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I: * Oggetto: R: RICHIESTA INTERVISTA - CIGNARALE REPORT**
1 messaggio

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A: [CG] Redazione Report
Oggetto: Re: *** Oggetto: R: RICHIESTA INTERVISTA - CIGNARALE REPORT

Gentili Signori,

Abbiamo ricevuto la vostra comunicazione e non possiamo non segnalarvi le nostre perplessità in ordine ai dati ivi riportati, che non ci risultano corretti e in relazione ai quali, in ogni caso, non riusciamo a comprendere la metodologia scientifica utilizzata.

Ciò posto, desideriamo sottolineare che tutti i nostri prodotti sono frutto di rigorosi studi e rispettano scrupolosamente i limiti stabiliti dalle normative vigenti.

A conferma di quanto precede, con particolare riferimento alle IWIK, alleghiamo il report redatto dalla nostra consulente scientifica.

Attenzione, la presente mail proviene da un mittente esterno alla rete aziendale RAI

Cordiali saluti,

KIWI

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Toxicological Summary Assessment for IWIK vape devices: Lead and Nickel

Confidential

Date: October 5, 2023
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1. Manufacturers product testing

This summary report has been written to document the toxicological assessment of IWIK vape devices based. This assessment has been conducted independently based on the available provided to Inter Scientific LTD. All assumptions underpinning the toxicological risk assessment have been presented within the document.

Assessment of toxicological exposure of metals has been performed for IWIK vape products. Testing was performed by Shenzhen TCT Testing Technology Co., Ltd. on May 31, 2022. Toxicological assessment of IWIK vape products is based on aerosol analysis (report no. TCT220526C013) applying International Standards (ISO) and French National Standards (AFNOR XP D90-300-3:2016) using ICP-MS with a detection limit of 0.0001µg/puff for Lead and Nickel. The results of testing are presented in the table below:

Table 1: Aerosol results form IWIK vape product testing by ICP-MS

Metal	CAS	Units	LoD	Result
Lead (Pb)	7439-92-1	µg/100 puffs	0.01	Not Detected
Nickel (Ni)	7440-03-0	µg/100 puffs	0.01	Not Detected

Product testing conforming to appropriate ISO standards, using validated methods as demonstrated non-detected heavy metals in the aerosol.

The data presented from the manufacturer was conducted in an independent testing laboratory.

2. Metals exposure and safety through inhalation

The safe level for metals inhalation can be derived from internationally recognised guidance, such as ICH Q3D, which permits a maximum daily exposure as follows:

- Lead = 5µg/day
- Nickel = 6µg/day

The French National Standard published by AFNOR, cites reasonable and foreseeable use of vape products to be up to 200 inhalations per day.

The maximum safe level of heavy metals, based on internationally recognised guidance is therefore:

- Lead = 25ng/inhalation
- Nickel = 30ng/inhalation

Published international standards for 'standardised' vape volume is defined as 55mL based on ISO 20768:2018. The above cited limits may therefore be converted to:

- Lead = 25ng/55mL inhalation
- Nickel = 30ng/55mL inhalation

The industry generated draft publicly available specification PAS 8855:2023 provides the following levels permitted in vaping products before a toxicological risk assessment being needed:

- Lead 50ng/100mL aerosol
- Nickel 50ng/100mL aerosol

Note: it is noted that the values set out in the BSI PAS are normalised values against the ICH Q3D threshold based on a 55mL inhalation volume (ISO20768:2018/Coresta CRM 81). Using these values is considered to result in an equivalent safety evaluation when using a standardised puff volume.

3. Toxicological Assessment of Metals in IWIK vape products:

Lead

Using the maximum level possible level determined in the manufacturers analysis, following internationally recognised standards for puffing topography (ISO 20768:2018), that being the reported limit of detection of the analytical method of 0.01µg/100 inhalations and using reasonable and foreseeable use patters as set out by AFNOR of 200 inhalations per day, and applying the permissible daily exposure (PDE) levels accepted within pharmaceutical products for inhalation, set out in ICH Q3D, the following toxicological evaluation and safety calculation has been determined:

Maximum possible lead from manufacturer testing: 0.01µg/100 inhalations
Foreseeable daily use = 200 inhalations
Maximum foreseeable lead exposure per day = 0.02µg per day

ICH Q3D safety threshold for lead = 5µg/day

Safety factor = 5µg per day/ 0.02µg per day exposure

Safety factor = 250

Based on a safety factor of 250, there is negligible toxicological risk assessed from reasonable and foreseeable use of IWIK vape products with respect to lead exposure.

Nickel

Using the maximum level possible level determined in the manufacturers analysis, following internationally recognised standards for puffing topography (ISO 20768:2018), that being the reported limit of detection of the analytical method of 0.01µg/100 inhalations and using reasonable and foreseeable use patters as set out by AFNOR of 200 inhalations per day, and applying the permissible daily exposure (PDE) levels accepted within pharmaceutical products for inhalation, set out in ICH Q3D, the following toxicological evaluation and safety calculation has been determined:

Maximum possible lead from manufacturer testing: 0.01µg/100 inhalations
Foreseeable daily use = 200 inhalations
Maximum foreseeable nickel exposure per day = 0.02µg per day

ICH Q3D safety threshold for nickel = 6µg/day

Safety factor = 6µg per day/ 0.02µg per day exposure

Safety factor = 300

Based on a safety factor of 300, there is negligible toxicological risk assessed from reasonable and foreseeable use of IWIK vape products with respect to nickel exposure.

5. Conclusion

Based on the data available from the manufacturer it has been possible to determine a safety factor for exposure of both lead and nickel. The lowest safety factor of 250 has been determined from reasonable and foreseeable use of IWIK vape products. A safety factor of 250 is large and so the toxicological risk from lead and nickel exposure is considered to be considerable low and far below that which would be expected from some pharmaceuticals.

To conclude, from the data available for the determination of toxicological assessment, there is sufficiently large safety factor to conclude that the risk presented from use of IWIK in relation to lead and nickel exposure is of low risk.

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Date: October 5, 2023