



MINISTERIO  
DE SANIDAD

## **Justification for removing a substance from CoRAP prior to evaluation**

**Substance Name (public name):** 3,5,5-trimethylhexanoic acid

**EC Number:** 221-975-0

**CAS Number:** 3302-10-1

**Authority:** Spain. Ministry of Health

**Date:** 22/03/2022

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

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

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

<input checked="" type="checkbox"/>	<b>The generation of information under Substance Evaluation is considered of low priority because</b>
	<p><input checked="" type="checkbox"/> Already ongoing or implemented regulatory process(es)</p> <p>A dossier evaluation process (compliance check) prior to substance evaluation is ongoing with the substance. As a result, comprehensive new information on reproductive toxicity (prenatal developmental toxicity study (OECD TG 414) and EOGRTS (OECD TG 443)) has been generated.</p> <p>Thus, we consider that the results of the new studies could already clarify the initial concern for reproductive toxicity and therefore, there would not be added value to initiate a SEv process.</p>
	<input type="checkbox"/> Registrants' (voluntary) action addresses concern
	<input type="checkbox"/> Other: