

# Product Dating Information

## Date of manufacture<sup>1</sup>

There are various regulations and industry standards defining the Date of manufacture for a batch. These definitions differ depending on the nature of the product, or the steps in the manufacturing process. Due to the extensive product portfolio supplied by our Life Science business, different definitions for the Date of manufacture may apply, including but not limited to the date of sterile filtration, milling, hydration, release of the bulk product, filling into primary packaging, or the end of the manufacturing run.

## Release Date<sup>2</sup>

During the release procedure of materials, analytical testing is performed according to our standard operating procedures. The Release Date is the point in time when all collected batch data (analytical results and, if applicable, manufacturing or vendor documentation) has been reviewed and confirmed to comply with product specifications and relevant quality requirements.

## Shelf Life<sup>3</sup>

Shelf Life refers to the period during which a product is expected to remain within established specifications, provided that it is stored under defined conditions<sup>4</sup>.

For materials where shelf life information is required, expiration or retest periods are available at batch level. When the date is indicated by month and year only, and no specific date is stated on the product label or elsewhere, the product is expected to meet the specifications until the last day of the month.

## Expiration Date (Expiry Date) or Use-By-Date<sup>5</sup>

The Expiration Date (or Use-By Date) is shown on the product label, certificate of analysis, or certificate of quality of a marketed batch. It designates the date prior to which the batch is expected to remain within specifications, provided that it is stored under defined conditions. After this date, the product must not be used.

## Retest Period/Retest Date<sup>6</sup>

The Retest Period is the duration during which the batch is expected to remain within specifications, provided that it is stored under defined conditions.

After the Retest Period/Retest Date, product samples should be examined to ensure compliance with the established specifications.

<sup>1</sup>. The Date of manufacture might also be expressed by the terms Manufacture Date, Manufactured Date Production Date, Mfg Date and Manufacturing Date

<sup>2</sup> The Release Date also might also be expressed by the terms Quality Release Date, Date of release, Date of QC Release, Date of examination, QA approval date and, if a lot has been re-released, as Retested Date.

<sup>3</sup>.The Shelf Life might also be expressed by the term Minimum Shelf Life.

<sup>4</sup> Storage conditions are indicated on the product label. In case a product can be stored without restrictions, no temperature range for storage will be displayed on the label.

<sup>5</sup>.The Expiration Date or Expiry Date might also be expressed by the term Exp Date.

<sup>6</sup>. The Retest Period/Retest Date might also be expressed by the term Recommended Retest Date.



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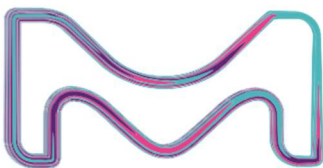
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### **Products with No Retest, Expiration or Use-by-Date**

The requirement to establish a shelf life depends on various factors such as product characteristics, intended application, and applicable regulations. This is also reflected in the Discriminating Quality Attributes of our M-Clarity™ Program.

For products with no Retest, Expiration, or Use-by date assigned, the only dates included on the certificate of analysis or certificate of quality may be the Release Date and/or Date of manufacture. We recommend handling these products according to the defined conditions as printed in our product literature, on our website product information pages, or on the product label. Customers should routinely inspect products to ensure integrity and performance. If needed, product use dates should be established by the customer based on their intended use.

For these products, our standard warranty of one year from the date of shipment applies. For further information on our warranty, please refer to the terms and conditions of sale.



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