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SuperUser EPA/ORD/CCTE/SCDCD

- User Settings
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- Substances
- L-Valine, N-(1-oxopentyl)-N-[[2'-(2...

Filtered aggr_1

8d1f45e0-1b02-4758-9d41-a57a05d74a1c

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
L-Valine, N-(1-oxopentyl)-N-[[2'-(2H-tetrazol-5-yl)[1,1'-biphenyl]-4-yl]methyl]-, phenylmethyl ester

- 7.2 Acute Toxicity
  3
- 7.3 Irritation / corrosion
  4
- 7.4 Sensitisation
  2
- 7.5 Repeated dose toxicity
  3
- 7.6 Genetic toxicity
  3
- 7.7 Carcinogenicity
- 7.8 Toxicity to reproduction
  3
  - 7.8.1 Toxicity to reproduction
    2
    - 35e5e03d-8f85-4b72-8b11-c7f3678d28bf
    - bd0570ed-5ec1-40aa-b9ee-57b12425f528
  - 7.8.2 Developmental toxicity / teratogenicity
    1
  - 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
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- Inherited templates

UUID 35e5e03d-8f85-4b72-8b11-c7f3678d28bf ☐ Hide empty fields

- Compare Document

0 1 0

Administrative data | Data source | Materials and methods | Results and discussion | Overall remarks, attachments | Applicant's summary and conclusion

Administrative data

Endpoint
one-generation reproductive 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 | 2004 | 2004-10-21

Data access

Data protection claimed

Materials and methods

Test guideline

Qualifier Guideline Version / remarks Deviations Actions 1
Qualifier
according to guideline
Guideline
OECD Guideline 415 [One-Generation Reproduction Toxicity Study (before 9 October 2017)]
Version / remarks
Deviations
2
Qualifier
according to guideline
Guideline
EU Method B.34 (One-Generation Reproduction Toxicity Test)
Version / remarks
Deviations

Principles of method if other than guideline

GLP compliance
yes

Limit test
no

Justification for study design

Test material

Test material information

- Unnamed | Unnamed | Tetrazolyl-valinesteramid (3-methyl-2-{pentanoyl-[2'-(1H-tetrazol-5-yl)-biphenyl-4-ylmethyl]-amino}-butyric acid benzyl ester) | EC 604-047-3 | 137863-20-8

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: gavage

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 examined

Description (incidence and severity)

Endocrine findings

Description (incidence and severity)

Urinalysis findings
not examined

Description (incidence and severity)

Behaviour (functional findings)
not examined

Description (incidence and severity)

Immunological findings
not examined

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
50 mg/kg bw/day
Based on
test mat.
Sex
female
Basis for effect level

- clinical signs
- mortality
- body weight and weight gain
- food consumption and compound intake
- organ weights and organ / body weight ratios
- gross pathology

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 1

☐ Key result
Critical effects observed
no
Lowest effective dose / conc.
System
Organ

Treatment related
Dose response relationship
Relevant for humans

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 1

☐ Key result
Dose descriptor
NOAEL
Generation
F1
Effect level
10 mg/kg bw/day
Based on
test mat.
Sex
male/female
Basis for effect level

- clinical signs
- mortality
- body weight and weight gain
- organ weights and organ / body weight ratios
- gross pathology

Remarks on result

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 1

☐ Key result
Critical effects observed
yes
Lowest effective dose / conc.
10 mg/kg bw/day (nominal)
System
other:
Organ

Treatment related
yes
Dose response relationship
yes
Relevant for humans
not specified

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)

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

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
no
Lowest effective dose / conc.
250 mg/kg bw/day
Treatment related
no
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

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