

WORKSAFE

APP204042 WORKSAFE ADVICE

WorkSafe advice on the application for approval to import for release

Xivana

22 October 2021

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1 INTRODUCTION

This is WorkSafe New Zealand's (WorkSafe) review of Application APP204042 (Xivana).

Every year 750-900 people die prematurely as a result of work-related ill-health, much of which is from chemical exposure. As the regulator of workplace health and safety, WorkSafe has a role in leading, influencing and leveraging the health and safety system to improve health and safety outcomes, and has firm targets and priorities to transform New Zealand's workplace health and safety performance.

WorkSafe's role in the wider health and safety system involves reviewing applications for new substance approvals and providing advice to the Environmental Protection Authority (EPA) to ensure that the risks associated with the use, handling, manufacture and storage of any new substances approved in New Zealand can be managed adequately.

The following report is based on the information provided with the application, from both applicant and the EPA.

2 APPROVAL PROCESS

The controls for hazardous substances and duties to mitigate the risks that hazardous substances pose sit under two regimes:

- the Hazardous Substances and New Organisms Act 1996 (HSNO) for non-work, public health and environmental risks, and
- The Health and Safety at Work Act 2015 (HSWA) for work-related risks (including the Health and Safety at Work (Hazardous Substances) Regulations 2017 (the HSW HS Regulations) and other regulations).

HSWA gives WorkSafe responsibility for setting, administering and enforcing controls to mitigate the health and safety risks of using, handling, storing or manufacturing hazardous substances in the workplace. Since December 2017, the workplace controls for hazardous substances have been set in the HS Regulations and relevant safe work instruments (SWI) under HSWA.

Under HSNO, the EPA is responsible for approving and classifying hazardous substances.

This division of roles requires the EPA and WorkSafe to work together to assess hazardous substances applications, to ensure the appropriate controls from each regime are applied to safeguard people (both at work and outside the workplace) and the environment.

The objectives of WorkSafe's participation in the hazardous substance applications process are to ensure that:

- hazardous substances at work are treated in a way that protects workers and other persons against harm to their health, safety, and welfare by eliminating or minimising risks arising from work, contributing to reduced incidence of work-related ill-health
- WorkSafe maintains a constructive and collaborative relationship with the EPA in assessing hazardous substance applications.

Consistent with the purpose of HSWA, regard must be had to the principle that workers and other persons should be given the highest level of protection against harm to their health, safety and welfare from hazards or risks arising from work, so far as is reasonably practicable.

Where existing controls under HSWA are not considered adequate, additional or varied controls may be imposed only by way of a safe work instrument.

3 RELEVANT REGULATIONS

In reviewing this application WorkSafe has considered the PCBU's obligations under:

- HSWA
- the Health and Safety at Work (General Risk and Workplace Management) Regulations 2016 (the HSW GRWM Regulations), and
- the HS Regulations.

In assessing the adequacy of the default hazardous substances controls, WorkSafe also takes account of other relevant requirements under the health and safety legislative framework, for example duties:

- to manage risks associated with substances hazardous to health by applying the hierarchy of controls (regulations 5 to 8 and 28 of the GRWM Regulations)
- to provide information, supervision, training and instruction (regulation 9 of the HSW GRWM Regulations)
- to provide workplace facilities (regulations 10-11 of the HSW GRWM Regulations) including ventilation and facilities to control airborne contaminants
- to provide personal protective equipment (regulation 15 of the GRWM Regulations)
- to carry out exposure monitoring and health monitoring (regulations 32-42 of the GRWM Regulations).

'Upstream duties', or the duty of a PBCU who designs, manufactures, imports or supplies a hazardous substance to ensure that a substance is without risks to the health and safety of persons so far as is reasonable practicable, may also apply (sections 39-42 of HSWA).

WorkSafe's advice to the EPA may refer to any of the above duties.

3.1 Upstream Duties

Upstream duties are relevant if a new substance has properties that make it more hazardous than existing similar products, for example, if it has a non-active ingredient (such as a surfactant) that is more hazardous than similar ingredients in similar products. The similar products demonstrate that it is possible to avoid the hazard.

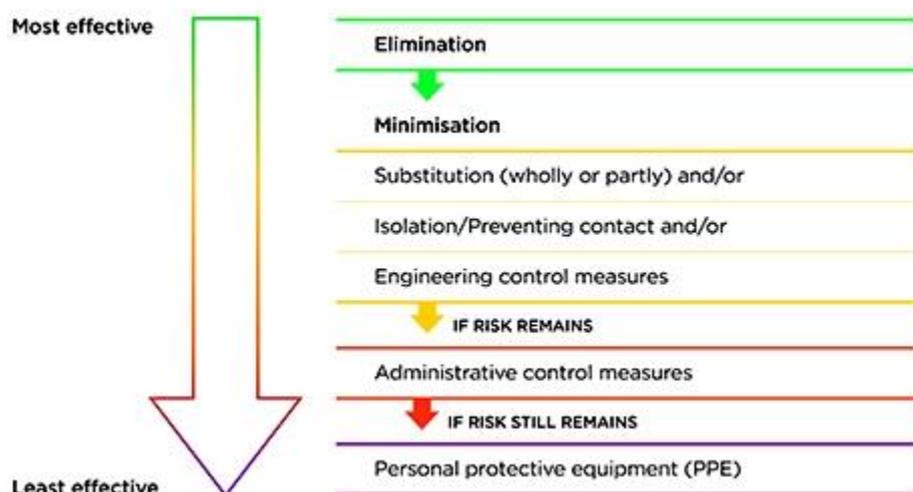
3.2 Hierarchy of Controls

Under section 30(1)(a) of HSWA the PCBU must eliminate risks to health and safety so far as is reasonably practicable. If this is not reasonably practicable, the PCBU must minimise the risks so far as is reasonably practicable following the hierarchy of controls.

The hierarchy of controls is set out in regulation 6 of the GRWM Regulations.

If elimination is not possible, a PCBU must consider (in this order):

- Substitution, isolation, engineering control measures
- administrative controls
- personal protective equipment (PPE): If risk remains after all other measures have been applied, the PCBU must supply and ensure the use of PPE .



Personal protective equipment (PPE) may need to be used or worn to minimise health risks but should only be used as an exposure control measure to minimise risk when other control measures alone can't adequately do so.

The decision to choose PPE in the absence of control measures higher up the hierarchy must be based on the principles of reasonable practicability. Considerations of cost alone is not sufficient to determine 'so far as is reasonably practicable'.

PPE should not be the first or only risk management method considered, and WorkSafe expects PCBUs to give preference to other controls that protect multiple at-risk workers at once. Regard must also be given to providing the highest level of protection for workers and others, so far as is reasonably practicable.

4 ASSESSMENT

This WorkSafe New Zealand (WorkSafe) review of application APP204042 (Xivana) does not propose setting any additional requirements to those already present under the the HSW HS Regulations.

WorkSafe has reviewed this application taking into consideration the PCBU's obligations under:

- (HSWA);
- the GRWM Regulations), and
- The HSW HS Regulations.

WorkSafe received the following documentation to assist with provision of advice for approval of this application:

- Application
- Science Memo
- Product label
- Confidential Appendix
- Mixture spreadsheet

5 ADVICE

WorkSafe has assessed the available information for APP204042 and considers that compliance with the HSW HS Regulations and HSW GRWM Regulations will be adequate to reduce the risks associated with the use of this substance in the workplace. While the regulations cover standard risk mitigation measures, occupational exposure in the workplace needs to be assessed at each site and appropriate controls put in place to mitigate the identified risks.

When using substances that have human health risks the PCBU must minimise the risks so far as is reasonably practicable by applying the hierarchy of controls set out in Regulation 6 GRWM Regulations.

Regulation 13.8 of the HSW HS Regulations requires that PPE must be worn when working with this substance to minimise the risks to the health and safety of workers.

However, PPE should only be used as a control measure for risk when other control measures (higher up the hierarchy of controls) do not mitigate the risk so far as is reasonably practicable. PPE should not be the first or only control considered, WorkSafe expects PCBUs to give preference to other controls that protect multiple at-risk workers at once.

Under Sections 39 - 42 of HSWA manufacturers/importers/suppliers have a duty to ensure substances manufactured, imported or supplied are without risk so far as is reasonably practicable. Applicants should be mindful of their duties under the Health and Safety at Work Act 2015 when they apply for approval of new substances, where possible new active ingredients that pose no human health risks should be developed.

In reviewing this application WorkSafe has noted that the EPA has not assigned any human health classifications to the active fluoxapiprolin. This is an good example of an upstream PCBU meeting their duties under section 39-42 of HSWA.

However, Xivana contains non active ingredient components that may not be required for the efficacy of the product and result in a contact sensitizing classification (6.5B) for the product.

Without further information from the applicant as to whether it is reasonably practicable to substitute the sensitizing components for non-hazardous components, WorkSafe is concerned that the duties under sections 39-42 may not have been met.