

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

1.1 Product identifier

Trade name or designation of the mixture 3-D Microemulsion®
Registration number(s) 01-2119474164-39-0010

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

Identified uses Soil and Groundwater Remediation.
Uses advised against None known

1.3 Details of the supplier of the safety data sheet

Company name Regenesis Ltd.
Address Cambridge House
Henry Street
Bath, Somerset
BA1 1BT
United Kingdom
Telephone number +44 (0) 1225 618161
E-mail address CustomerService@regenesis.com

1.4 Emergency telephone number

General in EU 112 (Available 24 hours a day. SDS/Product information may not be available for the Emergency Service.)
CHEMTREC For Dangerous Goods Incidents ONLY (spill, leak, fire, exposure or accident), call CHEMTREC 24/7 at:
International (+)1-703-527-3887
USA, Canada, Mexico (+)1-800-424-9300

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies:

2.1.1 Classification according to Regulation (EC) No 1272/2008 (CLP)

Eye. Dam. 1 – H318

2.2 Label elements

Hazard pictograms



Signal word Danger
Hazard Statements H318 Causes serious eye damage

Precautionary Statements	P280	Wear protective eye protection IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing Immediately call a POISON CENTER or doctor
	P305 + P351 + P338	
	P310	

2.3 Other hazards

The mixture does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Substance Name	EC No.	CAS No.	% w/w	REACH Registration No.	Index No.	Classification	Notes
HRC-PED	-	823190-10-9	48-53	01-2119474164-39-0010	N/A	Eye Dam. 1 – H318	HRC-PED contains lactic acid (EC No. 200-018-0, CAS No. 50-21-5) < 10% which is what the classification is based on Other constituents are non-hazardous
Fatty acids (neutralized)	204-007-1	112-80-1	30-35	-	-	Not classified as hazardous	
Glycerol tripolylactate	-	201167-72-8	<10	01-2119474164-39-0010	N/A	Not classified as hazardous	

The full text for all H-statements is displayed in Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes	Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
Following inhalation	Move to fresh air. Call a doctor if symptoms develop or persist.
Following skin contact	Take off contaminated clothing and wash it before reuse. Wash off with plenty of water. If skin irritation occurs: get medical advice/attention.
Following eye contact	Rinse eyes with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center or doctor.
Following ingestion	Rinse mouth. Do not induce vomiting. Get medical advice/attention if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Severe eye irritation. Permanent eye damage including blindness could result. Symptoms may include stinging, tearing, redness, swelling, and blurred vision.

4.3 Indication of any immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	Water spray. Carbon dioxide (CO ₂). Dry chemical powder. Foam
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire

5.2 Special hazards arising from the substance or mixture

During fire, gases hazardous to health may be formed. Combustion products may include: carbon oxides.

5.3 Advice for firefighters

Special protective equipment for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special firefighting procedures	Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not breathe vapour. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.

6.2 Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

6.3 Methods and material for containment and cleaning up

Large Spills: Stop the flow of material, if this is without risk. Use water spray to reduce vapours or divert vapour cloud drift. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

6.4 Reference to other sections

For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Do not breathe vapour. Do not get this material in contact with eyes. Avoid contact with eyes, skin, and clothing. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

7.2 Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store in a cool, dry, well-ventilated place. Store away from incompatible materials (see section 10 of the SDS). Recommended storage containers: plastic lined steel, plastic, glass, aluminum, stainless steel, or reinforced fiberglass.

7.3 Specific end use(s)

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values

Substance	Glycerol tripoly lactate
CAS No.	201167-72-8
No exposure limits noted	

Substance	Glycerol (mist)			
CAS No.	56-81-5			
Country	Limit value – eight hours		Limit value – short term	
	ppm	mg/m ³	ppm	mg/m ³
Australia	-	10 (1)	-	-
Belgium	-	10	-	-
Canada - Ontario	-	10	-	-
Canada - Québec	-	10	-	-
Finland	-	20	-	-
France	-	10	-	-
Germany (AGS)	-	200 (1)	-	400 (1)(2)
Germany (DFG)	-	200 (1)	-	400 (1)(2)
Ireland	-	10	-	-
New Zealand	-	10 (1)	-	-
Poland	-	10	-	-
Singapore	-	10	-	-
South Korea	-	10	-	-
Spain	-	10	-	-
Switzerland	-	50 inhalable aerosol	-	100 inhalable aerosol
USA - OSHA	-	15 inhalable aerosol	-	-
	-	5 respirable dust	-	-
United Kingdom	-	10	-	-
	Remarks			
Australia	(1) This value is for inhalable dust containing no asbestos and < 1% crystalline silica.			
Germany (AGS)	(1) Inhalable fraction (2) 15 minutes average value			
Germany (DFG)	(1) Inhalable fraction (2) 15 minutes average value			
New Zealand	(1) The value for inhalable dust containing no asbestos and less than 1% free silica.			

Substance	Lactic acid
CAS No.	50-21-5
No exposure limits noted	

Substance	Fatty acids (neutralized)
CAS No.	112-80-1
No exposure limits noted	

Recommended monitoring procedures: Follow standard monitoring procedures

Derived no effect levels (DNELs):

Glycerol

Exposure Route	Exposure Patterns	DNEL (workers)
Inhalation	Long term systemic	As no systemic toxicity hazard has been identified, there is no requirement to derive a systemic DNEL
	Short term systemic	
	Long term local	56 mg/m ³

	Short term local	No data available
Dermal	Long term systemic	No threshold effect and/or no dose-response relationship information available
	Short term systemic	
	Long term local	No threshold effect and/or no dose-response relationship information available
	Short term local	

Exposure Route	Exposure Patterns	DNEL (general population)
Inhalation	Long term systemic	No threshold effect and/or no dose-response relationship information available
	Short term systemic	
	Long term local	33 mg/m ³
	Short term local	No data available
Dermal	Long term systemic	No threshold effect and/or no dose-response relationship information available
	Short term systemic	
	Long term local	No threshold effect and/or no dose-response relationship information available
	Short term local	
Oral	Long term systemic	229 mg/kg bw/day
	Short term systemic	No data available

Lactic acid

Exposure Route	Exposure Patterns	DNEL (workers)
Inhalation	Long term systemic	No data available
	Short term systemic	
	Long term local	592 mg/m ³
	Short term local	No data available
Dermal	Long term systemic	No data available
	Short term systemic	No threshold effect and/or no dose-response relationship information available
	Long term local	No threshold effect and/or no dose-response relationship information available
	Short term local	

Exposure Route	Exposure Patterns	DNEL (general population)
Inhalation	Long term systemic	No data available
	Short term systemic	
	Long term local	296 mg/m ³
	Short term local	No data available
Dermal	Long term systemic	No threshold effect and/or no dose-response relationship information available
	Short term systemic	
	Long term local	No threshold effect and/or no dose-response relationship information available
	Short term local	
Oral	Long term systemic	35.4 mg/kg bw/day
	Short term systemic	No data available

Fatty acids (neutralized)

No information available

Predicted no effect concentrations (PNECs):

Glycerol

PNEC	Value
Aqua (freshwater)	0.885 mg/L

Aqua (marine water)	0.088 mg/L
STP	1000 mg/L
Sediment (freshwater)	3.3 mg/kg sediment dw
Sediment (marine water)	0.33 mg/kg sediment dw
Soil	0.141 mg/kg soil dw
Secondary poisoning	No potential for bioaccumulation

Lactic acid

PNEC	Value
Aqua (freshwater)	1.3 mg/L
Aqua (marine water)	No data available
STP	10 mg/L
Sediment (freshwater)	No data available
Sediment (marine water)	No data available
Soil	No data available
Secondary poisoning	No data available

Fatty acids (neutralized)

No information available

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Eye wash facilities and emergency shower must be available when handling this product.

8.2.2 Individual protection measures, such as personal protective equipment

General information	Use personal protective equipment as required. Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.
Eye/face protection	Wear approved, tight fitting indirect vented or non-vented safety goggles where splashing is probable. Face shield is recommended.
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves. Rubber, or vinyl-coated gloves are recommended
Other	Wear appropriate chemical resistant clothing.
Respiratory protection	If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.
Thermal	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

8.2.3 Environmental exposure controls

Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state	Liquid
Form	Semi-solid
Colour	Amber

Odour	Odourless
Odour threshold	No data available
pH	3 (3% solution/water)
Melting point/freezing point	No data available
Initial boiling point and boiling range	No data available
Flash point	> 93.3 °C (> 200.0 °F) Closed cup
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Upper/lower flammability or explosive limits	No data available
Vapour pressure	No data available
Vapour density	No data available
Relative density	0.9 – 1.1
Solubility(ies)	No data available
Partition coefficient: n-octanol/water	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidising properties	No data available
Other information	
Solubility (other)	Slightly soluble in acetone

SECTION 10: Stability and reactivity

10.1 Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2 Chemical stability	Undergoes hydrolysis in water to form lactic acid, glycerol, fatty acids.
10.3 Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4 Conditions to avoid	Temperatures exceeding the flash point. Contact with incompatible materials.
10.5 Incompatible materials	Strong oxidising agents. Bases. Acids.
10.6 Hazardous decomposition products	Thermal decomposition or combustion may produce: carbon oxides.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

3-D Microemulsion®

No data available on product itself. Classification determined based on toxicological data available on constituent substances.

Glycerol

<u>Acute toxicity</u>	<u>Species</u>	<u>Test Results</u>	<u>Method</u>
Oral LD50	Rat	LD50 27,200 mg/kg bw	No guideline followed; standard acute method
Inhalation LC50	Rat	LC50 > 2.75 mg/L (4hr, nominal)	No guideline followed; standard acute method
Dermal LD50	Guinea pig	LD50 > 56,750 mg/kg bw	No guideline followed; standard acute method
Skin corrosion/irritation	Rabbit	Not irritating	No guideline followed; published data
Serious eye damage/irritation	Rabbit	Not irritating	No guideline followed;

published data

Respiratory or skin sensitisation	No data available
Germ cell mutagenicity	Not considered to be mutagenic (equivalent/similar to OECD 471; equivalent/similar to OECD 476; equivalent/similar to OECD 482)
Carcinogenicity	Not considered to be carcinogenic; no guideline available, published data
Reproductive toxicity	Not considered to be reprotoxic; no guideline available, published data
STOT-single exposure	Not considered to cause specific target organic toxicity via single exposure
STOT-repeated exposure	Not considered to cause specific target organic toxicity via repeat exposure; equivalent/similar to OECD 452
Aspiration hazard	No data available; not considered to cause an aspiration hazard

Lactic acid

<u>Acute toxicity</u>	<u>Species</u>	<u>Test Results</u>	<u>Method</u>
Oral LD50	Rat	> 2,000 mg/kg bw	EPA OPP 81-1
Inhalation LC50	Rat	> 7.94 mg/L	OECD 403
Dermal LD50	Rabbit	> 2,000 mg/kg bw	EPA OPP 81-2
Skin corrosion/irritation	Causes skin irritation; based on a weight of evidence approach		
Serious eye damage/irritation	Chicken enucleated eye	Causes serious eye damage	No guideline followed
Respiratory or skin sensitisation	Guinea pig	Not sensitising	EPA OPP 81-6
Germ cell mutagenicity	Not considered to be mutagenic; no guideline followed (Ames test, chromosomal aberration test in vitro)		
Carcinogenicity	Rat	Not considered to be carcinogenic	No guideline followed
Reproductive toxicity	Not considered to be reprotoxic; no data available		
STOT-single exposure	Not considered to cause specific target organic toxicity via single exposure		
STOT-repeated exposure	Not considered to cause specific target organic toxicity via repeat exposure; no guideline followed		
Aspiration hazard	No data available; not considered to cause an aspiration hazard		

Fatty acids (neutralized)

No information available

SECTION 12: Ecological information

12.1 Toxicity

3-D Microemulsion®

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. No data available on product itself. Classification determined based on ecotoxicological data available on constituent substances.

Glycerol

<u>Ecotoxicological endpoint</u>	<u>Value</u>	<u>Species, Method</u>
Acute (short term toxicity): Fish	LC50 (96h) 54,000 mg/L	Oncorhynchus mykiss; no guideline followed
Crustacea	EC50 (24h) >10,000 mg/L	Daphnia magna; no guidelines followed
Algae/aquatic plants	EC3 (8d) > 10,000 mg/L	Scenedesmus quadricauda; no guideline followed
Activated sludge respiration	(comparable to) NOEC > 10,000 mg/L	Pseudomonas putida; no guideline followed

Chronic (long-term toxicity):	
Fish	No data available
Crustacea	No data available

Lactic acid

<u>Ecotoxicological endpoint</u>	<u>Value</u>	<u>Species, Method</u>
Acute (short term toxicity):		
Fish	LC50 (96h) 130 mg/L	Oncorhynchus mykiss; EPA-669/3-75-009
Crustacea	EC50 (48h) 130 mg/L	Daphnia magna; OECD 202
Algae/aquatic plants	NOEC 1.52 g/L	Pseudokirchneriella subcapitata; OECD 201
Activated sludge respiration	NOEC 100 mg/L	Activated sludge of predominantly domestic sewage; OECD 209
Chronic (long-term toxicity):		
Fish	No reliable data available	
Crustacea	No data available	

Fatty acids (neutralized)

No information available

12.2 Persistence and biodegradability

Material is readily degradable and undergoes hydrolysis in several hours.

12.3 Bioaccumulative potential

No data is available on the bioaccumulative potential of this product.

12.4 Mobility in soil

No data available of the mobility of this product.

12.5 Results of PBT and vPvB assessment

The constituent substances, and therefore the mixture, are not considered to be PBT or vPvB.

12.6 Other adverse effects

None known

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Residual waste	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN Number	N/A – not regulated as dangerous goods			
14.2 UN proper shipping name				
14.3 Transport hazard class(es) Class Subsidiary risk Label(s) Hazard No. Tunnel restriction code				
14.4 Packing group				
14.5 Environmental hazards				

14.6 Special precautions for user

Read safety instructions, SDS and emergency procedures before handling.

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

No information available

SECTION 15: Regulatory information

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

None identified

15.2 Chemical safety assessment

A chemical safety assessment has been performed for lactic acid.

SECTION 16: Regulatory information

This SDS supersedes the SDS dated 22 November 2017

The following amendments have been made:

- SDS has been fully revised in accordance with Regulation (EU) No 453/2010 and Regulation (EC) No. 1272/2008 (EU CLP) and in accordance with new information on the constituent substances registered under Regulation (EC) 1907/2006 (EU REACH)

List of abbreviations:

ADN: European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways.

ADR: European Agreement Concerning the International Carriage of Dangerous Goods by Road.

CAS: Chemical Abstract Service.

CEN: European Committee for Standardization (Comité Européen de Normalisation).

DNEL: Derived No-Effect Level. ECHA: European Chemical Agency.

IATA: International Air Transport Association. IBC: Intermediate Bulk Container. IMDG: International Maritime Dangerous Goods

MARPOL: International Convention for the Prevention of Pollution from Ships. PBT: Persistent, bioaccumulative, toxic.

PNEC: Predicted No-Effect Concentration.

RID: Regulations concerning the International Carriage of Dangerous Goods by Rail. vPvB: very Persistent, very Bioaccumulative.

References:

ECHA registered substances database, accessed July 2018

<https://echa.europa.eu/registration-dossier/-/registered-dossier/5165/1>

<https://echa.europa.eu/registration-dossier/-/registered-dossier/14481>

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any H-statements not written out in full under Sections 2 to 15:

H315 Causes skin irritation.

H318 Causes serious eye damage.

Training information

Follow training instructions when handling this material.

Disclaimer:

Regenesis cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.

ANNEX

EXPOSURE SCENARIOS

Exposure scenarios prepared by the lead registrant for lactic acid are provided in the tables immediately below. Exposure scenarios are not provided for the other components as registration of these was not required.

1. Exposure scenario 1: Generic exposure scenario for lactic acid; production, transport, downstream use

1.1 Exposure scenario

1.1.1 Description of activities and processes covered in the exposure scenario

Lactic acid is a non-toxic substance that is a basic metabolic and energetic building block in practically all life-forms, from bacteria to primates. It is not labelled for environmental effects or ecotoxicity, and is also not labelled for any human effects, with the exception of skin and eye irritation (Lactic acid is classified for skin as GHS: Category 2, and for eyes as GHS: Category 1). Note that the skin and eye irritation potential of lactic acid is a pH effect - buffered lactic acid, even up to 70% aqueous solutions is not irritating.

As such, no risk assessment for the environment is required, and no environmental exposure assessment is necessary. For human health, lactic acid is not labelled for any 'dose-effect' endpoint, and thus no quantitative risk assessment is necessary or possible.

Lactic acid is labelled for skin and eye irritation. Under the current classification and labelling requirements for preparations, preparations containing less than 10 % lactic acid do not have to be classified and labelled for skin irritation, and preparations containing less than 5 % lactic acid do not have to be classified for eye irritation.

No end use products are made from lactic acid that contain more than 5 % lactic acid, therefore no end use product has to be classified based solely on the presence of lactic acid.

Intermediate formulations and products, relevant in the preparation of any supported end use product, such as aqueous dilutions of lactic acid, may contain more than 5 % lactic acid, and thus may have to be labelled for irritation.

In all production, storage and transportation conditions and processes, regardless of use, where lactic acid, pure or as dilutions or formulations containing ≥ 5 % lactic acid, is handled, i.e. where there would be a potential for human exposure to a 'dangerous substance or preparation', risk management measures are already prescribed, and enforced, that exclude any possible skin and eye exposure to lactic acid. In all identified downstream uses where lactic acid, and its dilutions or formulations containing ≥ 5 % lactic acid are handled (such as the receipt of transported lactic acid, the storage of lactic acid, the introduction of lactic acid in any relevant process, the preparation, handling and storage of any intermediate dilution or formulation, all the way down to dilutions and products containing < 5 % lactic acid), i.e. where there would be a potential for human exposure to a 'dangerous substance or preparation', risk management measures are already prescribed, and enforced, that exclude any possible skin and eye exposure to lactic acid.

As such, a generic exposure scenario for all identified uses of lactic acid can be defined:

- For the environment, no hazards are identified, and no exposure assessment is required.
- For human exposure, the only identified hazards are skin and eye irritation, and due to RMM, no exposure to lactic acid or its relevant dilutions is possible. Exposure is 0.

9.1.1.2 Operational conditions related to frequency, duration and amount of use

Not relevant. For human exposure, the only identified hazards are skin and eye irritation, and due to RMM, no exposure to lactic acid or its relevant dilutions is possible. Exposure is 0.

9.1.1.3 Operational conditions and risk management measures related to product characteristics

In *all* production, storage and transportation conditions and processes, regardless of use, where lactic acid, pure or as dilutions or formulations containing ≥ 5 % lactic acid, is handled, i.e. where there would be a potential for human exposure to a 'dangerous substance or preparation', risk management measures are already prescribed, and enforced, that exclude any possible skin and eye exposure to lactic acid. In all identified downstream uses where lactic acid, and its dilutions or formulations containing ≥ 5 % lactic acid are handled (such as the receipt of transported lactic acid, the storage of lactic acid, the introduction of lactic acid in any relevant process, the preparation, handling and storage of any intermediate dilution or formulation, all the way down to dilutions and products containing < 5 % lactic acid), i.e. where there would be a potential for human exposure to a 'dangerous substance or preparation', risk management measures are already prescribed, and enforced, that exclude any possible skin and eye exposure to lactic acid.

Risk Management Measures:

HANDLING AND STORAGE

Handling

Technical measures/Precautions

Avoid temperatures above 200°C.

Safe handling advice

Wear personal protective equipment.

Do not breathe spray mist.

Storage

Technical measures/Storage conditions

Keep container tightly closed. Keep in properly labelled containers.

Incompatible products

No data available.

Packaging material

Plastic or stainless steel 316 L containers.

1.1.4 Operational conditions related to available dilution capacity and characteristics of exposed humans

For human exposure, the only identified hazards are skin and eye irritation, and due to RMM, no exposure to lactic acid or its relevant dilutions is possible. Exposure is 0.

1.1.5 Other operational conditions of use

For the environment, no hazards are identified, and no exposure assessment is required.

1.1.6 Risk management measures

Risk management measures below are relevant to the complete general exposure scenario. Implementation of the risk management measures excludes any possible skin and eye exposure to lactic acid. Effectiveness of the RMM therefore is 100 %.

EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering measures to reduce exposure

Ensure adequate ventilation, especially in confined areas.

Control parameters

None.

Personal protection equipment

Respiratory protection

Not required; except in case of aerosol formation.

Breathing apparatus needed only when aerosol or mist is formed.

Hand protection

Rubber gloves. Break through time > 8 hours.

Eye protection

Face-shield.

Skin and body protection

Long sleeved clothing, chemical resistant apron boots.

Hygiene measures

Avoid contact with skin. When using, do not eat, drink or smoke.

Remove and wash contaminated clothing before re-use.

1.1.7 Waste related measures

Not applicable. Lactic acid poses no threat to the environment.

1.2 Exposure estimation

Lactic acid is a non-toxic substance that is a basic metabolic and energetic building block in practically all life-forms, from bacteria to primates. It is not labelled for environmental effects or ecotoxicity, and is also not labelled for any human effects, with the exception of skin and eye irritation (Lactic acid is classified for skin as GHS: Category 2, and for eyes as GHS: Category 1). Note that the skin and eye irritation potential of lactic acid is a pH effect – buffered lactic acid, even up to 70 % aqueous solutions is not irritating.

For human health, lactic acid is not labelled for any 'dose-effect' endpoint, and thus no quantitative risk assessment is necessary or possible.

1.2.1 Workers exposure

In *all* production, storage and transportation conditions and processes, regardless of use, where lactic acid, pure or as dilutions or formulations containing ≥ 5 % lactic acid, is handled, i.e. where there would be a potential for human exposure to a 'dangerous substance or preparation', risk management measures are already prescribed, and enforced, that exclude any possible skin and eye exposure to lactic acid. In all identified downstream uses where lactic acid, and its dilutions or formulations containing ≥ 5 % lactic acid are handled (such as the receipt of transported lactic acid, the storage of lactic acid, the introduction of lactic acid in any relevant process, the preparation, handling and storage of any intermediate dilution or formulation, all the way down to dilutions and products containing < 5 % lactic acid), i.e. where there would be a potential for human exposure to a 'dangerous substance or preparation', risk management measures are already prescribed, and enforced, that exclude any possible skin and eye exposure to lactic acid.

1.2.1.1 Acute/Short term exposure

For human exposure, the only identified hazards are skin and eye irritation, and due to RMM, no exposure to lactic acid or its relevant dilutions is possible. Exposure is 0.

1.2.1.2 Long-term exposure

For human exposure, the only identified hazards are skin and eye irritation, and due to RMM, no exposure to lactic acid or its relevant dilutions is possible. Exposure is 0.

1.2.2 Consumer exposure

Lactic acid is labelled for skin and eye irritation. Under the current classification and labelling requirements for preparations, preparations containing less than 10 % lactic acid do not have to be classified and labelled for skin irritation, and preparations containing less than 5 % lactic acid do not have to be classified for eye irritation.

No end use products are made from lactic acid that contain more than 5 % lactic acid, therefore no end use product has to be classified based solely on the presence of lactic acid.

1.2.2.1 Acute/Short term exposure

Not relevant.

1.2.2.1 Long-term exposure

Not relevant.

1.2.3 Indirect exposure of humans via the environment (oral)

For human exposure, the only identified hazards are skin and eye irritation, and due to RMM, no exposure to lactic acid or its relevant dilutions is possible. Exposure is 0.

1.2.4 Environmental exposure

Lactic acid is a non-toxic substance that is a basic metabolic and energetic building block in practically all life-forms, from bacteria to primates. It is not labelled for environmental effects or ecotoxicity, and is also not labelled for any human effects, with the exception of skin and eye irritation (lactic acid is classified for skin as GHS: Category 2, and for eyes as GHS: Category 1). Note that the skin and eye irritation potential of lactic acid is a pH effect – buffered lactic acid, even up to 70 % aqueous solutions is not irritating.

As such, no risk assessment for the environment is required, and no environmental exposure assessment is necessary.

1.2.4.1 Environmental releases

Not relevant.

1.2.4.2 Exposure concentration in sewage treatment plants (STP)

Not relevant.

1.2.4.3 Exposure concentration in aquatic pelagic compartment

Not relevant.

1.2.4.4 Exposure concentration in sediments

Not relevant.

1.2.4.5 Exposure concentrations in soil and groundwater

Not relevant.

1.2.4.6 Atmospheric compartment

Not relevant.

1.2.4.7 Exposure concentration relevant for the food chain (secondary poisoning)

Not relevant.

2 Regional exposure concentrations

For the environment, no hazards are identified, and no exposure assessment is required.

For human exposure, the only identified hazards are skin and eye irritation, and due to RMM, no exposure to lactic acid or its relevant dilutions is possible. Exposure is 0.