<u>Succinct summary of representative risk management</u> <u>measures (RMMs) and operational conditions (OCs)</u>

Public version

Substance: Annex XIV entry #42: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylate,

covering well-defined substances and UVCB substances, polymers and

homologues

(Triton[™] X-100, Triton[™] X-405, Triton[™] X-705)

Applicant: Siemens Healthcare Diagnostics Products GmbH

Site: Marburg, Germany

Use #4: Widespread use by professional workers - Use of IVD-kit reagents on

diagnostic analyser systems

Use #5: Widespread use by professional workers - Use of IVD-wash solutions on

diagnostic analyser systems

Date: 16.10.2020, final

Exposure Scenario (ES) 4: Widespread use by professional workers – Use #4 - Use of IVD-kit reagents on diagnostic analyser systems

ECS and WCS	Task (ERC/spERC or PROC)	Annual amount per site (2021)	Technical RMMs, including:	Organisational RMMs, including:	PPE (characterist ics)	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)
ECS 1	ERC 8a Use of IVD-kit reagents on diagnostic analyser systems	n.a.	- automatic process - after use OPE containing solutions are mainly collected and discharged to communal wastewater*** - solid waste is disposed of for incineration**	 only well trained personnel* high laboratory and hygienic standard* 			0 - 67%	water: 33 - 100% air: no release soil: no release	9
WCS 1	PROC 15: Use of IVD-kit reagents on diagnostic analyser systems		- basic general ventilation	 8 h/day only well trained personnel* high laboratory and hygienic standard* 	laboratory PPE: gloves, goggles, coats and shoes	OPE concentration: < 5%			
WCS 2	PROC 8b: collection of OPE-containing wastewater and discharge to communal waste water		- basic general ventilation	- 8 h/day - only well trained personnel* - high laboratory and hygienic standard*	laboratory PPE: gloves, goggles, coats and shoes	OPE concentration: < 0.01%			
WCS 3	PROC21: collection, transport and disposal of solid waste		- basic general ventilation	 - 8 h/day - only well trained personnel* - high laboratory and hygienic standard* 	laboratory PPE: gloves, goggles, coats and shoes	OPE concentration: < 0.1%			

Exposure Scenario (ES) 5: Widespread use by professional workers – Use #5 - Use of IVD-kit wash-solutions on diagnostic analyser systems

ECS and WCS	Task (ERC/spERC or PROC)	Annual amount per site (2021)	Technical RMMs, including:	Organisational RMMs, including:	PPE (characterist ics)	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)
ECS 1	ERC 8a Use of IVD-wash solutions on diagnostic analyser systems	n.a.	- automatic process - after use OPnEO containing solutions are mainly collected and discharged to communal wastewater*** - solid waste is disposed of for incineration**	- only well trained personnel* - high laboratory and hygienic standard*			0 - 85 %	water: 15 - 100% air: no release soil: no release	9
WCS 1	PROC 5, PROC 8a: dilution of IVD- wash solutions		- basic general ventilation	- 8 h/day - only well trained personnel* - high laboratory and hygienic standard*	laboratory PPE: gloves, goggles, coats and shoes	OPE concentration: < 5%			
WCS 2	PROC 15: Use of IVD-wash solutions on diagnostic analyser systems		- basic general ventilation	- 8 h/day - only well trained personnel* - high laboratory and hygienic standard*	laboratory PPE: gloves, goggles, coats and shoes	OPE concentration: < 5%			
WCS 3	PROC 8b: collection of OPE- containing wastewater and discharge to communal waste water		- basic general ventilation	- 8 h/day - only well trained personnel* - high laboratory and hygienic standard*	laboratory PPE: gloves, goggles, coats and shoes	OPE concentration: < 0.01%			

ECS and WCS	Task (ERC/spERC or PROC)	Annual amount per site (2021)	Technical RMMs, including:	Organisational RMMs, including:	PPE (characterist ics)	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)
WCS 4	PROC21: collection, transport and disposal of solid waste		- basic general ventilation	- 8 h/day - only well trained personnel* - high laboratory and hygienic standard*	laboratory PPE: gloves, goggles, coats and shoes	OPE concentration: < 0.1%			

^{*} All steps are performed by trained personnel.

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

^{**} this means: Collection of any physical materials which may be contaminated with OPnEO, subsequent disposal and incineration of these items as solid waste

^{***} in compliance with EU framework legislation on waste water and waste