Diacetyl and acetyl propionyl in the news, yet again.

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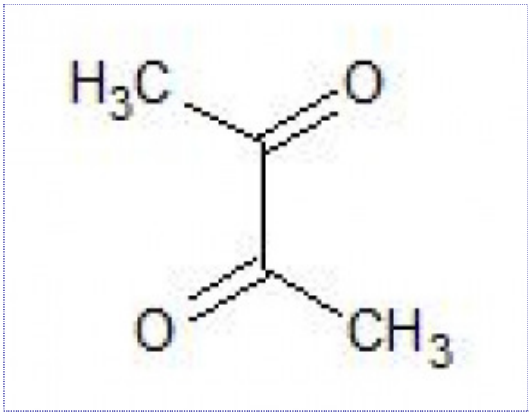
10, Dec, 2015

By Tom Pruen



A recent study conducted by researchers at the T.H. Chan School of Public Health (part of Harvard University) examined levels of three flavouring compounds in refills and liquids for e-cigs[i].

What was done?

The exact detail of what was tested is a little unclear, since details of the hardware tested are not included:

"Electronic cigarette cartridges, liquids, and their associated devices and batteries were purchased online and in retail locations."

Clearly some of these were prefilled or disposable products, while others were liquid, with a variety of hardware. No information seems to have been recorded about design, capacity, resistance, power or even brand of hardware for the liquid tests.

Samples were collected using a filter (validated by the capture of powdered flavouring, which seems suboptimal), using a rather extreme eight second puff. Samples were collected until the products stopped producing vapour, so the number of puffs taken will have been dependant on the volume of the tank/cartomiser used.

Blank samples were also taken, although four out of seven of these, rather oddly, showed detectable levels of the flavourings of interest. These values were used to correct detected levels.

What was found?

The flavourings were reported in levels of micrograms per e-cigarette. This potentially skews the results, since the size of the tank or cartomiser used was not reported. Larger tanks/cartomisers will have produced more puffs and, even if the levels in the liquid were lower, overall more diacetyl (DA) and acetyl propionyl (AP) will have been

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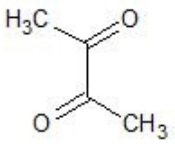
Detected levels ranged from undetectable, for all compounds to maxima of 239 µg/e-cig for DA, 64µg/e-cig for AP and 529 µg/e-cig for acetoin. However, all these maxima are from a single sample. Almost all samples were below 20µg/e-cig for DA and AP. Levels of acetoin detected were more varied.

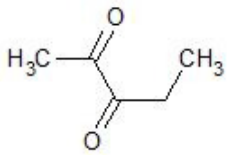
Since neither the volume of liquid used, nor the number of puffs was reported, it is not possible to relate the values back to a concentration in liquid, or in vapour.

The wider context

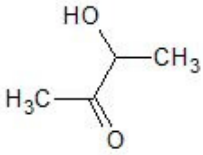
There is some confusion about the risks associated with these flavouring chemicals. In our view (and indeed that of our toxicological consultants), the available data does support a risk associated with the inhalation of DA and AP at high levels. The risk is of damage to the lungs known as 'popcorn lung' as it was first found in workers exposed during the production of popcorn, but is more correctly called Bronchitis Obliterans (BO). BO is a very specific type of inflammation and fibrosis (effectively scarring) of tissue within the lung, leading to a permanent reduction in lung function. Similar data does not exist for acetoin, and while both DA and AP are structurally very similar, acetoin is somewhat different. (Both DA and AP are short chain di-ketones, while acetoin is a monoketone, with an alcohol group in place of the second ketone).



Diacetyl



Acetyl propionyl



Acetoin

Based on the available data, the toxicological assessment we had carried out estimated that a level "as a puff concentration, might be expected to be protective against an increased early onset of this disease [BO]" for both DA and AP was 3.6mg/m^3. This can be back-calculated to a level in liquid, using some reasonably conservative assumptions, 0.01ml of liquid vapourised into a puff of 55ml with no dilution (there will be a peak concentration which is rapidly diluted by continuing inhalation of air), of 20µg/ml.

Since the levels for almost all fell below 20µg, and most products fell below 10µg for a whole 'e-cigarette', it would seem implausible that many levels would exceed this threshold, and in fact most are going to be significantly below it.

The equivalent limit for acetoin was 1.53g/m^3, corresponding to a level in liquid of 8.4mg/ml

(A word of caution, however – these assumptions apply to standard use of an e-cig, more extreme use patterns, such as 'cloud chasing', don't really have any available data on liquid vapourised per puff, and may well fall outside of this).

On the basis of this, while the chemicals were detected, these levels (in almost all cases) do not appear to be at levels which would create an intolerable level of risk. It should be noted, however that the existing occupational limits would also imply a tolerable daily dose of 60ug, evenly spread, and this might be exceeded using some of these products.

However, it should be noted that levels of DA in cigarettes are approximately 350µg/cigarette (Fujioka and Shibamoto, 2006)[ii]. **As such, if there is a risk associated with DA and AP in e-cigarettes it is still significantly lower than the risk associated with the levels found in cigarettes, even before the other components of smoke (which are absent from e-cigs) are taken into account.**

ECITA has always maintained a policy that DA and AP should not be used as flavourings for electronic cigarettes, and this is a policy we will maintain. Our policy has resulted in some of our member companies having to recall products, when routine testing has detected unacceptably high levels.

This was also reflected in the British Standards Institution PAS 54115 (which we sponsored and provided Technical Authorship for), with the support of the Steering Group. The French trade association, FIVAPE, also included it in the Afnor experimental standard it produced. Other trade associations, such as Canada's ECTA have introduced more nuanced limits[iii], and there is a general consensus that levels of these chemicals need to be controlled and minimised. The industry as a whole is committed to improving the safety of its products, and this is a trend we can expect to continue.

We have been pleased to see the awareness of this issue spreading in the industry, in no small part because of active research into this (for example some very good work carried out by Farsalinos et al, 2015[iv]. Dr Farsalinos has also commented on the Harvard study, and this is also worth a read[v]). This still needs to be put in the context of the purpose and use of e-cigarettes – they are a harm reduction alternative to smoked tobacco, and this evidence does nothing to disprove that.

The take home message

The use of e-cigarettes is much safer than continuing to smoke, and this is the message that MUST be delivered to smokers if lives are not to be recklessly endangered by inappropriate risk communication.

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[i] http://ehp.niehs.nih.gov/wp-content/uploads/advpub/2015/12/ehp.1510185.acco.pdf

[ii] http://onlinelibrary.wiley.com/doi/10.1002/tox.20153/pdf

[iii] http://www.ectaofcanada.com/pagedisp.php?section=E-Liquid_Testing

[iv] http://ntr.oxfordjournals.org/content/17/2/168.short

[v] http://www.ecigarette-research.org/research/index.php/whats-new/whatsnew-2015/236-da2

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Comments

Diacetyl detected in blanks

Permalink Submitted by Chris Price (not verified) on Thu, 2015-12-10 16:26

Detection of target compounds in blanks or clean chambers generally indicates that blanks were tested after the main test samples. The test equipment was contaminated by previous samples.

This is a problem frequently seen in ecig vapour testing carried out by researchers who normally test cigarette smoke, as they cannot comprehend the contamination issues. The problem is that cigarette smoking machines or even ad hoc rigs do not behave the same way with smoke and liquid-based aerosols ('vapour'). Alcohol-based excipients with flavourings provide far more severe cross-contamination problems than smoke, and most researchers appear unqualified to deal with such issues. For example, the inter-sample cleaning protocols need to be part of the listed protocols for such studies, where any credence is expected to be given to the results.

For junk science such as the quoted study, with no documented test samples or test materials or protocols of any kind or reference sample, the best description is incompetent junk cooked up by amateurs for the purpose of funding applications. It's a successful business model.

As science, a class of 14 year olds can do better, under instruction from a decent teacher.

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