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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Chemical in Duratone HT

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

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

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

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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/1525	Halliburton Australia Pty Ltd	Chemical in Duratone HT	ND*	≤ 100 tonnes per annum	Additive in drilling fluids

*ND = not determined

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 of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).
However the notified chemical contains an impurity that has been associated with carcinogenic effects via the inhalation route.

Human health risk assessment
Provide that control measures are in place to minimise worker exposure to the notified chemical including the use of personal protective equipment (particularly respiratory protection) and ventilated environments, 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
Based on the low hazard and reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical where dust or aerosols are generated:
  - Local exhaust ventilation and/or appropriate extraction systems where possible;
  - Good general ventilation

- 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 the product:
  - Avoid contact with skin and eyes
  - Use of low-dust handling techniques
  - Observance of relevant exposure standards (e.g. for silica and atmospheric dust)

- 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 the product:
  - Coveralls, impervious gloves, goggles
  - Respiratory protection where dusts or aerosols of the notified chemical are generated

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 of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

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

Emergency procedures

- Spills or accidental release of the notified 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(2) of the Act; if
  - the function or use of the chemical has changed from additive in drilling fluids, or is likely to change significantly;
  - the amount of chemical being introduced has increased, or is likely to increase, significantly;
  - the chemical has begun to be manufactured in Australia;
  - 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 (M)SDS of a product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Halliburton Australia Pty Ltd (ABN: 73 009 000 775)
Level 17, 444 Queen Street,
Brisbane QLD 4000

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, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, details of physico-chemical, toxicological and ecotoxicological studies, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for vapour pressure, hydrolysis as a function of pH, absorption/desorption, dissociation constant and flash point.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
REACH 2014

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Duratone HT (containing the notified chemical at 60-100%)

MOLECULAR WEIGHT
> 10,000 Da

ANALYTICAL DATA
Reference NMR, IR, GPC and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

HAZARDOUS IMPURITIES

Chemical Name	Quartz (SiO_2)		
CAS No.	14808-60-7	*Weight %*	<5%
Hazardous Properties	Exposure Standard TWA 0.1 mg/m^3 Crystalline silica in the form of quartz is carcinogenic to humans (Group 1; IARC, 2012).		

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)
None

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: A brown to black powder

Property	Value	Data Source/Justification
Melting Point	> 500 °C	Measured*
Boiling Point	Not determined	Expected to be very high based on melting point
Density	~1200 kg/m^3 at 20 °C	Measured*
Vapour Pressure	Not determined	Expected to be low based on melting point
Water Solubility	< 1 × 10^{-3} g/L	Measured*
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities. However, the notified chemical is not expected to be significantly hydrolysed under normal environmental conditions (pH 4-9).
Partition Coefficient (n-octanol/water)	Not determined	The notified chemical is an emulsifier and will tend to accumulate at the phase interface of octanol and water and/or form emulsions
Adsorption/Desorption	Not determined	The notified chemical is expected to associate with soil, sediment and sludge based on its polarity, high molecular weight and low water solubility.
Dissociation Constant	Not determined	The notified chemical is a salt, and therefore it is expected to be ionised in the environment.
Particle Size	Inhalable fraction (< 100 μm): <50% by weight Respirable fraction (< 10 μm): <2% by weight	Measured*
Flash Point	Not determined	The substance is a non-volatile solid
Flammability (solid)	Not highly flammable	Measured*
Autoignition Temperature	>200 °C	Measured*
Explosive Properties	Non-explosive	Measured*
Oxidising Properties	Non-oxidising (at up to 60% mixtures with cellulose)	Measured*

*Details of the study are exempt information

Reactivity
Expected to be stable under normal conditions of use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified 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 not be manufactured or reformulated in Australia. The notified chemical will be imported as a component of a formulated product (60-100% concentration).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-100	10-100	10-100	10-100	10-100

PORT OF ENTRY
Fremantle (WA), Melbourne, Brisbane and Adelaide.

IDENTITY OF MANUFACTURER/RECIPIENTS
Halliburton Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The product Duratone HT containing the notified chemical will be imported in 25 kg sacks on shrink-wrapped pallets. Prior to transportation, the product containing the notified chemical will be temporarily stored at holding warehouses at entry ports.

The product will be transported by truck to on-shore drilling sites or by a combination of trucks and ship to off-shore sites.

USE
Duratone HT containing the notified chemical at 60-100% will be used as an additive in drilling fluids in off-shore or on-shore well drilling operations. Duratone HT will be used with primary and secondary emulsifiers forming a stable emulsion during high pressure high temperature (HPHT) drilling applications.

OPERATION DESCRIPTION
The notified chemical will be imported into Australia as a component of a formulated product in powder form. There will be no further formulation of the notified chemical. However, during end-use in off-shore or on-shore well drilling operations, the product in powder form containing the notified chemical will be mixed with other ingredients and then incorporated into the fluid system. The mixture will then be pumped into the well, where it will disperse within the drilling fluid system. After the completion of drilling operations, the drilling mud containing the notified chemical is expected to be pumped out for disposal, recycling, or re-use for both on-shore and off-shore settings. Most handling and use of the product containing the notified chemical is expected to occur outdoors.

When muds are reconditioned for reuse, as typically done for oil-based muds, the drill cuttings are typically treated in a thermal unit to reclaim as much oil as possible. Most of the notified chemical adhering to the drill cuttings would likely be removed with the liquid phase or thermally degraded during this process.

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)*
Engineer	< 1	70
Drill Rig Contractor	< 1	70

EXPOSURE DETAILS
Transport and storage workers are not likely to be exposed to the product containing the notified chemical except in the case of an accident involving damage to the sealed containers of the product.

Dermal, ocular, and inhalation exposure of workers to the notified chemical may occur during transfer, mixing of the product to prepare the treatment mixture, connecting the pump lines, pumping of the treatment mixture into the well and during maintenance and cleaning of equipment. Workers will wear appropriate personal protective equipment (PPE), while handling the product such as impervious rubber gloves, rubber apron, chemical goggles/glasses and respirators. Moreover, operations will be performed in ventilated areas.

6.1.2. Public Exposure

The notified chemical is intended only for use in the oil and gas industry. Public exposure to the notified chemical is not expected except in the unlikely event of an accident occurring during road transport. Exposure to the public is therefore expected to be negligible.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the following table. Details of the studies are exempt information.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	LC50 > 2 mg/L/4 hour; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Rat, repeat dose inhalation toxicity – reproductive and developmental toxicity 4-6 weeks.	NOAEC > 0.2 mg/L for systemic and reproductive / developmental effects
Mutagenicity – *in vitro* bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* chromosome aberration	non genotoxic
Genotoxicity – *in vitro* mouse lymphoma	non mutagenic

Toxicokinetics, metabolism and distribution.

Absorption across the gastrointestinal tract and dermal absorption may occur. However, the extent of absorption is likely to be limited by the high molecular weight of the notified chemical (>10,000 Da).

Acute toxicity.

The notified chemical is of low acute oral, dermal, and inhalation toxicity. The tests were performed according to the OECD Test Guideline 420, 402 and 403 respectively.

Irritation and sensitisation.

The notified chemical was not a skin irritant in a rabbit study carried out according to the OECD TG 404. In an eye irritation study carried out to OECD TG 405, conjunctival effects occurred but resolved by 24 hours post dose administration.

The notified chemical was not a skin sensitiser when tested at up to 60% in a Local Lymph Node Assay.

Repeated dose toxicity with reproductive/developmental toxicity screening.

In a combined repeated inhalation dose toxicity test with reproduction and developmental toxicity screening in rats, (OECD TG 422), the NOAEC was set at the highest dose tested (> 0.2 mg/L) for repeated dose systemic effects and for reproductive / developmental effects. However, effects in the lung were noted at this dose, which are expected to be related to deposition of the pigmented material in the lung. These included dark discolouration, increased lung weights, multifocal alveolar macrophage accumulation and areas of bronchiolo-alveolar hyperplasia. Necrosis, degeneration or fibrosis was not present.

Mutagenicity/Genotoxicity.

The notified chemical was negative, with and without metabolic activation, in three *in vitro* studies – a bacterial reverse mutation study, a chromosome aberration study and a mouse lymphoma assay. Overall the results do not raise a concern for genotoxicity.

Impurities

The notified chemical contains up to 5% quartz as an impurity. Crystalline silica in the form of quartz causes cancer of the lung (IARC, 2012). A recent Canadian evaluation of quartz considered that adequate data exists for a threshold approach to risk characterisation. It also reported that numerous epidemiological studies have identified a positive correlation between workplace exposure to crystalline silica and increased risks of lung cancer; however there is little evidence that low-level exposure to silica causes adverse health effects in man. Aggressive engineering controls to reduce silica dust in the workplace have shown to reduce silicosis (Environment and Health Canada, 2013). IARC (2012) notes that effects after long residency in the lung have not been systematically assessed.

Health hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System of 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 toxicity profile of the notified chemical, adverse lung effects may occur after repeated inhalation exposure that may be related to lung overloading. The chemical also contains an impurity that has been associated with carcinogenic effects following inhalation exposure. Based on the particle size data submitted, a fraction of the notified chemical is in the respirable particle size range.

Workers handling Duratone HT in powder form at the drilling sites may have inhalation exposure, and therefore be at risk of these effects. However, the risk to workers would be minimised by workplace controls to reduce exposure. The notifier has stated that such controls will be available to workers. Provided that control measures are in place to minimise worker exposure to the notified chemical, including well ventilated environments, safe work practices to reduce generation of dust/aerosols and the use of PPE (particularly respiratory protection), the risk to workers from use of the notified chemical is not considered to be unreasonable.

6.3.2. Public Health
The public is not expected to be exposed to the notified chemical except in an event of an accident during road transport; hence the risk to the public from use of the notified chemical 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 not be manufactured or reformulated in Australia. The notified chemical will be imported by the notifier as a finished end-use product. Therefore, release of the notified chemical from these activities is not expected. Release of the notified chemical to the environment during import, storage, and transport is also unlikely. Release from residues in storage and shipping containers is expected to be minimal. Empty containers are expected to be disposed of in accordance with local requirements. Spills or accidental release of the notified chemical are expected to be contained and disposed of in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE
For a typical application in a well, approximately 2,700 – 5,400 kg of product per treatment, corresponding to approximately 1,620 – 5,400 kg of the notified chemical are expected to be used per treatment. During end-use in off-shore or on-shore well drilling operations, the product in powder form, containing 60 –100% of the notified chemical, will be mixed with other ingredients and then incorporated into an oil- or synthetic-based fluid system. The mixture will then be pumped into the well, where it will disperse within the drilling fluid system. After the completion of drilling operations, the drilling mud containing the notified chemical is expected to be pumped out for disposal, recycling, or re-use for both on-shore and off-shore settings. It is expected that 75% of the product containing the notified chemical will be brought back up from the well and re-used. The remaining 25% of the product containing the notified chemical that cannot be re-used is expected to be disposed of in accordance with local regulations.

When muds are reconditioned for re-use, as typically occurs with oil-based mud, the drill cuttings are typically treated in a thermal unit to reclaim as much oil as possible. Most of the notified chemical adhering to the drill cuttings would likely be removed with the liquid phase or thermally degraded during this process.

RELEASE OF CHEMICAL FROM DISPOSAL
Disposal of oil and synthetic drilling fluid is rare due to the high value of the fluid and the significant disposal costs. All reasonable means may be taken to economically retain and reuse the fluids.

If the mud cannot be re-used, it will be sent to a registered disposal facility. The solids containing most of the notified chemical are expected to be sent to landfill or a tailings dam for disposal. Furthermore, solids which have been generated through mechanical separation to recondition the fluid are also expected to be sent to landfill.

7.1.2. Environmental Fate

The notified chemical is not expected to biodegrade rapidly based on the provided study. The notified chemical is not considered readily biodegradable according to the OECD guidelines. Therefore, the notified chemical is persistent in the environment. The notified chemical is not expected to be bioaccumulative due to its high molecular weight. Given the presence of polar functional groups and its high molecular weight, the notified chemical is expected to bind strongly to soil and/or sediment soon after entering the water/sediment system.

In most circumstances, the notified chemical will be incorporated into the bulk drilling fluid and share the fate of the drilling mud. The mud systems will be pumped from wells for disposal, recycling or reuse after the completion of drilling operations. Oil-based drilling mud is expected to be re-used and is not expected to be directly released to the water environment. For on-shore applications, the mud solids are expected to be sent to landfill or a tailings dam. In landfill or tailings dams, the notified chemical is not expected to be mobile based on its strong potential to bind to soil/sediment and low water solubility.

In the ocean, the notified chemical is expected to bind to sediment. In all cases, the notified chemical is expected to ultimately degrade via biotic or abiotic pathways to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

Off-shore application

The notified chemical will be used as an additive in drilling fluids in oil- or synthetic-based drilling fluid systems in off-shore or on-shore drilling operations. The standard risk assessment procedure (modelling using CHARM by Thatcher et al., 2005) cannot be used in these cases to derive the predicted environmental concentration (PEC). This is because CHARM does not consider drilling chemicals containing organic phase fluids (oil based and synthetic based fluids).

A predicted environmental concentration (PEC) has not been calculated in this assessment. Based on the assessed used pattern, the amount of the notified chemical expected to be discharged to the sea is insignificant. Since the notified chemical has very low water solubility and high molecular weight, the notified chemical released to the sea is expected to bind to sediment and be removed from the seawater column. Hence, the notified chemical is not expected to reach ecotoxicologically significant concentrations in the marine environment. Based on the potential low hazard of the notified chemical, the risk to the marine environment is not considered to be unreasonable.

On-shore application

Based on the information provided by the notifier, significant release of the notified chemical to the aquatic environment from on-shore use is not expected. Therefore, the calculation of a PEC for on-shore applications was not assessed to be necessary.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. Details of the studies are exempt information.

Endpoint	*Result*	*Assessment Conclusion*
Marine Fish Toxicity	96 h LL50 > 1000 mg/L (WAF)	Not harmful at saturation to fish
Marine Copepod Toxicity	48 h EL50 > 1000 mg/L (WAF)	Not harmful at saturation to aquatic invertebrates
Marine Algal Toxicity	72 h EL50 > 100 mg/L (WAF)	Not harmful at saturation to algae
Marine Sediment Re-worker Toxicity	10 d LL50 > > 10,000 mg/kg dried sediment	Not harmful at saturation to sediment re-workers
Inhibition of Bacterial Respiration	EC50 (3 h) > 1000 mg/L	Not harmful to microbial respiration up to its water solubility limit

WAF: Water Accommodated Fraction

The notified chemical is not harmful to the aquatic organisms up to its limit of water solubility. Therefore, the notified chemical has not been formally classified for the acute and long-term hazard under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS, United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

A predicted no effect concentration (PNEC) has not been calculated as the notified chemical is not considered to be harmful to aquatic biota up to the limit of its solubility in water.

7.3. Environmental Risk Assessment

A risk quotient RQ (PEC/PNEC) has not been derived since neither the PEC nor the PNEC is calculated. The notified chemical is expected to degrade in soil/sediment, although it is expected to be neither readily biodegradable, nor be bioaccumulative. Based on the low hazard and the assessed use pattern of the notified chemical, it is not expected to pose an unreasonable risk to the environment.

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