




**SAFETY DATA SHEET**  
**Nicardipine Hydrochloride In 0.9% Sodium Chloride Caplin Steriles Limited**

**SECTION 1: IDENTIFICATION**

<b>GHS Product Identifier</b>	:	Nicardipine Hydrochloride In 0.9% Sodium Chloride 20 mg/200 mL & 40 mg/200 mL
<b>Chemical Name</b>	:	NICARDIPINE HYDROCHLORIDE
<b>Other means of identification</b>	:	Not Available
<b>Product Code</b>	:	Not Available
<b>Product Type</b>	:	Regulated Pharmaceutical Ingredient
<b>Container Information</b>	:	200 mL Polypropylene bags
<b><u>Relevant identified uses of the substance or mixture and uses advised against</u></b>		
<b>Identified Uses</b>	:	Calcium Channel Blocker for the short-term treatment of hypertension when oral therapy is not feasible
<b>Supplier Details</b>	:	Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.
<b>Emergency Telephone Number</b>	:	+91-4467901901/02/03

**SECTION 2: HAZARDS IDENTIFICATION**

<b>OSHA/HCS Status</b>	:	This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)
<b>Classification of the substance or mixture</b>	:	SKIN CORROSION/IRRITATION - Category 2 SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A
<b>BVL Hazard category</b>	:	2
<b><u>GHS Label Elements</u></b>		
<b>Hazard pictograms</b>		
<b>Signal Word</b>	:	Warning
<b>Hazard Statements</b>	:	H319 - Causes serious eye irritation. H315 - Causes skin irritation.
<b>This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.</b>		
<b><u>Precautionary Statements</u></b>		
<b>Prevention</b>	:	P280 - Wear protective gloves. Wear eye or face protection. P264 - Wash hands thoroughly after handling.
<b>Response</b>	:	P302 + P352 + P362+P364 - IF ON SKIN: Wash with plenty of soap and water. Take off contaminated clothing and wash it before reuse.



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		P332 + P313 - If skin irritation occurs: Get medical attention. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists: Get medical attention.
<b>Storage</b>	:	Not applicable
<b>Disposal</b>	:	Not applicable
<b>Hazards not otherwise classified</b>	:	None known

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

<b>Substance/Mixture</b>	:	Mixture
<b>Chemical Name</b>	:	NICARDIPINE HYDROCHLORIDE
<b>Other means of identification</b>	:	Not Available.
<b><u>CAS Number/Other Identifiers</u></b>		
<b>Product Code</b>	:	Not Available.
<b>Ingredients</b>		<b>%</b> <b>CAS Number</b>
Nicardipine Hydrochloride		1-5                      54527-84-3
Hydrochloric Acid		1-5                      7647-01-0
<b>Occupational exposure limits, if available, are listed in Section 8.</b>		
<b>See Package Insert for further information.</b>		

The exact percentage (concentration) in the composition has been withheld as a trade secret in accordance with paragraph (i) of §1910.1200.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8

See Package Insert for further information.

**SECTION 4: FIRST AID MEASURES**

<b><u>Description of necessary first aid measures</u></b>		
<b>Eye Contact</b>	:	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention.
<b>Inhalation</b>	:	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are



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		severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
<b>Skin Contact</b>	:	Flush contaminated skin with plenty of water. Continue to rinse for at least 20 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.
<b>Ingestion</b>	:	Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
<b>Other Measures</b>	:	Not available

**Most important symptoms/effects, acute and delayed**

**Potential Acute Health Effects**

<b>Eye Contact</b>	:	Causes serious eye irritation.
<b>Inhalation</b>	:	No known significant effects or critical hazards.
<b>Skin Contact</b>	:	Causes skin irritation
<b>Ingestion</b>	:	No known significant effects or critical hazards.

**Over-Exposure Signs/Symptoms**

<b>Eye Contact</b>	:	Adverse symptoms may include the following: pain or irritation, Watering, redness
<b>Inhalation</b>	:	No known significant effects or critical hazards.
<b>Skin Contact</b>	:	Adverse symptoms may include the following: pain or irritation, redness
<b>Ingestion</b>	:	No known significant effects or critical hazards.

**Indication of immediate medical attention and special treatment needed, if necessary**

<b>Notes to Physician</b>	:	In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
<b>Specific Treatments</b>	:	No specific treatment
<b>Protection of first-aiders</b>	:	No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation

**See toxicological information (Section 11)**



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**SECTION 5: FIRE FIGHTING MEASURES**

<b>Extinguishing Media</b>	
<b>Suitable Extinguishing Media</b>	: Use an extinguishing agent suitable for the surrounding fire.
<b>Unsuitable extinguishing media</b>	: None known.
<b>Specific hazards arising from the chemical</b>	: No specific fire or explosion hazard
<b>Hazardous thermal decomposition products</b>	: Decomposition products may include the following materials: carbon dioxide, carbon monoxide, nitrogen oxides, halogenated compounds, metal oxide/oxides
<b>Special protective actions for fire-fighters</b>	: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
<b>Special protective equipment for fire-fighters</b>	: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

<b><u>Personal precautions, protective equipment and emergency procedures</u></b>	
<b>For Non-emergency Personnel</b>	: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
<b>For Emergency Responders</b>	: If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For nonemergency personnel"
<b>Environmental Precautions</b>	: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).
<b><u>Methods and materials for containment and cleaning up</u></b>	
<b>Spill</b>	: Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the



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	same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.
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**SECTION 7: HANDLING AND STORAGE**

<b><u>Precautions for safe handling</u></b>	
<b>Protective measures</b>	Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
<b>Advice on general occupational hygiene</b>	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures. Remove contaminated clothing and protective equipment before entering eating areas.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept Upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

**SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION**

<b><u>Control Parameters</u></b>		
<b>Occupational Exposure Limits</b>	<b>Ingredient name</b>	<b>Exposure limits</b>
	Nicardipine Hydrochloride	None.
	Hydrochloric acid	<b>ACGIH TLV (United States, 3/2017).</b> C: 2 ppm <b>NIOSH REL (United States, 10/2016).</b> CEIL: 5 ppm CEIL: 7 mg/m <sup>3</sup> <b>OSHA PEL (United States, 6/2016).</b> CEIL: 5 ppm CEIL: 7 mg/m <sup>3</sup>
<b>Appropriate Engineering Controls</b>	Good general ventilation should be sufficient to control worker exposure to airborne contaminants.	



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<b>Environmental Exposure Controls</b>	:	Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.
<b><u>Individual Protection Measures</u></b>		
<b>Hygiene Measures</b>	:	Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
<b>Eye/face Protection</b>	:	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.
<b>Body Protection</b>	:	Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
<b>Hand Protection</b>	:	Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
<b>Other Skin Protection</b>	:	Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
<b>Respiratory Protection</b>	:	Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

<b><u>Appearance</u></b>		
<b>Physical State</b>	:	Liquid
<b>Color</b>	:	Clear yellow solution
<b>Odor</b>	:	No data available
<b>Odor Threshold</b>	:	No data available



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<b>pH</b>	:	3 – 5 [Conc. (% w/w): 100%]
<b>Melting Point</b>	:	No data Available
<b>Boiling Point</b>	:	No data Available
<b>Flash Point</b>	:	No data Available
<b>Freezing Point (°C.)</b>	:	No data Available
<b>Specific gravity</b>	:	No data Available
<b>Evaporation Rate</b>	:	No data Available
<b>Flammability (Solid, gas)</b>	:	No data Available
<b>Lower and Upper Explosive (flammable) limits</b>	:	No data Available
<b>Vapour Pressure</b>	:	No data Available
<b>Vapor Density</b>	:	No data Available
<b>Relative Density</b>	:	No data Available
<b>Solubility</b>	:	Very Soluble in water and in alcohol
<b>Partition Coefficient: n-octanol/water</b>	:	No data Available
<b>Auto Ignition Temperature</b>	:	No data Available
<b>Decomposition Temperature</b>	:	No data Available
<b>Viscosity</b>	:	No data Available

**SECTION 10: STABILITY AND REACTIVITY**

<b>Reactivity</b>	:	No specific test data related to reactivity available for this product or its ingredients.
<b>Chemical Stability</b>	:	Light, oxygen & heat sources
<b>Possibility of Hazardous Reactions</b>	:	Under normal conditions of storage and use, hazardous reactions will not occur
<b>Conditions to Avoid</b>	:	No specific data
<b>Incompatible Materials</b>	:	Reactive or incompatible with the following materials: oxidizing materials
<b>Hazardous Decomposition Products</b>	:	Under normal conditions of storage and use, hazardous decomposition products should not be produced



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**SECTION 11: TOXICOLOGICAL INFORMATION**

<b><u>Information on toxicological effects</u></b>		
<b>Effects of acute exposure :</b>		
		<b>LD50 Oral (mg/kg)</b>
<b>Chemical Name</b>		<b>rat</b>
Nicardipine Hydrochloride		184
<b>Irritancy of Product</b>	:	There is no data Available
<b>Skin and Respiratory Sensitization</b>	:	There is no data Available
<b>Mutagenicity</b>	:	There is no data Available
<b><u>Carcinogenicity</u></b>	:	Hydrochloric acid is classified ad IARC 3.
<b>Reproductive Toxicity</b>	:	There is no data Available
<b>Teratogenicity</b>	:	There is no data Available
<b>Specific Target Organ Toxicity (Single Exposure)</b>	:	Hydrochloric acid Category 3 Respiratory tract irritation
<b>Specific Target Organ Toxicity (Repeated Exposure)</b>	:	There is no data available.
<b>Aspiration Hazard</b>	:	There is no data available.
<b>Information on the likely Routes of Exposure</b>	:	Dermal contact. Eye contact. Inhalation. Ingestion.
<b><u>Potential acute health effects</u></b>		
<b>Eye Contact</b>	:	Causes serious eye irritation
<b>Inhalation</b>	:	No known significant effects or critical hazards
<b>Skin Contact</b>	:	Causes skin irritation
<b>Ingestion</b>	:	No known significant effects or critical hazards
<b><u>Symptoms related to the physical, chemical and toxicological characteristics</u></b>		
<b>Eye Contact</b>	:	Adverse symptoms may include pain or irritation, watering, redness.
<b>Inhalation</b>	:	No known significant effects or critical hazards.
<b>Skin Contact</b>	:	Adverse symptoms may include irritation, redness.
<b>Ingestion</b>	:	No known significant effects or critical hazards.
<b><u>Delayed and immediate effects and also chronic effects from short and long term exposure</u></b>		
<b><u>Short Term Exposure</u></b>		
<b>Potential Immediate Effects</b>	:	No known significant effects or critical hazards.



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<b>Potential Delayed Effects</b>	:	No known significant effects or critical hazards.	
<b><u>Long Term Exposure</u></b>			
<b>Potential Immediate Effects</b>	:	No known significant effects or critical hazards.	
<b>Potential Delayed Effects</b>	:	No known significant effects or critical hazards.	
<b><u>Potential Chronic Health Effects</u></b>			
<b>General</b>	:	No known significant effects or critical hazards.	
<b>Carcinogenicity</b>	:	No known significant effects or critical hazards.	
<b>Mutagenicity</b>	:	No known significant effects or critical hazards.	
<b>Teratogenicity</b>	:	No known significant effects or critical hazards.	
<b>Developmental Effects</b>	:	No known significant effects or critical hazards.	
<b>Fertility Effects</b>	:	No known significant effects or critical hazards.	
<b><u>Numerical measures of toxicity</u></b>			
<b>Acute Toxicity Estimates</b>	:	<b>Route</b>	<b>ATE value</b>
		Oral	9752 mg/kg
		Dermal	15900 mg/kg
		Inhalation (Vapors)	159 mg/L

**SECTION 12: ECOLOGICAL INFORMATION**

		<b>Ingredient name</b>	<b>Result</b>	<b>Species</b>	<b>Exposure</b>
<b>Toxicity</b>		Hydrochloric acid	Acute LC50 240000 µg/L Marine water	Crustaceans - Carcinus maenas - Adult	48 hours
			Acute LC50 282 ppm Fresh water	Fish - Gambusia affinis - Adult	96 hours
<b>Persistence and degradability</b>	:	There is no data available.			
<b>Bioaccumulative potential</b>	:	There is no data available.			
<b>Mobility in soil</b>	:	<b>Soil/water partition coefficient (KOC)</b>	Not available.		
		<b>Other adverse effects</b>	No known significant effects or critical hazards		

**SECTION 13: DISPOSAL CONSIDERATIONS**

<b>Waste Disposal</b>	:	The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of
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		untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.
<b>Contaminated Packaging</b>	:	There is no data available.

**SECTION 14: TRANSPORT INFORMATION**

<b>Special Shipping Information (general)</b>		There is no data available.
<b>Specific Local Transport Information or Classifications</b>	:	<b>Transport within user's premises:</b> always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**SECTION 15: REGULATORY INFORMATION**

<b>FDA</b>		Nicardipine Hydrochloride in 0.9% Sodium Chloride is an approved prescription medication.				
<b>U.S. Federal Regulations</b>	:	United States inventory (TSCA 8b): Not determined. Clean Water Act (CWA) 311: Hydrochloric acid Clean Air Act (CAA) 112 regulated toxic substances: Hydrochloric acid				
<b>Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)</b>	:	Listed				
<b>Clean Air Act Section 602 Class I Substances</b>	:	Not listed				
<b>Clean Air Act Section 602 Class II Substances</b>	:	Not listed				
<b>DEA List I Chemicals (Precursor Chemicals)</b>	:	Not listed				
<b>DEA List II Chemicals (Essential Chemicals)</b>	:	Listed				
<b>SARA 302/304:</b>						
<b>Name</b>	<b>%</b>	<b>EHS</b>	<b>SARA 302 TPQ</b>		<b>SARA 304 RQ</b>	
			<b>(lbs)</b>	<b>(gallons)</b>	<b>(lbs)</b>	<b>(gallons)</b>
hydrochloric acid	≥1 - ≤2.9	Yes	500	-	5000	-
<b>SARA 304 RQ</b>	:	250000 lbs / 113500 kg				
<b>SARA 311/312</b>	:	SKIN CORROSION/IRRITATION - Category 2 SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A				



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		Nicardipine Hydrochloride	ACUTE TOXICITY (oral) - Category 3 ACUTE TOXICITY (dermal) - Category 3 ACUTE TOXICITY (inhalation) - Category 3		
		Hydrochloric acid	SKIN CORROSION/IRRITATION - Category 1B SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 1 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3		
<b>SARA 313</b>	:		<b>Product name</b>	<b>CAS number</b>	<b>%</b>
		Form R - Reporting requirements	Hydrochloric acid	7647-01-0	≥1 - ≤2.9
		Supplier notification	Hydrochloric acid	7647-01-0	≥1 - ≤2.9
SARA 313 notifications must not be detached from the SDS and any copying and redistribution of the SDS shall include copying and redistribution of the notice attached to copies of the SDS subsequently redistributed.					
<b>State Regulations</b>	:	Based on this product's use, the requirements of the OSHA Bloodborne pathogen Standard (29 CFR 1910.1030) are applicable.			
<b>Massachusetts</b>	:	The following components are listed: Hydrochloric acid			
<b>New York</b>	:	The following components are listed: Hydrochloric acid			
<b>New Jersey</b>	:	The following components are listed: Hydrochloric acid			
<b>Pennsylvania</b>	:	The following components are listed: Hydrochloric acid			
<b>California Prop. 65</b>	:	California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.			

**SECTION 16: OTHER INFORMATION**

**Procedure used to derive the classification**

<b>Classification</b>	<b>Justification</b>
<b>SKIN CORROSION/IRRITATION - Category 2 SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A</b>	<b>Calculation method Calculation method</b>

**Abbreviations:**

ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association



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IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)

UN = United Nations

**History:**

<b>Issued Date</b>	:	27.10.25
<b>Revision Date</b>	:	NA
<b>Version</b>	:	00

**Notice to Reader**

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

----End of SDS---