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Safety Data Sheet acc. to OSHA HCS

Printing date 01/18/2021 Reviewed on 01/18/2021

1 Identification

· Product identifier

· Product name: Atorvastatin Acetonide tert-Butyl Ester

· Part number: TRC-A791745-10MG

· CAS Number: 125971-95-1 · EC number: 700-258-0

· Application of the substance / the mixture Reference material for laboratory use only

· Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

VHGLGC Standards 276 Abby Road Manchester, NH 03103 UNITED STATES OF AMERICA

· Information department:

Product safety department

eMail: sds-request@lgcgroup.com

· Emergency telephone number:

For Hazardous Materials or Dangerous Goods Incident

Spill, Leak, Fire Exposure, or Accident

Call CHEMTREC:

1-800-424-9300 USA & Canada Rest of the world +1 703-741-5970

2 Hazard(s) identification

· Classification of the substance or mixture

The substance is not classified, according to the Globally Harmonized System (GHS).

- · Label elements
- · GHS label elements Not applicable
- · Hazard pictograms Not applicable
- · Signal word Not applicable
- · Hazard statements Not applicable
- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 1Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



1 Health = 1



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- · Other hazards
- · Results of PBT and vPvB assessment
- \cdot **PBT:** Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

- · Chemical characterization: Substances
- · CAS No. Description

125971-95-1 Atorvastatin Acetonide tert-Butyl Ester

- · Identification number(s) -
- · EC number: 700-258-0
- · RTECS: -

4 First-aid measures

- · Description of first aid measures
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- $\cdot \textit{After skin contact:} \ \textit{Immediately wash with water and soap and rinse thoroughly}.$
- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: Rinse mouth. Do not induce vomiting.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
- · Suitable extinguishing agents: Use fire fighting measures that suit the environment.
- · Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

- · Advice for firefighters
- · Protective equipment: Wear self-contained respiratory protective device.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Wear protective clothing.
- · Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up: Pick up mechanically.
- · Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

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- · Protective Action Criteria for Chemicals
- · PAC-1: Substance is not listed.
- · PAC-2: Substance is not listed.
- · PAC-3: Substance is not listed.

7 Handling and storage

- · Handling:
- · Precautions for safe handling Store in cool, dry place in tightly closed receptacles.
- · Information about protection against explosions and fires: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:

Please refer to the manufacturers certificate for specific storage and transport temperature conditions.

Store only in the original receptacle unless other advice is given on the CoA.

Keep container in a well-ventilated place. Keep away from sources of ignition and heat.

- Information about storage in one common storage facility: Store away from foodstuffs.
- · Further information about storage conditions: None.
- \cdot *Specific end use*(s) *No further relevant information available.*

8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
- · Components with limit values that require monitoring at the workplace: Not required.
- · Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

· Breathing equipment:

Not required.

Use suitable respiratory protective device in case of insufficient ventilation.

· Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374



· Material of gloves Butyl rubber, BR

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Product name: Atorvastatin Acetonide tert-Butyl Ester

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· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Safety glasses

9 Physical and chemical properties
· Information on basic physical and chemical properties · General Information

Form: Solid
Color: White
Odor: Odorless
Odor threshold: Not determined.

• pH-value: Not applicable.

· Change in condition

· Appearance:

Melting point/Melting range: 147 °C (296.6 °F)
Boiling point/Boiling range: Not determined.

• Flash point: Not applicable.

· Flammability (solid, gaseous): Not determined.

Ignition temperature: Not determined
 Decomposition temperature: Not determined.

· Auto igniting: Not determined.

· Danger of explosion: Not determined.

· Explosion limits:

Lower:Not determined.Upper:Not determined.

· Vapor pressure: Not applicable.

Density: Not determined.
Relative density Not determined.
Vapor density Not applicable.
Evaporation rate Not applicable.

· Solubility in / Miscibility with
· Water:

Soluble in Dichloromethane and Ethyl Acetate
Not determined.

· Partition coefficient (n-octanol/water): Not determined.

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Viscosity:
Dynamic:
Kinematic:
Not applicable.
Not applicable.

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· Other information

No further relevant information available.

10 Stability and reactivity

· Reactivity

Stable under normal conditions.

No further relevant information available.

- · Chemical stability Stable under normal conditions.
- · Thermal decomposition / conditions to be avoided:

Formation of toxic gases is possible during heating or in case of fire.

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid Heat.
- · Incompatible materials: Strong oxidizing agents.
- · Hazardous decomposition products: Formation of toxic gases is possible during heating or in case of fire.

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · LD/LC50 values that are relevant for classification:

 Oral
 LD50
 >2,000 mg/kg (rat)

 Dermal
 LD50
 >2,000 mg/kg (rat)

- Primary irritant effect:
- · on the skin: Based on available data, the classification criteria are not met.
- · on the eye: Based on available data, the classification criteria are not met.
- · Sensitization: Based on available data, the classification criteria are not met.
- $\cdot \textit{Additional toxicological information:}$

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

The substance is not subject to classification.

- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer) Substance is not listed.
- · NTP (National Toxicology Program) Substance is not listed.
- · OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.

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- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
- · Recommendation: Dispose in accordance with national regulations.

UN-Number	
DOT, ADR, IMDG, IATA	Not applicable
DOT, ADR, IMDG, IATA	Not applicable
Transport hazard class(es)	
DOT, ADR, ADN, IMDG, IATA	
Class	Not applicable
Packing group	
DOT, ADR, ÎMDG, IATA	Not applicable
Environmental hazards:	Not applicable.
Special precautions for user	Not applicable.
Transport in bulk according to Annex	II of
MARPOL73/78 and the IBC Code	Not applicable.
Transport/Additional information:	Not dangerous according to the above specifications.
UN ''Model Regulation'':	Not applicable

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.

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- · Sara
- · Section 355 (extremely hazardous substances): Substance is not listed.
- · Section 313 (Specific toxic chemical listings): Substance is not listed.
- · TSCA (Toxic Substances Control Act): Substance is not listed.
- · Hazardous Air Pollutants Substance is not listed.
- · Proposition 65
- · Chemicals known to cause cancer: Substance is not listed.
- · Chemicals known to cause reproductive toxicity for females: Substance is not listed.
- · Chemicals known to cause reproductive toxicity for males: Substance is not listed.
- · Chemicals known to cause developmental toxicity: Substance is not listed.
- · Carcinogenic categories
- · EPA (Environmental Protection Agency) Substance is not listed.
- · TLV (Threshold Limit Value established by ACGIH) Substance is not listed.
- · NIOSH-Ca (National Institute for Occupational Safety and Health) Substance is not listed.
- · Hazard pictograms Not applicable
- · Signal word Not applicable
- · Hazard statements Not applicable
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

The information in this Safety Data Sheet meets the requirements of the United States OCCUPATIONAL SAFETY AND HEALTH ACT and regulations promulgated thereunder (29 CFR 1910.1200 et. seq.) This document is intended only as a guide to the appropriate precautionary handling of the material by a person trained in, or supervised by a person trained in, chemical handling. The user is responsible for determining the application. Depending on usage, protective clothing including eye and face guards and respirators must be used to avoid contact with material or breathing chemical vapors/fumes. Exposure to this product may have serious adverse health effects. This chemical may interact with other substances. Since the potential uses are so varied, we cannot warn of all of the potential dangers of use or interaction with other chemicals or materials. We warrant that the chemical meets the specifications set forth on the label. We (LGC/VHG/ARMI) disclaim any other warranties, expressed or implied with regard to the product supplied hereunder, its merchantability or its fitness for a particular purpose. The user should recognize that this product can cause severe injury and even death, especially if improperly handled or the known dangers of use are not heeded. Read all precautionary information.

- · Contact:
- · Date of preparation / last revision 01/18/2021 / -
- · Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health

TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit

· Sources

Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended 2011, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition, IUCLID.

· Data compared to the previous version altered. All sections have been updated.

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