



Name: Poly[oxy(methyl-1,2-ethanediyl)], alpha, alpha'-[(1-methylethylidene)di-4, 1-phenylene]bis[omega-hyd... / 37353-75-6

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

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Poly[oxy(methyl-1,2-ethanediyl)], alpha, alpha'-[(1- methylethylidene)di-4, 1- phenylene]bis[omega-hydroxy- CORE

General information

Identification

SUBSTANCE: Poly[oxy(methyl-1,2-ethanediyl)], alpha, alpha'-[(1-methylethylidene)di-4, 1-phenylene]bis[omega-hydroxy-

UUID: 8e317b70-f413-4fe3-ae86-c2452462eff0

Dossier UUID:

Author: Dra

Date: 2018-03-12T14:02:09.791+09:00

Remarks:

Substance name

Poly[oxy(methyl-1,2-ethanediyl)], alpha, alpha'-[(1-methylethylidene)di-4, 1-phenylene]bis[omega-hydroxy-

Other identifiers

Identifier

common name

Identity

(propoxylated bisphenol A)

Legal entity

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

Identification of substance

Reference substance

[Poly\[oxy\(methyl-1,2-ethanediyl\)\], alpha, alpha'-\[\(1-methylethylidene\)di-4, 1-phenylene\]bis\[omega-hyd... / 37353-75-6](#)

EC number

EC name

CAS number

CAS name

37353-75-6

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: 80a9032f-b0ab-4b31-b427-2eaa33f91e43

Dossier UUID:

Author: Dra

Date: 2018-08-27T11:13:21.221+09:00

Remarks:

Administrative data

Endpoint

acute toxicity: oral

Type of information

experimental study

Adequacy of study

key study

Robust study summary

true

Used for classification

false

Used for SDS

false

Reliability

1 (reliable without restriction)

Rationale for reliability incl. deficiencies

guideline study

Reliability 1

Data source

Reference

[Single Dose Oral Toxicity Test of Poly\[oxy\(methyl-1,2-ethanediyl\)\], alpha, alpha'-\[\(1-methylethylidene\)di-4, 1-phenylene\]bis\[omega-hydroxy-](#)
MHLW (Ministry of Health, Labour and Welfare), Japan / study report

Data access

data published

Materials and methods

Test guideline

Qualifier

according to

Guideline

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

GLP compliance

yes

Test type

acute toxic class method

Limit test

yes

Test material

Test material information

[Poly\[oxy\(methyl-1,2-ethanediyl\)\], alpha, alpha'-\[\(1-methylethylidene\)di-4, 1-phenylene\]bis\[omega-hyd...](#)

Specific details on test material used for the study

- Lot No.: L3-6S005-A (Sanyo Chemical Industries, Ltd.)
- Purity: >99%
- Solubility: insoluble in water
- Physical state: Colorless liquid
- Storage condition of test material: in cool (2-6 °C) and dark place

Test animals

Species

rat
common species

Strain

Crj: CD(SD)
rat

Sex

female

Details on test animals and environmental conditions

TEST ANIMALS

- Source: Charles River Japan Inc.
- Age at the time of purchase: 9 weeks old
- Weight at dosing: 229-246 g
- Used animal number: A total of 12 females (3 animals/step)
- Housing: Three animal/cage
- Diet (e.g. ad libitum): Ad libitum
- Water (e.g. ad libitum): Ad libitum
- Acclimation period: 5 days.

ENVIRONMENTAL CONDITIONS

- Temperature (°C): 22±3
- Humidity (%): 55±10
- Ventilation (per hr): >10 times

- Photoperiod (hrs light / hrs dark): 12/12

Administration / exposure

Route of administration

oral: gavage

Vehicle

water

Details on oral exposure

MAXIMUM DOSE VOLUME APPLIED: 10 ml/kg b.w.

Doses

2000 mg/kg bw (1st and 2nd steps)

No. of animals per sex per dose

3 females/dose

Control animals

no

Details on study design

- Duration of observation period following administration: 14 days
- Frequency of observations: for one hour after dosing, and 2 h, 4h, and 6 h after dosing. Twice a day on the next day of dosing. Thereafter once a day.
- Frequency of weighing: Days 1 (before administration), 4, 8 and 15
- Necropsy of survivors performed: Yes

Statistics

Not used

Results and discussion

Effect levels

Key result

true

Sex

female

Dose descriptor

LD50

Effect level

> 2000 mg/kg bw

Based on

act. ingr.

Mortality

No deaths were observed in the first and second dosing groups.

Clinical signs

Salivation in 1 animal (1st dosing) and restlessness in 3 and 2 animals (1st and 2nd dosing) were observed immediately after dosing but recovered within 30 min. Decrease in locomotor activity was

observed in all animals on the day of dosing. Diarrhea and soiled fur were observed during the observation period.

Body weight

There were no changes related to the test substance.

Gross pathology

There were no changes related to the test substance.

Applicant's summary and conclusion

Conclusions

The acute oral LD50 of propoxylated bisphenol A was >2000 mg/kg bw in female rats based on the study conducted according to the OECD TG 423 .

Repeated dose toxicity: oral

ENDPOINT_STUDY_RECORD: Repeated dose toxicity: oral.001

UUID: 8696becf-df8e-4514-a09d-b37c260ef68d

Dossier UUID:

Author: Dra

Date: 2018-03-30T09:07:33.060+09:00

Remarks:

Administrative data

Endpoint

repeated dose toxicity: oral, other

Type of information

experimental study

Adequacy of study

key study

Robust study summary

false

Used for classification

false

Used for SDS

false

Reliability

1 (reliable without restriction)

Rationale for reliability incl. deficiencies

guideline study

Reliability 1

Cross-reference

Reason / purpose

reference to same study

Related information

[OECD / Toxicity to reproduction / Toxicity to reproduction.001 / Poly\[oxy\(methyl-1,2-ethanediyl\)\], alpha, alpha'-\[\(1-methylethylidene\)di-4, 1-phenylene\]bis\[omega-hyd...](#)

Data source

Reference

[A combined repeated dose/reproductive developmental toxicity study of 4,4'-isopropylidenediphenol, p... / Ministry of Health, Labor and Welfare, Japan / study report](#)

Data access

data published

Materials and methods

Test guideline

Qualifier

according to

Guideline

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

Deviations

no

GLP compliance

yes

Limit test

no

Test material

Specific details on test material used for the study

- Name of test material (as cited in study report): 4,4'-isopropylidenediphenol, propoxylated
- Analytical purity: > 99%
- Storage condition of test material: at a cold (temperature 2-6 °C) and dark place, with airtight stopper.
- Stability under test conditions: The stability of test material was identified by analysis of the remainder.

Test animals

Species

rat

common rodent species

Strain

other: CrI:CD(SD)

Sex

male/female

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

- Source: Charles River Japan, Inc., Tsukuba Breeding Center.
- Age at study initiation: 10 weeks old
- Weight at study initiation: male 361 g (329-385 g), female 228 g (199-253 g)
- Housing: Animals were individually housed in bracket-type metallic wire-mesh cages (265W × 426D × 200H mm), Dams were bred individually or with individual littermates in polycarbonate cages with flat floors (265W x 426D x 200H mm) and standard bedding.
- Diet: Solid feed (MR stock: Nosan Corporation) was given ad libitum.
- Water: Tap water was given ad libitum.
- Acclimation period: 12 days

ENVIRONMENTAL CONDITIONS

- Temperature (°C): 22±3 (actual temperature: 22.2-25.0 °C)
- Humidity (%): 55±10% (actual humidity: 45-58%)

- Air changes (per hr): >10
- Photoperiod (hrs dark / hrs light): 12 hr dark/12 hr light (light: 7:00~19:00)

Administration / exposure

Route of administration

oral: gavage

Vehicle

olive oil

Details on oral exposure

- Amount of vehicle (if gavage): 5 mL/kg
- Dosing volume: 5 mL/kg

Analytical verification of doses or concentrations

yes

Duration of treatment / exposure

(P) Males: 42 days including 14 days pre-mating

(P) Females: 42-53 days including 14 days pre-mating, mating and gestation periods and the days until day 4 of lactation

Female (no mating, 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.	
30	mg/kg bw/day (actual dose received)
Dose / conc.	
120	mg/kg bw/day (actual dose received)
Dose / conc.	
500	mg/kg bw/day (actual dose received)

No. of animals per sex per dose

Main group: 12 animals/sex/dose

Satellite (Recovery) group: 5 males/dose and 5 females/dose (0 and 500 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 of 500 mg/kg bw/day was selected as an expected obvious toxic dose, and the lowest dose of 30 mg/kg bw/day was selected as an expected no toxic dose. The middle dose levels of 120 mg/kg bw/day were selected.
- Rationale for animal assignment (if not random): Body weight-balanced randomization

[14-day preliminary study]

A 14-day repeated dose oral toxicity test (CrI:CD(SD) rats, doses: 0 (olive oil), 50, 100, 200, 500 or 1000 mg/kg bw/day). At 100 mg/kg bw/day or more, Salivation, tendency of suppress weight gain, high value trend of total cholesterol were observed. At 500 mg/kg bw/day or more, High value of liver and adrenal gland weight, total protein, albumin, and calcium, and reduced prothrombin time were observed. At 1000 mg/kg bw/day, changes of general condition, obvious suppression of weight gain, death of one male and two females were observed.

Examinations

Observations and examinations performed and frequency

CAGE SIDE OBSERVATIONS: Yes

- Time schedule: 3 times/day (am: before and after administration; pm) during the administration period. 2 times/day (am and pm) during the recovery period.

DETAILED CLINICAL OBSERVATIONS: Yes

- Time schedule: Once before the start of administration, and once every week by the end of the study period.

BODY WEIGHT: Yes

- Time schedule for examinations:

Males were weighed on Day 1, 7, 14, 21, 28, 35, and 42 of administration, and weighed on Day 7 and 14 of recovery.

Female satellite groups were weighted same frequencies to male recovery groups.

Females in the main groups were weighed on Day 1, 7 and 14 of administration and copulated female s were weighed on Day 0, 7, 14 and 20 of gestation, and days 0 and 4 of lactation.

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 in the main and recovery groups; on Day 1, 7, 14, 21, 28, 35, and 41 of administration, and on Day 7 and 13 of recovery.

Female satellite groups were weighted same frequencies to male recovery groups.

Females in the main group; on Day 1, 7 and 14 of administration and copulated females were weighed on Day 0, 7, 14 and 20 of gestation, and days 0 and 3 of lactation.

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: ether

- Animals fasted: Yes

- How many animals: 5 animals/sex/group

- Parameters examined included RBC, hemoglobin, hematocrit, MCV, MCH, MCHC, platelet, reticulocyte, PT, APTT, WBC and differential WBC.

CLINICAL CHEMISTRY: Yes

- Time schedule for collection of blood: At the end of administration period, or at the end of recovery period in both sexes
- Animals fasted: Yes
- How many animals: 5 animals/sex/group
- Parameters examined included total protein, albumin, A/G ratio, total bilirubin, glucose, total cholesterol, triglyceride, phospholipid, AST, ALT, LDH, ChE, ALP, gamma-GTP, BUN, creatinine, Na, K, Cl, Ca and IP.

URINALYSIS OF MALES: Yes

- Time schedule for collection of urine (male only): On Day 37 of administration, and on Day 9 of recovery.
- Metabolism cages used for collection of urine: Yes
- How many animals: 5 animals/group
- Parameters examined included color, cloudy, urine volume, specific gravity, pH, protein, glucose, ketone body, bilirubin, occult blood and urobilinogen.

NEUROBEHAVIOURAL EXAMINATION: Yes

- Time schedule for examinations: On week 6 of the administration period, and on week 2 of the recovery period
- Dose groups that were examined: All dose groups (5 animals/sex/group)
- Battery of functions tested: sensory activity (hearing reaction, eye sight reaction, sense of touch reaction, pain reaction, pupil reflex, righting reflex), grip strength, motor activity

Sacrifice and pathology

GROSS PATHOLOGY: Yes

ORGAN WEIBHT: Yes [brain, thymus, heart, liver, kidney, adrenal gland, spleen, seminal vesicle, testis, epididymis, pituitary, thyroid]

HISTOPATHOLOGY: Yes, [brain, pituitary, spinal cord, thyroid, parathyroid, heart, thymus, trachea, lung, liver, kidney, adrenal, spleen, stomach, small intestine, large intestine, sciatic nerve, bone, bone marrow, lymph nodes (mesenteric and cervical lymph nodes), urinary bladder, testis, seminal vesicle, prostate, epididymis, mammary gland, ovary, uterus and gross abnormalities site.]

Statistics

As for parametric data (grip strength, locomotor activity, body weight, body weight gain, food consumption, hematology and clinical chemistry data, organ weights, quantitative urinalysis data, number of corpora lutea, number of implantation sites, number of pups born, number of pups alive, number of stillborn), the values of means and standard deviations were calculated per group. When more than three groups exist in the test group, Bartlett test for variance was done, and if the variance was homogenous, ANOVA was applied. If the variance was not homogenous or data was non-parametric (differential WBC percentage, qualitative urinalysis data, stages of spermatogenesis, length of the estrous cycle, implantation index, delivery index, live birth index, viability index.), Kruskal-Wallis rank sum test was used. Consequently, if the result was significant, Dunnett multiple comparison or Dunnett typed method was used for detection of statistical significance against control group. When the number of the test group was two, F-test was used as for parametric data.

Then, student's t-test or Aspin-Welch's t-test was applied depending on the result of homogeneity of variance. While, as for non-parametric data, Man-Whitney's U-test was applied. Furthermore, as for categorized data (incidence of abnormal findings in clinical observation, detailed observation, sensory functional examination, necropsy and histopathology, copulation index, fertility index, gestation index), Fischer's exact test was used. In any tests, level of significance was set at 5%.

Results and discussion

Results of examinations

Clinical signs

effects observed, treatment-related

Description (incidence and severity)

[treatment-related effect]:

Slight ptosis was observed in two males at 500 mg/kg bw/day. Moderate decrease in locomotor activity and emaciation were observed in one male at 500 mg/kg bw/day. Slight emaciation was observed in one female at 500 mg/kg bw/day.

[non-treatment-related]:

Salivation was observed in eleven males and eleven females at 120 mg/kg bw/day, in all males and females at 500 mg/kg bw/day. This finding was considered to be a repelling reaction to administration liquid and not to be related to toxicity of the test substance.

Mortality

mortality observed, treatment-related

Description (incidence)

One female died at 500 mg/kg bw/day on gestation day 22.

Body weight and weight changes

effects observed, treatment-related

Description (incidence and severity)

Depression of body weight gains were observed in males at 500 mg/kg bw/day.

Food consumption and compound intake (if feeding study)

effects observed, non-treatment-related

Description (incidence and severity)

Increased food consumption was observed in males at 500 mg/kg bw/day and in females at 120 mg/kg bw/day on Day 14 of administration only. These variations were without dose-related trends. Therefore, these variations were considered to be incidental and not to be related to treatment of the test substance.

Food efficiency

not examined

Water consumption and compound intake (if drinking water study)

not examined

Ophthalmological findings

not examined

Haematological findings

effects observed, non-treatment-related

Description (incidence and severity)

Decreased MCH and PT were observed in male at 500 mg/kg bw/day. At decreased MCH, however, this variation was within ranges of historical control data, and erythrocyte count and hemoglobin concentration showed no changes. Therefore, this variation was considered to be incidental and not to be related to treatment of the test substance. At decreased PT, however, this variation was not extendable and was not seen in females. Therefore this variation was a toxicologically meaningless change.

At the end of recovery period, decreased neutrophil ratio in differentiation of leukocyte was observed in males at 500 mg/kg bw/day and decreased APTT was observed in females at 500 mg/kg bw/day. However, these variations were within ranges of historical control data, and were not present at the end of the administration period. Therefore, these variations were considered to be incidental and not to be related to treatment of the test substance.

Clinical biochemistry findings

effects observed, treatment-related

Description (incidence and severity)

Decreased total protein was observed in males at 120 and 500 mg/kg bw/day. Decreased albumin was observed in males at 500 mg/kg bw/day and increased total cholesterol was observed in both sexes at 500 mg/kg bw/day.

Urinalysis findings

effects observed, non-treatment-related

Description (incidence and severity)

At the end of recovery period, decreased K value was observed in females at 500 mg/kg bw/day. This value was within range of historical control data. Therefore, this variation was considered to be incidental and not to be related to treatment of the test substance.

Behaviour (functional findings)

no effects observed

Organ weight findings including organ / body weight ratios

effects observed, treatment-related

Description (incidence and severity)

[treatment-related effect]:

At the end of administration period, increases in absolute and relative liver weights were observed in males at 500 mg/kg bw/day and increases in relative liver weight was observed in females at 500 mg/kg bw/day.

[non-treatment-related]:

Increases in relative kidney weight and relative brain weight were observed in males at 500 mg/kg bw/day. However, these changes were considered due to the reduction in terminal body weights. Therefore these changes were no toxicological meaning.

Gross pathological findings

effects observed, treatment-related

Description (incidence and severity)

Slight enlargement of liver was observed in both sexes at 500 mg/kg bw/day.

Histopathological findings: non-neoplastic

effects observed, treatment-related

Description (incidence and severity)

Liver: Slight hypertrophy of centrilobular hepatocyte was observed in four males and five females at 500 mg/kg bw/day.

Small intestine: Dilatation of lacteal was observed in two males and one female at 120 mg/kg bw/day, and five males and five females at 500 mg/kg bw/day.

Histopathological findings: neoplastic

not examined

Effect levels

Key result
true

Dose descriptor
NOAEL

Effect level

30

mg/kg bw/day (actual dose received)

Based on
test mat.

Sex
male/female

Basis for effect level

clinical biochemistry

Decreased total protein was observed in males at 120 and 500 mg/kg bw/day.

histopathology: non-neoplastic

Small intestine: Dilatation of lacteal was observed in two males and one female at 120 mg/kg bw/day, and five males and five females at 500 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.

http://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF37353-75-6d.pdf

Applicant's summary and conclusion

Executive summary

In the combined repeated dose and reproductive/developmental screening test, SD rats were treated orally with the test substance at the doses of 0, 30, 120 and 500 mg/kg bw/day, Males were dosed for 42 days including 14-days

pre-mating and mating periods. Females were dosed during the periods of pre-mating, mating, gestation and days until day 4 of lactation. As a result, decreased total protein was observed in males at 120 and 500 mg/kg bw/day. Dilatation of lacteal on small intestine was observed in two males and one female at 120 mg/kg bw/day, and five males and five females at 500 mg/kg bw/day.

On the basis of these effects, NOAEL for repeated-dose toxicity was determined to be 30 mg/kg bw/day in male and female rats.

Genetic toxicity in vitro

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.001

UUID: 27f76f6d-0cbb-4647-b89c-dc5c92232f00

Dossier UUID:

Author: SuperUser

Date: 2019-09-03T14:42:40.873+09:00

Remarks:

Administrative data

Endpoint

in vitro gene mutation study in bacteria

Type of information

experimental study

Adequacy of study

key study

Robust study summary

true

Used for classification

false

Used for SDS

false

Reliability

1 (reliable without restriction)

Rationale for reliability incl. deficiencies

guideline study

Reliability 1

Data source

Reference

[Reverse Mutation Test of Poly\[oxy\(methyl-1,2-ethanediyl\)\], alpha, alpha'-\[\(1-methylethylidene\)di-4,1-... / MHLW \(Ministry of Health, Labour and Welfare\), Japan / study report](#)

Data access

data published

Materials and methods

Test guideline

Qualifier

according to

Guideline

OECD Guideline 471 (Bacterial Reverse Mutation Assay)

in vitro gene mutation study in bacteria

Qualifier
according to

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

GLP compliance
yes

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

Test material

Test material information

Poly[oxy(methyl-1,2-ethanediyl)], alpha, alpha'-[(1-methylethylidene)di-4, 1-phenylene]bis[omega-hyd...

Specific details on test material used for the study

- Lot No.: L3-6S005-A (Sanyo Chemical Industries, Ltd.)
- Purity: >99%
- Solubility: insoluble in water
- Physical state: Colorless liquid
- Storage condition of test material: in cool (2-6 °C) and dark place

Method

Species / strain

Species / strain

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

Metabolic activation

with and without

Metabolic activation system

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

Test concentrations with justification for top dose

Preliminary test

+/- S9 mix: 0, 20, 50, 100, 200, 500, 1000, 2000, 5000 µg/plate

Main test

+/- S9 mix: 0, 156, 313, 625, 1250, 2500, 5000 µg/plate

Vehicle

DMSO

Controls

Negative controls

yes

Solvent controls

yes

Positive control substance

9-aminoacridine

9-aminoacridine hydrochloride (-S9 mix: TA1537)

sodium azide

(-S9 mix: TA1535)

other: -S9 mix: 2-(2-Furyl)-3-(5-nitro-2-furyl) acrylamide (TA 100, TA98 and WP2 uvrA/pKM101),
+S9 mix: 2-aminoanthracene (all strains)

Details on test system and conditions

METHOD OF APPLICATION: Preincubation

DURATION- Preincubation period: 20 min at 37°C

- Exposure duration:48 hrs

NUMBER OF PLATES: 3

NUMBER OF REPLICATIONS: 2

DETERMINATION OF CYTOTOXICITY- Method: other: growth inhibition

Evaluation criteria

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

Statistics

Not used

Results and discussion

Test results

Key result

false

Species / strain

S. typhimurium TA 1535
bacteria

Metabolic activation

with and without

Genotoxicity

negative

Cytotoxicity

no, but tested up to limit concentrations

Vehicle controls valid

yes

Negative controls valid

yes

Positive controls valid

yes

Key result

false

Species / strain

S. typhimurium TA 1537

bacteria

Metabolic activation

with and without

Genotoxicity

negative

Cytotoxicity

no, but tested up to limit concentrations

Vehicle controls valid

yes

Negative controls valid

yes

Positive controls valid

yes

Key result

false

Species / strain

S. typhimurium TA 98
bacteria

Metabolic activation

with and without

Genotoxicity

negative

Cytotoxicity

no, but tested up to limit concentrations

Vehicle controls valid

yes

Negative controls valid

yes

Positive controls valid

yes

Key result

false

Species / strain

S. typhimurium TA 100
bacteria

Metabolic activation

with and without

Genotoxicity

negative

Cytotoxicity

no, but tested up to limit concentrations

Vehicle controls valid

yes

Negative controls valid

yes

Positive controls valid

yes

Key result

false

Species / strain

E. coli WP2 uvr A pKM 101
bacteria

Metabolic activation

with and without

Genotoxicity

negative

Cytotoxicity

no, but tested up to limit concentrations

Vehicle controls valid

yes

Negative controls valid

yes

Positive controls valid

yes

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/PDF37353-75-6e.pdf

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

Applicant's summary and conclusion

Conclusions

Interpretation of results' negative

Executive summary

In a bacterial reverse mutation assay using *Salmonella typhimurium* TA100, TA1535, TA98, and TA1537, and *Escherichia coli* WP2uvrA/pKM101 (OECD TG 471), propoxylated bisphenol A was negative with or without metabolic activation.

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.002

UUID: 3e09de1c-fd13-448e-a365-e81dd0038b46

Dossier UUID:

Author: SuperUser

Date: 2019-09-03T16:25:34.633+09:00

Remarks:

Administrative data

Endpoint

in vitro cytogenicity / chromosome aberration study in mammalian cells

Type of information

experimental study

Adequacy of study

key study

Robust study summary

true

Used for classification

false

Used for SDS

false

Reliability

1 (reliable without restriction)

Rationale for reliability incl. deficiencies

guideline study

Reliability 1

Data source

Reference

[In Vitro Chromosomal Aberration Test of Poly\[oxy\(methyl-1,2-ethanediyl\)\], alpha,alpha'-\[\(1-methyleth... / MHLW \(Ministry of Health, Labour and Welfare\), Japan / study report](#)

Data access

data published

Materials and methods

Test guideline

Qualifier

according to

Guideline

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

Qualifier

according to

Guideline

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

GLP compliance

yes

Type of assay

in vitro mammalian chromosome aberration test

in vitro cytogenicity / chromosome aberration study in mammalian cells

Test material

Test material information

[Poly\[oxy\(methyl-1,2-ethanediyl\)\], alpha, alpha'-\[\(1-methylethylidene\)di-4, 1-phenylene\]bis\[omega-hyd...](#)

Specific details on test material used for the study

- Lot No.: L3-6S005-A (Sanyo Chemical Industries, Ltd.)
- Purity: >99%
- Solubility: insoluble in water
- Physical state: Colorless liquid
- Storage condition of test material: in cool (2-6 °C) and dark place

Method

Species / strain**Species / strain**

other: Chinese hamster lung(CHL/IU) cells

Metabolic activation

with and without

Metabolic activation system

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

Test concentrations with justification for top dose

Cell growth inhibition study

short-term treatment (-S9 mix): 0, 46.88, 93.75, 187.5, 375, 750, 1500, 3000 µg/mL

short-term treatment (+S9 mix): 0, 46.88, 93.75, 187.5, 375, 750, 1500, 3000 µg/mL

continuous treatment (24 hrs and 48 hrs): 0, 46.88, 93.75, 187.5, 375, 750, 1500, 3000 µg/mL

Main study

short-term treatment

-S9: 0, 12.5, 25, 50, 75, 100 µg/mL

+S9: 0, 25, 50, 100, 150, 200 µg/mL

+S9: 0, 100, 125, 150 µg/mL (confirmation test)

Contentious treatment

-S9: 0, 6.25, 12.5, 25, 50, 100 µg/mL

-S9: 0, 50, 60, 75, 100 µg/mL (confirmation test)

Vehicle

DMSO

Controls

Negative controls

no

Solvent controls

yes

Positive controls

yes

Positive control substance

benzo(a)pyrene

+S9 mix

mitomycin C

-S9 mix

Details on test system and conditions

METHOD OF APPLICATION: Exposure duration:

short-term treatment: 6 hrs + 18 hr

contentious treatment: 24 hrs

SPINDLE INHIBITOR: Colcemid

STAIN: Giemsa stain for 20 min.

NUMBER OF REPLICATIONS: 3

NUMBER OF CELLS EVALUATED: 200 cells /concentration (100 cells/plate x 2)

DETERMINATION OF CYTOTOXICITY

- Method: relative total growth

Evaluation criteria

For the evaluation of the frequencies of structural aberrations and of polyploidy induced, statistical analysis was employed. When significant deference (<5%) was obtained by the multiple chi-square test, Fisher's exact test was employed to compare the vehicle control group and each concentration group. When frequencies of chromosomal aberrations were significantly increased in ≥ 2 concentration groups, and when concentration dependent increase was observed, it was judged to be positive.

Results and discussion

Test results

Key result

false

Species / strain

other: Chinese hamster lung (CHL/IU) cells

Metabolic activation

with

Genotoxicity

negative

Cytotoxicity

yes (at 75 and 100 $\mu\text{g}/\text{mL}$)

Vehicle controls valid

yes

Positive controls valid

yes

Key result

false

Species / strain

other: Chinese hamster lung (CHL/IU) cells

Metabolic activation

without

Genotoxicity

negative

Cytotoxicity

yes (short-term treatment: at 150 and 200 µg/mL, contentious treatment: at 60, 75, 100 µg/mL)

Vehicle controls valid

yes

Positive controls valid

yes

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/PDF37353-75-6f.pdf

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

Applicant's summary and conclusion _____

Conclusions

Interpretation of results: negative with and without metabolic activation

Executive summary

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

Toxicity to reproduction

ENDPOINT_STUDY_RECORD: Toxicity to reproduction.001

UUID: 5205a094-5fbf-456c-86b0-764132010499

Dossier UUID:

Author: Dra

Date: 2018-03-30T09:07:33.013+09:00

Remarks:

Administrative data

Endpoint

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

Type of information

experimental study

Adequacy of study

key study

Robust study summary

false

Used for classification

false

Used for SDS

false

Reliability

1 (reliable without restriction)

Rationale for reliability incl. deficiencies

guideline study

Reliability 1

Cross-reference

Reason / purpose

reference to same study

Related information

[OECD / Repeated dose toxicity: oral / Repeated dose toxicity: oral.001 / Poly\[oxy\(methyl-1,2-ethanediyl\)\], alpha, alpha'-\[\(1-methylethylidene\)di-4, 1-phenylene\]bis\[omega-hyd...](#)

Data source

Reference

[A combined repeated dose/reproductive developmental toxicity study of 4,4'-isopropylidenediphenol, p... / Ministry of Health, Labor and Welfare, Japan / study report](#)

Data access

data published

Materials and methods

Test guideline

Qualifier

according to

Guideline

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

Deviations

no

GLP compliance

yes

Limit test

no

Test material

Specific details on test material used for the study

- Analytical purity: > 99%
- Storage condition of test material: at a cold (temperature 2-6 °C) and dark place, with airtight stopper.
- Stability under test conditions: The stability of test material was identified by analysis of the remainder.

Test animals

Species

rat

Strain

other: CrI:CD(SD)

Sex

male/female

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

- Source: Charles River Japan, Inc., Tsukuba Breeding Center.
- Age at study initiation: 10 weeks old
- Weight at study initiation: male 361 g (329-385 g), female 228 g (199-253 g)
- Housing: Animals were housed individually, bracket-type metallic wire-mesh cages (265W × 426D × 200H mm), Dams were bred individually or with individual littermates in polycarbonate cages with flat floors (265W × 426D × 200H mm) and standard bedding.
- Diet: Solid feed (MR stock: Nosan Corporation) was given ad libitum.
- Water: Tap water was given ad libitum.
- Acclimation period: 12 days

ENVIRONMENTAL CONDITIONS

- Temperature (°C): 22±3 (actual temperature: 22.2-25.0 °C)
- Humidity (%): 55±10% (actual humidity: 45-58%)
- Air changes (per hr): >10
- Photoperiod (hrs dark / hrs light): 12 hr dark/12 hr light (light: 7:00~19:00)

Administration / exposure

Route of administration

oral: gavage

Vehicle

olive oil

Details on exposure

- Amount of vehicle (if gavage): 5 mL/kg
- Dosing volume: 5 mL/kg

Analytical verification of doses or concentrations

yes

Duration of treatment / exposure

(P) Males: 42 days including 14 days pre-mating (P) Females: 42-53 days including 14 days pre-mating, mating and gestation periods and the days until day 4 of lactation
Female (no mating, 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.	
30	mg/kg bw/day (actual dose received)
Dose / conc.	
120	mg/kg bw/day (actual dose received)
Dose / conc.	
500	mg/kg bw/day (actual dose received)

No. of animals per sex per dose

Main group: 12 animals/sex/dose

Satellite (Recovery) group: 5 males/dose and 5 females/dose (0 and 300 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 of 500 mg/kg bw/day was selected as an expected obvious toxic dose, and the lowest dose of 30 mg/kg bw/day was selected as an expected no toxic dose. The middle dose levels of 120 mg/kg bw/day were selected.
- Rationale for animal assignment (if not random): Body weight-balanced randomization

[14-day preliminary study]

A 14-day repeated dose oral toxicity test (CrI:CD(SD) rats, doses: 0 (olive oil), 50, 100, 200, 500 or 1000 mg/kg bw/day). At 100 mg/kg bw/day or more, Salivation, tendency of suppress weight gain, high value trend of total cholesterol were observed. At 500 mg/kg bw/day or more, High value of liver and adrenal gland weight, total protein, albumin, and calcium, and reduced prothrombin time were observed. At 1000 mg/kg bw/day, changes of general condition, obvious suppression of weight gain, death of one male and two females were observed.

Examinations

Parental animals: Observations and examinations

CAGE SIDE OBSERVATIONS: Yes

- Time schedule: 3 times/day (am: before and after administration; pm) during the administration period. 2 times/day (am and pm) during the recovery period.

DETAILED CLINICAL OBSERVATIONS: Yes

- Time schedule: Once before the start of administration, and once every week by the end of the study period.

BODY WEIGHT: Yes

- Time schedule for examinations:

Males were weighed on Day 1, 7, 14, 21, 28, 35, and 42 of administration, and weighed on Day 7 and 14 of recovery.

Female satellite groups were weighed same frequencies to male recovery groups.

Females in the main groups were weighed on Day 1, 7 and 14 of administration and copulated female s were weighed on Day 0, 7, 14 and 20 of gestation, and days 0 and 4 of lactation.

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 in the main and recovery groups; on Day 1, 7, 14, 21, 28, 35, and 41 of administration, and on Day 7 and 13 of recovery.

Female satellite groups were weighed same frequencies to male recovery groups.

Females in the main group; on Day 1, 7 and 14 of administration and copulated females were weighed on Day 0, 7, 14 and 20 of gestation, and days 0 and 3 of lactation.

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: ether

- Animals fasted: Yes

- How many animals: 5 animals/sex/group

- Parameters examined included RBC, hemoglobin, hematocrit, MCV, MCH, MCHC, platelet, reticulocyte, PT, APTT, WBC and differential WBC.

CLINICAL CHEMISTRY: Yes

- Time schedule for collection of blood: At the end of administration period, or at the end of recovery period in both sexes

- Animals fasted: Yes

- How many animals: 5 animals/sex/group

- Parameters examined included total protein, albumin, A/G ratio, total bilirubin, glucose, total cholesterol, triglyceride, phospholipid, AST, ALT, LDH, ChE, ALP, gamma-GTP, BUN, creatinine, Na, K, Cl, Ca and IP.

URINALYSIS OF MALES: Yes

- Time schedule for collection of urine (male only): On Day 37 of administration, and on Day 9 of recovery.
- Metabolism cages used for collection of urine: Yes
- How many animals: 5 animals/group
- Parameters examined included color, cloudy, urine volume, specific gravity, pH, protein, glucose, ketone body, bilirubin, occult blood and urobilinogen.

NEUROBEHAVIOURAL EXAMINATION: Yes

- Time schedule for examinations: On week 6 of the administration period, and on week 2 of the recovery period
- Dose groups that were examined: All dose groups (5 animals/sex/group)
- Battery of functions tested: sensory activity (hearing reaction, eye sight reaction, sense of touch reaction, pain reaction, pupil reflex, righting reflex), grip strength, motor activity

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.

Sperm parameters (parental animals)

Parameters examined in all P male parental generations: testis weight, epididymis weight, histopathological examinations for testes, epididymides, seminal vesicle including coagulating gland and ventral prostate.

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, weight gain, physical or behavioral abnormalities.

Postmortem examinations (parental animals)

METHOD OF SACRIFICED: All animals were sacrificed by exsanguination under ether anesthesia. SACRIFICE: Male animals: On Day 42, Maternal animals: on Day 5 of lactation, and Male recovery and female satellite animals: on next Day 14 of recovery.

GROSS PATHOLOGY: Yes

ORGAN WEIBHT: Yes [brain, thymus, heart, liver, kidney, adrenal gland, spleen, seminal vesicle, testis, epididymis, pituitary, thyroid]

HISTOPATHOLOGY: Yes, [brain, pituitary, spinal cord, thyroid, parathyroid, heart, thymus, trachea, lung, liver, kidney, adrenal, spleen, stomach, small intestine, large intestine, sciatic nerve, bone, bone marrow, lymph nodes (mesenteric and cervical lymph nodes), urinary bladder, testis, seminal vesicle, prostate, epididymis, mammary gland, ovary, uterus and gross abnormalities site.]

Postmortem examinations (offspring)

SACRIFICE

- The F1 offspring were sacrificed at 4 days of age.

GROSS NECROPSY

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

HISTOPATHOLOGY / ORGAN WEIGHTS

- Not examined.

Statistics

As for parametric data (grip strength, locomotor activity, body weight, body weight gain, food consumption, hematology and clinical chemistry data, organ weights, quantitative urinalysis data, number of corpora lutea, number of implantation sites, number of pups born, number of pups alive, number of stillborn), the values of means and standard deviations were calculated per group. When more than three groups exist in the test group, Bartlett test for variance was done, and if the variance was homogenous, ANOVA was applied. If the variance was not homogenous or data was non-parametric

(differential WBC percentage, qualitative urinalysis data, stages of spermatogenesis, length of the estrous cycle, implantation index, delivery index, live birth index, viability index,), Kruskal-Wallis rank sum test was used. Consequently, if the result was significant, Dunnett multiple comparison or Dunnett typed method was used for detection of statistical significance against control group. When the number of the test group was two, F-test was used as for parametric data.

Then, student's t-test or Aspin-Welch's t-test was applied depending on the result of homogeneity of variance. While, as for non-parametric data, Man-Whitney's U-test was applied. Furthermore, as for categorized data (incidence of abnormal findings in clinical observation, detailed observation, sensory functional examination, necropsy and histopathology, copulation index, fertility index, gestation index), Fischer's exact test was used. In any tests, level of significance was set at 5%.

Reproductive indices

Estrous cycle: Mean days from metestrus I (III) to next III.

Copulation index (%) = (No. of pairs with successful copulation/No. of pairs mated) × 100

Fertility index (%) = (No. of pregnant females/No. of pairs with successful copulation) × 100

Gestation index (%) = (No. of females with live pups/No. of pregnant females) × 100

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

Delivery index (%) = (No. of pups born/No. of implantation sites) × 100

Live birth index (%) = (No. of live pups on day 0/No. of pups born) × 100

Sex ratio = Total number of male pups/Total number of female pups

Offspring viability indices

Viability index (%) = (No. of live pups on day 4/No. of live pups on day 0) × 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

Mortality

mortality observed, treatment-related

Description (incidence)

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, non-treatment-related

Description (incidence and severity)

See 7.5.1 Repeated dose toxicity: oral.001

Food efficiency

not examined

Water consumption and compound intake (if drinking water study)

not examined

Ophthalmological findings

not examined

Haematological findings

effects observed, non-treatment-related

Description (incidence and severity)

See 7.5.1 Repeated dose toxicity: oral.001

Clinical biochemistry findings

effects observed, treatment-related

Description (incidence and severity)

See 7.5.1 Repeated dose toxicity: oral.001

Urinalysis findings

effects observed, non-treatment-related

Description (incidence and severity)

See 7.5.1 Repeated dose toxicity: oral.001

Behaviour (functional findings)

no effects observed

Description (incidence and severity)

See 7.5.1 Repeated dose toxicity: oral.001

Immunological findings

not examined

Organ weight findings including organ / body weight ratios

effects observed, treatment-related

Description (incidence and severity)

See 7.5.1 Repeated dose toxicity: oral.001

Gross pathological findings

effects observed, treatment-related

Description (incidence and severity)

See 7.5.1 Repeated dose toxicity: oral.001

Neuropathological findings

not examined

Histopathological findings: non-neoplastic

effects observed, treatment-related

Description (incidence and severity)

See 7.5.1 Repeated dose toxicity: oral.001

Histopathological findings: neoplastic

not examined

Reproductive function / performance (P0)

Reproductive function: estrous cycle

effects observed, treatment-related

Description (incidence and severity)

Disorder of estrous cycle was observed in five females at 500 mg/kg bw/day.

Reproductive function: sperm measures

effects observed, non-treatment-related

Description (incidence and severity)

Increase the number of spermatogonia in seminiferous epithelia at Stage XII in males at 500 mg/kg bw/day. However, test substance related histopathological changes were not observed in testis. Therefore, these variations were considered to be incidental and not to be related to treatment of the test substance.

Reproductive performance

no effects observed

Effect levels (P0)

Key result

true

Dose descriptor

NOAEL

Effect level

120

mg/kg bw/day (actual dose received)

Based on

test mat.

Sex

male/female

Basis for effect level

reproductive function (estrous cycle)

Disorder of estrous cycle was observed in five females at 500 mg/kg bw/day.

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)

Decrease of body weight in offsprings at 500 mg/kg bw/day.

Sexual maturation

no effects observed

Gross pathological findings

no effects observed

Effect levels (F1)

Key result

true

Dose descriptor

NOAEL

Generation

F1

Effect level

120

mg/kg bw/day (actual dose received)

Based on

test mat.

Sex

male/female

Basis for effect level

body weight and weight gain

Decrease of body weight in offsprings at 500 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.

http://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF37353-75-6d.pdf

Applicant's summary and conclusion

Executive summary

In the combined repeated dose and reproductive/developmental screening test, SD rats were treated orally with the test substance at the doses of 0, 30, 120 and 500 mg/kg bw/day, Males were dosed for 42 days including 14-days

pre-mating and mating periods. Females were dosed during the periods of pre-mating, mating, gestation and days until day 4 of lactation. As a result, decrease of body weight in offsprings at 500 mg/kg bw/day. Disorder of estrous cycle was observed in five females at 500 mg/kg bw/day. On the basis of these effects, NOAEL for reproductive and developmental toxicity was determined to be 120 mg/kg bw/day in parental animals and F1 offspring.

References

**LITERATURE: A combined repeated dose/
reproductive developmental toxicity study of
4,4'-isopropylidenediphenol, propoxylated
by oral administration in rats.**

UUID: 09124065-e91d-43d9-b827-dde035e817a6

Dossier UUID:

Author: Dra

Date: 2018-03-23T10:30:59.000+09:00

Remarks:

General information

Reference Type

study report

Title

A combined repeated dose/reproductive developmental toxicity study of 4,4'-isopropylidenediphenol, propoxylated by oral administration in rats.

Author

Ministry of Health, Labor and Welfare, Japan

Testing facility

Research institute for animal science in biochemistry and toxicology (RIAS)

Study no.

06-119

LITERATURE: In Vitro Chromosomal Aberration Test of Poly[oxy(methyl-1,2-ethanediyl)], alpha,alpha'-[(1-methylethylidene)di-4,1-phenylene]bis[omega-hydroxy- on Cultured Chinese Hamster Cells

UUID: 22376bec-6ca3-41c1-be78-2055d7a999e2

Dossier UUID:

Author: Dra

Date: 2018-08-27T11:19:37.626+09:00

Remarks:

General information

Reference Type

study report

Title

In Vitro Chromosomal Aberration Test of Poly[oxy(methyl-1,2-ethanediyl)], alpha,alpha'-[(1-methylethylidene)di-4,1-phenylene]bis[omega-hydroxy- on Cultured Chinese Hamster Cells

Author

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

Year

2010

Bibliographic source

Japan Existing Chemical Data Base (JECDB) http://dra4.nihs.go.jp/mhlw_data/jsp/SearchPageENG.jsp

Testing facility

Research Institute for Animal Science in Biochemistry and Toxicology

Report no.

06-117

LEGAL_ENTITY: National Institute of Health Sciences

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

Dossier UUID:

Author: SuperUser

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

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

General information

Legal entity name

National Institute of Health Sciences

Remarks

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

Identifiers

Other IT system identifiers

IT system LEO
ID 10767
IT system IUCLID4
ID 16558402024DIV750

Contact information

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Town

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Region / State

Kanagawa

Country

Japan

Contact persons

Person

Hirose, Akihiko; National Institute of Health Sciences, Japan

Last name

Hirose

First name

Akihiko

Organisation

National Institute of Health Sciences, Japan

Department

Division of Risk Assessment

Title

Dr

Country

Japan

REFERENCE_SUBSTANCE: Poly[oxy(methyl-1,2-ethanediyl)], alpha, alpha'-[(1-methylethylidene)di-4, 1-phenylene]bis[omega-hydroxy-

UUID: 837cba43-f251-440d-9b53-5dad38755d76

Dossier UUID:

Author: Dra

Date: 2018-03-12T14:03:59.301+09:00

Remarks:

General information

Reference substance name

Poly[oxy(methyl-1,2-ethanediyl)], alpha, alpha'-[(1-methylethylidene)di-4, 1-phenylene]bis[omega-hydroxy-

Reference substance information

Synonyms

Identifier

common name

Identity

propoxylated bisphenol A

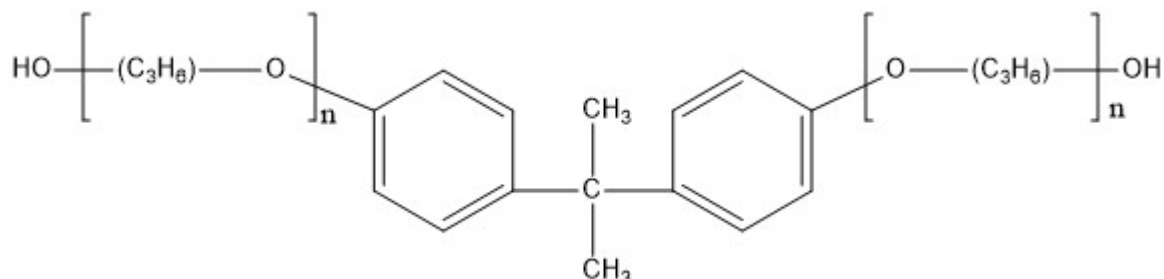
CAS information

CAS number

37353-75-6

Molecular and structural information

Structural formula



Remarks

n=a: 0.0%, n=2: 5.7%, n=3: 11.4%, n=4: 22.1%, n=5: 24.9%, n=6: 18.1%, n=7: 10.2%, n>=8: 7.6%

TEST_MATERIAL_INFORMATION: Poly[oxy(methyl-1,2-ethanediyl)], alpha, alpha'-[(1-methylethylidene)di-4, 1-phenylene]bis[omega-hydroxy- (propoxylated bisphenol A)]

UUID: d1071874-285f-4e11-a1ef-104305f8c05b

Dossier UUID:

Author: Dra

Date: 2018-03-12T10:09:35.259+09:00

Remarks:

Name

Poly[oxy(methyl-1,2-ethanediyl)], alpha, alpha'-[(1-methylethylidene)di-4, 1-phenylene]bis[omega-hydroxy- (propoxylated bisphenol A)]

LITERATURE: Reverse Mutation Test of Poly[oxy(methyl-1,2-ethanediyl)], alpha, alpha'-[(1-methylethylidene)di-4,1-phenylene]bis[omega-hydroxy- on Bacteria.

UUID: bc242e28-071f-4dd3-86ef-4d2a968eb55a

Dossier UUID:

Author: Dra

Date: 2018-08-27T11:18:57.107+09:00

Remarks:

General information

Reference Type

study report

Title

Reverse Mutation Test of Poly[oxy(methyl-1,2-ethanediyl)], alpha, alpha'-[(1-methylethylidene)di-4,1-phenylene]bis[omega-hydroxy- on Bacteria.

Author

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

Year

2010

Bibliographic source

Japan Existing Chemical Data Base (JECDB) http://dra4.nihs.go.jp/mhlw_data/jsp/SearchPageENG.jsp

Testing facility

Research Institute for Animal Science in Biochemistry and Toxicology

Report no.

06-116

LITERATURE: Single Dose Oral Toxicity Test of Poly[oxy(methyl-1,2-ethanediyl)], alpha, alpha'-[(1-methylethylidene)di-4, 1-phenylene]bis[omega-hydroxy- in Rats

UUID: ad2bcf2a-f8b2-4095-ae57-0ca84ab65616

Dossier UUID:

Author: Dra

Date: 2018-08-27T11:17:48.378+09:00

Remarks:

General information

Reference Type

study report

Title

Single Dose Oral Toxicity Test of Poly[oxy(methyl-1,2-ethanediyl)], alpha, alpha'-[(1-methylethylidene)di-4, 1-phenylene]bis[omega-hydroxy- in Rats

Author

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

Year

2010

Bibliographic source

Japan Existing Chemical Data Base (JECDB) http://dra4.nihs.go.jp/mhlw_data/jsp/Se archPageENG.jsp

Testing facility

Research Institute for Animal Science in Biochemistry and Toxicology

Report no.

06-118