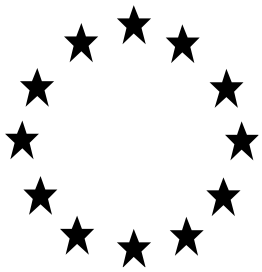
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



L(+) lactic acid

Product-types 02, 03 and 04

(Disinfectants and algaecides not intended for direct application to humans or animals, Veterinary Hygiene and Disinfectants in food and feed areas)

June 2017

eCA: Germany

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of the active substance L(+) lactic acid as product-types 02, 03 and 04 (Disinfectants and algaecides not intended for direct application to humans or animals, Veterinary Hygiene and Disinfectants in food and feed areas), carried out in the context of the work programme for the review of existing active substances provided for in Article 89 of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

L(+) lactic acid (CAS-No 79-33-4) was notified as an existing active substance, by Purac Biochem, hereafter referred to as applicant, in product types 2, 3 and 4.

Regulation (EU) No 1062/2014 of 4th of August 2014 lays down the detailed rules for the evaluation of dossier and for the decision-making process.

In accordance with the provisions of Article 6 of that Regulation, Germany was designated as Rapporteur Member State to carry out the assessment on basis of the dossiers submitted by the applicant. The deadline for submission of a complete dossier for (L)+ Lactic acid as an active substance in Product Types 2, 3 and 4 was 31st of July 2007.

On 17th of July 2007, German competent authorities received the dossiers from the applicant. The Rapporteur Member State accepted the dossiers as complete for the purpose of the evaluation on 25th of February 2008.

For the implementation of the common principles of Annex VI, the content and conclusions of this document shall be taken into account

1.2. Purpose of the assessment report

The aim of the assessment report is to support the opinion of the Biocidal Products Committee and a decision on the approval of L(+) lactic acid for product-types 02, 03 and 04 and, should it be approved, to facilitate the authorisation of individual biocidal products. In the evaluation of applications for product authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available from the Agency web-site shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data for that purpose has been granted to that applicant.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

The active substance L(+) lactic acid($C_3H_6O_3$) is a carboxylic acid. L(+) lactic acid and D(-) Lactic acid are the two optical isomers of the chiral substance Lactic acid.
The chemical name of the active substance L(+) lactic acid is (S)-2-Hydroxypropanoic acid (according to IUPAC nomenclature). The substance is CAS and EC listed (CAS-No. 79-33-4, EC-No. 201-196-2). The minimum purity of the active substance as manufactured is ≥ 95.5% w/w.
Pure lactic acid is a crystalline solid. The active substance is marketed as an aqueous solution (88% / 93% L(+) lactic acid), which appears as a colourless to yellow light brown liquid with a characteristic odour.
The melting point of pure lactic acid was determined to be 53.0°C, the boiling point for the pure lactic acid could not be determined, but was calculated to be 204.2°C. The relative density of L(+) lactic acid is 1.213 at 20°C. The calculated vapour pressure for pure L(+) lactic acid is 0.4 Pa at 20°C. Pure L(+) lactic acid is completely miscible with water and is highly soluble in methanol (78.6% w/w at 20°C). Pure L(+) lactic acid has an octanol/water partition coefficient of -0.74 (T = 20 °C, degree of oligomerization of non-extracted aqueous L(+) lactic acid solution n= 1). Higher degrees of oligomerisation of L(+) lactic acid solutions (because of the existence of an equilibrium system of L(+) lactic acid with several oligomers) result in higher partition coefficients (n = 1.36: log P_{OW} = 0.42; n = 1.98: log P_{OW} = - 0.05).

For the detection and identification of the active substance L(+) lactic acid a titration method is used in addition to chromatographical methods. The methods are described in Document III-A 4.1.

Relevant residues in food of plant and animal origin and in the environmental compartments arising from the application of L(+) lactic acid are not expected. Therefore, residue analytical methods for L(+) lactic acid in food of plant and animal origin, in soil, air, drinking and surface water are not required. Since L(+) lactic acid is not classified as toxic or very toxic, analytical methods in body fluids and tissues are not required.

Identity, Physico-chemical Properties and Method of Analysis of the biocidal products

Oscar (PT2)

Oscar contains 2% L(+) lactic acid and is a clear colourless liquid with a characteristic odour. Concerning the other physico-chemical data given for the biocidal product Oscar, no final study reports were submitted. Therefore, the given data could not be validated. Furthermore, not all information about the physico-chemical and technical properties of Oscar is given. A complete product dossier is not necessary at the approval stage due to the agreement at the 22nd CA-Meeting. The physico-chemical and technical characteristics must be tested for the stage of product authorization.

Due to the nature of the biocidal products (ready-to-use products), the biocidal product “Oscar” (contains 2% L(+) lactic acid) is not expected to exhibit any hazardous physical-chemical properties.

For the detection and identification of the active substance L(+) lactic acid in the biocidal product Oscar HPLC with UV detection is used. The methods are described in Document III-B 4.1.

No residues are expected in soil, air, drinking and surface water, as well as in food and feeding stuffs and in animal and human body fluids and tissues.

No analytical methods for the determination of non-active ingredients are submitted. They were not considered necessary as no relevant residues of non-active ingredients are expected.

Filmadine (PT3)

Filmadine contains 8% L(+) lactic acid and is an orange liquid solution without specific odour. Concerning the other physical-chemical data given for the biocidal product Filmadine, no final study reports were submitted. Therefore, the given data could not be validated. Furthermore, not all information about the physical-chemical and technical properties is given. A complete product dossier is not necessary at stage of active substance approval due to the agreement at the 22nd CA-Meeting. The physical-chemical and technical characteristics must be tested for the stage of product authorisation.

Due to the nature of the biocidal products (ready-to-use products), the biocidal product "Filmadine" (contains 8% L(+) lactic acid) is not expected to exhibit any hazardous physical-chemical properties.

For the detection and identification of the active substance L(+) lactic acid in the biocidal product Filmadine HPLC with UV detection is used. The methods are described in document IIIB 4.1.

No residues are expected in soil, air, drinking and surface water, as well as in food and feeding stuffs and in animal and human body fluids and tissues.

No analytical methods for the determination of non-active ingredients are submitted. They were not considered necessary as no relevant residues of non-active ingredients are expected.

Dummy product (PT4)

Only information for a dummy product is given. The dummy product is a model formulation and consists of 93% active substance No further information about the physico-chemical properties and method of analysis are submitted. The applicant refers to the active substance. The given data could not be validated. The physical-chemical and technical characteristics must be determined for the stage of product authorization.

The biocidal product "Dummy Product PT4" is identical to the active substance: an aqueous solution of 93% lactic acid. Due to the nature of the biocidal product it is not expected to exhibit any hazardous physical-chemical properties.

No residues are expected in soil, air, drinking and surface water, as well as in food and feeding stuffs and in animal and human body fluids and tissues.

No analytical methods for the determination of non-active ingredients are submitted. They were not considered necessary as no relevant residues of non-active ingredients are expected.

2.1.2. Intended Uses and Efficacy

Oscar (PT2)

L(+) lactic acid is intended to be used as a ready to use product for treating surfaces in bathrooms (general public) in order to prevent growth of bacteria and fungi.

The effectiveness of L(+) lactic acid was shown by studies performed with the biocidal product “Oscar” containing 2% L(+) lactic acid.

The performed tests provide reliable results for basic efficacy assessment. The biocidal product showed basic efficacy against bacteria and basic fungistatic activity.

The following results could be derived from the studies with the ready-to-use product:

- Oscar shows a basic fungistatic activity against A*spergillus niger* (efficacy against yeast was not tested) in the presence of 5% fetal bovine serum organic soil after 7 days.
- Oscar showed basic efficacy against *Staphylococcus aureus, Klebsiella pneumoniae* and *Escherichia coli* (log 3 reduction) for inanimate non-food contact surfaces in the presence of 5% fetal bovine serum organic soil load after 1 min contact period.
- Under the same conditions Oscar was not sufficiently effective against Vancomycin resistant *Enterococcus faecalis* for inanimate non-food contact hard surfaces.

The studies performed are sufficient at the approval stage. However, efficacy shall be reviewed in accordance with the relevant guidance documents in the framework of active substance renewal and relevant data shall be provided in the scope of product authorisation.

Filmadine (PT3)

The intended use of the biocidal product Filmadine is dipping of cow teats after milking (only non-medicinal teat disinfection) by professional users.

The bactericidal activity of L(+) lactic acid was investigated by studies performed with the biocidal product Filmadine (containing 8% Lactic acid).

The performed tests provide reliable results for basic efficacy assessment. The following results could be derived from the studies:

The product Filmadine shows:

- a bactericidal efficacy against *Staphylococcus aureus* and *Escherichia coli* after a contact time of 10 min in the presence of an interfering substance at a concentration of 85% (corresponding to a L(+) lactic acid concentration of 6.8%).

L(+) lactic acid shows a basic bactericidal activity on samples of the target organisms (amongst others: *Staphylococcus aureus, Streptococcus agalactiae, Streptococcus uberis, Streptococcus dysgalactiae, Escherichia coli)* after a contact time of 10-30 minutes at concentrations of 6.1-6.8%.

The studies performed are sufficient at the approval stage. However, efficacy shall be reviewed in accordance with the relevant guidance documents in the framework of active substance renewal and relevant data shall be provided in the scope of product authorisation.

Development of resistance is considered unlikely due to the non-specific mode of action.

Dummy product (PT4)

The intended use of the biocidal product is the disinfection of tanks against bacteria in the brewery industry.
The bactericidal activity of L(+) lactic acid was investigated by studies performed with the biocidal product containing 3% lactic acid and 2.5% sodium laureth-2 sulfate (SLeS).

The performed tests provide reliable results for basic efficacy assessment. The following results could be derived from the studies:
The dummy product containing 3% L(+) lactic acid and 2.5% Sodium Laureth-2 Sulfate (SLeS) shows a basic bactericidal activity after a contact time of 5 minutes. Additionally it was shown that 2.5% SLeS is not effective if used alone. Therefore, a basic bactericidal activity of 3% L(+) lactic acid can be concluded.
The studies performed are sufficient at the approval stage.

The information provided is only sufficient to show a basic efficacy of L(+) lactic acid. This is accepted in the frame of the approval. Within the frame of product authorisation, essentially more information has to be provided: To support the claim bactericidal further laboratory tests would be necessary. Additionally, further tests in the field of use have to be provided, also tests showing an activity against further organisms, inter alia fungi relevant for the specific field of use.
At least the tests listed in EN 14885 for the respective field of use or comparable tests have to be provided in the frame of product authorisation. As not for all possible label claims an EN norm exists, further tests might be necessary depending on the specific label claim.

Mode of action

In solution, L(+) lactic acid exists in a pH-dependent equilibrium between the undissociated and dissociated form. Only in its undissociated state, the acid is able to pass the cell membrane. At a relatively low pH, the uncharged acid enters the cell. Inside the cell, the L(+) lactic acid dissociates due to the higher pH. The molecules remain inside the cell, because the resulting ions cannot pass the membrane. The pH inside the cell is lowered and metabolic reactions are inhibited. Further effects are also reported. Decrease of the membrane permeability for amino acids, organic acids, phosphates resulting in uncoupling of both substrate transport and oxidative phosphorylation from the electrin transport system. Furthermore, an inhibition of the glycolysis by the lactate ion is observed.

No resistance to lactic acid has been observed in the course of the efficacy studies. Furthermore, development of resistance is considered unlikely due to the non-specific mode of action (Doc III B5.11).

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and Labelling

Classification and Labelling of L(+) lactic acid

Table 2-1 Proposed classification of L(+) lactic acid based on Regulation (EC) No 1272/2008

Classification	Hazard class, category, and statements	Wording
	Eye Dam. 1; H318 Skin Irrit. 2; H315	Causes serious eye damage Causes skin irritation

In addition, STOT SE3; H335 "May cause respiratory irritation" was proposed in the CLH dossier submitted to ECHA, but this was not considered during the evaluation of the biocide dossier.

Table 2-2 Proposed labelling of L (+) lactic acid based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	GHS05	
Signal Word	Danger	
Hazard statements	H315 H318	Causes skin irritation Causes serious eye damage
Supp. Hazard statements	-	-
Precautionary statements	P264 P280 P302 + P352 P305 + P351 + P338 P310 P363	Wash … thoroughly after handling Wear protective gloves / protective clothing / eye protection / face protection IF ON SKIN: wash with plenty of soap and water IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing Immediately call a POISON CENTER or doctor / physician Wash contaminated clothing before use

Classification and Labelling of the biocidal product Oscar (PT2)

Table 2-3 Proposed classification the biocidal product Oscar based on Regulation (EC) No 1272/2008

Classification	Hazard class and category hazard statements	Wording
	Eye Irrit. 2 H319	Causes serious eye irritation

Table 2-4 Proposed labelling of the biocidal product Oscar based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	GHS07	
Signal Word	Warning	
Hazard statements	H319	Causes serious eye irritation
Precautionary statements	P101 P102 P305+P351+P338 P337+P313	If medical advice is needed, have product container or label at hand. Keep out of reach of children. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Summary & Conclusion:

The classification and labelling proposed by the eCA is in accordance with the participant's classification of L(+) lactic acid as 'Irritating to skin/Risk of serious damage to eyes' (Xi; R 38/41; Eye Dam. 1, H318; Skin Irrit. 2, H315).

Due to results from animal testing the biocidal product Oscar (positive findings in an OECD guideline 405 compliant eye irritation study with rabbits) has to be classified and labelled as Eye Irrit. 2, H319.

Classification and Labelling of the biocidal product Filmadine (PT3)

Table 2-5 Proposed classification the biocidal product Filmadine based on Regulation (EC) No 1272/2008

Classification	Hazard class and category hazard statements	Wording
	none	none

Remark:

The active substance content in the representative product "Filmadine" is above the concentration limit for classification with Eye Dam. 1, H318. However, based on the results of an eye irritation study in rabbits no classification is required. Classification with Skin Irrit. 2, H315 is not required based on the calculation method (the concentration limit for classification with Skin Irrit. 2 is not exceeded) and also based on the results of a skin irritation study.

Table 2-6 Proposed labelling of the biocidal product Filmadine based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	-	-
Signal Word	-	-
Hazard statements	-	-
Precautionary statements	-	-

Remark:

As 'Filmadine' is neither classified nor labelled "isolated" Precautionary statements should not be assigned in this context.

Classification and Labelling of the biocidal dummy product (PT4)

Table 2-7 Proposed classification of the biocidal dummy product PT4 based on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	GHS05	
Signal Word	Danger	
Hazard statements	H315 H318	Causes skin irritation Causes serious eye damage
Suppl. Hazard statements	-	-
Precautionary statements	P264 P280 P302 + P352 P305 + P351 + P338 P310 P362 + 364	Wash … thoroughly after handling Wear protective gloves/protective clothing/eye protection/face protection IF ON SKIN: Wash with plenty of soap and water IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing Immediately call a POISON CENTER or doctor/physician Take off contaminated clothing. And wash it before reuse.

Remark:

The number of the Precautionary statements is quite big but they were nearly all recommended in Annex I of Regulation (EC) No 1272/2008 based on the given Hazard statements and could only partly be reduced so to lose no essential information.

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Effects assessment

L(+) lactic acid is a naturally occurring alpha-hydroxy acid found in plants, animals, and humans. Major sources of L(+) lactic acid in the human organism are endogenous production (e. g. via anaerobic catabolism of glycogen and glucose) production by gastrointestinal microorganisms and uptake via food. The production of L(+) lactic acid as an intermediary metabolite in a 70 kg resting man is estimated to be in the range of 117-230 g/d but can be much higher during exercise. The mean daily per capita intake of L(+) lactic acid and D(-) Lactic acid from milk and milk products has been estimated to be approximately 1 g in Switzerland (Walther, 2006). The estimated overall intake via food in the EU and the USA is estimated to be 1.65-2.76 g/person/day (DocIII6.2.01).

L(+) lactic acid has been approved in the EU as a food additive without an ADI or upper limit (*quantum satis;* Dir. 95/2/EC), as a cosmetics ingredient, and as veterinary medicinal product without the requirement for MRL setting (EMEA 2008).

Except for acute toxicity, data on the toxicological profile of L(+) lactic acid as submitted by the participant consist of published literature. Most of these data do not meet the quality standards of GLP and guideline studies, the reporting of the studies is often insufficient, in some cases only secondary literature is available. Thus, only few studies are to some extent suitable for risk assessment purposes, and it is not possible to address every endpoint necessary for a complete evaluation.
Furthermore, in older publications, it is often not reported if L(+) lactic acid was used or the racemate of D and L isomers. D(-) Lactic acid is considered to be more toxic than L(+) lactic acid: It is excreted less effectively by neonates and can cause lactate acidosis (Walther, 2006). Therefore, the use of racemate-derived data seems to be justified, as the results would overestimate the toxicity of L(+) lactic acid.
In summary, the common core data set as required by Annex II of Dir. 98/8/EC was not sufficiently supported by toxicological data in the dossier submitted by the applicant. Nevertheless, based on the generally accepted low toxicity profile of L(+) lactic acid, as well as the high baseline exposure of the general population by food and endogenous metabolism, the justification that submission of further toxicity studies is not necessary owing to the nature of this naturally occurring active substance found in plants, animals, and humans was considered acceptable to the RMS.

Absorption, Distribution, Excretion, and Metabolism

Lactate/lactic acid forms an integral part of normal mammalian intermediary metabolism, produced by reduction of pyruvate. Physiological plasma levels in man range between 1 mM at rest and 10 mM during exercise. Very similar levels have been reported in other mammalian species. Monocarboxylate transport proteins (MCT) facilitate the distribution of lactate between organs, cells and subcellular organelles and may be involved in gastrointestinal lactate absorption and renal lactate elimination. Cytosolic and mitochondrial lactate dehydrogenases (LDH/mLDH) convert lactate into pyruvate, consuming NAD+ and producing NADH. Via stepwise metabolism involving oxaloacetate and phosphoenolpyruvate as intermediates, pyruvate is utilised for gluconeogenesis ((1) in Figure 1). Alternatively, metabolites of pyruvate (oxaloacetate, acetyl-CoA) are consumed in the tricarboxylic (citric) acid cycle (TCA, (2)) generating NADH, ATP and ultimately CO_2. Finally, pyruvate may be transaminated to the amino acid L-alanine (3). Gluconeogenesis occurs mainly in the liver and is energy-consuming. Increased cellular levels of lactate influence pathways of cellular metabolism, leading to a decrease in the generation of pyruvate from other sources such as glucose by reduction of glycogenolysis and glycolysis, or leading to enhanced gluconeogenesis (Gladden, 2004; Sterenborg, 2007). Total normal lactate turnover at rest has been determined as 1.6 – 2 g/kg bw/d in humans and as 2.3 – 3.5 and 4.9 – 8.1 in

dogs and rats, respectively, supporting applicability of allometric scaling (Connor and Woods, 1982).

Following application by gavage (oral), external L(+) lactic acid is absorbed rapidly in rats with one half being removed from the GI-tract within 2-3 hours (Cori, 1930). Of 2 g/kg administered to rats via gavage, 42 % were converted into CO_2 and presumably exhaled within 6 hours (Andersen, 1998). Complete utilization of orally administered lactate has also been reported in dogs (Andersen, 1998). In humans, a volume of distribution of approx. 0.5 L/kg was determined after intravenous application of an unknown dose. 88 % of this dose was exhaled as CO_2 and the total turnover rate was 2.3 g/kg bw/d (Andersen, 1998), and thus similar to that reported above (Connor & Woods, 1982). Lactic acid that is not metabolised to CO_2 may be utilised for the synthesis of biomacromolecules, including glycogen or proteins (Cori & Cori, 1929; Andersen, 1998). Feeding of pigs and rats with a daily dose of 1.9 and 5.8 g/kg bw/d which is roughly equivalent to the lactic turnover rate at rest resulted only in a slight increase of L(+)-lactate plasma levels by 0.03 g/L (from 0.26 g/L) and 0.04 g/L (from 0.23 g/L), respectively. At the same time, elimination in urine was minimal with increases in L(+)-lactate concentrations by 0.02 and 0.07 g/L, corresponding to < 0.01 g/kg bw/d (less than 1 % of dose) at an estimated urine volume of 100 mL/kg bw/d (Everts et al., 2000). It can therefore be concluded, that the lactate turnover rate is tightly regulated and is not saturated at total lactate load of 200 % compared to the value at rest. In contrast, Abramson & Eggleton (1927) reported between 7 and 42 % renal excretion following bolus injection of 5.4 to 30 g/kg bw in dogs. Notably, the percentage excreted with urine was correlated to urine volume, suggesting glomerular filtration as the main mechanism under these conditions.

Although a OECD guideline study regarding the toxicokinetics of L(+) lactic acid is not available, the wealth of data generated in animal and human studies can be brought in agreement and allows for adequate characterisation of the a.s.: Oral administration of lactic acid is followed by fast and practically complete absorption from the GI-tract with an absorption half-life in the order of 2-3 hours, even at high doses in the range of g/kg bw. Distribution occurs into a volume of approx. 0.5 L/kg bw and systemic L(+) lactic acid is cleared rapidly at a rate (at rest) of approx. 1.8 g/kg bw/d in humans. In dogs and rats, normal clearance rates are approx. 3 and 6 g/kg bw/d, respectively. Absorbed L(+) lactic acid adds to the plasma background level of around 1 mM at rest in humans and slightly higher values in animals. Metabolic conversion of L(+) lactic acid into CO_2 or biomacromolecules (glycogen etc.) accounts for the majority of its clearance. Significant renal elimination was observed only following bolus injection of large doses, but not after protracted application such as infusion of feeding. Minimal increases in plasma lactic acid concentrations following feeding of large doses that were in the range of the normal background turnover rate (i.e. ~ 5 g/kg in rats) suggest that the clearance capacity for lactic acid is significantly larger than this background turnover rate and that the enzymatic and transport processes involved are well regulated within this range.

Dermal absorption of various L(+) lactic acid formulations was tested on human and pig skin *ex vivo* over 6 hours (Andersen, 1998; Sah et al., 1998) and in rats *in vivo* over 3 days (Andersen, 1998). Data on the technical product was not provided. Depending on the formulation and the pH, dermal absorption *ex vivo* ranged from 10 to 30 % in human and from 7 to 32 % in pig skin. Absorption was higher at pH 3 or 3.8 (lowest pH tested) than at pH 7 and was different depending on formulation, with a decrease in the order o/w > w/o/w > w/o. Dermal penetration of L(+) lactic acid from a 5 % o/w cream formulation through rat skin was 50 % in 3 days (Andersen, 1998). These data as well as the physicochemical properties of the technical product support the default value of 75 % dermal absorption as realistic worst-case assumption. According to the EFSA guidance on dermal absorption (2012) this default value should be used for products containing ≤ 5% active substance. For products containing > 5% active substance the default value of 25 % should be used

Acute Toxicity
L(+) lactic acid is of low toxicity in the rat after oral, dermal, and inhalation exposure. The oral LD_{50} of lactic acid in the rat is 3543 mg/kg bw, the dermal LD_{50} in the rabbit is > 2000 mg/kg bw and the inhalation LC_{50} in the rat is 7.94 mg/L air x 4 h (aerosol, nose only exposure). Main effects observed in oral studies were ataxia, lethargy, prostration, irregular breathing and local irritation of the gastrointestinal tract. In a dermal study in the rabbit signs of corrosivity were observed. Weight loss in females, rapid, shallow breathing, hunched posture, and lacrimation were the main toxicological signs observed in an acute inhalation toxicity study.

Classification and labelling for acute toxicity according to Regulation (EC) No 1272/2008:
Not required

Skin irritation/corrosivity
Skin irritation/corrosivity studies with L(+) lactic acid were performed in rabbits, guinea pigs, pigs, and humans and with a biobarrier/chemical detection system *in vitro*. In rabbits, full thickness destruction indicative of corrosivity was observed with 88 % L(+) lactic acid (pH 1.83) and 50 % L(+) lactic acid. This result was confirmed by an in vitro Corrositex assay which revealed a biobarrier break through at a time of only 31 minutes of 90 % L(+) lactic acid (< 3 min: R35; 3 min to 4 h: R34). No irritation or corrosivity was observed in rabbits when a 10 % aqueous dilution of L(+) lactic acid was tested (Prinsen, 1995).

However, experience from humans and studies in guinea pigs, pigs, and humans revealed that these species are much less sensitive to dermal exposure to the a.s.. In these studies, L(+) lactic acid was tested non-irritant in concentrations up to 88 % (pig, guinea pig (single exposure)) or irritant (human (concentrated), guinea pig (24 % and 80 %, repeated exposure)). Thus, from the patch test studies in humans, the RMS decided that the results from the rabbit which seems to be extremely sensitive to L(+) lactic acid are an overestimate for humans and results of guinea pig (repeated exposure) and humans are relevant for the classification of L(+) lactic acid in this case.

Eye irritation
Since concentrated L(+) lactic acid has a pH < 2 no eye irritation studies in rabbits were performed due to animal welfare considerations. Instead, a chicken enucleated eye test (*in vitro*) was performed and revealed a highly damaging potential of L(+) lactic acid of the eye (severe corneal opacity, corneal swelling and fluorescein retention).

Classification and labelling for skin and eye irritation according to Regulation (EC) No 1272/2008:
H315: Causes skin irritation
H318: Causes serious eye damage

Sensitisation
In a Buehler test with 9 inductions L(+) lactic acid was non-sensitising (0/10 animals sensitised). Induction and challenge were performed with 80 % (100 % SY-83; first 2 inductions and challenge) and 24 % L(+) lactic acid (30 % SY-83). While only slightly irritating in the range-finding studies, these concentrations proved to be highly irritating after repeated exposure. Irritation reactions were pinpoint pitting and eschar formation with only slight redness and were considered not to be sensitisation reactions as the reactions observed differed from usually observed sensitisation reactions and similar reactions were observed in naive control animals.
Furthermore, considering the high endogenous exposure and exposure via food it is highly unlikely that sensitisation to L(+) lactic acid develops.

Classification and labelling for sensitisation according to Regulation (EC) No 1272/2008:
Not required

Short-term Toxicity
The results of the submitted study can only be used as a very rough approximation for a NOAEL for L(+) lactic acid because the effects observed (decrease in food consumption and body weight gain) might be due to high calcium intake, palatability problems and/or malabsorption due to local gastrointestinal irritation (provoked by calcium or lactate). Thus, in the view of the RMS, it is inadequate for use of the obtained NOAEL for derivation of reference values.

Classification and labelling for short term toxicity according to Regulation (EC) No 1272/2008:
Not required

Genotoxicity

In vitro tests:

Two Ames tests revealed no genotoxic potential of L(+) lactic acid (Ishidate et al. 1984 and Al-Ani & Al-Lami 1988) in the absence or presence of S9 mix. A chromosomal aberration assay (Ishidate et al. 1984) in Chinese hamster fibroblasts was negative, too. A chromosomal aberration assay (Morita et al. 1990) showed cytotoxicity and clastogenic effects at unphysiologically low pH of 5.7-6.7 of L(+) lactic acid in Chinese hamster ovary cells. The authors judged L(+) lactic acid as non-clastogenic and the results as "pseudo-positive". Overall, L(+) lactic acid proved to be devoid of mutagenic or clastogenic effects at non-cytotoxic concentrations and pH in *in vitro* tests. Thus, and because of the high background exposure via food and endogenous metabolism, no further studies are required.

In vivo tests:

No studies submitted- not required.

Classification and labelling for genotoxicity according to Regulation (EC) No 1272/2008:
Not required

Chronic Toxicity / Carcinogenicity
The results of the submitted study can only be used as a very rough approximation for a NOAEL for L(+) lactic acid because the effects observed (decrease in food consumption and body weight gain) might be due to high calcium intake, low water/food intake (no data presented in the publication) and/or malabsorption due to local gastrointestinal irritation (provoked by calcium or lactate). Thus, in the view of the RMS, it is inadequate to use the obtained NOAEL for derivation of reference values. Since no statistically significant differences in the tumour rates between control animals and calcium lactate treated animals were observed it can be assumed that lactate/lactic acid has no carcinogenic potential.

Classification and labelling for chronic toxicity / carcinogenicity according to Regulation (EC) No 1272/2008:
Not required

Reproduction Toxicity

Teratogenicity
Two publications investigating potential developmental effects of lactic acid are available. Colomina et al. investigated the developmental toxicity of 570 mg/kg bw/d lactic acid in

mice. They observed a slight albeit not statistically significant decrease in foetal weight and a statistically significant delayed ossification of parietal bones which might be due to the decreased foetal weight. Thus, these findings were not considered as a substance-specific developmental toxicity effect (in accordance with Carney & Kimmel, 2007).

Fertility
No studies were submitted for this endpoint. However, in the view of the RMS no further studies are required, based on the fact that L(+) lactic acid is an endogenous mammalian metabolite and a common, naturally occurring food constituent and physiological exposure and nutritional uptake is likely to exceed exposure via the biocidal product by far.

Classification and labelling for reproduction toxicity according to Regulation (EC) No 1272/2008:
Not required

Neurotoxicity
No studies on neurotoxicity of L(+) lactic acid were submitted. From the high exposure to L(+) lactic acid as natural food ingredient and food additive there are no concerns about a possible neurotoxic potential. Thus, in the view of the RMS no further studies are required.

Classification and labelling for neurotoxicity according to Regulation (EC) No 1272/2008:
Not required

Further Studies
None

Medical Data
A case report from a fatal accidental poisoning is available from the literature. A woman received ~33 g lactic acid (100 ml of a 33 % aqueous solution) via duodenum tube in a hospital. She reported immediate pain, vomited blood and had blood in the urine. She developed dyspnoea and cyanosis and died 12 h after administration. Necropsy revealed corrosion of the stomach and the duodenum with necroses, haemorrhages, bleeding, and thromboses of most blood vessels of the gastrointestinal tract. Tissue distribution 4 d post mortem revealed high lactic acid levels in the gastrointestinal tract.

Summary & Conclusion
L(+) lactic acid is an endogenous alpha-hydroxy acid of generally low toxicity. Due to its acidity it is, however, considered to be a skin irritant and severe eye irritant.
Based on irritating effect, a **dermal NOAEC** for acute, medium-term and long-term exposure of **10 % L(+) lactic acid** was derived from rabbit irritation/corrosion studies: 88 % and 50 % L(+) lactic acid were corrosive in rabbits (88 % were irritant in human patch tests); 10 % were non-irritant in rabbits and guinea pigs (range-finding Buehler test). As the rabbit is the most sensitive species it seems to be reasonable to assume that this concentration would be without effect on human skin.
Because of the very low systemic toxicity of L(+) lactic acid, derivation of any systemic toxicological reference dose was regarded unnecessary. Considering the intended uses, exposure is estimated to be clearly below endogenous production (>100 g/person/day) and dietary exposure (>1 g/person/day). Therefore, neither an ADI nor an ARfD have been set. Likewise, L-(+)-lactic acid has been approved in the EU as a food additive without an ADI or upper limit (*quantum satis;* Dir. 95/2/EC), as a cosmetics ingredient, and as veterinary medicinal product without the requirement for MRL setting (EMEA 2008).

Summarising the study results and all considerations above, the a.s. L(+) lactic acid requires classification/labelling according to REGULATION (EC) NO 1272/2008:
Eye Dam. 1, H318; Skin Irrit. 2, H315

2.2.1.2. Exposure assessment

Exposure of Professionals

PT2:

Since the biocidal product 'Oscar' is a ready-to-use consumer product, an exposure assessment for professionals has not been performed and no risk characterisation for professionals is required.

PT3:

The active substance L(+) lactic acid and the biocidal product Filmadine are produced in the EU. The biocidal product is a liquid ready-for-use concentrate with maximum 8% a.s.. According to the applicant, Filmadine is applied between milking sessions by dipping the cow's teats manually into the liquid solution. The dipping procedure of cow`s teats is characterised by using a type of cup which should avoid spilling designed as a dual compartment anti-spill cup with a volume of 250 ml. Only 2 L of the biocidal product are handled per milking event; this corresponds to 4 L Filmadine per day. Furthermore, the product characteristics of higher viscosity will decrease the possibility of spillage.

The following scenarios are covered by the exposure assessment in this report:

- Dipping of cow`s teats (scenario 1)
- Secondary exposure to L(+) lactic acid (scenario 2)

Scenario 1:

Inhalation exposure in scenario 1 during the phases Mixing and/or Loading and Post-Application is assessed as negligible due to the low vapour pressure of the active substance, the characteristics of the biocidal product and the small surface area of dip cups. During the application phase exposure to vapour seems likely and is therefore calculated using ConsExpo.

Dermal exposure to the biocidal product during all phases is possible.

Dermal exposure for loading of dip cups is assessed with Mixing & Loading model 4 of the TNsG Human Exposure to Biocidal Products as proposed by HEEG. The same model is used to calculate hand exposure during emptying and cleaning of dip cups, process equipment and tools after the milking events (Post-Application).

For calculation of dermal exposure during application pre-disinfection is assessed. This includes, in the first step, the application of dipping solution onto the cow´s teats. Before starting the milking process, pre-dipped teats have to be dried off with a dry, single service towel. The tasks dipping and drying of teats are assessed separately. For calculation of teat dipping Dipping model 4 (Guidance document "Biocides Human Health Exposure Methodology, Oct. 2015) is used. Since the model provided values for hand exposure inside gloves (actual hand exposure), a multiplication factor of 100 is used for the conversion of actual to potential hand exposure (HEEG opinion on the assessment of potential and actual hand exposure, 2008). The assessment of teat drying is performed using ConsExpo (Disinfectant products Fact Sheet: Disinfectant Products, Disinfectant for use indoors – Exposure during wiping). Since ConsExpo considers a wet cloth whereas teats shall be dried with a dry tissue, the transfer factor implied by the ConsExpo model was lowered by a factor 10 as further refinement.

Scenario 2:

For secondary exposure (scenario 2) inhalation exposure to the active substance is excluded. Dermal exposure may occur accidentally and will be in the same order of magnitude assessed for the dipping procedure.

PT4:

The active substance L(+) lactic acid is produced within the EU. The biocidal product "Dummy Product PT4" is 93% L(+) lactic acid, in aqueous solution.

The biocidal product is intended for professional use, only, for disinfecting vessels in breweries immediately after each emptying of the vessel

The following scenarios are covered by the exposure assessment in this report:

- Disinfection of brewery vessels (scenario 1)
- Secondary exposure to active substance L(+) lactic acid (scenario 2)

Scenario 1:

It is assumed here that the only potential inhalation and dermal exposure takes place during the loading phase to a brewery vessel, all other stages of the application of "Dummy Product PT4" are fully automated (dilution of the 93% L(+) lactic acid solution to a solution with 3% a.s. and the emptying of the vessel after disinfection). The loading process could be performed manually or by refilling the 'cleaning-in-place' (CIP) system. Contact with the b.p. during the residence time in the vessel is assumed to be excluded.

The assessment of potential inhalation exposure during loading phase (scenario 1) is based on the HEEG opinion recommendation for simple loading using data from EUROPOEM II model "Professional pouring formulation from a container into a fixed receiving vessel" (Guidance document "Biocides Human Health Exposure Methodology", Oct. 2015), as expressed as mg/kg (mg exposure / kg applied biocidal product). It is assumed that one vessel is treated per day for 2 minutes.

Dermal exposure is only expected during manual filling of the solution into the brewery vessel (mixing & loading phase). The assessment of potential dermal exposure is based on the same model used for the assumed inhalation exposure (EUROPOEM II model)

Scenario 2:

For secondary exposure (scenario 2) potential inhalation and dermal exposure to the active substance is excluded, since residues of L(+) lactic acid are left inside the brewery vessel where contact is assumed to be impossible.

Exposure of Non-Professionals

PT2*:*

Primary Exposure
The primary non-professional use of the biocidal product Oscar is the application in residential bathrooms.

Table 2-8 Summary of primary internal exposure of non-professional users to L(+) lactic acid from Oscar

	Inhalation exposure (mg/kg bw/d)	Dermal exposure (mg/kg bw/d)	Oral exposure (non respirable) (mg/kg bw/d)	All routes (mg/kg bw/d)
Modelled data				
Spraying Long-term exposure - internal dose	0.001	0.058	0.010	0.069
Wiping Long-term exposure - internal dose	-	0.387	-	0.387
Total Long-term exposure - internal dose	**0.001**	**0.445**	**0.010**	**0.456**

Secondary Exposure

Secondary exposure to the biocidal product may occur after spray application of the biocidal product Oscar. Toddlers might be exposed dermally by rubbing off contaminated surfaces and subsequently orally by licking their hands.

Table 2-9 Summary of secondary internal exposure of toddlers to L(+) lactic acid from Oscar

	Inhalation exposure (mg/kg bw)	Dermal exposure (mg/kg bw)	Oral exposure (mg/kg bw)	All routes (mg/kg bw)
Modelled data				
Rubbing off acute exposure - internal dose	-	3.12	0.042	3.16

No residues in food are likely to occur as a result of the proposed PT2 use.

PT3:

Primary Exposure:
The biocidal product Filmadine is restricted to professional use. Non-professions applications are not intended. Thus, non-professional exposure assessment is not required.

Secondary Exposure:
The biocidal product is applied in cow stables for disinfection of cow's teats by dipping. Commonly, the general public has no access to cow stables. Thus, contact to the biocidal

product via dipping cups or the packed liquid is very unlikely. It is also not expected that the general public get in contact with treated udders, neither inside the stable nor outside on the grassland. In summary, secondary exposure of non-professionals and the general public is not expected.

Residues in food from the intended PT3 use are expected to be low compared to naturally occurring levels in food. Therefore, the intended use does not significantly contribute to consumer exposure to lactic acid.

PT4:

The biocidal model formulation is intended for professional (industrial) use only, e.g. in brewing industry. Thus, non-professional primary exposure is not expected.

Secondary Exposure

The biocidal model formulation is applied in industrial cleaning/disinfection processes. After use it is rinsed with drinking water and disposed via waste water. The general public has in general no access to the application sites and contact to the biocidal product and its residues are not expected.

Residues in food from the intended PT4 use are expected to be low compared to naturally occurring levels in food. Therefore, the intended use does not significantly contribute to consumer exposure to lactic acid.

2.2.1.3. Risk characterisation

Risk Assessment for Professionals

PT2:

The biocidal product is a ready-to-use “trigger-spray” for bathroom cleaning (“Oscar”). The intended use of Oscar is by consumers only in their own residential bathrooms. Professional use of Oscar is not expected by the participant. However, it is not excluded that professionals with a profession that does not involve biocides (e.g. professional cleaner, housekeeper) use the product in their work environment. The rapporteur assumes that the pattern of use is similar to the pattern of use of consumers. Therefore the exposure assessment and the risk characterisation of professionals using the consumer product are estimated to be in the same range as for non-professionals (see chapter: *Exposure of Non-professionals* and chapter: *Risk assessment for Non-professionals).*

PT3*:*

Systemic effects

Because of very low systemic toxicity of L(+) lactic acid, derivation of any systemic toxicological reference dose was regarded not necessary, however, the exposure estimates are compared with endogenous production of L(+) lactic acid to carry out the risk characterization for systemic effects.

If the total internal body burden is lower than the reference dose (endogenous production), health risks leading to concern are not anticipated.

For scenario 1 (teat disinfection – dipping) estimated uptake / endogenous production is below 100% and thus a safe use is identified.

Local effects

Due to its acidity, irritation reaction of skin can arise from dermal exposure to L(+) lactic acid.

As the rabbit is the most sensitive species it seems reasonable that the concentration of 10% derived from the result of irritation / corrosion studies in rabbits would be without effect on human skin. Thus, 10% L(+) lactic acid is set as dermal AEC for acute, medium-term and long-term exposure for humans.

Considering scenario 1 (teat disinfection – dipping) the L(+) lactic acid concentration in the products to AEC ratio is below 100% and no concern is identified for local effects.

Overall assessment

According to the risk assessment above, handling and use of the active substance L(+) lactic acid does not lead to concern for professionals. With respect to the exposure scenario evaluated, there is no reason for restrictions on use or other conditions for authorization from an occupational point of view. It is essential to indicate, that the conclusion only applies to the active substance in the biocidal product (and not to other ingredients).

Scenario	**Conclusion risk assessment systemic effects**	**Conclusion risk assessment local dermal effects**	**Overall conclusion**	**Included RMM**
1 - teat disinfection - dipping	acceptable	acceptable	acceptable	none

PT4:

Systemic effects

Because of very low systemic toxicity of L (+) lactic acid, derivation of any systemic toxicological reference dose was regarded not necessary; however, the exposure estimates are compared with endogenous production of L (+) lactic acid to carry out the risk characterisation for systemic effects.

If the total internal body burden is lower than the reference dose (endogenous production), health risks leading to concern are not anticipated.

For scenario 1 (disinfection of brewery vessels) estimated uptake / endogenous production is below 100 % and thus a safe use is identified.

Local effects

Due to its acidity, irritation reactions of skin and respiratory tract as well as eye damage can arise from either dermal or inhalation exposure to L (+) lactic acid.

As the rabbit is the most sensitive species it seems reasonable that the concentration of 10 % derived from the results of irritation/corrosion studies in rabbits would be without effect on human skin. Thus, 10 % L (+) lactic acid is set as dermal AEC for acute, medium-term and long-term exposure for humans.

Considering scenario 1 (disinfection of brewery vessels) the only human exposure takes place during the mixing and loading phase of 93 % L (+) lactic acid to the vessel. Application and post-application phases are fully automatic and no further contact by professionals to the disinfectant is expected. Dermal exposure to the 93 % L (+) lactic acid might result in skin irritation and eye damage, therefore a refinement of the exposure estimate is considered reasonable.

With the proposed safety protection measures (gloves and eye protection, see below) the reduction of dermal and eye contact minimizes the anticipated health risks to an acceptable level.

Concerning irritant properties in the respiratory tract of L (+) lactic acid the RMS assesses inhalation exposure to be marginal so that no adverse effects are expected.

Overall assessment

For exposure scenario 1 – disinfection of brewery vessels the risk assessment does not indicate a concern taking into account the described protection measures. With respect to the exposure scenario evaluated, there is no reason for restrictions on use or other conditions for authorisation from an occupational point of view. It is essential to indicate, that the conclusion only applies to the active substance in the biocidal product (and not to other ingredients).

Scenario	Conclusion risk assessment systemic effects	Conclusion risk assessment local dermal effects	Overall conclusion	Included RMM
1- disinfection of brewery vessels	acceptable	acceptable	acceptable	gloves and eye protection

Safety Measures for Professionals

PT2:

See Chapter: *Safety Measures for Non-Professionals*

PT3*:*

Safety measures concerning systemic exposure are not necessary as no concern was assessed.

PT4:

Due to local effects (Skin Irrit. 2, Eye Dam. 1, H315 Causes skin irritation, H318 Causes serious eye damage) protective gloves and eye protection (e.g. safety goggles) have to be worn. Concerning local respiratory effects due to irritant properties of L(+) lactic acid, the RMS assesses inhalation respiratory exposure to be marginal so that no adverse effects are expected. Based on the systemic risk assessment, no protection measures are necessary.

Risk Assessment for Non-Professionals

PT2:

No critical endpoints of systemic toxicity have been identified for L(+) lactic acid. Primary and secondary exposure to this active substance by application of the biocidal product Oscar is considered low compared to endogenous formation (in maximum 0.0316%). Compared to minimum daily food intake the relevant potential primary / secondary exposure is in maximum 3.16%. Thus, it is concluded that exposure to L(+) lactic acid by use of the biocidal product Oscar does not reveal any risk to human health.

PT3, PT4:

Primary and secondary exposure of non-professional users and the general public is not expected.

Safety Measures for Non-Professionals

PT2:

Specific measures are not required. The biocidal product has to be labelled as prescribed in Regulation (EC) No 1272/2008.

PT3, PT4:

Contact of non-professionals and the general public to the biocidal product is not expected. Specific measures are not required.

Local Risk Assessment

PT2:

Based on an eye irritation study, the biocidal product Oscar is classified as Eye Irrit. 2, H319. For this hazard a quantitative risk assessment is not necessary. Due to the qualitative risk assessment (refer to Doc II, chapter 12.3.1.1), risk mitigation measures triggered by this hazard are covered by the corresponding precautionary statements as provided in chapter 2.1.3. The corresponding precautionary statement P280 is considered not necessary due to the intended use. An additional labelling with “Avoid contact with eyes” in the instructions for use is considered appropriate for this hazard in combination with the intended use.

The concentration of L(+) lactic acid in the biocidal product Oscar (2 %) is below the dermal NOAEC (10 %).

2.2.2. Environmental Risk Assessment

The environmental risk characterisation is based on the concept of releases of the active substance (a.s.) to the environment taking into account all relevant life cycle stages.

PT2:

The derivation of predicted no effect concentrations (PNEC) for lactic acid (Doc. II-4) as well as the estimation of predicted environmental concentrations (PEC) resulting from the use of

the biocidal product (b.p.) “Oscar” (Doc. II-8.3) in all relevant environmental compartments were performed according to the Technical Guidance Document (TGD) on Risk Assessment (EU, 2003) and to the Environmental Emission Scenarios for PT 2 (van der Poel, March 2001, RIVM report 601450008).

PT3:

The derivation of predicted no effect concentrations (PNEC) for lactic acid (Doc. II-4) as well as the estimation of predicted environmental concentrations (PEC) resulting from the use of the biocidal product (b.p.) “Filmadine” (Doc. II-8.3) in all relevant environmental compartments were performed according to the Technical Guidance Document (TGD) on Risk Assessment (EU, 2003) and to the Environmental Emission Scenarios for PT 2 (EC, 2011).

PT4:

The derivation of predicted no effect concentrations (PNEC) for lactic acid (Doc. II-4) as well as the estimation of predicted environmental concentrations (PEC) resulting from the use of the biocidal dummy product (Doc. II-8.3) in all relevant environmental compartments were performed according to the Technical Guidance Document (TGD) on Risk Assessment (EU, 2003) and to the Environmental Emission Scenarios for PT 4 (EC, 2011).

2.2.2.1. Fate and distribution in the environment

Biodegradation

A test on ready biodegradability was performed according to the Dutch Guidelines NEN 6633 and NEN 6634. The degradation of the a.s. after 20 days was 60 and 67% at concentrations of 2 and 4 mg/l, respectively. However, the level of degradation within 10 days cannot be assessed. Therefore L(+) lactic acid is classified as readily biodegradable but failing 10-days window criterion. The resulting rate constant in the STP was set to k_{STP} = 0.3 /h.

During BPC WG ENV V 2016, the members of WG ENV requested a literature search regarding a.s. degradation in soil. The information provided by the applicant substantiated that the current assessment of the biodegradation behaviour of the a.s in soil (default degradation half-live of 90-days) is overly conservative. For product authorisation, the submission of a new study on the ready biodegradability with appropriate test design in order to address the 10-day window is required.

Anaerobic biodegradation

No study on anaerobic biodegradation was submitted by the applicant and it was not required by RMS. In the environmental risk assessment the worst-case assumption of no biodegradation of a.s. in manure/slurry was used.

Abiotic Degradation

L(+) lactic acid possesses only one hydrolysable group the acid group. For hydrolysis of the acid group, the dissociation constant (pK) of 3.8 should be taken into account. As no further hydrolysable groups are available, no further data on hydrolysis is considered necessary. The UV-spectrum of L(+) lactic acid shows that no absorbance in the wavelength range of 290-800 nm takes place. Therefore, L(+) lactic acid cannot undergo direct photolysis in sunlight.
The vapour pressure of L(+) lactic acid is 0.4 Pa at 20°C and direct evaporation is not expected, consequently. The Henry’s constant (3.6×10^{-5} Pa $\times$ m^3/mol at 20°C) indicates low volatility from water. In air L(+) lactic acid will be degraded by indirect photodegradation. The half-life of L(+) lactic acid was estimated to be 2.71 d, which corresponds to a value of 3.91 d for the chemical lifetime in the troposphere.

Distribution and Mobility

A HPLC-screening test according to the OECD test guideline (TG) No. 121 was performed to estimate the K_{OC} of lactic acid. The retention time of L(+) lactic acid in this test was lower than the retention time of the reference substance phenol with the known log K_{OC} of 1.32. Therefore it was concluded, that the log K_{OC} of L(+) lactic acid is < 1.32 (K_{OC} < 20.9 L/kg). The RMS decided to use a rounded K_{OC} of 20 L/kg for the environmental exposure assessment. L(+) lactic acid can be classified as substance with high mobility in soil.
The distribution in the sewage treatment plant was calculated by RMS using the SimpleTreat 3.0-model. Due to a lack of information on the fulfilment of the 10-day window criterion (rate constant for STP concluded by RMS: 0.3 /h) the following release fractions were assessed: to air 0.0%, water 32.5%, sludge 0.2% and degraded fraction 67.3%.

Bioaccumulation

Experimentally derived data on the bioaccumulation potential of the a.s. are not available neither for the aquatic nor the terrestrial compartment, respectively. Hence, the bioconcentration factors (BCF) for the aquatic compartment (BCF_{fish} = 0.048 L/kg) and the terrestrial compartment ($BCF_{earthworm}$ = 6.78 L/kg) were assessed on the basis of the log K_{OW} of -0.74 according to the standard equations given in the TGD on Risk Assessment (Doc. II-4). Since both BCFs as well as other indicators (e.g. surface tension) indicate a low bioaccumulation potential of the a.s. in the environment, experimental studies are not required.

2.2.2.2. Effects assessment

Aquatic Compartment

For the assessment of effects on the aquatic compartment, acute data for fish, invertebrates and algae are available. These data were derived from ecotoxicological studies submitted by the applicant, from a literature survey and from QSAR estimations, both conducted by RMS. Although the experimental studies on fish and invertebrates were considered to be invalid (RI = 3), algae were identified to be the most sensitive organisms with the aid of the QSAR estimations. Thus, the $PNEC_{water}$ was derived from the E_rC_{50} (3,900 mg a.s./L) that was assessed in a valid experimental study on the inhibition of algal growth (Doc. III-A7.4.1.3; RI = 2) by applying an assessment factor of 1,000.

$PNEC_{water}$ = 3.9 mg a.s./L

Sediment

Since no tests on the toxicity of L(+) lactic acid on sediment dwelling organisms were provided, the PNEC for sediment was derived by applying the equilibrium partitioning method (EPM) according to the TGD on Risk Assessment (Doc. II-4).

$PNEC_{sed}$ = 4.8 mg a.s./kg ww

Inhibition of microbial activity (STP)

In a test on the respiration inhibition of activated sludge according to the OECD guideline 209, the NOEC was assessed to be ≥100 mg a.s./L (nominal), the EC_{50} >100 mg a.s./L (nominal). For the risk assessment a NOEC of 100 mg a.s./L was used as a worst case. For the derivation of the $PNEC_{microorganisms,\ STP}$ an assessment factor of 10 was applied in accordance with the TGD on Risk Assessment (Doc. II-4).

$PNEC_{microorganisms,\ STP}$ = 10 mg a.s./L

Terrestrial Compartment

Data to address the ecotoxicity of L(+) lactic acid for terrestrial organisms were not submitted by the applicant since direct exposure as well as adsorption of the a.s. to soil is not expected to occur. Instead, a $PNEC_{soil}$ was calculated by applying the EPM according to the TGD on Risk Assessment (Doc. II-4).

$PNEC_{soil}$ of 1.9 mg a.s./kg ww

Atmosphere

L(+) lactic acid is not considered to be used as fumigant. The vapour pressure of L(+) lactic acid is 0.4 Pa at 20°C and the Henry constant is 3.6×10^{-5} indicating that direct evaporation and volatility from water are expected to be insignificant. In general, emissions of L(+) lactic acid to the atmosphere are unlikely to occur. Due to an estimated half-life in the atmosphere of 2.71 d corresponding to 3.91 d for the chemical lifetime the potential for long-range transport of L(+) lactic acid in air is indicated (ref. to Annex D of the Stockholm Convention on Persistent Organic Pollutants (17th May 2004): "... a chemical that migrates significantly through the air, its half-life in air should be greater than two days ..."). However, according to the TGD on Risk Assessment (EU, 2003) effects on stratospheric ozone and acidification are not expected because L(+) lactic acid does not contain halogens, nitrogen or sulphur substituents. L(+) lactic acid shows no absorption bands in the so-called atmospheric window (range from 800 to 1200 nm). Therefore, L(+) lactic acid has no global-warming potential.

Secondary Poisoning

As indicated by the BCF_{fish} (0.048 L/kg) and the $BCF_{earthworm}$ (6.78 L/kg) as well as by the surface tension (70.7 mN/m), the bioaccumulation potential of L(+) lactic acid and thus the risk of secondary poisoning is considered to be low.

Summary of PNECs

Table 2-10 Summary of the selected PNEC values used for the risk characterisation part

Environmental compartment	PNEC
$PNEC_{water}$	3.9 mg a.s./L
$PNEC_{sed}$	4.8 mg a.s./kg ww
$PNEC_{microorganism, STP}$	10 mg a.s./L
$PNEC_{soil}$	1.9 mg a.s/kg ww

2.2.2.3. PBT and POP assessment

The PBT assessment for L(+) lactic acid was performed according to the guidance given in the TGD on risk assessment (EU, 2003) as well as following the REACH Regulation (EC) No. 1907/2006:

P criterion:
Half-life > 40 d in freshwater or > 120 d in freshwater sediment or > 120 d in soil

(according to the REACH legislation)

vP criterion:
Half-life > 60 d in freshwater or > 180 d in freshwater sediment or > 180 d in soil (according to the REACH legislation)

B criterion:
BCF > 2000 L/kg
vB criterion:
BCF > 5000 L/kg

T criterion:
Long-term NOEC for freshwater organism < 0.01 mg/L or CMR or endocrine disrupting effects

L(+) lactic acid is considered to be neither persistent (readily biodegradable but failing the 10-days window criterion) nor bioaccumulative (BCF_{fish} = 0.048 L/kg; $BCF_{earthworm}$ = 6.78 L/kg), nor does L(+) lactic acid fulfil the toxicity criterion ($NOEC_{algae}$ = 1.1 g a.s./L). Hence, the P, vP as well as the B, vB and the T criterions are not fulfilled.

Conclusion:
The active substance L(+) lactic acid is neither a PBT nor a vP/vB - candidate.

Assessment of Endocrine Disrupting Properties (ED)
There is no indication for endocrine disrupting properties of the a.s.

2.2.2.4. Exposure assessment

PT2:

The b.p "Oscar", a ready-to-use solution containing 2% (w/w) of lactic acid, is used for the disinfection of bathrooms. For the environmental exposure assessment of the b.p. the following life cycle stages are selected to be relevant:

- production of a.s.
- formulation of b.p.
- private use of the b.p. as ready-to-use solution as bathroom disinfectant

The environmental release estimations and the PECs for the life cycle stages "production" and "formulation" can be found in Doc. II-8.3, but were not taken into account for the environmental risk assessment in accordance with the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012).

L(+) lactic acid is intended to be added to a bathroom cleaner for private use. Hence, the b.p. will be applied indoors and so exposure of the environmental compartments surface water and sediment will occur via the Sewage Treatment Plant (STP). In addition, natural emissions of L(+) lactic acid to the aquatic compartment (via urine and faeces to STP) should be considered. According to Berkow (1981) a total excretion of L(+) lactic acid per day should be assumed for the emission calculation. The environmental compartments soil and groundwater may be affected by the field application of sewage sludge. According to the ESD for PT 2 (RIVM, 2001) no exposure of the compartment air is foreseen and under

consideration of the intrinsic properties of L(+) lactic acid it is scientifically justifiable that the exposure of the air compartment is assumed as negligible.

In the Emission Scenario Document for Product Type 2 (RIVM, 2001), two emission scenarios for disinfectants used in the sanitary sector are presented: (1) based on tonnage and (2) based on consumption. According to the Report on the Workshop for PT 1-6 (EU, 2008) both approaches shall be presented by RMS in the CA report. Based on the calculation of the break-even point the most suitable scenario should be used. For L(+) lactic acid in PT 2 the scenario based on annual tonnage was used (Doc. II-8.3).

To get a better understanding for the relation between the anthropogenic emission vs emission due to biocidal use eCA decided to calculate PEC value for both emission pathways.

PT3:

The (b.p.) Filmadine is used by farmers (professional use) for the manual dipping of cows´ teats after milking. Filmadine is a ready-to-use product containing 8% lactic acid (w/w) in water, as well as a small amount of formulants to increase the viscosity. Only the cows´ teats are covered with a thin film to protect them until the next milking. For the environmental exposure assessment of the b.p. the following life cycle stages are selected to be relevant:

- production of a.s.,
- formulation of b.p.,
- professional use of the b.p. as “ready to use solution” as teat dipping disinfectant.

The environmental release estimations and the PECs for the life cycle stages “production” and “formulation” can be found in Doc. II-8.3, but were not taken into account for the environmental risk assessment in accordance with the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012).

For the environmental release estimation and the PEC assessment of the life cycle “professional use of b.p. as teat dipping disinfectant” two emission pathways have to be taken into consideration due to the intended use of the b.p.. Depending on whether the cows are milked in the stable or in a milking parlour outside the stable, L(+) lactic acid will be emitted to slurry or to waste water, respectively. In the latter case, the exposure to the environment will occur via the Sewage Treatment Plant (STP) and the application of sewage sludge to agricultural areas. Natural emission of L(+) lactic acid to the aquatic compartment (via urine and faeces to STP) should be considered, too.

However, subsequent to the possible use of the b.p. in the stable, the application of slurry to agricultural soil poses the second emission pathway of relevance. The detailed description of emission pathways as well as the calculation of the environmental exposure is presented in Doc II-8.3.

According to the ESD for PT 3 (EC, 2011) no exposure of the compartment air is foreseen (no data are given for an air fraction) and under consideration of the intrinsic properties of L(+) lactic acid (see Doc. II-4, chapter 4.2.2) it is scientifically justifiable that the exposure of the air compartment is assumed as negligible.

PT4:

The biocidal dummy product is used to disinfect single brewing vessels in different sized breweries. For environmental exposure assessment of the b.p the following life cycle stages are selected to be relevant:

- production of a.s.,
- formulation of b.p.,
- professional use of the b.p. as disinfectant in breweries.

The environmental release estimations and the PECs for the life cycle stages “production” and “formulation” can be found in Doc. II-8.3, but were not taken into account for the environmental risk assessment in accordance with the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012).

The disinfectant L(+) lactic acid is a component of the biocidal dummy product which is used for the disinfection of single brewing vessels in different sized breweries. The biocidal product (b.p) will be applied indoors, which results in the exposure of the environmental compartments surface water and sediment via the Sewage Treatment Plant (STP). In addition, natural emissions of L(+) lactic acid to the aquatic compartment (via urine and faeces to STP) should be considered. According to Berkow (1981) a total excretion of L(+) lactic acid per day should be assumed for the emission calculation. The environmental compartments soil and groundwater may be affected by the field application of sewage sludge on agricultural soil. According to ESD for Product Type 4 (EC, 2011) no exposure of the compartment air is foreseen (no data are given for an air fraction) and under consideration of the intrinsic properties of L(+) lactic acid (see Doc II-4, chapter 4.1.2.2) it is scientifically justifiable that the exposure of the air could be assumed as negligible.

In the draft Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas (EC, 2011), an emission scenario for estimating the release of disinfectants from entire plants (e.g. breweries) is presented. The emission estimation is based on the annual amount of the a.s used in the model plant. This calculation is presented in Doc IIB-8.3.

To get a better understanding for the relation between the anthropogenic emission vs emission due to biocidal use RMS decided to calculate PEC values for both emission pathways.

Aggregated environmental Exposure Assessment

Article 19(2) of the BPR (EU, 2012) states that “the evaluation […] shall take into account the following factors: […] (d) cumulative effects, (e) synergistic effects.” This is further elaborated in Annex VI (common principles for the evaluation of biocidal products) where it is stated that the risks associated with the relevant individual components of the b.p. shall be assessed, taking into account any cumulative and synergistic effects. This refers to the environmental risk assessment of an a.s. which is contained in different products of the same Product Type (PT) or of different PTs.
L(+) lactic acid is notified for inclusion in the Union list of active substances approved for use in biocidal products in PT 1, 2, 3, 4 and 6. For all mentioned PTs, DE is RMS. In the respective CA reports the following uses are considered: PT 1 – hand soap, PT 2 - disinfectant bathroom cleaner for private uses; PT 3 - non-medical teat dips disinfection (only STP-pathway assessed); PT 4 - disinfection of breweries (small, average and large sized brewery); PT 6 - a) manual washing-up liquid and b) fabric conditioner.
In RMS’s opinion each of the above mentioned intended uses can lead to an overlap in time and space in different environmental compartments. The main entry paths into the

environment are equal for all applications mentioned above (via STP), thus a combination of exposures to L(+) lactic acid for all affected environmental compartments is both possible and realistic. Consequently, an environmental evaluation considering aggregated risks according to BPR is feasible in technical terms.
According to the "Decision tree on the need for estimation of aggregated exposure" (BIP6.7 Decision Tree Agg Expo), the requirement for aggregated exposure estimations was checked for L(+) lactic acid. L(+) lactic acid is also regulated in other regulatory areas (e.g. cosmetics regulation, food legislation). The amount of L(+) lactic acid that is used annually for biocidal purposes amounts to 5% of the total production and import volume of L(+) lactic acid in the EU in 2012. Thus, the biocidal use of L(+) lactic acid accounts for less than 10% of the total production and import volume in the EU. The intended uses (hand soap, bathroom cleaner, teat dips disinfection, disinfection in breweries, manual washing-up liquid and fabric conditioner) are widely dispersive and do not represent a specific emission pattern. Consequently, it has been concluded that no aggregated exposure assessment for a.s. L(+) lactic acid has to be performed.

2.2.2.5. Risk characterisation

Aquatic Compartment including Sediment

PT2:

Table 2–11 PEC/PNEC ratios for the use of the b.p. in PT 2 as bathroom disinfectant for private use concerning STP, surface water and sediment

Compartment	PEC [µg a.s./L]	PNEC [µg a.s./L]	PEC/PNEC
STP	153.56	10,000	0.0154
Surface water	15.36	3,900	0.0039
Compartment	**PEC [µg a.s./kg]**	**PNEC [µg a.s./kg ww]**	**PEC/PNEC**
Sediment	18.7	4,820	0.0039

The estimated PEC/PNEC ratios for the relevant compartments are below the trigger value of 1 (Table 2-9). Thus, the use of the b.p. "Oscar" containing 2% of L(+) lactic acid indicates no unacceptable risk for the aquatic compartment.

PT3:

The risk characterisation for the environment was conducted for two emission pathways, depending on whether the b.p. is used in a milking parlour or in the stable. By the use of the b.p. in a milking parlour the release to the environment occurs via the STP and the application of sewage sludge to agricultural areas. However, the use of the b.p. in the stable is accompanied with releases of the a.s. to the slurry, resulting in the direct release to the environment by the application of slurry to agricultural soil and the run-off related discharge of lactic acid into surface waters

Aquatic Compartment including Sediment

Table 2–12 PEC/PNEC ratios for the use of the b.p. "Filmadine" (professional use in PT3) 3 as disinfectant for cows teats in a milking parlour and the related emission to waste water

Compartment	PEC [µg a.s./L]	PNEC [µg a.s./L]	PEC/PNEC
STP	11.38	10,000	0.001
Surface water	1.14	3,900	0.0003
Compartment	**PEC [µg a.s./kg]**	**PNEC [µg a.s./kg ww]**	**PEC/PNEC**
Sediment	1.38	4,820	0.0003

Table 2–13 PEC/PNEC ratios resulting from the use of the b.p. "Filmadine" (professional use in PT 3) as a disinfectant for cows' teats in stable and the related application of the slurry to agricultural areas

Compartment	Application area	PEC [µg a.s./L]	PNEC [µg a.s./L]	PEC/PNEC
Surface water	Arable land	26.6	3,900	0.007
	Grassland (with degradation)	63.8	3,900	0.02
Compartment	**Application area**	**PEC [µg a.s./kg]**	**PNEC [µg a.s./kg ww]**	**PEC/PNEC**
Sediment	Arable land	32.4	4,820	0.007
	Grassland (with degradation)	77.7	4,820	0.02

Conclusions to the risk assessment:

The estimated PEC/PNEC ratios for the relevant compartments for both emission scenarios are below the trigger value of 1 (Table 2-12, Table 2-13). Thus, the use of the b.p. "Filmadine" containing 8% (w/w) of L(+) lactic acid indicates no unacceptable risk for the aquatic compartment.

PT4:

Table 2–14 PEC/PNEC ratios for the use of the b.p. in PT 4 as a disinfectant in small, average and large breweries concerning STP, surface water and sediment

Size of brewery	small	average	large		small	average	large
Compartment	PEC [µg a.s./L]			PNEC [µg a.s./L]	PEC/PNEC		
STP	146.25	190	7,180	10,000	0.0146	0.02	0.7180
Surface water	14.62	19	718	3,900	0.0037	0.005	0.1841
Compartment	PEC [µg a.s./kg]			PNEC [µg a.s./kg ww]	PEC/PNEC		
Sediment	17.8	23.13	874.09	4,820	0.0037	0.005	0.1841

The estimated PEC/PNEC ratios for the relevant compartments are below the trigger value of 1 for each size of breweries (Table 2-14). Thus, the use of the biocidal dummy product, which is identical to the a.s. L(+) lactic acid, indicated no unacceptable risk for the aquatic compartment.

Terrestrial Compartment including Groundwater

PT2:

Table 2–15 PEC/PNEC ratios for the use of the b.p. as bathroom disinfectant for private use concerning soil and groundwater

Compartment	**PEC [µg a.s./kg]**	**PNEC [µg a.s./kg ww]**	**PEC/PNEC**
Soil	3.42	1,900	0.0018
Compartment	**PEC [µg a.s./L]**	**Trigger value [µg/L][1]**	**Risk quotient[2]**
Groundwater	3.76	0.1	37.6

[1]Quality standard for pesticides and biocidal products according to Directive 98/83/EC
[2] Prior to the refinement of the exposure assessment for groundwater with FOCUS PEARL

The PEC/PNEC ratio for soil is below the trigger value of 1, while the concentration in groundwater exceeds the quality standard for pesticides and biocidal products according to Directive 98/83/EC for drinking water (Table 2–15). Thus, the groundwater assessment was refined at a second tier with the FOCUS PEARL model, which considers potential mobility of L(+) lactic acid in soils and the leaching behaviour to groundwater. It could be demonstrated that for one arable land scenario (Sevilla) and for all grassland scenarios the average concentration of L(+) lactic acid closest to the 80th percentile is below the trigger value of 0.1 µg/L. According to the conclusion of the 47th CA meeting in July 2012 the risk for the groundwater compartment is acceptable if there is at least one safe scenario for each of both areas. Hence, the RMS comes to the conclusion, that the use of the b.p.

"Oscar" containing 2% of L(+) lactic acid indicates no unacceptable risk for the terrestrial compartment including groundwater.

PT3:

Table 2–16 PEC/PNEC ratios resulting from the use of the b.p. "Filmadine" (professional use in PT 3) as a disinfectant for cows teats in a milking parlour and the related application of sewage sludge to agricultural areas

Compartment	PEC [µg a.s./kg]	PNEC [µg a.s./kg ww]	PEC/PNEC
Soil	0.25	1,900	0.0001
Compartment	**PEC [µg a.s./L]**	**Trigger value [µg/L][1]**	**Risk quotient[2]**
Groundwater	0.28	0.1	2.8

[1]Quality standard for pesticides according to Directive 98/83/EC
[2] Prior to the refinement of the exposure assessment for groundwater with FOCUS PEARL

Table 2–17 PEC/PNEC ratios resulting from the use of the b.p. "Filmadine" (professional use in PT 3) as a disinfectant for cows' teats in the stable and the related application of slurry to agricultural areas

Compartment	Application area	PEC [µg a.s./kg]	PNEC [µg a.s./kg ww]	PEC/PNEC
Soil	Arable land	125.1	1,900	0.07
	Grassland (with degradation)	300.4	1,900	0.16
Compartment	**Application area**	**PEC [µg a.s./L]**	**Trigger value [µg/L][1]**	**Risk quotient**
Groundwater	Arable land	265.9	0.1	2659
	Grassland (with degradation)	638.3	0.1	6383

[1]Quality standard for pesticides according to Directive 98/83/EC
[2] Prior to the refinement of the exposure assessment for groundwater with FOCUS PEARL

Conclusions to the risk assessment:

The PEC/PNEC ratio for soil is below the trigger value of 1 for both intended emission scenarios (application of sewage sludge and slurry; Table 2-16, Table 2-17).

The exposure assessment for the application of slurry as well as of sewage sludge to agricultural areas results in a groundwater concentration above the maximum permissible concentration of 0.1 µg/L in groundwater (Table 2-16, Table 2-17). Even the refinement of PECgroundwater with the FOCUS PEARL model did not reveal a concentration below the trigger value of 0.1 µg/L and thus, no safe application of slurry to agricultural areas can be demonstrated (Appendix 1). Nevertheless, since the use of the b.p. "Filmadine" (containing 8% (w/w) of L(+) Lactic acid) in a milking parlour (connected to STP) was found not to come along with unacceptable risks in groundwater, one safe use for the application of sewage sludge could be demonstrated for the terrestrial compartment (Appendix 1).

PT4:

Table 2-18 PEC/PNEC ratios for the use of the b.p. as disinfectant for small, average and large breweries concerning soil and groundwater

Size of brewery	small	average	large		small	average	large
Compartment	**PEC [µg a.s./kg]**			**PNEC [µg a.s./kg]**	**PEC/PNEC**		
Soil	3.25	4.23	160	1,900	0.0017	0.002	0.0842
Compartment	**PEC [µg a.s./L]**			**Trigger value [µg a.s./L][1]**	**Risk quotient[2]**		
Groundwater	3.58	4.66	176	0.1	35.8	46.6	1,760

[1]Quality standard for pesticides and biocidal products according to Directive 2006/118/EC (Annex I)
[2] Prior to the refinement of the exposure assessment for groundwater with FOCUS PEARL

The PEC/PNEC ratio for soil is below the trigger value of 1, while the concentration in groundwater exceeds the quality standard for pesticides according to Directive 98/83/EC for drinking water (Table 2–18). Thus, the groundwater assessment was refined at a second tier with the FOCUS PEARL model, which considers potential mobility of L(+) lactic acid in soils and the leaching behaviour to groundwater. It could be demonstrated that for one arable land scenario (Sevilla) and for seven grassland scenarios the average concentration of L(+) lactic acid closest to the 80th percentile is below the trigger value of 0.1 µg/L. According to the conclusion of the 47th CA meeting in July 2012 the risk for the groundwater compartment is acceptable if there is at least one safe scenario for each of both areas. Hence, the RMS comes to the conclusion, that the use of the biocidal dummy product, which is identical to the a.s. L(+) Lactic acid, indicates no unacceptable risk for the terrestrial compartment and groundwater.

Atmosphere

Due to the intended use of the b.p. and on the basis of the available substance information the environmental risk of L(+) lactic acid for the atmosphere is assumed to be insignificant.

Aggregated Risk Assessment

Since the amount of L(+) lactic acid that is used annually in biocidal products accounts for less than 10% compared to the annual production and import volume of L(+) lactic acid in the EU, no aggregated risk assessment was performed.

Overall Conclusion from the Environment Risk Characterisation

PT2:

Considering the intended use (bathroom disinfectant) of the b.p. "Oscar" containing the active substance L(+) lactic acid at a concentration of 2% in Product Type 2 (Disinfectants and algaecides not intended for direct application to humans or animals) no unacceptable risk for the environment is indicated. In addition, no potential for bioaccumulation and consequently no concern for secondary poisoning were identified. Moreover, L(+) lactic acid is no PBT candidate.

PT3:

On the basis of the risk assessment for the different environmental compartments, the RMS comes to the conclusion that only one of the intended uses of the b.p. “filmadine” containing the active substance L(+) lactic acid at a concentration of 8% (w/w) for the manual dipping of cows’ teats after milking entails no unacceptable risk for the environment. The use of the biocidal product in a milking parlour turned out to represent a safe use scenario thus, the requirements for the approval of the a.s. L(+) Lactic acid in product-type 3 (veterinary hygiene) are met.

In addition, no potential for bioaccumulation and consequently no concern for secondary poisoning were identified. Moreover, L(+) Lactic acid is no PBT candidate.

PT4:

Considering the intended use of the biocidal dummy product, which is identical to the a.s. L(+) Lactic acid, and that is used for disinfection purposes in breweries (Product Type 4: Food and feed area) no unacceptable risk for the environment is indicated. In addition, no potential for bioaccumulation and consequently no concern for secondary poisoning were identified. Moreover, L(+) lactic acid is no PBT candidate.

2.3. Overall conclusions

The outcome of the assessment for L(+) lactic acid in product-type 2, 3 and 4 is specified in the BPC opinions following discussions at the 20th meeting of the Biocidal Products Committee (BPC). The BPC opinions are available from the ECHA website.

2.4. Requirement for further information related to the reference biocidal product

For the authorisation of products, a study on ready biodegradability, in which the 10-days window criterion is assessed, may be submitted to allow an improved exposure assessment (especially for groundwater), when necessary.

2.5. List of endpoints

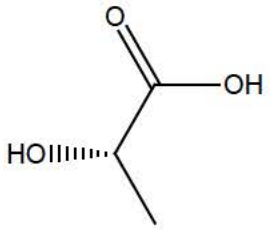
The most important endpoints, as identified during the evaluation process, are listed in Appendix I.

Appendix I: List of endpoints

Chapter 1:Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Name)	L(+) lactic acid
Product-type	02 (disinfectants and algaecides not intended for direct application to humans or animals), 03 (Veterinary Hygiene), 04 (disinfectants in food and feed areas)

Identity

Chemical name (IUPAC)	(S)-2-Hydroxypropanoic acid
Chemical name (CA)	Propanoic acid, 2-hydroxy-, (2S)-
CAS No	79-33-4
EC No	201-196-2
Other substance No.	
Minimum purity of the active substance as manufactured (g/kg or g/l)	≥ 95.5% w/w Existence of an equilibrium system of L(+) lactic acid with several oligomers
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	Not applicable
Molecular formula	$C_3H_6O_3$
Molecular mass	90.08 g/mol
Structural formula	 (S)-2-hydroxypropanoic acid

Physical and chemical properties

Melting point (state purity)	53°C (pure, crystalline solid L(+) lactic acid) Supercooled viscous: no melting until – 80°C (93% L(+) lactic acid, equilibrium system)
Boiling point (state purity)	204.2 °C (calculated)(100 % L-(+)-Lactic acid) Not determinable (93 % L-(+)-Lactic acid, equilibrium system)
Thermal stability / Temperature of decomposition	Not applicable

Appearance (state purity)	Liquid (aqueous solution, 88 % / 93 % L-(+)-Lactic acid), colourless to yellow light brown odour: characteristic
Relative density (state purity)	1.213 (T = 20 °C, 93 % L-(+)-Lactic acid, equilibrium system)
Surface tension (state temperature and concentration of the test solution)	70.7 mN/m (1 g/l 93 % L-(+)-Lactic acid, equilibrium system)
Vapour pressure (in Pa, state temperature)	0.4 Pa (T = 20 °C, 100 % L-(+)-Lactic acid, calculated) no analytically determined vapour pressure value available for a 93 % L-(+)-Lactic acid solution
Henry's law constant (Pa m^3 mol^{-1})	Because of the equilibrium system only hypothetical
Solubility in water (g/l or mg/l, state temperature)	completely miscible with water (100 % L-(+)-Lactic acid)
Solubility in organic solvents (in g/l or mg/l, state temperature)	soluble in polar solvents (e.g. alcohols, ketons), poorly soluble / insoluble in non-polar solvents …… ≈600 g/L in Methanol ≈ 250 g/L in 2-Ethylhexanol <0.1 g/L in Hexane ≈ 350 g/L in Ethylacetate <1 g/L in Toluene ≈ 250 g/L in Diethylether ≈430 g/L in 2-Butanone (T = 20 °C, only the monomeric L-(+)-Lactic acid (free acid) is determined, oligomers are not considered, only estimated values)
Stability in organic solvents used in biocidal products including relevant breakdown products	Not applicable
Partition coefficient (log P_{OW}) (state temperature)	-0.74 (T = 20 °C, 100 % L-(+)-Lactic acid, degree of oligomerisation n = 1)

	-0.42 (T = 20 °C, degree of oligomerisation n = 1.36) -0.05 (T = 20 °C, degree of oligomerisation n = 1.98) -0.74 (T = 20 °C, 100 % L-(+)-Lactic acid) The determination of the partition coefficient n-octanol/water of a 93 % L(+) lactic acid solution is not scientific, because of the existence of an equilibrium system of L(+) lactic acid with several oligomers (higher partition coefficients).
Dissociation constant	pKa = 3.86, T = 22.5 °C (crystalline L-(+)-Lactic acid)
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Maximum absorption at 210 nm No absorption > 290 nm
Flammability or flash point	No flash point was determined up to 100°C
Explosive properties	No explosive properties
Oxidising properties	No oxidising properties

Classification and proposed labelling

with regard to human health

Proposed classification of L(+) lactic acid based on Regulation (EC) No 1272/2008

Classification	**Hazard class, category, and statements**	**Wording**
	Eye Dam. 1, H318 Skin Irrit. 2, H315	Causes serious eye damage Causes skin irritation

Proposed labelling of L(+) Lactic based on Regulation (EC) No 1272/2008

	Labelling	**Wording**
Pictograms	GHS05	
Signal Word	Danger	
Hazard statements	H315 H318	Causes skin irritation Causes serious eye damage

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	The determination of L(+) lactic acid could be done with several titration methods. The validated titration method with sodium hydroxide respectively back titration with sulfuric acid is capable to determine free and, or total lactic acid. After derivatization the Methyl esters of S- and R-lactic acid are separated on a chiral GC column, and the ratio determined from the FID-generated peak surfaces areas. L(+) lactic acid oligomers and cyclic dimers are determined by a UV/HPLC method.
Impurities in technical active substance (principle of method)	Organic acid impurities are determined and quantified by a GC/MS method based on derivatization of acids to methyl esters. Methyl esters of organic acids are separated on two different GC columns for a positive identification, and quantified from the FID-generated peak surfaces areas.

Analytical methods for residues

Soil (principle of method and LOQ)	Not applicable, no relevant residues expected by the CA
Air (principle of method and LOQ)	Not applicable, no relevant residues expected by the CA
Water (principle of method and LOQ)	Not applicable, no relevant residues expected by the CA
Body fluids and tissues (principle of method and LOQ)	Not applicable, active substance not classified as toxic or very toxic
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not applicable, no relevant residues expected by the CA
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not applicable, no relevant residues expected by the CA

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	100%, rapid

Rate and extent of dermal absorption*:	Default values in the absence of data for the biocidal product: 25% for products containing > 5% a.s. 75 % for products containing ≤ 5% a.s. Values from studies with other formulations (rate dependent on pH and formulation): • 30-32 % at pH 3/3.8 (human (PEG-100 stearate, laureth-4) and pig (o/w emulsion) skin *ex vivo*); • 11 % at pH 3.8 (pig skin *ex vivo*, w/o emulsion) • 7-10 % at pH 7 (human (PEG-100 stearate, laureth-4) and pig (o/w emulsion) skin *ex vivo*) 50 % within 3 days (rat *in vivo*, o/w; pH not stated)
Distribution:	V_d ~ 0.5 L/kg bw, widely distributed
Potential for accumulation:	No evidence for accumulation
Rate and extent of excretion:	Predominantly metabolic elimination via CO_2 or synthesis of biomolecules (glucose, glycogen, amino acids, polypeptides); ~ 1.8 g/kg bw/d endogenous turnover rate at rest in humans; turnover capacity: > 200 % turnover rate at rest
Toxicologically significant metabolite(s)	None

* the dermal absorption value is applicable for the active substance and might not be usable in product authorization

Acute toxicity

Rat LD_{50} oral	3543 mg/kg bw*
Rat LD_{50} dermal	> 2000 mg/kg bw*
Rat LC_{50} inhalation	> 7.94 mg/L air x 4 h* (aerosol, nose only)

Skin corrosion / irritation	Irritant (human patch test, single exposure (concentrated lactic acid); guinea pig, repeated exposure (≥ 24%)) **H315**
Eye irritation	Irritant (Chicken enucleated Eye test), Risk of serious damage to eyes

	H318
Respiratory tract irritation	No data submitted
Skin sensitisation (test method used and result)	Not sensitising (Buehler)*

* 80 % L-(+)-lactic acid

Respiratory sensitisation (test method used and result)	No data submitted

Repeated dose toxicity

Short term

Species / target / critical effect	Oral: no valid data, justification accepted Dermal (Buehler, guinea pig): local irritation effects: pinpoint pitting, eschar formation **H315**
Relevant oral NOAEL / LOAEL	No valid data, justification accepted
Relevant dermal NOAEL / LOAEL	Systemic effects: no data, justification accepted Local effects: < 24 % L(+) lactic acid
Relevant inhalation NOAEL / LOAEL	No data, justification accepted

Subchronic

Species/ target / critical effect	See short term
Relevant oral NOAEL / LOAEL	
Relevant dermal NOAEL / LOAEL	
Relevant inhalation NOAEL / LOAEL	

Long term

Species/ target / critical effect	No valid data, justification accepted
Relevant oral NOAEL / LOAEL	
Relevant dermal NOAEL / LOAEL	
Relevant inhalation NOAEL / LOAEL	

Genotoxicity	Non-mutagenic in *in vitro* assays. (Ames test, chromosomal aberration)

Carcinogenicity

Species/type of tumour	Rat: no tumours observed

Relevant NOAEL/LOAEL	Rat: ~880 mg/kg bw/d (highest dose tested)

Reproductive toxicity

Developmental toxicity

Species/ Developmental target / critical effect	Mouse: no specific effects observed
Relevant maternal NOAEL	570 mg/kg bw/d (highest dose tested)
Relevant developmental NOAEL	570 mg/kg bw/d (highest dose tested)

Fertility

Species/critical effect	No data, justification accepted
Relevant parental NOAEL	
Relevant offspring NOAEL	
Relevant fertility NOAEL	

Neurotoxicity

Species/ target/critical effect	No data, not required

Developmental Neurotoxicity

Species/ target/critical effect	No data, not required

Immunotoxicity

Species/ target/critical effect	No data, not required

Developmental Immunotoxicity

Species/ target/critical effect	No data, not required

Other toxicological studies

No data, not required

Medical data

Case report, fatal accidental intoxication: Administration of ca. 30 g lactic acid by duodenal tube resulted in pain, vomiting, gastrointestinal haemorrhages, corrosion, bleeding and necroses of the duodenum; death within 12 h

Summary

	Value	Study	Safety factor
$AEL_{long-term}$	Not allocated – not necessary		

$AEL_{medium\text{-}term}$	Not allocated – not necessary
$AEL_{short\text{-}term}$	Not allocated – not necessary
ADI[1]	Not allocated – not necessary
ARfD	Not allocated – not necessary
$NOAEC_{dermal\text{-}acute,\ -\ medium\text{-}term,\ long\text{-}term}$	10% L(+) lactic acid*

*Derived from rabbit irritation/corrosion studies: 88% and 50 % L(+) lactic acid were corrosive in rabbits (88 % were irritant in human patch tests); 10 % were non-irritant in rabbits and guinea pigs (range-finding Buehler test). As the rabbit is the most sensitive species it seems to be reasonable to assume that this concentration would be without effect on human skin

MRLs

Relevant commodities	Additional uses as food additive (in Germany under Zusatzstoff-Zulassungsverordnung) and VMP (under Regulation (EWG) 2377/90 No MRLs available

Reference value for groundwater

According to BPR Annex VI, point 68	

Dermal absorption

Study (*in vitro*/*vivo*), species tested	See LoEP, chapter 3, Absorption, distribution, metabolism and excretion in mammals
Formulation (formulation type and including concentration(s) tested, vehicle)	
Dermal absorption values used in risk assessment	Default values

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	No hydrolysis
pH 5	
pH 9	
Other pH: *[indicate the value]*	
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Not applicable, no absorption maximum > 290nm

[1] If residues in food or feed.

Readily biodegradable (yes/no)	Yes, but 10-day window cannot be assessed
Inherent biodegradable (yes/no)	
Biodegradation in freshwater	
Biodegradation in seawater	
Non-extractable residues	
Distribution in water / sediment systems (active substance)	
Distribution in water / sediment systems (metabolites)	

Route and rate of degradation in soil

Mineralization (aerobic)	
Laboratory studies (range or median, with number of measurements, with regression coefficient)	
DT_{50lab} (20°C, aerobic):	
DT_{90lab} (20°C, aerobic):	
DT_{50lab} (10°C, aerobic):	
DT_{50lab} (20°C, anaerobic):	
degradation in the saturated zone:	
Field studies (state location, range or median with number of measurements)	
DT_{50f}:	
DT_{90f}:	
Anaerobic degradation	
Soil photolysis	
Non-extractable residues	
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	
Soil accumulation and plateau concentration	

Adsorption / desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	K_{OC} was estimated by HPLC-screening test according to the OECD test guideline (TG) No. 121: K_{OC} < 20.9 L/kg → RMS used the rounded value of 20 L/kg for K_{OC} for environmental exposures calculations Not stated in the HPLC-screening test

Fate and behaviour in air

Direct photolysis in air	
Quantum yield of direct photolysis	
Photo-oxidative degradation in air	tropospherical half-life of Lactic acid: 2.71 d (reaction with OH radicals; OH radical concentration = 5 x 10^5 OH radicals/cm^3, global 24-hours-mean)
Volatilization	Henry's law constant indicates low volatility

Reference value for groundwater

According to BPR Annex VI, point 68	

Monitoring data, if available

Soil (indicate location and type of study)	
Surface water (indicate location and type of study)	
Ground water (indicate location and type of study)	
Air (indicate location and type of study)	

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity
Fish			
Oncorhynchus mykiss (Salmo gairdneri) *Lepomis macrochirus*	96 h	Mortality	(LC_{50} = 130 mg a.s./L)[1] (LC_{50} =130 mg a.s./L)[1]
QSAR		Mortality	LC_{50} = 177 g a.s./L

Invertebrates			
Daphnia magna	48 h	Mortality	(EC_{50} = 156 mg a.s./L)[1]
QSAR		Mortality	EC_{50} = 78.8 g a.s./L
Algae			
Selenastrum capricornutum	70.5 h	Growth inhibition	(E_rC_{50} = 3.9 g a.s./L)[1] (NOE_rC = 1.1 g a.s./L)
QSAR		Growth inhibition	21.3 g a.s./L
Microorganisms			
Activated sludge from municipal sewage treatment plant (treating predominantly domestic sewage)	3 h, static	Respiration inhibition	EC_{50} > 100 mg a.s./L (nominal) NOEC ≥ 100 mg a.s./L (nominal)

[1)] Effect values are considered to be related to low pH and were thus not taken into account for PNEC derivation

Chapter 6: Other End Points

Residues in food and feed from the intended use of L(+) lactic acid in PT2, 3 and 4 biocidal products are not expected. Therefore, dietary exposure of humans from the use of lactic acid as a biocide of PT2 can be excluded. In addition to its proposed biocidal use, lactic acid is used as a food additive (in Germany under Zusatzstoff-Zulassungsverordnung) and a VMP (under Regulation (EWG) 2377/90). No MRL`s exist for these uses.

Appendix II: List of Intended Uses

PT2

L(+) lactic acid is a bactericide and fungistatic agent which is intended to be used for treating of surfaces in bathrooms (general public) in order to prevent growth of potentially harmful organisms.

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks:
				Type	Conc. of a.s.	method kind	number min max	interval between applications (min)	g a.s./L min max	water L/m² min max	g a.s./m² min max	
PT2: Disinfection of bathrooms bactericide and fungistatic	EU	Oscar	Bacteria (household), fungi (mold, mildew)	Spray liquid	2.2 %	Trigger sprayer	-	No label restrictions	No label restrictions			-

PT3

L(+) lactic acid is a bactericide which is intended to be used for dipping of cow teats after milking in order to reduce the number of mastitis pathogens.

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks:
				Type	Conc. of a.s.	method kind	number min max	interval between applications (min)	g a.s./L min max	water L/m² min max	g a.s./m² min max	
bactericide against mastitis pathogens	EU	Filmadine	Mastitis pathogens	Viscous liquid	8%	Dipping with anti-spill cup	used twice a day after milking	No label restrictions	Maximum volume of 20 mL/cow/day is used			-

PT4

Lactic acid is a bactericide which is intended to be used in breweries as a disinfectant of tanks.

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks:
				Type	Conc. of a.s.	method kind	number min max	interval between applications (min)	g a.s./L min max	water L/m² min max	g a.s./m² min max	
bactericide	EU	dummy product	Bacteria	Liquid	3%	Soaking of tank	Once per day	No label restrictions	3% lactic acid			After 25 minutes tank is emptied and rinsed with drinking water.

Appendix III: HUMAN HEALTH TABLES FOR RISK CHARACTERISATION

PT2:

Table 1: Professional Users – Primary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated oral uptake [mg/kg b.w/day]	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (no PPE)	Not applicable only non-professional use								
Tier 2 (Refinement, PPE or other risk mitigation measures – Specify)	Not applicable only non-professional use								

Table 2: Non Professional Users – Primary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated oral uptake [mg/kg b.w/day]	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (no PPE)	Household use, spraying and wiping (combined), long-term exposure	0.010	0.001	0.445	0.456	Not derived	n.a.	n.a.	n.a.
Tier 2 Refinement or other risk mitigation measures – Specify)	Not required								

Table 3: Indirect Exposure as a result of use – Secondary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 Short term Scenario	Contact to wet surfaces, rubbing off	-	3.12	0.042	3.16	Not derived	n.a.	n.a.	n.a.
Exposure Scenario		Estimated Internal Exposure				Relevant NOAEL/ LOAEL	AF MOE_{ref}	MOE	Exposure /AEL

(indicate duration)		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]	[mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)			
Tier 2 (Refinement - Specify) Short Term Scenario	Not required								

Table 4: Indirect Exposure as a result of use – Secondary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (Worst Case) Chronic Scenario	Not expected	-	-	-	-	Not derived	n.a.	n.a.	n.a.
		Estimated Internal Exposure				Relevant NOAEL/	AF MOE_{ref}	MOE	Exposure /AEL

Exposure Scenario (indicate duration)						LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)			
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 2 (Refinement-Specify) Chronic Scenario	Not required								

PT3

Table 1: Professional Users – Primary Exposure

Table 1a: professional users – primary exposure, systemic effects (L (+) lactic acid, PT 03)

exposure scenario		Estimated internal exposure[1]				Endogenous production[4] [mg/kg bw/day]	estimated total uptake/ endogenous production
		oral uptake [mg/kg bw/day]	inhalation uptake[2] [mg/kg bw/day]	dermal uptake[3] [mg/kg bw/day]	total uptake [mg/kg bw/day]		
1 - teat disinfection - dipping	Tier 1 (no PPE)	-	2.50	24.35	26.85	1667	0.02
	Tier 2 (PPE: protective gloves, protective coverall [5])	-	2.50	0.50	3.00		1.80×10^{-3}

[1] It is noted that for clarity reasons systemic exposure values are rounded to two decimal places. Other values are rounded to either two, one or any decimal places. However, the underlying calculations are based on unrounded exposure values.
[2] based on the assumption of 100 % absorption by inhalation, breathing volume of 10 m^3 per shift and 60 kg body weight
[3] based on the assumption of 25 % dermal absorption and 60 kg body weight
[4] because of very low systemic toxicity of L (+) lactic acid, derivation of any systemic toxicological reference dose was regarded unnecessary, however, the exposure estimates are compared with endogenous production of L (+) lactic acid
[5] for details see chapter 8.2.2

Table 1b: professional users – primary exposure, local effects (L (+) lactic acid, PT 03)

exposure scenario	concentration in the product [%]	relevant reference value[1] [%]	concentration in the product / reference value
1 - teat disinfection - dipping	8	10	0,8

[1]dermal AEC, derived from rabbit irritation/corrosion studies, as the rabbit is the most sensitive species it seems reasonable to assume that this concentration would be without effect on human skin

Table 2: Non Professional Users – Primary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated oral uptake [mg/kg b.w/day]	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (no PPE)	Not expected	-	-	-	-	Not derived	n.a.	n.a.	n.a.
Tier 2 Refinement or other risk mitigation measures – Specify)	Not required								

Table 3: Indirect Exposure as a result of use – Secondary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 Short term Scenario	Not expected	-	-	-	-	Not derived	n.a.	n.a.	n.a.
Exposure Scenario		Estimated Internal Exposure				Relevant NOAEL/ LOAEL	AF MOE_{ref}	MOE	Exposure /AEL

(indicate duration)		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]	[mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)			
Tier 2 (Refinement - Specify) Short Term Scenario	Not required								

Table 4: indirect exposure as a result of use – secondary exposure (L (+) lactic acid, PT 03) – professional user

exposure scenario	estimated internal exposure				Relevant reference value [mg/kg bw/d]	Estimated total uptake / reference value
	inhalation uptake [mg/kg bw/d]	dermal uptake [mg/kg bw/d]	oral uptake [mg/kg bw/d]	total uptake [mg/kg bw/d]		
Tier 1 chronic scenario	in the same order of magnitude assessed for the application procedure					

PT4:

Table 1: Professional Users – Primary Exposure, systemic effects (L (+) lactic

Table 1a: professional users – primary exposure acid, PT 04)

exposure scenario		Estimated internal exposure[1]				Endogenous production[4] [mg/kg bw/d]	estimated total uptake / endogenous production
		oral uptake [mg/kg bw/d]	inhalation uptake[2] [mg/kg bw/d]	dermal uptake[3] [mg/kg bw/d]	total uptake [mg/kg bw/d]		
1 – disinfection of brewery vessels	Tier 1 (no PPE)	-	2.25×10^{-3}	0.19	0.19	1667	1.13×10^{-4}
	Tier 2 (PPE: gloves)	-	2.25×10^{-3}	0.02	0.05		3.23×10^{-5}

[1] It is noted that for clarity reasons systemic exposure values are rounded to two decimal places. Other values are rounded to either two, one or any decimal places. However, the underlying calculations are based on unrounded exposure values.
[2] based on the assumption of 100 % absorption by inhalation, breathing volume of 10 m^3 per shift and 60 kg body weight
[3] based on the assumption of 25 % dermal absorption and 60 kg body weight
[4] because of very low systemic toxicity of L (+) lactic acid, derivation of any systemic toxicological reference dose was regarded unnecessary, however, the exposure estimates are compared with endogenous production of L (+) lactic acid

Table 1b: professional users – primary exposure, local effects (L (+) lactic acid, PT 04)

exposure scenario	concentration in the product [%]	relevant reference value[1] [%]	concentration in the product / reference value
1 – disinfection of brewery vessels	93	10	9.30

[1]dermal AEC, derived from rabbit irritation/corrosion studies, as the rabbit is the most sensitive species it seems reasonable to assume that this concentration would be without effect on human skin

Table 2: Non Professional Users – Primary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated oral uptake [mg/kg b.w/day]	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (no PPE)	Not expected	-	-	-	-	Not derived	n.a.	n.a.	n.a.
Tier 2 Refinement or other risk mitigation measures – Specify)	Not required								

Table 3: Indirect Exposure as a result of use – Secondary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]				
Tier 1 Short term Scenario	Not expected	-	-	-	-	Not derived	n.a.	n.a.	n.a.
Exposure Scenario		Estimated Internal Exposure				Relevant NOAEL/ LOAEL	AF MOE_{ref}	MOE	Exposure /AEL

(indicate duration)		estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day]	estimated oral uptake [mg/kg b.w/day]	estimated total uptake [mg/kg b.w/day]	[mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)			
Tier 2 (Refinement - Specify) Short Term Scenario	Not required								

Table 4: Indirect Exposure as a result of use – Secondary Exposure

exposure scenario	estimated internal exposure				Relevant reference value [mg/kg bw/d]	Estimated total uptake / reference value
	inhalation uptake [mg/kg bw/d]	dermal uptake [mg/kg bw/d]	oral uptake [mg/kg bw/d]	total uptake [mg/kg bw/d]		
Tier 1 chronic scenario	not required					

Appendix IV: LIST OF STUDIES

Data protection is claimed by the applicant in accordance with Article 60 of Regulation (EU) No 528/2012.

Doc II

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
Doc II A3	Abramson, H.A., Eggleton, P.	1927	The utilization of intravenous sodium r-lactate. I. Excretion by kidneys and intestines. J. Biol. Chem. 75: 745-752.	No	Published
Doc II A3	Carney, E.W, Kimmel, C.A	2007	Interpretation of skeletal variations for human risk assessment: delayed ossification and wavy ribs. Birth Defect Research (Part B) 80:473-496.	No	Published
Doc II A3*	Colomina, M.T, Gomez, M., Domingo, J.L., LLobet, J.M., Corbella, J.	1992	Concurrent ingestion of lactate and aluminum can result in developmental toxicity in mice. Res Comm Chem Pathol Pharmacol 77(1):95-106.	No	Published
Doc II A3	Cori, C.F., Cori, G.T.	1929	Glycogen formation in the liver from d- and l-lactic acid. J. Biol. Chem. 81: 389-403.	No	Published
Doc II A3	Cori, G.T.	1930	Studie on intestinal absorption. I. The absorption of lactic acid. J. Biol. Chem. 87: 13-18.	No	Published
Doc II A3	D'Amour, F.E.	1934	Effects of feeding sodium bicarbonate or lactic acid upon the sex ratio in rats. Science 79(2038):61-62.	No	Published
Doc II A3	EFSA	2012	Guidance on Dermal Absorption, EFSA Panel on Plant Protection Products and their Residues (PPR), EFSA Journal 2012;10(4):2665	No	Published
Doc II A3	EMEA	2008	Status on MRL procedures. MRL assessments in the context of Council Regulation (EEC) No. 2377/90. http://www.emea.europa.eu/pdfs/vet/mrls/076599en.pdf	No	Published
Doc II A3	EC	1995	European Parliament and Council Directive No. 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners. http://ec.europa.eu/food/fs/sfp/addit_flavor/flav11_en.pdf	No	Published

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
Doc II A3	Fühner, H.	1932	Milchsäure-Vergiftung, tödliche, medizinale. Arch Toxicol 3(1):71-74	No	Published
Doc II A3	Gladden, L.B.	2004	Lactate metabolism: a new paradigm for the third millennium. J Physiol. 558:5-30.	No	Published
Doc II A3	Hagenfeldt, L., Hagenfeldt, K.	1972	Gas chromatographic-mass spectrometric analysis of organic acids in amniotic fluid. Clin Chim Acta 42:219-224.	No	Published
Doc II A3*	Sah, A., Mukherjee, S., Wickett, R.R.	1998	An in vitro study of the effect of formulation variables and product structure on percutaneous absorption of lactic acid. J Cosmet Sci 49:257-273.	No	Published
Doc II A3	Sims, C.J., Fujito, D.T., Burholt, D.R., Dadok, J., Giles, H.R., Wilkinson, A.	1993	Quantification of human aminiotic fluid constituents by high resolution proton nuclear magnetic resonance (NMR) spectroscopy. Prenatal Diagnosis 13:473-480.	No	Published
Doc II A3	Walther, B.	2006	Milchsäure in Lebensmitteln und ihre Bedeutung für die menschliche Ernährung. Technisch-wissenschaftliche Information, ALP Science 2006, Nr. 505.	No	Published
Doc II A3*	York, M., Griffiths, H.A., Whittle, E., Basketter, D.A.	1996	Evaluation of a human patch test for the identification and classification of skin irritation potential. Contact Dermatitis 34:204-212.	No	Published
Doc II A4	EC	2000	Technical Guidance Document in support of the Directive 98/8/EC concerning the placing of biocidal products on the market, Guidance on data requirements for active substances and biocidal products (TNsG) , October 2000	No	Publication
Doc II A4	EC	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Part II;	No	Publication

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
			Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2		
Doc II A4	EU	2007	Regulation (EC) No 1272/2008 of the European Parliament and on the Council of 16 December 2008 on classification, labelling and packing of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006	No	Publication
Doc II A4	Hooftman, R.N.	1992	Evaluation of the toxicity of lactic acid and lactates to aquatic organisms; TNO Report nr. IMW-R 92/256	Yes	Purac
Doc II A4	Lyman et al.	1983	Handbook of chemical property estimation methods, McGraw-Hill Inc.; New York	No	Publication
Doc II A4	McCall, P.J. et al	1981	Measurement of Sorption Coefficients of organic Chemicals and their use in Environmental Fate Analysis; Test protocols for Environmental Fate & Movement of Toxicants (1981); Proceedings of Symposium AOAC, 21.-22.10.1980, Washington, DC	No	Publication
Doc II A4	OECD	2000	OECD 106 “Adsorption -- Desorption Using a Batch Equilibrium Method”	No	Publication
Doc II A4	OECD	2001	OECD 121 “Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC)”	No	Publication
Doc II A4	OECD	1984	OECD 202 “Daphnia sp., Acute Immobilisation Testand Reproduction Test"	No	Publication
Doc II A4	OECD	1992	OECD 301D “Ready Biodegradability”	No	Publication
Doc II A4	Saha, N.C. et al.	2006	Comparative toxicity of three organic acids to freshwater	No	Publication

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
			organisms and their impact on aquatic ecosystems; Human and Ecological Risk Assessment, Vol. 12, No. 1: pp 192-202		
Doc II A4	Sansone, F.J. et al.	1987	Adsorption of short-chain organic acids onto nearshore marine sediments; Geochim Cosmochim Acta, Vol. 51, pp. 1889-96	No	Publication
Doc II A4	The Netherlands	1987	NEN 6633 “Water-Determination of Oxygen Demand (COD)” Dutch Guideline	No	Publication
Doc II A4	The Netherlands	1991	NEN 6634 “Water-Determination of Biochemical Oxygen Demand after n days (BOD)” Dutch Guideline	No	Publication
Doc II A4	UNEP	2004	Stockholm Convention on Persistent Organic Pollutants (POP), entered into force 17 May 2004	No	Publication
Doc II A4	US EPA	1997	US EPA standard 660/3-75-009 “Methods of acute toxicity test with fish, macroinvertebrates and amphibians”	No	Publication
Doc II B6.5	EC	1999	Directive 1999/45/EC - classification, packaging and labelling of dangerous preparations	No	Publication
Doc II B6.5	EC	2008	REGULATION (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006	No	Publication
Doc II B8	EC	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Part II; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2	No	Publication

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
Doc II B8	EC	2004	Supplement to the methodology for risk evaluation of biocides Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product type 1)	No	Publication
Doc II B8	OECD	2008	OECD Series on emissions scenario document; Number 18: Emissions scenario document for insectides, acaricides and products to control other arthropods for household and professional uses	No	Publication
Doc II B8	RIVM	2001	Supplement to the methodology for risk evaluation of biocides. Emission Scenarios Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector)	No	Publication
Doc II B8	Holten, C.H.	1971	Lactic acid; properties and chemistry of lactic acid and derivates, Verlag Chemie; Weinheim/Bergstr., Germany	No	Publication
Doc II B8	Berkow, R.	1982	The Merck Manual of Diagnosis and Therapy, Merck Sharp & Dohme Research Laboratiories, Merck & Co., Inc. Rahway, N.J., 14. Edition	No	Publication
Doc II B8	CA Meeting	2008	EU Workshop PT 1-6 Report, document: “CA-Nov08-Doc[1].6.3 - Workshop Report PT1-6_CA_31_final_track_ changes”	No	No owner
Doc II B8	Lyman et al.	1983	Handbook of chemical property estimation methods, McGraw-Hill Inc.; New York	No	Publication
Doc II B8	McCall, P.J. et al	1981	Measurement of Sorption Coefficients of organic Chemicals and their use in Environmental Fate Analysis; Test protocols for Environmental Fate & Movement of Toxicants (1981); Proceedings of Symposium AOAC, 21.-22.10.1980, Washington, DC	No	Publication
Doc II B8	EC	2003	FOCUS Surface water scenarios in the EU evaluation process	No	Publication

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
			under 91/414/EEC; SANCO/4802/2001-rev.2 final		
Doc II B8	EC	2000	FOCUS groundwater scenarios in the EU review of active substances ". Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000 Rev.2	No	Publication
Doc II B8	EU	2012	Biocidal Products Regulation (BPR), 528/2012/EU concerning the making available on the market and use of biocidal products	No	Publication
Doc II B8	EC	2002	TNsG on Annex I inclusion. Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market. Principles and Practical Procedures for the inclusion of active substances in Annexes I, IA and IB, April 2002	No	Publication
Doc III B8 (PT3)	EC	2010	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products	No	Publication
Doc II B8 (PT3)	ECHA	2002 2007	Human exposure to biocidal products – Technical notes for guidance (TNsG 2002), ECHA, Helsinki, Finland, 2002 Human exposure to biocidal products – Technical notes for guidance (TNsG 2007), ECHA, Helsinki, Finland, 2007	No	Publication
Doc II B8 (PT3)	HEEG	2008	HEEG opinion 1: HEEG opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale	No	Publication
Doc II B8 (PT3)	OECD	2006	OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14, Emission Scenario Document for Insecticides for Stables and Manure Storage Systems, JT00197426, Organization for Economic Co-	No	Publication

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
			operation and Development		
Doc II B8 (PT3, 4)	HEEG	2010	HEEG opinion 9: Default protection factors for protective clothing and gloves	No	Publication
Doc II B8 (PT3)	BPC Ad hoc Working Group on Human Exposure	2015	Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure "Methods and models to assess exposure to biocidal products in different product types" (Version 1, 2015)	No	Publication
Doc II B8 (PT3)	HEEG	2008	HEEG opinion 2: HEEG Opinion on the assessment of Potential & Actual Hand Exposure	No	Publication
Doc II B8 (PT3)	Prud'homme de Lodder, L.C.H. et al	2006	ConsExpo Disinfectant products Fact Sheet: Disinfectant Products (RIVM report 320005003/2006), National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands	No	Publication
Doc II (PT3) B8	EC	2002	TNsG on Annex I inclusion. Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market. Principles and Practical Procedures for the inclusion of active substances in Annexes I, IA and IB, April 2002	No	Publication
Doc II B8 (PT4)	EC	2011	Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas	No	Publication
Doc IIB 8 (PT4)	EC	2007	TNsG Human Exposure Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market. Human Exposure to Biocidal Products - Guidance on Exposure Estimation	No	Publication
Doc IIB 8 (PT4)	HEEG	2008	HEEG opinion 1 – Mixing loading model 7 alternatives	No	published
Doc IIB 8	ECHA	2015	Biocides Human Health Exposure Methodology (version	No	published

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			1. October 2015)		
Doc II C12 (PT4)	HHEG	2010	Default protection factors for protective clothing and gloves	No	Publication
Doc II C13	EC	2006	Groundwater Directive (GWD), Council Directive 2006/118/EG on the protection of groundwater against pollution and deterioration	No	Publication
Doc II C13	EC	2006	REACH-VO Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, authorisation and restriction of chemicals (REACH) establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC, Commission Directives 91/155/EEC, 93/105/EC and 2000/21/EC	No	Publication
Doc II C13	EC	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Part II; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2	No	Publication
Doc II C13	EC	2000	FOCUS groundwater scenarios in the EU review of active substances ". Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000 Rev.2	No	Publication
Doc II C13 (PT3)	EC	2010	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products	No	Publication
Doc II	EC	2010	Emission Scenario Document	No	Publication

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
C13 (PT4)			for Product Type 4: Disinfectant used in food and feed areas		
Doc II C15 (PT4)	HEEG	2010	Default protection factors for protective clothing and gloves	No	Publication
Doc II C15 (PT4)	UK-Health and Safety Executive (HSE)		UK-Control Guidance Sheet G312 http://www.coshh-essentials.org.uk/assets/live/G312.pdf	No	Publication

Doc IIIA

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
A2-01 Included in the confidential part	Black, J.	2002	Letter to Purac concerning the identity of SY-83. Entek corporation, no number. Not GLP, not published	Y	Purac
A3.1.1-01	Van Dongen, A.P.M.	2006a	Expert Statement. Melting point of L(+) lactic acid. Purac expert statement. Purac, no report no. Not GLP, unpublished.	Y	Purac
A3.1.1-02	Holten, C.H.	1971a	Lactic acid. Properties and Chemistry of Lactic Acid and Derivates. Chapter IV: Physical properties. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. Not GLP, published.	N	-
A3.1.1-03	Rahmani, R.	2002	The chiral resolution of lactic acid and sodium lactate. Student report. Purac, no report no. Not GLP, unpublished.	Y	Purac
A3.1.2-01	Van Dongen, A.P.M.	2006b	Expert Statement. Boiling point of L(+) lactic acid. Purac expert statement. Purac, no report no. Not GLP, unpublished.	Y	Purac
A3.1.2-02 is a cross reference to A3.1.1-02	Holten, C.H.	1971a	Lactic acid. Properties and Chemistry of Lactic Acid and Derivates. Chapter IV: Physical properties. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. Not GLP, published.	N	-
A3.1.2-03	PURAC	No date	Physical properties of lactic acid. Purac internal data.. Purac, no report no. Not GLP, unpublished	Y	Purac
A3.1.2-04	EPIsuite	No date	Results of the EPIWIN calculation.	Y	Purac

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			Generated with the program EPIsuite v3.20 (February 2007). US Environmental Protection Agency. Not GLP, not published		
A3.1.3-01	Van Dongen, A.P.M.	2006c	Expert Statement. Liquid Density of L(+) lactic acid. Purac expert statement. Purac, no report no. Not GLP, unpublished.	Y	Purac
A3.1.3-02 is a cross reference to A3.1.1-02	Holten, C.H.	1971a	Lactic acid. Properties and Chemistry of Lactic Acid and Derivates. Chapter IV: Physical properties. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. Not GLP, published.	N	-
A3.1.3-03	Korevaar, L.	1996	Physical properties lactic acid solutions Purac internal report Purac report no. 95-80 Not GLP	Y	Purac
A3.2-01	Van Dongen, A.P.M.	2006d	Expert Statement. Vapour pressure of L(+) lactic acid. Purac expert statement. Purac, no report no. Not GLP, unpublished.	Y	Purac
A3.2.1-01	Van Dongen, A.P.M.	2006e	Expert Statement. Henry's law contant of L(+) lactic acid. Purac expert statement. Purac, no report no. Not GLP, unpublished.	Y	Purac
A3.2.1-02 Is a cross-reference to A3.1.2-04	EPIsuite	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
A3.4-02	Holten, C.H.	1971b	Lactic acid. Properties and Chemistry of Lactic Acid and Derivatives. Chapter VI: Spectra. Verlag Chemie GmbH, Weinheim/Bergstr. Germany.	N	-

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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A3.4-03	Holten, C.H.	1971c	Lactic acid. Properties and Chemistry of Lactic Acid and Derivates. Chapter XIX: Stability of Crystalline L-(+)-Lactic Acid. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. Not GLP, published.	N	-
A3.5-01	Van Dongen, A.P.M.	2007a	Expert Statement. Solubility of L(+) lactic acid. Purac expert statement. Purac, no report no. Not GLP, unpublished.	Y	Purac
A3.5-02 is a cross reference to A3.1.1-02	Holten, C.H.	1971a	Lactic acid. Properties and Chemistry of Lactic Acid and Derivates. Chapter IV: Physical properties. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. Not GLP, published.	N	-
A3.6-01	Van Dongen, A.P.M.	2007b	Expert Statement. Dissociation constant (pKa) of L(+) lactic acid. Purac expert statement. Purac, no report no. Not GLP, unpublished.	Y	Purac
A3.6-02	Holten, C.H.	1971d	Lactic acid. Properties and Chemistry of Lactic Acid and Derivates. Chapter V: Physical chemistry. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. Not GLP, published.	N	-
A3.6-03	Heesen, G.J.	1970	Bepaling van de zuursterkte van melkzuur en lactoylmelkzuur Purac Internal report. Purac, no report no. Not GLP, unpublished.	N	Purac
A3.7-01 is a cross reference to A3.5-01	Van Dongen, A.P.M.	2007a	Expert Statement. Solubility of L(+) lactic acid. Purac expert statement. Purac, no report no.	Y	Purac

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A3.7-02	Van Krieken, J.	1993	Solubility of lactic acid crystals in organic solvents Purac Internal report. Purac, report no. 115 Not GLP, unpublished.	Y	Purac
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
A3.9-02 Is a cross-reference to A3.1.2-04	EPIsuite	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
A3.9-03	European Chemicals Bureau	2000	IUCLID dataset L(+) lactic acid European Chemicals Bureau IUCLID-file European HPV program Not GLP. published	N	-
A3.10-01	Van Dongen, A.P.M.	2007d	Expert Statement. Stability of L(+) lactic acid. Purac expert statement. Purac, no report no. Not GLP, unpublished.	Y	Purac
A3.10-02	Lobbes, R.P.	1998	Stress-testing of lactic acid Purac internal report Purac, no report no. Not GLP, unpublished	Y	Purac
A3.12-01 is a cross reference to A3.1.1-02	Holten, C.H.	1971a	Lactic acid. Properties and Chemistry of Lactic Acid and Derivates. Chapter IV: Physical properties. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. Not GLP, published.	N	-
A3.13-01	Van Dongen, A.P.M.	2007e	Expert Statement. Surface tension of L(+) lactic acid. Purac expert statement.	Y	Purac

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
			Purac, no report no. Not GLP, unpublished.		
A3.13-02 is a cross reference to A3.1.1-02	Holten, C.H.	1971a	Lactic acid. Properties and Chemistry of Lactic Acid and Derivates. Chapter IV: Physical properties. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. Not GLP, published.	N	-
A3.13-03 is a cross-reference to A3.1.3-03	Korevaar, L.	1996	Physical properties lactic acid solutions Purac internal report Purac report no. 95-80 Not GLP	Y	Purac
A3.14-01	Van Dongen, A.P.M.	2007f	Expert Statement. Viscosity of L(+) lactic acid. Purac expert statement. Purac, no report no. Not GLP, unpublished.	Y	Purac
A3.14-02 is a cross reference to A3.1.1-02	Holten, C.H.	1971a	Lactic acid. Properties and Chemistry of Lactic Acid and Derivates. Chapter IV: Physical properties. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. Not GLP, published.	N	-
A3.14-03 is a cross reference to A3.1.3-03	Korevaar, L.	1996	Physical properties lactic acid solutions Purac internal report Purac report no. 95-80 Not GLP	Y	Purac
A3.17-01 Is a cross reference to A3.10-01	Van Dongen, A.P.M.	2007d	Expert Statement. Stability of L(+) lactic acid. Purac expert statement.	Y	Purac

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
			Purac, no report no. Not GLP, unpublished.		
A4.1-01	Holten, C.H.	1971e	Lactic acid. Properties and Chemistry of Lactic Acid and Derivates. Chapter XVIII: Analytical chemistry. Verlag Chemie GmbH, Weinheim/Bergstr. Germany. Not GLP, published.	N	-
A4.1-02	Anonymous	1968	Milchsäure, Acidium lacticum. Deutsches Arzneibuch, 7th edition, Deutscher Apotheker-Verlag, Stuttgart, Govi-Verlag GmbH, Frankfurt, p. 680-681. Not GLP, published	No	-
A4.1-03	Klein, J.	2001	Assay of Lactic acid. Purac Document no. AMLAC009 Not GLP, unpublished	Yes	Purac
A4.1-04	Klein, J.	2000	Standardization of 1N hydrochloric acid Purac Document no. AMSTD002 Not GLP, unpublished	Yes	Purac
A4.1-05	Klein, J.	2000	Standardization of 1N sodium hydroxide Purac Document no. AMSTD003 Not GLP, unpublished	Yes	Purac
A4.2-01	Klein, J.	2007	Lactic acid in earth Purac Document no. AMENV001 Not GLP, unpublished	Yes	Purac
A5-01	Alakomi, H.-L., Skyttä, E., Saarela, M., Mattila-Sandholm, T., Latva-Kala, K., Helander, I.M.	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, published.	N	-
A6.1.1-01*	[redacted]	1984	Acute oral LD50 study in rats using SY-83 Toxicogenics Inc. Report nr. 410-1369 GLP, Unpublished	Y	Purac
A6.1.1-02	[redacted]	1983	Acute oral toxicity study in rats using SY-83 at a dose level of 5 grams per kilogram of body weight Toxicogenics Inc. Report nr. 410-	Y	Purac

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
			1353 GLP, Unpublished		
A6.1.1-03	[redacted]	1998	Acute oral toxicity study with manganese-L-lactate in rats TNO Report nr. V98.598 GLP, Unpublished	Y	Purac
A6.1.1-04	[redacted]	1998	Acute oral toxicity study with magnesium-L-lactate in rats TNO Report nr. V98.597 GLP, Unpublished	Y	Purac
A6.1.1-05	[redacted]	1998	Acute oral toxicity study with ferrous-L-lactate in rats TNO Report nr. V98.410 GLP, Unpublished	Y	Purac
A6.1.2-01*	[redacted]	1983	Acute dermal toxicity study in rabbits using SY-83 at a dose level of 2 grams per kilogram of body weight Toxicogenics Inc. Report nr. 410-1354 GLP, Unpublished	Y	Purac
A6.1.3-01*	[redacted]	1987	Acute inhalation toxicity study of SY-83 in the rat Microbiological Associated Inc. Report nr. I-7083.112 GLP, Unpublished	Y	Purac
A6.1.4-01*	[redacted]	1996	Chicken Enucleated Eye Test with three samples of lactic acid; an alternative to the Draize eye irritation test with albino rabbits TNO Report nr. V96.157 GLP, Unpublished	Y	Purac
A6.1.4-02	[redacted]	1983	Primary dermal irritation study in rabbits using SY-83 Toxicogenics Inc. Report nr. 410-1355 GLP, Unpublished	Y	Purac
A6.1.4-03	[redacted]	1986	Acute dermal irritation/corrosion test with lactic acid (50%) in albino rabbits TNO Report nr. V86.015/250067 GLP, Unpublished	Y	Purac
A6.1.4-04	[redacted]	1995	Acute dermal irritation/corrosion study with a 10% aqueous solution of lactic acid in albino rabbits	Y	Purac

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
			TNO Report nr. V95.387 GLP, Unpublished		
A6.1.4-05	[redacted]	1996	Acute dermal irritation/corrosion study with Purac BF S36 and Purac BF S/30 in albino rabbits TNO Report nr. V96.677 GLP, Unpublished	Y	Purac
A6.1.4-06	[redacted]	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	[redacted]	1987	Acute dermal irritation/corrosion study with lactic acid (50%) in pigs TNO Report nr. V87.406/270419 GLP, Unpublished	Y	Purac
A6.1.4-08	[redacted]	1986	Lactic acid Q88: a skin corrosivity test in guinea pigs Inveresk Research International Report nr. 3625 GLP, Unpublished	Y	Purac
A6.1.4-09	[redacted]	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
A6.1.4-10	Harbell, J.W.	1994	Corrositex Continuous Time Monitor Assay Microbiological Associates Inc. Report nr. A000449 Not GLP, Unpublished	Y	Purac
A6.1.4-11*	Andersen, F.A.	1997	Safety assessment of glycolic acid, ammonium, calcium, potassium, and sodium glycolate, methyl, ethyl, ptopyl, 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	N	-

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			Toxicology, Vol.17, Suppl.1 Not GLP, Published		
A6.1.5-01*	[redacted]	1986	Dermal sensitization study in guinea pigs with SY-83 American Biogenics Corporation, Report nr. 480-2750 GLP, Unpublished	Y	Purac
A6.2-01	Sterenborg, I.	2007	Lactic acid as biocidal active substance. Statement to address requirements of Directive 98/8/EC. ENVIRON report nr. PU-LBD-20070039 Not GLP, Unpublished	Y	Purac
A6.2-02	Miller, B.F., Fattor, J.A., Jacobs, K.A., Horning, M.A., Navazio, F., Lindinger, M., I., and Brooks, G.A.	2002	Lactate and glucose interactions during rest and exercise in men: effect of exogenous lactate infusion. Journal of Physiology, Vol.544, Nr.3, p.963-975 Not GLP, Published	N	-
A6.2-03	Philp, A., Macdonald, A.L., Watt, P.W.	2005	Lactate – a signal coordinating cell and systemic function. The Journal of Experimental Biology, Vol.208, p.4561-4575 Not GLP, Published	N	-
A6.2-04	Connor, H. Woods, H.F	1982	Metabolic acidosis. Pitman Books Ltd London (Ciba Foundation symposium 87) p. 214-234 Not GLP, Published	N	-
A6.4-01	Matsushima, Y., Onodera, H., Nagaoka, T., Todate, A., Shibutani, M., Maekawa, A., Kurokawa, Y., Hayashi, Y.	1989	Subchronic Oral Toxicity study of Calcium lactate in F344 Rats Bulletin of the National Institute of Hygienic Sciences, Tokyo (Eisei Shikenjo Hokuku) Vol. 107: pp 78-83 Not GLP, Published	N	-
A6.5-01	Maekawa, A., Matsushima, H., Onodera, H., Shibutani, M., Yoshida, J., Kodama, Y., Kurokawa, Y., Hayashi, Y.	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	-

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
A6.6-01 Is a cross-reference to A6.1.4-11	Andersen, F.A.	1997	Safety assessment of glycolic acid, ammonium, calcium, potassium, and sodium glycolate, methyl, ethyl, ptopyl, 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	-
A6.6-02*	Ishidate, M. Jr., Sofuni, T., Yoshikawa, K., Hayashi, M., Nohmi, T., Sawada, M., Matsuoaka, A.	1984	Primary mutagenicity screening of food additives currently used in Japan. Food Chem. Tox. Vol. 22, p. 623-636 Not GLP, Published	N	-
A6.6.1-01	Demerec, M., Bertani, G., Flint, J.	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	-
A6.6.1-02*	Al-Ani, F.Y., Al-Lami, S.K.	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	-
A6.6.2-01	Morita, T., Takeda, K., Okumura, K.	1990	Evaluation of clastogenicity of formic acid, acetic acid and lactic acid on cultured mammalian cells. Mutation Research, Vol. 240, p. 195-202. Not GLP, Published	N	-
A6.7-01 Is a cross reference to A6.5-01	Maekawa, A., Matsushima, H., Onodera, H., Shibutani, M., Yoshida, J., Kodama, Y., Kurokawa, Y., Hayashi, Y.	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	-

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A6.7-02 Is a cross-reference to A6.1.4-11	Andersen, F.A.	1997	Safety assessment of glycolic acid, ammonium, calcium, potassium, and sodium glycolate, methyl, ethyl, ptopyl, 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	-
A7.1.1.2.1-01	Hanstveit, A.O., Pullens, M.A.H.L.	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
A7.1.1.2.1-02	Bowmer, C.T., Hooftman, R.N., Hanstveit, A.O., Venderbosch, P.W.M., Van der Hoeven, N.	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	-
A7.1.3	Baltussen, E.	2008	Estimation of the adsorption coefficient (Koc) of lactic acid 93% aq on soil and on sewage sludge using high performace liquid chromatography (HPLC) Notox Document 489046 GLP, Unpublished	Y	Purac
A7.1.3	Sansone, F.J., Andrews, C.C., Okamoto, M.Y.	1987	Adsorption of short-chain organic acids onto nearshore marine sediments Geochim Cosmochim Acta, Vol. 51, pp. 1889-96 Not GLP, Published	N	-
A7.4.1.1-01	[redacted]	1992	The acute toxicity of L(+) lactic acid to Brachydanio rerio (OECD Guideline No. 203) TNO Report nr. IMW-91-0076-02 GLP, Unpublished	Y	Purac
A7.4.1.1-02	[redacted]	1984	Acute toxicity of SY-83 to rainbow trout (Salmo gairdneri)	Y	Purac

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	[redacted]		ABC Inc. Report nr. #32147 GLP, Unpublished		
A7.4.1.1-03	[redacted]	1984	Acute toxicity of SY-83 to bluegill sunfish (Lepomis macrochirus) ABC Inc. Report nr. #32146 GLP, Unpublished	Y	Purac
A7.4.1.1-04	Hooftman, R.N.	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
A7.4.1.1-05	Saha, N.C., Bhunia, F., Kaviraj, A.	2006	Comparative toxicity of three organic acids to freshwater organisms and their impact on aquatic ecosystems Human and Ecological Risk Assessment, Vol. 12, No. 1: pp 192-202 Not GLP, Published	N	-
A7.4.1.1-06 Is a cross-reference to A7.1.1.2.1-02	Bowmer, C.T., Hooftman, R.N., Hanstveit, A.O., Venderbosch, P.W.M., Van der Hoeven, N.	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	-
A7.4.1.2-01	Hooftman, R.N., Kauffman-Van Bommel, J.A., Van Drongelen-Sevenhuijsen, D.	1992	The acute toxicity of L(+) lactic acid to *Daphnia magna* (OECD Guideline No. 202, 48h) TNO Report nr. IMW-91-0076-01 GLP, Unpublished	Y	Purac
A7.4.1.2-02	Forbis, A.D., Burgess, D., Georgie, L.	1984	Acute toxicity of SY-83 to Daphnia magna ABC Inc. Report nr. #32148 GLP, Unpublished	Y	Purac
A7.4.1.2-03 Is a cross-reference to A7.1.1.2.1-02	Bowmer, C.T., Hooftman, R.N., Hanstveit, A.O., Venderbosch, P.W.M., Van der Hoeven, N.	1998	The ecotoxicity and the biodegradability of lactic acid, alkyl lactate esters and lactate salts Chemosphere, Vol. 37, No. 7, pp. 1317-1333	N	-

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			Not GLP, Published		
A7.4.1.2-04 Is a cross-reference to A7.4.1.1-04	Hooftman, R.N.	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
A7.4.1.2-05 Is a cross-reference to A7.4.1.1-05	Saha, N.C., Bhunia, F., Kaviraj, A.	2006	Comparative toxicity of three organic acids to freshwater organisms and their impact on aquatic ecosystems Human and Ecological Risk Assessment, Vol. 12, No. 1: pp 192-202 Not GLP, Published	N	-
A7.4.1.3-01	Hanstveit, A.O., Oldersma, H.	1992	Effect of L(+) lactic acid on the growth of the alga Selenastrum capricornutum (OECD 201) TNO Report nr. IMW-91-0076-05 GLP, Unpublished	Y	Purac
A7.4.1.3-02 Is a cross-reference to A7.1.1.2.1-02	Bowmer, C.T., Hooftman, R.N., Hanstveit, A.O., Venderbosch, P.W.M., Van der Hoeven, N.	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	-
A7.4.1.3-03 Is a cross-reference to A7.4.1.1-04	Hooftman, R.N.	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
A7.4.1.4-01	Bouwman, L.M.	2007	Activated sludge respiration inhibition test with PURAC HS 88 NOTOX Project nr. 483211	Y	Purac

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
			GLP, Unpublished		
A7.5.3.1.1-01	Beavers, J.B.	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	Beavers, J.B.	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	Beavers, J.B.	1984	A dietary LC50 study in the mallard with SY-83 Wildlife International Ltd. Report nr. 203-102 Not GLP, Unpublished	Y	Purac
A7.5.4.1-01	Dingledine, J.	1985	A dermal contact LD50 study in honey bees with SY-83 Wildlife International Ltd. Report nr. 203-108 Not GLP, Unpublished	Y	Purac
A8-01	Purac Biochem	2004	Material Safety Data Sheet Purac Biochem Ref. SD0010/2004-01, dated 6 April 2004 Not GLP, Published	N	-

*Key studies

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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
IIIB 5.10-01	Nada, S.	2004a	EPA Hard surface mildew-fungistatic test ATS Labs, Project No. A01562 GLP, Unpublished	Yes	S.C. Johnson and Son.Inc.

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
IIIB 5.10-02	Nada, S.	2004b	Standard test method for efficacy of sanitizers recommended for inanimate non-food contact surfaces (modification for spray product application). Test organisms: *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352) ATS Labs, Project No. A01582 GLP, Unpublished	Yes	S.C. Johnson and Son.Inc
IIIB 5.10-03	Rottjakob,D.	2004	Standard test method for efficacy of sanitizers recommended for inanimate non-food contact surfaces (modification for spray product application). Test organisms: *Escherichia coli* (ATCC 11229) and *Enterococcus faecalis* (ATCC 51575) ATS Labs, Project No. A01795 GLP, Unpublished	Yes	S.C. Johnson and Son.Inc