Name: 4-chloro-m-cresol / 59-50-7

Legal entity owner: National Institute of Health Sciences / Kawasaki / Japan

Printing date: 2018-03-12T13:56:15.452+09:00

Table of Contents

4-chloro-m-cresol

CORE

General information

Identification

SUBSTANCE: 4-chloro-m-cresol

UUID: 053ede1d-07b6-42db-ba58-88a6a246d151
Dossier UUID:
Author: Dra
Date: 2018-02-27T15:49:36.714+09:00
Remarks:

Substance name
4-chloro-m-cresol

Other identifiers

Identifier
CAS number

Identity
59-50-7

Legal entity
National Institute of Health Sciences / Kawasaki / Japan

Identification of substance

Reference substance
4-chloro-m-cresol / 59-50-7

EC number	EC name
CAS number	CAS name
59-50-7	
IUPAC name	

Role in the supply chain

Manufacturer
false

Importer
false

Only representative
false

Downstream user
false

OECD

Health Effects

Genetic toxicity in vitro

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.001

UUID: 764bbe55-ffa6-468b-b592-12facb8c9342
Dossier UUID:
Author: Dra
Date: 2018-03-02T12:02:58.365+09:00
Remarks:

Administrative data

Endpoint
in vitro gene mutation study in bacteria

Type of information
experimental study

Adequacy of study
key study

Robust study summary
true

Used for classification
false

Used for SDS
false

Reliability
1 (reliable without restriction)

Rationale for reliability incl. deficiencies
guideline study
Reliability 1

Data source

Reference

Reverse Mutation Test of 4-chloro-m-cresol on Bacteria / MHLW (Ministry of Health, Labour and Welfare), Japan / study report

Data access
data published

Materials and methods

Test guideline

Qualifier
according to

Guideline
OECD Guideline 471 (Bacterial Reverse Mutation Assay)
in vitro gene mutation study in bacteria

Qualifier
according to

Guideline
JAPAN: Guidelines for Screening Mutagenicity Testing Of Chemicals
genetic toxicity in vitro, other

GLP compliance
yes

Type of assay
bacterial reverse mutation assay
in vitro gene mutation study in bacteria

Test material

Specific details on test material used for the study
- Name of test material (as cited in study report): 4-chloro-m-cresol
- CAS No.: 59-50-7
Lot No.: ASL1407
- Purity: 100%
- Supplier: Wako Pure Chemical Industries, Ltd.
- Boiling point : 235°C
- Melting point/Freezing point: 65.7°C
- Vapor pressure: 0.05 mmHg (20°C)
- Solubility: 1 g/260 mL (20°C) in water.
- Physical state: white powder
- Storage condition of test material: stored at room temperature (21.1-25.3°C), light shielding

Method

Species / strain

Species / strain
S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and E. coli WP2
bacteria

Metabolic activation
with and without

Metabolic activation system
S9 mix; SD male rat liver, induced by phenobarbital and 5,6-benzoflavone

Test concentrations with justification for top dose
Preliminary study
+/-S9 mix:1.22, 4.88, 19.5, 78.1, 313, 1250, 5000 µg/plate
(growth inhibition was observed at >=313µg/plate in TA100 and TA1535 and at >=1250µg/plate in WP2uvrA/pKM101, TA98, and TA1537)

Main study
+/-S9 mix: 9.77, 19.5, 39.1, 78.1, 156, 313, 625 µg/plate (TA100, TA1535 strains)
+/-S9 mix: 19.5, 39.1, 78.1, 156, 313, 625, 1250 µg/plate (WP2uvrA/pKM101, TA98, TA1537 strains)

Vehicle
- Vehicle(s)/solvent(s) used: DMSO

Controls

Solvent controls
yes

Positive controls
yes

Positive control substance
9-aminoacridine
  9-aminoacridine hydrochloride, -S9mix: (TA1537)
sodium azide
  -S9 mix: (TA1535)
other: 2-(2-Furyl)-3-(5-nitro-2-furyl) acrylamide
  -S9mix: (TA 100, TA98 and WP2 uvrA/pKM101)

Remarks
-S9mix

Solvent controls
yes

Positive controls
yes

Positive control substance
other: 2-aminoanthracene
  (all strains)

Remarks
+S9 mix

Details on test system and conditions
METHOD OF APPLICATION: Preincubation
DURATION- Preincubation period: 20 min at 37°C
 - Exposure duration:48 hrs
NUMBER OF PLATES: 3
NUMBER OF REPLICATIONS: 2
DETERMINATION OF CYTOTOXICITY- Method: other: growth inhibition

Evaluation criteria
A chemical was judged to be mutagenic when the mean number of revertant colonies per plate increased more than twice that of the negative control and when the dose-related and reproducible i ncrease was observed.

Statistics
not used

Results and discussion

Test results

Key result
false

Species / strain
S. typhimurium TA 100
bacteria

Metabolic activation
with and without

Genotoxicity
negative

Cytotoxicity
yes +/-S9: at =>313 µg/plate

Vehicle controls valid
yes

Positive controls valid
yes

Key result
false

Species / strain
S. typhimurium TA 1535
bacteria

Metabolic activation
with and without

Genotoxicity
negative

Cytotoxicity
yes +/-S9: at =>313 µg/plate

Vehicle controls valid
yes

Positive controls valid
yes

Key result
false

Species / strain
E. coli WP2 uvr A pKM 101
bacteria

Metabolic activation
with and without

Genotoxicity
negative

Cytotoxicity
yes -S9mix: at=>625 µg/plate, +S9mix: at 1250 µg/plate

Vehicle controls valid
yes

Positive controls valid
yes

Key result
false

Species / strain
S. typhimurium TA 98
bacteria

Metabolic activation
with and without

Genotoxicity
negative

Cytotoxicity
yes +/-S9mix: at =>625 µg/plate

Vehicle controls valid
yes

Positive controls valid
yes

Key result
false

Species / strain
S. typhimurium TA 1537
bacteria

Metabolic activation
with and without

Genotoxicity
negative

Cytotoxicity
yes +/-S9mix: at =>625 µg/plate

Vehicle controls valid
yes

Positive controls valid
yes

Any other information on results incl. tables

Figures and Tables (in Japanese) are available in the following full report of the study. http://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF59-50-7e.pdf

Applicant's summary and conclusion

Conclusions

In a bacterial reverse mutation assay using Salmonella typhimurium TA100, TA1535, TA98, and TA1537, and Escherichia coli WP2uvrA/pKM101 (OECD TG 471), 4-chloro-m-cresol was negative with or without metabolic activation.

ENDPOINT_STUDY_RECORD: Genetic toxicity in vitro.002

UUID: 126966d5-1d1f-48a0-8437-c0fb2b9ac1e2
Dossier UUID:
Author: Dra
Date: 2018-03-02T12:10:54.707+09:00
Remarks:

Administrative data

Endpoint
in vitro cytogenicity / chromosome aberration study in mammalian cells

Type of information
experimental study

Adequacy of study
key study

Robust study summary
true

Used for classification
false

Used for SDS
false

Reliability
1 (reliable without restriction)

Rationale for reliability incl. deficiencies
guideline study
Reliability 1

Data source

Reference

In Vitro Chromosomal Aberration Test of 4-chloro-m-cresol on Cultured Chinese Hamster Cells / MHLW (Ministry of Health, Labour and Welfare), Japan / study report

Materials and methods

Test guideline

Qualifier
according to

Guideline
OECD Guideline 473 (In Vitro Mammalian Chromosome Aberration Test)
in vitro cytogenicity / chromosome aberration study in mammalian cells

Qualifier
according to

Guideline
JAPAN: Guidelines for Screening Mutagenicity Testing Of Chemicals

genetic toxicity in vitro, other

GLP compliance
yes

Type of assay
in vitro mammalian chromosome aberration test
in vitro cytogenicity / chromosome aberration study in mammalian cells

Test material

Specific details on test material used for the study
- Name of test material (as cited in study report): 4-chloro-m-cresol
- CAS No.: 59-50-7
Lot No.: ASL1407
- Purity: 100%
- Supplier: Wako Pure Chemical Industries, Ltd.
- Boiling point : 235°C
- Melting point/Freezing point: 65.7°C
- Vapor pressure: 0.05 mmHg (20°C)
- Solubility: 1 g/260 mL (20°C) in water.
- Physical state: white powder
- Storage condition of test material: stored at room temperature (21.1-25.3°C), light shielding

Method

Species / strain

Species / strain
other:

Details on mammalian cell lines (if applicable)
Chinese hamster lung(CHL/IU) cells

Metabolic activation
with and without

Metabolic activation system
S9 mix; SD male rat liver, induced by phenobarbital and 5,6-benzoflavone

Test concentrations with justification for top dose
Preliminary study
50, 500, 5000 µg/mL (100% growth inhibition was observed at 500 µg/mL and higher)
Main study
[short-term treatment (6 h)] (+/-S9 mix): 50, 100, 200, 300, 400, 500 µg/mL
[continuous treatment (24 h)]: 50, 100, 150, 200, 250, 300 µg/mL

Vehicle
DMSO

Controls

Negative controls
no

Solvent controls
yes

True negative controls
no

Positive controls
yes

Positive control substance
benzo(a)pyrene
+S9 mix
mitomycin C
-S9 mix

Details on test system and conditions
METHOD OF APPLICATION: Exposure duration: [short-term treatment]:6 hrs + 18 hr, [continuous treatment]: 24h
STAIN: Giemsa stain (3 v/v%) for 10 min.
NUMBER OF REPLICATIONS: 2
NUMBER OF CELLS EVALUATED: 1000 cells /concentration
DETERMINATION OF CYTOTOXICITY- Method: relative total growth

Evaluation criteria
For the evaluation of the frequencies of structural aberrations and of polyploidy induced, the following criteria were employed.
For the evaluation of the frequencies of structural aberrations and of polyploidy induced, the following criteria were employed.
Appearance incidence of cell with chromosomal aberrations: Negative(-): less than 5%, Equivocal(±): 5% or more and less than 10%, Positive(+): 10% or more

Statistics
Not used

Results and discussion

Test results

Key result
false

Species / strain
other: Chinese hamster lung(CHL/IU) cells

Metabolic activation
with and without

Genotoxicity
negative

Cytotoxicity
yes

Vehicle controls valid
yes

Negative controls valid
not examined

Positive controls valid
yes

Additional information on results
Figures and Tables (in Japanese) are available in the following full report of the study. http://dra4.nihs.go.jp/mhlw_data/home/pdf/PDF59-50-7f.pdf

Applicant's summary and conclusion

Conclusions
Negative with and without metabolic activation

Executive summary

The in vitro chromosomal aberration test using CHL/IU cells (OECD TG 473) was negative with and without metabolic activation.

References

REFERENCE_SUBSTANCE: 4-chloro-m-cresol

UUID: fa2f9d53-ba31-416b-964a-93e8166287ef
Dossier UUID:
Author: Dra
Date: 2018-02-27T14:37:55.390+09:00
Remarks:

General information

Reference substance name
4-chloro-m-cresol

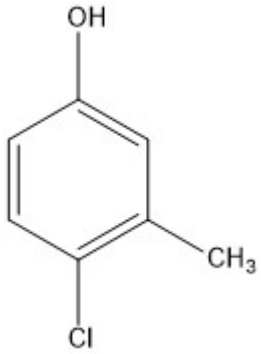
Reference substance information

CAS information

CAS number
59-50-7

Molecular and structural information

Structural formula



LITERATURE: In Vitro Chromosomal Aberration Test of 4-chloro-m-cresol on Cultured Chinese Hamster Cells

UUID: 073bdd8b-cbe0-45d4-92e8-d80334293bb1
Dossier UUID:
Author: Dra
Date: 2018-02-27T16:54:46.649+09:00
Remarks:

General information

Reference Type
study report

Title
In Vitro Chromosomal Aberration Test of 4-chloro-m-cresol on Cultured Chinese Hamster Cells

Author
MHLW (Ministry of Health, Labour and Welfare), Japan

Year
2007

Bibliographic source
Japan Existing Chemical Data Base (JECDB) http://dra4.nihs.go.jp/mhlw_data/jsp/SearchPageENG.jsp

Testing facility
Mitsubishi Safety Institute Ltd.

Report no.
B060313

LEGAL_ENTITY: National Institute of Health Sciences

UUID: IUC4-b036ff75-0f3c-323b-b200-ed5f46cf5101
Dossier UUID:
Author: Dra
Date: 2018-02-27T15:56:45.710+09:00
Remarks:

General information

Legal entity name
National Institute of Health Sciences

Identifiers

Other IT system identifiers

IT system
LEO

ID
10767

IT system
IUCLID4

ID
16558402024DIV750

Contact information

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Region / State
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Hirose

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Organisation
National Institute of Health Sciences, Japan

Department
Division of Risk Assessment

Title
Dr

Country
Japan

LITERATURE: Reverse Mutation Test of 4-chloro-m-cresol on Bacteria

UUID: 6c7ed821-3dcf-4cf8-84b3-97085910a4cb
Dossier UUID:
Author: Dra
Date: 2018-02-27T16:44:27.228+09:00
Remarks:

General information

Reference Type
study report

Title
Reverse Mutation Test of 4-chloro-m-cresol on Bacteria

Author
MHLW (Ministry of Health, Labour and Welfare), Japan

Year
2007

Bibliographic source
Japan Existing Chemical Data Base (JECDB) http://dra4.nihs.go.jp/mhlw_data/jsp/SearchPageENG.jsp

Testing facility
Mitsubishi Safety Institute Ltd.

Report no.
B060312