

Office of Environmental Enforcement,  
McCumiskey House,  
Richview,  
Clonskeagh Road,  
Dublin 14

**Re: Notification of Condition 1.4 Activities at SK biotek**

25<sup>th</sup> November 2024

To whom it concerns,

In accordance with condition 1.4 of our IE Licence (P0014-04), please find attached information on a new process and the associated new materials to the site. This does not present a material change to the nature or quantity of emissions as it will run in place of existing processes.

This process is called SKIE-0022. This correspondence relates to step 1 of SKIE-0022, also known as SKIE-0022-11.

Table 1 below lists the materials used in SKIE-0022-11, the quantity per batch and their location prior to use. The new materials (not previously used on site) are highlighted in bold and summary details of these new materials is outlined in Table 2. SKIE-0022-11 also requires the use of an existing DCU which vents to the atmosphere via minor emission points A3-106 (see location map below).

Powder solid materials are stored indoors in the main warehouse building whereas liquid materials are stored in the external drum storage sheds or in bulk tanks. The drum store sheds are adequately bunded and roofed to protect from the elements. The only special storage requirement is for sodium azide which must be stored at ground level.

Regarding waste streams, prior to a manufacturing campaign commencing, the waste streams associated with the campaign are identified to ensure that all waste is classified to ensure the correct disposal routes. Initially all aqueous waste streams will either be drummed or sent to bulk tank for offsite incineration or recovery.

Following the initial campaign, if an aqueous waste stream is identified that could potentially be treated in the onsite Wastewater Treatment Plant (WWTP), analysis of this waste stream will be undertaken as per site procedure "*Testing of Wastestreams to Determine Suitability of Discharges to WWTP*". Such tests may include pH, COD, BOD, OP, SO<sub>4</sub>, FI, solvents, metals, and respiration inhibition depending on the constituents of the waste stream.

Regarding air emissions, a review of the impact of this process on the Thermal Oxidiser has determined that there will be no impact to any existing ELVs as set out in P0014-04.

As stated above, SKIE-022-11 will require the use of an existing DCU which vents to the atmosphere via approved minor emission vent A3-106. DCUs are contained systems that are used to handle materials while providing protection to the operator. Hence, the use of DCUs is designed to improve containment, operator

protection and spill containment. Table 3 below details the materials required to be charged via these DCUs along with their associated calculated emissions.

These calculated emissions are based on worst case scenario's and compared against their respective BAT emission limits as set out in table 6.1 in the "*BAT Guidance Note for the Pharmaceutical & Other Speciality Organic Chemical Sector*". To quantify the emissions, calculations for SKIE-0022-11 were completed to calculate VOC vent emissions from batch and continuous processes using EPA equations in a process environment. The emission calculations are presented in Table 3 below and attached in excel format.

Ethanol, TFA and n-Heptane are the solvents in SKIE-0022-11 that are charged via DCU and emitted to the atmosphere via approved minor emission points, A3-88 and A3-106. Ethanol is listed as a Class II organic as per *Appendix 8 - Classification of Speciated Organics, EPA Air Emissions Guidance Note (AG2)* and is compared against the Class II ELV. n-Heptane is listed as a class II organic as per *Appendix 8 - Classification of Speciated Organics, EPA Air Emissions Guidance Note (AG2)* and is compared against the Class III ELV. TFA has no individual organic class as per *Appendix 8 - Classification of Speciated Organics, EPA Air Emissions Guidance Note (AG2)* and is therefore compared against the Class III ELV.

The calculations in Table 3 have determined the emissions for Ethanol, TFA and n-Heptane are well within their mass flow ELV assigned and thus can be considered as minor emissions which can vent through the minor emission points. Please note that these solvents/reagents will not all be charged at the same time.

Notwithstanding the fact that the above worst case calculated emissions are within their BAT ELVs, the site completed an assessment of significance regarding the cumulative impact of the site's air emissions. This was requested by the Agency during a site visit in Jan 2019 (SV17662). This assessment report was submitted to the Agency in Aug 2019 (LR043625). The report concluded that the cumulative impact of both the major and minor emission sources on site (all emitting simultaneously) would be highly unlikely to result in the exceedance of any of the relevant ELVs in the vicinity of the site. Given the fact that all major and minor emissions on site do not emit simultaneously, SK biotek are of the opinion that these DCU emissions are not significant and that the manufacture of this new process will not affect SK biotek's ability to comply with any existing ELVs as set out in P0014-04.

Can you confirm that this correspondence is to the satisfaction of the Agency?

Yours sincerely,  
Conor Smyth  
01 813 9450

**Table 1: List of materials, quantities and storage SKIE-0022-11**

Material Description	Projected quantity / batch	Unit of Measure	Storage Location
Ethyl acetate	1494	L	Bulk tank
De-ionised water	4045	L	City water, treated on-site
Toluene	3817	L	Bulk tank
Tetrahydrofuran	5632	L	Bulk tank
Ethanol	3662	KG	Drum storage
Dimethyl sulfoxide (DMSO)	467.5	KG	Drum storage
Sodium azide	27.71	KG	Warehouse
Lithium hydroxide monohydrate	19.04	KG	Warehouse
Trifluoroacetic acid (TFA)	0.0595	KG	Drum storage
Sodium hydroxide 30% solution	93.3	KG	Drum storage
n-Heptane	1326	KG	Drum storage
<b>Methyl-3-formyl-2-nitrobenzoate (Aromatic Idehyde)</b>	85	KG	Warehouse
<b>Aniline ESA Salt</b>	166.6	KG	Warehouse
<b>Copper (II) triflate</b>	0.85	KG	Warehouse

**Table 2: Summary information on new materials for SKIE-0022-11**

Name CAS No.	Signal word	Explosive Limit: Flashpoint: Autoignition Temp.:	LD 50	UN No.	Hazard Statements
<b>Methyl-3-formyl-2-nitrobenzoate (Aromatic aldehyde)</b> <b>(CAS No: 138229-59-1)</b>	Warning	No data available No data available No data available	No data available	No UN number available	H314 Causes skin irritation H319 Causes serious eye irritation H335 May cause respiratory irritation
<b>Aniline ESA Salt</b> <b>(CAS No: 2248017-49-2)</b>	None	No data available No data available No data available	No data available	No UN number available	None
<b>Copper (II) triflate</b> <b>(CAS No: 34946-82-2)</b>	None	No data available No data available No data available	No data available	No UN number available	None

**Note: See MSDS attached for supplementary information**

**EMISSIONS TO ATMOSPHERE – Table 3 Minor atmospheric emissions SKIE-0022-11**

Emission Point Code (i)	Description of source of emission(s)	Emission details (ii)					Abatement system employed. (if relevant)
		Material	kg/m <sup>3</sup> (iii)	kg/h	Mass Flow ELV (kg/hr)	kg/year	
A3-106	P3 DCU	Ethanol	4.48E-06	0.0121	<b>0.5</b>	0.0242 (assuming 2hrs operation)	N/A
		Ethanol as Carbon	2.33E-06	0.0063	<b>0.5</b>	0.0126 (assuming 2hrs operation)	N/A
		TFA	1.64E-06	0.0044	<b>0.5</b>	0.0089 (assuming 2hrs operation)	N/A
		TFA as Carbon	3.45E-07	0.0009	<b>0.5</b>	0.0019 (assuming 2hrs operation)	N/A
		n-Heptane	6.06E-06	0.0164	<b>0.5</b>	0.0327 (assuming 2hrs operation)	N/A
		n-Heptane as Carbon	5.08E-06	0.0137	<b>0.5</b>	0.0274 (assuming 2hrs operation)	N/A

Directors: Joyce Fitzharris (Ireland), Jonathan Horkan (Ireland), Lee Dong Hoon (Republic of Korea),  
 Company Secretary: Kathleen Mc Keon (Ireland)  
 Incorporated in Dublin, Ireland. No. 605650, Registered Office: Watery Lane, Swords, Co. Dublin, Ireland.

