Final Screening Assessment for 52 Substances with High Hazard Potential on the Domestic Substances List

Chemical Abstracts Service Registry Numbers

55-18-5	79-16-3	122-60-1	569-61-9	10034-93-2	55290-64-7
59-88-1	94-58-6	123-39-7	591-78-6	10046-00-1	103122-66-3
60-35-5	96-09-3	123-73-9	593-60-2	13463-39-3	
62-50-0	96-18-4	131-18-0	606-20-2	13840-56-7	
62-55-5	100-63-0	131-52-2	615-28-1	15545-48-9	
66-27-3	101-61-1	135-20-6	823-40-5	24602-86-6	
75-25-2	106-87-6	136-35-6	1120-71-4	25321-14-6	
76-01-7	110-88-3	141-90-2	1694-09-3	25376-45-8	
78-88-6	115-28-6	331-39-5	3296-90-0	26447-14-3	
79-00-5	116-14-3	492-80-8	4170-30-3	39156-41-7	

Environment Canada

Health Canada

May 2013

Introduction

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) requires the Minister of the Environment and the Minister of Health to conduct screening assessments of substances that have met the categorization criteria set out in the Act to determine whether these substances present or may present a risk to the environment or human health.

Based on the information obtained through the categorization process, the Ministers identified a number of substances as priorities for further assessment. The 52 substances included in this assessment were identified as priorities because they had been identified as posing a high hazard to human health based on classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity or reproductive toxicity. Fifteen of the 52 substances were also determined to meet categorization criteria for persistence or bioaccumulation, and inherent toxicity to human or non-human organisms (Environment Canada 2003, 2006), under subsection 73(1) of CEPA 1999. Categorization results are presented in Appendix A and B.

Screening assessments focus on information critical to determining whether a substance meets the criteria as set out in section 64 of CEPA 1999[1]. Screening assessments examine scientific information and develop conclusions by incorporating a weight-of-evidence approach and precaution.

The Ministers of the Environment and of Health have conducted this screening assessment for these substances. The critical information and considerations upon which the assessment is based are summarized below. Since the publication of the draft assessment report, additional information was received on thiophanate-methyl (CAS Registry No. 23564-05-8), which indicates that is being used in Canada. As a result, this substance has since been removed from the assessment and will be considered for further assessment in the future.

Summary of Information Used as Basis for this Screening Assessment

To establish whether certain substances were currently being manufactured in or imported into Canada, a survey was conducted by issuing a *Notice with Respect to Selected Substances Identified as Priority for Action* pursuant to paragraphs 71(1)(*a*) and (*b*) of CEPA 1999. The Notice was published in Part I of the *Canada Gazette* on March 4, 2006 (Canada 2006). The 14 substances from that survey being considered in this assessment are listed in Appendix A.

An additional survey was conducted by issuing a *Notice with Respect to Certain Inanimate Substances (Chemicals) on the Domestic Substances List* pursuant to paragraphs 71(1)(b) of

[1] A determination of whether one or more of the criteria of section 64 are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and the use of consumer products. A conclusion under CEPA 1999 is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Controlled Products Regulations*, which is part of regulatory framework for the Workplace Hazardous Materials Information System [WHMIS] for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA 1999 does not preclude actions being taken under other sections of CEPA 1999 or other Acts.

CEPA 1999. The Notice was published in Part I of the *Canada Gazette* on October 3, 2009 (Canada 2009). The 38 substances from that survey being considered in this assessment are listed in Appendix B.

In response to these notices, there were no reports of industrial activity (import or manufacture) with respect to these substances in Canada above the reporting threshold of 100 kg for the relevant reporting year. These results indicate that currently these substances are not in use above the specified reporting threshold. Entry characterization consisted of additionally searching for information on releases and sources of the substance in relevant databases, particularly to identify direct exposure potential to the general population (CNS 2010; Canada [1978]; DPD 2010; NHPID 2010; LNHPD 2010; EAFUS 2010; HPD 2010; HSDB c1993-2008). Searches for these substances were conducted up to November 2010, and no information was found on current uses or releases of these substances in Canada. Therefore, the likelihood of exposure to these substances in Canada resulting from commercial activity is low and hence the potential risks to human health or the environment are considered to be low.

Additional information obtained and assessed following categorization indicates a lack of any significant commercial activity for these substances. Consequently, no further collection or analysis of information relevant to the health and/or environmental effects of these substances has been conducted. Therefore, the decisions on human health hazard potential and persistence, bioaccumulation and inherent toxicity properties made during categorization remain unchanged.

Conclusion

Based on available information, and until new information is received indicating that these 52 substances are entering, or may enter the environment, from commercial activity or from other sources, it is concluded that they do not meet any of the criteria as set out in section 64 of CEPA 1999.

As substances listed on the DSL, import and manufacture of these substances in Canada are not currently subject to notification under subsection 81(1). Given their potential high hazard for human health, there is concern that new activities for the above substances which have not been identified or assessed under CEPA, 1999 could lead to the substances meeting the criteria set out in section 64 of CEPA, 1999. Therefore, the *Domestic Substances List* will be amended, under subsection 87(3) of the Act, to indicate that the above substances be subject to the Significant New Activity provisions specified under subsection 81(3) of the Act, to ensure that any new manufacture, import or use of any of these substances in quantities greater than 100 kg/year is notified and will undergo ecological and human health risk assessments as specified in section 83 of the Act, prior to the substance being considered for introduction into Canada.

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Appendix A: Categorization criteria

Appendix A: Categorization results for 14 substances determined to be no longer in commercial use in Canada above the specified reporting threshold from the *Notice with Respect to Selected Substances Identified as Priority for Action* pursuant to paragraphs 71(1)(*a*) and (*b*) of CEPA 1999, published in Part I of the *Canada Gazette* on March 4, 2006 (Canada 2006)

CAS RN[1]	DSL Name	Classified for Carcinogenicity[2]	Classified for Developmental Toxicity[2]	Classified for Genotoxicity[2]	Classified for Reproductive Toxicity[2]	Persistent	Bioaccumulative	Inherently Toxic to aquatic organisms	Meets s.73 criteria[3]
55-18-5	Ethanamine, N-ethyl-N-nitroso-	X							
62-50-0	Methanesulfonic acid, ethyl ester	X							
66-27-3	Methanesulfonic acid, methyl ester	X							
79-16-3	Acetamide, N-methyl-		X						
94-58-6	1,3-Benzodioxole, 5-propyl-	X							
115-28-6	Bicyclo[2.2.1]hept-5-ene-2,3-dicarboxylic acid, 1,4,5,6,7,7-hexachloro-	X				X			X
123-39-7	Formamide, N-methyl-		X						
123-73-9	2-Butenal, (E)-	X		X					
331-39-5	2-Propenoic acid, 3-(3,4-dihydroxyphenyl)-	X							
593-60-2	Ethene, bromo-	X							
615-28-1	1,2-Benzenediamine, dihydrochloride	X		X					
25376-45-8	1,3-Benzenediamine, ar-methyl-	X							
39156-41-7	1,3-Benzenediamine, 4-methoxy-, sulfate (1:1)	X		X					
55290-64-7	1,4-Dithiin, 2,3-dihydro-5,6-dimethyl-, 1,1,4,4-tetraoxide	X							

[1] CAS RN – Chemical Abstracts Service Registry Number

[2] For more information on the criteria used to determine substance classifications, see Appendix C.

[3] Persistent or bioaccumulative and inherently toxic to human beings (based on carcinogenicity) or to non-human organisms (based on inherent toxicity to aquatic organisms).

Appendix B: Categorization criteria

Appendix B: Categorization results for 38 substances determined to be no longer in commercial use in Canada above the reporting threshold from the *Notice with Respect to Certain Inanimate Substances (Chemicals) on the Domestic Substances List* pursuant to paragraphs 71(1)(b) of CEPA 1999, published in Part I of the *Canada Gazette* on October 3, 2009 (Canada 2009)

CAS RN[1]	DSL Name	Classified for Carcinogenicity[2]	Classified for Developmental Toxicity[2]	Classified for Genotoxicity[2]	Classified for Reproductive Toxicity[2]	Persistent	Bioaccu-mulative	Inherently Toxic to aquatic organisms	Meets section 73 criteria[3]
59-88-1	Hydrazine, phenyl-, monohydrochloride	X		X					
60-35-5	Acetamide	X							
62-55-5	Ethanethioamide	X							
75-25-2	Methane, tribromo-	X				X			X
76-01-7	Ethane, pentachloro-	X				X			X
78-88-6	1-Propene, 2,3-dichloro-			X					
79-00-5	Ethane, 1,1,2-trichloro-	X[4]				X			
96-09-3	Oxirane, phenyl-	X				X			X
96-18-4	Propane, 1,2,3-trichloro-	X			X	X			X
100-63-0	Hydrazine, phenyl-	X		X					
101-61-1	Benzenamine, 4,4'-methylenebis[N,N-dimethyl-	X				X		X	X
106-87-6	7-Oxabicyclo[4.1.0]heptane, 3-oxiranyl-	X							
110-88-3	1,3,5-Trioxane		X						
116-14-3	Ethene, tetrafluoro-	X				X			X
122-60-1	Oxirane, (phenoxymethyl)-	X		X					
131-18-0	1,2-Benzenedicarboxylic acid, dipentyl ester		X		X			X	
131-52-2	Phenol, pentachloro-, sodium salt	X				X		X	X
135-20-6	Benzenamine, N-hydroxy-N-nitroso-, ammonium salt	X							
136-35-6	1-Triazene, 1,3-diphenyl-	X							
141-90-2	4(1H)-Pyrimidinone, 2,3-dihydro-2-thioxo-	X							
492-80-8	Benzenamine, 4,4'-carbonimidoylbis[N,N-dimethyl-	X						X	

569-61-9	Benzenamine, 4-[(4-aminophenyl)(4-imino-2,5-cyclohexadien-1-ylidene)methyl]-, monohydrochloride	X							
591-78-6	2-Hexanone				X				
606-20-2	Benzene, 2-methyl-1,3-dinitro-	X	X	X	X	X			X
823-40-5	1,3-Benzenediamine, 2-methyl-	X		X					
1120-71-4	1,2-Oxathiolane, 2,2-dioxide	X							
1694-09-3	Benzenemethanaminium, N-[4-[[4-(dimethylamino)phenyl][4-[ethyl[(3-sulfophenyl)methyl]amino]phenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-3-sulfo-, hydroxide, inner salt, sodium salt	X				X			X
3296-90-0	1,3-Propanediol, 2,2-bis(bromomethyl)-	X				X			X
4170-30-3	2-Butenal			X					
10034-93-2	Hydrazine, sulfate (1:1)	X				X		X	X
10046-00-1	Hydroxylamine, sulfate (1:1) (salt)	X				X		X	X
13463-39-3	Nickel carbonyl (Ni(CO)4), (T-4)-	X	X			X		X	X
13840-56-7	Boric acid (H3BO3), sodium salt		X		X	X			
15545-48-9	Urea, N'-(3-chloro-4-methylphenyl)-N,N-dimethyl-	X	X					X	
24602-86-6	Morpholine, 2,6-dimethyl-4-tridecyl-	X	X	X	X		X	X	X
25321-14-6	Benzene, methyldinitro-	X		XX	X			X	
26447-14-3	Oxirane, [(methylphenoxy)methyl]-	X		XX					
103122-66-3	Carbamic acid, [(2-methylpropoxy)thioxomethyl]-, ethyl ester	X		X					

[1] CAS RN – Chemical Abstracts Service Registry Number.
[2] For more information on the criteria used to determine substance classifications, see Appendix C.
[3] Persistent or bioaccumulative and inherently toxic to human beings (based on carcinogenicity) or to non-human organisms (based on inherent toxicity to aquatic organisms).
[4] Identified after completion of categorization in 2006.

Appendix C: Criteria used for obtaining results from the Simple Hazard tool

Carcinogenicity is determined by one or more of the following criteria:

European Community (ESIS c1995-2010)

- Category 1 (Known to be carcinogenic to humans)
- Category 2 (Regarded as if carcinogenic to humans)
- Category 3 (Causes concern for humans owing to possible carcinogenic effects)

Health Canada (Guidelines for Canadian Drinking Water Quality) (Health Canada 1995)

- Group I (Carcinogenic to humans)
- Group II (Probably carcinogenic to humans)
- Groups IIIA and IIIB (Possibly carcinogenic to humans)

International Agency for Research on Cancer (IARC 2010)

- Group 1 (Carcinogenic to humans)
- Group 2A (Probably carcinogenic to humans)
- Group 2B (Possibly carcinogenic to humans)

National Toxicology Program (NTP 2010)

- Known to be a human carcinogen
- Reasonably anticipated to be a human carcinogen

United States Environmental Protection Agency (US EPA) 1986 Carcinogenicity Guidelines (U.S. EPA 1987)

- Group A (Human carcinogen)
- Groups B1 and B2 (Probable human carcinogen)
- Group C (Possible human carcinogen)

US EPA 2003 Carcinogenicity Guidelines (U.S. EPA 2003)

- Carcinogenic to humans
- Likely to be carcinogenic to humans
- Suggestive evidence of carcinogenicity, but not sufficient to assess
- Human carcinogenic potential

Developmental Toxicity is determined by one of the following criteria:

European Community (ESIS c1995-2010)

- Category 1 (Known to cause developmental toxicity in humans)
- Category 2 (Regarded as if they cause developmental toxicity in humans)

- Category 3 (Causes concern for humans owing to possible developmental toxic effects)

Genotoxicity is determined by one of the following criteria:

European Community (ESIS c1995-2010)

- Category 1 (Known to be mutagenic to humans)
- Category 2 (Regarded as if mutagenic to humans)
- Category 3 (Causes concern for humans owing to possible mutagenic effects)

Reproductive Toxicity is determined by one of the following criteria:

European Community (ESIS c1995-2010)

- Category 1 (Known to impair fertility in humans)
- Category 2 (Regarded as if they impair fertility in humans)
- Category 3 (Causes concern for human fertility)