

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

**2-nitrotoluene**

**CAS No: 88-72-2**

**EINECS No: 201-853-3**

**Communication from the Commission on the results of the risk evaluation and the risk reduction strategies for the substances: 2-nitrotoluene and 2,4-dinitrotoluene**

(Text with EEA relevance)

(2008/C 134/02)

Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances <sup>(1)</sup> 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 2364/2000 concerning the fourth list <sup>(2)</sup> of priority substances as foreseen under Regulation (EEC) No 793/93:

- 2-nitrotoluene,
- 2,4-dinitrotoluene.

The rapporteur Member State designated pursuant to those Regulations 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 <sup>(3)</sup> and have suggested a strategy for limiting the risks in accordance with Regulation (EEC) No 793/93.

The Scientific Committee on Health and Environmental Risks (SCHER) has been consulted and has 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 Committee.

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 2008/405/EC <sup>(4)</sup>, provides the results of risk evaluations <sup>(5)</sup> and strategies for limiting the risks for the above mentioned 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.

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<sup>(1)</sup> OJ L 84, 5.4.1993, p. 1.

<sup>(2)</sup> OJ L 273, 26.10.2000, p. 1.

<sup>(3)</sup> OJ L 161, 29.6.1994, p. 3.

<sup>(4)</sup> OJ L 141, 31.5.2008.

<sup>(5)</sup> 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/>

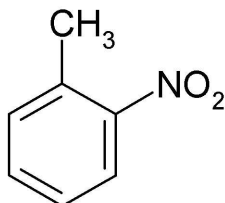
## ANNEX

## PART 1

CAS No 88-72-2

Eines No 201-853-3

Structural formula:



Eines name:	2-nitrotoluene
IUPAC name:	2-nitrotoluene
Rapporteur:	Spain
Classification <sup>(1)</sup> :	Carc. Cat. 2; R45 Muta. Cat. 2; R46 Repr. Cat. 3; R62 Xn; R22 N; R51-53

The risk assessment<sup>(2)</sup> is based on current 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, based on the available information, determined that in the European Community the substance 2-nitrotoluene is used in the synthesis of intermediates for the manufacture of agricultural and rubber chemicals, explosives, heat sensitive colorants, azo and sulphur dyes, and in the organic synthesis of a wide variety of compounds including petrochemicals, pesticides and pharmaceuticals. The 2-nitrotoluene is mainly synthesised by the nitration of toluene and once manufactured is largely used on-site for production of o-toluidine or 2,4-dinitrotoluene.

This substance has not been tested for sensitisation and consequently the risk assessment does not evaluate the risks to any population of sensitisation. This test has not been required, as the substance has been identified as a non-threshold carcinogen, which will require control measures that would not be influenced by further information on whether the substance is a sensitiser or not.

**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 during production and further processing. This conclusion is reached because:

- concerns for mutagenicity and carcinogenicity as a consequence of inhalation and dermal exposure,
- concerns for repeated dose toxicity and toxicity for reproduction (fertility and development) as a consequence of dermal exposure.

<sup>(1)</sup> This chemical substance is included in the Annex I of Directive 67/548/EEC. 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).

<sup>(2)</sup> 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 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:

- exposure of consumers is not assumed to exist.

The conclusion of the assessment of the risks to

#### HUMANS EXPOSED VIA THE ENVIRONMENT

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

- concerns for carcinogenicity as a consequence of inhalation and oral exposure arising from a local site, and for mutagenicity as a consequence of inhalation and oral exposure arising from all local sites as well as from regional exposure resulting from production and further processing of the substance.

The conclusion of the assessment of the risks to

#### HUMAN HEALTH (physico-chemical 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**

The conclusion of the assessment of the risks to the

#### ATMOSPHERE, AQUATIC ECOSYSTEM (including STP and sediment) and TERRESTRIAL ECOSYSTEM

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

- the risk assessment shows that risks related to the environmental spheres mentioned above 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

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

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

### **STRATEGY FOR LIMITING RISKS**

for WORKERS

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.

for HUMANS EXPOSED VIA THE ENVIRONMENT

The existing legislative measures for the protection of humans exposed via the environment, in particular the provisions under Council Directive 2008/1/EC <sup>(1)</sup>, are considered sufficient to address identified risk to the general public.

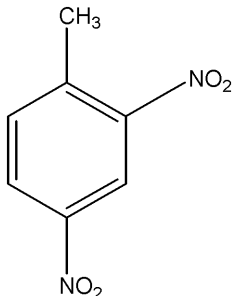
(1) OJ L 24, 29.1.2008, p. 8.

## PART 2

CAS No 121-14-2

Einecs No 204-450-0

Structural formula:



Einecs name:	2,4-dinitrotoluene
IUPAC name:	1,3-dinitro-4-methylbenzene
Rapporteur:	Spain
Classification (1):	Carc. Cat. 2; R45 Muta. Cat. 3; R68 Repr.Cat. 3; R62 T; R23/24/25 Xn; R48/22 N; R51-53

The risk assessment (2) is based on current 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, based on the available information, determined that in the European Community the substance 2,4-dinitrotoluene is used as a chemical intermediate in the production of toluene-2,4-diisocyanate (TDI), from toluene-2,4-diamine (TDA). This application uses about 99 % of the 2,4-dinitrotoluene production.

## 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 mutagenicity and carcinogenicity as a consequence of inhalation and dermal exposure arising from all worker scenarios,
- concerns for repeated dose toxicity and toxicity for reproduction (fertility) as a consequence of dermal exposure arising from manufacture and use of explosives,
- concerns for repeated dose toxicity and toxicity for reproduction (fertility) as a consequence of inhalation arising from manufacture of explosives.

(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 corrected by OJ L 216, 16.6.2004, p. 3).

(2) 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 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:

- exposure of consumers is not assumed to exist.

The conclusion of the assessment of the risks to

#### HUMANS EXPOSED VIA THE ENVIRONMENT

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

- concerns for mutagenicity and carcinogenicity as a consequence of inhalation and oral exposure arising from one local scenario.

Risks can not be excluded for all other exposure scenarios, as the substance is identified as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

The conclusion of the assessment of the risks to

#### HUMAN HEALTH (physico-chemical 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**

The conclusion of the assessment of the risks to the

#### ATMOSPHERE and TERRESTRIAL ECOSYSTEM

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

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to the

#### AQUATIC ECOSYSTEM (including sediment)

is that there is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

The risk assessment shows that there is a need for risk reduction measures for the aquatic compartment and for sediment-dwelling organisms on one local site. It is expected that any risk reduction measure for surface water would also reduce the risks for sediments.

The conclusion of the assessment of the risks to

#### MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

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.

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**STRATEGY FOR LIMITING RISKS**

for WORKERS

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.

for HUMANS EXPOSED VIA THE ENVIRONMENT

The existing legislative measures for the protection of humans exposed via the environment, in particular the provisions under Directive 2008/1/EC, are considered sufficient to address identified risks to the general public.

for ENVIRONMENT

To facilitate permitting and monitoring under Directive 2008/1/EC (Integrated Pollution Prevention and Control) 2,4-DNT should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT).

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## RECOMMENDATIONS

## COMMISSION

## COMMISSION RECOMMENDATION

of 28 May 2008

**on risk reduction measures for the substances 2-nitrotoluene and 2,4-dinitrotoluene***(notified under document number C(2008) 2233)***(Text with EEA relevance)**

(2008/405/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 <sup>(1)</sup> 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 2364/2000 of 25 October 2000 concerning the fourth list of priority substances as foreseen under Council Regulation (EEC) No 793/93 <sup>(2)</sup>:

— 2-nitrotoluene,

— 2,4-dinitrotoluene.

(2) The rapporteur Member State designated pursuant to those Regulations 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 <sup>(3)</sup> and has suggested a strategy for limiting the risks.

(3) The Scientific Committee on Health and Environmental Risks (SCHER) has been consulted and has issued opinions with respect to the risk evaluations carried out by the rapporteur. The opinions have been published on the website of the Scientific Committee.

(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 <sup>(4)</sup>.

(5) It is appropriate, on the basis of that evaluation, to recommend certain risk reduction measures for certain substances. For the substances which are not specifically listed, there are no recommendations for the addressees of this Recommendation.

(6) The risk reduction measures recommended for workers should be considered within the framework of the legislation for workers protection, which is considered to provide an adequate framework to limit the risks of the relevant substances to the extent needed.

(7) 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,

<sup>(1)</sup> 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).

<sup>(2)</sup> OJ L 273, 26.10.2000, p. 5.

<sup>(3)</sup> OJ L 161, 29.6.1994, p. 3.

<sup>(4)</sup> OJ C 134, 31.5.2008, p. 4.



HEREBY RECOMMENDS:

SECTION 1

**2,4-DINITROTOLUENE**

(CAS No 121-14-2; Eines No 204-450-0)

**Risk reduction measures for the environment (1, 2, 3)**

1. Competent authorities in the Member States concerned should lay down, in the permits issued under Directive 2008/1/EC of the European Parliament and of the Commission <sup>(1)</sup>, conditions, emission limit values or equivalent parameters or technical measures regarding 2,4-dinitrotoluene in order to operate according to the Best Available Techniques (BAT) taking into account the technical characteristic of the installations concerned, their geographical location and the local environmental conditions.
2. Member States should carefully monitor the implementation of BAT regarding 2,4-dinitrotoluene and report any important developments to the Commission in the framework of the exchange of information on BAT.

3. Local emissions to the aquatic environment and via air emissions of 2,4-DNT should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

SECTION 2

**ADDRESSEES**

4. This Recommendation is addressed to all sectors importing, producing, transporting, storing, formulating into a preparation or other processing, using, disposing or recovering the substances and to the Member States.

Done at Brussels, 28 May 2008.

*For the Commission*  
Stavros DIMAS  
*Member of the Commission*

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<sup>(1)</sup> OJ L 24, 29.1.2008, p. 8.