

Prepared for: General Distribution

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## CONFIRMATION STATEMENTS FOR DATWYLER COMPOUND FM457

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### **Dry natural rubber, natural rubber latex and any of its derivatives:**

Compound FM457 is not made with dry natural rubber, natural rubber latex or any of its derivatives.

### **Nitrosamines:**

The recipe of compound FM457 does not contain rubber chemicals that are associated with the formation of one of the eight most volatile hazardous N-Nitrosamines (cfr. ASTM F1313-90, dd. 2005).

### **MCBT:**

Compound FM457 does not contain 2-mercaptobenzothiazole (MCBT, also named MBT), or any of its derivatives.

### **BSE/TSE:**

For the raw materials of rubber compound FM457, Datwyler has obtained a BSE/TSE certification from its suppliers confirming that such products are either of vegetable origin or are manufactured in severe process conditions for inactivation of prions as described in the EMA/410/01-rev.3 (Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products) (2011/C 73/01) and in the European Pharmacopoeia 5.2.8. "Minimizing the risk of transmitting Animal Spongiform Encephalopathy Agents."

For all above statements, this does not exclude the presence of negligible traces due to unknown impurities in the components supplied by external parties.

The absence has not been checked by tests.

### **Heavy Metals:**

Compound FM457 fulfils the European Community Guideline 94/62/EC for heavy metals in packaging materials and the CONEG regulation on reduction of toxics in Packaging Law.

Both directives state that packaging components should not contain more than 100 ppm of Lead (Pb), Cadmium (Cd), Mercury (Hg) and Hexavalent Chromium (VI) (Cr).

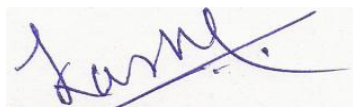
Compliance has been documented by experiment.

Where the regulated metals are present at levels below the values stated above, they were not intentionally added during the manufacturing process.

All above confirmations apply to the rubber products as it leaves its manufacturing facilities and do not cover any further treatment thereafter.

This confirmation statement replaces all previous ones related to this matter.

Datwyler,



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