CONSIDERATIONS OF ALTERNATIVE METHODS ON TESTING PROPOSALS IN YOUR REGISTRATION

Please complete this form and provide information for each of the points below.

If you have more than one testing proposal, please copy and paste the three bullet points within the same document and complete the details as appropriate for each testing proposal.

This document will be published on ECHA website along with the third party consultation on the testing proposal(s).

Public substance name: Potassium 3-sulphonatopropyl acrylate
EC Number (omit if confidential): 250-465-0
CAS Number (omit if confidential): 31098-20-1

Date of considerations: 8 May 2020

- **Hazard endpoint for which vertebrate testing was proposed:**

  Genetic toxicity in vivo with the Potassium 3-sulphonatopropyl acrylate substance

- **Considerations that the general adaptation possibilities of Annex XI of the REACH Regulation were not adequate to generate the necessary information** (instruction: please address all points below):

  - available GLP studies

    The in vitro genetic toxicity of Potassium-3-sulphonatopropyl acrylate (SPA) was assessed in a bacterial reverse mutation assay (Ames test), which was performed according to OECD guideline 471 and under GLP conditions (Jones, 1993). Reliability 1. The test substance was not mutagenic, with and without metabolic activation, under the conditions of the test.

    The clastogenic activity of the test substance was investigated in an in vitro mammalian chromosome aberration test in cultured peripheral human lymphocytes performed according to OECD guideline 473 and GLP (Lauenstein, 2014). Reliability 1. Thus, the test substance was considered to be not clastogenic under the conditions of this test.

    A mouse lymphoma assay in cultured mammalian cells (L5178Y TK +/-) was performed according to OECD guideline 476 and in compliance with GLP (Spruth, 2015). Reliability 1. Under the test conditions, SPA showed a clear concentration-related increase in mutant frequency, but did not exhibit a clastogenic potential at the tested concentrations. In conclusion, SPA is mutagenic in the mouse lymphoma forward mutation assay with and without metabolic activation.

  - available non-GLP studies

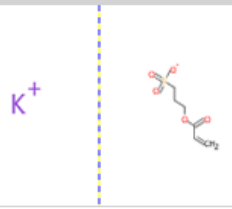
    none

- historical human data

  none

- (Q)SAR

  QSAR Toolbox profiling results on genotoxicity/carcinogenicity:

	A	B	C	D	E
1					Chemical #1
2	**Substance identity**				
3	Structure				
4	CAS number				31098-20-1
5	Chemical name				SPA
6	Other identifier				
7	SMILES				[K+].[O-]S(=O)(=O)CCCOC(=O)C=C
8					
9	**Profilers**				
10	***Endpoint Specific***				
11	in vitro mutagenicity (Ames test) alerts by ISS				No alert found
12	DNA alerts for AMES, CA and MNT by OASIS				No alert found
13	in vivo mutagenicity (Micronucleus) alerts by ISS				No alert found
14	Carcinogenicity (genotox and nongenotox) alerts by ISS				No alert found
15	Protein binding alerts for Chromosomal aberration by OASIS				No alert found
16					
17	**Measured and predicted data**				
18					
19	**Predictions**				
20	***Other predictions***				
21	*sublevel*	*endpoint*	*value*	*unit*	*species, duration, test type, type of method, assay, strain, test guideline, year, reference,*
22					
23	* 0 chemical(s) were marked private and not exported.				

  Based on QSAR Toolbox no corresponding alerts found.

- *in vitro* methods

  see available GLP studies above

- weight of evidence

  no adequate data available

- grouping and read-across

  Source chemical Potassium 3-sulphonatopropyl methacrylate (EC Number 250-466-6) is a close structural analogon to target substance Potassium 3-sulphonatopropyl acrylate.

Available genotoxicity data for Potassium 3-sulphonatopropyl methacrylate:

in vitro, reliability 2: Gene mutation (Bacterial reverse mutation test / Ames test), S. typhimurium TA1535, TA 1537, TA 98, TA100, up to 5000 µg/plate with and without metabolic activation (OECD 471, GLP): negative ± S9

in vitro, reliability 2: Gene mutation (Bacterial reverse mutation test / Ames test), S. typhimurium TA1535, TA 1537, TA 98, TA100, TA 1538, up to 5000 µg/plate with and without metabolic activation (OECD 471, GLP): negative ± S9

in vitro, reliability 1: chromosome aberration, V79 cells, up to 5000 µg/plate with and without metabolic activation (OECD 473, GLP): negative ± S9

in vitro, reliability 1: Gene mutation in mammalian cells (HPRT assay), V79 cells, up to 5000 µg/plate with and without metabolic activation (OECD 476, GLP): negative ± S9

No adequate in-vivo data available.

- substance-tailored exposure driven testing [if applicable]

  not applicable

- [approaches in addition to above [if applicable]

  not applicable

- other reasons [if applicable]

  not applicable

- **Considerations that the specific adaptation possibilities of Annexes VI to X (and column 2 thereof) were not applicable** (instruction: free text):

  According to REACH Regulation, Annex VIII, 8.4. Mutagenicity, column 2, “Appropriate in vivo mutagenicity studies shall be considered in case of a positive result in any of the genotoxicity studies in Annex VII or VIII.”

  No adequate data from an in vivo cytogenicity test are available. The substance is not known to be carcinogenic category 1A or 1B or germ cell mutagenic category 1A, 1B or 2. No adequate data from a reliable in vivo mammalian gene mutation test are available.

  Annex IX: If there is a positive result in any of the in vitrogenotoxicity studies in Annex VII or VIII and there are no results available from an in vivostudy already, an appropriate in vivo somatic cell genotoxicity study shall be proposed by the registrant.

  Based on the positive result in the mouse lymphoma assay according to OECD 476 in L5178Y (TK+/-) mouse lymphoma cells and as there are no results available from an in vivo genetic toxicity study, an in vivo mammalian alkaline comet assay in rats following OECD 489 is proposed in order to fulfil the information requirements according to Annex VIII, Column II, 8.4.