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SuperUser EPA/ORD/CCTE/SCDCD

- User Settings
- Logout

- Dashboard
- Substances
- 4,4'-methylenedi-2,6-xyleneol

Filtered aggr_1

17f312a7-4cfd-479a-b588-5259b31810fe

View Dossiers

Validate

- Export to i6z
- Extract to dataset
- Create component PDF/RTF
- Create document PDF/RTF
- Compare
- Generate report
- Dissemination preview

Type at least 3 characters

REACH Complete
4,4'-methylenedi-2,6-xyleneol

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- 3 Manufacture, use and exposure
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- 8c73c361-b1e9-4b4e-be9f-f52689a7589a

- 7e5faace-03ae-440f-b9a4-21f71850b632

- 3bd65249-6971-4a05-98df-c44313e5cf4e

- 5f30c275-4824-480b-9d9d-84e9b1b140ca

- b056496c-f5f7-482e-b7c9-adbf4c9848c5

- 8d1888c3-af23-4565-b8f4-971a9d01ef66

- cbb64842-3f9f-47a8-a58b-b8d822b6765b

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teratogenicity

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UUID b056496c-f5f7-482e-b7c9-adbf4c9848c5 ☐ Hide empty fields

-



Administrative data



Endpoint
fertility, other

Type of information
experimental study

Adequacy of study
weight of evidence

☐ Robust study summary

☐ Used for classification

☐ Used for SDS

Study period

Reliability
2 (reliable with restrictions)

Rationale for reliability incl. deficiencies

Data waiving

Justification for data waiving

Justification for type of information

Attached justification

Attached justification Reason / purpose Actions

Cross-reference

Reason / purpose for cross-reference Related information Remarks Actions

Data source

Reference

- publication | Unnamed | 1994

Data access

Data protection claimed

Materials and methods

Test guideline

Qualifier Guideline Version / remarks Deviations Actions 1

Qualifier
no guideline available
Guideline

Version / remarks

Deviations

Principles of method if other than guideline

GLP compliance

not specified

Limit test

no

Justification for study design

Test material

Test material information

- Unnamed | Unnamed | 6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol | 119-47-1 | Unnamed | 2,2'-methylenebis(6-tert-butyl-4-methylphenol) | EC 204-327-1 | 119-47-1

Additional test material information

Specific details on test material used for the study

Specific details on test material used for the study (confidential)

Test animals

Species

rat

Strain

Wistar

Details on species / strain selection

Sex

male/female

Details on test animals or test system and environmental conditions

Administration / exposure

Route of administration

oral: feed

Type of inhalation exposure (if applicable)

Mass median aerodynamic diameter (MMAD)

Geometric standard deviation (GSD)

Remarks on MMAD

Vehicle

Details on exposure

Details on mating procedure

Analytical verification of doses or concentrations

Details on analytical verification of doses or concentrations

Duration of treatment / exposure

Frequency of treatment

Details on study schedule

Doses / concentrations

Dose / conc. Remarks Actions

No. of animals per sex per dose

Control animals

Details on study design

Positive control

Examinations

Parental animals: Observations and examinations

Oestrous cyclicity (parental animals)

Sperm parameters (parental animals)

Litter observations

Postmortem examinations (parental animals)

Postmortem examinations (offspring)

Statistics

Reproductive indices

Offspring viability indices

Any other information on materials and methods incl. tables

Results and discussion

Results: P0 (first parental generation)

General toxicity (P0)

Clinical signs

Description (incidence and severity)

Dermal irritation (if dermal study)

Description (incidence and severity)

Mortality

Description (incidence)

Body weight and weight changes

Description (incidence and severity)

Food consumption and compound intake (if feeding study)

Description (incidence and severity)

Food efficiency

Description (incidence and severity)

Water consumption and compound intake (if drinking water study)

Description (incidence and severity)

Ophthalmological findings

Description (incidence and severity)

Haematological findings

Description (incidence and severity)

Clinical biochemistry findings
not specified

Description (incidence and severity)

Endocrine findings

Description (incidence and severity)

Urinalysis findings
not specified

Description (incidence and severity)

Behaviour (functional findings)
not specified

Description (incidence and severity)

Immunological findings
not specified

Description (incidence and severity)

Organ weight findings including organ / body weight ratios

Description (incidence and severity)

Gross pathological findings

Description (incidence and severity)

Neuropathological findings

Description (incidence and severity)

Histopathological findings: non-neoplastic

Description (incidence and severity)

Histopathological findings: neoplastic

Description (incidence and severity)

Other effects

Description (incidence and severity)

Reproductive function / performance (P0)

Reproductive function: oestrous cycle

Description (incidence and severity)

Reproductive function: sperm measures

Description (incidence and severity)

Reproductive performance

Description (incidence and severity)

Details on results (P0)

Effect levels (P0)

Key result Dose descriptor Effect level Based on Sex Basis for effect level Remarks on result Actions 1

☐ Key result

Dose descriptor

NOAEL

Effect level

12.7 mg/kg bw/day (nominal)

Based on
test mat.

Sex

male

Basis for effect level

- organ weights and organ / body weight ratios
- gross pathology
- histopathology: non-neoplastic
- other:

Remarks on result

2

☐ Key result

Dose descriptor

LOAEL

Effect level

42.3 mg/kg bw/day (nominal)

Based on
test mat.

Sex

male

Basis for effect level

- other:

Remarks on result

3

☐ Key result

Dose descriptor

NOAEL

Effect level

54.2 mg/kg bw/day (nominal)

Based on
test mat.

Sex

female

Basis for effect level

- organ weights and organ / body weight ratios
- gross pathology
- histopathology: non-neoplastic
- other:

Remarks on result

Target system / organ toxicity (P0)

Key result Critical effects observed Lowest effective dose / conc. System Organ Treatment related Dose response relationship Relevant for humans Actions

Results: P1 (second parental generation)

General toxicity (P1)

Clinical signs

Description (incidence and severity)

Dermal irritation (if dermal study)

Description (incidence and severity)

Mortality

Description (incidence)

Body weight and weight changes

Description (incidence and severity)

Food consumption and compound intake (if feeding study)

Description (incidence and severity)

Food efficiency

Description (incidence and severity)

Water consumption and compound intake (if drinking water study)

Description (incidence and severity)

Ophthalmological findings

Description (incidence and severity)

Haematological findings

Description (incidence and severity)

Clinical biochemistry findings

Description (incidence and severity)

Endocrine findings

Description (incidence and severity)

Urinalysis findings

Description (incidence and severity)

Behaviour (functional findings)

Description (incidence and severity)

Immunological findings

Description (incidence and severity)

Organ weight findings including organ / body weight ratios

Description (incidence and severity)

Gross pathological findings

Description (incidence and severity)

Neuropathological findings

Description (incidence and severity)

Histopathological findings: non-neoplastic

Description (incidence and severity)

Histopathological findings: neoplastic

Description (incidence and severity)

Other effects

Description (incidence and severity)

Details on results

Reproductive function / performance (P1)

Reproductive function: oestrous cycle

Description (incidence and severity)

Reproductive function: sperm measures

Description (incidence and severity)

Reproductive performance

Description (incidence and severity)

Details on results (P1)

Effect levels (P1)

Key result Dose descriptor Effect level Based on Sex Basis for effect level Remarks on result Actions

Target system / organ toxicity (P1)

Key result Critical effects observed Lowest effective dose / conc. System Organ Treatment related Dose response relationship Relevant for humans Actions

Results: F1 generation

General toxicity (F1)

Clinical signs

Description (incidence and severity)

Dermal irritation (if dermal study)

Description (incidence and severity)

Mortality / viability

Description (incidence and severity)

Body weight and weight changes

Description (incidence and severity)

Food consumption and compound intake (if feeding study)

Description (incidence and severity)

Food efficiency

Description (incidence and severity)

Water consumption and compound intake (if drinking water study)

Description (incidence and severity)

Ophthalmological findings

Description (incidence and severity)

Haematological findings

Description (incidence and severity)

Clinical biochemistry findings

Description (incidence and severity)

Urinalysis findings

Description (incidence and severity)

Sexual maturation

Description (incidence and severity)

Anogenital distance (AGD)

Description (incidence and severity)

Nipple retention in male pups

Description (incidence and severity)

Organ weight findings including organ / body weight ratios

Description (incidence and severity)

Gross pathological findings

Description (incidence and severity)

Histopathological findings

Description (incidence and severity)

Other effects

Description (incidence and severity)

Developmental neurotoxicity (F1)

Behaviour (functional findings)

Description (incidence and severity)

Developmental immunotoxicity (F1)

Developmental immunotoxicity

Description (incidence and severity)

Details on results (F1)

Effect levels (F1)

Key result Dose descriptor Generation Effect level Based on Sex Basis for effect level Remarks on result Actions

Target system / organ toxicity (F1)

Key result Critical effects observed Lowest effective dose / conc. System Organ Treatment related Dose response relationship Relevant for humans Actions

Results: F2 generation

General toxicity (F2)

Clinical signs

Description (incidence and severity)

Dermal irritation (if dermal study)

Description (incidence and severity)

Mortality / viability

Description (incidence and severity)

Body weight and weight changes

Description (incidence and severity)

Food consumption and compound intake (if feeding study)

Description (incidence and severity)

Food efficiency

Description (incidence and severity)

Water consumption and compound intake (if drinking water study)

Description (incidence and severity)
Ophthalmological findings
Description (incidence and severity)
Haematological findings
Description (incidence and severity)
Clinical biochemistry findings
Description (incidence and severity)
Urinalysis findings
Description (incidence and severity)
Sexual maturation
Description (incidence and severity)
Anogenital distance (AGD)
Description (incidence and severity)
Nipple retention in male pups
Description (incidence and severity)
Organ weight findings including organ / body weight ratios
Description (incidence and severity)
Gross pathological findings
Description (incidence and severity)
Histopathological findings
Description (incidence and severity)
Other effects
Description (incidence and severity)
Developmental neurotoxicity (F2)
Behaviour (functional findings)
Description (incidence and severity)
Developmental immunotoxicity (F2)
Developmental immunotoxicity
Description (incidence and severity)
Details on results (F2)
Effect levels (F2)

Target system / organ toxicity (F2)

Key result Critical effects observed Lowest effective dose / conc. System Organ Treatment related Dose response relationship Relevant for humans Actions

Overall reproductive toxicity

Key result Reproductive effects observed Lowest effective dose / conc. Treatment related Relation to other toxic effects Dose response relationship Relevant for humans Actions 1

☐ Key result
Reproductive effects observed
not specified
Lowest effective dose / conc.
Treatment related
Relation to other toxic effects
Dose response relationship
Relevant for humans

Any other information on results incl. tables

Overall remarks, attachments

Overall remarks

Attachments

Type Attached (confidential) document Attached (sanitised) documents for publication Remarks Actions

Illustration (picture/graph)

Applicant's summary and conclusion

Conclusions

Executive summary

TOP

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Inventory manager

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- Test material
- Literature reference

User management

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About IUCLID

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