Final Product Specification	Nr.: **SP A107/1**	Revision: 6
EVICROL		
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1. PURPOSE

The objective of this specification is to determine product requirements which must Evicrol comply with before release for distribution. This specification serves for communication with customers.

2. PRODUCT DESCRIPTION

Evicrol is a chemically-cured restorative composite designed for the creation of durable and aesthetic dental restorations. Its powder-liquid system allows material of an optimum consistency to be made for different clinical cases and is compatible with other composite systems.

3. INDICATION FOR USE

Evicrol composite is indicated for class III and class V restorations. It can also be used for fractured incisal edges - class IV restorations.

4. PRODUCT TRADENAME

EVICROL™
Chemically-Cured Restorative Macrofilled Composite

5. MATERIAL FORM

Evicrol powder is fine, loose powder in 4 different shades.

Evicrol liquid is viscous, clear liquid, of light yellow to yellow-brown colour, free of mechanical impurities, of acid reaction.

Evicrol etching solution is colourless to light green liquid, free of mechanical impurities.

6. PRODUCT PACKAGING

Evicrol	min. 36.4 g plv. No. 21 min. 9.1 g plv. No. 25, 27, 45 min. 23.66 g liq. min. 12.75 g etching solution	40 g of powder shade No.21 + 3 x 10 g of powder shade No.25, No. 27, No. 45 in PS vessels; 26 g of liquid in PE bottle, 14 g of Evicrol etching solution in glass bottle, dosing spoon, dropper, 30x plastic mixing spatulas, paper mixing pads and IFU in cardboard box

7. PRODUCT REQUIREMENTS

Requirement	**Target**	**Unit**	**Test Method**
Homogeneity	Homogeneous powder with even pigment distribution	-	ZP 3121111
Working Time	Min. 90	s	ISO 4049
Setting Time	Max. 5	min	ZP 3121111 ISO 4049
Flexural strength	Min. 50	MPa	ISO 4049
Compressive strength	Min. 170	MPa	ZP 3121111
Water sorption	Max. 40	$\mu g/mm^3$	ISO 4049
Solubility	Max. 7.5	$\mu g/mm^3$	ISO 4049
Shade	Delta E - Max. 3 Opacity $C_{0\text{-}70}$ - Max. 68	%	ZP 3121111
Colour stability after irridation and water sorption	No more than a slight change in a colour shall be observed	-	ISO 4049
Microbiological Safety	Compliant to SOP 10-110	-	SOP 10-110

8. STORAGE CONDITIONS

Store in a dry and dark place at 5°C to 25°C, in a well-sealed container.

9. SHELF LIFE

Product shelf life is 2 years from the date of manufacturing.

10. ABBREVIATIONS

JKJ	Quality Control and Quality Assurance
liq.	liquidum (liquid)
plv.	pulvis (powder)
SOP	Standard Operating Procedure

SP	Specification
ZP	Testing Instruction

11. RELATED DOCUMENTS	
SOP 05-101	Level III controlled documentation
SOP 10-107	Statistical control of products in primary packaging and finished products
SOP 10-110	Microbiological testing and evaluation
ZP 3121111	Evicrol plv. No. 21
ISO 4049	Dentistry – Polymer-based restorative materials

12. REVISION SUMMARY

JKJ manager is responsible for specification modifications according to SOP 05-101.

Chapter No.	Description	Nr. of Pages	Revision	Date of issue
-	Complete version SP A 107/1, include annexes	3 + 2	1	19.04.2005
-	Package size, content of original package, raw material	3 + 2	2	20.12.2005
-	Package size, carried out tests, raw materials, distribution slip	3 + 2	3	6.11.2009
-	Revised Chap. 3 and 5, modified sections 4.3. and 4.5.3. according to valid Test Procedure. Revised distribution list and composition (item names, specified pigments), changed the composition of Evicrol etch. solution.	3 + 2	4	05.11.2015
2., 4.1., 4.3., App.	Modified Characteristics (Chap. 2) and Description in section 4.1. Updated section 4.3. (number of grinding pad and measuring spoons). Updated composition (pigments in the appendix. Updated by the actual template for MC..	3	5	4.12.2020
-	New layout implemented, Translated to english Section **1. Purpose -** *,specification is part of*	4	6	The date of issue

	registration documentation' removed Section **2. Product description** updated to be in line with TF & IFU Section **3. Indication for Use** added Section **4. Product tradename** (orig. 4.1.) updated to be in line with TF Section **6. Product packaging** (orig. 4.3. and 4.5.1) section mergeded and updated to be in line with TF Sampling plan section (orig. 4.4.) and statistic control sections (orig. 4.5.2) removed Section **7. Product requirements** (orig. 4.5.3.) updated according to Design Input Summary Section **10. Abbreviations** (orig. 3.) updated Section Appendix (orig. 6.) removed Section **12. Revision summary** updated (orig. 7. and 7.1. sections merged) Section Distribution (orig. 9.) removed			

13. APPROVAL
Master Control