# "How safe is Aspartame's ADI?"

"**ANS" Scientific meeting 9th April – Presentation notes by:-**

**James McDonald - UK Aspartame Awareness Campaign (UKAAC)**

---

Good Morning My name is James McDonald representing the UK Aspartame Awareness Campaign. My credentials are 35 years in the Methanol industry, in senior management positions…. I am here to Progress our challenge to the current ADI of aspartame, based on its Methanol content and new supporting evidence from the EFSA Draft Opinion…..

The current ADI of aspartame (40mg/kg) was established by Searle 40 years ago; ever since then, it has been universally accepted by all national food safety authorities, without any questioning of the original Searle assessment….

To achieve aspartame's ADI Searle fed the whole aspartame molecule to rats ignoring any possible toxicity from its constituents or breakdown products.
Searle explained its logic for this, they said "*If there was any problem with a particular component or breakdown product, it would show up in the testing*" We can find no evidence in the literature that shows any studies were carried out on aspartame's individual components or breakdown products to establish any possible toxic effects; with the exception of DKP.

Without a shred of evidence to support it, Searle leads us to assume that the NO-AELs of all aspartame's components and breakdown products are safe at 40mg/kg.

Let's look at what Searle left covered up and what successive Food safety authorities in 40years, have failed to discover.

| NO-AEL for aspartame **4000mg/kg** contains:- | | | New NO-AELs | New Aspartame ADI's |
|---|---|---|---|---|
| 10% | 400mg/kg | Methanol | 11.4m/kg | 1.14mg/kg |
| 50% | 2000mg/kg | Phenylalanine | 2000mg/kg | 40mg/kg |
| 40% | 1600mg/kg | Aspartic acid | 750mg/kg | 18.75mg/kg |

By any stretch of the imagination **an ADI of 40mg/kg for aspartame is too high**

By some coincidence the ADI based on Phenylalanine is correct but the other two components indicate the ADI should have been considerably lower, methanol and its 1st metabolite formaldehyde, the most toxic component – 35 times lower. Methanol – has been a well known severe metabolic toxin in humans for over 100 years - it was judged by Searle to be **"Not of Concern**"

The reason Searle's rats did not react to the 400mg/kg of methanol in Searle's NO-AEL, is because rats are at least 15 times more resistant to methanol than humans. The LD50 for rats consuming methanol is 5628mg/kg - 400mg/kg of methanol is like a food to them.

The current ADI of aspartame is wrong - because the NO-AEL in Searle's 1970's studies is wrong. Scientists believe the effect of a NO-AEL of aspartame in rats is supposed to be directly transferrable to humans…. but is it? As we saw above the 10% Methanol in Searle's NO-AEL of aspartame is 400mg/kg… the lethal dose of pure methanol in humans is 343mg/kg,… Therefore / if an acute dose of 4000mg/kg of aspartame was administered to a human - the methanol content alone would probably kill them in days - Please note:

**A NO-AEL of Aspartame in RATS…..Is NOT a NO-AEL of METHANOL in humans.** (Repeat)

EFSA, in this full review of the safety of aspartame did not review or reassess the safety of aspartame's ADI ??

**This omission alone renders the entire DRAFT OPINION UNSAFE**

In 2009 using publically available scientific data from the MSDS (Material Safety Data Sheet) for methanol, we established a blinding dose of methanol in humans to be 114mg/kg, the fatal dose to be 343mg/kg and a conservative NO-AEL of 11.4mg/kg

The simple calculations and logic which supports our new evidence has been suppressed by FSA and EFSA since 2009 they have never acknowledged challenged nor refuted our work, they simply ignore it. …Risk assessment agencies failing to include the toxicity of aspartame's most dangerous chemical, when establishing an ADI of a product intended for use in our food, are surely **guilty of gross negligence.**

Methanol is aspartame's best kept secret but its 1st metabolite FORMALDEHYDE is the real killer / this is not a popular scientific view. It is one hypothesised in a new book "While Science sleeps" by Woodrow C. Monte. Monte is Emeritus Professor of nutrition and food sciences, Arizona State University; he is a Long term US aspartame campaigner and provides the science supporting our work.

In 2009, 2010, 2011, 2012 and 2013 we made EFSA and FSA well aware of our concerns over aspartames methanol & formaldehyde. We offered our new evidence for consideration in the last 2 aspartame reviews – Our offer was refused both times and this Draft Opinion again makes no mention of our work -
**How can you have a Risk Assessment and not include ALL the evidence.**

---

Our families have been unknowingly consuming excessive levels of aspartame constituents for 30 years - 35 times more methanol and formaldehyde and more than twice the DKP and aspartic acid. It is alarming to think what the long term health consequences of this might be – anecdotal evidence perhaps?

It is now time to mention the **UK- Hull Pilot Study; S**et up by FSA in 2009 it seeks to examine people who declare sensitivity to aspartame, to see if they are telling the truth. This first nationally funded study directly challenges the safety of aspartame; unfortunately, the original 18 month Pilot Study is now two and a half years late, its budget is overspent by 200% - and the results are not now due until June this year.

In correspondence with EFSA in 2010, 2011 and 2012 we insisted that the Pilot Study results were of such importance, that a full review of aspartame without including them would **render any opinion unsafe** –FSA has shared its results with EFSA, yet the Draft Opinion does not even mention the Pilot Study???
**How can you have a Risk Assessment and not include ALL the evidence –** also what did FSA reveal to EFSA?

---

How can EFSA justify its claim that aspartame is safe, whilst relying predominantly on ancient, biased industry studies. COT in 1992, after receiving questions on their decision to accept these early animal studies replied -*"The flaws do not invalidate the conclusions of the studies and that they can be accepted as part of the safety evaluation of aspartame"* and so it remains today 20 years later.
-
**How can any responsible risk assessment body, accept such conclusions as credible after 40 years**?

With 30 years experience of aspartame in our food / the benefit of advances in modern testing techniques / new and innovative scientific thinking and a wealth of independent scientific and anecdotal evidence, contradicting the claim that aspartame as safe. It is high time we brought all this to bear in a new independent review of aspartame, operating on the precautionary principal –

**"Aspartame is not safe, until unequivocally proven otherwise**"

For all these reasons we believe this Draft Opinion to be flawed, unsafe and does not confirm the safety of aspartame. We call for it to be set aside and a new independent group formed to review aspartame again, taking account of ALL the evidence available.

Any new review must first establish an unquestionable, safe, NO-AEL and ADI for aspartame. Without these the review will be compromised.

James McDonald (UKAAC) 28th March 2013 bigmac2@freenetname.co.uk