

**Dulcogas® Chewable Tablets**

Version 1.0      Revision Date: 06/03/2015      MSDS Number: 000000039302      Date of last issue: -  
Date of first issue: 06/03/2015

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**SECTION 1. IDENTIFICATION**

Product name : Dulcogas® chewable tablets, Dulcogas® sachets

Synonyms : Active ingredient: Simeticone  
Dulcogas® chewable tablets, Dulcogas® sachets

Product code : 000000039302

**Manufacturer or supplier's details**

Company name of supplier : Boehringer-Ingelheim Pharmaceuticals, Incorporated

Address : 900 Ridgebury Road  
Ridgefield, Connecticut  
06877-0368

Emergency telephone number : +1-800-424-9300 CHEMTREC Emergency Phone Number  
CHEMTREC – 24 Hours

Routine Contact Number : (203) 778-7759

**Recommended use of the chemical and restrictions on use**

Recommended use : Medicine  
Mixture for production of finished medicinal products.

Prepared by : Corp. Div. EHS & Sustainability / Global EHS Services  
[EHS-service@boehringer-ingelheim.com](mailto:EHS-service@boehringer-ingelheim.com)

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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification (Hazard Communication Standard (HCS) 29 CFR 1910.1200)**

Not a hazardous substance or mixture.

**GHS Label element (Hazard Communication Standard (HCS) 29 CFR 1910.1200)**

Not a hazardous substance or mixture.

**Other hazards**

None known.

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

Substance / Mixture : Mixture

**Hazardous components**

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**SECTION 4. FIRST AID MEASURES**

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- General advice : Remove from exposure, lie down.  
Take off immediately all contaminated clothing.  
Victim to lie down in the recovery position, cover and keep him warm.  
First Aid responders should pay attention to self-protection and use the recommended protective clothing
- If inhaled : Move to fresh air.  
Call a physician immediately.
- In case of skin contact : Wash off immediately with plenty of water.  
Call a physician immediately.
- In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.  
Keep eye wide open while rinsing.  
Call a physician immediately.
- If swallowed : Rinse mouth.  
Drink plenty of water.  
Call a physician immediately.
- Most important symptoms and effects, both acute and delayed : None known.
- Notes to physician : Observe the summary of product characteristics of proprietary medicinal products
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**SECTION 5. FIREFIGHTING MEASURES**

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Water  
Dry chemical  
Foam  
Carbon dioxide (CO<sub>2</sub>)
- Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes.  
Can be released in case of fire:  
Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Hydrogen chloride gas
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.  
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.  
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
- Special protective equipment for firefighters : Self-contained breathing apparatus (EN 133)  
complete suit protecting against chemicals

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Wear personal protective equipment.  
Refer to protective measures listed in sections 7 and 8.  
Ensure adequate ventilation.  
Never return spills in original containers for re-use.
- Environmental precautions : Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : Cleaning operations should be carried out only while wearing breathing apparatus.  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
Non-sparking tools should be used.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Clean-up methods - large spillage  
Dampen, pick up mechanically and dispose of.  
Clean-up methods - small spillage  
Use approved industrial vacuum cleaner for removal.  
Keep in suitable, closed containers for disposal.
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**SECTION 7. HANDLING AND STORAGE**

- Advice on protection against fire and explosion : Avoid dust formation. Take precautionary measures against static discharges.
- Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.  
Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces.  
Minimize dust generation and accumulation.  
Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.  
Breathing must be protected when large quantities are decanted without local exhaust ventilation.  
Keep container closed when not in use.
- Conditions for safe storage : Keep container tightly closed.  
Protect from heat and direct sunlight.  
Jointless smooth floor
- Materials to avoid : Keep away from food, drink and animal feedingstuffs.  
Advice on Segregation
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**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

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**Engineering measures** : It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment.  
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).  
Use only appropriately classified electrical equipment and powered industrial trucks.

**Personal protective equipment**

Respiratory protection : Respirator must be worn if exposed to dust.  
half mask (EN 140)  
particle filter P2

Hand protection Material : Chemical resistant gloves made of butyl rubber or nitrile rubber category III according to EN 374.  
Directive : Protective gloves against chemicals and micro-organisms

Eye protection : Safety glasses with side-shields

Skin and body protection : Laboratory: laboratory coat; factory: disposable Overall.

Protective measures : Handle in accordance with good industrial hygiene and safety practice.  
Do not breathe dust.  
Avoid contact with skin, eyes and clothing.

Hygiene measures : General industrial hygiene practice.  
Wash hands and face before breaks and immediately after handling the product.  
Keep working clothes separately.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : solid

pH : No data available

Melting point/range : Not applicable

Boiling point/boiling range : Not applicable

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : No data available

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Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapour pressure	: Not applicable
Relative vapour density	: Not applicable
Relative density	: No data available
Bulk density	: No data available
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, dynamic	: Not applicable
Explosive properties	: Not tested

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity	: No dangerous reaction known under conditions of normal use.
Chemical stability	: No decomposition if stored and applied as directed.
Possibility of hazardous reactions	: Accumulation of fine dust may entail the risk of a dust explosion in the presence of air.
Conditions to avoid	: Extremes of temperature and direct sunlight.
Incompatible materials	: No data available
Hazardous decomposition products	: No data available

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity	: Remarks: No data available
Acute inhalation toxicity	: Remarks: No data available

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Acute dermal toxicity                      : Remarks: No data available

**Skin corrosion/irritation**

Not classified based on available information.

**Product:**

Remarks: No data available

**Serious eye damage/eye irritation**

Not classified based on available information.

**Product:**

Remarks: No data available

**Respiratory or skin sensitisation**

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

**Product:**

Remarks: No data available

**Germ cell mutagenicity**

Not classified based on available information.

**Product:**

Genotoxicity in vitro                      : Remarks: No data available

Genotoxicity in vivo                        : Remarks: No data available

**Carcinogenicity**

Not classified based on available information.

**Product:**

Remarks: No data available

**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.

**OSHA**

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

**NTP**

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity**

Not classified based on available information.

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Effects on fertility :  
Remarks: No data available

Effects on foetal development :  
Remarks: No data available

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**Aspiration toxicity**

Not classified based on available information.

**Product:**

No data available

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Product:**

Toxicity to fish :  
Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates :  
Remarks: No data available

Toxicity to algae :  
Remarks: No data available

Toxicity to fish (Chronic toxicity) :  
Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) :  
Remarks: No data available

Toxicity to bacteria :  
Remarks: No data available

**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available

**Other adverse effects****Product:**

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Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances  
 Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.  
 Uncontaminated packaging can be recycled.

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**SECTION 14. TRANSPORT INFORMATION****International Regulation****Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**National Regulations****SECTION 15. REGULATORY INFORMATION****EPCRA - Emergency Planning and Community Right-to-Know Act**

**SARA 311/312 Hazards** : No SARA Hazards

**SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

**Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.



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This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.  
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

**Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

**Pennsylvania Right To Know**

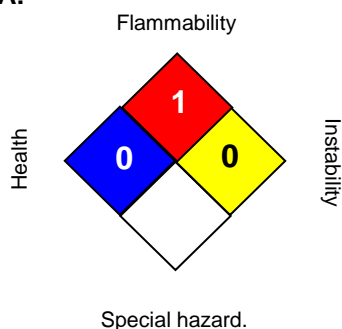
Simethicone	8050-81-5	90 - 100 %
Ungefährliche galenische Hilfsstoffe	Not Assigned	90 - 100 %

**New Jersey Right To Know**

Simethicone	8050-81-5	90 - 100 %
Ungefährliche galenische Hilfsstoffe	Not Assigned	90 - 100 %

**California Prop 65**

: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

**SECTION 16. OTHER INFORMATION****Further information****NFPA:****HMIS III:**

<b>HEALTH</b>	<b>0</b>
<b>FLAMMABILITY</b>	<b>1</b>
<b>PHYSICAL HAZARD</b>	<b>0</b>

0 = not significant, 1 =Slight,  
2 = Moderate, 3 = High  
4 = Extreme, \* = Chronic

Vertical lines in the left hand margin indicate an amendment from the previous version. Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a

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guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.