according to 1907/2006/EC, Article 31

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

· 1.1 Product identifier

- · Trade name: Malic acid
- · Article number: 102405
- · CAS Number:
- 6915-15-7
- · EC number:

230-022-8

- **1.2 Relevant identified uses of the substance or mixture and uses advised against** No further relevant information available.
- Application of the substance / the mixture Additive for cosmetic or pharmaceutic preparations Pharmaceutical intermediate pH-corrective agent

· 1.3 Details of the supplier of the safety data sheet

Fagron UK Ltd 4B Coquet St Newcastle upon Tyne England NE1 2QB Tel. 0845 6522525

- Further information obtainable from: Emergency response telephone number: +44 (0) 845 652 2525
- **1.4 Emergency telephone number:** Emergency response telephone number: +44 (0) 845 652 2525

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008
- Eye Irrit. 2 H319 Causes serious eye irritation.
- · 2.2 Label elements
- Labelling according to Regulation (EC) No 1272/2008
 The substance is classified and labelled according to the GB CLP regulation.
 Hazard pictograms



Signal word Warning
 Hazard statements

 H319 Causes serious eye irritation.

 Precautionary statements

 P264
 Wash 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.

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

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· 2.3 Other hazards

- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.1 Chemical characterisation: Substances
- · CAS No. Description
- CAS: 6915-15-7 Malic acid
- · Identification number(s)
- · EC number: 230-022-8

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Generally the product does not irritate the skin.
- After eye contact:
- Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- After swallowing: If symptoms persist consult doctor.
- · 4.2 Most important symptoms and effects, both acute and delayed
- No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- Suitable extinguishing agents:
- Fire-extinguishing powder
- Foam
- Water spray

Use fire extinguishing methods suitable to surrounding conditions.

- 5.2 Special hazards arising from the substance or mixture
- In case of fire, the following can be released:
- Carbon monoxide (CO)
- · 5.3 Advice for firefighters
- · Protective equipment: Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 6.4 Reference to other sections
- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

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SECTION 7: Handling and storage

• 7.1 Precautions for safe handling No special precautions are necessary if used correctly. • Information about fire - and explosion protection: No special measures required.

- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:

· Requirements to be met by storerooms and receptacles: No special requirements.

- Information about storage in one common storage facility: Not required.
- Further information about storage conditions: Keep container tightly sealed.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- Additional information about design of technical facilities: No further data; see item 7.
- · Ingredients with limit values that require monitoring at the workplace: Not required.
- Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- Personal protective equipment:
- · General protective and hygienic measures:
- Keep away from foodstuffs, beverages and feed.
- Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

- Avoid contact with the eyes.
- Avoid contact with the eyes and skin.
- Respiratory protection: Not required.
- Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:



Tightly sealed goggles

· Body protection: Protective work clothing

SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information
- · Appearance: Form:

Crystalline powder

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Colour:	White
· Odour:	Odourless
· Odour threshold:	Not determined.
· pH-value:	Not applicable.
 Change in condition 	
Melting point/freezing point:	131°C
Initial boiling point and boiling range	: Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gas):	Product is not flammable.
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Not determined.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	187.5 g/m³
· Vapour pressure:	Not applicable.
· Density at 20°C:	1.615 g/cm ³
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with	
water at 20°C:	647 g/l
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

· Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

Oral LD50 3500 mg/kg (rat)

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Dermal LD50 20000 mg/kg (rabbit) Inhalative LC50/4 h 1306 mg/l (rat) • Primary irritant effect: • Skin corrosion/irritation Based on available data, the classification criteria are not met. • Serious eye damage/irritation Based on available data, the classification criteria are not met. • Serious eye damage/irritation Causes serious eye irritation. • Respiratory or skin sensitisation Based on available data, the classification criteria are not retria are not retria are not retria are not retria classification criteria are not retria are not retria classification. • CMR effects (carcinogenity, mutagenicity and toxicity for reproduction) • Germ cell mutagenicity Based on available data, the classification criteria are not met.
 Primary irritant effect: Skin corrosion/irritation Based on available data, the classification criteria are not met. Serious eye damage/irritation Causes serious eye irritation. Respiratory or skin sensitisation Based on available data, the classification criteria are not r Additional toxicological information: CMR effects (carcinogenity, mutagenicity and toxicity for reproduction) Germ cell mutagenicity Based on available data, the classification criteria are not met.
 Skin corrosion/irritation Based on available data, the classification criteria are not met. Serious eye damage/irritation Causes serious eye irritation. Respiratory or skin sensitisation Based on available data, the classification criteria are not r Additional toxicological information: CMR effects (carcinogenity, mutagenicity and toxicity for reproduction) Germ cell mutagenicity Based on available data, the classification criteria are not met.
 Carcinogenicity Based on available data, the classification criteria are not met. Reproductive toxicity Based on available data, the classification criteria are not met. STOT-single exposure Based on available data, the classification criteria are not met. STOT-repeated exposure Based on available data, the classification criteria are not met.

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· Uncleaned packaging:

• Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

· 14.1 UN-Number · ADR, IMDG, IATA

not regulated

 \cdot 14.2 UN proper shipping name \cdot ADR, IMDG, IATA

not regulated

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Trade name: Malic acid

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not regulated	
not regulated	
Not applicable.	
Not applicable.	
inex II	
Not applicable.	
not regulated	
-	not regulated not regulated Not applicable. Not applicable. nex II Not applicable.

SECTION 15: Regulatory information

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

- Directive 2012/18/EU
- · Named dangerous substances ANNEX I Substance is not listed.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Department issuing SDS:

Fagron UK

Quality Assurance

- · Contact: guality@fagron.co.uk
- Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Eye Irrit. 2: Serious eye damage/eye irritation - Category 2

·* Data compared to the previous version altered.



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