1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier

Name of the product : Carisoprodol Tablets

Trade Name : Not Available

Chemical Name : N-isopropyl-2-methyl-2-propyl-1,3-propanediol dicarbamate

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

Intended use : Pharmaceutical product for the treatment of painful musculoskeletal conditions

1.3 Details of the supplier of the safety data sheet

Supplier : Strides Shasun Limited,
Unit II, R. S. No. 32, 33 & 34, PIMS Road,
Periyakalapet, Puducherry - 605014
Telephone No. : +91-413-2650900

1.4 Emergency Telephone No.

+91-413-2650918

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]

Skin irritation (Category 2)

Sensitization – skin (Category 1)

Specific Target Organ Toxicity – Repeated (Category 2)

Classification according to Directive 67/548/EEC or 1999/45/EC

Overexposures can causes irritation to contaminated skin during normal use and handling. Susceptible individual who have had allergic reactions to products containing Carisoprodol, Corn Starch or any other ingredients in this product, may experience allergic reactions after exposure to this product. Therapeutic use of Carisoprodol can cause adverse symptoms on the cardiovascular system, urinary system, central nervous system, gastrointestinal system, hematologic system and skin.

2.2 Label Elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Pictogram 

Signal Word : Warning

Hazard Statement(s)

H315	: Causes skin irritation
H317	: May cause an allergic skin reaction
H373	: Causes damage to organs through prolonged or repeated exposure

Precautionary Statement(s)

P260	: Do not breathe dust/fume/gas/mist/vapours/spray
P264	: Wash hands thoroughly after handling
P272	: Contaminated work clothing should not be allowed out of the workplace
P280	: Wear protective gloves/protective clothing/eye protection/face protection
P314	: Get medical advice/attention if you feel unwell
P362	: Take off contaminated clothing and wash before reuse
P363	: Wash contaminated clothing before use.
P332 + P313	: If skin irritation occurs: Get medical advice/attention
P333 + P313	: If skin irritation or rash occurs: Get medical advice/attention

Supplemental Hazard Statements: None

According to European Directive 67/548/EEC as amended

Hazard symbol(s)

Risk Phrases

R33	: Danger of cumulative effects
R38	: Causes irritation to skin
R43	: May cause sensitization by skin contact
R48	: Danger of serious damage to health by prolonged exposure

2.3 Other Hazards

If heated to high temperatures for a prolonged period, the product may ignite. When involved in fire, this material may decompose and produce irritating vapors and toxic compounds including carbon oxides, nitrogen oxides, etc.

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

Not a substance in accordance with Directive 1999/45/EC.

3.2. Mixtures

Ingredients	Active / Inactive	CAS No.	EINECS No.	% w/v
Carisoprodol	Active	78-44-4	201-118-7	Proprietary
Corn Starch	Inactive	9005-25-8	232-679-6	Proprietary
Microcrystalline Cellulose	Inactive	9004-34-6	232-674-9	Proprietary
Croscarmellose Sodium	Inactive	74811-65-7	None listed	Proprietary
Povidone	Inactive	9003-39-8	None listed	Proprietary
Magnesium Stearate	Inactive	557-04-0	209-150-3	Proprietary

4. FIRST AID MEASURES

4.1. Description of first aid measures:

Eye contact

Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

Skin contact

Basic hygiene should prevent any problems. Flush skin with soap solution and water for at least 15 minutes after removing contaminated clothing and shoes. Victim must seek immediate medical attention, especially if an adverse reaction occurs. Wash contaminated cloth before reuse.

Ingestion

Never give anything by mouth to an unconscious person. If professional advice is not available, DO NOT induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

Inhalation

If airborne dusts generated by this product are inhaled, remove victim to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give medical oxygen. Seek medical atte4ntion if adverse effect continues.

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

Medical Conditions Aggravated by Exposure: Pre-existing allergies, blood disease caused by an allergy or reaction to any other medicine, drug abuse or dependence, or history of, kidney disease or liver disease, porphyria, cardiovascular conditions, conditions causing urinary retention, angle-closed glaucoma and increased intra-ocular pressure in eyes may be aggravated by chronic overexposures to this product.

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

Recommendations to Physicians: This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treatment is symptomatic and suppo0rtive. Empty the stomach as quickly as possible by emesis, followed by gastric lavage. Should respiration or blood pressure become compromised, respiratory assistance, central nervous system stimulants, and pressor agents should be administered cautiously as indicated.

Since over dosage is often deliberate, patients may attempt suicide by other means during the recovery phase. Deaths by deliberate or accidental over dosage have occurred with this class of drugs.

5. FIRE FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media

Use extinguishing media appropriate for surrounding fire. Use Water spray, Dry chemical powder (DCP), Carbon di oxide (Co_2) or foam.

5.2. Special hazards arising from the substance or mixture

Under Fire conditions, it decomposes and emits toxic compounds like carbon oxides, nitrogen oxides, and hydrogen chloride.

5.3. Advice for firefighters

Wear self-contained breathing apparatus, Fire proximate suit for firefighting.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use proper personal protective equipment as indicated in Section 8.

Do not eat, drink or smoke while cleaning up. Use a self-contained respirator, a mask with filter or a filtering mask. Wear protective clothing, safety glasses and impervious gloves. Ensure adequate ventilation. Avoid all sources of ignition; hot surfaces and open flames.

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3. Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Avoid prolonged repeated skin contact and breathing dust. Wash thoroughly after handling. Use with adequate ventilation. Minimize dust generation and accumulation. Avoid contact with eyes, skin, and clothing. Keep container tightly closed. Avoid ingestion and inhalation.

7.2. Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

7.3. Specific end use(s)

Further information not available.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control Parameters

Occupational Exposure Limits

Chemical Name	ACGIH – TLVs		NIOSH – RELs		OSHA – PELs	
	TWA ($mg/m^{3)}$	STEL (mg/m^3)	TWA (mg/m^3)	STEL (mg/m^3)	TWA (mg/m^3)	STEL (mg/m^3)
Carisoprodol	Not Established	Not Established	Not Established	Not Established	Not Established	Not Established

Corn Starch	10	Not Established	Not Established	Not Established	10 (total dust), 5 (resp. frac)	Not Established
Microcrystalline cellulose	10	Not Established	Not Established	Not Established	10 (total dust), 5 (resp. frac)	Not Established
Croscarmellose sodium	10	Not Established	Not Established	Not Established	10 (total dust), 5 (resp. frac)	Not Established
Povidone	Not Established	Not Established	Not Established	Not Established	Not Established	Not Established
Magnesium Stearate	10	Not Established	Not Established	Not Established	Not Established	Not Established

8.2. Exposure Controls

Appropriate Engineering Controls

Use adequate general or local exhaust ventilation to keep airborne concentrations below the permissible exposure limits.

Personal Protective Equipment

Eye Protection

Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166 or NIOSH.

Skin Protection

Wear appropriate protective gloves to prevent skin exposure. Wear appropriate protective clothing to prevent skin exposure.

Respiratory Protection

A respirator is not required for routine conditions of us of this product. If respiratory protection is needed, use a full-face/half-face piece with particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical State : Tablets

pH : Not available

Vapor Pressure : Not available.

Vapor Density	**:** Not available.
Evaporation Rate	**:** Not available.
Viscosity	**:** Not available.
Boiling Point	**:** Not available
Freezing/Melting Point	**:** Not available
Auto ignition Temperature	**:** Not available.
Flash Point	**:** Not available
Decomposition Temperature	**:** Not available.
NFPA Rating	**:** (estimated) Health: 2; Flammability: 1; Reactivity: 0
Explosive Limits	**:** Not available.
Solubility	**:** Not available.
Specific Gravity/Density	**:** Not available.

9.2. Other information

No further relevant information available.

10. STABILITY AND REACTIVITY

10.1 Reactivity

No data available

10.2. Chemical Stability

Stable at room temperature in closed containers under normal storage and handling conditions.

10.3. Possibility of hazardous reactions

Not Applicable

10.4. Conditions to Avoid

Avoid heat, light, and contact with incompatible chemicals.

10.5. Incompatible Materials

This product is generally compatible with other common materials in a medical facility. Acid, causgtics, and other chemicals that could affect its performance should be avoided.

10.6. Hazardous Decomposition Products

If exposed to extremely high temperatures, the product of thermal decomposition may include irritating fumes and toxic gases (e.g carbon oxides, nitrogen oxides and hydrogen chloride).

11 - TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute Toxicity details

LD50/LC50:

LD50 (oral – rat) 1320 mg/kg; LD50 (oral – mouse) 1800 mg/kg

Potential Health Effects

Eye/Skin Contact : Contact with the skin may cause mild irritation, which is alleviated upon rinsing. Prolonged or repeated skin contact may cause dermatitis (dry, red skin). Contact with the eyes of airborne dusts generated by this product may cause mild to moderate irritation, redness, and tearing.

Skin Absorption : This product and its components are not known to be absorbed through intact skin.

Inhalation : Inhalation of airborne dusts generated by this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.

Ingestion : Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product caused by poor hygiene practices may cause adverse symptoms.

Target Organs : ACUTE: Industrial exposure: skin and eyes. Therapeutic Doses: Gastrointestinal system, respiratory system skin, ears.

CHRONIC: Industrial exposure: skin. Therapeutic Doses: Musculoskeletal system, cardiovascular system, liver, kidneys, central nervous system, gastrointestinal system, urogenital system, reproductive system and skin.

Chronic Exposure: Prolonged or repeated exposure may cause adverse effects to the target organs.

Signs and symptoms of overexposure

Symptoms of ingestion overexposure may include Drowsiness, dizziness, clumsiness, headache, fast heart rate, upset stomach, vomiting, fainting, mental depression, skin rash, shortness of breath, difficulty breathing, stuffy nose, fever, weakness, burning in the eyes, red or bloodshot eyes, transient quadriplegia, ataxia, temporary loss of vision, blurred or double vision or other change in vision, diplopia, mydriasis, dysarthria, agitation, euphoria, confusion, and disorientation. Rarely reported symptoms can include: blood in urine, bloody or black, tarry stools, cough or hoarseness, fast or irregular breathing, tightness on chest and/or wheezing, hives, itching, or redness, lower back or side pain, muscle cramps or pain (not present before treatment or more painful than before treatment), painful or difficult urination, pain, tenderness, heat,

redness, pinpoint red spots on skin, puffiness or swelling of the eyelids or around the eyes, sores, ulcers, or white spots on lips or in mouth, sore throat and fever with or without chills, swollen and/or painful glands, unusual bruising or bleeding, unusual tiredness or weakness, vomiting of blood or material that looks like coffee grounds, yellow eyes or skin.

Symptoms of prolonged or repeated ingestion, as may occur when poor industrial hygiene is practiced, may include those described for “Other Potential Health Effects”. There are reports of anaphylactic reactions from persons taking therapeutic doses of products containing Carisoprodol. Symptoms can include skin rash, erythema multiforme, pruritus, and eosinophilia. Severe reactions have been manifested by asthmatic episodes, fever, weakness, dizziness, angioneurotic edema, smarting eyes, hypontension, and anaphylactoid shock.

Germ cell mutagenicity

Carisoprodol is not reported to cause mutagenic effects and teratogenic effects in humans in therapeutic doses.

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

Carisoprodol passes into the breast mild and may cause drowsiness or stomach upset in nursing babies. Carisoprodol was evaluated for reproductive toxicity in CD-1 (Swill) mice using the Reproductive Assessment by Continuous Breeding Protocol (RACB). Continuous cohabitation phase was set at 0, 300, 750, and 1500 mg/kg/day, in corn oil gavage. When high dose killed 10% of males and 20% of females after < 1 week exposure, the high dose level was reduced to 1200 mg/kg/day. During 14 weeks of cohabitation, with daily dosing of Carisoprodol, there was no effect on the ability of the animals to produce litters. However, the proportion of pups born alive, and absolute and adjusted live pup weight, was decreased in the high-dose group compared to the controls. Evaluation of the control and 1200 mg/kg/day dose groups found no effect of Carisoprodol on any measure of reproductive function. There was no effect of 1200 mg/kg/day Carisoprodol on sperm concentration, motility, or morphology. Relative right epididymis weight was significantly increased over the control group for high-dose males. There was no effect of Carisoprodol on estrous cyclicity. No treatment-related histopathology in the kidney, liver, or reproductive organs was observed in either males or females exposed to 1200 mg/kg/day Carisoprodol. Indications of generalized toxicity included tranquilization, and reduced body weight in high-dose females. There was no effect of Carisoprodol on indices of mating, pregnancy or fertility, the proportion of pups born alive, the sex ratio of live pups, unadjusted live pup weight, or average number of days to litter. The number of pups/litter (females and the sexes combined) was reduced in the high dose group. Adjusted live pup weight was significantly

decreased in the mid- and high-dose groups. At necropsy, there was no effect of treatment on the relative weight of any male or female reproductive organs; spermatid head count was significantly reduced at all dose levels. Indications of generalized toxicity included decreased survival of the pups through postnatal day 21 at 750 mg/kg/day dosage (females and sexes combined), 1200 mg/kg/day (sexes combined), and decreased body weight for males at doses of 750 and/or 1200 mg/kg/day, and for females at all dose groups. In summary, despite indications of generalized toxicity, only minimal effects of Carisoprodol on the reproductive processes were observed in the test animal and their offspring at the doses used in this study.

12 - ECOLOGICAL INFORMATION

12.1 Toxicity

No further relevant information available

12.2. Persistence and degradability

No further relevant information available

12.3. Bio accumulative potential

No further relevant information available

12.4. Mobility in soil

No further relevant information available

12.5. Results of PBT and vPvB assessment

No further relevant information available

12.6. Other adverse effects

No further relevant information available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product waste, including contaminated materials from spill cleanup, must be handled in accordance with local or international regulations. Waste should be incinerated in accordance with local or international regulations.

14. TRANSPORT INFORMATION

14.1. UN Number

Not applicable

14.2 Proper shipping Name

Carisoprodol Tablets

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

No data available

14.6. Special precautions for user

Not available

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not available

15 - REGULATORY INFORMATION

This safety datasheet complies with the requirements of Commission Regulation (EU) No. 453/2010

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

Not available

15.2. Chemical safety assessment

Not available

16. OTHER INFORMATION

No information available

As of the date of issuance, we are providing information regarding this material with the good faith belief it is accurate. However, this safety data sheet does not constitute a warranty of any kind, expressed or implied. It is the user's responsibility to implement policies for the safe handling and use of this product, and to determine the suitability of this information for their purpose. In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with medical or remediation personnel.

Abbreviation:

ACGIH - American Conference of Governmental Industrial Hygienists

NIOSH - The National Institute for Occupational Safety and Health

OSHA - Occupational Safety and Health Administration

LD - Lethal Dose

TLV - Threshold Limit Value

REL - Recommended Exposure Limit

PEL - Permissible Exposure Limit

CAS - Chemical Abstract Service

NFPA – National Fire Protection Association

Document Change History

REV. No.	ISSUE DATE	DETAILS OF CHANGE	JUSTIFICATION	SUPERSEDES
00	07.12.2015	New Document	For Implementation	Nil