File No: STD/1501

March 2014

# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

# PUBLIC REPORT

# Chemical in TERIC ME682/60 Surfactant

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 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:

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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 CHEMICAL	INTRODUCTION VOLUME	USE
STD/1501	Huntsman	Chemical in TERIC	No	$\leq$ 5000 tonne/s	Component of laundry
	Corporation	ME682/60		per annum	detergent and
	Australia Pty Ltd	Surfactant		_	dishwashing liquid

# **CONCLUSIONS AND REGULATORY OBLIGATIONS**

#### **Hazard classification**

Based on the available information, the notified chemical is 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).

The environmental hazard classification according to the *Globally Harmonised System for the Classification* and Labelling of Chemicals (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	Hazard statement
Acute Category 3	H402- Harmful to aquatic life

#### Human health risk assessment

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

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

#### **Environmental risk assessment**

On the basis of the PEC/PNEC ratio and the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

#### Recommendations

CONTROL MEASURES

- 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 chemical in TERIC ME682/60 Surfactant at the manufacture and reformulation sites:
  - 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 chemical in
  TERIC ME682/60 Surfactant:
  - Coveralls
  - Impermeable gloves
  - Safety goggles

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 chemical 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 chemical should be disposed of to landfill.

#### Emergency procedures

• Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent 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 chemical 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
  - the concentration of the notified chemical in laundry detergents or dishwashing liquids is proposed to exceed 10%;

or

- (2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from component of laundry detergent and dishwashing liquid, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 5000 tonne per year, or is likely to increase, significantly;
  - the method of manufacture of the chemical in Australia has changed, or is likely to change, in a way that may result in an increased risk of an adverse effect of the chemical on occupational health and safety, public health, or the environment;
  - additional information has become available to the person as to an adverse effect of the 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.

No additional secondary notification conditions are stipulated.

#### Material Safety Data Sheet

The MSDS of the product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

# **ASSESSMENT DETAILS**

#### 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Huntsman Corporation Australia Pty Ltd (ABN: 67 083 984 187) Gate 3, 765 Ballarat Road

**DEER PARK VIC 3023** 

NOTIFICATION CATEGORY

Standard: Chemical other than polymer (more than 1 tonne per year).

#### 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, manufacture volume and site of manufacture/reformulation

# VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: melting point, density, vapour pressure, hydrolysis as a function of pH, partition coefficient, absorption/desorption, dissociation constant, flash point, flammability, autoignition temperature, explosive properties, oxidising properties, ready biodegradability and bioaccumulation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S) None

NOTIFICATION IN OTHER COUNTRIES USA, Canada

# 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

TERIC ME682/60 Surfactant (containing the notified chemical at 30-60%)

MOLECULAR WEIGHT

> 500 Da

ANALYTICAL DATA

Reference NMR and IR spectra were provided.

## 3. COMPOSITION

DEGREE OF PURITY 30-60%

#### 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: clear amber liquid\*

Property	Value	Data Source/Justification
Melting Point	13 °C	MSDS*
Boiling Point	Not determined	The notified chemical is expected to decompose before it boils.
Density	1043 kg/m³ (temperature unknown)	MSDS*
Vapour Pressure	Expected to be $< 3.04 \times 10^{-12} \text{ kPa}$ at 25 °C	Calculated (modified Grain method)
Water Solubility	300 - 400 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical is water soluble and contains functionalities that may slowly hydrolyse under environmental conditions (pH 4-9)
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to phase boundaries based on its surface activity
Adsorption/Desorption	Not determined	Expected to sorb to soil, sediment and

		sludge due to its surface activity
Dissociation Constant	Not determined	Not expected as the notified chemical
		does not contain any dissociable
		functionalities
Particle Size	Not determined	Liquid
Flash Point	> 200 °C (closed cup) (pressure	MSDS*
	unknown)	
Autoignition Temperature	Not determined	Expected to be high based on the
		flashpoint.
Explosive Properties	Not determined	Contains no explosophores that would
		imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that would
5 1		imply oxidative properties.

<sup>\*</sup>For TERIC ME682/60 Surfactant (containing the notified chemical at 30-60%)

#### DISCUSSION OF PROPERTIES

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

#### Reactivity

The notified chemical is expected to be stable under normal conditions of use. However, it will react with strong oxidising agents.

#### Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified chemical 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 chemical will be manufactured at 30-60% concentration in Australia

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

Year	1	2	3	4	5
Tonnes	< 1000	< 1000	1000-5000	1000-5000	1000-5000

#### PORT OF ENTRY

Manufactured in Australia

# IDENTITY OF MANUFACTURER/RECIPIENTS

The notified chemical will be manufactured, stored and reformulated in sites located in Sydney, New South Wales.

## TRANSPORTATION AND PACKAGING

The TERIC ME 682/60 surfactant product and formulated products containing the notified chemical will be transported by road.

The TERIC ME 682/60 surfactant product will be packed into 205 L steel drums, 1000 L intermediate bulk containers (IBCs) and 20,000 L isotainers (road tankers). Product formulated with the notified chemical will be packed in 1L and 2L plastic bottles as well as 1kg, 1.5kg, 2.5kg and 5kg cardboard boxes.

#### USE

Component of laundry detergent and dishwashing liquid.

#### OPERATION DESCRIPTION

# Manufacture

Product containing the notified chemical will be manufactured from its starting materials with heating in closed reactors. When reaction is complete the resulting solution containing the notified chemical at < 60%

concentration will be transferred into 205 L drums, IBCs or isotanks. Samples of the product solution containing the notified chemical will be taken for quality control testing.

Reformulation for liquid laundry and manual dishwashing detergents

Product containing the notified chemical will typically be transferred from the drum by inserting a dip pipe and pumping to a closed blending tank under local exhaust ventilation. After blending into liquid laundry and dishwashing detergents, the end-use product containing < 10% of the notified chemical will be transferred via automatic filling machines into appropriate containers for distribution to retail outlets.

# Reformulation for powdered laundry detergents

Products containing the notified chemical will be transferred to holding tanks by automated pumping equipment following arrival at the reformulation sites.

Powdered laundry detergents will be made by a spray drying process including three steps: crutching, spray drying and post-addition.

Crutching involves mixing detergent raw materials together in a blending vessel to form a thick slurry (containing the notified chemical at < 10%). The slurry will be transferred from the holding tank to the blend vessel using dedicated pipework and then pumped as a stream of droplets into a spray drying tower and dried to form hollow powder beads. The spray dried beads will then be mixed with small amounts of other dry ingredients to produce laundry powders containing < 5% of the notified chemical. It will then be conveyed to the packing area for distribution to retail outlets.

# End-use by consumers and professional workers

Consumers will open the laundry product containers (containing < 10% of the notified chemical) and manually measure out the required volume of the product (typically 50 mL or 50 g). The product will be measured using the cap of the container or into a plastic measuring/dispensing cup before adding to the washing machine. After the washing process the consumers will remove washed clothes from the machine. At this stage the notified chemical will be largely rinsed from the clothes.

The laundry detergent may also be used for hand-washing of clothes. The dish washing liquid will be used by the public for hand-washing of dishes.

The laundry detergent and dishwashing liquid containing < 10% the notified chemical are expected to be used by kitchen workers at restaurants and laundry workers.

#### 6. HUMAN HEALTH IMPLICATIONS

## 6.1. Exposure Assessment

# 6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	Exposure Duration	Exposure Frequency
	(hours/day)	(days/year)
Process operators – manufacture	1	150
Packaging line - manufacture	1	150
Quality control / laboratory technicians - manufacture	2	150
Process operators - reformulation	2	200
Packaging line - reformulation	4-8	200
Quality control / laboratory technicians - reformulation	2	200
Transport workers	2	240
Warehouse staff	2	240
Retail staff	2	365
Professional laundry and kitchen workers	8-12	200

**EXPOSURE DETAILS** 

Transportation and Storage

Worker exposure to the notified chemical during the transport and storage of the notified chemical and product containing it is not expected, except in the event of an accident where packaging may be breached.

#### Manufacture

During manufacture of product containing the notified chemical, dermal and ocular exposure of workers to the notified chemical at up to 60% concentration may occur during quality control analysis, connection and disconnection of transfer lines, and cleaning and maintenance of equipment. Exposure is expected to be minimised through the use of enclosed systems and personal protective equipment (PPE) such as coveralls, safety glasses and impervious gloves.

# Reformulation

Warehouse and blending workers may experience dermal and ocular exposure to the notified chemical at up to 60% from spills and splashes while opening the containers, transfer of the contents, blending and filling the packages for liquid or powder laundry detergent and liquid dishing liquid. Workers involved in quality control, cleaning and maintenance may experience dermal and ocular exposure to the notified chemical.

Inhalation exposure during formulation of liquid laundry detergents or dishwashing liquid is expected to be low due to the relatively high molecular weight and subsequent formulation into an aqueous mixture, unless aerosols are generated during processing. During formulation of powder laundry detergents, inhalation exposure to the chemical at up to 10% is possible if the dusts are generated from the powder, however, such exposure is expected to be minimised by the enclosed systems used for this procedure.

Exposure to the notified chemical is expected to be minimised through the use of enclosed and automated processes during transfer and blending of the notified chemical where possible. Exposure to the notified chemical is expected to be further minimised through the use of personal protective equipment (PPE) including coverall, protective gloves and goggles.

#### Retail workers

Retail workers are not expected to be exposed to the notified chemical except in the event of an accidental package breach. In this case, dermal and ocular exposure may occur; however, exposure is expected to be minimised by the use of appropriate PPE including gloves and protective clothing during clean-up of any spills.

# Professional laundry and kitchen workers

Laundry workers may have the potential for dermal and ocular exposure to finished products containing less than 10% of the notified chemical. Exposure may occur during measuring and dispensing of the laundry product. Workers may wear gloves and protective clothing when handling the laundry products and eye contact is expected to be avoided. During the laundry operations, the notified chemical in the finished products will be diluted by a substantial amount of water and largely rinsed off from the clothes at the end of the washing cycle. Therefore, exposure from handling washed clothes is expected to be low. It is expected that kitchen workers at restaurants will use dishing liquid containing the notified chemical at < 10% in a similar manner.

#### 6.1.2. Public Exposure

Incidental dermal and ocular exposure of the public to liquid laundry and dish washing detergents containing up to 10% of notified chemical may occur through spills and splashes. It is expected that any spilt material would be washed from the skin.

In addition, household consumers carrying out laundry hand washing have potential for dermal and accidental ocular exposure to the diluted detergent containing the notified chemical at < 10%. The public may also come into incidental contact with wash water containing the laundry or dish washing detergents at low dilutions.

Significant exposure to the notified chemical from washed clothing/linen and dishes/cutlery is not expected to occur as the chemical is further diluted in the wash and is expected to be rinsed from the washed articles prior to drying.

# 6.2. Human Health Effects Assessment

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

Endpoint	Result and Assessment Conclusion
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity

Rat, acute dermal toxicity
Rabbit, skin irritation
Rabbit, eye irritation
Guinea pig, skin sensitisation – non-adjuvant test
Rat, repeat dose oral toxicity with reproduction/developmental toxicity screening
Mutagenicity – bacterial reverse mutation
Genotoxicity – in vivo mammalian erythrocyte micronucleus test

LD50 > 2000 mg/kg bw; low toxicity slightly irritating slightly irritating no evidence of sensitisation

NOAEL (systemic and reproductive) = 1000 mg/kg bw/day non mutagenic non genotoxic

#### Toxicokinetics, metabolism and distribution

No toxicokinetic data on the notified chemical were submitted. Absorption across biological membranes is not expected due to the relatively high molecular weight (> 500 Da).

#### Acute toxicity

The notified chemical was of low acute oral (LD50 >2000 mg/kg bw) and dermal (LD50 >2000 mg/kg bw) toxicity to rats.

#### Irritation and sensitisation

The notified chemical was slightly irritating to the skin and eyes. The notified chemical was not a skin sensitiser in a guinea pig skin sensitisation study using the Buehler method. It is also noted that the notified chemical does not contain any structural alerts for sensitisation.

#### Repeated dose toxicity

In a combined repeat dose toxicity study with a reproduction/developmental screening test, rats were administered the notified chemical by gavage at 0, 250, 500 or 1000 mg/kg bw/day. Rats were paired and mated after 14 days dosing and allowed to produce offspring. Males were sacrificed following approximately 7 weeks dosing. Females showing no evidence of copulation were sacrificed on days 52 to 54. Females with offspring and offspring were sacrificed on post-delivery day 5. The NOAEL for systemic toxicity and reproductive toxicity was established as 1000 mg/kg bw/day, based on the lack of adverse effects. Therefore, the notified chemical is of low repeated dose toxicity. There was no evidence of reproductive or developmental effects in this screening study.

## Mutagenicity/Genotoxicity

The notified chemical was not mutagenic in a bacterial reverse mutation assay. The notified chemical was not clastogenic in an *in vivo* mammalian erythrocyte micronucleus test. It is also noted that during the range finding test associated with the micronucleus assay, intraperitoneal administration of the test substance at higher concentrations than those used in the main assay resulted in the death of many of the test animals. Overall, the available evidence indicates that the notified chemical is unlikely to be mutagenic or genotoxic.

# Health hazard classification

Based on the available information, the notified chemical is 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

The notified chemical is expected to be slightly irritating to the skin and eyes. There is potential for dermal and ocular exposure of workers to the notified polymer at concentrations of < 60% during manufacture and reformulation processes. Exposure should be minimised through the stated use of enclosed, automated processes, local exhaust ventilation and PPE. Other workers, including commercial laundry and kitchen workers, may be exposed to products containing the notified chemical at 10% or less. These workers may use PPE to lower exposure.

Overall, the risk to workers from exposure to the notified chemical is not considered to be unreasonable, given the toxicological profile of the notified chemical and the expected use of engineering controls and PPE.

#### 6.3.2. Public Health

The public may have dermal or ocular exposure to laundry washing products and dish washing liquid containing the notified chemical at concentrations of 10% or less. The risk of irritant effects from the notified chemical at these concentrations is considered to be low, even in the absence of PPE.

The repeat dose toxicity potential was estimated by calculation of the margin of exposure (MoE) of the notified chemical, based on the use of laundry detergent and dish washing liquid and the NOAEL of 1000 mg/kg bw/day for the notified chemical. A MoE value of > 100 is considered acceptable to account for intra- and inter-species differences. Using the abovementioned NOAEL, a MoE of 139 was estimated, which is considered acceptable.

Overall, the risk to public health associated with the proposed use of the notified chemical in laundry detergent and dish washing liquid 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 chemical will be manufactured in Australia. The raw material will be transferred into an enclosed reactor and the manufacturing process is expected to be fully automatic. Therefore, significant release of the notified chemical to the environment from accidental splashes, drips or spills is not expected during manufacturing processes. It is estimated by the notifier that up to 37 kg/washout of the notified chemical may be released in rinsing water from the cleaning of the reactors. The rinsing water is expected to be directed, as indicated by the notifier, to a single sewage treatment plant (average flow capacity of 456 ML/day) and be subsequently discharged to the ocean.

Products containing the notified chemical will be blended locally to prepare laundry and dishwashing detergent products. The blending and packing processes are semi-automatic and will occur in enclosed systems. Therefore, significant release of the notified chemical to the environment from accidental splashes, drips and spills is not expected during reformulation/packing processes. It is estimated by the notifier that up to 18 kg/day of the notified chemical may be released to reformulators' effluent treatment systems from the rising of blend vessels and filling lines, and residues remaining in empty containers. The effluent containing the notified chemical is expected to be discharged to a single sewage treatment plant (average flow capacity of 456 ML/day) and be subsequently discharged to the ocean.

#### RELEASE OF CHEMICAL FROM USE

During use as a component of laundry and dishwashing products, approximately the entire volume of the notified chemical is expected to be released to sewers. Spills are expected to be cleaned up with an appropriate sorbent material, which is expected to be disposed of to landfill, or spills may be washed to sewers. Residues of the notified chemical in the empty containers are likely to be rinsed and be added into the washing machine or domestic wastewater via the sink, or disposed of to landfill with the empty containers.

# RELEASE OF CHEMICAL FROM DISPOSAL

Small amounts of the notified chemical (60 kg/day estimated by the notifier) may remain as residues in empty containers, which are expected to be disposed of to landfill along with the empty containers.

# 7.1.2. Environmental Fate

The product containing the notified chemical obtained 72.4% biodegradation over 28 days and the 10-day window was satisfied. Therefore, the notified chemical is expected to rapidly biodegrade and is not expected to persist in the environment. For the details of the environmental fate study please refer to Appendix C.

The majority of the notified chemical is expected to be released to sewage treatment plants (STPs) via domestic wastewater. In wastewater treatment processes, a high proportion of the notified chemical is expected to be removed from STP influent due to its expected sorption to sludge and sediment, and rapid biodegradation. The sludge containing the notified chemical may be sent to landfill or applied to soils for land remediation. Notified chemical released to surface waters is expected to partition to suspended solids and organic matter, or to disperse and degrade. Consequently, the notified chemical is not expected be significantly bioavailable. The potential for the notified chemical to bioaccumulate is low based on its surfactant properties, degradability and high

molecular weight. The notified chemical is expected to ultimately degrade biotically and abiotically to form water and oxides of carbon.

#### 7.1.3. Predicted Environmental Concentration (PEC)

The release of the notified chemical to water compartments may result from the cleaning of equipment during the manufacture and reformulation processes, and from the use of the detergent products.

## Predicted Environmental Concentration from manufacture and reformulation

The Predicted Environmental Concentration from manufacture and reformulation (PEC<sub>production</sub>) has been calculated based on the point-source release of the notified chemical from the cleaning of the reactors. It is estimated by the notifier that up to 55 kg/day (= 37 kg/washout from manufacturing + 18 kg/day from reformulation) of the notified chemical will be released as industrial wastewater to a single site STP with a flow capacity of 456 ML/day. Based on its biodegradation potential (readily biodegradable), surfactant properties and literature data (EI, 1999), 99% of the notified chemical is estimated to be removed from the STP effluent by degradation or adsorption to STP sludge or sediment. Under a worst case scenario, the PEC<sub>production</sub> has been calculated for both riverine and ocean as summarised in the table below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Daily chemical release:	55	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	456	ML/day
Removal within STP	99%	
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	1.21	μg/L
PEC - Ocean:	0.121	μg/L

# Predicted Environmental Concentration from use

The majority of the notified chemical is expected to be released to sewers following its use as household detergent products. It is assumed that all of the notified chemical that was not lost during manufacturing and reformulation process will be discharged into sewers following its use. Therefore, up to 13643.63 kg/day (=  $5,000,000 \text{ kg} \div 365 \text{ days} - 55 \text{ kg/day}$ ) of the notified chemical will be discharged into sewers nationwide. Assuming 99% removal of the notified chemical in the sewage treatment processes, the resultant Predicted Environmental Concentration from use (PEC<sub>use</sub>) in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment				
Daily chemical release:	13643.63	kg/day		
Water use	200	L/person/day		
Population of Australia (Millions)	22.613	million		
Removal within STP	99%	Mitigation		
Daily effluent production:	4,523	ML		
Dilution Factor - River	1.0			
Dilution Factor - Ocean	10.0			
PEC - River:	30.17	μg/L		
PEC - Ocean:	3.02	μg/L		

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 30 g/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m³ and a soil-mixing zone of 10 cm, the concentration of the notified chemical may approximate 0.2 g/kg in applied soil. This assumes that degradation of the notified chemical occurs in the soil within 1 year from application. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated biosolids application, the concentration of notified chemical in the applied soil in 5 and 10 years may approximate 1 g/kg and 2g/kg, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be  $1000~L/m^2/year$  (10~ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10~cm of soil (density  $1500~kg/m^3$ ). Using these assumptions, irrigation with a concentration of  $30.17~\mu g/L$  may potentially result in a soil concentration of approximately 0.201~mg/kg. Assuming accumulation of the notified chemical in soil for 5~and~10~years~under~repeated~irrigation, the

concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 1.01 mg/kg and 2.01 mg/kg, respectively.

Based on the above calculations, the notified chemical in STP effluent due to the combined releases to STP from manufacture, reformulation and use is  $31.38 \,\mu\text{g/L}$  (=  $1.21 \,\mu\text{g/L} + 30.17 \,\mu\text{g/L}$ ). Therefore, the PECs for the aquatic compartments are calculated as follows:

Predicted Environmental Concentration (PEC) for release to the aquatic compartment				
Combined effluent concentration	31.38	μg/L		
Dilution Factor – River	1			
Dilution Factor – Ocean	10			
PEC – River	31.38	$\mu g/L$		
PEC – Ocean	3.14	μg/L		

#### 7.2. Environmental Effects Assessment

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

Endpoint	Result	Assessment Conclusion
Fish Toxicity	96 hours LC50 > 100 mg/L	Not harmful to fish
Daphnia Toxicity	48 hours $EC50 > 100.1 \text{ mg/L}$	Not harmful to aquatic invertebrates
Algal Toxicity	72 hours $E_rC50 = 23.1 \text{ mg/L}$	Harmful to algae

Based on the toxicity of the notified chemical to algae, the notified chemical is considered to be harmful to aquatic organisms under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009). Therefore, the notified chemical is formally classified as "Acute Category 3; Harmful to aquatic life" under the GHS.

Based on its acute toxicity, biodegradability and expected low bioaccumulation potential, the notified chemical is not formally classified under the GHS for the chronic hazard.

# 7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) for the notified chemical has been calculated and is presented in the table below. The PNEC is calculated based on the endpoint of the most sensitive species for the notified chemical (algae,  $E_rC50 = 23.1 \text{ mg/L}$ ). An assessment factor of 100 has been used as acute toxicity endpoints for three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment						
$E_r$ C50 (Alga).	23.1	mg/L				
Assessment Factor	100					
PNEC:	231	μg/L				

#### 7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	31.38	231	0.14
Q - Ocean:	3.14	231	0.014

The risk quotient (Q = PEC/PNEC) for riverine and ocean environments are calculated to be < 1 based on the calculated PEC and PNEC values. Based on its surfactant properties, the notified chemical is not expected to bioaccumulate significantly in aquatic organisms. Furthermore, the notified chemical is not expected to persist in the environment. On the basis of PEC/PNEC ratio and the assessed use pattern, the notified chemical is not expected to be released at ecotoxicologically significant concentrations in the aquatic environment and is therefore not considered to pose an unreasonable risk to the aquatic environment.

# **APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**

Water Solubility 300 - 400 g/L at 20 °C

Method In house method

Remarks Flask Method. The notified chemical was added into water at various concentrations from

10% in water to 100% surfactant. The viscosity of each solution was measured using

Viscometer.

The solutions were clear at the concentrations  $\leq 30\%$  (weight/weight). At the concentration

of 40%, the solution was observed to be clear and very viscous. Gel formed when the

concentration increased to 60%.

Test Facility Huntsman (2013)

# APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

#### **B.1.** Acute toxicity – oral

TEST SUBSTANCE Notified chemical (> 90%)

METHOD OECD TG 425 Acute Oral Toxicity: Up-and-Down Procedure.

Species/Strain Rat/Sprague Dawley Vehicle Distilled water

Remarks - Method Minor protocol deviations were deemed unlikely to have an adverse

impact on the integrity of the data or the validity of the study conclusion.

#### RESULTS

Group	Number and Sex of Animals	Dose mg/kg bw	Mortality
1	1 F	175	0
2	1 F	550	0
3	3 F	2000	0

LD50 > 2000 mg/kg bw

Signs of Toxicity All animals appeared normal during the course of the study.

Effects in Organs No visible lesions were observed in any of the animals at terminal

necropsy.

Remarks - Results No biologically significant effect was seen on body weight in the animals

on days 8 and 15 (the days during the study on which body weight was

recorded).

CONCLUSION The test substance is of low toxicity via the oral route.

TEST FACILITY Calvert Laboratories, Inc. (2005a)

#### **B.2.** Acute toxicity – dermal

TEST SUBSTANCE Notified chemical (> 90%)

METHOD OECD TG 402 Acute Dermal Toxicity – Limit Test.

Species/Strain Rat/Sprague Dawley

Vehicle None
Type of dressing Occlusive

Remarks - Method Minor protocol deviations were deemed unlikely to have an adverse

impact on the integrity of the data or the validity of the study conclusion.

#### RESULTS

Number and Sex	Dose	Mortality
of Animals	mg/kg bw	
5 per sex	2000	0

LD50 > 2000 mg/kg bw

Signs of Toxicity - Local No clinical signs were observed throughout the study.

Effects in Organs No visible lesions were observed in any of the animals at terminal

necropsy.

Remarks - Results All animals exhibited normal increases in body weight between days 1 and

15.

CONCLUSION The test substance is of low toxicity via the dermal route.

TEST FACILITY Calvert Laboratories, Inc. (2005b)

#### **B.3.** Irritation – skin

TEST SUBSTANCE Notified chemical (> 90%)

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain Rabbit/New Zealand White

Number of Animals 3 M Vehicle None Observation Period 6 days

Type of Dressing Semi-occlusive.

Remarks - Method The test substance was first tested under the in vitro technique of the

Corrositex system.

The exposure periods for in vivo testing were 3 and 60 minutes and 4

hours, respectively.

Minor protocol deviations were deemed unlikely to have an adverse impact on the integrity of the data or the validity of the study conclusion.

#### RESULTS

Lesion		ean Sco. nimal N	-	Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
	1	2	3			
Erythema/Eschar	1	1.3	2	2	< 6 days	0
Oedema	0	0	0.3	2	< 2 days	0

<sup>\*</sup>Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal following 4 hour exposure to the test substance.

Remarks - Results

There was no detectable reaction below the Corrositex disc (in the CDS) up to 22 hours and 23 minutes after instillation of the test substance onto the top of the biobarrier disc.

The most severe dermal responses observed for the in vivo animals testing are:

3 minute exposure: no erythema and no oedema were observed;

60 minute exposure: very slightly (barely perceptible) erythema and no

oedema were observed;

4 hour exposure: well-defined erythema and slight oedema were observed.

CONCLUSION The test substance is slightly irritating to the skin.

TEST FACILITY Calvert Laboratories, Inc. (2005c)

# **B.4.** Irritation – eye

TEST SUBSTANCE Notified chemical (> 90%)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain Rabbit/New Zealand White

Number of Animals 3 F
Observation Period 72 hours

Remarks - Method Minor protocol deviations were deemed unlikely to have an adverse impact

on the integrity of the data or the validity of the study conclusion.

#### RESULTS

Lesion	Mean Score*	Maximum	Maximum Duration	Maximum Value at End
	Animal No.	Value	of Any Effect	of Observation Period

-	1	2	3			
Conjunctiva: redness	0.7	0.3	0.3	1	< 72 hours	0
Conjunctiva: chemosis	0.3	0.7	0.7	2	< 48 hours	0
Conjunctiva: discharge	0.3	0.7	0.7	2	< 48 hours	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

<sup>\*</sup>Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results Positive scores for redness, chemosis and/or discharge were observed at 1

and 24 hours post-dose. Conjunctival redness (score =1) was observed in one animal at 48 hours after administration. No other signs of irritation were observed during the remainder of the study and the study was

terminated following the 72 hour ocular reading.

CONCLUSION The test substance is slightly irritating to the eye.

TEST FACILITY Calvert Laboratories, Inc. (2005d)

# **B.5.** Skin sensitisation

TEST SUBSTANCE Notified chemical (> 90%)

METHOD OECD TG 406 Skin Sensitisation - Buehler Method.

Species/Strain Guinea pig/Hartley

PRELIMINARY STUDY Maximum Non-irritating Concentration:

topical: 25%

MAIN STUDY

Number of Animals Test Group: 20 Control Group: 10

INDUCTION PHASE Induction Concentration:

topical: 25%

Signs of Irritation All dermal irritation scores at the 24- and 48-hour observations were zero

for the test and vehicle control animals.

CHALLENGE PHASE

challenge topical: 5%

Remarks - Method Minor protocol deviations were deemed unlikely to have an adverse

impact on the integrity of the data or the validity of the study conclusion.

# RESULTS

Animal	Challenge Concentration	Number of Animals Showing Skin Reaction challenge		
		24 h	48 h	
Test Group	5%	0/20	0/20	
Control Group	80%	0/10	0/10	

Remarks - Results There were no signs of systemic toxicity and all animals showed normal

weight gain during the study.

The positive control group, induced and challenged with DNCB (1-chloro-2,4-dinitrobenzene), exhibited the anticipated positive responses at challenge, indicating that the methods employed in this study were valid.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the

test substance under the conditions of the test.

TEST FACILITY Calvert Laboratories, Inc. (2005e)

**B.6.** Repeat dose toxicity

TEST SUBSTANCE Notified chemical (> 90%)

METHOD OECD TG 422 Combined Repeated Dose Toxicity Study with the

Reproduction/Developmental Toxicity Screening Test.

Species/Strain Rat/Wistar Hannover

Route of Administration Oral – gavage

Exposure Information Total exposure days: 36 - 37 days (males), up to 52 - 54 days (females

showing no evidence of copulation)

Dose regimen: 7 days per week

Vehicle Corn oil

Remarks - Method Rats were treated with the test substance by gavage for 14 days then paired

for mating on day 15 for a maximum of 14 days. Animals were separated when evidence of mating was noted. Males were sacrificed on days 36 to 37. Females showing no evidence of copulation were sacrificed on days 52 to 54. Females with offspring and offspring were sacrificed on post-

delivery day 5.

#### RESULTS

Group	Number and Sex	Dose	Mortality
	of Animals	mg/kg bw/day	
control	12 per sex	0	0
control recovery	5 per sex	0	0
low dose	12 per sex	250	0
mid dose	12 per sex	500	0
high dose	12 per sex	1000	0
high dose recovery	5 per sex	1000	0

#### Clinical Observations

No effects on body weight, body weight gain and food consumption were observed. No effects were observed in the functional observational battery, clotting parameters or organ weights.

#### Laboratory Findings - Clinical Chemistry, Haematology, Urinalysis

Treated high dose recovery males displayed statistically significant differences in some haematological parameters, with haematocrit, mean corpuscular haemoglobin concentration and total blood cell count outside the historical data. However, these variations were moderate in magnitude and were close to the normal range, and were considered by study authors as a normal biological variation.

Treated high dose recovery males showed statistically significantly lower mean total white blood cell count and lymphocytes. High dose females displayed statistically significantly higher white blood cell count. The lymphocyte values were found to be within the historical range.

Mean urea nitrogen was found to be statistically significantly higher in all treated males compared to controls. However, given that the differences were not dose related, and were within historical control ranges, these were not considered to be related to treatment with the test substance.

Female rats exposed to 1000 mg/kg/day had significantly higher mean sodium and treated high dose recovery females showed statistically significant differences in urea nitrogen and albumin. These differences were considered incidental in nature, and were not supported by similar differences in the corresponding high dose and recovery animals. These differences were not considered as adverse effects by the study authors.

# Effects in Organs

No macroscopic or microscopic findings related to test substance administration were observed.

#### Effects on reproduction and offspring

None of the mating or gestation parameters was considered to have been affected by treatment with the test substance. No statistically significant differences were found between the numbers of the dead pups from treated and control dams. No clinical signs were observed in pups until the final observation at day 4 postnatal. No test substance-related pup mortality occurred. The mean body weight of pups on day 0 and 4 postnatal were similar in all groups. The necropsy evaluation did not reveal any findings in pups.

#### CONCLUSION

The NOAEL for systemic and reproductive toxicity was established as 1000 mg/kg bw/day under the conditions of the study, based on the lack of adverse effects at all treatment levels.

TEST FACILITY BIOAGRI Laboratories (2012)

#### **B.7.** Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical (> 90%)

**METHOD** OECD TG 471 Bacterial Reverse Mutation Test.

Plate incorporation procedure

S. typhimurium: TA1535, TA1537, TA98, TA100 Species/Strain

E. coli: WP2uvrA

Metabolic Activation System

Concentration Range in

Main Test

Vehicle

Remarks - Method

Aroclor 1254-induced rat liver S9

a) With metabolic activation: 0, 50, 150, 500, 1500, 5000 μg/plate b) Without metabolic activation: 0, 50, 150, 500, 1500, 5000 μg/plate

Dimethyl sulfoxide (DMSO)

Minor protocol deviations were deemed unlikely to have an adverse impact on the integrity of the data or the validity of the study conclusion.

#### RESULTS

Metabolic	Test Substance Concentration (µg/plate) Resulting in:				
Activation	Cytotoxicity in	Cytotoxicity in	Precipitation	Genotoxic Effect	
	Preliminary Test	Main Test			
Absent					
Test	> 5000	> 5000	> 5000	negative	
Present					
Test	> 5000	> 5000	> 5000	negative	

Remarks - Results Neither precipitation nor appreciable toxicity was observed. No positive

mutagenic responses were observed with any of test strains in either the

presence or absence of S9 activation.

All criteria for a valid study were met as described in the protocol.

CONCLUSION The test substance was not mutagenic to bacteria under the conditions of

the test.

**TEST FACILITY** BioReliance (2005)

# Genotoxicity - in vivo

TEST SUBSTANCE Notified chemical (> 50%)

**METHOD** OECD TG 474 Mammalian Erythrocyte Micronucleus Test.

Species/Strain Mice/ICR

Route of Administration Intraperitoneal administration

Vehicle Purified water

Remarks - Method No protocol deviations.

> In the dose range finding study, mortality was observed in all mice at 500, 1000, 1500 and 2000 mg/kg and in 2/3 male and 2/3 female mice at 250 mg/kg. Piloerection, lethargy, prostration and/or hunched position were among the clinical signs observed in the 250, 500 or 1000 mg/kg treatment groups. Reductions of up to 16% in the mean body weights (by study day

3) were observed in the surviving mice at 250 mg/kg.

Group	Number and Sex	Dose	Sacrifice Time
	of Animals	mg/kg bw	hours
I (vehicle control)	10 per sex	0	24, 48
II (low dose)	5 per sex	25	24
III (mid dose)	5 per sex	50	24
IV (high dose)	10 per sex	100	24, 48
V (positive control, CP)	5 per sex	50	24

CP=cyclophosphamide.

RESULTS

**Doses Producing Toxicity** 

No mortality was observed in any of the treatment groups. All mice in the vehicle control groups appeared normal during the study. Piloerection was observed in all test substance treatment groups.

Genotoxic Effects

No appreciable reductions in the ratio of polychromatic erythrocytes (PCEs) to total erythrocytes in the test substance groups relative to the respective vehicle control groups were observed, suggesting the test substance did not markedly inhibit erythropoiesis.

No statistically significant increase in the incidence of micronucleated polychromatic erythrocytes in test substance groups relative to the respective vehicle control groups was observed in male or female mice at 24 or 48 hours after dose administration.

Remarks - Results

The positive control induced a statistically significant increase in the incidence of microcleated PCEs in both male and female mice. The number of micronucleated PCEs in the vehicle control groups did not exceed the historical vehicle control range. Based upon this, the test was considered valid.

There is no definitive evidence indicating that the test substance reached the bone marrow of the mice.

CONCLUSION

The test substance was not clastogenic under the conditions of this in vivo micronucleus test.

TEST FACILITY

BioReliance (2012)

# APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

#### **C.1.** Environmental Fate

#### C.1.1. Ready biodegradability

TEST SUBSTANCE Product containing the notified chemical (> 90%)

METHOD OPPTS 835.3310: CO<sub>2</sub> Evolution Test.

Inoculum Activated sludge

Exposure Period 28 days Auxiliary Solvent None

Analytical Monitoring CO<sub>2</sub> measurement by chemical titration

Remarks - Method The test was conducted in accordance with the test guideline above. There

were no significant deviations from the protocol reported.

#### RESULTS

	Test substance		Aniline
Day	% Degradation ( $CO_2$ evolution)	Day	% Degradation (CO2 evolution)
3	7.60	3	-0.46
7	35.1	7	31.1
14	63.6	14	63.4
20	68.2	20	67.1
28	72.4	28	69.8

Remarks - Results The validity criteria for the test were satisfied.

The test substance attained 72.4% degradation after 28 days and the 10-day window criteria were satisfied. The test substance was considered to be readily biodegradable.

, .

The degradation of toxicity control was 79% over 28 days, implying that the test substance was not toxic to the sewage treatment microorganisms

used in the study.

CONCLUSION The notified chemical is readily biodegradable.

TEST FACILITY Stillmeadow (2007)

#### C.2. Ecotoxicological Investigations

#### C.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified chemical

METHOD OECD TG 203 Fish, Acute Toxicity Test - Static.

Species Zebra Fish (Danio rerio)

Exposure Period 96 hours Auxiliary Solvent None

Water Hardness 4 mg CaCO<sub>3</sub>/L
Analytical Monitoring Not applicable
Remarks – Method A stock solution was prepared by adding the test substance directly into

dilution water. The test media with lower concentrations of the test substance were prepared by serial dilution of the stock solution. The test substance appeared to be fully dissolved at the concentration of 6.3, 12.5,

and 25 mg/L. The test solutions at the concentrations of 50 and 100 mg/L were observed cloudy. This may due to the formation of micelle at the nominal concentration of 50 and 100 mg/L given the notified chemical has

surfactant activity.

The water hardness of the test media was 4 mg CaO<sub>3</sub>/L, not within the range of 10–250 mg CaCO<sub>3</sub>/L as recommended by the test guideline. This deviation may not significantly affect the test results. Good Laboratory Practices (GLP) were followed.

#### RESULTS

Concent	tration mg/L	Number of Fish	Mortality (%)				
Nominal	Actual	-	2 h	24 h	48 h	72 h	96 h
Control	-	7	0	0	0	0	0
6.3	Not determined	7	0	0	0	0	0
12.5	Not determined	7	0	0	0	0	0
25	Not determined	7	0	0	0	0	14
50	Not determined	7	0	0	0	0	0
100	Not determined	7	0	0	0	0	14

LC50 > 100 mg/L at 96 hours. NOEC 100 mg/L at 96 hours.

guideline were satisfied.

The actual concentrations of the test substance in the test media were not measured. The results above were based on nominal concentrations.

CONCLUSION The notified chemical is not harmful to fish.

TEST FACILITY Ecotox (2013a)

#### C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test – Static.

Species Daphnia magna
Exposure Period 48 hours

Auxiliary Solvent None

Water Hardness 150 mg CaCO<sub>3</sub>/L Analytical Monitoring Not applicable Remarks - Method A stock solution

A stock solution was prepared by adding the test substance directly into dilution water. The test media with lower concentrations of the test substance were prepared by serial dilution of the stock solution. The test substance appeared to be fully dissolved in the test media at each of the test concentrations from 3.1-100.1 mg/L.

Twenty daphnids (5 daphnids per replicate) were exposed to the test media at different nominal concentrations. The test was conducted in accordance with the test guideline without significant deviation from the protocol. Good Laboratory Practices (GLP) were followed.

#### RESULTS

Concentration mg/L		Number of D. magna	Number Immobilised (%)	
Nominal	Actual		24 h	48 h
Control	-	20	0	0
3.1	Not determined	20	0	0
6.3	Not determined	20	0	0
12.5	Not determined	20	0	5
25	Not determined	20	0	10
50.1	Not determined	20	0	5
100.1	Not determined	20	0	15

LC50 > 100.1 mg/L at 48 hours

NOEC 100.1 mg/L at 48 hours

guideline were satisfied.

The actual concentrations of the test substance in the test media were not measured. The results above were based on nominal concentrations.

CONCLUSION The notified chemical is not harmful to aquatic invertebrates.

TEST FACILITY Ecotox (2013b)

# C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species Pseudokirchneriella subcapitata

Exposure Period 72 hours

Concentration Range Nominal: Control, 0.8, 1.6, 3.1, 6.3, 12.5 and 25 mg/L

Actual: Not Determined

Auxiliary Solvent None

Water Hardness 30 mg CaCO<sub>3</sub>/L Analytical Monitoring Not applicable

dilution water. The test media with lower concentrations of the test substance were prepared by serial dilution of the stock solution. The test substance appeared to be fully dissolved in the test media at each of the

test concentrations from 0.8-25 mg/L.

The test was conducted in accordance with the test guideline without significant deviation from the protocol Good Laboratory Practices (GLP)

significant deviation from the protocol. Good Laboratory Practices (GLP)

were followed.

Results

Biomass		Growth		
$E_bC50$	$NOE_bC$	$E_rC50$	$NOE_rC$	
mg/L at 72h	mg/L at 72 h	mg/L at 72 h	mg/L at 72 h	
4.6	1.6	23.1	1.6	
(95% confidence limit: 4.2-5.1 mg/L)		(95% confidence limit: 18.4-31.9 mg/L)		

guideline were satisfied.

The actual concentrations of the test substance in the test media were not

measured. The results above were based on nominal concentrations.

CONCLUSION The notified chemical is harmful to algae.

TEST FACILITY Ecotox (2013c)

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