



Name: poly(oxy-1,2-ethanediyl),alpha,alpha'- [(1-methylethylidene)di-4,1-phenylene]bis[omega-hydroxy- / 32492-61-8

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

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Table of Contents

poly(oxy-1,2-ethanediyl),alpha,alpha'- [(1-methylethylidene)di-4,1-phenylene]bis[omega-hydroxy-	1
CORE	1
1 General information	1
1.1 Identification	1
Identification	1
OECD	3
D Health Effects	3
60 Acute toxicity: oral	3
Acute toxicity: oral.001	3
67 Repeated dose toxicity: oral	5
Repeated dose toxicity: oral.001	5
70 Genetic toxicity in vitro	13
Genetic toxicity in vitro.001	13
Genetic toxicity in vitro.002	18
73 Toxicity to reproduction	22
Toxicity to reproduction.001	22
References	31
A combined repeated dose/reproductive developmental toxicity study of 4,4'-Isopropylidenediphenol, ethoxylated by oral administration in rats.	31
In Vitro Chromosomal Aberration Test of poly(oxy-1,2-ethanediyl),alpha,alpha'-[(1-methylethylidene)di-4,1-phenylene]bis[omega-hydroxy- on Cultured Chinese Hamster Cells	32
National Institute of Health Sciences	33
poly(oxy-1,2-ethanediyl),alpha,alpha'- [(1-methylethylidene)di-4,1-phenylene]bis[omega-hydroxy-	35
poly(oxy-1,2-ethanediyl),alpha,alpha'-[(1-methylethylidene)di-4,1-phenylene]bis[omega-hydroxy-	36
Reverse Mutation Test of poly(oxy-1,2-ethanediyl),alpha,alpha'- [(1-methylethylidene)di-4,1-phenylene]bis[omega-hydroxy-	37

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

General information

Identification

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

UUID: 3361b877-d877-4ef7-9b93-95cba0844f45

Dossier UUID:

Author: SuperUser

Date: 2019-03-27T10:07:28.377+09:00

Remarks:

Substance name

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

Other identifiers

Identifier

CAS number

Identity

32492-61-8

Legal entity

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

Identification of substance

Reference substance

[poly\(oxy-1,2-ethanediyl\),alpha,alpha'- \[\(1-methylethylidene\)di-4,1-phenylene\]bis\[omega-hydroxy- / 32492-61-8](#)

EC number

EC name

CAS number

CAS name

32492-61-8

IUPAC name

Type of substance

Type of substance

polymer

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: f2830c60-32a8-46fb-b925-046b067f65fc

Dossier UUID:

Author: SuperUser

Date: 2019-02-07T10:18:33.482+09:00

Remarks:

Administrative data

Endpoint

acute toxicity: oral

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

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

Specific details on test material used for the study

- Lot No.: L3-6S004-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

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 2h, 4h, and 6h 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

Repeated dose toxicity: oral

ENDPOINT_STUDY_RECORD: Repeated dose toxicity: oral.001

UUID: d1051a9d-25f1-480e-b81c-20d6fee17c1e

Dossier UUID:

Author: SuperUser

Date: 2019-03-27T10:07:42.126+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\(oxy-1,2-ethanediyl\),alpha,alpha'- \[\(1-methylethylidene\)di-4,1-phenylene\]bis\[omega-hydroxy- / 32...](#)

Data source

Reference

[A combined repeated dose/reproductive developmental toxicity study of 4,4'-Isopropylidenediphenol, e... / 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, ethoxylated
- 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., Atsugi Breeding Center.
- Age at study initiation: 10 weeks old
- Weight at study initiation: male 361 g (334-396 g), female 235 g (216-260 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: 22.1-25.0°C)
- Humidity (%): 55±10% (actual humidity: 46-60%)
- 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: 42-47 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)
Dose / conc.	
1000	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 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 of 1000 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 and 500 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 500 mg/kg bw/day or more, salivation, low value trend of urinary ketone bodies, high value trend of total cholesterol and liver weight were observed. At 1000 mg/kg bw/day, high value trend of blood calcium, and reduced prothrombin time 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 weighed same frequencies to male recovery groups.

Females in the main groups were weighed 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 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

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 and uterus.]

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, non-treatment-related

Description (incidence and severity)

Transient salivation was observed in all males and females at 500 and 1,000 mg/kg bw/day.

Mortality

no mortality observed

Body weight and weight changes

effects observed, treatment-related

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

effects observed, treatment-related

Clinical biochemistry findings

effects observed, treatment-related

Urinalysis findings

no effects observed

Behaviour (functional findings)

no effects observed

Organ weight findings including organ / body weight ratios

effects observed, treatment-related

Gross pathological findings

no effects observed

Histopathological findings: non-neoplastic

effects observed, treatment-related

Histopathological findings: neoplastic

not examined

Details on results

CLINICAL SIGNS AND MORTALITY:

Mortality: There was no death.

Clinical signs: Transient salivation was observed in all males and females at 500 and 1,000 mg/kg bw/day.

DETAILED CLINICAL OBSERVATIONS, MANIPULATIVE TEST, GRIP STRENGTH TEST AND L OCOMOTOR ACTIVITY MEASUREMENT: There were no changes related to the test substance.

BODY WEIGHT:

[At the dosing period]

Depression of body weight gains were observed in males at 1000 mg/kg bw/day.

[At the recovery period]

There were no changes related to the test substance in any groups.

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

HAEMATOLOGY:

[At the end of dosing period]: Decrease in RBC, hemoglobin concentration and hematocrit value, and increases in reticulocyte count were observed in females at 1000 mg/kg bw/day.

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

CLINICAL CHEMISTRY:

[At the end of dosing period]: Increases in total cholesterol and Ca were observed in males at 500 mg/kg bw/day. Increase in total cholesterol were observed in males and females at 1000 mg/kg bw/day. Increase in ALT and Ca were observed in females at 1000 mg/kg bw/day.

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

URINALYSES OF MALES: There were no changes related to the test substance in any groups at the dosing and recovery periods.

ORGAN WEIGHTS:

[At the end of dosing period]

Increase in absolute and relative liver weights were observed in females at 500 and 1000 mg/kg bw/day. Increase in relative liver weights were observed in males at 500 and 1000 mg/kg bw/day groups. Increase in absolute and relative kidney weights were observed in males at 500 mg/kg bw/day. Increase in relative kidney weights were observed in males at 1000 mg/kg bw/day.

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

GROSS PATHOLOGY: There were no changes related to the test substance in any groups at the end of dosing and recovery periods.

HISTOPATHOLOGY: NON-NEOPLASTIC:

[At the end of dosing period]

Liver: Slightly centrilobular hypertrophy hepatocyte was observed in two males and three females at 500 mg/kg bw/day and three males and five females at 1000 mg/kg bw/day.

Kidney: Moderately basophilic change in the proximal tubule was observed in one male at 500 mg/kg bw/day and two males at 1000 mg/kg bw/day.

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

Effect levels

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 organ weights and organ / body weight ratios Increase in liver weight was observed in males and females at 500 mg/kg bw/day. histopathology: non-neoplastic Liver: Centrilobular hypertrophy hepatocyte was observed in males and females at 500 mg/kg bw/day or more.

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/PDF32492-61-8d.pdf

Applicant's summary and conclusion

Executive summary

A combined repeated-dose toxicity study with a reproduction/developmental toxicity screening test was performed in accordance with OECD TG422. Male and female rats (12 animals/sex/dose) were administered 4,4'-Isopropylidenediphenol, ethoxylated at 0 (vehicle: olive oil), 30, 120, 500, and 1,000 mg/kg bw/day. Including a 14-day pre-mating period and a subsequent mating period, males were dosed for 42 days. Females were dosed for 42–47 days, including 14-day pre-mating, mating, and gestation periods, until lactation day 4. Of the 12 males dosed at 0 and 1,000 mg/kg bw/day, 5 were treated as a recovery group. Five additional females receiving 0 and 1,000 mg/kg bw/day were treated as a satellite group. These females were dosed with 4,4'-Isopropylidenediphenol, ethoxylated for 42 days, without mating, and examined after a 14-day recovery.

Decreased body weight was observed in males in the 1,000 mg/kg bw/day group. Decreases in RBC, hemoglobin and hematocrit and increases in the reticulocyte of females in the 1,000 mg/kg bw/day group were observed toward the end of the administration period. The total cholesterol and Ca levels were increased in males receiving 500 and 1,000 mg/kg bw/day and in females at 1,000 mg/kg bw/day. Increases in ALT were observed in females at 1000 mg/kg bw/day. In both sexes, the absolute and/or relative liver weights were increased at 500 mg/kg bw/day and greater. Relative kidney weight were also greater in males at 500 mg/kg bw/day and greater. Histopathological analysis also revealed a hypertrophy of centrilobular hepatocytes for both sexes as well as a basophilic tubule of the kidney in males at 500 and 1,000 mg/kg bw/day. Such changes were no longer observed after the recovery period. Judging from the effects on the liver and kidney of the 4,4'-Isopropylidenediphenol, ethoxylated at 500 mg/kg bw/day, it was concluded that the NOAEL for the repeated-dose toxicity in rats was 120 mg/kg bw/day.

Genetic toxicity in vitro

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.001

UUID: f374b9fd-1bad-4b60-9026-a0c04477715d

Dossier UUID:

Author: SuperUser

Date: 2019-09-03T15:58:32.321+09:00

Remarks:

Administrative data

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\(oxy-1,2-ethanediyl\),alpha,alpha'- \[\(1-methylethylidene\)di-4,1-phenylen... / Ministry of Health, Labour and Welfare \(MHLW\), 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

GLP compliance

yes

Type of assay

bacterial reverse mutation assay
in vitro gene mutation study in bacteria

Test material

Test material information

[poly\(oxy-1,2-ethanediyl\),alpha,alpha'-\[\(1-methylethylidene\)di-4,1-phenylene\]bis\[omega-hydroxy-](#)

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: Rat liver, induced with phenobarbital and 5,6-benzoflavone

Test concentrations with justification for top dose

Dosage of each strain with or without S9 mix

-S9 mix: 0, 62.5, 125, 250, 500, 1000 and 2000 µg /plate (TA strains) and 156, 313, 625, 1250, 2500, and 5000 µg/plate (E. coli WP2)

+S9 mix: 0, 156, 313, 625, 1250, 2500, 5000 µg /plate (All strains)

Maximum concentration was established based on the result of the preliminary test at concentration up to 5000 ug/plate. In this test, the growth inhibition was observed at 2000 µg/plate and higher for S. typhimurium TA100, TA1535, TA98 and TA1537 without S9 mix.

Vehicle

DMSO

Controls

Negative controls

no

Solvent controls

yes

True negative controls

no

Positive controls

yes

Positive control substance

9-aminoacridine

without S9 mix (TA1537)

sodium azide

without S9 mix (TA1535)

other: 2-(2-Furyl)-3-(5-nitro -2-furyl)acrylamide (without S9 mix TA100, TA98, WP2uvrA), 2-Aminoanthracene (with S9 mix 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

yes at 1000 µg/plate (-S9mix), 2500 and 5000 µg/plate (+S9 mix)

Vehicle 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

yes at 2000 µg/plate (-S9 mix), 2500 and 5000 µg/plate (+S9 mix)

Vehicle 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

yes at 2000 µg/plate (-S9 mix), 2500 and 5000 µg/plate (+S9 mix)

Vehicle 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

yes at 2000 µg/plate (-S9 mix), 2500 and 5000 µg/plate (+S9 mix)

Vehicle 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

Positive controls valid

yes

Additional information on results

There were no precipitation in any test concentration.

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/PDF32492-61-8e.pdf

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

Overall remarks, attachments _____**Attached background material****Attached document**

32492618 Ames.xlsx / 42.643 KB (application/vnd.openxmlformats-officedocument.spreadsheetml.sheet)

Remarks

Tables for Ames test

Applicant's summary and conclusion _____**Conclusions**

In a bacterial reverse mutation assay using *S. typhimurium* TA100, TA1535, TA98, and TA1537, and *E. coli* WP2uvrA/pKM101 (OECD TG 471), negative results were obtained for poly(oxy-1,2-ethanediyl),alpha,alpha'-[(1-methylethylidene)di-4,1-phenylene]bis[omega-hydroxy- with or without metabolic activation.

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.002

UUID: bd9559d0-e698-4b78-a7f3-891552987e48

Dossier UUID:

Author: SuperUser

Date: 2019-09-03T15:58:59.641+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\(oxy-1,2-ethanediyl\),alpha,alpha'- \[\(1-methylethylidene\)... / MHLW, Japan / study report](#)

Data access

data published

Materials and methods

Test guideline

Qualifier

according to

Guideline

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

Qualifier

according to

Guideline

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

GLP compliance

yes

Test material**Test material information**

[poly\(oxy-1,2-ethanediyl\),alpha,alpha'-\[\(1-methylethylidene\)di-4,1-phenylene\]bis\[omega-hydroxy-](#)

Specific details on test material used for the study

- Lot No.: L3-6S004-A (Sanyo Chemical Industries, Ltd.)
- Purity: >99%
- Solubility: insoluble in water
- Physical state: Colorless liquid
- Storage condition of test material: in cool (2-6 degree C) and dark place

Method**Species / strain****Species / strain**

other:

Details on mammalian cell lines (if applicable)

Chinese hamster lung(CHL/IU) cell

Metabolic activation

with and without

Metabolic activation system

S9 mix: Rat liver, induced with phenobarbital and 5,6- benzoflavone

Test concentrations with justification for top dose

Cell-growth inhibition test was conducted up to the limited concentration of 3000 µg/mL (maximum concentration to be prepared)

- Short term treatment, +/-S9 mix: concentration of 50% cell-growth inhibition was determined as 375-750 µg/mL
- Continuous treatment (24 h): concentration of 50% cell-growth inhibition was determined as 187.5-375 µg/mL
- Continuous treatment (48 h): concentration of 50% cell-growth inhibition was determined as 187.5 µg/mL

Vehicle

DMSO

Controls**Negative controls**

no

Solvent controls

yes

True negative controls

no

Positive controls

yes

Positive control substance

other: 1-Methyl-3nitro-1-nitrosoguanidine (without S9 mix) 3,4-Benzo[a]pyrene (with S9 mix)

Details on test system and conditions

METHOD OF APPLICATION: Exposure duration: [short-term treatment]:6 hrs + 18 hr, [continuous treatment]: 24h

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

Plates/test: 4

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

true

Species / strain

other: Chinese hamster lung(CHL/IU) cells

Metabolic activation

with and without

Genotoxicity

positive

Cytotoxicity

yes

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/PDF32492-61-8f.pdf

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

Overall remarks, attachments

Attached background material

Attached document

32492-61-8 Chromosome.xlsx / 50.783 KB (application/vnd.openxmlformats-officedocument.spreadsheetml.sheet)

Remarks

Tables for chromosome aberration tests

Applicant's summary and conclusion

Conclusions

Poly(oxy-1,2-ethanediyl),alpha,alpha'- [(1-methylethylidene)di-4,1-phenylene]bis[omega-hydroxy-induced structural aberrations for the short-term study with and without S9 mix. Positive and vehicle control groups were valid.

Executive summary

In an in vitro chromosomal aberration test using CHL/IU cells (OECD TG 473), positive results were obtained with or without metabolic activation.

Toxicity to reproduction

ENDPOINT_STUDY_RECORD: Toxicity to reproduction.001

UUID: 127203f9-63e8-4583-90a4-8ce936e9259b

Dossier UUID:

Author: SuperUser

Date: 2019-03-27T10:07:42.141+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\(oxy-1,2-ethanediyl\),alpha,alpha'- \[\(1-methylethylidene\)di-4,1-phenylene\]bis\[omega-hydroxy- / 32...](#)

Data source

Reference

[A combined repeated dose/reproductive developmental toxicity study of 4,4'-Isopropylidenediphenol, e... / 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, ethoxylated
- 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: Crl:CD(SD)

Sex

male/female

Details on test animals 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 361 g (334-396 g), female 235 g (216-260 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: 22.1-25.0°C)
- Humidity (%): 55±10% (actual humidity: 46-60%)
- 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: 42-47 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)
Dose / conc.	
1000	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 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 of 1000 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 and 500 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 500 mg/kg bw/day or more, salivation, low value trend of urinary ketone bodies, high value trend of total cholesterol and liver weight were observed. At 1000 mg/kg bw/day, high value trend of blood calcium, and reduced prothrombin time 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 females 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 WEIGHT: 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 and uterus.]

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 metaeatus 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, non-treatment-related

Description (incidence and severity)

See 7.5.1

Mortality

no mortality observed

Body weight and weight changes

effects observed, treatment-related

Description (incidence and severity)

See 7.5.1

Food consumption and compound intake (if feeding study)

no effects observed

Food efficiency

not examined

Water consumption and compound intake (if drinking water study)

not examined

Ophthalmological findings

not examined

Haematological findings

effects observed, treatment-related

Description (incidence and severity)

See 7.5.1

Clinical biochemistry findings

effects observed, treatment-related

Description (incidence and severity)

See 7.5.1

Urinalysis findings

no effects observed

Behaviour (functional findings)

no effects observed

Immunological findings

not examined

Organ weight findings including organ / body weight ratios

effects observed, treatment-related

Description (incidence and severity)

See 7.5.1

Gross pathological findings

no effects observed

Neuropathological findings

not examined

Histopathological findings: non-neoplastic

effects observed, treatment-related

Description (incidence and severity)

See 7.5.1

Histopathological findings: neoplastic

not examined

Reproductive function / performance (P0)

Reproductive function: estrous cycle

no effects observed

Reproductive function: sperm measures

no effects observed

Reproductive performance

no effects observed

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

other: No effects on reproduction

Results: F1 generation _____

General toxicity (F1) _____

Clinical signs

no effects observed

Mortality / viability

no mortality observed

Body weight and weight changes

no effects observed

Gross pathological findings

no effects observed

Effect levels (F1) _____

Key result

true

Dose descriptor

NOAEL

Generation

F1

Effect level

1000

mg/kg bw/day (actual dose received)

Based on

test mat.

Sex

male/female

Basis for effect level

other: No effects on development

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/PDF32492-61-8d.pdf

Applicant's summary and conclusion

Executive summary

In the combined repeated-dose toxicity study together with a toxicity screening test of reproduction and development (OECD TG422) described above, reproduction and development were not observed to be affected. The NOAEL for the toxicity of 4,4'-isopropylidenediphenol, ethoxylated to rat reproduction and development was estimated to be 1,000 mg/kg bw/day (the highest dose tested).

References

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

UUID: c3bab17e-0137-47ed-b811-e57f1f580c8c

Dossier UUID:

Author: SuperUser

Date: 2019-03-22T10:30:43.000+09:00

Remarks:

General information

Reference Type

study report

Title

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

Author

Ministry of Health, Labor and Welfare, Japan

Bibliographic source

Japan Existing Chemical Data Base (JCDB)

Testing facility

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

Report no.

06-123

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

UUID: 73366170-1230-469e-8ac5-4388a11e323c

Dossier UUID:

Author: SuperUser

Date: 2019-02-15T09:57:10.306+09:00

Remarks:

General information

Reference Type

study report

Title

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

Author

MHLW, Japan

Bibliographic source

http://dra4.nihs.go.jp/mhlw_data/jsp/SearchPageENG.jsp

Testing facility

Research Institute for Animal Science in Biochemistry and Toxicology (RIAS)

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

Contact address

Address 1

Tonomachi 3-25-26

Address 2

Kawasaki-ku

Postal code

210-9501

Town

Kawasaki

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

UUID: 2a195910-823f-4f39-9d75-df85cfc04647**Dossier UUID:****Author:** SuperUser**Date:** 2019-02-13T16:15:41.279+09:00**Remarks:**

General information

Reference substance name

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

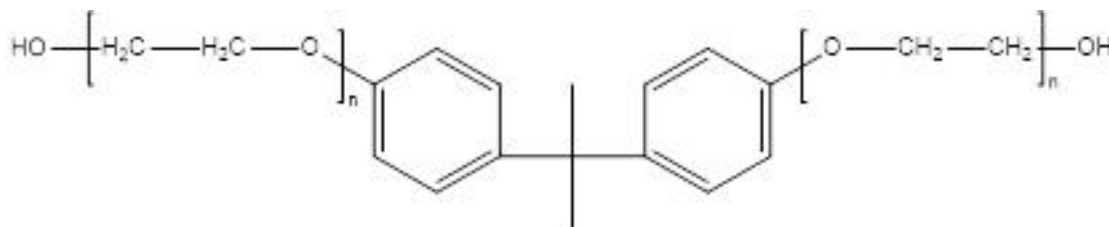
Reference substance information

CAS information

CAS number

32492-61-8

Molecular and structural information

Structural formula**Remarks**

[Molar ratio] 1 mole:0.0%, 2 moles: 5.6%, 3 moles: 16.9%, 4 moles:23.3%, 5 moles: 21.1%, 6 moles: 15.8%, 7 moles: 8.2%, 8 moles: 4.0%, >= 9 moles: 5.1%

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

UUID: 58a72914-84d0-48e3-986e-f8e6d37e3d07

Dossier UUID:

Author: SuperUser

Date: 2019-02-13T16:31:11.137+09:00

Remarks:

Name

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

Composition

Reference substance

poly(oxy-1,2-ethanediyl),alpha,alpha'- [(1-methylethylidene)di-4,1-phenylene]bis[omega-hydroxy- / 32492-61-8

EC number

EC name

CAS number

CAS name

32492-61-8

IUPAC name

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

UUID: b4cfffab-f224-43b9-89b6-ad7d9aa6328c

Dossier UUID:

Author: SuperUser

Date: 2019-02-13T16:02:43.377+09:00

Remarks:

General information

Reference Type

study report

Title

Reverse Mutation Test of poly(oxy-1,2-ethanediyl),alpha,alpha'- [(1-methylethylidene)di-4,1-phenylene]bis[omega-hydroxy-

Author

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

Bibliographic source

JECDB(http://dra4.nihs.go.jp/mhlw_data/jsp/SearchPageENG.jsp)

Testing facility

Research Institute for Animal Science in Biochemistry and Toxicology (RIAS)