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

## SuperUser EPA/ORD/CCTE/SCDCD

- User Settings
- Logout
- Dashboard
- Substances
- Maleic anhydride

## Filtered aggr\_1

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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 Maleic anhydride

- 1 General information
  - 40
- 2 Classification & Labelling and PBT assessment
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
   22
- 5 Environmental fate and pathways
  - 26
- 6 Ecotoxicological information 40
- 7 Toxicological information

55

- o 8953aec9-84cb-406c-b1d5-c43b07b4db3c
- o 7.1 Toxicokinetics, metabolism and distribution

<ul> <li>7.2 Acute Toxicity</li> </ul>		
7		
<ul><li>7.3 Irritation / corrosion</li><li>6</li></ul>		
<ul> <li>7.4 Sensitisation</li> </ul>		
4		
<ul> <li>7.5 Repeated dose toxicity</li> <li>9</li> </ul>		
<ul> <li>7.5.1 Repeated dose toxicity: oral</li> </ul>		
5		
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7f3a36ba14e6		
<ul><li>4a4687d4-600c-4c15-bd2b- 5c0d21710363</li></ul>		
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■ 7735d98e-a28f-4ea9-baa0-		
4409ac2fae26		
<ul><li>0d7e4019-f25a-40b2-8303- aed0415980c8</li></ul>		
■ 7.5.2 Repeated dose toxicity: inhalation		
4		
<ul> <li>7.5.3 Repeated dose toxicity: dermal</li> </ul>		
<ul> <li>7.5.4 Repeated dose toxicity: other routes</li> </ul>		
<ul> <li>7.6 Genetic toxicity</li> </ul>		
7		
<ul> <li>7.7 Carcinogenicity</li> </ul>		
7.8 Toxicity to reproduction		
3		
<ul> <li>7.9 Specific investigations</li> </ul>		
<ul> <li>7.10 Exposure related observations in humans</li> </ul>		
16		
<ul> <li>7.11 Toxic effects on livestock and pets</li> <li>7.12 Additional toxicological information</li> </ul>		
8 Analytical methods		
<ul> <li>9 Residues in food and feedingstuffs</li> </ul>		
10 Effectiveness against target organisms		
<ul><li>11 Guidance on safe use</li><li>12 Literature search</li></ul>		
<ul><li>12 Literature search</li><li>13 Assessment reports</li></ul>		
14 Information requirements		
Inherited templates		
UUID 0d7e4019-f25a-40b2-8303-aed0415980c8  Hide empty fields		
Compare Document		
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U		
Administrative data Data source Materials and methods	Results and discussion	Overall remarks, attachments
rational and methods	Accurate and discussion	5 Foran Formanio, attachments
Applicant's summary and conclusion		
U		

Endpoint chronic toxicity: oral
Type of information experimental study
Adequacy of study weight of evidence
Robust study summary
Used for classification
Used for SDS
Study period
Reliability 2 (reliable with restrictions)
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
<ul> <li>study report   Unnamed   1984   1984-10-23</li> <li>review article or handbook   Unnamed   2004</li> </ul>
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 452 (Chronic Toxicity Studies)
Version / remarks Deviations

Principles of method if other than guideline
GLP compliance not specified
Limit test no
Test material
Test material information
• Unnamed   Unnamed   2,5-dihydrofuran-2,5-dione   EC 203-571-6   108-31-6
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 Fischer 344
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
Details on route of administration
Vehicle
Details on oral exposure
Analytical verification of doses or concentrations
Details on analytical verification of doses or concentrations
Duration of treatment / exposure 2 years
Frequency of treatment
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
Optional endpoint(s)
Other examinations
Statistics
Any other information on materials and methods incl. tables
Results and discussion
Results of examinations
Clinical signs
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

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
Effect levels
# Key result Dose descriptor Effect level Based on Sex Basis for effect level Remarks on result Actions 1  Key result Dose descriptor NOEL Effect level 10 mg/kg bw/day (nominal) Based on test mat. Sex male/female Basis for effect level
# Key result Dose descriptor Effect level Based on Sex Basis for effect level Remarks on result Actions 1    Key result

• body weight and weight gain

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 1  Key result Critical effects observed not specified Lowest effective dose / conc. System Organ
Treatment related Dose response relationship Relevant for humans
Any other information on results incl. tables
Overall remarks, attachments
Overall remarks
# Type Attached (confidential) document Attached (sanitised) documents for publication Remarks Actions
Illustration (picture/graph)
Applicant's summary and conclusion
Conclusions
Executive summary
TOP
Dashboard •
Substances •
Mixtures / Products  •
Articles •
Categories
Toolbox
<ul><li>Template</li><li>Manage Reports</li></ul>
Inventory manager
<ul><li>Contact</li><li>Legal entity</li></ul>

• Sites

Reference substanceTest material

• Literature reference

# User management

- User Settings Users
- Roles

# About IUCLID

- About
- Help