

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material	IMITREX NASAL SPRAY
Synonym(s)	IMITREX NASAL SPRAY 5 MG * IMITREX NASAL SPRAY 20 MG * IMITREX INTRANASAL * IMIGRAN NASAL SPRAY * IMIGRAN INTRANASAL * IMIGRAN NASAL NASENSPRAY 20 MG * IMIGRAN NASAL MITE NASENSPRAY 10 MG * IMIGRANE INTRANASAL * NDC NO 0173-0523-00 * NDC NO 0173-0524-00 * SUMATRIPTAN, FORMULATED PRODUCT
Company Name	<p>GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK</p> <p>UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response</p> <p>GlaxoSmithKline, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response</p>

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
NON-HAZARDOUS INGREDIENTS	Unassigned	80 to 95	
SUMATRIPTAN BASE	103628-46-2	5 to 20	

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
Health	Caution - Potent pharmaceutical agent. Exposure might occur via ingestion; skin; eyes. Possible effects of overexposure in the workplace include: irritation; inflamed nasal cavity; changes in heart rate; increased blood pressure; dizziness; visual disturbances; weakness; salivation; headache; feelings of heaviness or pressure; tingling; drowsiness; flushing; fatigue.
Environment	Dangerous for the environment. Harmful to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

4. FIRST-AID MEASURES

Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
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Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Medical treatment in cases of overexposure should be treated as an overdose of a 5-hydroxytryptamine agonist. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	None for occupational exposure.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	This product is non-combustible, although the packaging is combustible.
Extinguishing Media	Water is recommended for fires involving packaging.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

HANDLING

General Requirements	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
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STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	SUMATRIPTAN BASE
GSK Occupational Hazard Category	3
GSK Occupational Exposure Limit	50 mcg/m ³ (8 HR TWA) 100 mcg/m ³ (15 MIN STEL)
ENGINEERING CONTROLS	
Containment	Open handling may result in overexposure.
Ventilation	Local exhaust ventilation (LEV) should be used in conjunction with other control measures as a means of removing material incidentally released.

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Administrative Entry to the working area should be controlled. Only authorised personnel may enter the working area.

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection Wear approved safety glasses with side shields or cover goggles if eye contact is possible.

Other Equipment or Procedures Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling. An eye wash station should be available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Solution.

pH of Aqueous Solutions 5.4 to 5.6

10. STABILITY AND REACTIVITY

Stability DO NOT FREEZE - dispose of properly if frozen.

Conditions to Avoid None for normal handling of this product.

11. TOXICOLOGY INFORMATION

Pharmacological Effects This product contains active ingredient(s) with the following activity: a 5-hydroxytryptamine agonist.

Target Organ Effects No specific target organ effects have been identified.

Routes of Exposure

Oral Toxicity Not expected to be toxic following ingestion.

Inhalation Toxicity Overexposure may result in irritation of the respiratory tract.

Skin Effects Irritation is not expected following direct contact.

Eye Effects Irritation is not expected following direct contact with eyes.

Sensitisation Sensitisation (allergic skin reaction) is not expected.

Genetic Toxicity Not expected to be genotoxic under occupational exposure conditions.

Carcinogenicity No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

Reproductive Effects Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

Other Adverse Effects None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary This product contains an active ingredient that has been tested and which may be harmful if released directly to the environment. Appropriate precautions should be taken to limit release of this material to the environment. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active pharmaceutical ingredient which is the majority component is provided below.

ECOTOXICITY**Aquatic**

Activated Sludge Respiration This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.

IC50: 536 mg/l, 3 Hours, Activated sludge, Nominal

Algal This material contains an active pharmaceutical ingredient that is harmful to algae.

IC50: 26 mg/l, 72 Hours, Scenedesmus subspicatus, green algae, Measured

NOEC: 8.9 mg/l, 72 Hours, Scenedesmus subspicatus, green algae, Measured

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Daphnid	<p>This material contains an active pharmaceutical ingredient that is not toxic to daphnids. This material contains an active pharmaceutical ingredient that is harmful to daphnids in chronic toxicity studies.</p> <p>EC50: 206 mg/l, 48 Hours, Daphnia pulex, Measured NOEC: 142 mg/l, 48 Hours, Daphnia pulex, Measured Chronic LOEC: 71 mg/l, 8 Days, Ceriodaphnia dubia, Static renewal test Chronic NOEC: 23 mg/l, 8 Days</p>
Fish	<p>This material contains an active pharmaceutical ingredient that is not toxic to fish.</p> <p>Juvenile Salmo gairdneri, rainbow trout EC50: > 71 mg/l, 96 Hours, Measured Juvenile Salmo gairdneri, rainbow trout NOEC: 71 mg/l, 96 Hours, Measured</p>
MOBILITY	
Solubility	This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.
Volatility	<p>This material contains an active pharmaceutical ingredient that will not readily enter into air from water.</p> <p>Henry's Law Constant < 9.00E-13 atm m³/mol</p>
Distribution	<p>Octanol/Water Distribution Coefficient (log Dow): -2 at pH 5 Octanol/Water Distribution Coefficient (log Dow): -2.3 at pH 7 Octanol/Water Distribution Coefficient (log Dow): -0.5 at pH 9</p>
Adsorption	<p>This material contains an active pharmaceutical ingredient that is likely to adsorb to soil or sediment. This material contains an active pharmaceutical ingredient that is likely to adsorb to sludges and other biomass.</p> <p>Soil Sediment Sorption (log K_{oc}): 3.52 to 3.57</p>
Partitioning	This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.
PERSISTENCE/DEGRADATION	
Hydrolysis	This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water. Hydrolysis is unlikely to be a significant depletion mechanism.
Photolysis	<p>This material contains an active pharmaceutical ingredient that is likely to undergo photodegradation.</p> <p>UV/Visible Spectrum: 293 nm at pH 7</p>
Biodegradation	<p>This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment. This mixture contains an active pharmaceutical ingredient that slowly undergoes biodegradation in soil.</p> <p>Aerobic - Ready Percent Degradation: 1 %, 28 days</p> <p>Aerobic - Inherent Percent Degradation: 100 %, 28 days, Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge</p> <p>Aerobic - Soil Percent Degradation: 32.1 to 40.2 %, 64 days</p>

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations	Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.
Regulatory Requirements	Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Transport Information	Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.
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15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification	This product is classified as hazardous according to the OSHA Hazard Communication Standard.
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Other US Regulations

TSCA Status	Exempt
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16. OTHER INFORMATION

References GSK Hazard Determination

SDS Version Number 11

SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	
IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY	

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.