

Nouryon response to proposal for Acute Tox 3 classification for potassium chlorate 2020-06-22

The change of classification of potassium chlorate from Acute Tox 4 to Acute Tox 3 is based on several poisoning cases with sodium and potassium chlorate that occurred mostly in the 60's and 70's. The incidents were mostly suicide attempts and not related to industrial or professional use of potassium chlorate.

As the classification of potassium chlorate as Acute tox 4 is based on poisoning cases an LD50 value cannot be established and indeed according to the Guidance on the Application of the CLP Criteria (v.5, July 2017) "The minimum dose or concentration or range shown or expected to cause mortality after a single human exposure can be used to derive the human ATE directly, without any adjustments or uncertainty factors". However, having regard to the wording in the guidance ("can" as opposed to "shall"), we understand that this is not a mandatory principle.

As mentioned above the reported cases are suicide and/or poisoning incidents; these are not controlled studies and there may be underlying illness or a history of other substance abuse. This is not clear from the publications as most of them do not have many details and only numbers are reported. As stated previously, due to vomiting occurring, sometimes rapidly after ingestion, the absorbed quantity is often uncertain. Therefore, variability occurs in the doses causing lethality.

The guidance states that "minimum dose or concentration or range" "can be used" to derive the ATE directly.

In the light of the quality of the data and related uncertainties we believe there is no logical choice to use the minimum dose as the basis for the ATE. As it is stated that in many cases, the lethal dose in human are above 20 g (332 mg/kg bw) (Helliwell and Nunn, 1979) and also NTP stated that death has been most frequently associated with doses of 20 g (333 mg/kw bw) or greater, although recovery has been noted in patients who ingested as much as 200 g (3333 mg/kw bw) (NTP 2005).

Therefore, we do not agree with the suggested 83 mg/kg bw as the basis for ATE derivation and in the case of sodium and potassium chlorate still suggests 332 mg/kg bw as the relevant starting point for deriving the ATE.