

ULTRA PROTECT SPF50+ SUNSCREEN WITH INSECT REPELLENT Concept Laboratories

Chemwatch: 5469-63 Version No: 2.1.5.2

Safety Data Sheet according to WHS Regulations (Hazardous Chemicals) Amendment 2020 and ADG requirements

Chemwatch Hazard Alert Code: 2

Issue Date: 02/06/2021 Print Date: 02/06/2021 S.GHS.AUS.EN

SECTION 1 Identification of the substance / mixture and of the company / undertaking

Product Identifier

Product name	ULTRA PROTECT SPF50+ SUNSCREEN WITH INSECT REPELLENT
Chemical Name	Not Applicable
Synonyms	Not Available
Chemical formula	Not Applicable
Other means of identification	Not Available

Relevant identified uses of the substance or mixture and uses advised against

	Sunscreen. Follow on pack instructions.
Relevant identified uses SDS are intended for use in the workplace. For domestic-use products, refer to consumer labe	
	Use according to manufacturer's directions.

Details of the supplier of the safety data sheet

Registered company name	Concept Laboratories
Address	2 /20 Premier Circuit Warana QLD 4575 Australia
Telephone	+617 5437 9303
Fax	+617 5437 9553
Website	http://www.conceptlabs.com.au/
Email	Not Available

Emergency telephone number

Association / Organisation	Concept Laboratories	CHEMWATCH EMERGENCY RESPONSE
Emergency telephone numbers	13 11 26	+61 2 9186 1132
Other emergency telephone numbers	Not Available	+61 1800 951 288

Once connected and if the message is not in your prefered language then please dial 01

SECTION 2 Hazards identification

Classification of the substance or mixture

HAZARDOUS CHEMICAL. NON-DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.

ChemWatch Hazard Ratings

	Min	Max	
Flammability	0		
Toxicity	0		0 = Minimum
Body Contact	2	1	1 = Low
Reactivity	0		2 = Moderate
Chronic	2	1	3 = High 4 = Extreme

Poisons Schedule	Not Applicable
Classification ^[1]	Eye Irritation Category 2A, Acute Aquatic Hazard Category 3, Chronic Aquatic Hazard Category 3
Legend:	1. Classified by Chernwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

Label elements

Hazard pictogram(s)



Signal word	Warning	
Hazard statement(s)		
H319	Causes serious eye irritation.	
H412	Harmful to aquatic life with long lasting effects.	
Precautionary statement(s) Ge	neral	
P101	If medical advice is needed, have product container or label at hand.	
P102	Keep out of reach of children.	
P103	Read carefully and follow all instructions.	
Precautionary statement(s) Pre	evention	
P273	Avoid release to the environment.	
P280	Wear protective gloves, protective clothing, eye protection and face protection.	
Precautionary statement(s) Re	sponse	
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	
P337+P313	If eye irritation persists: Get medical advice/attention.	
Precautionary statement(s) Storage Not Applicable		
Precautionary statement(s) Dis	sposal	
P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.	
SECTION 3 Composition / ir	nformation on ingredients	

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
113-48-4	5-<10	2-ethylhexyl bicycloheptene dicarboximide
134-62-3	5-<10	N.N-diethyl-m-toluamide
6197-30-4	1-<5	octocrylene
38102-62-4	1-<5	3-(4-methylbenzylidene)camphor
61791-14-8	1-<5	cocoamine, ethoxylated
Not Available	balance	Ingredients determined not to be hazardous
Not Available		includes
7732-18-5	30-60	water
Legend:	1. Classified by Chernwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 4. Classification drawn from C&L * EU IOELVs available	

SECTION 4 First aid measures

Description of first aid measures

Eye Contact	 If this product comes in contact with the eyes: Wash out immediately with fresh running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	 If skin contact occurs: Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
Inhalation	 If fumes, aerosols or combustion products are inhaled remove from contaminated area. Other measures are usually unnecessary.
Ingestion	 If swallowed do NOT induce vomiting. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Seek medical advice.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Firefighting measures

Extinguishing media

The product contains a substantial proportion of water, therefore there are no restrictions on the type of extinguishing media which may be used. Choice of extinguishing media should take into account surrounding areas

Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances. In such an event consider:

- foam.
- dry chemical powder.
- carbon dioxide.

Special hazards arising from the substrate or mixture Fire Incompatibility None known.

Advice for firefighters	
Fire Fighting	 Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. Use fire fighting procedures suitable for surrounding area. DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.
Fire/Explosion Hazard	 The material is not readily combustible under normal conditions. However, it will break down under fire conditions and the organic component may burn. Not considered to be a significant fire risk. Heat may cause expansion or decomposition with violent rupture of containers. Decomposes on heating and may produce toxic fumes of carbon monoxide (CO). May emit acrid smoke. Decomposes on heating and produces toxic fumes of: carbon dioxide (CO2) nitrogen oxides (NOx) other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes.
HAZCHEM	Not Applicable

SECTION 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	 Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Contain and absorb spill with sand, earth, inert material or vermiculite. Wipe up. Place in a suitable, labelled container for waste disposal.
Major Spills	 Moderate hazard. Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves. Prevent, by any means available, spillage from entering drains or water course. Stop leak if safe to do so. Contain spill with sand, earth or vermiculite. Collect recoverable product into labelled containers for recycling. Neutralise/decontaminate residue (see Section 13 for specific agent). Collect solid residues and seal in labelled drums for disposal. Wash area and prevent runoff into drains. After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using. If contamination of drains or waterways occurs, advise emergency services.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage

Precautions for safe handling	
Safe handling	 Limit all unnecessary personal contact. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Avoid contact with incompatible materials. When handling, DO NOT eat, drink or smoke. Keep containers securely sealed when not in use. Avoid physical damage to containers.

	 Always wash hands with soap and water after handling. Work clothes should be laundered separately. Use good occupational work practice. Observe manufacturer's storage and handling recommendations contained within this SDS. Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.
Other information	 Store in original containers. Keep containers securely sealed. No smoking, naked lights or ignition sources. Store in a cool, dry, well-ventilated area. Store away from incompatible materials and foodstuff containers. Protect containers against physical damage and check regularly for leaks. Observe manufacturer's storage and handling recommendations contained within this SDS.

Conditions for safe storage, including any incompatibilities

······································	······································	
Suitable container	 Polyethylene or polypropylene container. Packing as recommended by manufacturer. Check all containers are clearly labelled and free from leaks. 	
Storage incompatibility	 Avoid reaction with oxidising agents, bases and strong reducing agents. Avoid strong acids, acid chlorides, acid anhydrides and chloroformates. 	

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Not Available

Emergency Limits

Ingredient	TEEL-1	TEEL-2		TEEL-3
ULTRA PROTECT SPF50+ SUNSCREEN WITH INSECT REPELLENT	Not Available	Not Available		Not Available
Ingredient	Original IDLH		Revised IDLH	
2-ethylhexyl bicycloheptene dicarboximide	Not Available		Not Available	
N,N-diethyl-m-toluamide	Not Available		Not Available	
octocrylene	Not Available		Not Available	
3-(4-methylbenzylidene)camphor	Not Available		Not Available	
cocoamine, ethoxylated	Not Available		Not Available	
water	Not Available		Not Available	

11			
L	Occupational	Exposure	Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
2-ethylhexyl bicycloheptene dicarboximide	E	≤ 0.1 ppm
N,N-diethyl-m-toluamide	E	≤ 0.1 ppm
octocrylene	E	≤ 0.1 ppm
3-(4-methylbenzylidene)camphor	E	≤ 0.01 mg/m³
cocoamine, ethoxylated	E	≤ 0.1 ppm
Notes:	Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a	

range of exposure concentrations that are expected to protect worker health.

Exposure controls

Appropriate engineering controls	General exhaust is adequate under normal operating conditions.
Personal protection	
Eye and face protection	 No special equipment for minor exposure i.e. when handling small quantities. OTHERWISE: Safety glasses with side shields. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]

Hands/feet protection	No special equipment needed when handling small quantities. OTHERWISE: Wear general protective gloves, e.g. light weight rubber gloves.
Body protection	See Other protection below
Other protection	No special equipment needed when handling small quantities. OTHERWISE: • Overalls. • Barrier cream. • Eyewash unit.

Respiratory protection

Type AK-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

- Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content.
- The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.
- Cartridge performance is affected by humidity. Cartridges should be changed after 2 hr of continuous use unless it is determined that the humidity is less than 75%, in which case, cartridges can be used for 4 hr. Used cartridges should be discarded daily, regardless of the length of time used

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Smooth, white glossy lotion with a characteristic odour; mixes with water.		
Physical state	Liquid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	6-7	Decomposition temperature	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Miscible	pH as a solution (%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	 Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

Information on toxicological effects

Inhaled	The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
Ingestion	Accidental ingestion of the material may be damaging to the health of the individual. Swallowing DEET has caused irritability, bizarre movements, depressed muscle stretch reflex, low blood pressure, seizures and coma. Toxic doses in rats have produced excessive tear secretion, shedding of bloody tears, depression, tremors, coma and convulsions before death.
Skin Contact	Not considered an irritant through normal use. Discontinue use if irritation occurs
Eye	This material can cause eye irritation and damage in some persons.

ULIKA PROTECT SPF50+	TOXICITY	IRRITATION
SUNSCREEN WITH INSECT REPELLENT	Not Available	Not Available
	ΤΟΧΙΟΙΤΥ	IRRITATION
2-ethylhexyl bicycloheptene	dermal (rat) LD50: >5000 mg/kg ^[1]	Eye: no adverse effect observed (not irritating) ^[1]
dicarboximide	Inhalation(Rat) LC50; 1.94 mg/l4h ^[1]	Skin: no adverse effect observed (not irritating) ^[1]
	Oral(Rat) LD50; 5000 mg/kg ^[1]	
	ΤΟΧΙΟΙΤΥ	IRRITATION
N N disting as to becoming	dermal (mouse) LD50: 3157.32 mg/kg ^[2]	Eye (rabbit) : 10 mg - moderate
N,N-diethyl-m-toluamide	Oral(Mouse) LD50; 1170 mg/kg ^[2]	Eye (rabbit): 100 mg
		Skin (rabbit): 500 mg - moderate
	ΤΟΧΙΟΙΤΥ	IRRITATION
octocrylene	dermal (rat) LD50: >2000 mg/kg ^[1]	Eye : Not irritating
	Oral(Rat) LD50; >5000 mg/kg ^[1]	Skin : Not irritating
	ΤΟΧΙϹΙΤΥ	IRRITATION
-(4-methylbenzylidene)camphor	dermal (rat) LD50: >5000 mg/kg ^[2]	Eye: no adverse effect observed (not irritating) ^[1]
	Oral(Dog) LD50; >5000 mg/kg ^[2]	Skin: no adverse effect observed (not irritating) $\!\!\!\![^{1]}$
	ΤΟΧΙΟΙΤΥ	IRRITATION
cocoamine, etnoxylated	Oral(Rat) LD50; 750 mg/kg ^[2]	Eye (rabbit): 100 mg - moderate
	ΤΟΧΙϹΙΤΥ	IRRITATION
water	Oral(Rat) LD50; >90000 mg/kg ^[2]	Not Available
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

2-ETHYLHEXYL BICYCLOHEPTENE DICARBOXIMIDE	MGK-264 affects the liver cells and causes benign tumours of the liver and thyroid, and has been identified as possibly causing cancer in humans. At higher doses, MGK-264 may reduce viability of offspring. It did not affect reproductive performance. It is of low concern regarding mutations or genetic toxicity. It appears to be absorbed and excreted with little breakdown product retained.
N,N-DIETHYL-M-TOLUAMIDE	For N,N-diethyl-m-toluamide (Deet) Acute toxicity: Different preparations of Deet with different proportions of the m-isomer produced different oral LD50s. Rats killed by dosages in the LD50 range showed lacrimation, chromodacryorrhea, depression, prostration, tremors, and asphyxial convulsions. Respiratory failure usually preceded cardiac failure. In rabbits, an intravenous dosage of 75 mg/kg was rapidly fatal, but 50 mg/kg was not. Five doses at the rate of 25 mg/kg/day produced no cumulative effect, except for injury of the initima of some veins used for injection. Single dermal application to rabbits at rates of 2 or 4 ml/kg produced no systemic effect, but did produce mild to moderate erythema. Repeated dermal application of 50% solutions for 13 weeks at the rate of 2 ml/kg/day produced no evidence of systemic toxicity but did produce desquamation, coriaceousness, dryness, and fissuring in the same species. Except for some scarring, these lesions cleared within 3 weeks. Instillation of Deet into the eyes of rabbits produced mild to moderate edema of the nictitating membrane, lacrimation, conjunctivitis, and some corneal injury, as revealed by fluorescein staining. After 5 days, all eyes appeared normal. No sensitisation was seen in guinea pigs . Animals topically exposed to Dee thave developed dermal and ocular reactions. Dermal effects including erythema, desquamation and scarring in rabbits and profuse sweating, irritation and exfoliation in horses have been reported following repeated applications of Deet at a concentrations of 50 percent or greater. Direct ocular application of either diluted (30 or 40 percent Deet) or undiluted Deet in rabbits has produced edema, tearing, conjunctivitis, pus and clouding in the eyes. Repeated dermal application in humans of insect repellents containing Deet can produce a variety of skin reactions in humans. Cases of localized skin irritation, large painful bisters and permanent scarring of skin at the crease of the elbow have been reported in soldiers

microscopic changes. One child was reported to be heterozygous for ornithine carbamoyl transferase deficiency (a sex linked enzyme deficiency which may produce effects similar to those reported above) and it has been hypothesised that children with this enzyme disorder may be at greater risk of adverse reactions to Deet. This enzyme deficiency which usually causes infant death in males is of variable severity in females. Accidental and deliberate ingestion of Deet-containing products has produced neurotoxic effects similar to those described following dermal exposure .

Generalised seizures have also been temporally associated with the use of Deet-containing insect repellent on skin. These cases differ from those described above in that they involved males (four boys aged 3-7 years and one 29-year-old adult), had few associated neurotoxic effects and resolved rapidly. Lower exposure to Deet in these males (four of five males had either one or two dermal applications) may have accounted for the effects being less severe than in females. That the majority of identified neurotoxic cases involved children raises concerns that this subpopulation is at greater risk of adverse reaction following exposure to Deet than are adults.

Signs and symptoms of more subtle neurotoxicity have also been associated with extensive dermal application of Deet in adults. Questionnaire results indicate that Everglades National Park employees having extensive Deet exposure were more likely to have insomnia, mood disturbances and impaired cognitive function than were lesser exposed co-workers. A young male who repeatedly applied Deet to his skin prior to spending prolonged periods in a sauna was reported to develop acute manic psychosis characterized by aggressive behavior, delusions and hyperactivity.

Either o-DET or p-DET, or both occur as impurities in commercial m-DET (Deet). A thorough study of the o-and p-isomers showed that the o-isomer is slightly more toxic than the others (oral LD50 1,210 mg/kg in rats). However, no alarming difference was found, and it was concluded that the presence of 5% of o-DET or p-DET as impurities in the

Chronic toxicity: When rats were fed Deet at a dietary level of 10,000 ppm for about 200 days, their growth rate was decreased without a decrease in food intake. There was a significant increase in the relative weight of the testes and liver in males, of the liver and spleen in females, and the kidneys of both males and females. Some of these changes were seen in lesser degree at a dietary level of 1,000 ppm. No gross or significant histological changes were seen at any dietary level and no changes of any kind were noted at 100 ppm or 500 ppm (about 25 mg/kg/day).

Essentially identical results were found in other subacute dermal and feeding studies each carried out on rats, rabbits, and dogs. In
hese oral studies, 2,000 ppm proved to be a no-effect-level. Oral administration of Deet to dogs at rates of 100 and 300 mg/kg/day
caused tremor and hyperactivity and occasional vomiting, but no other effects. Blood studies (hemoglobin, haematocrit, sedimentation
ate, platelet counts, total and differential white cell counts) on dogs receiving 300 mg/kg orally or dermally or on rabbits receiving 300
ng/kg dermally revealed no effect on the haematopoietic system. Gross and microscopic examination of the organs of all three species
revealed only slight kidney damage in rabbits typical of that associated with burns of the skin. Thirteen other organs, including liver,
spleen, and bone marrow, were normal in the three species .

No systemic toxicity was observed in rats exposed 8 hours/day, 5 days/week for 7 weeks to air saturated with Deet. No toxic effects were observed in rats exposed for 6 hours to an aerosol of Deet. No gross or significant histological changes were seen . **Organ Toxicity:** Hypertrophy of the kidneys and liver and effects of mild central nervous system stimulation including tremors and hyperactivity were noted in animals following repeated exposure. Significant testicular hypertrophy was observed in male rats repeatedly fed a diet containing from 48 to 531 mg/kg/day of Dee

Reproductive Effects: When Deet was applied to the skin of rats at the rate of 1,000 mg/kg/day throughout pregnancy, implantation was reduced significantly. Prenatal mortality was 34.1%, compared with 20.9% in the control. Mortality between birth and weaning was 44.0%, compared to 15.7% in the control. Injury was less (but probably significant) at a dosage of 100 mg/kg/day throughout pregnancy.

Teratogenic Effects: A dermal teratology study was conducted on rabbits. Groups of 20 pregnant rabbits received daily dermal applications of 0, 50, 100, 500, 1000, or 5000 mg Deet/kg/day in ethanol on shaved backs from day 0 through day 29 of gestation. There were no significant differences between control and treated animals with respect to the fertility index, number of implantations per animal, or number of fetuses per animal. In addition, treatment did not change fetal weight, fetal length or placental weights and no increases in the incidence of skeletal or soft issue anomalies were observed in treated groups when compared with untreated controls. This study demonstrated that Deet has no teratogenic or embryotoxic effects in rabbits exposed dermally to technical Deet. An additional supplementary teratology study was conducted on rats. Groups of 20 pregnant rats were daily administered 10 ml of peanut oil containing 0, 8, 20 or 80 mg/kg/Deet by gavage from day 5 through day 15 of gestation. No significant differences were reported between control and treated mothers with respect to fertility, fetuses per animal. In addition, a related increase was observed in the number of resorptions per dam

Carcinogenicity: Researchers fed Deet to male and female rats in the diet for two years at doses of 10, 30, or 100 mg/kg/day, and 30, 100, or 400 mg/kg/day, respectively. Researchers fed mice 250, 500, or 1,000 mg/kg/day for 18 months, and dogs 30, 100, or 400 mg/kg/day. No specific target organ toxicity or oncogenicity was observed in any of the animals.Researchers often use studies designed to test for mutagenicity to screen chemicals for carcinogenicity. Sufficient evidence indicates that DEET does not have significant potential for mutagenicity

Fate in Humans and Animals: Deet is absorbed promptly from the skin and distributed to all organs including the brain and the foetus. The compound is excreted in the milk but primarily in the urine

Reproductive effector in rats

 OCTOCRYLENE
 Where no "official" classification for acrylates and methacrylates exists, there have been cautious attempts to create classifications in the absence of contrary evidence. For example

 Monalkyl or monoarylesters of acrylic acids should be classified as R36/37/38 and R51/53
 Monoalkyl or monoarylesters of methacrylic acid should be classified as R36/37/38

 Based on the available oncogenicity data and without a better understanding of the carcinogenic mechanism the Health and Environmental Review Division (HERD), Office of Toxic Substances (OTS), of the US EPA previously concluded that all chemicals that contain the acrylate or methacrylate moiety (CH2=C(CH3)COO) should be considered to be a carcinogenic hazard unless shown otherwise by adequate testing.

This position has now been revised and acrylates and methacrylates are no longer *de facto* carcinogens. No mutagenic and teratogenic properties * Esperis MSDS

The following information refers to contact allergens as a group and may not be specific to this product.

Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.

3-(4-METHYLBENZYLIDENE)CAMPHOR

Animal testing shows that 3-(4, -methylbenzylidene)camphor [abbreviated to MBC] can affect thyroid gland function. It has not been shown to cause skin irritation or sensitisation, birth defects or genetic damage. However, as thyroid disturbances such as goitre are in general associated with an increased risk of thyroid cancer, the use of 4-MBC should be of concern and any thyroid disturbances should be treated with great caution.

The toxicological evaluation is on the UV-filter 3-2 benzylidenebornan-2-one (3-BC) have been reported. (Scientific Committee on Consumer Safety (SCCS); June 2013 Acute oral toxicity is low

Irritation/Sensitisation Tests for primary irritation of the skin and for irritation of the skin on repeated administration show only

	slight effects at 6%. Tests for photo-toxicity and for photo-sensitisation were negative, although a positive control was not used for
	the latter, Repeated dose toxicity One 6 week oral study in the rat showed dose related increases in plasma triiodothyronine in males, significant at 50 mg/kg bw/day, and in plasma thyroxine in females, significant at 28 25 and 50 mg/kg bw/day. In two 90 day oral toxicity studies in the rat, elevated plasma lipids were observed in 30 female rats at doses as low as 20 mg/kg bw/day, although this was not statistically significant at this dose. No NOAEL can be derived from these experiments. Reproductive toxicity . In a teratogenicity study in rats, embryo-toxicity was observed at 50 mg/kg bw/day and above was observed. The observed major external/visceral abnormalities (at 100 and 150 mg/kg bw/day), most plausibly result from retarded development and in utero pressure (the finding of retarded ossification is in line with this hypothesis). The development of these effects may be associated with the maternal toxicity. The NOAEL for maternal toxicity and embryo-toxicity this study is 15 mg/kg
	bw/day. This value was used for the margin of safety (MOS) calculation. Endocrine activity In some studies, effect of 3-BC on rats sexual behaviour and oestrous cycle at low doses (2.4 and 7 mg/kg body weight/day) were reported. These effects may be due to endocrine activity of 3-BC. Multiple hormonal activities of 3-BC have indeed been reported in vitro: estrogenic and anti-estrogenic effects as well as anti-androgenic activities. 3-BC was not found to exhibit androgenic activity. In vivo, the expression of target genes (ERalpha, ERbeta, SRC-1 and PR (progesterone receptor)) has been shown to be altered (increased or reduced, depending on the anatomical brain area) in both males and females rats at all 1 doses (0.24, 0.7, 2.4 and 7 mg/kg body weight/day).
	The SCCS considers that the use of 3-benzylidene-camphor as a UV-filter 20 in cosmetic products in a concentration up 2.0% is not
	sare Concerning the potential endocrine disruptor properties of 3-BC, multiple hormonal activities of 3-BC have been reported in vitro: estrogenic and anti-estrogenic effects as well anti-androgenic activities. In vivo, the expression of target genes (ERalpha, ERbeta, SRC-1 and PR (progesterone receptor)) has been shown to be altered in both males and females rats at doses lower than the NOAEL used to calculate the MOS. Due to some shortcomings in the studies, the results need to be confirmed. The French Agency, Agence française de sécurité sanitaire des produits de santé (AFSSAPS) states that the hazard characterisation for this substance is considered incomplete. In addition, the no observed adverse effect level (NOAEL) and the cutaneous absorption rate used by the AFSSAPS in connection with the risk assessment results in insufficient margin of safety to ensure consumer safety in accordance with the SCCS's notes of guidance. Finally, as endocrine disruption effects were observed in the studies published 28 in the scientific literature, in the current state of knowledge, the French authorities consider 29 that it is not possible to conclude that there is no risk to human.
	Alkyl amine polyalkoxylates are not acutely toxic by the oral and dermal routes of exposure, or via inhalation under normal use conditions. Concentrated materials are generally corrosive, eye and skin irritants and may be dermal sensitizers. There is no evidence that alkyl amine polyalkoxylates are neurotoxic, mutagenic, or clastogenic.
	surfactants are often corrosive and irritating in concentrated solutions, as indicated by the acute toxicity studies for these inert materials. It is possible that some of the observed toxicity seen in the repeated studies, such as diarrhea or decreased body weight gain, can be attributed to the corrosive and irritating nature of these surfactants. Generally, lower molecular weight AAPs (lower carbon chain units and less alkoxylation) may potentially be more bioavailable because they may be more easily absorbed and distributed than higher molecular weight compounds. Thus overall, the longer chain carbon amine higher polyalkoxylates should be less bioavailable. There are no dermal absorption data on the AAPs. However, data on functionally and structurally similar surfactants suggest that
	dermal absorption of the AAPs is likely to be low. Following subchronic exposure to rats, some gastrointestinal irritation was observed, but no specific target organ toxicity or neurotoxicity was seen. In subchronic studies in rats and/or dogs, the most sensitive effects noted were increased mortality, clinical signs (salivation, wheezing, emesis, and/or soft faeces), cataracts, cellular changes in the stomach, and liver effects characterized by enzyme induction, and pigment accumulation in Kupffer cells and bile canaliculi. There was no increased susceptibility to the offspring of rats following in utero exposure in two prenatal developmental toxicity studies. However, there is evidence of increased susceptibility in a reproductive screening study in rats. In rat developmental studies, no adverse fetal effects were seen, even at maternally toxic doses. No effects were observed on estrous cyclicity, spermatogenic endpoints, or testosterone and thyroid levels in a two-generation rat reproduction study. However, reproductive
	and offspring toxicity were noted for AAPs based on litter loss, increase mean number of unaccounted-for implantation sites and decreased mean number of unaccounted-for implantation sites and
COCOAMINE, ETHOXYLATED	Very little metabolism information is available for the alkyl amine polyalkoxylates. However, it is possible to predict mammalian metabolism based on studies for the alkyl alcohol alkoxylates, which are another class of surfactants. It has been proposed that the primary metabolic pathway involves the excretion of the polyalkoxylate moiety and conversion of the alkyl amine group to a fatty acid that is then converted via oxidative degradation to carbon dioxide and water. In general, the gastrointestinal absorption of AAPs with relatively short alkoxylate chain lengths is expected to be rapid and extensive, while less absorption is likely for the more extensively
	polyalkoxylated AAPs with larger molecular weights. No structural alerts for potential carcinogenicity of both a representative alkyl amine polyalkoxylate, as well as a possible metabolite/degradate of alkyl amine polyalkoxylate that had been extensively dealkylated, with the amine group intact have been identified Alkyl amine polyalkoxylates are not expected to be carcinogenic. Therefore a cancer dietary exposure assessment is not necessary to assess cancer risk.
	amine polyalkoxylates do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that alkyl amine polyalkoxylates do not have a common mechanism of toxicity with other substances
	Alkyl Amine Polyalkoxylates (JITF CST 4 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations. June 2009 http://beta.regulations.gov/document/EPA-HQ-OPP-2008-0738-0005
	with R38 and R41. Laboratory testing shows that the fatty acid amide, cocoamide DEA, causes occupational allergic contact dermatitis, and that allergy to
	this substance is becoming more common. Alkanolamides are manufactured by condensation of diethanolamine and the methyl ester of long chain fatty acids. Polyethers (such as ethoxylated surfactants and polyethylene glycols) are highly susceptible to being oxidized in the air. They then form
	Animal testing reveals that whole the pure, non-oxidised surfactant is non-sensitizing, many of the oxidation products are sensitisers. The oxidization products also cause irritation.
2-ETHYLHEXYL BICYCLOHEPTENE DICARBOXIMIDE & N,N-DIETHYL- M-TOLUAMIDE	The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.
N,N-DIETHYL-M-TOLUAMIDE & COCOAMINE, ETHOXYLATED	The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.
OCTOCRYLENE & COCOAMINE, ETHOXYLATED	Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden

onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.

OCTOCRYLENE & V	OCTOCRYLENE & WATER No significant acute toxicological data identified in literature search.		
Acute Toxicity	×	Carcinogenicity	×
Skin Irritation/Corrosion	×	Reproductivity	×
Serious Eye Damage/Irritation	×	STOT - Single Exposure	×
Respiratory or Skin sensitisation	×	STOT - Repeated Exposure	×
Mutagenicity	×	Aspiration Hazard	×
		Legend: X − Data either no ✓ − Data available	t available or does not fill the criteria for classification to make classification

SECTION 12 Ecological information

ULTRA PROTECT SPF50+	Endpoint	Test Duration (hr)	Species	Value	Source
SUNSCREEN WITH INSECT REPELLENT	Not Available	Not Available	Not Available	Not Available	Not Availabl
	Endpoint	Test Duration (hr)	Species	Value	Sourc
	ErC50	72h	Algae or other aquatic plants	>4.38mg/l	2
2-ethylhexyl bicycloheptene	EC50	72h	Algae or other aquatic plants	>1.63<2.7mg/l	2
dicarboximide	LC50	96h	Fish	0.138-0.211mg/L	4
	EC50	48h	Crustacea	1.995-4.83mg/L	4
	NOEC(ECx)	96h	Crustacea	<0.077mg/l	2
	Endpoint	Test Duration (hr)	Species	Value	Sourc
	BCF	1008h	Fish	0.8-2.4	7
N,N-diethyl-m-toluamide	EC50	48h	Crustacea	55.776-99.6mg/L	4
	LC50	96h	Fish	70.965mg/L	4
	NOEC(ECx)	504h	Crustacea	3.7mg/l	4
	Endpoint	Test Duration (hr)	Species	Value	Sour
	EC50(ECx)	48h	Crustacea	>0.023mg/l	2
octocrylene	EC50	72h	Algae or other aquatic plants	>220mg/l	2
	LC50	96h	Fish	>10000mg/	2
	EC50	48h	Crustacea	>0.023mg/l	2
	Endpoint	Test Duration (hr)	Species	Value	Sour
<i></i>	LC50	96h	Fish	>0.74mg/	2
(4-methylbenzylidene)camphor	EC50	48h	Crustacea	0.56mg/l	2
	NOEC(ECx)	504h	Crustacea	0.1mg/l	2
	Endpoint	Test Duration (hr)	Species	Value	Sour
	NOEC(ECx)	96h	Fish	0.1mg/l	2
cocoamine, etnoxylated	LC50	96h	Fish	0.1mg/l	2
	EC50	48h	Crustacea	0.17mg/	2
	Endpoint	Test Duration (hr)	Species	Value	Source
water	Not Available	Not Available	Not Available	Not Available	Not Availab

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters.

Wastes resulting from use of the product must be disposed of on site or at approved waste sites. For UV Filters:

Aquatic Fate/Ecotoxicity: UV filters have been detected in surface water, wastewater and fish, and some of them having an action similar to that of an estrogen in fish. At present, little is known about their additional hormonal activities in different hormonal receptor systems despite their increasing use and environmental persistence. Besides estrogenic activity, UV

filters may have additional activities, both agonistic and antagonistic, in aquatic organisms. Although most of the UV filters exert hormonal effects at concentrations that are orders of magnitude higher than in the environment, wide distribution and exposure to UV filter mixtures may have environmental consequences due to additive effects. The UV filters 4-methylbenzylidene camphor, benzophenone-3, benzophenone-4, octyl methoxycinnamate, octocrylene and hormosalate that repeatedly were detected in the aquatic environment, may contribute with their multiple hormonal activities in a complex manner to the mixture of endocrine disrupting chemicals already present in surface water and fish. For most of the UV filters with multiple hormonal activities residues in the aquatic environment and in biota are not yet known, and therefore their environmental relevance remains elusive. **DO NOT** discharge into sever or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
2-ethylhexyl bicycloheptene dicarboximide	HIGH	HIGH
N,N-diethyl-m-toluamide	HIGH	HIGH
3-(4-methylbenzylidene)camphor	HIGH	HIGH
water	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
2-ethylhexyl bicycloheptene dicarboximide	LOW (LogKOW = 3.7)
N,N-diethyl-m-toluamide	LOW (BCF = 2.4)
3-(4-methylbenzylidene)camphor	HIGH (LogKOW = 5.2537)

Mobility in soil

Ingredient	Mobility
2-ethylhexyl bicycloheptene dicarboximide	LOW (KOC = 10410)
N,N-diethyl-m-toluamide	LOW (KOC = 536.6)
3-(4-methylbenzylidene)camphor	LOW (KOC = 14560)

SECTION 13 Disposal considerations

Waste treatment methods Containers may still present a chemical hazard/ danger when empty. Return to supplier for reuse/ recycling if possible. Otherwise F If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill. Where possible retain label warnings and SDS and observe all notices pertaining to the product. Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked. A Hierarchy of Controls seems to be common - the user should investigate: Reduction Reuse Recycling Disposal (if all else fails) This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been Product / Packaging disposal contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. DO NOT allow wash water from cleaning or process equipment to enter drains It may be necessary to collect all wash water for treatment before disposal In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. Where in doubt contact the responsible authority. Recycle wherever possible. Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified. Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or incineration in a licensed apparatus (after admixture with suitable combustible material). Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

SECTION 14 Transport information

Labels Required		
Marine Pollutant	NO	
HAZCHEM	Not Applicable	

Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code

Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
2-ethylhexyl bicycloheptene dicarboximide	Not Available
N,N-diethyl-m-toluamide	Not Available
octocrylene	Not Available
3-(4-methylbenzylidene)camphor	Not Available
cocoamine, ethoxylated	Not Available
water	Not Available

Transport in bulk in accordance with the ICG Code

Product name	Ship Type
2-ethylhexyl bicycloheptene dicarboximide	Not Available
N,N-diethyl-m-toluamide	Not Available
octocrylene	Not Available
3-(4-methylbenzylidene)camphor	Not Available
cocoamine, ethoxylated	Not Available
water	Not Available

SECTION 15 Regulatory information

Safety, health and environmental regulations / legislation specific for the substance or mixture

2-ethylhexyl bicycloheptene dica	rboximide is found on the following regulatory lists	3
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5		Australian Inventory of Industrial Chemicals (AIIC)
N,N-diethyl-m-toluamide is found	I on the following regulatory lists	
Australia Hazardous Chemical Infor	rmation System (HCIS) - Hazardous Chemicals	Australian Inventory of Industrial Chemicals (AIIC)
Australia Standard for the Uniform S Schedule 5	Scheduling of Medicines and Poisons (SUSMP) -	
octocrylene is found on the follow	wing regulatory lists	
Australian Inventory of Industrial Ch	nemicals (AIIC)	
3-(4-methylbenzylidene)camphor	is found on the following regulatory lists	
Australian Inventory of Industrial Ch	nemicals (AIIC)	
cocoamine, ethoxylated is found	on the following regulatory lists	
Australia Standard for the Uniform S Schedule 5	Scheduling of Medicines and Poisons (SUSMP) -	Australian Inventory of Industrial Chemicals (AIIC)
water is found on the following re	egulatory lists	
Australian Inventory of Industrial Ch	nemicals (AIIC)	
National Inventory Status		
National Inventory	Status	
Australia - AIIC / Australia Non-Industrial Use	Yes	
Canada - DSL	Yes	
Canada - NDSL	No (2-ethylhexyl bicycloheptene dicarboximide; N,N-diethyl-m-toluamide; octocrylene; 3-(4-methylbenzylidene)camphor; cocoamine, ethoxylated; water)	
China - IECSC	Yes	
Europe - EINEC / ELINCS / NLP	Yes	
Japan - ENCS	No (3-(4-methylbenzylidene)camphor)	
Korea - KECI	No (2-ethylhexyl bicycloheptene dicarboximide; 3-(4-methylbenzylidene)camphor)	
New Zealand - NZIoC	Yes	
Philippines - PICCS	Yes	
USA - TSCA	No (2-ethylhexyl bicycloheptene dicarboximide)	
Taiwan - TCSI	Yes	
Mexico - INSQ	No (3-(4-methylbenzylidene)camphor)	
Vietnam - NCI	Yes	
Russia - FBEPH	No (2-ethylhexyl bicycloheptene dicarboximide; 3-(4	-methylbenzylidene)camphor)
Legend:	Yes = All CAS declared ingredients are on the inven No = One or more of the CAS listed ingredients are	tory not on the inventory and are not exempt from listing(see specific ingredients in brackets)

SECTION 16 Other information

Revision Date	02/06/2021
Initial Date	02/06/2021

SDS Version Summarv

Version	Date of Update	Sections Updated
2.1.2.1	26/04/2021	Regulation Change
2.1.3.1	03/05/2021	Regulation Change
2.1.4.1	06/05/2021	Regulation Change
2.1.5.1	10/05/2021	Regulation Change
2.1.5.2	30/05/2021	Template Change
2.1.5.2	02/06/2021	Classification

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC-TWA: Permissible Concentration-Time Weighted Average PC-STEL: Permissible Concentration-Short Term Exposure Limit IARC: International Agency for Research on Cancer ACGIH: American Conference of Governmental Industrial Hygienists STEL: Short Term Exposure Limit TEEL: Temporary Emergency Exposure Limit。 IDLH: Immediately Dangerous to Life or Health Concentrations ES: Exposure Standard OSF: Odour Safety Factor NOAEL :No Observed Adverse Effect Level LOAEL: Lowest Observed Adverse Effect Level TLV: Threshold Limit Value LOD: Limit Of Detection OTV: Odour Threshold Value BCF: BioConcentration Factors BEI: Biological Exposure Index AIIC: Australian Inventory of Industrial Chemicals **DSL: Domestic Substances List** NDSL: Non-Domestic Substances List IECSC: Inventory of Existing Chemical Substance in China EINECS: European INventory of Existing Commercial chemical Substances ELINCS: European List of Notified Chemical Substances NLP: No-Longer Polymers ENCS: Existing and New Chemical Substances Inventory KECI: Korea Existing Chemicals Inventory NZIoC: New Zealand Inventory of Chemicals PICCS: Philippine Inventory of Chemicals and Chemical Substances TSCA: Toxic Substances Control Act TCSI: Taiwan Chemical Substance Inventory INSQ: Inventario Nacional de Sustancias Químicas NCI: National Chemical Inventory FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

This document is copyright.

Apart from any fair dealing for the purposes of private study, research, review or criticism, as permitted under the Copyright Act, no part may be reproduced by any process without written permission from CHEMWATCH.

TEL (+61 3) 9572 4700.