

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

### 1.1 Product identifier

Trade name or designation of the mixture    Hydrogen Release Compound PRIMER (HRC PRIMER®)  
 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)

Skin Irrit. 2 – H315

Eye. Dam. 1 – H318

### 2.2 Label elements

Hazard pictograms



Signal word    Danger

Hazard Statements                                H315    Causes skin irritation  
     H318    Causes serious eye damage

|                          |   |  |
|--------------------------|---|--|
| Precautionary Statements | P264<br>P280<br>P302 + P352<br>P305 + P351 + P338<br><br>P310<br>P362 | Wash hands thoroughly after handling<br>Wear protective gloves/eye/face protection<br>IF ON SKIN: Wash with plenty of water<br>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing<br>Immediately call a POISON CENTER or doctor<br>Take off contaminated clothing and wash it before reuse |
|--------------------------|---|--|

### 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                            |
|--------------------------|-----------|-------------|-------|------------------------|-----------|---|
| Lactic acid              | 200-018-0 | 50-21-5     | 90    | 01-2119474164-39-0010  | N/A       | Skin Irrit. 2 – H315<br>Eye Dam. 1 – H318 |
| Glycerol tripoly lactate | -         | 201167-72-8 | 6-7   | N/A                    | N/A       | Not classified as hazardous               |
| Glycerol                 | 200-289-5 | 56-81-5     | 3-4   | N/A                    | 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 <sub>2</sub> ). 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)

Soil and Groundwater Remediation

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

Occupational exposure limit values

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

|                          |                          |
|--------------------------|--------------------------|
| 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 <sup>3</sup>    | ppm                      | mg/m <sup>3</sup>     |
| 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.    |                      |                          |                       |

Recommended monitoring procedures: Follow standard monitoring procedures

Derived no effect levels (DNELs):

#### Lactic acid

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

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

### 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 <sup>3</sup>  |
|                | 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 <sup>3</sup>   |
|                | 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  |

Predicted no effect concentrations (PNECs):

### 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 |

#### 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 |

## 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   | Viscous gel/liquid    |
| 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                                  | No data available     |
| 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                             | 1.1 – 1.3             |
| 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                                    | 150,000 – 300,000 cP  |
| Explosive properties                         | No data available     |
| Oxidising properties                         | No data available     |
| Other information                            |                       |
| Solubility (other)                           | Acetone, DMSO         |

## 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.  |
| 10.3 Possibility of hazardous reactions | No dangerous reaction known under conditions of normal use.   |
| 10.4 Conditions to avoid                | 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, phosphorus compounds, metal oxides. |

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Hydrogen Release Compound PRIMER (HRC PRIMER®)

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

#### 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   |                                   |                       |

### 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   |                                 |  |

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Hydrogen Release Compound PRIMER (HRC PRIMER®)

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.

#### 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):<br>Fish | No reliable data available |   |
| Crustacea                             | No data available          |   |

Glycerol

| <u>Ecotoxicological endpoint</u>      | <u>Value</u>                       | <u>Species, Method</u>                         |
|---------------------------------------|------------------------------------|--|
| Acute (short term toxicity):<br>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):<br>Fish | No data available                  |  |
| Crustacea                             | No data 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)<br>Class<br>Subsidiary risk<br>Label(s)<br>Hazard No.<br>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 11 October 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:

Hydrogen Release Compound PRIMER (HRC PRIMER®)  
923940 Version #: 03

Revision Date: 03/08/2018

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  $\geq 5$  % 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  $\geq 5$  % 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  $\geq 5$  % 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  $\geq 5\%$  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  $\geq 5$  % 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  $\geq 5$  % 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.