

Summary table of RMM and OC

Legal name of Authorisation Holder(s):	Abbott Laboratories Limited
Submitted by:	Abbott Laboratories Limited
Date:	17 December 2024
Substance:	4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated
Use title:	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.
Use number:	1

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Public Version
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated

Part A

1. SUMMARY OF RISK MANAGEMENT MEASURES

Professional use as a surfactant in the final use of In-Vitro Diagnostic Devices (IVDs) for clinical testing using ARCHITECT and Alinity automated analyser systems (detailed info can be found in section 9.1 of the CSR)

ECS and WCS	Task (ERC/spERC or PROC)	Widespread use Annual amount (tonnes /year)	Technical RMMs	Organisational RMMs	PPE (characteristics)	Effectiveness of wastewater and waste air treatment (for ERC)	Release factors: water, air and soil (for ERC)	Transformation scenario	Local release rate	
ECS 1	Professional use of IVD reagents ERC 8a	0.01-0.1 (██████) From all customer sites combined <div style="border: 1px solid black; padding: 2px; display: inline-block;">CBI a</div>	Analysers are completely closed systems such as fume cupboard, to avoid air emissions. 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	Biological STP: Standard [Effectiveness Water: 57.08% for 4-tert-OP; 0.23 % for 4-tert-OPnEO] Air: N/A	Release factor before RMM: Water: 10-100 (██████) % Air: 10-100 (██████) % Soil: 0% Release factor after RMM Water: 10-100 (██████) % Air: 0% Soil: 0%	100% transformation 4-tert-OPnEO into 4-tert-OP	Water: ██████ kg/day 4-tert-OPnEO; ██████ kg/day 4-tert-OP Air: 0 kg/day 4-tert-OPnEO and 4-tert-OP Soil: 0 kg/day 4-tert-OPnEO and 4-tert-OP	<div style="border: 1px solid black; padding: 2px; display: inline-block;">CBI a c</div>
								0% transformation 4-tert-OPnEO into 4-tert-OP	Water: ██████ kg/day 4-tert-OPnEO; ██████ kg/day 4-tert-OP Air: 0 kg/day 4-tert-OPnEO and 4-tert-OP Soil: 0 kg/day 4-tert-OPnEO and 4-tert-OP	<div style="border: 1px solid black; padding: 2px; display: inline-block;">CBI c</div>

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								2.5% transformation 4-tert-OPnEO into 4-tert-OP	Water: █████ kg/day 4-tert-OPnEO; █████ kg/day 4-tert-OP Air: 0 kg/day 4-tert-OPnEO and 4-tert-OP Soil: 0 kg/day 4-tert-OPnEO and 4-tert-OP
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	N/A

CBI a c

Abbreviations: WCS=Worker contributing scenario, ECS=Environmental Contributing Scenario, * ERC=Environmental Release Category (or spERC if available), PROC= Process category, PPE=Personal Protective Equipment