

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

Creation Date 31-Mar-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: (R)-N-FMOC-alpha-Methylvaline Cat No.: 441140000; 441141000; 441145000

Molecular Formula C21 H23 N O4

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

Recommended Use Laboratory chemicals. No Information available Uses advised against

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

Based on available data, the classification criteria are not met

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Full text of Hazard Statements: see section 16

2.2. Label elements

EUH210 - Safety data sheet available on request

2.3. Other hazards

Contains a known or suspected endocrine disruptor Contains a substance on the National Authorities Endocrine Disruptor Lists

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
(R)-N-FMOC-alpha-Methylvaline	616867-28-8		>90	-
Methyl tert-butyl ether	1634-04-4	EEC No. 216-653-1	<10	Flam. Liq. 2 (H225) Skin Irrit. 2 (H315)

Full text of Hazard Statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

General Advice If symptoms persist, call a physician.

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 Clean mouth with water and drink afterwards plenty of water. Get medical attention if

symptoms occur.

Inhalation Remove to fresh air. Get medical attention immediately if symptoms occur.

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

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

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None reasonably foreseeable.

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

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

Thermal decomposition can lead to release of irritating gases and vapors. Flammable.

Hazardous Combustion Products

Thermal decomposition can lead to release of irritating gases and vapors, Carbon monoxide (CO), Carbon dioxide (CO₂), Nitrogen oxides (NOx).

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. Use personal protective equipment as required. Avoid dust formation.

6.2. Environmental precautions

Should not be released into the environment. See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Sweep up and shovel into suitable containers for disposal. Avoid dust formation.

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. Avoid ingestion and inhalation. Avoid contact with skin, eyes or clothing. Avoid dust formation.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do

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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.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Store under an inert atmosphere. Keep refrigerated. Flammables area.

Technical Rules for Hazardous Substances (TRGS) 510 Class 11 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): **EU** - Commission Directive (EU) 2019/1831 of 24 October 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC **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
Methyl tert-butyl ether	STEL: 100 ppm 15 min	TWA: 50 ppm (8h)	TWA: 50 ppm 8 hr.
	STEL: 367 mg/m ³ 15 min	TWA: 183.5 mg/m ³ (8h)	TWA: 183.5 mg/m ³ 8 hr.
	TWA: 50 ppm 8 hr	STEL: 100 ppm (15min)	STEL: 100 ppm 15 min
	TWA: 183.5 mg/m ³ 8 hr	STEL: 367 mg/m ³ (15min)	STEL: 367 mg/m ³ 15 min

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 (Dermal)	Acute effects systemic (Dermal)	Chronic effects local (Dermal)	Chronic effects systemic (Dermal)
Methyl tert-butyl ether 1634-04-4 (<10)				DNEL = 5100mg/kg bw/dav

Component	Acute effects local (Inhalation)	Acute effects systemic (Inhalation)	Chronic effects local (Inhalation)	Chronic effects systemic (Inhalation)
Methyl tert-butyl ether 1634-04-4 (<10)	DNEL = 357mg/m ³			DNEL = 178.5mg/m ³

Predicted No Effect Concentration (PNEC)

See values below.

Component	Fresh water	Fresh water	Water Intermittent	Microorganisms in	Soil (Agriculture)
		sediment		sewage treatment	
Methyl tert-butyl ether	PNEC = 5.1mg/L	PNEC = 23mg/kg	PNEC = 47.2mg/L	PNEC = 71mg/L	PNEC = 1.56mg/kg
1634-04-4 (<10)	-	sediment dw	-		soil dw

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Component	Marine water	Marine water sediment	Marine water intermittent	Food chain	Air
Methyl tert-butyl ether	PNEC = 0.26mg/L	PNEC = 1.17mg/kg			
1634-04-4 (<10)		sediment dw			

8.2. Exposure controls

Engineering Measures

Ensure that eyewash stations and safety showers are close to the workstation location. Ensure adequate ventilation, especially in confined areas.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

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
Nitrile rubber	See manufacturers	-	EN 374	(minimum requirement)
Neoprene Natural rubber	recommendations			
PVC				

Skin and body protection Long sleeved clothing.

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.

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

are exceeded or if irritation or other symptoms are experienced

Small scale/Laboratory use Maintain adequate ventilation

Environmental exposure controls No information available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical State Solid

Appearance White

Odor Characteristic
Odor Threshold No data available

Melting Point/Range 37 - 53 °C / 98.6 - 127.4 °F

Softening Point No data available
Boiling Point/Range No information available

Flammability (liquid) Not applicable Solid

Flammability (solid,gas) No information available

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Solid

Solid

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Explosion Limits No data available

Flash Point No information available Method - No information available

Autoignition Temperature
Decomposition Temperature
pH

No data available
No data available
No information available

Viscosity Not applicable

Water Solubility No information available

Solubility in other solvents

No information available

Partition Coefficient (n-octanol/water)

Componentlog PowMethyl tert-butyl ether1.06

Vapor Pressure
Density / Specific Gravity
Bulk Density
Vapor Density
No data available
No data available
No data available
Not applicable

Particle characteristics No data available

9.2. Other information

Molecular Formula C21 H23 N O4 Molecular Weight 353.42

Evaporation Rate Not applicable - Solid

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

None known, based on information available

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

10.4. Conditions to avoid

Incompatible products. Excess heat. Avoid dust formation.

10.5. Incompatible materials

Strong oxidizing agents. Strong acids.

10.6. Hazardous decomposition products

Thermal decomposition can lead to release of irritating gases and vapors. Carbon monoxide (CO). Carbon dioxide (CO₂). Nitrogen oxides (NOx).

monoxide (CO). Carbon dioxide (CO2). Nitrogen oxides (NOX).

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

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

Toxicology data for the components

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Methyl tert-butyl ether	LD50 = 2963 mg/kg (Rat)	LD50 = 10000 mg/kg (Rabbit)	LC50 = 85 mg/L (Rat) 4 h

(b) skin corrosion/irritation; No data available

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

(d) respiratory or skin sensitization;

Respiratory No data available Skin No data available

(e) germ cell mutagenicity; No data available

(f) carcinogenicity; No data available

The table below indicates whether each agency has listed any ingredient as a carcinogen

(g) reproductive toxicity; No data available

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure; No data available

Target Organs None known.

(j) aspiration hazard; Not applicable

Solid

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

Contains a substance on the National Authorities Endocrine Disruptor Lists

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity Ecotoxicity effects

Component	Freshwater Fish	Water Flea	Freshwater Algae
Methyl tert-butyl ether	887 mg/L LC50 96 h	EC50: = 542 mg/L, 48h	800 mg/L EC50 > 72 h
	100 mg/L LC50 96 h	(Daphnia magna)	184 mg/L EC50 = 96 h
	929 mg/L LC50 96 h		-
	672 mg/L LC50 96 h		

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Component	Microtox	M-Factor
Methyl tert-butyl ether	EC50 = 11.4 mg/L 30 min	
	EC50 = 8.23 mg/L 5 min	
	EC50 = 9.67 mg/L 15 min	

12.2. Persistence and degradability No information available

12.3. Bioaccumulative potential No information available

Component	log Pow	Bioconcentration factor (BCF)
Methyl tert-butyl ether	1.06	No data available

12.4. Mobility in soil No information available .

12.5. Results of PBT and vPvB

assessment

No data available for assessment.

12.6. Endocrine disrupting

properties

Endocrine Disruptor Information

Assess endocrine disrupting properties for the environment

Contains a substance on the National Authorities Endocrine Disruptor Lists.

Component	EU - Endocrine Disrupters Candidate List	EU - Endocrine Disruptors - Evaluated
•		Substances
Methyl tert-butyl ether	Group III Chemical	

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

Waste is classified as hazardous. Dispose of in accordance with the European Directives on waste and hazardous waste. Dispose of in accordance with local regulations.

on waste and nazardous waste. Dispose of in accordance with local regulations.

Contaminated Packaging Dispose of this container to hazardous or special waste collection point. Empty containers

retain product residue, (liquid and/or vapor), and can be dangerous. Keep product and

empty container away from heat and sources of ignition.

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. Do not flush to sewer. Can be landfilled or incinerated, when in compliance with

local regulations. Do not empty into drains.

SECTION 14: TRANSPORT INFORMATION

IMDG/IMO

(R)-N-FMOC-alpha-Methylvaline

14.1. UN number UN3175

14.2. UN proper shipping name Solids containing flammable liquid, n.o.s

Technical Shipping Name Isopropyl alcohol

14.3. Transport hazard class(es) 4.1 Subsidiary Hazard Class + 14.4. Packing group II

ADR

14.1. UN number UN3175

14.2. UN proper shipping name Solids containing flammable liquid, n.o.s

Technical Shipping Name Isopropyl alcohol

14.3. Transport hazard class(es) 4.1 14.4. Packing group II

IATA

14.1. UN number UN3175

14.2. UN proper shipping name Solids containing flammable liquid, n.o.s

Technical Shipping Name Isopropyl alcohol

14.3. Transport hazard class(es) 4.1 14.4. Packing group II

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

OFOTION 45 DECLI ATORY INFORM

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
(R)-N-FMOC-alpha-Methylvaline	616867-28-8	-	-	-	-	-	-	-	-
Methyl tert-butyl ether	1634-04-4	216-653-1	-	-	Х	X	KE-23648	X	Х

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	AICS	NZIoC	PICCS
(R)-N-FMOC-alpha-Methylvaline	616867-28-8	-	-	-	-	-	-	-
Methyl tert-butyl ether	1634-04-4	X	ACTIVE	X	-	X	X	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

Component	CAS No	REACH (1907/2006) -	REACH (1907/2006) -	REACH Regulation (EC
		Annex XIV - Substances	Annex XVII - Restrictions	1907/2006) article 59 -
		Subject to Authorization	on Certain Dangerous	Candidate List of
			Substances	Substances of Very High
				Concern (SVHC)

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	(R)-N-FMOC-alpha-Methylvaline	616867-28-8	•	ı	-
Г	Methyl tert-butyl ether	1634-04-4	-	Use restricted. See item	-
				75.	
				(see link for restriction	
				details)	

REACH links

https://echa.europa.eu/substances-restricted-under-reach

Seveso III Directive (2012/18/EC)

Component	CAS No	, ,	, ,
		Notification	Requirements
(R)-N-FMOC-alpha-Methylva	616867-28-8	Not applicable	Not applicable
line			
Methyl tert-butyl ether	1634-04-4	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 .

Take note of Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values

National Regulations

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		
Methyl tert-butyl ether	WGK1			

Component	France - INRS (Tables of occupational diseases)
Methyl tert-butyl ether	Tableaux des maladies professionnelles (TMP) - RG 84

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

H225 - Highly flammable liquid and vapor

H315 - Causes skin irritation

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Legend

CAS - Chemical Abstracts Service

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

EINECS/ELINCS - European Inventory of Existing Commercial Chemical

Substances/EU List of Notified Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

IECSC - Chinese Inventory of Existing Chemical Substances **KECL** - Korean Existing and Evaluated Chemical Substances DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

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

OECD - Organisation for Economic Co-operation and Development

BCF - Bioconcentration factor

ICAO/IATA - International Civil Aviation Organization/International Air Transport Association

MARPOL - International Convention for the Prevention of Pollution from

Ships

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 **Environmental hazards** Calculation method

Training Advice

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

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit and standards.

First aid for chemical exposure, including the use of eye wash and safety showers.

31-Mar-2011 **Creation Date Revision Date** 13-Oct-2023

Revision Summary SDS sections updated.

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