

Table 1

Evaluation of Cytotoxicity of Symphyse 3VSI and its Extracts Using the Agar Diffusion Method
(24-hour Data)

Group ^a	Decolorization cm ^b	Zone Index	Cell Lysis		Cell Response	Cytotoxicity
			%	Index		
Negative Control	0	0	0	0	0/0	None
Symphyse 3VSI	0	0	0	0	0/0	None
Extract of						
Symphyse 3VSI	0	0	0	0	0/0	None
Positive Control	1.45±0.00	5	63.8±4.8	4	5/4	Severe

^a Negative control: filter disk with 50µl, sterile culture medium without serum; Positive control: filter disk with 50µl phenol.

^b N=4. The distance from the sample (cm) = (Diameter of Decolorization Zone + Diameter of the sample)/2. The value of 1.45 cm indicates a decolorization of the entire culture well (3.5 cm in diameter): 3.0 cm x2 + 06 cm (Diameter of the sample). Decolorization index is 1 if the decolorization Zone is limited to the area under the sample (Appendix A).

Table 2

Evaluation of Cytotoxicity of Symphyse 3VSI and its Extracts Using the Agar Diffusion Method
(48-hour Data)

Group ^a	Decolorization cm ^b	Zone Index	Cell Lysis		Cell Response	Cytotoxicity
			%	Index		
Negative Control	0	0	0	0	0/0	None
Symphyse 3VSI	0	0	0	0	0/0	None
Extract of						
Symphyse 3VSI	0	0	0	0	0/0	None
Positive Control	1.45±0.00	5	87.5±2.9	5	5/5	Severe

^a Negative control: filter disk with 50µl, sterile culture medium without serum ; Positive control: filter disk with 50µl phenol.

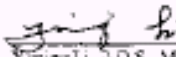
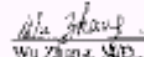
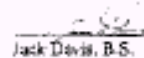
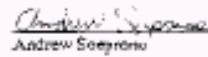
^b N=4. The distance from the sample (cm) = (Diameter of Decolorization Zone + Diameter of the sample)/2. The value of 1.45 cm indicates a decolorization of the entire culture well (3.5 cm in diameter): 3.0 cm x2 + 06 cm (Diameter of the sample). Decolorization index is 1 if the decolorization Zone is limited to the area under the sample (Appendix A).

Conclusion

Symphyse 3VSI is not cytotoxic as evaluated using the agar diffusion method.

References

- International Organization for Standardization (ISO) (1992) International Standard Biological Evaluation of Medical Devices - Part 5: Test for Cytotoxicity *in vitro* Methods. ISO 10993-5.
- International Organization for Standardization (ISO) (1997) Dentistry-preclinical evaluation of biocompatibility of medical devices used in dentistry - Test methods for dental materials ISO 7405


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