DOMO Engineering Plastics US Safety Data Sheet mass Compounds 0700BL Series

Ecomass Compounds 0700BI 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 Compounds: 0700BI Series

Form: Plastic Compound (Acrylonitrile-Butadiene-Styrene) & Metallic Powder Mixture

(Pellets)

1(b) Other means of identification

ΔRS

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

1. Uses: Thermoplastic Polymer for Injection Molding and Extrusion

2. Restrictions on Uses: None

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

DOMO Engineering Plastics US 4917 Golden Parkway, Suite 300

Buford, GA 30518

770-237-2311 1(e) Emergency phone number

770-237-2311

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. Severe over-exposure may result in nausea, headache, chills, and fever. See below for additional effects. Secondary operations, such as grinding, sanding, or sawing can produce dust which may present an explosion or respiratory

hazard.

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 irritation. 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 barium sulfate 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)
(ABS) Acrylonitrile-Butadiene-Styrene	(CAS No) 9003-56-9	< 100	Not classified
Barium Sulfate	(CAS No) 7727-43-7	< 100	Hazardous based on components

SECTION 4: First Aid Measures

4(a) Description of First Aid Measures

No known effects during normal usage. If inhalation of processing vapors from

After Inhalation: overheating or combustion, supply fresh air. In cases of severe exposure, nausea

and headache can also occur. Consult physician.

After Skin Contact: No known effects. Wash 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. Rinse 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, dry chemical, carbon dioxide (CO₂), or "Alcohol" foam. For large fires use water spray for its cooling capacity to reduce chances of reignition, 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: Flash point : >660 °F (>349 °C). Not flammable under ordinary use conditions but

will burn and produce dense black smoke. The following hazardous products of combustion can occur: hydrogen cyanide (hydrocyanic acid) (traces), hydrocarbon

fragments, and trace amounts of oxides of carbon and nitrogen.

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 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: Avoid 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 may 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. 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 may 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. 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 - ABS (Acrylonitrile-Butadiene-Styrene)

	Form	TWA (Time Weighted Average)
ACGIH	Inhalable Particles	10 mg/m³
	Respirable Particles	3 mg/m ³

OSHA Table Z-1	Form	PEL (Permissable Exposure Limit)
Limits for Air	Respirable Fraction	5 mg/m ³
Contaminants	Total Dust	15 mg/m ³

	Form	TWA (Time Weighted Average)
	Respirable Fraction	15 ppm
OSHA Table Z-3	Total Dust	50 ppm
	Respirable Fraction	5 mg/m ³
	Total Dust	15 mg/m³

Exposure Control Limits - Barium Sulfate

ACGIH	Form	TWA (Time Weighted Average)
ACGIH	as Barium Sulfate	10 mg/m³

OSHA Table Z-1	Form	PEL (Permissible Exposure Limit)
Air Contominants	Respirable Fraction	5 mg/m ³
Air Contaminants	Total Dust	15 mg/m³

	Form	IDLH (Immediately Dangerous to Life or Health)
NIOSH IDLH	Respirable Fraction	5 mg/m ³
	Total Dust	15 mg/m ³

8(b) Appropriate Engineering Controls

Use local exhaust ventilation during processing to reduce exposures below above limits. Processing fume condensate may be a fire hazard and toxic; remove periodically from exhaust hoods, ductwork, and other surfaces using appropriate personal protection. 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. Use full-face shield when cleaning processing vapor

condensates from hood, ducts, and other surfaces.

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. Grease-like processing vapor condensates on ventilation ductwork, molds, and other surfaces can cause irritation and injury to skin. 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 parliculate 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

9(f)

9(g)

9(n)

9(a) Physical state:	Solid
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Appearance/Form: Pellets; porous to dense

Color: Various: tan, copper, gray or black - dependent on filler material

9(b) Odor: Essentially odorless, may be faint odor

9(c) Odor threshold: Not determined9(d) pH: No data available

9(e) Melting point: This product does not exhibit a sharp melting point but softens gradually over a

wide range of temperatures.

Softening point: 150-180 °F (66-82 °C)

Freezing point: Not Applicable

Boiling point: Not Applicable

Flash point: 660 °F (349 °C)

9(h) Evaporation rate: Not Applicable, Solid9(i) Flammability (solid, gas): No data available

9(j) Upper / Lower Flammability: No data available
Explosive Limits: Not determined

9(k) Vapor pressure: Not Applicable, Solid
 9(l) Vapor Density: Not Applicable, Solid
 9(m) Relative density: Specific Gravity: 1 - 3

Solubility (water): 68 °F (20 °C) insoluble
Solubility (other): No data available

9(o) Partition Coefficient: No data available
9(p) Auto-Ignition Temperature: >752 °F (>400 °C)
9(q) Decomposition temperature: >572 °F (>300 °C)

9(r) Viscosity, Kinematic: Not Applicable
Viscosity, Dynamic: Not Applicable

Other Oxidizing properties: No data available

SECTION 10: Stability and Reactivity

10(a) Reactivity: Non-reactive. The product is stable under normal handling and storage conditions.

10(b) Chemical Stability: Stable under ambient conditions. Hazardous polymerization does not occur.

10(c) Possibility of Hazardous Reactions: Non-reactive. The product is stable under normal handling and storage conditions.

10(d) Conditions to Avoid: Avoid prolonged exposure to heat or UV light since this may affect product

properties. Product will burn when exposed to continuous sources of ignition. To avoid thermal decomposition (>572 °F (>300 °C)), avoid elevated temperatures which can result in the formation of gaseous decomposition products, some of which may be hazardous. Do not allow product to remain in barrel at elevated temperatures for extended periods of time. See Hazardous Decomposition below.

10(e) Incompatible Materials: Avoid contact with strong oxidizing agents.

10(f) Hazardous Decomposition: Hazardous vapors from heated product are not expected to be generated under

normal processing temperatures and conditions. Process vapors under recommended processing conditions may include trace levels of hydrocarbons, styrene, acrylonitrile, acrolein, acetaldehyde, acetophenone, ethyl benzene, cumene, alpha methylstyrene, 4-vinylcyclohexene, phenols. Although highly dependent on temperature and environmental conditions, a variety of thermal decomposition products may be present if the product is overheated (>572 °F (>300 °C)), is smoldering, or catches fire. The following hazardous toxic, flammable, and/or corrosive products of combustion can occur: hydrogen cyanide

(hydrocyanic acid) (traces), hydrocarbon fragments, and trace amounts of oxides of

carbon (CO_x), and nitrogen (NO_x).

SECTION 11: Toxicological Information

11(a) Routes of Exposure

Aspiration hazard: (Rat) LD50 > 5,000 mg/kg (estimated).

Skin corrosion/irritation: Not irritating. (Rabbit) LD50 > 2,000 mg/kg (estimated).

Serious eye damage/irritation: Resin particles, like other inert materials, are mechanically irritating to eyes.

Respiratory: Pellet ingestion unlikely due to physical form.

Ingestion: Pellet ingestion unlikely due to physical form.

11(b) Symptoms See Section 4

11(c) Effects - Short and Long Term

Germ Cell Mutagenicity: Not classified; (No data available)
Carcinogenicity: Not classified; (No data available)

11(d) Toxicity

Toxicity Overview:

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

CAS-No.	Chemical Name	Effect	Target Organ
7727 42 7	7727-43-7 Barium Sulfate	Irritant	Respiratory system
7727-43-7		Systemic effects	Eyes, Respiratory system

Chronic Toxicity: Styrene: Genotoxicity - In several in vitro bacterial mutagenicity tests using

Salmonella typhimurium tester strains TA98, TA100, TA1535, and TA1537 at concentrations up to 1 mg/plate, styrene has been found to test negative without metabolic activation and has tested either equivocal or negative with metabolic activation. In standard mammalian cells tested in vitro, no mutagenicity was observed. When using in vivo test systems, styrene did not induce chromosome aberrations in mouse bone marrow cells but did increase sister chromatid exchanges (SCE) at concentration of 250 ppm and above for 14 days.

Subchronic Toxicity:

Styrene: Many repeat dose toxicity studies are available in several test animal species following both oral and inhalation exposure. In rats dosed orally, effects on liver (changes in enzyme levels and increased weight) were consistently observed at concentrations of 350 mg/kg and higher. Gastrointestinal irritation and kidney weight changes are observed at higher doses. Findings were similar for beagle dogs. The no observed effect levels (NOEL) ranged from 100 mg/kg/day to about 300 mg/kg/day, depending on the duration of exposure. A series of inhalation studies were conducted in the 1940s and 1950s. Rats, guinea pigs, rabbits, and monkeys were exposed up to 8 hours/day, 5 days/week for 6 months to 650 to 2000 ppm (3 – 9.3 mg/L) and consistent signs of significant eye and nose irritation were observed at 1300 ppm and above. Histopathological lesions at this concentration typically consisted of pulmonary lesions.

Special Studies:

Styrene: A reproduction study in rats exposed to 125 and 250 ppm in drinking water (approximately 14-21 mg/kg/day) produced no treatment-related effects on reproductive performance over 3- generations. The only treatment related findings were reduced pup survival index in the F1 and F2 offspring. There was no evidence of developmental effects and no other effects were reported. The parental NOEL was 250 ppm and the NOEL for the F1 and F2 offspring was 125 ppm. In developmental toxicity studies in rats, rabbits, and hamsters styrene was not a selective toxicant to the fetus and was toxic at only those doses that produced maternal toxicity.

In humans, styrene is associated with central nervous system depression (headache, fatigue, nausea, and dizziness) at inhalation concentrations greater than 50 ppm. Styrene has also been reported to reduce sensory nerve conductions in occupation settings after exposure to 100 ppm or more. Styrene has also been reported to produce color vision deficiencies (dyschromatopsia) at concentrations greater than 8 ppm (averaging 24 ppm). Twelve epidemiology studies have been reported for styrene and half have supported the hypothesis that styrene produces lymphatic and hematopoetic cancers (LHC). However, those that show an increase of LHC have generally been small in size (limited statistical power), have shown no dose-response relationship, and/or had multiple chemical exposures. Of the six studies that have not shown an association with styrene and LHC, these studies tended to be larger in size (higher statistical power), had an older study population, and had good exposure data. Overall, the weight of evidence suggests that there is not an association of LHC and styrene exposure in humans.

In a recent inhalation cancer bioassay, Sprague Dawley derived rats (70/sex/group) were exposed whole body to styrene vapor at 0, 50, 200, 500, or 1000 ppm 6 h/day 5 days / week for 104 weeks. Males exposed to 500 and 1000 ppm and females exposed to 200 ppm and higher gained significantly less weight than the controls. There were no changes of toxicologic significance in hematology, clinical chemistry, urinalysis, or organ weights. Styrene-related non-neoplastic histopathologic changes were confined to the olfactory epithelium of the nasal mucosa. The incidence and severity were related to dose. There was no evidence that styrene exposure caused treatment related increases of any tumor type in males or females or in the number of tumor bearing rats in the exposed groups compared to controls.

In 2-year carcinogenicity bioassays conducted by the National Toxicology Program, rats and mice (50/sex/group) received 0, 500, 1000, or 2000 mg/kg/day and 0, 150, or 300 mg/kg/day, respectively, via oral gavage. In male or female rats and female mice there was no significant difference in tumor incidence when compared to the control groups. In male mice there was a positive association between styrene dose and the incidence of the combination of adenomas and carcinomas of the lung. However, due to the high background incidence of this tumor type in male mice, no firm conclusion was drawn for the carcinogenicity.

In a study that administered styrene (125 and 250 ppm) in the drinking water of rats for 2 years, there was no evidence of carcinogenicity. In other chronic inhalation toxicity studies, rats were exposed to styrene via inhalation at concentrations up to 300 ppm for 4-6 hours/day, 5 days/week, for 1 year or up to 1000 ppm for 2 years. There was a slightly increased, but not statistically significant, incidence of mammary tumors in the females in both studies. Because the control incidence was also high and there was no dose-response relationship the studies were considered to be negative.

Additional Health Hazard Information:

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)

11(e) Listings

IARC Group: Not Listed

SECTION 12: Ecological 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 barium sulfate particles contained in the mixture.

12(a) Ecotoxicity Each barium sulfate powder particle is bound in a polymer matrix mixture and is

insoluble in water, thus not expected to be harmful to aquatic organisms.

12(b) Persistence and degradability Each barium sulfate powder particle is bound in a polymer matrix mixture and is

insoluble in water, thus not expected to be biodegradable.

12(c) Bioaccumulative potential Each barium sulfate powder particle is bound in a polymer matrix mixture and is

insoluble in water, thus not expected to bioaccumulate.

12(d) Mobility in Soil Insoluble in waterNo data available

12(e) Other Adverse effects 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. Collected processing fume condensates and incinerator ash should be tested to determine waste classification. 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. SDS Ecomass Compound 0700BI Series V.3 08-15-2016_

This product contains one or more substances that are listed with the state of California as a hazardous waste:

Chemical Name	California Hazardous Waste Status
Barium Sulfate 7727-43-7	Toxic soluble

SECTION 14: Transport Information

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

14(a) UN Number: None
 14(b) UN Number Shipping Name: None
 14(c) Transport Hazard Class(es): None
 14(d) Packing Group: None

14(e) Environmental Hazards: Not a marine pollutant

14(f)Transport in Bulk:None14(g)Special Precautions:None

SECTION 15: Regulatory Information

US Federal Regulations

SARA - Section 302 Extremely Hazardous Chemicals:

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:

Barium Sulfate Acute health hazard

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 %
Barium Sulfate	7727-43-7	< 100	1.0

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
None		

Clean Water Act						
Component	CWA -	CWA - Reportable	CWA - Toxic	CWA - Priority Pollutants		
None						

Clean Air Act - Not applicable

Unless specifically identified in this section, the components in this product are not considered hazardous by OSHA:
None

Chemical Inventory Status

European Inventory of Existing Commercial Chemical	EU, EINECS	Listed
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)	Listed
Japan. ENCS - Existing & New Chemical Substances Inventory	ENCS (JP)	Listed
Japan. ISHL - Inventory of Chemical Substances	ISHL (JP)	Listed
Korea. Korean Existing Chemicals Inventory	KECI (KR)	Listed
Philippines Inventory of Chemicals and Chemical Substances	PICCS (PH)	Listed
Australian Inventory of Chemical Substances	AICS	Listed

US State Regulations

California Prop. 65: Components in this product known to the State of California to cause cancer, birth defects, or any other reproductive defects are listed below:

Chemical Name	Weight %	California Proposition 65:	
Acrylonitrile 107-13-1	<100 ppm	Type of Toxicity: cancer	
Ethylbenzene 100-41-4	<100 ppm	Type of Toxicity: cancer	

SECTION 16: Other Information

Revision Date: August 15, 2016

Version Number: 03

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

LCSO 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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