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**Name:** Poly(vinylidene fluoride) / 24937-79-9

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**Legal entity owner:** National Institute of Health Sciences, Japan

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**Printing date:** 2020-10-01T13:57:38.195+09:00

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# Poly(vinylidene fluoride)

## CORE

### General information

#### FIXED\_RECORD: Assessment approach

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**UUID:** 13df30ec-da98-39fe-86c8-ad15f57e5bde

**Dossier UUID:**

**Author:** SuperUser

**Date:** 2020-03-24T16:02:19.000+09:00

**Remarks:**

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# OECD

## Health Effects

### Repeated dose toxicity: oral

ENDPOINT\_STUDY\_RECORD: Repeated dose toxicity: oral.001

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**UUID:** 6b72b7b2-9dae-4e5c-8848-0458217e8135

**Dossier UUID:**

**Author:** SuperUser

**Date:** 2020-10-01T11:37:56.338+09:00

**Remarks:**

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## Administrative data

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**Endpoint**

short-term repeated dose toxicity: oral

**Type of information**

experimental study

**Adequacy of study**

key study

**Robust study summary**

false

**Used for classification**

false

**Used for SDS**

false

**Reliability**

1 (reliable without restriction)

**Rationale for reliability incl. deficiencies**

other: The study was conducted in accordance with Test Guidelines and under GLP

**Cross-reference**

**Reason / purpose**

reference to same study 7.8.1 Toxicity to reproduction: Toxicity to reproduction. 001

**Related information**

[OECD / Toxicity to reproduction / Toxicity to reproduction.001 / Poly\(vinylidene fluoride\) / 24937-79-9](#)

## Data source

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**Reference**

[Combined repeated dose toxicity study with the reproductive/developmental toxicity screening test of... / Ministry of Health, Labour and Welfare \(MHLW\), Japan / study report](#)

**Data access**

data published

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## Materials and methods

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### 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

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**Test material information**

Poly(vinylidene fluoride)

**Specific details on test material used for the study**

- Name of test material (as cited in study report): Ethene, 1,1-difluoro-, homopolymer
- Analytical purity: 100%
- Storage condition of test material: Cold and dark place (3 - 6°C)
- Stability under test conditions: The stability of test material was identified by analysis of the remainder.

## Test animals

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**Species**

rat

common rodent species

**Strain**

other: Crl:CD(SD)

**Sex**

male/female

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

- Source: Charles River Japan, Inc., Atsugi Breeding Center.
- Age at study initiation: 10 weeks old
- Weight at study initiation: Male: 383 g (353-423 g), Female: 246 g (224-270 g)
- Housing: Animals were individually housed in bracket-type metallic wire-mesh cages (254W × 350D × 170H mm), from gestation day 17 to lactation day 4, Dams were bred individually or with individual littermates in plastic cages (340W x 400D x 185H mm) and bedding.
- Diet: Solid feed (NMF: Oriental Yeast Co., Ltd.) was given ad libitum.
- Water: Tap water was given ad libitum.
- Acclimation period: 17 days

**ENVIRONMENTAL CONDITIONS**

- Temperature (°C): 23±3 (actual temperature: 23-25°C)

- Humidity (%): 50±20% (actual humidity: 38-54%)
- Air changes (per hr): 10-15
- Photoperiod (hrs dark / hrs light): 12 hr dark/12 hr light (light: 7:00~19:00)

## Administration / exposure

### Route of administration

oral: gavage

### Vehicle

corn oil

### Details on oral exposure

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

### Analytical verification of doses or concentrations

yes

### Details on analytical verification of doses or concentrations

Test suspensions at each concentration to be used for males in week 1 and six week of administration were analyzed by gravimetric method at BoZo Research Center Inc. Results showed that the concentration of test article in each concentration was 99.0 to 102.5% of the nominal concentration and both values were within the acceptable range (concentration: percentage of nominal concentration, 100±10%)

### Duration of treatment / exposure

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

(P) Females: 42-46 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

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

### No. of animals per sex per dose

Main group: 12 females/dose (0, 100, 300, and 1000 mg/kg bw/day), 7, 12, 12, and 7 males/dose (0, 100, 300, and 1000 mg/kg bw/day)

Satellite group: 5 females/dose (0 and 1000 mg/kg bw/day)

Recovery group: 5 males/dose and 5 females (satellite group)/dose (0 and 1000 mg/kg bw/day)

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### **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 100 mg/kg bw/day was selected as an expected no toxic dose. The middle dose levels of 300 mg/kg bw/day were selected.

[14-day preliminary study]

A 14-day repeated dose oral toxicity test (CrI:CD(SD) rats, doses: 0, 100, 300 or 1000 mg/kg bw/day). Even in the 1000 mg/kg bw/day group, no effects related to the test substance were observed in general condition, body weight, food consumption, hematology, blood biochemistry, organ weight, and necropsy.

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

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## **Examinations**

### **Observations and examinations performed and frequency**

CAGE SIDE OBSERVATIONS: Yes

- Time schedule: 3 times/day (before administration, immediately after administration and 2 hours after administration) during the administration period. Once a day during the recovery period.

DETAILED CLINICAL OBSERVATIONS: Yes

- Time schedule:

Male main and female satellite groups: once before the start of administration, once every weekly during the administration.

Female main group: once before the start of administration, days 1, 7, 14 and 20 of gestation, and day 4 of lactation.

Male and female recovery groups: once before the start of administration, once every weekly during the administration and recovery periods.

BODY WEIGHT: Yes

- Time schedule for examinations:

Males in the main and females satellite groups were weighed on days 1, 4, 8, 11, 15, 18, 22, 25, 29, 32, 36, 39 and 42 of administration and on the day of necropsy, and males and females in the recovery groups were weighed on days 1, 4, 8, 11 and 14 of recovery and on the day of necropsy in addition to the measurement days for males in the main groups.

Females in the main groups were weighed on days 1, 4, 8, 11 and 15 of administration (uncopulated animals were weighed on days 18 and 22 of administration as well), days 0, 4, 7, 11, 14, 17 and 20 of gestation, days 0 and 4 of lactation and the day of necropsy.

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 females satellite groups on days 1, 4, 8, 11, 15, 32, 36, 39 and 42 of administration; males and females in the recovery groups on days 1, 4, 8, 11 and 14 of recovery in addition to the measurement days for males in the main groups; and females in the main groups on days 1, 4, 8, 11 and 15 of administration, days 1, 4, 7, 11, 14, 17 and 20 of gestation and days 2 and 4 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

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- How many animals:

All animals/sex/group (Control and 1000 mg/kg/day),

5 animals/sex/group (100 and 300 mg/kg/day)

- Parameters examined: red blood cell count, hemoglobin, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, reticulocyte percentage, platelet count, white blood cell count, differential white blood cell count, absolute number of each white blood cell, prothrombin time, activated partial thromboplastin time, fibrinogen.

**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:

All animals/sex/group (Control and 1000 mg/kg/day),

5 animals/sex/group (100 and 300 mg/kg/day)

- Parameters checked: ALP, total cholesterol, triglyceride, phospholipids, total bilirubin, glucose, blood urea nitrogen, creatinine, sodium, potassium, chloride, calcium, inorganic phosphorus, total protein, albumin, A/G ratio, AST (GOT), ALT (GPT), LDH,  $\gamma$ -GTP

**URINALYSIS:** Yes

- Time schedule for collection of urine: final week of administration (days 36 to 37 of administration) and in the final week of recovery (days 8 to 9 of recovery)

- Metabolism cages used for collection of urine: Yes

A urine collector to collect four-hour urine samples under fasting but ad libitum drinking conditions, followed by collection of 20-hour urine samples under ad libitum feeding and drinking conditions.

- How many animals: 5 animals/group

- Parameters checked: pH, protein, ketones, glucose, occult blood, bilirubin, urobilinogen, color, sediment, urine volume (4-hour volume), osmotic pressure, urine volume (20-hour volume), water intake (24-hour volume)

**BLOOD HORMONE:** Yes

- Time schedule for collection of serum: Same as clinical chemistry

- Animals fasted: Yes

- How many animals:

All animals/sex/group (Control and 1000 mg/kg/day),

5 animals/sex/group (100 and 300 mg/kg/day)

- Parameters checked: Triiodothyronine (T3), Thyroxine (T4), and thyroid stimulating hormone (TSH)

**NEUROBEHAVIOURAL EXAMINATION:** Yes

- Time schedule for examinations:

Males in the main groups: final week of administration (day 40 of administration)

Females in the main groups: lactation day 4 (day 42 to day 44 of administration) after necropsy of F1 pups

Males and females in the recovery groups: final week of administration (day 40 of administration) and in the final week of recovery (day 12 of recovery).

- Dose groups that were examined: All dose groups (5 animals/sex/group)

- Battery of functions tested:

1) Manipulative Test. Auditory response, approach response, touch response, tail pinch response, pupillary reflex, aerial righting reflex, landing foot splay

2) Measurement of Grip Strength. Following manipulative test, grip strength of forelimb and hind limb was measured by CPU gauge MODEL-RX-5 (AIKOH Engineering Co., Ltd.).

3) Measurement of Motor Activity. Following measurement of grip strength, motor activity was measured by a motor activity sensor for experimental animals NS-AS01 (Neuro Science, Inc). The measurement was conducted for 1 hour, and measured values at 10-minute intervals and from 0 to 60 minutes were collected.

**Sacrifice and pathology**

**GROSS PATHOLOGY:** Yes



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ORGAN WEIBHT: Yes [brain, pituitary, thyroids (including parathyroids), adrenal gland, thymus, spleen, heart, liver, kidney, testis, epididymis, ovary, uterus]

HISTOPATHOLOGY: Yes, [cerebrum, cerebellum (including pons) , pituitary, spinal cord (thoracic), sciatic nerve, eye ball, thyroid, parathyroid, adrenal glands, thymus, spleen, submandibular lymph nodes, mesenteric lymph nodes, heart, trachea, lung (including bronchial), stomach, duodenum, jejunum, ileum, cecum, colon, rectum, liver, kidney, bladder, testis, epididymis, ovary, uterus, vagina, prostate, seminal vesicles, sternum and femur (including bone marrows),and macroscopic lesions]

### **Statistics**

The data were analyzed for homogeneity of variance by the Bartlett test. If variances were homogeneous, data was analyzed by the Dunnett test, whereas heterogeneous data was analyzed by the Dunnett type mean rank test ( $p < 0.05$ , two-sided).

In the recovery test, these values of two groups were analyzed by F test. If variances were homogeneous, data was analyzed by the Student t-test, whereas heterogeneous data was analyzed by the Aspin-Welch t-test ( $p < 0.05$ , two-sided).

## **Results and discussion**

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### **Results of examinations**

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#### **Clinical signs**

no effects observed

#### **Mortality**

no mortality observed

#### **Body weight and weight changes**

no effects observed

#### **Food consumption and compound intake (if feeding study)**

no effects observed

#### **Food efficiency**

not examined

#### **Water consumption and compound intake (if drinking water study)**

not examined

#### **Ophthalmological findings**

not examined

#### **Haematological findings**

no effects observed

#### **Clinical biochemistry findings**

no effects observed

#### **Description (incidence and severity)**

Including blood hormones (T3, T4, TSH)

#### **Urinalysis findings**

no effects observed

#### **Behaviour (functional findings)**

no effects observed

#### **Immunological findings**

not examined

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**Organ weight findings including organ / body weight ratios**

effects observed, treatment-related

**Gross pathological findings**

no effects observed

**Neuropathological findings**

not examined

**Histopathological findings: non-neoplastic**

no effects observed

**Histopathological findings: neoplastic**

not examined

**Details on results****CLINICAL SIGNS AND MORTALITY:**

Mortality: There was no death.

Clinical signs: There were no effects related to the test substance in any groups at the dosing and recovery periods.

DETAILED CLINICAL OBSERVATIONS: There were no changes related to the test substance in any groups at the dosing and recovery periods.

**BODY WEIGHT:**

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

**FOOD CONSUMPTION:**

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

**URINALYSIS:**

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

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

**HAEMATOLOGY:**

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

**CLINICAL CHEMISTRY (Including blood hormones (T3, T4, TSH)):**

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

**ORGAN WEIGHTS:**

[At the end of dosing period]: Increases in absolute and relative weights of pituitary were observed in mating females receiving 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:**

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

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## Effect levels

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

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## Any other information on results incl. tables

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

[https://dra4.nihs.go.jp/mhlw\\_data/home/pdf/PDF24937-79-9d.pdf](https://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF24937-79-9d.pdf)

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## Applicant's summary and conclusion

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**Conclusions**

The NOAEL for the rat repeated dose toxicity of poly(vinylidene fluoride) was regarded as 1000 mg/kg bw/day, the highest dose tested.

**Executive summary**

A combined repeated-dose toxicity study with the reproduction/developmental toxicity screening test was done according to OECD TG 422. Male and female rats (12 animals/sex/dose) were administered with poly(vinylidene fluoride) via oral gavage at doses of 0 [vehicle: corn oil], 100, 300, and 1,000 mg/kg bw/day. Males (12/dose) were treated with poly(vinylidene fluoride) for 42 days, which include a 14-day pre-mating period and a subsequent mating period, while females (12/dose) were treated for 42–46 days, including 14-day pre-mating, mating, and gestation periods until lactation day 4. Among the 12 males that were treated with 0 and 1,000 mg/kg bw/day, 5 were assigned as the recovery group. Additional 10 females administered with 0 and 1,000 mg/kg bw/day were assigned as a satellite group and treated with poly(vinylidene fluoride) for 42 days, with no mating, and examined after a 14-day recovery period.

No deaths were recorded, and there are no changes in clinical signs, manipulative test, grip strength, motor activity, body weight, food consumption, urinalysis, hematology, blood chemistry, gross pathological findings, and histopathological findings as a result of treatment in any of the dose groups for both males and females at the end of the treatment and recovery periods. Although absolute and

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relative weights of pituitary were significantly increased in the mating group females receiving 1,000 mg/kg bw/day at the end of the administration period, these changes were not considered to be adverse effects since there were no histological abnormalities and effect on endocrine organs observed. Since there is no toxicological alteration, the NOAEL for repeated-dose toxicity of poly(vinylidene fluoride) was 1,000 mg/kg bw/day in rats.

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## Genetic toxicity in vitro

ENDPOINT\_STUDY\_RECORD: Genetic toxicity in vitro.001

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**UUID:** a0f7c7bc-890b-49f4-acce-b078078cdd0c

**Dossier UUID:**

**Author:** SuperUser

**Date:** 2020-03-26T15:48:56.248+09:00

**Remarks:**

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## Administrative data

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### Endpoint

in vitro gene mutation study in bacteria

### Type of information

experimental study

### Adequacy of study

key study

### Robust study summary

false

### Used for classification

false

### Used for SDS

false

### Reliability

1 (reliable without restriction)

### Rationale for reliability incl. deficiencies

other: OECD Test Guideline study under GLP condition

## Data source

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### Reference

[Reverse Mutation Test of Ethene, 1,1-difluoro-, homopolymer on Bacteria. / Ministry of Health, Labour and Welfare \(MHLW\), Japan / study report](#)

### Data access

data published

## Materials and methods

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### Test guideline

#### Qualifier

according to

#### Guideline

OECD Guideline 471 (Bacterial Reverse Mutation Assay)  
in vitro gene mutation study in bacteria

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**Deviations**

no

**GLP compliance**

yes

**Type of assay**

bacterial reverse mutation assay  
in vitro gene mutation study in bacteria

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**Test material****Test material information**

Poly(vinylidene fluoride)

**Specific details on test material used for the study**

- Name of test material (as cited in study report): Ethene, 1,1-difluoro-, homopolymer  
- Analytical purity: 100%

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**Method****Species / strain****Species / strain / cell type**

S. typhimurium TA 1535, TA 1537, TA 98 and TA 100  
bacteria

**Species / strain / cell type**

E. coli WP2 uvr A pKM 101  
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**

-S9 mix:

2.44, 4.88, 9.77, 19.5, 39.1, 78.1 µg/plate (TA100, TA1535, TA98, TA1537 strains)

313, 625, 1250, 2500, 5000 µg/plate (WP2uvrA/pKM101 strain)

+S9 mix:

313, 625, 1250, 2500, 5000 µg/plate (TA100, TA1535, TA98, TA1537 strains),

313, 625, 1250, 2500, 5000 µg/plate (WP2uvrA/pKM101 strain)

Maximum concentration was established based on the result of the preliminary test at concentration up to 5000 µg/plate. In this test, the growth inhibition was observed at 78.1 µg/plate and above for S. typhimurium TA strains without S9 mix.

**Vehicle / solvent**

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

**Controls****Untreated negative controls**

no

**Negative solvent / vehicle controls**

yes

**True negative controls**

no

**Positive controls**

yes

**Positive control substance**

other: -S9 mix: 2-(2-Furyl)-3-(5-nitro-2-furyl) acrylamide, sodium azide and 2-Methoxy-6-chloro-9-[3-(2-chloroethyl)-aminopropylamino]acridine 2HCl; +S9 mix: 2-aminoanthracene, benzo(a)pyrene

**Details on test system and experimental conditions**

METHOD OF APPLICATION: Preincubation

DURATION- Preincubation period: 20 min at 37°C

- Exposure duration: 48 or 48.5 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**

no

## Results and discussion

**Test results****Key result**

true

**Species / strain**

S. typhimurium TA 1535  
bacteria

**Metabolic activation**

with and without

**Genotoxicity**

negative

**Cytotoxicity / choice of top concentrations**

cytotoxicity -S9 mix: 39.1 µg/plate or more

**Vehicle controls validity**

valid

**Untreated negative controls validity**

not examined

**Positive controls validity**

valid

**Key result**

true

---

**Species / strain**

S. typhimurium TA 1537  
bacteria

**Metabolic activation**

with and without

**Genotoxicity**

negative

**Cytotoxicity / choice of top concentrations**

cytotoxicity -S9 mix: 39.1 µg/plate or more

**Vehicle controls validity**

valid

**Untreated negative controls validity**

not examined

**Positive controls validity**

valid

---

**Key result**

true

**Species / strain**

S. typhimurium TA 98  
bacteria

**Metabolic activation**

with and without

**Genotoxicity**

negative

**Cytotoxicity / choice of top concentrations**

cytotoxicity -S9 mix: 39.1 µg/plate or more

**Vehicle controls validity**

valid

**Untreated negative controls validity**

not examined

**Positive controls validity**

valid

---

**Key result**

true

**Species / strain**

S. typhimurium TA 100  
bacteria

**Metabolic activation**

with and without

**Genotoxicity**

negative



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**Cytotoxicity / choice of top concentrations**

cytotoxicity -S9 mix: 78.1 µg/plate or more

**Vehicle controls validity**

valid

**Untreated negative controls validity**

not examined

**Positive controls validity**

valid

**Key result**

true

**Species / strain**

E. coli WP2 uvr A pKM 101  
bacteria

**Metabolic activation**

with and without

**Genotoxicity**

negative

**Cytotoxicity / choice of top concentrations**

no cytotoxicity

**Vehicle controls validity**

valid

**Untreated negative controls validity**

not examined

**Positive controls validity**

valid

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**Any other information on results incl. tables**

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

[https://dra4.nihs.go.jp/mhlw\\_data/home/pdf/PDF24937-79-9e.pdf](https://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF24937-79-9e.pdf)

Please also see the attached files (Tables in English)

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

24937799.xlsx / 45.121 KB ( application/vnd.openxmlformats-officedocument.spreadsheetml.sheet)

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**Applicant's summary and conclusion**

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**Conclusions**

Interpretation of results (migrated information): negative

In a bacterial reverse mutation assay using *Salmonella typhimurium* TA100, TA1535, TA98, and TA 1537, and *Escherichia coli* WP2uvrA/pKM101 (OECD TG 471), poly(vinylidene fluoride) was negative with or without metabolic activation.

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## ENDPOINT\_STUDY\_RECORD: Genetic toxicity in vitro.002

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**UUID:** 3d730d72-66ac-4216-9f5c-81212252ee18

**Dossier UUID:**

**Author:** SuperUser

**Date:** 2020-03-18T15:31:25.000+09:00

**Remarks:**

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## Administrative data

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**Endpoint**

in vitro cytogenicity / chromosome aberration study in mammalian cells

**Type of information**

experimental study

**Adequacy of study**

key study

**Robust study summary**

false

**Used for classification**

false

**Used for SDS**

false

**Reliability**

1 (reliable without restriction)

**Rationale for reliability incl. deficiencies**

other: OECD Test Guideline study under GLP condition

## Data source

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**Reference**

[In Vitro Chromosomal Aberration Test of Ethene, 1,1-difluoro-, homopolymer on Cultured Chinese Hamst... / Ministry of Health, Labour and Welfare \(MHLW\), Japan / study report](#)

**Data access**

data published

## Materials and methods

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**Test guideline**

**Qualifier**

according to

**Guideline**

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

**Deviations**

no

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**Qualifier**

according to

**Guideline**

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

**Deviations**

no

**GLP compliance**

yes

**Type of assay**

other: in vitro mammalian chromosome aberration test

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**Test material****Test material information**

Poly(vinylidene fluoride)

**Specific details on test material used for the study**

- Name of test material (as cited in study report): Ethene, 1,1-difluoro-, homopolymer
- Analytical purity: 100%

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**Method****Species / strain****Species / strain / cell type**

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

- S9 mix (short-term treatment): 39.1, 78.1, 156, 313, 625, 1250, 2500, 5000 ug/mL
  - +S9 mix (short-term treatment): 39.1, 78.1, 156, 313, 625, 1250, 2500, 5000 ug/mL
  - S9 mix (continuous treatment, 24hr): 39.1, 78.1, 156, 313, 625, 1250, 2500, 5000 ug/mL
  - S9 mix (continuous treatment, 48hr): 39.1, 78.1, 156, 313, 625, 1250, 2500, 5000 ug/mL
- Main study
- S9 (short-term treatment): 512, 640, 800, 1000, 1250 ug/mL
  - +S9 (short-term treatment): 410, 512, 640, 800, 1000 ug/mL
  - S9 (continuous treatment, 24hr): 1020, 1280, 1600, 2000, 2500 ug/mL
  - S9 (continuous treatment, 48hr): 512, 640, 800, 1000, 1250 ug/mL

**Vehicle / solvent**

- Vehicle(s)/solvent(s) used: 0.5% CNC Na

**Controls****Untreated negative controls**

no

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**Negative solvent / vehicle controls**

yes

**True negative controls**

no

**Positive controls**

yes

**Positive control substance**

other: [-S9]: mitomycin C; [+S9]: cyclophosphamide

**Details on test system and experimental conditions**

METHOD OF APPLICATION: Exposure duration: [short-term treatment]:6 hrs + 18 hr, [continuous treatment]: 24, 48 hrs

SPINDLE INHIBITOR: Colcemid

STAIN: Giemsa stain (2 v/v%) for 15 min.

NUMBER OF REPLICATIONS: 2

NUMBER OF CELLS EVALUATED: 100 + 100 cells /concentration

DETERMINATION OF CYTOTOXICITY

- Method: relative total growth

**Evaluation criteria**

For the evaluation of the frequencies of structural aberrations and of polyploidy induced, the following criteria were employed. Appearance incidence of cell with chromosomal aberrations: Negative (-): less than 5%, Equivocal( $\pm$ ): 5% or more and less than 10%, Positive(+): 10% or more

**Statistics**

no

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**Results and discussion****Test results****Key result**

true

**Species / strain**

other: Chinese hamster lung (CHL/IU) cells

**Metabolic activation**

with and without

**Genotoxicity**

negative

**Cytotoxicity / choice of top concentrations**

no cytotoxicity

**Vehicle controls validity**

valid

**Untreated negative controls validity**

not examined

**Positive controls validity**

valid

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**Any other information on results incl. tables**

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

[https://dra4.nihs.go.jp/mhlw\\_data/home/pdf/PDF24937-79-9f.pdf](https://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF24937-79-9f.pdf)

## **Applicant's summary and conclusion**

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### **Conclusions**

Interpretation of results (migrated information): negative with or without metabolic activation

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

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## Toxicity to reproduction

### ENDPOINT\_STUDY\_RECORD: Toxicity to reproduction.001

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**UUID:** d0b6a385-1c2e-4eb6-b155-1a7213a45699

**Dossier UUID:**

**Author:** SuperUser

**Date:** 2020-10-01T11:42:26.266+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**

other: OECD Test Guideline study under GLP condition

**Cross-reference**

**Reason / purpose**

reference to same study 7.5.1 Repeated dose toxicity: oral: Repeated dose toxicity: oral. 001

**Related information**

[OECD / Repeated dose toxicity: oral / Repeated dose toxicity: oral.001 / Poly\(vinylidene fluoride\) / 24937-79-9](#)

## Data source

---

**Reference**

[Combined repeated dose toxicity study with the reproductive/developmental toxicity screening test of... / Ministry of Health, Labour and Welfare \(MHLW\), Japan / study report](#)

**Data access**

data published

## Materials and methods

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## Test guideline

**Qualifier**

according to

**Guideline**

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

**Deviations**

no

**GLP compliance**

yes

**Limit test**

no

---

## Test material

**Test material information**

[Poly\(vinylidene fluoride\)](#)

**Specific details on test material used for the study**

- Name of test material (as cited in study report): Ethene, 1,1-difluoro-, homopolymer
- Analytical purity: 100%
- Storage condition of test material: at a room temperature (15-23°C), protected from light
- 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: 383 g (353-423 g), Female: 246 g (224-270 g)
- Housing: Animals were individually housed in bracket-type metallic wire-mesh cages (254W × 350D × 170H mm), from gestation day 17 to lactation day 4, Dams were bred individually or with individual littermates in plastic cages (340W x 400D x 185H mm) and bedding.
- Diet: Solid feed (NMF: Oriental Yeast Co., Ltd.) was given ad libitum.
- Water: Tap water was given ad libitum.
- Acclimation period: 17 days

**ENVIRONMENTAL CONDITIONS**

- Temperature (°C): 23±3 (actual temperature: 23-25°C)
- Humidity (%): 50±20% (actual humidity: 38-54%)
- Air changes (per hr): 10-15
- Photoperiod (hrs dark / hrs light): 12 hr dark/12 hr light (light: 7:00~19:00)



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## Administration / exposure

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### Route of administration

oral: gavage

### Vehicle

corn oil

### Details on exposure

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

### Details on mating procedure

- M/F ratio per cage: 1/1
- Length of cohabitation: up to 4 days
- Proof of pregnancy: vaginal plug / sperm in vaginal smear referred to as day 0 of pregnancy

### Analytical verification of doses or concentrations

yes

### Details on analytical verification of doses or concentrations

Test suspensions at each concentration to be used for males in week 1 and six week of administration were analyzed by gravimetric method at BoZo Research Center Inc. Results showed that the concentration of test article in each concentration was 99.0 to 102.5% of the nominal concentration and both values were within the acceptable range (concentration: percentage of nominal concentration, 100±10%)

### Duration of treatment / exposure

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

(P) Females: 41-46 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

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

### No. of animals per sex per dose

Main group: 12 females/dose (0, 100, 300, and 1000 mg/kg bw/day), 7, 12, 12, and 7 males/dose (0, 100, 300, and 1000 mg/kg bw/day)

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Satellite group: 5 females/dose (0 and 1000 mg/kg bw/day)  
Recovery group: 5 males/dose and 5 females (satellite group)/dose (0 and 1000 mg/kg bw/day)

### **Control animals**

yes, concurrent no treatment

### **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 100 mg/kg bw/day was selected as an expected no toxic dose. The middle dose levels of 300 mg/kg bw/day were selected.

[14-day preliminary study]

A 14-day repeated dose oral toxicity test (CrI:CD(SD) rats, doses: 0, 100, 300 or 1000 mg/kg bw/day). Even in the 1000 mg/kg bw/day group, no effects related to the test substance were observed in general condition, body weight, food consumption, hematology, blood biochemistry, organ weight, and necropsy.

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

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## **Examinations**

### **Parental animals: Observations and examinations**

CAGE SIDE OBSERVATIONS: Yes

- Time schedule: 3 times/day (before administration, immediately after administration and 2 hours after administration) during the administration period. Once a day during the recovery period.

DETAILED CLINICAL OBSERVATIONS: Yes

- Time schedule:

Male main and female satellite groups: once before the start of administration, once every weekly during the administration.

Female main group: once before the start of administration, days 1, 7, 14 and 20 of gestation, and day 4 of lactation.

Male and female recovery groups: once before the start of administration, once every weekly during the administration and recovery periods.

BODY WEIGHT: Yes

- Time schedule for examinations:

Males in the main and females satellite groups were weighed on days 1, 4, 8, 11, 15, 18, 22, 25, 29, 32, 36, 39 and 42 of administration and on the day of necropsy, and males and females in the recovery groups were weighed on days 1, 4, 8, 11 and 14 of recovery and on the day of necropsy in addition to the measurement days for males in the main groups.

Females in the main groups were weighed on days 1, 4, 8, 11 and 15 of administration (uncopulated animals were weighed on days 18 and 22 of administration as well), days 0, 4, 7, 11, 14, 17 and 20 of gestation, days 0 and 4 of lactation and the day of necropsy.

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 females satellite groups on days 1, 4, 8, 11, 15, 32, 36, 39 and 42 of administration; males and females in the recovery groups on days 1, 4, 8, 11 and 14 of recovery in addition to the measurement days for males in the main groups; and females in the main groups on days 1, 4, 8, 11 and 15 of administration, days 1, 4, 7, 11, 14, 17 and 20 of gestation and days 2 and 4 of lactation.

OPHTHALMOSCOPIC EXAMINATION: No

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**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:  
All animals/sex/group (Control and 1000 mg/kg/day),  
5 animals/sex/group (100 and 300 mg/kg/day)
- Parameters examined: red blood cell count, hemoglobin, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, reticulocyte percentage, platelet count, white blood cell count, differential white blood cell count, absolute number of each white blood cell, prothrombin time, activated partial thromboplastin time, fibrinogen.

**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:  
All animals/sex/group (Control and 1000 mg/kg/day),  
5 animals/sex/group (100 and 300 mg/kg/day)
- Parameters checked: ALP, total cholesterol, triglyceride, phospholipids, total bilirubin, glucose, blood urea nitrogen, creatinine, sodium, potassium, chloride, calcium, inorganic phosphorus, total protein, albumin, A/G ratio, AST (GOT), ALT (GPT), LDH,  $\gamma$ -GTP

**URINALYSIS: Yes**

- Time schedule for collection of urine: final week of administration (days 36 to 37 of administration) and in the final week of recovery (days 8 to 9 of recovery)
- Metabolism cages used for collection of urine: Yes  
A urine collector to collect four-hour urine samples under fasting but ad libitum drinking conditions, followed by collection of 20-hour urine samples under ad libitum feeding and drinking conditions.
- How many animals: 5 animals/group
- Parameters checked: pH, protein, ketones, glucose, occult blood, bilirubin, urobilinogen, color, sediment, urine volume (4-hour volume), osmotic pressure, urine volume (20-hour volume), water intake (24-hour volume)

**BLOOD HORMONE: Yes**

- Time schedule for collection of serum: Same as clinical chemistry
- Animals fasted: Yes
- How many animals:  
All animals/sex/group (Control and 1000 mg/kg/day),  
5 animals/sex/group (100 and 300 mg/kg/day)
- Parameters checked: Triiodothyronine (T3), Thyroxin (T4), and thyroid stimulating hormone (TSH)

**NEUROBEHAVIOURAL EXAMINATION: Yes**

- Time schedule for examinations:  
Males in the main groups: final week of administration (day 40 of administration)  
Females in the main groups: lactation day 4 (day 42 to day 44 of administration) after necropsy of F1 pups  
Males and females in the recovery groups: final week of administration (day 40 of administration) and in the final week of recovery (day 12 of recovery).
- Dose groups that were examined: All dose groups (5 animals/sex/group)
- Battery of functions tested:
  - 1) Manipulative Test. Auditory response, approach response, touch response, tail pinch response, pupillary reflex, aerial righting reflex, landing foot splay
  - 2) Measurement of Grip Strength. Following manipulative test, grip strength of forelimb and hind limb was measured by CPU gauge MODEL-RX-5 (AIKOH Engineering Co., Ltd.).
  - 3) Measurement of Motor Activity. Following measurement of grip strength, motor activity was measured by a motor activity sensor for experimental animals NS-AS01 (Neuro Science, Inc). The

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measurement was conducted for 1 hour, and measured values at 10-minute intervals and from 0 to 60 minutes were collected.

#### **Oestrous cyclicity (parental animals)**

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

#### **Sperm parameters (parental animals)**

Parameters examined in all P male parental generations: testis weight, epididymis weight, histopathological examinations for testes, epididymides, seminal vesicle 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, and weight gain. GROSS EXAMINATION OF DEAD PUPS: Yes, for external and internal abnormalities.

#### **Postmortem examinations (parental animals)**

METHOD OF SACRIFICED: All animals were sacrificed by exsanguination under ether anesthesia. SACRIFICE: Male main and female satellite animals: On next day after the last administration (Day 43), Maternal animals: on Day 4 of lactation, and male and females recovery animals: on Day 14 of recovery.

GROSS PATHOLOGY: Yes

ORGAN WEIGHT: Yes [brain, pituitary, thyroids (including parathyroids), adrenal gland, thymus, spleen, heart, liver, kidney, testis, epididymis, ovary, uterus]

HISTOPATHOLOGY: Yes, [cerebrum, cerebellum (including pons), pituitary, spinal cord (thoracic), sciatic nerve, eye ball, thyroid, parathyroid, adrenal glands, thymus, spleen, submandibular lymph nodes, mesenteric lymph nodes, heart, trachea, lung (including bronchial), stomach, duodenum, jejunum, ileum, cecum, colon, rectum, liver, kidney, bladder, testis, epididymis, ovary, uterus, vagina, prostate, seminal vesicles, sternum and femur (including bone marrows), and macroscopic lesions]

#### **Postmortem examinations (offspring)**

SACRIFICE

- The F1 offsprings were euthanized on PND4 by exsanguination under ether anesthesia.

GROSS NECROPSY: Yes

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

HISTOPATHOLOGY / ORGAN WEIGHTS

- Not examined.

#### **Statistics**

The data were analyzed for homogeneity of variance by the Bartlett test. If variances were homogeneous, data was analyzed by the Dunnett test, whereas heterogeneous data was analyzed by the Dunnett type mean rank test ( $p < 0.05$ , two-sided).

In the recovery test, these values of two groups were analyzed by F test. If variances were homogeneous, data was analyzed by the Student t-test, whereas heterogeneous data was analyzed by the Aspin-Welch t-test ( $p < 0.05$ , two-sided).

#### **Reproductive indices**

Each parameter was determined by the following equations:

Copulation index (%) = (No. of copulated animals / No. of mated animals) × 100

Fertility index (%) = (No. of pregnant females / No. of copulated females) × 100

Insemination index (%) = (No. of impregnated males / No. of copulated males) × 100

Gestation length (days) = No. of days from pregnancy 0 to delivery 0

Delivery index (%) = (No. of females which delivered liveborns / No. of pregnant females) × 100

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

Stillborn index (%) = (No. of stillborn / No of liveborns and stillborns) × 100

Live birth index (%) = (No. of liveborn / No. of implantation sites) × 100

---

External abnormalities (%) = (No. of pups with external abnormalities / No. of liveborns) × 100  
Sex ratio = No. of liveborns males / No. of liveborns

**Offspring viability indices**

Viability index on postnatal day 4 (%) = (No. of live pups on day 4 / No. of liveborns on day 0) × 100

## Results and discussion

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### Results: P0 (first parental generation)

---

#### General toxicity (P0)

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**Clinical signs**

no effects observed

**Mortality**

no mortality observed

**Body weight and weight changes**

no effects observed

**Food consumption and compound intake (if feeding study)**

no effects observed

**Food efficiency**

not examined

**Water consumption and compound intake (if drinking water study)**

not examined

**Ophthalmological findings**

not examined

**Haematological findings**

no effects observed

**Clinical biochemistry findings**

no effects observed

**Description (incidence and severity)**

Including blood hormones (T3, T4, TSH)

**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**

no effects observed

**Histopathological findings: neoplastic**

not examined

---

**Reproductive function / performance (P0)****Reproductive function: oestrous cycle**

no effects observed

**Reproductive function: sperm measures**

not examined

**Reproductive performance**

no effects observed

---

**Details on results (P0)****1) Estrous Cycle**

There were no animals showing abnormal estrous cycles, and there were no significant differences in the average length of the estrous cycle between the control group and any treatment groups.

**2) Results of Mating**

There were no significant differences in the incidence of females with irregular estrus cycle, mating period with the number of estrus and day of conceiving, copulation index, and fertility index between the control group and any treatment groups.

**3) Delivery Data and Delivery**

There were no significant differences in the gestation length, number of corpora lutea, number of implantation sites, implantation index, and delivery index between the control group and any treatment groups.

**Organ weight findings**

See 7.5.1

---

**Effect levels (P0)**

<b>Key result</b>	true
<b>Dose descriptor</b>	NOAEL
<b>Effect level</b>	1000 mg/kg bw/day (actual dose received)
<b>Based on</b>	test mat.
<b>Sex</b>	male/female
<b>Basis for effect level</b>	other: No effects on reproduction

---

**Results: F1 generation**

---

## General toxicity (F1)

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### 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

## Overall reproductive toxicity

---

### Key result

true

### Reproductive effects observed

no

## Any other information on results incl. tables

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

[https://dra4.nihs.go.jp/mhlw\\_data/home/pdf/PDF24937-79-9d.pdf](https://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF24937-79-9d.pdf)

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## Applicant's summary and conclusion

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### Conclusions

In the combined repeated oral dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422), there were no effects on reproductive and developmental parameters up to 1000 mg/kg bw/day. The NOAEL for the rat reproductive/developmental toxicity of poly(vinylidene fluoride) was regarded as 1000 mg/kg bw/day, the highest dose tested.

### Executive summary

A combined repeated-dose toxicity study with the reproduction/developmental toxicity screening test was done according to OECD TG 422. Male and female rats (12 animals/sex/dose) were administered with poly(vinylidene fluoride) via oral gavage at doses of 0 [vehicle: corn oil], 100, 300, and 1,000 mg/kg bw/day. Males (12/dose) were treated with poly(vinylidene fluoride) for 42 days, which include a 14-day pre-mating period and a subsequent mating period, while females (12/dose) were treated for 42–46 days, including 14-day pre-mating, mating, and gestation periods until lactation day 4. Among the 12 males that were treated with 0 and 1,000 mg/kg bw/day, 5 were assigned as the recovery group. Additional 10 females administered with 0 and 1,000 mg/kg bw/day were assigned as a satellite group and treated with poly(vinylidene fluoride) for 42 days, with no mating, and examined after a 14-day recovery period.

No mortalities were recorded with any dose in the treatment period. There were also no effects on reproductive toxicity (fertility and reproductive organs) and developmental toxicity up to the highest dose. Since the effects were not even observed at 1,000 mg/kg bw/day administration, the NOAEL for the reproduction and development toxicity was 1,000 mg/kg bw/day in rats.



---

# DOMAIN

## SUBSTANCE: Poly(vinylidene fluoride)

---

**UUID:** 58fabled0-ffb6-4832-a52a-68b0254373e5

**Dossier UUID:**

**Author:** SuperUser

**Date:** 2020-10-01T11:42:26.266+09:00

**Remarks:**

---

**Substance name**

Poly(vinylidene fluoride)

**Public name**

Poly(vinylidene fluoride)

**Legal entity**

[National Institute of Health Sciences, Japan](#)

**Contact persons**

**Person**

[Hirose, Akihiko; National Institute of Health Sciences](#)

**Last name**

Hirose

**First name**

Akihiko

**Organisation**

National Institute of Health Sciences

**Department**

Division of Risk Assessment

**Title**

Dr.

**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](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.

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## Identification of substance

**Reference substance**

[Poly\(vinylidene fluoride\) / 24937-79-9](#)

**EC number**

**EC name**

**CAS number**

**CAS name**

24937-79-9

---

IUPAC name

## Role in the supply chain

---

**Manufacturer**

false

**Importer**

false

**Only representative**

false

**Downstream user**

false

---

# References

## LEGAL\_ENTITY: National Institute of Health Sciences, Japan

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**UUID:** 0952b3b9-2d0c-4bc8-925e-b069be7789b7

**Dossier UUID:**

**Author:** SuperUser

**Date:** 2020-02-19T14:42:16.272+09:00

**Remarks:**

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## General information

---

**Legal entity name**

National Institute of Health Sciences, Japan

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# TEST\_MATERIAL\_INFORMATION: Poly(vinylidene fluoride)

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**UUID:** c3b4dfc1-9c21-48ce-880a-179d65b21980

**Dossier UUID:**

**Author:** SuperUser

**Date:** 2019-12-19T11:08:15.000+09:00

**Remarks:**

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**Name**

Poly(vinylidene fluoride)

**Composition** \_\_\_\_\_

**Other characteristics** \_\_\_\_\_

**Details on test material**

Ethene, 1,1-difluoro-, homopolymer

---

# LITERATURE: Combined repeated dose toxicity study with the reproductive/d evelopmental toxicity screening test of poly(vinylidene fluoride) by oral administration in rats

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**UUID:** 501cbd53-ea23-4a62-afc4-b636c00c9016

**Dossier UUID:**

**Author:** SuperUser

**Date:** 2020-03-24T11:49:15.000+09:00

**Remarks:**

---

## General information

---

**Reference Type**  
study report

**Title**  
Combined repeated dose toxicity study with the reproductive/developmental toxicity screening test of poly(vinylidene fluoride) by oral administration in rats

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

**Bibliographic source**  
available in the web of Japan Existing Chemical Data Base (JECDB) [https://dra4.nihs.go.jp/mhlw\\_data/home/pdf/PDF24937-79-9d.pdf](https://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF24937-79-9d.pdf)

**Testing facility**  
BoZo Research Center

**Report no.**  
R-1052

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# CONTACT: Hirose, Akihiko; National Institute of Health Sciences

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**UUID:** 4293b0a1-fb1d-47d7-a0f7-2f93622aeb27

**Dossier UUID:**

**Author:** SuperUser

**Date:** 2020-02-20T15:27:47.410+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](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.

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## General information

---

**Last name**

Hirose

**First name**

Akihiko

**Organisation**

National Institute of Health Sciences

**Department**

Division of Risk Assessment

**Title**

Dr.

**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](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.

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# LITERATURE: In Vitro Chromosomal Aberration Test of Ethene, 1,1-difluoro-, homopolymer on Cultured Chinese Hamster Cells.

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**UUID:** 1b8db8a3-1553-4e0d-ad4c-e5ebb8553366

**Dossier UUID:**

**Author:** SuperUser

**Date:** 2020-03-17T15:50:22.000+09:00

**Remarks:**

---

## General information

---

### Reference Type

study report

### Title

In Vitro Chromosomal Aberration Test of Ethene, 1,1-difluoro-, homopolymer on Cultured Chinese Hamster Cells.

### Author

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

### Bibliographic source

Japan Existing Chemical Data Base (JECDB) [https://dra4.nihs.go.jp/mhlw\\_data/home/pdf/PDF24937-79-9f.pdf](https://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF24937-79-9f.pdf)

### Testing facility

Bozo Research Center Inc.

### Report no.

M-1409

---

# REFERENCE\_SUBSTANCE: Poly(vinylidene fluoride)

---

**UUID:** db0c1926-d11d-4c34-86dd-2e1f01a8813b

**Dossier UUID:**

**Author:** SuperUser

**Date:** 2019-12-19T11:29:09.000+09:00

**Remarks:**

---

## General information

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**Reference substance name**

Poly(vinylidene fluoride)

## Reference substance information

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**Synonyms**

**Identifier**

other:

**Identity**

Ethene, 1,1-difluoro-, homopolymer

## CAS information

---

**CAS number**

24937-79-9



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# TEST\_MATERIAL\_INFORMATION: Poly(vinylidene fluoride)

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**UUID:** b7f31c31-2461-4add-9952-ce918e0bba34

**Dossier UUID:**

**Author:** SuperUser

**Date:** 2019-12-19T10:46:05.000+09:00

**Remarks:**

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**Name**

Poly(vinylidene fluoride)

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# LITERATURE: Reverse Mutation Test of Ethene, 1,1-difluoro-, homopolymer on Bacteria.

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**UUID:** 1720bd45-bcf5-4f69-928d-7c145f7d72bc

**Dossier UUID:**

**Author:** SuperUser

**Date:** 2020-03-17T15:42:57.000+09:00

**Remarks:**

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## General information

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**Reference Type**

study report

**Title**

Reverse Mutation Test of Ethene, 1,1-difluoro-, homopolymer on Bacteria.

**Author**

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

**Bibliographic source**

Japan Existing Chemical Data Base (JECDB) [https://dra4.nihs.go.jp/mhlw\\_data/home/pdf/PDF24937-79-9e.pdf](https://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF24937-79-9e.pdf)

**Testing facility**

Bozo Research Center Inc.

**Report no.**

T-0468