

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

**Legal name of applicant(s):** *Abbott Diagnostics GmbH*

**Submitted by:** *Abbott Diagnostics GmbH*

**Substance:** *4-Nonylphenol, branched and linear, ethoxylated*

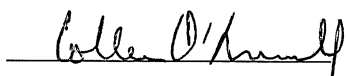
**Use Numbers and titles:** *1. Professional use as a surfactant in an onboard solution (Detergent B) as an accessory to In-Vitro Diagnostic Devices to wash the reagent probes, the mixers and the reaction cuvettes between tests to prevent interference with the test result on ARCHITECT and Alinity automated analyser systems.*

## DECLARATION

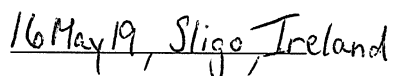
The Applicant is aware of the fact that evidence might be requested by ECHA to support information provided in this document.

Also, we, Abbott Diagnostics GmbH 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> May 2019** 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  
Program Director, Global Technical Operations  
Abbott Ireland  
Finisklin Business Park,  
Sligo,  
Ireland

**ES1: Professional use as a surfactant in an onboard solution (Detergent B) as an accessory to In-Vitro Diagnostic Test kits to wash the reagent probes, the mixers and the reaction cuvettes between tests to prevent interference with the test result on ARCHITECT and Alinity 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)
<b>ECS 1</b>	Professional use of onboard solution ERC 8a	0.03 to 0.3 <b>a</b>	Analysers are completely closed systems.  Solution cartridges and bottles have spill proof caps.	Onboard solutions and instruments 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: 58.97%]  Air: N/A	<b>Initial release factor:</b> Water: 10-100 ( <b>b</b> ) % Air: 0% Soil: 0% <b>Final release factor</b> Water: 10-100 ( <b>b</b> ) % Air: 0% Soil: 0%  <b>Local release rate:</b> ≤ 2.46g/day 4-NP	9.1.1
<b>WCS</b>	Activity includes the professional use of the onboard solutions which includes solution dilution, when required (PROC 5), and manually loading and unloading of containers onto the enclosed analysers systems (PROC 0).	N/A	Analysers are completely closed systems.  Solution cartridges and bottles have spill proof caps.  There is limited, controlled manual intervention.  Sample analysis takes place inside the closed instrument	Onboard solutions and instruments are handled only by trained professional clinical technicians.  Technical training and guidance material; instrument operations manuals, safety data sheets (SDS).  Use of Ready to Use solution minimises need for dilution task.	N/A	N/A		N/A	

**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