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

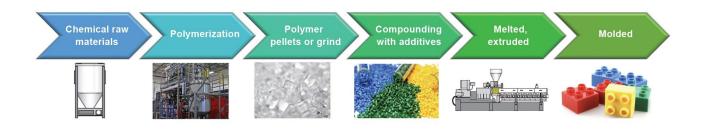


Figure 1. Example of polymer product manufacturing process steps.

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

Empower on Local a	s System/Admin	istrator	New	>		
	Empower [®] 3		Open Clone Properties	Ctrl+O		
 Configure the System Perform administrative tasks in co Run Samples 		\Rightarrow	Backup Project Restore Project(s) Backup Database	Π		
Select Project and Chromatograp Browse Projects View and select Project to open.	hic systems to acquire data.		Import Libraries/S Export Libraries Export Spectra Restore Pre 3.0 Lib			
Logout	🔁 Login new user		Exit	11		
Restore Project(s) Wizard	- Start Software					
	project backup file	es, the project ves in this directo	m. If the directory contain vill be restored. If there a bry, a batch restore of a s	are no single		
	If necessary, use yo software to restore t backup set to the ab directory.	he	Start Backup Software	ə		
	Once the restore directory is loaded, press 'Next' on this screen to complete the process.					
	Options	for the restore process is star	Microsoft Backup, set the function to 'Alternate Loc ted, you will be prompted	cation'. When the		

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.

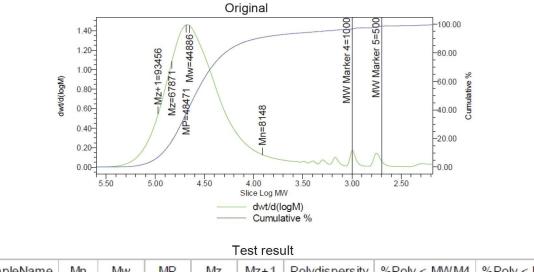


K Reach Report

Information on GPC Test							
Sample Name: Sample Type: Vial:	Polystyrene Std 3, Sample 1, Narrow Standard, Broad Unknown 1:B,1, 1:B,3, 1:B,2, 1:A,2	Acquired By: Date Acquired: Acq. Method Set:	System Wednesday, April 29, 2015 9:37:10 APC Demo S3 40C 1ml				
Injection #: Injection Volume: Run Time: Sample Set Name:	1 10.00 ul 5.0 Minutes	Date Processed: Processing Method: Proc. Chnl. Descr.: Chemical Name	Wednesday, April 13, 2022 2:34:41 Deminar PM 2Add effect 400k800 RI Polystyrene				
Name Testing Lab Location	Waters Testing Lab	CAS RN Number	123456				
Department Software Supplier	Milford, MA Quality Control Empower 3 Software Build 3471 Waters	Column Name Column Part Numbe Purity	Styragel 123456 99.900				

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.



	SampleName	Mn	Mw	MP	Mz	Mz+1	Polydispersity	%Poly < MWM4	%Poly < MW M5
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-polymerchromatography-apc-system.html> .
- 6. Empower Instrument Control & Drivers <https://www.waters.com/waters/en_US/Waters-CDS-instrumentsdrivers/nav.htm?cid=135042160> .

Featured Products

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

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

720007818, December 2022

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