

Section A2.10
Annex Point IIA2.10

**Exposure data in conformity with Annex VIIA to
Council Directive 92/32/EEC (OJ No L, 05.06.1992,
p. 1) amending Council Directive 67/548/EEC**

Subsection

Official
use only

**2.10.1 Human exposure
towards active
substance**

The human exposure during production and its use in biocides, is limited in relation to the human exposure by the total production and use of lactic acid (food, pharmaceutical, cosmetics, and feed).

2.10.1.1 Production

i) Description of
process

The total production in or import into Europe of L(+) lactic acid in 2005 was in the range of 70.000 ton. The portion produced for biocides in 2005 was less than 1.5% of total production.

ii) Workplace
description

The production of lactic acid in modern factories (PURAC factories are all certified for ISO 9001 and ISO 14001) is in closed installations and packed in containers by automatic filling equipment. Human exposure during production only possible when equipment is failing or by human failures. An estimation of 0.1% losses by failures/leakages, thus for biocide production a loss of 1000 kg. This estimation is based on industrial experience and the yields of the factories. Only a small part of that will be human exposure, as the spill will come on the ground mainly and maybe 100 kg lactic acid on the skin of the production personnel. This amount is spread over the year and over several persons working in 5 shifts in a continuous process.

iii) Inhalation
exposure

iv) Dermal
exposure

The operators are instructed to wear rubber gloves.(break through time > 8 hours); face-shield; long sleeved clothing, and chemical resistant apron boots.

2.10.1.2 Intended use(s)

1. Professional

Users

i) Description of
application process

L(+)lactic acid will be used in biocide product types 2 (private area & public health), 3 (veterinary hygiene), 4 (food and feed disinfectants) and 6 (in-can preservatives). For all these applications its use in 2005 was 1000 ton and it will grow to more than 2000 ton in 2008. These biocides will be used in cleaning and washing formulations on surfaces (toilet, bathrooms, and kitchen) and normally will not come in contact with humans. Also in the food and feed area it is used to disinfect the food processing areas, to clean the facilities, under normal use conditions it will not be exposed to persons.

ii) Workplace
description

iii) Inhalation
exposure

iv) Dermal
exposure

In practice it can be estimated that some biocide formulation, not intended, can come in contact with human skin or by oral intake, maybe 1% of the formulation, thus 10-20 ton per year. Compared with the intended use of L(+)lactic acid in food and cosmetics in Europe this amount is not significant and not relevant.

**2. Non-
professional Users
including the general
public**

(i) via inhalational
contact

L(+)lactic acid will be used in biocide product types 2 (private area & public health), 3 (veterinary hygiene), 4 (food and feed disinfectants) and 6 (in-can preservatives). For all these applications its use in 2005

(ii) via skin contact

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<p>(iii) via drinking water</p> <p>(iv) via food</p> <p>(v) indirect via environment</p>	<p>was 1000 ton and it will grow to more than 2000 ton in 2008. These biocides will be used in cleaning and washing formulations on surfaces (toilet, bathrooms, and kitchen) and normally will not come in contact with humans. Also in the food and feed area it is used to disinfect the food processing areas, to clean the facilities, under normal use conditions it will not be exposed to persons.</p> <p>In practice it can be estimated that some biocide formulation, not intended, can come in contact with human skin or by oral intake, maybe 1% of the formulation, thus 10-20 ton per year. Compared with the intended use of L(+)lactic acid in food and cosmetics in Europe this amount is not significant and not relevant.</p>	
<p>2.10.2 Environmental exposure towards active substance</p>	<p>99% of the active substance in biocide formulations, after its use, will be found on surfaces and on the ground where it will be washed away with water. Thus practically all material will turn up in the drain and in via sewer-pipes come in wastewater treatment facilities of the cities. L(+)lactic acid is biodegradable and will be degraded to CO₂ and water in the sewer and wastewater treatment facility.</p>	
<p>2.10.2.1 Production</p>		
<p>(i) Releases into water</p> <p>(ii) Releases into air</p> <p>(iii) Waste disposal</p>	<p>During production a loss of 0.1% via leakages/spills is estimated based on a long experience with the production of lactic acid, thus 1-2 ton per year for the active substance. Practically all material will be washed away as it is very good water soluble and will turn up in the drain and sewer-pipes and finally be degraded in the waste water treatment facility of the factories of PURAC.</p>	
<p>2.10.2.2 Intended use(s)</p>		
<p>Affected compartment(s):</p> <p>water</p> <p>sediment</p> <p>air</p> <p>soil</p> <p>Predicted concentration in the affected compartment(s)</p> <p>water</p> <p>sediment</p> <p>air</p> <p>soil</p>	<p>99% of the active substance (1000 ton in 2005 and 2000 ton in 2008) will be found on surfaces and on the ground. After its use, the water soluble biocide will be flushed with water and will turn up in the drain and sewer-pipes of the municipality and the wastewater facility of the cities, where the biodegradable L(+)lactic acid is degraded into CO₂ and water.</p>	<p>X</p>

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Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2009/04/27
Materials and methods	<p>The applicant's statement regarding the emission to the environment from production of the a.s. is deemed to be plausible by RMS. During national authorisation of b.p. having lactic acid as a.s., the emission to the environment via formulation shall be considered.</p> <p><u>General comments to chapter 2.10.2.2 Intended use(s)</u></p> <p>Exposure data relevant for the life cycle stage "use" are missing. However, emission estimation for this life cycle stage is described by the applicant in Doc II-B, chapter 8.3. With respect to the different intended uses within the different PT's, the influence of emissions on the environmental compartments should be discussed more differentiated.</p> <p>The active substance (a.s.) is produced in the chemical industry within the EU. The exposure during the production of the a.s. is not assessed by the rapporteur under the requirements of the BPD. However, the rapporteur assumes that the production is performed in conformity with national and European occupational safety and health regulations.</p>
Conclusion	Exposure data of the a.s. are sufficient with regard to the life cycle stages considered. More detailed information as well as missing information is given in Doc II-B, chapter 8.3.
Reliability	
Acceptability	acceptable
Remarks	
COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>
Results and discussion	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	