

## HEAL response to ANSES proposal to classify Lithium Salts - lithium carbonate, lithium chloride, lithium hydroxide - as toxic to reproduction 1A



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The Health and Environment Alliance (HEAL) welcomes the opportunity to comment on France's proposal to classify three Lithium salts - lithium carbonate, lithium chloride, lithium hydroxide - as toxic to reproduction 1A and fully supports this initiative.

The supporting CLH dossier is comprehensive and the methodology used to report on the scientific evidence available on different endpoints is very clear and transparent.

## **AS REGARDS REPRODUCTIVE TOXICITY:**

- The description of the methodology is particularly clear and we welcome the transparent reporting about the strength of the various studies investigated.
- Sexual functions and fertility: We concur with the MSCA conclusion that despite the overall negative findings in the
  two-generation study, the findings of two other important and strong studies (the 90-day/mating study and the
  studies on male reproduction) clearly demonstrate effects on fertility. Therefore, we fully support the proposal for a
  classification of the three lithium salts in category 1B for reproductive toxicity.
- Development: We agree that human data can be considered strong supportive evidence of the developmental effects of the substance and that the warning about increased malformation rates among children exposed in utero to lithium via lithium-based drugs add to such evidence. We are in favour of the proposal for classification of lithium in category 1A for development.

BASED ON THE ABOVE, WE SUPPORT THE PROPOSED CLASSIFICATION: REPR. 1A, H 360FD; MAY DAMAGE FERTILITY, MAY DAMAGE THE UNBORN CHILD.

Natacha Cingotti, Senior Policy Officer, Health and Chemicals Health and Environment Alliance (HEAL) E-mail: natacha@env-health.org

Tel: +32 2 234 36 45

The Health and Environment Alliance (HEAL) is the leading not-for-profit organisation addressing how the environment affects human health in the European Union (EU) and beyond. HEAL works to shape laws and policies that promote planetary and human health and protect those most affected by pollution, and raise awareness on the benefits of environmental action for health.

HEAL's over 80 member organisations include international, European, national and local groups of health professionals, not-for-profit health insurers, patients, citizens, women, youth, and environmental experts representing over 200 million people across the 53 countries of the WHO European Region.

As an alliance, HEAL brings independent and expert evidence from the health community to EU and global decision-making processes to inspire disease prevention and to promote a toxic-free, low-carbon, fair and healthy future.

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