File No: STD/1480

December 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Isocyanic acid, polymethylenepolyphenylene ester, polymer with 2-methyloxirane polymer with oxirane ether with 1,2,3-propanetriol (3:1), 2-hydroxyethyl methacrylate-blocked

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This 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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1480	Pacific Environment Operations Pty Ltd	Isocyanic acid, polymethylenepolyphenylene ester, polymer with 2-methyloxirane polymer with oxirane ether with 1,2,3-propanetriol (3:1), 2-hydroxyethyl methacrylate-blocked	ND*	≤ 70 tonnes per annum	Resin for fabrication of glass-reinforced parts

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As no toxicity data were provided, the notified polymer cannot be classified according to the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS), as adopted for industrial chemicals in Australia, or the Approved Criteria for Classifying Hazardous Substances (NOHSC, 2004).

Human health risk assessment
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

Environmental risk assessment
On the basis of the assessed use pattern and assumed low hazard, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced:
  - Enclosed, automated systems where possible

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
  - Avoid contact with skin and eyes

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
  - Eye protection
  - Coveralls
  - Impervious gloves

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

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

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

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of 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 polymer is listed on the Australian Inventory of Chemical Substances (AICS).

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

(1) Under Section 64(1) of the Act; if
  - additional information becomes available on the human health toxicity of the notified polymer;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from resin for fabrication of glass-reinforced parts , or is likely to change significantly;
  - the amount of polymer being introduced has increased, or is likely to increase, significantly;
  - the polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the polymer 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.

(Material) Safety Data Sheet
The (M)SDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Pacific Environment Operations Pty Ltd (ABN: 86 127 101 642)
Suite 1, Level 1, 146 Arthur Street
NORTH SYDNEY NSW 2060

NOTIFICATION CATEGORY
Standard: Synthetic polymer with Mn < 1,000 Da (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: for all physico-chemical endpoints

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Crestapol 1210 (product containing the notified polymer at up to 31% concentration)
Crestapol 1212 (product containing the notified polymer at up to 36% concentration)

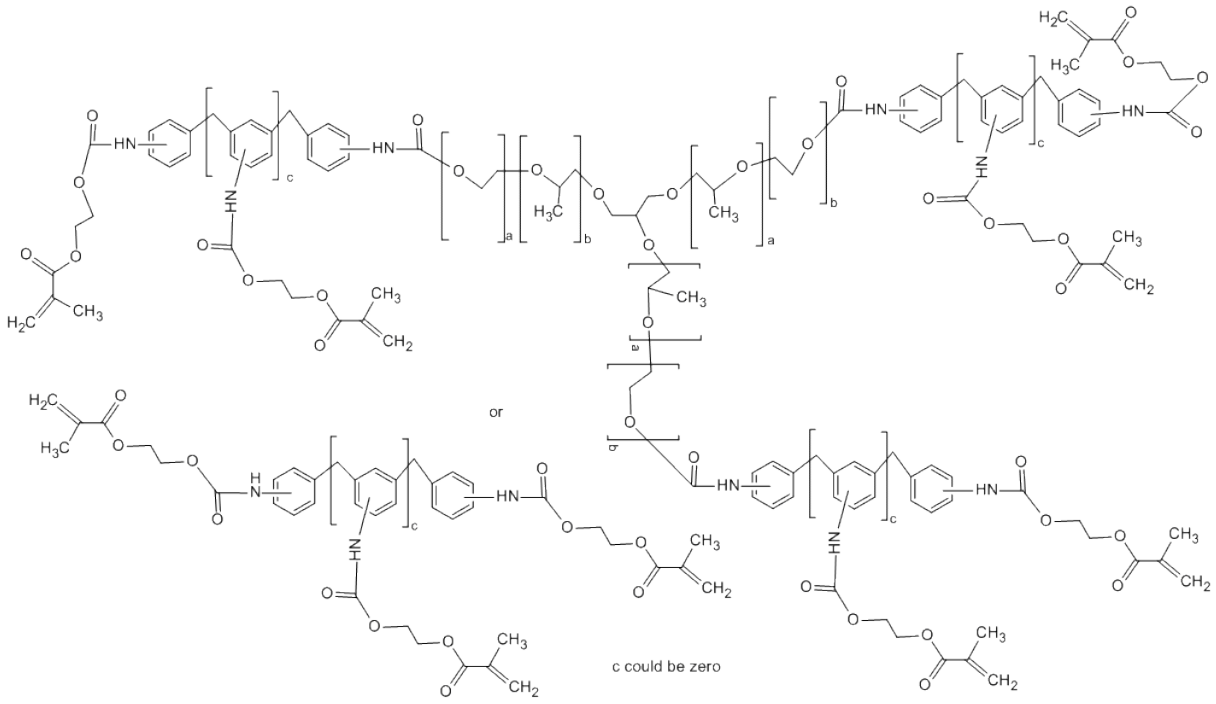
CAS NUMBER
1445867-43-5

CHEMICAL NAME
Isocyanic acid, polymethylenepolyphenylene ester, polymer with 2-methyloxirane polymer with oxirane ether with 1,2,3-propanetriol (3:1), 2-hydroxyethyl methacrylate-blocked

OTHER NAME(S)
PD10022 (notified polymer)
Crystic Crestapol PD10022 (product containing the notified polymer)

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	999 Da
Weight Average Molecular Weight (Mw)	4,619 Da
Polydispersity Index (Mw/Mn)	4.6
% of Low MW Species <1,000 Da	49.4%
% of Low MW Species <500 Da	10.2%

ANALYTICAL DATA

Reference GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 94.5%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	2-Propenoic acid, 2-methyl-, 2-hydroxyethyl ester		
CAS No.	868-77-9	*Weight %*	3.5
Hazardous Properties	Xi; R36/38; R43 Conc. ≥ 20%: Xi; R36/38; R43 ≥ 1% Conc. < 20%: Xi; R43		

Chemical Name	Isocyanic acid, polymethylenepolyphenylene ester		
CAS No.	9016-87-9	*Weight %*	< 0.3
Hazardous Properties	Isocyanates are irritating to the skin and the mucous membranes, from localised itching to more or less widespread eczema, eyes (lacrimation is often found than conjunctivitis), and respiratory systems (information provided by the notifier)		

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)

Chemical Name	Oxirane, 2-methyl-, polymer with oxirane, ether with 1,2,3-propanetriol (3:1)		
CAS No.	9082-00-2	*Weight %*	1.7

ADDITIVES/ADJUVANTS
None

POLYMER CONSTITUENTS

Chemical Name	*CAS No.*	*Weight % starting*	*Weight % residual*
Oxirane, 2-methyl-, polymer with oxirane, ether with 1,2,3-propanetriol (3:1)	9082-00-2	< 20	< 5
2-Propenoic acid, 2-methyl-, 2-hydroxyethyl ester	868-77-9	< 50	< 5
Isocyanic acid, polymethylenepolyphenylene ester	9016-87-9	< 50	< 5

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The notified polymer is stable under normal conditions.

DEGRADATION PRODUCTS
Degradation products are expected to be oxides of nitrogen and carbon.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: viscous liquid

Property	**Value**	**Data Source/Justification**
Melting Point/Freezing Point	-45 - -30 °C	Estimated
Boiling Point*	50-150 °C at 101.3 kPa	SDS
Density*	1,100-1,200 kg/m^3 at 20 °C	SDS
Vapour Pressure	1 × 10^{-8} kPa at 25 °C	Estimated
Water Solubility	Not determined	The notified polymer is expected to have limited solubility in water based on its predominantly hydrophobic structure.
Hydrolysis as a Function of pH	Not determined.	Contains hydrolysable functionality. However, based on its assumed limited water solubility, it is expected to hydrolyse very slowly in the environmental pH range (4–9) at ambient temperature.
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is expected to partition from water to octanol based on its highly hydrophobic structure.
Adsorption/Desorption	Not determined	Expected to adsorb to soil, sediment and sludge and have low mobility in soil based on its hydrophobicity.
Dissociation Constant	Not determined	Does not contain any readily dissociable functional groups.
Flash Point	Not determined	Imported in organic solvent
Autoignition Temperature	Not determined	Imported in organic solvent
Explosive Properties	Not determined	Not expected to be explosive based on structure
Oxidising Properties	Not determined	Not expected to be oxidising based on structure

* For imported product containing the notified polymer at up to 36% concentration

DISCUSSION OF PROPERTIES

Reactivity
The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported as a component of a formulated product in organic solvent at up to 36% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	5	40	50	60	70

PORT OF ENTRY
Sydney, Brisbane, Perth and Melbourne

IDENTITY OF RECIPIENTS
Pacific Environment Operations Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be introduced as part of a formulation packaged in 25 kg, 200 kg and 1 tonne containers by sea and transported by road or rail in Australia.

USE
Resin for fabrication of glass-reinforced parts by closed-mould and pultrusion processing.

OPERATION DESCRIPTION
There will be no reformulation or repackaging of the product containing the notified polymer prior to distribution to end users.

At the end use sites the liquid resin containing up to 36% notified polymer will be dispensed into a mixer where pigment and initiators will be added to make the final mix containing the notified polymer at ~12% concentration. The final mix will then be pumped into a closed mould system or incorporated using vacuum infusion. The material reacts with atmospheric moisture at the time of application to form an inert solid matrix. Any excess will be cleaned using a specially formulated cleaning product and a cloth.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport	2-3	10-15
Application	8	260

EXPOSURE DETAILS
Transport and Storage:
Transport and storage workers are not expected to be exposed to the notified polymer except in the unlikely event of an accident.

Application:

Dermal and ocular exposure to the notified polymer at up to 36% may occur during the manual addition of the notified polymer to mixing equipment and the application equipment. Dermal exposure may also occur during mixing, application and cleaning of the applied product, and during equipment maintenance and cleaning.

To minimise exposure to the notified polymer, the end users will wear eye protection, coveralls and impervious gloves. Where ventilation is not sufficient, a ventilator/mask will be worn.

Workers may make dermal contact with the notified polymer once the formulation is dried to the substrate, however once dried the formulation will form a film that will contain and immobilise the notified polymer.

6.1.2. Public Exposure

The notified polymer is present in formulations which are for industrial use only. In the unlikely event that the general public come in contact with the cured substrate containing the notified polymer, the polymer will be fully reacted into the matrix and will not be bioavailable.

6.2. Human Health Effects Assessment

No toxicity data is available for the notified polymer. As a worst case scenario to estimate the toxicity of the notified polymer, the notifier has provided information for the monomer in the notified polymer that contains the functional group of concern i.e. 2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester (CAS No. 868-77-9) (other name: 2-hydroxyethyl methacrylate, HEMA).

Toxicokinetics, metabolism and distribution

Absorption of the notified polymer across biological membranes is likely to be limited, based on the relatively high molecular weight (999 Da) and expected low water solubility. However there are significant levels of low molecular weight species and the possibility of absorption cannot be ruled out.

Acute toxicity

HEMA is of low acute oral (LD50 > 4,000 mg/kg bw) and dermal (LD50 > 3,000 mg/kg bw) toxicity (SIDS, 2001). Based on this information and given the high molecular weight of the notified polymer limiting absorption, the notified polymer is expected to be of low acute oral and dermal toxicity.

Irritation

HEMA is classified as a skin and eye irritant (ECHA Classification and Labelling Inventory). The notified polymer may therefore have the potential to be irritating; however, this may be limited by the high molecular weight of the notified polymer.

Sensitisation

HEMA is classified as a skin sensitiser (ECHA Classification and Labelling Inventory). The notified polymer may therefore have the potential to be sensitising; however, this may be limited by the limited potential for the notified polymer to be dermally absorbed.

Repeated dose toxicity

In a combined repeat dose developmental reproductive screening assay (OECD TG 422) HEMA was administered to rats at concentrations of 30, 100, 300, and 1,000 mg/kg bw/day. In males, systemic toxicity was seen only at the highest dose level, 1,000 mg/kg bw/day, after 49 days of treatment. These signs included salivation, suppression of body weight gain, decreased feed consumption, increased relative liver weights, decreased triglycerides and increased K, Cl, or inorganic phosphorous. Relative kidney weights were increased at 100 mg/kg/day or higher. Findings related to renal histopathology were found only at 1,000 mg/kg/day, the high (limit) dose group, of mild severity. One of 12 animals in this group died.

In females, HEMA was administered from 14 day prior to mating through the 3rd day of lactation. Six of the 12 animals died in the high dose group, 1,000 mg/kg/day. Agonal effects or general weakness preceded death. There was suppression of body weight gain, decreased feed consumption, increased absolute and relative kidney weights, and neutrophilic cellular infiltration in the renal papillae and medulla. Histopathologic changes included a slightly softened spinal cord of one animal of those dying. The NOAEL for repeat dose toxicity in males and females was determined to be 30 mg/kg bw/day.

In the six surviving females, HEMA produced no sign of reproductive or developmental toxicity up to 1,000 mg/kg bw/day, the limit dose. Thus, the NOAEL was 1,000 mg/kg bw/day for both reproduction (both sexes, adults) and developmental (offspring) toxicity.

Based on the results of this study, the notified polymer may have the potential to cause systemic toxicity; however, this may be limited by the limited potential for the notified polymer to be absorbed.

Mutagenicity/Genotoxicity
HEMA was not mutagenic in bacteria but was clastogenic and induced polyploidy in mammalian cells *in vitro*. It, however, did not induce micronuclei in rat bone marrow up to the maximum tolerated dose. Based on the weight of evidence, it was concluded that HEMA was not genotoxic *in vivo*, as it did not induce micronuclei in bone marrow (SIDS, 2001).

Health hazard classification
As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the toxicological profile for HEMA as a worst case scenario to estimate the toxicity of the notified polymer, the notified polymer may have the potential to be irritating to the skin and eyes and sensitising. There is also the potential to cause systemic toxicity. However given the high molecular weight of the notified polymer and expected limited potential for absorption, the potential for these toxicity effects is low but cannot be ruled out given the significant levels of low molecular weight species.

Workers may be exposed to the notified polymer at 36% concentration. At these concentrations there is the potential risk for irritation, sensitisation and systemic toxicity. Use of the notified polymer is therefore only considered reasonable when sufficient engineering controls, safe work practices and personal protective equipment (PPE) are used to greatly reduce the potential for exposure. The notifier states that workers will use PPE including eye protection, coveralls, and imperious gloves when handling the notified polymer.

Therefore, provided that the stated PPE is used to limit exposure, the risk to the health of workers is not considered to be unreasonable.

6.3.2. Public Health
The notified polymer will be used in industrial settings only and will not be sold to the public. The public may come into contact with the cured substrate containing the notified polymer. However, once the notified polymer is cured, it will be fully reacted into the matrix and will not be bioavailable. Therefore, when used in the proposed manner, the risk to public health is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The resins containing the notified polymer for fabrication of glass-reinforced parts will not be manufactured, reformulated or repackaged in Australia. Therefore, release of the notified polymer from these activities is not expected.

RELEASE OF CHEMICAL FROM USE
The finished resin containing the notified polymer will be used in industrial settings. The composite articles will be manufactured using an industrial process which is expected to be semi-automated. The engineering controls are expected to be in place; hence no direct environmental release of the notified polymer from end use is predicted. Any solid wastes containing the notified polymer are expected to be disposed of to landfill. Equipment used to apply the formulations is expected to be rinsed with solvent.

The waste solvent containing the notified polymer is expected to be absorbed in vermiculite, dry sand or earth and placed into containers. Disposal will be to a licensed waste disposal site in accordance with local Waste Disposal Authority.

RELEASE OF CHEMICAL FROM DISPOSAL
Most of the notified polymer will be irreversibly bound within a hardened composite coating, following the composite fabrication, become immobile and inert, and ultimately end up in landfill at the end of its useful life.

7.1.2. Environmental Fate
No environmental fate data were submitted. The majority of the notified polymer is expected to be irreversibly cured within an inert polymer matrix bound to articles following its use in fabrication of glass-reinforced parts and pultrusion processing. The majority of the notified polymer is expected to be disposed of to landfill as waste from spills, residues in empty import containers, and articles at the end of their useful life. Notified polymer that is disposed of to landfill is expected to remain associated with the substrate to which it has been applied and in its cured form it is not expected to be bioavailable nor biodegradable. Notified polymer in solid waste disposed of to landfill is not likely to be mobile due to its expected limited water solubility and incorporation into an inert matrix. The notified polymer will undergo slow biotic and abiotic degradation processes in landfill, or by thermal decomposition, to form water, and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)
The predicted environmental concentration (PEC) was not calculated as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.2. Environmental Effects Assessment
No ecotoxicity data were submitted. Polymers without significant ionic functionality are generally of low concern to the environment. The ECOSAR estimations for aquatic toxicity data indicated that the notified polymer is not toxic at its solubility limit.

7.2.1. Predicted No-Effect Concentration
A predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.3. Environmental Risk Assessment
The risk quotient (Q = PEC/PNEC) for the notified polymer has not been calculated as release to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern. The majority of the notified polymer will eventually be disposed of to landfill following its use. In its cured state the notified polymer will be irreversibly bound into an inert matrix and is unlikely to leach or be bioavailable. On the basis of the assessed use pattern and assumed low hazard, the notified polymer is not considered to pose an unreasonable risk to the environment.

BIBLIOGRAPHY

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

SIDS (2001) SIDS Initial Assessment Profile for 2-hydroxyethyl methacrylate. SIAM 13, 6-9 November 2001.

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.