

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture  
Product name : Carbolic gentian violet  
Product code : 320960

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

##### 1.2.1. Relevant identified uses

Main use category : For professional use only  
Use of the substance/mixture : In vitro diagnostic medical device.

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

RAL DIAGNOSTICS  
Site Montesquieu  
33650 MARTILLAC - FRANCE  
T 33 05 57 96 04 04 - F 33 05 57 96 04 05  
[commercial@ral-diagnostics.fr](mailto:commercial@ral-diagnostics.fr) - [www.ral-diagnostics.com](http://www.ral-diagnostics.com)

#### 1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD Msida	+356 2545 6504	
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

##### Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

#### 2.3. Other hazards

No additional information available

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### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethyl alcohol substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5 (REACH-no) 01-2119457610-43	1 - 5	Flam. Liq. 2, H225
Phenol	(CAS-No.) 108-95-2 (EC-No.) 203-632-7 (EC Index-No.) 604-001-00-2	< = 1	Muta. 2, H341 Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Oral), H301 STOT RE 2, H373 Skin Corr. 1B, H314
C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride substance listed as REACH Candidate ([4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) [with ≥ 0.1% of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)])	(CAS-No.) 548-62-9 (EC-No.) 208-953-6 (EC Index-No.) 612-204-00-2 (REACH-no) 02-2119824931-38	< = 0,2	Carc. 2, H351 Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

#### Specific concentration limits:

Name	Product identifier	Specific concentration limits
Phenol	(CAS-No.) 108-95-2 (EC-No.) 203-632-7 (EC Index-No.) 604-001-00-2	( 1 ≤ C < 3) Eye Irrit. 2, H319 ( 1 ≤ C < 3) Skin Irrit. 2, H315 ( 3 ≤ C < 100) Skin Corr. 1B, H314

Full text of H-statements: see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

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

No additional information available

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

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

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### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

### 5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

#### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

### 6.2. Environmental precautions

Avoid release to the environment.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.

Other information : Dispose of materials or solid residues at an authorized site.

### 6.4. Reference to other sections

For further information refer to section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place.

Storage temperature : 15 – 25 °C

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

Phenol (108-95-2)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Phenol
IOEL TWA	8 mg/m <sup>3</sup>
IOEL STEL	16 mg/m <sup>3</sup>
IOEL STEL [ppm]	4 ppm
Notes	skin
Regulatory reference	COMMISSION DIRECTIVE 2009/161/EU

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<b>Phenol (108-95-2)</b>	
<b>EU - Biological Limit Value (BLV)</b>	
Local name	Phenol
BLV	120 mg/g creatinine Parameter: phenol - Medium: urine
Regulatory reference	SCOEL List of recommended health-based BLVs and BGVs
<b>Ireland - Occupational Exposure Limits</b>	
Local name	Phenol
OEL TWA [1]	8 mg/m <sup>3</sup>
OEL TWA [2]	2 ppm
OEL STEL	16 mg/m <sup>3</sup>
OEL STEL [ppm]	4 ppm
Notes (IE)	Sk (Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body), IOELV (Indicative Occupational Exposure Limit Values)
Regulatory reference	Chemical Agents Code of Practice 2020
<b>Malta - Occupational Exposure Limits</b>	
Local name	Phenol
OEL TWA	8 mg/m <sup>3</sup>
OEL TWA [ppm]	2 ppm
OEL STEL	16 mg/m <sup>3</sup>
OEL STEL [ppm]	4 ppm
Remark (MT)	Skin # Ġilda
Regulatory reference	S.L.424.24 - Chemical Agents at Work Regulations (L.N.57 of 2018)
<b>United Kingdom - Occupational Exposure Limits</b>	
Local name	Phenol
WEL TWA (OEL TWA) [1]	7.8 mg/m <sup>3</sup>
WEL TWA (OEL TWA) [2]	2 ppm
WEL STEL (OEL STEL)	16 mg/m <sup>3</sup>
WEL STEL (OEL STEL) [ppm]	4 ppm
Remark (WEL)	Sk (Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity)
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE
<b>Ethyl alcohol (64-17-5)</b>	
<b>Ireland - Occupational Exposure Limits</b>	
Local name	Ethanol [Ethyl alcohol]
OEL STEL [ppm]	1000 ppm
Regulatory reference	Chemical Agents Code of Practice 2020
<b>United Kingdom - Occupational Exposure Limits</b>	
Local name	Ethanol
WEL TWA (OEL TWA) [1]	1920 mg/m <sup>3</sup>
WEL TWA (OEL TWA) [2]	1000 ppm
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

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### **8.1.2. Recommended monitoring procedures**

No additional information available

### **8.1.3. Air contaminants formed**

No additional information available

### **8.1.4. DNEL and PNEC**

No additional information available

### **8.1.5. Control banding**

No additional information available

## **8.2. Exposure controls**

### **8.2.1. Appropriate engineering controls**

#### **Appropriate engineering controls:**

Ensure good ventilation of the work station.

### **8.2.2. Personal protection equipment**

#### **Personal protective equipment symbol(s):**



#### **8.2.2.1. Eye and face protection**

<b>Eye protection:</b>
Safety glasses

#### **8.2.2.2. Skin protection**

<b>Skin and body protection:</b>
Wear suitable protective clothing

<b>Hand protection:</b>
Protective gloves

#### **8.2.2.3. Respiratory protection**

<b>Respiratory protection:</b>
In case of insufficient ventilation, wear suitable respiratory equipment

#### **8.2.2.4. Thermal hazards**

No additional information available

### **8.2.3. Environmental exposure controls**

#### **Environmental exposure controls:**

Avoid release to the environment.

## **SECTION 9: Physical and chemical properties**

### **9.1. Information on basic physical and chemical properties**

Physical state	: Liquid
Appearance	: clear.
Colour	: Violet.
Odour	: Phenolic.
Odour threshold	: No data available

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pH	: 4 – 6
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: > 60 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: 4 – 6
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

### **9.2. Other information**

No additional information available

## **SECTION 10: Stability and reactivity**

### **10.1. Reactivity**

The product is non-reactive under normal conditions of use, storage and transport.

### **10.2. Chemical stability**

Stable under normal conditions.

### **10.3. Possibility of hazardous reactions**

No dangerous reactions known under normal conditions of use.

### **10.4. Conditions to avoid**

None under recommended storage and handling conditions (see section 7).

### **10.5. Incompatible materials**

No additional information available

### **10.6. Hazardous decomposition products**

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## **SECTION 11: Toxicological information**

### **11.1 Information on toxicological effects**

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

<b>Phenol (108-95-2)</b>	
LD50 oral rat	650 mg/kg Source: ECHA
LD50 dermal rat	625 mg/kg Source: ECHA
LC50 Inhalation - Rat	900 mg/m <sup>3</sup> 8 Hours

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LC50 Inhalation - Rat (Dust/Mist)	1.27 mg/l Source: ECHA
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LD50 oral	711 mg/kg
LD50 dermal rat	> 6869 mg/kg

### Ethyl alcohol (64-17-5)

LD50 oral rat	15010 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 401 (Acute Oral Toxicity), 95% CL: 14450 - 15560
LD50 oral	8300 mg/kg bodyweight Animal: mouse
LD50 dermal rat	> 2000 mg/kg
LC50 Inhalation - Rat	> 20 mg/l

Skin corrosion/irritation	: Not classified pH: 4 – 6
Serious eye damage/irritation	: Not classified pH: 4 – 6
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

### Phenol (108-95-2)

IARC group	3 - Not classifiable
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### Ethyl alcohol (64-17-5)

IARC group	1 - Carcinogenic to humans
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### C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (548-62-9)

NOAEL (chronic, oral, animal/male, 2 years)	250 mg/kg bodyweight mouse
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Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified

### Phenol (108-95-2)

LOAEL (dermal, rat/rabbit, 90 days)	260 mg/kg bodyweight Animal: rabbit
NOAEL (dermal, rat/rabbit, 90 days)	130 mg/kg bodyweight Animal: rabbit
STOT-repeated exposure	May cause damage to organs through prolonged or repeated exposure.

### Ethyl alcohol (64-17-5)

NOAEL (subchronic, oral, animal/male, 90 days)	< 9700 mg/kg bodyweight Animal: mouse, Animal sex: male, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)
NOAEL (subchronic, oral, animal/female, 90 days)	> 9400 mg/kg bodyweight Animal: mouse, Animal sex: female, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)

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Aspiration hazard : Not classified

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.

Hazardous to the aquatic environment, short-term (acute) : Not classified

Hazardous to the aquatic environment, long-term (chronic) : Not classified

Phenol (108-95-2)	
LC50 - Fish [1]	21.93 mg/l Source: ECHA
EC50 - Crustacea [1]	3.1 mg/l Source: ECHA
EC50 72h - Algae [1]	180 mg/l Test organisms (species): <i>Dunaliella tertiolecta</i>
EC50 72h - Algae [2]	217.6 mg/l Test organisms (species): <i>Dunaliella tertiolecta</i>
EC50 96h - Algae [1]	61.1 mg/l Source: ECHA
NOEC (chronic)	0.16 mg/l Test organisms (species): <i>Daphnia magna</i> Duration: '16 d'
NOEC chronic fish	0.077 mg/l Test organisms (species): other: <i>Cirrhina mrigala</i> Duration: '60 d'
NOEC chronic crustacea	0.46 mg/l

C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (548-62-9)	
LC50 - Fish [1]	82 µg/l
EC50 - Crustacea [1]	350 µg/l
EC50 72h - Algae [1]	0.21 mg/l Test organisms (species): <i>Pseudokirchneriella subcapitata</i> (previous names: <i>Raphidocelis subcapitata</i> , <i>Selenastrum capricornutum</i> )

Ethyl alcohol (64-17-5)	
LC50 - Fish [1]	14.2 g/l Test organisms (species): <i>Pimephales promelas</i>
EC50 72h - Algae [1]	1900 – 1970 mg/l (marine water)
EC50 96h - Algae [1]	275 mg/l (freshwater)
ErC50 algae	275 mg/l Source: ECHA
NOEC (chronic)	9.6 mg/l Test organisms (species): <i>Daphnia magna</i> Duration: '9 d'
NOEC chronic fish	250 mg/l

#### 12.2. Persistence and degradability

Phenol (108-95-2)	
Persistence and degradability	Readily biodegradable.

C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (548-62-9)	
Persistence and degradability	Not readily biodegradable.
BOD (% of ThOD)	0.12 % ThOD
Biodegradation	10 %



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Ethyl alcohol (64-17-5)	
Persistence and degradability	Readily biodegradable.

### 12.3. Bioaccumulative potential

Phenol (108-95-2)	
BCF - Fish [1]	2 mg/l (Danio rerio) - 5h
Bioconcentration factor (BCF REACH)	17.5
Partition coefficient n-octanol/water (Log Pow)	1.46 Source: HSDB

Ethyl alcohol (64-17-5)	
Partition coefficient n-octanol/water (Log Pow)	-0.32 Source: ICSC
Bioaccumulative potential	No bioaccumulation.

### 12.4. Mobility in soil

Phenol (108-95-2)	
Mobility in soil	14 – 73 Source: ECHA

### 12.5. Results of PBT and vPvB assessment

Component	
C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (548-62-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

### 12.6. Other adverse effects

Other adverse effects : Not release to the environment.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container in accordance with licensed collector's sorting instructions.

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.2. UN proper shipping name</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.3. Transport hazard class(es)</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.4. Packing group</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.5. Environmental hazards</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

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### 14.6. Special precautions for user

#### Overland transport

Not regulated

#### Transport by sea

Not regulated

#### Air transport

Not regulated

#### Inland waterway transport

Not regulated

#### Rail transport

Not regulated

### 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

#### 15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains a substance on the REACH candidate list in concentration  $\geq 0.1\%$  or with a lower specific limit: [4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) [with  $\geq 0.1\%$  of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] (EC 208-953-6, CAS 548-62-9)

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

### Indication of changes:

Section	Changed item	Change	Comments
	Supersedes	Modified	
	Revision date	Modified	

### Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level

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DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

### Full text of H- and EUH-statements:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Carc. 2	Carcinogenicity, Category 2
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
Muta. 2	Germ cell mutagenicity, Category 2
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2

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STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H341	Suspected of causing genetic defects.
H351	Suspected of causing cancer.
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.

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.