

**Succinct summary of representative risk management measures  
(RMMs) and operational conditions (OCs)**

**Legal name of applicant(s):** *Abbott Laboratories Limited*

**Submitted by:** *Abbott Laboratories Limited*

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

**Use Numbers and titles:** *1. Professional use as a surfactant, in Wash Buffer components used in conjunction with FISH test kits and/or their Laboratory Developed Test (LDT) equivalents, in clinical diagnostic use for medical analysis of human tissue and blood samples to identify characteristic genetic abnormalities related to specific disease conditions.*

**DECLARATION**

The Applicant is aware of the fact that evidence might be requested to support information provided in this document.

We, Abbott Laboratories Limited, request that the information blanked out in the “public version” of the Succinct Summary of Risk Management Measures and Operating Conditions is not disclosed. We hereby declare that, to the best of our knowledge as of today **16<sup>th</sup> June 2022** the information is not publicly available, and in accordance with the due measures of protection that we have implemented, a member of the public should not be able to obtain access to this information without our consent or that of the third party whose commercial interests are at stake.

Signature:



Tim Zurow  
Director, Global Technical Operations  
Abbott Laboratories Limited

Date, Place:



Succinct Summary of Risk Management Measures and Operating Conditions  
Public Version  
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated

**ES1 Professional use as a surfactant, in Wash Buffer components used in conjunction with FISH test kits and/or their Laboratory Developed Test (LDT) equivalents, in clinical diagnostic use for medical analysis of human tissue and blood samples to identify characteristic genetic abnormalities related to specific disease conditions.**

ECS and WCS	Task (ERC/spERC or PROC)	Annual amount per site (tonnes/year)	Technical RMMs, including: *Containment, *Ventilation (general, LEV...) *customized technical installation, etc	Organisational RMMs, including: *Duration and Frequency of exposure *OSH management system *Supervision *Monitoring arrangements *Training, etc	PPE (characteristics)	Other conditions	Effectiveness of waste water and waste air treatment (for ERC)	Release factors: water, air and soil (for ERC)	Detailed info. in CSR (section)
<b>ECS 1</b>	Professional use of wash buffer  ERC 8a	0 – 0.1 (a)	Wash Buffers are loaded onto the instrument in designed wash basins.  Used in laboratory setting.	Onboard solutions and instruments are handled only by trained professional clinical technicians.  Technical training and guidance material; product manuals, safety data sheets (SDS) and instructions for use.  Advise Downstream users on benefits of optimized test batching to reduce liquid waste generation.	N/A	N/A	Biological STP: Standard [Effectiveness Water: 56.99%]  Air: N/A	<b>Initial release factor:</b> Water: 10-100 D % Air: 0% Soil: 0% <b>Final release factor</b> Water: 10-100 D % Air 0% Soil 0%  <b>Local release rate:</b> 0.138g (1 set/day) for most users; up to (0.693)g (5 sets/day) for the largest-volume user of 4-tert- OP/day	9.1.1

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WCS	Activity includes the professional use of wash buffers, used with final test kits at laboratory – either manual test or partially automated assays. Task may include solution dilution or use of Ready to Use containers. PROC 15	N/A	<p>There is limited, controlled manual intervention for ready to use &amp; instrument usage.</p> <p>Used in laboratory setting.</p> <p>Wash buffers loaded onto the instrument in designed wash basins.</p>	<p>Wash buffers and instruments are handled only by trained professional clinical technicians.</p> <p>Technical training and guidance material; product manuals, safety data sheets (SDS) and instructions for use.</p> <p>Use of Ready to Use solution minimises need for dilution task.</p> <p>Advise Downstream users on benefits of optimized test batching to reduce usage of wash buffer and thereby reduce use and handling frequency.</p>	N/A	N/A		N/A	
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**Abbreviations:** WCS=Worker contributing scenario, ECS=Environmental Contributing Scenario, \* ERC=Environmental Release Category (or spERC if available) , PROC= Process category, LEV=Local Exhaust Ventilation, PPE=Personal Protective Equipment