SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING

Contact information

General

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Product identifier Carprofen

Synonyms Carprofen Chewable Tablet

Trade names Carprofen Chewable Tablet

Chemical family Mixture - contains a substituted carbazole

Relevant identified uses of the substance or mixture and uses advised against Bulk formulated pharmaceutical mixture/Formulated pharmaceutical product/ mixture packaged in final form for patient use; contains carprofen - a non-steroidal anti-inflammatory medication.

Note This SDS is written to address potential worker health and safety issues associated with the handling of the formulated drug product.

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SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture **Drugs in the finished state and intended for the final user are not subject to labeling in the US, EU or Canada.** Please consult the prescribing/packaging information. **The classification and labeling listed below is for bulk Carprofen Chewable Tablets.**

Regulation (EC) 1272/ 2008 [GHS] Skin Sensitizer - Category 1. Specific Target Organ Toxicity (repeated exposure) - Category 2.

Directive 67/548/EEC or 1999/45/EC Xi - R43; Xn - R48/22

Label elements

SECTION 2 - HAZARDS IDENTIFICATION …continued

CLP/GHS hazard pictogram

CLP/GHS signal word

Warning

CLP/GHS hazard statements

H317 - May cause allergic skin reaction. H373 - May cause damage to gastrointestinal (GI) tract through prolonged or repeated exposure.

CLP/GHS precautionary statements

P260 - Do not breathe dust. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/eye protection/face protection. P302 + P352 - If on skin: Wash with plenty of soap and water. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P314 - Get medical advice/attention if you feel unwell. P363 - Wash contaminated clothing before reuse. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

EU symbol/indication of danger

Xi - Irritant; Xn - Harmful

Risk (R) Phrase(s)

R43 - May cause sensitization by skin contact. R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Safety Advice

S24 - Avoid contact with skin. S36/37 - Wear suitable protective clothing and gloves.

Other hazards

Contains carprofen - a non-steroidal anti-inflammatory drug (NSAID). Common adverse effects with therapeutic use of NSAIDs include mild gastrointestinal disturbances. Carprofen has been reported to cause photoallergic contact dermatitis following occupational exposure.

US Signal word

Warning

US Hazard overview

Contains carprofen. May cause an allergic skin reaction. May cause gastrointestinal tract damage based on animal data.

Note

This mixture is classified as dangerous according to directive 1999/45/EC, Regulation EC No 1272/2008 (EU CLP) and applicable US communication regulations. See Section 16 for full text of EU and GHS classifications. The EU symbol/indicator of danger, R Phrases and Safety Advice are based on Directive 67/548/EEC or 1999/45/EC. The GHS classifications are based on Regulation (EC) 1272/2008.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS #	EINECS/ ELINCS#	Amount	EU Classification	GHS Classification
Carprofen	52263-47-5	N/A	<5%	Toxic - T: R25, R48/22; Irritant - Xi: R43	ATO3: H301; STOT-R1:H372; SS1: H317
Cellulose	9004-34-6	232-674-9	<30%	Not classified	Not classified
Magnesium Stearate	557-04-0	209-150-3	<5%	Not classified	Not classified

Note The ingredient(s) listed above are considered dangerous/hazardous or are the active ingredient. Cellulose and magnesium stearate are included because they have OELs. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of EU and GHS classifications. The EU classification is based on Directive 67/548/EEC and the GHS classification is based on Regulation (EC) 1272/2008.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

Immediate Medical Attention Needed No. If exposed or concerned: Get medical advice/attention.

Eye Contact If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.

Skin Contact Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

Inhalation Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

Ingestion Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

Protection of first aid responders See Section 8 for Exposure Controls/Personal Protection recommendations.

Most important symptoms and effects, both acute and delayed See Sections 2 and 11.

Indication of immediate medical attention and special treatment needed, if necessary Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

SECTION 5 - FIREFIGHTING MEASURES

Extinguishing media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Specific hazards arising from the substance or mixture	No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen, hydrochloric acid, or other chlorine-, magnesium-, and sodium-containing compounds.
Flammability/ Explosivity	No explosivity or flammability data identified. High airborne concentrations of finely divided organic particles can potentially explode if ignited.
Advice for firefighters	Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not crush, break or chip tablets. Do not breathe dust.
Environmental precautions	Do not empty into drains. Avoid release to the environment.
Methods and material for containment and cleaning up	If tablets are spilled, scoop up and dispose of in a manner that is compliant with federal, state or local laws. If tablets are crushed/broken or if handling bulk formulation, DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Scoop up broken pieces. Add excess liquid to allow the material to enter solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container suitable for disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice.
Reference to other sections	See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling	If tablets are crushed or broken, or if handling bulk core tablet formulation, dust containing drug substance may be released. Minimize dust generation and accumulation. Follow recommendations for handling bulk formulated/packaged pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Wash thoroughly after handling. Avoid breathing dust.
Conditions for safe storage including any incompatibilities	Store at controlled room temperatures, 68-77°F (20-25°C).

SECTION 7 - HANDLING AND STORAGE …continued

Specific end use(s) No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters/ Occupational Exposure Limit Values

Compound	Issuer	Type	OEL
Carprofen	--	--	--
Cellulose	ACGIH, Australia, Belgium, Estonia, France, Portugal, Romania, Singapore, Spain	TWA-8 HR	10 mg/m³
	Ireland, United Kingdom	TWA-8 HR	10 mg/m³ (inhalable dust); 4 mg/m³ (respirable dust)
	Ireland	STEL	20 mg/m³ (total inhalable dust)
	Latvia	TWA-8 HR	2 mg/m³
	Mexico	TWA-8 HR/STEL	10/20 mg/m³
	NIOSH	TWA-8 HR	10 mg/m³ (total dust); 5 mg/m³ (respirable dust)
	OSHA	TWA-8 HR	15 mg/m³ (total dust); 5 mg/m³ (respirable fraction)
	United Kingdom	STEL	20 mg/m³ (inhalable dust); 12 mg/m³ (respirable dust)
Magnesium Stearate	ACGIH	TWA-8 HR	10 mg/m³ (stearates)
	Lithuania	TWA-8 HR	3 mg/m³
	Sweden	TWA-8 HR	5 mg/m³

Exposure/Engineering controls None required for normal handling of packaged product. If tablets are crushed or broken, or if handling bulk formulation: Control exposures to below the band(s) for the active pharmaceutical ingredient(s) (if available). Otherwise, selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at dust-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling of powders. High-energy operations such as milling, particle sizing, spraying or fluidizing should be done within an approved emission control or containment system.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION …continued

Respiratory protection	None required for normal handling of packaged product. If tablets are crushed or broken, or if handling bulk formulation: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine powder handling tasks, an approved and properly fitted air-purifying respirator with HEPA filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a powered air-purifying respirator equipped with HEPA filters or combination filters or a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where a lower level of respiratory protection may not provide adequate protection.
Hand protection	None required for normal handling of packaged product. Wear nitrile or other impervious gloves if skin contact with tablets or with formulated mixture is possible. Double gloves may be considered.
Skin protection	Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.
Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Environmental Exposure Controls	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
Other protective measures	Wash hands in the event of contact with this substance, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Chewable tablet
Color	No information identified.
Odor	No information identified.
Odor threshold	No information identified.
pH	Not applicable.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES …continued

Melting point/ freezing point	No information identified.
Initial boiling point and boiling range	No information identified.
Flash point	No information identified.
Evaporation rate	No information identified.
Flammability (solid, gas)	No information identified.
Upper/lower flammability or explosive limits	No information identified.
Vapor pressure	No information identified.
Vapor density	No information identified.
Relative density	No information identified.
Water solubility	No information identified.
Solvent solubility	No information identified.
Partition coefficient (*n-octanol/water*)	No information identified.
Auto-ignition temperature	No information identified.
Decomposition temperature	No information identified.
Viscosity	No information identified.
Explosive properties	No information identified.
Oxidizing properties	No information identified.
Other information	
Molecular weight	Not applicable (Mixture).
Molecular formula	Not applicable (Mixture).

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	No information identified.
Chemical stability	Chemically stable; pharmacological stability not guaranteed beyond expiration date imprinted on package.

SECTION 10 - STABILITY AND REACTIVITY …continued

Possibility of hazardous reactions Not expected to occur.

Conditions to avoid No information identified.

Incompatible materials No information identified.

Hazardous decomposition products No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Note **Data for the mixture were limited. Therefore, data describing the active ingredient(s) and/or the individual ingredients were included where applicable.**

Information on toxicological effects

Route of entry Tablet content may be absorbed by ingestion. If tablets are crushed or broken, or handling bulk material, mixture may also be absorbed by inhalation and skin contact.

Acute toxicity

Compound	Type	Route	Species	Dose
Carprofen	LD_{50}	Oral	Mice	282 mg/kg
	LD_{50}	Oral	Rats	149 mg/kg
Cellulose	LC_{50}	Inhalation	Rat	>5800 mg/m³/4h
	LD_{50}	Oral	Rat	>5000 mg/kg
	LD_{50}	Dermal	Rabbit	>2000 mg/kg
Magnesium Stearate	LC_{50}	Inhalation	Rat	>2000 mg/m³

Irritation/Corrosion Carprofen is non-irritating to rabbits.

Sensitization Carprofen is considered a dermal sensitizer, based on effects reported following occupational exposure. It was not a sensitizer in guinea pigs.

STOT-single exposure No data identified.

STOT-repeated exposure/Repeat-dose toxicity In oral rat studies ≥6 months duration, doses of 10 mg/kg/day caused mortality, intestinal ulceration, and peritonitis. The NOAEL in a 2-year rat study was 1 mg/kg/day.

Reproductive toxicity Carprofen caused no adverse effects in a number of laboratory species. Details were not identified.

Developmental toxicity Carprofen was not teratogenic or fetotoxic in animal studies. Details were not identified.

SECTION 11 - TOXICOLOGICAL INFORMATION …continued

Genotoxicity Carprofen was non-mutagenic in the Ames bacterial mutagenicity assay, in mammalian cell mutagenicity assays, and *in vivo* mutagenicity assays. It was non-clastogenic in an *in vitro* mammalian cell assay.

Carcinogenicity Carprofen was non-carcinogenic in 2-year rat and mouse studies. No components of the product present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

Aspiration hazard No data available.

Human health data See "Section 2 - Other Hazards"

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

Compound	Type	Species	Concentration
Carprofen	--	--	--
Cellulose	--	--	--
Magnesium Stearate	--	--	--

Persistence and Degradability No data available.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Results of PBT and vPvB assessment Not performed.

Other adverse effects No data available.

Note The environmental characteristics of this product/mixture have not been fully investigated. Releases to the environment should be avoided.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

SECTION 14 - TRANSPORT INFORMATION

Transport	Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
UN number	None assigned.
UN proper shipping name	None assigned.
Transport hazard classes and packing group	None assigned.
Environmental hazards	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
Special precautions for users	Avoid release to the environment.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 15 - REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture	This SDS complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines. Consult your local/regional authorities for more information.
Chemical safety assessment	Not conducted.
OSHA Hazardous	Yes. Warning. Contains carprofen. May cause an allergic skin reaction. May cause gastrointestinal tract damage based on animal data.
WHMIS classification	Drugs are not subject to WHMIS. This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.
TSCA status	Drugs are exempt from TSCA.
SARA section 313	Not listed.
California proposition 65	Not listed.
Additional information	No other information identified.

SECTION 16 - OTHER INFORMATION

Full text of R phrases and EU Classifications	T - Toxic. R25 - Toxic if swallowed. Xi - Irritant. R43 - May cause sensitization by skin contact. Xn - Harmful. R48/22 - Danger of serious damage to health by prolonged exposure.
Full text of H phrases, P phrases and GHS classification	ATO3 - Acute Toxicity (Oral) Category 3. H301 - Toxic if swallowed. STOT-R1 - Specific Target Organ Toxicity Following Repeat Exposure Category 1. H372 - Causes damage to GI tract through prolonged or repeated exposure. STOT-R2 - Specific Target Organ Toxicity Following Repeated Exposure Category 2. H373 - May cause damage to GI tract through prolonged or repeated exposure. SS1 - Skin sensitizer Category 1. H317 - May cause an allergic skin reaction.
Sources of data	Information from published literature and internal company data.
Abbreviations	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System
Revisions	This is the first version of this SDS.
Disclaimer	The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is

Disclaimer …continued

accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.