File No: STD/1436 and STD/1437

January 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

STD/1436: Blocked Isocyanate in Desmodur PL 340
STD/1437: Blocked Isocyanate in Desmodur PL 350

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 Sustainability, Environment, Water, Population and Communities.

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

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICALS	INTRODUCTION VOLUME	USE
STD/1436 STD/1437	Bayer MaterialScience and PPG Industries Australia Pty Ltd	STD/1436: Blocked Isocyanate in Desmodur PL 340 STD/1437: Blocked Isocyanate in Desmodur PL 350	ND*	STD/1436: ≤ 20 tonnes per annum STD/1437: ≤ 20 tonnes per annum	Coating agents for metal surfaces

*ND – not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemicals are not recommended for classification 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 chemicals are not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment
On the basis of the assessed use pattern and expected low hazard to aquatic life, the notified chemicals are 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 chemicals:
  - Enclosed and automated systems during reformulation, where possible
  - Spray operations conducted within dedicated spray booths

- 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 chemicals:
  - Avoid skin and eye contact
  - Avoid inhalation of aerosols

- 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 chemicals:
  - Eye protection, coveralls and protective gloves

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012) or relevant State or Territory Code of Practice.

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

- If products and mixtures containing the notified chemicals 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

- The notified chemicals should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemicals 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 chemicals are 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
  - The notified chemicals are proposed to be used as coating agent for metal surfaces with food contact;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemicals has changed from coating agent for metal surfaces, or is likely to change significantly;
  - the amount of chemicals being introduced has increased from 20 tonnes per annum each, or is likely to increase, significantly;
  - the chemicals have begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemicals 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 notified chemicals provided by the notifier were 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)
Bayer MaterialScience (ABN: 18 086 237 765)
17-19 Wangara Road

CHELTENHAM VIC 3192

PPG Industries Australia Pty Ltd (ABN: 82 055 500 939)
McNaughton Road
CLAYTON VIC 3168

NOTIFICATION CATEGORY
STD/1436 - Standard: Chemical other than polymer (more than 1 tonne per year).

STD/1437 - Standard (Reduced fee notification): Chemical other than polymer (more than 1 tonne per year) – Chemical is being notified at the same time as a similar chemical.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants, use details, import volume and analogue details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
STD/1436: Variation to the schedule of data requirements is claimed for all physico-chemical endpoints (except for hydrolysis as a function of pH), acute dermal toxicity, eye irritation, repeated dose toxicity, chromosome damage *in vitro*, genotoxic damage *in vivo*.

STD/1437: Variation to the schedule of data requirements is claimed for all physico-chemical endpoints, acute oral toxicity, acute dermal toxicity, skin irritation, eye irritation, repeated dose toxicity, induction of point mutations, chromosome damage *in vitro*, genotoxic damage *in vivo*.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
STD/1436: Desmodur PL 340 (contains the notified chemical at 60% concentration)
STD/1437: Desmodur PL 350 (contains the notified chemical at 75% concentration)

MOLECULAR WEIGHT
UVCB chemicals with a NAMW > 1,000 Da (STD/1436 & STD/1437)

ANALYTICAL DATA
Reference NMR and IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95% (STD/1436 & STD/1437)

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: The notified chemicals will be synthesised in solvent and not isolated. The imported notified chemicals in solvent solution at 60-75% concentration are yellowish liquids.

Property	Value		Data Source/Justification
	STD/1436	**STD/1437**	
Melting Point	350 °C	350 °C	Calculated (MPBPVP v1.43; US EPA, 2009)
Boiling Point	1,300 °C at	1,203 °C at	Calculated. Thermal

	101.3 kPa	101.3 kPa	deblocking of the isocyanate group is expected at > 120°C.
Density	1,030 kg/m^3 at 20 °C	1,110 kg/m^3 at 20 °C	(M)SDS. For the imported products containing the notified chemicals at 60-75% in solvent solution.
Vapour Pressure	4.52 x 10^{-35} kPa at 25 °C	3.3 x 10^{-32} kPa at 25 °C	Calculated (MPBPVP v1.43; US EPA, 2009)
Water Extractability	≤ 0.11% at 20 °C, pH 2 ≤ 0.057% at 37 °C, pH 7 ≤ 0.12% at 20 °C, pH 9	≤ 0.11% at 20 °C, pH 2 ≤ 0.057% at 37 °C, pH 7 ≤ 0.12% at 20 °C, pH 9	Measured for STD/1436; water extractability of STD/1436 as analogue data for STD/1437.
Hydrolysis as a Function of pH	Stable at 40 °C for 24 hours, pH 1.2 Stable at 40 °C for 336 hours, pH 4 Stable at 40 °C for 336 hours, pH 7 Stable at 40 °C for 336 hours, pH 9	Stable at 40 °C for 24 hours, pH 1.2 Stable at 40 °C for 336 hours, pH 4 Stable at 40 °C for 336 hours, pH 7 Stable at 40 °C for 336 hours, pH 9	Measured for STD/1436; stability of STD/1436 as analogue data for STD/1437. The notified chemicals contain hydrolysable groups. However, significant hydrolysis is not expected under environmental conditions due to their limited water solubilities.
Partition Coefficient (n-octanol/water)	log Pow = 15.17 at 25 °C	log Pow = 10.50 at 25 °C	Calculated for the representative species of STD/1436 and STD/1437, respectively. (KOWWIN v1.68, US EPA 2011)
Adsorption/Desorption	log K_{oc} = 6.92 at 25 °C (MCI method) log K_{oc} = 8.89 at 25 °C (Pow method)	log K_{oc} = 6.54 at 25 °C (MCI method) log K_{oc} = 7.32 at 25 °C (Pow method)	Calculated for the representative species of STD/1436 and STD/1437, respectively. (KOCWIN v2.00, US EPA, 2011)
Dissociation Constant	Not determined	Not determined	Due to their limited water solubilities, the notified chemicals may not be readily ionisable although they contain potentially cationic groups
Flash Point	Not determined	Not determined	Expected to be high based on the high molecular weight
Flammability	Not determined	Not determined	Not expected to be flammable
Autoignition Temperature	Not determined	Not determined	Not expected to undergo autoignition
Explosive Properties	Not determined	Not determined	Not expected to be explosive - does not contain explosophores.
Oxidising Properties	Not determined	Not determined	Not expected to oxidise

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
The notified chemicals are expected to be stable at ambient temperatures.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemicals are 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
STD/1436: Introduced as a solvent solution at a concentration of 60% or as a component of finished coatings at concentrations up to 10%.

STD/1437 Introduced as a solvent solution at a concentration of 75% or as a component of finished coatings at concentrations up to 10%.

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

	Year	*1*	*2*	*3*	*4*	*5*
STD/1436	*Tonnes*	5-20	5-20	5-20	5-20	5-20
STD/1437	*Tonnes*	5-20	5-20	5-20	5-20	5-20

PORT OF ENTRY
Melbourne and Sydney

TRANSPORTATION AND PACKAGING
The notified chemicals imported in solvent solution at 60-75% concentration will be packed in 205 L steel drums. The finished coatings containing up to 10% of each of the notified chemicals will be imported or packed after formulation in Australia in 20 L cans or 205 L steel drums. Transportation within Australia will mainly be by road.

USE
The notified chemicals will be used to formulate one-pack polyurethane baking coatings that will be applied on metal substrates.

OPERATION DESCRIPTION
The notified chemicals will be imported in finished coating products or at 60-75% concentration for local reformulation into coating products.

Reformulation

Reformulation of the notified chemicals into coating products will involve transfer of the notified chemicals from the import containers by metered dosing to a mixing vessel. The notified chemicals will then be mixed with other ingredients in a sealed vessel fitted with a high-speed mixer and local exhaust ventilation system. Each batch will be quality checked and adjustments made as required. The resultant coatings will be filtered prior to being dispensed into 20 L cans or 205 L drums under exhaust ventilation for supply to customers. The final concentration of the notified chemicals in the final coating products will be up to 10%. Coating products containing the notified chemical will be stored at the reformulation site and distributed to end-users.

End-use

Workers will open cans of the coating containing the notified chemicals in a mixing room. If additional thinning is required, the worker will transfer the coating to a container where additional ingredients will be added. The coating will then be transferred to a reservoir for spray equipment application. The reservoir may be a pressure pot or a cup attached to the spray gun that feeds the gun through aspiration or gravity. When supplied in 205L drums, workers will open the drums containing the coating and connect transfer lines and pumping equipment to the drum. The transfer line will be connected to the spray equipment. The formulated coating products will be

applied to the metal substrate by airless spray. The spray applications will occur in an enclosed spray booth which is supplied with local exhaust ventilation and filters to remove any overspray.

After the metal substrate has been sprayed, the substrate will be transferred along a conveyor into an oven for heat-curing of the coating. The oven will be supplied with local exhaust ventilation.

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)*
Transportation and Storage	1-2	20
Reformulation	4-8	20
QC Staff	1	20
Maintenance	1-2	20
Spray painting	8	300

EXPOSURE DETAILS

Transport and Storage

Transport and warehousing workers are only expected to come into contact with the notified chemicals through accidental leaks and spillages.

Reformulation

Workers may be exposed to the notified chemicals (concentration of up to 75%) via dermal and ocular exposure during charging of the mixer, blending, filtering, dispensing, quality control testing/adjustment, and cleaning. Some inhalation exposure may also occur during blending due to the possible release of aerosols. Exposure is expected to be lowered by the use of local exhaust ventilation systems, the closure of the system when high speed stirring occurs, the wearing of a respirator where ventilation is inadequate, and the wearing of personal protective equipment (PPE), including coveralls, goggles, and impervious gloves.

End-Use

Spray painters may come into contact with the notified chemicals at concentrations of up to 10% through dermal and ocular routes from direct contact with drips, spills and splashes during transfer of the coating to the spraying equipment, equipment cleaning and maintenance, and spray application. Exposure is expected to be lowered by the wearing of personal protective equipment during these operations.

Workers may also be exposed to the notified chemicals (concentration of up to 10%) by inhalation of aerosols containing the notified chemicals during spray application. However, exposure is expected to be minimal as the application will occur in a ventilated, automated and enclosed spray booth.

After application and once heat cured, the coating containing the notified chemicals will be cured into an inert matrix and the notified chemicals will hence be unavailable for exposure.

6.1.2. Public Exposure

Coatings containing the notified chemical will not be used by the public. The general public may come in contact with metal substrates that have been coated with products containing the notified chemicals; however once cured and dried, public exposure to the notified chemicals is not expected to occur. The metal substrates that are coated with products containing the notified chemicals will not have food contact applications.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemicals and analogues are summarised in the following table. For full details of the studies conducted on the notified chemicals, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*			
	STD/1436	**STD/1437**	**Analogue 1**	**Analogue 2**
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity	-	LD50 > 14000 mg/kg bw; low toxicity	LD50 > 2500 mg/kg bw; low toxicity
Rat, acute dermal toxicity	-	-	-	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	-	-	LC50 >5.01mg/L/4hr (aerosol); low toxicity	LC50 > 0.39 mg/L/4hr (females) LC50 > 0.543 mg/L/4hr (males) (aerosol, head/nose only); toxic
Rabbit, skin irritation	slightly irritating	-	-	-
Rabbit, eye irritation	-	-	slightly irritating	slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test.	-	no evidence of sensitisation	-	-
Mouse, skin sensitisation – local lymph node assay (modified assay)	no evidence of sensitisation	-	-	-
Rat, repeat dose inhalation toxicity	-	-	NOAEC 0.0029 mg/L (13 weeks, 5 days/week, 6 hr/day); toxic	NOAEC 0.0043 mg/L (3 weeks, 5 days/week, 6 hr/day); toxic NOAEC 0.0033 mg/L (subchronic, head/nose only); toxic
Mutagenicity – bacterial reverse mutation	non mutagenic	-	non mutagenic	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration	-	-	non genotoxic	non genotoxic
Genotoxicity – in vitro mammalian cell gene mutation	-	-	non genotoxic	non genotoxic

Toxicokinetics.

The notified chemicals are UVCB substances. They have a high molecular weight (NAMW > 1000 Da), predicted low water solubility and high lipophilicity. Although there is a high percentage of low molecular weight species < 1000 Da, there is a low percentage (< 3%) of low molecular weight species < 500 Da, hence absorption across biological membranes is expected to be limited for the notified chemicals.

Acute toxicity.

The results of studies on the notified chemicals and the analogues indicate that the notified chemicals are of low acute oral and dermal toxicity. Analogue 2 was found to be acutely toxic via inhalation, whilst analogue 1 was of

low acute inhalation toxicity. Both analogues contain a particular functional group that is known to result in respiratory effects, including pulmonary toxicity. This functional group is not present in either of the notified chemicals. For this reason it is expected that the notified chemicals will have lower inhalation toxicity than either of the analogues and are thus expected to be of low acute inhalation toxicity.

Irritation and sensitisation.
The results of studies on one of the notified chemicals and the analogues suggest that the notified chemicals are slightly irritating to the skin. The analogues were found to be slightly irritating to the eyes. However, the notified chemicals contain a functional group that is a structural alert for serious eye damage but which is not present in either of the analogues. As such, the notified chemicals may be irritating to the eyes. Skin sensitisation studies on the notified chemicals indicate that they are not expected to be sensitisers.
Repeated Dose Toxicity.
No repeated dose toxicity data were provided for the notified chemicals.

Repeated dose inhalation toxicity studies have been performed on the two analogues. The results of these studies indicate that the analogues are toxic following prolonged inhalation exposure. These effects are likely due to the presence of a particular functional group in the analogues that has been associated with pulmonary toxicity.

The notified chemicals do not contain any known structural alerts for systemic toxicity and absorption across biological membranes is expected to be limited, hence toxicity from repeated exposure is not expected.

Mutagenicity/Genotoxicity.
One of the notified chemicals was found to be not mutagenic in a bacterial reverse mutation assay. The analogues were not genotoxic in a number of *in vitro* studies. Although the analogues do not contain a functional group present in the notified chemicals, this functional group is not known to be associated with genotoxic effects. Based on the weight of evidence, the notified chemicals are not likely to be genotoxic.

Health hazard classification
Based on the available information, the notified chemicals are not recommended for classification 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 available information, the notified chemicals are slightly irritating to the skin and may be irritating to the eyes. Toxicity from repeated exposure is not expected, based on the absence of any known structural alerts for systemic toxicity and the limited potential for the notified chemicals to be absorbed across biological membranes.

Ocular, inhalation and dermal exposure of workers to the notified chemicals at concentrations up to 75% may occur during reformulation operations. These exposures are expected to be lowered by the use of engineering controls and personal protective equipment. As such, the risk to workers of irritation and toxic effects from repeated exposure to the notified chemicals during reformulation is not considered to be unreasonable.

Workers may also experience ocular, inhalation and dermal exposure to the notified chemicals at concentrations up to 10% during spray operations. These exposures are expected to be lowered mainly by the use of enclosed spray booths supplied with local exhaust ventilation and personal protective equipment. As such, the risk to workers of irritation and toxic effects from repeated exposure to the notified chemicals during end use spray operations is not considered to be unreasonable.

Overall, the risk to works from use of the notified chemicals under the occupational settings described is not considered unreasonable.

6.3.2. Public Health
The public may come into contact with surfaces that have been coated with coatings containing the notified chemicals; however, once cured, the notified chemicals will not be bioavailable. Therefore, when used in the proposed manner, the risk to public health from exposure to the notified chemicals 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 notified chemicals may be imported as components of finished coating products or as raw material for local reformulation into paint/coating products. Any spills of the notified chemicals during transportation and storage are expected to be contained with adsorbent material and be disposed of to landfill. During reformulation processes, the release of the notified chemicals may occur due to spills, leaks and solvents for equipment cleaning. These wastes, estimated by the notifier to account for less than 1% of total annual import volume of the notified chemicals, are expected to be collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The formulated paint/coating products will be applied to metal substrates by airless spray in enclosed spray booths. The main release of notified chemicals during industrial spray painting operations will come from overspray, accounting for up to 20% of the annual import volume. Overspray, accidental spills (0.2%) and washings for equipment cleaning (1%) are expected to be collected and disposed of to landfill in accordance with local, State and Federal regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

Most of the notified chemicals are expected to share the fate of the coating articles to which they have been applied and either be thermally decomposed during metal reclamation processes or disposed of to landfill. Residues in empty containers containing up to 3% of the imported quantity of notified chemicals (up to 1% in imported containers and 2% in empty end-use containers) are expected to be disposed of to landfill.

7.1.2. Environmental Fate

The majority of the notified chemicals are expected to be incorporated into an inert matrix following its normal use as components in metal coatings. The notified chemicals are not expected to be bioavailable nor biodegradable in this form. Notified chemicals in solid waste disposed of to landfill are not expected to be mobile due to their limited water solubilities and estimated high n-octanol/water partition coefficients and soil adsorption coefficients for the representative species. Significant amounts of notified chemicals are not expected to be released to the aquatic environment.

The notified chemicals are not expected to rapidly degrade in landfill (biodegradability is 0% and 23% for STD/1436 and STD/1437 over 28 days, respectively). However, bioaccumulation of the notified chemicals is unlikely due to their high molecular weight and limited water solubilities. The notified chemicals are UVCB substances that contain high percentage of low molecular weight species. However, the majority of these low molecular weight species are reported to have molecular weight just below the regulatory bioaccumulation threshold of 1000 Da and therefore, most of them are expected to have limited potential to cross biological membranes and be bioaccumulative. The low bioaccumulation factors estimated for low molecular weight representatives (BCF < 100) also indicate that these low molecular weight components have limited potential for bioaccumulation (BCFBAF, v 3.01; US EPA 2011).

The notified chemicals will eventually degrade in landfill, or by thermal decomposition during metal reclamation processes, to form water, oxides of carbon and nitrogen. For the details of the environmental fate studies please refer to Appendix C.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated for the notified chemicals as, based on their assessed use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified chemicals are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result**		*Assessment Conclusion*
	STD/1436	*STD/1437*	
Fish Toxicity	LC50 (96 h) > 100 mg/L	LC50 (96 h) > 100 mg/L	Not harmful to fish up to the limit of their water solubilities
Daphnia Toxicity	EC50 (48 h) > 100 mg/L	EC50 (48 h) > 100 mg/L	Not harmful to aquatic invertebrates up to the limit of their water solubilities
Algal Toxicity	E_rC50 (72 h) > 100 mg/L	E_rC50 (72 h) > 100 mg/L	Not harmful to algae up the limit of their water solubilities
Inhibition of Bacterial Respiration	EC50 (3 h) > 10000 mg/L	EC50 (0.5 h) > 10000 mg/L	Not inhibitory to activated sludge

* Based on nominal concentration of the test substances in the tests.

Toxicity endpoints reported here for above species are all above the water solubility of the notified chemicals. Based on these toxicity endpoints, the notified chemicals are not considered to be harmful to aquatic life up to the limit of their water solubilities under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) and therefore are not classified for acute and long term hazard.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified chemicals as, based on their assessed use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.3. Environmental Risk Assessment

The risk quotients (Q = PEC/PNEC) for the notified chemicals have not been calculated as PEC and PNEC are not available. The notified chemicals are not considered to pose an unreasonable risk to the environment based on their expected low hazard to aquatic life and assessed used pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Extractability ≤ 0.11% at 20 °C, pH 2
≤ 0.057% at 37 °C, pH 7
≤ 0.12% at 20 °C, pH 9

Method OECD TG 120, Solution/Extraction behaviour of polymer in water.

Remarks Flask Method. Determined for STD/1436. The notified chemicals of STD/1436 and STD/1437 have very similar chemical structures and are expected to have very similar physical-chemical properties. Therefore, It is acceptable to use the water extractability values of STD/1436 as analogue data for STD/1437.

The water extractability values reported in "Results" section of the report (0.11%, 0.057% and 0.12% at pH 2, 7 and 9, respectively) were slightly different with that reported in the "Summary" (0.047%, 0.024% and 0.049% at pH 2, 7 and 9, respectively). There was no raw data to check the most appropriate values. Therefore, the water extractability values are reported as the upper limits.

Test Facility KIST (2004)

Stability test

Method Guideline of National Institute of Environmental Research (in Korea) with reference of OECD TG 111

pH	*T (°C)*	*Stable Duration*
1.2	40	24 hours
4	40	2 weeks
7	40	2 weeks
9	40	2 weeks

Remarks Determined for STD/1436, which is considered to be acceptable as analogue data for STD/1437.

A sample of the test substance was agitated at 40 °C for 24 hours at pH 1.2 and for 2 weeks at pH 4, 7 and 9, respectively. The insoluble part was separated by filtration and characterised by GPC, FT-IR and ^{1}H-NMR to investigate mass or structural changes at acidic and alkaline conditions. The amount of total carbon content in the filtrate was determined by TOC analyser. No structural or molecular weight changes were observed over the determination of the test.

Test Facility KIST (2004)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical (STD/1436)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar
Vehicle	Polyethylene glycol 400
Remarks - Method	No significant protocol deviations.

RESULTS

LD50	> 2000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	None
Remarks - Results	No mortalities were observed from the 6 females dosed with 2000 mg/kg bw

CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Bayer HealthCare (2007a)

B.2. Irritation – skin

TEST SUBSTANCE	Notified chemical (STD/1436)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Corn oil
Observation Period	72 hr
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	1(1hr)	< 24hr	0
Oedema	0	0	0	0	-	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

CONCLUSION	The notified chemical is slightly irritating to the skin.
TEST FACILITY	Bayer HealthCare (2007b)

B.3. Skin sensitisation

TEST SUBSTANCE	Notified chemical (STD/1437 ~75% concentration in solvent solution)
METHOD	OECD TG 406 Skin Sensitisation – Non-adjuvant Buehler test
Species/Strain	Guinea pig/Hsd Poc:DH
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 25%
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
INDUCTION PHASE	Induction Concentration: topical: 50%

Signs of Irritation	Skin effects of grade 1 were observed in 6/20 animals after the first induction, 3/20 animals after the second induction, and 4/20 animals after the third induction.
CHALLENGE PHASE	
1st challenge	topical: 25%
Remarks - Method	No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		30 h	*54 h*
Test Group	25%	1/20	1/20
Control Group	25%	1/10	1/10

Remarks - Results	None
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Bayer (1998a)

B.4. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Notified chemical (STD/1436)
METHOD	Adaptation of OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain	Mouse/Hsd Win:NMRI
Vehicle	Methyl ethyl ketone
Remarks - Method	A modified LLNA was performed, involving the measurement of lymph node weights and cell counts rather than radioactive labelling. In addition, measurements of ear swelling and ear weight were taken to indicate the irritating potential of the test substance. For the mice strain used in this study, the "positive level" for cell count index is 1.4, and for ear swelling is 0.02 mm. This non-radioactive method has undergone inter- and intra-laboratory trials in Europe which showed good reproducibility and sensitivity when compared to the established radioactive method (Ehling et al, 2005a and 2005b). Due to the solubility of the test substance the highest dose concentration was limited to 30%.

RESULTS

Concentration (% w/w)	*Proliferative response*		*Irritant response*	
	Lymph node weight index	*Cell count index*	*Ear swelling index (day 4)*	*Ear weight index (day 4)*
0	1.00	1.00	1.00	1.00
3	1.10	1.12	1.02	1.00
10	0.81	0.81	1.02	0.96
30	1.29†	1.24	1.05	1.02

† Statistically significant increase ($p \leq 0.05$)

Remarks - Results	There was a statistically significant increase in lymph node weight index at the highest dose. The study authors suggest that this may be due to irritation. The "positive" level was not reached during this study.

CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	Bayer HealthCare (2007c)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical (STD/1436)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure/Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA102, TA100
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction
Concentration Range in Main Test	a) With metabolic activation: 0 - 5000 µg/plate b) Without metabolic activation: 0 - 5000 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	No significant protocol deviations. Test 1 was performed using the plate incorporation procedure, whilst Test 2 used the pre incubation procedure. Due to precipitation doses ranging from 0 – 3200 µg/plate were chosen for Test 2.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	≥ 1581	≥ 500	Negative
Test 2	≥1600	≥ 500	Negative
Present			
Test 1	≥ 1581	≥ 500	Negative
Test 2	≥ 1600	≥ 500	Negative

CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Bayer HealthCare (2007d)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical (STD/1436)
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Chemical oxygen demand (COD) Biochemical oxygen demand (BOD)
Remarks - Method	The test substance (25 mg) was weighed on aluminium foil. The aluminium foil and test substance were added into 250 ml mineral medium containing inoculum to prepare a nominal test concentration of 100 mg/L. The tests were conducted according to the test guideline above without significant deviations from the protocol.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation (BOD)*	*Day*	*% Degradation (BOD)*
7	0	7	77.1
14	0	14	86
21	0	21	88.2
28	0	28	89.2

Remarks - Results	All validity criteria for the test were satisfied. The biodegradability of the reference substance was determined to be greater than 35% in the toxicity tests, indicating that the concentration of the test substance did not show toxic effects to bacteria.
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	Bayer (2007a)

C.1.2. Ready biodegradability

TEST SUBSTANCE	Notified chemical (STD/1437)
METHOD	Council Directive 92/96 EEC, Method C.4-D
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biochemical oxygen demand (BOD)
Remarks - Method	The test substance was suspended in a mineral medium at a nominal concentration of 100 mg/L. The tests were conducted according to the test guideline above without significant deviations from the protocol.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation (BOD)*	*Day*	*% Degradation (BOD)*
6	9	6	46
12	17	12	61
20	21	20	65
28	23	28	67

Remarks - Results	All validity criteria for the test were satisfied excepted that difference of extremes of replicate values did not meet the criteria of less than 20%. The degradability of the test substance was determined to be 35% and 10%, respectively, in two parallel tests. However, this deviation is not considered to effect the conclusion for biodegradability.
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	Bayer (1998b)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical (STD/1436)
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static
Species	Zebra fish (*Danio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	271 mg $CaCO_3$/L
Analytical Monitoring	Dissolved organic carbon (DOC)
Remarks – Method	The test substance (503.3 mg) was dissolved into 5 L of dilution water to prepare a nominal test concentration of 100 mg/L. The solution was treated for 1 hour in an ultrasonic bath, followed with stirring for 24 hours. The undissolved particles of the test substance were removed by filtration. A limit test was conducted at the nominal concentration of 100 mg/L, or at the limit of its solubility in the test medium. The test was conducted according to the guideline above with a deviation from the protocol, whereby the water hardness in the fish toxicity test media was 271 mg $CaCO_3$/L instead of 10-250 mg $CaCO_3$/L as suggested. However, this deviation is not considered to have adverse effects on the results.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*				
Nominal	*Actual*		*0h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	< 5	10	0	0	0	0	0
100	< 5	10	0	0	0	0	0

LC50	> 100 mg/L at 96 hours (based on nominal concentration)
Remarks – Results	The results were reported in terms of nominal concentration. The actual concentration was determined to be less than 5 mg/L for a nominal concentration of 100 mg/L, which is below the quantitative detection limit of DOC method. No abnormal symptoms were observed for living fish at the test concentration. All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not harmful to fish up to the limit of its solubility in the test media
TEST FACILITY	Bayer (2007b)

C.2.2. Acute toxicity to fish

TEST SUBSTANCE: Notified chemical (STD/1437)

METHOD: Council Directive 92/96 EEC, C.1 Acute Toxicity for Fish - Static

Species	Zebra fish (*Brachydanio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not determined
Analytical Monitoring	Not reported
Remarks – Method	The test substance was dissolved in water to prepare nominal concentration of 100, 316 and 1000 mg/L. The solution was homogenized for 60 seconds by means of ultra-turrax unit. Undissolved particles of the test substance were not removed from the test media by filtration or centrifugation due to their sticky consistence. The tests were conducted in according to the guideline above. No deviation from the protocol was reported.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*				
Nominal	*Actual*		*0 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	-	10	0	0	0	0	0
100	-	10	0	0	0	0	0
316	-	10	0	0	0	0	0
1000	-	10	0	70	80	80	100

LC0	316 mg/L at 96 hours (based on nominal concentration)
LC100	1000 mg/L at 96 hours (based on nominal concentration)
Remarks – Results	At the nominal concentration of 316 mg/L: after 2 hour exposure, 10 fishes were observed to show abnormal symptoms. At the nominal concentration of 1000 mg/L: after 2 hour exposure, 10 fishes were observed to show abnormal symptoms; after 24 hours exposure, 3 fishes gasping for air; after 48 hours exposure, 2 fish sluggish, lethargic swimming action; after 72 hours exposure, 1 fish motionless and 1fish sluggish, lethargic swimming action. The results were reported in terms of nominal concentration. The actual concentration was not determined as the undissolved particles could not be removed from the test solution. The actual concentration of the test substance should be far below the value reported here due to the low water solubility of the test substance. Therefore, the results should be considered with caution.

CONCLUSION: The notified chemical is not harmful to fish up to the limit of its solubility in the test media

TEST FACILITY: Bayer (1998c)

C.2.3. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical (STD/1436)
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – Static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	278.5 mg $CaCO_3$/L
Analytical Monitoring	Dissolved organic carbon (DOC)
Remarks - Method	The test substance (120.3 mg) was dissolved into 1 L of dilution water to prepare a nominal concentration of 100 mg/L. The solution was treated in an ultrasonic bath for 1 hour, followed with stirring for 24 hours. The undissolved particles of the test substance were removed by filtration. A limit test was conducted at the nominal concentration of 100 mg/L, or at the limit of its solubility in the test medium. The test was conducted according to the guideline above with a deviation from the protocol, whereby the water hardness in test media was 278.5 mg $CaCO_3$/L instead of 140-250 mg $CaCO_3$/L as suggested. However, this deviation is not considered to have adverse effects on the results.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	< 5	20	0	0
100	< 5	20	0	0

EC50	> 100 mg/L at 48 hours (based on nominal concentration)
Remarks - Results	The results were reported in terms of nominal concentration. The actual concentration was determined to be less than 5 mg/L for a nominal concentration of 100 mg/L, which is below the quantitative detection limit of DOC method. All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not harmful to aquatic invertebrates up to the limits of its solubility in the test media
TEST FACILITY	Bayer (2007c)

C.2.4. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical (STD/1437)
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – Static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	278.46 mg $CaCO_3$/L
Analytical Monitoring	Dissolved organic carbon (DOC)
Remarks - Method	The test substance (105.1 mg) was dissolved into 1 L of dilution water to prepare a nominal concentration of 100 mg/L. The solution was treated for 60 seconds with an ultra turrax and for 10 minutes in an ultrasonic bath, followed with stirring for 24 hours. The undissolved particles of the test substance were removed by filtration.

A limit test was conducted at the nominal concentration of 100 mg/L, or at the limit of its solubility in the test medium. The test was conducted according to the guideline above with a deviation from the protocol, whereby the water hardness of the test media was 278.46 mg $CaCO_3$/L instead of 140-250 mg $CaCO_3$/L.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	< 5	20	0	0
100	< 5	20	0	0

EC50 > 100 mg/L at 48 hours (based on nominal concentration)

Remarks - Results The results were reported in terms of nominal concentration. The actual concentration was determined to be less than 5 mg/L for a nominal concentration of 100 mg/L, which is below the quantitative detection limit of DOC method. All validity criteria for the test were satisfied.

CONCLUSION The notified chemical is not harmful to aquatic invertebrates up to the limits of its solubility in the test media

TEST FACILITY Bayer (2007d)

C.2.5. Algal growth inhibition test

TEST SUBSTANCE Notified chemical (STD/1436)

METHOD OECD 201, Algal, Growth Inhibition Test.
Species *Desmodesmus subspicatus*
Exposure Period 72 hours
Concentration Range Nominal: 100 mg/L
Actual: < 5 mg/L
Auxiliary Solvent None
Water Hardness 22.5 mg $CaCO_3$/L
Analytical Monitoring Dissolved organic carbon (DOC)
Remarks - Method The test substance (125.1 mg) was dissolved into 1 L of dilution water to prepare a nominal concentration of 100 mg/L. The solution was treated for 1 hour in an ultrasonic bath, followed with stirring for 24 hours. The undissolved particles of the test substance were removed by filtration.

A limited test was conducted at the nominal concentration of 100 mg/L, or at the limit of its solubility in the test medium, according to the guideline above without significant deviation from the protocol.

RESULTS

Biomass		*Growth*	
E_bC50 mg/L at 72 h	*NOE_bC mg/L*	*E_rC50 mg/L at 72 h*	*NOE_rC mg/L*
> 100	Not reported	> 100	Not reported

Remarks - Results The results were reported in terms of nominal concentration. The actual concentration was determined to be less than 5 mg/L for a nominal concentration of 100 mg/L, which is below the quantitative detection limit of DOC method. All validity criteria for the test were satisfied.

CONCLUSION The notified chemical is not harmful to algae up to the limits of its

solubility in the test media

TEST FACILITY Bayer (2006)

C.2.6. Algal growth inhibition test

TEST SUBSTANCE Notified chemical (STD/1437)

METHOD OECD 201, Algal, Growth Inhibition Test.

Species	*Desmodesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L Actual: < 5 mg/L
Auxiliary Solvent	None
Water Hardness	22.5 mg $CaCO_3$/L
Analytical Monitoring	Dissolved organic carbon (DOC)
Remarks - Method	The test substance (124.9 mg) was dissolved into 1 L of dilution water to prepare a nominal concentration of 100 mg/L. The solution was treated for 60 seconds with an ultra turrax, followed with stirring for 24 hours. The undissolved particles of the test substance were removed by filtration. A limit test was conducted at the nominal concentration of 100 mg/L, or at the limit of its solubility in the test medium, according to the guideline above without significant deviation from the protocol.

RESULTS

Biomass		*Growth*	
E_bC50	*NOE_bC*	*E_rC50*	*NOE_rC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
> 100	Not reported	> 100	Not reported

Remarks - Results The results were reported in terms of nominal concentration. The actual concentration was determined to be less than 5 mg/L for a nominal concentration of 100 mg/L, which is below the quantitative detection limit of DOC method. All validity criteria for the test were satisfied.

CONCLUSION The notified chemical is not harmful to algae up to the limits of its solubility in the test media

TEST FACILITY Bayer (2007e)

C.2.7. Inhibition of microbial activity

TEST SUBSTANCE Notified chemical (STD/1436)

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test.

Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: 100, 1000, and 10,000 mg/L Actual: Not determined
Remarks – Method	Conducted according to the guidelines above without significant deviations from the protocol.

RESULTS

EC50 > 10,000 mg/L at 3 hours

Remarks – Results	The results were reported in terms of nominal concentration as the actual concentration was not determined for the test substance. All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not expected to inhibit microbial respiration
TEST FACILITY	Bayer (2007f)

C.2.8. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical (STD/1437)
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	30 minutes
Concentration Range	Nominal: 100, 1000, and 10,000 mg/L Actual: Not determined
Remarks – Method	Conducted according to the guidelines above without significant deviations from the protocol.
RESULTS	
EC50	> 10,000 mg/L at 0.5 hours
Remarks – Results	The results were reported in terms of nominal concentration as the actual concentration was not determined for the test substance. All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not expected to inhibit microbial respiration
TEST FACILITY	Bayer (1998d)

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