

Pfizer Ireland Pharmaceuticals  
Ringaskiddy Active Pharmaceutical Ingredient Plant  
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## Pfizer Ireland Pharmaceuticals



Enforcement Team B,  
Office of Environmental Enforcement,  
South/South West Region,  
Environmental Protection Agency,  
Inniscarra,  
Co. Cork.

**14-Jul-2021**

**Ref. IE Licence Register Number P0013-05 (Pfizer Ringaskiddy)**

**Re: For Agency Approval: Update to site inventory of materials:**

Dear Sir/Madam,

We wish to note that it's planned to introduce the following new materials on site.

1. PF-06955943-01 [TYK 2/JAK 1]
2. Acetophenone and Benzyl alcohol

1. PF-06955943-01 [TYK 2/JAK 1]

It's planned to introduce PF-06955943-01 [TYK 2/JAK 1] to conduct trials on continuous manufacturing equipment in the Kilo Technology Laboratory, KTL. Generally Active Pharmaceutical Ingredients [API's] are manufactured on a batch basis by organic synthesis using unit operations such as crystallisation, isolation, filtration and drying. All API manufactured to date in Ringaskiddy is on a batch basis.

Continuous manufacturing involves the non-stop manufacture of a product in one continuous manufacturing process. It involves a more efficient method of API manufacture which transitions away from traditional batch reactors to a continuous process by organic synthesis using the same unit operations as described above. This technology will enable faster, more standardized and efficient start-up of small molecule API's. Continuous

manufacturing techniques are becoming more common in the pharmaceutical industry. Pfizer Ringaskiddy plan to conduct trials on this technique in the KTL facility.

The KTL plan to trial a continuous manufacturing skid for approximately 12 weeks. While the equipment will be in use for approximately 12 weeks, it's planned to conduct trials with this product for an approximate period of time up to 4-6 weeks. For the remaining time, trials will be conducted using existing pre-approved API's.

SDS for PF-06955943-01 is attached in Appendix 1. We confirm that this material doesn't have any Hazard [H] phrases.

We confirm that there are no new parameters introduced in emissions to air. PF-06955943-01 is a solid and non-volatile. It's dissolved in 2-Methyl-THF/methanol/water in a dissolution vessel of 20 litre capacity approximately. This vessel feeds the 1 litre vessels that are part of the skid which in turn feed the filtration chambers. Isopropanol is used for the cake washes. Air emissions associated with the trials will consist mostly of nitrogen, which must be added to the vessel for safety purposes to ensure headspace inertion. The skid consists of 5 chambers, at any one time, each chamber will only contain 30mls. Cake is filtered and washed in each chamber. Process is run at a temperature of < 5°C except the drying process. Emissions from the continuous manufacturing skid and vessel are vented through one vent which is connected to the scrubber and carbon bed and exhausted through previously approved minor emission point 201 M 003. The predicted volumetric flow through minor emission point 201M003 from the trials is 3.5m<sup>3</sup>/hr nitrogen. Modelling was conducted on air emissions through the header from the continuous skid based on volumes of solvents [2-Methyl-THF and methanol] used. Results of the modelling confirm that VOC emissions are negligible from these trials.

Minor emission point 201M003 was approved by the Agency for the Kilo Technology Laboratory (KTL) on 17th August 2007 (EPA Ref: P0013-04/ap9nod.doc). We note that the Kilo laboratory is a standalone laboratory which focuses on improvements to organic synthesis efficiency, such as yield optimisation, non-isolation, crystallisation optimisation, reagent use optimisation, trial of new equipment, cycle time reduction, etc. The Kilo laboratory runs trials and pilots on a low-kilo scale and operates small scale skid-mounted equipment and fumehoods. The laboratory does not manufacture for commercial purposes or on a larger scale. Given the small-scale activities performed, the Kilo laboratory does not connect to any of the main on-site air abatement systems. However, in accordance with best practice for at-source reduction, the laboratory vessels have condensers and the laboratory incorporates an inline mini-scrubber/carbon cartridge.

Table 1:

Emission Point Code	Easting	Northing	Description of source of emission(s)	Emission details				Abatement system employed (if relevant)
				Parameter/ Material	mg/Nm <sup>3</sup>	kg/h	kg/year	
201M003	176474	064814	Kilo Technology Laboratory (vent from small skid mounted equipment)	Nitrogen, trace solvent	n/a <sup>Note 1</sup>	n/a <sup>Note 1</sup>	n/a <sup>Note 1</sup>	n/a <sup>Note 2</sup>

*Note 1: Air emission prior to treatment is nitrogen, which will have a volumetric flow rate of 3.5m<sup>3</sup>/hr*

*Note 2: Given the small-scale activities performed, the KTL does not connect to any of the main on-site air abatement systems. However, in accordance with best practice for at-source reduction, laboratory vessels have condensers and the laboratory incorporates an inline mini-scrubber/carbon cartridge. Minor emission point 201M003 was approved by the Agency for the Kilo Technology Laboratory (KTL) on 17th August 2007 (EPA Ref: P0013-04/ap9nod.doc).*

We confirm that waste streams from the continuous manufacturing skid will be sent off site for treatment. All waste from the KTL is transferred into drums and sent off site for treatment. Waste from the KTL isn't treated in the WWTP. This process will generate one waste stream consisting of methanol/2-Methyl-THF/IPA/trace product and will be transferred to drums and sent off-site for treatment.

## 2. Acetophenone and Benzyl alcohol

We wish to note that it's planned to introduce Acetophenone and Benzyl alcohol for the purposes of chromatography trials in the KTL facility.

As stated above, the Kilo laboratory is a standalone laboratory which focuses on improvements to organic synthesis efficiency, such as yield optimisation, reagent use optimisation, trial of new equipment, trial of new techniques, etc. They are in the process of developing the capability using chromatography to separate an Active Pharmaceutical Ingredient [API] from an impurity.

The trial will consist of adding a mixture of the new proposed materials [acetophenone and Benzyl alcohol] to a silica gel chromatography column and eluting them with a mobile phase of Ethyl acetate/Isopropanol/hexane. The materials will be eluted with solvents, a portion of the fractions collected will be concentrated by distillation and the acetophenone and Benzyl alcohol materials will be isolated. Trials will be conducted on a demo chromatography skid. It's planned to conduct 10-15 runs, the separation of materials on each unit will take approximately 1hr. Column and associated vessels are operated at ambient temperature.

SDS for the materials are attached in Appendix 1. We confirm that no new Hazard [H] Phrases are being added to the Site Inventory of Materials. H302 [acute toxicity, oral] and H319 [eye irritation] are assigned to both materials and H332 [acute toxicity, inhalation] is also assigned to Benzyl alcohol. These H-Phrases are routinely used, materials with these H-Phrases were previously notified and approved by the Agency.

We confirm that there are no new parameters introduced in emissions to air. Acetophenone and Benzyl alcohol are non-volatile. Ethyl acetate/Isopropanol/hexane is used as mobile phase made up in DC 1101 vessel at ambient temperature. Vessel is inerted with nitrogen. Emissions from the vessel are connected to the scrubber and carbon bed and exhausted through previously approved minor emission point 201 M 003. The predicted volumetric flow through minor emission point 201M003 is 3.5m<sup>3</sup>/hr nitrogen which is the nitrogen sweep through the header system.

The chromatography skid is equipped with its own solvent/mobile phase storage vessel, column and fraction receiver vessels located in laminar Air Flow Booth DB-1171-01 which is connected to previously approved minor emission point 201M001. The predicted volumetric flow through minor emission point 201M001 is 14,000m<sup>3</sup>/hr

air based on extract fan design. Modelling was conducted on air emissions from the chromatography skid based on volumes used and the results of the modelling confirm that VOC emissions are negligible.

Table 2:

Emission Point Code	Easting	Northing	Description of source of emission(s)	Emission details				Abatement system employed (if relevant)
				Parameter/ Material	mg/Nm <sup>3</sup>	kg/h	kg/year	
201M003	176474	064814	Kilo Technology Laboratory (vent from small skid mounted equipment)	Nitrogen, trace solvent	n/a <sup>Note 1</sup>	n/a <sup>Note 1</sup>	n/a <sup>Note 1</sup>	n/a <sup>Note 2</sup>
201M001			Laminar Air Flow Booth DB-1171-01	Air, trace solvent	n/a <sup>Note 3</sup>	n/a <sup>Note 3</sup>	n/a <sup>Note 3</sup>	n/a <sup>Note 4</sup>

*Note 1: Air emission prior to treatment is nitrogen, which will have a volumetric flow rate of 3.5m<sup>3</sup>/hr*

*Note 2: Given the small-scale activities performed, the KTL does not connect to any of the main on-site air abatement systems. However, in accordance with best practice for at-source reduction, laboratory vessels have condensers and the laboratory incorporates an inline mini-scrubber/carbon cartridge. Minor emission point 201M003 was approved by the Agency for the Kilo Technology Laboratory (KTL) on 17th August 2007 (EPA Ref: P0013-04/ap9nod.doc).*

*Note 3: Air emission prior to treatment is nitrogen, which will have a volumetric flow rate of 14,000m<sup>3</sup>/hr*

*Note 4: Minor emission point 201M001 was approved by the Agency for the Kilo Technology Laboratory (KTL) on 17th August 2007 (EPA Ref: P0013-04/ap9nod.doc).*

We confirm that waste streams from the chromatography trials will be transferred to drums and sent off site for treatment. All waste from the KTL is transferred into drums and sent off site for treatment. Waste from the KTL isn't treated in the WWTP.

In summary, there will be no environmental impact resulting from the use of these materials in the KTL.

In accordance with Agency guidance, the Site Inventory of Materials shall be updated to include the above materials and shall be retained onsite for inspection by the Agency as required.

We trust that this is to the satisfaction of the Agency.

Yours sincerely,

**Pfizer Ireland Pharmaceuticals**  
Ringaskiddy Active Pharmaceutical Ingredient Plant

***Geraldine Rooney***

Geraldine Rooney  
Environment, Health and Safety Department

# Appendix 1:



# SAFETY DATA SHEET

Revision date: 31-Oct-2018

Version: 1.0

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** PF-06955943-01

**Trade Name:** Not established

**Chemical Family:** Not determined

**CAS Number:** Proprietary

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical process intermediate

### Details of the Supplier of the Safety Data Sheet

Pfizer WRD  
445 Eastern Point Road  
Groton, Connecticut  
USA  
1-800-879-3477

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

### Emergency telephone number (North America):

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

### Emergency telephone number (Australia):

International CHEMTREC (24 hours): +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

**GHS - Classification:** Not classified as hazardous

### US OSHA Specific - Classification

**Physical Hazard:** Combustible Dust

### Label Elements

**Signal Word:** Warning

**Hazard Statements:** May form combustible dust concentrations in air

### Other Hazards

An Occupational Exposure Value has been established for this substance ( see Section 8 ).

### Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
PF-06955943-01	Proprietary	Not Listed	Not Listed	100

**Additional Information:** Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of Exposure:** No data available

**Medical Conditions Aggravated by Exposure:** None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire. May include oxides of carbon and nitrogen and products of chlorine.

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

#### Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area thoroughly.

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**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Ground and bond all bulk transfer equipment. Avoid open handling. Minimize dust generation. Use local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

**Specific end use(s):** Pharmaceutical process intermediate

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

#### PF-06955943-01

**Pfizer Occupational Exposure Band (OEB):** OEB 3 - Contact Hazards Unknown (control exposure to the range of 10ug/m<sup>3</sup> to < 100ug/m<sup>3</sup>)

#### Exposure Controls

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

**Hands:** Wear 2 layers of impervious disposable gloves (e.g. Nitrile, etc.) to prevent skin contact. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:** Wear safety goggles as minimum protection. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:** Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:** Under normal conditions of use, if the applicable Occupational Exposure Band (OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Solid	<b>Color:</b>	White to off-white
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	C21 H27 Cl2 N7	<b>Molecular Weight:</b>	448.40
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
<b>PF-06955943-01</b>			
No data available			
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	No data available		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Viscosity:</b>	No data available		
<b>Flammability:</b>			
<b>Autoignition Temperature (Solid) (°C):</b>		No data available	
<b>Flammability (Solids):</b>		No data available	
<b>Flash Point (Liquid) (°C):</b>		No data available	
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>		No data available	
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>		No data available	

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products:</b>	No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

**General Information:** Toxicological properties have not been investigated.

**Carcinogen Status:** Not listed as a carcinogen by IARC, NTP or US OSHA.

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### 12. ECOLOGICAL INFORMATION

<b>Environmental Overview:</b>	Environmental properties have not been investigated. Releases to the environment should be avoided.
<b>Toxicity:</b>	No data available
<b>Persistence and Degradability:</b>	No data available
<b>Bio-accumulative Potential:</b>	No data available
<b>Mobility in Soil:</b>	No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is not regulated for transportation / carriage.

Transportation classification is based on data and/or procedures that may not be reflected on this document. The classification was conducted as per defining criteria in the international transportation regulations and the shipper's knowledge of the material.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

PF-06955943-01	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

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### 16. OTHER INFORMATION

**Data Sources:** Pfizer proprietary drug development information.  
**Revision date:** 31-Oct-2018  
Product Stewardship Hazard Communications  
**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**

**SAFETY DATA SHEET**

according to Regulation (EC) No. 1907/2006

Version 6.6

Revision Date 24.02.2021

Print Date 29.04.2021

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifiers**

Product name : Acetophenone

Product Number : W200905

Brand : Aldrich

Index-No. : 606-042-00-1

REACH No. : 01-2119533169-37-0007

CAS-No. : 98-86-2

**1.2 Relevant identified uses of the substance or mixture and uses advised against**

Identified uses : Laboratory chemicals, Manufacture of substances

**1.3 Details of the supplier of the safety data sheet**Company : Merck Life Science N.V.  
Haarlerbergweg 21 A  
1101 CH AMSTERDAM  
NETHERLANDS (THE)

Telephone : +31 078 620-5411

Fax : +31 078 620-5421

E-mail address : technischeservicebenelux@merckgroup.com

**1.4 Emergency telephone**Emergency Phone # : +(31)-858880596 (CHEMTREC)  
112 (Alarmnummer)**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

Eye irritation (Category 2), H319

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)	
H302	Harmful if swallowed.
H319	Causes serious eye irritation.
Precautionary statement(s)	
P301 + P312 + P330	IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Supplemental Hazard Statements	none

#### Reduced Labeling (<= 125 ml)

Pictogram	
Signal word	Warning
Hazard statement(s)	none
Precautionary statement(s)	none
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.

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## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Synonyms	:	Methyl phenyl ketone
Formula	:	C <sub>9</sub> H <sub>8</sub> O
Molecular weight	:	120,15 g/mol
CAS-No.	:	98-86-2
EC-No.	:	202-708-7
Index-No.	:	606-042-00-1

Component	Classification	Concentration
<b>acetophenone</b>		
CAS-No.	98-86-2	Acute Tox. 4; Eye Irrit. 2; H302, H319
EC-No.	202-708-7	
Index-No.	606-042-00-1	
		>= 90 - <= 100 %

For the full text of the H-Statements mentioned in this Section, see Section 16.



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## SECTION 4: First aid measures

### 4.1 Description of first-aid measures

#### General advice

Consult a physician. Show this material safety data sheet to the doctor in attendance.

#### If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

#### In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

#### In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

#### If swallowed

Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

### 4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

### 4.3 Indication of any immediate medical attention and special treatment needed

No data available

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

#### Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

#### Unsuitable extinguishing media

Do NOT use water jet.

### 5.2 Special hazards arising from the substance or mixture

Carbon oxides  
Combustible.

### 5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

### 5.4 Further information

Use water spray to cool unopened containers.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Beware of vapors accumulating to form explosive concentrations. Vapors can accumulate in low areas. For personal protection see section 8.

### 6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.



### 6.3 Methods and materials for containment and cleaning up

Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). Keep in suitable, closed containers for disposal.

### 6.4 Reference to other sections

For disposal see section 13.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

#### Advice on safe handling

Avoid contact with skin and eyes. Avoid inhalation of vapor or mist.

#### Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking. Take measures to prevent the build up of electrostatic charge.

#### Hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

For precautions see section 2.2.

### 7.2 Conditions for safe storage, including any incompatibilities

#### Storage conditions

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

### 7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

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## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Ingredients with workplace control parameters

### 8.2 Exposure controls

#### Personal protective equipment

##### Eye/face protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

##### Skin protection

The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.



### Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

### Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

### Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

a) Appearance	Form: clear, liquid Color: colorless
b) Odor	pleasant
c) Odor Threshold	No data available
d) pH	No data available
e) Melting point/freezing point	Melting point/freezing point: 20 °C
f) Initial boiling point and boiling range	202 °C at 1.013 hPa
g) Flash point	82 °C - closed cup - DIN 51758
h) Evaporation rate	No data available
i) Flammability (solid, gas)	No data available
j) Upper/lower flammability or explosive limits	Upper explosion limit: 5,2 %(V) Lower explosion limit: 1,4 %(V)
k) Vapor pressure	0,45 hPa at 25 °C
l) Vapor density	4,15 - (Air = 1.0)
m) Relative density	1,03 at 20 °C
n) Water solubility	6,3 g/l at 25 °C - soluble
o) Partition coefficient: n-octanol/water	log Pow: 1,61 at 25 °C - Bioaccumulation is not expected.
p) Autoignition temperature	535 °C at 1.013 hPa
q) Decomposition temperature	No data available



- r) Viscosity                      Viscosity, kinematic: No data available  
  Viscosity, dynamic: No data available
- s) Explosive properties    No data available
- t) Oxidizing properties    No data available

## 9.2 Other safety information

Surface tension            39,04 mN/m at 25 °C

Relative vapor density    4,15 - (Air = 1.0)

---

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No data available

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

No data available

### 10.4 Conditions to avoid

Heat, flames and sparks.

### 10.5 Incompatible materials

Strong oxidizing agents, Strong bases, Strong reducing agents

### 10.6 Hazardous decomposition products

In the event of fire: see section 5

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

No data available

#### Skin corrosion/irritation

No data available

#### Serious eye damage/eye irritation

No data available

#### Respiratory or skin sensitization

No data available

#### Germ cell mutagenicity

No data available

#### Carcinogenicity

IARC:        No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

#### Reproductive toxicity

No data available



**Specific target organ toxicity - single exposure**

No data available

**Specific target organ toxicity - repeated exposure**

No data available

**Aspiration hazard**

No data available

**11.2 Additional Information**

RTECS: AM5250000

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**SECTION 12: Ecological information****12.1 Toxicity**

No data available

**12.2 Persistence and degradability**

No data available

**12.3 Bioaccumulative potential**

No data available

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment**

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.

**12.6 Other adverse effects**

Harmful to aquatic life.

---

**SECTION 13: Disposal considerations****13.1 Waste treatment methods****Product**

Offer surplus and non-recyclable solutions to a licensed disposal company. Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

**Contaminated packaging**

Dispose of as unused product.

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**SECTION 14: Transport information****14.1 UN number**

ADR/RID: -

IMDG: -

IATA: 3334

**14.2 UN proper shipping name**

ADR/RID: Not dangerous goods





information in the document regarding the product remains unchanged and matches the product ordered. For further information please contact [mlsbranding@sial.com](mailto:mlsbranding@sial.com).



**SAFETY DATA SHEET**

according to Regulation (EC) No. 1907/2006

Version 7.0

Revision Date 25.11.2019

Print Date 29.04.2021

GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifiers**

Product name : Benzyl alcohol

Product Number : 108006

Brand : SIGALD

Index-No. : 603-057-00-5

REACH No. : 01-2119492630-38-XXXX

CAS-No. : 100-51-6

**1.2 Relevant identified uses of the substance or mixture and uses advised against**

Identified uses : Laboratory chemicals, Manufacture of substances

**1.3 Details of the supplier of the safety data sheet**

Company : Merck Life Science N.V.  
Haarlerbergweg 21 A  
1101 CH AMSTERDAM  
NETHERLANDS (THE)

Telephone : +31 078 620-5411

Fax : +31 078 620-5421

E-mail address : technischeservicebenelux@merckgroup.com

**1.4 Emergency telephone number**

Emergency Phone # : +(31)-858880596 (CHEMTREC)  
112 (Alarmnummer)

**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  
Acute toxicity, Inhalation (Category 4), H332  
Eye irritation (Category 2), H319

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

SIGALD- 108006

Page 1 of 9

The life science business of Merck operates as MilliporeSigma in the US and Canada



Hazard statement(s)	
H302 + H332	Harmful if swallowed or if inhaled.
H319	Causes serious eye irritation.
Precautionary statement(s)	
P301 + P312 + P330	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
P304 + P340 + P312	IF INHALED: Remove person to fresh air and keep comfortable for breathing. 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.
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.

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## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Synonyms	: Benzenemethanol
Formula	: C <sub>7</sub> H <sub>8</sub> O
Molecular weight	: 108,14 g/mol
CAS-No.	: 100-51-6
EC-No.	: 202-859-9
Index-No.	: 603-057-00-5

Component	Classification	Concentration
<b>Benzyl alcohol</b>		
	Acute Tox. 4; Eye Irrit. 2; H302, H332, H319	<= 100 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

---

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

#### If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

#### In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

#### In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.



**If swallowed**

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

**4.2 Most important symptoms and effects, both acute and delayed**

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

**4.3 Indication of any immediate medical attention and special treatment needed**

No data available

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**SECTION 5: Firefighting measures****5.1 Extinguishing media****Suitable extinguishing media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

**5.2 Special hazards arising from the substance or mixture**

Carbon oxides  
Combustible.

**5.3 Advice for firefighters**

Wear self-contained breathing apparatus for firefighting if necessary.

**5.4 Further information**

No data available

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**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation.

For personal protection see section 8.

**6.2 Environmental precautions**

Do not let product enter drains.

**6.3 Methods and materials for containment and cleaning up**

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

**6.4 Reference to other sections**

For disposal see section 13.

---

**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

Avoid contact with skin and eyes. Avoid inhalation of vapour or mist.

For precautions see section 2.2.

**7.2 Conditions for safe storage, including any incompatibilities**

Keep container tightly closed in a dry and well-ventilated place. Store in cool place.

Handle and store under inert gas. hygroscopic

**7.3 Specific end use(s)**

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated



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## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Components with workplace control parameters

### 8.2 Exposure controls

#### Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

#### Personal protective equipment

##### Eye/face protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

##### Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

##### Full contact

Material: butyl-rubber

Minimum layer thickness: 0,3 mm

Break through time: 480 min

Material tested: Butoject® (KCL 897 / Aldrich Z677647, Size M)

##### Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0,4 mm

Break through time: 43 min

Material tested: Camatril® (KCL 730 / Aldrich Z677442, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

##### Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

##### Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and



components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

### **Control of environmental exposure**

Do not let product enter drains.

---

## **SECTION 9: Physical and chemical properties**

### **9.1 Information on basic physical and chemical properties**

a) Appearance	Form: liquid
b) Odour	No data available
c) Odour Threshold	No data available
d) pH	No data available
e) Melting point/freezing point	Melting point/range: -16 - -13 °C
f) Initial boiling point and boiling range	203 - 205 °C
g) Flash point	101 °C - DIN 51758
h) Evaporation rate	No data available
i) Flammability (solid, gas)	No data available
j) Upper/lower flammability or explosive limits	Upper explosion limit: 13 %(V) Lower explosion limit: 1,3 %(V)
k) Vapour pressure	No data available
l) Vapour density	No data available
m) Relative density	1,045 g/mL at 25 °C
n) Water solubility	No data available
o) Partition coefficient: n-octanol/water	log Pow: 1,05 at 20 °C - Bioaccumulation is not expected.
p) Auto-ignition temperature	No data available
q) Decomposition temperature	No data available
r) Viscosity	No data available
s) Explosive properties	No data available
t) Oxidizing properties	No data available

### **9.2 Other safety information**

Dissociation constant 15,4 at 25 °C



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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No data available

### 10.2 Chemical stability

hygroscopic

Stable under recommended storage conditions.

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

No data available

### 10.4 Conditions to avoid

A mixture of benzyl alcohol and 58% sulfuric acid decomposed violently when heated to 180°C. Benzyl alcohol containing 1.4% hydrogen bromide and 1.1% of an iron(II) salt polymerized exothermally when heated above 100°C.

### 10.5 Incompatible materials

Strong oxidizing agents

### 10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides

Other decomposition products - No data available

In the event of fire: see section 5

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

LD50 Oral - Rat - male - 1.620 mg/kg

Remarks: (ECHA)

LD50 Oral - Rat - 1.230 mg/kg

Remarks: Behavioral:Somnolence (general depressed activity). Behavioral:Excitement. Behavioral:Coma.

LD50 Oral - Rat - male - 1.620 mg/kg

LC50 Inhalation - Rat - male and female - 4 h - > 4,178 mg/l  
(OECD Test Guideline 403)

Remarks: (Regulation (EC) No 1272/2008, Annex VI)

#### Skin corrosion/irritation

Skin - Rabbit

Result: No skin irritation - 4 h

(OECD Test Guideline 404)

#### Serious eye damage/eye irritation

Eyes - Rabbit

Result: irritating

(OECD Test Guideline 405)

Eyes - Rabbit

Result: slight irritation

(OECD Test Guideline 405)

Remarks: (Regulation (EC) No 1272/2008, Annex VI)

#### Respiratory or skin sensitisation

Maximisation Test



Result: negative  
(OECD Test Guideline 406)

### **Germ cell mutagenicity**

### **Carcinogenicity**

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

### **Reproductive toxicity**

#### **Specific target organ toxicity - single exposure**

No data available

#### **Specific target organ toxicity - repeated exposure**

No data available

### **Aspiration hazard**

No data available

### **Additional Information**

RTECS: DN3150000

Central nervous system depression

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Liver - Irregularities - Based on Human Evidence

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## **SECTION 12: Ecological information**

### **12.1 Toxicity**

Toxicity to fish	static test LC50 - Pimephales promelas (fathead minnow) - 460 mg/l - 96 h (US-EPA)
Toxicity to daphnia and other aquatic invertebrates	Immobilization EC50 - Daphnia magna (Water flea) - 230 mg/l - 48 h (OECD Test Guideline 202)
Toxicity to algae	static test ErC50 - Pseudokirchneriella subcapitata (green algae) - 700 mg/l - 72 h (OECD Test Guideline 201)

### **12.2 Persistence and degradability**

Biodegradability	aerobic - Exposure time 14 d Result: 92 - 96 % - Readily biodegradable. (OECD Test Guideline 301C) aerobic - Exposure time 21 d Result: 95 - 97 % - Readily biodegradable. (OECD Test Guideline 301A)
Biochemical Oxygen Demand (BOD)	1.550 mg/g Remarks: (Lit.)
Theoretical oxygen demand	2.515 mg/g Remarks: (IUCLID)
Ratio BOD/ThBOD	62 %





This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006. REACH - Restrictions on the manufacture, : placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)

## 15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out

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## SECTION 16: Other information

### Full text of H-Statements referred to under sections 2 and 3.

H302	Harmful if swallowed.
H302 + H332	Harmful if swallowed or if inhaled.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.

### Further information

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