

Revision Date 18/04/2017
Date of the previous version 24/06/2015

SAFETY DATA SHEET
Version 4 - EN

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Zinc L-Lactate
Trade name PURAMEX® ZN
PURAMEX® ZN Fine

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

Recommended Use Food, Specialty chemical. See annex for more detailed information.
Uses advised against No information available.

1.3. Details of the supplier of the safety data sheet

Purac Biochem
Arkelsedijk 46
NL-4206 AC Gorinchem
The Netherlands
Tel.: +31 183 695695
Fax: +31 183 695604
E-mail: sds@corbion.com

1.4. Emergency telephone number

UK National Health Service (NHS) call 111 or, in life-threatening emergencies, call 999

WAL National Health Service (NHS) call 0845 46 47

IE National Poisons Information Centre
+353 1 809 2566 or +353 1 837 9964 (only for healthcare professionals)

Purac Biochem
+31 183 695695

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification according to EU
Regulation 1272/2008/EC

Acute oral toxicity	Category 4 - H302
Serious eye damage/eye irritation	Category 1 - H318
Acute aquatic toxicity	Category 1 - H400
Chronic aquatic toxicity	Category 3 - H412

For the full text of the H-Statements mentioned in this section, see Section 16.

2.2. Label elements

Zinc L-Lactate

Revision Date 18/04/2017


Signal word
Danger
Hazard Statements

H302 - Harmful if swallowed
H318 - Causes serious eye damage
H410 - Very toxic to aquatic life with long lasting effects

Precautionary Statements

P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P273 - Avoid release to the environment
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

Contains

Zinc dilactate

2.3 Other hazards

This product does not meet the criteria for PBT or vPvB in accordance with Annex XIII of REACH.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Chemical Name	EC-No	CAS-No	Weight %	Classification (1272/2008/EC)	REACH Registration Number
Zinc dilactate	240-178-9	16039-53-5	>88	Acute Tox. 4 H302 Eye Dam. 1 H318 Aquatic Acute 1 H400 Aquatic Chronic 3 H412	01-2119987101-41-000

For the full text of the H-Statements mentioned in this section, see Section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

General advice	Keep person warm and at rest. When symptoms persist or in all cases of doubt seek medical advice. Wash contaminated clothing before reuse.
Eye contact	Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Consult a physician.
Skin contact	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Get medical attention immediately if symptoms occur.
Ingestion	Rinse mouth. Do not induce vomiting without medical advice. Risk of product entering the lungs on vomiting after ingestion. Consult a physician.
Inhalation	Move to fresh air. Get medical attention immediately if symptoms occur.
Protection of first-aiders	Use personal protective equipment. Avoid contact with skin, eyes and clothing.

4.2. Most important symptoms and effects, both acute and delayed

Main symptoms	If in eyes: Burning feeling, Redness, Pain. If swallowed: Gastrointestinal discomfort.
----------------------	--

4.3. Indication of any immediate medical attention and special treatment needed

Notes to physician	Treat symptomatically. Symptoms may be delayed.
---------------------------	---

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media	Water spray, Foam, Dry powder, Carbon dioxide (CO ₂).
Unsuitable Extinguishing Media	Do not use a solid water stream as it may scatter and spread fire.

5.2. Special hazards arising from the substance or mixture

Special Hazard	None in particular.
-----------------------	---------------------

5.3. Advice for firefighters

Fire fighting measures	Evacuate non-essential personnel. Move containers from fire area if you can do it without risk. Keep containers and surroundings cool with water spray. Prevent fire extinguishing water from contaminating surface water or the ground water system.
Special protective equipment for fire-fighters	Wear self-contained breathing apparatus and protective suit.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Evacuate personnel to safe areas. Do not touch or walk through spilled material. Avoid dust formation. Avoid contact with skin, eyes and clothing. Do not breathe dust. Use personal protective equipment. Ensure adequate ventilation.

6.2. Environmental precautions

Should not be released into the environment. Prevent further leakage or spillage if safe to do so.

6.3 Methods and material for containment and cleaning up

Avoid dust formation. Wet all spilled material. Sweep up and shovel into suitable containers for disposal. Following product recovery, flush area with water.

6.4. Reference to other sections

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not breathe dust. Ensure adequate ventilation. Wear personal protective equipment. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. See annex for more detailed information.

7.2. Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Keep containers tightly closed in a cool, well-ventilated place. Keep at temperatures below 200 °C / 392 °F. Incompatible with oxidising agents.

7.3. Specific end use(s)

No information available.

Zinc L-Lactate

Revision Date 18/04/2017

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits Contains no substances with occupational exposure limit values.

Biological Limit Values Not established.

Recommended monitoring procedures No information available.

Derived No Effect Level (DNEL)

Chemical Name	Worker - inhalative, long-term - systemic	Worker - dermal, long-term - systemic	Worker - oral, long-term - systemic	Worker - inhalative, short-term - systemic	Worker - dermal, short-term - systemic
Zinc dilactate	9.25 mg/m ³	30.8 mg/kg bw/d	3 mg/kg bw/d		

Chemical Name	Consumer - inhalative, long-term - systemic	Consumer - dermal, long-term - systemic	Consumer - oral, long-term - systemic	Consumer - inhalative, short-term - systemic	Consumer - dermal, short-term - local and systemic
Zinc dilactate	4.63 mg/m ³	30.8 mg/kg bw/d	3 mg/kg bw/d		

Predicted No Effect Concentration (PNEC)

Chemical Name	Freshwater	Marine water	Intermittent release	Sewage treatment plant	Freshwater sediment	Marine sediment	Soil	Oral
Zinc dilactate	76.7 µg/L	22.7 µg/L		193.6 µg/L	438.6 mg/kg dw	210.3 mg/kg dw	132.5 mg/kg dw	

8.2. Exposure controls

Appropriate engineering controls Ensure adequate ventilation, especially in confined areas. Keep at temperatures below 200 °C / 392 °F. See annex for more detailed information.

Individual protection measures, such as personal protective equipment

Eye Protection

Safety glasses with side-shields (EN166).

Hand Protection

Protective gloves (EN374): Butyl rubber. Glove thickness: 0.5 mm. Break through time: >8 hours.

Skin and body protection

Long sleeved clothing.

Respiratory protection

In case of insufficient ventilation wear suitable respiratory equipment.

Recommended Filter Type

P2 / FFP2.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Workers must be trained in the proper use and handling of this product as required under applicable regulations. Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product. Wash contaminated clothing before re-use.

Environmental Exposure Controls

The product should not be allowed to enter drains, water courses or the soil.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state @20°C	Solid
Appearance	Powder (Crystalline)
Colour	White
Odour	Characteristic
pH	5 (@ 10%)
Melting/freezing point	>200 °C / >392 °F
Boiling point/boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limits in Air	No information available
Vapour pressure	No information available
Vapour density	No information available
Relative density	No information available
Solubility	
Water solubility	55 g/l (@25°C)
Partition Coefficient (n-octanol/water)	No information available
Autoignition temperature	No information available
Decomposition temperature	>200 °C / >392 °F
Viscosity, dynamic	No information available
Explosive properties	No information available
Oxidising properties	No information available

9.2 Other information

Bulk Density	900 kg/m ³
---------------------	-----------------------

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

No information available.

10.2. Chemical stability

Stable under recommended storage conditions

10.3 Possibility of hazardous reactions

No information available.

10.4. Conditions to avoid

Dust formation. To avoid thermal decomposition, do not overheat.

10.5. Incompatible materials

Strong oxidising agents.

10.6. Hazardous decomposition products

Carbon oxides. Thermal decomposition can lead to release of irritating gases and vapours.

Zinc L-Lactate

Revision Date 18/04/2017

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity
Ingestion

Harmful if swallowed.

Skin contact

No known effect.

Inhalation

No known effect.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Zinc dilactate	500 - 2000 mg/kg bw (Rat)		

Skin corrosion/irritation

No known effect

Serious eye damage/irritation

Causes serious eye damage.

Chemical Name	Skin corrosion/irritation	Serious eye damage/irritation
Zinc dilactate		EU Method B.5, In vivo, Rabbit Result: Irritating

Respiratory or skin sensitisation

No known effect.

Germ cell mutagenicity

Not known to cause heritable genetic damage.

Carcinogenicity

Contains no ingredient listed as a carcinogen.

Reproductive toxicity

Not known to cause birth defects or have a deleterious effect on a developing fetus. Not known to adversely affect reproductive functions and organs.

STOT-single exposure

No known effect.

STOT-repeated exposure

No known effect.

Aspiration hazard

No known effect.

Zinc L-Lactate

Revision Date 18/04/2017

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Very toxic to aquatic life with long lasting effects.

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to microorganisms	Toxicity to daphnia and other aquatic invertebrates
Zinc dilactate	EC50: 0.52 mg/L 96h Pseudokirchnerella subcapitata	LC50: 100 mg/L 96h Danio rerio		EC50: 8.9 mg/L 48h Daphnia magna

12.2. Persistence and degradability

Readily biodegradable.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

No information available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues / unused products Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: TRANSPORT INFORMATION

According to: ADR, RID, ADN, IMDG, IATA/ICAO.

14.1. UN number

3077

14.2. UN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (. Zinc dilactate.).

14.3. Transport hazard class(es)

Hazard class 9

14.4. Packing group

Packing Group III

14.5 Environmental hazards

Not applicable.

14.6 Special precautions for user

Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable.

SECTION 15: REGULATORY INFORMATION

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

Restrictions on use None.

Other Regulations No information available.

15.2 Chemical safety assessment

Not available.

Zinc L-Lactate

Revision Date 18/04/2017

SECTION 16: OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3

H302 - Harmful if swallowed
H318 - Causes serious eye damage
H400 - Very toxic to aquatic life
H412 - Harmful to aquatic life with long lasting effects

Revision Note

Indication of the changes made to the previous version of the SDS: Derived No Effect Level (DNEL), Annex.

Training Advice

Workers must be trained in the proper use and handling of this product as required under applicable regulations.

Abbreviations and acronyms

REACH: Registration, Evaluation, Authorisation and Restriction of Chemical substances
EC: European Commission
STOT: Specific Target Organ Toxicity
PBT: Persistent, Bioaccumulative, Toxic
vPvB: very Persistent and very Bioaccumulating
ADR: Accord européen relatif au transport international des marchandises Dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
ADN: Accord européen relatif au transport international des marchandises Dangereuses par voies de Navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
RID: Règlement concernant le transport international ferroviaire des marchandises dangereuses (Regulations for the International Transport of Dangerous Goods by Rail)
IMDG: International Maritime Dangerous Goods Code
ICAO: International Civil Aviation Organization

SDS No.

CO00009

Subformat

COEU

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 and Regulation (EC) No. 2015/830. Label element according to Regulation (EC) No 1272/2008.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet

1. EXPOSURE SCENARIO

Exposure scenario	1
Title	Formulation [mixing] of preparations and/or re-packaging
Use Descriptor	
Environmental release categories	ERC2 - Formulation of mixtures
Product category	PC0 - Other Products
Process categories	PROC3 - Use in closed batch process (synthesis or formulation); Industrial setting PROC 8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities

2. CONDITIONS OF USE AFFECTING EXPOSURE

2.1 Contributing Scenario - Environment

Control of environmental exposure	
Product characteristics	Solid
Environmental Release Category	ERC2 - Formulation of mixtures
Amounts used	Daily amount per site <=4.0 t/d Annual amount per site <=400.0 t/y
Conditions and Measures Related to Municipal Sewage Treatment	Municipal sewage treatment plant is assumed Assumed on-site sewage treatment plant flow - pH adjustment and Filtration / Sedimentation - Metal salts (excluding Ni) Assumed domestic sewage treatment plant flow (m3/d): >=2000 m3/d
Conditions and measures related to external recovery of waste	Dispose of waste product or used containers according to local regulations
Other Operational Conditions of Use Affecting Environment	Receiving surface water flow is >=18000 m3/d

2.2 Contributing Scenario - Worker & Consumer

Control of worker exposure	
Process category	PROC3 - Use in closed batch process (synthesis or formulation)
Product characteristics	Solid Covers percentage substance in the product up to 100 %
Frequency and duration of use	Covers daily exposures up to 8 hours
Technical conditions and measures to control dispersion from source towards the worker	Provide a basic standard of general ventilation (1 to 3 air changes per hour)
Conditions and Measures Related to Personal Protection, Hygiene, and Health Evaluation	Supervision in place to check that the RMMs in place are being used correctly and OCs followed Ensure control measures are regularly inspected and maintained Use in closed batch process (synthesis or formulation) With occasional controlled exposure
Other operational conditions affecting worker exposure	Assumes use at not more than 20°C above ambient temperature Indoor use
Process category	PROC8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
Product characteristics	Solid Covers percentage substance in the product up to 100 %

Frequency and duration of use	≤4 h/d
Technical conditions and measures to control dispersion from source towards the worker	Provide a basic standard of general ventilation (1 to 3 air changes per hour)
Conditions and Measures Related to Personal Protection, Hygiene, and Health Evaluation	Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training For further specification, refer to section 8 of the SDS
Other operational conditions affecting worker exposure	Assumes use at not more than 20°C above ambient temperature Indoor use

3. EXPOSURE ESTIMATION AND REFERENCE TO ITS SOURCE

Environment Exposure Estimation	
Environmental Release Category	ERC2 - Formulation of mixtures
Release to Water	0.8 kg/d
Release to Air	100 kg/d
Release to Soil	0.4 kg/d
Freshwater	5.38E-3 mg/L; RCR 0.07
Freshwater sediment	0.025 mg/kg dw; RCR <0.01
Marine water	5.36E-4 mg/L; RCR 0.024
Marine sediment	2.49E-3 mg/kg dw; RCR <0.01
Sewage treatment plant	0.051 mg/L; RCR 0.261
Soil	0.035 mg/kg dw; RCR <0.01
Man via environment - Inhalation	7.62E-3 mg/m ³ ; RCR <0.01
Man via environment - Oral	0.012 mg/kg bw/d; RCR <0.01
Man via environment - Combined Routes	RCR <0.01

Health Exposure Estimation	
Process category	PROC3 - Use in closed batch process (synthesis or formulation)
Worker - inhalative, long-term - systemic	1 mg/m ³ (TRA Workers 3.0); RCR 0.108
Worker - dermal, long-term - systemic	0.69 mg/kg bw/d (TRA Workers 3.0); RCR 0.022
Worker - combined, long-term - systemic	RCR 0.131

Process category	PROC8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
Worker - inhalative, long-term - systemic	3 mg/m ³ (TRA Workers 3.0); RCR 0.324
Worker - dermal, long-term - systemic	1.371 mg/kg bw/d (TRA Workers 3.0); RCR 0.045
Worker - combined, long-term - systemic	RCR 0.369

4. GUIDANCE TO CHECK COMPLIANCE WITH THE EXPOSURE SCENARIO

Environmental Exposure Controls

Used EUSES model	EUSES v2.1
Non-standard assumptions	No information available.
Risk assessment	Risk Characterisation Ratio (RCR), Calculation method.
Predicted No Effect Concentration (PNEC)	See section 8 for more information.

Control of worker exposure

ECETOC TRA	The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated.
-------------------	---

Risk assessment

Risk Characterisation Ratio (RCR), Calculation method.

Derived No Effect Level (DNEL)

Worker - inhalative, long-term - systemic
 Worker - dermal, long-term - systemic
 Worker - combined, long-term - systemic
 See section 8 for more information

Guidance to check compliance with the exposure scenario

If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

For scaling see: ECETOC TRA, ART, STOFFENMANAGER, EUSES.

Further information on the assumptions contained in this exposure scenario can be found at: Website Model, ECETOC TRA and RIVM report 601450009, "Emission scenario document for biocides", 2001.

Workplace measurements:

Refer to European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) or equivalent national standard(s).

Refer to European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) or equivalent national standard(s).

Refer to European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) or equivalent national standard(s).

Annex No. COE0012 /COES

1. EXPOSURE SCENARIO

Exposure scenario

2

Title

Formulation [mixing] of preparations and/or re-packaging

Use Descriptor

Environmental release categories

ERC2 - Formulation of mixtures

Product category

PC31 - Polishes and wax blends
PC35 - Washing and cleaning products (including solvent based products)

Process categories

PROC4 - Use in batch and other process (synthesis) where opportunity for exposure arises
PROC 8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
PROC9 - Transfer of substance or mixture into small containers (dedicated filling line, including weighing)

2. CONDITIONS OF USE AFFECTING EXPOSURE

2.1 Contributing Scenario - Environment

Control of environmental exposure	
Product characteristics	Solid
Environmental Release Category	ERC2 - Formulation of mixtures
Amounts used	Daily amount per site <=2.0 t/d Annual amount per site <=200.0 t/y
Conditions and Measures Related to Municipal Sewage Treatment	Municipal sewage treatment plant is assumed Assumed on-site sewage treatment plant flow - pH adjustment and Filtration / Sedimentation - Metal salts (excluding Ni) Assumed domestic sewage treatment plant flow (m3/d): >=2000 m3/d
Conditions and measures related to external recovery of waste	Dispose of waste product or used containers according to local regulations
Other Operational Conditions of Use Affecting Environment	Receiving surface water flow is >=18000 m3/d

2.2 Contributing Scenario - Worker & Consumer

Control of worker exposure	
Process category	PROC4 - Use in batch and other process (synthesis) where opportunity for exposure arises
Product characteristics	Solid Covers percentage substance in the product up to 100 %
Frequency and duration of use	≤4 h/d
Technical conditions and measures to control dispersion from source towards the worker	Provide a basic standard of general ventilation (1 to 3 air changes per hour)
Conditions and Measures Related to Personal Protection, Hygiene, and Health Evaluation	Supervision in place to check that the RMMs in place are being used correctly and OCs followed Ensure control measures are regularly inspected and maintained
Other operational conditions affecting worker exposure	Assumes use at not more than 20°C above ambient temperature Indoor use
Process category	PROC8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities

Product characteristics	Solid Covers percentage substance in the product up to 100 %
Frequency and duration of use	≤4 h/d
Technical conditions and measures to control dispersion from source towards the worker	Provide a basic standard of general ventilation (1 to 3 air changes per hour)
Conditions and Measures Related to Personal Protection, Hygiene, and Health Evaluation	Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training For further specification, refer to section 8 of the SDS
Other operational conditions affecting worker exposure	Assumes use at not more than 20°C above ambient temperature Indoor use

Process category	PROC9 - Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
Product characteristics	Solid Covers percentage substance in the product up to 100 %
Frequency and duration of use	≤4 h/d
Technical conditions and measures to control dispersion from source towards the worker	Provide a basic standard of general ventilation (1 to 3 air changes per hour)
Conditions and Measures Related to Personal Protection, Hygiene, and Health Evaluation	Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training For further specification, refer to section 8 of the SDS
Other operational conditions affecting worker exposure	Assumes use at not more than 20°C above ambient temperature Indoor use

3. EXPOSURE ESTIMATION AND REFERENCE TO ITS SOURCE

Environment Exposure Estimation	
Environmental Release Category	ERC2 - Formulation of mixtures
Release to Water	0.4 kg/d
Release to Air	50 kg/d
Release to Soil	0.2 kg/d
Freshwater	2.85E-3 mg/L; RCR 0.037
Freshwater sediment	0.013 mg/kg dw; RCR <0.01
Marine water	2.83E-4 mg/L; RCR 0.012
Marine sediment	1.32E-3 mg/kg dw; RCR <0.01
Sewage treatment plant	0.025 mg/L; RCR 0.131
Soil	0.018 mg/kg dw; RCR <0.01
Man via environment - Inhalation	3.81E-3 mg/m ³ ; RCR <0.01
Man via environment - Oral	6.16E-3 mg/kg bw/d; RCR <0.01
Man via environment - Combined Routes	RCR <0.01

Health Exposure Estimation	
Process category	PROC4 - Use in batch and other process (synthesis) where opportunity for exposure arises
Worker - inhalative, long-term - systemic	3 mg/m ³ (TRA Workers 3.0); RCR 0.324
Worker - dermal, long-term - systemic	6.86 mg/kg bw/d (TRA Workers 3.0); RCR 0.223
Worker - combined, long-term - systemic	RCR 0.547

Process category	PROC8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
Worker - inhalative, long-term - systemic	3 mg/m ³ (TRA Workers 3.0); RCR 0.324
Worker - dermal, long-term - systemic	1.371 mg/kg bw/d (TRA Workers 3.0); RCR 0.045
Worker - combined, long-term - systemic	RCR 0.369

Process category	PROC9 - Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
Worker - inhalative, long-term - systemic	3 mg/m ³ (TRA Workers 3.0); RCR 0.324

Worker - dermal, long-term - systemic	0.686 mg/kg bw/d (TRA Workers 3.0); RCR 0.022
Worker - combined, long-term - systemic	RCR 0.347

4. GUIDANCE TO CHECK COMPLIANCE WITH THE EXPOSURE SCENARIO

Environmental Exposure Controls

Used EUSES model	EUSES v2.1
Non-standard assumptions	No information available.
Risk assessment	Risk Characterisation Ratio (RCR), Calculation method.
Predicted No Effect Concentration (PNEC)	See section 8 for more information.

Control of worker exposure

ECETOC TRA	The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated.
Risk assessment	Risk Characterisation Ratio (RCR), Calculation method.
Derived No Effect Level (DNEL)	Worker - inhalative, long-term - systemic Worker - dermal, long-term - systemic Worker - combined, long-term - systemic See section 8 for more information

Guidance to check compliance with the exposure scenario

If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

For scaling see: ECETOC TRA, ART, STOFFENMANAGER, EUSES.

Further information on the assumptions contained in this exposure scenario can be found at: Website Model, ECETOC TRA and RIVM report 601450009, "Emission scenario document for biocides", 2001.

Workplace measurements:

Refer to European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) or equivalent national standard(s).

Refer to European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) or equivalent national standard(s).

Refer to European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) or equivalent national standard(s).

Annex No. COE0013 /COES

1. EXPOSURE SCENARIO

Exposure scenario	3
Title	Formulation [mixing] of preparations and/or re-packaging
Use Descriptor	
Environmental release categories	ERC2 - Formulation of mixtures
Product category	PC39 - Cosmetics, personal care products
Process categories	PROC4 - Use in batch and other process (synthesis) where opportunity for exposure arises PROC 8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC9 - Transfer of substance or mixture into small containers (dedicated filling line, including weighing)

2. CONDITIONS OF USE AFFECTING EXPOSURE

2.1 Contributing Scenario - Environment

Control of environmental exposure	
Product characteristics	Solid
Environmental Release Category	ERC2 - Formulation of mixtures
Amounts used	Daily amount per site <=4.0 t/d Annual amount per site <=400.0 t/y
Conditions and Measures Related to Municipal Sewage Treatment	Municipal sewage treatment plant is assumed Assumed on-site sewage treatment plant flow - pH adjustment and Filtration / Sedimentation - Metal salts (excluding Ni) Assumed domestic sewage treatment plant flow (m3/d): >=2000 m3/d
Conditions and measures related to external recovery of waste	Dispose of waste product or used containers according to local regulations
Other Operational Conditions of Use Affecting Environment	Receiving surface water flow is >=18000 m3/d

2.2 Contributing Scenario - Worker & Consumer

Control of worker exposure	
Process category	PROC4 - Use in batch and other process (synthesis) where opportunity for exposure arises
Product characteristics	Solid Covers percentage substance in the product up to 100 %
Frequency and duration of use	≤4 h/d
Technical conditions and measures to control dispersion from source towards the worker	Provide a basic standard of general ventilation (1 to 3 air changes per hour)
Conditions and Measures Related to Personal Protection, Hygiene, and Health Evaluation	Supervision in place to check that the RMMs in place are being used correctly and OCs followed Ensure control measures are regularly inspected and maintained
Other operational conditions affecting worker exposure	Assumes use at not more than 20°C above ambient temperature Indoor use
Process category	PROC8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
Product characteristics	Solid

	Covers percentage substance in the product up to 100 %
Frequency and duration of use	≤4 h/d
Technical conditions and measures to control dispersion from source towards the worker	Provide a basic standard of general ventilation (1 to 3 air changes per hour)
Conditions and Measures Related to Personal Protection, Hygiene, and Health Evaluation	Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training For further specification, refer to section 8 of the SDS
Other operational conditions affecting worker exposure	Assumes use at not more than 20°C above ambient temperature Indoor use
Process category	PROC9 - Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
Product characteristics	Solid Covers percentage substance in the product up to 100 %
Frequency and duration of use	≤4 h/d
Technical conditions and measures to control dispersion from source towards the worker	Provide a basic standard of general ventilation (1 to 3 air changes per hour)
Conditions and Measures Related to Personal Protection, Hygiene, and Health Evaluation	Wear suitable gloves tested to EN 374 For further specification, refer to section 8 of the SDS
Other operational conditions affecting worker exposure	Assumes use at not more than 20°C above ambient temperature Indoor use

3. EXPOSURE ESTIMATION AND REFERENCE TO ITS SOURCE

Environment Exposure Estimation	
Environmental Release Category	ERC2 - Formulation of mixtures
Release to Water	0.8 kg/d
Release to Air	100 kg/d
Release to Soil	0.4 kg/d
Freshwater	5.38E-3 mg/L; RCR 0.07
Freshwater sediment	0.025 mg/kg dw; RCR <0.01
Marine water	5.36E-4 mg/L; RCR 0.024
Marine sediment	2.49E-3 mg/kg dw; RCR <0.01
Sewage treatment plant	0.051 mg/L; RCR 0.261
Soil	0.035 mg/kg dw; RCR <0.01
Man via environment - Inhalation	7.62E-3 mg/m ³ ; RCR <0.01
Man via environment - Oral	0.012 mg/kg bw/d; RCR <0.01
Man via environment - Combined Routes	RCR <0.01

Health Exposure Estimation	
Process category	PROC4 - Use in batch and other process (synthesis) where opportunity for exposure arises
Worker - inhalative, long-term - systemic	3 mg/m ³ (TRA Workers 3.0); RCR 0.324
Worker - dermal, long-term - systemic	6.86 mg/kg bw/d (TRA Workers 3.0); RCR 0.223
Worker - combined, long-term - systemic	RCR 0.547

Process category	PROC8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
Worker - inhalative, long-term - systemic	3 mg/m ³ (TRA Workers 3.0); RCR 0.324
Worker - dermal, long-term - systemic	1.371 mg/kg bw/d (TRA Workers 3.0); RCR 0.045
Worker - combined, long-term - systemic	RCR 0.369

Process category	PROC9 - Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
Worker - inhalative, long-term - systemic	3 mg/m ³ (TRA Workers 3.0); RCR 0.324
Worker - dermal, long-term - systemic	1.372 mg/kg bw/d (TRA Workers 3.0); RCR 0.045

Worker - combined, long-term - systemic	RCR 0.369
---	-----------

4. GUIDANCE TO CHECK COMPLIANCE WITH THE EXPOSURE SCENARIO

Environmental Exposure Controls

Used EUSES model	EUSES v2.1
Non-standard assumptions	No information available.
Risk assessment	Risk Characterisation Ratio (RCR), Calculation method.
Predicted No Effect Concentration (PNEC)	See section 8 for more information.

Control of worker exposure

ECETOC TRA	The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated.
Risk assessment	Risk Characterisation Ratio (RCR), Calculation method.
Derived No Effect Level (DNEL)	Worker - inhalative, long-term - systemic Worker - dermal, long-term - systemic Worker - combined, long-term - systemic See section 8 for more information

Guidance to check compliance with the exposure scenario

If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

For scaling see: ECETOC TRA, ART, STOFFENMANAGER, EUSES.

Further information on the assumptions contained in this exposure scenario can be found at: Website Model, ECETOC TRA and RIVM report 601450009, "Emission scenario document for biocides", 2001.

Workplace measurements:

Refer to European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) or equivalent national standard(s).

Refer to European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) or equivalent national standard(s).

Refer to European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) or equivalent national standard(s).

Annex No. COE0014 /COES

1. EXPOSURE SCENARIO

Exposure scenario	4
Title	Professional use
<u>Use Descriptor</u>	
Sector of use	SU0 - Other
Environmental release categories	ERC8a - Wide dispersive indoor use of processing aids in open systems
Product category	PC31 - Polishes and wax blends PC35 - Washing and cleaning products (including solvent based products)
Process categories	PROC8a - Transfer of substance or mixture (charging/discharging) from/to vessels/large containers at non dedicated facilities PROC 8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC9 - Transfer of substance or mixture into small containers (dedicated filling line, including weighing) PROC10 - Roller application or brushing PROC11 - Non industrial spraying PROC13 - Treatment of articles by dipping and pouring

2. CONDITIONS OF USE AFFECTING EXPOSURE

2.1 Contributing Scenario - Environment

Control of environmental exposure	
Product characteristics	Solid
Environmental Release Category	ERC8a - Wide dispersive indoor use of processing aids in open systems
Conditions and Measures Related to Municipal Sewage Treatment	Municipal sewage treatment plant is assumed
Conditions and measures related to external recovery of waste	Dispose of waste product or used containers according to local regulations

2.2 Contributing Scenario - Worker & Consumer

Control of worker exposure	
Process category	PROC8a - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non dedicated facilities
Product characteristics	Solid Covers percentage substance in the product up to 100 %
Frequency and duration of use	≤4 h/d
Technical conditions and measures to control dispersion from source towards the worker	Provide a basic standard of general ventilation (1 to 3 air changes per hour)
Conditions and Measures Related to Personal Protection, Hygiene, and Health Evaluation	Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training For further specification, refer to section 8 of the SDS
Other operational conditions affecting worker exposure	Assumes use at not more than 20°C above ambient temperature Indoor use
Process category	PROC8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large

	containers at dedicated facilities
Product characteristics	Solid Covers percentage substance in the product up to 100 %
Frequency and duration of use	≤4 h/d
Technical conditions and measures to control dispersion from source towards the worker	Provide a basic standard of general ventilation (1 to 3 air changes per hour)
Conditions and Measures Related to Personal Protection, Hygiene, and Health Evaluation	Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training For further specification, refer to section 8 of the SDS
Other operational conditions affecting worker exposure	Assumes use at not more than 20°C above ambient temperature Indoor use

Process category	PROC9 - Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
Product characteristics	Solid Grainy Covers percentage substance in the product up to 100 %
Frequency and duration of use	≤4 h/d
Technical conditions and measures to control dispersion from source towards the worker	Provide a basic standard of general ventilation (1 to 3 air changes per hour)
Conditions and Measures Related to Personal Protection, Hygiene, and Health Evaluation	Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training For further specification, refer to section 8 of the SDS
Other operational conditions affecting worker exposure	Assumes use at not more than 20°C above ambient temperature Indoor use

Process category	PROC10 - Roller application or brushing
Product characteristics	Solid Covers percentage substance in the product up to 5 %
Frequency and duration of use	Covers daily exposures up to 8 hours
Technical conditions and measures to control dispersion from source towards the worker	Provide a basic standard of general ventilation (1 to 3 air changes per hour)
Other operational conditions affecting worker exposure	Assumes use at not more than 20°C above ambient temperature Indoor use

Process category	PROC11 - Non industrial spraying
Product characteristics	Solid Covers percentage substance in the product up to 10 %
Frequency and duration of use	≤1 h/d
Technical conditions and measures to control dispersion from source towards the worker	Provide a basic standard of general ventilation (1 to 3 air changes per hour)
Conditions and Measures Related to Personal Protection, Hygiene, and Health Evaluation	Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training For further specification, refer to section 8 of the SDS
Other operational conditions affecting worker exposure	Assumes use at not more than 20°C above ambient temperature Indoor use

Process category	PROC13 - Treatment of articles by dipping and pouring
Product characteristics	Solid Covers percentage substance in the product up to 10 %
Frequency and duration of use	≤4 h/d
Technical conditions and measures to control dispersion from source towards the worker	Provide a basic standard of general ventilation (1 to 3 air changes per hour)
Conditions and Measures Related to Personal Protection, Hygiene, and Health Evaluation	Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training For further specification, refer to section 8 of the SDS

Evaluation	
Other operational conditions affecting worker exposure	Assumes use at not more than 20°C above ambient temperature Indoor use

3. EXPOSURE ESTIMATION AND REFERENCE TO ITS SOURCE

Environment Exposure Estimation	
Environmental Release Category	ERC8a - Wide dispersive indoor use of processing aids in open systems
Release to Water	0.11 kg/d
Release to Air	- kg/d
Release to Soil	- kg/d
Freshwater	1.01E-3 mg/L; RCR 0.013
Freshwater sediment	4.7E-3 mg/kg dw; RCR <0.01
Marine water	9.99E-5 mg/L; RCR <0.01
Marine sediment	4.64E-4 mg/kg dw; RCR <0.01
Sewage treatment plant	6.94E-3 mg/L; RCR 0.036
Soil	8.31E-4 mg/kg dw; RCR <0.01
Man via environment - Inhalation	1.81E-11 mg/m ³ ; RCR <0.01
Man via environment - Oral	2.31E-4 mg/kg bw/d; RCR <0.01
Man via environment - Combined Routes	RCR <0.01
Health Exposure Estimation	
Process category	PROC8a - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non dedicated facilities
Worker - inhalative, long-term - systemic	6 mg/m ³ (TRA Workers 3.0); RCR 0.649
Worker - dermal, long-term - systemic	1.371 mg/kg bw/d (TRA Workers 3.0); RCR 0.045
Worker - combined, long-term - systemic	RCR 0.693
Process category	PROC8b - Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
Worker - inhalative, long-term - systemic	3 mg/m ³ (TRA Workers 3.0); RCR 0.324
Worker - dermal, long-term - systemic	1.371 mg/kg bw/d (TRA Workers 3.0); RCR 0.045
Worker - combined, long-term - systemic	RCR 0.369
Process category	PROC9 - Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
Worker - inhalative, long-term - systemic	3 mg/m ³ (TRA Workers 3.0); RCR 0.324
Worker - dermal, long-term - systemic	0.686 mg/kg bw/d (TRA Workers 3.0); RCR 0.022
Worker - combined, long-term - systemic	RCR 0.347
Process category	PROC10 - Roller application or brushing
Worker - inhalative, long-term - systemic	0.1 mg/m ³ (TRA Workers 3.0); RCR 0.011
Worker - dermal, long-term - systemic	5.486 mg/kg bw/d (TRA Workers 3.0); RCR 0.178
Worker - combined, long-term - systemic	RCR 0.189
Process category	PROC11 - Non industrial spraying
Worker - inhalative, long-term - systemic	2.4 mg/m ³ (TRA Workers 3.0); RCR 0.26
Worker - dermal, long-term - systemic	6.428 mg/kg bw/d (TRA Workers 3.0); RCR 0.209
Worker - combined, long-term - systemic	RCR 0.468
Process category	PROC13 - Treatment of articles by dipping and pouring
Worker - inhalative, long-term - systemic	1.8 mg/m ³ (TRA Workers 3.0); RCR 0.195
Worker - dermal, long-term - systemic	0.823 mg/kg bw/d (TRA Workers 3.0); RCR 0.027
Worker - combined, long-term - systemic	RCR 0.221

4. GUIDANCE TO CHECK COMPLIANCE WITH THE EXPOSURE SCENARIO

Environmental Exposure Controls

Used EUSES model	EUSES v2.1
Non-standard assumptions	No information available.
Risk assessment	Risk Characterisation Ratio (RCR), Calculation method.
Predicted No Effect Concentration (PNEC)	See section 8 for more information.

Control of worker exposure

ECETOC TRA	The ECETOC TRA tool has been used to estimate workplace exposures unless otherwise indicated.
Risk assessment	Risk Characterisation Ratio (RCR), Calculation method.
Derived No Effect Level (DNEL)	Worker - inhalative, long-term - systemic Worker - dermal, long-term - systemic Worker - combined, long-term - systemic See section 8 for more information

Guidance to check compliance with the exposure scenario

If scaling reveals a condition of unsafe use (i.e., RCRs > 1), additional RMMs or a site-specific chemical safety assessment is required.

For scaling see: ECETOC TRA, ART, STOFFENMANAGER, EUSES.

Further information on the assumptions contained in this exposure scenario can be found at: Website Model, ECETOC TRA and RIVM report 601450009, "Emission scenario document for biocides", 2001.

Workplace measurements:

Refer to European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) or equivalent national standard(s).

Refer to European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) or equivalent national standard(s).

Refer to European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) or equivalent national standard(s).

Annex No. COE0015 /COES