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

New Substances Notifications 19179, 19180, 19182, 19184, and 19186 (Confidential Accession Numbers 19214-2, 19215-3, 19216-4, 19217-5, 19218-6)

### **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 substances and have determined based on the available information, that when used as notified, the substances are 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.

A significant new activity (SNAc) notice was adopted for each notified substance based on uncertainties regarding potential new activities, and the potential environmental and/or human health impacts that could arise as a result. The associated SNAc notices outline information requirements for those activities and were published in the <u>Canada Gazette Part I, Vol. 151, No. 52</u> on December 30, 2017. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substance undergoes further assessment and risk management consideration.

### Substance identities

The following five substances were submitted as Consolidated New Substances Notifications (NSNs), which take place when the technical information provided for one substance is used to address the technical information requirements for the remaining substances. The substances in Consolidated Notifications are very similar and are expected to have the same exposure and hazard profiles.

The notified chemical substances of unknown or variable composition, complex reaction products or biological materials (UVCBs) are:

- NSN 19179: Quaternary ammonium compounds, benzylalkyldimethyl, salts with bentonite (Confidential Accession No. 19214-2)
- NSN 19180: Quaternary ammonium compounds, dialkyldimethyl, salts with bentonite (Confidential Accession No. 19215-3)
- NSN 19182: Quaternary ammonium compounds, bis(derivative oil alkyl)dimethyl, salts with smectite group minerals (Confidential Accession No. 19216-4)
- NSN. 19184: Quaternary ammonium compounds benzylalkyldimethyl, salts with smectite group minerals (Confidential Accession No. 19217-5)
- NSN 19186: Quaternary ammonium compounds, dialkylmethyl, salts with smectite group minerals (Confidential Accession No. 19218-6)

# Notified and potential activities

The substances are proposed to be manufactured in and/or imported into Canada in quantities greater

than 10 000 kg/yr for the notified use in paints and coatings. Potential uses may include cosmetics, adhesives and sealants, and drilling fluids.

### Environmental fate and behaviour

Based on their physical and chemical properties, if the substances are released to the environment, they will tend to partition to soil and sediment. The substances are composed largely of an insoluble, inorganic bentonite component and a small, quaternary organic component. The bentonite component is expected to be persistent in these compartments because of its insolubility and resistance to biodegradation. However, the quaternary organic component is not expected to be persistent in soil and sediment based on the biodegradability of an analogue substance (10-30% over 28 days). The substances are not expected to bioaccumulate in aquatic organisms based on their very low to low water solubility (<10 mg/L) which limits their bioavailability in water.

# **Ecological assessment**

Based on the available hazard information on structurally related chemicals, the substances are expected to have low acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration  $(LC_{50}) > 100 \text{ mg/L}$ ). The substances are expected to have low acute toxicity in soil invertebrates (no adverse effects observed at highest tested concentration). Using the  $LC_{50}$  from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 30 to account for acute to chronic extrapolation and species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be between 1000 and 10 000  $\mu$ g/L, which was used to estimate the ecological risk.

The notified and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substances throughout their life cycle. Environmental exposure from the notified activities is expected to be mainly from formulation and blending by release of the substances to water resulting in a predicted environmental concentration (PEC) between 0.01 and 10  $\mu$ g/L. For potential activities, environmental exposure is expected to be mainly by release of the substances to water resulting in a PEC between 10 and 100  $\mu$ g/L for manufacturing and between 0.01 and 0.1 for consumer use in cosmetics and personal care products.

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 substances are unlikely to cause ecological harm in Canada.

### Human health assessment

Based on the available hazard information on the substances and surrogate data on structurally related chemicals, the substance is expected to have a low acute toxicity by the oral, dermal and inhalation routes (oral and dermal median lethal dose > 2000 mg/kg body weight; inhalation LC<sub>50</sub> >5 mg/L/4hr and >20 mg/L/1hr) and low subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) >300 mg/kg-bw/day). They are not skin sensitizers (0-8% response (guinea pig maximization test) and no adverse effects in human repeated insult patch test). They are not expected to be mutagenic *in vitro* or clastogenic *in vivo*. Therefore, the notified substances are unlikely to cause genetic damage. The point of departure (POD) was calculated to be between 1000 and 10 000 mg/kg-bw/day based on the NOAEL of the oral subchronic toxicity study in mammalian test animals.

When the notified substances are used in paints and coatings, direct exposure of the general population could be at levels between 0.1 and 1 mg/kg-bw for skin contact from brush or roller painting. Spray painting could lead to inhalation exposure levels between 0.1 and 1 mg/kg-bw as well as ingestion of inhaled particles at levels between 0.01 and 0.1 mg/kg-bw. Once the paint or coating is dried, consumers may also come into contact with end-use products containing the substances; however, direct exposure is not expected because the substances will be bounded within the 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 is expected to be at levels between  $10^{-6}$  and  $10^{-5}$  mg/kg-bw/day for adults and between  $10^{-4}$  and  $10^{-3}$  mg/kg-bw/day for children.

If potential uses of the substances were to include cosmetics, direct exposure of the general population is expected to be mainly by contact with the skin at levels between 0.1 and 1 mg/kg-bw/day. If potential uses of the substances were to include sealants and adhesives, direct exposure of the general population is expected to be by contact with the skin at levels between 0.01 and 0.1 mg/kg-bw/day. Potential uses of the substances could lead to indirect exposure of the general population from environmental media such as drinking water at levels conservatively estimated to be between 10<sup>-4</sup> and 10<sup>-3</sup> mg/kg-bw/day for children and adults. If the substances are used in drilling fluids, direct and indirect exposure of the general population media is not expected given the specialized industrial use of the substance which would limit public exposure.

Based on a comparison of the POD to estimated human exposure, the substances are not likely to pose a significant health risk to the general population, and are therefore unlikely to be harmful to human health.

### Nanomaterial considerations

The substances are potential nanomaterials that may exhibit significantly different physical chemical properties, environmental fate, toxicity, and exposure potential. While the substances were not notified with particle sizes on the nanometer scale, there is evidence that they may be available industrially, commercially and in consumer products in the form of nanoparticles in the 1-100 nanometer size range. Consequently, more information is necessary to better characterize potential environmental and health risks.

# Assessment conclusion

When the substances are used as notified, they are not suspected to be harmful to human health or environment within the meaning of the criteria under section 64 of the Act. However, it is suspected that a significant new activity in relation to the notified substances could result in the substances meeting those criteria.

Due to the identified potential for engineering or use of the notified substances at the nanometer scale and the uncertainty predicting environmental fate, hazard and exposure in those scenarios, SNAc notices were published to obtain information to ensure that the substances undergo further assessment prior to their use as nanomaterials. SNAc Notices No. 19179, 19180, 19182, 19184, and 19186 were published in the *Canada Gazette* Part I, Vol. 151, No. 52 on December 30, 2017. A conclusion under CEPA, on these substances, 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.