

Certificate of Compliance

for

BALINIT® DLC
BALINIT® TRITON
(Diamond-like Carbon and Chromium)

Products of

Oerlikon Surface Solutions AG
9496 Balzers / Liechtenstein

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Issued by

Envigo
Regulatory Consulting
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CERTIFICATE

of compliance with the
Inventory of Effective Food Contact Substance Notifications acc. to 21 USC §348 Sec. 409
and
Article 3 of Regulation (EC) No 1935/2004
for

BALINIT[®] DLC / BALINIT[®] TRITON
(Diamond-like Carbon and Chromium)

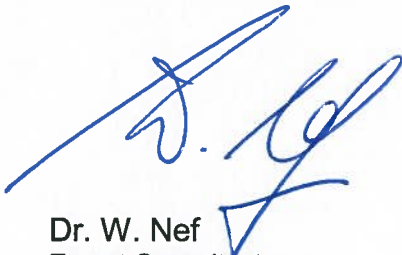
as a surface coating for repeat-use food processing and food packaging equipment.

The detailed composition of BALINIT[®] DLC / BALINIT[®] TRITON was disclosed by **Oerlikon Surface Solutions AG, 9496 Balzers / Liechtenstein** on September 9th, 2015 and was evaluated by **Envigo, Regulatory Consulting, CH-4452 Itingen / Switzerland** for compliance with the Inventory of Effective Food Contact Substance Notifications according to 21 USC §348 Section 409 and with Article 3 of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food (European Framework Regulation). BALINIT[®] DLC / BALINIT[®] TRITON has been cleared by FDA with Food Contact Substance Notification No 301 and may therefore come in contact with food in the United States of America, provided that the limitations as mentioned below are met. Based on the information provided with above mentioned Food Contact Substance Notification we conclude that BALINIT[®] DLC / BALINIT[®] TRITON meets the safety requirement according to Article 3 of Regulation (EC) No 1935/2004 and may therefore be used in Europe in contact with food, provided that the limitations as mentioned below are met.

Limitations

The maximum thickness of the diamond-like layer shall not exceed 2 micrometers and the maximum thickness of the chromium interface layer shall not exceed 1 micrometer. The surface coating may be used in contact with all types of food under Conditions of Use A through H as described in Table 2, see <http://www.accessdata.fda.gov/scripts/cdrh/Cfdocs/cfCFR/CFRSearch.cfm?fr=176.170>

This certificate is based on the information provided to Envigo Regulatory Consulting and on the present legislation as mentioned above. The validity expires in case of any modification of the formulation or any change of the legislation.



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Itingen, October 10th, 2015
Expiration date: October 9th, 2018
Envigo Project E02741 NEW