April 12, 2019

Re: Tychem® NP530 Inquiry on Food Contact Regulations

To Whom It May Concern;

Below are statements concerning Tychem® NP530.

1. FDA Food Contact Regulation (21 CFR 177.2600)

DuPont Tychem® NP530 as sold by DuPont meets the Federal Food, Drug and Cosmetic Act (FDA) requirements of Title 21 of the United States Code of Regulations for rubber articles intended for repeated use (21 CFR 177.2600).

2. **European Food Contact Regulation**

The DuPont Tychem® NP530 as sold by DuPont is in conformity with the following national references and Council of Europe Resolutions:

1) Italian Ministerial Decree of 21 March 1973, (Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale. G.U. n. 104 del 20 aprile 1973 as amended.)
2) Netherlands regulatory requirements, Chapter III of the Dutch packaging and food utensils regulations (RVG) for rubber products in contact with food (Staatscourant No. 8531 of the 27/03/2014)
3) Spanish Royal Decree 847/2011
4) Council of Europe Resolution AP (2004)4 on rubber products intended to come into contact with foodstuffs.

The DuPont Tychem® NP530 sold by DuPont meets the requirements of the specific migration limits (SML) based on calculation. In addition, the overall migration tests were carried out according to the rules for migration testing by Regulation (EU) N° 10/2011 and the rules of the series of standards EN 1186. DuPont Tychem® NP530 sold by DuPont has shown that the limits are met with acetic acid 3% (w/v), ethanol 10% (v/v) and ethanol 50% (v/v) simulants at the test conditions of 2 hours at 70 °C by third extraction, while ethanol 95% (v/v) simulants at the test conditions of 2 hours at 60 °C by third extraction slightly exceeds the limit allowing to apply a reduction factor of 2 or more.

The DuPont Tychem® NP530 sold by DuPont is produced according to the quality management systems which meet the requirements of the Good Manufacturing Practices of Commission Regulation (EC) N° 2023/2006.

Based on the above information, the product meets the requirements of the Regulation (EC) N° 1935/2004 on Materials and articles intended to come into contact with food and can be used in the countries of the European Community for repeated food contact use with all types of food including fatty food with a fatty food reduction factor of 2 or more, up to 2 hours of contact time and 60°C, with the exception of fatty food for which no fatty food reduction factor applies.

The information and certifications provided herein are based on data we believe to be reliable, to the best of our knowledge. The information and certifications apply only to the specific material designated herein as sold by DuPont and do not apply to use in any process or in combination with any other material. They are provided at the request of and without charge to our customers. Accordingly, DuPont cannot guarantee or warrant such certifications or information and assumes no liability for their use.

Please contact me if you have questions.

Sincerely,

Hannah Suh

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