

New Substances Advisory Note 2015-04

Clarification in relation to certain micro-organisms listed by Chemical Abstract Services (CAS) Registry Number on the Domestic Substances List

This advisory note has been prepared to inform importers and manufacturers of new substances in Canada that some micro-organisms are listed on the *Domestic Substances List* with a *Chemical Abstract Services Registry Number* to refer to the inanimate (not living) product of these micro-organisms.

Background

The *Domestic Substances List* (DSL) is a comprehensive compilation of all known substances that have been or continue to be in Canadian commerce. The DSL is the sole basis for determining whether a substance is new for the purposes of the *Canadian Environmental Protection Act, 1999* (the *Act*). Substances are added to the DSL using a unique substance identifier.

The DSL includes the original list, published in the *Canada Gazette*, Part II, on May 4, 1994 and all subsequent additions. The different parts of the DSL are enclosed in appendix 1.

Unique substance identifier

Substances that are chemicals and polymers are listed in Part 1 and 2 of the public portion of the DSL and are identified by their *Chemical Abstract Services* (CAS) Registry Number¹. CAS Registry Numbers are unique, unmistakable identifier for chemicals and polymers. A CAS Registry Number itself has no inherent chemical significance but provides an unambiguous way to identify a chemical, polymers, or a molecular structure when there are many possible systematic, generic, proprietary or trivial names. This applies to organic and inorganic compounds, metals, alloys, minerals, and polymers.

Substances that are animate products of biotechnology (*i.e.*, living organisms) are listed in Part 5 and 6 of the DSL and are identified by their Taxonomic designation (*e.g.*, species and/or strain) and, when available, their culture collection [*e.g.*, the *American Type Culture Collection* (ATCC)] number. Substances that are bio-chemicals and bio-polymers are identified by their *Enzyme Commission*² (EC) number. This information ensures that the substance identification is unique.

¹ The CAS Registry Number is the property of the American Chemical Society, any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior written permission.

² The Enzyme Commission (EC) number is the property of the International Union of Biochemistry and Molecular Biology, any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior written permission.

Living Organisms found on Part 1 and 2 of the public portion of the DSL

A CAS Registry Number is occasionally assigned in relation to a micro-organism to describe the inanimate (dead) product of that micro-organism. This CAS Registry Number may be added to Part 1 or 2 of the public portion of the DSL. For example, CAS Registry Number 68876-77-7 has been assigned by the Chemical Abstract Services in relation to the substance *Saccharomyces cerevisiae*, but it is used to describe the processed yeast products of *Saccharomyces cerevisiae*, such as yeast extract.

Submitting a New Substances Notification

Any company or individual who plans to import or manufacture a micro-organism that is a living organism not specified in part 5 or 6 of the public portion of the DSL will have to provide a complete notification dossier under the *New Substances Notification Regulations (Organisms)* prior to import or manufacture even if the substance is specified on Part 1 or 2 of the public portion of the DSL.

Pre-Notification Consultation

Although not required, the New Substances program recommends that any person intending to import or manufacture a substances (including a micro-organism) that is not on the DSL to request a *Pre-notification Consultation* (PNC). A PNC is an option for any person who wishes to consult with the New Substances (NS) program during the planning or preparation of their New Substances Notification package to discuss any questions or concerns they have about the prescribed information.

Contact information

If you have any questions, please contact a Substances Management Information Line expert:

Telephone: 1-800-567-1999 (toll-free in Canada)
1-819-938-3232 (outside Canada)

Facsimile: 1-819-938-5212

E-mail: ec.substances.ec@canada.ca

For additional information or documentation regarding the Regulations, please visit the New Substances Website (<http://www.ec.gc.ca/subsnouvelles-newssubs/>).

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Signed on: December 10, 2015

Appendix 1 – Parts of the Domestic Substances List

The following table summarizes the different parts of the DSL, published in the *Canada Gazette*, Part II on July 4, 2001 (<http://publications.gc.ca/gazette/archives/p2/2001/2001-07-04/pdf/q2-13514.pdf>), and how substances (including micro-organisms) are identified and listed:

Domestic Substances List (DSL) §66(1), 87(1) and (5), 105(1) and 112(1)	
Part 1	Public Inventory for chemicals and polymers identified by their Chemical Abstract Services (CAS) Registry Number.
Part 2	Public Inventory for chemicals and polymers subject to a Significant New Activity (SNAc) notices identified by their CAS Registry Number.
Part 3	Confidential Inventory for chemicals and polymers identified by their masked names in accordance with the <i>Masked Name Regulations</i> , and by their Confidential Substance Identity Number assigned by Environment and Climate Change Canada.
Part 4	Confidential Inventory for chemicals and polymers subject to a SNAc identified by their masked names in accordance with the <i>Masked Name Regulations</i> , and by their Confidential Substance Identity Number assigned by Environment and Climate Change Canada.
Part 5	Public inventory for inanimate biotechnology products and living organisms identified by their Culture Collection (e.g., American Type Culture Collection (ATCC)) for living organisms or Enzyme Commission (EC) Number assigned by the International Union of Biochemistry and Molecular Biology (IUBMB) for Enzymes or by their Chemical Abstract Services for inanimate products of biotechnology other than enzymes.
Part 6	Public inventory for inanimate biotechnology products and living organisms subject to a SNAc and identified by their Culture Collection [e.g., American Type Culture Collection (ATCC)] for living organisms or EC Number for Enzymes or by their CAS Registry Number for inanimate products of biotechnology other than enzymes.
Part 7	Confidential inventory for inanimate biotechnology products and living organisms identified by their masked names in accordance with the <i>Masked Name Regulations</i> , and by their Confidential Substance Identity Number assigned by Environment and Climate Change Canada.
Part 8	Confidential inventory for inanimate biotechnology products and living organisms subject to a SNAc and identified by their masked names in accordance with the <i>Masked Name Regulations</i> , and by their Confidential Substance Identity Number assigned by Environment and Climate Change Canada.

