Please find below the Commission Communication and the Commission Recommendation for the substance

trizinc bis(orthophosphate)

CAS-No.: 7779-90-0 EINECS-No.: 231-944-3 II

(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS AND BODIES

COMMISSION

Communication from the Commission on the results of the risk evaluation and the risk reduction strategies for the substances: zinc oxide; zinc sulphate; trizinc bis(orthophosphate)

(Text with EEA relevance)

(2008/C 155/01)

Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (1) involves the data reporting, priority setting, risk evaluation and, where necessary, development of strategies for limiting the risks of existing substances.

In the framework of Regulation (EEC) No 793/93 the following substances have been identified as priority substances for evaluation in accordance with Commission Regulation (EC) No 2268/95 (2) concerning the second list of priority substances as foreseen under Regulation (EEC) No 793/93:

- zinc oxide,
- zinc sulphate,
- trizinc bis(orthophosphate).

The rapporteur Member State designated pursuant to this Regulation has completed the risk evaluation activities with regard to man and the environment for those substances in accordance with Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances (3) and has suggested a strategy for limiting the risks in accordance with Regulation (EEC) No 793/93.

The Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) and the Scientific Committee on Health and Environmental Risks (SCHER) have been consulted and have issued an opinion with respect to the risk evaluations carried out by the rapporteur. These opinions can be found on the website of the Scientific Committees.

Article 11(2) of Regulation (EEC) No 793/93 stipulates that the results of the risk evaluation and the recommended strategy for limiting the risks shall be adopted at Community level and published by the Commission. This Communication, together with the corresponding Commission Recommendation 2008/468/EC (4), provides the results of risk evaluations (3) and strategies for limiting the risks for the above mentioned substances.

⁽¹⁾ OJ L 84, 5.4.1993, p. 1.

⁽²⁾ OJL 231, 28.9.1995, p. 18. (3) OJL 161, 29.6.1994, p. 3.

OJL 161, 20.6.2008.

The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the Internet site of the European Chemicals Bureau: http://ecb.jrc.it/existing-substances/

The results of the risk evaluation and strategies for limiting the risks provided for in this communication are in accordance with the opinion of the Committee set up pursuant to Article 15(1) of Regulation (EEC) No 793/93.

ANNEX

PART 1

CAS No: 1314-13-2

Einecs No: 215-222-5

Structural formula: ZnO

Einecs name: Zinc oxide

IUPAC name: Zinc oxide

Rapporteur: The Netherlands

Classification (1): N; R50-53

The risk assessment is based on practices related to the life-cycle of the substance produced in or imported into the European Community as described in the risk assessment forwarded to the Commission by the Member State Rapporteur. The risk assessment has been conducted in accordance with the methodology for metals applicable at the time and in line with the Technical Guidance Document on Risk Assessment in support of Commission Regulation (EC) No 1488/94 on risk assessment for existing substances.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used in rubber compounding material, in glass and ceramic products. Other uses are as a corrosion inhibitor in paint, as raw material for the production of zinc chemicals, as fuel and lubricant additives, and as a zinc addition in fertilisers, animal feeds and human vitamin elements. Uses as nanomaterials have not been assessed.

RISK ASSESSMENT

A. Human health

The conclusion of the assessment of the risks to

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for metal fume fever as a consequence of acute inhalation toxicity during welding of zinc coated steel,
- concerns for systemic effects, as a consequence after repeated dermal exposure and repeated combined exposure (inhalation and dermal) arising from use of paint containing zinc oxide.

The conclusion of the assessment of the risks to

CONSUMERS

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

 — the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

 the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

⁽¹) The classification of the substance is established by Commission Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the 29th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 152, 30.4.2004, p. 1, amended by OJ L 216, 16.6.2004, p. 3).

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

 the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

Conclusions are given on local scenarios only. The conclusions regarding the regional risks to the environment as described in the risk assessment for zinc metal (Einecs No 231-175-3) apply as well.

The conclusions of the assessment of the risks to

ATMOSPHERE

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

 the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusions of the assessment of the risks to the

AQUATIC ECOSYSTEM INCLUDING SEDIMENT

- 1.1. is that there is a need for specific measures to limit the risks for the specific scenarios listed below. This conclusion is reached because of:
 - concerns for effects on the local aquatic (including sediment) environment as a consequence of exposure arising from the production at one site (sediment only) and from the use in the glass processing industry, ferrites industry (sediment only), varistor industry, catalysts processing, lubricants formulation, paints processing, cosmetics pharmaceuticals formulation and cosmetics pharmaceuticals private use (sediment only). For a number of production sites and processing scenarios (having emissions to water) no immediate concern has been identified but a potential risk at local scale cannot be excluded due to possible existence of high regional background concentrations of zinc.
- 1.2. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied for all local scenarios, including concerning secondary poisoning, except for those listed under point 1.1 above. This conclusion is reached because:
 - the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to the

TERRESTRIAL ECOSYSTEM

- 2.1. is that there is a need for specific measures to limit the risks. This conclusion is reached because of:
 - concerns for the local terrestrial environment as a consequence of exposure arising from use in the glass processing industry, formulation of lubricants and formulation of cosmetics pharmaceuticals.
- 2.2. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied, for all local scenarios, including concerning secondary poisoning, except for those listed under point 2.1 above. This conclusion is reached because:
 - the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

- 3.1. is that there is a need for limiting the risks for some, but not all, local scenarios. This conclusion is reached because of:
 - concerns for micro-organisms in the sewage treatment plant as a consequence of exposure arising from the use in the glass processing industry, varistor industry, catalysts processing, lubricants formulation, paints processing and cosmetics pharmaceuticals formulation.

- 3.2. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied for all local scenarios, except for those listed under point 3.1 above. This conclusion is reached because:
 - the risk assessment shows that risks are not expected. Risk reduction measures already being applied are consid-

STRATEGY FOR LIMITING RISKS

For WORKERS

The legislation for workers' protection currently into force at Community level is generally considered to give an adequate framework to limit the risks of zinc oxide to the extent needed and shall apply. Furthermore, based on the results of the risk assessment report, it is recommended:

— to establish at Community level occupational exposure limit values for welding fumes according to Directive 98/24/EC (1) or Directive 2004/37/EC (2) as appropriate.

For the ENVIRONMENT

It is recommended:

- to consider under Directive 2008/1/EC (3) and Directive 2000/60/EC (4) if additional risk management is needed for other sources of zinc emissions than those from the produced and imported chemical (for instance natural sources, mining activities, historical pollution and the use of other zinc compounds), which the risk reduction strategy has identified as contributing significantly to the emissions of zinc to the aquatic compartment,
- to facilitate permitting and monitoring under Directive 2008/1/EC, zinc oxide should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT).

PART 2

Einecs No: 231-793-3

CAS No: 7733-02-0

Structural formula: ZnSO₄

Zinc sulphate Einecs name:

IUPAC name: Zinc sulphate

The Netherlands Rapporteur:

Classification (5): Xn; R22

R41

N; R50-53

The risk assessment is based on practices related to the life-cycle of the substance produced in or imported into the European Community as described in the risk assessment forwarded to the Commission by the Member State Rapporteur. The risk assessment has been conducted in accordance with the methodology for metals applicable at the time and in line with the Technical Guidance Document on Risk Assessment in support of Regulation (EC) No 1488/94 on risk assessment for existing substances.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used for the production of fertilisers and pesticides, for agriculture pharmaceutical purposes such as feedstuff additives, and in the chemical industry. Other uses are applications in the viscose production, as flotation agent in the mining industry, as corrosion inhibitor in the galvanising industry and in water treatment processes. Uses as nanomaterials have not been assessed.

⁽¹) OJ L 131, 5.5.1998, p. 11. (²) OJ L 158, 30.4.2004, p. 50.

OJ L 24, 29.1.2008, p. 8.
OJ L 327, 22.12.2000, p. 1.
The classification of the substance is established by Commission Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the 29th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 152, 30.4.2004, p. 1, amended by OJ L 216, 16.6.2004, p. 3).

RISK ASSESSMENT

A. Human health

The conclusion of the assessment of the risks to

WORKERS

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

 — the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

CONSUMERS

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

 the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

 the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

 — the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

Conclusions are given on local scenarios only. The conclusions regarding the regional risks to the environment as described in the risk assessment for zinc metal (Einecs No 231-175-3) apply as well.

The conclusions of the assessment of the risks to

ATMOSPHERE

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

 the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusions of the assessment of the risks to the

AQUATIC ECOSYSTEM INCLUDING SEDIMENT

- 1.1. is that there is a need for specific measures to limit the risks. This conclusion is reached because of:
 - concerns for effects on the local aquatic environment as a consequence of exposure arising from the use by the agricultural fertiliser industry (formulation). For the use in agricultural feed industry (formulation) no immediate concern has been identified but a potential risk at local scale cannot be excluded due to possible existence of high regional background concentrations of zinc,
 - concerns for effects on sediment dwelling organisms as a consequence of local exposure arising from the use in the agricultural fertiliser industry (formulation), agricultural feed industry (formulation) and chemical industry (processing). For a number of processing scenarios no immediate concern has been identified but a potential risk at local scale cannot be excluded due to possible existence of high regional background concentrations of zinc.
- 1.2. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied for all local scenarios, including concerning secondary poisoning, except for those listed under point 1.1 above. This conclusion is reached because:
 - the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to the

TERRESTRIAL ECOSYSTEM

- 2.1. is that there is a need for specific measures to limit the risks. This conclusion is reached because of:
 - concerns for the local terrestrial environment as a consequence of exposure arising from the use in chemical industry (processing), agricultural pesticide industry (processing) and agricultural fertiliser industry (formulation).
- 2.2. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied, for all local scenarios, including concerning secondary poisoning, except for those listed under point 2.1 above. This conclusion is reached because:
 - the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

- 3.1. is that there is a need for limiting the risks. This conclusion is reached because of:
 - concerns for micro-organisms in the sewage treatment plant as a consequence of exposure arising from the use in chemical industry (processing), agricultural pesticide industry (processing) and agricultural fertiliser industry
- 3.2. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied for all local scenarios, except for those listed under point 3.1 above. This conclusion is
 - the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

For ENVIRONMENT

It is recommended:

- to consider under Directive 2008/1/EC (1) and Directive 2000/60/EC (2) if additional risk management is needed for other sources of zinc emissions than those from the produced and imported chemical (for instance natural sources, mining activities, historical pollution and the use of other zinc compounds), which the risk reduction strategy has identified as contributing significantly to the emissions of zinc to the aquatic compartment,
- to facilitate permitting and monitoring under Directive 2008/1/EC, zinc sulphate should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT).

PART 3

CAS No: 7779-90-0

Einecs No: 231-944-3

Structural formula: $Zn_3(PO_4)$

Einecs name: Trizinc bis(orthophosphate) IUPAC name: Trizinc bis(orthophosphate)

The Netherlands Rapporteur: Classification (3): N; R50-53

The risk assessment is based on practices related to the life-cycle of the substance produced in or imported into the European Community as described in the risk assessment forwarded to the Commission by the Member State Rapporteur. The risk assessment has been conducted in accordance with the methodology for metals applicable at the time and in line with the Technical Guidance Document on Risk Assessment in support of Regulation (EC) No 1488/94 on risk assessment for existing substances.

OJ L 24, 29.1.2008, p. 8. OJ L 327, 22.12.2000, p. 1.

The classification of the substance is established by Commission Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the 29th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 152, 30.4.2004, p. 1, amended by OJ L 216, 16.6.2004, p. 3).

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an active inorganic anticorrosive pigment in primers and paints for corrosion protection of metal substrates in paint, lacquers and varnishes industry. Uses as nanomaterials have not been assessed.

RISK ASSESSMENT

A. Human health

The conclusion of the assessment of the risks to

WORKERS

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

 — the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

CONSUMERS

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

 the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

 the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

 the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

Conclusions are given on local scenarios only. The conclusions regarding the regional risks to the environment as described in the risk assessment for zinc metal (Einecs No 231-175-3) apply as well.

The conclusions of the assessment of the risks to

ATMOSPHERE

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

 the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusions of the assessment of the risks to the

AQUATIC ECOSYSTEM INCLUDING SEDIMENT

- 1.1. is that there is a need for specific measures to limit the risks. This conclusion is reached because of:
 - concerns for effects on the local aquatic environment (including sediment) as a consequence of exposure arising from the use by the paint industry (formulation and processing).

- 1.2. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied for all local scenarios, including concerning secondary poisoning, except for those listed under point 1.1 above. This conclusion is reached because:
 - the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to the

TERRESTRIAL ECOSYSTEM

- 2.1. is that there is a need for specific measures to limit the risks. This conclusion is reached because of:
 - concerns for the local terrestrial environment as a consequence of exposure arising from the use by the paint industry (formulation).
- 2.2. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied, for all local scenarios, including concerning secondary poisoning, except for those listed under point 2.1 above. This conclusion is reached because:
 - the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

- 3.1. is that there is a need for limiting the risks. This conclusion is reached because of:
 - concerns for micro-organisms in the sewage treatment plant as a consequence of exposure arising from the use in the paint industry (formulation and processing).
- 3.2. is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied for all local scenarios, except for those listed under point 3.1 above. This conclusion is reached because:
 - the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

For ENVIRONMENT

It is recommended:

- to consider under Directive 2008/1/EC (¹) and Directive 2000/60/EC (²) if additional risk management is needed for other sources of zinc emissions than those from the produced and imported chemical (for instance natural sources, mining activities, historical pollution and the use of other zinc compounds), which the risk reduction strategy has identified as contributing significantly to the emissions of zinc to the aquatic compartment,
- to facilitate permitting and monitoring under Directive 2008/1/EC, trizinc bis(orthophosphate) should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT).

⁽¹⁾ OJ L 24, 29.1.2008, p. 8.

⁽²) OJ L 327, 22.12.2000, p. 1.

RECOMMENDATIONS

COMMISSION

COMMISSION RECOMMENDATION

of 30 May 2008

on risk reduction measures for the substances zinc oxide, zinc sulphate and trizinc bis(orthophosphate)

(notified under document number C(2008) 2322)

(Text with EEA relevance)

(2008/468/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (1) and in particular Article 11(2) thereof,

Whereas:

- (1) In the framework of Regulation (EEC) No 793/93 the following substances have been identified as priority substances for evaluation in accordance with Commission Regulation (EC) No 2268/95 of 27 September 1995 concerning the second list of priority substances as foreseen under Regulation (EEC) No 793/93 (2):
 - zinc oxide,
 - zinc sulphate,
 - trizinc bis(orthophosphate).
- (2) The Member State designated as rapporteur pursuant to this Commission Regulation has completed the risk evaluation activities with regard to man and the environment for those substances in accordance with

Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93 (3) and has suggested a strategy for limiting the risks.

- (3) The Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) and the Scientific Committee on Health and Environmental Risks (SCHER) have been consulted and have issued opinions with respect to the risk evaluations carried out by the rapporteur. The opinions have been published on the website of those Scientific Committees.
- (4) The results of the risk evaluation and further results of the strategies for limiting the risks are set out in the corresponding Commission Communication (4).
- (5) It is appropriate, on the basis of that evaluation, to recommend risk reduction measures for the substances covered by this Recommendation and the Communication.
- (6) The risk reduction measures provided for in this recommendation are in accordance with the opinion of the Committee set up pursuant to Article 15(1) of Regulation (EEC) No 793/93,

OJ L 84, 5.4.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ OJ L 231, 28.9.1995, p. 18.

⁽³⁾ OJ L 161, 29.6.1994, p. 3.

⁽⁴⁾ OJ C 155, 20.6.2008, p. 1.

HEREBY RECOMMENDS:

SECTION 1

ZINC OXIDE

(CAS No 1314-13-2; Einecs No 215-222-5)

ZINC SULPHATE

(CAS No 7733-02-0; Einecs No 231-793-3)

TRIZINC BIS(ORTHOPHOSPHATE)

(CAS No 7779-90-0; Einecs No 231-944-3)

Risk reduction measures for the environment (1, 2, 3, 4 and 5)

- 1. For the river basins where emissions of zinc may cause a risk, the Member States concerned should establish environmental quality standards (hereafter EQS). The national pollution reduction measures to achieve those EQS in 2015 should be included in the river basin management plans in line with the provisions of Directive 2000/60/EC of the European Parliament and of the Council (¹).
- 2. The Member States should provide information to the Commission on the contribution of zinc sources and pathways to the aquatic environment, on possible controls and also on the levels of zinc in the aquatic environment, in order to consider possible inclusion of zinc in the next review of Annex X to Directive 2000/60/EC.
- 3. The competent authorities in the Member States concerned should lay down conditions, emission limit values or

equivalent parameters or technical measures regarding zinc and zinc compounds in the permits issued under Directive 2008/1/EC of the European Parliament and of the Council (²) in order for installations to operate according to the best available techniques (hereafter BAT) taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions.

- 4. Member States should carefully monitor the implementation of BAT regarding zinc and zinc compounds and report any important developments to the Commission in the framework of the exchange of information on BAT.
- 5. Local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

SECTION 2

ADDRESSEES

6. This Recommendation is addressed to Member States.

Done at Brussels, 30 May 2008.

For the Commission
Stavros DIMAS
Member of the Commission

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