Format for

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

Version 1.1

August 2015

Use of diglyme as a process solvent in one step of the manufacturing of an Active Pharmaceutical Ingredient used in an anti-protozoal drug.

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 (section)
ECS 1	ERC 4	22-35 mt/year	Batch process in closed system.	4 to 6 campaigns per year. Process step which involves the use of diglyme lasts 2 weeks for each campaign.			No release to water or soil. Solvent recovery by distillation. Waste collected in storage tanks and incinerated on site.	Water: 0% Air: 0.01% Soil: 0%	9.0.1 and 9.1.1
WCS 1	PROC 8b		Transfer of substance from drum to reactor with flexible ventilation hose connected to scrubber on the drum.	Duration: 1 hour. Operators receive specific activity training for working with CMR products and the use of PPE.	Chemical protective suits (Nomex®), air respirator (carbon cartridge ABEK2HGP3 with screw-on filter DIN 148 in aluminium housing) and solvent resistant protective nitrile rubber gloves (EN374).				9.0.1, 9.02.3 and 9.1.2
WCS 2	PROC 1		Manufacturing process occurs in completely closed reactors that are connected to other equipment by hard piping.	Duration: < 8 hours. Operators receive specific activity training for working with CMR products and the use of PPE.	Chemical protective suits (Nomex®), solvent-resistant gloves (EN374) and boots.				9.0.1, 9.02.3 and 9.1.3
WCS 3	PROC 3		Batch process in closed system.	Duration: < 8 hours. Operators receive specific activity training for	Chemical protective suits (Nomex®), solvent-resistant gloves (EN374) and				9.0.1, 9.02.3 and 9.1.4

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				working with CMR products and the use of PPE.	boots.				
WCS 4	PROC 4		Batch process in closed system.	Duration: < 8 hours. Operators receive specific activity training for working with CMR products and the use of PPE.	Chemical protective suits (Nomex®), solvent-resistant gloves (EN374) and boots.				9.0.1, 9.0.2.3 and 9.1.5
WCS 5	PROC 8a		Maintenance and cleaning operations. Cleaning procedure is done in closed conditions. All maintenance operations are done after complete decontamination of the equipment.	Duration: < 4 hours. Operators receive specific activity training for working with CMR products and the use of PPE.	Chemical protective suits (Nomex®), air respirator (carbon cartridge ABEK2HGP3 with screw-on filter DIN 148 in aluminium housing), solvent resistant protective nitrile rubber gloves (EN374) and boots.				9.0.1, 9.0.2.3 and 9.1.6
WCS 6	PROC 9		Sampling for quality control from the reactor is conducted using an integrated process sampler that allows tight attachment of the sample jar and is enclosed in a sealable box.	Duration: < 1 hour. Operators receive specific activity training for working with CMR products and the use of PPE.	Chemical protective suits (Nomex®), air respirator (carbon cartridge ABEK2HGP3 with screw-on filter DIN 148 in aluminium housing) and solvent resistant protective nitrile rubber gloves (EN374).				9.0.1, 9.0.2.3 and 9.1.7

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WCS 7	PROC 15		Quality control in laboratory All activities performed in a fume hood.	Duration: < 1 hour. Technicians receive specific activity training for working with CMR products and the use of PPE.	Safety goggles and nitrile gloves (EN374				9.0.1. 9.0.2.3 and 9.1.8

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