IPEC FEDERATION

The International Pharmaceutical Excipients Council

Best Practices for European REACH Restriction on Synthetic Polymer Microparticles

for Pharmaceutical Excipients

Version 1
2025

This document represents voluntary guidance for the excipient industry and the contents should not be interpreted as regulatory requirements. Alternatives to the approaches in this guide may be used to achieve an equivalent level of assurance for excipient quality.

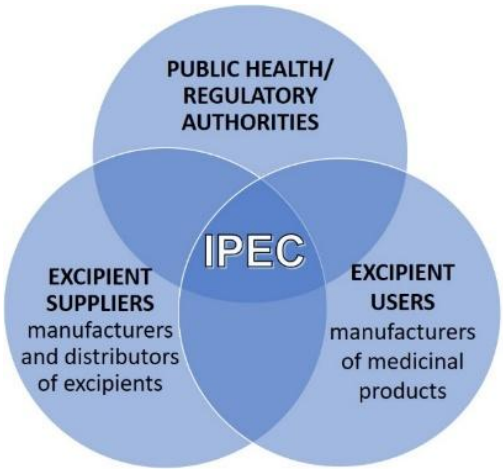
This guide was created to help companies understand current expectations on this topic and is not intended for use by third party certification bodies to conduct audits or to certify compliance with the guide.

FOREWORD

The International Pharmaceutical Excipients Council (IPEC) is an international industry association formed by excipient **manufacturer**s, **distributor**s, and end-users. At the current writing there are regional pharmaceutical excipient industry associations located in the Americas, Europe, Japan, China, and India. IPEC's objective is to contribute to the international excipient standards development and harmonization, provide information useful for new excipient development and introduction, and offer best practice and guidance concerning excipient development.

IPEC has three major **stakeholder** groups:

1. Excipient manufacturers and distributors, defined as **supplier**s in this document,
2. Medicinal (drug) product manufacturers, defined as *excipient users* in this document, and
3. Public health and regulatory authorities.



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This guide is intended to be voluntary, to indicate best practice, and to be globally applicable. However, it should be recognized that the laws and regulations applying to excipients will vary from region to region and country. In addition, the rules and regulations are continually evolving. It is the responsibility of the reader to review the most current version of any applicable regulatory requirement. Versions referenced in the guide were based on versions available at the time the guide was published.

In this guide, pharmaceutical excipient(s) will be referred as excipient(s). This guide may be applied to veterinary medicines, as appropriate and include reference to specific veterinary guidance and regulations.

Throughout the guide, **justification** implies that a decision is made based on scientific, quality and/or regulatory considerations.

This guide offers best practice and guidance for preparing and sharing microparticle data needed to justify certain excipient derogations that could apply to **REACH** restriction of **synthetic** polymer microparticles [1] and offers a streamlined process for ensuring compliance with regulatory requirements for both polymer manufacturers, suppliers and downstream industrial users who are typically drug product manufacturers.

This document should be read in conjunction with:

- The Regulation - Annex XVII of EC 1907/2006 Entry 78 (EU 2023/2055)
- The Guidance - REACH restriction of synthetic polymer microparticles (Entry 78 of Annex XVII REACH, as introduced by Commission Regulation (EU) 2023/2055) –
    - Explanatory Guide Part I - Narrative
    - Explanatory Guide Part II – Q&A
    - Explanatory Guide Part III – Annexes
- The Reporting Requirements - Implementation of the reporting requirements of the REACH restriction on microplastics. Reporting Requirements Final ECHA Apr 2025 v1.1

NOTE: Refer to the "International Pharmaceutical Excipients Council Glossary: General Glossary of Terms and Acronyms" for definitions [2].

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