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

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Submitted by: *Sanofi Pasteur*

Substance: 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated

Use title: *Use of Octoxynol 9 for virus splitting and inactivation step in the manufacturing of Influenza vaccines*

Use number: *Use 1*

May 2020

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 (page)
ECS 1	ERC 4:	0.095 tonnes/ year total	**Existing flu building**. Disposable graduating cylinder for measuring/delivering Octoxynol-9 implemented and incineration of it. Capture and incineration of supernatant from the centrifuge rotor. Waste material from the diafiltration process contained until it is thermally decontaminated on-site. It is then transferred to the wastewater collection system at the site exit and discharged to the municipal wastewater treatment facility	**Existing flu building**.	Not applicable	Contaminated waste products (e.g. PPE) is incinerated in accordance with existing procedures.	Wastewater is treated at the municipal wastewater treatment facility. No release to air, soil or sediment from the site.	Water: <0.5 Air: 0 (no release to air) Soil: 0 (no release to soil)	
ECS 1	ERC 4:	0.095 tonnes/ year total	**New flu building**. Automated system for measuring and delivering Octoxynol-9. Capture and incineration of diafiltration waste material and supernatant from the centrifuge rotor.	**New flu building**.		Contaminated waste products (e.g. PPE) is incinerated in accordance with existing procedures.	Wastewater is treated at the municipal wastewater treatment facility. No release to air, soil or sediment from the site.	Water: <0.01 Air: 0 (no release to air) Soil: 0 (no release to soil)	.

WCS 1	PROC0; PROC 15			Daily, approximately 8 hours. Occupational management system, SOPs	PPE				