

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

Creation Date 14-Mar-2013 Revision Date 20-Oct-2023 Revision Number 9

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

1.1. Product identifier

Product Description: <u>DL-Malic acid</u>
Cat No. : <u>DL-Malic acid</u>
M/1350/53

Synonyms DL-Hydroxysuccinic acid

 CAS No
 6915-15-7

 EC No
 230-022-8

 Molecular Formula
 C4 H6 O5

REACH registration number 01-2119552463-40-0007

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

Recommended Use Laboratory chemicals.

Sector of use SU3 - Industrial uses: Uses of substances as such or in preparations at industrial sites

Product category PC21 - Laboratory chemicals

Process categories PROC15 - Use as a laboratory reagent

Environmental release category ERC6a - Industrial use resulting in manufacture of another substance (use of intermediates)

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

Tel: 01509 231166

Chemtrec US: (800) 424-9300 Chemtrec EU: 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

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Based on available data, the classification criteria are not met

Health hazards

Serious Eye Damage/Eye Irritation

Category 2 (H319)

Environmental hazards

Based on available data, the classification criteria are not met

Full text of Hazard Statements: see section 16

2.2. Label elements



Signal Word

Warning

Hazard Statements

H319 - Causes serious eye irritation

Precautionary Statements

P264 - Wash face, hands and any exposed skin thoroughly after handling

P280 - Wear eye protection/ face protection

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P337 + P313 - If eye irritation persists: Get medical advice/attention

2.3. Other hazards

Substance is not considered persistent, bioaccumulative and toxic (PBT) / very persistent and very bioaccumulative (vPvB)

Toxic to terrestrial vertebrates

This product does not contain any known or suspected endocrine disruptors

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Component	CAS No	EC No	Weight %	CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567
Malic acid	6915-15-7	EEC No. 230-022-8	<=100	Eye Irrit. 2 (H319)

REACH registration number	01-2119552463-40-0007
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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. If skin irritation persists,

call a physician.

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

symptoms occur.

Inhalation Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if

symptoms occur.

Self-Protection of the First Aider Ensure that medical personnel are aware of the material(s) involved, take precautions to

protect themselves and prevent spread of contamination.

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

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. Chemical 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.

Hazardous Combustion Products

Carbon monoxide (CO), Carbon dioxide (CO2).

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

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Use personal protective equipment as required. Ensure adequate ventilation. Avoid dust formation.

6.2. Environmental precautions

Should not be released into the environment.

6.3. Methods and material for containment and cleaning up

Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.

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. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. 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 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 in a dry, cool and well-ventilated place. Keep container tightly closed.

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

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

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

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Component	ent Acute effects local Acute effects (Dermal) systemic (Dermal)		Chronic effects local (Dermal)	Chronic effects systemic (Dermal)	
Malic acid 6915-15-7 (<=100)	DNEL = 1mg/cm2	DNEL = 40mg/kg bw/day	DNEL = 1mg/cm2	DNEL = 2mg/kg bw/day DNEL = 5.2mg/kg bw/day	

Component	Acute effects local	Acute effects	Chronic effects local	Chronic effects		
	(Inhalation)	systemic (Inhalation)	(Inhalation)	systemic (Inhalation)		
Malic acid	$DNEL = 104mg/m^3$	$DNEL = 104mg/m^3$	$DNEL = 32mg/m^3$	DNEL = 5.33 mg/m ³		
6915-15-7 (<=100)	-	_	-	$DNEL = 36.6 mg/m^3$		

Predicted No Effect Concentration (PNEC)

See values below.

Component	Fresh water	Fresh water sediment		Microorganisms in sewage treatment	, ,
Malic acid	PNEC = 0.1mg/L	Sediment	PNEC = 1mg/L	PNEC = 3mg/L	
6915-15-7 (<=100)	, and the second se				

Component	Marine water	Marine water sediment	Marine water intermittent	Food chain	Air
Malic acid	PNEC = 0.01mg/L				
6915-15-7 (<=100)					

8.2. Exposure controls

Engineering Measures

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

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 Goggles (European standard - EN 166)

Hand Protection Protective gloves

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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 When workers are facing concentrations above the exposure limit they must use

appropriate certified respirators.

To protect the wearer, respiratory protective equipment must be the correct fit and be used

and maintained properly

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

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are exceeded or if irritation or other symptoms are experienced **Recommended Filter type:** Particulates filter conforming to EN 143

Small scale/Laboratory use Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure

limits are exceeded or if irritation or other symptoms are experienced.

Recommended half mask:- Particle filtering: EN149:2001 When RPE is used a face piece Fit Test should be conducted

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 Off-white Odor Odorless

Odor Threshold No data available

Melting Point/Range 128 - 132 °C / 262.4 - 269.6 °F

Softening Point No data available

Boiling Point/Range No information available °C / °F Estimated Flammability (liquid) Not applicable Solid

Flammability (solid,gas) No information available

Explosion Limits No data available

Flash Point 203 °C / 397.4 °F Method - No information available

Autoignition Temperature 340 °C / 644 °F Decomposition Temperature > 225 °C - < 235 °C

pH ~ 2 1% aq. solution

Viscosity Not applicable Solid

Water Solubility
Very soluble: 647 g/L @ 20 °C
Solubility in other solvents
No information available

Partition Coefficient (n-octanol/water)

Component log Pow Malic acid -1.26

 Vapor Pressure
 0.00039 Pa @ 25 °C

 Density / Specific Gravity
 1.615 g/cm3 @20°C

 Bulk Density
 1615 kg/m³ @ 20°C

Vapor Density Not applicable Solid

Particle characteristics No data available

9.2. Other information

Molecular FormulaC4 H6 O5Molecular Weight134.09

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 normal conditions.

10.3. Possibility of hazardous reactions

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Hazardous Polymerization

Hazardous polymerization does not occur.

Hazardous Reactions

None under normal processing.

10.4. Conditions to avoid

Excess heat. Incompatible products.

10.5. Incompatible materials

Bases. Metals. Reducing Agent.

10.6. Hazardous decomposition products

Carbon monoxide (CO). Carbon dioxide (CO2).

SECTION 11: TOXICOLOGICAL INFORMATION

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

Product Information

(a) acute toxicity;

OralBased on available data, the classification criteria are not metDermalBased on available data, the classification criteria are not metInhalationBased on available data, the classification criteria are not met

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation		
Malic acid	3500 mg/kg bw (Rat)	>20000 mg/kg bw (Rabbit)	>1.306 mg/L air (analytical) 4h		
			(Rat)		

(b) skin corrosion/irritation; Based on available data, the classification criteria are not met

(c) serious eye damage/irritation; Category 2 Based on available data, the classification criteria are not met

(d) respiratory or skin sensitization;

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

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

(e) germ cell mutagenicity; Based on available data, the classification criteria are not met

(f) carcinogenicity; Based on available data, the classification criteria are not met

There are no known carcinogenic chemicals in this product

(g) reproductive toxicity; Based on available data, the classification criteria are not met

(h) STOT-single exposure; Based on available data, the classification criteria are not met

(i) STOT-repeated exposure; Based on available data, the classification criteria are not met

Target Organs None known.

(j) aspiration hazard; Not applicable

Solid

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Other Adverse Effects

The toxicological properties have not been fully investigated.

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

Do not empty into drains.

Component	Freshwater Fish	Water Flea	Freshwater Algae		
Malic acid	LC50: > 100 mg/L 96h (OECD	LC50 = 240 mg/L 48h (OECD	EC50 > 100 mg/L 72h (OECD		
	203)	202)	201)		

Component	Microtox	M-Factor		
Malic acid	EC50 > 300mg/L 3h (OECD 209)			

12.2. Persistence and degradability

Persistence

Persistence is unlikely.

12.3. Bioaccumulative potential Bioaccumulation is unlikely

Component	log Pow	Bioconcentration factor (BCF)
Malic acid	-1.26	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

12.5. Results of PBT and vPvB

assessment

Substance is not considered persistent, bioaccumulative and toxic (PBT) / very persistent

and very bioaccumulative (vPvB).

12.6. Endocrine disrupting

properties

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

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.

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

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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 empty into drains. Solutions with low pH-value must be neutralized before

discharge.

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

14.5. Environmental hazards No hazards identified

No special precautions required. 14.6. Special precautions for user

CAS No

14.7. Maritime transport in bulk according to IMO instruments

SECTION 15: REGULATORY INFORMATION

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

Not applicable, packaged goods

International Inventories

Component

China, X = listed, Australia, U.S.A. (TSCA), Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Australia (AICS), Korea (KECL), China (IECSC), Japan (ENCS), Philippines (PICCS), Japan (ISHL), Japan (ISHL). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

EINECS ELINCS NLP IECSC TCSI KECL ENCS

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l. N	lalic acid	6915-15-7	230-022-8	-	-	Х	X	KE-20414	Х	Х
Co	mponent	CAS No	TSCA		ventory ation - Inactive	DSL	NDSL	AICS	NZIoC	PICCS
N	lalic acid	6915-15-7	X	ACT	IVE	X	-	X	X	X

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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		REACH (1907/2006) - Annex XIV - Substances Subject to Authorization	J	REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
Malic acid	6915-15-7	-	-	-

Seveso III Directive (2012/18/EC)

Component	CAS No	Seveso III Directive (2012/18/EC) -	Seveso III Directive (2012/18/EC) -	
		Qualifying Quantities for Major Accident	Qualifying Quantities for Safety Report	
		Notification	Requirements	
Malic acid	6915-15-7	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

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

WGK Classification

Water endangering class = 3 (self classification)

15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

SECTION 16: OTHER INFORMATION

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

H319 - Causes serious eye irritation

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

Substances List

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PICCS - Philippines Inventory of Chemicals and Chemical Substances

ACGIH - American Conference of Governmental Industrial Hygienists

IECSC - Chinese Inventory of Existing Chemical Substances **KECL** - Korean Existing and Evaluated Chemical Substances

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

ENCS - Japanese Existing and New Chemical Substances

Predicted No Effect Concentration (PNEC)

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50% **POW** - Partition coefficient Octanol:Water

VOC - (Volatile Organic Compound)

vPvB - very Persistent, very Bioaccumulative

ADR - European Agreement Concerning the International Carriage of

Dangerous Goods by Road

WEL - Workplace Exposure Limit

DNEL - Derived No Effect Level

LC50 - Lethal Concentration 50%

RPE - Respiratory Protective Equipment

NOEC - No Observed Effect Concentration **PBT** - Persistent, Bioaccumulative, Toxic

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 Shins

ATE - Acute Toxicity Estimate

Key literature references and sources for data

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

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

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.

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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