

**Duo Fusion® , solid, chewable tablet**

Version	Revision Date:	MSDS Number:	Date of last issue: -
1.0	10/14/2015	000000046735	Date of first issue: 10/14/2015

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**SECTION 1. IDENTIFICATION**

Product name : Duo Fusion® , solid, chewable tablet

Synonyms : with API: famotidine + calcium carbonate + magnesium hydroxide  
DUO Fusion® Berry

Product code : 000000046735

**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 : 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)**

Skin irritation : Category 2

Eye irritation : Category 2A

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

Hazard pictograms :



Signal word : Warning

Hazard statements : H315 Causes skin irritation.  
H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**  
P264 Wash skin thoroughly after handling.

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P280 Wear eye protection/ face protection.

P280 Wear protective gloves.

**Response:**

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P332 + P313 If skin irritation occurs: Get medical advice/ attention.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

P362 Take off contaminated clothing and wash before reuse.

**Other hazards**

None known.

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

Substance / Mixture : Mixture

**Hazardous components**

Chemical Name	CAS-No.	Concentration (%)
Calcium carbonate	471-34-1	82.1
Magnesium hydroxide	1309-42-8	16.9
Amifatidine (MK-208)	76824-35-6	1

**SECTION 4. FIRST AID MEASURES**

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 : Causes skin irritation.  
Causes serious eye irritation.

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delayed

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>)  
Sulphur oxides

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.  
Keep people away from and upwind of spill/leak.  
Ensure adequate ventilation.

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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Never return spills in original containers for re-use.

**SECTION 7. HANDLING AND STORAGE**

- Advice on protection against fire and explosion : Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Avoid dust formation.
- 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 tightly closed in a dry and cool place. Keep in a well-ventilated place. Protect from heat and direct sunlight. Jointless smooth floor
- Materials to avoid : Keep away from food, drink and animal feedingstuffs. Advice on Segregation

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Components with workplace control parameters**

Components	Basis	Factor	Category	Values	Remark
3-(((2-(Diaminomethylene)amino)-4-thiazolyl)methyl)thio)-N-sulfamoylpropionamide 76824-35-6, 76824-35-6	ECL		2	100 µg/m <sup>3</sup> )	
BIEL = Boehringer Ingelheim Exposure Limit					

- 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 de-

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signed 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 : No personal respiratory protective equipment normally required.  
Respirator must be worn if exposed to dust.  
half mask (EN 140)  
particle filter P2
- Hand protection Material : Nitrile rubber  
Break through time : 480 min  
Glove thickness : 0.43 mm  
Directive : Protective gloves against chemicals and micro-organisms  
Protective index : Class 6
- 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.  
Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.
- 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
- Colour : No data available
- Odour : odourless
- Odour Threshold : No data available
- pH : No data available
- Melting point/range : Not applicable
- Boiling point/boiling range : Not applicable

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Flash point	: Not applicable
Evaporation rate	: Not applicable
Flammability (solid, gas)	: No data available
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
Oxidizing properties	: No data available

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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 reac- tions	: Dust may form explosive mixture in 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 : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

**Components:****Calcium carbonate:**

Acute oral toxicity : LD50 (Rat): = 6,450 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

**Magnesium hydroxide:**

Acute oral toxicity : LD50 (Rat): = 8,500 mg/kg

Acute inhalation toxicity : Assessment: The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.

Acute dermal toxicity : Remarks: No data available

**Amifatidine (MK-208):**

Acute oral toxicity : LD50 (Rat): > 4,049 mg/kg  
LD50 (Mouse): > 4,868 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

**Skin corrosion/irritation**

Causes skin irritation.

**Components:****Calcium carbonate:**

Species: Rabbit  
Method: OECD Test Guideline 404  
Result: No skin irritation

**Magnesium hydroxide:**

Result: Irritating to skin.

**Amifatidine (MK-208):**

Remarks: No data available

**Serious eye damage/eye irritation**

Causes serious eye irritation.

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**Components:****Calcium carbonate:**

Species: Rabbit  
Result: No eye irritation  
Method: OECD Test Guideline 405

**Magnesium hydroxide:**

Species: Rabbit  
Result: Irritating to eyes.

**Amifatidine (MK-208):**

Remarks: No data available

**Respiratory or skin sensitisation**

Skin sensitisation: Not classified based on available information.  
Respiratory sensitisation: Not classified based on available information.

**Components:****Calcium carbonate:**

Result: No data available

**Magnesium hydroxide:**

Remarks: No data available

**Amifatidine (MK-208):**

Remarks: No data available

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Calcium carbonate:**

Genotoxicity in vitro                      : Remarks: No data available

Genotoxicity in vivo                        : Remarks: No data available

**Magnesium hydroxide:**

Genotoxicity in vitro                      : Remarks: No data available

Genotoxicity in vivo                        : Remarks: No data available

**Amifatidine (MK-208):**

Genotoxicity in vitro                      : Remarks: No data available

Genotoxicity in vivo                        : Remarks: No data available

**Carcinogenicity**

Not classified based on available information.

**Components:****Calcium carbonate:**

Remarks: No data available



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**Magnesium hydroxide:**

Remarks: No data available

**Amifatidine (MK-208):**

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.

**Components:****Calcium carbonate:**

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

**Magnesium hydroxide:**

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

**Amifatidine (MK-208):**

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

**STOT - single exposure**

Not classified based on available information.

**Components:****Calcium carbonate:**

Remarks: No data available

**Magnesium hydroxide:**

Remarks: No data available

**Amifatidine (MK-208):**

Remarks: No data available

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**STOT - repeated exposure**

Not classified based on available information.

**Components:****Calcium carbonate:**

Remarks: No data available

**Magnesium hydroxide:**

Remarks: No data available

**Amifatidine (MK-208):**

Remarks: No data available

**Aspiration toxicity**

Not classified based on available information.

**Components:****Calcium carbonate:**

No data available

**Amifatidine (MK-208):**

No data available

**Further information****Components:****Amifatidine (MK-208):**

Remarks: May be harmful by inhalation, ingestion, skin absorption.

Caution - substance not yet tested completely.

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Calcium carbonate:**

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

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**Magnesium hydroxide:**

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

**Amifatidine (MK-208):**

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****Components:****Calcium carbonate:**

Biodegradability : Remarks: No data available

**Magnesium hydroxide:**

Biodegradability : Remarks: No data available

**Amifatidine (MK-208):**

Biodegradability : Remarks: No data available

**Bioaccumulative potential****Components:****Calcium carbonate:**

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: Not applicable

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**Magnesium hydroxide:**

Bioaccumulation : Remarks: No data available

**Amifatidine (MK-208):**

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: No data available

**Mobility in soil****Components:****Calcium carbonate:**

Distribution among environmental compartments : Remarks: No data available

**Amifatidine (MK-208):**

Distribution among environmental compartments : Remarks: No data available

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

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).

Additional ecological information : No data available

**Components:****Amifatidine (MK-208):**

Additional ecological information : No data available

**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****IATA-DGR**

Not regulated as a dangerous good

**IMDG-Code**

Not regulated as a dangerous good

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

Not applicable for product as supplied.

**National Regulations****49 CFR**

Not regulated as a dangerous good

**SECTION 15. REGULATORY INFORMATION****TSCA list** : Not relevant**EPCRA - Emergency Planning and Community Right-to-Know Act****SARA 311/312 Hazards** : Acute Health Hazard**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 I 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.

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.

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**Pennsylvania Right To Know**

Calcium carbonate	471-34-1	70 - 90 %
Magnesium hydroxide	1309-42-8	10 - 20 %

**New Jersey Right To Know**

Calcium carbonate	471-34-1	70 - 90 %
Magnesium hydroxide	1309-42-8	10 - 20 %
Amifatidine (MK-208)	76824-35-6	1 - 5 %

**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.

**The components of this product are reported in the following inventories:**

REACH : Not in compliance with the inventory

: Calcium carbonate  
: Magnesium hydroxide  
: Amifatidine (MK-208)

CH INV : Not in compliance with the inventory

: Calcium carbonate  
: Magnesium hydroxide  
: Amifatidine (MK-208)

TSCA : Not On TSCA Inventory

: Calcium carbonate  
: Magnesium hydroxide  
: Amifatidine (MK-208)

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

: Calcium carbonate  
: Magnesium hydroxide  
: Amifatidine (MK-208)

CEPA : Not in compliance with the inventory

: Calcium carbonate  
: Magnesium hydroxide  
: Amifatidine (MK-208)

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AICS : Not in compliance with the inventory  
: Calcium carbonate  
: Magnesium hydroxide  
: Amifatidine (MK-208)

NZloC : Not in compliance with the inventory  
: Calcium carbonate  
: Magnesium hydroxide  
: Amifatidine (MK-208)

ENCS : Not in compliance with the inventory  
: Calcium carbonate  
: Magnesium hydroxide  
: Amifatidine (MK-208)

ISHL : Not in compliance with the inventory  
: Calcium carbonate  
: Magnesium hydroxide  
: Amifatidine (MK-208)

KECI : Not in compliance with the inventory  
: Calcium carbonate  
: Magnesium hydroxide  
: Amifatidine (MK-208)

PICCS : Not in compliance with the inventory  
: Calcium carbonate  
: Magnesium hydroxide  
: Amifatidine (MK-208)

IECSC : Not in compliance with the inventory  
: Calcium carbonate  
: Magnesium hydroxide

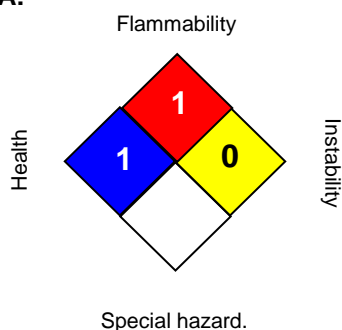
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: Amifatidine (MK-208)

**Inventories**

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

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

<b>HEALTH</b>	<b>2</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.

Revision Date : 10/14/2015

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 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.