AfA Baxter AG

Submission number: KA600552-65

Communication number: AFA-C-2114511618-50-01/F

Substance: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated

Use name: *Use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (as a detergent) for virus inactivation via S/D (Solvent/Detergent) treatment in recombinant and plasma-derived medicinal products*

Answers to RAC questions

For the Vienna Pilot plant, please provide a non-confidential range for the following figure, to allow reference to be made to them in the RAC opinion:

- **number of days of use / releases of 4-tert-OPnEO per year (cf. response to RAC question 12 / 05 / 2020 – page 3)**

Daily use at the site on (80-120) days per year

From the description you have provided in your previous responses, we understand that the manufacturing equipment in the Vienna pilot plant is completely separated from the regular wastewater stream (as in Orth), ensuring that any liquid waste containing OPnEO is directed to hazardous waste (incineration)? Please confirm that our understanding is correct? If not, what are the monitoring plans foreseen in the waste water to verify that there is zero releases in the waste water?

We confirm the committee's understanding of the Vienna pilot plant commercial production line being completely separated from the regular wastewater stream, ensuring any liquid waste containing OPnEO is directed to hazardous waste (incineration), is correct.