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BACTINYL INSTRUMENTATION 20 ML(*50) - LB920930

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SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2015/830)

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

1.1. Product identifier

Product name: BACTINYL INSTRUMENTATION 20 ML(*50)

Product code: LB920930.

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

Cleaning disinfectant for medical devices

Professional use

1.3. Details of the supplier of the safety data sheet

Registered company name: ORAPI HYGIENE.

Address: 12, RUE PIERRE MENDES FRANCE.69120.VAULX-EN-VELIN.FRANCE.

Telephone: +33 (0)4 37 42 23 03. Fax: +33 (0)4 37 57 18 27.

fds@orapi.com

1.4. Emergency telephone number: +33 (0)1 45 42 59 59.

Association/Organisation: INRS / ORFILA http://www.centres-antipoison.net.

Other emergency numbers

Emergency Action: In the event of a medical enquiry involving this product, please contact your doctor or local hospital accident and emergency department.

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Skin corrosion, Category 1B (Skin Corr. 1B, H314).

Serious eye damage, Category 1 (Eye Dam. 1, H318).

Hazardous to the aquatic environment - Acute hazard, Category 1 (Aquatic Acute 1, H400).

Hazardous to the aquatic environment - Chronic hazard, Category 2 (Aquatic Chronic 2, H411).

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

2.2. Label elements

Detergent mixture (see section 15).

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms:





GHS05

GHS09

Signal Word : DANGER

Product identifiers:

CAS 7173-51-5 CHLORURE DE DIDECYLDIMETHYLAMMONIUM

Hazard statements:

H314 Causes severe skin burns and eye damage.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements - Prevention:

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statements - Response:

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or

shower].

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P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and

easy to do. Continue rinsing.

P312 Call a POISON CENTER or doctor if you feel unwell.

Precautionary statements - Disposal:

P501 Dispose of contents/container as hazardous waste.

2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) >= 0.1% published by the European CHemicals Agency (ECHA) under article 57 of REACH: http://echa.europa.eu/fr/candidate-list-table

The mixture fulfils neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Composition:

Identification	(EC) 1272/2008	Note	%
INDEX: 612_131_006B	GHS07, GHS05, GHS09		10 <= x % < 25
CAS: 7173-51-5	Dgr		
	Acute Tox. 4, H302		
CHLORURE DE	Skin Corr. 1B, H314		
DIDECYLDIMETHYLAMMONIUM	Eye Dam. 1, H318		
	Aquatic Chronic 2, H411		
	Aquatic Acute 1, H400		
	M Acute = 10		
INDEX: 68424_81B	GHS07, GHS05, GHS09		10 <= x % < 25
CAS: 68424-85-1	Dgr		
EC: 270-325-2	Met. Corr. 1, H290		
	Acute Tox. 4, H302		
COMPOSE DE L ION AMMONIUM	Skin Corr. 1B, H314		
QUATERNAIRE, BENZYLALKYL EN C12-16	Aquatic Acute 1, H400		
DIMETHYLES CHLORURES	M Acute = 10		
	Aquatic Chronic 1, H410		
	M Chronic = 1		
INDEX: 603-117-00-0	GHS02, GHS07	[1]	2.5 <= x % < 10
CAS: 67-63-0	Dgr		
EC: 200-661-7	Flam. Liq. 2, H225		
REACH: 01-2119457558-25	Eye Irrit. 2, H319		
	STOT SE 3, H336		
PROPAN-2-OL			
INDEX: 0070	GHS07, GHS05		2.5 <= x % < 10
CAS: 69011-36-5	Dgr		
EC: 931-138-8	Acute Tox. 4, H302		
REACH: 01-2119976362-32	Eye Dam. 1, H318		
ISOTRIDECANOL, ETHOXYLATED			

Information on ingredients:

[1] Substance for which maximum workplace exposure limits are available.

SECTION 4: FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

4.1. Description of first aid measures

In the event of splashes or contact with eyes:

Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open.

Regardless of the initial state, refer the patient to an ophthalmologist and show him the label.

In the event of splashes or contact with skin:

Remove any soiled or splashed clothing immediately.

Watch out for any remaining product between skin and clothing, watches, shoes, etc.

If the contaminated area is widespread and/or there is damage to the skin, a doctor must be consulted or the patient transferred to hospital.

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In the event of swallowing:

Do not give the patient anything orally.

In the event of swallowing, if the quantity is small (no more than one mouthful), rinse the mouth with water and consult a doctor.

Keep the person exposed at rest. Do not force vomiting.

Seek medical attention immediately, showing the label.

If swallowed accidentally, call a doctor to ascertain whether observation and hospital care will be necessary. Show the label.

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

No data available.

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

No data available.

SECTION 5 : FIREFIGHTING MEASURES

Non-flammable.

5.1. Extinguishing media

Suitable methods of extinction

In the event of a fire, use:

- sprayed water or water mist
- foam
- multipurpose ABC powder
- BC powder
- carbon dioxide (CO2)

Unsuitable methods of extinction

In the event of a fire, do not use:

- water jet

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

In the event of a fire, the following may be formed:

- carbon monoxide (CO)
- carbon dioxide (CO2)

5.3. Advice for firefighters

No data available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

For non first aid worker

Avoid any contact with the skin and eyes.

For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

6.2. Environmental precautions

Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Neutralise with an acidic decontaminant.

If the ground is contaminated, once the product has been recovered by sponging with an inert and non-combustible absorbent material, wash the contaminated area in plenty of water.

Clean preferably with a detergent, do not use solvents.

6.4. Reference to other sections

No data available.

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SECTION 7: HANDLING AND STORAGE

Requirements relating to storage premises apply to all facilities where the mixture is handled.

7.1. Precautions for safe handling

Always wash hands after handling.

Remove and wash contaminated clothing before re-using.

Ensure that there is adequate ventilation, especially in confined areas.

Emergency showers and eye wash stations will be required in facilities where the mixture is handled constantly.

Fire prevention:

Handle in well-ventilated areas.

Prevent access by unauthorised personnel.

Recommended equipment and procedures:

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Packages which have been opened must be reclosed carefully and stored in an upright position.

Prohibited equipment and procedures:

No smoking, eating or drinking in areas where the mixture is used.

7.2. Conditions for safe storage, including any incompatibilities

No data available.

Storage

Keep the container tightly closed in a dry, well-ventilated place.

The floor must be impermeable and form a collecting basin so that, in the event of an accidental spillage, the liquid cannot spread beyond this area.

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Packaging

Always keep in packaging made of an identical material to the original.

7.3. Specific end use(s)

No data available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Occupational exposure limits:

· ACGIH TLV (American Conference of Governmental Industrial Hygienists, Threshold Limit Values, 2010):

CAS	TWA:	STEL:	Ceiling:	Definition:	Criteria:
67-63-0	200 ppm	400 ppm		A4; BEI	

- Germany - AGW (BAuA - TRGS 900, 21/06/2010) :

CAS	VME :	VME :	Excess	Notes
67-63-0		200 ppm 500 mg/m3		2(II)

- France (INRS - ED984 :2012) :

CAS	VME-ppm:	VME-mg/m3:	VLE-ppm:	VLE-mg/m3:	Notes:	TMP No:
67-63-0	-	-	400	980	-	84

- UK / WEL (Workplace exposure limits, EH40/2005, 2007) :

CAS	TWA:	STEL:	Ceiling:	Definition:	Criteria:
67-63-0	400 ppm	500 ppm			
	999 mg/m3	1250 mg/m3			

Derived no effect level (DNEL) or derived minimum effect level (DMEL):

PROPAN-2-OL (CAS: 67-63-0)

Final use: Workers.
Exposure method: Dermal contact.

Potential health effects: Long term systemic effects.

DNEL: 888 mg/kg body weight/day

Exposure method: Inhalation.

Potential health effects: Long term systemic effects.

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DNEL: 500 mg of substance/m3

Final use: Consumers. Exposure method: Ingestion.

Potential health effects: Long term systemic effects. DNEL: 26 mg/kg body weight/day

Exposure method: Dermal contact.

Potential health effects: Long term systemic effects. DNEL: 319 mg/kg body weight/day

Exposure method: Inhalation.

Potential health effects: Long term systemic effects. DNEL: 89 mg of substance/m3

Predicted no effect concentration (PNEC):

PROPAN-2-OL (CAS: 67-63-0)

Environmental compartment: Soil. PNEC: 28 mg/kg

Environmental compartment: Fresh water. PNEC: 140.9 mg/l

Environmental compartment: Sea water. PNEC: 140.9 mg/l

Environmental compartment: Intermittent waste water.

PNEC: 140.9 mg/l

Fresh water sediment. Environmental compartment:

PNEC: 552 mg/kg

Environmental compartment: Marine sediment. PNEC: 552 mg/kg

Environmental compartment: Waste water treatment plant.

PNEC: 2251 mg/l

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

- Eye / face protection

Avoid contact with eyes.

Use eye protectors designed to protect against liquid splashes

Before handling, wear safety goggles with protective sides accordance with standard EN166.

In the event of high danger, protect the face with a face shield.

Prescription glasses are not considered as protection.

Individuals wearing contact lenses should wear prescription glasses during work where they may be exposed to irritant vapours.

Provide eyewash stations in facilities where the product is handled constantly.

- Hand protection

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN374.

Gloves must be selected according to the application and duration of use at the workstation.

Protective gloves need to be selected according to their suitability for the workstation in question: other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.

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Type of gloves recommended:

- Nitrile rubber (butadiene-acrylonitrile copolymer rubber (NBR))

Recommended properties:

- Impervious gloves in accordance with standard EN374

- Body protection

Avoid skin contact.

Wear suitable protective clothing.

Suitable type of protective clothing:

In the event of substantial spatter, wear liquid-tight protective clothing against chemical risks (type 3) in accordance with EN14605 to prevent skin contact.

In the event of a risk of splashing, wear protective clothing against chemical risks (type 6) in accordance with EN13034 to prevent skin contact.

Wear suitable protective clothing and, in particular, an apron and boots. These items of clothing shall be maintained in good condition and cleaned after use.

Suitable type of protective boots:

In the event of minor spatter, wear protective boots or half-boots against chemical risks in accordance with standard EN13832-2.

In the event of prolonged contact, wear boots or half-boots with liquid-chemical-resistant and waterproof soles and uppers in accordance with standard EN13832-3.

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information:

Physical state: Fluid liquid.

Colour: colorless Olor : Pino

Important health, safety and environmental information

pH: Not stated.

Slightly basic.

Boiling point/boiling range : Not relevant.
Flash point interval : Not relevant.

Vapour pressure (50°C): Between 175 kPa and 300 kPa inclusive.

Density: = 1
Water solubility: Soluble.
Melting point/melting range: Not specified.
Self-ignition temperature: Not relevant.
Decomposition point/decomposition range: Not specified.

9.2. Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

When exposed to high temperatures, the mixture can release hazardous decomposition products, such as carbon monoxide and dioxide, fumes and nitrogen oxide.

10.4. Conditions to avoid

Avoid:

- frost
- heat
- exposure to light

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10.5. Incompatible materials

Keep away from:

- acids
- oxidising agents

10.6. Hazardous decomposition products

The thermal decomposition may release/form:

- carbon monoxide (CO)
- carbon dioxide (CO2)

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

May cause irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following exposure between three minutes and one hour.

Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discolouration due to blanching of the skin, complete areas of alopecia, and scars.

11.1.1. Substances

Acute toxicity:

ISOTRIDECANOL, ETHOXYLATED (CAS: 69011-36-5)

Oral route : $300 < LD50 \le 2000 \text{ mg/kg}$

Species: Rat

Dermal route : LD50 > 2000 mg/kg

Species: Rabbit

COMPOSE DE L ION AMMONIUM QUATERNAIRE, BENZYLALKYL EN C12-16 DIMETHYLES CHLORURES (CAS: 68424-85-1)

Oral route : LD50 = 795 mg/kg

Species: Rat

Skin corrosion/skin irritation :

ISOTRIDECANOL, ETHOXYLATED (CAS: 69011-36-5)

Irritation: No observed effect.

 $Average \ score < 1.5$

Serious damage to eyes/eye irritation:

ISOTRIDECANOL, ETHOXYLATED (CAS: 69011-36-5)

Causes serious eye damage.

Corneal haze: Average score >= 3

Species : Rabbit

Respiratory or skin sensitisation:

ISOTRIDECANOL, ETHOXYLATED (CAS: 69011-36-5)

Guinea Pig Maximisation Test (GMPT): Non-sensitiser.

Germ cell mutagenicity:

ISOTRIDECANOL, ETHOXYLATED (CAS: 69011-36-5)

No mutagenic effect.

Carcinogenicity:

ISOTRIDECANOL, ETHOXYLATED (CAS: 69011-36-5)

Carcinogenicity Test: Negative.

No carcinogenic effect.

Reproductive toxicant:

ISOTRIDECANOL, ETHOXYLATED (CAS: 69011-36-5)

No toxic effect for reproduction

11.1.2. Mixture

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No toxicological data available for the mixture.

SECTION 12: ECOLOGICAL INFORMATION

Very toxic to aquatic life with long lasting effects.

The product must not be allowed to run into drains or waterways.

12.1. Toxicity

12.1.1. Substances

ISOTRIDECANOL, ETHOXYLATED (CAS: 69011-36-5)

Fish toxicity: LC50 > 1 mg/l

Species : Cyprinus carpio Duration of exposure : 96 h

OECD Guideline 203 (Fish, Acute Toxicity Test)

Crustacean toxicity: EC50 > 1 mg/l

Species : Daphnia magna Duration of exposure : 48 h

OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

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NOEC = 2.6 mg/l Species : Daphnia magna Duration of exposure : 21 days

OECD Guideline 211 (Daphnia magna Reproduction Test)

Algae toxicity: ECr50 > 1 mg/l

Species: Desmodesmus subspicatus

Duration of exposure: 72 h

OECD Guideline 201 (Alga, Growth Inhibition Test)

COMPOSE DE L ION AMMONIUM QUATERNAIRE, BENZYLALKYL EN C12-16 DIMETHYLES CHLORURES (CAS: 68424-85-1)

Fish toxicity: LC50 = 0.085 mg/l

Factor M = 10

Species : Oncorhynchus mykiss Duration of exposure : 96 h

OECD Guideline 203 (Fish, Acute Toxicity Test)

Crustacean toxicity: EC50 = 0.016 mg/l

Species : Daphnia magna Duration of exposure : 48 h

NOEC = 0.025 mg/l Species : Daphnia magna

OECD Guideline 211 (Daphnia magna Reproduction Test)

Algae toxicity: ECr50 = 0.025 mg/l

Species: Selenastrum capricornutum

Duration of exposure: 72 h

OECD Guideline 201 (Alga, Growth Inhibition Test)

EC10 mg/l Factor M = 1

Species: Selenastrum capricornutum

Duration of exposure: 72 h

OECD Guideline 201 (Alga, Growth Inhibition Test)

CHLORURE DE DIDECYLDIMETHYLAMMONIUM (CAS: 7173-51-5)

Fish toxicity: 0.01 < LC50 <= 0.1 mg/l

Factor M = 10

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Duration of exposure: 96 h

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

12.2.1. Substances

ISOTRIDECANOL, ETHOXYLATED (CAS: 69011-36-5)

Biodegradability: no degradability data is available, the substance is considered as not degrading

quickly.

COMPOSE DE L ION AMMONIUM QUATERNAIRE, BENZYLALKYL EN C12-16 DIMETHYLES CHLORURES (CAS: 68424-85-1)

Biodegradability: Rapidly degradable.

CHLORURE DE DIDECYLDIMETHYLAMMONIUM (CAS: 7173-51-5)

Biodegradability: Rapidly degradable.

12.3. Bioaccumulative potential

12.3.1. Substances

ISOTRIDECANOL, ETHOXYLATED (CAS: 69011-36-5)

Octanol/water partition coefficient : log Koe > 5000

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

Waste:

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging:

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

SECTION 14: TRANSPORT INFORMATION

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2015 - IMDG 2014 - ICAO/IATA 2016).

14.1. UN number

3267

14.2. UN proper shipping name

UN3267=CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S.

(chlorure de didecyldimethylammonium, compose de l ion ammonium quaternaire, benzylalkyl en c12-16 dimethyles chlorures)

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14.3. Transport hazard class(es)

- Classification:



8

14.4. Packing group

П

14.5. Environmental hazards

- Environmentally hazardous material:



14.6. Special precautions for user

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	8	C7	II	8	80	1 L	274	E2	2	E

IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ
	8	-	II	1 L	F-A,S-B	274	E2

IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ
	8	-	II	851	1 L	855	30 L	A3	E2
								A803	
	8	-	II	Y840	0.5 L	-	-	A3	E2
								A803	

For limited quantities, see part 2.7 of the OACI/IATA and chapter 3.4 of the ADR and IMDG.

For excepted quantities, see part 2.6 of the OACI/IATA and chapter 3.5 of the ADR and IMDG.

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

No data available.

SECTION 15: REGULATORY INFORMATION

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

- Classification and labelling information included in section 2:

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 2016/1179. (ATP 9)
- Container information:

No data available.

- Particular provisions :

No data available.

- Labelling for detergents (EC Regulation No. 648/2004,907/2006):

- less than 5 %: nonionic surfactants
- disinfectants
- perfumes
- allergenic fragrances :

aldehyde hexylcinnamique

methylionone

linalool

coumarin

15.2. Chemical safety assessment

No data available.

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SECTION 16: OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

Wording of the phrases mentioned in section 3:

H225	Highly flammable liquid and vapour.
H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

Abbreviations:

DNEL: Derived No-Effect Level

PNEC: Predicted No-Effect Concentration

ADR: European agreement concerning the international carriage of dangerous goods by Road.

IMDG: International Maritime Dangerous Goods. IATA: International Air Transport Association. ICAO: International Civil Aviation Organisation

RID: Regulations concerning the International carriage of Dangerous goods by rail.

 $WGK: Wasserge fahrdungsklasse \ (Water\ Hazard\ Class).$

GHS05 : Corrosion GHS09 : Environment

PBT: Persistent, bioaccumulable and toxic. vPvB: Very persistent, very bioaccumulable. SVHC: Substances of very high concern.