

Arguments concerning the Testing Proposal submitted for STPP, February 2010

According to Annex IX of EC regulation No 1907/2006, for substances manufactured or imported at a tonnage greater than 100 tonnes/yr the applicant must propose a subchronic (90 day) study by the most appropriate route of exposure.

Column 2 of Annex IX states that the study need not be performed if:

- A reliable short term (28 day) study is available showing severe toxicity effects according to the criteria for classifying a substance as R48, for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor, allows the extrapolation towards the NOAEL-90 days for the same route of exposure,

or

- A reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used.

The first criteria for exposure based waiving requires that it is demonstrated and documented that exposures in all scenarios is well below an appropriate derived no-effect level (DNEL) or predicted no effect concentration (PNEC) derived under specific conditionsⁱ (Commission regulation (EC) No 134/2009 amending regulation (EC) No 1907/2006 (5)).

Sodium tripolyphosphate is not classified as dangerous according to Directive 67/548/EEC, Directive 1999/45/EEC or Regulation (EC) No 127/2008 and therefore exposure scenarios and risk characterisation are not required.

A reliability 2 chronic (2-year) oral feed study (Hodge 1959) is available and the Consortium is aware of a reliability 3 subacute (28-day) inhalation study. The owners of this unpublished subacute study (1971) assigned a reliability of 2 to the study. On viewing the study report, this has been downgraded by the Consortium to reliability 3 due to the lack of histopathological data, this conforms to the data owner company's own summary made at the time which indicates that full conclusions must await the histopathology report, but the owner concluded not to perform further investigation and there is no histopathology report for the study. The study does not contradict the no classification status of Sodium tripolyphosphate.

In accordance with the requirements of Annex IX, the Consortium is proposing to perform a 90-day inhalation study in the rat but would argue that this is not justified taking into account the requirements of REACH to minimise animal testingⁱⁱ and for the following reasons:

1. As sodium tripolyphosphate is not classified, there is no requirement to generate exposure scenarios, therefore there will be no predicted concentrations and no risk characterisation.
2. Due to the lack of exposure scenarios, it is not possible to identify the most relevant route of exposure for testing.
3. A reliable chronic (2-year) oral study is available and as the most likely route of exposure is not identified due to the lack of exposure scenarios, it is proposed to generate the inhalation DNEL using route to route extrapolation from the oral study
4. Sodium tripolyphosphate is very soluble (148g/L at 20°C) and is likely to undergo enzymatic hydrolysis to orthophosphate in the lung. Toxicity is anticipated to be similar to that exhibited by oral exposure.
5. Sodium tripolyphosphate is listed on the US FDA GRAS (generally recognised as safe) food additive inventory and most inorganic phosphates (including sodium tripolyphosphate and sodium orthophosphate) are generally considered to be harmless.

ⁱ For the purpose of subparagraph 3.2(a)(ii), without prejudice to column 2 of section 8.6 of annexes IX and X, a DNEL derived from a 28 day repeated dose toxicity study shall not be considered appropriate to omit a 90-day repeated dose toxicity study.

ⁱⁱ Regulation (EC) No 1907/2006. Title III Data sharing and avoidance of unnecessary testing, Article 25(1) In order to avoid animal testing, testing on vertebrate animals for the purposes of this regulation shall be undertaken only as a last resort.