

# Hovione

## NEW PROCESS EPA APPLICATION

### CX21

EPA Submission Date: 13<sup>th</sup> November 2020

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## 1.0 PROCESS OVERVIEW

<b><i>Proposed Start Date:</i></b>	Target 09 <sup>th</sup> September 2020
<b><i>Quantity per batch</i></b>	5000kgs (approx. batch size final step)
<b><i>No. of Batches:</i></b>	Up to 40 batches per/year.

## 1.1 PROCESS DESCRIPTION

Product in an aqueous solution is charged to a Tank, Sodium Dihydrogen Phosphate Monohydrate is then added if necessary. pH adjustment is completed if necessary, to pH 6. Purified water (PUW) is added and the aqueous solution is transferred through inline filters to the spray dryer. The dried material will be discharged and packed.

## 2.0 EMISSIONS TO ATMOSPHERE

The primary equipment and tanks used in drying are vented to a common condenser and SLA system for treatment and vented via CB1-02. Air Emissions from the CX21 process will not inorganic material, sulphates, and ammonia.

There are no solvent vapours associated with either the pH adjustment or the drying step in Building 10

## 3.0 EMISSIONS TO SEWER

### 3.1 CHARACTERISTICS OF EMISSIONS TO SEWER

- The volume expected has been reviewed, the site WWTP has sufficient capacity to treat this waste and remain in compliance with the Emission Limit Values specified in Schedule B.

#### FUTURE PROCESS: CX21

Description	Main source <sup>a</sup>		Prior to treatment				Treatment <sup>b</sup>	As discharged				Monitoring frequency
	Parameter	mg/L	Max. hourly avg. mg/L	Max. daily avg. mg/L	Max. kg/day	Max kg/year		Max. hourly avg. mg/L	Max. daily avg. mg/L	Max. kg/day	Max. kg/year	
Water Condensate (904552) <b>2.3l/kg product or 10,580L /batch</b>	Chemical Oxygen Demand (COD)						<input checked="" type="checkbox"/> Equalisation <input checked="" type="checkbox"/> pH adjustment <input checked="" type="checkbox"/> Activated Sludge <input checked="" type="checkbox"/> Clarification					Every day (Once per day)
	Suspended Solids											Every day (Once per day)
	Ammonia-N											Every day (Once per day)
	PO <sub>4</sub> -P											Every day (Once per day)
	pH		6.0-6.4					6 - 9				Continuous

- A reference should be made to the main activity/process for each parameter.
- Briefly describe the treatment and give a reference for details in the application.

Assumption: Process in production for approximately 50 weeks/year.

The discharge concentration is based on this stream contribution for the discharged treated wastewater.

N/D = not detected.

## 4. WASTE GENERATION AND DISPOSAL

### 4.1. CHARACTERISTICS OF WASTE FOR OFFSITE DISPOSAL

#### Waste Generation and Disposal from the CX02 Process

##### Organic Waste:

There are no organic waste streams generated during this process.

##### Solid Waste:

Any “fines” generated during the above drying process will be collected in a dedicated bag filter within the building. This material will be packaged and either returned to customer, retained by Hovione for development work, reprocessed, reprocessed or sent for incineration.

Waste Material	Quantity L / Batch	Further Treatment	Recovery / Reuse / Recycle	Final Disposal	Toxicological and Environmental Information
'Fines' from spray drying process		Any “fines” generated during the above drying process will be collected in a dedicated bag filter within the building. This material will be packaged and either returned to customer, retained by Hovione for development work, reprocessed or sent for incineration.			<u>CX21 (Product)</u> This substance is not acutely toxic to aquatic organisms at its maximum solubility. The substance is not expected to inhibit waste water treatment microorganisms. Fish LC50/96hrs >220mg/l; Daphnia EC50/48hrs >96mg/l. In the environment, this substance is expected to remain in water or migrate through the soil to groundwater and persist. The substance is expected to persist in water. Long term effects and bioaccumulation are not expected.

## 5.0 LIST OF CHEMICAL REACTIONS / OPERATIONS

The following operations occur in the CX21 process

- Neutralisation
- Drying

## 6.0 LIST OF RAW MATERIALS, INTERMEDIATES AND PRODUCTS

6.1 TABLE 1

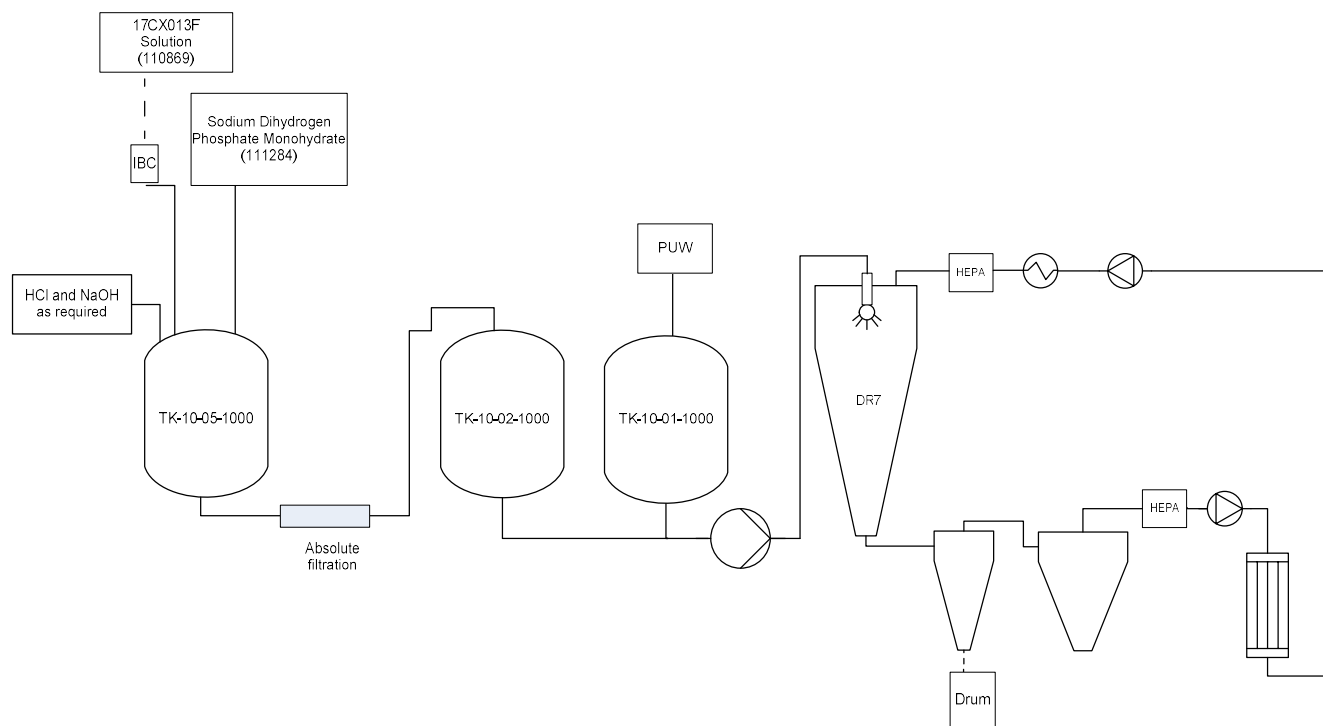
Material/Chemical	TA Luft Class 1, 2 or 3	Odour			EU Lists I and II			
					(Tick and specify Group/Family Number)			
		Odourous		Threshold µg/m3	Dangerous Substances Directive76/464/EEC		Groundwater Directive80/68/EEC	
		Yes/No	Description		List I	List II +129	List I	List II
17CX013F	N/ap	No	Not Applicable	Not Applicable	-	-	-	-
17CX21 (Product)	N/ap	No	Not Applicable	Not Applicable	-	-	-	-
Sodium Dihydrogen Phosphate Monohydrate	N/ap	No	Not Available	Not Applicable	-	-	-	-
Dilute Sodium hydroxide solution (0.5% w/w)	N/ap	No	Odourless	Not Applicable	-	-	-	-
Dilute Hydrochloric acid solution (0.5% w/w)	N/ap	Yes	Pungent	Not available	-	-	-	-

6.2 TABLE 2

Material/ Chemical	CAS Number	Risk Phase	Safety Phase	Danger Category	Quantity per kg /product	Usage per Batch (kg)
17CX013F	182410-00-0	WGK 3	H317 P261, P280, P302+P352, P333+P313, P362+P364 P501	Warning	0.996kg (dry)	4600 kg(dry wt.)
17CX21 (Product)	182410-00-0	WGK 3	H317 P261, P280, P302+P352, P333+P313, P362+P364 P501	Warning	1kg	4600 kg (product)
Sodium Dihydrogen Phosphate Monohydrate	10049-21-5	WGK 1	No data	Not Available	0.00031kg	0.240 kg (batch dependant)
Dilute Sodium hydroxide solution (0.5%)	1310-73-2	WGK 1	H290: H314: P280:P301 + P330 + P331: P305 + P351 + P338: P308 + P310	Corrosive	Dependant on pH adjustment requirements	Dependant on pH adjustment requirements
Dilute Hydrochloric acid solution (0.5%)	7647-01-0	WGK1	H290 - H314 - H335, P280 - P303 + P361 + P353 - P305 + P351 + P338 + P310	Danger	Dependant on pH adjustment requirements	Dependant on pH adjustment requirements

## 7.0 PROCESS FLOW DIAGRAM

**CX21 Process Train Hovione**





#### **8.0 CLEANER TECHNOLOGIES**

Bulk solvents will be used where possible in this process.