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

Legal name of applicant:	*Abbott Laboratories Limited*
Submitted by:	*Abbott Laboratories Limited*
Substance:	4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated
Use Numbers and titles:	*Professional use as a surfactant in the final use of In-Vitro Diagnostic Devices (IVDs) for clinical testing using ARCHITECT Alinity and ABBOTT PRISM automated analyser systems*

DECLARATION

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

Also, we, Abbott Laboratories Limited, request that the information blanked out in the "public version" of the Succinct summary of representative risk management measures and operational conditions is not disclosed. We hereby declare that, to the best of our knowledge as of today, **30th September 2021**, 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: Date, Place:

Colleen O'Donnell 30 Sep 21, Sligo Ireland

Colleen O'Donnell
Program Director, Global Technical Operations
Abbott Ireland
Finisklin Business Park,
Sligo,
Ireland

ES1: Professional use as a surfactant in the final use of In-Vitro Diagnostic Devices (IVDs) for clinical testing using ARCHITECT Alinity and ABBOTT PRISM automated analyser systems

ECS and WCS	Task (ERC/spERC or PROC)	Annual amount per site (tonnes/year)	Technical RMMs	Organisational RMMs	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)
ECS1	Professional use of IVD reagents ERC 8a	0.1-1 ([a])	Analysers are completely closed systems. Reagent cartridges and bottles have spill proof caps.	Instruments and reagents are handled only by trained professional clinical technicians Technical training and guidance material; instrument operations manuals, safety data sheets (SDS)	N/A	N/A	Biological STP: Standard [Effectiveness Water: 56.99%] Air: N/A	**Initial release factor:** Water: 10-100 [b] % Air: 0% Soil: 0% **Final release factor** Water: 10-100 [b] % Air: 0% Soil: 0% **Local release rate:** Water: 2.2 x 10^{-5} OP kg/day 4-tert-OP (Wide dispersive use)	9.2
WCS	The activity includes the end use of the IVD reagents. The only manual step involves loading and unloading of containers of reagents onto the enclosed automated analyser systems PROC 0		Analysers are completely closed systems. Reagent cartridges and bottles have spill proof caps. There is limited, controlled manual intervention. Sample analysis takes place inside the closed instrument	Instruments and reagents are handled only by trained professional clinical technicians Technical training and guidance material; instrument operations manuals, safety data sheets (SDS).	N/A	N/A	N/A	N/A	9.2

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