



Scientific Committee on Consumer Safety

SCCS

**ADDENDUM to the OPINION SCCS/1489/12 on
Zinc oxide (nano form)**

COLIPA S76

The SCCS adopted this addendum by written procedure on 23 July 2013

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCCS

The Committee shall provide opinions on questions concerning all types of health and safety risks (notably chemical, biological, mechanical and other physical risks) of non-food consumer products (for example: cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products such as detergents, etc.) and services (for example: tattooing, artificial sun tanning, etc.).

Scientific Committee members

Ulrike Bernauer, Qasim Chaudhry, Pieter Coenraads, Gisela Degen, Maria Dusinska, David Gawrodger, Werner Lilienblum, Andreas Luch, Elsa Nielsen, Thomas Platzek, Suresh Chandra Rastogi, Christophe Rousselle, Jan van Benthem.

Contact

European Commission
Health & Consumers
Directorate C: Public Health
Unit C2 – Health Information/ Secretariat of the Scientific Committee
Office: HTC 03/073 L-2920 Luxembourg
SANCO-C2-SCCS@ec.europa.eu

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SCCS members

Dr. Q. Chaudhry (chairman)
Dr. W. Lilienblum
Dr. S. Ch. Rastogi
Prof. Th. Platzek
Dr. M. Dusinska
Prof. N. Monteiro-Rivière
Dr. U. Bernauer

External experts

Dr. W. de Jong (rapporteur)
Prof. T. Jung
Prof. T. Sanner
Dr. Sh. Doak
Dr. O. Bussolati

For the revision

SCCS members

Dr. U. Bernauer
Dr. Q. Chaudhry (chairman)
Dr. M. Dusinska
Dr. W. Lilienblum
Prof. Th. Platzek
Dr. S. Ch. Rastogi
Dr. J. van Benthem

SCENIHR members

Prof. P. H. M. Hoet
Dr. K. Rydzynski

External experts

Dr. O. Bussolati
Dr. W. H. de Jong (rapporteur)
Dr. S. H. Doak
Prof. Th. Jung
Prof. T. Sanner
Dr. N. von Götz

This opinion has been subject to a commenting period of six weeks after its initial publication. Comments received during this time have been considered by the SCCS and discussed in the subsequent plenary meeting. Where appropriate, the text of the relevant sections of the opinion has been modified or explanations have been added. In the cases where the SCCS after consideration and discussion of the comments, has decided to maintain its initial views, the opinion (or the section concerned) has remained unchanged. Revised opinions carry the date of revision.

Keywords: SCCS, scientific opinion, UV filter, S76, Zinc oxide (nano form), directive 76/768/ECC, CAS 1314-13-2, EC 215-222-5

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1. BACKGROUND

In the opinion on Zinc oxide adopted on the 18 September 2012 (SCCS/1489/12), the SCCS considers that the use of nano forms and non-nano forms of ZnO at concentrations of up to 25% as a UV filter in sunscreens are safe, with the specific following considerations:

In summary, it is concluded on the basis of available evidence that the use of ZnO nanoparticles with the characteristics as indicated below, at a concentration up to 25% as a UV-filter in sunscreens, can be considered not to pose a risk of adverse effects in humans after dermal application. This does not apply to other applications that might lead to inhalation exposure to ZnO nanoparticles (such as sprayable products). Also, this assessment only applies to ZnO nanoparticles that are included in this dossier, or are similar materials that have the following characteristics:

- ZnO nanoparticles of purity $\geq 99\%$, with wurtzite crystalline structure and physical appearance as described in the dossier, i.e. clusters that are rod-like, star-like and/or isometric shapes.
- ZnO nanoparticles with a median diameter (D50: 50% of the number below this diameter) of the particle number size distribution between 30 nm and 55 nm, and the D1 (1% below this size) above 20 nm.
- ZnO nanoparticles that are either uncoated, or coated with triethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilanetriethoxycaprylylsilane cross-polymer, or octyl triethoxy silane.
- ZnO nanoparticles that have a comparable solubility to that reported in the dossier, i.e. below 50 mg/L (approximately the maximum solubility of the ZnO nanomaterials for which data are provided in the dossier).

In January 2013, Cosmetics Europe¹ submitted a document in which they proposed their own – broader - interpretation of the characteristics laid out in the scientific opinion on zinc oxide in nano form. In particular, they proposed the purity requirements to be reduced to 96% (as data on one of the material with 96% purity were provided in the submission), the median diameter of the particle number size distribution to be accepted when it is greater than 30 nm, the possible coatings to be extended to all (authorized or not prohibited) cosmetic ingredients, and the omission of the solubility specification.

Both the Commission's services and the Member States expressed doubts regarding this interpretation, and therefore seek a clarification from the SCCS.

¹ Cosmetics Europe, ex- COLIPA –: European Cosmetics Toiletry and Perfumery Association

2. TERMS OF REFERENCE

On the basis of the submitted document, does the SCCS consider safe the use of ZnO nanoparticles at a concentration up to 25% as a UV-filter in sunscreens with the characteristics as following indicated:

- 1. ZnO nanoparticles of purity ≥96%, with wurtzite crystalline structure and physical appearance as clusters that are rod-like, star-like and/or isometric shapes.*
- 2. ZnO nanoparticles with a median diameter (D50: 50% of the number below this diameter) of the particle number size distribution above 30 nm, and the D1 (1% below this size) above 20 nm.*
- 3. ZnO nanoparticles that are either uncoated, or coated with cosmetic ingredients*
- 4. ZnO nanoparticles without specifying any solubility*

3. OPINION

SCCS responses to the request for clarifications on the scientific opinion SCCS/1489/2012 on zinc oxide nano intended for use as a UV filter.

The SCCS has received a request regarding further clarifications on the scientific opinion SCCS/1489/2012 on zinc oxide nano as UV filter in cosmetics. In this request specific questions were asked dealing with the characteristics of similar zinc oxide nanoparticles that would be considered to pose no or limited risk when used as UV filters in sunscreens. The SCCS is asked to consider the proposal of Cosmetics Europe (formerly COLIPA) for a broader interpretation of the characteristics of similar materials of zinc oxide nanoparticles compared to those that were evaluated in the submitted zinc oxide dossier COLIPA S76. The proposed characteristics are discussed below:

Old text:

- ZnO nanoparticles of purity $\geq 99\%$, with wurtzite crystalline structure and physical appearance as described in the dossier, i.e. clusters that are rod-like, star-like and/or isometric shapes.

Text question:

- ZnO nanoparticles of purity $\geq 96\%$, with wurtzite crystalline structure and physical appearance as clusters that are rod-like, star-like and/or isometric shapes

Cosmetics Europe mentions correctly that one of the evaluated ZnO nanoparticles had a stated purity of $\geq 96\%$. In their comments on the published Opinion on ZnO nano it is stated that the specifications for the ZnO nanoparticles with a purity of $\geq 96\%$, show that the impurities responsible for the reduced purity, compared to the 99% pure ZnO nanomaterials, were carbon dioxide and water. The SCCS agrees with Cosmetics Europe that these specific impurities pose no risk for use in humans when applied on the skin. Thus, ZnO nanoparticles of purity $\geq 96\%$, with wurtzite crystalline structure and physical appearance as clusters that are rod-like, star-like and/or isometric shapes, are considered by the SCCS to pose a limited or no risk when used for skin applications only (e.g. as used in sunscreens), as long as the impurities present are carbon dioxide and water. However, the SCCS stresses the fact that other impurities should be below 1% in total. Any impurities above 1% should be restricted to carbon dioxide and water only, resulting in a purity of the final ZnO nanoparticle preparation of $\geq 96\%$.

In summary, the SCCS considers ZnO nanoparticles to pose no or limited risk when the ZnO nanoparticles have a purity $\geq 96\%$, with wurtzite crystalline structure and physical appearance as clusters that are rod-like, star-like and/or isometric shapes, provided that the impurities consist only of carbon dioxide and water, and that any other impurities are below 1% in total. In consideration of this, the parameter describing the purity of ZnO nanomaterial should be adapted as follows:

ZnO nanoparticles of purity $\geq 96\%$, with wurtzite crystalline structure and physical appearance as clusters that are rod-like, star-like and/or isometric shapes, with impurities consisting only of carbon dioxide and water, whilst any other impurities are less than 1% in total.

Old text:

- ZnO nanoparticles with a median diameter (D50: 50% of the number below this diameter) of the particle number size distribution between 30 nm and 55 nm, and the D1 (1% below this size) above 20 nm.

Text question:

- ZnO nanoparticles with a median diameter (D50: 50% of the number below this diameter) of the particle number size distribution above 30 nm, and the D1 (1% below this size) above 20nm.

The SCCS agrees with the explanation of Cosmetics Europe that concerns with a risk of nanoparticles to be generally associated with a decrease in particle size. So, the SCCS considers ZnO nanoparticles to pose no or limited risk when ZnO nanoparticles with a median diameter (D50: 50% of the number below this diameter) of the particle number size distribution above 30 nm, and the D1 (1% below this size) above 20nm, are used as ingredient for cosmetics applied on the skin. The characteristic describing the size of the ZnO nanomaterial should be adapted as follows:

ZnO nanoparticles with a median diameter (D50: 50% of the number below this diameter) of the particle number size distribution above 30 nm, and the D1 (1% below this size) above 20 nm.

Old text:

- ZnO nanoparticles that are either uncoated, or coated with triethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilanetriethoxycaprylylsilane cross-polymer, or octyl triethoxy silane.

Text question:

- ZnO nanoparticles are either coated or uncoated with cosmetic ingredients.

In the submitted dossier only a limited number of coating materials were used as coatings for the ZnO nanomaterials. Therefore these were mentioned in the characteristics for similar ZnO nanomaterials. However, the SCCS agrees with Cosmetics Europe that the currently used cosmetic ingredients would pose limited to no risk when used on the skin. As cosmetic ingredients may change over time, the SCCS has objections on the use of cosmetic ingredients in general as coatings for ZnO nanomaterials. The characteristic describing the coatings of similar ZnO nanomaterial should therefore be adapted as follows:

ZnO nanoparticles that are either uncoated or coated with triethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilanetriethoxycaprylylsilane cross-polymer, or octyl triethoxy silane. Other cosmetic ingredients can be used as coatings as long as they are demonstrated to the SCCS to be safe and do not affect the particle properties related to behaviour and/or effects, compared to the nanomaterials covered in the current opinion.

Old text:

- ZnO nanoparticles that have a comparable solubility to that reported in the dossier, i.e. below 50 mg/L (approximately the maximum solubility of the ZnO nanomaterials for which data are provided in the dossier).

Text question:

- ZnO nanoparticles without specifying solubility.

The SCCS agrees with the comments of Cosmetics Europe that in the Cosmetics Regulation EC 1223/2009 coming in force July 2013 a nanomaterial is defined as being "insoluble and biopersistent". However, the Regulation also has the possibility that the definition may be adapted based on future progressing insights and/or international agreement. Also, the publication of the EC's "Recommendation for the definition of a nanomaterial" in October 2011 may by its publication already be considered a reason to adapt the definition as mentioned in the Regulation EC 1223/2009. The SCCS considers the low solubility of ZnO nanoparticles as an important characteristic for a similar ZnO nanomaterial. ZnO nanomaterial has a low solubility (< 50 mg/L) and part of the toxicity of ZnO nanoparticles is considered to be associated with the release of Zn ions. The evaluated ZnO nanomaterials had a solubility <50 mg/L, so possible effects of solubilized Zn ions were therefore included in the toxic responses evaluated. In view of this, the SCCS concludes that the characteristic describing the limitation relating to the solubility of similar ZnO nanomaterials should not be adapted and remain as previously formulated.

ZnO nanoparticles that have a comparable solubility to that reported in the dossier,

i.e. below 50 mg/L (approximately the maximum solubility of the ZnO nanomaterials for which data are provided in the dossier).

Toxicological Evaluation

Repeated dose, 90 days inhalation toxicity – Study summary

Study design

Date of study report: 30 September 2011 – Final Draft Report

Guideline/method: Modified sub-chronic 90 days inhalation study in compliance with OECD guideline 413, including a recovery period of up to 28 days.

Species/Strain: Rat, Wistar – Males only

Group size: 65 male rats per group

Test substance: a) Z-COTE® HP1 (content W/W: 98%) is coated on the surface with triethoxycaprylylsilane (CAS # 2943-75-1; content W/W: 2%)
b) Zinc Oxide 205532, Microscaled Size Powder

Batch: a) NPL Ref#: ZB250#65
b) NPL Ref#: ZrA250#60

Purity: See under test substance (information on Z-Cote and Z-COTE® HP1 is presented in chemistry section)

Particle size: Not indicated for this study (information on the non coated Z-Cote particle size distribution is presented in chemistry section of the ZnO submission/Opinion)

Route: inhalation

Concentrations: a) 0, 0.3, 1.5 and 4.5 mg/m³
b) 0, 4.5 mg/m³

Exposure period: 90 days

Frequency of exposure: 6h/day, 5 days/week

Type of exposure: Nose-only exposure

Exposure conditions: Flow-past nose-only exposure system, 1 l/min to each rat.

Generator system: Dispersion of the dry powder was obtained by feeding the powder through a high-pressure, high-velocity pressurized air dispersion nozzle, developed by Fraunhofer ITEM (Koch, 1988).

Generation

procedure: The test substance was used unchanged. For each nose-only exposure unit, the aerosol was generated by a high-pressure pneumatic disperser. The disperser was fed with the test substance under computerized control, i.e. with a feed back loop to the actual aerosol concentrations measured by an aerosol photometer. The control group was exposed to conditioned air.

Observations: The following examinations were done at the end of the exposure period (day 1 after exposure) and after a recovery period of 8 and 28 days after 90 days exposure: Clinical observation, body weight, food consumption, necropsy/macroscopical observation, haematology and clinical chemistry, urinalysis, gross pathology, histopathology, bronchoalveolar lavage, cell proliferation in the lung, toxicokinetics, electron microscopy in lung tissue.

Recovery period: 28 days

GLP: Yes (see SCCS comment)

Published: No

The objectives of this study were:

1. To investigate the toxicity of Z-COTE® HP1 after a 90-day nose-only inhalation study and to analyze the effects after an additional 28-day post-inhalation period
2. To establish exposure-dose-response relationships of the inhaled test item in rats after subchronic exposure and to compare the effects observed for the nanoscaled ZCOTE ® HP1 (with functionalized surface) with a reference material i.e. a microscaled ZnO;
3. To use an experimental design adapted from OECD guideline 413 with additional endpoints (bronchoalveolar lavage, cell proliferation, electron microscope analysis, toxicokinetics) in order to address potential nanoparticle-specific aspects of toxicity.

Experimental design

Group 1	Clean air control	
Group 2	Z-COTE® HP1 low	(aerosol concentration 0.3 mg/m ³)
Group 3	Z-COTE® HP1 mid	(aerosol concentration 1.5 mg/m ³)
Group 4	Z-COTE® HP1 high	(aerosol concentration 4.5 mg/m ³)
Group 5	Micron scaled ZnO	(aerosol concentration 4.5 mg/m ³)

Table 3 indicates the experimental design of the study presenting the study groups. However, the exposure time in Table 3 is indicated to be 14 days. Tables 4 and 5 indicate an exposure of 90 days.

The measurement of the doses as presented in Table 4 showed that the intended doses were indeed obtained.

Table 4 Measurement of doses obtained during the study. NOTE Only mean data are obtained from Table 4.

Mean	0.31	0.31	1.49	1.48	4.45	4.45	4.40	4.50
SD	0.03	0.03	0.12	0.12	0.61	0.45	0.30	0.21
Target Values	0.3		1.5		4.5		4.5	

Results

In this study the sub-chronic effects of Z-COTE® HP1 were investigated in a 90 days inhalation study in male Wistar rats. Moreover these effects were compared to the effects induced by micron scaled ZnO.

Clinical observations did not identify any treatment-related findings or mortality. No biologically relevant changes were observed in the treatment groups when compared to the control animals. For the mid dose group a body weight reduction was noted at days 28 and 35 of about 3% of the control animals. From day 42 to day 90 and after exposure days 91, 98 and day 119 no difference in weight was observed for the mid dose group when compared to the control group. Food consumption showed some statistically significant changes but these were not considered as treatment related.

Micron-sized ZnO induced a small but statistically significant increase in the lung weights at the investigated dose of 4.5 mg/m³ when compared to the controls. This weight effect was not observed after exposure to the other test group (Z-COTE® HP1). For some organs (testis, epididymis, kidney) a one sided increase in the absolute and relative weight was noted without clear dose response effect. Both substances did not induce other significant changes in the weight of other organs. Gross pathology showed only the presence of some incidental alterations.

No statistically significant or biologically relevant changes were found in haematological parameters, clinical chemistry or in urinalysis of any test group as compared to the control animals. In line with the above observations no signs of systemic toxicity were identified after sub-chronic inhalation exposure to both nano-scale ZnO coated with triethoxycaprylylsilane and micron scaled ZnO.

In the bronchoalveolar lavage fluid (BALF) only exposure to the micro-ZnO induced lung inflammation at day 1 after exposure as indicated by an influx of polymorphonuclear granulocytes (PMNs), lymphocytes, and increase in LDH, beta-glucuronidase and total protein. These results indicate lung inflammation and cellular damage. LDH was increased in high dose Z-COTE® HP1. This reaction was absent on day 8 after exposure and on day 29 after exposure. On day 1 after exposure only one animal of the Z-COTE® HP1 treated groups (group 2, low dose) showed lung inflammation similar to micro-ZnO. The results presented indicate also a statistical difference in total protein in BALF between high dose group Z-COTE® HP1 with controls (high dose group 112.2 ± 8.7 vs control 79.6 ± 9.2 total protein). 'Reactive oxygen species' (ROI) in BALF macrophages were affected in the mid and high dose of Z-COTE® HP1, and the micro-ZnO, which was reduced in at day 8 after exposure and not present anymore at day 29 after exposure. For cytokines in the BALF only CINC-1 (rat analogue of IL-8) was increased in the micro-ZnO only.

At the end of the exposure period local effects were observed in the nasal and perinasal cavities and were identified as slight degeneration and multifocal hyperplasia of the olfactory epithelium. These effects were only observed in the group exposed to micron scaled ZnO. Less pronounced local tissue damage was found in the other treatment groups but was found reversible at the end of the recovery period. These changes were considered as test-item related.

Investigation of the lower respiratory tract revealed limited local inflammatory effects in the lungs (granulocyte and mononuclear cell infiltration) at the end of the exposure period. Multifocal accumulation of particle laden macrophages were observed in a dose-dependent way in all ZnO (nano- and micron scaled) exposed groups. Exposure related interstitial inflammation (slight mononuclear cell infiltration) was observed in the high dose Z-COTE® HP1, and the micro-ZnO groups. At 29 days after exposure both for the clean air control animals and the high dose Z-COTE® HP1 and microscaled ZnO interstitial inflammation was similar (3/10).

(Multi)focal very slight bronchiolo-alveolar hyperplasia, mainly of the bronchiolar type was observed exclusively in the Z-COTE® HP1 high dose and microscaled ZnO groups, and was

interpreted as an adaptive response. Investigation of cell proliferation did not reveal any indication of a hyperplastic response.

At the end of the recovery period all these observed effects / lesions were reduced in severity or fully reversible.

Slight lymphoid hyperplasia in lung associated lymph nodes was mainly observed in microscaled ZnO treated animals (4/10), while it was 1/10 in all groups treated with Z-COTE® HP1. This lymphoid hyperplasia was still present at day 29 after exposure. This indicates an ongoing stimulation of the immune system (immune response) in the draining lung lymph nodes. This can be seen as adaptive response to the particle challenge in the lungs.

At TEM evaluation electron dense structures, composed of irregular homogeneous to fine granular materials, were observed in macrophages and lung cells in all treatment groups including the control clean air exposed animals. These structures were not further identified but did not resemble nanoparticles similar to Z-COTE® HP1.

Toxicokinetics investigation supported the rapid dissolution of ZnO from lung tissue. Moreover no accumulation of Zn in any body compartment was found herewith supporting the rapid elimination.

In the study four animals were found dead or killed moribund, the cause of death being in two animals a purulent and necrotizing inflammation of the urogenital organs, in one animal due to a pronounced malignant lymphoma, and in one animal due to unknown cause. These observations were not treatment related.

Conclusions

The study authors concluded that transient local effects on the respiratory tract were only observed in the highest dose group for this 90 days inhalation study. A NOAEL of 1.5 g/m³ can be identified for the test item Z-COTE® HP1. Under the conditions of this test no persistent toxicity was found and all lesions were found to be recovered within the 28 day post exposure period.

SCCS comments

The file received for the study report was not signed by the study director and/or scientists involved. The report was supposedly to be published by the end of 2012, however, it was not found on Cefic website (June 2013).

Size distributions of both nano- and micron-sized ZnO particles used in the study were not provided. It was indicated in the report that the characterization of these materials would be done within the OECD sponsorship programme.

BALF isolation reference (Henderson et al., 1987) cited but not listed in references.

Table 3 indicates experimental design of the study presenting the study groups. However, the exposure time in Table 3 is indicated to be 14 days. Tables 5 and 6 indicate the right exposure time of 90 days.

Page 25/170 indicates an extra dose group (group 5) of Z-COTE® for the histopathology evaluation. This group is not indicated in the study design. There may be a possibility for confusion between the dose group 4 Z-COTE® HP1, the dose group 5 Z-COTE® (non-existent), and the dose group 6 (microscaled ZnO).

Regarding BALF: The method of collecting BAL was mentioned twice in the report, once using 2 times 4 ml for cytological and biochemical parameters, and once using 5 times 5 ml for oxidative stress and immunotoxicological parameters. For both lavages the same

animals were used. Some explanation might have given insight to how and why this was done. Statistical difference in total protein in BALF between high dose group Z-COTE® HP1 with controls not mentioned (high dose group 112.2 ± 8.7 vs control 79.6 ± 9.2 total protein).

The NOAEL derived by the study authors is based on both observations in BAL and lung histopathology occurring at the high dose group and not in mid dose group of 1.5 mg/m^3 . However, the SCCS concludes on a NOAEL of 0.3 mg/ m^3 in view of the ongoing activation of lung macrophages and lung draining lymph nodes.

4. CONCLUSION

The SCCS concludes that ZnO nanomaterials with the following characteristics can be considered similar to the ZnO nanomaterials as evaluated in opinion SCCS/1489/12 and thus pose no or limited risk for use on the skin as UV filter in sunscreen formulations:

1. *ZnO nanoparticles of purity $\geq 96\%$, with wurtzite crystalline structure and physical appearance as clusters that are rod-like, star-like and/or isometric shapes, with impurities consisting only of carbon dioxide and water, whilst any other impurities are less than 1% in total.*
2. *ZnO nanoparticles with a median diameter (D_{50} : 50% of the number below this diameter) of the particle number size distribution above 30 nm, and the D_1 (1% below this size) above 20nm.*
3. *ZnO nanoparticles that are either uncoated or coated with triethoxycaprylylsilane, dimethicone, dimethoxydiphenylsilane triethoxycaprylylsilane cross-polymer, or octyl triethoxy silane. Other cosmetic ingredients can be used as coatings as long as they are demonstrated to the SCCS to be safe and do not affect the particle properties related to behaviour and/or effects, compared to the nanomaterials covered in the current opinion.*
4. *ZnO nanoparticles that have a comparable solubility to that reported in the dossier, i.e. below 50 mg/L (approximately the maximum solubility of the ZnO nanomaterials for which data are provided in the dossier).*

The submitted 90 days inhalation study resulted in a NOAEL of 0.3 mg/m^3 . However these new data do not address the concerns relating to the lung exposure and the potential manifestation of harmful effects.

5. MINORITY OPINION

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6. REFERENCES

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