QUALITY ASSURANCE & CONTROL SYSTEMS Ltd
1 Antigonis str., 14451 Metamorfossi, Greece **W** : www. qacslab.com
T : + 30 210 2934745 **E** : info@qacslab.com

T E S T R E P O R T
23 26 00353

S T A B I L I T Y T E S T R E P O R T

3 MONTHS PROTOCOL

RD0053-T(FM)-C(TRA)-F(LW)-R(01)

DEPESCHE VERTRIEB GmbH & Co. KG

MAY 2024

PRODUCT DESCRIPTION

The product "RD0053-T(FM)-C(TRA)-F(LW)-R(01)" is a clear skin care product (leave on), of characteristic odor that is kept in a plastic container.

TEST PRODUCT DESCRIPTION

PRODUCT MANUFACTURED BY	:	**DEPESCHE VERTRIEB GmbH & Co. KG**
RECEIPT DATE	:	**06/12/2023**
STUDY PERIOD	:	**15/01/2024 - 08/04/2024**
LAB ID	:	**23 26 00353**
TEST PRODUCT	:	**RD0053-T(FM)-C(TRA)-F(LW)-R(01)**
PRODUCT TYPE	:	**STABILITY (3 MONTHS)**
LOT	:	**PRE PRODUCTION**
STUDY SPONSOR	:	**DEPESCHE VERTRIEB GmbH & Co. KG**

OBJECTIVE

The objective of stability testing is to ensure that the cosmetic product maintains its intended physical, chemical and microbiological quality and properties, as well as its functionality and aesthetics when stored under appropriate conditions. Main scope is to provide data by foreseeing the stability of the product overtime within its useful life span and the compatibility between the formulation and the container material.

METHOD DESIGN

The method was designed to include testing of the attributes of the cosmetic product that are susceptible to change during storage and are likely to influence quality, safety, and performance characteristics. The testing covers the sensorial, physical, chemical, and microbiological attributes, the preservation system and its efficacy. Analytical procedures are performed in accordance with documented protocols. For the measurable attributes, a ± 20 % variation from the initial assay value (time zero) is set as the action limit. A stable product should meet standard requirements for sensorial, physical and microbiological properties. A sample stored at room temperature is considered as reference for sensorial properties.

REFERENCES

- ICH Q 1 A (R2)
- EC 1223/2009
- COLIPA Guide on stability testing of cosmetic products, 2004
- IFSCC Monograph No2 The Fundamentals of Stability Testing
- ISO/TR 18811:2018

PROTOCOL

The stability study may include the evaluation of the below attributes at specific storage conditions and time intervals.

- Organoleptic: appearance, color, odor and texture.
- Physical-chemical: pH, weight, assay of preservatives, viscosity, peroxide value, UV filters.
- Microbiological parameters: microbial count and preservation efficacy test.
- Compatibility between product and container

STABILITY ROOM TEMPERATURE (RT-25°C)

The samples are stored at room temperature (25°C ± 2°C). At the beginning of the stability (week 0) all parameters are evaluated (time zero). Organoleptic - physicochemical controls are carried out weekly.

STABILITY ACCELERATED (40°C/75% RH)

The samples are stored in a chamber (40°C ± 2°C / 75% RH). Organoleptic - physicochemical controls are carried out weekly. Compatibility between the formulation and the container material is monitored on a weekly basis. Upon conclusion of the study (3 months) apart from the above parameters assay of preservatives (or challenge test) are performed.

STABILITY REFRIGERATOR (5°C)

The samples are stored in a refrigerator (5°C ± 2°C). Organoleptic - physicochemical controls are carried out weekly.

STABILITY CYCLES

The samples are stored in a freezer (-20°C ± 2°C) for eight hours and permitted to thaw at room temperature. The organoleptic and sensorial attributes are evaluated. The same samples are left at room temperature (25°C ± 2°C) for 16 hours and then reevaluated. The study is completed after five -5- days, during which a total of 5 freeze – thaw cycles are completed.

STABILITY DARK & WINDOW

Samples are kept in a closed cabinet (dark) and artificial light (fluorescent lighting). Organoleptic sensorial attributes, are evaluated weekly. The study is completed within three months.

STABILITY TEST SCHEDULE AND PLANNING

The test schedule of the product has been adjusted according to its nature and formula.

The following parameters are not assessed:
- Weight (performed for volatile products)

The time schedule below describes the time intervals at which samples stored at different conditions are tested and what tests are applied at each examination.

TIME (WEEKS)	5°C	25°C	40°C / 75% RH	DARK-WINDOW	FREEZE-THAW CYCLES (-20°C FOR 8 HOURS TO 25°C FOR 16 HOURS)
0	P	P	P	P	P
1	P	P	P	P	P
2	P	P	P	P	-
3	P	P	P	P	-
4	P	P	P	P	-
5	P	P	P	P	-
6	P	P	P	P	-
7	P	P	P	P	-
8	P	P	P	P	-
9	P	P	P	P	-
10	P	P	P	P	-
11	P	P	P	P	-
12	P	P	P	P	-

Where:
P: Appearance, Odor, Texture, Viscosity, Color, pH, Weight Loss, Packaging Compatibility
A: Assay of active constituents
C: Preservative challenge tests
X: Assay of preservatives
M: Microbial count
-: Not tested

RAW DATA

CUSTOMER	:	**DEPESCHE VERTRIEB GmbH & Co. KG**
PRODUCT	:	**RD0053-T(FM)-C(TRA)-F(LW)-R(01)**
LAB ID	:	**23 26 00353**
MANUFACTURE BATCH	:	**PRE PRODUCTION**
STABILITY START DATE	:	**15/01/2024**
MANUFACTURE DATE	:	

TEMPERATURE 25°C

START DATE	WEEKS	APPEARANCE	ODOR	TEXTURE	COLOR	pH
15/01/2024	0	OK	OK	OK	OK	5.76
22/01/2024	1	OK	OK	OK	OK	
29/01/2024	2	OK	OK	OK	OK	
05/02/2024	3	OK	OK	OK	OK	
12/02/2024	4	OK	OK	OK	OK	
19/02/2024	5	OK	OK	OK	OK	
26/02/2024	6	OK	OK	OK	OK	5.74
04/03/2024	7	OK	OK	OK	OK	
11/03/2024	8	OK	OK	OK	OK	
18/03/2024	9	OK	OK	OK	OK	
25/03/2024	10	OK	OK	OK	OK	
01/04/2024	11	OK	OK	OK	OK	
08/04/2024	12	OK	OK	OK	OK	5.72

RAW DATA *(continued)*

CUSTOMER	:	**DEPESCHE VERTRIEB GmbH & Co. KG**
PRODUCT	:	**RD0053-T(FM)-C(TRA)-F(LW)-R(01)**
LAB ID	:	**23 26 00353**
MANUFACTURE BATCH	:	**PRE PRODUCTION**
STABILITY START DATE	:	**15/01/2024**
MANUFACTURE DATE	:	

TEMPERATURE 40°C / 75% RH

START DATE	WEEKS	APPEARANCE	ODOR	TEXTURE	COLOR	pH
15/01/2024	0	OK	OK	OK	OK	5.76
22/01/2024	1	OK	OK	OK	OK	
29/01/2024	2	OK	OK	OK	OK	
05/02/2024	3	OK	OK	OK	OK	
12/02/2024	4	OK	OK	OK	OK	
19/02/2024	5	OK	OK	OK	OK	
26/02/2024	6	OK	OK	OK	OK	5.74
04/03/2024	7	OK	OK	OK	OK	
11/03/2024	8	OK	OK	OK	OK	
18/03/2024	9	OK	OK	OK	OK	
25/03/2024	10	OK	OK	OK	OK	
01/04/2024	11	OK	OK	OK	OK	
08/04/2024	12	OK	OK	OK	OK	5.72

RAW DATA *(continued)*

CUSTOMER	:	**DEPESCHE VERTRIEB GmbH & Co. KG**
PRODUCT	:	**RD0053-T(FM)-C(TRA)-F(LW)-R(01)**
LAB ID	:	**23 26 00353**
MANUFACTURE BATCH	:	**PRE PRODUCTION**
STABILITY START DATE	:	**15/01/2024**
MANUFACTURE DATE	:	

TEMPERATURE 40°C / 75% RH *(continued)*

START DATE	WEEKS	ASSAY PHENOXYETHANOL %
15/01/2024	0	0.27
22/01/2024	1	-
29/01/2024	2	-
05/02/2024	3	-
12/02/2024	4	-
19/02/2024	5	-
26/02/2024	6	-
04/03/2024	7	-
11/03/2024	8	-
18/03/2024	9	-
25/03/2024	10	-
01/04/2024	11	-
08/04/2024	12	0.27

RAW DATA *(continued)*

CUSTOMER	:	**DEPESCHE VERTRIEB GmbH & Co. KG**
PRODUCT	:	**RD0053-T(FM)-C(TRA)-F(LW)-R(01)**
LAB ID	:	**23 26 00353**
MANUFACTURE BATCH	:	**PRE PRODUCTION**
STABILITY START DATE	:	**15/01/2024**
MANUFACTURE DATE	:	

TEMPERATURE 5°C

START DATE	WEEKS	APPEARANCE	ODOR	TEXTURE	COLOR	pH
15/01/2024	0	OK	OK	OK	OK	5.76
22/01/2024	1	OK	OK	OK	OK	
29/01/2024	2	OK	OK	OK	OK	
05/02/2024	3	OK	OK	OK	OK	
12/02/2024	4	OK	OK	OK	OK	
19/02/2024	5	OK	OK	OK	OK	
26/02/2024	6	OK	OK	OK	OK	5.74
04/03/2024	7	OK	OK	OK	OK	
11/03/2024	8	OK	OK	OK	OK	
18/03/2024	9	OK	OK	OK	OK	
25/03/2024	10	OK	OK	OK	OK	
01/04/2024	11	OK	OK	OK	OK	
08/04/2024	12	OK	OK	OK	OK	5.72

RAW DATA *(continued)*

CUSTOMER	:	**DEPESCHE VERTRIEB GmbH & Co. KG**
PRODUCT	:	**RD0053-T(FM)-C(TRA)-F(LW)-R(01)**
LAB ID	:	**23 26 00353**
MANUFACTURE BATCH	:	**PRE PRODUCTION**
STABILITY START DATE	:	**15/01/2024**
MANUFACTURE DATE	:	

-20°C FOR 8 HOURS TO 25°C FOR 16 HOURS

START DATE	CYCLES	TIME	APPEARANCE	ODOR	TEXTURE	COLOR
15/01/2024	END RT	09:00	OK	OK	OK	OK
	END FREEZING	16:00	OK	OK	OK	OK
16/01/2024	END RT	09:00	OK	OK	OK	OK
	END FREEZING	16:00	OK	OK	OK	OK
17/01/2024	END RT	09:00	OK	OK	OK	OK
	END FREEZING	16:00	OK	OK	OK	OK
18/01/2024	END RT	09:00	OK	OK	OK	OK
	END FREEZING	16:00	OK	OK	OK	OK
19/01/2024	END RT	09:00	OK	OK	OK	OK
	END FREEZING	16:00	OK	OK	OK	OK

RAW DATA *(continued)*

CUSTOMER	:	**DEPESCHE VERTRIEB GmbH & Co. KG**
PRODUCT	:	**RD0053-T(FM)-C(TRA)-F(LW)-R(01)**
LAB ID	:	**23 26 00353**
MANUFACTURE BATCH	:	**PRE PRODUCTION**
STABILITY START DATE	:	**15/01/2024**
MANUFACTURE DATE	:	

DARK & WINDOW

START DATE	WEEKS	DARK				WINDOW			
		APPEARANCE	ODOR	TEXTURE	COLOR	APPEARANCE	ODOR	TEXTURE	COLOR
15/01/2024	0	OK	OK	OK	OK	OK	OK	OK	OK
22/01/2024	1	OK	OK	OK	OK	OK	OK	OK	OK
29/01/2024	2	OK	OK	OK	OK	OK	OK	OK	OK
05/02/2024	3	OK	OK	OK	OK	OK	OK	OK	OK
12/02/2024	4	OK	OK	OK	OK	OK	OK	OK	OK
19/02/2024	5	OK	OK	OK	OK	OK	OK	OK	OK
26/02/2024	6	OK	OK	OK	OK	OK	OK	OK	OK
04/03/2024	7	OK	OK	OK	OK	OK	OK	OK	OK
11/03/2024	8	OK	OK	OK	OK	OK	OK	OK	OK
18/03/2024	9	OK	OK	OK	OK	OK	OK	OK	OK
25/03/2024	10	OK	OK	OK	OK	OK	OK	OK	OK
01/04/2024	11	OK	OK	OK	OK	OK	OK	OK	OK
08/04/2024	12	OK	OK	OK	OK	OK	OK	OK	OK

REMARKS

Compatibility Remarks:

At the end of the stability study the product was also tested for phthalates with the below results:

Benzyl Butyl Phthalate: <1 mg/kg
Di-n-Butyl Phthalate: <1 mg/kg
Diethylhexyl Phthalate: <1 mg/kg
Di (2-methoxyethyl) Phthalate: <1 mg/kg
Di-n-Pentyl Phthalate: <1 mg/kg
Diisobutyl Phthalate: <1 mg/kg

The compatibility of the product within its container was assessed weekly. No alterations on the container were observed. There was no product leakage or any deterioration of the container.

Stability Remarks:

At the start and end of the accelerated study, the preservation system was tested to ensure its stability.The results are shown below:

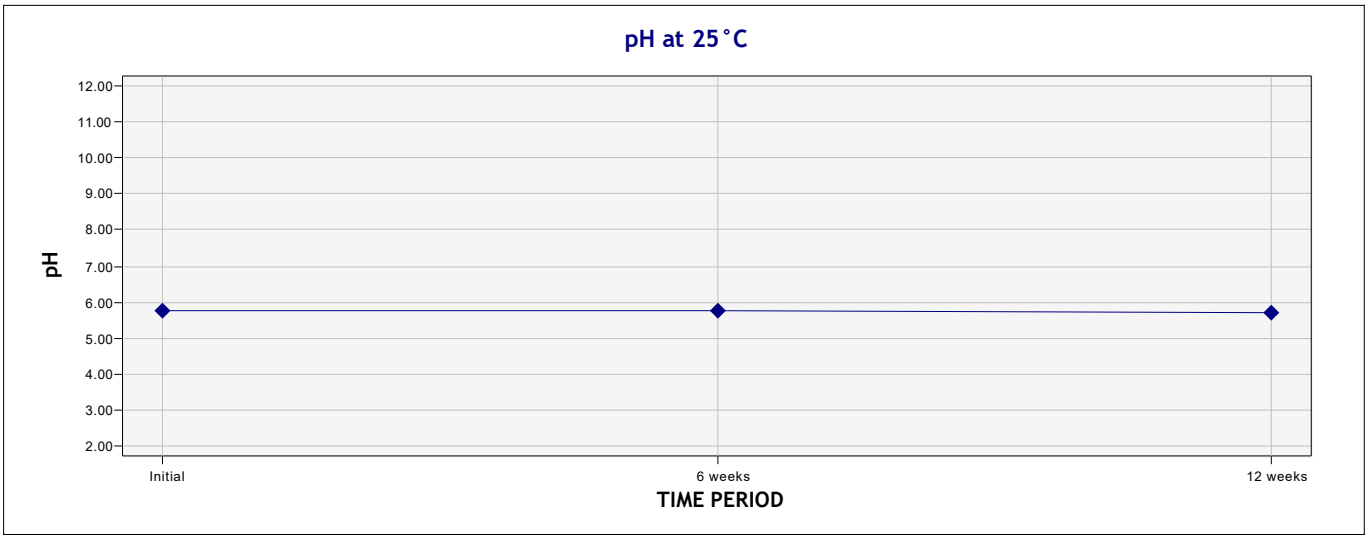
Parameter	Start	End	Variation*(%)
Symsave H (%)	0.19	0.20	5.3

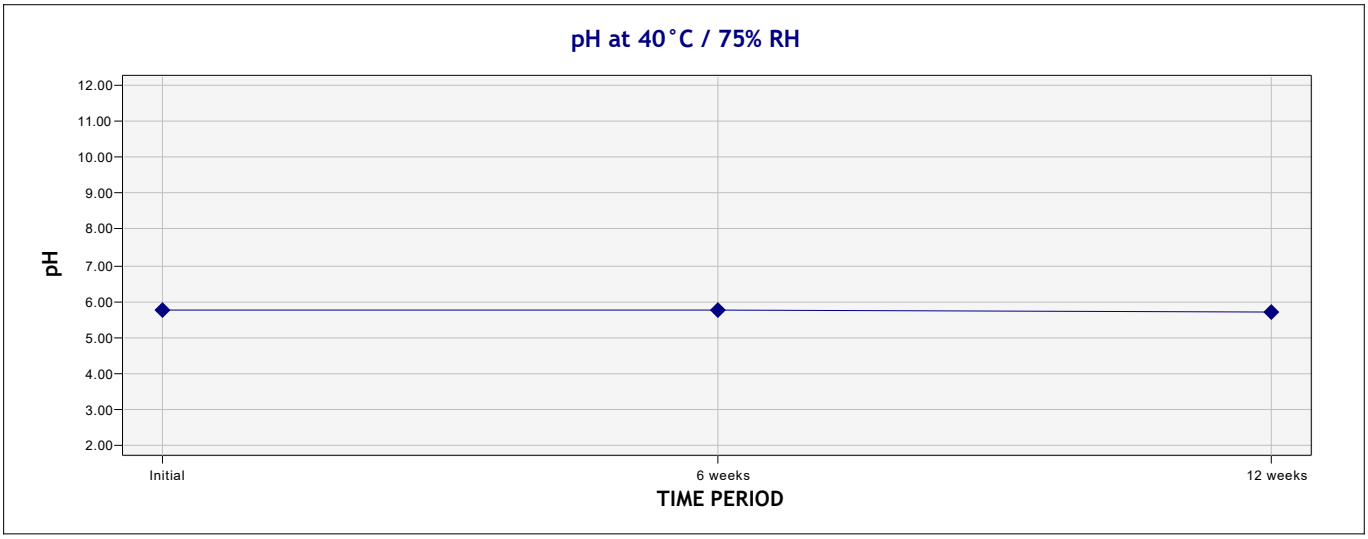
*Any variation less than 20.0% is considered acceptable and within limits.

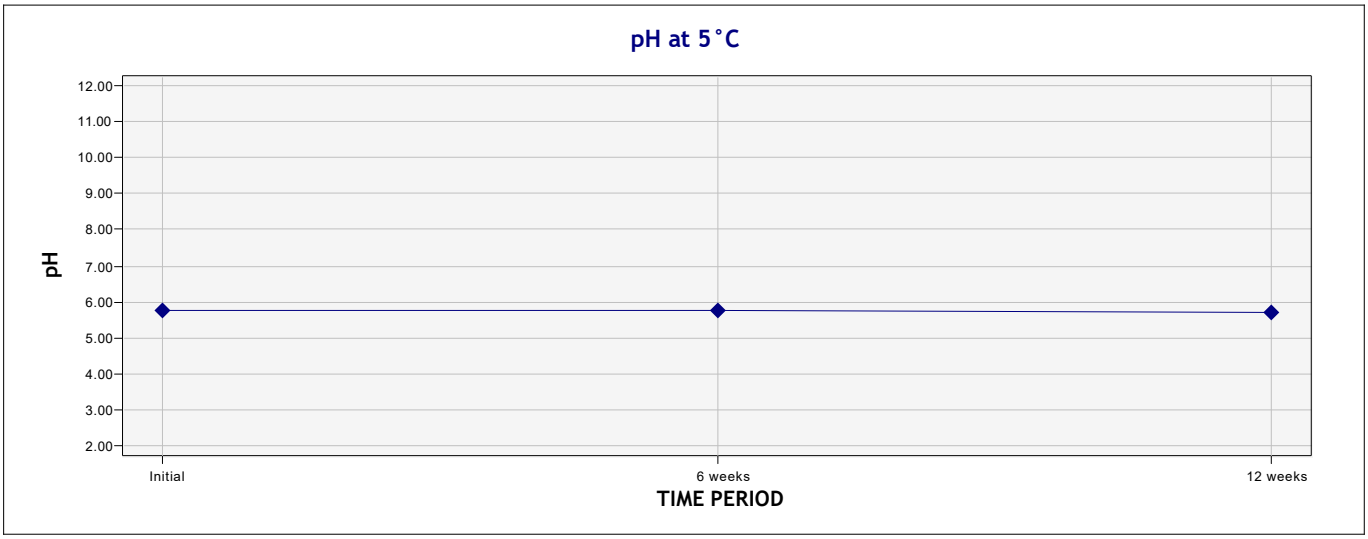
Quality Assurance & Control Systems Ltd.,1 Antigonis St., 144 51, Athens, Greece
Tel: +30 210 2934745 • Fax: +30 210 2934606 • email: info@qacs.gr • website: www.qacslab.com

GRAPHS

pH

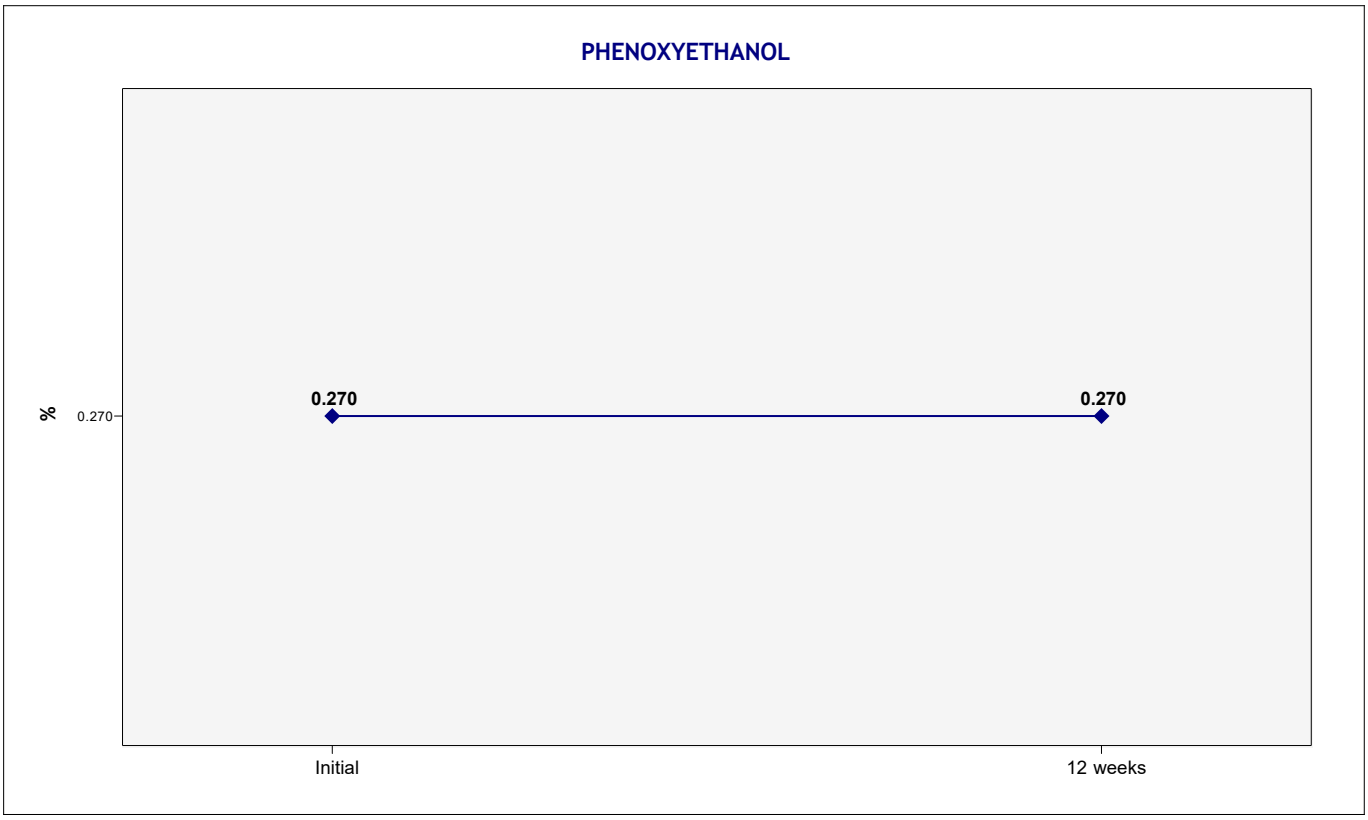






GRAPHS *(continued)*

PRESERVATIVE ASSAYS AT 40°C / 75% RH



Quality Assurance & Control Systems Ltd.,1 Antigonis St., 144 51, Athens, Greece
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TEST PRODUCT DESCRIPTION

PRODUCT MANUFACTURED BY	:	**DEPESCHE VERTRIEB GmbH & Co. KG**
RECEIPT DATE	:	**06/12/2023**
STUDY PERIOD	:	**15/01/2024 - 08/04/2024**
LAB ID	:	**23 26 00353**
TEST PRODUCT	:	**RD0053-T(FM)-C(TRA)-F(LW)-R(01)**
PRODUCT TYPE	:	**STABILITY (3 MONTHS)**
LOT	:	**PRE PRODUCTION**
STUDY SPONSOR	:	**DEPESCHE VERTRIEB GmbH & Co. KG**

CONCLUSION

The following aspects of the product were evaluated within the frame of this study:
- Chemical stability,
- Compatibility between the contents and the container
- Organoleptic
- Physical

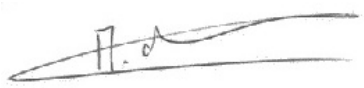
Note: A product was also kept as a reference in an inert, impermeable container with which it does not interact and which fully protects it from the ambient atmosphere.

At the end of the 3 months study period all organoleptic and physico-chemical parameters met the specifications and the acceptance criteria.

At the end of the test period the compatibility between the product and its container was found to be acceptable.

The findings presented in the current study confirm that the product “RD0053-T(FM)-C(TRA)-F(LW)-R(01)” presented satisfactory sensorial and physical characteristics, for a period of 3 months under accelerated storage conditions.
Taking into consideration the above stability study, a shelf-life of 12 months can be attributed to the product.

Study Manager :
Printed name : Panagiotis Nikolakis
Date : 14/05/2024



This document has been electronically signed by those names that appear on this report and are the authorized signatories.

PRODUCT PHOTO