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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: DENTO VIRACTIS INSTRUGERM 51

Product code: 2990-027-1.

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

Disinfectant cleaner for cleaning and pre-disinfection by immersion of medical devices before sterilization or chemical disinfection.

1.3. Details of the supplier of the safety data sheet

Registered company name: CADENCE.

Address: 2 bis, chemin du Loup.93290.TREMBLAY-EN-FRANCE.FRANCE.

Telephone: +33 (0)1 45 91 31 82. Fax: +33 (0)1 48 65 67 23.

info@cfpm-medical.fr

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

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

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

Acute oral toxicity, Category 4 (Acute Tox. 4, H302).

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).

The mixture is a disinfectant product for medical device use.

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

Hazard pictograms:







GHS05

S05 GHS

GHS07

GHS09

Signal Word : DANGER

Product identifiers:

CAS 26183-52-8 ETHOXYLATED ALCOHOL C10

EC 219-145-8 N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE

EC 230-525-2 DIDECYLDIMETHYLAMMONIUM CHLORIDE

 $Hazard\ statements:$

H302 Harmful if swallowed.

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

Precautionary statements - Prevention :

P264 Wash hands thoroughly after handling.
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.

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

shower.

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

easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER or a doctor.

P391 Collect spillage.

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) $\geq 0.1\%$ 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:

Composition:			Lac
Identification	(EC) 1272/2008	Note	%
CAS: 26183-52-8	GHS07, GHS05		10 <= x % < 25
	Dgr		
ETHOXYLATED ALCOHOL C10	Acute Tox. 4, H302		
	Eye Dam. 1, H318		
CAS: 2372-82-9	GHS06, GHS05, GHS09, GHS08		2.5 <= x % < 10
EC: 219-145-8	Dgr		
REACH: 01-2119980592-29	Acute Tox. 3, H301		
	Skin Corr. 1B, H314		
N-(3-AMINOPROPYL)-N-DODECYLPROP			
E-1,3-DIAMINE	STOT RE 2, H373		
2 1,0 211111112	Aquatic Acute 1, H400		
	M Acute = 10		
	Aquatic Chronic 1, H410		
	M Chronic = 1		
CAS: 7173-51-5	GHS07, GHS05, GHS09		2.5 <= x % < 10
EC: 230-525-2	Dgr		2.5 \= \(\) \(\) \(\)
EC. 230-323-2	Acute Tox. 4, H302		
DIDECYLDIMETHYLAMMONIUM	Skin Corr. 1B, H314		
CHLORIDE	Eye Dam. 1, H318		
CHLORIDE			
	Aquatic Chronic 2, H411		
	Aquatic Acute 1, H400 M Acute = 10		
040 57 55 (M Acute = 10	F11	0 (0 2 5
CAS: 57-55-6		[1]	$0 \le x \% \le 2.5$
EC: 200-338-0			
REACH: 01-2119456816-28			
DD ODLY ENE GLYGOL			
PROPYLENE GLYCOL	GMG02	643	0 . ~ ~
INDEX: 603-002-00-5	GHS02	[1]	$0 \le x \% \le 2.5$
CAS: 64-17-5	Dgr		
EC: 200-578-6	Flam. Liq. 2, H225		
REACH: 01-2119457610-43			
ETHANOL			
CAS: 5538-95-4	GHS07, GHS05, GHS09		$0 \le x \% \le 2.5$
EC: 226-902-6	Dgr		
	Acute Tox. 4, H302		
N-DODÉCYLPROPANE-1,3-DIAMINE	Skin Corr. 1A, H314		
	Eye Dam. 1, H318		
	Aquatic Acute 1, H400		
	M Acute = 1		

(Full text of H-phrases: see section 16)

Information on ingredients:

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

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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.

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, administer activated medical charcoal 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)

Chemical powders, carbon dioxide and other extinguishing gas are suitable for small fires.

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

Fire-fighting personnel are to be equipped with autonomous insulating breathing apparatus.

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).

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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.

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.

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

Fire prevention:

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 away from food and drink, including those for animals.

Store at a temperature between 5°C and 35°C.

The floor of the premises will be impermeable and will form a retention basin so that in case of an accidental spill the liquid can not spread out.

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

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

No data available.

Occupational exposure limits:

- UK / WEL (Workplace exposure limits, EH40/2005, 2011):

CAS	TWA:	STEL:	Ceiling:	Definition:	Criteria:
57-55-6	150 ppm	- ppm			
	474 mg/m ³	- mg/m³			
64-17-5	1000 ppm	- ppm			
	1920 mg/m ³	- mg/m³			

8.2. Exposure controls

Used at the dose of use, the product is not classified and does not require the wearing of personal protective equipment

The solution remains a chemical to handle with care.

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.

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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.

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- 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.

Type of gloves recommended:

- Nitrile rubber (butadiene-acrylonitrile copolymer rubber (NBR))
- Natural latex
- PVC (polyvinyl chloride)

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.

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:

Boiling point/boiling range:

Flash Point Interval:

Physical state: Fluid liquid.

Color: Colorless to pale yellow

Odor: Typical.

Important health, safety and environmental information

pH: 10.50 +/- 0.50.

Not relevant. FP > 100°C. Not relevant.

Slightly basic.

Vapour pressure (50°C):

Density:

1.00 +/- 0.01

Water solubility:

Dilutable.

Melting point/melting range:

Not relevant.

Self-ignition temperature:

Not relevant.

Decomposition point/decomposition range:

Not relevant.

9.2. Other information

pH at 0.5% in demineralised water. 10.00 ± 0.50 .

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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

No data available.

10.4. Conditions to avoid

Avoid:

- frost

10.5. Incompatible materials

Aluminum.

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

Harmful if swallowed.

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:

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Oral route : LD50 = 329 mg/kg

Species: Rat

OECD Guideline 401 (Acute Oral Toxicity)

Dermal route : LD50 > 1000 mg/kg Species : Rabbit

N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE (CAS: 2372-82-9)

Oral route : LD50 = 261 mg/kg

Species: Rat

OECD Guideline 401 (Acute Oral Toxicity)

Skin corrosion/skin irritation:

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Corrosivity: Causes severe skin burns.

OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Effect observed: Overall irritation score

Species: Rabbit

OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE (CAS: 2372-82-9)

Corrosivity: Causes severe skin burns.

Species: Rabbit

OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Respiratory or skin sensitisation:

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

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Buehler Test: Non-sensitiser.

Species : Guinea pig Other guideline

N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE (CAS: 2372-82-9)

Buehler Test: Non-sensitiser.

Species: Guinea pig

REACH Method B.6 (Skin Sensitisation)

Germ cell mutagenicity:

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Mutagenesis (in vivo): Negative.

Species: Rat

OECD Guideline 475 (Mammalian Bone Marrow Chromosome Aberration Test)

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Mutagenesis (in vitro): Negative.

Species: Bacteria

OECD Guideline 471 (Bacterial Reverse Mutation Assay)

Ames test (in vitro): Negative.

N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE (CAS: 2372-82-9)

No mutagenic effect.

OECD Guideline 471 (Bacterial Reverse Mutation Assay)

Ames test (in vitro): Negative.

11.1.2. Mixture

No toxicological data available for the mixture.

$Monograph(s) \ from \ the \ IARC \ (International \ Agency \ for \ Research \ on \ Cancer):$

CAS 64-17-5: IARC Group 1: The agent is carcinogenic to humans.

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

ETHOXYLATED ALCOHOL C10 (CAS: 26183-52-8)

Crustacean toxicity: EC50 = 15 mg/l

Species : Daphnia sp. Duration of exposure : 48 h

OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

Algae toxicity: ECr50 = 19.6 mg/l

Duration of exposure : 72 h

OECD Guideline 201 (Alga, Growth Inhibition Test)

N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE (CAS: 2372-82-9)

Fish toxicity: 0.1 < LC50 <= 1 mg/l

Factor M = 1 Species : Danio rerio Duration of exposure : 96 h

OECD Guideline 203 (Fish, Acute Toxicity Test)

Crustacean toxicity: $0.01 \le EC50 \le 0.1 \text{ mg/l}$

Factor M = 10

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Species : Daphnia magna Duration of exposure : 48 h

OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

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0,01 < NOEC <= 0,1 mg/l Species : Daphnia magna Duration of exposure : 21 days

OECD Guideline 211 (Daphnia magna Reproduction Test)

Algae toxicity: $0.01 \le ECr50 \le 0.1 \text{ mg/l}$

Factor M = 10

Species: Pseudokirchnerella subcapitata

Duration of exposure: 72 h

OECD Guideline 201 (Alga, Growth Inhibition Test)

 $0,001 \le NOEC \le 0,01 \text{ mg/l}$

Factor M = 1

Species: Pseudokirchnerella subcapitata

Duration of exposure: 72 h

OECD Guideline 201 (Alga, Growth Inhibition Test)

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Fish toxicity: LC50 = 0.5 mg/l

Factor M = 1

Species : Brachydanio rerio Duration of exposure : 96 h

Crustacean toxicity: EC50 = 0.03 mg/l

Species : Daphnia magna Duration of exposure : 48 h

NOEC = 0.021 mg/l Species : Daphnia magna Duration of exposure : 21 days

OECD Guideline 211 (Daphnia magna Reproduction Test)

Algae toxicity: ECr50 = 0.06 mg/l

 $Species: Selenastrum\ capricornutum$

Duration of exposure : 96 h

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

Surfactants in this preparation comply with the standards of biodegradability as defined in Regulation (EC) No 648/2004 on detergents.

The data proving this statement shall be made available to the competent authorities of the Member States and shall be supplied to them at their express request or at the request of the detergent manufacturer.

12.2.1. Substances

DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS: 7173-51-5)

Biodegradability: Rapidly degradable.

N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE (CAS: 2372-82-9)

Biodegradability: Rapidly degradable.

ETHOXYLATED ALCOHOL C10 (CAS: 26183-52-8)

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

quickly.

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12.3. Bioaccumulative potential

No data available.

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 2019 - IMDG 2018 - ICAO/IATA 2019).

14.1. UN number

3267

14.2. UN proper shipping name

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

(n-(3-aminopropyl)-n-dodecylpropane-1,3-diamine, didecyldimethylammonium chloride)

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

							TT 111	
							Handling	1
8	-	II	1 L	F-A, S-B	274	E2	Category B	SGG18 SG35
							SW2	

IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ

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	8	-	II	851	1 L	855	30 L	A3 A803	E2
	8	-	II	Y840	0.5 L	-	-	A3 A803	E2

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. 2018/1480 (ATP 13)
- EU Regulation No. 1272/2008 amended by EU Regulation No. 2019/521 (ATP 12)

- Container information:

No data available.

- Particular provisions :

No data available.

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

- less than 5 %: phosphonates
- 5 % or over but less than 15 %: cationic surfactants
- 5 % or over but less than 15 %: amphoteric surfactants
- 5 % or over but less than 15 % : nonionic surfactants
- disinfectants

15.2. Chemical safety assessment

No data available.

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.

Version PRO.

Wording of the phrases mentioned in section 3:

H225 Highly flammable liquid and vapour.

H301 Toxic if swallowed. H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

H373 May cause damage to organs through prolonged or repeated exposure .

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:

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: Wassergefahrdungsklasse (Water Hazard Class).

GHS05: Corrosion

GHS07 : Exclamation mark GHS09 : Environment

PBT: Persistent, bioaccumulable and toxic.

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vPvB : Very persistent, very bioaccumulable. SVHC: Substances of very high concern.