

Section A8

Measures necessary to protect man, animals and the environment

Official
use onlySubsection
(Annex Point)

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| 8.1 | Recommended methods and precautions concerning handling, use, storage, transport or fire (IIA8.1) | |
| 8.1.0 | Methods and precautions concerning placing on the market | Packaging material: plastic or stainless steel 316 L containers. |
| 8.1.1 | Methods and precautions concerning production, handling and use of the active substance and its formulations | Avoid temperatures above 200 °C, wear personal protective equipment, and do not breathe spray mist. |
| 8.1.2 | Methods and precautions concerning storage of the active substance and its formulations | Keep container tightly closed, keep in properly labelled containers. |
| 8.1.3 | Methods and precautions concerning transport of the active substance and its formulations | Not classified as dangerous in the meaning of transport regulations. |
| 8.1.4 | Methods and precautions concerning fire of the active substance and its formulations | Suitable extinguishing media: water carbon dioxide (CO ₂), foam. No unsuitable extinguishing media. Specific hazards: thermal decomposition can lead to release of irritating gases and vapours. Special protective equipment for fire-fighters: personal protective equipment. Specific methods: standard procedure for chemical fires. |
| 8.2 | In case of fire, nature of reaction products, combustion gases, etc. (IIA8.2) | Thermal decomposition can lead to the release of irritating gases and vapours. |

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| 8.3 | | Emergency measures in case of an accident (IIA8.3) |
| 8.3.1 | Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available | <p>General advice: Show the safety data sheet to the doctor in attendance.</p> <p>Inhalation: Immediate medical attention is not required. Move to fresh air.</p> <p>Skin contact: Immediate medical attention is not required. Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.</p> <p>Eye contact: Immediate medical attention is not required. Rinse immediately with plenty of water also under the eyelids for at least 15 minutes. If eye irritation persists consult a specialist.</p> <p>Ingestion: Immediate medical attention is required. Drink plenty of water. Do not induce vomiting. Call a physician immediately.</p> <p>Protection of first-aid workers: Wear protective equipment.</p> |
| 8.3.2 | Emergency measures to protect the environment | Waste from residues can be disposed as waste water, landfilled or incinerated, when in compliance with local regulations. |
| 8.4 | | Possibility of destruction or decontamination following release in or on the following: (a) Air; (b) Water, including drinking water; (c) Soil (IIA8.4) |
| 8.4.1 | Possibility of destruction or decontamination following release in the air | Substance will be decomposed rapidly. |
| 8.4.2 | Possibility of destruction or decontamination following release in water, including drinking water | Substance will be decomposed rapidly. |
| 8.4.3 | Possibility of destruction or decontamination following release in or on soil | Substance will be decomposed rapidly. |
| 8.5 | | Procedures for waste management of the active substance for industry or professional users e.g. possibility of re-use or recycling, neutralisation, conditions for controlled discharge, and incineration (IIA8.5) |
| 8.5.1 | Possibility of re-use or recycling | Empty containers should be taken for local recycling recovery or waste disposal. |
| 8.5.2 | Possibility of neutralisation of effects | Not applicable |

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| 8.5.3 Conditions for controlled discharge including leachate qualities on disposal | Waste from residues can be disposed as waste water, landfilled, or incinerated, when in compliance with local regulations. |
| 8.5.4 Conditions for controlled incineration | No specific conditions. |
| 8.6 | Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms (IIA8.6) Not applicable |
| 8.7 | Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances (IIA8.7) Not applicable |

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

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|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Date | 2008-08-06 / 2009/04/28 |
| Materials and methods | Recommendations about protective measures are given on the basis of expert judgement. Any results of studies about e.g. the effectiveness of PPE are not reported by the participant. |
| Results and discussion | Applicants version is acceptable (environmental) |
| Conclusion | Applicants version is acceptable (environmental) |
| Reliability | Additional information about protective measures has to be given by the participant. |
| Acceptability | Not applicable |
| Acceptability | Acceptable but incomplete |
| Remarks | Acceptable (environmental) |

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8.1.1 Methods and precautions concerning production, handling and use of the active substance and its formulations

- *1 The information about PPE is not provided in the necessary quality. For all of these precautions specifications about kind and quality are not given. The PPE has to be described more detailed, e. g. the material, the thickness and the penetration time of the gloves(EN 374), the type of the eye protection (EN 166), the material of the work clothing and if necessary the mask and filter type of the respiratory protection. In the safety data sheet for the active substance (chapter 8) the participant also has to provide this more detailed information concerning PPE.

8.1.4 Methods and precautions concerning fire of the active substance and its formulations

- *2 The PPE is described in general terms. Quality standards are not provided by the participant.

Safety Data Sheet

No. 8 Exposure Controls / Personal Protection:

The PPE has to be described more detailed, e.g. the thickness of the gloves (EN 374) and the material of the work clothing.

As the resistance of chemical protection gloves does not apply for all gloves of the same material and thickness (but strongly depends on the quality of raw material, production process, etc.) and the choice of wrong protection gloves can be more harmful than wearing none, the provided information should be amended by preferably one definite brand proven to protect from all hazardous substances of the product (for at least 30 minutes), confirmed in writing by the glove supplier.

Date

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

Section A9. CLASSIFICATION AND LABELLING

The classification of lactic acid according to the criteria set out in Directive 67/548/EC and Directive 1999/45/EC is as follows:

SYMBOL:

- Xi: irritant

LABEL FOR SUPPLY:

Xi



Irritant


RISK PHRASES:

- R38: Irritating to skin
- R41: Risk of serious damage to eyes

SAFETY PHRASES:

- S24: Avoid contact with skin
- S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
- S37/39: Wear suitable gloves and eye/face protection

| Evaluation by Competent Authorities | |
|--------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | EVALUATION BY RAPPORTEUR MEMBER STATE |
| Date | 2008/07/23 |
| Evaluation | L(+) lactic acid is not listed in Annex I of Council Directive 67/548/EEC (up to 29 th ATP). The classification proposed by the applicant regarding R41 is in accordance with the criteria set out in Directive 67/548/EC. |

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| Conclusion | <p>The applicant's proposal regarding the R phrases is justified: Xi, R38 (Irritating to skin), R41(Risk of serious damage to eyes) According to GHS the following classification and labeling is warranted:</p>  <p>Eye Dam. 1, H318: Causes serious eye damage Skin Irrit. 2, H315: Causes skin irritation</p> |
| Remarks | None |
| Date | COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i> <i>Give date of comments submitted</i> |
| Evaluation of applicant's justification | <i>Discuss if deviating from view of rapporteur member state</i> |
| Conclusion | <i>Discuss if deviating from view of rapporteur member state</i> |
| Remarks | |

| Evaluation by Competent Authorities | |
|--------------------------------------------|------------------------------------------------------------------------------------------------|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | EVALUATION BY RAPPORTEUR MEMBER STATE |
| Date | 2009/04/15 (Environment) |
| Materials and methods | Applicants version is acceptable |
| Results and discussion | Applicants version is acceptable |
| Conclusion | acceptable |
| Reliability | |
| Acceptability | acceptable |
| Remarks | No classification and labelling for environmental risks are required. |
| Date | |
| Results and discussion | |
| Conclusion | |
| Reliability | |
| Acceptability | |
| Remarks | |

APPENDIX to Doc III A – Reference list sorted by author

Reference List geordnet nach Autoren

| Author(s) | Section No / Reference No | Year | Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published | Data Protection Claimed (Yes/No) | Owner |
|-----------------------------------------------------------------------------------------------|----------------------------------------------|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-------|
| Alakomi, H.-L., Skyttä, E., Saarela, M., Mattila-Sandholm, T., Latva-Kala, K., Helander, I.M. | A5-01 | 2000 | Lactic acid permeabilizes Gram-negative bacteria by disrupting the outer membrane. Applied and Environmental Microbiology, Vol. 66, No.5, p.2001-2005. Not GLP, unpublished | N | - |
| Al-Ani, F.Y., Al-Lami, S.K. | A6.6.1-02* | 1988 | Absence of mutagenic activity of acidity regulators in the Ames Salmonella/microsome test. Mutation Research, Vol. 206, p. 467-470 Not GLP, Published | N | - |
| Andersen, F.A. | A6.1.4-11* | 1997 | Safety assessment of glycolic acid, ammonium, calcium, potassium, and sodium glycolate, methyl, ethyl, propyl, and butyl glycolate, and lactic acid, ammonium calcium, potassium, sodium, and TEA-lactate, methyl, ethyl, isopropyl, and butyl lactate, and lauryl, myristyl, and cetyl lactate Cosmetic Ingredients Review, final report. International Journal of Toxicology, Vol.17, Suppl.1 Not GLP, Published | N | - |
| Andersen, F.A. | A6.6-01 Is a cross-reference to A6.1.4-11 | 1997 | Safety assessment of glycolic acid, ammonium, calcium, potassium, and sodium glycolate, methyl, ethyl, propyl, and butyl glycolate, and lactic acid, ammonium calcium, potassium, sodium, and TEA-lactate, methyl, ethyl, isopropyl, and butyl lactate, and lauryl, myristyl, and cetyl lactate Cosmetic Ingredients Review, final report. International Journal of Toxicology, Vol.17, Suppl.1 Not GLP, Published | N | - |
| Andersen, F.A. | A6.7-02 Is a cross-reference to A6.1.4-11 | 1997 | Safety assessment of glycolic acid, ammonium, calcium, potassium, and sodium glycolate, methyl, ethyl, propyl, and butyl glycolate, and lactic acid, ammonium calcium, potassium, sodium, and TEA-lactate, methyl, ethyl, isopropyl, and butyl lactate, and lauryl, myristyl, and cetyl lactate | N | - |

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|----------------------------------------------------------------------------------------------------|------------------------------------------------------|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-------|
| | | | Cosmetic Ingredients Review, final report. International Journal of Toxicology, Vol.17, Suppl.1 Not GLP, Published | | |
| Anonymous | A4.1-02 | 1968 | Milchsäure, Acidium lacticum. Deutsches Arzneibuch, 7 th edition, Deutscher Apotheker-Verlag, Stuttgart, Govi-Verlag GmbH, Frankfurt, p. 680-681. Not GLP, unpublished | No | - |
| Baltussen, E. | A7.1.3 | 2008 | Estimation of the adsorption coefficient (Koc) of lactic acid 93% aq on soil and on sewage sludge using high performance liquid chromatography (HPLC) Notox Document 489046, GLP, Unpublished | Y | Purac |
| ██████████ | A7.5.3.1.1-01 | 1984 | An acute oral toxicity study in the bobwhite with SY-83 Wildlife International Ltd. Report nr. 203-103, Not GLP, Unpublished | Y | Purac |
| ██████████ | A7.5.3.1.2-01 | 1984 | A dietary LC50 study in the bobwhite with SY-83 Wildlife International Ltd. Report nr. 203-101; Not GLP, Unpublished | Y | Purac |
| ██████████ | A7.5.3.1.2-02 | 1984 | A dietary LC50 study in the mallard with SY-83 Wildlife International Ltd. Report nr. 203-102, Not GLP, Unpublished | Y | Purac |
| Black, J. | A2-01 Included in the confidential part | 2002 | Letter to Purac concerning the identity of SY-83. Entek corporation, no number Not GLP, not published | Y | Purac |
| Bouwman, L.M. | A7.4.1.4-01 | 2007 | Activated sludge respiration inhibition test with PURAC HS 88, NOTOX Project nr. 483211, GLP, Published | Y | Purac |
| Bowmer, C.T., Hooftman, R.N., Hanstveit, A.O., Venderbosch, P.W.M., Van der Hoeven, N. | A7.1.1.2.1-02 | 1998 | The ecotoxicity and the biodegradability of lactic acid, alkyl lactate esters and lactate salts, Chemosphere, Vol. 37, No. 7, pp. 1317-1333, Not GLP, Published | N | - |
| Bowmer, C.T., Hooftman, R.N., Hanstveit, A.O., Venderbosch, P.W.M., Van der Hoeven, N. | A7.4.1.1-06 Is a cross-reference to A7.1.1.2.1-02 | 1998 | The ecotoxicity and the biodegradability of lactic acid, alkyl lactate esters and lactate salts Chemosphere, Vol. 37, No. 7, pp. 1317-1333, Not GLP, Published | N | - |
| Bowmer, C.T., Hooftman, R.N., Hanstveit, A.O., Venderbosch, P.W.M., Van der Hoeven, N. | A7.4.1.2-03 Is a cross-reference to A7.1.1.2.1-02 | 1998 | The ecotoxicity and the biodegradability of lactic acid, alkyl lactate esters and lactate salts; Chemosphere, Vol. 37, No. 7, pp. 1317-1333, Not GLP, Published | N | - |

| Author(s) | Section No / Reference No | Year | Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published | Data Protection Claimed (Yes/No) | Owner |
|----------------------------------------------------------------------------------------------------|---------------------------------------------------------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-------|
| Bowmer, C.T., Hooftman, R.N., Hanstveit, A.O., Venderbosch, P.W.M., Van der Hoeven, N. | A7.4.1.3-02 Is a cross-reference to A7.1.1.2.1-02 | 1998 | The ecotoxicity and the biodegradability of lactic acid, alkyl lactate esters and lactate salts, Chemosphere, Vol. 37, No. 7, pp. 1317-1333, Not GLP, Published | N | - |
| Connor, H. Woods, H.F | A6.2-04 | 1982 | Metabolic acidosis. Pitman Books Ltd London (Ciba Foundation symposium 87) p. 214-234 Not GLP, Published | N | - |
| ██████████ ██████████ | A6.1.4-08 | 1986 | Lactic acid Q88: a skin corrosivity test in guinea pigs Inveresk Research International Report nr. 3625 GLP, Unpublished | Y | Purac |
| ██████████ | A6.1.3-01* | 1987 | Acute inhalation toxicity study of SY-83 in the rat Microbiological Associated Inc. Report nr. I-7083.112 GLP, Unpublished | Y | Purac |
| Demerec, M., Bertani, G., Flint, J. | A6.6.1-01 | 1951 | A survey of chemicals for mutagenic action on E.coli The American Naturalist, Vol. 85, no. 821: pp 119-136 Not GLP, Published | N | - |
| Dingledine, J. | A7.5.4.1-01 | 1985 | A dermal contact LD50 study in honey bees with SY-83 Wildlife International Ltd. Report nr. 203-108, Not Glp, Unpublished | Y | Purac |
| EPIsuite | A3.1.2-04 | No date | Results of the EPIWIN calculation. Generated with the program EPIsuite v3.20 (February 2007). US Environmental Protection Agency. Not GLP, not published | Y | Purac |
| EPIsuite | A3.2.1-02 Is a cross-reference to A3.1.2-04 | No date | Results of the EPIWIN calculation. Generated with the program EPIsuite v3.20 (February 2007). US Environmental Protection Agency., Not GLP, not published | Y | Purac |
| EPIsuite | A3.9-02 Is a cross-reference to A3.1.2-04 | No date | Results of the EPIWIN calculation. Generated with the program EPIsuite v3.20 (February 2007). US Environmental Protection Agency Not GLP, not published | Y | Purac |
| European Chemicals Bureau | A3.9-03 | 2000 | IUCLID dataset L(+) lactic acid European Chemicals Bureau IUCLID-file European HPV program Not GLP. published | N | - |
| ██████████ ██████████ | A7.4.1.1-02 | 1984 | Acute toxicity of SY-83 to rainbow trout (Salmo gairdneri) | Y | Purac |

| Author(s) | Section No / Reference No | Year | Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published | Data Protection Claimed (Yes/No) | Owner |
|----------------------------------------|---------------------------------------------|-------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-------|
| | | | ABC Inc. Report nr. #32147 GLP, Unpublished | | |
| ██████████ ██████████ | A7.4.1.1-03 | 1984 | Acute toxicity of SY-83 to bluegill sunfish (<i>Lepomis macrochirus</i>) ABC Inc. Report nr. #32146, GLP, Unpublished | Y | Purac |
| Forbis, A.D., Burgess, D., Georgie, L. | A7.4.1.2-02 | 1984 | Acute toxicity of SY-83 to <i>Daphnia magna</i> ; ABC Inc. Report nr. #32148, GLP, Unpublished | Y | Purac |
| Hanstveit, A.O., Oldersma, H. | A7.4.1.3-01 | 1992 | Effect of L(+) lactic acid on the growth of the alga <i>Selenastrum capricornutum</i> (OECD 201), TNO Report nr. IMW-91-0076-05, GLP, Unpublished | Y | Purac |
| Hanstveit, A.O., Pullens, M.A.H.L. | A7.1.1.2.1-01 | 1993 | BOD and COD of the product L(+) lactic acid according to EC Test Guidelines C.8 and C.9 TNO Report nr. IMW-R 92/018, GLP, Unpublished | Y | Purac |
| Harbell, J.W. | A6.1.4-10 | 1994 | Corrositex Continuous Time Monitor Assay Microbiological Associates Inc. Report nr. A000449 Not GLP, Unpublished | Y | Purac |
| Heesen, G.J. | A3.6-03 | 1970 | Bepaling van de zuursterkte van melkzuur en lactoymelkzuur Purac Internal report. Purac, no report no Not GLP, unpublished. | N | Purac |
| Holten, C.H. | A3.1.1-02 | 1971a | Lactic acid. Properties and Chemistry of Lactic Acid and Derivatives. Chapter IV: Physical properties. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. Not GLP, published. | N | - |
| Holten, C.H. | A3.1.2-02 is a cross reference to A3.1.1-02 | 1971a | Lactic acid. Properties and Chemistry of Lactic Acid and Derivatives. Chapter IV: Physical properties. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. Not GLP, published | N | - |
| Holten, C.H. | A3.1.3-02 is a cross reference to A3.1.1-02 | 1971a | Lactic acid. Properties and Chemistry of Lactic Acid and Derivatives. Chapter IV: Physical properties. | N | - |
| Holten, C.H. | A3.4-02 | 1971b | Lactic acid. Properties and Chemistry of Lactic Acid and Derivatives. Chapter VI: Spectra. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. Not GLP, published. | N | - |
| Holten, C.H. | A3.4-03 | 1971c | Lactic acid. Properties and Chemistry of | N | - |

| Author(s) | Section No / Reference No | Year | Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published | Data Protection Claimed (Yes/No) | Owner |
|----------------|-------------------------------------------------|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-------|
| | | | Lactic Acid and Derivatives. Chapter XIX: Stability of Crystalline L-(+)-Lactic Acid.XIX: Stability of Crystalline L-(+)-Lactic Acid. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. | | |
| Holten, C.H. | A3.5-02 is a cross reference to A3.1.1-02 | 1971a | Lactic acid. Properties and Chemistry of Lactic Acid and Derivatives. Chapter IV: Physical properties. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. Not GLP, published | N | - |
| Holten, C.H. | A3.6-02 | 1971d | Lactic acid. Properties and Chemistry of Lactic Acid and Derivatives. Chapter V: Physical chemistry. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. Not GLP, published | N | - |
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| Holten, C.H. | A3.13-02 is a cross reference to A3.1.1-02 | 1971a | Lactic acid. Properties and Chemistry of Lactic Acid and Derivatives. Chapter IV: Physical properties. Verlag Chemie GmbH, Weinheim/Bergstr. Germany Not GLP, published | N | - |
| Holten, C.H. | A3.14-02 is a cross reference to A3.1.1-02 | 1971a | Lactic acid. Properties and Chemistry of Lactic Acid and Derivatives. Chapter IV: Physical properties. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. Not GLP, published | N | - |
| Holten, C.H. | A4.1-01 | 1971e | Lactic acid. Properties and Chemistry of Lactic Acid and Derivatives. Chapter XVIII: Analytical chemistry. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. Not GLP, unpublished | N | - |
| Hooftman, R.N. | A7.4.1.1-04 | 1992 | Evaluation of the toxicity of lactic acid and lactates to aquatic organisms TNO Report nr. IMW-R 92/256, Not GLP, Unpublished | Y | Purac |
| Hooftman, R.N. | A7.4.1.2-04 Is a cross-reference to A7.4.1.1-04 | 1992 | Evaluation of the toxicity of lactic acid and lactates to aquatic organisms TNO Report nr. IMW-R 92/256, Not GLP, Unpublished | Y | Purac |

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|------------------------------------------------------------------------------------------------------------|----------------------------------------------------|------|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-------|
| Hooftman, R.N. | A7.4.1.3-03 Is a cross-reference to A7.4.1.1-04 | 1992 | Evaluation of the toxicity of lactic acid and lactates to aquatic organisms TNO Report nr. IMW-R 92/256, Not GLP, Unpublished | Y | Purac |
| Hooftman, R.N., Kauffman-Van Bommel, J.A., Van Drongelen- Sevenhuijsen, D. | A7.4.1.1-01 | 1992 | The acute toxicity of L(+) lactic acid to <i>Brachydanio rerio</i> (OECD Guideline No. 203) TNO Report nr. IMW-91-0076-02 GLP, Unpublished | Y | Purac |
| Hooftman, R.N., Kauffman-Van Bommel, J.A., Van Drongelen- Sevenhuijsen, D. | A7.4.1.2-01 | 1992 | The acute toxicity of L(+) lactic acid to <i>Daphnia magna</i> (OECD Guideline No. 202, 48h) TNO Report nr. IMW-91-0076-01 GLP, Unpublished | Y | Purac |
| Ishidate, M. Jr., Sofuni, T., Yoshikawa, K., Hayashi, M., Nohmi, T., Sawada, M., Matsuoaka, A. | A6.6-02* | 1984 | Primary mutagenicity screening of food additives currently used in Japan. Food Chem. Tox. Vol. 22, p. 623-636 Not GLP, Published | N | - |
| Klein, J. | A4.1-03 | 2001 | Assay of Lactic acid. Purac Document no. AMLAC009 Not GLP, unpublished | Yes | Purac |
| Klein, J. | A4.1-04 | 2000 | Standardization of 1N hydrochloric acid Purac Document no. AMSTD002 Not GLP, unpublished | Yes | Purac |
| Klein, J. | A4.1-05 | 2000 | Standardization of 1N sodium hydroxide Purac Document no. AMSTD003 Not GLP, unpublished | Yes | Purac |
| Klein, J. | A4.2-01 | 2007 | Lactic acid in earth Purac Document no. AMENV001 Not GLP, unpublished | Yes | Purac |
| Korevaar, L. | A3.1.3-03 | 1996 | Physical properties lactic acid solutions Purac internal report Purac report no. 95-80 Not GLP | Y | Purac |
| Korevaar, L. | A3.13-03 is a cross-reference to A3.1.3-03 | 1996 | Physical properties lactic acid solutions Purac internal report Not GLP | Y | Purac |
| Korevaar, L. | A3.14-03 is a cross reference to A3.1.3-03 | 1996 | Physical properties lactic acid solutions Purac internal report Purac report no. 95-80 Not GLP | Y | Purac |
| | A6.1.5-01* | 1986 | Dermal sensitization study in guinea pigs with SY-83 American Biogenics Corporation, Report nr. 480-2750 GLP, Unpublished | Y | Purac |
| Lobbes, R.P. | A3.10-02 | 1998 | Stress-testing of lactic acid Purac internal report | Y | Purac |

| Author(s) | Section No / Reference No | Year | Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published | Data Protection Claimed (Yes/No) | Owner |
|-------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-------|
| | | | Not GLP, unpublished | | |
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| Maekawa, A., Matsushima, H., Onodera, H., Shibutani, M., Yoshida, J., Kodama, Y., Kurokawa, Y., Hayashi, Y. | A6.7-01 Is a cross reference to A6.5-01 | 1991 | Long-term carcinogenicity/carcinogenicity study of calcium lactate in F344 rats Food and Chemical Toxicology, Vol. 29, No. 9: pp 589-594 Not GLP, Published | N | - |
| Matsushima, Y., Onodera, H., Nagaoka, T., Todate, A., Shibutani, M., Maekawa, A., Kurokawa, Y., Hayashi, Y. | A6.4-01 | 1989 | Subchronic Oral Toxicity study of Calcium lactate in F344 Rats Bulletin of the National Institute of Hygienic Sciences, Tokyo (Eisei Shikenjo Hokoku) Vol. 107: pp 78-83 Not GLP, Published | N | - |
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| Philp, A., Macdonald, A.L., Watt, P.W. | A6.2-03 | 2005 | Lactate – a signal coordinating cell and systemic function. The Journal of Experimental Biology, Vol.208, p.4561-4575 Not GLP, Published | N | - |
| ██████████ | A6.1.1-03 | 1998 | Acute oral toxicity study with manganese-L-lactate in rats TNO Report nr. V98.598 GLP, Unpublished | Y | Purac |
| ██████████ | A6.1.1-04 | 1998 | Acute oral toxicity study with magnesium-L-lactate in rats TNO Report nr. V98.597 GLP, Unpublished | Y | Purac |
| ██████████ | A6.1.1-05 | 1998 | Acute oral toxicity study with ferrous-L-lactate in rats TNO Report nr. V98.410 GLP, Unpublished | Y | Purac |

| Author(s) | Section No / Reference No | Year | Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published | Data Protection Claimed (Yes/No) | Owner |
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| ██████████ | A6.1.4-06 | 1987 | Acute dermal irritation/corrosion study with lactic acid (88%) in pigs TNO Report nr. V87.405/270419 GLP, Unpublished | Y | Purac |
| ██████████ | A6.1.4-07 | 1987 | Acute dermal irritation/corrosion study with lactic acid (50%) in pigs TNO Report nr. V87.406/270419 GLP, Unpublished | Y | Purac |
| ██████████ | A6.1.4-09 | 1996 | In vitro skin irritation study in rabbit and human skin organ cultures after 30 minutes exposure to lactic acid and lactic acid esters TNO Report nr. V96.636 GLP, Unpublished | Y | Purac |
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| Van Dongen, A.P.M. | A3.13-01 | 2007e | Expert Statement. Surface tension of L(+) lactic acid. Purac expert statement. Purac, no report no. Not GLP, unpublished | Y | Purac |
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| Van Dongen, A.P.M. | A3.17-01 Is a cross reference to A3.10-01 | 2007d | Expert Statement. Stability of L(+) lactic acid. Purac expert statement. Purac, no report no. Not GLP, unpublished | Y | Purac |
| Van Krieken, J. | A3.5-03 | 1993 | Phasediagram water / L(+)-lactic acid Purac Internal report. Purac, no report no Not GLP, unpublished | Y | Purac |
| Van Krieken, J. | A3.7-02 | 1993 | Solubility of lactic acid crystals in organic solvents Purac Internal report. Purac, report no. 115 Not GLP, unpublished | Y | Purac |
| | A6.1.1-01* | 1984 | Acute oral LD50 study in rats using SY-83 Toxicogenics Inc. Report nr. 410-1369 GLP, Unpublished | Y | Purac |

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* *key studies*

APPENDIX to Doc III A – Reference list sorted by sections

Reference List geordnet nach Section Numbers

| Section No / Reference No | Author(s) | Year | Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published | Data Protection Claimed (Yes/No) | Owner |
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| A3.9-01 | Van Dongen, A.P.M. | 2007c | Expert Statement. Partition Coefficient Octanol/water of L(+) lactic acid. Purac expert statement. Purac, no report no. Not GLP, unpublished. | Y | Purac |
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| Section No / Reference No | Author(s) | Year | Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published | Data Protection Claimed (Yes/No) | Owner |
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