INDUSTRIAL BIOTECHNOLOGY RESEARCH CENTRE
Building 19, SIRIM Complex
1, Persiaran Dato' Menteri, Section 2, P. O. Box 7035
40700 Shah Alam, Selangor Darul Ehsan, MALAYSIA
Tel: 603 - 5544 6953 / 6960 Fax: 603 - 5544 6988
Website: www.sirim.my

TEST REPORT

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Job No.	:	J0826/21
Applicant	:	SIRIM QAS International Sdn. Bhd. Chemical and Consumer Section, Building 16, SIRIM Berhad.
Manufacturer / Company	:	SIKA Services AG
Sample/Trade Name	:	Sikaflex®PRO-3 Purform
Reference Standard / Method of Test	:	1. BS 6920-1:2014. Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on the quality of the water.- Part 1: Specification (LWI-238-01) 2. BS 6920-2.1:2014. Suitability of non-metallic materials and products for use in contact with water intended for human consumption with regard to their effect on the quality of the water - Part 2: Methods of test - Section 2.1: Samples for testing. (LWI-238-01) 3. BS 6920-2.5:2000+A2:2014. Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on the quality of the water - Part 2: Methods of test - Section 2.5: The extraction of substances that may be of concern to public health (LWI-238-01)
Description of Sample	:	Received one sample consisting of four sample pieces in good condition for testing with the following identification: 1. Model/Brand/Marking: Not provided 2. Reference No: J20211400942 3. Designation: Not provided 4. Date of Manufacture: Not provided 5. Nature of Material: Not provided 6. Storage Condition: Room temperature 7. Colour: Grey 8. Shape/Form: Cylinder 9. Dimension: Approximately height 52 mm, diameter 12 mm 10. Appearance: Solid smooth surface 11. Opacity: Opaque
Date Received	:	27 July 2021
Issue Date	:	11 November 2021

Note: This Test Report supersedes the previous Test Report no. R0826/21/B19/01 dated 12 August 2021 which has been withdrawn and therefore not valid.

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APPROVED SIGNATORIES

We, the undersigned, declare that the methods, results and data contained in this report faithfully reflect the procedures used and raw data collected throughout the testing.

11 NOV 2021

(SUZAINI BADRUDIN)
Reviewer
Industrial Biotechnology Research Centre
SIRIM Berhad

Date

11 NOV 2021

(NOOR RABIHAH AID)
Analyst
Industrial Biotechnology Research Centre
SIRIM Berhad

Date

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1.0 Test timetable

Receipt of sample:	27 July 2021
Maintenance of cell culture:	20 July 2021– 27 July 2021
Extraction procedure:	02 August 2021– 03 August 2021
Preparation of cells:	03 August 2021
Growth procedure:	03 August 2021– 04 August 2021
End of test:	04 August 2021

2.0 Test method

2.1 Test summary

A screening procedure (simple cytotoxicity test) to test leachates from the **Sikaflex®PRO-3 Purform** biologically active compound was carried out according to BS 6920. Leachates from the sample after a 24-hour extraction at (23±2) °C was used to prepare growth medium. The morphology of a mammalian cell line following a 24-hour culture in the growth medium was observed. NO OTHER TESTS WERE UNDERTAKEN ON THIS PRODUCT.

2.2 Significance and rationale

This method is only an initial screening test for substances potentially hazardous to health and suitable for all non-metallic materials that may be used in contact with water intended for human consumption. A satisfactory result indicates that the leachate probably does not contain significant amounts of acutely toxic substances, but it does not indicate the absence of small quantities of substances, which may be harmful on prolonged exposure.

2.3 Cell culture

American Type Culture Collection CCL-1, NCTC clone 929 Areolar Fibroblast Mouse.

2.4 Test procedure

The procedure was divided into three stages as follows.

2.4.1 Cell culture maintenance

Cells were grown in tissue culture grade flasks and routinely examined to ensure they remain healthy.

2.4.2 Sample extraction and preparation of growth media

The sample pieces were extracted in 500 mL of reverse osmosis water at (23±2) °C for 24 hours. A validation solution (800 mg/L zinc sulfate) and a blank were included in the test. Portions of the sample extracts, validation solution and blank were used to dilute the concentrated growth medium. Freshly trypsinized cells was added to each preparation and transferred into a 24-well tissue culture plate. The extracts were assessed in replicates of three. The plate was incubated at (37±1) °C in a humidified atmosphere of 5 % carbon dioxide and 95 % air for 24 hours.

2.4.3 Effect on cell culture

The condition of cells in each well was examined microscopically. The presence or absence of a confluent cell layer, the presence of any irregular shaped cell or cells showing signs or 'rounding off', and the appearance of any cells floating in the growth medium was recorded.

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3.0 Results

The table below shows cytotoxicity effects **Sikaflex®PRO-3 Purform**

	Replicates	Effects on cell culture
Extract of Sample group	A	Healthy confluent monolayer
	B	Healthy confluent monolayer
	C	Healthy confluent monolayer
Validation solution	A	Cells 'rounding off' and floating. No monolayer
	B	Cells 'rounding off' and floating. No monolayer
	C	Cells 'rounding off' and floating. No monolayer
Blank	A	Healthy confluent monolayer
	B	Healthy confluent monolayer
	C	Healthy confluent monolayer

4.0 Analysis and interpretation

Cell cultures in the extract of sample group showed healthy confluent monolayer, comparable to the blank, which indicate a non-cytotoxic response. Monolayer of cell culture was not present in the validation solution. The cells showed severe 'rounding off' and floating in the validation solution preparation, which indicate a cytotoxic response.

5.0 Conclusion

The sample **Sikaflex®PRO-3 Purform** exhibited no cytotoxicity response under the conditions of this test. On the basis of these results, the sample tested complied with all the requirements of BS 6920: Part 1:2014, Clause 7.

INDUSTRIAL BIOTECHNOLOGY RESEARCH CENTRE * SIRIM BERHAD

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