

Official Information Act Request

Requester's details

Date: 23 September 2021

Name: [REDACTED]

Organisation: [REDACTED]

Email: [REDACTED]

Reference number: ENQ-42544-H5F1S0

Dear [REDACTED]

I refer to your request for information received on 13 September 2021. You have referred to the Advice to the Decision-making Committee on APP204176: Pfizer SARS-CoV-2 vaccine BNT162b2 (COMIRNATY) dated 3 February 2021, regarding whether Comirnaty is an organism, and asked for the following information:

Can you please advise what consideration has been given to whether Comirnaty is a hazardous substance under the Hazardous Substances and New Organisms Act, as it relates to these ingredients:

mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose

Can you please disclose information about whether that falls within the statutory definition of a "hazardous substance", by reference to each subparagraph to the s 2 definition (in a similar way to the 3 February report).

Also, has the EPA actually analysed Comirnaty to determine its ingredients and biochemistry, or has the EPA simply acted on information provided by the manufacturer?

Questions one and two

No consideration was given to whether Comirnaty is a hazardous substance under the Hazardous Substances and New Organisms Act, as human medicines are exempt from the hazardous substances parts of the Act, per clause 6 of the Hazardous Substances (Hazard Classification) Notice 2020: https://gazette.govt.nz/assets/pdf-cache/2020/2020-au4842.pdf?2020-12-17_22%3A50%3A42=.

Question three

The EPA's assessment relied on information provided by the manufacturer. The EPA did not conduct a chemical analysis of the product.

If you would like to know more about our role in approving in COVID-19 vaccines - including this particular one – this may be of interest: <https://www.epa.govt.nz/about-us/our-role-in-covid-19-vaccines/>

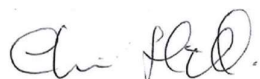
Finally, if you are interested in learning more about how the vaccine works, you may find this article interesting: <https://www.epa.govt.nz/community-involvement/science-corner/sars-cov-2-vaccines-and-the-hsno-act/>

You have the right to seek an investigation and review by the Ombudsman of this decision. You can contact the Ombudsman on 0800 802 602, or by email at info@ombudsman.parliament.nz

If you have any further queries, please do not hesitate to contact us via ministerials@epa.govt.nz

We may publish your request and our response on our website, www.epa.govt.nz. We make OIA responses available so others can read more about the work we do and the questions we are asked. Any information that might identify you will be removed to protect your privacy.

Yours sincerely



Dr Christopher Hill
General Manager, Hazardous Substances and New Organisms