SAFETY DATA SHEET

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

Material
PROMACTA TABLETS

Synonym(s)
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

Company Name
GlaxoSmithKline, Corporate Environment, Health & Safety
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Multi-language response

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Transport Emergency (non EU) +1-703-527-3887
US number, available 24 hours
Multi-language response

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

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS #</th>
<th>Percent</th>
<th>EC-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELTROMBOPAG OLAMINE</td>
<td>496775-62-3</td>
<td>1.8 to 87.6</td>
<td></td>
</tr>
<tr>
<td>NON-HAZARDOUS INGREDIENTS</td>
<td>Unassigned</td>
<td>12.4 to 98.2</td>
<td></td>
</tr>
</tbody>
</table>
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.

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

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.

Medical Conditions

Caused by Exposure

None for occupational exposure.

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.

Antidotes

No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards

Not expected for the product, although the packaging is combustible.

Extinguishing Media

Water or foam extinguishers are recommended. Carbon dioxide or dry powder extinguishers may be ineffective.

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

Avoid breaking or crushing tablets.

STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

OCCUPATIONAL EXPOSURE LIMITS

<table>
<thead>
<tr>
<th>INGREDIENT</th>
<th>ELTROMBOPAG OLAMINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSK Occupational Hazard</td>
<td>Category 3</td>
</tr>
<tr>
<td>GSK Occupational Exposure Limit</td>
<td>100 mcg/m3 (8 HR TWA)</td>
</tr>
</tbody>
</table>

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**: 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**
Activated Sludge Respiration
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

Daphnid
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

Fish
This material contains an active pharmaceutical ingredient that is toxic to fish.
EC50: 3.3 mg/l, 96 Hours, Static renewal test Juvenile Oncorhyncus mykiss, rainbow trout
NOEC: 2.1 mg/l, 96 Hours

Other Species - Aquatic
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

MOBILITY

Solubility
This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.

Adsorption
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):

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 may have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION

Biodegradation
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.

BIOACCUMULATION

Bioaccumulation
This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.
Bioconcentration Factor: 1 to 39 Calculated

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 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
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.
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.

Classification
This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

Other US Regulations
TSCA Status
Exempt

16. OTHER INFORMATION

References
GSK Hazard Determination

SDS Version Number
12

SDS Sections Updated

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.