Identification of the Substance/Preparation and of the Company/Undertaking

1.1 Product Type: Articulating Papers impregnated 200 micron

1.2 Trade Name: Bausch Articulating Papers with progressive color transfer

1.2.1 Ref-No.: BK 01, BK 1001, BK 03, BK 05, BK 02, BK 04, BK 1002, BK 101, BK 102

1.3 Company: Dr. Jean Bausch GmbH & Co.KG
Oskar-Schindler-Straße 4  E-Mail: info@bauschdental.de
D-50769 Köln – Germany  Transportation: +49-221-70936-0
Phone: +49-221-70936-0  Emergencies: +49-172-2601451
Fax: +49-221-70969-66

Hazard Identification

The product contains no hazard ingredient. No unusual hazards expected from normal use.

Composition/Information on Ingredients

Paper-like nonwoven impregnated with oil, pigment, wax mixture

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>Concentration, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pigment blue C.I.27</td>
<td>25869-00-5</td>
<td>10 %</td>
</tr>
<tr>
<td>CI Pigment red 170</td>
<td>2786-76-7</td>
<td>10 %</td>
</tr>
<tr>
<td>white mineral oil</td>
<td>pharmaceutical quality</td>
<td>50 %</td>
</tr>
<tr>
<td>natural waxes</td>
<td>cosmetic/pharmaceutical quality</td>
<td>30 %</td>
</tr>
</tbody>
</table>

First-Aid Measures

Skin Contact: Skin discoloration may occur, wash off with soap and water.
Ingestion – not known, but if ingested – seek medical attention.
Manufactured materials listed as non-toxic.
Eye contact: Remove contact lenses. Begin flushing them immediately with cool water and continue to do so for approximately 15 minutes. Seek immediate medical attention.

Fire-Fighting Measures

Flash Point: 300°F and above
Extinguishing Media: Water, water fog, foam, CO2, dry chemicals
Special Fire Fighting Procedures: No special procedures
Fire & Explosion Hazard: No unusual hazards.

Accidental Release Measures

Clean up excess material & place in container for disposal, treat as office waste.

Handling and Storage

Store in cool dry areas avoid sparks, flame and excessive heat

Exposure Controls/Personal Protection

General room ventilation plus local exhaust at points of emission to reduce exposure to vapors during processing. No personal protective equipment required for normal use.
9 Physical and Chemical Properties
   Paper, no distinct odor

10 Stability and Reactivity
   • Chemical Stability: Stable
   • Hazardous Polymerization: Will not occur
   • Reacts with: None Known

11 Toxicological Information
   No data available

12 Ecological Data
   No data available

13 Disposal Considerations
   Dispose of all waste material in accordance with all applicable federal, state and local regulations

14 Transport Information
   DOT Information: No regulated

15 Regulatory Information
   • International: Canada: All components are either listed on or exempt from Canadian (DSL).
   • Federal (USA): All components are either listed on or exempt from TSCA.
   • Sec. 872.6140 Articulation paper.
     (a) Identification. Articulation paper is a device composed of paper coated with an ink dye intended to be described.
     placed between the patient's upper and lower teeth when the teeth are in the bite position to locate uneven or high areas.

     (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of 820.180, with respect to general requirements concerning records, and 820.198, with respect to complaint files.


16 Other Information
   No data available

Prepared By: Peter Bausch
Translated By: Peter Bausch
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