

EPA Application Form

4. Activity and Capacity

4.6.2 - Raw Materials, Intermediates and Products - Attachment

Organisation Name:

AbbVie Ireland NL BV.

Application I.D.:

LA001712

Details of Process related Raw Materials, Intermediates, Products, etc., used or generated on the site

Complete the table below for all process related raw materials, intermediates, products, etc., used or generated on the site **Note 1** - See notes below table for further information

Note: Add additional rows in to this table if required. (Please copy the existing formatting into added rows).

Ref. No. or Code	Material/ Substance ⁽²⁾	CAS Number	Danger Category ⁽³⁾	Amount Stored (tonnes)	Annual Usage (tonnes)	Nature of Use	Hazard Statement ⁽⁴⁾	Odour		
								Odourous Yes/No	Description	Threshold µg/m3
1	MOBIL VACTRA OIL NO. 2	128-37-0 (2,6-di-tert-butyl-p-cresol < 0.25 %)	NA	<0.1	<0.1	Utilities	NA	Yes	characteristic	No data available
2	MOBILGEAR 600XP 320 20L (Gear Oil) - Mixture	1330-78-5 (TRICRESYL PHOSPHATE 0.1 - < 0.25%) 68955-53-3 (Amines 0.1 - < 0.25%)	Warning: toxic for reproduction	<0.2	<0.5	Utilities	H361	Yes	characteristic	No data available
3	CASTROL AWH-M 68 HYDRAULIC (CASTROL HYSPIIN AWH-M 68)	NA	NA	<0.002	<0.003	Utilities	NA	No data available	No data available	No data available
4	MOBILGEAR 600XP 680	1330-78-5 (TRICRESYL PHOSPHATE 0.1 - < 0.25%) 68955-53-3 (Amines 0.1 - < 0.25%)	Warning: toxic for reproduction	<0.002	<0.002	Utilities	H361	Yes	characteristic	No data available
5	CASTROL MAGNA BD 68 (CASTROL MAGNA BD 68)	NA	NA	<0.02	<0.02	Utilities	NA	Yes	Mild	No data available
6	CASTROL OPTILEB GR UF00 GREASE - Mixture. Contains petroleum.	8042-47-5 (white mineral oil, petroleum ≤5 %)	Non Hazardous	<0.02	<0.02	Utilities	Non Hazardous	No data available	No data available	No data available
7	CASTROL HYSPIIN AWS 46 20 LTS (Hydraulic Fluid) - Mixture. Contains highly refined base oil.	NA	NA	<0.05	<0.1	Utilities	NA	No data available	No data available	No data available
8	R134a - Tetrafluoroethane	811-97-2	Warning: explosive gas	<1 (within chillers only)	<1	Utilities (new and existing)	H280	Yes	Faint ethereal odour	No data available
9	R407c - Hydrofluorocarbons blend	811-97-2 354-33-6 75-10-5	Warning: explosive gas	<0.2 (within chillers only)	<0.2	Utilities	H280	Yes	Faint ethereal odour	No data available

Raw Materials, Intermediates and Products cont...

Ref. No. or Code (repeated)	Pollutants (Tick and specify Group/Family Number)				Controlled Substances REACH SVHC ⁽⁶⁾	Relevant hazardous substance? ⁽⁷⁾ Yes/No
	EC EO (Surface Waters) Regulations 2009		EC EO (Groundwater) Regulations 2010			
	Specific pollutants	Priority (hazardous) substances	Hazardous ⁽⁵⁾	Non-hazardous ⁽⁵⁾		
1	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	No
2	Not Listed	Not Listed	Not Listed	Not listed	Not Listed	No
3	Not Listed	Not Listed	N/A	N/A	N/A	N/A
4	Not Listed	Not Listed	Not Listed	Not listed	Not Listed	No
5	Not Listed	Not Listed	N/A	N/A	N/A	N/A
6	Not Listed	Not Listed	Yes (petroleum)	No	Yes (mineral oil)	No
7	Not Listed	Not Listed	N/A	N/A	N/A	N/A
8	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	No
9	Not Listed	Not Listed	Yes (Pentafluoroethane & Difluoromethane)	No	Not Listed	No

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								Odourous Yes/No	Description	Threshold µg/m3
10	R717 - Ammonia	7664-41-7	Danger: flammable, explosive gas, toxic, harmful, sensitising, dangerous to the environment	<0.3 (within chillers only)	<0.3	Utilities	H221 H280 H331 H314 H318 H400 H411	Yes	ammoniacal	Odour threshold is subjective and is inadequate to warn of over exposure
11	R410a - difluoromethane, pentafluoroethane	75-10-5 354-33-6	Danger: extremely flammable, explosive, mutagenic, carcinogenic	<1 (within chillers only)	<1	Utilities	H280 H220 H340 H350	Yes	Faint ethereal odour	No data available
12	R404a - Hydrofluorocarbons blend	354-33-6 420-46-2 811-97-2	Danger: extremely flammable, explosive	<0.2 (within chillers only)	<0.2	Utilities (new and existing)	H280 H220	Yes	Faint ethereal odour	No data available
13	SYLTHERM XLT# Heat Transfer Fluid	63148-62-9	Warning: Flammable	<1200 L (within Lyo only)	<1200 L	Lyo unit	Flammable liquids - Category 3	Yes	Odorless to mild	No data available
14	Kendall® Four Seasons Hydraulic Fluid	64742-54-7 64742-62-7	N/A	<200 L (within Lyo only)	<200 L	Lyo unit	N/A	Yes	Petroleum	No data available
15	Emkarate RL46H COMPRESSOR OIL	N/A	N/A	<100 L (within Lyo only)	<100 L	Lyo unit	N/A	Yes	Mild	No data available
16	Mechanical Pump Oil - white mineral oil (petroleum)	8042-47-5	N/A	<5 L (within Lyo only)	<5 L	Lyo unit	N/A	No data available	No data available	No data available
17	Fomblin YVAC Vacuum Pump oil	69991-67-9	N/A	<2 L (within Lyo only)	<2 L	Lyo unit	N/A	No	N/A	N/A
18	Mobil SHC629 150cst SLOT DOOR GEARBOX OIL	N/A	N/A	<2 L (within Lyo only)	<2 L	Lyo unit	N/A	Yes	characteristic	No data available
19	NOVACROSS CLEANER 5LTR each (NOVACROSS)	63449-41-2 68439-45-2	Warning: Irritant	<0.01	<0.05	Cleaning	H319	Yes	characteristic	No data available

Raw Materials, Intermediates and Products cont...

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	EC EO (Surface Waters) Regulations 2009		EC EO (Groundwater) Regulations 2010			
	Specific pollutants	Priority (hazardous) substances	Hazardous ⁽⁵⁾	Non-hazardous ⁽⁵⁾		
10	Not listed	Not listed	No	Yes	Not listed	Yes
11	Not listed	Not listed	Yes	No	Not listed	No
12	Not listed	Not listed	Yes	No	Not listed	No
13	Not listed	Not listed	Not Listed	Not listed	Not listed	No
14	Not listed	Not listed	Yes (Petroleum distillate)	No	Not listed	N/A
15	N/A	N/A	N/A	N/A	NA	N/A
16	Not Listed	Not listed	Yes (petroleum)	No	Yes (mineral oil)	N/A
17	Not Listed	Not listed	Not Listed	Not listed	Not listed	N/A
18	N/A	N/A	N/A	N/A	NA	N/A
19	Not listed	Not listed	Undetermined (Alcohols (C12) ethoxylated))	Undetermined (Alcohols (C12) ethoxylated))	Not listed	No

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								Odourous Yes/No	Description	Threshold µg/m3
20	100885537 DI TEGO 2000 VT25 2X5L W134 per case of 2 (TEGO 2000 VT25)	139734-65-9	NA	<0.05	<0.05	Cleaning	NA	Yes	Product specific	Not applicable
21	DOMINO WL-200 WASH (Printing Ink related material)	78-93-3 (Butone)	Danger: Highly flammable, irritant, harmful	<0.005	<0.005	medical device production/ manufacturing	H225, H319, H336	Yes	Ketonic	0.00032 ppm
22	WD-40 LUBRICANT	64742-47-8 64742-58-1 64742-53-6 64742-56-9 64742-65-0 64742-47-8	Danger: Harmful, very toxic (fatal), flammable	<0.01	<0.01	medical device production/ manufacturing	H226 H304 H336	Yes	characteristic	No data available
23	BUTANE GAS (SERVISOL BUTANE REFILL)	68512-91-4	Danger: extremely flammable	<0.02	<0.02	medical device production/ manufacturing	H220	Yes	characteristic	No data available
24	VIDEOJET INK CARTRIDGE V459-D (Mixture, Solvent)	78-93-3 (butanone), 108-21-4 (isopropyl acetate), 64-17-5 (ethanol), 616-45-5 (2-pyrrolidone), 8047-99-2 (N-ethyl-o(or p)-toluenesulphonamide), 67-63-0 (propan-2-ol)	Danger: Highly flammable, irritant, harmful	<0.01	<0.01	medical device production/ manufacturing	H225 H319 H336	Yes	No data available	Highest known value: 100 ppm. Weighted average: 22 ppm.
25	VIDEOJET MAKE-UP V701-D (VIDEOJET MAKE-UP FLUID V701-D)	78-93-3 108-21-4 64-17-5	Danger: Highly flammable, irritant, harmful	<0.02	<0.1	bio medical production/ manufacturing	H225 H319 H336	Yes	No data available	Highest known value: 100 ppm. Weighted average: 21 ppm.
26	CLEANING SOLUTION, 1 LITER (VIDEOJET CLEANING SOLUTION V901-Q)	78-93-3	Danger: Highly flammable, irritant, harmful	<0.02	<0.02	medical device production/ manufacturing	H225 H319 H336	Yes	No data available	Highest known value: 10 ppm. Weighted average: 10 ppm.

Raw Materials, Intermediates and Products cont...

Ref. No. or Code (repeated)	Pollutants (Tick and specify Group/Family Number)				Controlled Substances REACH SVHC ⁽⁶⁾	Relevant hazardous substance? ⁽⁷⁾ Yes/No
	EC EO (Surface Waters) Regulations 2009		EC EO (Groundwater) Regulations 2010			
	Specific pollutants	Priority (hazardous) substances	Hazardous ⁽⁵⁾	Non-hazardous ⁽⁵⁾		
20	Not listed	Not listed	Not listed	Not listed	Not listed	N/A
21	Not Listed	Not Listed	Not Listed	Not listed	Not Listed	No
22	Not Listed	Not Listed	Yes (Petroleum distillate)	No	Not Listed	No
23	Not Listed	Not Listed	Yes	No	Not Listed	No
24	Not Listed	Not Listed	Undetermined (ethanol)	Undetermined (ethanol)	Not Listed	No
25	Not Listed	Not Listed	Undetermined (ethanol)	Undetermined (ethanol)	Not Listed	No
26	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	No

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								Odourous Yes/No	Description	Threshold µg/m3
27	Tosh Ink (ST 01-UV)	123-86-4 13048-33-4 15625-89-5 67906-98-3 63225-53-6 7473-98-5 75980-60-8 119-61-9 108-65-6	Warning: flammable, irritant, dangerous for environment, harmful	<0.5	<1	medical device production/ manufacturing	H226 H319 H315 H317 H336 H412	Yes	Acrylic	No data available
28	Tosh Thinner (DILUENTE 2)	108-94-1 108-65-6 123-86-4	Danger: flammable, very toxic, harmful, irritant, dangerous for environment	<0.5	<0.5	medical device production/ manufacturing	H226 H302 H304 H318 H315 H335 H336 H411	Yes	typical of solvents	No data available
29	Ambersil Label & Adhesive Remover 200ML SIZE	64-17-5 586-62-9 5131-66-8 124-38-9 67-63-0 78-93-3	Danger: Irritant, harmful, extremely flammable, dangerous for environment	<0.005	<0.005	medical device production/ manufacturing	H222 H229 H315 H317 H319 H336 H411	Yes	characteristic	No data available
30	IPA 70%	67-63-0	Danger: Highly flammable, irritant, harmful	<0.05	<0.5	medical device production/ manufacturing	H224 H336 H319	Yes	Alcoholic	No data available
31	IPA 99.7%	67-63-0	Danger: Highly flammable, irritant, harmful	<0.05	<0.05	medical device production/ manufacturing	H225 H336 H319	Yes	Alcoholic	No data available
32	IPA wipes (70%)	67-63-0	Warning: Highly flammable, irritant, harmful	< 0.2 (0.09 of pure solvent from packs)	< 2 (1.04 of pure solvent from packs)	Pharma production/ manufacturing	H224 H336 H319	Yes	Alcoholic	No data available
33	HIBISCRUB 5LTR per 5L (HIBISCRUB)	1643-20-5 67-63-0 56-81-5 18472-51-0	Danger: dangerous for environment, toxic	<0.05	<0.1	medical device production/ manufacturing	H318 H400 H410 H411	Yes	Citrus fruits	No data available

Raw Materials, Intermediates and Products cont...

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	EC EO (Surface Waters) Regulations 2009		EC EO (Groundwater) Regulations 2010			
	Specific pollutants	Priority (hazardous) substances	Hazardous ⁽⁵⁾	Non-hazardous ⁽⁵⁾		
27	Not Listed	Not Listed	Undetermined (Benzophenone)	Undetermined (Benzophenone)	Not Listed	Yes
28	Not listed	Not listed	Not listed	Not listed	Not listed	Yes
29	Not listed	Not listed	Undetermined (ethanol and propan-2-ol)	Undetermined (ethanol and propan-2-ol)	Not listed	Yes
30	Not listed	Not listed	Undetermined (propan-2- ol)	Undetermined (propan-2- ol)	Not listed	No
31	Not listed	Not listed	Undetermined (propan-2- ol)	Undetermined (propan-2- ol)	Not listed	No
32	Not listed	Not listed	Undetermined (propan-2- ol)	Undetermined (propan-2- ol)	Not listed	No
33	Not listed	Not listed	Undetermined (Glycerol)	Undetermined (Glycerol)	Not listed	Yes

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								Odourous Yes/No	Description	Threshold µg/m3
34	Tecothane TT-2076A-W35 (Polyether Aromatic - Medical)	N/A	NA	<0.1	<0.1	medical device production/ manufacturing	NA	Yes	Slight	No data available
35	Colorite PVC 7566IG-015 (Polyvinyl Chloride (PVC) Compound)	NA	NA	<0.5	<0.1	medical device production/ manufacturing	NA	No data available	No data available	No data available
36	POM Hostaform MT12U01 (HOSTAFORM MT 12U01)	50-00-0	NA	<10	<20	medical device production/ manufacturing	NA	Yes	slight, specific	No data available
37	Compounded Novodur HD M203FC 703175 Grey (Novodur® HD M203FC)	9003-56-9	NA	<50	<100	medical device production/ manufacturing	NA	Yes	characteristic	No data available
38	Compounded Novodur HD M203FC 018646 Whit (Novodur® HD M203FC)	9003-56-9	NA	<1	0	medical device production/ manufacturing	NA	Yes	characteristic	No data available
39	Compounded TPE Thermoplast TM5 ADT-999 (THERMOLAST TM5ADT-999)	NA	NA	<1	<1	medical device production/ manufacturing	NA	Yes	characteristic	No data available
40	Lexan HP1	NA	NA	<20	0	medical device production/ manufacturing	NA	None or slight	None or slight	No data available
41	Thermoplast TM5 ADT-998 (Thermolast TM5ADT)	NA	NA	<3	<2	medical device production/ manufacturing	NA	Yes	characteristic	Not applicable
42	TM6ADT (MC/AD1 Series) Natural Colour (THERMOLAST TM6ADT)	NA	NA	<0.2	<0.1	medical device production/ manufacturing	NA	Yes	characteristic	Not applicable

Raw Materials, Intermediates and Products cont...

Ref. No. or Code (repeated)	Pollutants (Tick and specify Group/Family Number)				Controlled Substances REACH SVHC ⁽⁶⁾	Relevant hazardous substance? ⁽⁷⁾ Yes/No
	EC EO (Surface Waters) Regulations 2009		EC EO (Groundwater) Regulations 2010			
	Specific pollutants	Priority (hazardous) substances	Hazardous ⁽⁵⁾	Non-hazardous ⁽⁵⁾		
34	Not listed	Not listed	Not listed	Not listed	N/A	N/A
35	Not listed	Not listed	Not listed	Not listed	N/A	N/A
36	Not listed	Not listed	No	Yes	Not listed	N/A
37	Not listed	Not listed	Not listed	Not listed	Not listed	N/A
38	Not listed	Not listed	Not listed	Not listed	Not listed	N/A
39	NA	NA	NA	NA	NA	NA
40	NA	NA	NA	NA	NA	NA
41	NA	NA	NA	NA	NA	NA
42	NA	NA	NA	NA	NA	NA

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								Odourous Yes/No	Description	Threshold µg/m3
43	HOSTAFORM MT8U01-POM (HOSTAFORM MT8U01)	50-00-0	NA	<0.2	<0.1	medical device production/ manufacturing	NA	Yes	slight, specific	No data available
44	ABSPC 754M Pantone Cool Grey 6 50593	13463-67-7	Warning	<0.1	0	medical device production/ manufacturing	May form combustible dust concentrations in air	Yes	ether-like	No data available
45	ELASTOLLAN S95A55N TPU (ELASTOLLAN S95A55N)	NA	NA	<0.2	0	medical device production/ manufacturing	NA	No	Not applicable	Not applicable
46	HOSTAFORM C13031 (HOSTAFORM C 13031)	50-00-0	NA	<20	<30	medical device production/ manufacturing	NA	Yes	slight, specific	No data available
47	ISPLEN PB 176 N4M (Polipropileno Isplen PB-176-N4M)	NA	NA	<60	<130	medical device production/ manufacturing	NA	No	Not applicable	Not applicable
48	Acetal Hostaform C 13021 (HOSTAFORM C 13021)	50-00-0	NA	<20	<10	medical device production/ manufacturing	NA	Yes	slight, specific	No data available
49	TPE THERMOLAST TC4HAZ (TPE TC4HAZ)	NA	NA	<1	<0.5	medical device production/ manufacturing	NA	Yes	Odour typical for polymers	No data available
50	Mevopur Black M09M176011 (Mevopur-Black M09M176011-ZN)	36443-68-2 (0.5-1%)	NA	<1	<1	medical device production/ manufacturing	NA	Yes	characteristic	Not applicable
51	Mevopur Yellow M01M176008 (Mevopur-Yellow M01M176008-ZN)	NA	NA	<0.05	<0.05	medical device production/ manufacturing	NA	Yes	characteristic	Not applicable
52	Mevopur Red PP3M17605028200 (Mevopur-Red PP3M176050-ZN)	NA	NA	<1	<2	medical device production/ manufacturing	NA	Yes	characteristic	Not applicable
53	Mevopur Grey PP7M176039 (Mevopur-Grey PP7M176039-ZN)	NA	NA	<5	<2	medical device production/ manufacturing	NA	Yes	characteristic	Not applicable
54	CORRSHIELD MD4100	7632-00-0 231-555-9 7631-95-0 231-551-7 1310-73-2 215-185-5	Danger: corrosive, harmful, sensitising	N/A (not stored onsite)	100L	medical device production/ manufacturing	H290 H302 H314 H318	Yes	Mild	No data available

Raw Materials, Intermediates and Products cont...

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	EC EO (Surface Waters) Regulations 2009		EC EO (Groundwater) Regulations 2010			
	Specific pollutants	Priority (hazardous) substances	Hazardous ⁽⁵⁾	Non-hazardous ⁽⁵⁾		
43	Not listed	Not listed	No	Yes	Not listed	N/A
44	Not listed	Not listed	Not listed	Not listed	Not listed	No
45	NA	NA	NA	NA	Not listed	NA
46	Not listed	Not listed	No	Yes	Not listed	N/A
47	NA	NA	NA	NA	NA	NA
48	Not listed	Not listed	No	Yes	Not listed	N/A
49	NA	NA	NA	NA	NA	NA
50	Not listed	Not listed	Not listed	Not listed	Not listed	N/A
51	NA	NA	NA	NA	NA	NA
52	NA	NA	NA	NA	NA	NA
53	NA	NA	NA	NA	NA	NA
54	Not Listed	Not Listed	Undetermined	Undetermined	Not Listed	No

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								Odourous Yes/No	Description	Threshold µg/m3
55	Hydrochloric acid 1 mol/L	7647-01-0	Warning: Corrosive, Irritant, harmful, sensitising	<10 L	<30 L	Pharma production/ manufacturing	H335 H314 H290	No	N/A	N/A
56	Acetic Acid (glacial)	64-19-7	Danger: Corrosive, Flammable, harmful, sensitising	<1 kg	<3 kg	Pharma production/ manufacturing	H314 H226 H290	Yes	stinging	0.2 - 100.1 ppm
57	DMA	127-19-5	Danger: Harmful, Irritant, toxic for reproduction	<15 L	<50 L	Pharma production/ manufacturing	H312 H332 H319 H360D	Yes	Ammonia odour	No data available
58	Dimethyl sulfoxide	67-68-5	NA	<0.1	<0.5	Pharma production/ manufacturing	NA	No data available	No data available	No data available
59	EDTA	60-00-4	Warning: Irritant	<0.002	<0.01	Pharma production/ manufacturing	H319	No	N/A	N/A
60	Toxin 1	cyto-toxin	Danger: very toxic (fatal), mutagenic, carcinogenic, toxic for reproduction	< 0.1 kg	<0.5 kg	Pharma production/ manufacturing	H300 H341 H351 H361	Not determined	Not determined	Not determined
61	MAB 1	NA	NA	< 60 L	<250 L	Pharma production/ manufacturing	NA	Not determined	Not determined	Not determined
62	Toxin 2	cyto-toxin	Danger: Toxic, mutagenic, carcinogenic, toxic to reproduction	< 1 kg	< 2 kg	Pharma production/ manufacturing	H301, H311, H331, H341, H351, H361	No data available	No data available	No data available
63	MAB 2	NA	NA	<150 L	< 500 L	Pharma production/ manufacturing	NA	Not determined	Not determined	Not determined
64	L-Histidine	71-00-1	NA	<0.02	<0.05	Pharma production/ manufacturing	NA	No	N/A	N/A
65	L-Histidine Monohydrochloride Monohydrate	5934-29-2	NA	<0.02	<0.1	Pharma production/ manufacturing	NA	Yes	weak characteristic odour	No data available

Raw Materials, Intermediates and Products cont...

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	EC EO (Surface Waters) Regulations 2009		EC EO (Groundwater) Regulations 2010			
	Specific pollutants	Priority (hazardous) substances	Hazardous ⁽⁵⁾	Non-hazardous ⁽⁵⁾		
55	Not listed	Not listed	Not listed	Not listed	Not listed	No
56	Not listed	Not listed	Undetermined	Undetermined	Not listed	No
57	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	No
58	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	N/A
59	Not listed	Not listed	Undetermined	Undetermined	Not listed	No
60	N/A	N/A	N/A	N/A	N/A	No
61	N/A	N/A	N/A	N/A	N/A	N/A
62	N/A	N/A	N/A	N/A	N/A	Yes
63	NA	NA	NA	NA	NA	NA
64	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	N/A
65	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	N/A

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Complete the table below for all process related raw materials, intermediates, products, etc., used or generated on the site **Note 1** - See notes below table for further information

Note: Add additional rows in to this table if required. (Please copy the existing formatting into added rows).

Ref. No. or Code	Material/ Substance ⁽²⁾	CAS Number	Danger Category ⁽³⁾	Amount Stored (tonnes)	Annual Usage (tonnes)	Nature of Use	Hazard Statement ⁽⁴⁾	Odour		
								Odourous Yes/No	Description	Threshold µg/m3
66	Ingredient 1	-	NA	<0.5 kg	<2 kg	Pharma production/ manufacturing	NA	Yes	No data available	No data available
67	Ingredient 2	-	Danger: harmful, sensitising	< 0.1 kg	<0.5 kg	Pharma production/ manufacturing	H314	No data available	No data available	No data available
68	NaOH Pellet	1310-73-2	Danger: Corrosive, irritant, harmful, sensitising	<0.01	<0.05	Pharma production/ manufacturing	H314 H290 H319	Yes	No data available	No data available
69	NaOH stock	1310-73-2	Danger: Corrosive, irritant, harmful, sensitising	<100 L	257 L	Pharma production/ manufacturing	H314 H290 H319	Yes	No data available	No data available
70	Polysorbate 20	9005-64-5	NA	<0.1 kg	<0.5 kg	Pharma production/ manufacturing	NA	No data available	No data available	No data available
71	Polysorbate 80	9005-65-6	NA	<0.1 kg	<0.5 kg	Pharma production/ manufacturing	NA	No	NA	NA
72	di-Potassium hydrogen phosphate anhydrous	04-11-58	NA	<0.05	<0.1	Pharma production/ manufacturing	NA	No	NA	NA
73	Sodium Acetate, Trihydrate	6131-90-4	Warning	<0.01	<0.05	Pharma production/ manufacturing	May form combustible dust concentrations in air	No	NA	NA
74	Sodium chloride	7647-14-5	Irritant	<0.01	<0.05	Pharma production/ manufacturing	H319	Yes	Other	No data available
75	Sucrose	57-50-1	N/A	<0.1	<0.5	Pharma production/ manufacturing	N/A	No	N/A	N/A
76	Tris Base	None (EC no. 201-064-4)	NA	<0.5 kg	< 2 kg	Pharma production/ manufacturing	NA	No	N/A	N/A
77	Glycol	57-55-6	Irritant	1m3	1m3	Chillers	H319	Yes	Practically Odourless.	N/A

Raw Materials, Intermediates and Products cont...

Ref. No. or Code (repeated)	Pollutants (Tick and specify Group/Family Number)				Controlled Substances REACH SVHC ⁽⁶⁾	Relevant hazardous substance? ⁽⁷⁾ Yes/No
	EC EO (Surface Waters) Regulations 2009		EC EO (Groundwater) Regulations 2010			
	Specific pollutants	Priority (hazardous) substances	Hazardous ⁽⁵⁾	Non-hazardous ⁽⁵⁾		
66	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	N/A
67	Not listed	Not listed	Not listed	Not listed	Not listed	No
68	Not listed	Not listed	Undetermined	Undetermined	Not listed	No
69	Not listed	Not listed	Undetermined	Undetermined	Not listed	No
70	Not listed	Not listed	Not listed	Not listed	Not listed	NA
71	NA	NA	NA	NA	Exempt (Sorbitan oleate)	NA
72	Not Listed	Not Listed	No	Yes	Not Listed	NA
73	Not listed	Not listed	Undetermined	Undetermined	Not listed	No
74	Not listed	Not listed	Undetermined	Undetermined	Not listed	No
75	Not listed	Not listed	Not listed	Not listed	Exempt	NA
76	Not listed	Not listed	Not listed	Not listed	N/A	N/A
77	Not listed	Not listed	Undetermined	Undetermined	Not listed	No

Details of Process related Raw Materials, Intermediates, Products, etc., used or generated on the site

Complete the table below for all process related raw materials, intermediates, products, etc., used or generated on the site **Note 1** - See notes below table for further information

Note: Add additional rows in to this table if required. (Please copy the existing formatting into added rows).

Ref. No. or Code	Material/ Substance ⁽²⁾	CAS Number	Danger Category ⁽³⁾	Amount Stored (tonnes)	Annual Usage (tonnes)	Nature of Use	Hazard Statement ⁽⁴⁾	Odour		
								Odourous Yes/No	Description	Threshold µg/m3
78	Diesel	68334-30-5	Warning: Flammable, carcinogenic, Irritant, mutagenic, very toxic, harmful, dangerous to the environment	10m3	6m3	emergency generator	H351 H304 H332 H315 H373 H226 H411	Yes	Aromatic	No data available
79	LPG	68476-85-7	Danger: Extremely Flammable, explosive if heated	30m3	2,000m3	Boilers	H220 H280	Yes	Distinctive	N/A
80	Liquid N	7727-37-9	Warning: May cause cryogenic burns	10m3	48m3	Lyophilisation	H281	No	N/A	N/A

Notes: 1 The details provided should be very comprehensive, all materials used, fuels, intermediates, laboratory chemicals and product should be included. Particular attention should be paid to materials and product consisting of, or containing, dangerous substances as described in the EU (Classification, Packaging, Labelling and Notification of Dangerous Substances) Regulations 2003 [SI 116/2003] as amended and Regulation (EC) No. 1272/2008. The list must classify these materials in accordance with both of these Regulations, and must specify the designated Hazard Statements. Hazard statements for each substance should be in accordance with Article 21 of the EC Regulation 1272/2008. The list must identify any Substances of Very High Concern (SVHC) listed in Annex XIV of the REACH Regulations (Regulation (EC) No 1907/2006) as amended and indicate whether the use has been authorised or is exempted in accordance with the Regulation. In the case(s) of exempted use(s) the list must state the basis for each intended exempted use concerned.

- 2 In cases where a material comprises a number of distinct and available dangerous substances, please give details for each component substance.
- 3 Article 2(2) of S.I. No. 116/2003.
- 4 EC Regulation 1272/2008 (Chemicals Act 2008 (13 of 2008) and 2010)
- 5 The EPA Classification of Hazardous and Non-Hazardous Substances in Groundwater, December 2010.
- 6 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.
- 7 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.

Raw Materials, Intermediates and Products cont...

Ref. No. or Code (repeated)	Pollutants (Tick and specify Group/Family Number)				Controlled Substances REACH SVHC ⁽⁶⁾	Relevant hazardous substance? ⁽⁷⁾ Yes/No
	EC EO (Surface Waters) Regulations 2009		EC EO (Groundwater) Regulations 2010			
	Specific pollutants	Priority (hazardous) substances	Hazardous ⁽⁵⁾	Non-hazardous ⁽⁵⁾		
78	Not listed	Not listed	Yes	No	Not listed	Yes
79	Not listed	Not listed	Not listed	Not listed	Not listed	No
80	Not listed	Not listed	Not listed	Not listed	Exempt	N/A