

ALKAZYME - 10..



## SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 453/2010)

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

#### 1.1. Product identifier

Product name : ALKAZYME

Product code : 10...

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

N/A

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

Registered company name : ALKAPHARM.

Address : Parc Biocitech - 102 avenue Gaston Roussel.93230.ROMAINVILLE.FRANCE.

Telephone : + 33 (0)1.41.50.59.80. Fax : + 33 (0)1.48.30.54.31 .

support.technique@alkapharm.fr

#### 1.4. Emergency telephone number : 01.45.42.59.59.

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.

Skin irritation, Category 2 (Skin Irrit. 2, H315).

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

May produce an allergic reaction (EUH208).

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

This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.

Eye irritation (Xi, R 36).

May produce an allergic reaction.

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

This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

#### 2.2. Label elements

Detergent mixture (see section 15).

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

Hazard pictograms :



GHS05

Signal Word :

DANGER

Product identifiers :

CAS 68439-46-3 ALCOOL ETHOXYLE C9 C11 8 OE

Additional labeling :

EUH208 Contains SUBTILISIN. May produce an allergic reaction.

Hazard statements :

H315 Causes skin irritation.

H318 Causes serious eye damage.

Precautionary statements - General :

P102 Keep out of reach of children.

Precautionary statements - Prevention :

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

**ALKAZYME - 10..**

Precautionary statements - Response :

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.  
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 doctor/physician.  
P362 Take off contaminated clothing and wash before reuse.

**2.3. Other hazards**

In use, may form flammable/explosive dust-air mixture.

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 satisfies 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                                                                                                   | 67/548/EEC                      | Note | %               |
|----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|---------------------------------|------|-----------------|
| INDEX: 011-005-00-2<br>CAS: 497-19-8<br>EC: 207-838-8<br>REACH: 01-2119485498-19<br><br>SODIUM CARBONATE | GHS07<br>Wng<br>Eye Irrit. 2, H319                                                                               | Xi<br>Xi;R36                    |      | 25 <= x % < 50  |
| CAS: 68439-46-3<br><br>ALCOOL ETHOXYLE C9 C11 8 OE                                                       | GHS07, GHS05<br>Dgr<br>Acute Tox. 4, H302<br>Eye Dam. 1, H318                                                    | Xn<br>Xn;R22<br>Xi;R41          |      | 2.5 <= x % < 10 |
| CAS: 7173-51-5<br>EC: 230-525-2<br><br>CHLORURE DE DIDECYL<br>DIMETHYLAMMONIUM                           | GHS06, GHS05, GHS09<br>Dgr<br>Acute Tox. 3, H301<br>Skin Corr. 1B, H314<br>Aquatic Acute 1, H400<br>M Acute = 10 | C,N<br>C;R34<br>Xn;R22<br>N;R50 |      | 2.5 <= x % < 10 |
| INDEX: 603-117-00-0<br>CAS: 67-63-0<br>EC: 200-661-7<br>REACH: 01-2119457558-25<br><br>PROPAN-2-OL       | GHS02, GHS07<br>Dgr<br>Flam. Liq. 2, H225<br>Eye Irrit. 2, H319<br>STOT SE 3, H336                               | Xi,F<br>Xi;R36<br>F;R11<br>R67  | [1]  | 0 <= x % < 2.5  |
| INDEX: 647-012-00-8<br>CAS: 9014-01-1<br>EC: 232-752-2<br>REACH: 01-2119480434-38<br><br>SUBTILISIN      | GHS08, GHS05, GHS07<br>Dgr<br>STOT SE 3, H335<br>Skin Irrit. 2, H315<br>Eye Dam. 1, H318<br>Resp. Sens. 1, H334  | Xn<br>Xn;R42<br>Xi;R37/38-R41   | [1]  | 0 <= x % < 2.5  |

**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 exposure by inhalation :**

In the event of an allergic reaction, seek medical attention.

**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.

If there is any redness, pain or visual impairment, consult an ophthalmologist.

**In the event of splashes or contact with skin :**

Remove contaminated clothing and wash the skin thoroughly with soap and water or a recognised cleaner.

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

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**ALKAZYME - 10..**

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In the event of an allergic reaction, seek medical attention.

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 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.

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**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 (CO<sub>2</sub>)

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 (CO<sub>2</sub>)

**5.3. Advice for firefighters**

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

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**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**

Retrieve the product by mechanical means (sweeping/vacuuming) : do not generate dust.

**6.4. Reference to other sections**

No data available.

**ALKAZYME - 10..**

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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.

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.

Avoid eye contact with this mixture at all times.

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**

N/A

**Storage**

Keep out of reach of children.

Keep the container tightly closed in a dry, 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.

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**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 | -         | -            | -          |

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

| CAS     | VME :     | VME :     | Excess | Notes  |
|---------|-----------|-----------|--------|--------|
| 67-63-0 | 200 ml/m3 | 500 mg/m3 | 2(II)  | DFG, Y |

- France (INRS - ED984 :2008) :

| 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 | -         | -            | -          |
| 9014-01-1 | 0.04 Åg/m3 | -       | -         | -            | -          |

**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.

Before handling powders or dust emission, wear mask goggles in accordance with standard EN166.

Prescription glasses are not considered as protection.

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

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**ALKAZYME - 10..**

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**- Hand protection**

Wear suitable protective gloves in the event of prolonged or repeated skin contact.

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))

Recommended properties :

- Impervious gloves in accordance with standard EN374

**- Body protection**

Avoid skin contact.

Wear suitable protective clothing.

These clothes shall be chosen to ensure there is no inflammation or irritation of the skin at the neck and wrist by contact with the powder

Suitable type of protective clothing :

Wear protective clothing against solid chemicals and particles suspended in the air (type 5) in accordance with standard EN13982-1 to prevent skin contact.

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.

**- Respiratory protection**

Avoid breathing dust.

Type of FFP mask :

Wear a disposable half-mask dust filter in accordance with standard EN149.

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**SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES**

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

**General information :**

Physical state : Powder or dust.

N/A

N/A

**Important health, safety and environmental information**

pH (aqueous solution) : 11.2 +/- 0.5 (0.5%)

pH : Not relevant.

Boiling point/boiling range : Not relevant.

Flash point interval : Not relevant.

Vapour pressure (50°C) : Not relevant.

Density : < 1

Water solubility : Soluble.

Melting point/melting range : Not relevant.

Self-ignition temperature : Not relevant.

Decomposition point/decomposition range : Not relevant.

**9.2. Other information**

No data available.

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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**

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 :

- formation of dusts

**ALKAZYME - 10..**

Dusts can form an explosive mixture with air.

**10.5. Incompatible materials**

**10.6. Hazardous decomposition products**

The thermal decomposition may release/form :

- carbon monoxide (CO)
- carbon dioxide (CO<sub>2</sub>)

**SECTION 11 : TOXICOLOGICAL INFORMATION**

**11.1. Information on toxicological effects**

May cause irreversible damage to the skin; namely inflammation of the skin or the formation of erythema and eschar or oedema following exposure up to four hours.

May have irreversible effects on the eyes, such as tissue damage in the eye, or serious physical decay of sight, which is not fully reversible by the end of observation at 21 days.

Serious eye damage is typified by the destruction of cornea, persistent corneal opacity and iritis.

**11.1.1. Substances**

**Acute toxicity :**

CHLORURE DE DIDECYL DIMETHYLAMMONIUM (CAS: 7173-51-5)

Oral route : LD50 = 238 mg/kg  
Species : Rat (recommended by the CLP)  
OECD Guideline 401 (Acute Oral Toxicity)

Dermal route : LD50 = 3342 mg/kg  
Species : Rabbit (recommended by the CLP)

**Skin corrosion/skin irritation :**

CHLORURE DE DIDECYL DIMETHYLAMMONIUM (CAS: 7173-51-5)

Corrosivity : Causes severe skin burns.

Effect observed : Overall irritation score  
Species : Rabbit (recommended by the CLP)  
OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

**Respiratory or skin sensitisation :**

CHLORURE DE DIDECYL DIMETHYLAMMONIUM (CAS: 7173-51-5)

Buehler Test : Non-sensitiser.  
Species : Others  
Other guideline

**Germ cell mutagenicity :**

CHLORURE DE DIDECYL DIMETHYLAMMONIUM (CAS: 7173-51-5)

Mutagenesis (in vivo) : Negative.  
Species : Rat  
OECD Guideline 475 (Mammalian Bone Marrow Chromosome Aberration Test)

Species : Bacteria  
OECD Guideline 471 (Bacterial Reverse Mutation Assay)

Ames test (in vitro) : Negative.

**11.1.2. Mixture**

**Acute toxicity :**

N/A  
N/A

**Skin corrosion/skin irritation :**

N/A

**Serious damage to eyes/eye irritation :**

N/A

**ALKAZYME - 10..**

**Respiratory or skin sensitisation :**

Contains at least one sensitising substance. May cause an allergic reaction.

N/A

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

CAS 67-63-0 : IARC Group 3 : The agent is not classifiable as to its carcinogenicity to humans.

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**SECTION 12 : ECOLOGICAL INFORMATION**

**12.1. Toxicity**

**12.1.1. Substances**

CHLORURE DE DIDECYL DIMETHYLAMMONIUM (CAS: 7173-51-5)

Fish toxicity : LC50 = 0.19 mg/l  
Factor M = 1  
Species : Pimephales promelas  
Duration of exposure : 96 h  
Other guideline

Crustacean toxicity : EC50 = 0.062 mg/l  
Factor M = 10  
Species : Daphnia magna  
Duration of exposure : 48 h  
Other guideline

Algae toxicity : ECr50 = 0.026 mg/l  
Factor M = 10  
Species : Pseudokirchnerella subcapitata  
Duration of exposure : 96 h  
OECD Guideline 201 (Alga, Growth Inhibition Test)

**12.1.2. Mixtures**

Fish toxicity : No observed effect.  
10 < LC50 ≤ 100 mg/l  
Species : Danio rerio  
Duration of exposure : 96 h  
OECD Guideline 203 (Fish, Acute Toxicity Test)  
EC50 = 2.9 mg/l  
Duration of exposure : 48 h  
ISO 6341 15 (Water quality - Determination of the Inhibition of the Mobility of Daphnia magna Straus (Cladocera, Crustacea))  
ECr50 = 39.6 mg/l  
Duration of exposure : 72 h  
ISO 8692 (Water Quality - Fresh Water Algal Growth Inhibition Test with Scenedesmus subspicatus and Selenastrum capricornutum)  
EC10 = 6.4 mg/l  
Duration of exposure : 72 h  
ISO 8692 (Water Quality - Fresh Water Algal Growth Inhibition Test with Scenedesmus subspicatus and Selenastrum capricornutum)

**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.

N/A

**12.2.1. Substances**

CHLORURE DE DIDECYL DIMETHYLAMMONIUM (CAS: 7173-51-5)

Biodegradability : Rapidly degradable.

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**ALKAZYME - 10..**

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**12.2.2. Mixtures**

no degradability data is available, the substance is considered as not degrading quickly.

Biodegradability :

Biodegradability in water : Easily biodegradable.  
Aerobic.

N/A

**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.

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**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.

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**SECTION 14 : TRANSPORT INFORMATION**

Exempt from transport classification and labelling.

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2013 - IMDG 2012 - ICAO/IATA 2014).

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**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:

- Directive 67/548/EEC and its adaptations
- Directive 1999/45/EC and its adaptations
- Regulation EC 1272/2008 modified by regulation EC 618/2012
- EU Regulation No. 1272/2008 amended by EU Regulation No. 758/2013.

**- Container information:**

No data available.

**- Particular provisions :**

No data available.

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

- 30 % and more : phosphates
- 5 % or over but less than 15 % : cationic surfactants
- 5 % or over but less than 15 % : nonionic surfactants
- enzymes
- disinfectants
- perfumes

**15.2. Chemical safety assessment**



**ALKAZYME - 10..**

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.

**In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.**

Hazard symbols :



Irritant

Contains :

Contains 647-012-00-8 SUBTILISIN. May produce an allergic reaction.

Risk phrase :

R 36 Irritating to eyes.

Safety phrase :

S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 60 This material and its container must be disposed of as hazardous waste.

S 2 Keep out of the reach of children.

**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.                                   |
| H315    | Causes skin irritation.                                                    |
| H318    | Causes serious eye damage.                                                 |
| H319    | Causes serious eye irritation.                                             |
| H334    | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| H335    | May cause respiratory irritation.                                          |
| H336    | May cause drowsiness or dizziness.                                         |
| H400    | Very toxic to aquatic life.                                                |
| R 11    | Highly flammable.                                                          |
| R 22    | Harmful if swallowed.                                                      |
| R 34    | Causes burns.                                                              |
| R 36    | Irritating to eyes.                                                        |
| R 37/38 | Irritating to respiratory system and skin.                                 |
| R 41    | Risk of serious damage to eyes.                                            |
| R 42    | May cause sensitization by inhalation.                                     |
| R 50    | Very toxic to aquatic organisms.                                           |
| R 67    | Vapours may cause drowsiness and dizziness.                                |

**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 : Wassergefährdungsklasse (Water Hazard Class).

GHS05 : Corrosion