Material Safety Data Sheet

Effective Date: 23/06/2025

Due Date: 22/06/2028

| Section 1 : Chemical Product Company Identification | |
|---|--|
| Product Name | ATORVASTATIN CA IMPURITY-E - IMP STD |
| CAT No. | KMA002071 |
| CAS No. | 1428118-38-0 |
| Identified uses | Pharmaceutical Reference Standard |
| Details of the Supplier Company | K. M. PHARMA SOLUTION PRIVATE LIMITED Unit No.101, Shivam Industrial park, Sarkhej-bavala NH=8A, At-Moraiya, Changodar, Ahmedabad (Gujarat), India-382213 |
| Telephone | +91 9898822121 |

Section 2 : Chemical Information

| Chemical Name | (3S,5S)-7-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5- (propan-2-yl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid Sodium salt (as per EP); Sodium (3S,5S)-7-[2-(4-fluorophenyl)-5- isopropyl-3-phenyl-4-(phenylcarbamoyl)-1H-pyrrol-1-yl]-3,5- dihydroxyheptanoate (as per USP) |
|-------------------|---|
| CAS No. | 1428118-38-0 |
| Molecular Weight | 557.6 : 23.0 |
| Molecular Formula | C33H34FN2O5 : Na |

Section 3 : Hazards Identification

| Emergency Overview: | | |
|---------------------------|-----------------|--|
| Appearance | Off White Solid | |
| Target Organs | NA | |
| Potential Health Effects: | | |
| Eye | NIL | |
| Skin | NIL | |
| Ingestion | NIL | |
| Inhalation | NIL | |
| Chronic | NIL | |



Section 4 : First Aid Measures

| Eye | Wash with plenty of water |
|--------------------|---|
| Skin | Wash with plenty of water |
| Ingestion | Medical assistance for gastric lavage. |
| Inhalation | Remove to fresh air, artificial respiration or oxygen if necessary. |
| Notes to Physician | Atorvastatin EP Impurity E (Na salt) can be washed with plenty of water in case of any exposure |

| Section 5 : Firefighting Measures | |
|------------------------------------|---|
| Extinguishing Media | Carbon dioxide, dry chemical powder, foam, water. |
| Unusual Fire and Explosion Hazards | None indicated |
| | |

| Section 6 : Accidental Release Measures | |
|---|--|
| Personal Precautions | Wear self-contained breathing apparatus, avoid dust formation. |
| Spills/Leaks | Wash with plenty of water, provide adequate ventilation. |
| | |

| Section 7 : Handlings and Storage | |
|-----------------------------------|----------------------|
| Handling | Wear surgical gloves |
| Storage | ~Storage |
| | |

| Section 8 : Exposure Controls, Personal Protection | |
|--|------------------------------------|
| Respiratory Protection | Self-contained breathing apparatus |
| Exposure Limits | NA |
| Eye Protection | Wear safety goggles |
| Other Protective Equipment | Protective clothing |
| Skin | Full sleeves apron |
| Clothing | Cotton |
| | |

| Section 9 : Physical and Chemical Properties | |
|--|-----------------|
| Appearance | Off White Solid |
| Odor | NA |
| Melting Point | NA |



| рН | NA |
|--|----------------------------------|
| Vapor Pressure | NA |
| Vapor Density | NA |
| Evaporation Rate | NA |
| Viscosity | NA |
| Boiling Point | NA |
| Decomposition Temp | NA |
| Auto ignition Temp. | NA |
| Flash Point | NA |
| NFPA Rating | NA |
| Flash Point NA NFPA Rating NA Explosion Limits NA Lower NA | |
| Lower | NA |
| Upper | NA |
| Solubility | *Refer in Additional information |
| Specific Gravity/Density | NA |
| | |

Section 10 : Stability and Reactivity

| Chemical Stability | ~ChemicalStability |
|--|-------------------------|
| Conditions to avoid | Direct contract to skin |
| Incompatibilities with other Materials | Кеер аway |
| Hazardous Decomposition Products | NIL |
| Hazardous Polymerization | NIL |

Section 11 : Toxicological Information

| CAS | NA |
|----------------------|--|
| LD50/LC50 | >10,000 mg/kg Remarks: Behavioral:Somnolence (general depressed activity) |
| Carcinogenicity | NIL |
| Epidemiology | NIL |
| Teratogenicity | NIL |
| Reproductive Effects | NIL |
| Neurotoxicity | NIL |



| Mutagencity | NIL |
|---------------|-----|
| Other Studies | NA |

Section 12 : Ecological Information

Data not available

Section 13 : Disposal Consideration

RCRA P-Series

Can be incinerated

NA

RCRA U-Series

Section 14 : Transport Consideration

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| UN-Number | |
|--|--|
| ADR/RID: IMDG: IATA: | |
| UN proper shipping name | |
| ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods | |
| Transport hazard class(es) | |
| ADR/RID: IMDG: IATA: | |
| Packaging Group | |
| ADR/RID: IMDG: IATA: | |
| Environmental hazards | |
| ADR/RID: No IMDG Marine pollutant: No IATA: No | |
| Special precautions for users | |
| Further information | |

| Section 15 : Regulatory Information | |
|-------------------------------------|--------------------------------------|
| TSCA | Attached the letter |
| Health & Safety Reporting List | No data available |
| Chemical Test Rules | Chemical analysis report is attached |



Section 16 : Additional Information

This product is not bioactive, non-radioactive. It is for R&D use only. Not for drug, household or other uses.

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge. It does not represent any guarantee of the product.

K.M. Pharma Solution Privato Limited

Pharma Control