Summary of Risk Assessment Conducted Pursuant to subsection 83(1) of the *Canadian Environmental Protection Act, 1999*

New Substances Notification 20114: Rape oil, reaction products with diethanolamine (Chemical Abstracts Service Registry Number 68187-80-4)

Regulatory decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA), and pursuant to section 83 of the Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance and have determined that it is not anticipated to enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long term harmful effect on the environment or its biological diversity, constitute or may constitute a danger to the environment on which life depends, or constitute or may constitute a danger in Canada to human life or health.

Substance identity

The notified chemical is rape oil, reaction products with diethanolamine (Chemical Abstracts Service Registry Number[1] 68187-80-4), and is a substance referred to as unknown or variable composition, complex reaction products or biological materials (UVCB).

Notified and potential activities

The substance is proposed to be manufactured in Canada in quantities greater than 10 000 kg/yr for the notified use as raw material in industrial applications. Potential uses may include consumer cleaning products and personal care products.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to water. The substance is not expected to be persistent in this compartment based on its expected ready and inherent biodegradation (60-85% over 28 days). The substance is not expected to bioaccumulate based on estimated low bioaccumulation and bioconcentration factors and its potential to be metabolized.

Ecological assessment

Based on the available hazard information, the substance is expected to have moderate acute toxicity to fish, aquatic invertebrates and algae (median lethal concentration and median effective concentration 1 to 100 mg/L), moderate chronic toxicity to fish (10% lethal concentration (LC_{10}) 0.1 to 10 mg/L) and high chronic toxicity to aquatic invertebrates (LC_{10} less than 0.1 mg/L). Using the LC_{10} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 2 to account for species

[1] The Chemical Abstracts Service Registry Number is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 10-100 µg/L, which was used to estimate the ecological risk.

The notified activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activities is expected to be mainly from blending, manufacturing and cleaning of transportation vessels by release of the substance to water resulting in predicted environmental concentrations (PECs) in the range of 0.1-1 µg/L, 1-10 mg/L and 10-100 µg/L, respectively. No potential activities which could significantly increase environmental risks compared to those notified were identified.

Comparing the PEC with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that the substance is unlikely to cause ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance is expected to have a low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight) and moderate subchronic toxicity following repeated dermal doses in mammalian test animals (90-day no-observed-adverse-effect level 20-200 mg/kg-bw/day). It is not expected to be mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a raw material in industrial uses, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be chemically reacted into a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water and air is expected to be at low levels given the low potential for environmental release. Potential uses of the substance include consumer cleaning products and personal care products, where direct exposure of the general population is expected to be mainly by contact with the skin. Indirect exposure of the general population from environmental media such as drinking water and air is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the potential low toxicity, the substance is not likely to pose a significant health risk to the general population, and is therefore unlikely to be harmful to human health.

Assessment conclusion

When the substance is used as notified or for other identified potential activities, it is not expected to be harmful to human health or the environment according to the criteria under section 64 of the Act.

A conclusion under CEPA, on this substance, is not relevant to, nor does it preclude an assessment against the hazard criteria for Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or *Hazardous Products Regulations* for products intended for the workplace.