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SuperUser EPA/ORD/CCTE/SCDCD

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- Tetrasodium N,N-bis(carboxylatometh...

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View Dossiers | Validate

- Export to i6z
- Extract to dataset
- Create component PDF/RTF
- Create document PDF/RTF
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- Generate report
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Type at least 3 characters

REACH Complete
Tetrasodium N,N-bis(carboxylatomethyl)-L-glutamate

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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
developmental toxicity

Type of information
experimental study

Adequacy of study
key study

☐ Robust study summary

☐ Used for classification

☐ Used for SDS

Study period

Reliability
1 (reliable without restriction)

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

- study report | Unnamed | 2019 | 2019-05-09

Data access

Data protection claimed

Materials and methods

Test guideline

Qualifier Guideline Version / remarks Deviations Actions 1
Qualifier
according to guideline
Guideline
OECD Guideline 414 (Prenatal Developmental Toxicity Study)
Version / remarks
Deviations
no

Principles of method if other than guideline

GLP compliance

yes (incl. QA statement)

Limit test
yes

Test material

Test material information

- Unnamed | Unnamed | tetrasodium 2-[bis(carboxylatomethyl)amino]pentanedioate | EC 257-573-7 | 51981-21-6

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
Wistar

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
>= 1000 mg/kg bw/day (actual dose received)
Based on
act. ingr.
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
>= 1000 mg/kg bw/day (actual dose received)
Based on
act. ingr.
Sex
male/female
Basis for effect level

- other:

Remarks on result

Fetal abnormalities

Key result Abnormalities Localisation Description (incidence and severity) Actions

Overall developmental toxicity

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
no
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

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