Extended - SAFETY DATA SHEET

Product: DL-Malic acid
Registration No: 01-2119552463-40-0000

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

1.1 Product identifier:

Product name : DL MALIC ACID
EC Number : 210-514-9
CAS Number : 617-48-1

1.2 Relevant Identified uses of the substance or mixture and uses advised against

Uses: Used in protective coatings, dyestuff, adhesives, polymer & resins, pharmaceutical applications, construction, fertilisers and for laboratory use (SU7, SU8, SU9, SU10, SU11, SU12, SU19 & PC1, PC9a, PC9b, PC12, PC18, PC19, PC21, PC23, PC26, PC29, PC32, PC35, PC36, PC37 & PROC5 PROC8a, PROC8b, & ERC1, ERC2, ERC6a, ERC6d, ERC8a, ERC8b, ERC8c, ERC8f & ERC10a)

The following Exposure Scenarios have been prepared:
ES1: Manufacture / Formulation
ES2: Further industrial use information
ES3 : Further industrial use (Intermediate)
ES4: Use of Formulated Product (Professional Use)
ES5: Use of Formulated Product (Domestic)

1.3 Details of the supplier

Name : Lapiz Europe Limited as OR for Thirumalai Chemicals Limited
Address : No: 204-206 Talbot House,
Imperial Drive Rayners Lane,
Harrow, Middlesex, HA2 7HH.
Tel:0208 429 5227; 0208 429 4455.
vnirmal.gandhi@lapizdigital.com

non-Community manufacturer:

Name : Thirumalai Chemicals Limited
Address : No-25A Sipcot Industrial Complex,
Ranipet – 632 403.
TamilNadu. India.
Tel:+91-4172-244441/2.
exports@thirumalaichemicals.com

1.4 Emergency Telephone Number

Lapiz Europe Limited as OR for Thirumalai Chemicals Limited:

Contact Number : 0208 429 5227; 0208 429 4455;

Thirumalai Chemicals Limited:

Contact Number : +91-4172-244441/2

SECTIION 2: Hazard Identification

2.1 Classification of the substance or mixture

Classification of the substance according to Regulation (EC) No 1272/2008

For Physico-chemical properties : Not Classified
For health hazards :
1.Acute Toxicity oral : Not classified.
2.Skin corrosion/irritation : Not classified.

3.Serious damage/eye irritation : Category 2.
4.Respiration sensitization : Not classified.
5.Skin sensitization : Not classified.
6.Specific target organ
Toxicity single(SPOT) : Not classified.
For environmental hazards : Not classified.

Classification of the substance according to Directive 67/548/EEC

Xi; Irritant

R36 Irritant; Irritating to eyes.

2.2 Label elements

Labelling of the substance according to Regulation (EC) No 1272/2008:

Hazard pictogram:

GHS07	

Signal word : **Warning**

Hazard statements:

H319: Causes serious eye irritation.

Precautionary statements:

P264: Wash hands thoroughly after handling.

P280: Wear protective gloves/protective clothing/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

Labelling of the substance according to Directive No 67/548/EEC:

Xi - irritant

R-phrases:

R36 - irritating to eyes

S-phrases:

S2 - keep out of the reach of children
S25 - avoid contact with eyes
S26 - in case of contact with eyes, rinse immediately with plenty of water and seek medical advice

SECTION 3: Composition information on ingredients

3.1 Substance

Substance name:	DL-MALIC ACID
Chemical formula:	$C4H6O5$
Synonym:	Hydroxybutanedioic acid, Hydroxysuccinic acid.
Concentration:	More than 99.5 % (W/W)
EC Number	210-514-9
CAS Number	617-48-1

Impurities:

No impurities relevant for classification and labeling.

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation	:	Remove to fresh air and keep at rest. Monitor respiratory function. If breathing is difficult, give oxygen. If necessary, give artificial respiration.
Skin Contact	:	Remove contaminated clothing and shoes. Wash with plenty of soap and Water
Eye Contact	:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Ingestion	:	inse mouth of victim with plenty of water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person

Seek Medical attention. Movement of the exposed individual from the area to fresh air is recommended.

Personal protective equipment for first aid responders is recommended.

4.2 Most important symptoms and effects, both acute and delayed

By inhalation: Dust or fumes can cause irritation of the nose throat and respiratory tract. Symptoms of exposure may include runny nose, coughing and nose bleeds, depending on severity of exposure. Severe over-exposure can produce lung damage, choking unconsciousness or death.
By skin contact: Hazardous in case of skin contact (corrosive, permeator). The amount of tissue damage depends on length of contact. Skin contact can produce inflammation, irritations and possible burning. Skin inflammation is characterized by itching scaling, reddening, or, occasionally, blistering.
By eye contact: Eye contact can result in corneal damage or blindness. Inflammation of the eye is characterized by redness, watering and itching.

By ingestion: Product ingestion causes irritations and possible burning to mouth, throat and stomach.
Chronic effects: Chronic exposure by inhalation or skin contact can cause allergic sensitization causes liver and kidney effects in laboratory animals.

4.3 Indication of any immediate medical attention and special treatment needed

Symptomatic treatment as required.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Carbon dioxide (CO2) foam, dry powder, sand for small fires.
For large fires use water jet or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture

Combustible material.May form flammable/explosive Vapour-air mixture.

5.3 Advice for firefighters

Special precautions for fire-fighters: Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.
Protection of fire-fighters: The fire fighters should wear full protective equipment and self - contained breathing apparatus with full face piece operated in positive pressure mode.
Other information: Do not get water inside containers/bags. Water spray or fog carefully applied to surface of the burning material can be used to extinguish the fire. Use water spray to prevent dust formation, absorb heat, keep containers cool and protect fire-exposed materials. Cool containers with flooding quantities of water until well after fire is out. Use water spray to flush spills from ignition source.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personal

(a) Use protective gloves, safety goggles and protective clothing

(b) Remove ignition sources. Do not touch spilled material unless wearing protective clothing. Avoid contact with skin and eye

6.2 Environmental precautions

Prevent from entering into watercourses, sewage and confined areas.

6.3 Methods and material for containment and cleaning up

Collect with a clean shovel, put in clean and dry vessels and cover them. Remove them from the spilling area.

(a) Neutralize traces of residues or very little spills that remained over the soil with sodium carbonate or bicarbonate and water, or alkaline substances.

(b) Collect with a clean shovel, put in clean and dry vessels and cover them. Remove them from spilling area.

6.4 Reference to other sections

See Section 8 for further advice on PPE and section 13 for further advice on disposal.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Avoid inhalation, contact with skin and eyes. Do not handle near incompatible materials. Use proper personal protective equipment.

Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Wash hands before eating, drinks, smoking or going to the toilet. Take off all contaminated clothing and wash before reuse.

7.2 Conditions for safe storage, including any incompatibilities

Store away from alkaline materials, oxidizers and strong acids. Copper oxide, nitric acid and sulfuric acid, sodium nitrite.

Avoid static electricity discharges.

Keep in original container, in a cool dry, well ventilated place. Keep away from food. Store locked up; keep out of reach of children.

7.3 Specific end use(s)

Refer exposure scenario attached.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Substance	Limit Value (8 hours)	Limit Value (15 mins)
Malic acid	NA	NA

DNELS

DNELS								
	Worker				General Population			
	Long term local effects	Long term systemic effects	Short term local effects	Short term systemic effects	Long term local effects	Long term systemic effects	Short term local effects	Short term systemic effects
Human oral	Not derived	Not derived	Not derived	Not derived	Not derived	30 mg/kg bw/day	Not derived	30 mg/kg bw/day
Human dermal	Not derived	50 mg/kg bw/day	Not derived	50 mg/kg bw/day	Not derived	30 mg/kg bw/day	Not derived	30 mg/kg bw/day
Human inhalation	Not derived	175 mg/m³	Not derived	175 mg/m³	Not derived	53 mg/m³	Not derived	53 mg/m³

PNECS

PNEC	
PNEC aqua (freshwater):	0.1 mg/L
PNEC aqua (marine water):	0.01 mg/L
PNEC aqua (intermittent releases):	1 mg/L
PNEC sediment (freshwater):	NA
PNEC sediment (marine water):	NA
PNEC soil:	NA
PNEC STP:	3 mg/L

8.2 Exposure Controls

Appropriate engineering controls

The best protection is to enclose the operation and/or provide local exhaust ventilation at the side of the chemical release.

It is recommended that safety shower and eye bath be available near the work area. Compressed air lines used for respiratory protection should be provided with purifiers. Wear adequate and proper personal protective equipment. Do not eat, drink or smoke while using this product. Wash hands before eating, drinking, smoking, or going to the toilet. Take off all contaminated clothing and wash before reuse.

PPE

(a) Eye/face protection Use protective safety goggles.

(b) Skin Protection: Use Latex or PVC gloves. Use safety leather shoes with rubber impermeable sole, with protective clothing to the body. Overalls with long sleeves and hood are recommended.

(c) Respiratory protection: Full face piece respirator with filter for organic vapors. In cases of high potential of exposure use a supplied-air respirator, full facepiece, operated in positive-pressure mode.

Environmental Exposure Controls

Prevent entry into drains, sewers and watercourses.

SECTION 9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

(a) Appearance : White Crystalline fine granules
(b) Odour : Odorless
(c) Odour threshold : No data
(d) pH : Acidic
(e) Melting/freezing point : 129 °C at 1013 hPa
(f) Boiling point : 150 ºC
(g) Flash point : Not Applicable – Solid
(h) Evaporation Rate : No data
(i) Flammability : Not Classified as flammable
(j) Upper/Lower flammability limited : Not applicable
(k) Vapor pressure : 0.00000293 mm Hg at 25 deg C
(l) Vapor density : No Data
(m) Relative Density : 1.6 g/cm2 at 20 °C
(n) Solubility in water : 500 g/L at 25 °C
(o) Solubility in other solvents : No Data
(p) Partition Co-efficient : Log Kow - 0.46
(q) Auto-ignition temperature : Not applicable
(r) Decomposition temperature : No decomposition reported below boiling point
(s) Viscosity : Not applicable
(t) Explosive properties : Not classified as explosive
(u) Oxidising properties : Not classified as oxidising

9.2 Other information

None

SECTION 10: Stability and reactivity

10.1 Reactivity

Stability and reactivity of Fumaric acid is not considered critical.

10.2 Chemical Stability

Stable under normal conditions of storage and handling polymerization will not occur

10.3 Possibility of hazardous reactions

Reacts with water. Reacts with certain metals (eg iron). Dust explosion hazard

10.4 Conditions to avoid

Avoid extreme heat. Avoid moisture.

10.5 Incompatible materials

Alkaline materials, oxidizers and strong acids. Copper oxide, nitric acid and sulfuric acid, sodium nitrite.

10.6 Hazardous decomposition products

Maleic Acid, Maleic Anhydride, Carbon Monoxide and Carbon Dioxide.

SECTION 11: Toxicological Information

11.1.1 Substances

11.1.1.1

(a) Acute toxicity	:	LD_{50} (oral, rats): 2000 mg/kg.
	:	LC_{50} (inhalation, rats): > 1.306 mg/L for 4hrs.
(b) Skin corrosion/irritation	:	slightly irritating.
(c) Serious eye damage/irritation	:	moderately irritating.
(d) Respiratory or skin sensitisation	:	Not Sensitizing.
(f) Germ cell mutagenicity	:	Negative.
(g) Carcinogenecity	:	Non carcinogenic.
(h) Reproductive toxicity	:	Not toxic to reproduction.

Hazard Class	Value	Test Method
Acute Toxicity	LD_{50} (oral, rats): 2000 mg/kg LC_{50} (inhalation, rats): >1.306 mg/m^3.	It is not proposed to classify fumaric acid for acute oral toxicity or for acute dermal toxicity based on experimental results. No classification is proposed for acute dermal toxicity since exposure is very limited due to large, non-respirable, particle size and the absence of adverse effects at the maximum practical atmosphere concentration

Skin /eye corrosion/irritation		Fumaric acid is listed on Annex I of Directive 67/548/EEC as an irritant to eyes (Xi; R36).The mild skin irritation observed was insufficient to justify classification of fumaric acid. Moderate, reversible eye irritation seen in the study discussed above shows that fumaric acid should remain classified for ocular irritation according to current EU criteria.Fumaric acid is classified as an eye irritant. It is assigned the symbol Xi and the risk-phrase R36 - irritating to the eyes according to Directive 67/548/EEC. It is assigned the pictogram GHS07 with the signal word warning and the hazard statement H319 "causes serious eye irritation". It is proposed to classify malic acid the same.
Respiratory or skin sensitisation		Read across to fumaric acid is considered valid and malic acid is concluded to have low toxicity.The rational for read across is that fumaric acid will metabolise in biological systems to malic acid. Fumaric acid is also slightly more fat soluble and is considered more likely to absorb to membranes and increase transport. It is not considered valid to perform further animal tests on malic acid.

Germ cell mutagenecity	Negative	Read across to malic acid is considered valid as metabolism of fumaric acid to malic acid is a key part of the Krebbs Cycle. Malic acid and fumaric acid accur naturally in many foods and synthetic forms of these acids are considered suitable as food additives.
Carcinogenecity	Non carcinogenic	Based on the evidence from mutagenicity assays and carcinogenesis investigations there are no indications of any human tumorigenic potential for fumaric acid. It is not classified as a Class 1, 2 or 3 mutagen nor for carcinogenicity and is recognised as showing no reasons for concern in its use in human foodstuffs as a widespread acidulant additive

SECTION 12: Ecological Information

12.1 Toxicity

Aquatic Toxicity

Short-term toxicity to fish
Brachydanio rerio (new name: Danio rerio)/fresh water/semi-static LC50 (96 hrs): >100 mg/L test mat.

Long-term toxicity to fish
In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) exposure estimation is not necessary

Short-term toxicity to aquatic invertebrates

Daphnia magna/fresh water/static EC50 (48 h): 240 mg/L test mat.

Long-term toxicity to aquatic invertebrates

In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) exposure estimation is not necessary.

Algae and aquatic plants

Pseudokirchnerella subcapitata (algae)/freshwater/static NOEC (72 h): >= 100 mg/L test mat.

Toxicity to sediment

In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) exposure estimation is not necessary.

Toxicity to soil macro-organisms

In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) exposure estimation is not necessary.

Resulting PNECs.

	Water	Sediment	Soil
PNEC	0.1 mg/l	n.a	n.a

12.2 Persistence and degradability

Abiotic degradation:

Photo degradation in air
No information is available. Information for this endpoint is not required under REACH.
Photo degradation in water
No information is available. Information for this endpoint is not required under REACH.
Hydrolysis
In accordance with REACH Annex VIII column 2, the study does not need to be conducted as the substance is readily biodegradable.

Biotic degradation

Degradation rate in water	Readily biodegradable ca. 67.5 after 28 d (CO2 evolution)
Degradation rate in sediment:	In accordance with REACH Annex VII column 2, the study does not need to be conducted as the substance is readily biodegradable.
Degradation rate in soil:	In accordance with REACH Annex VII column 2, the study does not need to be conducted as the substance is readily biodegradable.

12.3 Bioaccumulative potential

Aquatic bioaccumulation
In accordance with REACH Annex VII column 2, the study does not need to be conducted as the substance has a low potential for bioaccumulation (i. e. a log Kow < 3).

Terrestrial bioaccumulation
No information is available. Information for this endpoint is not required under REACH

12.4 Mobility in soil

Malic acid is readily biodegradable in water and mobility is not expected to be of concern.

12.5 Results of PBT and VpVb assessment

Malic acid is soluble and is readily biodegradable. The log Kow is well below levels of concern. It is not expected to persist or bioaccumulate in the environment.

12.6 Other adverse effects :

None Known

SECTION 13: Disposal considerations:

13.1 Waste treatment methods:

Prior to implementing land disposal of waste residue(including waste sludge), consult local legislation for adequate disposal methods.

Empty containers can retain product residues and shall be disposed in accordance with the provisions proposed for the product.

For more information refer Exposure scenario attached.

SECTION 14: Transport information:

14.1 UN number : Not applicable

14.2 UN proper shipping name : Not applicable

14.3 Transport hazard class :

Road transport ADR/RID	Maritime transport IMDG	Air transport ICAO/IATA
NA	NA	NA

14.4 Packaging group :

Maritime transport IMDG	Air transport ICAO/IATA
NA	NA

14.5 Environmental hazards :

None

14.6 Special precautions for user:

None

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code.

NA

SECTION 15: Regulatory information:

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

No specific regulations. Normal chemical safety and handling regulations will apply.

15.2: Chemical safety assessment

Yes

SECTION 16: Other information

Revision information: This is the first SDS produced in the new REACH format.

List of Abbreviations used in this SDS:

CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging Regulation (EC) no 1272/2008
DSD	Dangerous Substances Directive 67/548/EEC
DPD	Dangerous Preparations Directive 1999/45/EC
EC	European Community/Commission
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) no 1907/2006
vPvB	very Persistent, very Bioaccumulative

References: Full details of test reports can be viewed in the registration dossier, accessible through the ECHA CHEM website.

Training requirements for workers
No special training requirements.

The information provided in this safety data sheet is given in good faith and is correct to the best of our knowledge and information at the date of publication. It is designed only as guidance for safe handling, storage, transportation, use and disposal. No warranty is expressed (or) implied.

Annex Included:

Exposure scenario 1 – Manufacture / formulation

Exposure scenario

For the purposes of this assessment, production or formulation is no more than 200 t at any one site and takes place on a continuous process throughout the year (average 10 t per day, 200 days / year). Production takes place in dedicated plant under controlled conditions, with packing into bulk bags and lined drums. Manual handling is minimised, but engineering controls are in place to reduce the level of nuisance dust to less than 10 mg/m3 . Dust masks and coveralls are recommended for use by workers in proximity to production and packaging equipment.

Exposure estimation

Estimations on exposure can be made using technical guidance defaults for medium dust materials. However, in view of the slight irritation effects expect from excessive dermal contact or through eye contact, workers should be encouraged to reduce exposure through use of coveralls and perhaps eye protection. Although not tested for inhalation toxicity, it is expected that there will be slight irritation to the respiratory system and if the working environment has high levels of dust, workers need to use personal protection, such as dust masks. At atmospheric concentrations of over 10 mg/m3 (considered to be a nuisance dust level for non-hazardous materials) it is expected that there will be some discomfort to workers and risk management measures should keep exposure to below these levels.

A worker exposure to 10 mg/m3 for an 8 hour working shift doing light labour will inhale up to 80 mg per day; for a 70 kg worker, this equates to just over 1 mg/kg/day. With hands, face and ‘upper surface’ exposed, it is estimated from standard default factors in Table 14-4Chapter R14 of the CSA guidance, that the area exposed is 960 cm2. This would lead to exposure of approximately 14 mg/kg/day by dermal contact (Table 14-6).

Regarding environmental exposure, default assessments for manufacturing and formulating in technical guidance suggest up to 2% loss to waste water. This figure is considered high in view of the processes involved, but if 2% of production was lost, this would equate to 200 kg/day (based on 2000 t per annum). Once in the waste water stream, the substance would quickly degrade.

Using standard defaults, the local discharge rate is 2000 m3 / day with further 10 X dilution in surface water, leading to a final dilution to 10 mg/l in the absence of no degradation processes. Simple Treat assessment for biodegradation would suggest up to 80% removal in waste treatment.

Exposure Scenario 2 – Further industrial use formulation

Exposure scenario

Formulation takes place at a number of DU sites, preparing personal care and dye products. Due to the simplicity of the blending procedure, often in water based products, there is little opportunity for exposure to operators and virtually no waste. Traces of the substance may be discharged through waste water treatment systems as described above as a result of washing surfaces or equipment. Dust may be formed under certain handling conditions.

For the purposed of this exposure scenario, it is assumed that no single user site handles more than 50% of production; this means that no more than 1000 t per annum at any one site; it is also assumed that such processes are likely to take place over about 100 days per annum (10 t per day).

The formulation technique does not require the use of processing water for cooling, washing etc. and the only opportunity for this substance to enter the waste water stream is as a result of an accidental small spill of solid product or during transfer of solids for packaging. Exposure to workers is minimal and would be predominantly possible release of dust during transfer of the substance to the blending equipment. Engineering and personal protection control are recommended as part or risk management.

Exposure estimation

At atmospheric concentrations of over 10 mg/m3 (considered to be a nuisance dust level for non-hazardous materials) it is expected that there will be some discomfort to workers and risk management measures should keep exposure to below these levels.

A worker exposure to 10 mg/m3 for an 8 hour working shift doing light labour will inhale up to 80 mg per day; for a 70 kg worker, this equates to just over 1 mg/kg/day. With hands, face and ‘upper surface’ exposed, it is estimated from standard default factors in Table 14-4Chapter R14 of the CSA guidance, that the area exposed is 960 cm2. This would lead to exposure of approximately 14 mg/kg/day by dermal contact (Table 14-6).

Regarding environmental exposure, default assessments for manufacturing and formulating in technical guidance suggest up to 2% loss to waste water. This figure is considered high in view of the processes involved, but if 2% of production was lost, this would equate to 200 kg/day (based on 2000 t per annum). Once in the waste water stream, the substance would quickly degrade.

Using standard defaults, the local discharge rate is 2000 m3 / day with further 10 X dilution in surface water, leading to a final dilution to 10 mg/l in the absence of no degradation processes. Simple Treat assessment for biodegradation would suggest up to 80% removal in waste treatment.

Exposure Scenario 3 – Further industrial use (intermediates)

Exposure scenario

Chemical processing takes place at a limited number of sites for use as a chemical intermediate or processing aid where the substance is consumed. Many of these will be considered as ‘transported intermediates’ under strictly controlled conditions and there is little opportunity for exposure to operators and virtually no waste. Traces of the substance may be discharged through waste water treatment systems as described above as a result of washing surfaces or equipment. Dust may be formed under certain handling conditions.

For the purposed of this exposure scenario, it is assumed that no single user site handles more than 10% of production; this means that no more than 100 t per annum at any one site; it is also assumed that such processes are likely to take place over more than 10 days per annum (10 t per day).
The formulation technique does not require the use of processing water for cooling, washing etc. and the only opportunity for this substance to enter the waste water stream is as a result of an accidental small spill of solid product or during transfer of solids for packaging. Exposure to workers is minimal and would be predominantly possible release of dust during transfer of the substance to the blending equipment. Engineering and personal protection controls are recommended as part or risk management.

Exposure estimation

At atmospheric concentrations of over 10 mg/m3 (considered to be a nuisance dust level for non-hazardous materials) it is expected that there will be some discomfort to workers and risk management measures should keep exposure to below these levels.

A worker exposure to 10 mg/m3 for an 8 hour working shift doing light labour will inhale up to 80 mg per day; for a 70 kg worker, this equates to just over 1 mg/kg/day. With hands, face and ‘upper surface’ exposed, it is estimated from standard default factors in Table 14-4Chapter R14 of the CSA guidance, that the area exposed is 960 cm2. This would lead to exposure of approximately 14 mg/kg/day by dermal contact (Table 14-6).

Regarding environmental exposure, default assessments for manufacturing and formulating in technical guidance suggest up to 2% loss to waste water. This figure is considered high in view of the processes involved, but if 2% of production was lost, this would equate to 200 kg/day (based on 100 t per annum over 10 days minimum). Once in the waste water stream, the substance would quickly degrade.

Using standard defaults, the local discharge rate is 2000 m3 / day with further 10 X dilution in surface water, leading to a final dilution to 10 mg/l in the absence of no degradation processes. Simple Treat assessment for biodegradation would suggest up to 80% removal in waste treatment.

Exposure Scenario 4 – Use of formulated product (professional use)

Exposure scenario

The substance is supplied in mixtures for a number of applications including laboratory reagents and research applications. A major use is as a pH regulator and stabiliser and under these conditions; the substance will dissociate to form salts. During use, most of the substance will be consumed and will lose its identity.

Exposure estimation

Professional user exposure is minimal as only small quantities are typically handled and many applications will involve use of diluted (non-hazardous) levels of malic acid. Exposure characterisation is not considered further in view of the low hazard. Environmental controls will minimise exposure.

Exposure Scenario 5 – Use of formulated product (domestic)

Exposure scenario

The substance is supplied in mixtures containing low concentrations of malic acid. Use is generally limited to less than 5 g per household per day (supplier assumption, based on maximum one use of cosmetics and personal care products per day. During use, most of the substance will be consumed and will lose its identity. The purpose of the substance is to act as a pH regulator and as a result, various salts will be formed and discharge to the environment needs to be considered in terms of the malate ion.

Exposure estimation

It can be assumes that 100 % of the substance is discharged into waste water systems, based on normal defaults for consumer use. As a worst case scenario, it is assumed that every household in a small town of 10 000 people use 5 g/day per household, with an average of 2 people per household. This equates to 25 kg/day. The discharge of waste water in a town of 10000 is estimated to be a default of 2000 m3 / day with final dilution to surface water of 10. 25 kg/day would be equivalent to 1.25 mg/day and lower than the potential impact from production or formulating activity. It must be noted that the substance will also be used as food additives that is not being registered for REACH and that there is also supply of natural malic acid for consumer products (again, not being registered). The exposure from these exempt forms and uses of malic acid have not been considered.