

Anpak Orthopedic



SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2020/878)

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

1.1. Product identifier

Product name : Anpak Orthopedic

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

Sector of use (SU)

SU3 - Industrial uses

1.3. Details of the supplier of the safety data sheet

Registered company name : Saint-Gobain Rigips Alci Sanayi .

Address : Ilkbahar Mahallesi, 606. Sokak, No:8.06550.Cankaya Ankara .Turkiye.

Telephone : +90 (312) 463 63 63. Fax : +90 (312) 463 63 64.

<http://www.rshm.gov.tr/en/>

Information contact : [msds-formula@saint-gobain.com](mailto:msds-formula@saint-gobain.com)

1.4. Emergency telephone number : +90 0312 433 70 01.

Association/Organisation : Toxicology Department and Poisons Centre .

Other emergency numbers

UK : NHS - phone number 111 - Email : [sds.npis@nhs.net](mailto:sds.npis@nhs.net) / Ireland : National Poisons Information Centre - phone number : (01) 809 3000 - Email : [chemicalsinfo@beaumont.ie](mailto:chemicalsinfo@beaumont.ie)

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

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 a health hazard with the exception of possible occupational exposure thresholds (see paragraphs 3 and 8).

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

2.2. Label elements

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

No labelling requirements for this mixture.

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.

The mixture does not contain substances  $\geq 0.1\%$  with endocrine disrupting properties in accordance with the criteria of the Delegated Regulation (EU) 2017/2100 of the Commission or Regulation (EU) 2018/605 of the Commission.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Composition :

Identification	(EC) 1272/2008	Note	%
INDEX: PLATRE 1 CAS: 7778-18-9 EC: 231-900-3 REACH: 1-2119444918-26  CALCIUM SULPHATE		[1]	50 $\leq$ x % < 100
INDEX: GYPSE 2 CAS: 7778-18-9 EC: 2319003 REACH: 1-2119444918-26  CALCIUM SULFATE CASO4 + 2H2O		[1]	0 $\leq$ x % < 2.5

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.

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

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

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

#### In the event of swallowing :

Seek medical attention, showing the label.

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

No specific symptoms or effects have been reported.

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

None

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## SECTION 5 : FIREFIGHTING MEASURES

Non-flammable.

### 5.1. Extinguishing media

#### Suitable methods of extinction

Any means suitable for extinguishing surrounding fire.

#### Unsuitable methods of extinction

None.

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

None.

### 5.3. Advice for firefighters

Special protective equipment for fire-fighters: None.

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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 first aid worker

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

### 6.2. Environmental precautions

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

None.

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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.

#### 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.

#### Prohibited equipment and procedures :

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

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

No data available.

**Storage**

Store dry

**Packaging**

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

**7.3. Specific end use(s)**

See instructions for use

**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 :
7778-18-9	10 (l) mg/m <sup>3</sup>				
7778-18-9	10 (l) mg/m <sup>3</sup>				

- Germany - AGW (BAuA - TRGS 900, 02/2022) :

CAS	VME :	VME :	Excess	Notes
7778-18-9		6A mg/m <sup>3</sup>		
7778-18-9		6A mg/m <sup>3</sup>		

- Belgium (Royal decree of 11/05/2021) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
7778-18-9	10 mg/m <sup>3</sup>				
7778-18-9	10 mg/m <sup>3</sup>				

- France (INRS - Outils 65 / 2021-1849, 2021-1763, decree of 09/12/2021) :

CAS	VME-ppm :	VME-mg/m <sup>3</sup> :	VLE-ppm :	VLE-mg/m <sup>3</sup> :	Notes :	TMP No :
7778-18-9	-	10	-	-	-	-
7778-18-9	-	10	-	-	-	-

- Spain (Instituto Nacional de Seguridad e Higiene en el Trabajo (INSHT), 2019) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
7778-18-9	10 mg/m <sup>3</sup>			e	
7778-18-9	10 mg/m <sup>3</sup>			e	

**Derived no effect level (DNEL) or derived minimum effect level (DMEL):**CALCIUM SULFATE CASO<sub>4</sub> + 2H<sub>2</sub>O (CAS: 7778-18-9)**Final use:**

Exposure method: Inhalation.  
Potential health effects: Short term systemic effects.  
DNEL : 5082 mg of substance/m<sup>3</sup>

**Workers.**

Exposure method: Inhalation.  
Potential health effects: Long term systemic effects.  
DNEL : 21.17 mg of substance/m<sup>3</sup>

**Final use:**

Exposure method: Ingestion.  
Potential health effects: Short term systemic effects.  
DNEL : 11.4 mg/kg body weight/day

**Man exposed via the environment.**

Exposure method: Ingestion.  
Potential health effects: Long term systemic effects.  
DNEL : 1.52 mg/kg body weight/day

Exposure method: Inhalation.  
Potential health effects: Short term systemic effects.  
DNEL : 3811 mg of substance/m<sup>3</sup>

Exposure method: Inhalation.  
Potential health effects: Long term systemic effects.  
DNEL : 5.29 mg of substance/m<sup>3</sup>

CALCIUM SULPHATE (CAS: 7778-18-9)

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**Final use:**

Exposure method: Inhalation.  
Potential health effects: Short term systemic effects.  
DNEL : 5082 mg of substance/m3

Exposure method: Inhalation.  
Potential health effects: Long term systemic effects.  
DNEL : 21.17 mg of substance/m3

**Final use:**

Exposure method: Ingestion.  
Potential health effects: Short term systemic effects.  
DNEL : 11.4 mg/kg body weight/day

Exposure method: Ingestion.  
Potential health effects: Long term systemic effects.  
DNEL : 1.52 mg/kg body weight/day

Exposure method: Inhalation.  
Potential health effects: Short term systemic effects.  
DNEL : 3811 mg of substance/m3

Exposure method: Inhalation.  
Potential health effects: Long term systemic effects.  
DNEL : 5.29 mg of substance/m3

**Workers.**

**Man exposed via the environment.**

**Predicted no effect concentration (PNEC):**

CALCIUM SULFATE CASO<sub>4</sub> + 2H<sub>2</sub>O (CAS: 7778-18-9)  
Environmental compartment: Waste water treatment plant.  
PNEC : 100 mg/l

CALCIUM SULPHATE (CAS: 7778-18-9)  
Environmental compartment: Waste water treatment plant.  
PNEC : 100 mg/l

**8.2. Exposure controls**

**Personal protection measures, such as personal protective equipment**

Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE) :



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.

**- Hand protection**

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

Type of gloves recommended :

- Natural latex
- Nitrile rubber (butadiene-acrylonitrile copolymer rubber (NBR))
- PVC (polyvinyl chloride)
- Butyl Rubber (Isobutylene-isoprene copolymer)

**- Body protection**

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 inhaling dust.

Type of FFP mask :

Wear a disposable half-mask dust filter in accordance with standard EN149/A1.

## SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

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

#### Physical state

Physical state : Powder or dust.

#### Colour

Colour: Colour varies white. beige. light yellow. grey or reddish tinge or brick red

#### Odour

Odour threshold : Not stated.

Odour threshold : neutral

#### Melting point

Melting point/melting range : Not relevant.

#### Freezing point

Freezing point / Freezing range : Not stated.

#### Boiling point or initial boiling point and boiling range

Boiling point/boiling range : Not relevant.

#### Flammability

Flammability (solid, gas) : Not stated.

#### Lower and upper explosion limit

Explosive properties, lower explosivity limit (%) : Not stated.

Explosive properties, upper explosivity limit (%) : Not stated.

#### Flash point

Flash point interval : Not relevant.

#### Auto-ignition temperature

Self-ignition temperature : Not relevant.

#### Decomposition temperature

Decomposition point/decomposition range : Not relevant.

#### pH

pH (aqueous solution) : Not stated.

pH : Not relevant.

#### Kinematic viscosity

Viscosity : Not stated.

#### Solubility

Water solubility : Soluble.

Fat solubility : Not stated.

#### Partition coefficient n-octanol/water (log value)

Partition coefficient: n-octanol/water : Not stated.

#### Vapour pressure

Vapour pressure (50°C) : Not relevant.

#### Density and/or relative density

Density : Not stated.

#### Relative vapour density

Vapour density : Not stated.

### 9.2. Other information

No data available.

#### 9.2.1. Information with regard to physical hazard classes

No data available.

#### 9.2.2. Other safety characteristics

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

No data available.

### 10.4. Conditions to avoid

Avoid :

- formation of dusts

### 10.5. Incompatible materials

No data available.

### 10.6. Hazardous decomposition products

No data available.

## SECTION 11 : TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

No data available.

#### 11.1.1. Substances

##### Acute toxicity :

CALCIUM SULFATE CASO<sub>4</sub> + 2H<sub>2</sub>O (CAS: 7778-18-9)

Oral route : LD50 > 2000 mg/kg  
Species : Rat  
OECD Guideline 420 (Acute Oral ToxicityFixed Dose Method)

Inhalation route (n/a) : LC50 > 2.61 mg/l  
Species : Rat  
OECD Guideline 403 (Acute Inhalation Toxicity)

CALCIUM SULPHATE (CAS: 7778-18-9)

Oral route : LD50 > 2000 mg/kg  
Species : Rat  
OECD Guideline 420 (Acute Oral ToxicityFixed Dose Method)

Inhalation route (n/a) : LC50 > 2.61 mg/l  
Species : Rat  
OECD Guideline 403 (Acute Inhalation Toxicity)

##### Skin corrosion/skin irritation :

CALCIUM SULFATE CASO<sub>4</sub> + 2H<sub>2</sub>O (CAS: 7778-18-9)

Species : Rabbit  
OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Species : Rabbit  
OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

CALCIUM SULPHATE (CAS: 7778-18-9)

Species : Rabbit  
OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Species : Rabbit  
OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

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

CALCIUM SULFATE CASO<sub>4</sub> + 2H<sub>2</sub>O (CAS: 7778-18-9)

Species : Rabbit  
OECD Guideline 405 (Acute Eye Irritation / Corrosion)

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Species : Rabbit  
OECD Guideline 405 (Acute Eye Irritation / Corrosion)

Species : Rabbit  
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**CALCIUM SULPHATE (CAS: 7778-18-9)**

Species : Rabbit  
OECD Guideline 405 (Acute Eye Irritation / Corrosion)

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Species : Rabbit  
OECD Guideline 405 (Acute Eye Irritation / Corrosion)

**Respiratory or skin sensitisation :**

**CALCIUM SULFATE CASO<sub>4</sub> + 2H<sub>2</sub>O (CAS: 7778-18-9)**

Local lymph node stimulation test : Non-Sensitiser.  
Species : Guinea pig  
OECD Guideline 406 (Skin Sensitisation)

Guinea Pig Maximisation Test (GMPT) : Non-sensitiser.  
Species : Guinea pig  
OECD Guideline 406 (Skin Sensitisation)

Buehler Test : Non-sensitiser.  
Species : Guinea pig  
OECD Guideline 406 (Skin Sensitisation)

**CALCIUM SULPHATE (CAS: 7778-18-9)**

Local lymph node stimulation test : Non-Sensitiser.  
Species : Guinea pig  
OECD Guideline 406 (Skin Sensitisation)

Guinea Pig Maximisation Test (GMPT) : Non-sensitiser.  
Species : Guinea pig  
OECD Guideline 406 (Skin Sensitisation)

Buehler Test : Non-sensitiser.  
Species : Guinea pig  
OECD Guideline 406 (Skin Sensitisation)

**Germ cell mutagenicity :**

**CALCIUM SULFATE CASO<sub>4</sub> + 2H<sub>2</sub>O (CAS: 7778-18-9)**

No mutagenic effect.

Mutagenesis (in vivo) : Negative.  
Species : Mouse  
OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)

Mutagenesis (in vitro) : Negative.  
OECD Guideline 471 (Bacterial Reverse Mutation Assay)

**CALCIUM SULPHATE (CAS: 7778-18-9)**

No mutagenic effect.

Mutagenesis (in vivo) : Negative.  
Species : Mouse

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OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)  
Mutagenesis (in vitro) : Negative.  
OECD Guideline 471 (Bacterial Reverse Mutation Assay)

**Carcinogenicity :**

CALCIUM SULFATE CASO<sub>4</sub> + 2H<sub>2</sub>O (CAS: 7778-18-9)  
Carcinogenicity Test : Negative.  
No carcinogenic effect.

CALCIUM SULPHATE (CAS: 7778-18-9)  
Carcinogenicity Test : Negative.  
No carcinogenic effect.

**Reproductive toxicant :**

CALCIUM SULFATE CASO<sub>4</sub> + 2H<sub>2</sub>O (CAS: 7778-18-9)  
No toxic effect for reproduction  
Study on development : Species : Rat  
OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the  
Reproduction / Developmental Toxicity Screening Test)

CALCIUM SULPHATE (CAS: 7778-18-9)  
No toxic effect for reproduction  
Study on development : Species : Rat  
OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the  
Reproduction / Developmental Toxicity Screening Test)

**11.1.2. Mixture**

No toxicological data available for the mixture.

**11.2. Information on other hazards**

**SECTION 12 : ECOLOGICAL INFORMATION**

**12.1. Toxicity**

**12.1.1. Substances**

CALCIUM SULFATE CASO<sub>4</sub> + 2H<sub>2</sub>O (CAS: 7778-18-9)  
Fish toxicity : LC50 > 79 mg/l  
Species : Others  
Duration of exposure : 96 h  
OECD Guideline 203 (Fish, Acute Toxicity Test)

Crustacean toxicity : EC50 > 79 mg/l  
Species : Daphnia sp.  
Duration of exposure : 48 h  
OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

Algae toxicity : ECr50 > 79 mg/l  
Species : Scenedesmus capricornutum  
Duration of exposure : 72 h  
OECD Guideline 201 (Alga, Growth Inhibition Test)

CALCIUM SULPHATE (CAS: 7778-18-9)  
Fish toxicity : LC50 > 79 mg/l  
Species : Others  
Duration of exposure : 96 h  
OECD Guideline 203 (Fish, Acute Toxicity Test)

Crustacean toxicity : EC50 > 79 mg/l  
Species : Daphnia sp.  
Duration of exposure : 48 h  
OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

Algae toxicity : ECr50 > 79 mg/l  
Species : Selenastrum capricornutum



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Duration of exposure : 72 h  
OECD Guideline 201 (Alga, Growth Inhibition Test)

**12.1.2. Mixtures**

No aquatic toxicity data available for the mixture.

**12.2. Persistence and degradability**

Abiotic Degradation Physical- and photo-chemical elimination: The product hydrolyses quickly in the presence of water to: Calcium and Sulfate Ions The individual components are poorly eliminated from water.

Inorganic product which is not eliminable from water through biological cleaning processes.

**12.2.1. Substances**

CALCIUM SULFATE CASO<sub>4</sub> + 2H<sub>2</sub>O (CAS: 7778-18-9)

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

CALCIUM SULPHATE (CAS: 7778-18-9)

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

**12.3. Bioaccumulative potential**

Based on the n-octanol/water partition coefficient significant accumulation in organisms is not expected. No indication to bioaccumulation potential. The ecological data were measured on the hydrolysed product. According to experiences this product is inert and not degradable biologically.

**12.4. Mobility in soil**

Water-soluble solid. Natural constituent in soils. If product enters soil, it will be mobile and may contaminate groundwater

**12.5. Results of PBT and vPvB assessment**

This substance does not meet the criteria for classification as PBT or vPvB.

**12.6. Endocrine disrupting properties**

No data available.

**12.7. Other adverse effects**

According to the criteria of the European classification and labelling system, the substance/the product has not to be labelled as dangerous for the environment.

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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 codes / waste designations according to EWC

10 12 wastes from manufacture of ceramic goods, bricks, tiles and construction products

10 12 06 discarded moulds

**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.

**14.1. UN number or ID number**

-

**14.2. UN proper shipping name**

-

**14.3. Transport hazard class(es)**

-

**14.4. Packing group**

-

**14.5. Environmental hazards**

-

#### 14.6. Special precautions for user

-

#### 14.7. Maritime transport in bulk according to IMO instruments

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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:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 2022/692 (ATP 18)

##### - Container information:

The mixture does not contain any substance restricted under Annex XVII of Regulation (EC) No. 1907/2006 (REACH): <https://echa.europa.eu/substances-restricted-under-reach>.

##### - Particular provisions :

No data available.

#### 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.

#### Abbreviations :

LD50 : The dose of a test substance resulting in 50% lethality in a given time period.

LC50 : The concentration of a test substance resulting in 50% lethality in a given period.

EC50 : The effective concentration of substance that causes 50% of the maximum response.

ECr50 : The effective concentration of substance that causes 50% reduction in growth rate.

REACH : Registration, Evaluation, Authorization and Restriction of Chemical Substances.

DNEL : Derived No-Effect Level

PNEC : Predicted No-Effect Concentration

STEL : Short-term exposure limit

TWA : Time Weighted Averages

TMP : French Occupational Illness table

TLV : Threshold Limit Value (exposure)

AEV : Average Exposure Value.

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.

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.