

The change of classification of sodium chlorate from Acute Tox 4 to Acute Tox 3 is based on several poisoning cases with sodium chlorate that occurred mostly in the 60's and 70's when sodium chlorate was used as herbicide.

In 2009 a literature search was performed for sodium chlorate. No new poisoning cases with sodium chlorate were identified in the recent literature search.

The incidents were mostly suicide attempts and not related to industrial or professional use of potassium or sodium chlorate. Since more than a decade, chlorate is banned as herbicide and access of the general public is not permitted anymore.

Industrial use of sodium chlorate is mainly to produce ClO<sub>2</sub>, which is already classified as Acute Tox 2\*. The manufacturing process of sodium chlorate is made in such a way that exposure of sodium chlorate to workers is very low. Because NaClO<sub>3</sub> reacts strongly with organic materials, contact with workers is controlled; accidental oral poisoning will not happen even in case of loss of containment.

Fatalities via the oral route involving workers are not known.

As the classification of sodium 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.

A stronger Acute Tox classification will not help to protect workers and could even cause confusion amongst industry. We therefore suggest maintaining the acute tox 4 classification for both potassium and sodium chlorate.