

DEPARTMENT OF THE ENVIRONMENT

CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999

Significant New Activity Notice No. 15754

Significant New Activity Notice

(Section 85 of the *Canadian Environmental Protection Act, 1999*)

Whereas the Minister of the Environment and the Minister of Health have assessed information in respect of the substance Alkyl dioic acid, polymer with carbonic dichloride and carbopolycyclic diol, substituted phenyl ester;

Whereas the substance is not on the *Domestic Substances List*;

And whereas the Ministers suspect that a significant new activity in relation to the substance may result in the substance becoming toxic under the *Canadian Environmental Protection Act, 1999*;

Therefore, the Minister of the Environment indicates, pursuant to section 85 of that Act, that subsection 81(4) of the same Act applies with respect to the substance in accordance with the Annex.

JIM PRENTICE

Minister of the Environment

ANNEX

Information Requirements

(Section 85 of the *Canadian Environmental Protection Act, 1999*)

1. In relation to the substance Alkyl dioic acid, polymer with carbonic dichloride and carbopolycyclic diol, substituted phenyl ester, a significant new activity is

(a) the use of the substance, in any quantity, in baby bottles or food packaging materials intended for infants up to 18 months of age; or

(b) the use of any quantity of the substance where the quantity of unreacted residual Bisphenol A it contains exceeds 100 kilograms per calendar year.

2. A person that proposes a significant new activity set out in this Notice for this substance shall provide to the Minister of the Environment, at least 90 days prior to the commencement of the proposed significant new activity, the following information:

(a) a description of the proposed significant new activity in relation to the substance;

(b) the information specified in Schedule 9 to the *New Substances Notification Regulations (Chemicals and Polymers)*;

(c) the information specified in item 5 of Schedule 10 to those Regulations;

(d) for a new activity described in paragraph 1(a), in addition to the information prescribed in paragraphs (a) to (c) and (f), the following information must be provided:

(i) the test data and a test report from a study on the migration of the substance out of the product, conducted according to methodology described in the document from the Food and Drug Administration titled *Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations* that is current at the time the test data are developed, or any other similar study or information that will permit the assessment of the migration of the substance out of the product,

(ii) the hydrolysis rate of the substance as a function of pH and, if known, an identification of the products of the hydrolysis, and

(iii) any other information in the person's possession or to which they have access, that will permit the assessment of the exposure of the public to residual Bisphenol A and free Bisphenol A derived from the degradation of the substance;

(e) when the substance is manufactured in Canada as per the new activity described in paragraph 1(b), in addition to the information prescribed in paragraphs (a) to (c) and (f), the following information must be provided:

(i) a brief description of the manufacturing process that details precursors of the substance, reaction conditions (e.g. temperature, pressure, catalysts and reaction stoichiometry), and the nature (batch or continuous) and scale of the process,

(ii) a flow diagram of the manufacturing process that includes features such as process tanks, holding tanks and distillation towers, and

(iii) a brief description of the major steps in process operations, the chemical conversions, the points of entry of all feedstock and the points of release of the substance or Bisphenol A and the process to eliminate environmental releases; and

(f) any other information or data in respect of this substance in the person's possession or to which they have access, that is relevant in order to determine whether the substance is toxic or capable of becoming toxic.

3. The above information will be assessed within 90 days after the day on which it is received by the Minister of the Environment.

EXPLANATORY NOTE

(This explanatory note is not part of the Significant New Activity Notice.)

A Significant New Activity Notice is a legal instrument issued by the Minister of the Environment pursuant to section 85 of the *Canadian Environmental Protection Act, 1999*. The Significant New Activity Notice sets out the appropriate information that must be provided to the Minister for assessment prior to the commencement of a new activity as described in the Notice.

Substances that are not listed on the *Domestic Substances List* can be manufactured or imported only by the person who has met the requirements set

out in section 81 of the *Canadian Environmental Protection Act, 1999*. Under section 86 of the *Canadian Environmental Protection Act, 1999*, in circumstances where a Significant New Activity Notice is issued for a new substance, it is the responsibility of every person who transfers the physical possession or control of the substance to notify all persons to whom the possession or control is transferred of the obligation to comply with the Significant New Activity Notice and of the obligation to notify the Minister of the Environment of any new activity and all other information as described in the Notice. It is the responsibility of the users of the substance to be aware of and comply with the Significant New Activity Notice and to submit a Significant New Activity notification to the Minister prior to the commencement of a significant new activity associated with the substance. However, as mentioned in subsection 81(6) of the *Canadian Environmental Protection Act, 1999*, a Significant New Activity notification is not required when the proposed new activity is regulated under an act or regulations listed on Schedule 2 of the *Canadian Environmental Protection Act, 1999*.

A Significant New Activity Notice does not constitute an endorsement from Environment Canada or the Government of Canada of the substance to which it relates, or an exemption from any other laws or regulations that are in force in Canada and that may apply to this substance or activities involving the substance.