Summary of Public Comments received on the Challenge substance MVTFS (CAS 68952-02-3) Draft Screening Assessment Report for Batch 11

Comments on the draft screening assessment report for MVTFS to be addressed as part of the Chemicals Management Plan Challenge were provided by Inuit Tapiriit Kanatami (ITK) and Keepers of the Athabasca Watershed Alliance.

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

- Physical-Chemical Properties
- Assessment Methodology
- Uses & Releases
- Persistence and Bioaccumulation
- Fate
- Inherent Toxicity
- Data Gaps and Deficiencies
- Risk Characterization

TOPIC	COMMENT	RESPONSE
Physical-Chemical Properties	The substance was originally classified as an organic substance of Unknown, Variable Composition or Biological Material (UVCB), but was assessed as a polymer in the draft assessment. The implications of the change in classification are unclear.	The substance was re-classified and assessed as a polymer under the Challenge, as data was received demonstrating that the substance meets the definition of a polymer. Polymers are characterized by having chains of repeating units covering a range of molecular weights. Assessment approaches specific to polymers exist, and were applied in this case.
	It is not known whether impurities (residual monomers or by-products) may be present in consumer products imported into Canada.	Industries are obligated to report the quantity and the substance identity of MVTFS even if it is contained in products imported into Canada; however, it is recognized that importers may not always be aware of its presence in products. Based on gel permeation chromatography (GPC) analysis results, the smallest component in the polymer has a molecular weight of approximately 30 000 g/mol. This indicates that the polymer product in commerce in Canada does not contain any low molecular weight impurities.
	The assessment does not provide details or a Robust Study Summary of the confidential study on	GPC analysis procedures were well documented in the data submission, and the method was considered to meet the standard

	gel permeation chromatography (GPC). This study was used to determine the number average molecular weight (Mn) and the percentage of impurities, and identity of all of MVTFS in commerce in Canada. It is not clear whether the GPC study meets international requirements for analysis.	requirement; however details are confidential business information (CBI) and cannot be released in the assessment report. As mentioned in the assessment, all MVTFS imported into Canada were considered and assessed.
	A table is recommended to summarize each value of physical and chemical properties of MVTFS and "read-across" from its analogues.	A table has been added to summarize the available information on physical and chemical properties of MVTFS and its analogous polymers in the screening assessment report.
Assessment Methodology	When the experimental data was not available, QSAR models should have been used in the draft assessment.	QSAR models can only apply for a chemical with a molecular weight less than approximately 1 000 g/mol. The smallest component of MVTFS has a molecular weight as 30 000 g/mol, which is not suitable for using any QSAR model.
	The two analogues selected are significantly different in chemical structure, functional groups, and physical properties. Without data to validate the use of the analogues, the findings of the assessment on persistence, degradation, ecotoxicity and bioaccumulation are insufficient and cannot form the basis for any decision.	The differences between MVTFS and two analogues have been discussed in detail in the assessment. While recognizably different, the selected analogues, in particular polydimethylsiloxane (PDMS), are considered conservative (protective) for assessing persistence and bioaccumulation potentials and ecotoxicity for MVTFS.
	The Mass Flow Tool method used does not quantitatively account for releases to the environment. Losses in per cent do not provide an indication of the true nature of the losses.	The predicted environmental concentration and the overall risk characterization have been determined using the value of the upper bound of a reporting range, in which the exact value of use quantity fits. Releases to the environment were estimated as the fraction of the substance that might be released during its different life stages. Fractions are then applied to the upper bound of the reporting range used in exposure assessment in this case.
Uses and Releases	The assessment does not quantitatively account for releases from disposal.	There is no such information or model to calculate the migration from disposal site. However, such migration is expected to be low due to the large molecular weight and the low water solubility of MVTFS.
	In the assessment, loss via chemical transformation excludes loses through waste management and	Chemical transformation is considered as a separate loss process from waste management (wastewater treatment) in the life cycle

	wastewater treatment. The loss to land does not include transfers subsequent to a substance's use and service life (e.g., land application of biosolids and atmospheric deposition.)	of MVTFS. The loss to land only includes unintentional transfer or leakage to soil or paved/unpaved surfaces during the substance's use and service life (e.g., from the use of agricultural machinery or automobiles for some substances). The pathway of biosolid application was considered but given that releases to wastewater were small and that the substance is adsorbed to sludge, the impact on environmental organisms was not expected to be high. According to the substance's properties, releases to air are expected to be minimal and therefore atmospheric deposition is not expected to be an important pathway.
	The assessors have assumed that the potential for MVTFS to leach from landfill into groundwater is unlikely due to its very low water solubility, but this potential for leaching has not been examined. The assessment should consider the large volume of MVTFS noted in 1986 and determine the fate of this substance given its persistence.	Results from experimental studies indicate that high molecular weight siloxane polymers are immobile in soils. If released into soil, the polymer is expected to reside in that environmental medium. The assessment of MTFVS uses the latest information on the substance, and it is reasonable to consider the relevant data (i.e. the use quantity) for 2006 instead of the information obtained in 1986. There is no difference in the use code for MVTFS identified in 1986 and 2006. Persistence and fate were considered in the relevant sections.
Persistence and Bioaccumulation	There are some concerns with the finding that MVTFS does not persist in soil, while it does persist in sediment.	The breakdown of siloxane polymers relies on the clay in the dry soil. Water in sediment does not favour this reaction. Results from a number of degradation studies indicate that higher moisture contents may slow down the degradation rate, hence, the polymer degrades more rapidly in soil than in sediment.
	The claim that polymethyltrifluoropropylsiloxane (PMTFPS) and MVTFS degrade along their backbones in a manner similar to PDMS needs more explanation. This gap in reasoning, in turn, affects the use of the analogy between the degradation of PDMS and the degradation of MVTFS.	Degradation of MVTFS and PMTFPS can only take place either within the repeating unit (releasing the functional group) or along the backbone (shortening the chain). A simplified structure was used in a degradation model to simulate the degradation of MVTFS and PMTFPS. The results indicated that the breakdown would likely take place on the –Si-O-Si- backbone of the long chain of the polymer, in a similar

		pattern to the degradation of PDMS. Thus, PDMS is appropriate to be used as the analogue for assessing the potential of persistence for MVTFS.
Inherent Toxicity	Based on the toxicity data for the analogous polymer (PDMS), the assessment claims that MVTFS is not expected to possess significant hazard to either sediment-dwelling organisms or terrestrial species. This proposed determination is done under laboratory conditions using PDMS. It is unclear whether these conditions are realistic and applicable to MVTFS, and whether these findings are valid.	Determinations on PDMS were based on both field studies and laboratory experiments. The test conditions in laboratory experiments mimic simplified environmental conditions but key factors were designed to be as close to the real conditions as possible. Therefore, the results from the laboratory studies are considered valid.
	There is no evidence that siloxane monomers or polymers do not pose a genotoxicity potential. Given that confidence in health effects are acknowledged to be low, one cannot exclude the probability of adverse human health effects.	Confidence in the health effects database associated with MVTFS is low because no substance specific empirical data was identified. However, other siloxane compounds have previously been assessed under the Challenge program, and a literature search was conducted to gather health effects information on siloxane compounds. No evidence was identified to indicate that this group of compounds is associated with genotoxicity. Based on this finding, and considering that exposure of the general population to MVTFS is negligible, it is not anticipated that current uses of MVTFS in Canada would trigger any potential health concerns.
Data Gaps and Deficiencies	More information on the identity of MVTFS is needed, even if such information was determined by a confidential study.	The substance identity of MVTFS has been presented to the extent possible in the assessment report. The companies requested confidentiality of more specific data contained in their submissions under CEPA.
	Occupational exposure to MVTFS should be addressed.	Hazard information obtained from occupational settings, in particular, data from epidemiological investigations, would be considered in the assessments, if available. No empirical hazard data for MVTFS in humans or experimental animals were identified.
	A more thorough assessment that addresses data gaps and deficiencies is requested.	The Screening Assessment is based on the collective information that is currently available. The data gaps and deficiencies are recognized in the screening assessment and siloxane polymer

		analogues of MVTFS are used to fill in several data gaps. It is anticipated that the quantities of MVTFS released to the environment would not be significant and adverse effects are not expected.
	The claim of confidentiality in Canada and other countries is a tremendous impediment to obtaining information on the use of this substance.	Companies reporting information can request confidentiality under CEPA. The confidential business information (CBI) cannot be released in the assessment without the consent of the submitters. The use quantities in some European countries were also marked as confidential information in the database of Substances in Preparations in Nordic Countries (SPIN). No further information is available.
	The quantity of MVTFS contained in products that may be imported into Canada needs to be determined. There is no way of knowing the impact of exposure to MVTFS resulting from products.	Industries are obligated to report the quantity of MVTFS even if it is contained in products imported into Canada. However, it is recognized that importers may not always be aware of its presence in products. MVTFS in free form is expected to demonstrate maximum bioavailability, as opposed to when present in products, where the MVTFS will not be easily released. Thus MVTFS in free form is a conservative (protective) choice for assessing the potential impact of exposure to the polymer.
Risk Characterization	Because no data on concentrations of MVTFS have been identified relating to industrial use or consumer product release, the impact of disposal (landfill and incineration) is unknown. Therefore, it cannot be assumed that releases to media are insignificant and exposure to aquatic, sediment-dwelling organisms or terrestrial species is low. Similarly, one cannot assume that MVTFS is unlikely to cause ecological harm.	There is no environmental monitoring data of MVTFS identified. Due to its high molecular weight and very low water solubility, MVTFS is expected to be immobile and not likely to migrate into ground water from disposal sites. Therefore, release to water and partitioning into sediment is not significant. Considering its low potential for ecotoxicity, the overall hazard to the environmental organisms is not expected to be significant.
Vulnerable Populations	Exposure to vulnerable populations should be addressed.	The screening assessments are based on consideration of the available data and include various conservative exposure scenarios considered to account for both the general and vulnerable populations in Canada. If information is available indicating that a specific subpopulation could be susceptible, this

		information would be considered in the assessment.