

according to Regulation UK SI 2019/758 and UK SI 2020/1577 as amended

Creation Date 16-Sep-2011 Revision Date 13-Oct-2023 Revision Number 5

# SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Description: <u>OPTIZYME™ AAT II</u>

Cat No. : BP8041-1

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

Recommended Use Laboratory chemicals.
Uses advised against No Information available

1.3. Details of the supplier of the safety data sheet

Company

UK entity/business name

Fisher Scientific UK Bishop Meadow Road,

Loughborough, Leicestershire LE11 5RG,

United Kingdom

EU entity/business name

Thermo Fisher Scientific

Janssen Pharmaceuticalaan 3a, 2440 Geel,

Belgium

E-mail address begel.sdsdesk@thermofisher.com

1.4. Emergency telephone number

For information **US** call: 001-800-227-6701 / **Europe** call: +32 14 57 52 11 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No. **US**:001-800-424-9300 / **Europe**:001-703-527-3887

## **SECTION 2: HAZARDS IDENTIFICATION**

#### 2.1. Classification of the substance or mixture

CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567

## **Physical hazards**

Based on available data, the classification criteria are not met

#### **Health hazards**

Based on available data, the classification criteria are not met

#### **Environmental hazards**

OPTIZYME™ AAT II Revision Date 13-Oct-2023

Based on available data, the classification criteria are not met

Full text of Hazard Statements: see section 16

#### 2.2. Label elements

None required

#### 2.3. Other hazards

This product does not contain any known or suspected endocrine disruptors

## **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

### 3.2. Mixtures

Component	CAS No	EC No	Weight %	CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567
Water	7732-18-5	231-791-2	25 - 50	-
Glycerin	56-81-5	200-289-5	>50	-

Full text of Hazard Statements: see section 16

## **SECTION 4: FIRST AID MEASURES**

## 4.1. Description of first aid measures

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention.

**Skin Contact** Wash off immediately with plenty of water for at least 15 minutes. Get medical attention

immediately if symptoms occur.

Ingestion Rinse mouth. Never give anything by mouth to an unconscious person. Do NOT induce

vomiting. Get medical attention.

**Inhalation** Remove to fresh air. Get medical attention immediately if symptoms occur. If not breathing,

give artificial respiration.

Self-Protection of the First Aider No special precautions required.

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

No information available.

OPTIZYME™ AAT II Revision Date 13-Oct-2023

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

Notes to Physician Treat symptomatically.

## **SECTION 5: FIREFIGHTING MEASURES**

#### 5.1. Extinguishing media

#### **Suitable Extinguishing Media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Water spray, carbon dioxide (CO2), dry chemical, alcohol-resistant foam.

### Extinguishing media which must not be used for safety reasons

No information available.

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

No information available.

#### **Hazardous Combustion Products**

None under normal use conditions.

## 5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## **SECTION 6: ACCIDENTAL RELEASE MEASURES**

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

Ensure adequate ventilation.

#### 6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not flush into surface water or sanitary sewer system. See Section 12 for additional Ecological Information.

## 6.3. Methods and material for containment and cleaning up

Soak up with inert absorbent material. Use spark-proof tools and explosion-proof equipment.

#### 6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

## **SECTION 7: HANDLING AND STORAGE**

#### 7.1. Precautions for safe handling

Wear personal protective equipment/face protection. Ensure adequate ventilation.

#### **Hygiene Measures**

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

OPTIZYME™ AAT II Revision Date 13-Oct-2023

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

Keep container tightly closed in a dry and well-ventilated place. Store product at -20C.

Technical Rules for Hazardous Substances (TRGS) 510 Class 12 Storage Class (LGK) (Germany)

### 7.3. Specific end use(s)

Use in laboratories

## **SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1. Control parameters

## **Exposure limits**

List source(s): **UK** - EH40/2005 Work Exposure Limits, Fourth edition. Published 2020. **IRE** - 2021 Code of Practice for the Chemical Agents Regulations, Schedule 1. Published by the Health and Safety Authority

Component	The United Kingdom	European Union	Ireland
Glycerin	TWA: 10 mg/m <sup>3</sup> 8 hr (mist		TWA: 10 mg/m <sup>3</sup> 8 hr. (mist)
	only)		

### **Biological limit values**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

## Derived No Effect Level (DNEL) / Derived Minimum Effect Level (DMEL)

See table for values

Component	Acute effects local (Inhalation)	Acute effects systemic (Inhalation)	Chronic effects local (Inhalation)	Chronic effects systemic (Inhalation)
Glycerin 56-81-5 ( >50 )			DNEL = 56mg/m <sup>3</sup>	

## **Predicted No Effect Concentration (PNEC)**

See values below.

	Component	Fresh water	Fresh water	Water Intermittent	Microorganisms in	Soil (Agriculture)
L			sediment		sewage treatment	
Γ	Glycerin	PNEC = 0.885mg/L	PNEC = 3.3mg/kg	PNEC = 8.85mg/L	PNEC = 1000mg/L	PNEC =
L	56-81-5 ( >50 )	_	sediment dw	_		0.141mg/kg soil dw

	Component	Marine water	Marine water sediment	Marine water intermittent	Food chain	Air
	Glycerin	PNEC =	PNEC = 0.33mg/kg			
$\perp$	56-81-5 ( >50 )	0.0885mg/L	sediment dw			

#### 8.2. Exposure controls

### **Engineering Measures**

OPTIZYME™ AAT II Revision Date 13-Oct-2023

None under normal use conditions.

Personal protective equipment

**Eye Protection** Wear safety glasses with side shields (or goggles) (European standard - EN 166)

**Hand Protection** Protective gloves

Glove material Breakthrough time Glove thickness **EU** standard Glove comments See manufacturers **FN 374** Natural rubber (minimum requirement) Nitrile rubber recommendations Neoprene PVC

Long sleeved clothing. Skin and body protection

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

**Respiratory Protection** No protective equipment is needed under normal use conditions.

Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits Large scale/emergency use

are exceeded or if irritation or other symptoms are experienced

Liquid

Recommended Filter type: Particle filter

Maintain adequate ventilation Small scale/Laboratory use

**Environmental exposure controls** No information available.

## **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

## 9.1. Information on basic physical and chemical properties

**Physical State** Liquid

Colorless **Appearance** Odor Slight

**Odor Threshold** No data available Melting Point/Range No data available **Softening Point** No data available **Boiling Point/Range** No information available

Flammability (liquid) No data available Flammability (solid,gas) Not applicable

No data available **Explosion Limits** 

**Flash Point** Not applicable Method - No information available

Not applicable **Autoignition Temperature** No data available **Decomposition Temperature** Hq 7.4

Viscosity No data available

Water Solubility Miscible

Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

log Pow Component Glycerin -1.75

OPTIZYME™ AAT II Revision Date 13-Oct-2023

**Vapor Pressure** 

No data available

Density / Specific Gravity

No data available

Bulk Density Vapor Density Not applicable Liquid
No data available (Air = 1.0)

Particle characteristics

(liquid) Not applicable

9.2. Other information

## **SECTION 10: STABILITY AND REACTIVITY**

10.1. Reactivity

No

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous Polymerization Hazardous Reactions

No information available. No information available.

10.4. Conditions to avoid

No information available.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

None under normal use conditions.

## **SECTION 11: TOXICOLOGICAL INFORMATION**

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

### **Product Information**

(a) acute toxicity;

Oral Based on available data, the classification criteria are not met
Dermal Based on available data, the classification criteria are not met
Inhalation Based on available data, the classification criteria are not met

### Toxicology data for the components

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Water	-	-	=
Glycerin	12600 mg/kg ( Rat )	> 10 g/kg(Rabbit)	> 2.75 mg/L/4h ( Rat )(mist)

(b) skin corrosion/irritation; No data available

(c) serious eye damage/irritation; No data available

(d) respiratory or skin sensitization;

OPTIZYME™ AAT II Revision Date 13-Oct-2023

Respiratory No data available
Skin No data available

No information available

(e) germ cell mutagenicity; No data available

None known

(f) carcinogenicity; No data available

There are no known carcinogenic chemicals in this product

(g) reproductive toxicity; No data available

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure; No data available

Target Organs No information available.

(j) aspiration hazard; No data available

Symptoms / effects,both acute and No information available.

delayed

## 11.2. Information on other hazards

Endocrine Disrupting Properties Assess endocrine disrupting properties for human health. This product does not contain any

known or suspected endocrine disruptors.

## **SECTION 12: ECOLOGICAL INFORMATION**

12.1. Toxicity

Ecotoxicity effects

Component	Freshwater Fish	Water Flea	Freshwater Algae
Glycerin	LC50: 51 - 57 mL/L, 96h static (Oncorhynchus mykiss)		

## 12.2. Persistence and degradability

**Persistence** Miscible with water, Persistence is unlikely, based on information available.

## 12.3. Bioaccumulative potential

; Bioaccumulation is unlikely

Component	log Pow	Bioconcentration factor (BCF)
Glycerin	-1.75	No data available

12.4. Mobility in soil The product is water soluble, and may spread in water systems . Will likely be mobile in the

environment due to its water solubility. Highly mobile in soils

OPTIZYME™ AAT II Revision Date 13-Oct-2023

<u>assessment</u>

12.6. Endocrine disrupting

12.5. Results of PBT and vPvB

properties

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors

No data available for assessment.

12.7. Other adverse effects

Persistent Organic Pollutant
Ozone Depletion Potential

This product does not contain any known or suspected substance This product does not contain any known or suspected substance

## **SECTION 13: DISPOSAL CONSIDERATIONS**

13.1. Waste treatment methods

Waste from Residues/Unused

**Products** 

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Consult local, regional, and national hazardous waste regulations to

ensure complete and accurate classification.

Contaminated Packaging Empty remaining contents. Dispose of in accordance with local regulations. Do not re-use

empty containers.

European Waste Catalogue (EWC) According to the European Waste Catalog, Waste Codes are not product specific, but

application specific.

Other Information Waste codes should be assigned by the user based on the application for which the product

was used.

## **SECTION 14: TRANSPORT INFORMATION**

IMDG/IMO Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

ADR Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

IATA Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

OPTIZYME™ AAT II Revision Date 13-Oct-2023

**14.5. Environmental hazards**No hazards identified

**14.6. Special precautions for user** No special precautions required.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable, packaged goods

## **SECTION 15: REGULATORY INFORMATION**

## 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### **International Inventories**

Europe (EINECS/ELINCS/NLP), China (IECSC), Taiwan (TCSI), Korea (KECL), Japan (ENCS), Japan (ISHL), Canada (DSL/NDSL), Australia (AICS), New Zealand (NZIoC), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

Component	CAS No	EINECS	ELINCS	NLP	IECSC	TCSI	KECL	ENCS	ISHL
Water	7732-18-5	231-791-2	ı	ı	X	X	KE-35400	X	ı
Glycerin	56-81-5	200-289-5	-	-	Х	X	KE-29297	X	X

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	AICS	NZIoC	PICCS
Water	7732-18-5	X	ACTIVE	X	-	X	X	Х
Glycerin	56-81-5	Х	ACTIVE	Х	-	Х	Х	Х

Legend: X - Listed '-' - Not Listed KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

## Authorisation/Restrictions according to EU REACH

Not applicable

Component	CAS No	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization		REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
Water	7732-18-5	-	-	-
Glycerin	56-81-5	-	-	-

## Seveso III Directive (2012/18/EC)

Component	CAS No	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements
Water	7732-18-5	Not applicable	Not applicable
Glycerin	56-81-5	Not applicable	Not applicable

Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals

Not applicable

Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)? Not applicable

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work .

## **National Regulations**

OPTIZYME™ AAT II Revision Date 13-Oct-2023

UK - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment

**WGK Classification** Water endangering class = 1 (self classification)

Component	Germany - Water Classification (AwSV)	Germany - TA-Luft Class
Glycerin	WGK1	

#### 15.2. Chemical safety assessment

Chemical Safety Assessment/Reports (CSA/CSR) are not required for mixtures

### **SECTION 16: OTHER INFORMATION**

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

#### Legend

**CAS** - Chemical Abstracts Service

TSCA - United States Toxic Substances Control Act Section 8(b)

Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical DSL/NDSL - Canadian Domestic Substances List/Non-Domestic

Substances/EU List of Notified Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

**IECSC** - Chinese Inventory of Existing Chemical Substances

Substances List

**KECL** - Korean Existing and Evaluated Chemical Substances

**ENCS** - Japanese Existing and New Chemical Substances AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

**ACGIH** - American Conference of Governmental Industrial Hygienists

**DNEL** - Derived No Effect Level

RPE - Respiratory Protective Equipment

LC50 - Lethal Concentration 50%

NOEC - No Observed Effect Concentration

PBT - Persistent. Bioaccumulative. Toxic

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

Predicted No Effect Concentration (PNEC)

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%

POW - Partition coefficient Octanol:Water vPvB - very Persistent, very Bioaccumulative

ADR - European Agreement Concerning the International Carriage of

Dangerous Goods by Road

IMO/IMDG - International Maritime Organization/International Maritime

Dangerous Goods Code

Transport Association

**OECD** - Organisation for Economic Co-operation and Development

**BCF** - Bioconcentration factor

MARPOL - International Convention for the Prevention of Pollution from

ICAO/IATA - International Civil Aviation Organization/International Air

ATE - Acute Toxicity Estimate

VOC - (Volatile Organic Compound)

#### Key literature references and sources for data

https://echa.europa.eu/information-on-chemicals

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards On basis of test data **Health Hazards** Calculation method Calculation method **Environmental hazards** 

**Training Advice** 

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

16-Sep-2011 **Creation Date** 

OPTIZYME™ AAT II Revision Date 13-Oct-2023

Revision Date 13-Oct-2023 Revision Summary Not applicable.

This safety data sheet complies with Regulation UK SI 2019/758 and UK SI 2020/1577 as amended.

. . .

#### **Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

**End of Safety Data Sheet**