Nota de aplicación

Empower™ Polymer GPC Submission Template for Streamlined Regulatory Compliance

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This is an Application Brief and does not contain a detailed Experimental section.

Abstract

Regulation surrounding the manufacturing and/or importation of polymers world-wide is becoming more complex and tightly controlled by formal organizations in specific geographies, such as the Korean (K) Registration, Evaluation, Authorization, and restriction of Chemicals (REACh) and the European (EU) REACh. The molecular weight analysis of polymers using gel permeation chromatography (GPC) is a common characterization tool for submitting polymers to regulatory bureaus. Software used in the interpretation of GPC data for regulatory reports can be helpful in creating a workflow which enables the submission process to be less cumbersome. The Waters Empower CDS has templates for reporting GPC data which can be modified for individual regulatory needs, and there are templates available that address the new submission requirements.

Benefits

- Streamlined analytical workflow for polymer regulatory submission process
- Instrument analysis, data acquisition-processing, and polymer regulatory reporting template in one system
- Easily customizable template for unique regulatory needs

Introduction

The manufacturing of polymers and plastic-containing products is part of a world-wide economy, and each region of the world has a regulatory organization requiring a chemical compliance to protect human health and the environment from potential hazards of such chemical substances.[1] Polymers are near the beginning of the plastic product manufacturing chain (Figure 1), and the regulatory compliance of the polymer is needed throughout the processing stream in the formation of the final product. One such regulatory requirement is within the EU-REACh use of ISO 13885-1:2021 compliance for GPC analysis.[2]

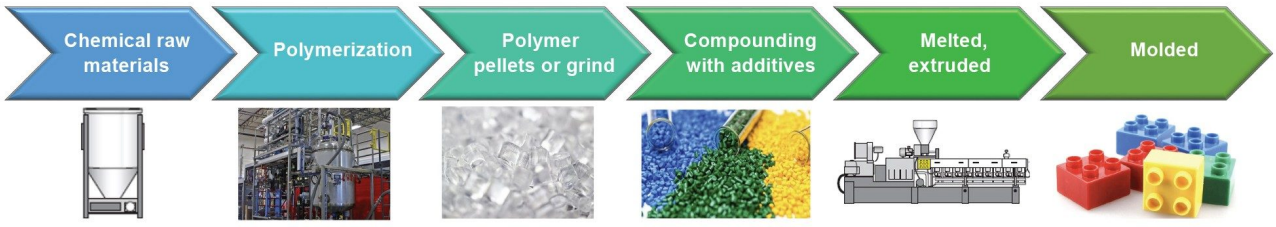


Figure 1. Example of polymer product manufacturing process steps.

Many pages of requirements are listed within the GPC analysis for REACh submission. Most polymer manufacturers have a template from which they start a submission process for their GPC data. Using an analytical instrument, data processing and reporting software combination that enables an automatic report generated after completing a GPC analysis would help streamline the entire workflow for regulatory submissions.

Experimental

Once the GPC analysis is completed, using Empower software, download the Empower project named "polymer regulatory submission template" to your desktop, and restore the project from the computer desktop to the Empower "Configure" table (Figure 2).[3]

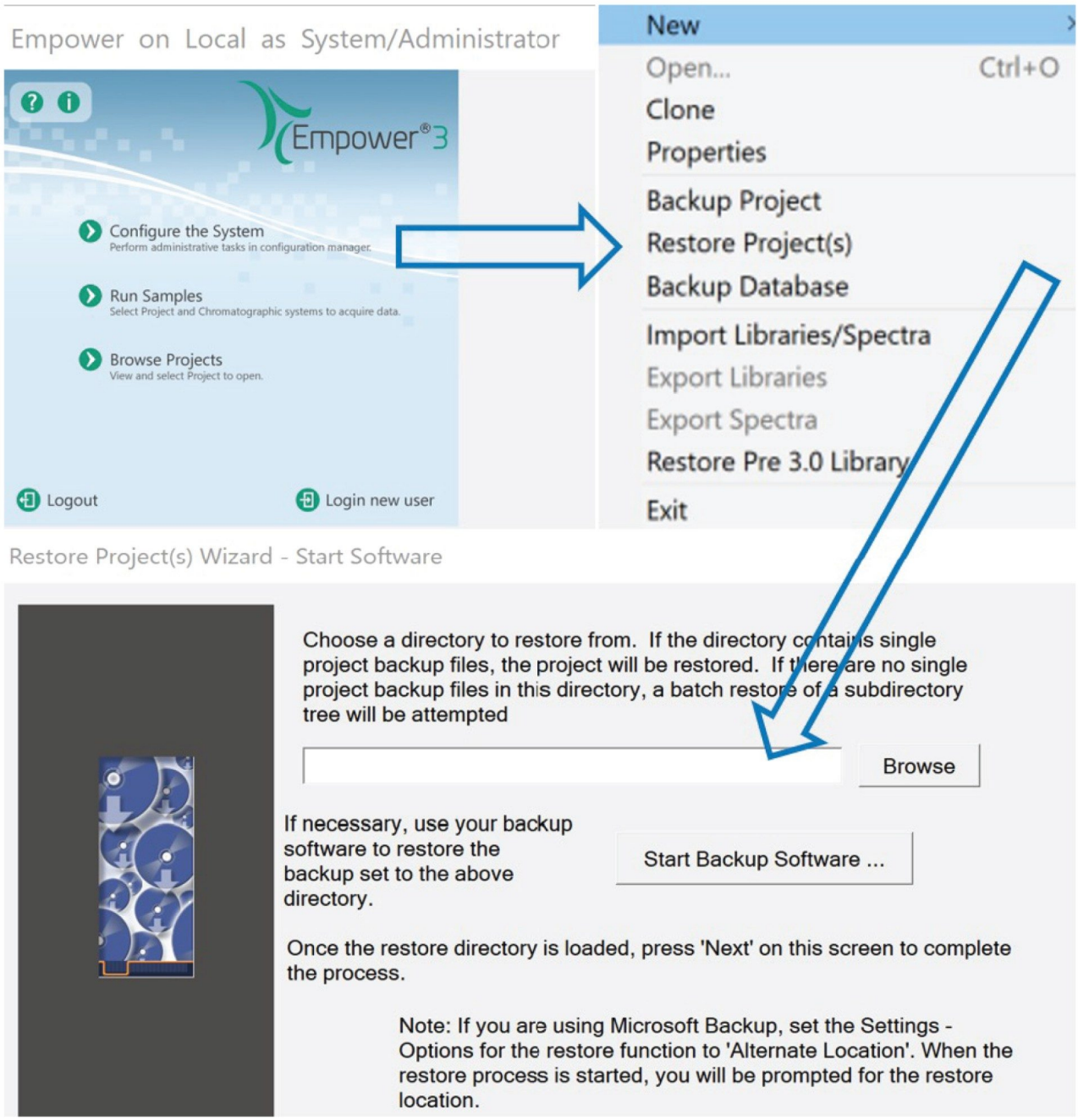


Figure 2. Diagram for restoring downloaded template to your system.

Results and Discussion

The template is customizable to accommodate unique commercial or regulatory requirements. The example information document header in figure 3 portrays common terms needing to be defined in the GPC report for polymer submission.

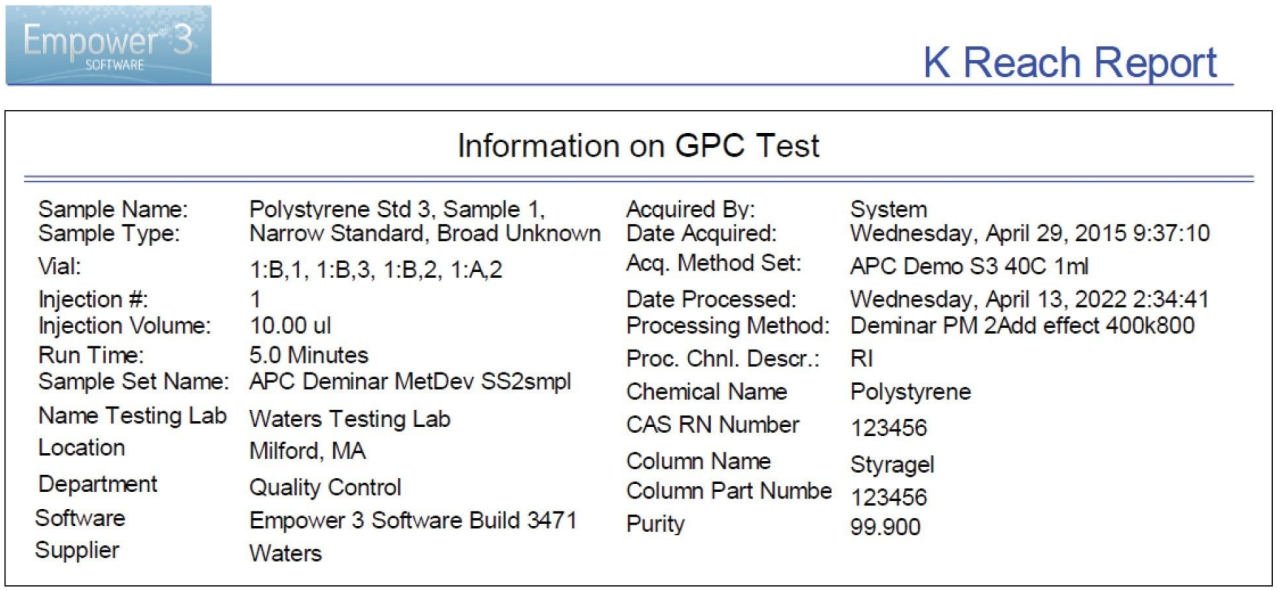
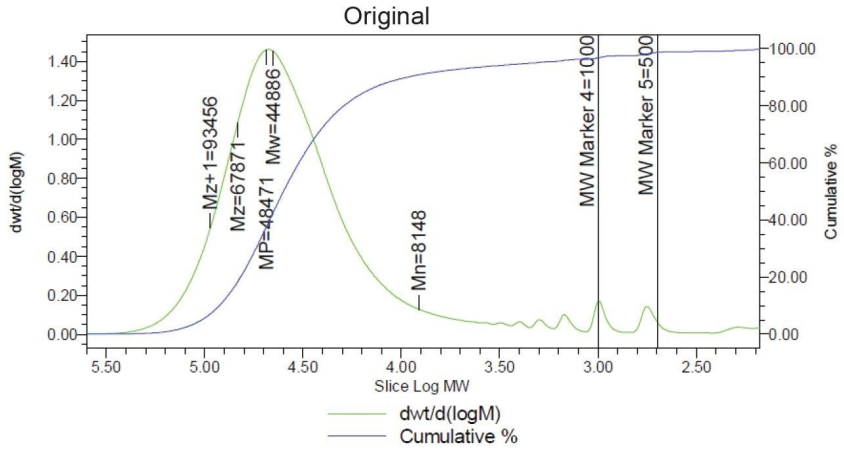


Figure 3. Empower K-REACh reporting template information header.

There are many other categories within the report that can be changed to reflect each sample analysis such as sample preparation, molecular weight markers (Figure 4), and signature authority.



Test result

	SampleName	Mn	Mw	MP	Mz	Mz+1	Polydispersity	%Poly < MWM4	%Poly < MWM5
1	Sample 1	8148	44886	48471	67871	93456	5.508541	2.990	1.051

Figure 4. Empower GPC molecular weight distribution and table from a polymer analysis using an advanced polymer chromatography (APC™) system.[5]

Conclusion

Empower 3 CDS software demonstrates the ability to produce customizable reporting templates that streamline the polymer GPC regulatory reporting submission process. The reporting template is easily changed using the custom fields for individual needs, and Empower compatibility encompasses many analytical instruments from various manufacturers listed on the Waters website.[6]

References

1. Berber, T., Article Suppliers and REACH, Chemical Watch, February 2018,

https://www.knoell.com/en/news/article-suppliers-and-reach <https://www.knoell.com/en/news/article-suppliers-and-reach> .

2. International Standard, SIST EN ISO 13885-1: 2021.
3. Empower Polymer Regulatory Submission Template, contact for template: Waters field service engineer,Neil_J_Lander@waters.com, or Jennifer_Gough@waters.com.
4. Empower GPC Getting Started Guide, https://www.waters.com/webassets/cms/support/docs/71500031303ra.pdf < https://www.waters.com/webassets/cms/support/docs/71500031303ra.pdf> .
5. ACQUITY Advanced Polymer Chromatography (APC) System < https://www.waters.com/nextgen/global/products/chromatography-systems/acquity-advanced-polymer-chromatography-apc-system.html> .
6. Empower Instrument Control & Drivers <https://www.waters.com/waters/en_US/Waters-CDS-instruments-drivers/nav.htm?cid=135042160> .

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ACQUITY Advanced Polymer Chromatography (APC) System < https://www.waters.com/nextgen/global/products/chromatography-systems/acquity-advanced-polymer-chromatography-apc-system.html>

Empower Chromatography Data System <https://www.waters.com/10190669>

720007818, December 2022