



SECTION 1: IDENTIFICATION	
<b>1.1 Product identifier</b>	
<b>Product name:</b>	Clavudale® (Tablets for cats and dogs). Available as 40mg/10mg, 200mg/50mg and 400mg/100mg.
<b>Synonyms:</b>	Not Available
<b>Proper Shipping name:</b>	Not Available
<b>Other means of identification:</b>	None
<b>1.2 Relevant identified uses of the substances or mixture and uses advised against</b>	
<b>Recommended uses:</b>	<p>For the treatment of bacterial infections susceptible to amoxicillin in combination with clavulanic acid where clinical experience and/or sensitivity testing indicates the product as the drug of choice.</p> <p>Uses include:</p> <ul style="list-style-type: none"> <li>• Skin infections (including deep and superficial pyodermas) associated with <i>Staphylococcus</i> spp. and <i>Streptococcus</i> spp.;</li> <li>• Infections of the oral cavity (mucous membrane) associated with <i>Clostridium</i> spp., <i>Corynebacterium</i> spp., <i>Staphylococcus</i> spp., <i>Streptococcus</i> spp., <i>Bacteroides</i> spp. and <i>Pasteurella</i> spp.;</li> <li>• Urinary tract infections associated with <i>Staphylococcus</i> spp., <i>Streptococcus</i> spp., <i>Escherichia coli</i> and <i>Proteus mirabilis</i>; Respiratory tract infections associated with <i>Staphylococcus</i> spp., <i>Streptococcus</i> spp., and <i>Pasteurella</i> spp.</li> <li>• Gastrointestinal infections associated with <i>Escherichia coli</i> and <i>Proteus mirabilis</i>.</li> </ul>
<b>Uses advised against:</b>	<p>Not for human use.</p> <p>Do not use in rabbits, guinea pigs, hamsters and gerbils.</p> <p>Do not use in animals with known hypersensitivity to penicillin or substances of the <math>\beta</math>-lactam group or any of the excipients.</p> <p>Do not use in animals with either oliguria or anuria associated with renal dysfunction.</p> <p>Do not use in cases of known resistance to the combination of amoxicillin and clavulanic acid.</p> <p>Do not handle this product if you know you are sensitized, or if you have been advised not to work with such preparations.</p>
<b>1.3 Details of the supplier of the substance or mixture</b>	
<b>Registered company name:</b>	Dechra Ltd



<b>Address:</b>	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK
<b>Telephone:</b>	+44 (0) 1756 791311
<b>Fax:</b>	+44 (0) 1756 798604
<b>Email:</b>	Not available
<b>1.4 Emergency Telephone Numbers</b>	
	+44 (0) 1756 791311

<b>SECTION 2: HAZARDS IDENTIFICATION</b>	
<b>2.1 Classification of the substance or mixture</b>	
<b>DSD Classification (EU):</b>	Not Available
<b>DPD Classification (EU)<sup>1</sup>:</b>	Not Available
<b>Classification according to regulation (EC) No 1272/2008 [CLP] (EU)<sup>1</sup>:</b>	Not Available
<b>2.2 Label Elements</b>	
<b>Signal Word:</b>	<b>WARNING</b>
<b>Hazard Statement(s)</b>	
Not available	
<b>Precautionary Statement(s) Prevention:</b>	
Not available	
<b>Precautionary Statement(s) Response:</b>	
Not available	
<b>Precautionary Statement(s) Storage:</b>	
Not available	
<b>Precautionary Statement(s) Disposal:</b>	
Not available	
<b>2.3 Other Hazard Information</b>	
Not available	



**SECTION 3: INFORMATION ON THE INGREDIENTS**

**3.1 Substances**

See section below for composition of mixtures

**3.2 Mixtures**

1.CAS No 2.EC Number 3.Index Number 4.REACH Number	% w/v	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 61336-70-7 2. Not Available 3. Not Available 4. Not Available	0.4 / 2.0 / 4.0	Amoxicillin (as Amoxicillin Trihydrate)	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Irritation Category 2, Respiratory Sensitizer Category 1, Skin Sensitization Category 1, STOT-SE (Resp. Irr.) Category 3; H315, H319, H334, H317, H335 <sup>1</sup>
1. 61177-45-5 2. 262-640-9 3. Not Available 4. Not Available	0.1 / 0.5 / 1.0	Clavulanic acid (as potassium clavulanate)	Not Applicable
N/a	Proprietary	Other ingredients determined not to be hazardous	N/a
<b>Legend:</b> 1. Classified by Chemwatch			

**SECTION 4: FIRST AID MEASURES**

**4.1 Description of first aid measures**

<b>Eye contact:</b>	In case of accidental contact of the product with the eyes rinse abundantly with fresh water. Seek medical attention, showing the package leaflet or the label to the medical practitioner.
<b>Skin contact:</b>	In case of accidental contact of the product with the skin, rinse abundantly with fresh water. If symptoms develop following exposure such as a skin rash, seek medical advice and show the medical practitioner this warning, along with the package leaflet or label.
<b>Inhalation:</b>	Unlikely to be a hazard due to the physical nature of the product. If difficulty in breathing develops or persists, seek medical attention.
<b>Ingestion:</b>	Never attempt to induct vomiting. Do not attempt to give any solid



	or liquid by mouth if the exposed subject is unconscious to semi-conscious. Wash out the mouth with water. If subject is fully conscious, give plenty of water to drink. Seek medical attention, showing the package leaflet or the label to the medical practitioner.
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**4.2 Most important symptoms and effects, both acute and delayed**

See Section 11

**4.3 Indication of immediate medical attention and special treatment needed**

Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Allergic reactions (skin reactions, anaphylaxis), blood dyscrasia and colitis may occasionally occur. In these cases, give symptomatic treatment.

**SECTION 5: FIRE FIGHTING MEASURES**

**5.1 Extinguishing media**

<b>Suitable:</b>	Water spray, carbon dioxide, dry chemical and foam, as appropriate for surrounding fire and materials.
<b>Unsuitable:</b>	None.

**5.2 Special hazards arising from the substance or mixture**

<b>Fire incompatibility:</b>	None known
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**5.3 Special protective actions for fire-fighters:**

<b>Firefighting:</b>	Alert Fire Brigade and tell them location and nature of hazard. Wear full breathing apparatus and self-contained breathing apparatus.
<b>Fire / explosion hazard:</b>	Non-flammable.  Hazardous combustion products: can emit toxic fumes (for bulk active).

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

**6.1 Personal precautions, protective equipment and emergency procedures**

For information on protective equipment, see section 8.

**6.2 Environmental Precautions**

Do not allow product to reach drains, sewage systems or any waterways.

**6.3 Methods and material for containment and cleaning up**

<b>Minor Spills:</b>	Flush residues and small spillages to waste with copious quantities of water.
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<b>Major Spills:</b>	Clean up all spills immediately. Large spills should be collected into an appropriate container for waste disposal. Control personal contact with the substance, by using protective equipment such as gloves and eye protection.
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## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

<b>Safe Handling:</b>	Handle this product with great care to avoid exposure, taking all recommended precautions. Wash hands immediately after administration of the product. When handling, <b>DO NOT</b> eat, drink or smoke. Observe manufacturer's storage and handling recommendations.
<b>Other Information:</b>	Keep out of the reach and sight of children. The tablet can be divided into halves.

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

<b>Suitable Container:</b>	Do not store above 25°C. Protect from light. Shelf life of the veterinary medicinal product as packaged for sale: 3 years. Shelf life after first opening the immediate packaging: 12 hours. Any divided tablet portions remaining after 12 hours should be discarded. Divided tablets should be stored in the blister pack.
<b>Storage incompatibility:</b>	None known.

### 7.3 Specific end uses

Not available
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## SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 Control parameters

#### DERIVED NO EFFECT LEVEL - DNEL

Not Available
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#### PREDICTED NO EFFECT LEVEL - PNEC

Not Available
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#### OCCUPATIONAL EXPOSURE LIMITS (OEL)

<b>INGREDIENT DATA:</b>
Not Available

<b>EMERGENCY LIMITS:</b>
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Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
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Not Available
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Ingredient	Original IDLH	Revised IDLH
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Not Available
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<b>8.2 Exposure controls</b>
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<b>Appropriate engineering controls:</b>	The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.
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<b>Personal protection:</b>	
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<b>Eye and face protection:</b>	Safety glasses with side shields / chemical goggles
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<b>Skin protection:</b>	See hand protection below
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<b>Hands/ feet protection:</b>	No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves
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<b>Body protection:</b>	Wear appropriate clothing
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<b>Other protection:</b>	No special equipment needed when handling small quantities
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<b>Thermal hazards:</b>	Not applicable
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<b>Respiratory protection:</b>	Not applicable
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<b>8.3 Environmental exposure controls</b>
See Section 12



**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

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

**Appearance:** Clavudale®: Pink, oblong, scored, meat flavoured tablets. The tablet can be divided into halves.  
 Amoxicillin Trihydrate: white or almost white crystalline powder  
 Potassium Clavulanate: white or almost white, hygroscopic, crystalline powder

**Container:** Polypropylene tubs with a low density polyethylene cap (push-fit) with a tamper evident ring, containing 500 or 1000 tablets.

**Physical state:** Solid

**Odour:** Not available

**Odour Threshold:** Not available

**pH (as supplied):** Not available

**Melting point / freezing point (degrees C):** Not available

**Initial boiling point and boiling range:** Not available

**Flash Point:** Not available

**Evaporation rate:** Not available

**Flammability:** Not available

**Upper/lower flammability or explosive limits:** Not available

**Vapour pressure:** Not available

**Relative Density (at degrees C):** Not available

**Solubility in water and solvents (mg/l):** Amoxicillin Trihydrate: slightly soluble in water  
 Potassium Clavulanate: Freely soluble in water

**Vapour density:** Not available

**Auto ignition temperature (degrees C):** Not available

**Decomposition temperature (degrees C):** Not available

**Viscosity: (degrees C):** Not available

**Explosive properties:** Not available

**Oxidising properties:** Not available

**Partition Coefficient:** Not available

**Molecular weight:** Amoxicillin Trihydrate: Not available  
 Potassium Clavulanate: 237.27

**Taste:** Meat-flavoured tablets.

**Surface tension:** Not available

**Volative component:** Not available

**Gas group:** Not available

**pH as a solution:** Not available

**VOC g/L:** Not available

**9.2 Other information**  
 Not Available

**10: REACTIVITY AND STABILITY**

<b>10.1 Reactivity:</b>	See Section 7.
<b>10.2 Chemical stability:</b>	Product is considered stable.
<b>10.3 Possibility of hazardous reactions:</b>	Stable under normal temperatures and conditions.



<b>10.4 Conditions to avoid:</b>	See section 7.
<b>10.5 Incompatible materials:</b>	See section 7.
<b>10.6 Hazardous decomposition:</b>	See Section 5.

**SECTION 11: TOXICOLOGICAL INFORMATION**

<b>Inhalation:</b>	Possibility of hypersensitivity following inhalation.	
<b>Ingestion:</b>	Mild gastrointestinal signs (diarrhoea and vomiting) may occur after administration of the product. Allergic reactions to these substances may occasionally be serious.	
<b>Skin contact:</b>	Possibility of an allergic reaction following skin contact. Allergic reactions to these substances may occasionally be serious.	
<b>Eye contact:</b>	Possibility of an allergic reaction following eye contact. Allergic reactions to these substances may occasionally be serious.	
<b>Chronic:</b>	Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa.  Allergic reactions (skin reactions, anaphylaxis), blood dyscrasia and colitis may occasionally occur.	
<b>Clavudale®:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Not Available	Not Available
<b>Amoxicillin Trihydrate:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Not Available	Not Available
<b>Potassium Clavulanate:</b>	<b>Acute toxicity</b>	<b>Irritation</b>
	Oral (rat) LD <sub>50</sub> : 7936 mg/kg <sup>1</sup>	Not Available

1. \* Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances.

<b>Skin corrosion / irritation:</b>
Not expected to cause skin corrosion or irritation.
<b>Serious eye damage / irritation:</b>
Not expected to cause serious eye damage or irritation.
<b>Respiratory or skin sensitization:</b>
May cause allergic reactions or hypersensitivity in some people.





<b>Germ cell mutagenicity:</b>
Not thought to produce any mutagenic potential.
<b>Carcinogenicity:</b>
Not thought to produce any carcinogenic potential.
<b>Reproductive toxicity:</b>
Laboratory studies in rats and mice have not produced any evidence of teratogenic or foetotoxic effects. No studies have been conducted in pregnant or lactating dogs or cats.
<b>STOT – single exposure:</b>
Not available
<b>STOT–repeated exposure:</b>
Not available
<b>Aspiration hazard:</b>
Not available

SECTION 12: ECOLOGICAL INFORMATION		
<b>12.1 Toxicity</b>		
No data available for ingredients		
<b>12.2 Persistence and degradability</b>		
Ingredient	Persistence: Water/soil	Persistence: Air
Amoxicillin Trihydrate	HIGH	HIGH
Potassium Clavulanate	Not available	Not available
<b>12.3 Bioaccumulative potential</b>		
Ingredient	Bioaccumulation	
Amoxicillin Trihydrate	LOW (LogKOW = 0.87)	
Potassium Clavulanate	Not available	
<b>12.4 Mobility in Soil</b>		
Ingredient	Mobility	
Amoxicillin Trihydrate	LOW (KOC = 865.5)	
Potassium Clavulanate	Not available	



<b>12.5 Results of PBT and vPvB assessment</b>
Not Available
<b>12.6 Other adverse effects</b>
Not Available

**SECTION 13: DISPOSAL CONSIDERATIONS**

<b>13.1 Waste treatment methods</b>	
<b>Product / packaging disposal:</b>	Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.  Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.  Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.
<b>Waste Treatment Options:</b>	Not Available
<b>Sewage Disposal Options:</b>	Not Available

**SECTION 14: TRANSPORT INFORMATION**

<b>Labels required:</b>	None	
<b>Marine pollutant:</b>	NO	
<b>Hazchem:</b>	Not Applicable	
<b>Land transport (ADR):</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	Class	N/a
	Sub risk	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazards</b>	N/a	



<b>14.6 Special precautions for user</b>	Special provisions	N/a
	Classification code	N/a
	Hazard Label	N/a
	Special provisions	N/a
	Limited quantity	N/a
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a	
<b>Air transport (ICAO-IATA / DGR):</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazards</b>	N/a	
<b>14.6 Special precautions for user</b>	Special provisions	N/a
	Cargo only packing instructions	N/a
	Cargo only maximum qty/pack	N/a
	Passenger and cargo packaging instructions	N/a
	Passenger and cargo maximum qty/pack	N/a
	Passenger and cargo limited quantity packing instructions	N/a
	Passenger and cargo limited maximum qty/pack	N/a



<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a	
<b>Sea transport (IMDG-Code / GGVSee):</b>		
<b>14.1 UN Number</b>	N/a	

<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	IMDG Class	N/a
	IMDG Sub risk	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazards</b>	N/a	
<b>14.6 Special precautions for user</b>	EMS Number	N/a
	Special provisions	N/a
	Limited quantities	N/a
<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a	
<b>Inland waterways transport (ADN):</b>		
<b>14.1 UN Number</b>	N/a	
<b>14.2 UN Proper Shipping Name</b>	N/a	
<b>14.3 Transport hazard class(es)</b>	N/a	N/a
<b>14.4 Packing group</b>	N/a	
<b>14.5 Environmental hazard</b>	N/a	
<b>14.6 Special precautions for user</b>	Classification Code	N/a
	Special provisions	N/a
	Limited quantity	N/a
	Equipment required	N/a
	Fire cones number	N/a



<b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	N/a
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**SECTION 15: REGULATORY INFORMATION**

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

**AMOXICILLIN TRIHYDRATE (61336-70-7) IS FOUND ON THE FOLLOWING REGULATORY LISTS:**

- European Customs Inventory of Chemical Substances ECICS (English)
- European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)

**POTASSIUM CLAVULUNATE (61177-45-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS:**

- European Customs Inventory of Chemical Substances ECICS (English)
- European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)

**15.2 Chemical Safety Assessment**

**ECHA SUMMARY**

<b>Ingredient</b>	<b>CAS number</b>	<b>Index Number</b>	<b>ECHA Dossier</b>
Amoxicillin Trihydrate	61336-70-7	Not Available	Not Available

<b>Harmonization (C&amp;L Inventory)</b>	<b>Hazard Class and Category Code(s)</b>	<b>Pictograms Signal Word Code(s)</b>	<b>Hazard Statement Code(s)</b>
1	Skin Sens. 1, Resp. Sens. 1	GHS08, Dgr	H317, H334
2	Skin Sens. 1, Resp. Sens. 1, Skin Irrit. 2, Eye Irrit. 2	GHS08, Dgr	H317, H334, H412, H332, H315, H319, H335
1	Resp. Sens. 1	GHS08, Dgr	H334
2	Resp. Sens. 1	GHS08, Dgr	H334
1	Skin Sens. 1, Resp. Sens. 1	GHS08, Dgr	H334, H317



2	Skin Sens. 1, Resp. Sens. 1, Aquatic Chronic 3	GHS08, Dgr	H317, H334, H412, H302
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

Ingredient	CAS number	Index Number	Hazard Statement Code(s)
Potassium Clavulanate	61177-45-5	Not Available	Not Available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Flam. Sol. 2, Self-heat. 2, Skin Sens. 1, Resp. Sens. 1	GHS02, GHS08, Dgr	H228, H252, H317, H334
2	Flam. Sol. 2, Self-heat. 2, Skin Sens. 1, Resp. Sens. 1, Eye Irrit. 2, Repr. 2, Flam. Sol. 1, Self-heat. 1, Water-react. 3, Skin Irrit. 2, STOT SE 3	GHS02, GHS08, Dgr	H228, H317, H334, H319, H361fd, H251, H261, H315, H335
1	Flam. Sol. 2, Self-heat. 2, Eye Irrit. 2	GHS02, GHS07, Wng	H228, H252, H319
2	Flam. Sol. 2, Self-heat. 2, Eye Irrit. 2	GHS02, GHS07, Wng	H228, H252, H319

Australia - AICS	N (Potassium Clavulanate)
Canada - DSL	N (Potassium Clavulanate)
Canada - NDSL	N (Potassium Clavulanate, Amoxicillin Trihydrate)
China - IECSC	N (Potassium Clavulanate, Amoxicillin Trihydrate)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (Potassium Clavulanate, Amoxicillin Trihydrate)
Korea - KECI	N (Potassium Clavulanate)
New Zealand - NZIoC	Y
Philippines - PICCS	N (Potassium Clavulanate)
USA - TSCA	N (Potassium Clavulanate, Amoxicillin Trihydrate)



**Legend:**

*Y = All ingredients are on the inventory  
N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)*

**SECTION 16: OTHER INFORMATION**

The SDS is written in accordance to guidelines specified by REACH, GHS and ECHA.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

- EN 166 Personal eye-protection
- EN 340 Protective clothing
- EN 374 Protective gloves against chemicals and micro-organisms
- EN 13832 Footwear protecting against chemicals
- EN 133 Respiratory protective devices

**Definitions and abbreviations**

- PC—TWA: Permissible Concentration-Time Weighted Average
- PC—STEL: Permissible Concentration-Short Term Exposure Limit
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit
- IDLH: Immediately Dangerous to Life or Health Concentrations

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