

Committee for Risk Assessment
RAC

Annex 2

Response to comments document (RCOM)
to the Opinion proposing harmonised classification
and labelling at EU level of

potassium sorbate

EC number: 246-376-1
CAS number: 24634-61-5

CLH-O-0000002524-78-03/A2

Adopted
6 March 2013

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

ECHA has compiled the comments received via the internet that refer to several hazard classes and entered them under each of the relevant categories/headings as comprehensively as possible. Please note that some of the comments might occur under several headings, when splitting the information provided is not reasonable.

Substance name: Potassium sorbate

EC number: 246-376-1

CAS number: 24634-61-5

Dossier submitter: Germany

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
26/06/2012	Denmark		MSCA	1
Comment received				
DK supports the proposed harmonised classification				
Dossier Submitter's Response				
RAC's response				
noted				
Date	Country	Organisation	Type of Organisation	Comment number
28/06/2012	France		MSCA	2
Comment received				
FR agrees with the classification proposal.				
Dossier Submitter's Response				
Thank you for the support				
RAC's response				
noted				

CARCINOGENICITY: no comments received

MUTAGENICITY: no comments received

TOXICITY TO REPRODUCTION: no comments received

RESPIRATORY SENSITISATION: no comments received

OTHER HAZARDS AND ENDPOINTS: no comments received

SKIN HAZARD: no comments received

Date	Country	Organisation	Type of Organisation	Comment number
25/06/2012	United Kingdom	HSE UKCA	MSCA	3
Comment received				
We agree with the proposed classification for skin irritation.				
Dossier Submitter's Response				
Thank you for the support				
RAC's response				
noted				

EYE HAZARD

Date	Country	Organisation	Type of Organisation	Comment number
25/06/2012	United Kingdom	HSE UKCA	MSCA	4
Comment received				
We agree with the proposed classification for eye irritation.				
Dossier Submitter's Response				
Thank you for the support				
RAC's response				
noted				

AQUATIC ENVIRONMENT HAZARD

Date	Country	Organisation	Type of Organisation	Comment number
28/06/2012	France		MSCA	5
Comment received				
FR agrees with the general conclusion dealing with the environmental classification of the substance. However please find below some minor comments dealing the environmental assessment of hazards of this substance.				
1. p7 and 13. The pKa of sorbic acid should be provided. Additionally, it should be more clearly explained that at environmental pH potassium sorbate is dissociated and the anionic form of sorbic acid will almost occur. At last, water solubility and vapour pressure for sorbic acid should be provided.				
2. p13, 4.2 Bioaccumulation. Please note that QSAR cannot be applied to ionic substance to determine BCF. However, the values of log Kow are sufficiently below the trigger value to state that bioaccumulation potential is low.				
3. IUCLID file, 6.1.3.2. Could you please add information about the validity criteria in the IUCLID file of the toxicity study on daphnia (Staebler, 2004b)?				
Dossier Submitter's Response				
1. DE agrees. The following entry should be added to table 1 on page 7: REACH ref Annex, § IX, 7.15 - Property Dissociation constant – IUCLID section 4.21 - Value pKa 4.69 – comment/reference Wilfinger, W.; 2003; report no. 20031274/01-PCDC. The explanation that at environmental pH potassium sorbate as dissociated is given in chapter 4.1.1 Biodegradation. Therefore, DE is of the opinion that an additional explanation is not required.				
Physico-chemical properties of (E,E)-2,4-Hexadienoic acid (CAS no 110-44-1; EC no 203-768-7):				
REACH ref Annex, §	Property	IUCLID section	Value	[enter comment/reference or delete column]
VII, 7.1	Physical state at 20°C and 101.3 kPa	4.1	Colorless to white needles or white powder	Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996., p. 3005
VII, 7.2	Melting/freezing point	4.2	134.5°C	MITI 1992. Biodegradation and bioaccumulation data of existing chemicals based on the CSCL Japan. Compild under the Safety Division Basic Industries

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON POTASSIUM SORBATE

				Bureau Ministry of International Trade & Industry, Japan. Edited by Chemicals Inspection & Testing Institute, Japan
VII, 7.3	Boiling point	4.3	228 °C with decomposition.	Gerhartz, W. (exec ed.). Ullmann's Encyclopedia of Industrial Chemistry. 5th ed. Vol A1: Deerfield Beach, FL: VCH Publishers, 1985 to Present., p. VA24 507
VII, 7.4	Relative density	4.4	1.204 at 19 °C/4 °C	Lide, D.R. (ed.). CRC Handbook of Chemistry and Physics. 76th ed. Boca Raton, FL: CRC Press Inc., 1995-1996., p. 3-185
VII, 7.5	Vapour pressure	4.6	50 mm Hg at 143 °C	Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996., p. 1489
VII, 7.6	Surface tension	4.10		
VII, 7.7	Water solubility	4.8	1.6 g/L	Budavari, S. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Whitehouse Station, NJ: Merck and Co., Inc., 1996., p. 8870
VII, 7.8	Partition coefficient n-octanol/water (log value)	4.7	pH 2,5: 1,32 at 20°C pH 6,5: -1,72 at 20°C (sorbic acid)	Heintze, A. (2002) report no. 0011364/01-PCPC
VII, 7.9	Flash point	4.11		
VII, 7.10	Flammability upon ignition (solids) Flammability in contact with water Pyrophoric properties	4.13		
VII, 7.11	Explosive properties	4.14		
VII, 7.12	Relative self-ignition temperature for solids	4.12		

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON POTASSIUM SORBATE

VII, 7.13	Oxidising properties	4.15		
	Heat of decomposition	4.19		
IX, 7.15	Dissociation constant	4.21	pKa 4.6	Sangster, J. 1989. Octanol-water partition coefficients of simple organic compounds. J. Phys. Chem. Ref. Data, Vol 18, No. 3: 1111 - 1229.
<p>2. 4.2 Bioaccumulation: We agree that QSAR cannot be applied to ionic substances. However, this does not change the outcome of the assessment.</p> <p>3. A reliability of 1 was given for the study on daphnia, as the study was performed according to standard test guideline and GLP. All validity criteria of the test guideline were fulfilled.</p>				
RAC's response				
noted				

REFERENCES: none

ATTACHMENTS RECEIVED: none