

RESEARCH TRENDS

HEAVY METAL IMPURITIES

- An Insight on reality of Cosmetic safety concern

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Periodically we must have seen sensational newspaper articles with headlines "Cosmetics horror: Nickel on your lips, mercury on cheeks". Such articles are based on some analysis reports of heavy metal impurities in leading cosmetic brands. This creates lot of concern in common consumers mind whether the reputed brand of cosmetics they use are really safe? This news creates ripples for some time and we may find news reporters



Contents

- 01 Heavy Metal Impurities
An insight on reality of
Cosmetic safety concern
- 03 Cosmetic Safety
Assessment
Challenge and Opportunity
- 04 ISCC Events 2014
A lookback on past events
- 06 Report of ISCC
Central Zone, Nagpur
Chapter
- 07 Events Calendar
A list of upcoming ISCC
events as well as Cosmetic
and Beauty Industry events

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interviewing executives of cosmetic companies. And then news subsides and everybody continues to use their favourite colours and brands.

What are heavy metals?

A heavy metal is a toxic metal. There is no standard definition assigning metals as heavy metals.

Examples of heavy metals include lead, mercury, cadmium, sometimes chromium. Less commonly, metals including iron, copper, zinc, aluminium, beryllium, cobalt, manganese and arsenic may be considered heavy metals.

Some metals play important roles in normal functions of the body. For instance, iron is necessary for blood oxygenation. However, when these metals accumulate they may have serious negative effects. Chromium is required in minuscule quantity for metabolism of glucose and fat. Copper is an element required for potent anti oxidant in body called SOD (super oxide dismutase)

Other metals, such as lead and mercury, do not have normal physical functions in the body. Cancerous breast biopsies show higher accumulations of iron, nickel, chromium, zinc, cadmium, mercury and lead than non-cancerous biopsies.

How heavy metals get contaminated in cosmetics

Heavy metals are found naturally in the environment in rocks, soil and water, and may therefore be found in pigments and other raw materials in all industries including the cosmetics industry.

In natural environment there is always a complex mixture of different elements. Many cosmetic raw materials come from mined sources or further modified by chemical process to purify them or further synthesis. In the process the traces of different elements which were present in the source raw material will remain as trace impurities. It is impossible to totally eliminate these traces.

RESEARCH TRENDS

When a cosmetic raw material is used it requires conscious understanding that how much of these trace impurities are permissible.

Who monitors the safety of cosmetics?

The safety of human being and animals are the main concerns of various governments across the globe. This is the prime purpose of formulating the laws for food drug and cosmetics. Forerunner of these laws is American drug and cosmetic act 1938.

This was soon followed by different countries formulating drug and cosmetic laws in their own format. These drug and cosmetic laws stipulate what kind of toxic or harmful ingredients should not be used and if impurities are present what is the permissible limit.

Heavy metals are toxic materials and are regulated in different drug and cosmetic laws of different countries.

General guidelines on limit of heavy metals based on exposure level

Across the globe there is no absolute consistency about which metals are considered as Heavy metals. The permissible limit specified is also not very consistent.

Harmful effect of heavy metals in human system is well documented. These toxic effects that manifest are based on degree of exposure. The limits are very stringent. Even



in this case quantity of consumption is taken into consideration and frequency of usage. Water is the highest consumption item and the permissible limits are extremely low.

All cosmetics are superficially applied and the exposure to harmful ingredients is through dermal exposure. Dermal absorption of heavy metals is typically low, with absorption of individual elements influenced by a number of factors including physical-chemical properties of the mixtures. Oral exposure can occur for cosmetics used in and around the mouth, as well as from hand-to-mouth contact after exposure to cosmetics containing heavy metal impurities. Inhalation exposure is expected to be negligible.

There are currently no common international standards for heavy metal impurities in

cosmetics. Each country has their own specifications for individual raw materials.

If we refer various country specific heavy metal impurity specifications we come across one somewhat common level.

Lead 20 PPM Maximum
Arsenic 3 PPM Maximum
Mercury 1 PPM Maximum

Regarding other heavy metals there is no uniformity of limits specified.

In India Drug & cosmetic act specifies heavy metals to be checked together as estimated as lead not exceeding 100 PPM. This includes all heavy metals without any specific mention.

Attached below is a comprehensive list of permissible heavy metals in cosmetics in different countries. As you may notice specifications have

been stipulated based on nature and source of raw material and possibility of other elements naturally coming along with intended items.

It is to be noted that some raw materials like Iron oxide can contain as high as 500 PPM of heavy metals other than lead (Refer EU spec). These raw materials are considered as safe based on usage pattern and dermal penetration being very low.

Understanding newspaper reports

Newspaper reports are highlighting Chromium and nickel traces found in lipsticks made by various reputed brands marketed in India. Before proceeding further we should know the current international standard for these metals Tolerable Daily Intake (TDI) Values from US EPA

(mg/kg-d)	
Chromium III	1.5
Chromium VI	0.003
Nickel	0.02

Exposure level of these metals in our daily life

Chromium and nickel are widely spread elements on earth. We find chromium in natural

drinking water, food grains and vegetables. Stainless steel contains 17% chromium and around 3% nickel. All our food processing storage, daily use utensils, machinery parts etc are made from stainless steel. Apart from this Chromium oxide green is a trivalent chromium compound a permissible colour in cosmetics.

As per WHO study estimated total intake of chromium from air water and food in UK is between 0.078 mg to 0.106mg /per day. The mean gastric absorption is less than 5%.

Guideline value set up by WHO for drinking water for Chromium is 0.05 mg/litre. UK expert group recommends 0.15mg /kg body weight maximum chromium exposure from foods. In other words maximum tolerable level of 10mg of chromium for a 60 kg body weight.

What is reported?

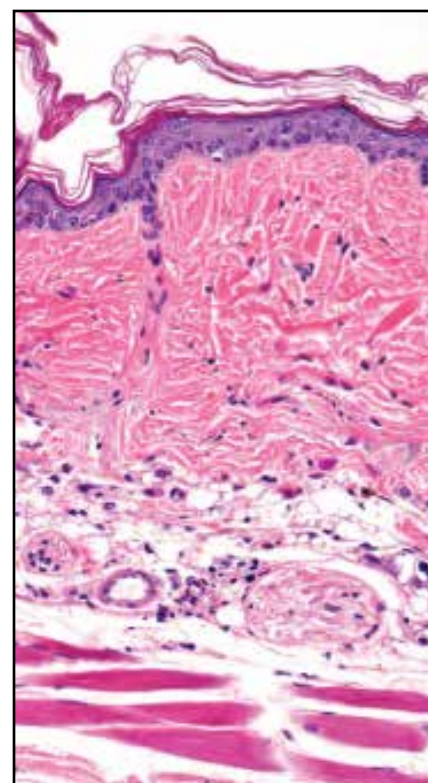
Some newspaper articles which have highlighted heavy metals in cosmetics are based on reports of certain agencies who have conducted this monitoring of heavy metals in cosmetics. They have based a concern on human exposure a probable harm. For example they have considered threshold limit of 0.0001 mg Chromium as ADI (average daily intake). This is actually a permissible limit for air inhalation particulate matter for

chromium (VI) for 50 kg person per day. None of the cosmetics contain hexavalent chromium. Strangely their calculations are based considering cosmetics like food items, multiplying average daily consumption and level of heavy metals found and using this figure as ADI (average daily intake). The assumption is 100% absorption when these products are applied on skin. Finally their report shows that these cosmetics contain 500 to 1500% permissible ADI. This is absolutely incorrect and an exaggeration beyond limit. Internationally there are different permissible limits for air water foods and cosmetics. We should not confuse and use one yardstick for others.

Conclusion

As of now Indian standards for heavy metal impurities in cosmetics is adequate. We should not get unnecessarily disturbed by sensational newspaper reporting. If at all the reported heavy metal impurities in cosmetics are considered beyond permissible level for cosmetics FDA should take appropriate action.

RESEARCH TRENDS



COSMETIC SAFETY ASSESSMENT— A CHALLENGE & AN OPPORTUNITY

The cosmetic industry has grown significantly in recent years, both in size as well as in complexity. Associated with the recent developments in novel ingredients, product formats and claims are the rapid changes in cosmetic regulations within India as well as internationally, which need a high level of focus. Formulators as well as ingredient suppliers need to have much greater understanding of the regulatory climate in order to navigate smoothly through the maze of Cosmetic Regulations.

One of the important aspects within cosmetic regulations is the area of Safety Assessment. With the EU, Israel and India imposing a ban on animal testing for cosmetics as well as import of cosmetics tested on animals, and some other countries contemplating the same; conventional safety assessment approach has been turned on its head and the cosmetic industry now needs to move even more rapidly towards incorporating newer alternatives in their safety assessment programme.

Skills associated with category-specific product safety assessment of formulations, raw materials, ingredients and additives as well as toxicological risk characterisation, exposure assessment and risk assessment are emerging requirements that are going to be mainstay and need special attention. Data mining and Data gap analysis – Read across, Group and Category approach by S.A.R., Q.S.A.R., T.T.C., AOP, Weight of Evidence (WoE), In-silico prediction of toxicity using OECD toolbox, EPA-Oncologic, Episuite, Toxtree, Japan and EU open source software as well as commercial software such as DEREK, TOPKAT, etc. coupled with validated alternate in-vitro techniques will see increased usage as preliminary methods to establish safety, prior to conducting human volunteer studies.

While on one hand, safety in cosmetics and toiletries is of prime importance, as only safe products should be allowed to be used by consumers; on the other hand, any human testing must be scientifically

HEAVY METAL IMPURITY SPECIFICATIONS IN DIFFERENT COUNTRIES FOR COSMETICS

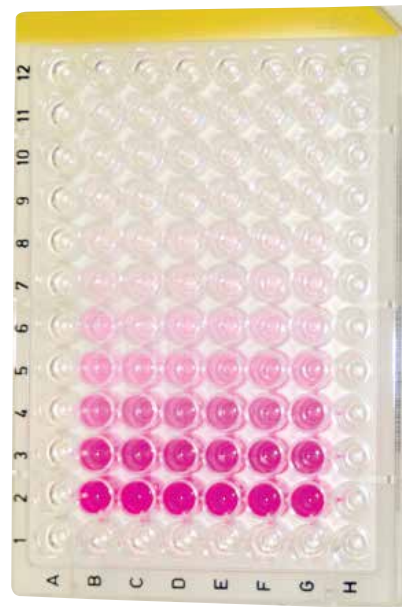
Product	Lead	Arsenic	Mercury	Nickel	Cobalt	Antimony	Cadmium	Copper	Zinc	Chromium	Heavy metals
Specification in USA											
D & C red 31	20	3	1								
Bismuth oxy chloride	20	3	1								
Chromium hydroxide green	20	3	1								
Ferric ferro cyanide	20	3	1	200	200						
Titanium Dioxide	10	1	1			2					
Zinc oxide	20	3	1				15				
Iron oxides	10	3	3								
Limits for Cosmetics in CANADA	10	3	3			5	3				
Limits for cosmetics in Germany	20	5	1			10	5				
Iron oxide E 172 EU cosmetics dir	20	5	1	200			5	50	100	100	
Limits in India as per D&C act 1940	20	2									100

justified, as unjustified and indiscriminate testing is unethical. This brings to the fore the role of the safety assessor in-charge of product safety evaluation, who needs to decide whether each new formula represents a minor adaptation without toxicological significance, a toxicologically important modification, or a new technological concept. Safety assessor's decision will become an important aspect of the safety-testing programme that is adopted.

Development of simple, cost effective and fully validated alternate methods covering each and every aspect of product safety is also an important area for consideration. With our honorable Prime Minister making a fervent

appeal to 'Make in India' a reality, it is an opportunity for eminent toxicologists across India to play a major role in leading as well as being part of the global validation programmes currently underway.

Changes in the regulations pertaining to cosmetic safety testing have thus opened avenues for new skills to be developed as well as for new roles within organizations in order to ensure that safety of the end user is not compromised. Tracking the developments that are taking place globally will help organizations to be updated on the most recent advances in this area; which would go a long way towards implementing the best practices towards ensuring safe cosmetics.



The author **Benedict M. Mascarenhas** is CMD of **EnvisBE Solutions Pvt. Ltd.** and **Honorary Secretary of The Indian Society of Cosmetic Chemists (ISCC)**. For further details, you can send your emails to ben_mas@envisbesolutions.com / ben.iscc.in@gmail.com

ISCC PAST EVENTS

1

HPCI 2014

Indian Society of Cosmetic Chemists (ISCC) organised a one day Seminar on "Emerging Trends in Cosmetics - Global Scenario". The seminar was well received by cosmetic industry with total 95 participants. The conference covered practical science and cutting edge industry development in the Global scenario. Eminent scientific, marketing, technical and regulatory experts of national and international repute contributed to the conference by sharing their knowledge with the participants.



2

One Day Conference on Current Regulatory Requirements for Cosmetics

Indian Society of Cosmetic Chemists (ISCC) in collaboration with Oil Technologists' Association of India - West Zone (OTAI-WZ) organised a one-day conference on "Current Regulatory Requirements for Cosmetics" on 7th of March 2014 at Courtyard Marriott (Mumbai) in order to provide an overview of the recent changes in the Indian Cosmetic Regulations, so that the cosmetic industry as well as all those involved with cosmetics are better poised to understand and comply with the requirements. The Indian Home & Personal Care Industry Association also supported this event.

The conference was organised with the aim of creating awareness about the changes introduced by Indian government in the Drugs and Cosmetics Act with regards to import of cosmetics, local manufacture and safety testing of cosmetics with the 3-fold objective of harmonizing the requirements with what is being followed internationally, better monitoring the influx of cosmetics coming into the country and providing better quality products to the consumer. Eminent legal experts and industry veterans shared their knowledge and experience on this subject for the benefit of the participants.



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REPORT OF ISCC - CENTRAL ZONE - NAGPUR CHAPTER

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Dr. Farhat Daud, Secretary (LAD College For Women, Nagpur)

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Ms. Smita Fadnis (Nikalas Mahila Mahavidyalaya, Nagpur) – Newsletter

Dr. Sangita Sahasrabuddhe & Mrs. Sana Ahmed (LAD College For Women, Nagpur) – Seminars & Workshops

Mrs. Shubhangi Chande & Dr. Seema Somalwar (Nikalas Mahila Mahavidyalaya, Nagpur) – Education

Dr. Jayashree Hazare & Mrs. Priya Digarse (LAD College For Women, Nagpur) – Books and Journals

Mr. Nagar Naik (Qualichem Laboratories, Nagpur) – External Speakers

RECENT ACTIVITIES



From L to R – DR. SHEELA KULKARNI President ISCC Central Zone, Dr. ADINATH WARE, GM –Technical Support, NV Organics, Delhi, Dr. HARSHA JHARIA, Vice Principal, LAD, MR RAVI KHANNA Marketing Mgr, and MS ANKITA JAIN, Mgr Tech Support, N V Organics.)

1

A Seminar cum Workshop was organized by Indian Society of Cosmetic Chemist, Central Zone in collaboration with Association of Cosmetic Technologist and Cosmotech Alumni Association of L.A.D at Dept of Cosmetic Technology, LAD & Smt. R.P. College For women Nagpur on 'Innovative Preservation Concepts and New age Emulsifier and Oil Components' and 'Phospholipids in Personal Care'. A Quiz was also conducted in which students won several prizes.

Dr Sheela Kulkarni, President ISCC CZ and HOD Dept of Cos Tech, LAD College welcomed the guests. Dr. Deepak Wasule, Dr. Farhat S.Daud, Dr. Sana Ahmed, Dr. Nibha Bajpai worked hard for the success of the programme.

Speakers – Mr. Ravi Khanna, Marketing Manager, Dr. Adinath Ware, GM-Technical. Ms Ankita Jain, Manager- Technical support and marketing (Alumni of Department of Cosmetic Technology).

2

A UGC sponsored National Seminar was organised by Department of Chemistry, S. S. Girls College Gondia in association with ISCC Central Zone S. S. Girls College, Gondia on 'The Chemistry of Cosmetics and its impact on Human health'. All Members of ISCC, CZ attended and presented research presentations.

PROMINENT ISCC MEMBERS PRESENT

Mr. Benedict Mascarenhas, Hon. Secretary, ISCC Mumbai – Key Note Speaker and presided over the function

President, ISCC Central Zone Dr. S. Kulkarni – Member of Legal Advisory committee and Chairperson for the Technical Session

Secretary Dr. F. Daud – Member of Editorial Board and coordinated for Research Presentations.

Dr. Seema Somalwar – Speaker, Tech Session

MEMBERS OF ISCC CENTRAL ZONE WHO WON PRIZES

Dr. Farhat Daud – 1st Prize Poster Presentation

Dr. Nibha Bajpai – 2nd Prize in Poster Presentation



From L To R – DR. MADHURI NASERE, Dean of Home Science, RTM Ngp University, DR. SHEELA KULKARNI, President, ISCC CZ, MR. BENEDICT MASCARENHAS, ISCC Hon. Secretary and CMD, EnvisBE Solutions Pvt. Ltd, Mumbai

EVENT CALENDAR 2015

COSMETIC AND BEAUTY INDUSTRY EVENTS 2015



HPCI 2015
MUMBAI INDIA
4 - 5 MARCH 2015

PCHI 2015
GUANGZHOU CHINA
12 - 14 MARCH 2015

COSMOPROF
BOLOGNA ITALY
20 - 23 MARCH 2015

IN-COSMETICS EUROPE
BARCELONA
14 - 16 APRIL 2015

NYSCC SUPPLIERS DAY 2015
EDISON N.J. USA
12 - 13 MAY 2015

GLOBAL REGULATORY SUMMIT
BRUSSELS BELGIUM
19 - 20 MAY 2015



BEAUTYWORLD MIDDLE EAST
DUBAI UAE
26 -28 MAY 2015

IFSCC CONFERENCE 2015
ZURICH SWITZERLAND
21 - 23 SEPT 2015

IN-COSMETICS BRAZIL
SAO PAULO BRAZIL
30 SEPT - 1 OCT 2015

IN-COSMETICS ASIA
BANGKOK THAILAND
3 - 5 NOV 2015

COSMOPROF ASIA
HONGKONG CHINA
11 - 13 NOV 2015

ISCC UPCOMING EVENTS

ISCC - Events Calendar 2015

SPF Regulations	July 2015
Industrial visit for students	August 2015
Lecture on Hair care	September 2015
PICASSA	October 2015

* Participation in ISCC Workshops is free for ISCC members. Charges for non-members vary according to the workshop. Additional Workshops and Conferences will be communicated through ISCC Announcers as and when finalised.

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