

Declaration of Compliance for metallic food contact material

Purpose of DoC

This DoC is issued for SuperExpanite processes intended in surface hardening of AISI316 material with a target of 20µm case depth (+/-3µm) and based on conformity report hereby attached demonstrates regulatory compliance with 1935/2004/EC and commission regulation 2023/2006 of the European Parliament and of the council.

1935/2004/EC: General principle

The principle underlying this Regulation is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.

1935/2004/EC: Article 3

Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could: (a) endanger human health; or (b) bring about an unacceptable change in the composition of the food; or (c) bring about a deterioration in the organoleptic characteristics thereof.

2023/2006: Article 6

The business operator shall establish and maintain an effective quality control system. 2. The quality control system shall include monitoring of the implementation and achievement of GMP and identify measures to correct any failure to achieve GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections

Restrictions:

This document is only valid in the situation where the part or parts supplied to Expanite for hardening is of the grades AISI316/AISI316L/ AISI316LN. The responsibility of ensuring correct alloy falls entirely on the supplier of parts to Expanite.

Documentation 1:

For 1935/2004/EC:

Summary of test 1: Teknologisk institut, Feb 2014 (attached):

No limits for the total migration of substances have been defined for metals in the EU legislation. The limit for total migration of substances for plastic materials is set to 10 mg/dm² {EC/10/2011}.

Summary of test 2: FCM Testing Aps (attached):

Test of AISI 316 steel product for repeated food contact.

Test will be carried out in accordance with Council of Europe Resolution CM/Res(2013)9 repeat test in 0,5% citric acid, for 2 hours at 70 degrees C, which documents compliance with contact with all types of food, under all contact conditions that includes heating up to 70°C for up to 2 hours or up to 100°C for up to 15 minutes, which is not followed by prolonged storage at room temperature or in a refrigerated state.

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Based on the total migration measured, stainless steel/ 316 treated with SuperExpanite® is found acceptable as food contact material under circumstances similar to or less extreme than the conditions under which the present test was conducted.

For 2023/2006:

See attached /509001/2015 certificate, demonstrating documented and controlled production process.

On behalf of Expanite A/S, Expanite GmbH & Expanite Inc.


Signature

23-1-2024
Date



Test report.

Report template no. 009

No.: 2023-1275

Date: 2023.11.26

Customer: EXPANITE A/S
Address: Industrivænget 34
3400 Hillerød

Product Name: Aisi 316 steel
Batch number: 43554.
Sampled by: Customer
Sample Receiving date: 2023.10.24
Testing Period: 2023.10.25 – 2023.11.17

Test of AISI 316 steel product for repeated food contact.

Tests will be carried out in accordance with Council of Europe Resolution CM/Res(2013)9 repeat test in 0.5% citric acid, for 2 hours at 70 degrees C, which documents compliance with contact with all types of food, under all contact conditions that includes heating up to 70 °C for up to 2 hours or up to 100 °C for up to 15 minutes, which is not followed by prolonged storage at room temperature or in a refrigerated state.

Test summary:**Type of analysis**

Specific migration of metals in steel

Conclusion

Pass

Regulation or protocol

Resolution CM / Res (2013) 9

Test results: See next page.

FCM•testing



Per Holst-Hansen
MSc/CEO

The analysis report may only be reproduced in extracts if FCM • testing has approved the extract in writing.
The results apply only to the analyzed samples.

FCM•testing ApS

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Test report.

No.: 2023-1275

Date: 2023.11.26

Report template no. 009

1: Migration performed according to resolution CM / Res (2013) 9, 11 June 2013[#]

Simulant	Test time	Test temperature
0,5% citric acid	2 hours ± 5 minute	70°C ± 2°C

Test results: repeat test

Test	Result Sum 1.+ 2. migration mg/kg	Limit Sum 1.+ 2. migration mg/kg*	Result 3.migration mg/kg	Limit 3.migration mg/kg*	Method RSD	Metod DL mg/l	Pass/Fail**
Silver (Ag)	N.D.	0,56	N.D.	0,08	10%	0,01	Pass
Aluminium (Al)	N.D.	35	N.D.	5	10%	0,01	Pass
Chromium (Cr)	0,11	1,75	N.D.	0,25	10%	0,01	Pass
Cobalt (Co)	0,02	0,14	0,003	0,02	10%	0,01	Pass
Copper (Cu)	N.D.	28	N.D.	4	10%	0,01	Pass
Iron (Fe)	4,6	280	N.D.	40	25%	0,01	Pass
Manganese (Mn)	N.D.	12,6	N.D.	1,8	10%	0,01	Pass
Molybdenum (Mo)	0,04	0,84	0,05	0,12	20%	0,01	Pass
Nickel (Ni)	0,58	0,98	0,095	0,14	10%	0,01	Pass
Tin (Sn)	N.D.	700	N.D.	100	10%	0,01	Pass
Vanadium (V)	N.D.	0,07	N.D.	0,01	10%	0,01	Pass
Zink (Zn)	N.D.	35	N.D.	5	10%	0,01	Pass
Antimony (Sb)	N.D.	0,28	N.D.	0,04	10%	0,01	Pass
Arsenic (As)	N.D.	0,014	N.D.	0,002	10%	0,001	Pass
Barium (Ba)	N.D.	8,4	N.D.	1,2	10%	0,01	Pass
Beryllium (Be)	N.D.	0,07	N.D.	0,01	10%	0,01	Pass
Cadmium (Cd)	N.D.	0,035	N.D.	0,005	10%	0,001	Pass
Lead (Pb)	N.D.	0,07	N.D.	0,01	10%	0,001	Pass
Lithium (Li)	N.D.	0,336	N.D.	0,048	10%	0,01	Pass
Mercury (Hg)	N.D.	0,021	N.D.	0,003	17%	0,001	Pass
Thallium (Tl)	N.D.	0,0007	N.D.	0,0001	10%	0,0001	Pass

* Limit values from Council of Europe Resolution CM / Res (2013) 9

** Compliance is in relation to Council of Europe Resolution CM / Res (2013) 9

The test is performed by accredited subcontractor SGS ISO 17025 test reg nr. 401, The test is not covered by the accreditation.

The analysis report may only be reproduced in extracts if FCM • testing has approved the extract in writing.
The results apply only to the analyzed samples.

FCM•testing ApS

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E-mail: Info@fcmtesting.com; Website: www.fcmtesting.com

Test report.

No.: 2023-1275

Date: 2023.11.26

Report template no. 009



Photo test item

*** End of Report***

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Stainless steel treated with SuperExpanite® as food contact material

Aim

To evaluate the migration properties of stainless steel (AISI 316) treated with SuperExpanite® (Expanite A/S, Industrivænget 34, 3400 Hillerød, Denmark) as food contact material.

Method

The worst-case use is assumed to be acidic food types at the exposure conditions 70 °C for 2 h. These test conditions may also represent uses where short periods of heating up to 100 °C occurs.

Total migration was measured by gravimetric methods using the food simulant 3 % acetic acid. Three consecutive extractions were performed and the 3rd extraction was analysed to represent application of the material for repeated use.

Three samples were analysed to account for variations.

Results

Table 1. Total migration measured by gravimetric analyses in 3 % acetic acid for 2 h in triplicate. Analyses were carried out on the third extraction.

Sample	A	B	C	Mean
Unit	mg/dm ²	mg/dm ²	mg/dm ²	mg/dm ²
Result	2.1	3.2	1.8	2.4

Data from Report No. 37885, DTI, Chemistry & Microbiology, Feb. 2014.

No limits for the total migration of substances have been defined for metals in the EU legislation. The limit for total migration of substances for plastic materials is set to 10 mg/dm² (EC/10/2011).

Based on the total migration measured, stainless steel 316 treated with SuperExpanite® is found acceptable as food contact material under circumstances similar to or less extreme than the conditions under which the present test was conducted.

February 2014
Cand scient Niels Elmegaard
Chief Consultant
Danish Technological Institute
Chemistry & Biotechnology

CERTIFICATE

Management system as per
BS EN ISO 14001:2015

In accordance with TÜV UK Ltd procedures, it is hereby certified that

Expanite A/S
Industrivænget 34
3400 Hillerød
Denmark



and as listed on the annex to this certificate

applies a management system in line with the above standard for the following scope:

Surface hardening and heat treatment of stainless steel and titanium. Design and development of surface hardening and heat treatment solutions.

Certificate No: GB01987
Annex No: GB01987/A
Audit Report No: 2023/31954



Valid until: 27/06/2025
Initial Certification: 28/06/2022
Effective Date: 27/04/2023



Signed for and on behalf of TÜV UK Ltd, the Certification Body

This certificate, which remains the property of TÜV UK Ltd, was issued in accordance with the TÜV UK Ltd auditing and certification procedures as amended from time to time and its validity is subject to regular surveillance audits

CERTIFICATE

Management system as per
BS EN ISO 14001:2015

In accordance with TÜV UK Ltd procedures, it is hereby certified that

Expanite GmbH
Benzstraße 2
72636 Frickenhausen
Germany



and as listed on the annex to this certificate

applies a management system in line with the above standard for the following scope:

Surface hardening and heat treatment of stainless steel and titanium. Design and development of surface hardening and heat treatment solutions.

The validity of this certificate and annex referred to depend on the validity of main certificate No.:GB01987

Certificate No: GB01987/01
Annex No: GB01987/A
Audit Report No: 2023/31954



Valid until: 27/06/2025
Initial Certification: 28/06/2025
Effective Date: 27/04/2023



Signed for and on behalf of TÜV UK Ltd, the Certification Body

This certificate, which remains the property of TÜV UK Ltd, was issued in accordance with the TÜV UK Ltd auditing and certification procedures as amended from time to time and its validity is subject to regular surveillance audits

CERTIFICATE

Management system as per
BS EN ISO 9001:2015

In accordance with TÜV UK Ltd procedures, it is hereby certified that

Expanite Inc.
8250 Boyle Parkway
Twinsburg, OH 44087-2200
USA



and as listed on the annex to this certificate

applies a management system in line with the above standard for the following scope:

Surface hardening and heat treatment of stainless steel and titanium. Design and development of surface hardening and heat treatment solutions.

The validity of this certificate and annex referred to depend on the validity of main certificate No.:GB01965

Certificate No: GB01965/02
Annex No: GB01965/A
Audit Report No: 2023/31954



Valid until: 13/03/2026
Initial Certification: 14/03/2020
Effective Date: 27/04/2023



Signed for and on behalf of TÜV UK Ltd, the Certification Body

This certificate, which remains the property of TÜV UK Ltd, was issued in accordance with the TÜV UK Ltd auditing and certification procedures as amended from time to time and its validity is subject to regular surveillance audits