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SuperUser EPA/ORD/CCTE/SCDCD

- User Settings
- Logout

- Dashboard
- Silicon dioxide

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REACH Complete
Silicon dioxide

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- Compare Document

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Administrative data

Data source

Materials and methods

Results and discussion

Overall remarks, attachments

Applicant's summary and conclusion

Administrative data

Endpoint
carcinogenicity: oral

Type of information
experimental study

Adequacy of study
supporting 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 1

Reason / purpose for cross-reference

reference to same study

Related information

Remarks

2

Reason / purpose for cross-reference

reference to other study

Related information

Remarks

Data source

Reference

- review article or handbook | Unnamed | 1997
 - publication | Unnamed | 1988
-

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 453 (Combined Chronic Toxicity / Carcinogenicity Studies)
Version / remarks
Deviations
yes

Principles of method if other than guideline

GLP compliance
not specified

Test material

Test material information

- Unnamed | Unnamed | dioxosilane | EC 231-545-4 | 7631-86-9

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
mouse

Strain
B6C3F1

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)

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

Duration of treatment / exposure

Frequency of treatment

Post exposure period

Doses / concentrations

Dose / conc. Remarks Actions

No. of animals per sex per dose

Control animals

Details on study design

Positive control

Examinations

Observations and examinations performed and frequency

Sacrifice and pathology

Other examinations

Statistics

Any other information on materials and methods incl. tables

Results and discussion

Results of examinations

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

Relevance of carcinogenic effects / potential

Effect levels

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

50000 ppm (nominal)

Based on

Sex

male/female

Basis for effect level

Remarks on result

2

☐ Key result

Dose descriptor

NOAEL

Effect level

ca. 5000 - ca. 7000 mg/kg bw/day (actual dose received)

Based on

Sex

male

Basis for effect level

- other:

Remarks on result

3

☐ Key result

Dose descriptor

NOAEL

Effect level

ca. 4000 - ca. 13000 mg/kg bw/day (actual dose received)

Based on

Sex

female

Basis for effect level

- other:

Remarks on result

Target system / organ toxicity

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

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

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Inventory manager

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- Reference substance
- Test material
- Literature reference

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