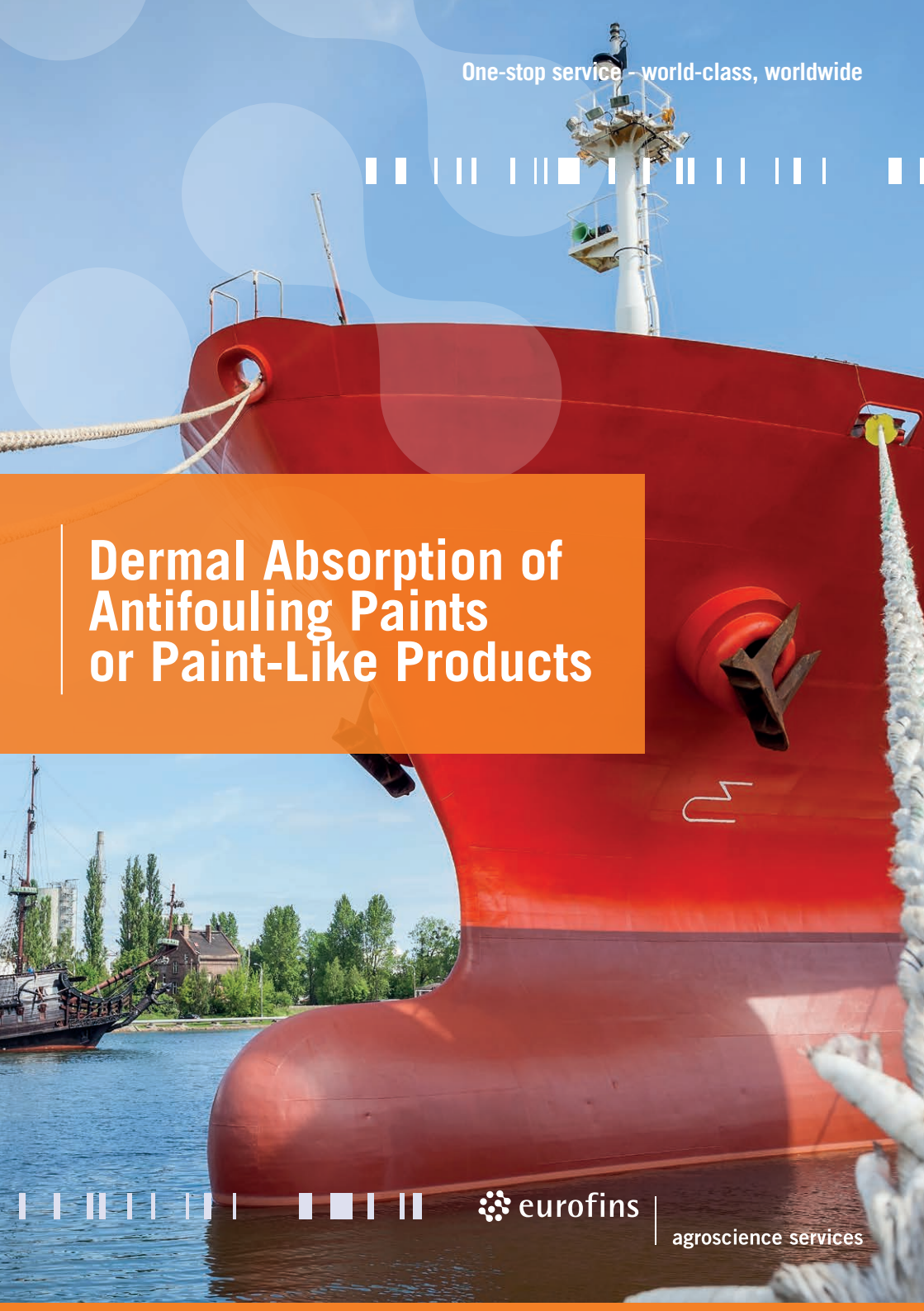

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Dermal Absorption of Antifouling Paints or Paint-Like Products

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Introduction to Anti Fouling

Eurofins Agroscience Services have conducted dermal absorption studies on plant protection products for over 15 years, following the requirements of EFSA Journal 2017 (1) and OECD Guidances No. 428 (2), N° 28 (3), N°156 (4).

Antifouling products are biocidal PT21 products applied to the hull of a boat to slow the growth of subaquatic organisms attaching to the hull. They are designed to harden on the surface of the vessel and remain for years in contact with water.

ECHA organized Workshops (5) (6) (7) to identify practical ways forward in performing and interpreting dermal absorption studies on antifouling products. The dermal absorption of an antifouling paint containing molecule X and copper was investigated.

Material and method

Eight human skin samples from four different donors were used for each active ingredient. No washing step was performed at the end of the exposure period, this was considered unnecessary because the paint would not be removed by washing.

24 hours after application, the cells were dismantled for analysis and tape stripping was performed.

A photo was taken at each tape strip in order to help in evaluating the amount of paint remaining in each tape strip and concluding on the number of tape strips that should be excluded from the absorbed part.

The paint was formulated by incorporation of 14C-X and analysed by liquid scintillation counting. Copper from the paint was directly analysed by ICP/MS.

Results and discussion

For both active ingredients, a mean recovery of 100% was obtained. After liquid scintillation counting analysis, the final total absorption was 1.05% of the applied dose for molecule X and after ICP/MS analysis, 0.995 % was obtained for copper, comparable to published data (i.e. 2% of dermal absorption was supported for molecule X and 0.08% to 0.41% for copper).

According to the ECHA Reports [5] [6], participants agreed that the material in the paint layer should be considered as non-absorbed, while recognising that there is currently no method to separate the paint layer and the stratum corneum. For several antifouling substances, the first five tape strips were excluded.

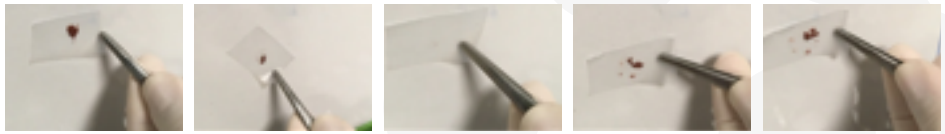
Based on the photos of tape strips, we could observe that almost all the paint was removed by the very first two strips. For some cells, some splinters were also observed in the three following tape strips. However, in a conservative approach, it was decided to exclude only the two first strips from the absorbed part, as recommended [1].

Example of photos taken from tape strips

1 - Almost all the paint was removed by the first two strips

Strip 1	Strip 2	Strip 3	Strip 4	Strip 5
97% of the applied dose	2% of the applied dose	0.08% of the applied dose	0.04% of the applied dose	0.05% of the applied dose

2 - The paint was removed by up to five strips



Strip 1	Strip 2	Strip 3	Strip 4	Strip 5
39% of the applied dose	14% of the applied dose	0.03% of the applied dose	29% of the applied dose	28% of the applied dose

References:

(1) Guidance on Dermal Absorption, EFSA Journal 2017; 15(6): 4873

(2) OECD guideline for the testing of chemicals: Test No. 428: Skin Absorption: in vitro method (13 April 2004)

(3) OECD guidance document for the conduct of skin absorption studies, OECD series on testing and assessment. Number 28, 05-Mar-2004 (ENV/JM/MONO(2004)2)

(4) OECD guidance notes on dermal absorption, OECD series on testing and assessment n°156, 18-Aug-2011 (ENV/JM/MONO(2011)36)

(5) ECHA Report of workshop on Dermal absorption from antifouling products and other matrices that form a dry fil during testing; 19 August 2016; 1(22)

(6) ECHA Report of workshop on Dermal absorption of PT 21 active substances; 9 December 2016; 1(9)

(7) https://circabc.europa.eu/w/browse/c2575378-3b9b-4f4c-85ca-c5311022347c

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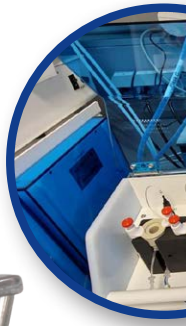

Eurofins Agroscience Services Group

easinfo@eurofins.com
www.eurofins.com/agroscienceservices