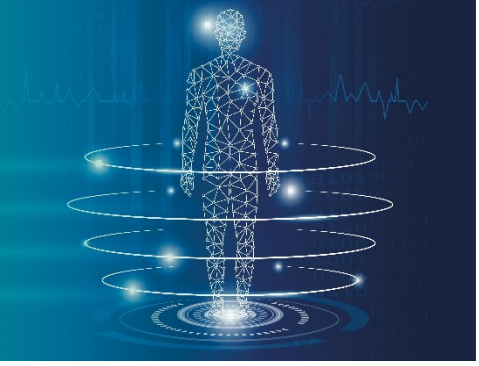

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TITOLO (maiuscolo)

EVALUATION OF BIOBASED SURFACTANTS AS POTENTIAL EXCIPIENTS FOR BIOMEDICAL APPLICATIONS: IN VITRO CYTOTOXICITY ASSESSMENT

Autore (i)

Enrica Chiesa[1], Martina Tamburriello[1], Giorgia Ballabio[2], Giuseppe Cappelletti[2], Sara Sangiorgio[2], Giovanna Speranza[2], Rossella Dorati[1]

Ente di appartenenza

[1] Department of Drug Sciences, University of Pavia, Viale Taramelli, 12, 27100, Pavia (PV), Italy
[2] Department of Chemistry, Università degli Studi di Milano, via Golgi 19, 20133, Milan (MI), Italy

Riassunto

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Surfactants that come from renewable biological sources such as plants, animals, or microorganisms are known as biobased surfactants. Biobased surfactants are a sustainable and environmentally friendly alternative compared to conventional surfactants derived from petrochemicals. Biodegradable, non-toxic, and produced using green chemistry principles are common features of them. In industries such as cosmetics, pharmaceuticals, agriculture, and environmental remediation, biobased surfactants have a variety of potential applications [1]. Their distinct characteristics lend themselves to their potential use as excipients in biomedical formulations, where their biocompatibility and low toxicity are particularly advantageous [2,3]. It is imperative to conduct a thorough evaluation, including in vitro cytotoxicity testing, to determine their safety and suitability for biomedical use. The work involved the assessment of in vitro cytotoxicity of biobased surfactants (sugar fatty acid esters, SFAEs) obtained from the main waste stream of the dairy industry.
Specifically, sugar-based surfactants were prepared by Fisher glycosylation of D-glucose or D-galactose with *n*-butanol under acidic conditions, followed by enzymatic esterification with molten palmitic acid, catalysed by CalB (Novozym® 435). The resulting pyranoside- and furanoside-based esters, each as couple of α and β anomers, were separated through flash column chromatography [4].
Safety characterization of samples of SFAE (glucopyranosides, glucofuranosides, galactopyranosides, and galactofuranosides), provided by the University of Milan, was carried out by performing in vitro cytotoxicity studies on human fibroblast cultures. To meet regulatory standards, substances that may be in contact with the human body must be biocompatible without any negative local or systemic effects. Non-clinical safety assessments, such as biocompatibility testing, are carried out on these substances before regulatory approval, in accordance with ISO 10993 guidelines.
Establishing reference materials that are known to induce either cytotoxic or non-cytotoxic responses was part of the validation process. Each experiment used DMSO as the positive control for cytotoxicity, and 2X DMEM as the positive control for non-cytotoxicity to guarantee method consistency. In addition, a synthetic surfactant, sucrose palmitate, was utilized for comparison. A compatible vehicle was used to disperse the SFAE samples for the cell line. The assessment of metabolic activity and membrane integrity was done using MTT and LDH assays after treatment.
The safety profile of all bio-based materials was superior to the control, sucrose palmitate, as demonstrated by the results obtained. The use of Prism 6, Version 6.0b of GraphPad software resulted in calculation of IC50 values (mg/mL) using experimental data. Compared to the control, the IC50 values for bio-based materials were higher. Additionally, it is evident that the type of sugar influences the biocompatibility of surfactants (IC50 of glucosides > IC50 of galactosides). LDH (Lactate Dehydrogenase) testing enabled evaluation of cell membrane damage in vitro after exposure to SFAE samples, data are consistent with MTT test.

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[4] S. Sangiorgio *et al* Colloids Interface Sci. Commun. 2022: 48, 100630.

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Autore di riferimento da contattare per ulteriori informazioni:

Nome e Cognome: Rossella Dorati

E-mail: rossella.dorati@unipv.it