SAFETY DATA SHEET

CLAVUSAN TABLETS

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

1.1. Product identifier

CLAVUSAN 50/12.5 mg tablets for cats and dogs
CLAVUSAN 250/62.5 mg tablets for cats and dogs
CLAVUSAN 500/125 mg tablets for dogs

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

For animal treatment only. Oral antibiotic.

1.3. Details of the supplier of the safety data sheet

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands
Tel.: +31 348 41 69 45
E-mail: info@alfasan.nl

1.4. Emergency telephone number

Alfasan Nederland B.V.
Tel: +31 348 416945

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Skin Corrosion/Irritation Category 2, Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 2A, Sensitisation (Respiratory) Category 1, Specific Target Organ Toxicity – Single Exposure (Respiratory Tract Irritation) Category 3, Carcinogenicity Category 1A

2.2. Label elements

Hazard Pictograms:

2.3. Hazard statements

H315 Causes skin irritation
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.

2.4 Precautionary statement(s) Prevention

P261 Avoid breathing dust/fumes.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves and clothing, eye protection and face protection.

P284	[In case of inadequate ventilation] wear respiratory protection.
P202	Do not handle until all safety precautions have been read and understood.
P264	Wash all exposed external body areas thoroughly after handling.
P272	Contaminated work clothing must not be allowed out of the workplace.

2.5 Precautionary statement(s) Response

P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER/ doctor/ physician/first aider.
P305+P351+ P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call a POISON CENTER/doctor/physician/first aider 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.
P302+P352	IF ON SKIN: Wash with plenty of water.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308+P313	IF exposed or concerned: Get medical advice/attention.

2.6 Precautionary statement(s) Storage

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

2.7 Precautionary statement(s) Disposal

P501 Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

	Cas-nummer
Amoxicillin trihydrate	61337-70-7
Potassium cavulanate	61177-45-5
Crospovidone	25249-54-1
Povidone	9003-39-8
Sodium starch glycolate, A	9063-38-1
Microcrystalline cellulose	9004-34-6
Silica, colloidal anhydrous	7631-86-9
Magnesium stearate	557-04-0
Sodium saccharine	128-44-9
Vanillin	121-33-5

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact:
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician if irritation persist.

Skin contact:
Immediately remove all contaminated clothing, including footwear. Wash off with soap and plenty of water. Consult a physician if irritation persist.

Inhalation:
The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

Ingestion:
If swallowed do NOT induce vomiting. Rinse mouth with water. Consult a physician.

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

See section 11.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

There is no restriction on the type of extinguisher which may be used.
Use extinguishing media appropriate for surrounding fire.

5.2. Special hazards arising from the substance or mixture

Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.

5.3. Advice for firefighters

Firefighters should wear inhalation protection as hazardous substances from the fire may be adsorbed on the silica particles. Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. Use fire fighting procedures suitable for surrounding area.
DO NOT approach containers suspected to be hot. Equipment should be thoroughly decontaminated after use.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

See section 8.

6.2. Environmental precautions

See section 12.

6.3. Methods and material for containment and cleaning up

Dike ahead of liquid spills for later disposal. Absorb liquid with inert material. Recover product and place in an appropriate container for disposal in accordance with local regulations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

When stored in the original, intact container, no specific handling and storage measures are necessary. No specific safety measures are required.

Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label and/or product insert information, away from incompatible substances.

7.3. Specific end use(s)

For animal treatment only. Adhere to guidelines of good distribution practice and good veterinary practice for handling and storage of this product.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Avoid contact with skin or eyes. Under normal conditions of use, no specific protective equipment is required. Under other conditions of use, wear protective clothing, gloves (latex or rubber), and safety glasses.

8.2. Exposure controls

If necessary, wear protective clothing, gloves (latex or rubber), and safety glasses.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Solid.
Appearance: White to slightly yellow tablets with a cross mark on one side.

9.2. Other information

Not applicable.

SECTION 10: Stability and reactivity

10.1. Reactivity

H azardous reactions will not occur under normal conditions.

10.2. Chemical stability

Stable under recommended handling and storage conditions.

10.3. Possibility of hazardous reactions

Stable under recommended handling and storage conditions.

10.4. Conditions to avoid

See section 7.

10.5. Incompatible materials

See section 7.

10.6. Hazardous decomposition products

Decomposition will not occur under normal conditions.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Inhaled
Evidence shows, or practical experience predicts, that the material produces irritation of the respiratory system, in a substantial number of individuals, following inhalation.

Ingestion
Accidental ingestion of the material may be damaging to the health of the individual.

Skin contact
Evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals.

Eye
Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals and/or may produce significant ocular lesions

Chronic
On the basis of epidemiological data, it has been concluded that prolonged inhalation of the material, in an occupational setting, is likely to produce cumulative health effects and may produce cancer in humans.

SECTION 12: Ecological information

12.1. Toxicity

No data available.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Data not yet available.

12.6. Other adverse effects

No data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Any unused product or waste materials derived from this product should be disposed of in accordance with local requirements. This product should not enter water courses as it may be persistent in the environment.

SECTION 14: Transport information

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Refer to Section 12 of this safety data sheet.

14.6. Special precautions for user

Refer to Section 7 of this safety data sheet.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable.

SECTION 15: Regulatory information

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

This product is authorised as a veterinary medicinal product in the European Union and conforms to all legal requirements on safety, health, and environmental aspects as laid down in the pharmaceutical legislation for medicinal products for veterinary use.

15.2. Chemical safety assessment

No specific chemical safety assessment has been performed for this product other than required for in the pharmaceutical legislation for medicinal products for veterinary use.

SECTION 16: Other information

This product is authorised as a veterinary medicinal product in the European Union.

Important: while the descriptions, data, and information contained herein are presented in good faith and believed to be accurate, it is provided for your guidance only. Because many factors may affect processing or application/use, we recommend that you make tests to determine the suitability of a product for your particular purpose prior to use. No warranties of any kind, either expressed or

implied, including warranties of merchantability or fitness for a particular purpose, are made regarding products described or data or information set forth, or that the products, data or information may be used without infringing the intellectual property rights of others. In no case shall the descriptions, information or data provided be considered a part of our terms and conditions of sale. Further, we assume no obligation or liability for the description, data, and information given or results obtained, all such being given and accepted at your risk.