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To the kind attention of the European Commission and in particular of the Commission for Agriculture and Health and for acknowledgment of the Italian Government in the figure of the Ministers and Undersecretaries for Health and Agricultural and Forestry Policies.

My name is Paolo Pelini, I am a Herbochemist, expert in Pharmacognostic and Cytotoxicological *Research of Plant Extracts.*

With this report and related preliminary scientific study, I want to bring to the attention of the European and national governmental bodies mentioned above some scientific aspects that in my opinion are relevant that could call into question the decision made by the European Commission regarding the banning of derivatives. Hydroxyanthracenic because Genotoxic and Carcinogenic considerations as expressed in Regulation (EU) 468/2021.

This technical-scientific report hopes to shed light on the issue of derivatives hydroxyanthracenics present in anthraquinone plants such as Aloe, waterfall, senna 'Frangola and some
forms of neoplasia as claimed by the European Commission on the basis of the report presented by the agency from EFSA.
In the opinion of the writer, the report presented by efsa lacks the scientific method beyond that of scientifically relevant data and has not been performed in a workmanlike manner!
set of old studies of a purely academic nature and not the result of research carried out from scratch but purely bibliographic as opposed to how such a delicate question as the culture between hydroxyanthracene derivatives and cancer
The first note to consider is the number of anthraquinone molecules used to develop
effect
genotoxic in vivo much higher than in harvest
present plant in the nature or in the extracts, while having to admit what a lofty tale it is to reach the threshold toxicity dose necessary for development I 'toxic effect at a statistically significant sample of guinea pigs, it must be said, however, that the effect of a single molecule such as aloin or aloe emodin etc. with respect to the phylocomplex present in a extracted as the action of the same phytocomplex which is a set of molecules interacts between them mitigating the effect of the single molecule,

Some of my studies in the preliminary phase that I report in this document are
demonstrating the action of the phytocomplex in mitigating the cellular development in vitro of an organism
template.
Furthermore
regarding in vitro studies
there is to take into account the sos test and the ames test as the sos test itself
admission also by the EFSA agency is not currently validated for genetic toxicology tests'
While the Ames test which consists of using Salmonella Thyphimurium bacteria)
as a model organism in which the gene for the production of the amino acid has been deficient
histidine necessary for the bacterium for development, in an agar culture medium, the role of the substance
genotoxic carcinogen and to reactivate the gene responsible for
production. of histidine restoring the development of the bacterial colony but such reactivation could
also being spontaneous is natural due to spontaneous mutations of the single colony moreover such test is not considered predictive, and cannot simulate the real internal condition of a
superior organism also considering the variant of the test which consists in adding to the soil
rat liver extract (S9) to simulate the biochemical and physiological action inside

of the organism which leads to the transformation of the procancerogenic molecule into carcinogenic metabolites.
But this in a eukaryotic organism is not so obvious, as there are a whole series of
DNA damage defense and repair mechanisms that are absolutely not comparable
to those of a prokaryotic cell which, as is known, is a cell with much more structure and *mechanisms*
simple compared to a eukaryotic cell
Last remark there is to say that it is not explained why the molecules were banned
present in Aloe and only the remaining anthraquinone plants have been taken care of, as studies phytochemicals demonstrate that aloe contains the lowest number of anthraquinone molecules compared to cascara, seine and buckthorn.

ORDER OF GREATER CONTENT OF HAD IN ANTHRACHINOMIC PLANTS:

CASCARA (Rhamnus Purshiana)
RABARBARO (*Rheum officinale*)
SENNA (Cassia acutifolia)
ALOE *spp.*
FRANGOLA (Rhamnus frangula L -)

CONTENTS ALOE EMODINA:
SENNA(Cassia acutifulia)
RABARBARO (*Rheum officinale*)
CASCARA (Rhamnus Purshiana)
FRANGOLA (Rhamnus frangula L.)
ALOE spp.

CONTENTS EMODINA
FRANGOL A (Rhamnus frangula L.)
CASCARA (Rhamnus Purshiana)
RABARBARO *Rheum officinale*)
SENNA (Cassia acutifulia)

ALOE spp.

PAOLO PELINI PRELIMINARY SCIENTIFIC STUDY:

STUDY ROLE OF HYDROXYANTHRACEN ON CELLULAR ACTIVITY

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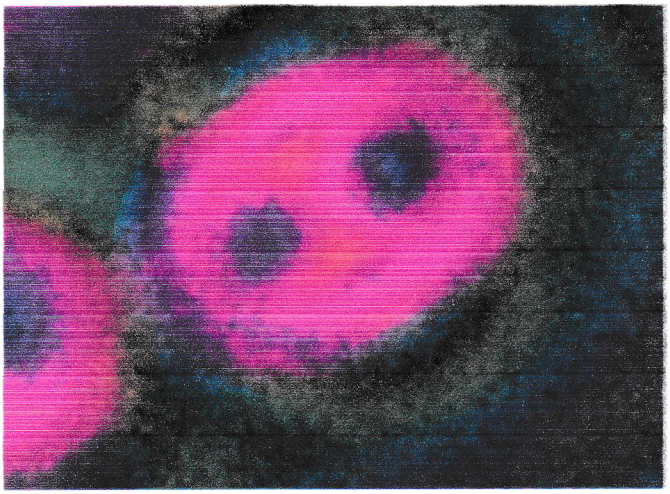
Abstract:

The purpose of this study was to determine the different action at cellular level in a biological model of Saccharomyces cervisiae yeast of single molecules of Hydroxyanthracene and the same action elicited by using the entire Aloe extract

STUDY DESCRIPTION:



Aloe ferox L. Anthraquinones were extracted from Aloin and Aloe

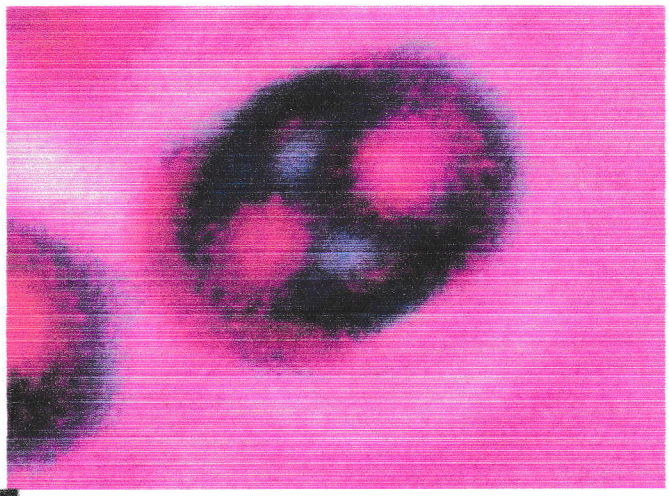
Emodin in ethyl acetate to mutate the biological model used for Saccaromyces Cervisiae, in

Nutrient Agar culture medium. In the medium where the cells were after 10 days where the cells

had been put in contact with a mixture of only Aloin and Aloe Emodin the cells appeared of

increased size and the nuclear activity was decidedly accelerated in the state of division

Anaphase **Fig. 1** and **Fig1A.**



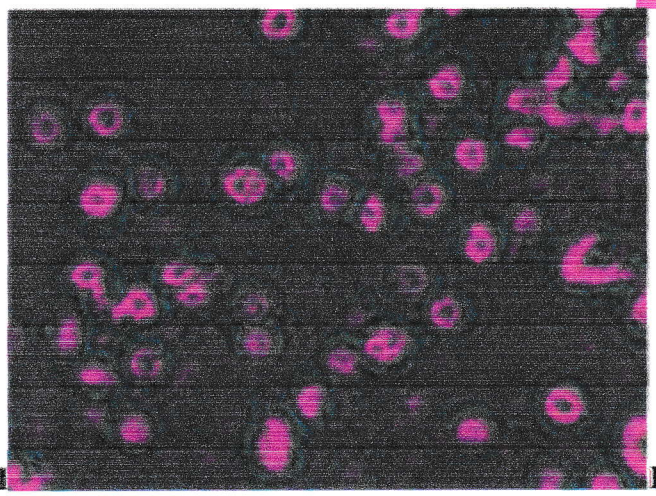


Fig1 **Fig 1A**

In the cells that came into contact with the phytocomplex **Fig1B**.

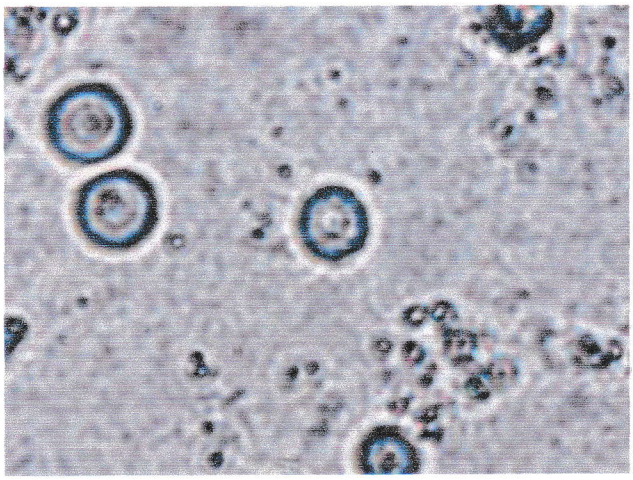


Fig1B

of the aloe plant, the

cells appeared in a quiescent or inactive state with dimensions and nuclear activity comparable to the control culture. In addition, it was possible to create a Genotoxicity scale of the single molecules of Aloe and Aloe Emodin where it was seen that Aloe Emodona has a greater genotoxic action than the metabolites resulting from the action of cytochrome P450 of Emodin and Aloin The aforementioned **Genotoxicity scale** is thus represented in order of toxicity from the most potentially genotoxic molecule to the lowest **Aloe Emodin> 2 Hydroxyemodin (Emodin Metabolite)> Emodin>**

Hydroxyemodin (Emodin metabolite)> Aloina s an inactive metabolity as it is transformed by cytochrome p450 into *Aloe Emodin* .

CONCLUSION:

All this suggests that if individual molecules may well have a role in mitotic acceleration and an influence on the nuclear activity of cells, these effects are mitigated if the entire Aloe extract and pool is considered.

Tale studio è pubblicato su i seguenti portali di Ricerca:

Zenodo Open Aire (CERN):

https://doi.org/10.5281/zenodo.5593834

ResearchGate:
http://dx.doi.org/10.13140/RG.2.2.36552.65284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