

Summary of Public Comments received on the Challenge substance Nickel BHMB (CAS 42739-61-7) Draft Screening Assessment Report for Batch 10

Comments on the draft screening assessment report for Nickel BHMB to be addressed as part of the Chemicals Management Plan Challenge were provided by the International Institute of Concern for Public Health (IICPH) & Crooked Creek Conservancy Society of Athabaska (CCCSA) and Chemical Sensitivities Manitoba (CSM).

A summary of comments and responses is included below, organized by topic:

- Inherent toxicity
- Data gaps and deficiencies
- Risk management

TOPIC	COMMENT	RESPONSE
Inherent toxicity	Data predicted with the use of computer models suggests that nickel BHMB may cause a high level of harm at low concentrations. However, only effects to animal life in water were investigated in detail, not in soil or sediment. Comparisons were not done between the potential for harm and potential releases of the chemical in soil and sediment despite the possibility that nickel BHMB may end up there.	The predicted data in the report was relevant to the animal life in found in water. No toxicity data has been identified for animal life that lives in sediment that may be exposed to nickel BHMB. Therefore, while no comparisons between potential harm and potential releases of nickel BHMB into the soil or sediment could be done, a conservative comparison was done for water which did not show a high level of risk. The toxicity to animal life living in sediment and soil is expected to be low. This is based on the low level of risk estimated for animal life living in the water, including a low expected bioavailability and low predicted level of bioaccumulation. Additional text has been added to the final screening assessment document to address this matter further.
	The predicted toxicity which is generated from computer models presented in the report, does not take into account potential harm that could be caused by the release of nickel into the environment.	The physical and chemical properties of nickel BHMB indicate that it is unlikely to break-down into small parts in the environment and nickel is not predicted to be released quickly from the compound. Also, the volume of nickel BHMB used in Canada is very low (<1000 kg) in comparison to natural background levels of nickel in Canada. Therefore, even if nickel from nickel BHMB is released into the environment, the overall contribution of this substance to nickel that exists naturally or is

		released by other human sources is expected to be very low.
	The Government of Canada's assessment of nickel compounds determined that dissolved and soluble forms of inorganic nickel are entering or may enter the environment and may have a harmful effect on the environment. Yet the draft screening assessment states that "because nickel BHMB is an organometallic substance and beyond the scope of the assessment, the same conclusions regarding potential environmental effects do not apply". The assumption that the conclusions on potential effects "do not" apply should not be made without evidence to corroborate this.	Nickel BHMB is expected to be relatively stable and nickel is not predicted to be released rapidly from the compound. Also, the volume of nickel BHMB used in Canada is very low (<1000 kg) in comparison to natural background levels of nickel. Given the very conservative industrial exposure scenario used for nickel BHMB, it is concluded that nickel BHMB presents a low risk to the aquatic environment."
	Nickel compounds which are grouped as oxidic, sulphidic and soluble have been classified as harmful to human health and the critical effect of these compounds is carcinogenicity. Data supporting this conclusion includes genotoxicity and carcinogenicity data from less soluble nickel compounds. However, because of its likely negligible exposure, the assessment considers human health risk to be low. Given the extent of its hazards listed above, including potential genotoxicity, this conclusion is not supported.	The Screening Assessment Report (SAR) addressed nickel BHMB alone. Although some nickel compounds have been previously grouped together and identified as harmful to human health as a whole, available data was limited to address the potential hazard of the individual compounds themselves. Similarly, no empirical health effects data for nickel BHMB were identified and it was not possible to assess its carcinogenic or genotoxic potential using QSAR models. Furthermore, whether or not a nickel compound could induce adverse effects in the body depends on whether or not sufficient amount of free nickel ions could be released from the compound and eventually reach the target tissue(s). Nickel BHMB is expected to be relatively stable and nickel is not predicted to be released rapidly from the compound. The potential for exposure to Nickel BHMB is already very low (use was below 1000 kg for the year 2006), consequently it is not considered a source of the oxidic, sulphidic and soluble nickel compounds classified as carcinogenic.). Therefore, this substance does not meet the criteria set out in section 64 of CEPA 1999 under current circumstances. However, as stated in the SAR, "Given the potential health hazards of this substance, there is concern that new activities that have not been identified or assessed could lead

		to this substance meeting the criteria set out in section 64 of the Act.” Therefore, it is proposed that the SNAC provision of CEPA be applied to this substance.
	Occupational exposure to nickel BHMB should be addressed.	No data related to nickel BHMB exposure in occupational settings were identified during the preparation of the screening assessment. When available, this information, in particular data from epidemiological investigations, is considered.
Data gaps and deficiencies	The assessment noted uncertainties, lack of information, and relied totally on models. It also confirmed that nickel BHMB is persistent in water, soil and sediment, and does have some bioaccumulation potential. Therefore, the finding that “nickel BHMB is unlikely to be causing harm to populations of aquatic organisms in Canada” cannot be substantiated.	While it is true that the majority of the data available for this substance were modelled and some uncertainties were identified, a conservative industrial exposure scenario was used for nickel BHMB. The predicted concentration for industrial releases was compared to a concentration where no harm is expected for animal life living in water. This comparison indicated a low risk..
Risk assessment management: Significant New Activity provision application	The application of the Significant New Activity (SNAC) provision is not sufficiently precautionary or preventative.	For a substance to meet section 64 of CEPA, 1999, it must pose a potential risk to environment or human health. CEPA 1999 defines harm to human health and the environment in terms of both intrinsic properties and exposure potential. There is low exposure potential for Nickel BHMB. Use of the SNAC provision will require that any proposed new manufacture, import, or use be subject to further assessment, which would determine if the new activity requires further risk management consideration.
	The amounts in waste need to be accounted for and the potential effects need to be considered.	Waste due to the use of nickel BHMB in the welding process are expected to be negligible.