SAFETY DATA SHEET

Version	Revision Date:	SDS Number:	Date of last issue: -
2.0	03.08.2017	12332	Date of first issue: 03.08.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

IMDUR TABLETS

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
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Alternative Names

Imdur Durules prolonged release tablets 30mg, 60mg, 120mg
Isosorbide 5-mononitrate tablets
Monodur Tablets

CAS No. : Not applicable

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : prophylaxis of angina pectoris

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards which do not result in classification

Absorbed through the lungs, gastrointestinal tract and skin.
May cause headache, flushing of the skin, dizziness, nausea and vomiting, and postural hypotension.
The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Isosorbide-5-mononitrate	16051-77-7	>= 20 - < 30
Celluloses	9004-34-6	>= 10 - < 20
Magnesium stearate	557-04-0	>= 1 - < 10

SECTION 4. FIRST AID MEASURES

If inhaled : Remove patient from exposure.
Obtain medical attention if ill effects occur.

In case of skin contact : Wash skin with soap and water.

In case of eye contact	:	Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention if ill effects remain.
If swallowed	:	Wash out mouth with water and give 200-300ml of water to drink. Do NOT induce vomiting as a First-Aid measure. Obtain medical attention if ill effects occur.
Most important symptoms and effects, both acute and delayed	:	Refer to sections 2 and 11
Notes to physician	:	Symptomatic treatment and supportive therapy as indicated. For further information consult the prescribing information.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	water spray, foam, dry powder or CO2.
Unsuitable extinguishing media	:	Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.
Specific hazards during firefighting	:	If involved in a fire, it may burn and emit noxious and toxic fumes.
Special protective equipment for firefighters	:	A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Avoid dispersal of dust in the air. Ensure suitable personal protection during removal of spillages. See Section 8.
Environmental precautions	:	Prevent entry into drains, sewers or watercourses.
Methods and materials for containment and cleaning up	:	Avoid dust generation. Transfer spilled tablets to a suitable container for disposal. Wash the spillage area with water.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling	:	Avoid contact with skin and eyes. Wash hands after use. Minimize dust generation and accumulation. The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.
Conditions for safe storage	:	Keep container tightly closed. Keep away from heat and sources of ignition. Protect from moisture.

Recommended storage temperature : < 30 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Isosorbide-5-mononitrate	16051-77-7	TWA	0.05 mg/m3	COM; HYG; Sk
Celluloses	9004-34-6	TWA	10 mg/m3	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 mg/m3	ACGIH
Magnesium stearate	557-04-0	TWA	10 mg/m3	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 mg/m3	ACGIH

Engineering measures : The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Prevent entry into drains, sewers or watercourses.

Personal protective equipment

Respiratory protection : Use a negative pressure air purifying respirator (half face mask) with filter class P3 if the risk assessment does not support the selection of other protection.

Eye protection : Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other protection.

Skin and body protection : Use protective clothing to protect against direct contact with the product if the risk assessment does not support the selection of other protection. Use impervious protective gloves to protect against direct contact with the product. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid.

Protective measures : The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

Decisions about whether the use of personal protective

equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc.
All the information above should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	film-coated tablets
Colour	:	30 mg - pink; 60 mg - yellow; 120 mg - white
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/range	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	No data available
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available

Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available
Minimum ignition energy	:	25 - 50 mJ

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No known reactivity hazard under normal conditions.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	None known.
Conditions to avoid	:	No conditions producing hazardous situations known.
Incompatible materials	:	None known.
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1.1 Acute toxicity

Not classified based on available information.

Components:

Isosorbide-5-mononitrate:

Acute oral toxicity	:	LD50 Oral (Rat): 1,300 - 1,600 mg/kg
Acute inhalation toxicity	:	Remarks: May cause effects as described under single exposure.(STOT)
Acute dermal toxicity	:	Remarks: Can be absorbed through skin causing systemic toxic effects.

11.1.2 Skin corrosion/irritation

Not classified based on available information.

Components:

Isosorbide-5-mononitrate:

Remarks: Unlikely to cause skin irritation.

11.1.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:

Isosorbide-5-mononitrate:

Remarks: May cause slight eye irritation.

11.1.4 Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Isosorbide-5-mononitrate:

Remarks: No information available.

11.1.5 Germ cell mutagenicity

Not classified based on available information.

Components:

Isosorbide-5-mononitrate:

Germ cell mutagenicity - Assessment	:	The substance is not considered to be genotoxic.

11.1.6 Carcinogenicity

Not classified based on available information.

Components:

Isosorbide-5-mononitrate:

Carcinogenicity - Assessment	:	No evidence of carcinogencity in animal studies.

11.1.7 Reproductive toxicity

Not classified based on available information.

Components:

Isosorbide-5-mononitrate:

Reproductive toxicity - Assessment	:	The substance is not considered to present a reproductive risk to man.

11.1.8 STOT - single exposure

Not classified based on available information.

Components:

Isosorbide-5-mononitrate:

Exposure routes: Inhalation, Oral, Dermal

Remarks: May cause headache, flushing of the skin, dizziness, nausea and vomiting, and postural hypotension.
Side effects reported from patients include myocardial infarction, tachycardia, angina pectoris, palpitation and vasospasm.

11.1.9 STOT - repeated exposure

Not classified based on available information.

Components:

Isosorbide-5-mononitrate:

Remarks: May cause effects as described under single exposure.(STOT)

11.1.10 Aspiration toxicity

Not classified based on available information.

Components:

Isosorbide-5-mononitrate:

No information available.

Further information

Product:

Remarks: This health hazard assessment is based on a consideration of the composition of this product.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Ecotoxicology Assessment

Chronic aquatic toxicity	:	This product has no known ecotoxicological effects. Remarks: No information on this formulation. The following information refers to active ingredient: Isosorbide-5-mononitrate:

Components:

Isosorbide-5-mononitrate:

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 120 mg/l Exposure time: 48 H Method: OECD Test Guideline 202 NOEC (Daphnia magna (Water flea)): 120 mg/l Exposure time: 48 H Method: OECD Test Guideline 202

Persistence and degradability

Components:

Isosorbide-5-mononitrate:

Biodegradability : Remarks: No degradation data available. The substance is assumed not to be rapidly degradable.

Bioaccumulative potential

Components:

Isosorbide-5-mononitrate:

Bioaccumulation : Remarks: No information available.

Mobility in soil

Components:

Isosorbide-5-mononitrate:

Mobility : Remarks: No information available.

Distribution among environmental compartments : Remarks: No information available.

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Disposal should be in accordance with local, state or national legislation.
Waste, even small quantities, should never be poured down drains, sewers or water courses.
Dispose of contents/ container to an approved incineration plant.

Contaminated packaging : Empty container will retain product residue. Observe all hazard precautions.

SECTION 14. TRANSPORT INFORMATION

Not classified as dangerous in the meaning of transport regulations.

SECTION 15. REGULATORY INFORMATION

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

In order to comply with legal duties it is necessary to consult local and national legislation.

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

The components of this product are reported in the following inventories:

REACH : Not listed

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Isosorbide-5-mononitrate 16051-77-7

AICS : Not listed

ENCS : Not listed

ISHL : Not listed

IECSC : Not listed

TCSI : Not listed

TSCA : Not On TSCA Inventory

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM – In-house occupational exposure limit; CPR - Controlled Products Regulations; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HYG – Analytical method for occupational exposure monitoring; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent,

Bioaccumulative and Toxic substance; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; Sen – Capable of causing respiratory sensitization; Sk – Can be absorbed through skin, thus contributing to systemic effects; STEL – Short-term exposure limit 15-minutes time-weighted average; TLV – Threshold Limit Value (ACGIH); TLV-C – Threshold Limit Value Ceiling limit (ACGIH); TSCA - Toxic Substances Control Act (United States); TWA – Long-term exposure limit 8h time-weighted average; UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Further information

Other information	:	The Safety Data Sheet has been updated to the SAP EH&S Standard template., This update affects all Sections of the Safety Data Sheet. Minor changes:, 1, 6, 8, 12, 13
Date format	:	dd.mm.yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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