

**Ecomass Technologies**  
**Safety Data Sheet**  
**Ecomass Compound 1700ZC Series**

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

**SECTION 1: Identification**

**1(a) Product Identifier used on label**

Ecomass Compound: 1700ZC Series  
Form: Plastic Compound: Polyamide 12 (PA12) & Metallic Powder Mixture (Pellets)

**1(b) Other means of identification**

Nylon 12

**1(c) Recommended use of the chemical and restrictions on use**

1. Uses: Thermoplastic for Injection Molding and Extrusion
2. Restrictions on Uses: None

**1(d) Name, address, & telephone number of the chemical manufacturer, importer, or supplier**

Ecomass Technologies  
4101 Parkstone Heights, Suite 380  
Austin, Texas 78746  
512-306-0020

**1(e) Emergency phone number**

512-306-0020

**SECTION 2: Hazard(s) Identification**

**2(a) Hazard Classification**

(GHS-US): Not classified as a hazardous substance or mixture.

**2(b) Label Elements**

Signal Word: None  
Pictogram: None  
Hazard Statements: None  
Supplemental Hazard Statement: Processing may release vapors and/or fumes which cause eye, skin, and respiratory tract irritation.

**2(c) Hazards not otherwise classified**

This material has not been evaluated as a whole. All ingredients are bound in a polymer matrix and potential for hazardous exposure as shipped is minimal. However, some fumes may be released upon heating and the end-user (fabricator) must take the necessary precautions (mechanical ventilation, respirator program, etc.) to protect his employees from exposure which may cause eye, skin, and respiratory tract infection. Prolonged or repeated exposure may cause: headache, drowsiness, nausea, weakness (severity of effects depends on extent of exposure). (See Section 8 - Exposure Controls / Personal Protection) The following ingredients are considered hazardous per OSHA 1910.1200:

1. Metallic Powder
2. Nuisance Dust

**2(d) Ingredients with unknown toxicity**

None

**SECTION 3: Composition / Information on Ingredients**

Products as manufactured are classified as non-hazardous and chemical disclosure is not required by regulation(s).

While not required, polymers and metal powders are described below with their CAS Number(s).

If a chemical is not specifically identified, it is considered proprietary.

Each stainless steel powder particle is a homogenous alloy of the components - iron, chromium, and nickel. Each stainless steel powder particle is bound in a polymer matrix mixture and potential for hazardous exposure as shipped is minimal.

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

Name	Product Identifier	%	Classification (GHS-US)
Polyamide (Azacyclotridecan-2-one, homopolymer)	(CAS No) 25038-74-8	< 100	Not classified
White mineral oil (petroleum)	(CAS No) 8042-47-5	<2	Not classified
Stainless Steel	(CAS No) 12597-68-1	< 100	Not classified
Iron	(CAS No) 7439-89-6	< 100	Not classified
Chromium	(CAS No) 7440-47-3	10 to 30	Not classified
Nickel	(CAS No) 7440-02-0	10 to 30	Carc. 2, Skin Sens. 1

#### SECTION 4: First Aid Measures

##### 4(a) Description of First Aid Measures

After Inhalation: No known effects. Supply fresh air. Consult physician.

After Skin Contact: No known effects. Flush contacted skin. If contact with molten product, immediately flush with cool water. Do not pull solidified product off skin. Seek medical treatment.

After Eye Contact: No known effects. Flush eyes with water. If contact with molten product, immediately flush with cool water. Seek medical treatment.

After Ingestion: No known effects. DO NOT induce vomiting. Seek medical treatment.

##### 4(b) Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: No known effects. Long term skin contact could cause skin dryness.

##### 4(c) Indication of any immediate medical attention and special treatment needed

Treat symptoms as above. No specific antidote. Consult physician and/or seek medical treatment.

#### SECTION 5: Fire Fighting Measures

##### 5(a) Suitable Extinguishing Media

Water spray, Carbon dioxide (CO<sub>2</sub>), Foam, Dry Chemical. For large fires use foam, water spray and call for fire-fighting assistance.

##### Unsuitable Extinguishing Media

Do not use a solid water stream, as it may scatter and spread fire.

##### 5(b) Specific hazards arising from the substance or mixture

Fire hazard: Not flammable but will burn and the following hazardous products of combustion can occur: Carbon Monoxide (CO), Ammonia, and Amino derivatives.

Explosion hazard: Static charge buildup can be a potential fire hazard when used in the presence of volatile, flammable vapors or in high airborne dust concentrations.

Reactivity: Non-reactive.

##### 5(c) Advice for Fire Fighters

Precautions: Use standard protective clothing for fire fighters. Self contained breathing apparatus (SCBA) should be worn to prevent inhalation of smoke and decomposition products in the event the material should burn. Decontaminate fire fighting equipment after use.

## SECTION 6: Accidental Release Measures

### 6(a) Personal precautions, protective equipment and emergency procedures

General measures: If spilled, may cause a fall or slipping hazard. Avoid dust generation. Keep away from ignition sources. Ensure proper ventilation.

Environmental: Prevent dispersal of spilled material and runoff and contact with soil, waterways, drains, and sewers. Prevent entry to sewers and public waters.

### 6(b) Methods and material for containment and cleaning up

Containment: Prevent further leakage or spillage if you can do so without risk. Ventilate the area. Shovel, scoop, sweep up or use industrial vacuum cleaner and return to original container. Products are non-hazardous waste. Proper disposal should be evaluated based on local, state, and federal regulations/legislation or directives. Users must determine if a report is required to EPA for any amounts of this material disposed of or otherwise released into the environment.

References: Refer to Sections 7, 8, and 13.

## SECTION 7: Handling and Storage

### 7(a) Precautions for Safe Handling

Prevent generation of dust and avoid breathing dust. If necessary, wear a dust mask. Avoid breathing processing fumes or vapors and use local exhaust above processing areas. Wash hands after use. Avoid eating, drinking and smoking in work areas. Handle in accordance with good industrial hygiene and safety practices. These practices include avoiding unnecessary exposure and removal of material from eyes, skin, and clothing. Take precautionary measures against static discharge. Earth/Ground processing equipment. Product has a tendency to accumulate static charge during transport, handling and processing. Considering the risks of electrostatic discharges, handling the products in potentially flammable atmospheres should be evaluated. Suitable precautions should be taken at all times, in particular when emptying bags or other packaging. Reducing the velocity of transport will reduce charging. Static charge buildup can be a potential fire hazard when used in the presence of volatile or flammable mixtures. Keep away from ignition sources. If product is processed into smaller particles, explosive hazardous conditions must be evaluated. When processing these products, maintain a fire watch if material reaches 225 °C (437 °F). Operating below these temperatures does not guarantee the absence of product degradation. The temperatures listed are indicated only for safety reasons (risk of fire and product degradation) and are not recommended for processing. Degradation of the polymer will start at lower temperatures depending on the specific processing conditions.

### 7(b) Conditions for safe storage, including any incompatibilities

Stable under recommended storage conditions. Do not store outside. Keep container dry. Keep in a cool, dry, well-ventilated place. Store in closed containers, in a secure area to prevent container damage and subsequent spillage. Store away from moisture and heat to maintain the technical properties of the product. Products contain an antioxidant to aid in stabilizing the polymer over its recommended 140 °F (60 °C) use and storage conditions. Exposure to direct sunlight or elevated temperatures over prolonged periods of time consumes the antioxidant at an increased rate and may lead to self-heating. Do not stack Flexible Intermediate Bulk Containers (FIBC's) or palletized bags. Avoid storage under pressure or at elevated temperatures above to minimize particulate clustering. Do not store above 140 °F (60 °C). Do not store with alkalis, oxidizers or acids.

### 7(c) Specific end use(s)

No additional information available.

**SECTION 8: Exposure Controls / Personal Protection**

**8(a) Exposure Control Limits - Polyamide 12**

ACGIH	Form	Time Weighted Average
	Inhalable Particles	10 mg/m <sup>3</sup>
	Respirable Particles	3 mg/m <sup>3</sup>

OSHA Table Z-1 Air Contaminants	Form	PEL
	Respirable Fraction	5 mg/m <sup>3</sup>
	Total Dust	15 mg/m <sup>3</sup>

**Exposure Control Limits - White Mineral Oil**

ACGIH	Form	Time Weighted Average
	Inhalable Particles	5 mg/m <sup>3</sup>
	Mist	5 mg/m <sup>3</sup>

**Exposure Control Limits - Stainless Steel Alloy Components**

**Exposure Control Limits - Iron Oxide**

ACGIH TLV	5.0 mg/m <sup>3</sup>
OSHA PEL	10.0 mg/m <sup>3</sup>
NIOSH IDLH	2500 mg/m <sup>3</sup> as iron
<i>IDLH = Immediately dangerous to life and health.</i>	

**Exposure Control Limits - Chromium**

CAS#	7440-47-3
EINECS#	231-157-5
ACGIH TLV	0.5 mg/m <sup>3</sup>
NIOSH IDLH	250 mg/m <sup>3</sup>
OSHA PEL	1.0 mg/m <sup>3</sup>
<i>IDLH = Immediately dangerous to life and health.</i>	
Chromium is on the SARA Title III, Section 313 Toxic Chemicals List	

**Exposure Control Limits - Nickel**

ACGIH TLV	1.5 mg/m <sup>3</sup>
NIOSH IDLH	10 mg/m <sup>3</sup>
OSHA PEL	1.0 mg/m <sup>3</sup>
<i>IDLH = Immediately dangerous to life and health.</i>	
Nickel is on the SARA Title III, Section 313 Toxic Chemicals List	

**8(b) Appropriate Engineering Controls**

Use local exhaust ventilation during processing to reduce exposures. When transferring products, earth/ground all subsequent equipment to minimize charges that may develop.

**8(c) Individual Protection Measures**

Personal protective equipment: Gloves. Safety Glasses. Protective Clothing.



Materials for protective clothing:	Standard issue work clothes, which may include apron, antistatic safety shoes or boots as necessary.
Eye protection:	Use good industrial practice to avoid eye contact. Wear Safety glasses with side-shields. Processing of this product releases vapors or fumes which may cause eye irritation. Where eye contact may be likely, wear chemical goggles and have eye flushing equipment available.
Skin:	Processing of this product releases vapors or fumes which may cause skin irritation. Minimize skin contamination by following good industrial hygiene practice. Wearing protective gloves is recommended. Use heat protective gloves when handling hot, molten product. Wash hands and contaminated skin thoroughly after contact with processing fumes or vapors or after handling the material.
Respiratory protection:	Avoid breathing dust. Avoid breathing processing fumes or vapors. During handling: if dust is generated, a particulate pre-filter is recommended and for high airborne dust concentrations, a cartridge designed for nuisance dust is recommended. During high temperature processing: use local exhaust ventilation when available. Consult respirator manufacturer to determine appropriate type equipment for a given application. Observe respirator use limitations specified by NIOSH or the manufacturer. For emergency and other conditions where there may be a potential for significant exposure or where exposure limit may be significantly exceeded, use an approved full face positive-pressure, self-contained breathing apparatus or positive-pressure airline with auxiliary self-contained air supply. Respiratory protection programs must comply with 29 CFR § 1910.134.

## SECTION 9: Physical and Chemical Properties

<b>9(a)</b>	<b>Physical state:</b>	Solid
	<b>Appearance/Form:</b>	Pellets; porous to dense
	<b>Color:</b>	Various: tan, copper, gray or black - dependent on filler material
<b>9(b)</b>	<b>Odor:</b>	Essentially odorless, may be faint odor
<b>9(c)</b>	<b>Odor threshold:</b>	Not determined
<b>9(d)</b>	<b>pH:</b>	No data available
<b>9(e)</b>	<b>Melting point/range:</b>	329 - 356 °F (165 - 180 °C)
	<b>Freezing point:</b>	Not Applicable
<b>9(f)</b>	<b>Boiling point:</b>	Not Applicable
<b>9(g)</b>	<b>Flash point:</b>	Not determined
<b>9(h)</b>	<b>Evaporation rate:</b>	Not Applicable, Solid
<b>9(i)</b>	<b>Flammability (solid, gas):</b>	See GHS Classification in Section 2
<b>9(j)</b>	<b>Upper / Lower Flammability:</b>	No data available
	<b>Explosive Limits:</b>	Not determined
<b>9(k)</b>	<b>Vapor pressure:</b>	Not Applicable, Solid
<b>9(l)</b>	<b>Vapor Density:</b>	Not Applicable, Solid
<b>9(m)</b>	<b>Relative density:</b>	Specific Gravity: 1 - 4.5
<b>9(n)</b>	<b>Solubility (water):</b>	Insoluble
	<b>Solubility (other):</b>	Soluble in: phenols; metacresol; benzyl alcohol (when hot); formic acid (concentrate), and sulfuric acid (concentrate)
		Partly Soluble in: methylene chloride (dichloromethane)
<b>9(o)</b>	<b>Partition Coefficient:</b>	No data available

<b>9(p)</b>	<b>Auto-Ignition Temperature:</b>	698 - 842 °F (370 - 450 °C) (Method: Standard ASTM D 1929-77 (B))
<b>9(q)</b>	<b>Decomposition temperature:</b>	>662 °F (>350 °C)
<b>9(r)</b>	<b>Viscosity, Kinematic:</b>	Not Applicable
	<b>Viscosity, Dynamic:</b>	Not Applicable
<b>Other</b>	<b>Oxidizing properties:</b>	No data available

## SECTION 10: Stability and Reactivity

<b>10(a)</b>	<b>Reactivity:</b>	Non-reactive. The product is stable under normal handling and storage conditions.
<b>10(b)</b>	<b>Chemical Stability:</b>	Stable under ambient conditions. Hazardous polymerization does not occur.
<b>10(c)</b>	<b>Possibility of Hazardous Reactions:</b>	Non-reactive. The product is stable under normal handling and storage conditions.
<b>10(d)</b>	<b>Conditions to Avoid:</b>	Avoid prolonged exposure to heat or UV light since this may affect product properties. Product will burn when exposed to continuous sources of ignition. See Hazardous Decomposition below.
<b>10(e)</b>	<b>Incompatible Materials:</b>	Avoid contact with strong acids and oxidizing agents.
<b>10(f)</b>	<b>Hazardous Decomposition:</b>	Hazardous vapors from heated product are not expected to be generated under normal processing temperatures and conditions. No hazardous decomposition under ambient temperatures. Although highly dependent on temperature and environmental conditions, a variety of thermal decomposition products may be present if the product is overheated, is smoldering, or catches fire. Thermal decomposition giving toxic, flammable, and / or corrosive products: ammonia, amino derivatives, and carbon monoxide.

## SECTION 11: Toxicological Information

This product is a mixture that has not been evaluated as a whole for health effects. Exposure effects listed below are based on existing health data for the individual components which comprise the mixture.

### Polyamide 12

<b>11(a)</b>	<b>Routes of Exposure</b>	
	Aspiration hazard:	Not classified
	Skin corrosion/irritation:	Not irritating. (Rabbit) (4 h)
	Serious eye damage/irritation:	Not classified
	Respiratory or skin sensitization:	Not classified
<b>11(b)</b>	<b>Symptoms</b>	See Section 4
<b>11(c)</b>	<b>Effects - Short and Long Term</b>	
	Germ Cell Mutagenicity:	Assessment in Vitro: No genetic changes were observed in a laboratory test using bacteria.
	Carcinogenicity:	Not classified; (No data available)
<b>11(d)</b>	<b>Toxicity</b>	
	Acute Toxicity:	Not classified
	Reproductive Toxicity:	Not classified; (No data available)
	Specific target organ toxicity (single exposure):	Not classified; (No data available)
	Specific target organ toxicity (repeated exposure):	Not classified; (No data available)
<b>11(e)</b>	<b>Listings</b>	

### White Mineral Oil (Petroleum)

<b>11(a)</b>	<b>Routes of Exposure</b>	
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Aspiration hazard: Practically nontoxic, (rat) LD50 > 5,000 mg/kg.  
 Skin corrosion/irritation: Non-irritating, (rabbit) Draize Test (24 h)  
 Slightly irritating, (guinea pig) Irritation Index: 1.0/8.0.  
 Serious eye damage/irritation: Slightly irritating, (rabbit) Irritation Index: 2/10.  
 Non-irritating, (rabbit) Draize Test  
 Skin sensitization: Guinea pig maximization test, (guinea pig) No skin allergy was observed.  
 Dermatitis, Acne.  
 Respiratory: Upper respiratory tract: chemical pneumonitis, phlegm, coughing, wheezing, (mist)

**11(b) Symptoms** See Section 4

**11(c) Effects - Short and Long Term**

Germ Cell Mutagenicity: Assessment in Vitro: No genetic changes were observed in a laboratory test using animal cells or bacteria.

Carcinogenicity: Chronic dermal administration to mouse / No increase in tumor incidence was reported.

Chronic inhalation administration to various animal species / No adverse effects reported.

Chronic subcutaneous injection administration to rodent / No increase in tumor incidence was reported.

**11(d) Toxicity**

Acute Toxicity: See Section 11(a)

Reproductive Toxicity: Exposure prior to mating, oral (rat) / No toxicity to reproduction.

Developmental Toxicity: Exposure during pregnancy, oral (rat) / No birth defects were observed.

Specific target organ toxicity (single exposure): Not classified; (No data available)

Specific target organ toxicity Not classified; (No data available)

**11(e) Listings**

**Stainless Steel**

**11(a) Routes of Exposure**

Inhalation: Particulates can be mechanically irritating.

Ingestion: May be harmful if swallowed

Eyes: Particulates can be mechanically irritating.

Skin: Experience shows no unusual skin hazard from routine handling.

**11(b) Symptoms** See Section 4

**11(c) Effects - Short and Long Term**

Carcinogenicity:

This product contains the following components which, in their pure form, have the following carcinogenicity data:

CAS-No.	Chemical Name	OSHA	IARC	NTP
7440-02-0	Nickel	No	2B	No

**IARC Carcinogen Classifications**

- 1 - The component is carcinogenic to humans.
- 2A - The component is probably carcinogenic to humans.
- 2B - The component is possibly carcinogenic to humans.

**NTP Carcinogen Classifications:**

- 1 - The component is known to be a human carcinogen.
- 2 - The component is reasonably anticipated to be a human carcinogen.

**11(d) Toxicity**

This product contains the following components which in their pure form have the following characteristics:

CAS-No.	Chemical Name	Effect	Target Organ
7439-89-6	Iron	Systemic effects	Eyes, Respiratory System
7440-47-3	Chromium	Systemic effects	Eyes, Skin, Respiratory System.
7440-02-0	Nickel	Systemic effects	Skin, Respiratory System.

**Additional Health Hazard Information:**

**Chromium 7440-47-3:** Bivalent and trivalent forms of chrome have a low order of acute toxicity, but may cause skin sensitization and irritation to the eyes. No effects have been reported for chromium (III) oxide, Chromium (III) compounds are not considered carcinogenic in animals or humans.

**Nickel 7440-02-0:** Skin sensitizer "nickel itch", with pulmonary, brain, liver, kidney, and muscle effects.

**11(e) Listings**

See 11(c)

**SECTION 12: Ecological Information**

<b>12(a) Ecotoxicity</b>	Iron, chromium, and nickel are components of the stainless steel alloy which is combined with the polymer in a matrix, thus not readily biodegradable.  White Mineral Oil (Petroleum): Not readily biodegradable. (28 d) 0 % / OECD Guideline 301 B. Octanol Water Partition Coefficient: log Pow > 6 (calculated) Aquatic Toxicity - Practically nontoxic. Lepomis macrochirus (Bluegill sunfish) 96 h > 10,000 mg/l
<b>12(b) Persistence and degradability</b>	Iron, chromium, and nickel are components of the stainless steel alloy which is combined with the polymer in a matrix, thus not readily biodegradable.
<b>12(c) Bioaccumulative potential</b>	Iron, chromium, and nickel are components of the stainless steel alloy which is combined with the polymer in a matrix, thus not readily bioaccumulative.
<b>12(d) Mobility in Soil</b>	No data available
<b>12(e) Other Adverse effects</b>	No data available

**SECTION 13: Disposal Considerations**

Where possible, recycling is preferred to disposal or incineration. If recycling is not an option, incinerate or dispose of in accordance with federal, state, and local regulations. Pigmented, filled, and/or solvent laden product may require special disposal practices in accordance with federal, state, and local regulations. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal, and other requirements listed in pertinent environmental permits. Note: Chemical additions to, processing of, or otherwise altering this material may make this waste management information incomplete, inaccurate, or otherwise inappropriate. Furthermore, state and local waste disposal requirements may be more restrictive or otherwise different from federal laws and regulations.

**SECTION 14: Transport Information**

In accordance with DOT and IMDG, this product is not regulated for transport.

<b>14(a)</b>	UN Number:	None
<b>14(b)</b>	UN Number Shipping Name:	None
<b>14(c)</b>	Transport Hazard Class(es):	None
<b>14(d)</b>	Packing Group:	None
<b>14(e)</b>	Environmental Hazards:	Not a marine pollutant
<b>14(f)</b>	Transport in Bulk:	None
<b>14(g)</b>	Special Precautions:	None



## SECTION 15: Regulatory Information

### US Federal Regulations

#### SARA - Section 302 Extremely Hazardous Chemicals:

Unless specifically identified in this section, the components in this product are either not SARA Section 302 regulated or regulated but present in negligible concentrations.

None

#### SARA - Section 311/312 Hazard Classes:

None

#### SARA - Section 313 Toxic Chemicals:

Unless specifically identified in this section, this material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Name	Product Identifier	Weight %	SARA 313 - Threshold Values %
Chromium	7440-47-3	10 to 30	
Nickel	7440-02-0	10 to 30	

#### CERCLA - Comprehensive Environmental Response, Compensation, & Liability Act - Reportable Quantity (RQ)

Unless specifically identified in this section, the components in this product are either not CERCLA regulated, regulated but present in negligible concentrations, or regulated with no assigned reportable quantity.

Name	Hazardous Substances RQs	CERCLA EHS RQs
Nickel	100 lb	None

<b>OSHA</b>	Unless specifically identified in this section, the components in this product are not considered hazardous by OSHA :
	This product is classified as hazardous based on the components contained in the stainless steel

### Chemical Inventory Status

European Inventory of Existing Commercial Chemical	EU, EINECS	Conforms
United States TSCA (Toxic Substances Control Act) Inventory	TSCA	Listed
Canadian Domestic Substances List	DSL	Listed
China. Inventory of Existing Chemical Substances Produced or Imported in China	IECSC (CN)	Conforms
Japan. ENCS - Existing & New Chemical Substances Inventory	ENCS (JP)	Conforms
Korea. Toxic Chemical Control Law List	TCCL (KR)	Conforms
Philippines Inventory of Chemicals and Chemical Substances	PICCS (PH)	Conforms
Australian Inventory of Chemical Substances	AICS	Conforms
New Zealand Inventory of Chemicals	NZIoC	Conforms

### US State Regulations

New Jersey Right to Know	No components are subject to the New Jersey Right to Know Act.
Pennsylvania Right to Know	Chemical Name: Azacyclotridecan-2-one, homopolymer CAS Number 25038-74-8
California Prop. 65	WARNING! This product contains chemicals known to the State of California to cause cancer, birth defects, or other reproductive defects.

## SECTION 16: Other Information

Revision Date: May 13, 2016

Version Number: 04

Ecomass® is a registered trademark.

### ABBREVIATIONS / ACRONYMS / REFERENCES:

AND	EU agreement for the International Transport of Dangerous Goods by Inland Waterways, as amended
ADR	EU agreement for the International Carriage of Dangerous Goods by Road, as amended
CAS	Chemical Abstracts Services (Division of the American Chemical Society)
GHS	Globally Harmonized System of Classification and Labelling of Chemicals, as amended
HMIS	Hazardous Materials Identification System
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IMDG	International Maritime Code for Dangerous Goods, as amended
LC50	Lethal Concentration of 50 Percent of Organisms
MARPOL	International Convention for the Prevention of Pollutants from Ships, 1973, as amended
MHLW	Japanese Ministry of Health, Labor, and Welfare
NFPA 704	National Fire Protection Association
OE	Oil Extended
OEL	Occupational Exposure Limit
RID	EU Standards Regulations Concerning the International Transport of Dangerous Goods by Rail
TLV	Threshold Limit Value
TWA	Time Weighted Average
UN	United Nation
USP	United States Pharmacopeia for the Testing of Biological Endpoints for Medical Devices

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