NATIONAL INSTITUTE OF PUBLIC HEALTH
Šrobárova 49/48
Praha 10
100 00
Czech Republic

YOUR REFERENCE:
DATE: November 23, 2022
OUR REFERENCE: SZU/15967/2022
3/22/112
EX 221434

Hana Bendová, M.Sc., Ph.D.
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Date: December 14, 2022

Prusa Polymers a.s.
Partyzánská 188/7A
170 00 Praha 7
Czech Republic

Subject: EXPERT OPINION on the assessment of human skin irritation.

SUBJECT OF APPLICATION:
Regarding your application of November 23, 2022 for evaluation of human skin irritation, we hereby report:

SUBMITTED SAMPLE:
TM 3/22/112: Prusament Resin Biobased60 Natural Yellow– post cured 10 min

Manufacturer:
Prusa Polymers a.s.
Partyzánská 188/7A
170 00 Praha 7
Czech Republic

SUBMITTED DOCUMENTATION:
Product material specification was not included.

PERFORMED TEST:
SOP 9/3 – Tests for irritation in vivo (ISO 10993-23:21 Biological evaluation of medical devices – Part 23, Articles 1, 2, 3, 4, 5, 7, 8, Annex A, Annex D – Article D.2, Annex E)

EXPERT OPINION:
Test was performed by the Centre for Laboratory Testing, accredited by the Czech Accreditation Institute (Accredited Laboratory No.1206), Centre of Toxicology and Health Safety.

CONCLUSION
The test material TM 3/22/112 is not regarded as a significant skin irritant.

National Institute of Public Health
Centre of Toxicology and Health Safety
Šrobárova 49/48, 100 00 Praha 10
Czech Republic

Dagmar Jírová, M.D., Ph.D.
Director
Centre of Toxicology and Health Safety

ANNEXES:
Test Report No. 3/22/112 – Test Report Evaluation of Human Skin Irritation

National Institute of Public Health
Centre for Laboratory Testing

Laboratories of Toxicology
Šrobárova 49/48, 100 00 Prague 10
Tel.: +420 267082439 E–mail: hana.bendova@szu.cz

L 1206

Laboratory No.1206, accredited by Czech Accreditation Institute
according to EN ISO/IEC 17025:2017

Test Report No.3/22/112

Customer: Prusa Polymers a.s.
Address: Partyzánská 188/7A, 170 00 Praha 7, Czech Republic
Reference No.: SZÚ/15967/2022

Test Material

Identification:

TM 3/22/112: Prusament Resin Biobased60 Natural Yellow – post cured 10 min

Laboratory Tests

SOP 9/3 Tests for irritation in vivo (ISO 10993-23: 2021 Biological evaluation of medical devices – Part 23, Articles 1, 2, 3, 4, 5, 7, 8, Annex A, Annex D - Article D.2, Annex E)

Sample reception date: 28.11.2022
Date of study: 29.11. – 2.12.2022
Date of issue: 2.12.2022
Number of pages: 7

National Institute of Public Health Center of Laboratories Testing laboratory No. 1206, accredited by CAI

Authorized by Technical Manager: Hana Bendová, M.Sc., Ph.D.

The tests were performed at the address of the laboratory. The test results refer only to the sample as submitted by the sponsor and to the objectives of the study. This test report does not substitute for any other document or certification of the product. Without written approval of the testing laboratory this report should not be reproduced in other form than as a whole.

TEST REPORT
EVALUATION OF HUMAN SKIN IRRITATION

Testing facility: Laboratories of Toxicology, Centre for Laboratory Testing, National Institute of Public Health, Šrobárova 49/48, 100 00 Prague 10, Czech Republic.

The test was carried out in compliance with: SOP 9/3 Test for irritation in vivo (ISO 10993-23 (2021): Part 23: articles 1, 2, 3, 4, 5, 7, 8, Annex A, Annex D – article D.2, Annex E)

Aim of the study: Assessment of the potential of the test material to produce dermal irritation.

The intended use/application of the test sample: photopolymer material.

MATERIALS AND METHODS

TEST MATERIAL (TM):

TM 3/22/112: Prusament Resin Biobased60 Natural Yellow – post cured 10 min

Customer:
Prusa Polymers a.s., Partyzánská 188/7A, 170 00 Praha 7, Czech Republic

PREPARATION OF MATERIALS FOR TESTING

Preparation of materials for testing was performed according to the Annex A.

Solid material
TM 3/22/112 : applied directly on skin (2.5 x 2.5 cm).

CONTROLS
Positive control (PC)
Sodium dodecyl sulfate (SDS) - 20% aqueous solution - applied directly on skin (0.4 ml).

PARTICIPANTS IN THE STUDY

The selection of volunteers and the test methods complied with the WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects (1964, amended 2013) and the International Ethical Guidelines for Health-related Research Involving Humans (CIOMS, 2016). The study was performed in accordance with ČSN EN ISO 14155 (2021) Clinical investigation of medical devices for human subjects — Good clinical practice. The study was approved by the Ethical Review Committee of the National Institute of Public Health.

The volunteers were selected on the basis of inclusion and non-inclusion criteria and for this purpose filled in a special form. The volunteers were clearly informed regarding the nature of the study, timetable, constraints and possible risks. They gave their written informed consent before participation in the study was permitted. All the documentation is strictly confidential. 30 volunteers took part in the study.

Table 1 – Demographic data

Subject Number	Subject Initials	Age	Gender
1	ŘM	48	F
2	BO	30	M
3	UR	59	F
4	HI	36	F
5	JM	51	F
6	OD	65	F
7	CHJ	36	M
8	JZ	55	F
9	VZ	61	F
10	SD	49	M
11	SM	47	M
12	BL	63	F
13	BJ	65	M
14	TJ	58	F
15	VA	55	F
16	RM	51	M
17	BI	60	M
18	PJ	32	M
19	AT	59	M
20	JM	28	M
21	JM	48	M
22	KJ	62	F
23	PD	61	F
24	HI	43	F
25	VK	59	F
26	BH	59	F
27	DM	45	F
28	BT	56	F
29	JT	59	F
30	PM	55	F

TEST PROCEDURE

Application of the test material
The solid test material TM 3/22/112 (2.5 x 2.5 cm) was applied in occlusion on the upper outer arm.
Occlusive: Hill Top Chambers (containing a gauze pad, diameter 1.8 cm), HILL TOP BIOLABS, USA

Application of the positive control
The positive control 20% SDS, 0.4 ml) was applied on the upper outer arm. Occlusive: Hill Top Chambers (containing a gauze pad, diameter 1.8 cm), HILL TOP BIOLABS, USA

Duration of exposure
The patches were applied progressively starting with duration of 15 min and 30 min, and up to 1h, 2h, 3 h and 4h. The test substance was removed by rinsing and gentle swabbing.

Clinical observation and grading of skin reactions
The reactions were assessed in the interval 0 h (immediately after patch removal), subsequently (1 ± 0,1) h up to (2 ± 0,2) h, (24 ± 2) h, (48 ± 2) h a (72 ± 2) h after patch removal. Skin reactions were graded and recorded according to the grading given in Tab. 2.

Table 2 – Human skin irritation test, grading scale

Description of response	Grading
No reaction	0
Weakly positive reaction (usually characterized by mild erythema and/or dryness across most of the treatment site)	1
Moderately positive reaction (usually distinct erythema or dryness, possibly spreading beyond of the treatment site)	2
Strongly positive reaction (strong and often spreading erythema with oedema and/or eschar formation)	3

Data evaluation / interpretation

The number of volunteers who developed a positive reaction after test material application (Tab. 3) and after positive control application (Tab. 4) at intervals (24 ± 2) h, (48 ± 2) h a (72 ± 2) h after patch removal was used for skin irritation evaluation.

The skin irritation potential hazard was determined by comparison of number of volunteers that produced skin reaction after test material application and number of volunteers that produced skin reaction after positive control application at intervals (24 ± 2) h, (48 ± 2) h a (72 ± 2) h after patch removal.

If the material produces a frequency of skin irritation in the test subjects which is substantially and significantly less than the positive control, it is not regarded as a significant skin irritant.

If the material produces a frequency of skin irritation in the test subjects which is similar to, or grater than, the positive control, it is regarded as a significant skin irritant.

Fisher´s exact test was used for the statistical treatment of the results.

RESULTS

The skin reactions are recorded in the Annex I.

ASSESSMENT OF RESULTS

Skin reactions after application of the test material were recorded for 0 of 30 volunteers. Skin reactions after application of the positive control were recorded for 30 of 30 volunteers. The Fisher´s exact test confirmed substantially and significantly lower frequency of the skin irritation in case of the test material application than in case of the positive control.

The test material TM 3/22/112 is not regarded as a significant skin irritant.

Test carried out by: Hana Bendová, M.Sc., Ph.D.

Principal investigator: Hana Bendová, M.Sc., Ph.D.

Annex I

Table 3 – TM 3/22/112 - observation and grading of skin reactions

Volunteer No.	Time interval / Grading		
	(24 ± 2) h after patch removal	(48 ± 2) after patch removal	(72 ± 2) h after patch removal
1	0	0	0
2	0	0	0
3	0	0	0
4	0	0	0
5	0	0	0
6	0	0	0
7	0	0	0
8	0	0	0
9	0	0	0
10	0	0	0
11	0	0	0
12	0	0	0
13	0	0	0
14	0	0	0
15	0	0	0
16	0	0	0
17	0	0	0
18	0	0	0
19	0	0	0
20	0	0	0
21	0	0	0
22	0	0	0
23	0	0	0
24	0	0	0
25	0	0	0
26	0	0	0
27	0	0	0
28	0	0	0
29	0	0	0
30	0	0	0

Table 4 - Positive control - observation and grading of skin reactions

Volunteer No.	Time interval / Grading		
	(24 ± 2) h after patch removal	(48 ± 2) after patch removal	(72 ± 2) h after patch removal
1	1	1	1
2	2	2	2
3	2	1	1
4	2	2	2
5	2	1	1
6	1	1	1
7	2	2	2
8	2	1	1
9	2	2	1
10	1	1	1
11	2	2	2
12	2	2	1
13	1	1	1
14	2	2	2
15	2	2	2
16	1	1	1
17	1	1	1
18	1	1	1
19	1	1	1
20	3	2	2
21	1	1	1
22	3	3	2
23	2	1	1
24	1	1	1
25	2	2	2
26	1	1	1
27	1	1	1
28	2	2	2
29	1	1	1
30	1	1	1

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