WCSR Advice 2017-10

SCIENTIFIC COMMITTEE REACH (WCSR)

ADVICE ON CARCINOGENICITY AND MUTAGENICITY OF POTASSIUM (E,E)-HEXA-2,4-DIENOATE

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1 Context

The BE CA requested an advice to support the manual screening process. The aim of the manual screening process by REACH competent authorities is to examine whether a preliminary concern can be detected for particular substances. The substances on which manual screenings are performed are prioritized either by ECHA through an IT screening (ECHA runs certain alert algorithms on all the REACH registered substances) or are selected by member states as national priorities.

For this particular substance, a concern was also identified by the ECHA IT system for carcinogenic and mutagenic properties.

The BE CA selected this substance for manual screening and needs to verify whether the IT alert can be confirmed.

Confirmation is needed on whether there are indications that the substance has carcinogenic or mutagenic properties on the basis of the available information on these endpoints in the registration dossier (chemical safety report) or in the public literature (if there is any available for this particular substance related to the carcinogenic or mutagenic concern).

The BE REACH CA will take this scientific evaluation of the carcinogenic and mutagenic endpoints into account in their decision making on the best way forward for the substance (f.i. Harmonised classification and labelling, substance evaluation, …) => This is not part of the WCSR task, but will be done by the BE CA.

The complete advice cannot be made publicly available due to the confidential nature of the contents. Therefore a summary of the advice and the conclusion are made available in this document.

Please note that the advice was concluded in 2017, information on this topic made available after this date is therefore not considered in this document.

2 Summary of the final advice

Short summary and overall relevance of the provided information (chemical safety report from REACH registration dossier) on germ cell mutagenicity:

No information on germ cell mutagenicity of potassium sorbate was found in the registration dossier or public literature. However, considering that overall no mutagenic potential of potassium sorbate was observed neither in vitro nor in vivo, an assessment of the germ cell effects is considered not necessary.

Short summary and overall relevance of the provided information on carcinogenicity:

Two carcinogenicity studies, one on rats (2 years), the second on mice (18 months) are reported in the chemical safety report. These studies are also available in the public literature. No other relevant carcinogenic studies were found in the public literature.

Both available studies were performed before the publication of the first OECD test guidelines.

The most important deviation from the test guideline was the fact that only two doses were used in the rat study and the fact that in both studies, the highest dose was largely exceeding the upper limit of 5%. On basis of the two studies, no carcinogenic potential activity could be demonstrated.

Potassium sorbate is an active substance approved under the EU 528/2012 as wood preservative and is under evaluation under the same regulation as preservative for products during storage.

Potassium sorbate has also been recently re-evaluated by EFSA as food additive (EFSA Journal 2015; 13(6): 4144). The same studies were evaluated and the panel of EFSA came to the same conclusion on the absence of carcinogenic effect of sorbic acid.

Is further testing needed to conclude on carcinogenicity/mutagenicity?

No, the available battery of in vitro and in vivo genotoxicity tests is sufficient to support the absence of genotoxic effects of potassium sorbate.

MEMBERS OF THE SCIENTIFIC COMMITTEE

The members are :

Willy Baeyens; Johan Bierkens; Marie-Noëlle Blaude; Steven Broekx; Peter Dubruel; Lieve Geerts; Lode Godderis; Walter Hecq; Birgit Mertens; Guy Schroyen; Stefaan Soenen; Guido Vanermen; Nicolas Van Larebeke; An Van Nieuwenhuyse; Jeroen Vanoirbeek; Reinhilde Weltens.

CONFLICT OF INTEREST

No member has declared any conflict of interest.

RAPPORTEUR(S)

The Scientific Committee REACH thanks the rapporteurs Marie-Noëlle Blaude and Birgit Mertens.

ADOPTION OF THE ADVICE

The Scientific Committee REACH advice was adopted by consensus on 03/05/2017. The publishing of this summary on the WCSR website has been approved by written vote on 30/06/2021.

LEGAL FRAMEWORK OF THE ADVICE

Cooperation agreement of 17 October 2011 between the Federal State, the Flemish Region, the Walloon Region and the Brussels Capital Region concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Ministerial decree of 8 July 2014 appointing the members of the Scientific Committee REACH established under Article 3, § 3 of the Cooperation Agreement of 17 October 2011 between the Federal State, the Flemish Region, the Walloon Region and the Brussels Capital Region concerning the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH)

Ministerial decree of 2 June 2016 on dismissal and appointment of members of the Scientific Committee REACH

Ministerial decree of 5 October 2016 on appointment of members of the Scientific Committee REACH

DISCLAIMER

The Scientific Committee REACH reserves, at any time, the right to change this advice when new information and data become available after the publication of this version. Please note that this advice dates back to 2017, therefore any information made available after this date is not taken into account.

President

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