Trisiloxane, octamethyl-, (MDM) – Chemical Abstracts Service Registry Number (CAS RN)107-51-7: NGO Response to Draft Screening Assessment & Risk Management Scope Documents in Batch 12 of the Industry Challenge of the Chemicals Management Plan (*Canada Gazette Part I, Vol. 145, No. 2* — January 8, 2011)

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Introduction

The Canadian Environmental Law Association (CELA) and Chemical Sensitivities Manitoba (CSM) are submitting the following comments in response to the *Canada Gazette,* Part I, Vol. 145, No. 2 – January 8, 2011 release of the draft assessment and risk management scope documents for Trisiloxane, octamethyl-, (MDM) – Chemical Abstracts Service Registry Number (CAS RN) 107-51-7, of the Chemicals Management Plan (CMP), Batch 12 of the Industry Challenge.

In this submission, we highlight the toxicological properties of MDM and make recommendations on the importance to fill the empirical data gaps as well as improve the data generated through the use of models. We have also highlighted the possible similarities in properties between MDM and other two volatile methylsiloxanes, D4 and D5, and the need to consider the cumulative effects of these two substances in conjunction with MDM. As a result, our organizations want to ensure that the government utilizes the full extent of its authority under *CEPA 1999* to promote and implement the elimination or phase out of the most toxic substances found in the Canadian market.

Participation in the Chemicals Management Plan

CELA (www.cela.ca) is a non-profit, public interest organization established in 1970 to use existing laws to protect the environment and to advocate for environmental law reform. It is also a legal aid clinic that provides legal services to citizens or citizens' groups who are otherwise unable to afford legal assistance. In addition, CELA also undertakes substantive environmental policy and legislation reform activities in the areas of access to justice, pollution and health, water sustainability and land use issues since its inception. Under its pollution and health program, CELA has been actively involved in matters that promote the prevention and elimination of toxic chemicals addressed in the *Canadian Environmental Protection Act*, including the categorization process and implementation of the CMP.

Chemical Sensitivities Manitoba (CSM), a volunteer organization, was founded in 1997 by four individuals who saw the need to address the affects of toxic chemicals on human health and the possible link between the onset of chemical sensitivities and chemical exposure and, in particular, chronic low-level exposure. CSM raises awareness of the presence of toxic chemicals in the home and the environment and strongly advocates for the safe substitution of these toxins.

Our respective organizations along with other Canadian environmental and health non-governmental organizations have submitted substantial comments on assessment results and proposed management options for substances in Batches 1 through 11 of the Industry Challenge, including the final assessments and draft risk management options for selected chemicals in Batches 1 to 9.

Our organizations have consistently highlighted our support of specific approaches and proposals related to the risk assessment approach for substances being assessed under the Challenge Program. However, we have also taken the public comment periods as opportunities to highlight the gaps and limitations in the risk-based approach (including screening assessments and the development of management measures) for specific chemicals. Consequently, we encourage decision makers to consider our comments and recommendations as ways for improving the current approach to the management of chemicals in Canada. Generally, commentaries and recommendations are intended to further strengthen and entrench the precautionary principle in the current decision making process and promote a higher level of accountability for all users, manufacturers, importers and sellers of chemicals in Canada. The application of the precautionary principle along with the objectives for pollution prevention form the cornerstone of the *Canadian Environmental Protection Act,1999* (CEPA 1999).

At this point in the implementation of the Chemicals Management Plan, there has been little to no change in the approach taken by the government in the way it conducts its risk management (including the assessment process) of substances. This approach has resulted in very few regulatory actions aimed at eliminating chemicals of concern in Canada. In this regard, our underlying concern is the potential impact to human health and environment that could result from permitting the on-going use, release, sale, import or disposal of these chemicals, even when limited control measures are applied.

Background of Screening Assessment for MDM

Categorization information and selected information for MDM based on the draft screening assessment report are summarized in Table 1.

Trisiloxane, octamethyl-, (MDM) - CAS RN: 107-51-7

Table 1: Final results of Categorization, Screening Level Risk Assessment (SLRA) & Risk Management Scope for Batch 12 substance of the Chemicals Management Plan (CMP), Challenge Program[1, 2]

Substance name & CAS RN	Results of Categorization (S. 73)	Decisions based on draft screening level risk assessment (SLRA)	Key human health concerns*	Risk management scope document proposed measures	Uses/sources, release & volume (kg)
Trisiloxane, octamethyl- (MDM) 107-51-7	P, B, iT	CEPA toxic P(air, sediment), B	No human health effects have been identified by international agencies.	If persistent and bioaccumulative, the risk management that will be considered is the implementation of regulatory controls toward virtually eliminating releases of the substance to the environment; or If the substance does not meet criteria for virtual elimination under CEPA 1999, the substance may be managed using a life-cycle approach to prevent or minimize its release into the environment.	USES Ingredient in industrial, medical and consumer products such as cleaning and degreasing products, lubricants, diluents and solvents, personal care products and cosmetics. Importation for 2006: 10, 000 – 100,000 Not manufactured in Canada. RELEASES • Most MDM is expected to be exported in end-use products;

[1] Environment Canada and Health Canada (a). January 2011. Draft Screening Assessment for the Challenge, Trisiloxane, octamethyl-, (MDM), Chemical Abstract Services Registry Number 107-51-7. See: http://www.ec.gc.ca/ese-ees/19584F14-D972-46A1-B71C-FA9A36FFB0FE/batch12_107-51-7_en.pdf

[2] Environment Canada and Health Canada (b). January 2011. Proposed Risk Management Approach for Hydrazine, CAS RN: 107-51-7. See: http://www.ec.gc.ca/ese-ees/BF03ABB4-6EDF-40F3-9456-D9081647C9FB/Batch10_302-01-2_rm_EN.pdf

					• emitted to air during industrial or consumer and commercial applications; • recycling of the substance during industrial use is also expected; • Releases to wastewater or disposal to landfill and incineration sites.

Note: P-persistence; B-bioaccumulation (Bioaccumulation Concentration or Bioaccumulation Factor); iT-Inherent toxicity). P and B findings are in accordance to the Persistence and Bioaccumulation Regulations under CEPA 1999.

* The chart does not include potential human health effects on analogues reviewed for MDM.

Trisiloxane, octamethyl-, (MDM), is a linear volatile methylsiloxane (linear VMS). In this document, it is referred to as MDM.

During the categorization process of substances on the Domestic Substances List, MDM, it was proposed that MDM may be entering or may 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, as it was thought to be persistent and bioaccumulative as prescribed under the *Persistent and Bioaccumulation Regulations* as well as being inherently toxic. It was also proposed that MDM met one or more of the criteria set out in section 64 of the CEPA 1999.

As a result of the categorization process, MDM was not considered to be a high priority for assessment of potential risks to human health. The predominant source of human exposure to MDM is likely to be through indoor air primarily through the use of cosmetics (considered a relevant route of exposure). Therefore, the government proposed that MDM does not constitute a danger to human life or health in Canada.

MDM is now on a list of newly designated high production volume (HPV) chemicals (internationally) that will be reviewed in the United States as part of an industry-led extended HPV initiative (EHPV) program.

MDM is imported into the country either as a pure substance, a mixture, as a component of finished products, or as a residual in silicone polymers and oligomers). Import activities have increased over the past 20 years. There is also significant export of products containing MDM. We are of the opinion that there will be imported consumer and industrial products containing MDM, however, this was not mentioned in the draft assessment.

The primary use of MDM is as an ingredient in the preparation of polydimethylsiloxane (PDMS) polymers, oligomers and mixtures. These PDMS formulations (polymers, oligomers, and mixtures) are used in a wide range of applications such as cosmetics, personal care, consumer, medical and industrial products. Its industrial applications include its use in paints, coatings and adhesives; plastics products; semiconductors and other electronic components and in the foundations, structures and exteriors of buildings.

MDM is not listed on Canada's Cosmetic Ingredient Hotlist as a restricted or prohibited substance. Currently, it is present in 240 cosmetic products including personal care products. In cosmetics, PDMS formulations are generally referred to as dimethicone and MDM could be present as an ingredient in the PDMS mixture or as an impurity from the processing of the PDMS polymers or oligomer. Depending on the property required, MDM could be present in its pure form in

some cosmetics. Appendix A provides additional information on the use of MDM in products controlled under the *Foods and Drugs Act* (Canada).[3]

MDM has a significant vapour pressure under ambient environmental conditions. It is very hydrophobic and has a low aqueous solubility (0.034mg/L).[4] The draft assessment used an experimental log K_{ow} of 6.60 for MDM indicating that it has the potential to be bioaccumulative in the environment.[5]

In Canada, MDM releases to the environment through industrial, consumer and commercial application are as follows:

- exported in end-use products (30.3%)
- emissions to air during industrial or consumer and commercial applications (42.9%)
- recycling (15.2%)
- losses to wastewater (5.2%)
- disposal to landfill (5.0%); and
- incineration sites (1.3%).[6]

It is uncertain if the figures above include MDM in imported consumer and industrial products.

As a result of recycling activities, MDM can be released to water, soil and landfill sites. Some MDM could be released to the air from waste water treatment facilities and to water from any effluent. Sludge from these facilities will likely contain MDM. This sludge, containing MDM, could be spread on agricultural lands.

The draft assessment concluded that once MDM is released to air, it will likely stay in that compartment. If released to water, it will likely be adsorbed onto suspended particles in the water column (93.2%) with 6.5% staying in the water column and 0.3% volatilizing to the air.[7] Because of its volatility and its tendency to adsorb to particles in the water column, it was suggested that both mechanisms are important in the water column. Taking into account its low water solubility (0.034 mg/L), there is the possibility that MDM will remain in the soil.[8]

In this assessment, MDM was assumed to be a Type I substance, one that partitions to all media.[9] It is important to note that there is ongoing controversy about the designation of toxicity under CEPA 1999 for two other volatile methyl

[3] Environment Canada and Health Canada (a). pg. 6-7.
[4] Ibid, p. 4.
[5] Ibid. p. 5.
[6] Ibid, p.8.
[7] Ibid, p.10.
[8] Ibid..p. 10.
[9] Ibid. p.11.

siloxanes (VMS), namely D4 and D5. While D4 has been found to be toxic under section 64 of CEPA, there is uncertainty about the bioaccumulation of D4 which will impact the type of management measures that will be developed. D5 is currently the focus of a Board of Review established under CEPA 1999.

While MDM, D4 and D5 share some similar properties as to their toxicity and environmental fate, further consideration of their cumulative impacts, including the possibility of synergy between these substances, should be investigated prior to the final assessment so that a better understanding of the potential impacts of these substances on the environment would be gained.

The draft screening assessment for MDM proposed the following:

- MDM is entering or may 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 and is therefore meeting one or more criteria under section 64 of CEPA 1999;
- MDM is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health; and
- MDM meets the criteria for persistence and bioaccumulation potential as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000).[10]

The draft assessment indicated that MDM will be considered for inclusion in the Domestic Substances List inventory update initiative. Also, where relevant, research and monitoring will support verification of assumptions used during the screening assessment and, where appropriate, the performance of potential control measures identified during the risk management phase.

Recommendation: Based on the draft screening report, we support the finding that MDM is toxic in accordance to section 64 of CEPA 1999.

Recommendation: A CEPA toxic designation and adding the substance to the Toxic Substances List (Schedule 1) of CEPA 1999 would require the development of management measures for MDM according to CEPA 1999.

Recommendation: The scope of the assessment should be expanded to include the cumulative impacts of MDM, D4, D5 and other similar volatile methylsiloxanes on the environment based on similarities in their chemical structures and their effects on various environmental media.

Comments & recommendations

[10] Ibid., p. 36.

Environmental persistence

Based on empirical and modelled data, the government concluded in the draft assessment that MDM meets the persistence criteria in air and sediment but does not meet the criteria for water and soil as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000).[11] We accept the finding that MDM is persistent based on the available data presented in the screening assessment and that it satisfies the criteria as outlined in the *Persistence and Bioaccumulation Regulations* under CEPA 1999.

Long range transport potential

The assessment concluded that the weight of evidence indicates that MDM has significant atmospheric transport potential to remote areas away from emission sources but can be effectively removed from the atmosphere via reaction with photochemically produced OH radicals. There are indications that MDM has a low potential to be deposited to water or soil in remote areas. According to the draft screening assessment, it has a low Arctic contamination potential (ACP).[12]

In a recent Norwegian Arctic study (Evenset et al. 2009), MDM was found in two of 16 cod liver samples.[13] It was also detected in 2 of 4 Atlantic cod liver samples in Norway (Schlabach et al. 2007).[14] While the presence of MDM in the liver could be attributed to *local* anthropogenic sources, the draft assessment stated that 'the findings may also represent evidence that under some circumstances MDM may be capable of travelling to regions remote from possible sources, including the Arctic.'[15] However, MDM was found to be below detection limits in sediment and seabird samples collected in the same region.[16]

Comments

- The presence of MDM in the cod livers warrants further investigation. Without further qualitative and quantitative investigation, it cannot be assumed that the presence of MDM in these species is solely as a result of anthropogenic activity.
- The screening assessment does not provide a full understanding of the cumulative impacts that the volatile methylsiloxanes, MDM, D4 and D5, may have on the environment with respect to long-range transport potential. For example, the examination of long range potential of these substances has not focused on the possible synergy between these siloxanes in the

[11] Ibid., p. 19.
[12] Ibid., p.16.
[13] Ibid. p. 16.
[14] Ibid., p. 19.
[15] Ibid., p.16.
[16] Ibid., p. 16.

atmosphere. More research needs to address synergy of siloxanes and the resulting impact on long-range transport potential and possible deposition.

Recommendation: Since volatile methylsiloxanes - MDM, D4 and D5 have some similar properties, we urge the government to consider the cumulative impact of these substances on biota in remote areas, away from point sources.

Recommendation: Further investigation and quantification of the sources of MDM and other volatile methylsiloxanes (D4, D5) in remote areas are required. These studies should expand their scope of work to examine the possible deposition of MDM, D4 and D5 as a result of long-range travel by air – as individual chemicals and possibly, cumulatively.

Recommendation: The possibility of deposition of MDM as a result of long-range transport should not be rejected by the government in the absence of substantial evidence. However, efforts should be focused on acquiring further knowledge in this area as this issue is pertinent to other volatile methyl siloxanes, such as D4 and D5.

Bioaccumulation

The experimental Log K_{ow} of 6.60 as used in the assessment indicates the potential of MDM to be bioaccumulative. This value would indicate that it meets the bioaccumulation criteria according to the *Persistence and Bioaccumulation Regulations* under CEPA 1999.

However, there is considerable debate as to whether the endpoints for bioaccumulation – bioaccumulation factor (BAF) / bioconcentration factor (BCF) as prescribed under the *Persistence and Bioaccumulation Regulations* (Canada 2000) (PB), are as appropriate as the biomagnification factor (BMF) and the trophic magnification factor (TMF), when determining the bioaccumation potential of a chemical. The assessment commented that while BMF data are not used directly in the determination of bioaccumulation potential based on the *PB Regulations* (Canada 2000), they may be considered as indicators of the potential for uptake and accumulation in biota.[17] It is our view that the Log K_{ow} value >5, as prescribed in the PB Regulations, provides adequate indication of a chemical's potential to bioaccumulate.

Experimental BCF data for MDM indicated the following values: 3610–5030 (0.0017 mg/L of MDM) and 5600–7730 (0.021 mg/L of MDM) (Drottar 2006).[18] Because of insufficient experimental data, modeling was done to determine other BCF values. From the assessment, the predicted BCF using the Arnot-Gobas

[17] Ibid., p. 17.
[18] Ibid., p. 17.

mass balance model (v1.11), a kinetic mass balance (kM) of 0.03/day for a 5% lipid content fish resulted in a BCF of 6309 for BDM, which is comparable to the steady-state BCFs, as reported above.[19] The modeled BAF was greater than 5000. The draft assessment indicated that evidence from one BMF study suggest the value to be less than one but the lipid-normalized BMF value being very close to one indicates the possibility that dietary exposures may significantly contribute to exposures in the environment.[20]

There is additional evidence of bioaccumulation of MDM as it has been detected in the liver of higher trophic level fish species (cod) as cited in the above section. This could also indicate possible food chain transfer. While the scope of the study was unable to conclude on the long term impacts of MDM in the liver, the presence of MDM in an organ should be of some concern. Because of these findings, the cumulative impact of these VMS should be investigated to determine if specific siloxanes are more likely to bioaccumulate as compared to other siloxanes.

It was concluded that MDM meets the bioaccumulation criterion (BAF or BCF ≥ 5000) as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000).

We are in agreement with the conclusion as stated above but we offer the following recommendations.

Recommendation: We support the finding that MDM is bioaccumulative in aquatic species according to the Persistence and Bioaccumulative Regulations (Canada 2000).

Recommendation: A conclusion that MDM is persistent and bioaccumulative should lead to the conclusion that management measures are required with virtual elimination of MDM should be the ultimate goal.

Recommendation: To address data gaps, additional empirical studies should be undertaken to decrease the uncertainty in the determination of the bioaccumulation potential of MDM. For example, the determination of BCF for MDM should include the consideration of fish species found in different food web chains relevant to Canadian waters.

Recommendation: We urge the government to consider the cumulative (including synergistic) effects of MDM in conjunction with other volatile methylsiloxanes (e.g. D4 and D5) when determining the effects of these substances in all environmental compartments.

[19] Ibid. p. 18-19.
[20] Ibid., p. 20.

Recommendation: Based on the evidence of MDM in the liver of higher trophic level fish species, consideration should be given to conduct additional studies to detect and measure MDM in the liver of different fish species.

Ecotoxicity

Water column

Based on the draft screening assessment for MDM, there were no observable adverse effects in the aquatic compartment at concentrations up to the water solubility of MDM (0.034 mg/L). The study conducted acute testing of rainbow trout, water flea and green alga and chronic testing for rainbow trout and water flea.[21]

In a 42 day bioaccumulation study (SEHS 2006), no adverse effects for the fathead minnows were reported at the concentrations tested (below the water solubility of MDM) but some mortalities were reported.[22] In reviewing all the data such as steady state concentration, the corresponding molar concentration, and the critical body residue range in fish, the draft screening assessment concluded that the chronic effects were from a narcosis mode of action and therefore, non-polar narcosis was considered to be the most likely mode of toxic action for MDM.[23]

Modelled data were also used to estimate the potential for aquatic toxicity but there were some uncertainties and problems associated with the modelled results. One major uncertainty is that organosilicones such as MDM, are not well represented in the training sets of the models which as a result, affect the validity of the results obtained from the study.

Sediment

In a 28-day toxicity test with the freshwater oligochaete *Lumbriculus variegates* in sediment spiked with MDM, there was a significant reduction of survival and reproduction at the lowest measured test concentration (1.6 mg/kg dry weight (dw)).[24] In another 28-day sediment toxicity testing with the freshwater midge, *Chironomus riparius,* the draft assessment indicated that a significant reduction in survival, development time, emergence ratios and development rates were observed.[25] Development rates were classified as the most sensitive endpoint from this study.

The adverse effects observed in these sediment species provide essential evidence of the potential impacts of MDM in this environmental compartment.

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[21] Ibid., p. 21.
[22] Ibid.
[23] Ibid., p. 21.
[24] Ibid.
[25] Ibid.

With MDM expected to distribute to the sediment once it has been released to water and its persistence in sediment, these observations confirm that MDM has an adverse impact on species found in sediment.

Other environmental compartments

There was no available data for the other environmental compartments.

We note the lack of empirical ecotoxicity data from the silicone industry for other environmental compartments other than the water column. Given the opportunities provided to stakeholders to provide toxicity data through the categorization process and the industry challenge under the Chemicals Management Plan, we find it unacceptable that industry has not provided government with the necessary data on the environmental toxicity of MDM for review. The absence of this data puts the onus on the government and other stakeholders to attempt to fill these data gaps. While it remains unclear if additional efforts are underway to address these data gaps, it should be stated that in the absence of toxicity data, adequate evidence to demonstrate sediment toxicity for MDM has been presented. Therefore, it would be appropriate to make conclusions on the toxicity of MDM based on the use of precaution.

However, taking into account the empirical data and some of the results through modeling, the draft screening concluded that it is unlikely that MDM will cause adverse effects in pelagic aquatic organisms at or near the limit of water solubility.

Comments

- Although there is empirical data for the aquatic environment, comparisons with some modeled data do not appear to be very reliable for reasons cited above. This is problematic as further verification and comparison of modeling and empirical data is not possible.
- Not all organosilicones are recent commercial substances but it is noted that the aquatic toxicity data is very recent. We question why the silicone industry has not been able to provide information on organosilicones that is required to improve the training sets of models. While we are aware this is problematic for some organosilicones, there are likely some that have more predictable toxicological properties based on their physical/chemical data. These could be used to improve the accuracy of the modeled data.

Recommendation: We urge the government to use the available data to conclude on the environmental toxicity of MDM applying the precautionary principle.

Recommendation: We urge the government to require additional empirical toxicity data for sediment for MDM in order to reduce the uncertainties in this environmental compartment.

Recommendation: To reduce the uncertainties in data generated through modeling, we urge the government to collaborate with stakeholders who may have information to improve the training sets for the models used for determining ecotoxicity and bioaccumulation. Improved training sets will result in modeled data that is more accurate and useful in situations where comparisons of empirical and modeled toxicological data are needed for verification and in cases when there is a lack of empirical toxicological data for a substance.

Ecological exposure assessment

There is a lack of Canadian data measuring the concentration of MDM in influent, effluent, sludge, and in the vicinity of sewage treatment plants. MDM has been detected in the influent and sludge from sewage treatment plants from several Nordic countries.[26] This monitoring data would create an expectation that MDM will be present in the influent, effluent and sludge from Canadian wastewater treatment plants (WWTPs) as well. As with other volatile methylsiloxanes such as D4 and D5, MDM in wastewater effluent and in sludge is available for release to the environment. No monitoring data was available to assess the concentration of MDM in the vicinity of the outfalls of any WWPTs and neither was there information to indicate the impact of MDM from the outfalls on the aquatic species and sediment in the vicinity of the outfalls and plants that grow in soil that may have been treated with sludge containing MDM. These gaps would provide areas for future studies.

However, based on information gathered about the presence of MDM in the liver of some fish found in remote areas, there is an indication that the substance is bioavailable and accumulates in certain tissues. There is no definite evidence of the source of MDM to indicate if there are local sources or if its presence results from long-range transport deposition.

We conclude that more ecological and biomonitoring for MDM may be required to understand the range of species and geographical areas where MDM may be detected. However, actions to manage MDM should not be delayed in the absence of monitoring data since preliminary evidence of presence of MDM in specific species indicate that the substance accumulates in some tissues.

Recommendation: We urge the government not to delay management measures on MDM due to the lack of monitoring data in aquatic species.

Recommendation: In order to improve the accuracy for determining the potential for MDM to do ecological harm in the aquatic environment, the government should undertake to estimate and integrate exposure levels of

[26] Ibid., p. 24.

MDM in various species in this media. This effort could include attaining empirical data of MDM levels in waste water treatment plants across Canada. There could be a specific focus to test for MDM in the influent, effluent, as well as looking at concentration levels with varying distances from the outfalls, and testing sediment impacted by the outfalls and the resulting sludge from these WWTPs. Collectively, this data should give indications of the extent of MDM present in this media and assess the possibility of harm.

Proposed risk management

The risk management for MDM will be determined by the results of the final screening assessment. If it is concluded that MDM meets one or more of the criteria under section 64 and the conditions under 77(4) of CEPA 1999 as being a persistent, bioaccumulative and inherently toxic substance, the risk management that will be considered is the implementation of regulatory controls toward virtually eliminating releases of the substance to the environment.

If the final screening assessment report does not conclude that MDM meets the conditions set out in subsection 77(4) of CEPA 1999, MDM will not be subject to the virtual elimination provisions under CEPA 1999 and may be managed using a life-cycle approach to prevent or minimize its release into the environment.

The results of the draft screening assessment indicated that MDM would need to have management measures developed. Given the vast number of industrial, consumer and commercial applications for MDM, we would urge the government to use its full authority to manage this chemical through regulations. Below, we have limited our comments on the risk management elements until additional details are released. However, we note that specific consideration should be given to the following approach:

1. Establish a regulatory management regime for MDM that will eliminate the use, import, generation, release, disposal and export of MDM from all its applications – industrial, consumer, and commercial;
2. Establish clear timelines for achieving reduction and elimination of MDM;
3. Focus in finding safe substitutes to MDM;
4. Consider how cumulative impacts from MDM and other similar siloxanes can be addressed through the development of management measures;
5. Prohibit the use of MDM in cosmetic, personal care products and consumer products, and
6. Develop measures that are protective of vulnerable populations including children, developing fetuses, people of low income, indigenous communities, people with chemical sensitivities and workers.

Conclusion

Evidence from the draft screening assessment suggest that MDM meets at least one of the criteria of section 64, CEPA 1999 and the criteria for persistence and bioaccumulation are satisfied as set out in the *Persistence and Bioaccumulation Regulations* (2000). While we recognize there are uncertainties in the data and our organizations have made recommendations accordingly, we suggest that MDM be subject to virtual elimination.

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Appendix A

Other database listings for MDM under the *Foods and Drugs Act* (Canada):[27]

- Natural Health Products Ingredients Database (NHPID) as an acceptable non-medicinal ingredient in natural health products;
- Not listed in the Licensed Natural Health Products Database (LNHPD. No current licensed natural health product containing this substance as a medicinal or non-medicinal ingredient is available;
- Not listed in the Drug Products Database (DPD) as a medicinal ingredient in pharmaceutical drugs (DPD 2010;
- Listed in the Therapeutic Product Directorate's internal Non-Medicinal Ingredients Database as a non-medicinal ingredient present in one marketed therapeutic product used in sunscreen applications;
- Not identified to be present as a medicinal ingredient or non-medicinal ingredient in veterinary drugs (DPD 2010)
- Not listed as an approved food additive under Division 16 of the *Food and Drug Regulations* (F&DR) (Canada 2010) and has not been identified as being present in the formulation of incidental additives or in food packaging materials. However, PDMS it is a permitted food additive as per Item D.1 of Table VIII, Division 16 of the *Food and Drug Regulations* (Canada 2010) commonly used a component of food processing aids for foam control in food applications.

[27] Ibid.