SAFETY DATA SHEET
Pitavastatin 3S,5R isomer Calcium Salt

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

1.1. Product identifier
Product name Pitavastatin 3S,5R isomer Calcium Salt
Product number IP145451
Synonyms; trade names bis[(3S,5R,6E)-7-[2-Cyclopropyl-4-(4-fluorophenyl)-3-quinolinyl]-3,5-dihydroxy-6-heptenoate] calcium salt
CAS number 254452-88-5

1.2. Relevant identified uses of the substance or mixture and uses advised against
Identified uses Laboratory reagent. Manufacture of substances. Research and development.

1.3. Details of the supplier of the safety data sheet
Supplier Carbosynth Ltd
8&9 Old Station Business Park
Compton
Berkshire
RG20 6NE
UK
+44 1635 578444
+44 1635 579444
info@carbosynth.com

1.4. Emergency telephone number
Emergency telephone +44 7887 998634

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
Classification (EC 1272/2008)
Physical hazards Not Classified
Health hazards Not Classified
Environmental hazards Not Classified

Additional information Caution. Not fully tested.

2.2. Label elements
Hazard statements NC Not Classified

2.3. Other hazards
No data available.

SECTION 3: Composition/information on ingredients
Pitavastatin 3S,5R isomer Calcium Salt

3.1. Substances

Product name: Pitavastatin 3S,5R isomer Calcium Salt

CAS number: 254452-88-5

Chemical formula: C₂₅H₂₄FNO₄·¹/₂Ca

SECTION 4: First aid measures

4.1. Description of first aid measures

General information: Get medical advice/attention if you feel unwell.

Inhalation: Remove person to fresh air and keep comfortable for breathing. If breathing stops, provide artificial respiration. When breathing is difficult, properly trained personnel may assist affected person by administering oxygen. Get medical attention if symptoms are severe or persist.

Ingestion: Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth thoroughly with water. Give plenty of water to drink. Get medical attention if symptoms are severe or persist.

Skin contact: Remove contaminated clothing. Rinse with water. Continue to rinse for at least 15 minutes. Wash contaminated clothing before reuse. Get medical attention if symptoms are severe or persist.

Eye contact: Rinse immediately with plenty of water. Continue to rinse for at least 15 minutes. Get medical attention if symptoms are severe or persist.

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

General information: See Section 11 for additional information on health hazards.

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

Notes for the doctor: Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: Extinguish with alcohol-resistant foam, carbon dioxide, dry powder or water fog. Use fire-extinguishing media suitable for the surrounding fire.

5.2. Special hazards arising from the substance or mixture

Specific hazards: None known.

Hazardous combustion products: Thermal decomposition or combustion products may include the following substances: Oxides of carbon. Oxides of nitrogen. Hydrogen fluoride (HF). Calcium oxide

5.3. Advice for firefighters

Special protective equipment for firefighters: Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing. Firefighter's clothing conforming to European standard EN469 (including helmets, protective boots and gloves) will provide a basic level of protection for chemical incidents. Use protective equipment appropriate for surrounding materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Wear protective clothing as described in Section 8 of this safety data sheet. No action shall be taken without appropriate training or involving any personal risk. Do not touch or walk into spilled material. Avoid inhalation of dust and vapours. Provide adequate ventilation. Keep unnecessary and unprotected personnel away from the spillage.
Pitavastatin 3S,5R isomer Calcium Salt

6.2. Environmental precautions

Environmental precautions

Avoid discharge into drains or watercourses or onto the ground.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up

Wear protective clothing as described in Section 8 of this safety data sheet. Collect powder using special dust vacuum cleaner with particle filter or carefully sweep into suitable waste disposal containers and seal securely. Clear up spills immediately and dispose of waste safely. Flush contaminated area with plenty of water. Wash thoroughly after dealing with a spillage. For waste disposal, see Section 13.

6.4. Reference to other sections

Reference to other sections

For personal protection, see Section 8. See Section 11 for additional information on health hazards. See Section 12 for additional information on ecological hazards. For waste disposal, see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions

Wear protective clothing as described in Section 8 of this safety data sheet. Wash hands thoroughly after handling. Provide adequate ventilation. Avoid generation and spreading of dust. Avoid contact with skin and eyes. Avoid inhalation of dust and vapours.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions

Keep container tightly closed. Store in a cool and well-ventilated place. Store at room temperature.

7.3. Specific end use(s)

Specific end use(s)

The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure Controls/personal protection

8.1. Control parameters

Occupational exposure limits

No exposure limits known for ingredient(s).

8.2. Exposure controls

Appropriate engineering controls

Provide adequate ventilation. Observe any occupational exposure limits for the product or ingredients.

Eye/face protection

Unless the assessment indicates a higher degree of protection is required, the following protection should be worn: Tight-fitting safety glasses. Personal protective equipment for eye and face protection should comply with European Standard EN166.

Hand protection

Wear protective gloves. To protect hands from chemicals, gloves should comply with European Standard EN374.

Other skin and body protection

Wear appropriate clothing to prevent repeated or prolonged skin contact.

Respiratory protection

Respiratory protection complying with an approved standard should be worn if a risk assessment indicates inhalation of contaminants is possible. Ensure all respiratory protective equipment is suitable for its intended use and is ‘CE’-marked. Particulate filters should comply with European Standard EN143. Full face mask respirators with replaceable filter cartridges should comply with European Standard EN136. Half mask and quarter mask respirators with replaceable filter cartridges should comply with European Standard EN140.
Pitavastatin 3S,5R isomer Calcium Salt

Environmental exposure controls
Keep container tightly sealed when not in use.

### SECTION 9: Physical and Chemical Properties

#### 9.1. Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Solid.</td>
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<tr>
<td>Colour</td>
<td>White/off-white.</td>
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<tr>
<td>Odour</td>
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</tr>
<tr>
<td>Odour threshold</td>
<td>No data available.</td>
</tr>
<tr>
<td>pH</td>
<td>No data available.</td>
</tr>
<tr>
<td>Melting point</td>
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<tr>
<td>Initial boiling point and range</td>
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<td>Flash point</td>
<td>No data available.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available.</td>
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<tr>
<td>Flammability (solid, gas)</td>
<td>No data available.</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
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</tr>
<tr>
<td>Vapour pressure</td>
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</tr>
<tr>
<td>Vapour density</td>
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</tr>
<tr>
<td>Relative density</td>
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</tr>
<tr>
<td>Solubility(ies)</td>
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</tr>
<tr>
<td>Partition coefficient</td>
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<tr>
<td>Auto-ignition temperature</td>
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<tr>
<td>Decomposition Temperature</td>
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<tr>
<td>Viscosity</td>
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<td>Explosive properties</td>
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<td>Oxidising properties</td>
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#### 9.2. Other information

<table>
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<tr>
<th>Property</th>
<th>Details</th>
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<tbody>
<tr>
<td>Molecular weight</td>
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### SECTION 10: Stability and Reactivity

#### 10.1. Reactivity

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<th>Property</th>
<th>Details</th>
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</thead>
<tbody>
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<td>Reactivity</td>
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#### 10.2. Chemical stability

<table>
<thead>
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<th>Property</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>Stability</td>
<td>Stable under the prescribed storage conditions.</td>
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</table>

#### 10.3. Possibility of hazardous reactions

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Possibility of hazardous reactions</td>
<td>No data available.</td>
</tr>
</tbody>
</table>

#### 10.4. Conditions to avoid


Pitavastatin 3S,5R isomer Calcium Salt

**Conditions to avoid**
No data available.

**10.5. Incompatible materials**
No data available.

**10.6. Hazardous decomposition products**
Hazardous decomposition products

**SECTION 11: Toxicological information**

**11.1. Information on toxicological effects**

**Toxicological effects**
Not regarded as a health hazard under current legislation.

**Acute toxicity - oral**
Notes (oral LD₅₀)
Based on available data the classification criteria are not met.

**Acute toxicity - dermal**
Notes (dermal LD₅₀)
Based on available data the classification criteria are not met.

**Acute toxicity - inhalation**
Notes (inhalation LC₅₀)
Based on available data the classification criteria are not met.

**Skin corrosion/irritation**
Animal data
Based on available data the classification criteria are not met.

**Serious eye damage/irritation**
Based on available data the classification criteria are not met.

**Respiratory sensitisation**
Based on available data the classification criteria are not met.

**Skin sensitisation**
Based on available data the classification criteria are not met.

**Germ cell mutagenicity**
Genotoxicity - in vitro
Based on available data the classification criteria are not met.

**Carcinogenicity**
Carcinogenicity
Based on available data the classification criteria are not met.

**IARC carcinogenicity**
None of the ingredients are listed or exempt.

**Reproductive toxicity**
Reproductive toxicity - fertility
Based on available data the classification criteria are not met.

**Reproductive toxicity - development**
Based on available data the classification criteria are not met.

**Specific target organ toxicity - single exposure**
STOT - single exposure
Not classified as a specific target organ toxicant after a single exposure.

**Specific target organ toxicity - repeated exposure**
STOT - repeated exposure
Not classified as a specific target organ toxicant after repeated exposure.

**Aspiration hazard**
Aspiration hazard
Not relevant. Solid.
# Pitavastatin 3S,5R isomer Calcium Salt

## General information
No specific health hazards known. Dust may irritate the eyes and the respiratory system. The severity of the symptoms described will vary dependent on the concentration and the length of exposure.

## Inhalation
Dust may irritate the respiratory system. Frequent inhalation of dust over a long period of time increases the risk of developing lung diseases.

## Ingestion
No specific symptoms known. May cause discomfort if swallowed.

## Skin contact
Prolonged contact may cause dryness of the skin.

## Eye contact
Dust may cause slight irritation.

## Route of exposure
Ingestion Inhalation Skin and/or eye contact

## Target organs
No specific target organs known.
SECTION 12: Ecological Information

Ecotoxicity
Not regarded as dangerous for the environment. However, large or frequent spills may have hazardous effects on the environment.

12.1. Toxicity
Toxicity
Based on available data the classification criteria are not met.

12.2. Persistence and degradability
Persistence and degradability
The degradability of the product is not known.

12.3. Bioaccumulative potential
Bioaccumulative potential
No data available on bioaccumulation.

Partition coefficient
No data available.

12.4. Mobility in soil
Mobility
No data available.

12.5. Results of PBT and vPvB assessment
Results of PBT and vPvB assessment
No data available.

12.6. Other adverse effects
Other adverse effects
None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods
General information
Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority. This material and its container must be disposed of in a safe way. When handling waste, the safety precautions applying to handling of the product should be considered.

SECTION 14: Transport information

General
The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number
Not applicable.

14.2. UN proper shipping name
Not applicable.

14.3. Transport hazard class(es)
No transport warning sign required.

14.4. Packing group
Not applicable.

14.5. Environmental hazards
Environmentally hazardous substance/marine pollutant
No.

14.6. Special precautions for user
Pitavastatin 3S,5R isomer Calcium Salt

Not applicable.

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

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

SECTION 15: Regulatory information

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

National regulations

- Health and Safety at Work etc. Act 1974 (as amended).
- The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (SI 2009 No. 1348) (as amended) ["CDG 2009"].
- EH40/2005 Workplace exposure limits.

EU legislation


15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Abbreviations and acronyms used in the safety data sheet

- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
- ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.
- RID: European Agreement concerning the International Carriage of Dangerous Goods by Rail.
- IATA: International Air Transport Association.
- CAS: Chemical Abstracts Service.
- ATE: Acute Toxicity Estimate.
- LC₅₀: Lethal Concentration to 50 % of a test population.
- LD₅₀: Lethal Dose to 50% of a test population (Median Lethal Dose).
- EC₅₀: 50% of maximal Effective Concentration.
- PBT: Persistent, Bioaccumulative and Toxic substance.
- vPvB: Very Persistent and Very Bioaccumulative.

Training advice

Only trained personnel should use this material.

Revision date

21/01/2019

Revision

1

SDS number

144926

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