**Record of Technical Anomaly**

**Technical Anomaly No: TA439**

**PART 1: Issue, impact assessment and signing open**

**Raised by:** Hannah Ford **Date: 21/03/22**

**OP / Method: OP224 Ethyl Carbamate**

**Analytical sequence initiated** *(where appropriate)***: EC0795**

**Details** *(please tick relevant box(es) and provide supplementary information where required)***:**

□ QC point(s) above/below ±2SD □ Bracketing standard(s) outside limits

□ QC point(s) above/below ±3SD □ QC Recovery outside limits

□ QC point(s) outside expanded uncertainty R Other *(add details below)*

The current internal standard for OP224 is made from parent chemical C-7155 Ethyl-D2 carbamate which lists on the label an expiry date of 21/03/2022. The certificate of analysis states that the chemical is “stable if stored under recommended conditions” but “after three years, the compound should be re-analysed for chemical purity before use.” The expiry date on the label is presumed therefore to be three years since manufacture. The chemical has only been in possession of SWRI since 16/09/2019 so cannot have been open for three years yet.

The “recommended conditions” according to the chemical MSDS are room temperature, with adequate ventilation – these conditions have been met. As the chemical is used as an internal standard, results are not being directly quantified against it and its purity only needs to remain consistent for the duration of each individual analytical run. Taking these factors into account, as well as the expense of deuterated standards, it is therefore appropriate to treat the date on the chemical label as a review date, not an expiry date.

The internal standard has been performing well with good peak shapes and peak areas that are consistent for the duration of each individual analytical run. Peak shapes and areas will continue to be monitored but the validity of the current internal standard solution will be extended until a year from its preparation date, 26/10/2022, at which point it will be reviewed again.

□ No apparent reason for this anomaly

**Recommended Action:**

R No action required out with the usual close monitoring of the Quality Control data in subsequent runs.

**Explanation why the issue does not impact data quality & why it isn’t a departure:**

As the chemical is used as an internal standard, results are not being directly quantified against it and its purity only needs to remain consistent for the duration of each individual analytical run.

**Management Review:**

***I agree to open this Technical Anomaly and confirm that this would not prevent results from being reported.***

**Authorised by:**

**(Technical/Services/Quality Manager)**

**Date:**

**PART 2: Follow-up actions and close-out**

**Follow-up actions conducted:**

□ No follow up required

**All analytical sequence(s) affected** *(where appropriate)***:**

**Signed off & closed by Quality Manager:**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_**

