

SAFETY DATA SHEET

according to 29 CFR 1910.1200 and GHS

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PanaKare™ Plus Tablets

Revision 0
Revision date 2019-02-27

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name	PanaKare™ Plus Tablets
Product code	09067, 09068

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

Product Use	[SU22] Professional uses: Public domain (administration, education, entertainment, services, craftsmen); [PC29] Pharmaceuticals;
Description	For animal use only. Not for human use. Permitted for use only by and under the supervision of licensed veterinarians.

1.3. Details of the supplier of the safety data sheet

Company	Neogen Corporation
Address	620 Lesher Place Lansing MI 48912 USA
Web	www.neogen.com
Telephone	517-372-9200/800-234-5333
Email	regulatorysupport@neogen.com

1.4. Emergency telephone number

Emergency telephone number	1-800-234-5333
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Further information

Manufactured By:	Neogen Corporation 944 Nandino Blvd. Lexington, KY 40511-1205 U.S.A.
Hotline(s):	Medical: United States (1-800-498-5743), International (1-651-523-0318). Spill/CHEMTREC: United States (1-800-424-9300), International (1-703-527-3887).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

2.1.2. Classification - GHS	Skin Irrit. 2: H315; Skin Sens. 1: H317; Eye Irrit. 2: H319; Resp. Sens. 1: H334; STOT SE 3: H335; Repr. 1B: H360;
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2.2. Label elements

Hazard pictograms



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2.2. Label elements

Signal Word	Danger
Hazard Statement	Skin Irrit. 2: H315 - Causes skin irritation. Skin Sens. 1: H317 - May cause an allergic skin reaction. Eye Irrit. 2: H319 - Causes serious eye irritation. Resp. Sens. 1: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled. STOT SE 3: H335 - May cause respiratory irritation. Repr. 1B: H360 - May damage fertility or the unborn child .
Precautionary Statement: Prevention	P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood. P261 - Avoid breathing dust/fume/gas/mist/vapours/spray. P264 - Wash thoroughly after handling. P271 - Use only outdoors or in a well-ventilated area. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P284 - [In case of inadequate ventilation] wear respiratory protection.
Precautionary Statement: Response	P302+P352 - IF ON SKIN: Wash with plenty of water/ . P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P308+P313 - IF exposed or concerned: Get medical advice/attention. P312 - Call a POISON CENTER/doctor/ /if you feel unwell. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention. P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER/doctor/ .
Precautionary Statement: Storage	P403+P233 - Store in a well-ventilated place. Keep container tightly closed. P405 - Store locked up.
Precautionary Statement: Disposal	P501 - Dispose of contents/container to an approved waste disposal facility in accordance with local and national regulations.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification
d- α -Tocopherol		59-02-9	233-466-0		1 - 10%	Skin Sens. 1: H317; Aquatic Chronic 4: H413;
Pancreatin		8049-47-6	232-468-9		40 - 50%	Skin Irrit. 2: H315; Eye Irrit. 2: H319; Resp. Sens. 1: H334; STOT SE 3: H335;
Microcrystalline cellulose (Cellulose)		9004-34-6			10 - 20%	
Vitamin A-1000		11103-57-4	234-328-2		1 - 10%	Skin Sens. 1: H317; Eye Irrit. 2: H319; Repr. 1B: H360; Aquatic Chronic 4: H413;
Colecalciferol	603-180-00-4	67-97-0	200-673-2		0 - 0.5%	Acute Tox. 2: H330; Acute Tox. 3: H311; Acute Tox. 3: H301; STOT RE 1: H372;

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Irritating to respiratory system. Inhalation may cause coughing, tightness of the chest and irritation of the respiratory system. Move the exposed person to fresh air. Seek medical attention.
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4.1. Description of first aid measures

Eye contact	Irritating to eyes. Rinse immediately with plenty of water for 15 minutes holding the eyelids open. Seek medical attention if irritation or symptoms persist.
Skin contact	Irritating to skin. May cause allergic reactions in susceptible people. Wash off immediately with plenty of soap and water. Remove contaminated clothing. Seek medical attention if irritation or symptoms persist.
Ingestion	Ingestion may cause nausea and vomiting. May cause harm to the unborn child. Seek medical attention if irritation or symptoms persist. DO NOT INDUCE VOMITING unless advised to do so by a doctor.

SECTION 5: Firefighting measures

5.1. Extinguishing media

	Use extinguishing media appropriate to the surrounding fire conditions.
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5.2. Special hazards arising from the substance or mixture

	Burning produces irritating, toxic and obnoxious fumes.
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5.3. Advice for firefighters

	Wear suitable respiratory equipment when necessary.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

	Ensure adequate ventilation of the working area. Wear suitable protective equipment.
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6.2. Environmental precautions

	Prevent further spillage if safe. Do not flush into surface water. Do not let product contaminate subsoil.
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6.3. Methods and material for containment and cleaning up

	Absorb with inert, absorbent material. Sweep up. Transfer to suitable, labelled containers for disposal. Clean spillage area thoroughly with plenty of water.
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6.4. Reference to other sections

	See section 2, 8, and 13 for further information.
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

	Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing. Refer to label for complete indications, dosing, storage, and handling.
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7.2. Conditions for safe storage, including any incompatibilities

	Keep in a cool, dry, well ventilated area. Keep at temperature not exceeding 35°C. Keep containers tightly closed. Store in correctly labelled containers. Refer to label for complete indications, dosing, storage, and handling.
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7.3. Specific end use(s)

	See section 1.2 for further information.
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Further information

	Keep out of reach of children.
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SECTION 8: Exposure controls/personal protection

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8.1. Control parameters

Exposure Limit Values

Microcrystalline cellulose (Cellulose)	ACGIH TLV TWA: 10 mg/m ³	ACGIH TLV STEL: -
	Notations: -	OSHA PEL 8hr TWA ppm: -
	OSHA PEL 8hr TWA mg m3: 15	Skin Designation: -
	NIOSH REL 10hr TWA ppm:	NIOSH REL 10hr TWA mg m3:
	NIOSH REL 15 min ST ppm:	NIOSH REL 15 min ST mg m3:

8.2. Exposure controls

	
Appropriate engineering controls	Ensure adequate ventilation of the working area.
Individual protection measures	Use as appropriate: Chemical resistant clothing.
Eye / face protection	Use as appropriate: Suitable eye protection.
Skin protection - Hand protection	Wear suitable gloves.
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

State	Tablet
Color	Light brown
Odor	Slight/Characteristic
Odour threshold	No data available
pH	No data available
Melting point	No data available
Freezing Point	No data available
Boiling point	Not applicable.
Flash point	No data available
Flammability limits	No data available
Vapor pressure	Not applicable.
Vapor density	Not applicable.
Relative density	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Explosive properties	Not applicable.
Oxidising properties	No data available
Solubility	Slightly soluble in water

9.2. Other information

VOC (Volatile organic compounds)	0 g/l
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No data available.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Keep away from sources of ignition - No smoking. Keep in a cool place away from direct sunlight.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Carbon oxides.

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

Acute toxicity	Prolonged or repeated exposure may cause: Damage to organs.
Skin corrosion/irritation	Causes skin irritation.
Serious eye damage/irritation	Causes serious eye irritation.
Respiratory or skin sensitisation	May cause allergic reactions in susceptible people.
Germ cell mutagenicity	No mutagenic effects reported.
Carcinogenicity	Not found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs, Volumes 1-112. Not listed in the National Toxicology Program (NTP) 13th Report on Carcinogens. Not listed in the OSHA standard 1910.1003 Carcinogens.
Reproductive toxicity	Adverse reproductive effects have been found in laboratory animals. May cause malformations or permanent structural changes in embryo/fetus.
STOT-single exposure	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Repeated or prolonged exposure	Avoid prolonged or repeated exposure. Discontinue use in animals showing signs of sensitivity.

11.1.4. Toxicological information

PanaKare™ Plus Tablets	Oral Rat LD50: 5747 Inhalation Rat LC50/4 h: 7.9	Dermal Rabbit LD50: 9340
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SECTION 12: Ecological information**12.2. Persistence and degradability**

No data available.

12.3. Bioaccumulative potential**Partition coefficient**

PanaKare™ Plus Tablets No data available

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Dispose of in compliance with all local and national regulations.

General information

Dispose of in compliance with all local and national regulations. Do not contaminate water by cleaning of equipment or disposal of wastes.

Disposal of packaging

Do NOT reuse empty containers. Empty containers can be sent for disposal or recycling.

SECTION 14: Transport information**14.1. UN number**

The product is not classified as dangerous for carriage.

14.2. UN proper shipping name

The product is not classified as dangerous for carriage.

14.3. Transport hazard class(es)

The product is not classified as dangerous for carriage.

14.4. Packing group

The product is not classified as dangerous for carriage.

14.5. Environmental hazards

The product is not classified as dangerous for carriage.

14.6. Special precautions for user

The product is not classified as dangerous for carriage.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

The product is not classified as dangerous for carriage.

Further information

The product is not classified as dangerous for carriage.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Regulations**

Hazard Communication Standard: 29 Code of Federal Regulations 1910.1200: Occupational Safety and Health Standards: Z: Toxic and Hazardous Substances: Hazard Communication.

All chemicals in this product are TSCA listed or excluded from listing, on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory. TSCA - United States Toxic Substances Control Act Section 8(b) Inventory. Materials are exempt from TSCA under Section 3(2)(B)(vi) when used in pharmaceutical application.

US State Regulations:

New Jersey Right-to-Know Hazardous Substance List:

This material contains no reportable components.

Pennsylvania Right-to-Know Hazardous Substance List:

This material contains no reportable components.

Rhode Island Right-to-Know Hazardous Substance List: This material contains no reportable

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

components.

Inventories

Ingredient	TSCA	MA	SARA313	CALPROP65	CWA307	CAA112	CWA311	SARA302	SARA304
Microcrystalline cellulose (Cellulose)	Y	N	N	N	N	N	N	N	N
Colecalciferol (9,10-Secocholesta-5,7,10(19)-trien-3-ol, (3.beta.,5Z,7E)-)	Y	N	N	N	N	N	N	N	N

Further information

The labeling requirements of the Federal Food, Drug, and Cosmetic Act differ from the classification criteria and hazard information required for safety data sheets and for workplace labels under the OSHA Hazard Communication Standard 29 CFR 1910.1200. Following is the hazard information as required on the drug label:

Keep out of reach of children. For animal use only. CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

NDC# 59051-9067-7, 59051-9067-5.

SECTION 16: Other information

Other information

Text of Hazard Statements in Section 3	<p>Skin Sens. 1: H317 - May cause an allergic skin reaction.</p> <p>Aquatic Chronic 4: H413 - May cause long lasting harmful effects to aquatic life.</p> <p>Skin Irrit. 2: H315 - Causes skin irritation.</p> <p>Eye Irrit. 2: H319 - Causes serious eye irritation.</p> <p>Resp. Sens. 1: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.</p> <p>STOT SE 3: H335 - May cause respiratory irritation.</p> <p>Repr. 1B: H360 - May damage fertility or the unborn child .</p> <p>Acute Tox. 3: H301 - Toxic if swallowed.</p> <p>Acute Tox. 3: H311 - Toxic in contact with skin.</p> <p>Acute Tox. 2: H330 - Fatal if inhaled.</p> <p>STOT RE 1: H372 - Causes damage to organs through prolonged or repeated exposure .</p>
Maximum content of VOC	0 g/l.

Further information

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