

Coaptite

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations
Issue date: 04/20/2023 Revision date: 04/20/2023 Version: 5.0



SECTION 1: Identification

1.1. Identification

Product form : Mixture
Product name : Coaptite
Other means of identification : Active ingredient: calcium hydroxylapatite

1.2. Recommended use and restrictions on use

Recommended use : Pharmaceuticals

1.3. Supplier

Merz North America, Inc
6501 Six Forks Road
Raleigh, NC 27615
USA

T +1 844-469-6379

www.merzusa.com

E-mail address of competent person responsible for the SDS: nick.nogalski@merz.com

1.4. Emergency telephone number

Emergency number : Hazmat Service Emergency Number: 800-373-7542
International Shipments: +1-484-951-2432

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Not classified

2.2. GHS Label elements, including precautionary statements

GHS US labeling

No labeling applicable

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

No additional information available

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of HazCom 2012

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SECTION 4: First-aid measures

4.1. Description of first aid measures

| | |
|---------------------------------------|--|
| First-aid measures after inhalation | : Remove person to fresh air and keep comfortable for breathing. |
| First-aid measures after skin contact | : Wash skin with plenty of water. |
| First-aid measures after eye contact | : Rinse eyes with water as a precaution. |
| First-aid measures after ingestion | : Call a poison center/doctor/physician if you feel unwell. |

4.2. Most important symptoms and effects (acute and delayed)

No additional information available

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

| | |
|--------------------------------|--|
| Suitable extinguishing media | : Water spray. Dry powder. Foam. Carbon dioxide. |
| Unsuitable extinguishing media | : Do not use a solid water stream as it may scatter and spread fire. |

5.2. Specific hazards arising from the chemical

| | |
|--|--|
| Fire hazard | : Product does not burn, fire-extinguishing activities according to surrounding. |
| Explosion hazard | : Product is not explosive. |
| Hazardous decomposition products in case of fire | : Toxic fumes may be released. |

5.3. Special protective equipment and precautions for fire-fighters

| | |
|--------------------------------|--|
| Protection during firefighting | : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing. |
|--------------------------------|--|

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

| | |
|------------------|---|
| General measures | : Avoid contact with eyes, skin or mucous membrane. |
|------------------|---|

6.1.1. For non-emergency personnel

| | |
|----------------------|----------------------------|
| Emergency procedures | : Ventilate spillage area. |
|----------------------|----------------------------|

6.1.2. For emergency responders

| | |
|----------------------|---|
| Protective equipment | : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection". |
|----------------------|---|

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

| | |
|-------------------------|---|
| Methods for cleaning up | : Take up liquid spill into absorbent material. |
| Other information | : Dispose of materials or solid residues at an authorized site. |

6.4. Reference to other sections

For further information refer to section 13.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

| | |
|-----------------------------------|---|
| Additional hazards when processed | : Not expected to present a significant hazard under anticipated conditions of normal use. |
| Precautions for safe handling | : Ensure good ventilation of the work station. Wear personal protective equipment. |
| Hygiene measures | : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. |

7.2. Conditions for safe storage, including any incompatibilities

| | |
|------------------------------|---|
| Storage conditions | : Store in a well-ventilated place. Keep cool. |
| Storage temperature | : 15 – 32 °C |
| Information on mixed storage | : Keep away from food, drink and animal feeding stuffs. |
| Storage area | : Keep out of frost. Store away from direct sunlight or other heat sources. |

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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No additional information available

8.2. Appropriate engineering controls

| | |
|----------------------------------|--|
| Appropriate engineering controls | : Ensure good ventilation of the work station. |
| Environmental exposure controls | : Avoid release to the environment. |

8.3. Individual protection measures/Personal protective equipment

Hand protection:

Not required for normal conditions of use. Use protective gloves in the event of intensive contact

Eye protection:

Not required for normal conditions of use. Use splash goggles when eye contact due to splashing is possible

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

No personal breathing protective equipment is normally required. Dust production: dust mask with filter type P2

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---------------------------|---------------------|
| Physical state | : Liquid |
| Appearance | : colloidal. |
| Color | : Opaque whitish |
| Odor | : odorless |
| Odor threshold | : No data available |
| pH | : 6.8 – 8 |
| pH solution concentration | : 100 % |
| Melting point | : No data available |

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| | |
|---|---|
| Freezing point | : No data available |
| Boiling point | : > 100 °C |
| Flash point | : Not applicable |
| Relative evaporation rate (butyl acetate=1) | : No data available |
| Flammability (solid, gas) | : Non flammable. |
| Vapor pressure | : No data available |
| Relative vapor density at 20°C | : No data available |
| Relative density | : No data available |
| Density | : 1.64 – 1.67 g/cm ³ (20 °C) |
| Solubility | : Water: Miscible |
| Log Pow | : No data available |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosion limits | : No data available |
| Explosive properties | : Product is not explosive. |
| Oxidizing properties | : Non oxidizing material. |

9.2. Other information

VOC content : 0 %

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

Strong acids, strong bases and oxidation agents.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

| | |
|-------------------------------|---------------------------------|
| Acute toxicity (oral) | : Not classified |
| Acute toxicity (dermal) | : Not classified |
| Acute toxicity (inhalation) | : Not classified |
| Skin corrosion/irritation | : Not classified pH: 6.8 – 8 |
| Serious eye damage/irritation | : Not classified pH: 6.8 – 8 |

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| | |
|-----------------------------------|---------------------|
| Respiratory or skin sensitization | : Not classified |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Not classified |
| STOT-single exposure | : Not classified |
| STOT-repeated exposure | : Not classified |
| Aspiration hazard | : Not classified |
| Viscosity, kinematic | : No data available |

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with DOT / TDG / IMDG / IATA

| DOT | TDG | IMDG | IATA |
|--|----------------|----------------|----------------|
| 14.1. UN number | | | |
| No dangerous goods as defined by the transport regulations | | | |
| 14.2. Proper Shipping Name | | | |
| Not applicable | Not applicable | Not applicable | Not applicable |
| 14.3. Transport hazard class(es) | | | |
| Not applicable | Not applicable | Not applicable | Not applicable |
| 14.4. Packing group | | | |
| Not applicable | Not applicable | Not applicable | Not applicable |

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| DOT | TDG | IMDG | IATA |
|--|----------------|----------------|----------------|
| 14.5. Environmental hazards | | | |
| Not applicable | Not applicable | Not applicable | Not applicable |
| No supplementary information available | | | |

14.6. Special precautions for user

DOT

No data available

TDG

No data available

IMDG

No data available

IATA

No data available

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

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

15.2. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

National regulations

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All components are listed on the DSL Inventory

15.3. US State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

SECTION 16: Other information

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Other information

: Data of sections 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities. The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge. The delivery specifications are contained in the corresponding product sheet. This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

| Abbreviations and acronyms | |
|-----------------------------------|---|
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ATE | Acute Toxicity Estimate |
| BCF | Bioconcentration factor |
| BLV | Biological limit value |
| BOD | Biochemical oxygen demand (BOD) |
| COD | Chemical oxygen demand (COD) |
| DMEL | Derived Minimal Effect level |
| DNEL | Derived-No Effect Level |
| EC-No. | European Community number |
| EC50 | Median effective concentration |
| EN | European Standard |
| IARC | International Agency for Research on Cancer |
| IATA | International Air Transport Association |
| IMDG | International Maritime Dangerous Goods |
| LC50 | Median lethal concentration |
| LD50 | Median lethal dose |
| LOAEL | Lowest Observed Adverse Effect Level |
| NOAEC | No-Observed Adverse Effect Concentration |
| NOAEL | No-Observed Adverse Effect Level |
| NOEC | No-Observed Effect Concentration |
| OECD | Organisation for Economic Co-operation and Development |
| OEL | Occupational Exposure Limit |
| PBT | Persistent Bioaccumulative Toxic |
| PNEC | Predicted No-Effect Concentration |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| SDS | Safety Data Sheet |
| STP | Sewage treatment plant |
| ThOD | Theoretical oxygen demand (ThOD) |
| TLM | Median Tolerance Limit |
| VOC | Volatile Organic Compounds |

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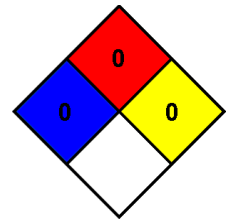
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| Abbreviations and acronyms | |
|----------------------------|---|
| CAS-No. | Chemical Abstract Service number |
| N.O.S. | Not Otherwise Specified |
| vPvB | Very Persistent and Very Bioaccumulative |
| ED | Endocrine disrupting properties |
| DOT | Department of Transport |
| TDG | Transportation of Dangerous Goods |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| GHS | Globally Harmonized System of Classification, Labelling and Packaging of Chemicals |
| IBC-Code | International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 |
| MARPOL 73/78 | MARPOL 73/78: International Convention for the Prevention of Pollution From Ships |
| ADG | Transport of Australian Dangerous Goods |

NFPA health hazard : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

NFPA fire hazard : 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand.

NFPA reactivity : 0 - Material that in themselves are normally stable, even under fire conditions.



Hazard Rating

Health : 0 Minimal Hazard - No significant risk to health

Flammability : 0 Minimal Hazard - Materials that will not burn

Physical : 0 Minimal Hazard - Materials that are normally stable, even under fire conditions, and will NOT react with water, polymerize, decompose, condense, or self-react. Non-Explosives.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should therefore not be construed as guaranteeing any specific property of the product.