RISK ASSESSMENT OF CHAMOMILE AS A TEA INGREDIENT WITHOUT NEW ANIMAL TESTS

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ABOUT UNILEVER
EVERYDAY, 2.5 BILLION PEOPLE USE UNILEVER PRODUCTS

85% CONSUMER IN DEVELOPING AND EMERGING MARKETS

2017 TURNOVER: €53 BILLION
2017营业额530亿欧元

>190 COUNTRIES
我们的产品在190个国家有销售

169,000
EMPLOYEES WORLDWIDE 全球雇员

3 DIVISIONS

BEAUTY & PERSONAL CARE

FOODS & REFRESHMENT

HOMECARE
We use scientific evidence-based risk and impact assessment methodologies (基于科学证据的风险和影响评估方法) to ensure that the risks / impacts of adverse human health and/or environmental effects from exposure to chemicals used in our products, processes & packaging are acceptably low.
SAFETY & ENVIRONMENTAL ASSURANCE CENTRE (SEAC)

PROTECTING CONSUMERS, WORKERS & OUR ENVIRONMENT BY ENSURING UNILEVER’S PRODUCTS & PROCESSES ARE SAFE & SUSTAINABLE BY DESIGN

通过从设计上保障联合利华产品和工艺的安全以及可持续性来保护我们的消费者，员工以及环境

CENTRE OF EXCELLENCE – SAFETY & ENVIRONMENTAL SUSTAINABILITY SCIENCES
卓越的安全与可持续科学中心

APPLYING SCIENCE
应用科学

GOVERNANCE
监管

We provide scientific evidence to manage safety risks & environmental impacts for new technologies

ADVANCING SCIENCE
推进科学

NEW CAPABILITY
能力建设

We harness the latest science to create new tools to assess innovations of the future

SHARING SCIENCE
分享科学

COLLABORATION
合作

We partner with leading scientists from around the globe
Non-Animal Test (NAT) in tox risk assessment has become more widely accepted due to;

- Development of science, e.g. increased human relevance
- Change in some regulations, e.g. cosmetics
- Consumers’ preference, e.g. vegan food, animal welfare)

Unilever has over 30 years’ experience in developing non-animal approaches for assuring product safety, collaborating with more than 50 key partners across the world and it is still leading further development in this area.

Chamomile can be used as an example to show how risk assessment of a novel food ingredient can be conducted without generating new animal data.
HISTORY OF SAFE USE (HOSU)

• Risk assessment of (usually) botanical materials which have a long history of use in certain parts of the world.

• Successfully applied to safety assessment of Novel foods:
  • History of safe use as applied to the safety assessment of novel foods and foods derived from genetically modified organisms’. (Constable A., et al., 2007)

• Based upon:
  • Composition of the material
  • The period over which the material has been consumed
  • How the material has been prepared and used
  • Results of existing toxicology studies and observations from human exposure
CHEMICAL COMPOSITION OF CHAMOMILE FLOWERS

Chamomile flowers contain a range of constituents

- Essential oil (0.3 – 1.9%)
- Flavonoids (up to 6%)
- Sesquiterpene lactones (0.03-0.2%)
- Coumarins (0.01%-0.08%)
- Spiroethers (cis- and trans en-in-dicycloethers)
- Phenolic acid & Polysaccharides

When infused in hot water, the following typical representative composition is achieved

- Flavonoids and their glycosides max detected 14.5mg/200ml (Raal et al., 2012)
- Polyphenols max detected 69.1mg/200ml (Raal et al., 2012)
- Mucilaginous constituents (polysaccharides)
- 10-15% of the essential oil available in the flower
- Coumarins herniarin and umbelliferone are also soluble in hot water, especially matricin is extracted
LONG HISTORY OF USE AND CONSUMPTION

First known use: 1550 BC
Ingredient of several branches of traditional medicine, such as Unani (i.e. Arabian medicine), Ayurveda, etc.
Used to treat gastro-intestinal complaints such as flatulence, colic and diarrhea and hysteria, etc.

Middle ages: popularity grew when people turned to Chamomile as a remedy for numerous medical complaints
Means of application:
- Tisane: herbal infusion that can be ingested or applied externally
- Essential oil: mainly external use and as cosmetic product (skin or hair) or for aromatherapy

Consumed widely in many countries, prepared as an infusion in hot water
One of the most popular medicinal and aromatic plants in Europe and beyond
Present on Chinese market in over 1200 cosmetic products (Mintel), registered on CFDA positive list (2015)

Extensive use in range of food, cosmetic and medicinal preparation for a history of over 3000 years, across the world, including China
EXISTING TOXICOLOGICAL DATA

Acute toxicity: non-acute toxicant according to GHS

Sub-chronic toxicity: no toxic effects from limited study available
  • Chamomile flowers water extract was administered orally to rats at 100 mg/kg bw/day for 6 weeks. No significant changes in mean body weight, liver and kidney weight, plasma lipid profile and liver/kidney toxicity biomarkers were reported.

Genotoxicity: no evidence of genotoxicity from the available studies
  • Chamomile flowers essential oil and water extract was non mutagenic when tested in vitro (Ames, bacteria) and in vivo (SCE, mouse)
  • Evidence of anti-genotoxicity properties
  • According to EMA guideline, no further testing is required (EMEA/HMPC/107079/2007)
Human studies: the available clinical data demonstrate a good safety profile for Chamomile preparations in adults, children and pregnant women.

- No adverse events reported for the consumption of Chamomile water extracts (infusion)
- Non-serious adverse events reported for Chamomile dry ethanolic extract (mainly gastrointestinal disturbances) in adults (incidence rate between 0.14 – 0.4)

Allergenicity: rare reports of hypersensitivity reactions after exposure to Chamomile, including very rare cases of anaphylactic reactions in people consuming Chamomile infusion.
ESTIMATING CONSUMPTION

National dietary surveys often don’t specify chamomile consumption, frequently classified as tea and/or herbal infusion consumption because of identical consumption pattern. Using tea data will estimate daily worst-case chamomile intake.

Per capita standard tea (Camellia sinensis) consumption per year (Statista, 2016)

- United Kingdom 1.9kg
- China 0.54kg

Using UK consumption data will reflect worst-case intake scenario for the Chinese consumer

Summary statistics daily tea consumption (volume) for UK consumers on population

<table>
<thead>
<tr>
<th>Percentage total survey</th>
<th>Mean</th>
<th>Std Dev</th>
<th>P95.0</th>
<th>P97.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>63.9%</td>
<td>521.421ml</td>
<td>402.283ml</td>
<td>1260.0ml</td>
<td>1486.0ml</td>
</tr>
</tbody>
</table>

Maximum estimated consumption

\[
\text{daily P95 intake of tea (1260 ml)} \times \text{maximum amount of camomile per portion (3 g)} \\
\text{average portion size (220 ml)}
\]

In the UK, maximum estimated intake of Chamomile flowers (dry weight), 17g leaf tea per day, consumption in China should be significantly lower
SUMMARY & CONCLUSION

Summary:

✓ Chamomile preparations have one of the longest history of human safe use ever recorded
✓ Components do not raise any safety issues
✓ No evidence of genotoxicity in available studies
✓ No evidence of toxicity from limited acute and sub-chronic studies
✓ Good safety profile in clinical studies
✓ No concern regarding allergenicity (if labelled)
✓ Chamomile-based cosmetic ingredients are included in CFDA positive list

• Current regulations in China requires animal tests for the approval of new food ingredient

• Historical use of Chamomile infusion, combined with the toxicological and human data, supports its continuing use without further investigation.
IMPORTANT TO COLLABORATE & FORM STAKEHOLDER PARTNERSHIPS
The Unilever China Consumer Product Safety Collaboration Center has been established at our Unilever Global R&D Center in Shanghai to partner with public and private stakeholders in China and to collaborate in key areas underpinning the safety of consumer products such as foods, personal and homecare products.
THANK YOU
谢谢