

TRIS(NONYLPHENYL) PHOSPHITE (TNPP)

CAS-No.: 26523-78-4

EINECS-No.: 247-759-6

Strategy For Limiting Risks (Workers)

Draft of 13th February 2008

Rapporteur for TNPP is Ministry of Spatial Planning and the Environment as well as the Ministry of Employment and Social Affairs in co-operation with the Ministry of Public Health.

This report has been prepared by French Agency for Environmental and Occupational Health Safety on behalf of the rapporteur who is responsible for the risk assessment and subsequently for the contents of this report.

Contact point

Henri Bastos
French Agency for Environmental and Occupational Health Safety (AFSSET)
253, avenue du général Leclerc
94701 Maisons-Alfort Cedex (France)
Phone : +33 1 56 29 19 30
mail: henri.bastos@afsset.fr

CONTENT

0 SUMMARY..... 3

1 BACKGROUND 4

2 WORKERS 4

Results of the risk assessment 4

3 CURRENT RISK REDUCTION MEASURES..... 6

Classification and labelling 6

Safety data sheets 6

Occupational safety and health regulations..... 7

Occupational exposure Limits..... 7

Personal Protection Equipment (PPE) against dermal exposure..... 7

Are existing controls sufficient to limit occupational risks?..... 7

4 POSSIBLE FURTHER RISK REDUCTION MEASURES..... 8

5 ASSESSMENT OF POSSIBLE FURTHER RISK REDUCTION MEASURES 8

6 FURTHER RISK REDUCTION MEASURES RECOMMENDED..... 8

0 Summary

It has been concluded from the risk assessment of TNPP that there is a concern due to skin sensitisation upon dermal contact during manufacture of the substance, manufacture of products containing TNPP and use of preparations containing TNPP.

Therefore a Risk Reduction Strategy with respect to worker has been developed. Classification of TNPP as a sensitizer was finalised in the Commission working group on the Classification and Labelling of Dangerous Substances in November 2005. As a result of its classification as hazardous substance, TNPP is subject to general regulations concerning its supply and handling and to the legislation for workers' protection currently in force at Community level. These regulations are generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply. Therefore, no further risk reduction measures are recommended.

1 Background

In the framework of EU Regulation 793/93 on the evaluation and control of the risks of existing substances data are gathered, priority substances are selected, their risks are assessed and, if necessary, strategies for limiting the risks are developed. The risk assessments covers the risks to man exposed directly at the workplace or as a consumer and indirectly through the environment and the risks to the environment.

Tris(nonylphenyl)phosphate (TNPP) is a substance on the fourth priority list (Regulation (EC) No. 2364/2000 of the Commission of 25.10.2000). It was selected for review due to concerns for human health (workers), particularly sensitization.

TNPP is a viscous liquid with a very low vapour pressure (0.05 Pa at 25°C), and a very high octanol-water partition coefficient of >8 and a high molecular weight of 689 g/mol-1. The purity of TNPP is reported as 95-100% with the main impurities being nonylphenol (< 5%) and phenol (<1%). Commercial products may contain 1,1',1''-nitriolotripropan-2-ol as an additive in concentrations of up to 1%. In Europe, TNPP is produced in closed systems at three sites, and about 25 to 35 facilities are processing TNPP for which consumption ranges from a few tones to over 4000 tones/year. At the time of the risk assessment report elaboration, production and import volumes were around 5,000 – 10,000 t/year.

The main use of TNPP is as a stabilizer and antioxidant in the processing of various plastic materials (PVC, LLDPE, HDPE and rubber), where it is used in concentrations of between 0.05 and 3%. Other uses are considered to be negligible.

2 Workers

Results of the risk assessment (table 1)

The major occupational routes of exposure to TNPP are inhalation and skin contact. Assuming proper hygiene measures are applied, oral exposure would normally not occur in the workplace.

Exposure may occur during manufacture of TNPP and during handling and further processing in the polymer industry. The following scenarios were regarded as relevant:

- scenario 1 : manufacture of TNPP (closed system, highest dermal exposure during maintenance)
- scenario 2 : manufacture of products containing TNPP (highest dermal exposure during transfer of substance)
- scenario 3 : use of preparations containing TNPP (very minor use, TNPP always < 1%)

No measured values were available and the assessment of exposure is based on model according to the EASE model (Estimation and Assessment of Substance Exposure, version 2) which give normally rather high values.

Table 1: Overview of the conclusions with respect to occupational risk characterisation

	Conclusions valid for the occupational scenarios					
	Scenario 1		Scenario 2		Scenario 3	
	MOS	Concl.	MOS	Concl.	MOS	Concl.
Acute toxicity - LD50 _{dermal} > 2000 mg/kg - LD50 _{oral} > 10000 mg/kg	n.a.	ii	n.a.	ii	n.a.	ii
Irritation - skin - eye	n.a.	ii	n.a.	ii	n.a.	ii
Sensitisation - dermal	n.a.	iii	n.a.	iii	n.a.	iii
Repeated Dose Toxicity, systemic effects - oral (rat, 167 mg/kg/day)	321	ii	69	ii	199	ii
Mutagenicity	n.a.	ii	n.a.	ii	n.a.	ii
Carcinogenicity	n.a.	ii	n.a.	ii	n.a.	ii
Reproductive toxicity, fertility -oral (rat, 200 mg/kg/day)	385	ii	87	ii	238	ii
Reproductive toxicity, developmental effects	n.a.	ii	n.a.	ii	n.a.	ii

n.a. not applicable

Conclusion iii is derived for sensitization in all scenarios (manufacture of the substance, manufacture of products and use of preparation). According to the risk evaluation, the conclusion is mitigated given the non dispersive use of the substance and the lack of reported case of sensitisation.

3 Current risk reduction measures

Classification and labelling

TNPP is not classified under Annex I of directive 67/548/EEC. Classification for human health effects was finalised in the Commission working group on the Classification and Labelling of Dangerous Substances in November 2005. Classification for environmental is not finalised and is subject to the conclusions of the TCNES.

Human health effects (adopted classification)

Symbol : Xi
R-phrase : R43 : May cause sensitisation by skin contact.
S-Phrases: S2: Keep out of the reach of children
S24: Avoid contact with skin.
S37: Wear suitable gloves.
S46: If swallowed, seek medical advice immediately and show this container or label

Environmental effects

To be updated

According to the preparations directive 1999/45/EEC even preparations that have not to be classified as sensitising but contain more than 1 % of a sensitising substance must have a special information on the package: "Contain "name of sensitising substance", May cause allergic reactions.

As a result of its classification as hazardous substance, TNPP is subject to general regulations concerning its supply and handling.

Safety data sheets

In accordance with article 31 (title IV) of Regulation (EC) No 1907/2006, the supplier of a substance or a preparation that meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC shall provide the recipient of the substance or preparation with a safety data sheet compiled in accordance with Annex II.

The information system for hazardous substances and preparations in the form of labelling and the safety data sheets is considered sufficient in principle to provide the user with sufficient information for the selection of suitable occupational safety measures. The SDS should contain all relevant information from the risk assessment report.

Occupational safety and health regulations

At the European level, the following directives are primarily applicable as general regulations for occupational safety and health of workers in the production and use of TNPP:

- 98/24/EC on the protection of workers from the risk related to exposure to chemical agent at work.
- 89/656/EEC on the use of personal protective equipment

Only limited knowledge is available about the extent to which the EU member states have in each case transposed these basic requirements into national law.

Occupational exposure Limits

There are no occupational exposure limits for TNPP. Considering the effect of concern and the low vapour pressure of TNPP, the fixation of an occupational exposure limit is not relevant.

Personal Protection Equipment (PPE) against dermal exposure

According to community Legislation, workers have to be provided with suitable PPE if their health is at risk due to exposure against chemicals. PPE that protects against the risks of TNPP is available and has to be indicated in the SDS. On account of the sensitising effect of TNPP the use of suitable protective equipment is general widely accepted and legally required, if dermal exposure cannot be excluded by other technical or organisational measures.

Are existing controls sufficient to limit occupational risks?

Because this risk of sensitisation can neither be quantified nor excluded (based, for example, on the assumption that proper personal protection use and work procedure might not be applied in most of the plants handling TNPP in EU), a general concern for skin sensitisation is expressed in all workers scenarios. This conclusion was mitigated given the non dispersive use of the substance and the lack of reported case of sensitisation at the existing production sites. Furthermore, as it is reported in the risk assessment report, risk reduction measures which should be applied as a result of the classification of TNPP as the proper use of personal protective equipment can effectively reduce sensitisation at the work place.

The legislation for workers' protection currently in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply. There are no further risks reduction measures proposed but, in order to ensure an effective enforcement of the current occupational regulation, there is a need to make the classification legally binding (i.e. TNPP should be added to the annex I of the directive 67/548/EEC or annex VI of the GHS regulation). As soon as the conclusions of the TCNES for the environmental classification are finalised, TNPP should be added to the next ATP proposal.

4 Possible further risk reduction measures

5 Assessment of possible further risk reduction measures

6 Further Risk Reduction Measures Recommended