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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

GULFTENE C14 ISOMERISED OLEFINS

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

GULFTENE C14 ISOMERISED OLEFINS

1. APPLICANT

Chevron Chemical Australia of 385 Bourke Street MELBOURNE VIC 3000 (ABRN 001 010 037) and Baker Hughes Inteq of 5 Stoneham Street BELMONT WA 6104 (ACN 004 752 050) have submitted a standard notification statement in support of their application for an assessment certificate for Gulftene C14 Isomerised Olefins (hereunder referred to as 'Gulftene 14').

2. IDENTITY OF THE CHEMICAL

The chemical identity and CAS number have been exempted from publication in the Full Public Report and the Summary Report.

Marketing Name:	Gulftene C14 Isomerised Olefins
Method of Detection and Determination:	Infrared (IR) analysis; High Performance Liquid Chromatography.
Spectral Data:	^{1}H, ^{13}C NMR and IR spectra; The spectral data provided is sufficient to characterise the major functionalities within the notified chemical mixture.

3. PHYSICAL AND CHEMICAL PROPERTIES

The data below is taken from the OECD Screening Information Data Set (SIDS) for 1-tetradecene (OECD 1992), which the notifier nominates for assessment of the physical and chemical properties of the notified chemical, Gulftene 14. Full test reports were not available for assessment purposes. The presented data is adequate for the assessment of physical hazards, and environmental fate and potential hazard of Gulftene 14.

Appearance at 20°C & 101.3 kPa:	Clear colourless to pale yellow, viscous liquid
Particle Size:	Not applicable- viscous liquid
Boiling Point:	232-234°C
Freezing Point:	-12°C
Specific Gravity:	0.7745 at 20°C
Kinematic Viscosity:	0.9×10^{-6} at 100°C
Vapour Pressure:	0.0019 kPa at 25°C
Vapour Density (Air = 1):	6.78
Water Solubility:	0.0004 mg/L at 25°C (estimated)
Surface Tension:	0.025 N/m at 20°C
Partition Co-efficient (n-octanol/water):	Log P_{ow} 7.3 (estimated)
Hydrolysis as a Function of pH:	Not applicable – see comments below
Adsorption/Desorption:	Not applicable – see comments below
Dissociation Constant:	Not applicable – see comments below
Henry's Law Constant:	8.48 atm-cu m/mole at 25°C
Flash Point:	110°C (closed cup) ISO 2719
Flammability Limits:	Upper Explosive Limit = 4.3% Lower Explosive Limit = 0.3%
Autoignition Temperature:	235-239°C
Explosive Properties:	Not explosive. Combustible
Reactivity/Stability:	Stable under normal conditions

Comments on Physico-Chemical Properties

The estimated very low water solubility of 0.4 μg/L is consistent with the hydrocarbon nature of the compound.

The Henry's Law Constant is a measure of the degree of partitioning of a compound between the aqueous phase and the atmosphere, and is calculated according to the relationship –

H = (Vapour pressure (Pa) x Molecular weight (g/mole))/ Water solubility (g/m^3).

For Gulftene 14, Henry's Law Constant is calculated to be 10^6 $Pa.m^3$/mole. This is a high value and indicates that the material will be appreciably volatile, and tend to partition strongly from the water phase to the atmosphere.

The estimated Log P_{ow} for 1-tetradecene is 7.3 (method of estimation was not specified). (Lyman 1990) give a method for the estimation of Log P_{ow} based on the molecular structure of a compound (the fragment method), and for 1-tetradecene this gives a Log P_{ow} of 6.11. This is slightly less than the value quoted in the SIDS (OECD 1992), but is nevertheless a large value reflecting the hydrocarbon nature of the material. Regardless of the estimation methods employed, a high Log P_{ow} value is expected for Gulftene 14.

No quantitative estimates for adsorption/desorption were provided, but the high values for Log P_{ow} indicate correspondingly large values for Log K_{oc}. (Lyman 1990) give a number of relations for estimation of Log K_{oc} from values of Log P_{ow}, all of which (as expected) give large values for this parameter. As an example, using the calculated value for Log P_{ow} of 6.11, their equation 4-8 which is –

$$\text{Log } K_{oc} = 0.544 \times \text{Log } P_{ow} + 1.377$$

gives a value for Log K_{oc} of 4.7. Values of Log K_{oc} in excess of 3 indicate high affinity for the organic component of soils and sediments, and low mobility in these media.

Gulftene 14 contains no groups that are susceptible to hydrolysis. Similarly, the molecules contain no acidic or basic functionalities and so dissociation constant data are not relevant.

Gulftene 14 is combustible. Gulftene 14 is stable during transport and is not chemically reactive.

4. PURITY OF THE CHEMICAL

Degree of Purity:	100%
Hazardous Impurities:	None
Non-hazardous Impurities (> 1% by weight):	None
Additives/Adjuvants:	None

5. USE VOLUME AND FORMULATION

5.1 Use

In Australia, Gulftene 14 is to be used as a base fluid for invert drilling fluid on offshore oil and natural gas drilling operations. Wider applications of Gulftene 14 include: metal working fluid, dielectric fluid, solvent applications, ingredient in detergents and as an intermediate in the production of paper sizing agents and lubricating additives.

This assessment of Gulftene 14 is limited to its use as a component of drilling fluids.

5.2 Volume and Transport

Gulftene 14 will not be manufactured in Australia, but will be imported in liquid form by sea in 200 L drums or 8 000 L marine isotanks. Drums are loaded into a container (78 drums per container) prior to shipment. Over the next five years the anticipated import volume of Gulftene 14 is up to 700 tonnes per annum. An annual import of 700 tonnes, (with a specific gravity of 0.76) equates to 900 000 L of Gulftene 14 and would require the importation of 4 500 drums, or 110 marine isotanks per annum. The notifier indicated that imports may exceed 700 tonnes per annum, but could not predict exact volumes.

The quantity of drilling fluid used in drilling the wells depends on drilling depth and number of holes drilled. The notifier indicated that a typical oil/gas drilling platform may use 150 tonnes of Gulftene 14 annually.

From the initial port of arrival the drums or isotanks containing Gulftene 14 are delivered by truck to a storage and drilling fluid blending facility. The prepared drilling fluid is transported by tanker truck to docks, pumped into storage tanks on ships, then transported to the offshore platform. Up to 300 m^3 of drilling fluid may be transported to the platform. The transfer of the fluid from the ship to storage tanks on the platform is effected using special hoses and couplings.

5.3 Formulation

The drilling fluid will be prepared at purpose built facilities at Dampier in WA. Gulftene 14 will be blended at 33-50% with water, emulsifiers, fluid loss additives, viscosity modifiers and barium sulphate[1] in high shear mixers and pumped to an onsite storage tank. While no details were provided in the submission, it is understood that the facilities at which drilling fluid is prepared are provided with adequate bunds to contain spills. All spilt material would be disposed of by incineration or by other accepted methods.

5.4 Drilling Operations

During drilling operations, the fluid is pumped down the drill shaft. It functions as a lubricant for the drills and a carrier fluid for removing the solid cuttings (ie the rock removed from the bore hole). Drilling fluid is pumped down the centre of the (hollow) drilling rods and is extruded through holes in the cutting head, which is of larger bore than the shaft of drilling rods. The fluid then fills the annular region between the bore hole (typically 31.1 cm in diameter (Cobby 1999) and the drilling shaft, and as it is pushed back towards the surface carries the drill cuttings with it. The solid cuttings are separated from the fluid through a

[1] The barium sulphate is used as a weighing agent to increase the density of the drilling fluid and control formation pressures in the wellbore during drilling operations.

series of solids separation units. The cuttings may contain up to 10% (w/w) of Gulftene 14 and are automatically discharged overboard through a pipe set a little below the sea surface but far above the sea floor.

While most of the drilling fluid is recovered in this manner, it is inevitable that some will remain adsorbed on the surface of the cuttings and may be entrained between the particles of solid waste and will be discarded with these cuttings. All drilling fluid, other than that adsorbed to the drill cuttings, is recovered and recirculated through the drill string on a continuous basis. No whole drilling fluid is discharged overboard. At the end of the drilling phase all the drilling fluid is recovered and returned to shore for storage until required on another well. It is important to note that stringent procedures are used to ensure that there is no loss of whole drilling fluid to the environment at any stage of the drilling and transport operations. Drilling fluids adhering to the disposed cuttings may constitute up to 10% by weight of the cuttings.

6. OCCUPATIONAL EXPOSURE

6.1 Number and Category of Workers

Import and Transportation: unknown;
Drill fluid preparation: 2 to 3 workers;
Drilling crew: approximately 20 workers per offshore platform.

6.2 Nature of Work Done

6.2.1 Dockside and Transport
Occupational exposure is not expected except in the event of a spill.

6.2.2 Drill Fluid Preparation
Using automated systems, operators blend Gulftene 14 with other components to produce the drilling fluid as described in Section 5. Preparation of the fluid takes about one to two hours depending on batch size. During preparation, potential for dermal and ocular contact to Gulftene 14 at 33 to 50% exists for workers sampling the drilling fluid for quality control (QC) analysis. Exposure to Gulftene 14 may also occur during maintenance of equipment or in the event of a spill. Formation of aerosol and consequent inhalation exposure is expected to be negligible given the automated addition systems and the high density of the drilling fluids.

6.2.3 Drilling
The large size of drilling equipment suggests that drill operators will have potential for exposure to high volumes of drilling fluid during manipulation of the drill when the drill bit is replaced or removed from the drill hole. There is potential for skin and eye contact during these activities. Formation of aerosol and consequent inhalation exposure is expected to be negligible given the high density of the drilling fluid.

6.2.4 Drum and Isotank Recycling

During the cleaning of drums and isotanks for recycling, workers may receive eye and skin contact to water-slop containing residual notified chemical.

6.3 Control Measures

Personal protective equipment is expected to be mandatory for drilling crews. The Material Safety Data Sheet (MSDS) for Gulftene 14 recommends impervious protective clothing, safety glasses with eye shields and nitrile, Viton, polyurethane, or chlorinated polyethylene gloves. In addition, an organic vapour (Type A) filter respirator is recommended where exposure to airborne material may occur.

6.4 Worker Education and Training

The notifier indicates that the pattern of use is non-dispersive that is, workers exposed to Gulftene 14 would be employees of the major international petroleum and drilling rig companies and would be educated and trained in all aspects of drilling operation safety and chemical hazards, to achieve adequate control of exposure. Transport workers would also be educated in the occupational health and safety aspects of petroleum derived products.

7. PUBLIC EXPOSURE

It is expected that during transport and storage the potential for exposure of the general public to the notified chemical will be low.

Onshore small spills should be cleaned up using appropriate technology such as sorbent materials or pumping before being transferred to suitable containers for recovery or disposal in accordance with local, state and federal regulations. Prompt attention to spillages will be needed to prevent spill and clean up material from entering waterways. All sources of ignition in the vicinity of the spill or released vapour should be eliminated. Where feasible and appropriate contaminated soil should be removed.

The chemical will only be used on offshore drilling platforms, and the public will not be exposed during this operation.

Cleaning of used drums and isotanks will remove more than 95% of Gulftene 14 from wastewater prior to discharge into sewers. Thus, disposal is unlikely to produce significant public exposure.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Very small quantities of Gulftene 14 may be left in the 200 L drums and isotanks which are subsequently steam cleaned and reconditioned. The resultant oil/water emulsion is passed to an on site waste treatment facility where the oils and water are separated and eventually

become incorporated into a waste sludge. The waste sludge is typically incinerated.

The use pattern of Gulftene 14 is such that all material used in drilling fluids is expected to be released with the waste drill cuttings to the marine environment. The drill cuttings may contain up to 10% of Gulftene 14 and are discharged through a pipe just below the surface to eventually settle to the sea floor. However, depending on factors such as particle size sea conditions, weather conditions and ocean currents, the deposition may take some time. Also, it is likely that the distribution would be disperse and that the discarded cuttings would be spread over a fairly wide area of the sea floor. A typical production drilling platform may have more than ten individual bore holes, each between one and four km in length.

Given that the typical diameter of a production hole is 31.1 cm, each platform is estimated to produce between 3 000 and 12 000 m^3 of rock cuttings with a weight of approximately 8 000 to 30 000 tonnes (Cobby 1999). Assuming that the cuttings contain 10% of drilling fluid, each pile of cuttings may contain up to 3 000 tonnes of discarded fluid. Note here that Gulftene 14 is one of a class of materials used in the preparation of the drilling fluids. These may include internal olefins, poly alpha olefins, linear alpha olefins, esters and acetals (Cobby 1999).

Also, some of the residual fluid may remain "entrained" between particles of rock cuttings and not adsorbed to the surface of these solids. After discharge overboard this material would be expected to migrate to the sea surface and could form a film on the surface of the water. The notifier acknowledged that while the formation of such a "slick" is possible it would be unlikely except during extremely still weather and sea conditions. Any surface film formed from the notified chemical in this manner could be expected to slowly spread from the vicinity of the drilling rig to be eventually broken up by wind and waves. Since the compound is very volatile (Henry's Law Constant around 10^6 Pa m^3/mole), it is expected that most of the material would evaporate from the surface and enter the atmosphere.

Nevertheless, once discharged overboard, it is likely that the drill cuttings with residual drilling fluid will persist for some time in the vicinity of the well. The notifier provided a copy of a paper (Oliver GA 1998), which summarised studies of the persistence of residual drilling fluids in the vicinity of three drilling rigs on the North West Shelf of WA. The results of this survey indicated that high levels of hydrocarbon can be measured for some years after cessation of drilling, although currents appear to disperse the contaminated material lowering overall concentrations. However, the paper did not address long term persistence of the hydrocarbons in the drilling fluids.

8.2 Fate

8.2.1 BIODEGRADATION

Gulftene 14 will be released in large quantities to the sea floor. Since conditions within the marine benthic zone may be either aerobic or anaerobic, it is necessary to consider the fate of the material in both these environments.

8.2.1.1 Aerobic Conditions - Freshwater Studies

The following tests were conducted on cogener substances, C20-24 alkenes, branched and linear, C16 alkenes and C14.

8.2.1.2 Ready Biodegradability - CO_2 Evolution Test (Safepharm Laboratories Limited 1998)

Test Substance: C20-24 alkenes, branched and linear

A Modified Sturm Test (OECD TG 301B) was conducted over 28 days with sewage sludge organisms. The test was conducted at 22°C and the test substance was initially present at a level of 20 mg carbon/L. After 28 days the concentration had decreased by 92%, and since the degradation had exceeded 60% ten days after reaching 10%, the material may be classified as readily biodegradable.

8.2.1.3 Ready Biodegradability – Closed Bottle Test (Huntingdon Research Centre 1993)

Test Substance: Gulftene 16

In the Closed Bottle Test (OECD TG 301 D) which monitors the level of dissolved oxygen in a closed test vessel, around 94% degradation was observed after 28 days. However, in this test 60% decrease in the theoretical oxygen demand had not been attained 10 days after attaining the 10% decrease in demand. Consequently, according to the criteria of the protocol, the C16 olefin test substance is classified as inherently biodegradable but not readily biodegradable. Based on the findings of this test and the one above for C20-24 alkenes, it is expected that Gulftene 14 would also exhibit a high degree of biodegradability under aerobic conditions in fresh water.

8.2.1.4 Ready Biodegradability – Modified MITI Test (I) (JETOC 1992)

Test Substance: C16

A summary report of a modified MITI (OECD 301 C) test indicated 55 to 77% degradation after 28 days. In another closed bottle test (performed according to the protocol of the closed bottle test OECD 301 D) only 31% degradation was achieved after 28 days. Since no test report accompanied this reference no comment can be offered on the difference between this result and that obtained in the test described above. However, this difference highlights the variability encountered in tests of this type.

8.2.1.5 Ready Biodegradability – Manometric Respirometry Test (Mather JI Latham M Tapp JF 1995)

Test Substance: Syn-Teq Mud containing C14-20 isomerised alpha olefins (present at between 30-50%)

This test was performed according to the protocols of OECD TG 301 F (Manometric Respirometry Test). The results indicated that the extent of biodegradation of the organic components of the drilling fluid reached 51% after 10 days and attained 62% after 20 days. However, no increase in degradation was observed over the subsequent 28 days of the trial. This may indicate that the isomerised olefins are degraded to a metabolite which is resistant to subsequent degradation processes. Since the isomerised olefins are the primary organic component of the "Syn-Teq" fluids, the results of this test indicate that the isomerised olefins are substantially biodegradable under aerobic conditions.

8.2.1.6 Ready Biodegradability - CO_2 Evolution Test (EU 1995)

Test Substance: C14

The results for a modified Sturm test indicated 48 to 55% degradation after 28 days incubation with sewage sludge bacteria. The full study was not provided.

8.2.1.7 Aerobic Conditions – Marine Studies

The degradation (mineralisation) of chemicals in the marine environment has not been researched as extensively as has degradation in freshwater environments. However, the notifier submitted reports for three biodegradation tests conducted with seawater.

Test Substance: C16-C18 isomerised olefins

The first report (Environment & Resource Technology Ltd 1995) detailed the conduct and results of a test conducted according to the protocols of OECD Test Guideline 306, which is a variation of the closed bottle biodegradation test (OECD TG 301 D). The test was conducted in naturally aerated seawater at 20°C, which had been fortified with minerals essential for bacterial growth over a 28-day period. The decrease in dissolved oxygen levels was monitored periodically (0, 5, 14 and 28 days), and indicated around 72% degradation over the 28-day test period. The soluble reference compound – sodium benzoate – exhibited 89.2% biodegradation after 28 days under the same test conditions. It was also noted that there was no apparent inhibition of bacterial activity resulting from exposure of the bacteria to the new material. Thus, the degree to which the soluble reference substance, sodium benzoate, was degraded was similar in media containing the new olefin compound, and in media containing none.

A second test performed by the same laboratory (Environment & Resource Technology Ltd 1999) using a different sample of material, but otherwise using the same test methodology (OECD TG 306) indicated 36% biodegradation over the 28 day test period. In this test, sodium benzoate was again used as the reference material and had degraded by 68%. A second part of this report gave the results of a marine ISO BODIS test for aerobic biodegradation. The methodology of this test is very similar to that of OECD TG 306, except that the closed sample bottles contain 33.3% air (by volume), and are agitated throughout the

test period in order to better simulate real marine conditions. Also, after each sample is taken (in this case at 7, 14, 21 and 28 days) the samples are aerated to re-establish oxygen saturation. The result of this test indicated 48% biodegradation of the C16-18 olefin after 28 days, while the reference compound (sodium benzoate) had degraded by 84%. The higher degree of degradation in the marine BODIS test is presumably due to the higher availability of oxygen.

The significant difference between the results obtained from the two OECD TG 306 tests, namely, 72% degradation in one test as opposed to 36% in the other, could reflect differences in the bacterial populations of the sea waters used as test media. Alternatively, differences in the degree and position of branching in the olefin chains of the samples used in each test or other factors could be responsible.

Overall, the results of these tests indicate that the new compound is at least potentially biodegradable under aerobic conditions. However, one of the reports (Environment & Resource Technology Ltd 1995) noted that the controlled conditions of a laboratory environment may not reflect those of the "real world", and that the actual rate of degradation for released material may be significantly slower. In particular it was observed that compound released with drill cuttings is likely to be adsorbed onto the surface of particles of drilling waste rather than being dispersed in the water column as in the laboratory tests.

In respect of the general question of biodegradation in marine environments, a preliminary report (ECETOC 1993) has concluded that if a chemical exhibits ready biodegradation under aerobic conditions in a freshwater environment, the available evidence indicates that it will also be degraded in the marine environment. The mechanisms for degradation may be either aerobic or anaerobic, but marine degradation rates are likely to be substantially reduced in comparison because of the low bacterial population in the marine environment. Low temperatures at the benthic interface would also decrease the rate of degradation.

8.2.1.8 Anaerobic Conditions - Freshwater Studies

Test Substance: C16/C18 isomerised olefin

This study (Environment & Resource Technology Ltd 1996) was conducted according to the protocol ISO/TC147/SC5/WG4 which may be similar to the ECETOC screening test (ECETOC 1988) whereby the test substance is incubated at 35°C over an extended period with sewerage digester sludge maintained under anaerobic conditions. The volume of evolved CO_2 and methane is measured periodically throughout the test period. The results indicated that after 56 days incubation under the test conditions, only 10.6% of the original carbon in the test substance had been metabolised to CO_2 and methane. Consequently, it was concluded that the material is only slowly degraded under anaerobic conditions.

The notifier also provided a second summary report (Mather JI Latham M Tapp JF 1995) on anaerobic biodegradation performed on another sample of the same material by a different laboratory. The protocols used in this test were those of ISO/CD11734, and indicated 58% degradation after 56 days incubation with sewage sludge and around 62% degradation after 77 days[2]. These results are significantly better than those of the first test, but since

[2] It should be noted that the Western Australian Department of Minerals and Energy requires that this test be performed on all drilling fluids which are to be used in drilling operations off the WA coast, Cobby (1999).

summaries only were provided for both studies, with no details of the test methods used, no further comment can be made. However, both tests indicated slow biodegradation, and as the tested material contained close congeners of the components of Gulftene 14, these components are likely to behave in a similar manner.

In addition to the summary reports described above the notifier provided a copy of a paper (Steber 1995) dealing specifically with the anaerobic degradation of drilling fluids components, two of which were alpha olefins. These tests were conducted using the ECETOC screening procedure with C14 alpha olefin (test duration 98 days) and with C16-18 alpha olefin (test duration 84 days), and the two compounds were degraded by 48.3 % and 22.4% respectively. Steber (1995) was of the opinion that these results indicate moderate potential for anaerobic biodegradation.

Some supplementary summary data on the anaerobic biodegradation of a synthetic drilling fluid (known as "Syn-Teq Mud") containing C14-20 isomerised alpha olefins (present at between[3] 30-50%) was also supplied by the notifiers (Croudace CP Tapp JF 1995). This test was also performed according to the protocols of ISO Draft Method ISO/CD11734 (see above). The results indicated that the extent of biodegradation of the drilling fluid reached 28% after 56 days and attained 55% after 70 days. Since the isomerised olefins are the primary organic component of the "Syn-Teq" fluids, the results of this test indicate that the isomerised olefins are substantially biodegradable under anaerobic conditions. However, since the test was not continued beyond 70 days, it is not possible to speculate on the ultimate degree of degradation which may have been attained. Also, the results were based on an organic carbon content of 35% in the drilling fluid, although no supporting analytical data accompanied the summary report.

8.2.1.9 Conclusion

The available data and literature references indicate that Gulftene 14 is probably susceptible to anaerobic biodegradation when released to the sea floor with waste drill cuttings. However, the rate and extent of degradation is uncertain, and it is possible that the rate of removal from the benthic regions will be slow, particularly the case in cold deep waters. Cobby (1999) indicates that the extent of biodegradation of organic fluids buried in piles of drill cuttings is limited, and that no substantial long term degradation occurs in these structures.

8.2.2 ABIOTIC DEGRADATION

Gulftene 14 contains no functional groups capable of hydrolysis, and it is expected that the major pathways for degradation will be through direct or indirect photochemical mechanisms.

Hydrogen abstraction by photochemically produced hydroxy radicals is accepted as the dominant mechanism for degradation of saturated hydrocarbon molecules in the atmosphere, while in the case of alkenes addition of hydroxy group to the double bond is dominant. OECD (1992) gives a procedure for calculating typical rate constants for these processes. For the Gulftene 14 the estimated rate constant for hydroxyl group addition gives k_{add} = 56.1 x 10^{-12} cm^3 /molecule/sec, while for hydrogen abstraction from the alkane portion the rate constant k_{abs} = 12.6 x 10^{-12} cm^3 /molecule/sec. Consequently, hydroxyl ion addition

[3] The reference indicated that the drilling mud used in the test contained 35% carbon.

is the dominant initial degradation process, and assuming an ambient hydroxyl radical concentration of 5 x 10^5 radicals/cm^3, the estimated atmospheric half-life is around 2.5 x 10^4 seconds (7 hours).

8.2.3 BIOACCUMULATION

8.2.3.1 Bioconcentration (Environment & Resource Technology Ltd 1994)

Test Substance: C16-C18 olefin

Determination of the bio-concentration factor (BCF) for the blue mussel *Mytilus edulis* was conducted in accordance with OECD Test Guideline 305 A-E. In this procedure the mussels were exposed to water saturated with the test substance (water temperature 18.2-18.4°C) in a flow through apparatus for ten days, then allowed to depurate for a period of 20 days. Samples of water and animal tissue were taken on five occasions during both the exposure and depuration phases, and analysed for the test substance. Log BCF was calculated from the rates of uptake and depuration of the compound according to the recommended procedures, and was determined between 4.1 and 5.4 (BCF between 12 600 and 251 000). These values are appropriate for the C16-C18 congener, and indicate significant potential for bio-concentration.

The BCF for a compound may also be estimated from Log P_{ow} using Quantitative Structure Activity Relationships (QSARs). (Lyman 1982) give a number of QSARs for this purpose but equation 5-2 is recommended for general estimation of the BCF from Log P_{ow}. This equation is –

$$\text{Log BCF} = 0.76 \times \text{Log } P_{ow} - 0.23,$$

and assuming a Log P_{ow} of 7, estimates Log BCF at 5.1 (BCF = 125 900), which agrees well with the experimental data above.

(Connell 1990) indicates that compounds with a molecular weight around 350 and a Log P_{ow} around 6 may have high potential for bioaccumulation. In the present case the molecular weight is 197, while Log P_{ow} appears to be between 6 and 8. Connell (1990) also remarks that the potential for bioaccumulation peaks when water solubility is around 2 x 10^{-6} mole/L, and drops off on either side of this value. The water solubility of Gulftene 14 is estimated to be less than <0.4 μg/L (less than 10^{-9} mole/L) and consequently while the modest molecular weight and large value for Log P_{ow} indicate large potential for bioaccumulation, this may be mitigated by the low water solubility.

It should be noted that the extent of bioaccumulation is also dependent on the rate of biodegradation, and while it is probable that after release into marine sediments the new material will be susceptible to anaerobic degradation, the rate of these processes is uncertain. Consequently, it must be concluded that the probability for bioaccumulation in marine organisms may be high.

9. EVALUATION OF TOXICOLOGICAL DATA

The notifier in support of their claim for Variation of Schedule Requirements for Gulftene 14, submitted toxicity data (full study reports) generated on homologue substances:

. C12, C14, C16 and C18 alpha olefins (AO);

. C16 and C18 alkenes (internal);

. a blend of C12-C16 AO;

. a blend of C20-C24 internal alkenes.

OECD SIDS Dossiers in HEDSET format for 1-dodecene and 1-tetradecene prepared for the 6th SIAM Meeting in June 1997 were also submitted by the notifier as were HEDSET Documents for 1-hexadecene and 1-octadecene. Each HEDSET document is a summary report that represents the available data on the nominated chemical. Where data gaps exist, data on other alkenes (C12 through to C30) where appropriate are substituted.

Many of the studies cited in the HEDSET documents are proprietary to other companies and not accessible to the notifier. As the full study reports were not available for this assessment, and according to the HEDSET documents the tests were not conducted according to established OECD/EC guidelines or GLP, they are treated in this report as supplementary data to the full study reports and appear in this section under the heading '…Other Alkenes'.

A summary of the toxicity of the alkene analogues are tabulated below.

Section	*Endpoint*	*Species*	*Test Substance*	*Result*
9.1	**Acute Toxicity**			
9.1.1	**Oral Toxicity**			
9.1.1.1		Rat/Wistar	C12 - C16 Alpha Olefin	LD_{50}>5 000 mg/kg
9.1.1.2		Rat/Wistar	C16 Alpha Olefin	LD_{50}>5 000 mg/kg
9.1.1.3		Rat/Sprague Dawley	C16 Isomerised	LD_{50}> 5 050 mg/kg
9.1.1.4		Rat/Sprague Dawley	C18 Isomerised	LD_{50}> 5 050 mg/kg
9.1.1.5		Rat/Sprague Dawley Crl:CD BR	C20 - C24 Alkenes, branched and linear	LD_{50}> 5 000 mg/kg
9.1.1.6	Acute Neurotoxicity	Rat/Sprague Dawley		No primary neurotoxic effects
9.1.1.7	Other Alkenes	Rat	C12 - C14 Olefin	LD_{50}>10 000 mg/kg
		Rat/CFE	C12 - C26 Olefin/Paraffin	LD_{50}>10 000 mg/kg
		Rat	C14 - C16 Olefin	LD_{50}>10 000 mg/kg
		Rat/CFE	C14 – C18 Olefin/Paraffin	LD_{50}>10 000 mg/kg
		Rat/CFE	C14 – C26 Olefin/Paraffin	LD_{50}>10 000 mg/kg
		Rat	C16 - C18 Olefin	LD_{50}>10 000 mg/kg
		Rat	C18 – C24 Olefins	LD_{50}>10 000 mg/kg
		Rat/CFE	C18 – C26 Olefin/Paraffin	LD_{50}>10 000 mg/kg
		Rat/CFE	C18 – C30 Olefin/Alcohol	LD_{50}>10 000 mg/kg

9.1.2	**Dermal Toxicity**			
9.1.2.1		Rabbit/ NZ White	C12 - C16 Alpha Olefin	LD_{50}>10 000 mg/kg
9.1.2.2		Rabbit/ NZ White	C16 Alpha Olefin	LD_{50}>10 000 mg/kg
9.1.2.3		Rabbit/ NZ White	C16 Isomerised	LD_{50}> 2 020 mg/kg
9.1.2.4		Rabbit/ NZ White	C18 Isomerised	LD_{50}> 2 020 mg/kg
9.1.2.5		Rat/ Sprague Dawley Crl:CD BR	C20 - C24 Alkenes, branched and linear	LD_{50}> 2 000 mg/kg
9.1.2.6	Other Alkenes	Rabbit/ NZ White	C12 - C14 Olefin	LD_{50}>10 000 mg/kg
		Rabbit/ NZ White	C12 - C26 Olefin/Paraffin	LD_{50}>10 000 mg/kg
		Rabbit/ NZ White	C14 – C16 Olefin	LD_{50}>10 000 mg/kg
		Rabbit/ NZ White	C14 - C18 Olefin	LD_{50}>10 000 mg/kg
		Rabbit/ NZ White	C14 – C18 Olefin/Paraffin	LD_{50}>10 000 mg/kg
		Rabbit/ NZ White	C14 – C26 Olefin/Paraffin	LD_{50}>10 000 mg/kg
		Rabbit/ NZ White	C16 - C18 Olefin	LD_{50}>10 000 mg/kg
		Rabbit/ NZ White	C18 – C24 Olefins	LD_{50}>10 000 mg/kg
		Rabbit/ NZ White	C18 – C26 Olefin/Paraffin	LD_{50}>10 000 mg/kg
		Rabbit/ NZ White	C18 – C30 Olefin/Alcohol.	LD_{50}>10 000 mg/kg
9.1.3	**Inhalation Toxicity**			
9.1.3.1		Rat/Wistar	C12 - C16 Alpha Olefins	LC_{50}> 9.9 mg/m^3 mist (1 hour)
9.1.3.2		Rat/Wistar	C16 Alpha Olefin	LC_{50}> 8.5 mg/m^3 mist (1 hour)
9.1.4	**Aspiration toxicity**	Rat/Wistar strain, Albino	n-alkenes C6 – C14; C18 - C19	Aspiration hazard

9.1.5	**Skin Irritation**			
9.1.5.1		Rabbit/NZ White	C12 – C16 Alpha Olefin	Slightly irritating
9.1.5.2		Rabbit/NZ White	C16 Alpha Olefin	Slightly irritating
9.1.5.3		Rabbit/NZ White	Gulftene 14	Slight to moderately irritating
9.1.5.4		Rabbit/NZ White	Gulftene 16	Slight to moderately irritating
9.1.5.5		Rabbit/NZ White	Gulftene 18	Slight to moderately irritating
9.1.5.6		Rabbit/NZ White	C16/C18 Alpha Olefins, Isomerised	Slight to moderately irritating
9.1.5.7		Rabbit/NZ White	C20 - C24 Alkenes, branched and linear	Non irritating
9.1.5.8	Other Alkenes	Rabbit/NZ White	C12 - C26 Olefin/Paraffin	Non irritating
		Rabbit/NZ White	C14 – C16 Olefin	Non irritating
		Rabbit/NZ White	C14 – C18 Olefin/Paraffin	Non irritating
		Rabbit/NZ White	C14 – C18 Olefin	Non irritating
		Rabbit/NZ White	C14 – C26 Olefin	Non irritating
		Rabbit/NZ White	C14 – C26 Olefin/Paraffin	Non irritating
		Rabbit/NZ White	C16	Non irritating
		Rabbit/NZ White	C16 - C18 Olefin	Non irritating
		Rabbit/NZ White	C18 – C24 Olefins	Non irritating
		Rabbit/NZ White	C18 – C26 Olefin/Paraffin	Non irritating
		Rabbit/NZ White	C18 – C30 Olefin/Alcohol	Non irritating
		Rabbit/NZ White	1-octadecene	Non irritating
		Rabbit/NZ White	Neodene 18 Alpha Olefin	Non irritating
		Rabbit/NZ White	SHOP Alpha Olefin C18	Non irritating
		Rabbit/NZ White	C18 – C24 Olefins	Non irritating
		Rabbit/NZ White	C18 – C26 Olefin/Paraffin	Non irritating
			C18 – C30 Olefin/Alcohol	Non irritating
9.1.5.9	Other Alkenes	Human	1-Octadecene	Irritating

9.1.6	**Eye Irritation**			
9.1.6.1		Rabbit/NZ White	C12 - C16 Alpha Olefin	Slightly irritating
9.1.6.2		Rabbit/NZ White	C16 Alpha Olefin	Slightly irritating
9.1.6.3		Rabbit/NZ White	C16/C18 Alpha olefins, isomerised	Slightly irritating
9.1.6.4		Rabbit/NZ White	C20 - 24 Alkenes, branched and linear	Very slightly irritating
9.1.6.5	Other Alkenes			
		Rabbit/NZ White	C12 – C14	Non irritating
		Rabbit/NZ White	C12 - C26 Olefin/Paraffin	Non irritating
		Rabbit/NZ White	C14 – C16	Non irritating
		Rabbit/NZ White	C14 – C18 Olefin/Paraffin	Non irritating
		Rabbit/NZ White	C14 – C18 Olefin	Non irritating
		Rabbit/NZ White	C14 – C18 Olefin/Paraffin	Non irritating
		Rabbit/NZ White	C14 – C26 Olefin	Non irritating
		Rabbit/NZ White	C14 – C26 Olefin/Paraffin	Non irritating
		Rabbit/NZ White	C18 – C24 Olefins	Non irritating
		Rabbit/NZ White	C18 – C26 Olefin/Paraffin	Non irritating
		Rabbit/NZ White	C18 – C30 Olefin/Alcohol	Non irritating

9.1.7	**Skin sensitisation**			
9.1.7.1	Landsteiner technique	Guineapig/albino	C12 – C16 Alpha Olefin	Non sensiting
9.1.7.2	Buehler technique	Guineapig/Hartley White	C16/C18 Alpha Olefins, isomerised	Non sensitising
9.1.7.3	Magnusson and Kligman	Guineapig/Dunkin Hartley White	C20 - 24 Alkenes, branched and linear	Non sensitising
9.1.7.4	Other Alkenes			
9.1.7.4.1	Buehler technique	Guineapig/strain not specified	Neodene 16 Alpha Olefin (1-hexadecene)	Non sensitising
9.1.7.4.2		Guineapig/strain not specified	Neodene 18 Alpha Olefin (1-octadecene)	Non sensitising
9.1.7.5	Other Alkenes Repeated Patch Insult Test	Human	Neodene 18 Alpha Olefin (1-octadecene)	Non sensitising
9.2	**Repeat Dose Toxicity**			
9.2.1	2-week, dermal	Rat/Fischer 344	Gulftene 12-16	NOAEL = 1 000 mg/kg
9.2.2	Other Alkenes 4-week, dermal	Rabbit/NZ White	C16 - C18	Slight hyperemia, exfoliation, oedema
9.2.3	Up to 51 days, oral	Rat/ Sprague Dawley Crl:CD BR VAF/Plus	1-tetradecene (blend from three suppliers)	NOAEL = 1 000 mg/kg/day for reproductive neurotoxic effects; NOAEL = 100 mg/kg/day for systemic effects in females. No NOAEL for males
9.2.4	13-week, oral	Rat/ Crl:CD BR	C20 - C24 Alkenes, Branched and Linear	NOAEL = 500 mg/kg/day

9.3	**Genetic Toxicity**			
9.3.1	***in vitro***			
9.3.1.1	Bacterial reverse mutation assay	*S.typhimurium, E.coli*	C20 - C24 Alkenes, branched and linear	Negative with & w'out activation
9.3.1.2	Unscheduled DNA Synthesis	Rat hepatocyte primary culture	Gulftene 12 – 16	Negative
9.3.1.3	BALB/3T3 Transformation Test	Mouse embryo cells BALB/3T3-A31-1-1	Gulftene 12 – 16	Negative
9.3.1.4	HGPRT Assay	Chinese Hamster Ovary cell	Gulftene 12 – 16	Negative with & w'out activation
9.3.1.5	Chromosome aberration	Human peripheral lymphocytes	C20-C24 Alkenes, branched and linear	Negative with & w'out activation
9.3.1.6	Other Alkenes			
	Bacterial Reverse Mutation Assay	*S.typhimurium, E.coli*	1-Octadecene	Negative with & w'out activation
	Mitotic Recombination	Rat liver RL1 cells.	1-Octadecene	Negative with & w'out activation
	Chromosome Aberration[H18]	Rat liver RL1 cells.	1-Octadecene	Negative with & w'out activation
9.3.2	***in vivo***			
9.3.2.1	Micronucleus Assay, intraperitoneal injection	Mouse/ Crl:CD-1 (ICR) BR	Gulftene 12 – 16	Negative
9.3.2.2	Micronucleus Assay, dermal administration	Mouse/Crl:CD-1 (ICR) BR	C20 - C24 Alkenes, branched and linear	Negative

9.1 Acute Toxicity

9.1.1 Acute Oral Toxicity

9.1.1.1 Acute Oral Toxicity of C12-C16 Alpha Olefin (Rinehart 1967)

Test Substance:	C12-C16 alpha Olefin (98.5% olefins, 1.5% saturates)
Species/strain:	Rat/Wistar
Number/sex of animals:	10 males
Observation period:	14 days
Method of administration:	Gavage 5 000 mg/kg or 10 000 mg/kg (dose volume of 2.65 – 3.50 mL/kg).
Test method:	US Federal Hazardous Substances Labelling Act
Clinical observations:	A few days after dosing, animals had very coarse oily fur over the whole body, particularly severe in the hindquarter area. This observation persisted for the remainder of the observation period.
Mortality:	Two deaths observed in the 10 000 mg/kg dose; considered to be due to pneumonia.
Morphological findings:	Not reported
LD_{50}:	> 5 000 mg/kg
Result:	C12-C16 Alpha Olefin was of very low acute oral toxicity in rats.

9.1.1.2 Acute Oral Toxicity of C16 Alpha Olefin (Rinehart 1967)

Test Substance:	C16 alpha Olefin (98.5% olefins, 1.5% saturates)
Species/strain:	Rat/Wistar
Number/sex of animals:	10 males
Observation period:	14 days
Method of administration:	Oral, gavage 5 000 mg/kg or 10 000 mg/kg (dose volume of 2.65 – 3.50 mL/kg).
Test method:	US Federal Hazardous Substances Labelling Act.

Clinical observations:	A few days after dosing, animals had very coarse oily fur over the whole body, particularly severe in the hindquarter area; Animals developed a weakness in the hindquarters which caused them to drag around the cage. This observation persisted for the remainder of the observation period.
Mortality:	Nil
Morphological findings:	Not reported.
LD_{50}:	> 5 000 mg/kg
Result:	C16 Alpha Olefin was of very low acute oral toxicity in rats.

9.1.1.3 Acute Oral Toxicity of C16 Isomerised Olefin (Hill Top Biolabs Inc 1993)

Test Substance:	C16 Isomerised Olefin
Species/strain:	Rat/Sprague Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	Oral, gavage 5 050 mg/kg (dose volume of 5.92 mL/kg)
Test method:	OECD TG 420 – fixed dose method
Clinical observations:	One female lost weight between Days 0 and 7 and one female failed to gain weight between days 7 and 14. Prominent in life observations included activity decrease piloerection and polyuria, which were no longer evident by Day 7. Alopecia was observed in all animals on Days 7 through 14.
Mortality:	Nil
Morphological findings:	No abnormalities detected.
LD_{50}:	> 5 050 mg/kg
Result:	C16 Isomerised Olefin was of very low acute oral toxicity in rats.

9.1.1.4 Acute Oral Toxicity of C18 Isomerised Olefin (Stillmeadow Inc 1993)

Test Substance:	C18 Isomerised Olefin
Species/strain:	Rat/Sprague Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	Oral, (gavage) 5 050 mg/kg (dose volume of 5.92 mL/kg)
Test method:	OECD TG 420 – fixed dose method
Clinical observations:	In life observations of note included diarrhoea, piloerection and polyuria, which were no longer evident by Day 11.
Mortality:	Nil
Morphological findings:	No abnormalities detected.
LD_{50}:	> 5 050 mg/kg
Result:	C18 Isomerised Olefin was of very low acute oral toxicity in rats.

9.1.1.5 Acute Oral Toxicity of C20-24 Alkenes, branched and linear (Safepharm Laboratories Limited 1998)

Test Substance:	C20-24 Alkenes, branched and linear
Species/strain:	Rat/Sprague Dawley Crl:CD BR
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	Oral, gavage 5 000 mg/kg (dose volume of 6.29 mL/kg)
Test method:	OECD TG 420 – fixed dose method
Clinical observations:	Hunched posture and piloerection in all animals on day of dosing;
Mortality:	One female found dead one day after dosing
Morphological findings:	The female found dead had haemorrhagic lungs, dark liver and dark kidneys; No abnormalities detected at terminal kill.

LD_{50}:	> 5 000 mg/kg
Result:	C20-24 Alkenes, branched and linear was of very low acute oral toxicity in rats.

9.1.1.6 Acute Neurotoxicity of Gulftene 16 (Bushy Run Research Center 1992)

Test substance:	Gulftene 16 (1-hexadecene)
Test substance purity, %:	1-hexadecene >93; 2-ethyl-1-tetradecene 2.0; 2-butyl-1-dodecene 2.0; 2-hexyl-1-decene 2.0; n-hexadecene <1.0.
Species/strain:	Rat/Sprague Dawley albino
Number/sex of animals:	5/sex/group
Doses:	0, 5 000, 10.000 mg/kg;
Method of administration:	Single oral dose by gavage of control or 5.0 g/kg dose. The 10.0 g/kg dose was divided into two, administered one hour apart by gavage.
Observation period:	14 days
Test method:	OECD TG 424
Mortality:	5 000 mg/kg – nil; 10 000 mg/kg – 2 of each sex 6 to 7 days after dosing. One female was euthanised.
Clinical observations:	Behavioural end points were evaluated: signs of toxicity included aggressive behaviour, pronounced postural and gait abnormalities and severe irritation of the periurogenital and perianal skin. These clinical signs were attributed to irritation to the abdominal and hindleg area rather than neurotoxic signs per se.
Necropsy:	Animals that died revealed red to bright red lungs, red/yellow intestines, distended intestine mottled dark liver and darkened kidneys. Survivors had no gross lesions.
Histopathology:	No histopathological lesions of the central or peripheral nervous system or pituitary glands.
LD_{50}:	> 10 000 mg/kg
Result:	Gulftene 16 did not appear to produce primary neurotoxicant effects.

9.1.1.7 Acute Oral Toxicity of Other Alkenes

The following data, unless otherwise indicated, are taken from HEDSET data sheets for 1-dodecene 1-tetradecene 1-hexadecene and 1-octadecene. The full study reports were not provided in the submission.

The HEDSET documents indicate these tests were not conducted in accordance with GLP or OECD or EC testing guidelines.

In each case rats were administered single oral doses of 10 g/kg of test substance.

Test Substance	*Comment*	*LD_{50}*
C12 - C14 olefin [H14]	-	>10 000 mg/kg
C12 - C26*	10 CFE rats, 5 males, 5 females.	>10 000 mg/kg
Olefin/Paraffin[H18]	Animals appeared hyporeactive.	
	All but one animal had good weight gain.	
C14-C16 olefin [H14]	-	>10 000 mg/kg
C14 – C18*	10 CFE rats, 5 males, 5 females.	>10 000 mg/kg
Olefin/Paraffin[H18]	All gained weight satisfactorily.	
C14 – C26*	10 CFE rats, 5 males, 5 females.	>10 000 mg/kg
Olefin/Paraffin[H18]	All gained weight satisfactorily.	
C16-C18 olefin[H16]	-	> 10 000 mg/kg
C18 – C24* Olefins[H18]	All gained weight satisfactorily.	>10 000 mg/kg
C18 – C26*	10 CFE rats, 5 males, 5 females.	>10 000 mg/kg
Olefin/Paraffin[H18]	All gained weight satisfactorily.	
C18 – C30*	10 CFE rats, 5 males, 5 females.	>10 000 mg/kg
Olefin/Alcohol[H18]	All gained weight satisfactorily.	
	Slight hyporeactivity was seen.	

* Purity not specified.
[H14] – (EU 1995).
[H16] – (EU 1995)
[H18] – (EU 1995)

Acute Dermal Toxicity

9.1.2.1 Acute Dermal Toxicity of C12-C16 Alpha Olefin (Rinehart 1967), 1967 #29])

Test Substance:	C12-C16 Alpha Olefin (98.5% olefin,1.5% saturates)
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	4 males
Method of administration:	10 000 mg/kg (dose volume 16 mL/kg) of test substance applied to an intact and abraded area of skin and held under semi occlusive dressing for 24 hours;.
Observation period:	14 days
Test method:	US Federal Hazardous Substances Labelling Act.
Mortality:	Nil.
Clinical observations:	Skin became very taut, dry and scaly, with no regrowth of hair at the treatment site
Morphological findings:	No abnormalities detected at necropsy.
LD_{50}:	> 10 000 mg/kg
Result:	C12-C16 Alpha Olefin was of low dermal toxicity in rats.

9.1.2.2 Acute Dermal Toxicity of C16 Alpha Olefin (Rinehart 1967)

Test Substance:	C16 Alpha Olefin (98.5% olefin,1.5% saturates)
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	4 males
Method of administration:	10 000 mg/kg (dose volume 16 mL/kg) of test substance applied to an intact and abraded area of skin and held under semi occlusive dressing for 24 hours.
Observation period:	14 days
Test method:	US Federal Hazardous Substances Labelling Act
Mortality:	One death due to broken neck
Clinical observations:	Skin became very taut, dry and scaly, with no regrowth of hair at the treatment site.

Morphological findings:	No abnormalities detected at necropsy.
LD_{50}:	> 10 000 mg/kg
Result:	C16 Alpha Olefin was of low dermal toxicity in rats.

9.1.2.3 Acute Dermal Toxicity of C16 Isomerised Olefin (Stillmeadow Inc 1993)

Test Substance:	C16 Isomerised Olefin
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	5/sex
Method of administration:	A single semi occluded application of 2 020 mg/kg bodyweight (dose volume 2.37 mL/kg); After 24 hours residual test substance was removed with tap water.
Observation period:	14 days
Test method:	OECD TG 402
Mortality:	One male died on Day 14 after final observations were made
Clinical observations:	The male that died had lost weight during the study. All other animals appeared normal for the duration of the study.
Morphological findings:	The male that died had mottled lungs with white nodules throughout. No abnormalities detected in other animals at necropsy
LD_{50}:	> 2 020 mg/kg
Result:	C16 Isomerised Olefin was of low dermal toxicity in rats.

9.1.2.4 Acute Dermal Toxicity of C18 Isomerised Olefin (Stillmeadow Inc 1993)

Test Substance:	C18 Isomerised Olefin
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	5/sex
Method of administration:	A single semi occluded application of 2 020 mg/kg bodyweight (dose volume 2.35 mL/kg); After 24 hours residual test substance was removed with tap water.

Observation period:	14 days
Clinical observations:	4 males and 4 females lost weight or failed to gain weight between Days 7 and 14; Slight diarrhoea in one female on Days 9 and 10.
Test method:	OECD TG 402
Mortality:	Nil
Morphological findings:	No abnormalities detected at necropsy.
LD_{50}:	> 2 020 mg/kg
Result:	C18 Isomerised Olefin was of low dermal toxicity in rats.

9.1.2.5 Acute Dermal Toxicity of C20-24 Alkenes, branched and linear (Safepharm Laboratories Limited 1998)

Test Substance:	C20-24 Alkenes, branched and linear
Species/strain:	Rat/ Sprague Dawley Crl:CD BR
Number/sex of animals:	5/sex
Method of administration:	A single semi occluded application of 2 000 mg/kg bw (dose volume 2.52 mL/kg); After 24 hours the treated site wiped clean with cotton wool moistened with liquid paraffin.
Observation period:	14 days. The treated sites were observed for evidence of dermal irritation approximately 30 minutes after bandage removal and on Days 3, 7, 10 and 14.
Clinical observations:	No signs of systemic toxicity noted.
Test method:	OECD TG 402
Mortality:	Nil
Dermal effects:	No erythema or oedema was observed (all individual scores were zero).
Morphological findings:	No abnormalities detected at necropsy.
LD_{50}:	> 2 000 mg/kg
Result:	C20-24 Alkenes, branched and linear was of low dermal toxicity in rats.

9.1.2.6 Acute Dermal Toxicity of Other Alkenes

The following data, unless otherwise indicated, are taken from HEDSET data sheets for 1-dodecene 1-tetradecene 1-hexadecene and 1-octadecene. The full study reports were not provided in the submission.

The HEDSET documents indicate these tests were not conducted in accordance with GLP or OECD or EC testing guidelines. In each case New Zealand white rabbits were administered single dermal doses of 10 000 mg/kg of test substance.

Test Substance	*Comment*	*LD_{50}*
C12-C14 olefin[H14]	-	>10 000 mg/kg
C12 - C26* Olefin/Paraffin[H18]	3/sex One animal died on Day 9 showing hyporeactivity and diarrhoea. Weight loss observed in 75% of animals. No pathology seen.	>10 000 mg/kg
C14 – C16* Olefin[H16]	6 animals, male and female. 24 hour exposure.	>10 000 mg/kg
C14 – C18 Olefin[H16]	6 animals, male and female. 24 hour exposure.	>10 000 mg/kg
C14 – C18* Olefin/Paraffin [H18]	3/sex. 24 hour exposure. All gained weight satisfactorily. No mortality. No pathology seen.	>10 000 mg/kg
C14 – C26* Olefin/Paraffin[H18]	3/sex. 24 hour exposure. All gained weight satisfactorily. No mortality.	>10 000 mg/kg
C16-C18[H16]	6 animals, male and female. 24 hour exposure.	>10 000 mg/kg
C18 – C24* Olefins [H18]	3/sex. All gained weight satisfactorily. No pathology seen. No mortality.	>10 000 mg/kg
C18 – C26* Olefin/Paraffin[H18]	3/sex. All gained weight satisfactorily. No pathology seen. No mortality.	>10 000 mg/kg
C18 – C30* Olefin/Alcohol [H18]	3/sex. All gained weight satisfactorily. No pathology seen. No mortality.	>10 000 mg/kg

* Purity not specified. [H14] (EU 1995) [H16] (EU 1995) [H18] (EU 1995)

9.1.3 Inhalation Toxicity

9.1.3.1 Acute Inhalation Toxicity of C12-C16 Alpha Olefin (Rinehart 1967)

Test Substance:	C12-C16 alpha Olefin (98.5% olefins, 1.5% saturates)
Species/strain:	Rat/Wistar
Number/sex of animals:	10 males
Observation period:	14 days
Method of administration:	Whole body exposure to saturated mists for one hour; exposure concentration to aerosol size of <8μm was 9 900 mg/m^3; and 0.45μm – 2.0 μm was 100 mg/m^3.
Test method:	US Federal Hazardous Substances Labelling Act.
Clinical observations:	Animals were drowsy upon removal from the chamber. Animals had very oily fur over.
Mortality:	Nil.
Morphological findings:	No gross pathology at necropsy.
LD_{50}:	> 9 900 mg/m^3 mist (1 hour)
Result:	C12-C16 Alpha Olefin was of low acute inhalation toxicity in rats.

9.1.3.2 Acute Inhalation Toxicity of C16 Alpha Olefin (Rinehart 1967)

Test Substance:	C16 alpha Olefin (98.5% olefins, 1.5% saturates)
Species/strain:	Rat/Wistar
Number/sex of animals:	10 males
Observation period:	14 days
Method of administration:	Whole body exposure to saturated mists for one hour; exposure concentration to aerosol size of <8μm was 8 500 mg/m^3; and 0.45μm – 2.0 μm was 150 mg/m^3.
Test method:	US Federal Hazardous Substances Labelling Act
Clinical observations:	Animals were drowsy upon removal from the chamber. Animals had very oily fur over.
Mortality:	Nil.

Morphological findings: No gross pathology at necropsy.

LD_{50}: > 8 500 mg/m^3 mist (1 hour)

Result: C16 Alpha Olefin was of low acute inhalation toxicity in rats.

9.1.3.3 Acute Inhalation Toxicity of C16-C18 Alkene (EU 1995)

The following data is taken from the HEDSET data sheet for 1-hexadecene. The full study report was not provided in the submission.

The HEDSET documents indicate this test was not conducted in accordance with GLP or established testing guidelines.

Test Substance	***Comment***	***LC_{50}***
C16-C18	No deaths in Sprague Dawley rats from one or four hour exposure to saturated vapours	No details given

9.1.4 Aspiration Toxicity (Gerarde 1963)

Test Substance: C6 - C18 alpha olefins; C19 beta olefin

Species/strain: Rat/Wistar strain, albino

Number/sex of animals: 4 or 5 males/group

Method of administration: 0.2 mL of test substance was placed in the mouth of rats anaesthesised to the point of apnoea. As the animals began to breathe the nostrils were held until the test substance had been aspirated or the animal regained consciousness.

Test method: In house investigation

Necropsy: All alkenes tested except hexene (difficult to dose because of volatility) were aspirated into the lungs but there was a distinct break in mortality between C14 and C16.
From C8 to C14 all treated animals died within 24 hours. At C16 there was no mortality. There was one mortality each with C18 and C19. Lung weights were increased in alkene treated animals compared to controls. The affected animals showed acute chemical pneumonitis.

Result: There is a significant aspiration hazard with C6-C14 alkenes

9.1.5 Acute Dermal Irritation

9.1.5.1 Acute Dermal Irritation of C12-C16 Alpha Olefin (Rinehart 1967)

Test substance:	C12-C16 Alpha Olefin (98.5% olefins, 1.5% saturates)
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	6 males
Observation period:	24 and 72 hours post exposure
Method of administration:	0.5 mL of the neat test substance was introduced under a 2.5 x 2.5 cm gauze patch to two intact and two abraded areas of skin of the rabbit; patches were secured in place with adhesive tape. Occlusive dressings were not used as test substance either evaporated rapidly or were completely absorbed.
Test method:	US Federal Hazardous Substances Labelling Act

Draize score intact skins:

Time after treatment	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6***
Erythema						
24 hours	0	0	0	1	1	1
72 hours	0	0	0	0	1	0
Oedema						
24 - 72 hours	*All individual scores were zero*					

[a] see Attachment 1 for Draize scales.

Draize score abraded skins:

Time after treatment	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6***
Erythema						
24 hours	1	1	0	1	1	1
72 hours	0	0	0	0	1	0
Oedema						
24 –72 hours	*All individual scores were zero*					

[a] see Attachment 1 for Draize scales.

Average Primary Irritation Score (total of all sites): 0.4

Comment: Very slight erythema was observed at intact and abraded sites. An increased incidence of erythema occurred at abraded sites.
No oedema observed at intact or abraded sites.

Result: C12-C16 was slightly irritating to the skin of rabbits.

9.1.5.2 Acute Dermal Irritation of C16 Alpha Olefin (Rinehart 1967)

Test substance: C16 Alpha Olefin (98.5% olefins, 1.5% saturates)

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 6 males

Observation period: 24 and 72 hours post exposure

Method of administration: 0.5 mL of the neat test substance was introduced under a 2.5 x 2.5 cm gauze patch to two intact and two abraded areas of skin of the rabbit; patches were secured in place with adhesive tape. Occlusive dressings were not used as test substance either evaporated rapidly or were completely absorbed.

Test method: US Federal Hazardous Substances Labelling Act

Draize score intact skins:

Time after treatment	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6***
Erythema						
24 hours	1	2	0	0	1	1
72 hours	0	1	0	0	0	0
Oedema						
24 - 72 hours	*All individual scores were zero*					

[a] see Attachment 1 for Draize scales.

Draize score abraded skins:

Time after treatment	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6***
Erythema						
24 hours	1	2	1	1	1	1
72 hours	0	1	0	0	0	0
Oedema						
24 - 72 hours	*All individual scores were zero*					

[a] see Attachment 1 for Draize scales.

Average Primary Irritation Score (total of all sites): 0.6

Comment: Very slight to well defined erythema was observed at intact and abraded sites. An increased incidence of erythema occurred at abraded sites.
No oedema observed at intact or abraded sites.

Result: C16 was slightly irritating to the skin of rabbits.

9.1.5.3 Acute Dermal Irritation of Gulftene 14 (Safepharm Laboratories Limited 1996)

Test substance:	Gulftene 14 (1-tetradecene)
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	5 males, 1 female
Observation period:	1, 24, 48, 72, 96 hours, 7 and 14 days post exposure
Method of administration:	A single semi occluded application of 0.5 mL of the neat test substance to intact skin; after 4 hours residual test substance was removed by gentle swabbing with 74% industrial grade methylated spirits; A contralateral area of untreated skin served as the control site. Control sites were similarly swabbed.
Test method:	OECD TG 404

Draize scores:

Time after treatment	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6F***
Erythema/Eschar Formation						
30 minutes	2R	2R	2R	2R	2R	1R
24 hours	2R	2R	2R	2R	2R	2R
48 hours	1R	1R	1R	1R	1R	1R
72 hours	1R	1R	1RD	1R	1R	1R
96 hours	0D	1DR	1DR	1DR	1DR	1DR
7 days	0D	0DR	0DR	0DR	0DR	0DR
14 days	0D	0D	0D	0D	0D	0D
Oedema						
30 minutes	2	2	2	3	2	2
24 hours	2	2	2	2	2	2
48 hours	1	1	1	1	1	1
72 hours	0	1	0	1	0	0
96 hours – 14 days	*All individual scores were zero*					

[a] see Attachment 1 for Draize scales.
D = desquamation (considered reversible)
R = reaction extends up to 5 cm beyond treatment site.

Mean group score (24, 48 & 72 hour observation):	Erythema/Eschar Formation: 1.3 Oedema: 1.1
Primary irritation index:	2.79
Comment:	Well defined erythema which cleared by Day 7 and slight to moderate oedema which cleared by 96 hours. Desquamation was noted at all treated skin sites during the study and persisted at the Day 14 observation. This was considered reversible.
Result:	Gulftene 14 was slight to moderately irritating to the skin of rabbits.

9.1.5.4 Acute Dermal Irritation of Gulftene 16 (Safepharm Laboratories Limited 1996)

Test substance:	Gulftene 16 (1-hexadecene)
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	5 males, 1 female
Observation period:	1, 24, 48, 72, 96 hours, 7 and 14 days post exposure
Method of administration:	A single semi occluded application of 0.5 mL of the neat test substance to intact skin; after 4 hours residual test substance was removed by gentle swabbing with 74% industrial grade methylated spirits; A contralateral area of untreated skin served as the control site. Control sites were similarly swabbed.
Test method:	OECD TG 404

Draize scores:

Time after treatment	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6F***
Erythema/Eschar Formation						
30 minutes	2R	2R	2R	2R	1	1R
24 hours	2R	2R	2R	2R	1R	2R
48 hours	1R	1R	1R	1R	1R	1R
72 hours	1DR	1DR	1DR	1R	1DR	1DR
96 hours	1DR	1DR	1DR	1DR	1DR	0D
7 days	0DR	0DR	0DR	0DR	0DR	0D
14 days	0D	0D	0D	0D	0D	0D
Oedema						
30 minutes	2	2	2	2	1	1
24 hours	2	2	2	2	1	1
48 hours	1	1	1	1	0	0
72 hours	0	1	1	0	0	0
96 hours – 14 days	*All individual scores were zero*					

[a] see Attachment 1 for Draize scales.
D = desquamation (considered reversible)
R = reaction extends up to 4 cm beyond treatment site.

Mean group score (24, 48 & 72 hour observation): Erythema/Eschar Formation: 1.3
Oedema: 0.9

Primary irritation index: 2.46

Comment: Very slight to well defined erythema that cleared by Day 7 and very slight to slight oedema that cleared by 96 hours. Desquamation was also noted and persisted at all treated sites at the Day 14 observation. This was considered to be a reversible effect.

Result: Gulftene 16 was slight to moderately irritating to the skin of rabbits.

9.1.5.5 Acute Dermal Irritation of Gulftene 18 (Safepharm Laboratories Limited 1996)

Test substance:	Gulftene 18 (1-octadecene)
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	5 males, 1 female
Observation period:	1, 24, 48, 72, 96 hours, 7 and 14 days post exposure
Method of administration:	A single semi occluded application of 0.5 mL of the neat test substance to intact skin; after 4 hours residual test substance was removed by gentle swabbing with 74% industrial grade methylated spirits; A contralateral area of untreated skin served as the control site. Control sites were similarly swabbed.
Test method:	OECD TG 404

Draize scores:

Time after treatment	***Animal #***					
	1	***2***	***3***	***4***	***5***	***6F***
Erythema/Eschar Formation						
30 minutes	1R	1R	2R*	1R*	1R	1R
24 hours	1R	1R	2R	2R	2R	1R
48 hours	1R	1	2R	2	2	1R
72 hours	1R	1	2R	2	2	1
96 hours	1DR	1	2DR	2D	1D	1D
7 days	0D	0D	0Cf	0Cf	0D	0D
14 days	0	0	0	0	0	0
Oedema						
30 minutes	1	1	1	1	0	0
24 hours	1	0	2	1	2	1
48 hours	0	0	2	1	2	0
72 hours	0	0	2	1	2	0
96 hours	0	0	2	1	1	0
7 – 14 days	*All individual scores were zero*					

[a] see Attachment 1 for Draize scales. F = female. D = desquamation.
R = reaction extends up to 5 cm beyond treatment site. Cf = crust formation.
* = very slight erythema noted at corresponding control site.

Mean group score (24, 48 & 72 hour observation):	Erythema/Eschar Formation: 1.5 Oedema: 0.9
Primary irritation index:	2.29
Comment:	Very slight or well defined erythema and very slight or slight oedema that cleared by Day 7. Other dermal reactions noted were desquamation and crust formation.
Result:	Gulftene 18 was slight to moderately irritating to the skin of rabbits

9.1.5.6 Acute Dermal Irritation of C16/C18 Alpha Olefins, Isomerised (Hill Top Biolabs Inc 1995)

Test substance:	C16/C18 Alpha Olefins, Isomerised
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	2 males, 1 female
Observation period:	1, 24, 48, 72, 96 hours, 7 and 14 days post exposure
Method of administration:	A single semi occluded application of 0.5 mL of the neat test substance to intact skin; after 4 hours residual test substance was removed by gentle swabbing with tap water; A contralateral area of untreated skin served as the control site. Control sites were similarly swabbed.
Test method:	OECD TG 404

Draize scores:

Time after treatment	***Animal #***		
	1	***2***	***3F***
Erythema/Eschar Formation			
30 minutes	2	2	2
24 hours	2	2	2
48 hours	1	2	1
72 hours	1	2	1
96 hours	1	1	1
7 days	0	1	1
14 days	0	0	0
Oedema			
30 minutes	1	2	1
24 hours	0	1	1
48 hours - 14 days	*All scores were zero*		

[a] see Attachment 1 for Draize scales. F = female.

Mean individual score (24, 48 & 72 hour observation): Erythema/Eschar Formation: 1.3, 2.0, 1.3.
Oedema: 0.0, 0.3, 0.3.

Primary irritation index: 2.2/8

Comment: Very slight to well defined erythema which persisted to the Day 7 observation. Very slight to defined oedema which cleared by the 48 hour observation.

Result: C16/C18 Alpha Olefins, Isomerised was slight to moderately irritating to the skin of rabbits.

9.1.5.7 Acute Dermal Irritation of C20-24 Alkenes, branched and linear (Safepharm Laboratories Limited 1998)

Test substance:	C20-24 Alkenes, branched and linear
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	6 males
Observation period:	1, 24, 48, 72 and 96 hours post exposure
Method of administration:	A single semi occluded application of 0.5 mL of the neat test substance to intact skin; after 4 hours residual test substance was removed by gentle swabbing with liquid paraffin; A contralateral area of untreated skin served as the control site. Control sites were similarly swabbed.
Test method:	OECD TG 404
Dermal effects:	No evidence of skin irritation was observed, all individual scores were zero.
Mean group score (24, 48 & 72 hour observation):	Erythema/eschar formation: 0.0 Oedema: 0.0
Result:	C20-24 Alkenes, branched and linear was non irritating to the skin of rabbits.

9.1.5.8 Acute Dermal Irritation of Other Alkenes (HEDSET 1-Octadecene)

The following data, unless otherwise indicated, are taken from HEDSET data sheets for 1-dodecene 1-tetradecene 1-hexadecene and 1-octadecene. The full study reports were not provided in the submission.

The HEDSET documents indicate these tests were not conducted in accordance with GLP or OECD or EC testing guidelines.

In each case New Zealand white rabbits were administered single dermal doses of 10 g/kg of test substance. The results below represent application of the test substance to non-abraded skin. The HEDSET documents reported each of the test substances as non-irritating.

Test Substance	***Mean group score (24, 48 & 72 hour observation)***	
	Erythema	***Oedema***
C12 - C26* Olefin/Paraffin[H18]	0.0[B]	0.0
C14 – C16* Olefin[H14]	PDS = 1.2[B]	-
C14 – C18* Olefin[H18]	PDS = 0.14[B]	-
C14-C18* Olefin/Paraffin [H18]	0.0[B]	0.0
C14 – C18* Olefin[H14]	PDS = 0.14[B]	-
C14 – C18* Olefin/Paraffin[H18]	0.0[B]	0.0
C14 - C26 olefin[H14]	PDS = 0.0[B]	-
C14 – C26* Olefin/Paraffin[H18]	0.0[B]	0.0
C16-C18 olefin[H16]	PDS = 0.2[B]	-
1-octadecene[H18]	1.2[AE]	0.1
Neodene 18 alpha olefin[H18]	2.17[A] (PII = 3.2)	0.94
SHOP alpha olefin C18 [H18]	1.2[A] (PII = 1.3)	0.1
C18 – C24* Olefins[H18]	0.0[B]	0.0
C18 – C26* Olefin/Paraffin[H18]	0.0[B]	0.0
C18 – C30* Olefin/Alcohol	0.0[B]	0.0
H18		

*Purity not specified.
[A] – 4 hour exposure period.
[B] – 24 hour exposure period.
[E] – Erythematous reaction persisted to Day 14. At Day 16 the skin was dry and flakey.
PDS – Primary Dermal Index Score.
PII – Primary Irritation Index.
[H14] (EU 1995)
[H16] (EU 1995)
[H18] (EU 1995)

9.1.5.9 Evaluation of Primary Skin Irritation in Humans of Neodene 18 alpha olefin (HEDSET 1-octadecene)

Test substance:	Neodene 18 alpha olefin (1-octadecene)
Number/sex of volunteers:	12 females, 6 males
Procedure:	Each volunteer received to the upper arm 0.2 mL (100%, 25%, 10% and 1% dilution in mineral oil) of test substance in a semi occluded patch for an exposure period of 24 hours Sodium lauryl sulphate (0.25% in water) served as the control.
Outcome:	Test sites were scored at 30 minutes and 24 hours after patch removal. Test substance at 100%: at the 30 minute observation, 16/18 volunteers exhibited moderate to strong erythema, oedema and papules. At 24 hours, 17 volunteers showed similar signs and 9 of these had effects spreading beyond the application site. Mean score: 4.28. Test substance at 25%, 10% and 1%: no evidence of irritation. Mean score:0. Control: two volunteers showed mild to moderate erythema. Mean score:0.22.
Result:	Neodene 18 alpha olefin was reported irritating to human skin

9.1.6 Eye Irritation

9.1.6.1 Acute Eye Irritation of C12-C16 Alpha Olefins (Rinehart 1967)

Test Substance:	C12-C16 Alpha Olefins (98.5% olefins, 1.5% saturates)
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	6 males
Observation period:	24, 48 and 72 hours post instillation
Test method:	US Federal Hazardous Substances Labelling Act

Draize scores of non irrigated eyes:

	Time after instillation								
Animal	***24 hours***			***48 hours***			***72 hours***		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	1	0	0	0	0	0	0	0	0
2	1	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	1	0	0
4	1	0	0	1	0	0	1	0	0
5	0	0	0	1	0	0	1	0	0
6	0	0	0	0	0	0	1	0	0
Cornea	*All individual scores were zero*								
Iris	*All individual scores were zero*								

[1] see Attachment 1 for Draize scales
r = redness c = chemosis d = discharge.

Ocular effects: Transient conjunctival redness;
No iridial or conjunctival effects noted (all individual scores were zero).

Mean group score (24, 48 & 72 hour observation):
Corneal opacity: 0.0
Iridial inflammation: 0.0
Conjunctival redness: 0.4
Conjunctival chemosis: 0.0

Result: C12-C16 Alpha Olefins were slightly irritating to the eyes of rabbits

9.1.6.2 Acute Eye Irritation of C16 Alpha Olefins (Rinehart 1967)

Test Substance: C16 Alpha Olefins (98.5% olefins, 1.5% saturates)

Species/strain: Rabbit/New Zealand White

Number/sex of animals: 6 males

Observation period: 24, 48 and 72 hours post instillation

Test method: US Federal Hazardous Substances Labelling Act

Draize scores of non irrigated eyes:

	Time after instillation								
Animal	***24 hours***			***48 hours***			***72 hours***		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	0	0	0	0	0	0	0	0	0
2	1	0	0	0	0	0	0	0	0
3	1	0	0	1	0	0	0	0	0
4	1	0	0	0	0	0	0	0	0
5	1	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0
Cornea	*All individual scores were zero*								
Iris	*All individual scores were zero*								

[1] see Attachment 1 for Draize scales
r = redness c = chemosis d = discharge.

Ocular effects: Transient conjunctival redness;
No iridial or conjunctival effects noted (all individual scores were zero).

Mean group score (24, 48 & 72 hour observation):
Corneal opacity: 0.0
Iridial inflammation: 0.0
Conjunctival redness: 0.3
Conjunctival chemosis: 0.0

Result: C16 Alpha Olefins were slightly irritating to the eyes of rabbits

9.1.6.3 Acute Eye Irritation of C16/C18 Alpha Olefins, Isomerised (Hill Top Biolabs Inc 1995)

Test Substance:	C16/C18 Alpha Olefins, Isomerised
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	1 male 2 females
Observation period:	1, 24, 48 and 72 hours post instillation
Method of administration, Irrigated eyes:	A single instillation of 0.1 mL of test substance into the conjunctival sac of one eye; The contralateral eye served as the control; The eyes were rinsed after 24 hours.
Test method:	OECD TG 405

Draize scores of irrigated eyes:

	Time after instillation											
Animal	***1 hour***			***24 hours***			***48 hours***			***72 hours***		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1M	1	1	0	0	0	0	0	0	0	0	0	0
2	1	1	0	1	1	0	0	0	0	0	0	0
3	1	1	0	1	0	0	0	0	0	0	0	0
Cornea	*All individual scores were zero*											
Iris	*All individual scores were zero*											

[1] see Attachment 1 for Draize scales
r = redness c = chemosis d = discharge. M = male.

Ocular effects:	Conjunctival redness was observed at the 1 hour and 24 hour observation; no iridial or conjunctival effects noted (all individual scores were zero).
Mean score for each animal (24, 48 & 72 hour observation):	Corneal opacity: 0.0; Iridial inflammation: 0.0; Conjunctival redness: 0.0, 0.33, 0.33; Conjunctival chemosis: 0.33, 0.0, 0.0.
Result:	C16/C18 Alpha Olefins, Isomerised was slightly irritating to the eyes of rabbits.

9.1.6.4 Acute Eye Irritation of C20-24 Alkenes, branched and linear (Safepharm Laboratories Limited 1998)

Test Substance:	C20-24 Alkenes, branched and linear
Species/strain:	Rabbit/New Zealand White
Number/sex of animals:	5 female 4 males
Observation period:	1, 24, 48 and 72 hours post instillation
Method of administration, Unirrigated eyes:	A single instillation of 0.1 mL of test substance into the conjunctival sac of the right eye of 6 rabbits; The left eye served as the control.
Method of administration, Irrigated eyes:	A single instillation of 0.1 mL of test substance into the conjunctival sac of the right eye of 3 rabbits, after 30 seconds the eye was gently irrigated with 100mL of lukewarm water for one minute; The left eye served as the control.
Test method:	OECD TG 405

Draize scores of non-irrigated eyes:

	Time after instillation											
Animal	***1 hour***			***24 hours***			***48 hours***			***72 hours***		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	0	0	0	0	0	0	0	0	0	0	0	0
2F	1	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0
4F	1	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0
6F	1	0	0	0	0	0	0	0	0	0	0	0
Cornea	*All individual scores were zero*											
Iris	*All individual scores were zero*											

[1] see Attachment 1 for Draize scales
r = redness c = chemosis d = discharge. F = female.

Draize scores of irrigated eyes:

	Time after instillation											
Animal	***1 hour***			***24 hours***			***48 hours***			***72 hours***		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1F	1	0	0	0	0	0	0	0	0	0	0	0
2F	0	0	0	0	0	0	0	0	0	0	0	0
3	1	0	0	0	0	0	0	0	0	0	0	0
Cornea	*All individual scores were zero*											
Iris	*All individual scores were zero*											

[1] see Attachment 1 for Draize scales
r = redness c = chemosis d = discharge. F = female.

Ocular effects, Non-irrigated eyes: Conjunctival redness was noted in 3 treated eyes at the 1 hour observation; all treated eyes appeared normal at the 24 hour observation;
No iridial or conjunctival effects noted

Mean group score (24, 48 & 72 hour observation):
Corneal opacity: 0.0
Iridial inflammation: 0.0
Conjunctival redness: 0.0
Conjunctival chemosis: 0.0

Ocular effects, Irrigated eyes: Conjunctival redness was noted in 2 treated eyes at the 1 hour observation; all treated eyes appeared normal at the 24 hour observation;
no iridial or conjunctival effects noted

Result: C20-24 Alkenes, branched and linear were very slightly irritating to the eyes of rabbits.

9.1.6.5 Acute Eye Irritation of Other Alkenes

The following data, unless otherwise indicated, are taken from HEDSET data sheets for 1-dodecene 1-tetradecene 1-hexadecene and 1-octadecene. The full study reports were not provided in the submission.

The HEDSET documents indicate these tests were not conducted in accordance with GLP or OECD or EC testing guidelines.

In each case the following test substances were instilled into the eyes of New Zealand white rabbits, without eye irrigation. The HEDSET documents reported each of the test substances as non-irritating.

Test Substance	***Mean group score (24, 48 & 72 hour observation)***			
	Corneal opacity	***Iridial inflammation***	***Conjunctival redness***	***Conjunctival chemosis***
C12 – C14[H14]	0.0	0.0	Draize Score = 3.0**	
C12 - C26* Olefin/Paraffin[H18]	0.0	0.0	0.2	0.06
C14 – C16[H14]	0.0	0.0	Draize Score = 2.1**	
C14 – C18* Olefin[H14]	0.0	0.0	Draize Score = 2.7**	
C14 – C18* Olefin/Paraffin[H18]	0.0	0.0	0.22	0.4
C14 – C26* Olefin[H14]	0.0	0.0	Draize Score = 2.7**	
C14 – C26* Olefin/Paraffin[H18]	0.0	0.0	0.1	0.3
C18 – C24* Olefins[H18]	0.0	0.0	0.5	0.6
C18 – C26* Olefin/Paraffin[H18]	0.0	0.0	0.2	0.3
C18 – C30* Olefin/Alcohol[H18]	0.0	0.0	0.5	0.6

*Purity not specified.
** Individual scores not given.
[H14] (EU 1995)
[H16] (EU 1995)
[H18] (EU 1995)

9.1.7 Skin Sensitisation

9.1.7.1 Skin Sensitisation of C12-C16 Alpha Olefins (Rinehart 1967)

Test substance:	C12 – C16 alpha olefin (98.5% olefins, 1.5% saturates)
Species/strain:	Guineapig/albino
Number of animals:	10 males/group
Test method:	Landsteiner technique cited in (Rinehart 1967), 1967 #29])
Induction procedure:	Test sites on the backs of animals were clipped and scored with a needle. 0.1mL of test substance was applied by glass rod to the test site three times weekly for nine applications. Positive control: 0.5% chlorodinitrobenzene in 50% ethyl alcohol; Vehicle control: 50% ethyl alcohol.
Challenge procedure:	Following a 2 week rest period after the last induction application 0.1 mL of test article was applied to the skin
Challenge Outcome:	No dermal response with test substance. The positive control, chlorodinitrobenzene responded appropriately
Result:	C12 – C16 alpha olefins was non sensitising to guineapig skin.

9.1.7.2 Skin Sensitisation of C16/C18 Alpha olefins, isomerised (Hill Top Biolabs Inc 1995)

Test substance:	C16/C18 Alpha olefins, isomerised
Species/strain:	Guineapig/Hartley White
Number of animals:	20 test animals 10 primary challenge naïve control animals; 10 rechallenge naïve control animals
Test method:	OECD TG 406 - Buehler test
Induction procedure:	Test animals: Days 1, 7 and 14: 0.3 mL of neat test substance in mineral oil applied, via a Hill Top Chamber, to the clipped skin of the left shoulder for a 6 hour period;
Challenge procedure:	1st challenge: test and naïve control animals: Day 28: same procedure as induction phase except 5% w/v test substance in mineral oil was applied to a previously non treated site. 2nd challenge: Day 35: same procedure as for 1st challenge except previously non exposed naïve animals were used. Grading of dermal responses occurred 24 and 48 hours post exposure.
Challenge outcome:	

1st challenge - number of animals exhibiting positive responses:

1st Challenge Concentration	***Test Animals***		***Naïve Control Animals***	
	24 hours[T]	***48 hours[T]***	***24 hours[T]***	***48 hours[T]***
5%	9*/19	10*/19	7*/10	8*/10
	10**/19	9**/19	3**/10	2**/10

T time after patch removal.
* number of animals exhibiting Grade +/- reaction, slight, patchy erythema.
** number of animals exhibiting Grade 1 reaction, slight but confluent, or moderate patchy erythema.

Comment: Test animals had a slightly greater incidence of Grade 1 reactions compared to the naïve control animals, suggesting that sensitisation may have been induced.
To confirm these results a 2nd challenge was conducted 7 days later using the same test animals and challenge concentration. Ten non previously exposed naïve animals were also concurrently treated with the test substance.

2nd challenge - number of animals exhibiting positive responses:

2nd Challenge Concentration	***Test Animals***		***Naïve Control Animals***	
	24 hours[T]	***48 hours[T]***	***24 hours[T]***	***48 hours[T]***
5%	9*/19 10**/19	11*/19 7**/19	5*/10 5**/10	3*/10 7**/10

[T] time after patch removal.
* number of animals exhibiting Grade +/- reactions.
** number of animals exhibiting Grade 1 reactions.

Comment: Following rechallenge the incidence of Grade 1 reactions was similar between test and control animals. The study authors concluded that sensitisation had not been induced.

Result: C16/C18 Alpha olefins, isomerised was not considered to be sensitising to guineapig skin

9.1.7.3 Skin Sensitisation of C20-24 Alkenes, branched and linear (Safepharm Laboratories Limited 1998)

Test substance:	C20-24 Alkenes, branched and linear
Species/strain:	Guineapig/Dunkin Hartley White
Number of animals:	20 test females, 10 control females
Test method:	OECD TG 406 Magnusson and Kligman Maximisation Method
Induction procedure:	Test animals: Day 1: three pairs of intradermal injections (0.1 mL) into the dorsal skin of the scapular region: - Freund's complete adjuvant (FCA) 1:1 in distilled water; - the test substance diluted to 25% w/v in arachis oil; - the test substance at 25% w/v emulsified in a 50:50 mixture of FCA and distilled water; Day 7 - filter paper saturated with the test substance as supplied was applied to the treated area and held under occlusive dressing for 48 hours; Control animals: treated similarly to the test animals omitting the test substance from the intradermal injections and topical application
Challenge procedure:	Test and Control Animals: Day 21: filter paper saturated with 75% v/v and 50% v/v of test substance in arachis oil, was applied to two sites on the left flank, and held under occlusive dressing for 24 hours;
Challenge Outcome:	Challenge concentration of 75%: no dermal reactions were noted in test or control animals; Challenge concentration of 50%: no dermal reactions were noted in test or control animals.
Result:	C20-24 Alkenes, branched and linear was non sensitising to guineapig skin.

9.1.7.4 Skin Sensitisation of Other Alkenes

9.1.7.4.1 Skin Sensitisation of Other Alkenes - Neodene 16 alpha olefin (Morris TD, 1992 cited in HEDSET, 1-hexadecene)

Test substance:	Neodene 16 alpha olefin (1-hexadecene)
Species/strain:	Guineapig/strain not specified
Number of animals:	20 test animals, 10 control animals, sex not specified
Test method:	Buehler technique
Induction/Challenge Procedure:	No details provided.
Challenge Outcome:	No details of dermal reactions provided.
Result:	Neodene 16 alpha olefin was reported non sensitising to guineapig skin.

9.1.7.4.2 Skin Sensitisation of Other Alkenes - Neodene 18 alpha olefin (Morris TD, 1992 cited in HEDSET (1-octadecene)

Test substance:	Neodene 18 alpha olefin (1-octadecene)
Species/strain:	Guineapig/strain not specified
Number of animals:	20 test animals, 10 control animals, sex not specified
Test method:	Buehler technique
Induction procedure:	Induction dose 5% in acetone.
Challenge procedure:	Challenge dose 2.5% in acetone.
Challenge Outcome:	No details of dermal reactions provided.
Result:	Neodene 18 alpha olefin was reported non sensitising to guineapig skin.

9.1.7.5 Human Repeated Patch Insult Test - Neodene 18 Alpha Olefin (EU 1995)

Test substance:	Neodene 18 alpha olefin (1-octadecene)
Number/sex of volunteers:	31 females, 5 males
Induction procedure:	Each volunteer received 0.2 mL (25% dilution in mineral oil) of test substance in a semi occluded patch exposure of 24 hours on 3 alternate days for weeks (9 induction exposures). A rest period of 10 – 17 days followed. Sodium lauryl sulphate (0.1% in water) served as the control.
Challenge procedure:	Each volunteer received 0.2 mL (25% dilution in mineral oil) of test substance in a semi occluded patch exposure to a naïve site on the upper arm for 24 hours.
Challenge Outcome:	No reaction to the to the test substance was reported.
Result:	Neodene 18 alpha olefin was reported non sensitising to human skin

9.2 Repeat Dose Toxicity

9.2.1 Repeated Dose Dermal Toxicity: 2 Week Using Gulftene 12-16 (Gulf Life Sciences Center 1983)

Test Substance:	Gulftene 12-16
Species/strain:	Rat/Fischer 344
Number/sex of animals:	5/sex/group
Dose/Study duration:	Doses of 0, 1.0, 2.0 g/kg applied once a day for a 6 hour exposure period, for a total of 9 doses over a 2-week period
Method of administration:	2.60 mL/kg of test substance applied to a clipped site of the back. An Elizabethan collar prevented animals interfering with the dose site. The vehicle was corn oil.
Test method:	OECD TG 410
Mortality:	Nil

Clinical observations:

Body weight gains were depressed in the 2.0 g/kg group. No test related toxic signs or symptoms were observed.

Dermal Reactions:

Individual Draize scores not provided.
1 000 mg/kg group:
Two animals showed very slight erythema (barely perceptible) after 6 treatments and a third animal after 7 treatments. All reactions persisted throughout the remainder of the study period. No oedema or other reactions were noted.
2 000 mg/kg group:
Dermal reactions were first noted after the second dose and all animals displayed a score of 4 (severe erythema (beet redness) to slight eschar formation) following the seventh treatment. Eschar formation was extensive and ranged from slight to moderate. Oedema ranged from very slight to slight from the fifth treatment onwards. Slight to moderate desquamation was detected in all animals after the second treatment persisting to the end of treatment. Fissuring was noted after the sixth treatment in females. Slight to moderate alopecia was detected in 8 animals after the eighth treatment.

Clinical Pathology:

No significant differences between test and control animals for clinical chemistry values or haematology indices.

Histopathology:

Organ Weights:
In animals of the 2 000 mg/kg group there was an absolute decrease in terminal body weights, associated with a decrease in absolute organ weights, particularly the liver.
Macroscopy:
All animals of the 2 000 mg/kg group displayed grossly visible lesions (erythema and erosions of the epithelium) of the skin at the treatment site. One female of the 1 000 mg/kg group had two small nodules in the liver.
Microscopy:
Animals at 2 000 mg/kg had moderate to marked thickening and hyperplasia of the stratified squamous epithelium and excessive accumulation of keratin on the skin surface. Several animals had small focal erosions of the epidermis with acute inflammation of the underlying dermis.
The one female with liver nodules in the liver had small focal areas of hyperplasia of the liver parenchyma.

Result:
Repeated dermal application of Gulftene 12-16 to rats resulted in decreased body weight at 2 000 mg/kg/day and severe dermal effects, but no systemic or organ toxicity. The NOAEL determined for this study was 1 000 mg/kg.

9.2.2 Repeated Dose Dermal Toxicity: 4 Week Using C16-C18 (EU 1995)

Full study report not provided.

C16-C18 was tested in a 4 week repeated dose skin irritation study in six New Zealand White rabbits. Twenty applications of 0.2 mL undiluted test substance was applied to the intrascapular region of each rabbit. Half of the rabbits had intact sites, half had abraded sites. Scoring of skin sites were made after each application. Average readings in abraded sites were slight hyperemia, and exfoliation; questionable folliculitis and questionable scabbing. Intact animals had average scores of slight hyperemia and oedema, questionable scabbing and no folliculitis.

9.2.3 Combined Repeated Dose Toxicity Study with Reproduction/Developmental Screening Test and Neurotoxicity Study in Rats using 1-tetradecene (Springborn Laboratories Inc 1995)

Test Substance:	1-tetradecene (the substance used was blended from three different suppliers of 1-tetradecene ie. NEODENE 14 alpha olefin (Shell); Alpha Olefin C14 (Albermarle); and Gulftene 14 (Chevron), in equal proportions)
Species/strain:	Rat/Sprague Dawley Crl:CD BR VAF/Plus
Number/sex of animals:	12 males/group 20 females/group (12 females assigned to breeding phase and 8 females assigned as satellite females)
Method of administration:	Oral (gavage)
Doses:	0, 100, 500 or 1 000 mg/kg/day (dose volume 5mL/kg) for a minimum of 42 days; vehicle corn oil.
Dosing Schedule:	<u>Males:</u> Day 0 to 28 - Pretreatment; Day 29 to 42 – Mating; Day 43 to 47 – Dosing after mating. <u>Satellite females:</u> Day 0 to 49 – Dosing period. <u>Breeding females:</u> Day 0 to 14 – Pretreatment; Day 15 to 42 – Dosing during mating and lactation; Day 43 to 51 - Dosing during lactation and until termination

Terminal kill schedule	Day 43 – euthanasia of unselected males (4 rats/sex/group). Days 45 to 47 – neurotoxicity and clinical pathology evaluations (8 rats/sex/group), histopathology (5 rats/sex/group). Days 42 to 51 – euthanasia and necropsy of breeding females (F_0)and F_1 pups.
Test methods:	OECD TG 422 (modified)

Mortality:

F_0 males and satellite females:
Nil.
F_0 females:
In the 500 mg/kg/day group, one female with evidence of mating failed to deliver and was euthanised on post breeding day 25 and one female was euthanised with total litter loss on Day 43.

Clinical observations:

F_0 males, satellite females and F_0 females:
Urine stain and salivation was noted in the 500 and 1 000 mg/kg/day groups. Other observations were noted sporadically.

Functional Observation Battery (FOB) and Motor Activity:
F_0 males and satellite females:
No test related differences in the FOB and motor activity tests between the control and treated groups.

Clinical Pathology:
F_0 males and satellite females:
Serum Chemistry:
Significantly increased alanine transferase (ALT) activity in males. In females, significantly decreased sodium values at all treatment doses and significantly increased cholesterol in the 500 and 1 000 mg/kg/day groups.

Haematology:
Slight decreases in mean erythrocyte count and haematocrit at all treatment doses and in haemoglobin and mean cell volume at 1 000 mg/kg/day in both sexes. However, these changes were only significant in females.
Significantly increased mean cell haemoglobin concentration in females of the 100 and 1 000 mg/kg/day group and in males of the 1 000 mg/kg/day group.

Pathology:
F_0 males and satellite females:
Organ Weights:
Significantly increased absolute liver weight and liver weight relative to brain weight in animals of the 500 and 1 000 mg/kg/day group.
Significant findings in females only were decreased spleen weight (relative to brain weights) in the 1 000 mg/kg/day group and increased kidney weight in the 500 mg/kg/day group.
Macroscopic:
In males, pitted kidneys were observed in the 500 and 1 000 mg/kg/day groups.
Microscopic:
Treatment related effects were observed in kidneys of all test males (dose-related increased eosinophillic hyaline droplets in the proximal convoluted tubules, a finding commonly associated with hydrocarbon nephropathy). Minimal to moderate hepatocellular vacuolation was observed in animals of the 500 and 1 000 mg/kg/day groups.

F_0 females:
Macroscopic:
No test related findings were observed. The animal euthanised on post breeding Day 25 was found to be non gravid. The animal euthanised on Day 43 was found to have implantation sites.

Fertility, Gestation, Parturition and Lactation:
Mating and fertility indices, precoital intervals and gestation length were comparable among the groups.

F_1 generation findings:
No treatment related developmental effects through to lactation Day 4.

Result:
Based upon liver weight increase and hepatocyte cytoplasmic vacuolation observed at 500 and 1 000 mg/kg/day, the No Observed Adverse Effect Level (NOAEL) determined for systemic toxicity in satellite females was 100 mg/kg/day. No NOAEL for systemic toxicity was established for males because of the presence of hydrocarbon nephropathy noted at all dose levels. The NOAEL for reproductive developmental or neurotoxicity was 1 000 mg/kg/day in both males and females.

9.2.4 Repeat Dose 13 Week Oral Toxicity Study in Rats Followed by a 4 Week Recovery Period using C20-C24 Alkenes, Branched and Linear (Huntingdon Life Sciences Limited 1999)

Test Substance:	C20-C24 Alkenes, Branched and Linear
Species/strain:	Rat/Crl:CD BR
Method of administration:	Oral (gavage)
Dose/Study duration:	0, 100, 500, 1 000 mg/kg/day for 13 weeks followed by a treatment free period of 4 weeks for high dose and control animals
Number/sex of animals:	10/sex/treatment and control groups; 10/sex/recovery groups (control and 1 000 mg/kg/day)
Test method:	OECD TG 408
Mortality:	Nil

Clinical observations:
No treatment related signs were observed on clinical signs, bodyweight, opthalmoscopy or neurobehaviour.

Clinical chemistry/Haematology
Clinical chemistry:
Significantly increased glucose levels at Week 13 in 500 and 1 000 mg/kg/day males. Glucose levels were normal in males of 1 000 mg/kg/day group at the end of the recovery period.
Haematology:
Decreased erythrocyte indices (packed cell volume of males and females, haemoglobin values of males and erythrocyte count of females) and prolonged haemostatic indices (males) in animals of the 1 000 mg/kg/day groups at Week 13. All indices were normal after the recovery period. Significantly increased platelet counts persisted in males of the 1 000 mg/kg/day at the end of the recovery period.

Pathology:
Organ weights:
Females at all treatment doses had significantly higher group mean liver weight. No dosage response was apparent. Males receiving 1 000 mg/kg/day had slightly increased mean body weight-adjusted liver weight. These changes were not apparent at the end of the recovery period. Significantly higher group mean absolute adrenal weights in females receiving 500 and 1 000 mg/kg/day. These changes were not apparent at the end of the recovery period.

Macroscopic:
No treatment related effects.

Microscopic:

Minimal centrilobular hepatocyte hypertrophy was observed in a small number of females of all treated groups, the incidence attaining statistical significance at the 1 000 mg/kg/day group. Significantly increased incidence of adrenal cortical hypertrophy in females of the 1 000 mg/kg/day group. Significantly increased incidence of epithelial hyperplasia of the limiting ridge[4] of the stomach in males receiving 1 000 mg/kg/day. None of these lesions were observed at the end of the recovery period.

Result:
The NOAEL is determined to be 500 mg/kg/day based upon effects on the stomach, liver and adrenals at 1 000 mg/kg/day.

9.2.5 Repeated Skin Irritation Study in Rabbits (EU 1995)

Full report not provided.

Test substances, n-hexadecene (pure) and a series of linear alkanes C7-C22 (pure) applied (0.5 to 0.6mL) to rabbit skin on 4 alternate days. A subjective evaluation of skin irritancy was graded on a scale of 0 to 8. C16 was severely irritating with a maximum score of 8. In the series of n-alkanes there was a relationship between carbon chain length and irritancy with maximum irritancy observed between C15 and C18.

9.3 Genotoxicity

9.3.1. *In Vitro*

9.3.1.1 Bacterial Reverse Mutation Test using C20-C24 alkenes, branched and linear (Safepharm Laboratories Limited 1998)

Test substance:	C20-C24 alkenes, branched and linear
Strains:	*Salmonella typhimurium* strains: TA 1535, TA 1537, TA 98, TA 100; *Escherichia coli* strain*:* WP2uvrA$^-$
Concentration range:	0, 15, 50, 150, 500, 1 500 and 5 000 µg/plate each concentration was tested in triplicate with or without metabolic activation, in two independent experiments; appropriate strain specific positive control reference substances were used
Metabolic activation system:	Liver fraction (S9) from rats pretreated with Aroclor 1254
Test method:	OECD TG 471 & 472 - plate incorporation method
Comment:	Precipitate noted at and above 1 500 µg/plate; No cytotoxicity was observed.

[4] This is considered to reflect local irritation of the test material in corn oil and since humans do not have a limiting ridge this effect is considered to be of no toxicological significance.

	There were no significant increases in revertant colony numbers at any concentration, in the presence or absence of metabolic activation. Concurrent positive controls used in the test induced marked increases in the frequency of revertant colonies and the activity of the S9 fraction was found to be satisfactory
Result:	C20-C24 alkenes, branched and linear were not considered mutagenic in the bacterial strains tested

9.3.1.2 Genetic Toxicology: DNA Damage and Repair/Unscheduled DNA Synthesis (UDS) using Gulftene 12-16 *In Vitro* (Gulf Life Sciences Center 1984)

Test substance:	Gulftene 12-16
Cells:	Primary hepatocytes from Fischer 344 rats
Dosing schedule:	0, 100, 1 000, 2 000, 4 000 μg/mL of test substance was tested in triplicate: Positive Control: 2-acetylaminofluorene 0.2 μg/mL; Cultures were exposed to test substance and 1 mCi/mL ^{3}H-thymidine for 18 hours.
Test method:	OECD TG 482
Comment:	In the range finding study, cytotoxicity was reported at and above 256 μg/mL. Toxicity data was not available for the main test. The test substance at any concentration did not elicit an increased mean net nuclear grain count above the concurrent negative control. The positive control gave the expected response for UDS.
Result:	Gulftene 12-16 was negative for unscheduled DNA synthesis

9.3.1.3 BALB/3T3 Transformation Test Using Gulftene 12-16 (Gulf Life Sciences Center 1983)

Test substance:	Gulftene 12-16
Cells:	Mouse embryo cells BALB/3T3-A31-1-1
Dosing schedule:	0, 10, 20, 30, 1 500 µg/mL of test substance was tested in duplicate: Positive Control: 3-methylcholanthrene 1 µg/mL; Cultures were exposed to test substance for two days.
Test method:	Not stated
Comment:	Cytotoxicity was evident at 20 µg/mL and above leaving only one viable dose level, 10 µg/mL. The number and type of transformed foci at any test substance concentration was not increased above the negative control. The positive control gave the expected response for transformation.
Result:	At the low dose available for adequate evaluation Gulftene 12-16 was negative for cell transformation.

9.3.1.4 *In Vitro* Mammalian Cell Gene Mutation Test: Chinese Hamster Ovary Cell/Hypoxanthine Guanine Phosphoribosyl Transferase Assay (HPRT) using Gulftene 12-16, (Gulf Life Sciences Center 1982)

Test substance:	Gulftene 12-16
Cells:	Chinese Hamster Ovary (CHO)
Metabolic activation system:	Liver fraction (S9) from rats pretreated with Aroclor 1254
Dosing schedule:	0, 4, 16, 128, 512, 1 024, 2 048 µg/mL each concentration was tested in triplicate with or without metabolic activation (S9), Positive controls: Without S9: ethyl methanesulphonate 100µg/mL; With S9: benzo[a]pyrene 4 µg/mL; Exposure period was 5 hours
Test method:	OECD TG 476 CHO cells, HGPRT locus

Comment:	Toxicity was observed at 1 024, 2 048 µg/mL in the presence and absence of metabolic activation; The test substance did not cause any significant increases in the incidence of mutant colonies in the presence or absence of metabolic activation; Positive controls used in the test caused marked increases in the incidence of mutant colonies and the activity of the S9 fraction was found to be satisfactory.
Result:	Gulftene 12-16 did not induce gene mutations in CHO cells.

9.3.1.5 *In Vitro* Chromosomal Aberration Test: Human Lymphocytes using C20-C24 alkenes, branched and linear (Safepharm Laboratories Limited 1998)

Test substance:	C20-C24 alkenes, branched and linear
Cells:	Human Peripheral Lymphocytes
Metabolic activation system:	Liver fraction (S9) from rats pretreated with Aroclor 1254

Dosing schedule:	Each concentration was tested in duplicate with or without metabolic activation (S9), in two independent experiments
	
	<u>Experiment 1 (repeat – see comment below):</u>
	without S9,
	0*, 78.13, 156.25, 312.5*, 625*, 1 250* ,2 500*
	5 000* µg/mL;
	treatment/harvest time = 4/20 hours;
	positive control: ethyl methanesulphonate 750µg/mL;
	
	with S9,
	0*, 39.06, 78.13, 156.25, 312.5*, 625*, 1 250*, 2 500*
	5 000* µg/mL,
	treatment/harvest time = 4/20 hours,
	positive control: cyclophosphamide 25µg/mL;
	
	<u>Experiment 2:</u>
	without S9,
	0*, 39.06, 78.13, 156.25, 312.5*, 625* 1 250*, 2 500*
	5 000* µg/mL;
	treatment/harvest time = 20/20 hours;
	positive control: ethyl methanesulphonate 500µg/mL;
	
	with S9 (increased to a final concentration of 2%),
	0*, 39.06 , 78.13, 156.25, 312.5*, 625* 1 250*, 2 500*
	5 000* µg/mL;
	treatment/harvest time: 4/20 hours,
	positive control: cyclophosphamide 25 µg/mL;

asterisk* indicates cultures selected for metaphase analysis

Test method: OECD TG 473

Comment: An initial experiment (data not included in report) revealed: doses of 2 500 and 5 000 g/mL were probably beyond the maximum practical dose; an aberrant cell at the highest dose contained multiple aberrations; and weak responses in the positive control. The experiment was repeated.
In the repeated Experiment 1 and Experiment 2, an oily layer was observed at and above 156.25 µg/mL and 312.5µg/mL in the presence and absence of metabolic activation, respectively.
No toxicity was observed at any concentration.
The test substance did not cause any significant increases in the incidence of cells with chromosomal aberrations, polyploidy or endoreplication, at the concentrations analysed in the presence or absence of metabolic activation.
Positive controls used in the test caused significant increases in the incidence of aberrant cells and the activity of the S9 fraction was found to be satisfactory.

Result: C20-C24 alkenes, branched and linear was not considered to be clastogenic under the conditions of this chromosomal aberration test.

9.3.1.6 *In Vitro* Genotoxicity of 1-octadecene (EU 1995)

The following data are taken from the HEDSET data sheet for 1-octadecene. The full study reports were not provided in the submission.

The HEDSET documents indicate these tests were not conducted in accordance with GLP or OECD or EC testing guidelines.

1-Octadecene was considered not mutagenic or clastogenic in the following test systems:

Test	*Comment*	*Result*
Bacterial Reverse Mutation Assay[H18]	*S. typhimurium* TA98, TA 100, TA 1535, TA 1537, TA 1538. *E. coli* WP2, WP2uvrA. 0.2 to 2 000 μg/plate; with and without metabolic activation.	Negative
Mitotic Recombination[H18]	*S.cerevisiae* JD1. 0.01 to 5.0 mg/mL; with and without metabolic activation.	Negative
Chromosome Aberration[H18]	Rat liver RL1 cells. 0 to 500 μg/mL as acetone solution. With and without metabolic activation.	Negative

9.3.2 *In Vivo*

9.3.2.1 Mammalian Erythrocyte Micronucleus Test Using Gulftene 12-16 (Gulf Life Sciences Center 1983)

Test substance:	Gulftene 12-16
Species/strain:	Mouse/Crl:CD-1 (ICR) BR
Number and sex of animals:	5/sex/group
Doses/Method of administration:	Test substance: 1 000, 2 500 or 5 000 mg/kg; Vehicle control: corn oil; Test and vehicle control administered dermally to shaven backs of mice once per day for 2 days; Positive control, cyclophosphamide 75 mg/kg, administered via intraperitoneal injection;

Sampling schedule:	Test and vehicle control animals were sacrificed 24 or 48 hours after last dosing; Positive control group animals were sacrificed 24 hours after dosing.
Clinical observations:	No mortality; No clinical signs of toxicity;
Micronuclei score:	No significant increase in micronucleated polychromatic erythrocytes (PCE) due to treatment with test substance at either sampling time; the positive control caused a significant increase in micronucleated PCE.
Test method:	OECD TG 474
Result:	Gulftene 12-16 did not induce a significant increase in micronucleated PCEs in bone marrow cells of the mouse *in vivo*.

9.3.2.2 Mammalian Erythrocyte Micronucleus Test Using C20-C24 alkenes, branched and linear (Safepharm Laboratories Limited 1998)

Test substance:	C20-C24 alkenes, branched and linear
Species/strain:	mouse/Crl:CD-1 (ICR) BR
Number and sex of animals:	7 males/24 hour, vehicle and positive control, and mid, low and high dose group; 7 males/48 hour, vehicle control and high dose group; 5 males/positive control group.
Doses/Method of administration:	Test substance: 500 mg/kg (low), 1 000 mg/kg (mid) or 2 000 mg/kg (high); Positive control: cyclophosphamide 50 mg/kg; Vehicle control: arachis oil; All administered via intraperitoneal injection at a constant volume of 10 mL/kg bw. Positive control was administered orally.
Sampling schedule:	Vehicle and positive control, low, mid and high dose animals were sacrificed 24 hours after dosing. Remaining animals of the vehicle control group and high dose animals were sacrificed 48 hours after dosing.
Clinical observations:	No mortality. No clinical signs of toxicity.
Micronuclei score:	No significant increase in micronucleated PCE due to treatment with test substance at either sampling time. No statistically significant decrease in the PCE/NCE ratio at

	24 or 48 hours. The positive control caused a significant increase in micronucleated PCE.
Test method:	OECD TG 474
Result:	C20-C24 alkenes, branched and linear did not induce a significant increase in micronucleated PCE in bone marrow cells of the mouse *in vivo*.

9.4 Overall Assessment of Toxicological Data

The toxicological data submitted on C12, C14, C16 and C18 alpha olefins, C16 and C18 alkenes isomerised, C12-C16 alpha olefin blend and a C20-C24 branched and linear alkenes, are accepted as representing the toxicity of the notified chemical, Gulftene 14. Data on other alkenes (C12 through to C30) were provided as OECD HEDSET documents. In this report the HEDSET data is supplementary to the full study reports.

Summary of Data on Analogue Alkenes and Extrapolated to Gulftene 14

Acute Toxicity

C12-C30 alkenes consistently displayed very low acute systemic toxicity. By oral and dermal routes, C12-C30 alkenes (alpha olefins, or isomerised alkenes, or blends thereof) showed LD_{50} values greater than 5 000 mg/kg in rats and greater than 2 000 mg/kg in rabbits, respectively. In rats exposed to saturated mists, the 1-hour inhalation LC_{50} for C12-C16 alpha olefins was > 9.9 mg/m^3 (nominal) and >8.5 mg/m^3 (nominal) for a C16 alpha olefin. Single oral doses of 5 000 mg/kg and 10 000 mg/kg of C16 alpha olefin resulted in pronounced gait and behavioural effects, which were considered to be reversible and secondary to the irritation caused by the test substance. There were no histopathological lesions in the central or peripheral nervous system or pituitary glands. Based on these findings, C16 alpha olefin was not considered to produce a primary neurotoxicant effect.

Analogue alkenes would not be classified as acutely toxic under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999).

On the basis of the similarities in chemical structure and physicochemical properties Gulftene 14 is very likely to share the same low order of acute oral, dermal and inhalation toxicity, and acute neurotoxicity as the analogue alkenes.

An experimental study in rats indicated a significant aspiration hazard with C6-C14 alpha olefins. Furthermore, the measured kinematic viscosities of C16, C18, C16/C18 blend and Gulftene 14 (Section 3) meet the criteria of aspiration hazard under the NOHSC *Approved Criteria for Classifying Hazardous Substances Classifying Hazardous Substances* (NOHSC 1999).

Skin Irritation

Slight, transient skin irritation was observed with a C12-C16 alpha olefin blend and a C16 alpha olefin following application to abraded and intact skin of rabbits. Later studies on C14, C16, C18 alpha olefins and C16/C18 alpha olefins, isomerised, revealed slight to moderate or moderate skin irritation in rabbits, typically persisting beyond the 72 hour observation. Desquamation was noted in all rabbits treated with C14, C16, C18 alpha olefins by the 96

hour observation and crust formation was observed in two animals treated with C18 alpha olefin. No skin irritancy was observed with C20-C24 branched and linear alkenes. Volunteers experienced moderate to strong erythema, oedema and papules following patch application of neat 1-octadecene for a 24 hour exposure period. Gulftene 14 is expected to have some irritant potential and skin drying effects.

Eye Irritation
Slight, transient eye irritation was observed in rabbits treated with C12-C16 alpha olefin blend, C16 alpha olefins, C16/C18 alpha olefins, isomerised, and C20-C24 alkenes, branched and linear. By analogy, Gulftene 14 is not expected to display prolonged or significant eye irritation.

Skin Sensitisation
The following alkenes were found to be non sensitising to guineapig skin: (C20-C24 alkenes, branched and linear (adjuvant type test); C16/C18 alpha olefins, isomerised and C16 and C18 alpha olefins (non-adjuvant type test)*; and C12-C16 alpha olefins (non-adjuvant type test, Landsteiner technique). C18 alpha olefin was reported non-sensitising in a Human Repeat Patch Insult Test*. Gulftene 14 is not expected to be dermally sensitising based upon the sensitisation studies conducted on analogue alkenes and the absence on Gulftene 14 of functional groups commonly associated with skin sensitisers.

Repeated Dose Toxicity
Oral
In a combined 4-week oral systemic, reproductive/developmental toxicity and neurotoxicity study in rats, 1-tetradecene at concentrations of 100, 500 or 1 000 mg/kg/day produced no systemic effects other than hepatocyte cytoplasmic vacuolation and increased liver weights in both sexes at and above 500 mg/kg/day and kidney effects in males at all doses consistent with male rat specific α_{2u}-globulin induced hydrocarbon nephropathy. Kidney effects are not considered relevant to human health, but precluded establishment of a NOAEL. The NOAEL in females was 100 mg/kg/day. In the same study, neurotoxicity was not observed in a functional observation battery or motor activity test. The NOAEL for neurotoxic effects was established at 1 000 mg/kg/day.

Rats dosed orally with C20-C24 alkenes, branched and linear, at 100, 500 or 1 000 mg/kg/day for 13 weeks were found to have an increased incidence of minimal centrilobular hepatocyte hypertrophy associated with increased liver weight, and minimal or slight cortical hypertrophy in the adrenals (with increases in adrenal weight) at 1 000 mg/kg/day. Observed changes were reversible during the 4-week recovery period. Based upon the effects on the liver and adrenals at 1 000 mg/kg/day, the NOAEL determined for this study is 500 mg/kg/day.

Dermal
Dermal application of 1 000 or 2 000 mg/kg/day of C12-C16 alpha olefins to rats for 2 weeks (9 applications) resulted in decreased body weight at 2 000 mg/kg/day and a severe irritant reaction, but no systemic or organ toxicity. The NOAEL is 1 000 mg/kg/day. Repeated dermal application of 0.2 mL/day C16-C18 alpha olefins to rabbits for 28 days (20 applications) produced slight hyperemia, exfoliation and scab formation at the site of application.

* Full study report not provided.

Gulftene 14 and the analogue alkenes share similar structures and are expected to share the same metabolic fate. Therefore, the biological activity of Gulftene 14 and its metabolites would be similar to that observed for C20-24 alkenes branched and linear, and 1-tetradecene in the repeat oral dose studies and the identified target organs would be the liver and adrenals and in male rats the kidney. However, no neurotoxicity is predicted for Gulftene 14. Repeated dermal exposure may cause moderate skin irritation and skin dryness.

Reproductive/Developmental Toxicity
1-Tetradecene administered orally, was evaluated for reproductive and developmental toxicity. Male rats were exposed for 28 days prior to mating, and through mating until euthanasia for a total of 44 consecutive days of dosing; females were dosed for 14 days prior to mating, during mating, gestation and lactation through euthanasia at lactation day 4 (41-55 consecutive days). Doses were 0, 100, 500 and 1 000 mg/kg/day. There was no evidence of impaired reproductive capabilities in the F_0 generation. There was no evidence of developmental toxicity in the F_1 generation. The NOAEL for reproductive/developmental effects was 1 000 mg/kg/day. As above, Gulftene 14 is expected to share the same metabolic fate and is not expected to cause adverse effects on reproduction or foetal development.

Genetic Toxicity
The C12-C24 alkenes did not display genotoxic activity in a broad range of *in vitro* studies: bacterial reverse mutation (C20-C24 alkenes); mitotic gene conversion in yeast (C12 alpha olefins); mammalian cell gene mutation, chromosome aberration and transformation; and unscheduled DNA synthesis (C12-C16 alpha olefins). In *in vivo* studies, dermal application of a C12-C16 blend of alpha olefins or intraperitoneal injection of C20-C24 alkenes branched and linear, to mice did not induce an increase in micronucleated bone marrow erythrocytes. Gulftene 14 and its metabolites are expected to be non genotoxic.

<u>Hazard Classification of Analogue Alkenes and Gulftene 14</u>
Assessment of the toxicological data of the alkene analogues against the NOHSC *Approved Criteria for Classifying Hazardous Substances*, indicate that Gulftene 14 would be considered hazardous based on potential aspiration hazard and skin drying effects following repeated or prolonged exposure. The overall hazard classification is Harmful (Xn) and the following risk phrase and safety phrases assigned:

R65 – May Cause Lung Damage if Swallowed;
R66 – Repeated Exposure May Cause Skin Dryness or Cracking[1];
S24/25 – Avoid Contact with Skin and Eyes;
S28 – After contact with skin, wash immediately with plenty of soap and water; and
S62 – If swallowed, do not induce vomiting: seek medical advice immediately and show this MSDS/label.

[1] This risk phrase has being recently adopted by the European Commission (European Commission 1998). Although yet to be adopted by NOHSC, R66 should be provisionally assigned to the Gulftene 14 based upon the defatting action observed with alkene analogues.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier provided data and reports on a variety of ecotoxicity tests in support of their application. The reports submitted were performed in accordance with OECD Test Guidelines.

Most of the ecotoxicity data provided is not specific to Gulftene 14, but describes test procedures and the results obtained with analogue substances. These substances include 1-tetradecene 1-hexadecene (Gulftene 16) and C20-24 alkenes, branched and linear and is acceptable as analogue data for Gulftene 14. Ecotoxicity data were provided for both freshwater and marine species. The same test data are applicable to the application Gulftene C16-18 olefins isomerised, assessed under NICNAS as NA/713.

10.1 Tests on Freshwater Species

A full suite of tests on freshwater species were performed on each of the following substances – 1-tetradecene 1-hexadecene (Gulftene 16) and C20-24 alkenes, branched and linear. The results of these tests are summarised in below.

	Test and Species		
	Acute Toxicity to Fish	***Immobilisation of Invertebrates***	***Inhibition of Algal Growth***
Test Substance*	Rainbow trout *Oncorhynchus mykiss*	Water Flea *Daphnia magna*	Green alga *Selenastrum capricornutum*
1-Tetradecene	**LL_{50} (96h)> 1 000 mg/L ***NOEL (96h)>1 000 mg/L	LL_{50} (48h)> 1 000 mg/L NOEL (48h)>1 000 mg/L	E_bL_{50} (72h) > 1 000 mg/L NOEL <1 000 mg/L
1-Hexadecene (Gulftene 16)	LL_{50} (96h)> 1 000 mg/L NOEL (96h)> 1 000 mg/L	LC_{50} (48h) = 53% WAF NOEL (48h) = 18%	E_bL_{50} (72h) > 1 000 mg/L NOEL <1 000 mg/L
C20-24 alkenes, branched and linear	LL_{50} > 1 000 mg/L NOEL > 1 000 mg/L	LL_{50} > 1 000 mg/L NOEL >1 000 mg/L	LL_{50} > 1 000 mg/L NOEL <1 000 mg/L

*Water Accomodation Fractions (WAF) loading 1 000 mg/L.
**LL_{50} refers to the nominal loading of test substance used to prepare the WAF media in which 50% of the test animals died at the end of the test period.
***NOEL refers to the WAF loading below which no toxic effects are observed.

10.1.1 1-tetradecene

10.1.1.1 Fish Acute Toxicity Test (Wildlife International Ltd 1995)

Range finding tests on rainbow trout were performed using WAF of the test substance made up in filtered well water (no chlorine) at nominal loadings of 0 (control), 10, 100 and 1 000 mg/L in accordance with OECD TG 303. The WAF test media were made up by stirring the requisite quantity of test substance into the water for around 24 hours, allowing to settle for approximately one hour, and then siphoning of the aqueous phase containing the WAF. The WAFs prepared in this manner were clear and colourless, and apparently devoid of undissolved material or oil droplets. The tests were conducted over a 96 hour period at a controlled temperature of 15±2°C, and the test media was replaced daily in a batchwise manner. Five fish were tested at each WAF loading, and no mortalities or behavioural aberrations were observed over the duration of the tests.

A definitive study was performed in duplicate using a control and the 1 000 mg/L WAF, with seven fish in each test vessel. The pH was always between 7.7 and 8.4, the temperature was 15±2°C, water hardness around 140 mg/L as $CaCO_3$ and the dissolved oxygen levels between 5.2 and 9.3 mg/L. Again, no deaths or other effects were observed in the test specimens. It is concluded that the test substance is not toxic to this species of fish, up to the limits of its water solubility.

10.1.1.2 Acute Immobilisation Test (Wildlife International Ltd 1995)

The range finding test for acute immobilisation for *Daphnia magna* was performed over 48 hours using WAFs of the test substance made up in filtered well water at nominal loadings of 0 (control), 10, 100 and 1 000 mg/L, and ten daphnia were tested at each concentration. The temperature was maintained at 20±1°C, and no irreversible immobilisation or other behavioural aberrations were observed over the 48 hour test period. A definitive test was performed using a WAF containing 1 000 mg/L of test substance. Four replicate tests were run, together with one control, with five daphnia per test vessel. Temperature was maintained at 20±1°C, pH was always between 8.4±0.1, while dissolved oxygen levels were between 7.9 and 8.1 mg/L. As with the range finding tests, no immobilisation or other effects were observed, and it is concluded that the test substance is not toxic to the daphnia up to the limits of its water solubility.

10.1.1.3 Alga Growth Inhibition Test (Wildlife International Ltd 1995)

Range finding tests on the green alga *Selanastrum capricornutum* with WAFs prepared at nominal loadings of up to 1 000 mg/L established that less than 50% inhibition of growth occurred up to the highest loading. Accordingly, the definitive test was conducted using only the WAF containing 1 000 mg/L, together with controls. Three replicates of the WAF containing medium were conducted, while six replicates of the control were used. The tests was performed over a 96 hour incubation period at 23±0.5°C at pH 7.4-8.7, and both algal biomass and the rate of biomass growth were measured. For the control group, greater than 16 fold increase in biomass took place over three days as reckoned from the area under the growth curve. However, for the WAF-containing group the growth was slightly attenuated, with 42% less growth (relative to the controls) recorded over 72 hours, and 30% less over the 96 hour observation period.

The results of this study indicate that the E_bL_{50} is greater than 1 000 mg/L (nominal WAF), but that the NOEL is less than 1 000 mg/L. The results indicate that 1-tetradecene is non toxic to this species up to the limits of its water solubility.

10.1.2 1-hexadecene

The tests were performed using essentially the same methodology as for the tests on 1-tetradecene. Again WAFs with nominal loadings up to 1 000 mg/L of test substance were used as media in the definitive tests.

10.1.2.1 Fish Acute Toxicity Test (Huntingdon Research Centre 1993)

Using OECD TG 303, the NOEL for rainbow trout was greater than 1 000 mg/L WAF loading.

10.1.2.2 Acute Immobilisation Test (Huntingdon Research Centre 1993)

The data for daphnia, conducted in media containing 1, 1.8, 3.2, 5.6, 10, 18, 32, 56 and 100% of the 1 000 mg/L WAF, indicate some immobilisation, and the 48 hour LL_{50} was calculated as 53% of the (nominal) 1 000 mg/L WAF, or nominally 530 mg/L. The corresponding NOEL was calculated as 18% of the 1 000 mg/L WAF, or nominally at a WAF prepared at 180 mg/L loading.

10.1.2.3 Alga Growth Inhibition Test (Huntingdon Research Centre 1993)

The test on green alga indicated no inhibitory effects for either growth of biomass, or rate of biomass production in media containing 100% WAF prepared at a loading of 1 000 mg/L.

10.1.2.4 Summary

Test results for 1-hexadecene were similar to those for 1-tetradecene and indicate that the 1-hexadecene is non toxic to the fresh water fish and alga against which it was tested. However, the results for daphnia indicated some immobilisation at nominal WAF loadings above 180 mg/L, but it difficult to establish the true significance of this result as there is no data on the actual levels to which the organisms were exposed.

10.1.3 C20-24 Alpha Olefins, Branched and Linear

10.1.3.1

- Fish Acute Toxicity Test (Safepharm Laboratories Limited 1998)
- Alga Growth Inhibition Test (Safepharm Laboratories Limited 1998)
- Acute Immobilisation Test (Safepharm Laboratories Limited 1998)

The definitive tests on all three species were performed using media made up with WAFs prepared at nominal loading of 1 000 mg/L of the test substance. The methodologies employed were in accordance with OECD TG 301, 302 and 303 essentially as described above. The daphnia test was conducted with four replicates (5 animals per test vessel) and the alga test was conducted with six replicates. In all cases the NOEL was greater than the 1 000 mg/L WAF loading, indicating this fraction as non toxic up to the limit of its water solubility.

10.1.3.2 Activated Sludge Respiration Inhibition Test (Safepharm Laboratories Limited 1998)

Using OECD TG 209, the study found that the test substance has no effect on aerobic bacterial metabolism after 3 hours exposure to media containing WAF prepared at 1 000 mg/L loading. Although the use pattern of Gulftene 14 is such that entry into the sewer system is unlikely, the results of this study are included for completeness. Similarly, in the various tests for aerobic biodegradation, the reports indicated no observable inhibition of bacterial respiration.

10.2 Tests on Marine Organisms

10.2.1 Exotic Species

Test reports and summary reports on the toxicity of C16-18 olefins isomerised, C14-20 olefins isomerised and drilling fluids containing these materials to a variety of Northern Hemisphere marine organisms were submitted and are summarised in the table below.

Test	***Species***	***Results (WAF - Nominal)***
Acute Toxicity to Fish	*Scopthalmus maximus*	*LL_{50}(96 h) > 10 000 mg/L
	(turbot)	NOEC (96 h) > 10 000 mg/L
Acute Toxicity to	*Mysidopsis bahia*	LL_{50}(96 h) > 195 g/L
Marine Shrimp	(mysid shrimp)	See notes below
Acute Toxicity to	*Mysidopsis bahia*	LL_{50}(96 h) > 53.8 g/L
Marine Shrimp	(mysid shrimp)	See notes below
Acute Toxicity to	*Acartia tonsa*	LL_{50}(48 h) > 10 000 mg/L
Marine Copepod		See notes below
Acute Toxicity to	*Acartia tonsa*	LL_{50}(48 h) > 10 000 mg/L
Marine Copepod		See notes below
Acute Toxicity to	*Corophium volutator*	LL_{50}(10 day) = 1 250 mg/kg
Marine Amphipod		See notes below
Acute Toxicity to	*Corophium volutator*	LL_{50}(10 day) = 1 560 mg/kg
Marine Amphipod		See notes below
Inhibition of Marine	*Skeletonema costatum*	E_bL_{50}(72 h) > 5 600 mg/L
Algal Growth		**NOEL(72 h) = 1 800 mg/L
Inhibition of Marine	*Skeletonema costatum*	E_bL_{50}(72 h) > 10 00 mg/L
Algal Growth		**NOEL(72 h) = 3 200 mg/L

*LL_{50} refers to the nominal loading of test substance used to prepare the WAF media in which 50% of the test animals died at the end of the test period.
**NOEL refers to the WAF loading below which no toxic effects are observed.

10.2.1.1 Fish Acute Toxicity Test (Environment & Resource Technology Ltd 1995)

The toxicity tests on C16-18 olefins to marine fish (turbot) were conducted over a 96-hour period using a semi static methodology (OECD TG 203) with renewal of the test media at 48 hours. The tests were conducted with five WAFs made up with nominal loadings of test substance between 1 000 and 10 000 mg/L, together with a control containing no test substance. Ten fish were exposed at each WAF loading, and the temperature was 15.4±0.7°C, the pH between 7.8 and 8.3, and the dissolved oxygen levels between 85 and 98% saturation. No fish mortality or aberrant behaviour was observed in any of the test vessels, and accordingly the LL_{50} is greater than 10 000 mg/L (nominal) loading, and the NOEL also greater than 10 000 mg/L. The test substance is considered non toxic to this species of marine fish up to the limit of its water solubility.

10.2.1.2 Decapod (Crustacean) Acute Toxicity Test (AnalytiKEM Environmental Laboratory 1993)

The tests on mysid shrimp were conducted according to the US EPA protocols (US EPA 1985; US EPA 1991). The tests used JCG-A2 which is a drilling fluid containing a high proportion of C16-18 olefins. The summary report provided did not elaborate on the full test methodology, but it appears that the tests were performed using WAFs prepared with 0 (control), 30, 60, 125, 250 and 500 g/L of the test substance in reconstituted sea water (20 g/L salt), with the resultant aqueous phase used for the tests. Three replicate tests were performed at each WAF loading and the control, using 20 animals in each test vessel (ie 60 animals tested at each WAF loading). The tests were conducted over a 96 hour period with the temperature maintained at 20±2°C. No significant mortality of the test animals was observed over the 96 hour test period for the WAFs prepared with 60 g/L loading, but after 96 hours exposure to 125 g/L, 10% of the animals had died, while after 96 hours the mortality was 78% and 100%, respectively for the 250 and 500 g/L preparations. Probit analysis furnished the LL_{50} WAF of 195 g/L, which indicates that exposure to very high levels of the test substance may be lethal for this species. It is difficult to establish the true significance of this result, but since the 96 hour LL_{50} is well in excess of 1 000 mg/L under normal levels of exposure the material may be classified as non toxic to this species.

A summary report of a second test on mysid shrimp conducted by the same laboratory (apparently using identical methodology) was also submitted, and the data indicated an LL_{50} > 1,000 g/L. n fact 45% mortality among the test animals was recorded after 96 hours exposure to the WAF prepared at 1 00 g/L. However, the nature of the test material was not specified, nor was it clear whether the test material was composed of the olefins themselves or a drilling fluid containing these chemicals. Accordingly, while the result is reported here, it is not entered in the table above.

A third test report on the toxicity of a drilling fluid containing C14-20 olefins to mysid shrimp was also submitted (Frederick P Sintiere K Melancon S 1999) (Croudace CP Tapp JF 1995). This test was also conducted over a 96 hour period using the same methodology as described above. The initial WAF preparation was made up at 10% v/v by stirring 200 mL of the drilling fluid into 1800 mL of sea water, and the tests were conducted with this, and successive dilutions of this WAF ie 50, 25, 12.5 and 6.25%, together with a sea water control. As above 60 mysids were exposed to each test WAF, and after 96 hours exposure to the 6.25% WAF 5 of the test animals had died, and the proportion of deaths increased at successively larger WAF loadings till 40 (of the initial 60) animals (ie 66%) had died after 96

hours exposure. Trimmed Spearman-Karber analysis of the data furnished an LC_{50} of 53.8 g/L (WAF). As above since the C14-20 olefins are a component of the drilling fluid, assuming the toxicity of the fluid is due to the olefin content, the results imply that the LC50 for the olefins may be significantly lower than 53.8 g/L. This result may also indicate that the C14-20 olefins are more toxic to this species of marine invertebrate than the C16-18 olefins.

10.2.1.3 Copepod (Crustacean) Acute Toxicity Test (Environment & Resource Technology Ltd 1995)

A test report on the effect of C16-18 alpha olefins isomerised, to the marine copepod *Acartia tonsa* (a herbivore) was submitted. This study was conducted in accordance with a US EPA test protocol (Standard Operating Procedure 106 (US EPA 1985) using WAF of the test substance prepared with nominal loadings of 1 000, 1 800, 3 200, 5 600 and 10 000 mg/L in sea water. The tests at each loading were conducted in duplicate with four replicate control tests (no test substance), with approximately 10 adult animals per test vessel. The test duration was 48 hours during which the animals were exposed to dim continuous illumination, while the temperature was maintained at 21±0.2°C and the pH and dissolved oxygen levels were 8.1±0.03 and 94% saturation, respectively. The pattern of animal mortality in this test was unusual in that zero mortality was observed at the highest nominal WAF loading (10 g/L), but up to 25% mortality occurred at the lower loadings, with no discernible pattern. This behaviour was exhibited by both sets of test replicates, while no deaths were recorded in any of the four controls. The results could not be analysed by the usual statistical methods, but it was concluded that the 48 hour LL_{50} was in excess of a WAF loading of 10 000 mg/L, and consequently the material can be considered to be non toxic to this species up to the limits of its water solubility. No explanation for the deaths observed at the lower WAF loadings was offered in the report.

10.2.1.4 Amphipod (Crustacean) Acute Toxicity Test (Environment & Resource Technology Ltd 1995)

The effect of C16-18 alpha olefins, isomerised to the marine amphipod, *Corophium volutator* (a benthic dwelling sediment reworker) was conducted in accordance with (US EPA 1985) test protocols for toxicity testing of chemicals to marine organisms. The test is performed by placing the test animals in beakers containing sediment, previously loaded with quantities of the test substance. In the present test, samples of sediment taken from the area in which the test animals originated, were prepared with nominal loadings of 100, 1 000, 3 200, 10 000 and 32 000 mg/kg of the test substance, on a wet weight basis. Around 100 grams of each preparation were placed in individual one litre tall form beakers and sea water added to bring the final volume to one litre. The tests at each loading were conducted in triplicate with five replicate controls with approximately 20 adult animals per test vessel. The test duration was 10 days, during which the animals were exposed to constant dim illumination, while the temperature was maintained at 18±1.5°C. The pH was 8.1±0.03 and dissolved oxygen levels maintained through continuous aeration were between 92 and 98% saturation, respectively. At the end of the 10-day test period, the sediment was sifted and the surviving animals counted (it was assumed that dead animals would have decomposed or have been consumed by the survivors). The data were analysed using the (US EPA 1991) method, and the 10-day LL_{50} was determined as 1 250 mg/kg. It is to be noted that this result expresses the nominal loading of the test substance relative to the weight of sediment in each test vessel. This result indicates that the test substance exhibits some toxicity to this species of sediment dwelling organism. Furthermore, it should be noted that the levels of chemical in the piles of drill

cuttings may be up to 100 000 mg/kg which is well in excess of 1 250 mg/kg. Consequently, the piles of drill cuttings may be toxic to this species.

10.2.1.5 Alga Growth Inhibition Test (Environment & Resource Technology Ltd 1995)

The tests on the effect of C16-18 alpha olefins, isomerised to the marine alga *Skeletonema costatum* was conducted in accordance with (US EPA 1985) using five WAFs of the test substance prepared with nominal loadings of test substance of 560, 1 000, 1 800, 3 200 and 5 600 mg/L in nutrient enriched sea water, and a control. The tests were conducted in duplicate over a 72 hour period at a temperature of 20°C and pH between 8.39 and 9.01. After 72 hours, a 4% inhibition in biomass was observed for the media containing 3 200 mg/L WAF, while 12% inhibition was observed for the media containing the highest WAF loading. Accordingly the NOEL is 1 800 mg/L, the 72 hour E_bL_{50} is greater than 5 600 mg/L, and the test substance may be considered to be practically non toxic to this species up to the limit of its water solubility.

The table above also contains entries for other tests on *Acartia tonsa* (marine copepod), and *Skeletenoma costatum* (marine algae) performed on material known as "Olefin Isomers IV". These tests were performed by the Norwegian Institute for Water Research, and summary reports only were provided. While the test samples were isomerised olefins intended for use in drilling fluids, there is no information on the relevant molecular weight range. However, the results listed are in general accord with those of the better detailed reports, and are included in the table for completion. Similarly, a test report on the toxicity of a Syn-Teq drilling fluid containing isomerised olefins to the sediment reworker *Corophium volutator* was also submitted with the application (Orkney Water Test Centre 1994). Again the exact nature of the olefin components of the fluid were not specified, but the results are in general agreement with those of the other test on this species, and need not be discussed further.

10.2.2 Indigenous Species

Toxicity testing on three representative species indigenous to the Western Australian marine environment has also been performed, and fairly detailed summary reports also included in the application. The results of these tests are tabulated below.

10.2.2.1 Toxicity Tests on Western Australian Marine Species (Tsvetnenko YB Evans LH Gorrie J)

Test	***Species***	***Results (WAF - Nominal)***
Acute Toxicity to Marine Invertebrate	*Penaeus monodon* (Tiger prawn)	LL_{50} (96 h)>21.7 g/L NOEL (96 h) = 11.2 g/L
Acute Toxicity to Marine Copepod	*Gladioferens imparipes* (copepod)	LL_{50} (48 h) >224.2 g/L NOEL (48 h) <1.90 g/L
Alga	*Isochrysis sp.*	LL_{50} (96 h)>242.4 g/L NOEL (96 h) < 0.09 g/L

All three tests were conducted with a synthetic drilling fluid known as SYN-TEQ supplied by Baker Hughes Inteq. This material was described as "a brown-grey suspension of a solid in a liquid". The specific gravity was given as 1.244 g/cm^3, and while the content of isomerised olefins in the material was not specified, this may be assumed to be between 30 and 50%.

10.2.2.2 Decapod (Crustacean) Acute Toxicity Test (Test Method (Chapman JC Johnston NAL Nelson PF Sunderman RM Thompson GB 1993)

The tests on tiger prawn were performed with WAFs prepared with nominal concentrations of the drilling fluid of 0, 1 008, 3 359, 11 196, 37 320 and 124 400 mg/L. The WAF test media were prepared by adding the appropriate quantity of homogenised drilling fluid to seawater, and then rolling this mixture for 20-hours to allow for assimilation of the chemicals into the water. Following this mixing procedure the vessels were allowed to stand to allow for solid/liquid phase separation, and the aqueous phase removed and subsequently used for the tests. The test at each concentration was performed over a 96-hour period at a controlled temperature of 27±1ºC in duplicate using 10 prawns in each test vessel. The test was conducted using semi-static methodology with daily renewal of the test media. The pH and dissolved oxygen levels were monitored throughout the test period and were always between 7.70-8.34 and 5.4-7.9 mg/L respectively.

No significant mortality was observed over the 96 hour period for the WAF of 11 196 mg/L or lower loadings, but after 48 hours exposure to the 37 320 mg/L WAF, 45% of the animals had died although only 30% mortality was observed for the highest WAF loading of 124 400 mg/L. However, after 72-hours exposure to the 37 320 mg/L WAF 75% of test animals had died and after 96 hours exposure 90% mortality was recorded. The data was analysed using the trimmed Spearman-Karber method to give the LL_{50} of 21 700 mg/L with upper and lower 95% confidence limits of 26 530 and 17 760 mg/L, respectively. The corresponding 96-hour NOEL was 11.2 g/L, and these results indicate that the drilling fluid containing the new olefins shows slight toxicity to this species of marine invertebrate. However, since the

drilling fluid contains 30-50% of the olefins, these chemicals themselves may have a LL_{50} significantly less than 21 700 mg/L. In respect of this point, Total Organic Carbon (TOC) analysis of the test media would have been useful in improving the LL_{50} estimates, but this analytical data were not provided in the summary report.

10.2.2.3 Copepod (Crustacean) Acute Toxicity Test (Test Method (US EPA 1991)

The tests on the marine copepod were performed with WAFs prepared with nominal concentrations of the drilling fluid of 0, 1 900, 6 100, 20 600, 67 100 and 224 200 mg/L. The WAF test media were prepared as described above. The test at each concentration was performed in triplicate using between 20 and 30 animals in each vessel. The test was performed over a 48-hour period, and the pH and dissolved oxygen levels were monitored throughout the test period and were always between 7.99-8.06 and 7.5-8.0 mg/L respectively.

There was increased mortality compared with the control (which itself exhibited 4.5% deaths among the test animals after 48 hours) at all WAF loadings, and the mortality results after 48 hours were 17.8, 15.9, 23.9, 25.7 and 35.3% at the respective WAF loadings of 1 900, 6 100, 20 600, 67 100 and 224 200 mg/L. The dose – response curve is quite shallow, and the 48 hour LL_{50} for this species was consequently found to be greater than 224 400 mg/L although the 48 hour NOEL was less than 1 900 g/L. The results indicate that the test material shows some toxicity to this species, but the flat nature of the dose – response over the large WAF loading range used in the tests may indicate that there is a toxic component in the drilling fluid which is assimilated into the water at approximately the same level at all WAF loadings. In respect of this point, measurements of the TOC content of the various WAF preparations would have been helpful in clarifying the observed effects.

10.2.2.4 Alga Growth Inhibition Test (Test Method OECD TG 201)

The tests on the marine alga were performed with WAFs prepared with nominal concentrations of the drilling fluid of 0, 91, 394, 1 939, 9 697, 48 484 and 242 424 mg/L. The test protocols were those of OECD TG 201 and the WAF test media were prepared as described above. The test at each concentration was performed in triplicate over a 96 hour period at a controlled temperature of 27±1ºC. The pH was monitored at the end of the test period and was always between 8.44 and 9.09. The algal biomass was determined using chlorophyll fluorescence intensity, and slight inhibition in the rate of increase of algal biomass was observed at all WAF loadings. However, this never exceeded 11.75 % and furthermore, showed no correlation with the WAF loading of the test media. The conclusion from these results is that the drilling fluid containing the new chemical has a 96 hour LL_{50} > 242 424 mg/L, and is consequently not toxic to this species of marine algae up to the limit of its water solubility. However, the 96-hour NOEL was less than 90 mg/L, which indicates that some toxic material appears to be present in the WAF preparations. As above, data on the TOC content of the WAFs would have been helpful in interpreting the results.

Overall, the results of the three tests on indigenous species do not indicate that the local species are any more or less sensitive to the notified chemical than are their Northern Hemisphere counterparts. It is difficult to draw more definite conclusions due to the differences in composition between the materials employed in the various tests.

10.3 Summary of Ecotoxicity Data

The results for the variety of ecotoxicity tests submitted with the notification indicate that the chemicals used in the tests are generally non-toxic to both fresh water and marine organisms up to the limits of their water solubilities. Some toxic effects were observed when daphnia, freshwater green alga, marine invertebrates were exposed to high concentrations of the test substances. In particular some toxic effects were also observed for the Western Australian species *Gladioferens imparipes* and *Isochrysis sp* when these were tested against a drilling fluid containing the notified chemical. However, it could not be ascertained whether these effects were due to toxicity imparted to the test media by the new olefin chemicals or by other components of the drilling fluid. It is also possible that these effects were due to physical factors rather than chemical toxicity.

Gulftene 14 (together with others notified as NA/713, NA/714, NA/728 and NA/729) may be used in oil drilling activities off the coast of Western Australia, an area host to a range of marine ecosystems having both ecological and economic importance. The available data indicates that the Australian marine species likely to be exposed to the notified chemical do not appear to be particularly sensitive to drilling fluids containing the notified chemical. However, the material may exhibit some toxicity to tiger prawns, and although the LL_{50} for both marine copepod and marine alga are greater than 10 000 mg/L some toxic effects on survival and growth rate were noted even at the lowest WAF loadings tested.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Gulftene 14 is a mixture of isomerised olefins used as a component of drilling fluids in off shore drilling operations for oil and natural gas. Almost all of the new chemical will be released to the marine environment as a result of disposal with waste drill cuttings. Gulftene 14 may comprise up to 10% of the weight of the drilling waste, which is likely to form piles on the sea floor under the drilling platforms. Overall, the notifier has indicated that up to 700 tonnes of Gulftene 14 may be released each year from drilling operations off the Australian coast. It is probable that four to five platforms may use drilling fluids containing Gulftene 14, each of which could release around 150 tonnes of the chemical each year. In calm sea conditions a small amount (not possible to quantify) of the chemical may form a “slick” on the water surface. This is expected to slowly evaporate to atmosphere degrade through reactions with hydroxyl radicals, with an initial degradation half-life in the vicinity of seven hours.

Most of the new chemical would ultimately become associated with benthic sediments. It is possible that 10 000 to 30 000 tonnes of drill cuttings may accumulate under a given platform, which could contain 1 000 to 3 000 tonnes of drilling fluid, including Gulftene 14. It is possible that this material would be spread over a relatively wide area of sea floor around each drilling platform. However, no details on this area were provided. In respect of this point, it is relevant to note that during the operational life of a drilling platform the cuttings usually remain in a mound directly below the platform, and to some degree are “shielded” from the dispersive effects of marine storms and currents by the platform itself. However, on decommissioning and removal of the platforms this protection is removed, allowing for much wider dispersal of the waste cuttings and the associated drilling fluid (Cobby 1999).

Marine sediments may be either aerobic or anaerobic and while Gulftene 14 is biodegradable under aerobic conditions, the available data from tests and from the literature indicates that it is also likely to be biodegradable under anaerobic conditions. However, the results are variable and anaerobic degradation in benthic marine sediments may be a relatively slow process due to factors such as low temperature and low density of bacteria. Biodegradation can only occur in the presence of adequate populations of bacteria, and since the conditions in the interior of piles of drill cuttings may not be conducive to the sustainability of such populations (eg through lack of appropriate nutrients), biodegradation may be very slow.

Under aerobic conditions, and assuming that the waste cutting pile can sustain a population of appropriate bacteria, the compounds will biodegrade to water and carbon dioxide. Under anaerobic conditions biodegradation will produce water, methane, carbon monoxide and carbon dioxide.

Gulftene 14 is very hydrophobic, and while the water solubility is very low, there is potential for bioaccumulation. Tests on the bio-concentration of the C16-18 alkene in blue mussel indicate a bio-concentration factor of 12 600 to 251 000. Given that the rate of biodegradation of the material may be very slow, there is potential for significant bioaccumulation in exposed organisms.

An extensive series of ecotoxicology tests have established that chemicals, which are close congeners of Gulftene 14, are generally non-toxic to both fresh water and marine organisms. However, some toxic effects have been observed when certain organisms are exposed to very high concentrations of the chemicals. These effects may be physical in origin. The drill cuttings may contain up to 10% of Gulftene 14, and it is conceivable that toxic levels could be exceeded in piles of drill wastes, or in the vicinity of these piles.

When used as a component of drilling fluid on off shore drilling, the available data indicates that Gulftene 14 may present a hazard to the marine environment when it is discarded with waste drill cuttings. In particular, there are uncertainties surrounding issues of biodegradation, bioaccumulation and ecotoxicity at the likely high exposure levels. Further, it is to be noted that the physical, chemical and biological processes occurring in deposits of marine drill cuttings are not well understood, and it is only recently that appropriate techniques for examination of the spoil piles have been developed (Black 1999). Consequently, while the present environmental hazard assessment has been based on all presently available data, it is possible that future studies may indicate other factors which should be considered in evaluating the environmental hazard of discarded organic based drilling fluids.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

For Gulftene 14, toxicological investigations on a range of analogous alkenes (C12, C14, C16 & C18 alpha olefins; a blend of C12-C16 alpha olefins; C16 & C18 internal alkenes; and C20-C24 branched and linear alkenes) have been made available this present review.

Analogue alkenes have very low acute oral, dermal and inhalation toxicity. They are slight eye irritants, but not sensitising to skin. Kinematic viscosity measurements, including that for Gulftene 14, and investigations of aspiration potential in rats on a range of alkenes indicates that these alkenes present as an aspiration hazard.

In acute skin irritation tests, analogue alkenes (except C20-C24 branched and linear alkenes) caused prolonged slight or slight to moderate skin irritation associated with desquamation. Repeat dermal application of C12-C16, C16-C18, or C16 caused severe skin irritation.

Repeated oral dose studies show that C20-24 alkenes branched and linear at high doses target the liver and adrenals. 1-Tetradecene at high doses also targets the liver and in male rats the kidney (hydrocarbon nephropathy – not relevant to human health). These alkenes are not neurotoxic, do not produce adverse effects on reproduction or foetal development and are not genotoxic.

Assessment of the toxicological data of the alkene analogues against the NOHSC *Approved Criteria for Classifying Hazardous Substances*, indicate that Gulftene 14 would be considered hazardous based on potential aspiration hazard and skin drying effects. The overall hazard classification is Harmful (Xn) and the following risk phrase and safety phrases relevant to health effects:

R65 – May Cause Lung Damage if Swallowed;
R66 – Repeated Exposure May Cause Skin Dryness or Cracking;
S24/25 – Avoid Contact with Skin and Eyes;
S28 – After contact with skin, wash immediately with plenty of soap and water; and
S62 – If swallowed, do not induce vomiting: seek medical advice immediately and show this MSDS/label.

Occupational Health and Safety
Occupational exposure may occur during preparation of drilling fluid, manipulation of contaminated drill bits and associated equipment and recycling of import containers. Gulftene 14 is viscous and has low vapour pressure. Consequently, inhalation is not considered a significant route of exposure under normal use conditions. Eye and skin contact is expected to be the main route of exposure. Gulftene 14 has low molecular weight, low water solubility and is lipophilic. The possibility of skin absorption through normal intact skin cannot be excluded. Furthermore, skin irritation and skin dryness may compromise the skin's barrier function and subsequent exposure of damaged skin may promote skin penetration of the notified chemical.

During drilling fluid preparation and use and container recycling, Gulftene 14 will be handled in a manner that is automated/mechanised, intermittent and non-dispersive, with workers required to wear personal protective equipment, namely impervious protective clothing,

safety glasses with eye shields and nitrile, Viton, polyurethane, or chlorinated polyethylene gloves. In view of the frequency of contact, pattern of use and control measures, eye and skin contact is expected to be minimal and the risk of adverse health effects arising from the use of Gulftene 14 is expected to be low. Aspiration into the lung after oral ingestion is a potential hazard; however, ingestion is not an expected route of occupational exposure.

During import and transport of Gulftene 14 or prepared drilling fluid, there is unlikely to be any worker exposure, except in the event of a spill. Exposure after a spill would be controlled by use of the recommended practices for spillage clean up given in the MSDS supplied by the notifier.

Public Health
Public contact will only occur following accidental exposure from a spill or with contact with water containing the notified chemical following cleaning of empty drums. Consequently, the potential for public exposure to the notified chemical during all phases of its life cycle is considered to be low. Based on the above, it is considered that Gulftene 14 will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

13.1 Occupational Health and Safety Matters

To minimise occupational exposure to Gulftene 14 the following guidelines and precautions should be observed:

- Workers should receive regular instruction on good occupational hygiene practices in order to minimise personal contact, and contamination of the work environment with Gulftene 14 and the formulations that contain it.

- Workers should be advised of the potential for occupational dermatoses following repeated skin exposure to Gulftene 14 and to report any skin changes to the occupational health and safety officer at their workplace. When an occupational skin disease occurs, the employer should review work practices and opportunities for contact with the substance and instigate preventive measures to ensure other workers do not develop the same condition. Further guidance on preventing the occurrence of occupational skin diseases can be found in the NOHSC guide *Occupational Diseases of the Skin* (NOHSC 1990).

- Personal protective equipment (PPE) should be used on all occasions where exposure to Gulftene 14 and the formulations that contain it occurs. The notifier recommends Nitrile, Viton, polyurethane, or chlorinated polyethylene gloves. Where exposure to airborne material may occur an organic vapour (Type A) filter respirator should be used. Chemical impervious clothing is necessary to prevent skin contact - consideration should be given to the ambient environment, physical requirements and other substances present when selecting protective clothing. Workers should be trained in the proper fit, correct use and maintenance of their protective gear. PPE Guidance in the selection, personal fit and maintenance of personal protective equipment can be obtained from:

Respiratory Protection	AS 1715 (SAA/SNZ 1994);
	AS 1716 (SAA/SNZ 1994);
Protective eyewear:	AS 1336 (SAA 1994)
	AS/NZS 1337 (SAA/SNZ 1992).
Chemical impermeable clothing:	AS 3765.2 (SAA 1990).
Impermeable gloves:	AS 2161.2 (SAA/SNZ 1998).
Occupational footwear:	AS/NZS 2210 (SAA/SNZ 1994).

- Workplace practices and control procedures consistent with provisions of State, Territory and Commonwealth legislation based on the *National Model Regulations for the Control of Workplace Hazardous Substances* must be in operation if products containing Gulftene 14 are determined to be hazardous.

- Gulftene 14 is identified as a Class 1 combustible liquid and should be stored, handled and used in accordance with AS 1940 (SAA 1993);

- Spillage of Gulftene 14 should be avoided. Spillages should be cleaned up promptly and in accordance with the instructions on the notifiers MSDS;

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

13.2 Environmental Matters

This assessment report is to be included in environmental management submissions where required under Commonwealth, State, or Northern Territory Petroleum (Submerged Lands) legislation.

14. MATERIAL SAFETY DATA SHEET

The MSDS for Gulftene 14 was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under subsection 64(1) of the Act the notifiers are to advise the Director within 28 days of the availability of data on the toxicity of formulated drilling fluid containing Gulftene 14 generated to meet Petroleum (Submerged Lands) legislation adopted by the Commonwealth, States, or the Northern Territory.

Under subsection 64(2) of the Act Secondary notification of Gulftene 14 shall also be required if any of the circumstances stipulated arise. This includes, in particular, if Gulftene 14 is used in an application other than as a component of drilling fluid for offshore drilling operations.

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Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	3 severe	Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage gross destruction	2 severe