

Attn: Ms Rojanasakul  
CDC/National Institute for Occupational Safety and Health  
1090 Tusculum Avenue, M/S C-34  
Cincinnati, OH, 45226-1198  
The USA

Date: 6 December 2021      Your ref: E-mails of June, 2021      Our ref: -  
Phone: +31 70 340 6631      E-mail: GR\_OSH@gr.nl      Encl: 1  
Subject: Comments on public draft advisory report *1-tert-butoxypropan-2-ol*

Dear Ms Rojanasakul,

Thank you for accepting the invitation to comment on the draft advisory report on the classification of 1-tert-butoxypropan-2-ol as a mutagenic and carcinogenic substance, which was published for public review in May 2021 by the Subcommittee on the classification of carcinogenic substances of the Dutch Expert Committee on Occupational Safety (DECOS) of the Health Council of the Netherlands. The Subcommittee appreciates the valuable comments made by NIOSH, which enables the Subcommittee to modify and improve its report.

On behalf of the President of the Health Council, I would like to inform you about the Subcommittee's replies, which are given on the next pages of this letter.

The final advisory report *1-tert-butoxypropan-2-ol* was published on the website of the Health Council ([www.healthcouncil.nl](http://www.healthcouncil.nl)) on 6 December 2021. Also on the website, you can find your comment and this letter, as well as all other comments and replies

Best regards,

Emma E.J. Kasteel, PhD (Ms)  
Scientific Secretary

## Comments on DECOS draft document on 1-tert-butoxypropan-2-ol

By Liying Rojanasakul, PhD. Research Biologist

PAGE NUMBER, LINE NUMBER	NIOSH COMMENT	Reply by the Subcommittee
<p>Page 19, line 10 Page 23, lines 13-16</p>	<p>Page 19, line 10: The committee concludes that “there is <b>no</b> evidence for carcinogenicity in <b>rats</b>.”</p> <p>Page 23, lines 13-16: “In a second well-conducted GLP study in male and female <b>rats</b> treated by whole-body inhalation, 1-<i>tert</i>-butoxypropan-2-ol caused a <b>significant positive trend</b> in the incidence of hepatocellular adenoma, and the occurrence of rare neoplasms of the renal tubules in males.”</p> <p>The two statements above are not consistent. Suggest using the phrase “insufficient evidence” or “no solid evidence” instead of “there is no evidence for carcinogenicity in rats” in the first statement.</p>	<p>Adapted</p>
<p>Page 23, lines 20-21</p>	<p>“There is <b>sufficient</b> evidence in experimental animals for the carcinogenicity of 1-<i>tert</i>-20 butoxypropan-2-ol.”</p> <p>This statement seems to be contradictory to the above statement, even though it is justified based on mouse data. Suggest using more specific wording.</p>	<p>This is the evaluation of the IARC, which is used to inform the Subcommittee, but is a separate evaluation of the substance. The wording is cited from the IARC monograph and is therefore not adjusted.</p>