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- 1,3-Cyclohexanedimethanamine, N1,N3...

## Filtered aggr_1

## c8636a42-2122-4587-b222-83066cf76852

View Dossiers | Validate

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

REACH Complete
1,3-Cyclohexanedimethanamine, N1,N3-bis(2-methylpropylidene)-

- 1 General information
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- 2 Classification & Labelling and PBT assessment
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- 7 Toxicological information
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  - 7.1 Toxicokinetics, metabolism and distribution

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- 7.2 Acute Toxicity
  3
- 7.3 Irritation / corrosion
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- 7.4 Sensitisation
  2
- 7.5 Repeated dose toxicity
  3
- 7.6 Genetic toxicity
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- 7.8 Toxicity to reproduction
  1
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    1
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  - 7.8.2 Developmental toxicity / teratogenicity
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- 7.9 Specific investigations
- 7.10 Exposure related observations in humans
- 7.11 Toxic effects on livestock and pets
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- 8 Analytical methods
- 9 Residues in food and feedingstuffs
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- 11 Guidance on safe use
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- 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
screening for reproductive / 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 | 2011 | 2011-10-28

Data access

Data protection claimed

#### Materials and methods

#### Test guideline

# Qualifier Guideline Version / remarks Deviations Actions 1
Qualifier
according to guideline
Guideline
OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test)
Version / remarks
Deviations
no
2
Qualifier
according to guideline
Guideline
other:
Version / remarks
Deviations
no

Principles of method if other than guideline

GLP compliance
yes (incl. QA statement)

Limit test
no

Justification for study design

#### Test material

Test material information

- Unnamed | Unnamed | Incorez 397 | Unnamed | (2-methylpropylidene)[(3-{[(2-methylpropylidene)amino]methyl}cyclohexyl)methyl]amine | EC 619-764-7 | 173904-11-5

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 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

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)

**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
250 mg/kg bw/day (nominal)
Based on
test mat.
Sex
male/female
Basis for effect level

- other:

Remarks on result
2

☐ Key result
Dose descriptor
NOAEL
Effect level
750 mg/kg bw/day (nominal)
Based on
test mat.
Sex
male/female
Basis for effect level

- other:

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

**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
750 mg/kg bw/day (nominal)
Based on
test mat.
Sex
male/female
Basis for effect level

- other:

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

---

**Results: F2 generation**

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**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
not specified
Lowest effective dose / conc.
Treatment related
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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