

**Committee for Risk Assessment**  
**RAC**

Annex 3  
**Records**

of the targeted consultation following the submission of  
additional information on acute inhalation toxicity on  
**3-iodo-2-propynyl butylcarbamate;**  
**3-iodoprop-2-yn-1-yl butylcarbamate**

**EC Number: 259-627-5**  
**CAS Number: 55406-53-6**

CLH-O-0000007358-66-01/F

**Adopted**  
**14 September 2023**

**RAC**  
COMMITTEE FOR RISK  
ASSESSMENT

**ANNEX 3 – RECORDS OF THE TARGETED CONSULTATION FOLLOWING THE SUBMISSION OF ADDITIONAL INFORMATION ON ACUTE INHALATION TOXICITY ON 3-IODO-2-PROPYNYL BUTYLCARBAMATE;**

**COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION**

The proposal for the harmonised classification and labelling (CLH) of 3-iodo-2-propynyl butylcarbamate; 3-iodoprop-2-yn-1-yl butylcarbamate (EC 259-627-5; CAS 55406-53-6) was submitted by Denmark and was subject to a consultation from 19/12/2022 to 17/02/2023. The comments received by that date are compiled in Annex 2 to the opinion.

After the consultation held from 19/12/2022 to 17/02/2023, the dossier submitter submitted to ECHA a document containing additional information on acute inhalation toxicity. This document was the subject of an ad hoc consultation from **21/04/2023 to 05/05/2023**. The comments received by that date are compiled below.

**Last data extracted on 17.05.2023**

**Substance name: 3-iodo-2-propynyl butylcarbamate; 3-iodoprop-2-yn-1-yl butylcarbamate**

**EC number: 259-627-5**

**CAS number: 55406-53-6**

**Dossier submitter: Denmark**

**GENERAL COMMENTS**

Date	Country	Organisation	Type of Organisation	Comment number
03.05.2023	Germany	European Union IPBC Task Force	Company-Manufacturer	1
Comment received				
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ECHA note – An attachment was submitted with the comment above. Refer to public attachment BC824-00001 IPBC Task Force comments targeted consultation acute inhal tox_2023-05-03.pdf				
RAC's response				
RAC has taken note of your comment.				

**OTHER HAZARDS AND ENDPOINTS – Acute Toxicity**

Date	Country	Organisation	Type of Organisation	Comment number
04.05.2023	Germany		Member State	2
Comment received				
Thank you for submission of new additional studies. These studies are not mentioned in the CLH-report and are not taken into account by the RAC so far. Thus, these studies can be considered for a re-evaluation of the classification. These additional studies give valuable insights in the acute inhalation toxicity of IPBC. The data lead to the assumption that the Wistar strain rats could be the most sensitive model compared to the Sprague-Dawley rat models mentioned in the CLH-report. The identified ATE allowed the classification of IPBC as Acute Tox 2 (H330). Therefore, the DE CA is able to support the modified classification as Acute Tox. 2 (H330) now.				
RAC's response				
RAC has taken note of your comment.				

**ANNEX 3 – RECORDS OF THE TARGETED CONSULTATION FOLLOWING THE SUBMISSION OF ADDITIONAL INFORMATION ON ACUTE INHALATION TOXICITY ON 3-IODO-2-PROPYNYL BUTYLCARBAMATE;**

Date	Country	Organisation	Type of Organisation	Comment number
03.05.2023	Germany	European Union IPBC Task Force	Company-Manufacturer	3
<b>Comment received</b>				
<p>On behalf of the European IPBC Task Force the following concerns regarding the two acute inhalation studies and their use during the CLH process are herewith communicated.</p> <p>The two studies do not belong to the IPBC data set used for the approval of IPBC as biocidal product and those studies were also not available for the renewal of IPBC as PT8 under the BPR.</p> <p>Interestingly, those two studies under consideration were already finalized / reported in 2014 but were not included by Denmark in the CLH report for which a public consultation was started in December 2022.</p> <p>After thorough review of the two robust study summaries in the targeted consultation, the European IPBC Task Force has major reservations to use those studies for harmonized classification and labelling for the following reasons since the results of the study are not considered reliable:</p> <ul style="list-style-type: none"> <li>- OECD 403 (2009) Test Guideline was not followed</li> <li>- IPBC Concentration in air is not accurately reported</li> <li>- High uncertainty regarding identity of the chemical(s) being applied to the animals</li> </ul> <p>To summarize, based on the available information there are several major deviations to OECD 403 (2009) and to GLP requirements: The most important points are the uncertainty regarding the chemical atmosphere to which the animals were exposed, the identity of the material in the exposure chamber in study 2. There are also reservations against the use of the study since from an animal welfare perspective those two studies would not have been necessary.</p> <p>Overall, the 2 studies do not qualify for a reliable assessment of acute inhalation toxicity of IPBC and should not be used for harmonized classification and labelling.</p> <p>For detailed reasoning please refer to the attached document.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment BC824-00001 IPBC Task Force comments targeted consultation acute inhal tox_2023-05-03.pdf</p>				
<b>RAC's response</b>				
<p>RAC has taken note of your comment.</p> <p>How the achieved concentrations of IPBC were measured in the two acute inhalation toxicity studies of IPBC from 2014 was clarified by the dossier submitter at the RAC-66 CLH WG meeting:</p> <p>The method used to determine the achieved atmospheric concentration of IPBC in Study 1, with a comparable method used in Study 2, was withdrawal via a port in an unoccupied exposure chamber of a known volume of the test atmosphere through a pre-weighed mineral filter. The filter was dried, and the difference between the pre- and post-filtration weight, and considering the volume of air sampled, was used to calculate the achieved atmospheric concentration.</p>				

**PUBLIC ATTACHMENTS**

1. BC824-00001 IPBC Task Force comments targeted consultation acute inhal tox\_2023-05-03.pdf [Please refer to comment No. 1, 3, 4]