24.896 KB (application/vnd.openxmlformats-officedocument.spreadsheetml.sheet)

Applicant's summary and conclusion

Conclusions
Interpretation of results (migrated information): negative

In a bacterial reverse mutation assay using Salmonella typhimurium TA100, TA1535, TA98, and TA 1537, and Escherichia coli WP2uvrA, undecanal was negative with or without metabolic activation.

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.002.

UUID:	40dec07e-578a-4619-81b0-99ee17174cb0
Dossier UUID:	
Author:	
Date:	2024-02-19T11:38:37.000+09:00
Remarks:	

Administrative data

Endpoint
in vitro chromosome aberration study in mammalian cells

Type of information
experimental study

Adequacy of study
key study

Robust study summary
false

Used for classification
false

Used for SDS
false

Study period: start date
2013-09-26

End date
2014-03-27

Reliability
1 (reliable without restriction)

Rationale for reliability incl. deficiencies
guideline study
Reliability 1

Data source

Reference

In Vitro Chromosomal Aberration Test of Undecanal on Cultured Chinese Hamster Cells. / Ministry of Health, Labour and Welfare (MHLW), Japan / study report

Data access
data published

Materials and methods

Test guideline

Qualifier
according to guideline

Guideline
JAPAN: Guidelines for Screening Mutagenicity Testing Of Chemicals
genetic toxicity in vitro, other

Version / remarks
Simiral to OECD TG 473 (In Vitro Mammalian Chromosomal Aberration Test)

Deviations
no

GLP compliance
yes (incl. QA statement)

Type of assay
in vitro mammalian chromosome aberration test
in vitro cytogenicity / chromosome aberration study in mammalian cells

Test material

Test material information
Undecanal

Specific details on test material used for the study
- Name of test material (as cited in study report): Undecanal
- Analytical purity: 98.8% (GC)
- Storage condition of test material: Sealed, nitrogen-filled after opening, dark, refrigerated (actual te
mperature: 3-6°C)
- Stability under test conditions: The stability of test material was identified by analysis of the re
mainder.

Method

Species / strain

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

Metabolic activation
with and without

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

Test concentrations
Cell growth inhibition study:
0.053, 0.11, 0.21, 0.43, 0.85, 1.7 mg/mL

Main study:
-S9 (short-term treatment): 0.017, 0.026, 0.039, 0.058, 0.087, 0.13 mg/mL
+S9 (short-term treatment): 0.053, 0.11, 0.21, 0.43, 0.85, 1.7 mg/mL
-S9 (continuous treatment, 24hr): 0.017, 0.026, 0.039, 0.058, 0.087, 0.13 mg/mL

Retest
+S9 (short-term treatment): 0.037, 0.055, 0.083, 0.12, 0.19, 0.28, 0.42 mg/mL

High dose level used
no

Justification for deviation from the high dose level
Chromosomal aberration test was carried out at several different doses of test substance selected fr
om the result of cell growth inhibition study.
Cell-growth inhibition study was conducted up to the limited concentration of 1.7 mμg/mL (10 mM)
In this study, precipitation and more than 50% cell growth inhibition were observed.
(See Additional information on results)

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

Controls

Untreated negative controls
no

Negative solvent / vehicle controls
yes

True negative controls
no

Positive controls
yes

Positive control substance
cyclophosphamide
+S9
mitomycin C
-S9

Details on test system and experimental conditions
METHOD OF APPLICATION:
Exposure duration:
- [short-term treatment]: 6 hrs + 18 hr,
- [continuous treatment]: 24 hrs
SPINDLE INHIBITOR: Colcemid
STAIN: Giemsa stain (3 v/v%) for 8 min.
NUMBER OF REPLICATIONS: 2
NUMBER OF CELLS EVALUATED:
- frequency of cells with structural chromosomal aberrations: 100 + 100 cells /concentration
- frequency of cells with numerical chromosome aberration: 400 + 400 cells /concentration

DETERMINATION OF CYTOTOXICITY
- Method: relative total growth

Evaluation criteria
The frequency of cells with structural chromosomal aberrations and polyploid cells was tested for si
gnificance by Fisher's exact test (one-sided test, P<0.01) between the negative control and test sub
stance treated groups. If a significant difference was observed, a Chochran-Armitage trend tests (on
e-sided test, P<0.01) was performed for dose dependency. The results of these tests were used as a r
eference for a comprehensive evaluation, taking into account biological considerations.

Statistics
Yes

Results and discussion

Test results

Key result
false

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

Metabolic activation
without

Genotoxicity
negative short term treatment

Cytotoxicity / choice of top concentrations
cytotoxicity Extreme cytotoxicity was observed at 0.13 mg/mL.

Vehicle controls validity
valid

Untreated negative controls validity
not examined

True negative controls validity
not examined

Positive controls validity
valid

Key result
false

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

Metabolic activation
with

Genotoxicity
negative short term treatment

Cytotoxicity / choice of top concentrations
cytotoxicity Extreme cytotoxicity was observed at 0.19 mg/mL.
Precipitation was observed in main study at 0.85 mg/mL and above, and in retest at 0.28 mg/mL and above.

Vehicle controls validity
valid

Untreated negative controls validity
not examined

True negative controls validity
not examined

Positive controls validity
valid

Key result
true

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

Metabolic activation
without

Genotoxicity
positive continuous treatment (24hr): Significant increases in polyploid cells were observed in the 0.026, 0.039 and 0.058 mg/mL (frequencies: 31, 32 and 32%, respectively).

Cytotoxicity / choice of top concentrations
cytotoxicity Extreme cytotoxicity was observed at 0.13 mg/mL.

Vehicle controls validity
valid

Untreated negative controls validity
not examined

True negative controls validity
not examined

Positive controls validity
valid

Additional information on results
RANGE-FINDING/SCREENING STUDIES (if applicable):
Cell-growth inhibition study was conducted up to the limited concentration of 1.7 mμg/mL (10 mM)
In this study, precipitation and more than 50% cell growth inhibition were observed.
- Precipitation:
Short term treatment (+S9 mix): above 0.053 mg/mL
Short term treatment (-S9 mix): above 0.43 mg/mL
Continuous treatment (24 h): above 0.85 mg/mL
- 50% cell-growth inhibition:
Short term treatment (+S9 mix): 0.31 mg/mL
Short term treatment (-S9 mix): 0.086 mg/mL
Continuous treatment (24 h): 0.85 mg/mL

Any other information on results incl. tables

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

https://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF112-44-7f.pdf

Applicant's summary and conclusion

Conclusions
Interpretation of results (migrated information): Positive without metabolic activation

An in vitro chromosomal aberration test using CHL/IU cells (Similar to OECD TG 473) showed that undecanal was positive for numerical chromosome aberration (polyploidy) without metabolic activ ation.

Toxicity to reproduction

Toxicity to reproduction

ENDPOINT_STUDY_RECORD: Toxicity to reproduction.001.

UUID:	852e23ce-3007-4101-bd13-46632a41432f
Dossier UUID:	
Author:	
Date:	2024-02-20T11:13:37.000+09:00
Remarks:	

Administrative data

Endpoint
reproductive toxicity, other A combined repeated dose/reproductive developmental toxicity study

Type of information
experimental study

Robust study summary
false

Used for classification
false

Used for SDS
false

Study period: start date
2013-09-18

End date
2014-03-25

Reliability
1 (reliable without restriction)

Rationale for reliability incl. deficiencies
guideline study
Reliability 1

Cross-reference

Reason / purpose for cross-reference
reference to same study

Related information
OECD / Repeated dose toxicity: oral / Repeated dose toxicity: oral.001. / Undecanal / undecanal / 112-44-7

Data source

Reference

Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test of / Ministry of Health, Labour and Welfare (MHLW), Japan / study report

Data access
data published

Materials and methods

Test guideline

Qualifier
according to guideline

Guideline
other: Guideline for Combined Repeated Dose Study with the Reproduction /Developmental Toxicity Screening Test in Mammalian Species (Chemical Substances Control Law of Japan)

Version / remarks
similar to OECD TG422

GLP compliance
yes (incl. QA statement)

Limit test
no

Test material

Test material information
Undecanal

Specific details on test material used for the study
- Name of test material (as cited in study report): Undecanal
- Analytical purity: 98.8% (GC)
- Storage condition of test material: Sealed, nitrogen-filled after opening, dark, refrigerated (actual te mperature: 3-6°C)
- Stability under test conditions: The stability of test material was identified by analysis of the re mainder

Test animals

Species
rat

Strain
other: Crl: CD(SD)

Sex
male/female

Details on test animals or test system and environmental conditions
TEST ANIMALS
- Source: Charles River Japan, Inc., Atsugi Breeding Center.
- Age at study initiation: 10 weeks old
- Weight at study initiation: Male: 374.2-428.4 g, Female: 230.4-267.6 g
- Housing: Animals were individually housed in bracket-type metallic wire-mesh cages (220W × 270D× 190H mm), from gestation day 18 to lactation day 4, Dams were bred individually or with individual littermates in plastic cages (350W × 400D × 180H mm) and bedding.
- Diet: Solid feed (CE-2: CLEA Japan Inc.) was given ad libitum.
- Water: Tap water was given ad libitum.
- Acclimation period: 13 days

ENVIRONMENTAL CONDITIONS
- Temperature (°C): 21.0-25.0 (actual temperature: 22.0-25.5°C)

- Humidity (%): 40.0-75.0% (actual humidity: 49.0-72.0%)
- Air changes (per hr): 15
- Photoperiod (hrs dark / hrs light): 12 hr dark/12 hr light (light: 7:00-19:00)

Administration / exposure

Route of administration
oral: gavage

Vehicle
corn oil

Details on exposure
- Amount of vehicle (if gavage): 4 mL/kg
- Dosing volume: 4 mL/kg

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
The concentrations of each test suspension used at day1 of administration were analyzed by HPLC. The results showed that the concentration of each test suspension was 101.5 to 104.5% of the nominal concentration.

Duration of treatment / exposure
Males: 42 days including 14 days pre-mating
Females (mating group): 41-55 days including 14 days pre-mating, mating and gestation periods and the days until day 4 of lactation (non-mated females: 52 days including 14 days pre-mating, and non-parturient females: until equivalent day 25 of gestation)
Female (non-mating group: satellite group): 42 days

Frequency of treatment
Once/day, 7 days/week

Doses / concentrations

Dose / conc.	
0	mg/kg bw/day (actual dose received)
Dose / conc.	
100	mg/kg bw/day (actual dose received)
Dose / conc.	
300	mg/kg bw/day (actual dose received)
Dose / conc.	
1000	mg/kg bw/day (actual dose received)

No. of animals per sex per dose
Mating group: 12 animals/sex /dose (0, 100, 300, and 1000 mg/kg bw/day)
Non-mating group (Satellite group): 10 females/dose (0 and 1000 mg/kg bw/day)
Recovery group: 5 males/dose in the mating group (0 and 1000 mg/kg bw/day) and 5 females/dose in the non-mating groups (0 and 1000 mg/kg bw/day)

Control animals
yes, concurrent vehicle

Details on study design
- Dose selection rationale: Based on the results of a 14-day preliminary study, the highest dose was 1000 mg/kg, which is the amount limit, and the intermediate and low doses were divided by a common ratio of 3, to 300 and 100 mg/kg respectively.

[14-day preliminary study]
A 14-day repeated dose oral toxicity test (Crl:CD(SD) rats, males and females, doses: 0, 250, 500 or 1000 mg/kg bw/ day. A transient decrease in locomotor activity was observed in one male and one female in the 1000 mg/kg bw/day group. No obvious toxicological changes were observed in body weight, hematology, blood biochemistry, and pathology.

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

Examinations

Parental animals: Observations and examinations
CAGE SIDE OBSERVATIONS: Yes
- Time schedule: 2 or more times/day (before administration, after administration) during the administ ration period. At least once a day during the recovery period.

DETAILED CLINICAL OBSERVATIONS: Yes
- Time schedule:
Males: At the end of acclimation period, Days 8, 15, 24, 30, 36, and 42 of administration and Days 7 an d 14 of recovery period.
Females in the mating groups: At the end of acclimation period and Days 8, 15, 24, 30, 36, and 42* of administration period. (*Note: For delivered females, once during lactation period (lactation day 0 to day 4).)
Females in the non-mating groups (satellite group): At the end of acclimation period, Days 8, 15, 24, 30, 36, and 42 of administration and Days 7 and 14 of recovery period.

BODY WEIGHT: Yes
- Time schedule for examinations:
Males: Days 1, 4, 7, 14, 21, 28, 35, and 42 of administration period and on the day of necropsy, and Days 1, 7 and 14 of recovery period and on the day of necropsy.
Females in the mating groups: Days 1, 4, 7, and 14 of administration period, Days 0, 7, 14, and 20 of gestation, Days 0 and 4 of lactation, and on the day of necropsy. For unmated females, Days 21, 28, 35, 42 and 49 of administration period and on the day of necropsy.
Females in the non-mating groups (satellite group): Days 1, 4, 7, 14, 21, 28, 35, and 42 of administra tion period and on the day of necropsy, and Days 1, 7 and 14 of recovery period and on the day of ne cropsy.

FOOD CONSUMPTION AND COMPOUND INTAKE (if feeding study):
- Food consumption: Yes
Measurement of food consumption was conducted on all animals at the following frequencies:
Males: Days 1-2, 7-8, 14-15, 29-30, 35-36 and 41-42 of administration period. Days 6-7 and 12-13 of recovery period.

Females in the mating groups: Days 1-2, 7-8 and 14-15 of administration period. Days 0-1, 7-8, 14-15, and 20-21 of gestation period. Days 3-4 of lactation period. For unmated females, Days 29-30, 35-36, 41-42 and 48-49 of administration period.
Females in the non-mating groups (satellite group): Days 1-2, 7-8, 14-15, 21-22, 29-30, 35-36 and 41-42 of administration period. Days 6-7 and 12-13 of recovery period.

OPHTHALMOSCOPIC EXAMINATION: No

HAEMATOLOGY: Yes
- Time schedule for collection of blood: At the end of administration period, or at the end of recovery period in both sexes
- Anaesthetic used for blood collection: Pentbarbital sodium
- Animals fasted: Yes
- How many animals:
5 animals/sex/group
- Parameters examined: red blood cell count (RBC), white blood cell count (WBC), differential white blood cell count, reticulocyte ratio, hemoglobin (HGB), mean corpuscular volume (MCV), platelet co unt, hematocrit, mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), activated partial thromboplastin time (APTT), prothrombin time (PT)
CLINICAL CHEMISTRY: Yes
- Time schedule for collection of blood: At the end of administration period, or at the end of recovery p eriod in both sexes
- Animals fasted: Yes
- How many animals:
5 animals/sex/group
- Parameters checked: total protein, albumin, A/G ratio, glucose, total cholesterol, triglyceride, phospholipids, AST, ALT, γ-GTP, LDH, bile acid, blood urea nitrogen, creatinine, total bilirubin, ALP, inorganic phosphorus, calcium, sodium, potassium, chloride

BLOOD HORMONE: No

URINALYSIS: Yes
- Time schedule for collection of urine: : On the final week of administration (Day 37 of administration) and on the final week of recovery (Day 13 of recovery) in males and females in the non-mating groups (satellite group).
- Metabolism cages used for collection of urine: Yes
- How many animals: 5 animals/group
- Parameters checked:
4-hour urine sample: color, turbidity, pH, occult blood, protein, glucose, ketone, urobilinogen, bilirubin, urinary sediments
24-hour urine sample: urine volume, specific gravity, sodium, potassium, chloride

NEUROBEHAVIOURAL (FUNCTIONAL) EXAMINATION: Yes
- Time schedule for examinations:
Males: On the final week of administration (Manipulative Test: Day 42, Measurement of Grip Strength and Motor Activity: Day 39). No examinations were performed during the recovery period.
Females in the mating group: On the final week of administration
Females in the non-mating groups (satellite group): On the final week of administration (Manipulativ e Test: Day 42, Measurement of Grip Strength and Motor Activity: Day 39). On day 14 of recovery peri od, Mesurement of Motor Activity were performed.
- Dose groups that were examined: All dose groups (5 animals/sex/group)
- Battery of functions tested:
1) Manipulative Test. Prayer's reaction, pupillary reflex, visual placing, startle reaction, withdrawal ref lex, eyelid reflex, and righting reflex.
2) Measurement of Grip Strength. Grip strength of forelimb and hindlimb were measured by grip stren gth meter, Chatillon (Columbus Instruments, LLC).

3) Measurement of Motor Activity. Motor activity was measured by a motor activity sensor for experi mental animals, SUPER-MEX (Muromachi Kikai. Co., Ltd.). The measurement was conducted for 20 min.

Oestrous cyclicity (parental animals)
Vaginal smears were collected from all females in the mating groups and microscopically examined every day from the day after the start of administration until the day copulation was confirmed. The average days of recurrence of estrous cycle and the frequency of animals deviated the normal estrus cycle during treatment period were calculated for each group.

Sperm parameters (parental animals)
Parameters examined in all P male parental generations: organ weight of testis, epididymis, prostate (ventral) and seminal vesicles, histopathological examinations for testis, epididymis, prostate, se minal vesicle and coagulating gland.

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

SACRIFICE:
- Males of mating groups and females of non-mating groups (satellite group):
On day 43 (next day after the last administration).
- Females of mating groups:
Delivered case: On day 5 of lactation period.
Undelivered case: On equivalent to day 26 of gestation period.
Unmated case: On day 53 (next day after the last administration).
- Males and females of recovery groups:
On day 15 of recovery period.

GROSS PATHOLOGY: Yes
ORGAN WEIGHT: Yes [brain, thyroid gland (including parathyroid gland), thymus, heart, liver, kidney, spleen, adrenal gland, testis, epididymis, prostate (ventral), seminal vesicles (including coagulating gland), ovary, uterus]
Note: The organ weights of the dams those unmated females and non-delivered females were exc luded from the evaluation.

HISTOPATHOLOGY: Yes [brain, spinal cord, pituitary gland, eyeball (Harderian gland), submandibular gland, sublingual gland, trachea, thyroid gland, parathyroid gland, thymus, heart, lung, bronchus, liver, kidney, spleen, pancreas, adrenal gland, stomach, duodenum, jejunum, ileum, cecum, colon, rectum, submandibular lymph node, mesenteric lymph node, testis, epididymis, prostate, seminal vesicle and coagulating gland, ovary, uterus, vagina, urinary bladder, femur and femur marrow, skeletal muscle, sciatic nerve, and gross abnormalities site]

Postmortem examinations (offspring)
SACRIFICE
- The F1 offsprings were euthanized on postnatal day 4 by exsanguination under sevoflurane anesthesia.

GROSS NECROPSY

- Gross necropsy consisted of external and internal examinations including the cervical, thoracic, and abdominal viscera.

HISTOPATHOLOGY / ORGAN WEIGTHS
- Not examined.

Statistics
Changes in estrous cyclicity, copulation index and fertility index were analyzed by Fisher's test (s ignificance level = 0.05).
Graded pathological data was analyzed by Mann-Whitney's U test and pathological data with number of positive and negative animals was analyzed by one-sided Fisher's test (significance level = 0.05).
In females, the tests were only performed on the animals necropsied on day 5 of lactation.
These data were analyzed using F-test for homogeneity of variance. The Student's t-test and t he Aspin-Welch's t-test were conducted for homogenous and non-homogenous distribution, res pectively to compare the control and individual treatment groups. Three or more groups setting, thes e data were analyzed using Bartlett's test for homogeneity of distribution. The Dunnett's multiple c omparison test after the ANOVA and the Dunnett's-type mean rank sum test after Kruskal-Wallis's H test were conducted for homogenous and non-homogenous distribution, respectively to compare the control and individual treatment groups. Significance level was set at 0.05 compared with the control group and among the groups.

Reproductive indices
Each parameter was determined by the following equations:
Copulation index (%) = (No. of copulated pares / No. of mated pares) × 100
Fertility index (%) = (No. of fertile males / No. of copulated pares) × 100
Delivery index (dams, %) = (No. of dams with live offspring / No. of pregnant dams) × 100
Implantation index (%) = (No. of implantation scars / No. of corpora lutea) × 100
Sex ratio = No. of male offspring / (No. of male offspring + No. of female offspring)
Delivery index (offspring) = (No. of offspring at birth/ No. of implantation scars) × 100
Birth index = (No. of live offspring at birth/No. of implantation scars) × 100
Live birth index = (No. of live offspring at birth/No. of offspring at birth) × 100

Offspring viability indices
Viability index on postnatal day 4 (%) = (No. of live pups on day 4 / No. of liveborns) × 100

Results and discussion

Results: P0 (first parental generation)

General toxicity (P0)

Clinical signs
effects observed, treatment-related

Description (incidence and severity)
See 7.5.1 Repeated dose toxicity. 001

Mortality
mortality observed, non-treatment-related

Description (incidence)
See 7.5.1 Repeated dose toxicity. 001

Body weight and weight changes
no effects observed

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

Food efficiency
not examined

Ophthalmological findings
not examined

Haematological findings
no effects observed

Clinical biochemistry findings
effects observed, treatment-related

Description (incidence and severity)
See 7.5.1 Repeated dose toxicity. 001

Endocrine findings
not examined

Urinalysis findings
no effects observed

Behaviour (functional findings)
no effects observed

Immunological findings
not examined

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

Gross pathological findings
no effects observed

Neuropathological findings
not examined

Histopathological findings: non-neoplastic
no effects observed

Histopathological findings: neoplastic
not examined

Reproductive function / performance (P0)

Reproductive function: oestrous cycle
no effects observed

Reproductive function: sperm measures
no effects observed

Reproductive performance
no effects observed

Details on results (P0)

General toxicity:
See 7.5.1 Repeated dose toxicity.001

Reproductive function / performance:
No effects were observed in males and females up to the 1000 mg/kg bw/day.

Effect levels (P0)

Key result
true

Dose descriptor
NOAEL

Effect level

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

Based on
test mat.

Sex
male/female

Basis for effect level
reproductive performance
No reproductive effects were observed in males and females up to 1000 mg/kg bw/day.

Key result
true

Dose descriptor
NOAEL

Effect level

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

Based on
test mat.

Sex
male

Basis for effect level
other:
No effects were observed in males up to 1000 mg/kg bw/day.

Key result
true

Dose descriptor
NOAEL

Effect level

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

Based on
test mat.

Sex
female

Basis for effect level
clinical biochemistry
A significant increase in AST was observed in non-mating females at 1000 mg/kg bw/day.

Results: F1 generation

General toxicity (F1)

Clinical signs
no effects observed

Mortality / viability
mortality observed, non-treatment-related

Body weight and weight changes
no effects observed

Gross pathological findings
no effects observed

Effect levels (F1)

Key result
true

Dose descriptor
NOAEL

Generation
F1

Effect level

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

Based on
test mat.

Sex
not specified

Basis for effect level
other:
There were no effects on developmental parameters.

Overall reproductive toxicity

Key result
false

Reproductive effects observed
no

Any other information on results incl. tables

Figures and Tables (in English) are available in the following full report of the study. https://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF112-44-7d.pdf

Applicant's summary and conclusion

Conclusions
A combined repeated oral dose toxicity study with the reproduction/developmental toxicity screening test was performed according to a Japanese guideline (similar to OECD TG 422). There were no effects on the reproductive and developmental parameters up to 1000 mg/kg bw/day.
The NOAELs for the rat reproductive/developmental toxicity of undecanal were regarded as 1000 mg/kg bw/day for males and females, and pups.

References

Reference Substances

REFERENCE_SUBSTANCE: undecanal

UUID: ECB5-0acdf996-62e2-44df-a025-5c6c7deb3a53
Dossier UUID:
Author:
Date: 2007-05-10T18:00:00.000+09:00
Remarks:

Reference substance name
undecanal

IUPAC name
undecanal

Inventory

Inventory number

Inventory name
undecanal

Inventory
EC Inventory

Inventory number
203-972-6

CAS number
112-44-7

Molecular formula
C11H22O

Description

CAS number
112-44-7

Synonyms

Synonyms

Identity
undecanal

Identity
Undecanal

Identity
Undecanal

Molecular and structural information

Molecular formula
C11H22O

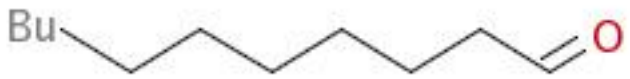
Molecular weight

170.2918

SMILES notation
CCCCCCCCCCC=O

InChI
InChI=1/C11H22O/c1-2-3-4-5-6-7-8-9-10-11-12/h11H,2-10H2,1H3

Structural formula



Related substances

Group / category information
DSL Category: Organics
USEPA Category: Aldehydes

Test Materials

TEST_MATERIAL_INFORMATION: Undecanal

UUID: cb760019-2210-4c7a-9ecd-a54b1bd56b3d
Dossier UUID:
Author:
Date: 2023-08-01T15:37:42.000+09:00
Remarks:

Name
Undecanal

Literatures

LITERATURE: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test of undecanal by oral administration in rats

UUID: 569539d8-3f6b-40bc-a0da-5b2b776a87bd
Dossier UUID:
Author:
Date: 2024-02-14T13:26:16.000+09:00
Remarks:

General information

Reference Type
study report

Title
Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test of undecanal by oral administration in rats

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

Year
2014

Bibliographic source
Japan Existing Chemical Data Base (JECDB)
https://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF112-44-7d.pdf

Testing facility
the Hatano Research Institute, Food and Drug Safety Center

Report date
2014-03-25

Report number
R-13-006

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

UUID: 82cd7b6d-8317-4fff-a3e0-b947cd0d2c4d
Dossier UUID:
Author:
Date: 2024-02-09T14:59:19.000+09:00
Remarks:

General information

Reference Type
study report

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

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

Year
2014

Bibliographic source
Japan Existing Chemical Data Base (JECDB)
https://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF112-44-7f.pdf

Testing facility
the Hatano Research Institute, Food and Drug Safety Center

Report date
2014-03-27

Report number
G-13-020

LITERATURE: Reverse Mutation Test of Undecanal on Bacteria.

UUID: 03554a89-2915-4aac-be92-2f5595a43284
Dossier UUID:
Author:
Date: 2024-02-14T14:20:54.000+09:00
Remarks:

General information

Reference Type
study report

Title
Reverse Mutation Test of Undecanal on Bacteria.

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

Year
2014

Bibliographic source
Japan Existing Chemical Data Base (JECDB)
https://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF112-44-7e.pdf

Testing facility
the Hatano Research Institute, Food and Drug Safety Center

Report date
2014-03-26

Report number
M-13-040