SAFETY DATA SHEET

1. Identification

Product identifier **IMITREX INJECTION**

Other means of identification

Synonyms IMITREX INJECTION 4 MG/0.5 ML * IMITREX INJECTION 6 MG/0.5 ML * IMIGRAN 6 MG INYECTABLE * MIGRANE 6 MG/0,5 ML, SOLUTION INJECTABLE POUR VOIE SOUS-CUTANEE EN SERINGUE PRE-REMPLIE * IMIGRAN 6 MG/0,5 ML RAZTOPINA ZA INJICIRANJE * IMIGRAN 6 MG/0,5 ML - SPRITZAMPULLEN * IMIGRAN 6 MG/0,5 ML SOLUZIONE INIETTABILE PER USO SOTTOCUTANEO * IMIGRAN 6 S.C. OPLOSSING VOOR INJECTIE VOOR SUBCUTAAN GEBRUIK * IMIGRAN ΕΝΈΣΙΜΟ ΔΙΆΛΥΜΑ * IMIGRAN OLDATOS INJEKCIÓ + AUTOINJEKTOR * 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 * IMIGRAN 12 MG/ML INJEKTIONESTE, LIUOS * IMIGRAN 12 MG/ML STUNGULYF, LAUSN * IMIGRAN 12 MG/ML INJEKSJONSVÆSKE, OPPLØSNING * IMIGRAN 12 MG/ML INJEKTIONSVÄTSKA, LÖSNING * IMIGRANE SYRINGE * SUMATRIPTAN SUCCINATE, FORMULATED PRODUCT

Recommended use Medicinal Product.

This safety data sheet (SDS) has been prepared in accordance with workplace safety standards which require identification of all known hazards of the material regardless of potential risk. The information is intended for people handling the material in the workplace. Warnings included may not apply in all cases. Needs may vary depending upon the potential for exposure in the workplace. The SDS is not intended to provide information relevant to final use of the material for the purpose intended. Consumers/Patients should consult prescribing information/package insert/product label or consult their chemist or physician.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

COMPANY NAME GSK

Address: 410 Blackwell Street
Durham, NC, 27701

Telephone: +1-888-825-5249 (GSK General Inquiries)
+1-877-844-8872 (ViiV General Inquiries)

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

3E GLOBAL INCIDENT RESPONSE

Telephone: +(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

Contract Number: 334878

2. Hazard(s) identification

Hazards for the product as sold

Physical hazards Not classified.

Health hazards Not classified.

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	Not available.
Response	Not available.
Storage	Not available.
Disposal	Not available.
Hazard(s) not otherwise classified (HNOC)	Caution - Pharmaceutical agent. See section 11 of the SDS for additional information on health hazards.
Supplemental information	None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS No./Unique ID	%
SUMATRIPTAN SUCCINATE	GR 43175C 3-(2-(DIMETHYLAMINO)ETHYL)-N-METH YL-1H-INDOLE-5-METHANESULPHONA MIDE SUCCINATE	103628-48-4	1.1 - 1.7
SODIUM CHLORIDE	COMMON SALT ROCK SALT SODIUM MONOCHLORIDE SALT SEA SALT TABLE SALT SALT, WHITE CRYSTALS, SOLAR	7647-14-5	0.7
Other components below reportable levels			>98.0

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	The following adverse effects have been noted with therapeutic use of this material: abnormal nervous system sensations; feelings of heaviness or pressure. Nausea, vomiting. Difficulty in breathing. May cause drowsiness and dizziness.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO_2).
Unsuitable extinguishing media	None known.
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	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.

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. Absorb in vermiculite, dry sand or earth and place into containers. 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 to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Avoid prolonged exposure. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store in tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

GSK

Components	Type	Value	Form
SODIUM CHLORIDE (CAS 7647-14-5)	OHC	1	>1000 - </=5000 mcg/m3
SUMATRIPTAN SUCCINATE (CAS 103628-48-4)	8 HR TWA	50 mcg/m3	

Biological limit values

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

Appropriate engineering controls

General ventilation normally adequate.

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.

GSK Exposure Control Band; OHC 3.

Individual protection measures, such as personal protective equipment

Eye/face protection

Not normally needed. If contact is likely, safety glasses with side shields are recommended..

Skin protection

Hand protection

Not normally needed. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time). Wear appropriate chemical resistant gloves.

Other

Not normally needed. Wear suitable protective clothing as protection against splashing or contamination..

Respiratory protection

No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Physical state	Liquid.
Form	Applicator pen. Vial
Color	Not available.
Odor	Not available.
Melting point/freezing point	Not available.
Boiling point or initial boiling point and boiling range	Not available.
Flammability	Not applicable.
Upper/lower flammability or explosive limits	
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Flash point	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
pH	> 4.5 - < 5
Kinematic viscosity	Not available.
Solubility	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Vapor pressure	Not available.
Density and/or relative density	Not available.
Vapor density	Not available.
Particle characteristics	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

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	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Health injuries are not expected as a result of occupational exposure or intended use.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Health injuries are not expected as a result of occupational exposure or intended use.
Symptoms related to the physical, chemical and toxicological characteristics	The following adverse effects have been noted with therapeutic use of this material: abnormal nervous system sensations; feelings of heaviness or pressure. Difficulty in breathing. Nausea, vomiting. May cause drowsiness and dizziness.

Information on toxicological effects

Acute toxicity Health injuries are not expected as a result of occupational exposure or intended use.

Components	Species	Test Results
SODIUM CHLORIDE (CAS 7647-14-5)		
Acute		
Oral		
LD50	Rat	3000 mg/kg
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

Skin corrosion/irritation No adverse effects due to skin contact are expected.

Corrosivity

SUMATRIPTAN SUCCINATE
Acute dermal irritation
Result: Negative

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye

SUMATRIPTAN SUCCINATE
OECD 405
Result: Mild irritant
Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

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. Health injuries are not expected as a result of occupational exposure or intended use.

Mutagenicity

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

Mutagenicity

SUMATRIPTAN SUCCINATE	Yeast Mutation Assay Result: Negative

Carcinogenicity No data available to indicate product or any components present at greater than 0.1% are carcinogenic. Carcinogenic effects are not expected as a result of occupational exposure.

SUMATRIPTAN SUCCINATE	10 - 160 mg/kg/day 2-year study Result: Negative Species: Rat 10 - 160 mg/kg/day 78 week study Result: Negative Species: Mouse

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Reproductivity

SUMATRIPTAN SUCCINATE	>= 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 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 50 mg/kg/day Fertility Result: Reduced success of insemination. Species: Rat 60 mg/kg/day Embryo-foetal development - Oral Result: NOAEL Species: Rabbit

Specific target organ toxicity - single exposure Not assigned. Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure Not assigned. Based on available data, the classification criteria are not met.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

Further information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

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

Components		Species	Test Results
SODIUM CHLORIDE (CAS 7647-14-5)			
Aquatic			
Acute			
Algae	EC50	Algae (Nitscheria linearis)	2430 mg/l, 5 days
Crustacea	EC50	Water flea (Daphnia magna)	3310 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Juvenile Lepomis macrochirus)	1295 mg/l, 96 hours Static test

Components		Species	Test Results
		Fathead minnow (Juvenile Pimephales promelas)	6390 mg/l, 96 hours Static test
		Goldfish (Adult Carassius auratus)	7000 mg/l, 96 hours
		Mosquito fish (Adult Gambusia affinis)	17550 mg/l, 96 hours Static test
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

Persistence and degradability No data is available on the degradability of this product.

Photolysis

UV/visible spectrum wavelength

SUMATRIPTAN SUCCINATE 290 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

SUMATRIPTAN SUCCINATE > 1 Years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

SUMATRIPTAN SUCCINATE 100 %, 16 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge
17 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge

Percent degradation (Aerobic biodegradation-ready)

SUMATRIPTAN SUCCINATE 1 %, 28 days

Percent degradation (Aerobic biodegradation-soil)

SUMATRIPTAN SUCCINATE 32 - 40 %, 64 days, Soil

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

SUMATRIPTAN SUCCINATE 0.93 (Measured).

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

SUMATRIPTAN SUCCINATE 3.52 - 3.57 Measured

Mobility in general Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
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.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as a dangerous good.

Read safety instructions, SDS and emergency procedures before handling.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to IMO instruments	Not applicable.

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	No

SARA 313 (TRI reporting)

Not regulated.

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.

US state regulations

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. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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	05-24-2018
Revision date	07-17-2025
Version #	17
HMIS® ratings	Health: 2 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 2 Flammability: 0 Instability: 0
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	This document has undergone significant changes and should be reviewed in its entirety.