



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

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

**EC Number:** 200-657-5

**CAS Number:** 67-51-6

**Authority:** Ministry of Health. Spain

**Date:** 17/03/2021

**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>
<ul style="list-style-type: none"> <li>• <i>Indicate the initial hazard ground of concern (e.g. suspected CMR, ED, PBT, as presented in chapter 5.3 of the CoRAP justification document)</i></li> <li>• <i>Provide the reasons for reconsidering their relevance.</i></li> </ul>	

<input type="checkbox"/>	<b>The initial exposure/risk ground of concern has been verified and considered of low priority</b>
<ul style="list-style-type: none"> <li>• <i>Indicate the initial exposure/risk ground of concern (e.g. wide dispersive use, consumer use, high RCR, as presented in chapter 5.3 of the CoRAP justification document)</i></li> <li>• <i>Provide the reasons for reconsidering their relevance.</i></li> </ul>	

<input checked="" type="checkbox"/>	<b>The generation of information under Substance Evaluation is considered of low priority because</b>
<input checked="" type="checkbox"/> Already ongoing or implemented regulatory risk management process(es) A compliance check prior to substance evaluation was performed with the substance. As a result, comprehensive new information on reproductive toxicity (prenatal developmental toxicity study (OECD TG 414) and EOGRTS with DIT cohort (OECD TG 443)) was generated. Thus, we consider that the results of the new studies clarify the initial concern for reproductive toxicity and therefore, substance evaluation is no longer needed for this substance. As part of the regulatory strategy for the alkylated pyrazoles, BE agreed to submit a proposal for harmonisation of the classification as toxic to reproduction by December 2021.	
<input type="checkbox"/> Registrants' (voluntary) action addresses concern <i>Specify</i>	
<input type="checkbox"/> Other: <i>Specify</i>	