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SuperUser EPA/ORD/CCTE/SCDCD

- User Settings
- Logout
- Dashboard
- Disodium 5-amino-4-hydroxy-3-(pheny...

Filtered aggr_1

040ee780-aff4-454e-862c-ec8bfce09ecf

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
Disodium 5-amino-4-hydroxy-3-(phenylazo)naphthalene-2,7-disulphonate

- 1 General information
4
- 2 Classification & Labelling and PBT assessment
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
19
- 5 Environmental fate and pathways
1
- 6 Ecotoxicological information
9
- 7 Toxicological information
58
 - 7.1 Toxicokinetics, metabolism and distribution
1
 - 7.2 Acute Toxicity

10

- 7.3 Irritation / corrosion

8

- 7.4 Sensitisation

5

- 7.5 Repeated dose toxicity

10

- 7.6 Genetic toxicity

13

- 7.7 Carcinogenicity

3

- 9a50a28e-eb25-4b2d-950c-d7d920a9cfa8
- 2cf6b35e-aba5-4356-b080-fc3ac9a4946f
- 7607c21d-be36-451f-8726-9f97d9fe9f19

- 7.8 Toxicity to reproduction

8

- 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

UUID 9a50a28e-eb25-4b2d-950c-d7d920a9cfa8 ☐ Hide empty fields

-

Administrative data

Endpoint

carcinogenicity: oral

Type of information

experimental study

Adequacy of study

weight of evidence

☐ Robust study summary

☐ Used for classification

☐ Used for SDS

Study period

Reliability
4 (not assignable)

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

- secondary source | Unnamed | 2007

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

Principles of method if other than guideline

GLP compliance

yes

Test material

Test material information

- Unnamed | Unnamed | disodium 5-amino-4-hydroxy-3-(phenylazo)naphthalene-2,7-disulphonate | EC 222-656-9 | 3567-66-6 | Unnamed | D&C Red 33

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

CD-1

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)

not specified

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

150 mg/kg bw/day (actual dose received)

Based on
test mat.

Sex

male

Basis for effect level

- other:

Remarks on result

2

☐ Key result

Dose descriptor

LOAEL

Effect level

181 mg/kg bw/day (actual dose received)

Based on
test mat.

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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