

## SAFETY DATA SHEET



### \* 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

<b>Material</b>	PROMACTA TABLETS
<b>Synonym(s)</b>	REVOLADE TABLETS * SB-497115-GR TABLETS * PROMACTA 5 MG TABLETS * PROMACTA 10 MG TABLETS * PROMACTA 12.5 MG TABLETS * PROMACTA 25 MG TABLETS * PROMACTA 50 MG TABLETS * PROMACTA 75 MG TABLETS * PROMACTA 100 MG TABLETS * NDC NO. 0007-4640-13 * NDC NO. 0007-4641-13 * ELTROMBOPAG OLAMINE, FORMULATED PRODUCT
<b>Company Name</b>	<p>GlaxoSmithKline, Corporate Environment, Health &amp; 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 &amp; 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. HAZARDS IDENTIFICATION

**Fire and Explosion Hazards**

Expected to be non-combustible.

**Health**

Caution - Pharmaceutical agent.

Severe eye irritant.

Exposure might occur via skin; eyes.

Possible effects of overexposure in the workplace include: increased blood coagulation; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); redness; pain.

Health effects information is based on hazards of components.

**Environment**

Dangerous for the environment. Toxic to aquatic organisms. May cause long-term adverse effects in the environment.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
ELTROMBOPAG OLAMINE	496775-62-3	1.8 to 87.6	
NON-HAZARDOUS INGREDIENTS	Unassigned	12.4 to 98.2	

#### 4. FIRST-AID MEASURES

<b>Ingestion</b>	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.
<b>Inhalation</b>	Physical form suggests that risk of inhalation exposure is negligible.
<b>Skin contact</b>	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.
<b>Eye contact</b>	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

#### NOTES TO HEALTH PROFESSIONALS

<b>Medical Treatment</b>	Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre. Because of the potential for acute or delayed eye damage, consider referral to an ophthalmologist.
<b>Medical Conditions Caused or Aggravated by Exposure</b>	None for occupational exposure.
<b>Health Surveillance Procedures</b>	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.
<b>Antidotes</b>	No specific antidotes are recommended.

#### 5. FIRE-FIGHTING MEASURES

<b>Fire and Explosion Hazards</b>	Not expected for the product, although the packaging is combustible.
<b>Extinguishing Media</b>	Water or foam extinguishers are recommended. Carbon dioxide or dry powder extinguishers may be ineffective.
<b>Special Firefighting Procedures</b>	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.
<b>Hazardous Combustion Products</b>	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

#### 6. ACCIDENTAL RELEASE MEASURES

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

#### 7. HANDLING AND STORAGE

##### HANDLING

**General Requirements** Avoid breaking or crushing tablets.

##### STORAGE

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

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## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

## OCCUPATIONAL EXPOSURE LIMITS

INGREDIENT ELTROMBOPAG OLAMINE

GSK Occupational Hazard Category 3

GSK Occupational Exposure Limit 100 mcg/m3 (8 HR TWA)

## 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.

Administrative Entry to the working area should be controlled. Restrict access to authorised personnel.

Other Equipment or Procedures Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Wash hands and arms thoroughly after handling.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

## Appearance

Physical Form Tablet.

## 10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.

Conditions to Avoid None for normal handling of this product.

## 11. TOXICOLOGY INFORMATION

Pharmacological Effects This preparation contains ingredient(s) with the following activity: a thrombopoietin (TPO) receptor 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 No studies have been conducted.

Skin Effects Irritation is not expected following direct contact.

Eye Effects Severe irritation might occur following direct contact with eyes.

Sensitisation Allergic skin reactions might occur following repeated contact with this material in susceptible individuals. Assessment based upon information from human exposure.

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 material contains an active pharmaceutical ingredient that has been tested and which may be harmful if released directly to the environment. This material contains an active pharmaceutical ingredient that may persist in 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.

## ECOTOXICITY

Aquatic

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<b>Activated Sludge Respiration</b>	This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms. IC50: > 320 mg/l, 3 Hours, Activated sludge NOEC: > 32 mg/l, 3 Hours, Activated sludge
<b>Daphnid</b>	This material contains an active pharmaceutical ingredient that is toxic to daphnids. EC50: 1.5 mg/l, 48 Hours, Daphnia magna, Static test NOEC: 0.54 mg/l, 48 Hours, Daphnia magna, Static test
<b>Fish</b>	This material contains an active pharmaceutical ingredient that is toxic to fish. EC50: 3.3 mg/l, 96 Hours, Static renewal test Juvenile Oncorhynchus mykiss, rainbow trout NOEC: 2.1 mg/l, 96 Hours
<b>Other Species - Aquatic</b>	This material is toxic to these organisms. LC50: Static renewal test Lemna minor EC50: 1.57 mg/l, 7 Days NOEC: 0.59 mg/l
<b>MOBILITY</b>	
<b>Solubility</b>	This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.
<b>Adsorption</b>	This material contains an active pharmaceutical ingredient that is not likely to adsorb to, or persist in, soil or sediment if released directly to the environment. Soil Sediment Sorption 2.39, Calculated at pH 5 (log Koc):
<b>Partitioning</b>	This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient may have the tendency to distribute into fats.
<b>PERSISTENCE/DEGRADATION</b>	
<b>Biodegradation</b>	This mixture contains an active pharmaceutical ingredient that is not readily nor inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and may persist in the environment. Aerobic - Inherent Percent Degradation: 18 %, 28 days, Modified MITI (II) Test.
<b>BIOACCUMULATION</b>	
<b>Bioaccumulation</b>	This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.
<b>Bioconcentration Factor:</b>	1 to 39 Calculated

## 13. DISPOSAL CONSIDERATIONS

<b>Disposal Recommendations</b>	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.
<b>Regulatory Requirements</b>	Observe all local and national regulations when disposing of this material.

## 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**

<b>Transport Information</b>	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
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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 dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

**Other US Regulations**

**TSCA Status** Exempt

16. OTHER INFORMATION
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**References** GSK Hazard Determination

**SDS Version Number** 12

**SDS Sections Updated****Sections**

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY

**Subsections**

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.