Pentaerythritol tetrakis (3-(3,5-di-tert-butyl-4hydroxyphenyl)propionate)

EC number: 229-722-6 | CAS number: 6683-19-8



Toxicological information

Toxicological Summary

Administrative data

Workers - Hazard via inhalation route

Systemic effects

Long term exposure

Hazard assessment conclusion:

DNEL (Derived No Effect Level)

Value

DNEL related information

DNEL derivation method:

other: The general exposure limit for dust is applied

Acute/short term exposure

Hazard assessment conclusion:

no hazard identified

DNFL related information

Local effects

Long term exposure

Hazard assessme no ha.

conclusion:

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osure

azard identified Hazarı conclus

DNEL relat rmationی

Workers - Hazard via dermal route

Systemic effects

Long term exposure

Hazard assessment DNFL (Derived No Effect Level) conclusion: Value: 89.2 mg/kg bw/day Most sensitive endpoint: repeated dose toxicity 16:01:33 Route of original study:

DNEL related information

ECHA FEACH Guidar ce DNEL derivation method:

Overall assessment factor \$\sqrt{50}\$ (AF):

Value:

Dose descriptor starting point:

NOAEL

Value:

446 mg/kg bw/day

4 460 mg/kg bw/day

Modified dose descriptor starting point:

NOAEL

Explanation for the modification of the dose descriptor starting point:

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The dermal route is typically covered by oral route information in the absence of data for this administration route. No data on skin permeation is available. However, since the test article has 20160003

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a molecular weight of > 500 and the log Pow is not within -1 to 4. a skin penetration of 10% can be assumed and the NOAEL is modified by a factor of 10 (ECHA GD chapter R7c).

	modified by a factor of 10 (EOTITE OB chapter 100).
AF for dose response relationship:	1 1.33
Justification:	The dose response relationship is considered unremarkable, therefore no additional factor is used.
AF for differences in duration of exposure:	1.12-07
Justification: 3	chronic study
AF for interspecies differences (allometric scaling):	4
Justification:	extrapolation from rat to human
AF for other interspecies differences:	2.5
Justification:	standard factor for remaining uncertainties
AF for intraspecies differences:	5
Justification:	standard factor for worker
AF for the quality of the whole database:	1 .33
Justification:	study valid and similar to guideline
AF for remaining uncertainties:	1/41-01-01
Justification:	The approach used for DNEL derivation is conservative. No further assessment factors are required.

Acute/short term exposure

Hazard assessment conclusion:

no hazard identified

DNEL related information

Local effects

Long term exposure

Hazard assessme no ha. ified conclusion:

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azard identified Hazar conclus

Workers - Hazard for the eyes

Local effects

Hazard assessment conclusion:

no hazard identified

Additional information - workers

Identification of relevant dose descriptor

The NOAEL of 446 mg/kg body weight observed in the chronic feeding study in rats was identifies as the most relevant value and was chosen for derivation of the DNEL.

General Population - Hazard via inhalation route

Systemic effects

Long term exposure

Hazard assessment

DNEL (Derived No Effect Level)

conclusion:

Value

Most sensitive endpoint:

repeated dose toxicity

7.7 mg/m³

Route of original study: Oral

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DNEL related information

DNEL derivation method: ECHA REACH Guidance 20160003 10.147.4.119 16:07:33

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Overall assessment factor (AF):	25		
Dose descriptor starting point:	NOAEL		
Value:	446 mg/kg bw/day 9		. 23
Modified dose descriptor starting point:	NOAEG A		4.119 16:07.
Value:	193.9 ng/m³		121:7-01
Explanation for the modification of the dose descriptor starting point:	Because no inhalation study is available, a route to route extrapolation was performed. The NOAEL (oral) has to be modified into a NOAEC (corrected) in accordance to guidance on information requirements and chemical safety assessment, Chapter R.8, ECHA, May 2008. Here, the NOAEL has to be divided by a factor of 1.15 m³/kg body weight. In addition, a default factor of 2 is applied to account for differences in oral and inhalative absorption properties. The corrected starting point is therefore:	20160003	10.147.4.119 16:07:33
	NOAEC (corrected) = 446 mg/kg / $1.15 \text{ m}^3/\text{kg} \times 0.5 = 193.9 \text{ mg/m}^3$		
AF for dose response relationship:	1		
Justification:	The dose response relationship is considered unremarkable, therefore no additional factor is used.		
AF for differences in duration of exposure:	7.33		1:33
Justification:	chronic study used as stating point		19 16:01
AF for interspecies differences (allometric scaling):	2022-01		10 17:07-07 16:07:33
Justification:	Allometric scaling is part of the route to route extrapol	2003	200
AF for other interspecies differences:	2.5	003	
Justification:	standard factor for r ining uncertaintie		
AF for intraspecies differences:	10		
Justification:	st cor for the al population		
AF for the quality of the database:			10.147.4.119 16:07:33
Justification:	study cc to guideline		119 16:01.
AF nir	1,47:101		147:07
Justifica	The approach used for DNEL derivation is conservative. No further assessment factors are required.	03	10.52-01
Acute/sho cerm exposi	ure	160005	V
Hazard assessment conclusion:	no hazard identified	20160003	
DNEL related information			
Local effects			
Long term exposure			
Hazard assessment conclusion:	no hazard identified		
Acute/short term exposi			<u>. 23</u>
Hazard assessment conclusion:	no hazard identified		119 16:07.50
DNEL related information	147.57.01		10.147.4.119 16:07:33
General Ropulation	Hazard via dermal route	160003	2021
-10000		16000	

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DNEL (Derived No Effect Level)

44.6 mg/kg bw/day

repeated dose toxicity

Systemic effects Long term exposure Hazard assessment

Most sensitive endpoint:

conclusion: Value:

Route of original study DNEL related information DNEL derivation method: ECHA REACH Guidance y ₁₆:01:33 Overall assessment factor 100 (AF): NOAEL Dose descriptor starting point 446 mg/kg bw/day Value: Modified dose descriptor NOAEL starting point: Value: 4 460 mg/kg bw/day Explanation for the The dermal route is typically covered by oral route information modification of the dose in the absence of data for this administration route. No data on descriptor starting point: skin permeation is available. However, since the test article has a molecular weight of > 500 and the log Pow is not within -1 to 4, a skin penetration of 10% can be assumed and the NOAEL is modified by a factor of 10 (ECHA GD chapter R7c) AF for dose response relationship: Justification The dose response relationship is considered unremarkable, therefore no additional factor is used. AF for differences in duration of exposure: Justification: AF for interspecies differences (allometric 2003 scaling): Justification extrapolation from rat to human AF for other interspecies 2.5 differences: Justification standard factor for re ining uncertainties AF for intraspecies 10 differences: Justification: sta or for the al population AF for the quality of the database mila to guideline Justification: study va A unce Justific ne approach used for DNEL derivation is conservative. No Ofurther assessment factors are required. Acute/sho. .erm exposure Hazard assessment no hazard identified **DNEL related information**

conclusion:

Local effects

Long term exposure

Hazard assessment conclusion:

no hazard identified

Acute/short term exposure

Hazard assessment conclusion:

no hazard identified

General Population - Hazard via oral route

Systemic effects

Long term exposure

Hazard assessment DNEL (Derived No Effect Level) conclusion:

Value: 4.6 mg/kg bw/day Most sensitive endpoint: repeated dose toxicity

Route of original study

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DNEL derivation method:	ECHA REACH Guidance		
Overall assessment factor (AF):	100		
Dose descriptor starting point:	NOAEL 119 6.01.33		
Value:	446 mg/kg bw/day		
AF for dose response relationship:	2022		
Justification:	The dose response relationship is considered unremarkable, therefore no additional factor is used.		
AF for differences in duration of exposure:	1		
Justification:	chronic study		
AF for interspecies differences (allometric scaling):	4		
Justification:	extrapolation from rat to human		
AF for other interspecies differences:	2.5		
Justification:	standard factor for remaining uncertainties		
AF for intraspecies differences:	10 4.19 6.01		
Justification:	standard factor for the general population		
AF for the quality of the whole database:	2622		
Justification:	Valid study similar to guideline		
AF for remaining uncertainties:	1		
Justification:	The approach used fr .VEL derivation is c nsei 2 further assessment ors are required.		
Acute/short term expos	ure		
Hazard assessment conclusion:	no hrufied		

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DNEL related info

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Hazard as

no hazard identified

Additional information - General Population

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