Polymer Assessment Methodology

Last Revision: November 2021

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REVISION HISTORY

REVISION DATE	SECTION(S)	TYPE OF CHANGE	AUTHORIZED BY
May 2017	All	The entire section 6 of the *Supplemental Guidance for the Cradle to Cradle Certified Product Standard Material Health Assessment Methodology, Version 3.0*, dated March 2015, entitled Guidance for Assessing Polymers, has been transferred into this document for clarity. Note that the section numbers between the v3.0 document and this document do not correspond. Section numbers listed to the left within the SECTIONS column of this table are for this document.	S. Klosterhaus
May 2017	2.2	This section has been clarified to indicate that, if available, toxicity data on the polymer itself should be used in completing the hazard profile for the polymer. The prior language made it sound as if data on monomers was to be used exclusively. The following clarification has also been added: Plausible exposure is assumed for any residual monomers subject to review, except via the route of inhalation (i.e. an exposure assessment may be completed for the inhalation route).	S. Klosterhaus
November 2021	All sections	Updated content to align with Version 4.0 of the Standard.	S. Klosterhaus
November 2021	Section 2.1	Updated subject to review threshold as outlined in Version 4.0 of the Standard to include residual monomers and oligomers at 100 ppm (or lower if the RSL limit is lower). Note: The subject to review limit for monomers under Version 3.1 remains at 1000 ppm.	S. Klosterhaus
November 2021	Section 2.2	Updated the exposure assessment section to indicate that an exposure assessment may be completed for monomers using the same method as for all other substances within the polymer under Version 4.0.	S. Klosterhaus
November 2021	Section 2.4	Added criteria for non-certifiable polymers per Version 4.0 of the Standard.	S. Klosterhaus

1 OVERVIEW

1.1 Purpose and Content

This document describes the methodology used to assign an A, B, C, X, or GREY material assessment rating to polymeric materials subject to review in a finished product that is applying for Cradle to Cradle certification. Due to their large molecular weight and limited solubility, toxicity data for polymers are generally not available. Polymeric materials in products being assessed for Cradle to Cradle certification are therefore assessed following this customized methodology, rather than the conventional Material Health Assessment Methodology.

1.2 Supporting Documents

The following documents are to be used in conjunction with this document:

- Cradle to Cradle Certified® Product Standard, Version 4.0
- Cradle to Cradle Certified® Product Standard, Version 3.1
- Cradle to Cradle Certified® Material Health Assessment Methodology
- Cradle to Cradle Certified® Product Standard User Guidance
- Any applicable Cradle to Cradle Certified® standard documents and methodology documents posted on the C2CPII website.

Visit the Cradle to Cradle Products Innovation Institute website to download the Standard documents and obtain the most current information regarding the product Standard (http://www.c2ccertified.org/product_certification/c2ccertified_product_standard).

2 ASSESSMENT OF POLYMERS

2.1 Chemicals subject to review

The chemicals subject to review in a polymeric material are:

- the base polymer (e.g., PET, polyethylene, polycarbonate)
- residual monomers, when present above the relevant threshold (see below)
- oligomers of known concern (e.g., styrene trimers and dimers)
- all additives, residual catalyst, etc., when present at a concentration ≥ 100 ppm (the subject to review threshold for nearly all other chemicals in a homogenous material).
- intentionally added lead, mercury, hexavalent chromium, cadmium, halogenated organic compounds, phthalates, blowing agents, or colorants, when present at any concentration

The subject to review thresholds for monomers are as specified by the Cradle to Cradle Certified Product Standard.

Under Version 4.0, monomers and oligomers[1] are subject to review if present at a concentration ≥ 100 ppm or above in a homogeneous material in the finished product. Exceptions exist in certain cases. In the case that a residual monomer is present on the Restricted Substances List, and the threshold indicated there is lower than 100 ppm, or a specific concentration limit (SCL) for any toxicity endpoint of a substance is below 100 ppm as indicated by the Table of Harmonized Entries in Annex VI to the Classification, Labelling, and Packaging of Substances and Mixtures regulation, the lower threshold applies[2].

Under Version 3.1, all residual monomers other than formaldehyde are subject to review if present at a concentration ≥ 1000 ppm in the polymeric material. Formaldehyde monomers are subject to review if present at a concentration ≥ 100 ppm in the polymeric material.

Residual monomer concentrations in the polymeric material can be determined from supplier statements or analytical measurements. The monomer concentration within a molded or extruded plastic part is assumed to be the same as the monomer concentration within the polymer pellet or resin as purchased from the polymer manufacturer unless testing shows otherwise.

2.2 Exposure Assessment Methodology

Under Version 4.0, an exposure assessment may be completed for monomers using the same method as for all other substances within the polymer. Per the Exposure Assessment Methodology, when the product has passed the Cradle to Cradle Certified VOC emissions testing requirement, inhalation exposure to volatiles may be assumed negligible. Note that under Version 4.0 of the Standard there are two categories of VOC emissions (low and very low). To assume negligible inhalation exposure to volatile substances under Version 4.0, the product or material must comply with one of the 'very low' emissions tests (see VOC Reference Document for a list of the applicable tests).

Under Version 3.1, plausible exposure is assumed for any residual monomers subject to review, except via the route of inhalation (i.e., an exposure assessment may be completed for the inhalation route).

A passed VOC emissions test at the product level may be used as indication that inhalation exposure is not relevant (following the Exposure Assessment Methodology as for other substances).

2.3 Material Assessment Methodology

The methodology used to assign A, B, C, X or GREY ratings to polymers is the same as the conventional Material Health Assessment Methodology with the following exceptions and special considerations:

[1] Oligomers are defined as material fraction with molecular weight < 500 Daltons (with reference to https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/polymer-exemption-guidance-manual).

[2] For example, vinyl chloride is on the Restricted Substances List with a threshold of 5 ppm or 1 ppm depending on application.

Base polymer – Hazard ratings for the base polymer are assigned to each endpoint based on toxicity data for the polymer itself when available, toxicity data for chemical analogs or the relevant polymer class, or toxicity data for the monomer(s) used in its production when data on the base polymer and/or analogs are not available. For copolymers (i.e., polymers composed of more than one type of monomer), when basing the assessment on the monomers, the hazard rating in each endpoint is based on the lowest hazard rating received by any of its constituent monomers for the endpoint (lowest in order of: 'red', 'grey', 'yellow', 'green').

When deriving risk flags for the base polymer, exposure is assumed to be not plausible and thus any red or grey hazard ratings translate to yellow risk flags, and yellow and green hazard ratings translate to green risk flags.

Residual monomers – If present above their relevant subject to review thresholds, residual monomers are assigned separate hazard ratings, risk flags, and single chemical risk ratings.

2.4 X Assessed Polymers and Non-Certifiable Polymers

Bisphenol-A (BPA)-based polymers or coatings (e.g., polycarbonate, etc.) used in toys, skin contact furniture applications, food contact applications, and baby applications are always assessed as X, regardless of residual monomer content.

All halogenated polymers will be either X assessed or not permitted for use (see Section 4.2 of Version 4.0 of the Standard or Section 3.3 of Version 3.1 of the Standard).

In addition, any non-biodegradable or non-compostable polymer (see the biodegradability definition for how biodegradability or compostability is determined/verified) that contains an additive that has been intentionally added for the purposes of enhancing degradation renders a product non-certifiable as per the product eligibility requirements stated in Section 2 of the Cradle to Cradle Certified Product Standard, Version 4.0.