

# Official Information Act Request

## Requester's details

**Date:** 28 April 2022

**Name:** [REDACTED]

**Email:** [REDACTED]

**Reference number:** ENQ-43737-D4Z0R5

Dear [REDACTED]

I refer to your request, which was partly transferred to the Environmental Protection Authority (EPA) by the Ministry of Health on 4 April 2022, for the following information:

- “1. Can you please tell me what is the daily exposure limit for ethylene oxide which is used in the sterilization process in the RAT (Rapid Antigen Test)?
2. What are the safe limits for children/ babies?
3. Is ethylene oxide carcinogenic?
4. What are the short and long term health effects of ethylene oxide?”

Please find our responses to your request below.

- 1. Can you please tell me what is the daily exposure limit for ethylene oxide which is used in the sterilization process in the RAT (Rapid Antigen Test)*

Tolerable exposure limits (TELs) are controls set by the EPA to manage the risks to human health posed by toxic substances. The EPA has not set any tolerable exposure limits for ethylene oxide.

This is because ethylene oxide was the subject of an older approval. When the Hazardous Substances and New Organisms (HSNO) Act was implemented, substances with existing approvals from earlier regimes were brought directly under the jurisdiction of the HSNO Act. We called these transfer approvals. We typically did not set TELs for industrial substances during transfers, with a few exceptions. However, we would typically set a TEL if we believed a member of the general public was going to be exposed to the substance outside of the workplace.

The following criteria are used when determining whether a TEL should be set for a substance:

- a. Likely to be present in air, water, or soil
- b. Likely to be encountered by people outside the workplace
- c. Likely to have a toxic effect.

In the case of RAT tests, exposure may be limited. Additionally, these tests would be considered a medical device, and therefore, Medsafe may be in a better position to provide more advice on exposure limits for people.

WorkSafe New Zealand does have a Workplace Exposure Standard (WES) value set for ethylene oxide.

#### [Workplace exposure standards and biological exposure indices](#)

#### *2. What are the safe limits for children/ babies?*

Based on the information the EPA currently holds, no tolerable exposure limits have been set for ethylene oxide, which means there are none set for children and babies.

#### *3. Is ethylene oxide carcinogenic?*

Yes, ethylene oxide has a carcinogenicity Category 1 classification – may cause cancer. Please see the note below regarding classifications.

#### *4. What are the short and long term health effects of ethylene oxide?*

You can find the hazard classifications and approval for ethylene oxide on the EPA website:

[Oxirane ethylene oxide HSR001059.pdf \(epa.govt.nz\)](#)

Please note that the classification is only indicative of the hazards but may not cover the risks of exposure to the substance itself. In the case of RATs, these are outside the scope of what we would typically look at under the Hazardous Substance and New Organisms (HSNO) Act framework and may be considered a manufactured article or medical device. In the case of medical devices, Medsafe may be able to provide more advice on the regulation of these. See the link below for exempt substances under the HSNO Act:

[Exempt substances and laboratories](#)

Additionally, ethylene oxide is also listed in Annex III of the Rotterdam Convention as a chemical subject to the prior informed consent procedure.

The Rotterdam Convention is a multilateral environmental agreement which promotes shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals to protect human health and the environment from potential harm.

New Zealand has made an import response (decision with respect to the import of ethylene oxide as a pesticide), which can be viewed on the Rotterdam Convention website:

[Rotterdam Convention website - country profiles](#)

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](mailto:info@ombudsman.parliament.nz)

If you have any further queries, please do not hesitate to contact us via [ministerials@epa.govt.nz](mailto:ministerials@epa.govt.nz)

We may publish your request and our response on our website, [www.epa.govt.nz](http://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

A handwritten signature in blue ink that reads "Chris Hill".

Dr Christopher Hill  
**General Manager, Hazardous Substances and New Organisms**