

**Table G.1(i) Details of Process related Raw Materials, Intermediates, Products, etc., used or generated on the site (for Dexmedetomidine )**

Ref. N <sup>o</sup> or Code	Material/ Substance <sup>(1)</sup>	CAS Number	Danger <sup>(2)</sup> Category	Amount Stored (T)	Annual Usage (T)	Nature of Use	R <sup>(3)</sup> - Phrase	S <sup>(3)</sup> - Phrase	Hazard Statement <sup>(4)</sup>
To be assigned	2,3-dimethyl magnesium bromide (0.5M in THF)	134640-85-0	Corrosive, Flammable, Warning	.0832	.0832	Raw Material	-	-	H225,H261, H302,H313, H316,H318, H335,H336
To be assigned	Tritylimidazole carboxaldehyde, TAH	33016-47-6	Toxic, Warning, Danger	.0128	.0128	Raw Material	-	-	-H315,H319, H355,H301, H362
To be assigned	Ammonium chloride	12125-02-9	Warning	0.0081	0.0081	Agent	-	-	H302,H319
To be assigned	Sodium Chloride	007647-14-5	-	.0008	0.0063	Agent	-	-	-
To be assigned	Butylated Hydroxytoluene, BHT	128-37-0	Warning	0.00001	0.0001	Stabiliser	-	-	H410, H400
To be assigned	Celite 545	68855-54-9	Warning	0.00088	0.007	Filtering Aid	-	-	H373
To be assigned	Manganese IV oxide	1313-13-9	Danger	.00117	.0094	Oxidiser	-	-	H302,H332, H373, H372, H272, H411
To be assigned	1,4-Dioxane stab	123-91-1	Danger	.02270	.1816	Solvent	-	-	H225, H319, H335, H351
To be assigned	Methyl-Magnesium chloride (3.0M in THF)	676-58-4, 109-99-9 (THF)	Danger, Warning, Corrosive, Flammable	0.00127	0.0012	Raw Material	-	-	H351,H225, H260,H314, H335, EUH014, EUH019
-	Solvent A	Used on site already- Details provided in licence application 2007							
-	Solvent B	Used on site already- Details provided in licence application 2007							

<b>Ref. N<sup>o</sup> or Code</b>	<b>Material/ Substance<sup>(1)</sup></b>	<b>CAS Number</b>	<b>Danger<sup>(2)</sup> Category</b>	<b>Amount Stored (T)</b>	<b>Annual Usage (T)</b>	<b>Nature of Use</b>	<b>R<sup>(3)</sup> - Phrase</b>	<b>S<sup>(3)</sup> - Phrase</b>	<b>Hazard Statement<sup>(4)</sup></b>
<b>To be assigned</b>	Intermediate A	176721-01-0	Danger	0.0015	0.012	Intermediate (Not isolated)	-	-	H301, H319, H361, H362
<b>To be assigned</b>	Intermediate B	176721-02-1	Danger	0.00686	.0343	Intermediate	-	-	H301, H319, H361, H362

Notes: 1. In cases where a material comprises a number of distinct and available dangerous substances, please give details for each component substance.

2. Article 2(2) of S.I. No. 116/2003. (*In SDS's where Danger Categories are not available the labelling and signal word details are noted*).

3. Schedules 9 and 10 of S.I. No. 62/2004 (as amended by S.I. No. 271/2008)

4. EC Regulation 1272/2008 (Chemicals Act 2008 (13 of 2008) and 2010)

**Table G.1(ii) Details of Process related Raw Materials, Intermediates, Products, etc., used or generated on the site (for Dexmedetomidine)**

Ref. N <sup>o</sup> or Code	Material/Substance	Odour			Pollutants (Tick and specify Group/Family Number)				Controlled Substances	Relevant hazardous substance <sup>(3)</sup>
		Odourous Yes/No	Description	Threshold ug/m <sup>3</sup>	EC EO (Surface Waters) Regulations 2009		EC EO Groundwater) Regulations 2010		REACH SVHC <sup>(2)</sup>	y/n
					Specific pollutants	Priority (hazardous) substances	Hazardous <sup>1</sup>	Non-hazardous <sup>1</sup>		
	2,3-dimethyl magnesium bromide (0.5M in THF)	Yes	Ether like odor	15990-147460mg/m <sup>3</sup>	Not Listed	Not Listed	√ *	-	< 1MT below REACH threshold	Y
	Tritylimidazolecarboxaldehyde, TAH	Weak odor	No data available	No data available	Not Listed	Not Listed	√ *	-	< 1MT below REACH threshold	Y
	Ammonium chloride	Odor less	N/A	N/A	Not Listed	Not Listed	√	-	< 1MT below REACH threshold	Y
	Sodium Chloride	Odor less	N/A	N/A	Not Listed	Not Listed	√ *	-	< 1MT below REACH threshold	Y
	Butylated Hydroxytoluene, BHT	No data available	No data available	No data available	Not Listed	Not Listed	√	-	< 1MT below REACH threshold	Y
	Celite 545	Odor less	N/A	N/A	Not Listed	Not Listed	-	√	< 1MT below REACH	N

									threshold	
	Manganese IV oxide	Odor less	N/A	N/A	Not Listed	Not Listed	√ *	-	< 1MT below REACH threshold	Y
	1,4-Dioxane stab	Ether like	Not determined	No data available	Not Listed	Not Listed	√	-	< 1MT below REACH threshold	Y
	Methyl-Magnesium chloride in THF	Yes	Ether like odor	15990-147460m g/m <sup>3</sup>	Not Listed	Not Listed	√	-	< 1MT below REACH threshold	Y
	Solvent A	Used on site already- Details provided in licence application 2007								
	Solvent B	Used on site already- Details provided in licence application 2007								
	Intermediate A	No data available	No data available	No data available	Not Listed	Not Listed	√ *	-	< 1MT below REACH threshold	Y
	Intermediate B	No data available	No data available	No data available	Not Listed	Not Listed	√ *	-	< 1MT below REACH threshold	Y

Note 1: The EPA Classification of Hazardous and Non-Hazardous Substances in Groundwater, December 2010.

Note 2: Where relevant, specify whether the substance is on the Authorisation List (Annex XIV Regulation (EC) No 1907/2006 as amended) or Restriction List (Annex XVII Regulation (EC) No 1907/2006 as amended). Also, indicate whether the use has been authorised or exempted in accordance with Regulation (EC) No 1907/2006 as amended.

Note 3: Relevant hazardous substances are those substances or mixtures defined within Article 3 of Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures which, as a result of their hazardousness, mobility, persistence and biodegradability (as well as other characteristics), are capable of contaminating soil or groundwater.

\*As per section 4.4 of EPA Classification of Hazardous and Non-Hazardous Substances in Groundwater, December 2010, these materials have been classified by default as hazardous as the materials do not have all the PBT (Persistence, Bioaccumulation and Toxicity) data available.