SAFETY DATA SHEET

1. Identification

Product identifier **IMITREX INJECTION**

Other means of identification Not available.

Synonym(s) IMITREX INJECTION 4 MG/0.5 ML * IMITREX INJECTION 6 MG/0.5 ML * IMITREX STATDOSE SYSTEM * IMITREX STATDOSE PEN * IMITREX INJECTION CATRIDGE PACK * IMITREX SINGLE DOSE VIAL 6 MG * IMIGRAN SUBJECT TREATMENT PACK 0.5 ML * IMIGRAN SUBJECT REFILL PACK 0.5 ML * IMIGRAN INJECTION 12 MG/ML * IMIGRANE SYRINGE * SUMATRIPTAN SUCCINATE, FORMULATED PRODUCT

Recommended use Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
SUMATRIPTAN SUCCINATE	GR 43175C 3-(2-(DIMETHYLAMINO)ETHYL)-N-METHYL SUCCINATE 357 (GW ACN)	103628-48-4	1.1 - < 1.7
Other components below reportable levels			>98.0

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention immediately.

Skin contact Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Remove and isolate contaminated clothing and shoes. Get medical attention immediately.

Eye contact In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Ingestion	Rinse mouth. Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
Most important symptoms/effects, acute and delayed	The following adverse effects have been noted with therapeutic use of this material: dizziness; drowsiness; abnormal nervous system sensations; difficult or irregular breathing; nausea; vomiting; feelings of heaviness or pressure; weakness; fatigue.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
General information	Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Not available.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Move container from fire area if it can be done without risk.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate personal protective equipment. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the MSDS.
Methods and materials for containment and cleaning up	Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent product from entering drains. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills in original containers for re-use. For waste disposal, see section 13 of the MSDS.
Environmental precautions	Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact during pregnancy/while nursing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Avoid release to the environment. Do not empty into drains.
Conditions for safe storage, including any incompatibilities	Store locked up. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
SUMATRIPTAN SUCCINATE (CAS 103628-48-4)	15 MIN STEL	100 mcg/m3	
	8 HR TWA	50 mcg/m3	
	OHC	3	REPRODUCTIVE HAZARD

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls	An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles). Wear a full-face respirator, if needed.
Hand protection	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.
Other	Not normally needed.
Respiratory protection	No personal respiratory protective equipment normally required.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	When using, do not eat, drink or smoke. Wash hands after handling and before eating. An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Solution.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	4.5 - 5
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion May be harmful if swallowed.

Inhalation Health injuries are not known or expected under normal use.

Skin contact Health injuries are not known or expected under normal use.

Eye contact Health injuries are not known or expected under normal use.

Symptoms related to the physical, chemical and toxicological characteristics The following adverse effects have been noted with therapeutic use of this material: dizziness; drowsiness; abnormal nervous system sensations; difficult or irregular breathing; nausea; vomiting; feelings of heaviness or pressure; weakness; fatigue.

Information on toxicological effects

Acute toxicity May be harmful if swallowed.

Components	Species	Test Results
SUMATRIPTAN SUCCINATE (CAS 103628-48-4)		
Acute		
Oral		
LD50	Mouse	> 1500 mg/kg
	Rat	> 2000 mg/kg
Chronic		
Oral		
NOAEL	Rat	5 mg/kg/day, 18 months
TD	Rat	>= 50 mg/kg/day
Subchronic		
Oral		
TD	Dog	<= 50 mg/kg/day, 60 weeks

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Serious eye damage/eye irritation Health injuries are not known or expected under normal use.

Eye

SUMATRIPTAN SUCCINATE	OECD 405 Result: Mild irritant Species: Rabbit

Respiratory sensitization Not established.

Skin sensitization This product is not expected to cause skin sensitization.

Sensitization

SUMATRIPTAN SUCCINATE	Topical Result: Negative Species: Guinea pig

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

SUMATRIPTAN SUCCINATE	<= 1000 mg/kg Micronucleus Test Result: Negative Species: Rat Ames, GLP Result: Negative Bacterial Fluctuation Test Result: Negative Chromosomal Aberration Assay In Vitro, GLP Result: Negative HPRT gene mutation in human lymphocytes Result: Negative WHO Nitrosation Assay Result: Negative Yeast Mutation Assay Result: Negative

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Carcinogenicity

SUMATRIPTAN SUCCINATE

10 - 160 mg/kg/day
Result: Negative
Species: Mouse
10 - 160 mg/kg/day
Result: Negative
Species: Rat

Reproductive toxicity Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.

SUMATRIPTAN SUCCINATE

100 mg/kg/day Fertility
Result: Reduced success of insemination.
Species: Rat
1000 mg/kg/day Pre- and Post-natal development
Result: Maternal toxicity; adverse foetal effects
50 mg/kg/day Embryo-foetal development- Oral
Result: NOAEL
Species: Rabbit
60 mg/kg/day Embryo-foetal development - Oral
Result: NOAEL
Species: Rabbit
>= 100 mg/kg/day Embryo-foetal development - Oral
Result: Maternal toxicity; adverse foetal effects
Species: Rat
>= 100 mg/kg/day Embryo-foetal development- Oral
Result: Maternal toxicity; adverse foetal effects
Species: Rabbit

Specific target organ toxicity - single exposure Circulatory system.

Specific target organ toxicity - repeated exposure None known.

Aspiration hazard Due to partial or complete lack of data the classification is not possible.

Chronic effects Prolonged exposure may cause chronic effects.

Further information None known.

12. Ecological information

Ecotoxicity Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test Results
SUMATRIPTAN SUCCINATE (CAS 103628-48-4)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 750 mg/l, 3 hours, OECD 209
Algae	EC50	Green algae (Scenedesmus subspicatus)	36 mg/l, 72 hours, OECD 201
	NOEC	Green algae (Scenedesmus subspicatus)	12.5 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia pulex)	290 mg/l, 48 hours, Static test, OECD 202
	NOEC	Water flea (Daphnia pulex)	200 mg/l, 48 hours
Fish	EC50	Rainbow trout (Juvenile Oncorhyncus mykiss)	> 100 mg/l, 96 hours, OECD 203
	NOEC	Rainbow trout (Juvenile Oncorhyncus mykiss)	100 mg/l, 96 hours
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	100 mg/l, 8 days, Static renewal test, EPA Method 1002
	NOEC	Daphnia	32 mg/l, 8 days

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

Photolysis

UV/visible spectrum wavelength

SUMATRIPTAN SUCCINATE 290 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

SUMATRIPTAN SUCCINATE	> 1 Years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-soil)

SUMATRIPTAN SUCCINATE	32 - 40 %, 64 days, Soil

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

SUMATRIPTAN SUCCINATE	0.93 (Measured).

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

SUMATRIPTAN SUCCINATE	3.52 - 3.57 Measured

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as a dangerous good.

IMDG

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

SARA 304 Emergency release notification

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 11-06-2013

Revision date 11-06-2013

Version # 14

Further information HMIS® is a registered trade and service mark of the NPCA.

References GSK Hazard Determination

Disclaimer The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Revision Information First-aid measures: Ingestion
Exposure controls/personal protection: Respiratory protection
Disposal considerations: Disposal instructions
Other information, including date of preparation or last revision: Further information