Compound		2-Ethylhexand	oic acid (2-EHA)	Data collection sheet (1/1)
N°CAS 149-57-5		CLP: Repr. 2 (H362	1)	
				
Organisation name	NSF#		BfR	Reach registrants
Risk value name	noncancer oral RfD		MOE	DNEL consumer*
Risk value (mg/m ³)	0.1 mg/kg _{bw} /day			3.5
Risk value (ppm)				
Reference period				
Year	2008			
Key study	Hendrickx et al., 1993		Juberg et al., 1998	3
Study type	developmental gavage study			
Species	rat		rats (male)	
Duration of exposure in key study	GD 6-15		subchronic	
Critical effect	skele malforn	etal and cardiac nation in offspring	liver toxicity	no information about DNEL derivation
Critical dose value	NOAEL	100 mg/kg _{bw} /day	NOAEL 61 mg/ kg _{bw} /day	long term inhalation DNEL (systemic effects) for the general population
Adjusted critical dose				no information about DNEL derivation
Single assessment factors (see table R.8.6)	intersp stuc	o. 10, intrasp. 10, ly duration 10		25
Other effects				
Confidence				
UF used LOAEL: UF intr	aspecies v	ariahility: IIFA inter	species variability. IIF	sused subchronic study: UEp data

UF_L used LOAEL; UF_H intraspecies variability; UF_A interspecies variability; UF_S used subchronic study; UF_D data deficiencies

*DNELs derived based on key studies selected for risk characterisation. ECHA data base last search Feb 2014.

National Sanitation Foundation (NSF), Ann Arbor - <u>http://www.techstreet.com/cgi-bin/detail?product_id=1601225</u>

Hendrickx, A.G., P.E. Peterson, R.W. Tyl, L.C. Fisher, L.J. Fosnight, M.F. Kubena, M.A. Vrabanic, and G.V. Katz. 1993. Assessment of the developmental toxicity of 2-ethylhexanoic acid in rats and rabbits. Fundam Appl Toxicol 20:199-209

Juberg, D.R., R.M. David, G.V. Katz, L.G. Bernard, D.R. Gordon, M.S. Vlaovic, and D.C. Topping. 1998. 2-Ethylhexanoic acid: Subchronic oral toxicity studies in the rat and mouse. Fd Chem Toxicol 36:429-436

Compound		2-Ethylhexanoic acid	Factsheet
Parameter	Note	Comments	Value / descriptor
EU-LCI value and status			
EU-LCI value	1	Mass/volume [µg/m ³]	150
EU-LCI status	2	Draft/final	Final
EU-LCI year of issue	3	Year when the EU-LCI value was issued	2014
General information			
CLP Index No	4	INDEX	607-230-00-6
EC No	5	EINECS — ELINCS — NLP	205-743-6
CAS No	6	Chemical Abstracts Service number	149-57-5
Harmonised CLP classification	7	Human health risk-related classification	Repr. 2, H361
Molar mass and conversion factor	8	[g/mol] and [ppm — mg/m ³]	144.21 1 ppm = 5.93 mg/m ³
Key data / database			
Key study, author(s), year	9	Critical study with lowest relevant effect level	Hendrickx et al. (1993)
Read-across compound	10	Where applicable	
Species	11	Rat etc. / human	Rat
Route/type of study	12	Inhalation, oral feed, etc.	Oral
Study length	13	Days, subchronic, chronic	(Gestation Days) 6-15
Exposure duration	14	Hours/day, days/week	
Critical endpoint	15	Effect(s), site of	Developmental malformation
Point of departure (POD)	16	LOAEC*L, NOAEC*L, NOEC*L, benchmark dose, etc.	NOAEL
POD value	17	[mg/m ³] or [ppm] or [mg/kg _{BW} ×d]	100 mg/kg/bw/d
Assessment factors (AF)	18		
Adjustment for exposure duration	19	Study exposure hours/day, days/week	1
Study length	20	$sa \rightarrow sc \rightarrow c$ (R8-5)	6
Route-to-route extrapolation factor	21	70 kg b.w., 20 m ³ /day	(3.5 applied by POD/TAF)
Dose-response	22 a	Reliability of dose-response, LOAEL → NOAEL	1
	22 b	Severity of effect (R 8-6d)	2
Interspecies differences	23 a	Allometric Metabolic rate (<i>R8-3</i>)	4
	23 b	Kinetic + dynamic	2.5
Intraspecies differences	24	Kinetic + dynamic Worker — general population	10
AF (sensitive population)	25	Children or other sensitive groups	1
Other adjustment factors	26	Completeness and consistency	2

Quality of whole database		Reliability of alternative data (R8-6 d,e)	
Result			
Summary of assessment factors	27	Total Assessment Factor (TAF)	2400
POD/TAF	28	Calculated value (µg/m ³ and ppb)	100 mg/2400 = 0.08 mg/kgbw/d x 70/20 = 145 μg/m ³ (24.4 ppb)
Molar adjustment factor	29	Used in read-across	
Rounded value	30	[µg/m³]	150
Additional comments	31		

Rationale section	32	

The LCI for 2-ethylhexanoic acid (2-EHA) is based on the NOAEL of 100 mg/kg-day for developmental toxicity in rats from the Hendrickx et al. (1993) study. The NOAEL for rats was based on skeletal and cardiac malformation in offspring. In the same study maternal toxicity occurred in rabbits. The corresponding NOAELs for rabbits are 25 mg/kg/day (maternal) and > or = 250 mg/kg/day (developmental).

A threshold effect based on induction of metallothionein for reproductive toxicity is assumed.

2-EHA is also a metabolite of Ethylhexanol and Di-ethylhexyladipat (DEHA).

Standard AFs for study length sa \rightarrow chr (6), intra- (10) and interspecies (10) extrapolation, a factor for severity of effect of 2 and a factor of 2 for quality of whole database (no inhalation study) were applied. These factors lead to a TAF of 2400. Route to route extrapolation is applied for a person weighing 70 kg and 20 m³ inhalation per day.

No data on odour thresholds and irritation thresholds were available.

References

Hendrickx, A.G. et al.. Assessment of the developmental toxicity of 2-ethylhexanoic acid in rats and rabbits. 1993. Fundam Appl Toxicol 20:199-209.