SECTION 1: IDENTIFICATION

1.1. Product Identifier
Product Form: Tablet
Product Name: XOSPATA® Tablets 40 mg
Chemical Name: Proprietary
Generic Name: Gilteritinib
Formula: Proprietary
Synonyms: ASP2215

1.2. Intended Use of the Product
Use of the Drug Product, ASP2215: Pharmaceutical research, manufacturing and clinical use. For professional use only.

1.3. Name, Address, and Telephone of the Responsible Party
Company
Astellas US LLC
2375 Waterview Drive
Northbrook, IL 60062
Tel.: 800-888-7704
www.us.astellas.com

1.4. Emergency Telephone Number
Emergency Number: 800-727-7003
Medical Communications

SECTION 2: HAZARDS IDENTIFICATION

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) It is in solid, final form for direct administration to the patient. Therefore, it is exempt from labeling, as defined in the 29 CFR 1910.1200(b)(5)(iii).

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) It is in solid, final form for direct administration to the patient. Therefore, it is exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)[6][vii].

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures
First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).
First-aid Measures After Inhalation: Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.
First-aid Measures After Skin Contact: Gently wash with plenty of soap and water followed by rinsing with water. Call a POISON CENTER or doctor/physician if you feel unwell.
First-aid Measures After Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if pain, blinking, or redness persist.
First-aid Measures After Ingestion: Do not induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor/physician.

4.2. Most important symptoms and effects, both acute and delayed
Symptoms/Injuries: Pharmaceutical. When handling in workplace settings, in quantities that are most likely above the therapeutic dose, this product may be harmful if absorbed through the eyes, skin, or respiratory tract.
Symptoms/Injuries After Inhalation: If tablet is crushed: May cause respiratory irritation.
Symptoms/Injuries After Skin Contact: If tablet is crushed: May cause skin irritation.
Symptoms/Injuries After Eye Contact: If tablet is crushed: May cause eye irritation.
Chronic Symptoms: Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure. Suspected of causing genetic defects.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed
If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media
Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.
Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.
5.2. Special Hazards Arising From the Substance or Mixture
Fire Hazard: Not considered flammable but may burn at high temperatures.
Explosion Hazard: Product is not explosive.
Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters
Precautionary Measures Fire: Exercise caution when fighting any chemical fire.
Firefighting Instructions: Use water spray or fog for cooling exposed containers.
Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.
Other Information: Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures
General Measures: Use only as directed.
6.1.1. For Non-emergency Personnel
Protective Equipment: Use appropriate personal protection equipment (PPE).
6.1.2. For Emergency Responders
Protective Equipment: Equip cleanup crew with proper protection.
Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.
6.2. Environmental Precautions
Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.
6.3. Methods and Material for Containment and Cleaning Up
For Containment: Contain and collect as any solid.
Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Contact competent authorities after a spill.
6.4. Reference to Other Sections
See Heading 8. Exposure controls and personal protection. For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling
Additional Hazards When Processed: Avoid breaking or crushing capsules.
Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.
7.2. Conditions for Safe Storage, Including Any Incompatibilities
Technical Measures: Comply with applicable regulations.
Storage Conditions: Store at 20° to 25 °C (68° to 77 °F); excursions permitted between 15° and 30 °C (59° and 86 °F) [see USP Controlled Room Temperature]. Protect from light. Tight containers.
Incompatible Materials: strong acids, strong bases and strong oxidants.
7.3. Specific End Use(s)
Pharmaceutical research, manufacturing and clinical use. For professional use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters
For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

<table>
<thead>
<tr>
<th>Iron oxide (Fe2O3) (1309-37-1)</th>
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</thead>
<tbody>
<tr>
<td><strong>USA ACGIH</strong></td>
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<tr>
<td><strong>USA ACGIH</strong></td>
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<tr>
<td><strong>USA NIOSH</strong></td>
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<td><strong>USA IDLH</strong></td>
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<td><strong>USA OSHA</strong></td>
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<table>
<thead>
<tr>
<th>Titanium dioxide (13463-67-7)</th>
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<tbody>
<tr>
<td><strong>USA ACGIH</strong></td>
</tr>
<tr>
<td><strong>USA ACGIH</strong></td>
</tr>
<tr>
<td><strong>USA NIOSH</strong></td>
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XOSPATA® Tablets 40 mg
Safety Data Sheet
According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

<table>
<thead>
<tr>
<th>Material</th>
<th>USA IDLH</th>
<th>USA OSHA</th>
<th>Talc (Mg3H2(SiO3)4) (14807-96-6)</th>
<th>USA ACGIH</th>
<th>USA NIOSH</th>
<th>USA IDLH (mg/m³)</th>
<th>USA ACGIH</th>
<th>USA IDLH (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>US IDLH (mg/m³)</td>
<td>OSHA PEL (TWA) (mg/m³)</td>
<td>0.3 mg/m³ (CIB 63-ultrafine, including engineered nanoscale)</td>
<td>2 mg/m³ (particulate matter containing no asbestos and &lt;1% crystalline silica, respirable particulate matter)</td>
<td>Not Classifiable as a Human Carcinogen containing no asbestos fibers</td>
<td>15 mg/m³ (total dust)</td>
<td>1000 mg/m³ (containing no asbestos and &lt;1% quartz)</td>
<td></td>
</tr>
</tbody>
</table>

8.2. Exposure Controls

Appropriate Engineering Controls: Ensure adequate ventilation, especially in confined areas. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.

Personal Protective Equipment: Not generally required. The use of personal protective equipment may be necessary as conditions warrant.

Materials for Protective Clothing: Chemically resistant materials and fabrics.
Hand Protection: Wear chemically resistant protective gloves.
Eye Protection: Chemical goggles or safety glasses.
Skin and Body Protection: Wear suitable protective clothing.
Respiratory Protection: None required under normal product handling conditions. Use NIOSH-approved dust mask if dust has the potential to become airborne.

Environmental Exposure Controls: Do not allow the product to be released into the environment.
Consumer Exposure Controls: Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State: Solid
Appearance: Light yellow tablet
Odor: No data available
Odor Threshold: No data available
pH: No data available
Evaporation Rate: No data available
Melting Point: No data available
Freezing Point: No data available
Boiling Point: No data available
Flash Point: No data available
Auto-ignition Temperature: No data available
 Decomposition Temperature: No data available
Flammability (solid, gas): No data available
Vapor Pressure: No data available
Relative Vapor Density at 20 °C: No data available
Relative Density: No data available
Solubility: No data available
Partition Coefficient: N-Octanol/Water: No data available
Viscosity: No data available
Molecular Weight Of Active Ingredient: Proprietary
9.2. Other Information
No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.


10.5. Incompatible Materials: strong acids, strong bases and strong oxidants.


SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Oral: Harmful if swallowed.

<table>
<thead>
<tr>
<th>XOSPATA® Tablets 40 mg</th>
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</thead>
<tbody>
<tr>
<td>ATE (Oral)</td>
<td>1,000.00 mg/kg body weight</td>
</tr>
<tr>
<td>ASP2215</td>
<td></td>
</tr>
<tr>
<td>Lethal Oral Dose in Rats</td>
<td>300 mg/kg</td>
</tr>
<tr>
<td>Polyethylene glycol (25322-68-3)</td>
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</tr>
<tr>
<td>LD50 Oral Rat</td>
<td>22 g/kg</td>
</tr>
<tr>
<td>Iron oxide (Fe2O3) (1309-37-1)</td>
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</tr>
<tr>
<td>LD50 Oral Rat</td>
<td>&gt; 10000 mg/kg</td>
</tr>
<tr>
<td>Titanium dioxide (13463-67-7)</td>
<td></td>
</tr>
<tr>
<td>LD50 Oral Rat</td>
<td>&gt; 10000 mg/kg</td>
</tr>
<tr>
<td>Cellulose hydroxypropyl methyl ether (9004-65-3)</td>
<td></td>
</tr>
<tr>
<td>LD50 Oral Rat</td>
<td>“= 4000 mg/kg</td>
</tr>
<tr>
<td>D-Mannitol (69-65-8)</td>
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</tr>
<tr>
<td>LD50 Oral Rat</td>
<td>13500 mg/kg</td>
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<tr>
<td>Magnesium stearate (557-04-0)</td>
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</tr>
<tr>
<td>LD50 Oral Rat</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Hydroxypropyl ether of cellulose (9004-64-2)</td>
<td></td>
</tr>
<tr>
<td>LD50 Oral Rat</td>
<td>10200 mg/kg</td>
</tr>
</tbody>
</table>

Skin Corrosion/Irritation: Not classified

ASP2215
Additional information
No local irritation studies have been conducted.
Negative in in vitro 3T3 NRU phototoxicity assay

Serious Eye Damage/Irritation: Not classified
Respiratory or Skin Sensitization: Not classified
Germ Cell Mutagenicity: Suspected of causing genetic defects.

ASP2215
Additional information
Bacterial reverse mutation assay: Negative
In vitro chromosomal aberration assay: Negative
In vivo mouse micronucleus study: Positive

Carcinogenicity: Not classified

Iron oxide (Fe2O3) (1309-37-1)
IARC group 3

Titanium dioxide (13463-67-7)
IARC group 2B

OSHA Hazard Communication Carcinogen List
In OSHA Hazard Communication Carcinogen list.

Talc (14807-96-6)
IARC group 3

National Toxicology Program (NTP) Status
Evidence of Carcinogenicity.

Reproductive Toxicity: Suspected of damaging fertility or the unborn child.
ASP2215

Additional information

In a rat embryo-fetal development study, decreased body weight and food consumption in dams, teratogenicity and embryo-fetal deaths were observed at 30 mg/kg/day. The NOAEL was 10 mg/kg/day for dams and embryo-fetal development.

Specific Target Organ Toxicity (Single Exposure): Not classified
Specific Target Organ Toxicity (Repeated Exposure): Causes damage to organs through prolonged or repeated exposure.

ASP2215

Additional information

In a rat 13-week repeated dose toxicity study, mortality was noted at 20 mg/kg/day. At 2.5 mg/kg/day and higher, target organ toxicities and secondary changes included; the eye, gastrointestinal tract, liver, kidney, lung, bone marrow, spleen, pancreas, various lymphoid tissue, and adrenal. After a 4-week recovery period, reversibility was shown.

In a dog 4-week repeated dose toxicity study, the NOAEL was 1 mg/kg/day. The lethal dose level was 10 mg/kg/day. At 2.5 mg/kg/day and higher, target organ toxicities and secondary changes included; the eye, gastrointestinal tract, liver, gallbladder, kidney, lung, bone marrow, lymphoid tissue, pancreas, adrenal, testis, epididymis, and oral mucosa. After a 4-week recovery period, reversibility was shown.

In a dog 13-week repeated dose toxicity study, the NOAEL was 1 mg/kg/day. The lethal dose level was 5 mg/kg/day. At 2.5 mg/kg/day or more, target organ toxicities and secondary changes were observed in the eye, gastrointestinal tract, liver, gallbladder, kidney, lung, broncus, bone marrow, various lymphoid tissue, pancreas, epithelial tissues including oral mucosa, urinary bladder, lacrimal gland, together with changes in organ weight and/or clinical pathology in some cases. After a 4-week recovery period, reversibility was shown.

Aspiration Hazard: Not classified
Symptoms/Injuries After Inhalation: If tablet is crushed: May cause respiratory irritation.
Symptoms/Injuries After Skin Contact: If tablet is crushed: May cause skin irritation.
Symptoms/Injuries After Eye Contact: If tablet is crushed: May cause eye irritation.
Symptoms/Injuries After Ingestion: Harmful if swallowed.
Chronic Symptoms: Suspected of damaging the unborn child. Causes damage to organs through prolonged or repeated exposure. Suspected of causing genetic defects.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Talc (14807-96-6)
LC50 Fish 1 > 100 g/l (Exposure time: 96 h - Species: Brachydanio rerio [semi-static])

12.2. Persistence and Degradability
No additional information available.

12.3. Bioaccumulative Potential

Talc (14807-96-6)
BCF fish 1 (no known bioaccumulation)

12.4. Mobility in Soil
No additional information available.

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents and container according to local, regional, national, and international regulations.

Ecology – Waste Materials: This material is hazardous to the aquatic environment. Keep out of sewers and waterways. Avoid release to the environment.
SECTION 14: TRANSPORT INFORMATION
14.1. In Accordance with DOT Not regulated for transport.
14.2. In Accordance with IMDG Not regulated for transport.
14.3. In Accordance with IATA Not regulated for transport.

SECTION 15: REGULATORY INFORMATION
15.1 US Federal Regulations Not applicable
15.2 US State Regulations Not applicable

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION
Date of Preparation or Latest Revision : 11/29/2018
Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

Astellas US GHS SDS