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SuperUser EPA/ORD/CCTE/SCDCD

- User Settings
- Logout
  
- Dashboard
- Substances
- Maleic acid

Filtered aggr\_1

198f9af6-680d-44de-a110-579a594a722d

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  
Maleic acid

- 1 General information  
2
- 2 Classification & Labelling and PBT assessment
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties  
20
- 5 Environmental fate and pathways  
10
- 6 Ecotoxicological information  
5
- 7 Toxicological information  
22
  - 7.1 Toxicokinetics, metabolism and distribution
  - 7.2 Acute Toxicity  
5

- 7.3 Irritation / corrosion  
3
- 7.4 Sensitisation  
2
- 7.5 Repeated dose toxicity  
5
- 7.6 Genetic toxicity  
2
- 7.7 Carcinogenicity  
1
- 7.8 Toxicity to reproduction  
2
  - 7.8.1 Toxicity to reproduction  
1
  - 7.8.2 Developmental toxicity /  
teratogenicity  
1
    - 381ce0a2-c5e5-4e6f-874a-  
82a8d806aced
  - 7.8.3 Toxicity to reproduction: other  
studies
- 7.9 Specific investigations  
1
- 7.10 Exposure related observations in humans
- 7.11 Toxic effects on livestock and pets
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- 8 Analytical methods
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- 12 Literature search
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Administrative data

Endpoint  
developmental toxicity

Type of information

experimental study

Adequacy of study

key study

☐ 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 | 1986
- publication | Unnamed | 1979 | 1979-02-20
- publication | Unnamed | 1991 | 1991-08-26
- secondary source | Unnamed | 1979
- secondary source | Unnamed | 1986
- secondary source | Unnamed | 1988
- secondary source | Unnamed | 1979

Data access

Data protection claimed

Materials and methods

Test guideline

# Qualifier Guideline Version / remarks Deviations Actions 1

Qualifier

equivalent or similar to guideline

Guideline

OECD Guideline 414 (Prenatal Developmental Toxicity Study)

Version / remarks

Deviations

yes

Principles of method if other than guideline

GLP compliance  
no

Limit test

Test material

Test material information

- Unnamed | Unnamed | furan-2,5-dione | EC 203-571-6 | 108-31-6

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  
other:

Details on test animals or test system and environmental conditions

Administration / exposure

Route of administration  
oral: gavage

Type of inhalation exposure (if applicable)

Vehicle

Mass median aerodynamic diameter (MMAD)

Geometric standard deviation (GSD)

Remarks on MMAD

Details on exposure

Analytical verification of doses or concentrations

Details on analytical verification of doses or concentrations

Details on mating procedure

Duration of treatment / exposure

Frequency of treatment

Duration of test

Doses / concentrations

# Dose / conc. Remarks Actions

No. of animals per sex per dose

Control animals

---

Details on study design

---

**Examinations**

---

Maternal examinations

---

Ovaries and uterine content

---

Blood sampling

---

Fetal examinations

---

Statistics

---

Indices

---

Historical control data

---

Any other information on materials and methods incl. tables

---

**Results and discussion**

---

**Results: maternal animals**

---

**General toxicity (maternal animals)**

---

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

**Maternal developmental toxicity**

Number of abortions

Description (incidence and severity)

Pre- and post-implantation loss

Description (incidence and severity)

Total litter losses by resorption

Description (incidence and severity)

Early or late resorptions

Description (incidence and severity)

Dead fetuses

---

Description (incidence and severity)

---

Changes in pregnancy duration

---

Description (incidence and severity)

---

Changes in number of pregnant

---

Description (incidence and severity)

---

Other effects

---

Description (incidence and severity)

---

Details on maternal toxic effects

---

**Effect levels (maternal animals)**

---

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

☐ Key result

Dose descriptor

NOAEL

Effect level

$\geq 140$  mg/kg bw/day

Based on

Basis for effect level

- other:

Remarks on result

---

**Maternal abnormalities**

---

# Key result Abnormalities Localisation Description (incidence and severity) Actions

---

**Results (fetuses)**

---

Fetal body weight changes

---

Description (incidence and severity)

---

Reduction in number of live offspring

---

Description (incidence and severity)

---

Changes in sex ratio

---

Description (incidence and severity)

---

Changes in litter size and weights

---

Description (incidence and severity)

---

Anogenital distance of all rodent fetuses

---

Description (incidence and severity)

---

Changes in postnatal survival

---

Description (incidence and severity)

---

External malformations

---

Description (incidence and severity)

---

Skeletal malformations

---

Description (incidence and severity)

---

Visceral malformations

---

Description (incidence and severity)

---

Other effects

---

Description (incidence and severity)

---

Details on embryotoxic / teratogenic effects

---

**Effect levels (fetuses)**

---

# 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

$\geq 140$  mg/kg bw/day

Based on

Sex

Basis for effect level

- other:

Remarks on result

2

☐ Key result

Dose descriptor

NOAEL

Effect level

$\geq 140$  mg/kg bw/day

Based on

Sex

Basis for effect level

- other:

Remarks on result

---

**Fetal abnormalities**

---

# Key result Abnormalities Localisation Description (incidence and severity) Actions 1

☐ Key result

Abnormalities

not specified

Localisation

Description (incidence and severity)

---

**Overall developmental toxicity**

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# Key result Developmental effects observed Lowest effective dose / conc. Treatment related Relation to maternal toxicity Dose response relationship Relevant for humans Actions 1

☐ Key result

Developmental effects observed

not specified



Lowest effective dose / conc.  
Treatment related  
Relation to maternal toxicity  
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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- Articles
- Categories

Toolbox

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- Manage Reports

Inventory manager

- Contact
- Legal entity
- Sites
- Reference substance
- Test material
- Literature reference

User management

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- Users
- Roles

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