



ASSESSOR
GUIDANCE
AMENDMENT:
BASE POLYMER
ASSESSMENT v1.1

REV 2022_06

1.0 Introduction

This guidance supplements ChemFORWARD Assessor Guidance v 1.1.

It provides guidance to Assessors in support of generating chemical hazard assessments (CHAs) of **base polymers** for inclusion in the ChemFORWARD application.

Polymeric materials will be evaluated by trade name in ChemFORWARD using the **ChemFORWARD SAFER Program** guidance.

2.0 Definitions

Base Polymer: a substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant and consists of less than a simple weight majority of molecules of the same molecular weight (1).

Substances with molecular weights below 1000 Daltons will be assessed as discreet chemical substances and not as base polymers (2).

Intentionally added constituents: chemical substances that are added to the base polymer or polymeric material because they are necessary for the intended performance of the base polymer or polymeric material. Examples of intentionally added constituents include the base polymer plus performance additives such as UV stabilizers, colorants, plasticizers, etc.

Polymer of low concern: A 'polymer of low concern' (PLC) is a polymer that is considered to be of low concern to human health and the environment because it meets all the criteria set by an authoritative regulatory agency, (3, 4, 5, 1). EPA and Safer Choice also have guidance on the assessment of polymers that can aid in a PLC assessment (2, 6).

Polymeric material: a base polymer and its constituents including additives and residual monomers and other impurities. Polymeric materials are evaluated via the ChemFORWARD SAFER program.

Residual: "Trace amounts of chemicals that are incidental to manufacturing. Residuals are not part of the intended chemical product, but are present because of factors such as the nature of the synthesis and engineering pathways used to produce the chemical. Residuals include: unintended by-products of chemical reactions that occur in product formulation and chemical synthesis, impurities in an ingredient that may arise from starting materials, incompletely reacted components, and degradation products". (1)

Residual of high concern: A residual that is assigned a ChemFORWARD "F" hazard band

regardless of its concentration. Residuals of high concern should be disclosed in the executive summary for the base polymer by the Assessors. Residuals of high concern may be subject to specified limits on restricted substances lists compiled by corporations, NGOs, or ecolabel/certification bodies such as Cradle to Cradle Certified.

3.0 Scope

Polymers may be assessed for the ChemFORWARD platform either as base polymers or as components of polymeric materials assessed via the ChemFORWARD SAFER program.

When a polymer is identified generically, i.e., without the benefit of knowing the trade name the manufacturer and detailed information on its constituents and residuals, it should be assessed as a **base polymer** and not as a polymeric material.

To assess a **polymeric material**, it is necessary to know the trade name and the manufacturer in order to obtain detailed information on the polymeric material's chemical attributes (i.e., MW ranges), the identity and concentrations of performance additives, as well as the identity and concentrations of residuals (e.g. monomers, catalysts, and other impurities).

4.0 Create the Base Polymer Chemical Hazard Assessment Entry

See Figure 1.

1. Create the CHA entry as you would for a non polymeric chemical
2. Click Chemical Attributes in the left margin of the ChemFORWARD application and fill in the chemical attributes fields
3. Fill out the relevant fields under the "Common" tab
4. Select the "Base Polymer" tab
5. Select "yes" in response to the question "is this substance a polymer"
6. Fill out the relevant fields illustrated in Figure 1 including the polymer attributes summarized in Table 1.

Common
Base Polymer
Inorganic
Botanical
Scores

Chemical Assessment

Chemical Attributes

- Chemical Attributes

Human Health (0/9)

- Carcinogenicity
- Mutagenicity
- Reproductive & Developmental Toxicity
- Endocrine Activity & Disruption
- Mammalian Toxicity
- Neurotoxicity
- Sensitization
- Corrosion / Irritation
- Aspiration

Environmental (0/5)

- Aquatic Toxicity
- Persistence
- Bioaccumulation
- Climatic Relevance
- Terrestrial Toxicity

Other (0/3)

- Other (Human Health & Physical Properties)
- Chemical Class
- Other (Environmental Health)

Appendices

- Appendices

Is this substance a polymer?
 Yes No

Polymer Attributes

<p>Polymer class</p> <input type="text" value="Enter polymer class"/>	<p>Polymer molecular formula</p> <input type="text" value="Enter polymer molecular formula"/>
<p>Polymer representative structure</p> <input type="text" value="Enter polymer representative structure"/>	<p>Polymer form</p> <input type="text" value="Enter polymer form"/>
<p>Polymer size (if a powder)</p> <input type="text" value="Enter polymer size"/>	<p>Overall polymer charge</p> <input type="text" value="Enter overall polymer charge"/>
<p>Molecular weight (MW) of polymer</p> <input type="text" value="Enter molecular weight of polymer"/>	<p>Number average (Mn)</p> <input type="text" value="Enter number average"/>
<p>Weighted average (Mw)</p> <input type="text" value="Enter weighted average"/>	
<p>Are the monomers blocked? <input type="radio"/> Yes <input type="radio"/> No</p>	
<p>Wt% of RFGs</p> <input type="text" value="Enter Wt% of RFGs"/> %	<p>Identify any Reactive Functional Groups (RFG)</p> <input type="text" value="Enter reactive functional groups (if any)"/>
<p>% of amine nitrogen (A-N)</p> <input type="text" value="Enter % of amine nitrogen (A-N)"/> %	<p>Cation generating group (if any)</p> <input type="text" value="Enter cation generating group (if any)"/>

Concern For Lung Effects

<p>Solubility</p> <input type="text" value="Enter solubility"/>	<p>Dispersability</p> <input type="text" value="Enter dispersability"/>
<p>Swellability</p> <input type="text" value="Enter swellability"/>	<p>Particle size</p> <input type="text" value="Enter particle size"/>
<p>Fibrous Properties</p> <input type="text" value="Enter fibrous properties"/>	

Figure 1. ChemFORWARD application interface for Assessor input

Table 1. Polymer attribute fields for the base polymer

- | | |
|---|--|
| <ul style="list-style-type: none"> • Polymer class • Polymer molecular formula • Polymer representative structure • Polymer form • Polymer size (if a powder) • Overall polymer charge • Molecular weight of polymer • Number average (Mn) • Weighted average (Mw) • Are the monomers blocked | <ul style="list-style-type: none"> • Identify any reactive functional groups (RFGs) - Examples include, but are not limited to: acrylates/methacrylates, epoxides, phenols, sulphonates, Isocyanates, etc (see Appendices) • Cation generating group (if any) • Concern for lung effects: <ul style="list-style-type: none"> • Solubility • Swellability • <u>Dispersability</u> • Particle size • Fibrous properties |
|---|--|

5.0 Provide Information on Likely Residuals and Impurities

Identify **likely residuals/impurities** (i.e. monomer, catalysts if known) in the Common Impurities field under the Common tab in Chemical Attributes.

Screen the likely residuals using the ChemFORWARD application (or via Pharos) to determine if they are residuals of high concern based on their rating as LT-1 in Pharos or otherwise assigned a ChemFORWARD “F” hazard band.

Report **likely** monomers and residuals (just identity, not concentrations) in the executive summary for the polymer. Identify the monomer(s) and residuals by chemical name and CAS number. Indicate if they are residuals of high concern.

6.0 Prepare the Base Polymer Hazard Assessment

Enter the data summary, rationale, confidence selection, classifications, etc. for each endpoint for the base polymer into the ChemFORWARD platform as described in the ChemFORWARD Assessor Guidance which is based on criteria from the Globally Harmonized System for the Classification and Labeling of Chemicals (GHS) (7) and the Cradle to Cradle Certified (C2CC) Material Health Assessment Methodology (MHAM) (8).

- 1) Check the base polymer against C2CC Restricted Substances List (9)
- 2) Review C2CC requirements for polymers containing halogens or Bisphenol A.
- 3) Assess all available hazard information for the base polymer assuming that no additives, residual monomers, or other residuals are present at or above 100 ppm.
 - a) Can you use empirical toxicity data to assess base polymer? If no,
 - b) Can you identify data for an appropriate analog with similar size and/or charge, or data on a polymer group with similar structural base components? If not,

- indicate data gaps.
- c) Monomers may be used as analogs as appropriate based on expert judgment.
- 4) Determine if the polymer has been classified as a Polymer of Low Concern Criteria (PLC) as defined by an authoritative regulatory agency (see Section 2.0 Definitions). Document PLC Status in the Regulatory Summary section under Chemical Attributes. PLC status may be used as part of the weight of evidence assessment and overall base polymer scoring.
 - a) PLC status may NOT be used to classify individual hazard endpoints but can be listed as additional information in the rationale.
 - 5) High molecular weight (generally >1000 g/mol) may be used, in part, to
 - a) Exempt data gaps for oral and dermal toxicity as per the ChemFORWARD Chemical Rating Scoring Guidance.
 - b) Inform weight of evidence. However, molecular weight may NOT be used to classify individual hazard endpoints.

7.0 Base Polymer Scoring

A single hazard rating for the base polymer will be generated by applying the C2CC MHAM chemical rating system (10) and ChemFORWARD hazard bands to the hazard summary table.

It is anticipated that many base polymers will be rated as grey/c due to data gaps.

If the polymer is evaluated and scored as a grey/c AND it would otherwise result in a ChemFORWARD hazard band of “U”, then PLC evaluation may be applied. The polymer with PLC status will retain the grey/c rating but the ChemFORWARD hazard band will be upgraded from “U” to “C”. If the ChemFORWARD assigned hazard band would otherwise be “F”, then PLC status does not apply.

For base polymer CHAs used towards C2CC certification, the base polymers are first assigned a hazard rating in ChemFORWARD and subsequently assigned a RISK rating by a C2CC Assessor using C2CC MHAM guidance based on the chemical rating of the base polymer and assuming minimal exposure with the following exceptions:

- Halogenated polymers receive an X Risk rating regardless of CHA results
- BPA based polymers used for children’s products receive an X Risk rating regardless of CHA results (11)

8.0 Reporting Results for Base Polymer CHA

Assessors should indicate in the executive summary that the assessment applies to the **base polymer** only and that the additives and residuals (including monomers and catalysts), are NOT part of the assessment.

Assessors should also note in the executive summary when it is likely that a residual of high concern (i.e., monomer or catalyst that is assigned an F hazard band) was used, that if present

at or above 100 ppm, would affect the rating of the polymeric/trade name material.

9.0 Conclusion and Overview

Figure 2 provides an overview of the process for preparing chemical hazard assessments for base polymers using the ChemFORWARD application. Guidance for preparing chemical hazard assessments for polymeric materials will be provided separately.

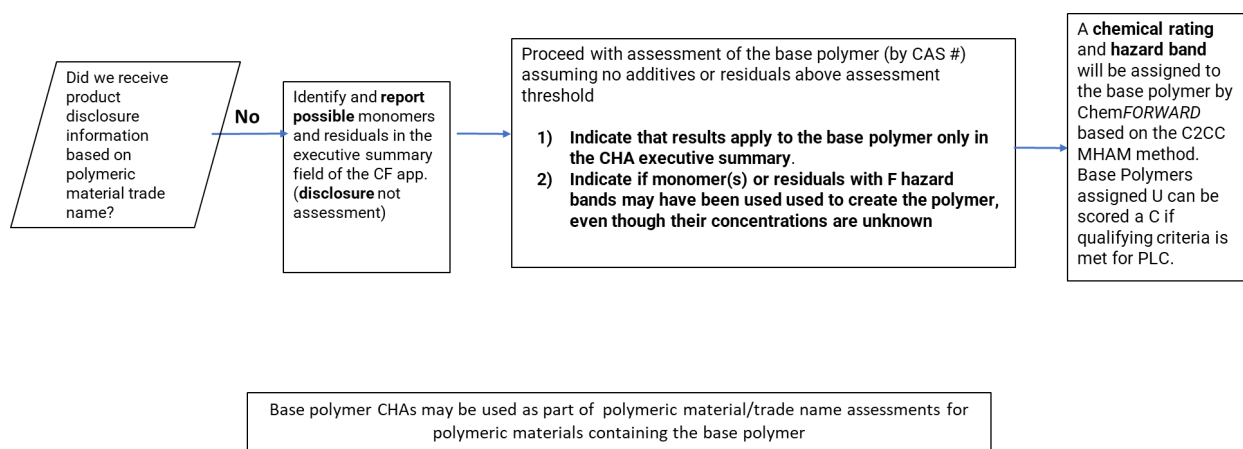


Figure 2. Overview of process for preparing a base polymer CHA

10.0 References

1. [The ECETOC Conceptual Framework for Polymer Risk Assessment \(CF4 Polymers\), Technical Report 133-1. May 2019.](#)
2. [Interpretive Assistance Document for Assessment of Polymers, Sustainable Futures Summary Assessment, EPA. June 2013.](#)
3. [Polymer of low concern \(PLC\) criteria | Australian Industrial Chemicals Introduction Scheme \(AICIS\)](#)
4. [Polymer Exemption for New Chemicals under the Toxic Substances Control Act, Exemption Guidance Manual. July 2021.](#)
5. [Technical assistance related to the review of REACH with regard to the registration requirements on polymer. Feb 2015.](#)
6. [EPA Safer Choice Criteria for Polymers. Nov 2021.](#)
7. [Globally Harmonized System of Classification and Labeling of Chemicals. Ninth revised edition.](#)
8. [C2CC Material Health Assessment Methodology. February 2022.](#)
9. [C2CC Restricted Substances List. March 2021.](#)
10. [C2CC Chemical Ratings.](#)
11. [C2CC Polymer Assessment Methodology. November 2021.](#)