

TL01 - Meclofenoxate version 4.0

Summary of Major Modifications

The Technical Letter on the reporting of analytical results for Meclofenoxate, TL01 – Meclofenoxate version 4.0, has been updated to include new guidance on the evaluation and reporting of analytical results for the *Marker of Use* of meclofenoxate: 4-Chlorophenoxyacetic acid (4-CPA).

According to recent research, the presence of 4-CPA in urine may originate not only from meclofenoxate *Use* or from food containing residues of 4-CPA, but also from Chlorphenesin, a non-prohibited substance that is used as a preserving agent in cosmetics and lotions or present, as Chlorphenesin carbamate, in an approved drug for the relief of muscle pain.

The Analysis and Reporting Requirements section has been updated to specify that an analytical result shall be reported as an *Adverse Analytical Finding (AAF)* for meclofenoxate only when meclofenoxate is identified in a *Sample* at an estimated concentration higher than (>) 50 ng/mL, or when 4-CPA is present at an estimated concentration higher than (>) 5 µg/mL in the absence of chlorphenesin or chlorphenesin carbamate *Metabolites*.

In order to summarize the conditions mentioned above, a Table 1 was also included in the Analysis and Reporting Requirements section.

This Technical Letter becomes effective immediately.