SAFETY DATA SHEETS

This SDS packet was issued with item:

078726772

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078792619 078937382

MATERIAL SAFETY DATA SHEET

Version No: MSDS/SIMV/DP-001 Effective Date: December 19, 2012

Simvastatin Tablets USP 10 mg, 20 mg, 40 mg and 80 mg

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Simvastatin Tablets USP 10 mg, 20 mg, 40 mg and 80 mg

Marketing Authorisation Holder

Accord Healthcare, Inc.,
1009 Slater Road,
Suite 210-B,
Durham, NC 27703, USA.
Telephone: 1-919-941-7878
Fax- 1-919-941-7881

Manufacturer

Intas Pharmaceuticals Ltd.
Plot No. 457, 458
Village-Matoda,
Bavla Road, Ta. Sanand,
Dist. Ahmedabad-382 210,
Gujarat, India

US Emergency Phone: Call CHEMTREC Day or Night: 1-800-424-9300

SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

Active: Simvastatin

Inactive: Microcrystalline cellulose, hydroxypropyl cellulose, hypromellose E5, croscarmellose sodium, ferric oxide red, lactose monohydrate, magnesium stearate, starch, talc, titanium dioxide, butylated hydroxyanisole, ascorbic acid, citric acid monohydrate, and triethyl citrate.

SECTION 3 - HAZARDS IDENTIFICATION

Adverse Effects: Adverse effects of statins may include muscle pain, weakness, stiffness, or tenderness; numbness or tingling in arms or legs; fever; unusual tiredness or weakness; headache; dizziness; constipation; diarrhea; gas; heartburn or indigestion; stomach pain; nausea; skin rash; decreased sexual ability; trouble sleeping; and upper respiratory infection. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

Overdose Effects: Not Found.

Acute: Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material; active liver disease or history of; active alcoholism; unexplained, persistent elevations in transaminase values; severe electrolyte, endocrine, or metabolic disorders; severe infection; myopathy; uncontrolled seizures; organ transplant with immunosuppressant therapy; kidney impairment; porphyria; and amyotrophic lateral sclerosis (ALS).

Cross Sensitivity: Persons sensitive to other HMG-CoA reductase inhibitors (e.g., fluvastatin, lovastatin, pravastatin) may be sensitive.

Target Organs: Liver.

SECTION 4 - EMERGENCY & FIRST AID MEASURES

Inhalation: May cause irritation. Remove to fresh air.

Eye: Causes irritation. Flush with copious quantities of water for at least 15 minutes.

Skin: Causes irritation. Flush with copious quantities of soap and water.

Ingestion: May cause irritation. Flush out mouth with water. This material is absorbed from the gastrointestinal tract.

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.

Note to Physicians
Overdose Treatment: Treatment of statin overdose should be symptomatic and supportive and may include the following:

1. Administer activated charcoal as an aqueous slurry.
2. For rhabdomyolysis, administer 0.9% saline to maintain urine output of 2 - 3 milliliters/kg/hour. Monitor fluid balance, serum electrolytes, CPK, liver enzymes, and renal function. Administer diuretics if needed to maintain urine output. Urinary alkalinization is not recommended.
3. Hemodialysis is not expected to enhance clearance. [Poisindex 2009]

SECTION 5 - FIRE FIGHTING MEASURES

Extinguisher Media: Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Spill Response: Wear approved respiratory protection, chemically compatible gloves, and protective clothing. Wipe up spillage or collect spillage using a high-efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.

SECTION 7 - HANDLING AND STORAGE

Handling: Avoid all contact and inhalation of dust, mists, and/or vapours associated with the material. Wash thoroughly after handling.

Storage : Store at 20°C to 25°C (68°F to 77°F).

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection: Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible.

Eye Protection: Safety glasses or goggles.

Protective Clothing: Protect exposed skin.

Exposure Limits: Industry: 0.025 mg/m3

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Description of Tablets:

The 10 mg tablets are brick red coloured, oval shaped, biconvex, film-coated tablets, debossed "S 4" on one side and plain on other side.

The 20 mg tablets are brick red coloured, oval shaped, biconvex, film-coated tablets, debossed "S 5" on one side and plain on other side.

The 40 mg tablets are brick red coloured, oval shaped, biconvex, film-coated tablets, debossed "S 6" on one side and plain on other side.

The 80 mg tablets are brick red coloured, capsule shaped, biconvex, film-coated tablets, debossed with "SMV" on one side and "80"on the other side.

SECTION 10 - STABILITY AND REACTIVITY

Stability: The product is stable

Conditions to Avoid: Heat and light.

Incompatibilities: Oxidizing agents

Polymerization: No

SECTION 11 - TOXICOLOGY INFORMATION

Oral Rat: LD50: 4438 mg/kg

Oral Mouse: LD50: 3 grams/kg

Other Toxicity Data: Oral Dog LD50: > 5 grams/kg

Irritancy Data: Skin/Rabbit: slight to moderate; Eye/Rabbit: slight

Listed as a Carcinogen by: NTP: No **IARC:** No **OSHA:** No

Other Carcinogenicity Data: A 72-week study in mice given doses up to 400 mg/kg/day found an increased incidence of liver carcinomas, liver adenomas, lung adenomas, and eye adenomas, but doses of 25 mg/kg/day did not cause tumors. A two-year study in rats given 25 mg/kg/day showed an increased incidence of thyroid follicular adenomas in females. Another two-year study in rats with doses of 50 and 100 mg/kg/day resulted in hepatocellular adenomas and carcinomas and an increased incidence of thyroid follicular cell adenomas and carcinomas.
A ten-year follow-up of the Scandinavian Simvastatin Survival Study showed no increased risk of mortality from cancer or higher incidence of cancer between patients randomized to simvastatin or placebo.

Mutagenicity Data: Simvastatin was not mutagenic in the Ames test in Salmonella typhimurium with or without activation, a chromosomal aberration assay in mouse bone marrow, an in vitro alkaline elution assay using rat or mouse hepatocytes, a V-79 mammalian cell forward mutation study, and an in vitro chromosome aberration study in Chinese hamster ovary cells.

Reproductive and Developmental Effects: Therapeutic use of statins during pregnancy is not recommended because they decrease cholesterol and may decrease cholesterol-derived substances essential for fetal development. Results of animal studies indicate that many statins are associated with adverse fetal outcomes at maternally toxic doses.

Simvastatin did not cause birth defects in studies with rats and rabbits given doses of 25 and 10 mg/kg/day, respectively. Decreased fertility was noted in male rats given 25 mg/kg for 34 weeks but this was not seen in an 11-week study at the same dosage level.

SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

Ecological Information: Simvastatin is toxic to aquatic species and may cause long-term adverse effects in the aquatic environment. LC50 Daphnia magna: 5.9 mg/liter

SECTION 13 - DISPOSAL INFORMATION

Waste must be disposed of in accordance with state, local and other environmental control regulations.

SECTION 14 - TRANSPORTATION INFORMATION

This product is not subject to the regulations for the safe transport of hazardous chemicals.

DOT: Not regulated
TDG: Not regulated
IATA: Not regulated
IMDG: Not regulated

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: Not found

International Regulatory Information: Not found

SECTION 16 - OTHER DATA

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall INTAS be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if INTAS has been advised of the possibility of such damages.