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Assessment of estrogen, androgen, thyroid and steroidogenic (EATS) mediated endocrine disrupting (ED) properties of PVP-iodine (CAS no. 25655-41-8)

Sponsor: Iodine Registration Group (IRG)

Reporting: [redacted]

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Introduction

With the date of 18 February 2020 the European Commission informed members of the Iodine Registration Group (IRG) that by having indications on endocrine disruptor (ED) properties of the active substances the early review has been started for iodine and PVP-iodine. In accordance with Article 15(1) of Regulation (EU) No 528/2012 the applicants got the opportunity to provide comments in this early review process.

Within this context, the IRG decided to prepare a full assessment of estrogen, androgen, thyroid and steroidogenic (EATS) mediated endocrine disrupting properties of iodine and PVP-iodine.

According to the Assessment Report of iodine (including PVP-iodine) for PT 1, 3, 4 and 22 (AR, 2013) in principle iodine should be regarded as the active substance as long as the iodophors are not considered as discrete active substances. Iodophors are preparations containing iodine complexed with a carrier and/or a solubilizing agent, such as povidone (PVP, Polyvinylpyrrolidone). There is a separate CAS-No assigned to PVP-iodine (25655-41-8) compared to iodine (7553-56-2). Nevertheless, it was concluded in the Assessment Report of iodine (including PVP-iodine) for PT 1, 3, 4 and 22 (AR, 2013) that although a complex is built there is no real reaction between iodine and PVP.

Iodine is the active component of the PVP-iodine complex and the substance which is relevant for the ED assessment. Therefore, the potential ED properties of iodine were assessed. Please refer to the document "Assessment of estrogen, androgen, thyroid and steroidogenic (EATS) mediated endocrine disrupting (ED) properties of iodine (CAS no. 7553-56-2)" (SCC, 2020). Nevertheless, also on the potential ED properties of PVP-iodine were assessed and presented in this document.

In Part A of the document a scientific statement on the assessment of T-mediated ED properties of iodine is provided, whereas Part B of the document focuses on the potential EAS-mediated ED properties of PVP-iodine.

Executive summary

Iodine, which represents the active component of PVP-iodine, is an essential dietary trace element (micronutrient), required as a structural and functional element of the thyroid hormones thyroxine (T4) and triiodothyronine (T3), which play critical roles in the carbohydrate, lipid, protein and mitochondrial energy metabolism and are particularly essential during embryogenesis and growth (WHO, 1989; EFSA, 2014). To ensure a sufficient intake and to prevent iodine deficiency disorders, iodine supplementation is required and recommended (WHO/FAO, 2004; EFSA, 2014).

The fact that (i) iodine is an essential dietary trace element with a defined key role in the biosynthesis of the thyroid hormones T4 and T3 (T modality of the hormone system) and the point that (ii) dietary intake and even food supplementation are recommended to ensure a sufficient iodine intake in the population show, that an entirely hazard based endocrine disruption (ED) assessment as outlined in the "Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009" (ED GD; ECHA/EFSA, 2018) especially with focus on T modality is not meaningful for iodine, and possibly beyond the scope of the Commission Delegated Regulation (EU) 2017/2100.

If the ED properties of iodine and other essential micronutrients would be assessed from a scientific perspective, the assessment should consider not only the hazard, but also take into account the potency and exposure. However, risk assessments for the approval of iodine (including PVP-iodine) as biocidal active substance and for the authorisation of iodine-based biocidal products already consider the upper limit (UL) of iodine intake which takes into account the endocrine effects of iodine and represents a conservative basis for the risk assessment. Therefore, regulating iodine as endocrine disrupting chemical (EDC) would not provide any additional safety.

Nevertheless, an assessment of potential EAS-mediated ED properties of PVP-iodine was performed according to the ED GD to make this information available for an independent assessment.

The present assessment was based on a weight of evidence approach and revealed that no EAS-related activity is attributable to PVP-iodine. Additionally no toxicologically significant EAS–mediated adversity was observed in the available data set. Therefore "*ED criteria regarding EAS modalities are not met*" for iodine.