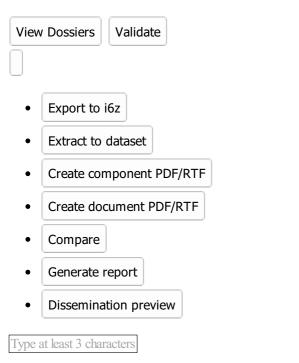
- Dossier preparation manuals
- <u>Q&A</u>
- <u>Create support request</u>
- IUCLID user community
- Additional information
- <u>Video tutorials</u>

SuperUser EPA/ORD/CCTE/SCDCD

- User Settings
- Logout
- Dashboard
- Tetrasodium N,N-bis(carboxylatometh...

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REACH Complete

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

- 1 General information
- 7
- 2 Classification & Labelling and PBT assessment
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties 22
- 5 Environmental fate and pathways 21
- 6 Ecotoxicological information 16
- 7 Toxicological information
 - 23

2

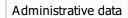
- 9bc1f261-e282-4e01-993d-80abd575ef7f
- $\circ~7.1$ Toxicokinetics, metabolism and distribution
- 7.2 Acute Toxicity

- 4
- 7.3 Irritation / corrosion 4
- 7.4 Sensitisation
- 2
 7.5 Repeated dose toxicity
 1
- 7.6 Genetic toxicity
 - 4
- 7.7 Carcinogenicity
- 7.8 Toxicity to reproduction
 - 5
- 7.8.1 Toxicity to reproduction
- 1
- 7.8.2 Developmental toxicity / teratogenicity
 - 4
 - 80ffcbe4-76a8-4c3f-af3b-411a5e5ce4e6
 - 72cbb421-ca57-47c8-8ac4-62fb9f00b80c
 - 11f7d7f4-a8c2-4c38-9c52e91cb927feda
 - e77f47cb-85ac-4152-9bffffa07b197439
- 7.8.3 Toxicity to reproduction: other
- studies
- 7.9 Specific investigations
- 7.10 Exposure related observations in humans
- 7.11 Toxic effects on livestock and pets
- 7.12 Additional toxicological information
- 8 Analytical methods
- 9 Residues in food and feedingstuffs
- 10 Effectiveness against target organisms
- 11 Guidance on safe use
- 12 Literature search
- 13 Assessment reports
- 14 Information requirements
- Inherited templates

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0 1 0



Data source Materials and methods

s 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

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 motorials and mothods includely
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

Basis for effect level

male/female

• 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

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

Conclusions

Executive summary

TOP

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 - Articles
- - Categories

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