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New Product Introduction – EPA Notification

"Project MARK"

20 January 2023

Priority: Urgent

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1. Introduction

Thermo Fisher Scientific is planning the introduction of a new product to the Cork site, 'Project MARK'. The product to be manufactured relates to the treatment of Lupus and COVID-19. Production activities are proposed to commence on 5th March 2023. This project is similar in scale and nature to other recent R&D notifications approved by the EPA i.e. small scale relative to the main products portfolio manufactured within the main production buildings.

As with all R&D projects the priority of this notification is urgent.

This request for approval in accordance with Condition 1.4 is in keeping with the guidelines from the EPA[1] on seeking alterations which state that:

"*An activity or process at an installation solely for research, development or testing of new products and processes are excluded and may be considered and approved by OEE. New products or processes at an installation adequately controlled by the conditions of the licence may be considered and approved by OEE.*"

The product will be manufactured in 5 Stages at the Cork Facility, resulting in the manufacture of 3 batches with an output of 41kg. The process is similar to many current and previous process stages manufactured at the Cork facility. Many of the common bulk solvents are being used and standard unit operations are being employed in existing infrastructure within Building 3. No changes to site management, infrastructure or control are required.

Within the existing building, the process uses existing modules and associated vent lines, drainage lines and abatement measures.

See Figure 1.1 for site layout and location of the proposed process stages. In terms of environmental operation and compliance, this process does not require a new main or minor emission point and can be readily facilitated and controlled within the existing conditions and limits of the site's IE Licence.

[1] https://www.epa.ie/pubs/advice/licensee/Licence%20Alteration%20Guidance%20rev%20MOC%2021-06-19.pdf

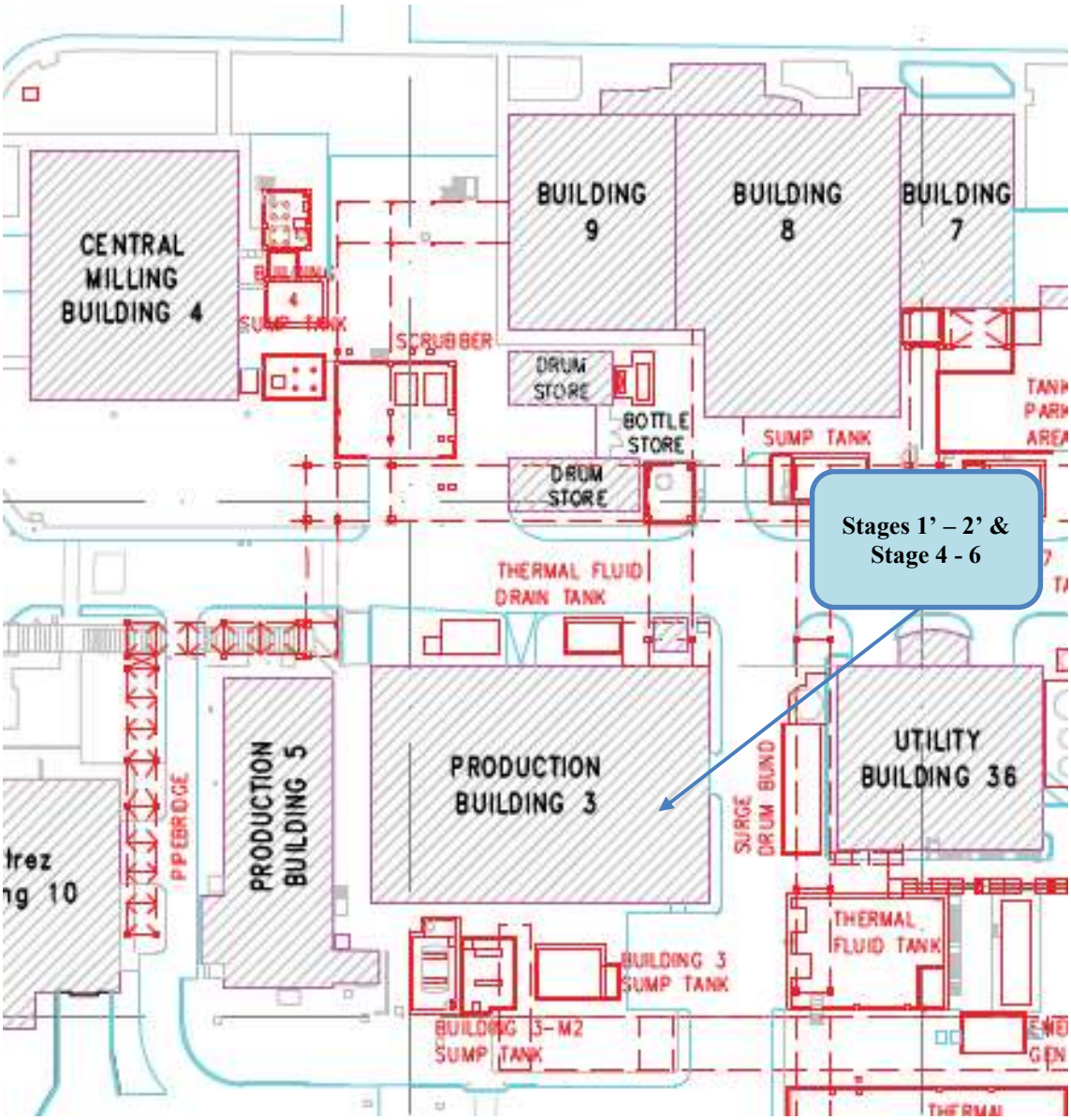

Figure 1.1 Site Layout and Location of Proposed Process for Project MARK

2. Process Description

As outlined above, there is no change to the range of processes to be carried out in Building 3. The proposed product will be generated in 5 stages with each stage comprising a number of unit operations.

The following main unit operations that will occur in the proposed process stages include:

- Charging of solvent and reagents

- Mixing in standard vessels
- Chemical reaction
- Distillation
- Separation
- Drying in filter dryer
- Milling
- Storage of final product in product warehouse.

Raw materials outlined in Table 2.1 will be subjected to various physical and chemical changes in order to produce the required chemical in the correct form. As a result, solid, liquid and gaseous emissions are generated. These emissions are subjected to physical and chemical treatment to remove any environmentally sensitive substances in accordance with IE Licence Reg. No. P0004-06 prior to discharge from the facility.

No changes to the existing abatement, treatment or recovery systems are required.

The associated environmental emissions for Project MARK are outlined in Figure 2.1.

TFS have reviewed the sites raw materials database and no new H phrases arise from the new raw materials on site. All new wastes to the incinerator are assessed in terms of compatibility with current waste streams as per standard operating procedure ENVP-063 Bulk Waste Characterisation and Storage Compatibility.

In addition, the incinerator burner management system and other critical safety interlocks are monitored and controlled by a Hima-Sella Programmable Logic Controller (PLC-19-004). PLC-19-004 is a dedicated Safety System associated with the incinerators. This will shut down the incinerator in the event of an exceedance of a safety parameter.

Figure 2.1 Project MARK Associated Environmental Emissions (Building 3)

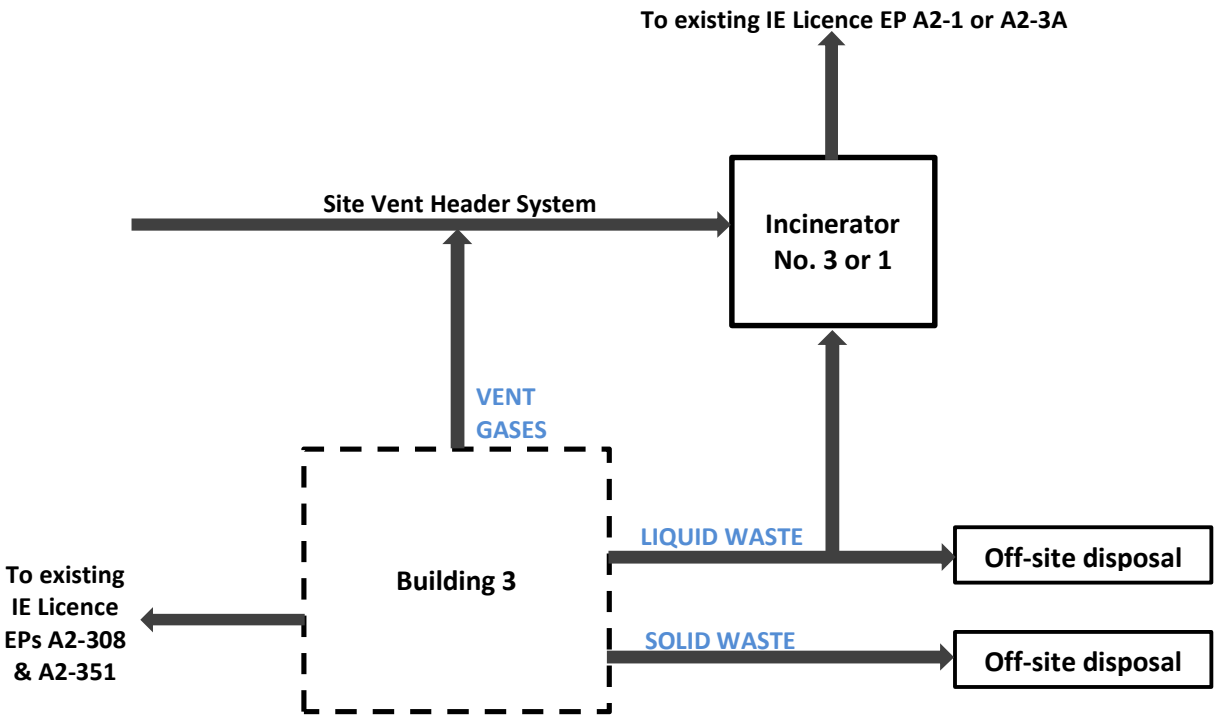

Table 2.1 Raw Materials Associated with Project MARK

Raw Material	New or Existing to Site	SDS Hazard Phrases (Further details in attachment for new chemicals)
Stage 1'		
MSC2741260A	New	H302
Sodium Acetate	Existing	Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.
Hydroxylamine hydrochloride	New	H302 + H312, H315, H317, H319, H351, H373, H400, H290
Ethanol (IMS)	Existing	H302, H332, H319, H371, H225
Water	Existing	n/a

Raw Material	New or Existing to Site	SDS Hazard Phrases (Further details in attachment for new chemicals)
Stage 2'		
MSC2741265A	New	Classification currently unavailable. Note any potential residual wastes will be incinerated.
Potassium Carbonate	New	H302, H315, H319, H335
Dimethyl Sulfoxide (DMSO)	Existing	Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.
Acetic anhydride	Existing	H302, H312, H330, H226
Water	Existing	n/a
Dichloromethane (DCM)	Existing	H315, H319, H336, H351, H373
Aluminium Oxide	New	Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.
Toluene	Existing	H304, H315, H336, H361d, H373, H226
Stage 4		
MSC2686659A	New	H302+H312+H332, H315, H319, H335
MSC2596854A	New	H315, H319, H335
Tris(Dibenzylideneacetone)Dipalladium(0) (Catalyst Pd2dba3)	New	H317, H411
S-Phos	New	Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.
Toluene	Existing	H304, H315, H336, H361d, H373, H225
Potassium hydroxide	New	H302, H314, H335, H290
Water	Existing	n/a
Ethyl Acetate	Existing	H319, H336, H225
N-Acetyl-L-cysteine	Existing	H319
Heptane	Existing	H304, H315, H336, H225

Raw Material	New or Existing to Site	SDS Hazard Phrases (Further details in attachment for new chemicals)
Stage 5		
MSC2685369A	New	Classification currently unavailable. Note any potential residual wastes will be incinerated.
Ethyl Acetate	Existing	H319, H336, H225
Hydrochloric Acid (HCl)	Existing	H314, H335, H225
Sodium Hydroxide	Existing	H314, H290
Water	Existing	n/a
Potassium Carbonate	New	H302, H315, H319, H335
Stage 6		
MSC2584939B	New	Classification currently unavailable. Note any potential residual wastes will be incinerated.
Potassium Carbonate	New	H302, H315, H319, H335
Water	Existing	n/a
Ethanol (IMS)	Existing	H302, H319, H371, H226
MSC2584939A API	New	Classification currently unavailable. Note any potential residual wastes will be incinerated.

3. Emissions

3.1 Emissions to Atmosphere

There are no new main or minor emission points to atmosphere. As outlined above, the process will use existing modules and associated vent lines and abatement measures. As illustrated in Figure 2.1, all organic vapours from the process will be vented to the onsite abatement system incinerator IN1931 or incinerator IN1951 (Licensed emission points A2-1 and A2-3A) via each buildings vent header system.

Venting from any dust handling activities such as solids charging, solids dig out, filters, dryers and from milling will be double HEPA filtered and routed to existing IE Licenced emission points A2-308 and A2-351.

3.1.1 Parameters from the Process

Parameters expected to arise in the emissions to air from the new process before it reaches the onsite abatement system (incinerator IN1931/ incinerator IN1951 (Licensed emission points A2-1/A2-3A)) are outlined in the following Table 3.1 along with the associated IE Licence ELVs.

Table 3.1 Parameters from the proposed new process to incinerator IN1931/ incinerator IN1951

Gaseous Waste pre abatement	Chemical Formula	Combustion Products	ELV in Licence Daily Average (mg/m^3)
Stage 1'			
IMS	C_2H_6O	CO, CO_2, H_2O	CO: 50
Stage 2'			
Dichloromethane, Dimethyl sulfoxide	CH_2Cl_2 C_2H_6OS	CO, CO_2, H_2O, HCl, SO_2	CO: 50 HCl: 10 SO_2: 50
Stage 4			
Toluene, Heptane, Ethyl Acetate	C_7H_8 C_7H_{16} $C_4H_8O_2$	CO, CO_2, H_2O	CO: 50
Stage 5			
HCl, Ethyl acetate, CO_2, Isobutylene	HCl $C_4H_8O_2$ CO_2 C_4H_8	CO, CO_2, H_2O, HCl	CO: 50 HCl: 10

Gaseous Waste pre abatement	Chemical Formula	Combustion Products	ELV in Licence Daily Average (mg/m³)
Stage 6			
IMS, CO_2	C_2H_6O CO_2	CO, CO_2, H_2O	CO: 50

It is assumed the maximum concentrations are above the relevant BAT threshold values and appropriate abatement in the form of incineration is being employed. As this is a batch process, gaseous emissions from this process to the vent header system and incineration are not continuous.

In both incinerators on site (A2-1 and A2-3A) waste liquids (see Table 3.2a below) and vent gases are incinerated at a temperature of 1150°C, in 5% excess oxygen and a two second residence time to ensure complete destruction of all organic components to CO_2 and H_2O. In addition, SO_2 and HCl would be anticipated from S and Cl containing wastes. No other combustion products are expected from the burning of liquid wastes and vent gases from the proposed process.

The following ELVs and continuous monitoring are in place within the IE Licence for both incinerators to address combustion products from all wastes incinerated.

Parameter	Units	Half Hour Average		Daily Average	10-minute average
Carbon monoxide (CO) Note 1	mg/m³	100		50	150
		Column A	Column B		
Total dust	mg/m³	30	10	10	-
Volatile organic compounds expressed as total organic carbon	mg/m³	20	10	10	-
Hydrogen chloride (HCl)	mg/m³	60	10	10	-
Hydrogen fluoride (HF)	mg/m³	4	2	1	-
Hydrogen bromide (HBr)	mg/m³	5	3	2	-
Sulphur dioxide (SO_2)	mg/m³	200	50	50	-
Oxides of Nitrogen (NO and NO_2 expressed as NO_2)	mg/m³	400	200	200	-

Parameter	Sampling Period	Emission Limit Value
Cadmium (as Cd) + thallium (as Tl), and their compounds Note 2	30minute – 8-hour sample	Total 0.05 mg/m³
Mercury (as Hg) and its compounds Note 2	30minute – 8-hour sample	0.05 mg/m³
Antimony (as Sb), arsenic (as As), lead (as Pb), chromium (as Cr), cobalt (as Co), copper (as Cu), manganese (as Mn), nickel (as Ni), and vanadium (as V) and their compounds Note 2	30minute – 8-hour sample	Total 0.5 mg/m³
Dioxins/furans (TEQ) Note 3	6 – 8-hour sample	0.1 ng/m³

No ELV including the flow ELV is likely to be exceeded during the manufacture of the new product. For context, Incinerator No. 3 was designed to burn up to 10,000 MT of hazardous waste per year and Incinerator No. 1 7,000 MT within the limits of our IE Licence. In 2022, a total of 3,671 MT of hazardous waste in total was burned on site. Therefore, there is significant spare capacity in terms of compliant incineration on site.

Notwithstanding the above, incinerator performance and emissions profiles will be monitored carefully during each new campaign on site.

It is not possible to estimate the pre-abatement particulate emissions concentrations for the emission point from the dust handling activities i.e. A2-308 and A2-351. There is no change in the dust handling activities and the same abatement measures (double HEPA filtration with >99.99% removal efficiencies) will be in place as for the particulate emission points attached to the process on site.

For existing emission points A2-308 and A2-351 the following monitoring programme will be put in place with 'Element Ireland' (ISO 17025 accredited) and in accordance with the requirements of EPA Air Emission Monitoring Guidance Note AG2.

Monitoring for total particulate matter (TPM), velocity and volumetric flow rate will be carried out in accordance with the following standards:

	Monitoring			
Parameter	Standard	Technical Procedure	Sampling Status	Testing Lab
Total Particulate Matter	EN 13284-1	CAT-TP-01	MCERTS	EET
Water Vapour	EN 14790	CAT-TP-05	MCERTS	EET
Velocity & Vol. Flow Rate	EN 16911-1 (MID)	CAT-TP-41	MCERTS	EET

Results will be compared against the following emission limits as specified within Schedule B.1 of the IE Licence to demonstrate that the emissions remain minor in nature:

Parameter	Emission Limit Value
Total Particulates	1 mg/m^3
Pharmaceutical dust - as active ingredient	0.15 mg/ m^3 at a mass flow >1 g/hour.

The above emission limit values apply to the following emission points as outlined in Schedule C.1.2 of the sites IE Licence:

Emission Point Reference Nos.: A2-12, A2-13, A2-14, A2-112, A2-116, A2-123, A2-124, A2-128, A2-146, A2-149, A2-150, A2-152, A2-162, A2-163, A2-166, A2-301, A2-303, A2-308, A2-316, A2-317, A2-318, A2-319, A2-320, A2-325, A2-328, A2-338, A2-339, A2-340, A2-341, A2-342, A2-343, A2-344, A2-345, A2-346, A2-347, A2-348, A2-351, A2-352, A2-353, A2-354, A2-355, A2-357 - A2-366 (inclusive).

Parameter	Monitoring Frequency	Analysis Method/Technique
Total particulates	Annually	Isokinetic/Gravimetric

3.2 Aqueous Emissions

As illustrated in Figure 2.1, aqueous waste will be routed to:

- either of the on-site incinerators IN1931/IN1951 which includes Licensed air emission points A2-1/A2-3A and internal aqueous emission point W1.
- Or offsite to an approved and permitted hazardous waste facility.

Tables 3.2a and 3.2b provides an overview of the constituents of aqueous waste streams.

Table 3.2a Liquid Waste Streams to On Site Incinerator

Waste Stream, L/Batch, Approx Composition	Chemical Formula	Combustion Products	ELV in Licence Daily Average (mg/m^3)
Stage 1'			
Stage 1' distillate and cake wash waste, 751 L. Constituents include IMS, water.	C_2H_6O H_2O	CO, CO_2, H_2O	CO: 50
Stage 2'			
Stage 2' cake wash waste (2 washes), 987.5 L. Constituents include DMSO, DCM, water.	C_2H_6OS CH_2Cl_2 H_2O	CO, CO_2, H_2O, SO2, HCl	CO: 50 HCl: 10 SO_2: 50
Stage 2' distillate waste, 490 L. Constituents include DCM.	CH_2Cl_2	CO, CO_2, H_2O, HCl	CO: 50 HCl: 10
Stage 2' solid filtration waste, 60 L. Constituents include Aluminum Oxide in Toluene.	Al_2O_3 C_7H_8	CO, CO_2, H_2O	CO: 50
Stage 4			
Stage 4 phase split waste (2 splits), 166 L. Constituents include Water, Potassium hydroxide.	KOH H_2O	CO, CO_2, H_2O	CO: 50
Stage 4 distillate waste, 581 L. Constituents include Ethyl Acetate, Toluene.	$C_4H_8O_2$ C_7H_8	CO, CO_2, H_2O	CO: 50
Stage 4 cake wash waste, 45 L. Constituents include Toluene, n-Heptane.	C_7H_8	CO, CO_2, H_2O	CO: 50

Waste Stream, L/Batch, Approx Composition	Chemical Formula	Combustion Products	ELV in Licence Daily Average (mg/m³)
	C_7H_{16}		
Stage 5			
Stage 5 mother liquor/cake wash waste, 30 L. Constituents include Ethyl Acetate, Water, HCl, KCl, Caustic.	$C_4H_8O_2$ H_2O HCl KCl NaOH	CO, CO_2, H_2O, HCl	CO: 50 HCl: 10
Stage 6			
Stage 6 cake wash waste, 1,150 L. Constituents include Potassium Carbonate, Water.	K_2CO_3 H_2O	CO, H_2O, CO_2	CO: 50

Table 3.2b Liquid Waste Stream for Off-Site Recovery

Waste Stream, L/Batch, Approx Composition	Chemical Formula	Qty	Treatment
Stage 4			
Stage 1 phase split waste (2 splits), 193 L. Constituents include Water, N-Acetyl-L-cysteine, Potassium Hydroxide, Solid Palladium.	H_2O C_2H_6O $C_5H_9NO_3S$ Pd	193L	Palladium Recovery

3.3 Emissions to Sewer

There are no emissions to sewer from the ThermoFisher site.

4. Solid Waste Generation and Disposal

All solid waste will be sent off site for incineration, in line with existing site procedures and IE Licence requirements.

Table 4.1 Solid Waste for off-site incineration

Solid Waste Material	Quantity (kg)	Further Treatment	Recovery / Reuse / Recycle	Final Disposal
Bags/liners etc.	2.5 drums approx. per batch	n/a	n/a	Off-site incineration

5. SDS Hazardous Data for <u>new</u> chemicals, raw materials and products to site

Item	H Phrase
MSC2741260A	**SECTION 2: Hazards identification** **2.1 Classification of the substance or mixture** **Classification according to Regulation (EC) No 1272/2008** Acute toxicity,oral,Category 4,H302 For the Full text of H- and EUH-phrases mentioned in this Section: see SECTION 16. **2.2 Label elements** **Labelling according to Regulation (EC) No 1272/2008** **Hazard pictograms**  **Signal word** **Hazard statements** H302 Harmful if swallowed **Precautionary statements** P264 Wash skin thouroughly after handling. P270 Do not eat, drink or smoke when using this product. P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. P330 Rinse mouth. P501 Dispose of contents/container to an approved waste disposal plant. **Supplemental Hazard information** None. **2.3 Other hazards** This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

Item	H Phrase
Hydroxylamine hydrochloride	**SECTION 2: Hazards identification** **2.1 Classification of the substance or mixture** **Classification according to Regulation (EC) No 1272/2008** Corrosive to Metals (Category 1), H290 Acute toxicity, Oral (Category 4), H302 Acute toxicity, Dermal (Category 4), H312 Skin irritation (Category 2), H315 Eye irritation (Category 2), H319 Skin sensitization (Category 1), H317 Carcinogenicity (Category 2), H351 Specific target organ toxicity - repeated exposure, Oral (Category 2), spleen, H373 Short-term (acute) aquatic hazard (Category 1), H400 For the full text of the H-Statements mentioned in this Section, see Section 16. **2.2 Label elements** **Labelling according Regulation (EC) No 1272/2008** Pictogram  Signal word: Warning Hazard statement(s) H290: May be corrosive to metals. H302 + H312: Harmful if swallowed or in contact with skin. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. H351: Suspected of causing cancer. H373: May cause damage to organs (spleen) through prolonged or repeated exposure if swallowed. H400: Very toxic to aquatic life. Precautionary statement(s) P273: Avoid release to the environment. P280: Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection. P301 + P312: IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. P302 + P352 + P312: IF ON SKIN: Wash with plenty of water.Call a POISON CENTER/ doctor if you feel unwell. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308 + P313: IF exposed or concerned: Get medical advice/ attention. Supplemental Hazard Statements: none **Reduced Labeling (<= 125 ml)** Pictogram  Signal word: Warning Hazard statement(s) H317: May cause an allergic skin reaction. H351: Suspected of causing cancer. Precautionary statement(s) P280: Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection. P308 + P313: IF exposed or concerned: Get medical advice/ attention. Supplemental Hazard Statements: none **2.3 Other hazards** This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Item	H Phrase
Potassium Carbonate	**2. Hazard identification**

Hazard Classification

Health Hazards

Acute toxicity (Oral)	Category 4
Skin Corrosion/Irritation	Category 2
Serious Eye Damage/Eye Irritation	Category 2A
Specific Target Organ Toxicity - Single Exposure	Category 3

Unknown toxicity - Health

Acute toxicity, inhalation, dust or mist	100 %

Label Elements

Hazard Symbol:

Signal Word: Warning

Hazard Statement: Harmful if swallowed.
Causes skin irritation.
Causes serious eye irritation.
May cause respiratory irritation.

Precautionary Statements

Prevention: Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection. Avoid breathing dust/fume/gas/mist/vapors/spray. Use only outdoors or in a well-ventilated area.

Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF ON SKIN: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Take off contaminated clothing. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF INHALED: Call a POISON CENTER or doctor/physician if you feel unwell.

Storage: Store in a well-ventilated place. Keep container tightly closed. Store locked up.

Disposal: Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

Other hazards which do not result in GHS classification: None.

Item	H Phrase
Aluminium Oxide	**SECTION 2: Hazards identification** **2.1 Classification of the substance or mixture** Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008. **2.2 Label elements** Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008. **2.3 Other hazards** This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
MSC2686659A	SECTION 3 - HAZARDS IDENTIFICATION Harmful if swallowed, inhaled or absorbed through skin. Material may be irritating to tissue of the mucous membranes and upper respiratory tract, eyes and skin.
MSC2596854A	**III. Hazards identification** Label precautionary statements "irritant": irritating to eyes, respiratory system and skin. In case of contact with eyes, rinse immediately with plenty of Water and seek medical advice. Wear suitable gloves and eye/face protection. **3.2 GHS Label elements, including precautionary statements** Pictogram  **Hazard statement(s)** H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation. **Precautionary statement(s)** P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray. P264 Wash skin thoroughly after handling. P271 Use only outdoors or in a well-ventilated area. P280 Wear protective gloves/ eye protection/ face protection. P302 + P352 IF ON SKIN: Wash with plenty of soap and water. P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312 Call a POISON CENTER or doctor/ physician if you feel unwell. P321 Specific treatment (see supplemental first aid instructions on this label). P332 + P313 If skin irritation occurs: Get medical advice/ attention. P337 + P313 If eye irritation persists: Get medical advice/ attention. P362 Take off contaminated clothing and wash before reuse. P403 + P233 Store in a well-ventilated place. Keep container tightly closed. P405 Store locked up. P501 Dispose of contents/ container to an approved waste disposal plant

Item	H Phrase
Catalyst Pd2dba3	**SECTION 2: Hazards identification** **2.1 Classification of the substance or mixture** **Classification according to Regulation (EC) No 1272/2008** Skin sensitization (Category 1), H317 Long-term (chronic) aquatic hazard (Category 2), H411 For the full text of the H-Statements mentioned in this Section, see Section 16. **2.2 Label elements** **Labelling according Regulation (EC) No 1272/2008** Pictogram  Signal word: Warning Hazard statement(s) H317: May cause an allergic skin reaction. H411: Toxic to aquatic life with long lasting effects. Precautionary statement(s) P261: Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray. P272: Contaminated work clothing should not be allowed out of the workplace. P273: Avoid release to the environment. P280: Wear protective gloves. P302 + P352: IF ON SKIN: Wash with plenty of water. P333 + P313: If skin irritation or rash occurs: Get medical advice/ attention. Supplemental Hazard Statements: none **Reduced Labeling (<= 125 ml)** Pictogram  Signal word: Warning Hazard statement(s) H317: May cause an allergic skin reaction. Precautionary statement(s) P261: Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray. P272: Contaminated work clothing should not be allowed out of the workplace. P280: Wear protective gloves. P302 + P352: IF ON SKIN: Wash with plenty of water. P333 + P313: If skin irritation or rash occurs: Get medical advice/ attention. Supplemental Hazard Statements: none **2.3 Other hazards** This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
S-Phos	**SECTION 2: Hazards identification** **2.1 Classification of the substance or mixture** Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. **2.2 Label elements** Not a hazardous substance or mixture. **2.3 Other hazards** This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Item	H Phrase
Potassium hydroxide	**2. Hazard(s) identification** **Classification** This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200) Corrosive to metals — Category 1 Acute oral toxicity — Category 4 Skin Corrosion/Irritation — Category 1 A Serious Eye Damage/Eye Irritation — Category 1 Specific target organ toxicity (single exposure) — Category 3 Target Organs - Respiratory system. **Label Elements** **Signal Word** Danger **Hazard Statements** May be corrosive to metals Harmful if swallowed Causes severe skin burns and eye damage May cause respiratory irritation  **Precautionary Statements** **Prevention** Wash face, hands and any exposed skin thoroughly after handling Do not eat, drink or smoke when using this product Do not breathe dust/fume/gas/mist/vapors/spray Wear protective gloves/protective clothing/eye protection/face protection Use only outdoors or in a well-ventilated area Keep only in original container **Response** Immediately call a POISON CENTER or doctor/physician **Inhalation** IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing **Skin** IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower Wash contaminated clothing before reuse **Eyes** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing **Ingestion** Rinse mouth Do NOT induce vomiting **Spills** Absorb spillage to prevent material damage **Storage** Store locked up Store in a well-ventilated place. Keep container tightly closed Store in corrosive resistant polypropylene container with a resistant inliner Store in a dry place **Disposal** Dispose of contents/container to an approved waste disposal plant **Hazards not otherwise classified (HNOC)** None identified
MSC2685369A	**2. Hazards identification** G3 substance. This substance is not classified as dangerous according to European Union legislation.
MSC2584939B	**2. Hazards identification** G3 substance. This substance is not classified as dangerous according to European Union legislation.
MSC2584939A API	**2. Hazards identification** G3 substance. This substance is not classified as dangerous according to European Union legislation.