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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

ZH72-1005

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Coatings Australia Pty Ltd (ABN: 91 092 127 501)
231-233 Newton Road
Wetherill Park NSW 2164

NOTIFICATION CATEGORY
Limited: Chemical other than polymer (less than 1 tonne per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

- Chemical names
- Other names
- CAS Number
- Molecular formula
- Structural Formula
- Molecular weight
- Spectral data
- Purity
- Identity of toxic or hazardous impurities
- % Weight of toxic of hazardous impurities
- Non-hazardous impurities
- Identity of additives/adjuvants
- % Weight of additives/adjuvants
- Import volume
- Concentration of the notified chemical in end-use products

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

- Melting point
- Boiling point
- Density
- Vapour Pressure
- Hydrolysis as a Function of pH
- Partition Co-efficient
- Absorption/Desorption
- Dissociation Constant
- Particle size
- Flash Point
- Flammability Limits
- Autoignition Temperature
- Explosive Properties
- Reactivity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
9-7 200 kg Chassis Primer (contains the notified chemical at <0.5% concentration)
9-7 Glasurit Steel Primer (contains the notified chemical at <0.5% concentration)

ANALYTICAL DATA
Reference IR spectrUM was provided.

3. COMPOSITION

DEGREE OF PURITY
>95%

4. PHYSICAL AND CHEMICAL PROPERTIES

The notified chemical exists in solvent and is never isolated. The following physico-chemical properties are for an accepted analogue, or the notified chemical in solvent, or the imported product unless otherwise stated.

Appearance at 20ºC and 101.3 kPa Grey liquid (the imported product)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	130ºC	Analogue data
Boiling Point	Not determined	
Density	1513 kg/m^3 at 20ºC	MSDS for the imported product
Vapour Pressure	Not determined	Predicted to be low
Water Solubility	≈ 0.001 g/L at 20ºC	Analogue data
Hydrolysis as a Function of pH	Not determined	See Appendix A
Partition Coefficient (n-octanol/water)	Not determined	Never isolated from solvent
Adsorption/Desorption	Not determined	See Appendix A
Dissociation Constant	Not determined	See Appendix A
Particle Size	Not applicable	Introduced in solution
Flash Point	277ºC	Analogue data
Flammability	Non flammable	Analogue data
Autoignition Temperature	421ºC	Analogue data
Explosive Properties	Not explosive	Analogue data/estimated

Discussion of Observed Effects

For full details of the physical-chemical properties tests please refer to Appendix A.

Reactivity:
Stable under normal environmental conditions and conditions of use.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported as a component of a finished coating product (containing the notified chemical at <0.5% concentration).

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<1	<1	<1	<1	<1

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Automotive OEM and car refinishing industry

TRANSPORTATION AND PACKAGING
The coating product containing the notified chemical will be imported in 200 kg steel drums and 25 kg metal cans, which are transported by road from the port of entry to the notifier's warehouse. The imported products are stored on-site until they are transported to the customer by road.

The finished product containing the notified chemical is classified as hazardous and a Dangerous Good Class 3: Flammable Liquid under the Australian Code of Practice for the Transport of Dangerous Goods by Road and Rail (FORS, 1998), due to the presence of the solvents ethylbenzene and xylene. Licensed transport carriers will carry out transportation of the coating product from the wharf to the notifier's site and to end-use customers.

USE
The finished coating product containing the notified chemical will be used for automotive OEM and refinish applications.

OPERATION DESCRIPTION
The coating product containing the notified chemical will not be reformulated or repackaged before end use.

At the OEM site, the paint containing < 0.5% of the notified chemical will be pumped into the circulating mix tank using a dedicated lance, pipework and pump. This paint will be pumped around a circulation system from which it is sprayed onto car bodies by robots and operators in a dedicated ventilated spray area. Operators spray the paint onto specific areas of the car that are not painted by the robots. The painted cars travel through an oven under exhaust ventilation where the notified chemical is cured, thereby forming the final paint film on the car. During production breaks, operators use cloths dampened with solvent to clean residual paint from the spray equipment.

At motor vehicle body shops, workers open containers, measure and load the coating product to spray equipment prior to application by spray painting. Quality control is conducted by laboratory personnel. Spray painting is usually conducted inside a down draft spray booth fitted with filters and water scrubbers. The levels of ventilation present in the spray booth will vary between workshops. In smaller motor vehicle body shops, spray applications may occur outside of a spray booth. The coating product is applied to car bodies using HVLP spray guns. Once spraying is completed or the topcoat has been exhausted, the spray equipment is drained and cleaned using solvents and rags.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure assessment

6.1.1. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration hrs/day*	*Exposure Frequency (days/year)*
Import			
Unloading at wharf	4	4	20
Delivery to notifier's warehouse for storage	4	4	20
Delivery of product to end users	10	1-2	40-50
Application			
Application operators	10	1-2	20
Maintenance personnel	2	1-2	20
Laboratory personnel	5	1-2	20

Exposure Details
At the OEM site, the spray application is robotic in enclosed dedicated spray area, therefore, workers'

exposure is minimal. Where some manual spray coating occurs (to certain areas of the car) the exposure details would be similar to the car refinishing site below.

Spray painters may come into contact with the notified chemical at a concentration of up to 0.5% through dermal and ocular routes from direct contact with drips, spills and splashes during transfer of the paint to the spraying equipment, manual paint application, and equipment cleaning and maintenance. Workers may also be exposed to the notified chemical (concentration up to 0.5%) by inhalation of paint aerosols containing the notified chemical during spray application. In the majority of car repair shops exposure is expected to be minimal as the spray paint is applied in a ventilated spray booth by workers using protective equipment. In car repair shops where spray booths are not used, the level of exposure per application is expected to be greater, however, exposure will be minimised by spray application in a well ventilated area and the use of PPE in accordance with the MSDS.

After application and once dried, the paint containing the notified chemical is cured into an inert matrix and the chemical is hence unavailable to exposure.

6.1.2. Public exposure

Products containing the notified chemical are not available for sale to the public and will only be used by professional spray painters. The potential for public exposure to the notified chemical during transport, manufacture, use and disposal is negligible. Members of the public may make dermal contact with automobiles coated with products containing the notified chemical. However, exposure will be negligible because the notified chemical is likely to be bound within a cured paint film.

6.2. Human health effects assessment

No toxicity data were submitted for the notified chemical. The results from toxicological investigations conducted on an acceptable analogue (one of six zinc compounds) were provided. Details of these studies can be found in a EU Risk Assessment Report on Zinc distearate (EU, 2004). This EU risk assessment is based on an assumption that after intake the biological activities of the zinc compounds are determined by the zinc cation. Hence, for systemic toxicity, all available toxicity data (independent of the tested zinc compound) have been taken into account. For local effects, only data from the specific zinc compound or data from zinc compounds with more or less the same solubility were used. Below is a summary from the EU report.

Toxicokinetics, metabolism and distribution

The zinc (Zn^{2+}) absorption process in the intestines includes both passive diffusion and a carrier-mediated process. The absorption can be influenced by several factors such as ligands in the diet and the zinc status. Quantitative data on the absorption of zinc following inhalation exposure (especially relevant in occupational settings) are not available. Some animal data suggest that pulmonary absorption is possible. Dermal absorption through the intact skin seems to be small (<2%) based on the results of the *in vivo* animals studies as well as the *in vitro* studies, but shortcomings were noted in all *in vivo* studies and none of these studies can be used quantitatively. Human data indicate that following single or repeated dermal exposure zinc can be taken up by the skin, whereas the relevance of this skin depot cannot be judged based on the available data.

Following absorption, it was concluded in the EU report that Zinc is distributed to all tissues and tissue fluids. It is a cofactor in over 200 enzyme systems.

Zinc is primarily excreted via feces, but can also be excreted via urine, saliva, hair loss, sweat, and mother milk.

Acute toxicity

Zinc distearate has low acute toxicity by all exposure routes. Based on this information the notified chemical is also considered to be of low acute oral, inhalation and dermal toxicity.

Irritation and Sensitisation

Limited data indicate that zinc distearate is not irritating to skin and eye. Based on this

information the notified chemical is also considered not to be a skin and eye irritant.

Data on skin sensitisation are not available for zinc distearate. However, based on zinc compound data and the fact that zinc oxide (ZnO) is not a skin sensitiser, it is consequently concluded that zinc distearate is not likely to be skin sensitising. Furthermore, zinc distearate has been widely used in pharmaceutical and cosmetic products at concentration of up ot 50% without reported irritation and skin sensitisation effects. Based on this information the notified chemical is also considered not to be a skin sensitiser.

Repeated dose toxicity
In two oral 13-week studies with zinc sulphate (one with rats and one with mice) and an oral 13-week study with zinc monoglycerolate in rats, the lowest oral No Observed Adverse Effect Level (NOAEL) of 31.52 mg//kg bw (≈ 13.26 mg Zn2+/kg bw) was found in the study with zinc monoglycerolate. At higher doses the most important effects were hypocupremia, and significant changes in the pancreas (focal acinar degeneration and necrosis) and the spleen (decreased number of pigmented macrophages) in rats.

A number of inhalation studies of short exposure duration (3-6 days, 3 hours/day) are available for ultrafine ZnO/m^3. A marginal Lowest Observed Adverse Effect Level (LOAEL) of 2.3 mg ultrafine ZnO/m^3 was identified based on changes in neutrophils and activities of lacate dehydrogenase and alkaline phosphatase in the pulmonary fluid. Other effects at higher doses included increased protein concentration, neutrophils, and enzyme activities in lung lavage fluids, accompanied with significant centriacinar inflammation of the pulmonary tissue; and a gradual decrease in total lung capacity, vital capacity and reduction of the carbon monoxide diffusing capacity, together with inflammatory changes and edema.

Studies in which humans were supplemented with zinc (as zinc gluconate) indicate that women are more sensitive to the effects of high zinc intake and that a dose of 50 mg Zn2+/day is considered a NOAEL. Therefore, it does not meet the criteria for classification of an R48 substance. At the LOAEL of 150 mg Zn2+/day, clinical signs and indications for disturbance of copper homeostasis (due to interactions between zinc and other trace elements, especially copper) have been observed.

Mutagenicity
Genotoxicity results vary widely. Conflicting results have been found, even in same test systems. Overall, the test results indicate that zinc has genotoxic potential in vitro based on positive results in mammalian test systems for gene mutations and chromosomal aberrations and on the positive in vitro UDS (Unscheduled DNA Synthesis) test. The positive result for chromosomal aberrations in vitro is considered overruled by negative in vivo tests for this endpoint. The positive sperm head abnormality test is considered sufficiently counterbalanced by two negative SLRL (Sex Linked Recessive Lethal) tests as well as two negative dominant lethal tests.

Based on the available data there is insufficient ground to classify zinc as genotoxic. It should be noted that the potential to induce gene mutations was not adequately tested in vivo. However, there is no clear evidence from the available data that zinc is genotoxic in vivo and without a clear indication for carcinogenicity (see below) guidance for further testing with respect to target tissue is not available.

Based on the summary above there is insufficient information to classify the notified chemical as genotoxic.

Carcinogenicity
The limited data available indicate that zinc deficiency or supplementation may influence carcinogenesis since promoting and inhibiting actions have been reported. However, there is no clear experimental or epidemiological evidence for a direct carcinogenic action of zinc or its compounds.

Toxicity for reproduction
A NOAEL of > 19.9 mg Zn^{2+}/kg bw/day for developmental toxicity in animals is adopted for zinc

compounds.

Available data in animals on zinc excess indicate that adverse effects on fertility and foetal development may occur at dose levels of 200 mg Zn2+/kg bw/day, in conjunction with other effects such as perturbation of parental and foetal copper homeostasis. In humans, additional zinc up to 0.3 mg Zn2+/kg bw/day during pregnancy did not result in adverse effects. With respect to effects on reproduction, zinc deficiency is known to result in impairment of fertility and of foetal development. As the margin between the dose at which human clinical signs are manifested and the dose at which animal reproductive effects have been reported is so high, it is considered unlikely that humans reproductive effects will occur at exposure levels at which clinical signs are not manifested.

Based on the available data the notified chemical cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The risk to workers handling paints containing the notified chemical at <0.5% is considered acceptable given the expected low toxicity, low concentration of the notified chemical in the product and the expected PPE that workers will use.

During spray application, the exposure to aerosols is minimised by the expected use of PPE, low concentration of the notified chemical in paints and use of spray booths. Workers' exposure to aerosols could be higher in car repair shops where spraying occurs outside a spray booth. However, based on low toxicity of the notified chemical, the risk to workers can be considered low if appropriate controls such as ventilation and PPE are in place at all workplaces where manual spray applications occur. Any health risks would be further reduced by spraying being carried out according to the *National Guidance Material for Spray Painting* (NOHSC, 1999).

6.3.2. Public health

Public exposure to the notified chemical is expected to be negligible. Once the paint is dried, the notified chemical in not expected to be bioavailabile. Therefore, the risk to public health is expected to be insignificant.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

There will be no release during manufacture or reformulation in Australia as these will not occur here. Apart from accidental spills, release of the notified chemical is not expected during shipping and transport. The relatively small size of the containers will limit the size of any spills in the event of a transport accident.

RELEASE OF CHEMICAL FROM USE

Release of the notified chemical to the environment may occur at motor vehicle workshops during preparation and application of the topcoat.

Overspray

A loss of 30% of the ready-for use material is achieved by the use of HVLP spray guns and slightly higher loss with the more outdated high pressure guns. The engineering controls for over-spray are typically spray booth filters and water scrubbers. The spray booth filters are usually renewed every 2-4 months. The filters and scrubber waters are disposed of generally via a licensed waste contactor. Usually, the filters will ultimately be disposed of to landfill.

Minor losses of the notified chemical may occur as a result of incidental spills during loading of topcoat into spray equipment. A small amount of waste may also be generated as a result of residues remaining in empty containers. It is estimated that up to 1% of the total annual volume may remain in containers, which is expected to be ultimately disposed of to landfill.

Cleaning of equipment
It is estimated that up to 5% loss will occur from cleaning of equipment after application procedures The rinsates and used rags are collected for disposal to landfill or by incineration.

RELEASE OF CHEMICAL FROM DISPOSAL
All wastes generated during application, are expected to be disposed of to landfill. Container residues will also be disposed to landfill. The notified chemical applied to vehicles is expected to share the fate of the vehicle, which may result in thermal decomposition to form various oxides of carbon and zinc during the metal reclamation process, or disposal to landfill. In landfill the notified chemical is expected to be entrapped within stable cured coatings matrices and should be relatively immobile. Over time the notified chemical is expected to degrade to form simple organic compounds and salts.

7.1.2 Environmental fate

No environmental fate data were submitted.

7.1.3 Predicted Environmental Concentration (PEC)

As aquatic release is not anticipated at any point in the lifecycle of the notified chemical, it is not possible to calculate a PEC. The majority of notified chemical is expected to eventually be disposed of to landfill or to be thermally decomposed during the reclamation of metal to which the notified chemical has been applied.

7.2. Environmental effects assessment

No ecotoxicity data were submitted.

7.2.1 Predicted No-Effect Concentration (PNEC)

As ecotoxicity data were not submitted, it is not possible to calculate a PNEC. The notified chemical has surface-active properties, however, the inherent potential for ecotoxicity is expected to be mitigated by the presence of calcium ions in the aquatic environment.

7.3. Environmental risk assessment

The lack of exposure of the chemical to the aquatic compartment, coupled with the expected low potential for ecotoxicity indicates that the notified chemical is unlikely to have an adverse effect on aquatic organisms.

8. CONCLUSIONS – SUMMARY OF RISK ASSESSMENT FOR THE ENVIRONMENT AND HUMAN HEALTH

8.1. Hazard classification

Based on the available data the notified chemical cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

8.2. Human health risk assessment

8.2.1. Occupational health and safety

Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable.

8.2.2. Public health

When used in the proposed manner the risk to the public is considered to be acceptable.

8.3. Environmental risk assessment

The notified chemical is not considered to pose a risk to the environment based on its reported use pattern.

9. MATERIAL SAFETY DATA SHEET

The MSDS of the product containing the notified chemical provided by the notifier was reviewed by NICNAS and is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant. The MSDS was found to be in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003).

10. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical in the imported coating product:
  - Local ventilation if spraying occurs outside of spray booth.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical in the imported coating product:
  - Avoid breathing spray.
  - Use of spray paints containing the notified chemical should be accordance with the National Guidance Material for Spray Painting (NOHSC, 1999) or relevant State and Territory Codes of Practice.

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.

- As the imported product containing the notified chemical is classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- The notified chemical should be disposed of to landfill.

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

11. REGULATORY OBLIGATIONS

This risk assessment is based on the information available at the time of notification. If the circumstances under which the notified chemical was assessed change a reassessment may be needed. Under the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if

- the importation volume exceeds one tonne per annum notified chemical.

or

(2) Under Section 64(2) of the Act; if

- the function or use of the notified chemical has changed from automotive coating, or is likely to change significantly;
- the amount of chemical being introduced has increased from one tonne, or is likely to increase, significantly;
- if the notified chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the notified chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

APPENDIX A: PHYSICO-CHEMICAL PROPERTIES

The notified chemical exists in solvent and is never isolated. The following physico-chemical properties are for an accepted analogue, or the notified chemical in solvent, or the imported product unless otherwise stated.

Melting Point/Freezing Point Not determined

Remarks The notified chemical exists in solvent and is never isolated. Attempts to isolate the notified chemical lead to chemical changes as shown by infrared determinations. The melting point of the analogue is 130ºC (EC, 2004).

Boiling Point Not determined

Remarks The notified chemical exists in solvent and is never isolated. Attempts to isolate the notified chemical lead to chemical changes as shown by infrared determinations. The notified chemical in solvent is expected to boil at the boiling point of the solvent (xylene) which is ~135 to 145ºC.

Vapour Pressure Not determined

Remarks The notified chemical exists in solvent and is never isolated. Attempts to isolate the notified chemical lead to chemical changes as shown by infrared determinations. Furthermore, vapour pressure of the notified chemical is predicted to be low based on the structure. The vapour pressure for the solvent (xylene) is 0.93 kPa to 1.20 kPa at 20 ºC.

Water Solubility Approximately 0.001g/L at 20 ºC

Remarks 150g of the solution containing the notified chemical was stirred for five hours together with 300 g of water.

10g of the aqueous phase was then taken off and the non-volatiles (1 hour/130 °C) were determined. Result: 0.178 % of the notified chemical had been extracted into the water phase.

However, IR spectrum showed chemical changes occurring on isolation of the notified chemical. Furthermore solubility of an acceptable analogue indicates that the true water solubility is approximately 0.001 g/L.

Water solubility for the analogue is:
0.79 mg/L at 15ºC
0.9 mg/L at 20 ºC
0.97 mg/L at 25 ºC

TEST FACILITY Not specified

Hydrolysis as a Function of pH Not determined

Remarks The notified chemical does not contain any groups which can be hydrolysed under environmental conditions (pH 4-9).

Partition Coefficient (n-octanol/water) Not determined

Remarks The notified chemical exists in solvent and is never isolated. Attempts to isolate the notified chemical lead to chemical changes as shown by infrared determinations.

Furthermore, the notified chemical also has surface-active properties and true partition coefficient can not be determined.

The partition coefficient for the analogue was reported to be 1.2.

Adsorption/Desorption Not determined

Remarks The notified chemical has surface-active properties and true adsorption/ desorption coefficient can not be determined. Based on water-octanol partition coefficient of the analogue, the notified chemical is not expected to bind strongly to organic matter in soil.

Dissociation Constant Not determined

Remarks The notified chemical contains carboxylate groups which are expected to have a pKa of 3-5.

Particle Size Not applicable

Remarks The notified chemical exists in solvent and is never isolated.

Flash Point Not determined

Remarks The notified chemical is not expected to be flammable. The flash point of the analogue was reported to 277ºC (EC, 2004).

Flammability Limits Not determined

Remarks The notified chemical is not expected to be flammable. The analogue was reported to be non flammable (EC, 2004).

Autoignition Temperature Not determined

Remarks The notified chemical is not expected to auto ignite. The auto flammability temperature for the analogue was reported to be 421ºC (EC, 2004).

Explosive Properties Not determined

Remarks The notified chemical is not expected to be explosive and does not contain any structural alters for explosivity. The analogue was reported to be not explosive (EC, 2004).

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