## Chemical Safety Practices Recommendations

**Nintedanib (OFEV, BIBF 1120)**

### Exposure Hazards

<table>
<thead>
<tr>
<th>Category 2 Warning</th>
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</tr>
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<tbody>
<tr>
<td>Toxic to Reproduction</td>
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</tr>
<tr>
<td>Suspected of Damaging Fertility or the Unborn Child</td>
<td>May Cause Damage to Hepatic, Circulatory, and Digestive Systems through Prolonged or Repeated Exposure</td>
</tr>
</tbody>
</table>

### Response to Exposure

<table>
<thead>
<tr>
<th>Oral</th>
<th>Dermal</th>
<th>Inhalation</th>
<th>Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rinse mouth; do not induce vomiting. Report to OHS.</td>
<td>Wash skin with soap and water for 15 minutes. Rinse eyes for 15 minutes. Report to OHS.</td>
<td>Leave area; go to clean air. Report to OHS.</td>
<td>Report to OHS.</td>
</tr>
</tbody>
</table>

### Special Precautions

Pregnant women should be extra cautious when working with or around Nintedanib. Discard garments as hazardous if contaminated with Nintedanib.

### Personal Protective Equipment

- Gloves (double) (Latex or Nitrile)
- Skin Protection (Suit or Scrubs or Lab Coat)
- Eye Protection (Safety-glasses or Goggles)
- Closed-toe shoes
- Use N100 respirator if engineering controls are not available.

### Engineering Controls

- Nintedanib powder- Chemical Fume Hood (CFH) (4)
- Nintedanib solution- CFH or Biosafety Cabinet (Class II, B2 BSC if aerosolized)
- Animal waste and bedding until one day after last treatment- CFH or Class II, B2 BSC

### Animal Handling

Avoid exposure to animal waste/tissue until one day after last treatment. (5, 6)

### Bedding Disposal

Dispose of bedding as hazardous material until one day after last treatment.

### Work Practices

Empty Nintedanib containers and unused Nintedanib must be disposed of as hazardous. Follow [LASP SOP 4.003F](#) for preparation, handling, dosing, and disposal of Nintedanib.

### References:


Questions or concerns: Please contact EHS, Ted Witte, [theodore.witte@nih.gov](mailto:theodore.witte@nih.gov) or 301-846-5860

Reviewed 4/23/2015 These recommendations are not final and may be updated.
Nintedanib is a Tyrosine Kinase Inhibitor used to prevent angiogenesis and tumor growth through the inhibition of the receptors VEGFR 1/2/3, FGFR 1/2/3, and PDGFR α/β. Only recently approved by the FDA for the treatment of Idiopathic Pulmonary Fibrosis in late 2014, it is not listed in “NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2014” but should be presumed to be a reproductive hazard, a conclusion shared by the FDA in its summary review. It is similar in nature and function to other TKIs such as Regorafenib, Dasatinib, Sorafenib, et ceterae. Therefore the toxicity is largely specific to rapidly developing tissues such as the developing fetus.

Nintedanib is very rapidly metabolized to an inactive metabolite by methyl esterase activity in both humans and mice, with the bulk of excretion of active drug occuring in the feces. Plasma drug levels in mice approach zero within 16-20 hours.

Questions or concerns: Please contact EHS, Ted Witte, theodore.witte@nih.gov or 301-846-5860
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