



Justification for removing a substance from CoRAP prior to evaluation

Substance Name (public name): Sodium 3-nitrobenzene sulphonate

EC Number: 204-857-3

CAS Number: 127-68-4

Authority: Health and Safety Authority, Ireland

Date: 21 March 2023

The priority for evaluating the substance has been reconsidered based on:

<input checked="" type="checkbox"/>	The initial hazard ground of concern has been verified and considered of low priority
<p>The initial hazard based concern related to reproductive toxicity, specifically an effect on fertility. The concern was based on an increase in absolute testes weight observed in a 90-day repeated dose toxicity study with sodium 3-nitrobenzene sulphonate and the structural similarity to nitrobenzene, which has a harmonised classification as Repr. 1B H360F due to effects on male fertility.</p> <p>No study investigating effects on fertility is reported in the registration dossier. An oral reproductive toxicity study, similar to OECD 421, with sodium 3-nitrobenzene sulphonate is reported on the Japan Existing Chemical Database (JECDB). In this study, no effect on fertility or pregnancy parameters was observed. With respect to male fertility, there was no effect on testes, epididymal, prostate or seminal vesicle weights, and no histopathological findings in these organs up to 1000 mg/kg bw/day. While an increase in absolute testes weight was observed in the 90-day repeated dose toxicity study, no histopathological effects in the testes, seminal vesicles or epididymides was observed in this study and there was no effect on sperm motility.</p> <p>While sodium 3-nitrobenzene sulphonate is structurally similar to nitrobenzene, the available data does not support a concern for effects on fertility for sodium 3-nitrobenzene sulphonate.</p> <p>The IE CA considers that based on the available information, the substance is of low priority for substance evaluation.</p>	

<input type="checkbox"/>	The initial exposure/risk ground of concern has been verified and considered of low priority

<input type="checkbox"/>	The generation of information under Substance Evaluation is considered of low priority because
	<input type="checkbox"/> Already ongoing or implemented regulatory process(es)
	<input type="checkbox"/> Registrants' (voluntary) action addresses concern
	<input type="checkbox"/> Other: