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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

C20-22 Alkyl Phosphate

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

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

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

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Bronson & Jacobs Pty Ltd (ABN: 81 000 063 249)
70 Marple Ave
Villawood, NSW, 2163

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS number, identities of study test facilities and study identification numbers.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physicochemical and toxicological endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
None.

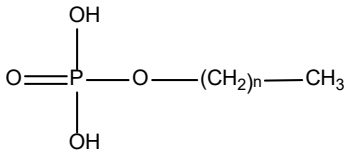
2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Sensanov WR (50-60% notified chemical)

OTHER NAME(S)
INCI name: C20-22 Alkyl Phosphate

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA
Sensanov WR is a multi-component substance that is obtained from the reaction of Alcohols, C_{20-22} with phosphoric anhydride. The notified chemical may be represented by the following structural formula:



where n = 19 or 21

Note that the monoalkyl phosphate is depicted in the above structure. The dialkyl phosphate is also present.

MOLECULAR WEIGHT
≥ 378.53 Da (molecular weight for $C_{20}H_{43}O_4P$)

ANALYTICAL DATA
IR reference spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY 50-60% notified chemical in Sensanov WR; purity of the notified chemical is higher.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	Phosphoric acid		
CAS No.	7664-38-2	*Weight %*	<1%
Hazardous Properties	C; R34 Conc. ≥25%: C; R34; ≥10% Conc. <25%: Xi; R36/38.		

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
None.

ADDITIVES/ADJUVANTS
None.

4. PHYSICAL AND CHEMICAL PROPERTIES

The following information on the physical and chemical properties is for Sensanov WR containing 50-60% notified chemical. No data were submitted for the notified chemical as it has not been isolated.

APPEARANCE AT 20°C AND 101.3 kPa: white solid (shavings).

Property	Value	Data Source/Justification
Melting Point	70-75 °C	MSDS
Specific Gravity	0.6	MSDS
Vapour Pressure	6.66×10^{-5} Pa at 25°C	Calculated
Water Solubility	$\leq 1 \times 10^{-3}$ g/L at 20°C	Measured
Hydrolysis as a Function of pH	Not determined	Expected to slowly hydrolyse under ambient environmental conditions.
Partition Coefficient (n-octanol/water)	Not determined	The notified chemical is an anionic emulsifier and will tend to accumulate at the phase interface of octanol and water and/or form emulsions.
Adsorption/Desorption	Not determined	The notified chemical is expected to partition to surfaces from water in the environment based on its surface activity.
Dissociation Constant	Not determined	The phosphate monoester components of the notified chemical will be ionised in the environmental pH range (4 - 9), based on the acidity constants for model phosphate monoesters (pK_{a1} = 1.5 and pK_{a2} = 6.58 (Guthrie, 1978)). The phosphate diester components of the notified chemical will be fully ionised in the environmental pH range based on the acidity of a model phosphate diester ((pK_a = 0.76) (Guthrie, 1978)).
Particle Size	Shavings: 4.0 - 2.8 mm (21.8%) 2.8 - 2.0 mm (32.1%) 2.0 - 1.4 mm (33.8%) <1.4 mm (12.2%)	Measured
Solid Flammability	Not considered to be highly flammable	Measured
Autoignition Temperature	*ca.* 220 °C	For Alcohols, C_{20-22}; stated on MSDS
Explosive Properties	Not determined	The notified chemical does not contain functional groups that would imply

explosive properties.

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

Reactivity
The notified chemical is stable under normal conditions of use. The MSDS for Sensanov WR advises incompatibility with strong oxidising agents.

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table the notified chemical is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia as a component of Sensanov WR (50-60% notified chemical) in PE lined bags (20 kg).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<1.0	<1.5	<2.0	<3.0	<5.0

PORT OF ENTRY
Sydney and Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS
Upon arrival in Australia, the notified chemical will be received by Bronson and Jacobs Pty Ltd and the CRT Group at the Sydney and Melbourne ports, respectively. The identities of the sites of reformulation are not yet known.

TRANSPORTATION AND PACKAGING
Sensanov WR (50-60% notified chemical) will be imported in 20 kg PE lined bags packaged in cardboard boxes and sealed by tape. The boxes will be transported by road to the notifier and/or reformulation sites. Following reformulation, end-use products containing the notified chemical will be distributed within Australia *via* road.

USE
The notified chemical is proposed to be used as an anionic emulsifier in cosmetic and personal care products at concentrations ≤3%. The notified chemical may be used in a variety of rinse-off and leave-on products, including make-up, moisturisers and hair-care products.

OPERATION DESCRIPTION
The procedures for incorporating the notified chemical into products will likely vary depending on the nature of the cosmetic and personal care products formulated, and may involve both automated and manual transfer steps. In general, it is expected that the notified chemical (as a 50-60% component of Sensanov WR) will be manually weighed into a container and transferred into a mixing vessel where it will be blended with other ingredients whilst closed. The resulting blend (containing the notified chemical at concentrations up to 3%) will then be filled into retail containers using automated filling machines. The finished products are then packed in shippers for distribution to retail outlets or salons.

The finished products containing the notified chemical (up to 3%) will be used by consumers and professionals such as hairdressers or workers in beauty salons. Depending on the nature of the product, these could be applied in a number of ways such as by hand, using an applicator or sprayed.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	8	4	12
Warehouse/store personnel	2	2	12
Compounder	1	6	12
Chemist/quality control	1	2	12
Packers	2	7	12
Salon workers	unspecified	unspecified	unspecified

EXPOSURE DETAILS

Transport and storage workers may come into contact with the notified chemical, as a component of Sensanov WR (50-60%) or end-use products (≤3%), only in the event of accidental rupture of containers.

During formulation, exposure to the notified chemical (up to 60%) may occur during weighing and transfer stages, quality control analysis and cleaning and maintenance of equipment. Exposure is expected to be minimised through the use of mechanical ventilation and personal protective equipment such as overalls, safety glasses and impervious gloves (MSDS of Sensanov WR). In addition, the use of respiratory protection is also recommended in situations where dusts may be generated.

Exposure to the notified chemical in end-use products may occur in professions where the services provided involve the application of cosmetic and personal care products to clients (e.g. hair dressers, workers in beauty salons). Such professionals may use some personal protective equipment to minimise repeated exposure, and good hygiene practices are expected to be in place. Exposure of such workers is expected to be of either a similar or higher level than that experienced by consumers using products containing the notified chemical.

6.1.2. Public exposure

There will be widespread and repeated exposure of the public to the notified chemical through the use of the rinse-off and leave-on cosmetic and personal care products. The principal route of exposure will be dermal, while ocular and inhalation exposure is also possible, particularly if products are applied by spray.

Data on typical use patterns of a number of product categories in which the notified chemical is proposed to be used are shown in the following table (European Commission, 2003; SCCP, 2006; Loretz *et al*. 2008). For the purpose of the exposure assessment, Australian use patterns for the various product categories are assumed to be similar to those in Europe. In the absence of dermal absorption data, the default dermal absorption of 100% was assumed for calculation purposes (European Commission, 2003). However, the actual level of dermal absorption may be lower than 100%. An adult bodyweight of 60 kg has been used for calculation purposes.

Product type	mg/event	events/day	**C** (%)	**RF**	**Daily exposure** (mg/day)	**Daily systemic exposure** (mg/kg bw/day)
Leave on						
Body lotion	8000	1	3	1	240	4
Eye and face make up*	110	1- 2 (1.5 used for calcs)	3	1	4.95	0.083
Face cream	1540	2	3	1	92.4	1.54
Lipstick	57	4	3	1	6.84	0.114
General purpose cream	1200	2	3	1	72	1.2
Rinse off						
Bath products	17000	0.29	3	0.001	0.148	0.0025
Facial cleansers	4060	1-2 (1 used for calcs)	3	0.01	1.22	0.0203
Facial masks	3700	0.1	3	0.1	1.11	0.0185
Make up remover	2500	1	3	0.1	7.5	0.125
Shower gel	5000	1.07	3	0.01	1.61	0.0268
Shampoo	10460	1	3	0.01	3.14	0.0523
Hair conditioner	14000	0.28	3	0.01	1.18	0.0196
TOTAL						**7.20**

* Sum of five different products: eye shadow; mascara; eyeliner; eyebrow pencil; and concealer
C = concentration; RF = retention factor; 100% dermal absorption assumed.
Daily exposure = mg/event x events/day x C(%/100) x RF; Daily systemic exposure = daily exposure x dermal absorption (%) /60 kg

The worst case scenario estimation using these assumptions is for a person who is a simultaneous user of all products listed in the above table. This would result in a combined internal dose from dermal exposure of 7.20 mg/kg bw/day.

6.2. Human health effects assessment

The results from toxicological investigations conducted on a preparation containing the notified chemical at 50-60% concentration are summarised in the table below. Details of these studies can be found in Appendix B.

*Endpoint**	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 >2,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 >2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, combined repeat dose oral toxicity and developmental/reproductive effects.	NOAEL >1,000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Mammalian Chromosome Aberration Test.	non genotoxic
Genotoxicity – in vitro Mammalian Cell Gene Mutation Test.	non genotoxic

*The text substance for all toxicological studies was Sensanov WR, which contains 50-60% notified chemical. The results stated refer to the test substance.

Toxicokinetics, metabolism and distribution.
While passive diffusion of the notified chemical across the gastrointestinal (GI) tract and dermal absorption may occur, it is expected to be limited by the low water solubility ($\leq 1 \times 10^{-3}$ g/L for Sensanov WR) and relatively high molecular weight ($\geq$ 378.53 Da) of the notified chemical.

Acute toxicity.

The notified chemical (tested at 50-60% concentration) was found to be of low acute oral and dermal toxicity in rats.

Irritation and Sensitisation.

The notified chemical (tested at 50-60% concentration) was not a skin irritant in rabbits. However, the notified chemical (tested at 50-60% concentration) was found to be irritating to the eyes of rabbits. The irritation scores obtained in the study (for 50-60% notified chemical) were not high enough to classify the chemical as an eye irritant. However, it is possible that at 100% concentration, classification as an eye irritant may be warranted.

The notified chemical (tested at <60% concentration) was not a skin sensitiser in guinea pigs (Magnus-Kligman method).

Repeated Dose Toxicity and Toxicity for Reproduction.

A combined repeated dose oral toxicity study with reproduction/developmental screening test in rats established a NOAEL for the test substance (50-60% notified chemical) of 1,000 mg/kg bw/day. Administration at this dosage level did not result in treatment-related mortality or any toxicologically significant behaviour or weight gain and did not induce changes in the organs/tissues. A NOEL of 1000 mg/kg bw/day was established in this study for reproductive performance and toxic effects on progeny.

Mutagenicity.

The notified chemical was not mutagenic in a bacterial reverse mutation study and was not clastogenic in an in vitro mammalian chromosome aberration test or in vitro mammalian cell gene mutation test.

Health hazard classification

Based on the data provided the notified chemical is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The main risk associated with the notified chemical is its potential to cause eye irritation. Exposure of workers to the notified chemical at up to 60% concentration may occur during formulation of cosmetics. At such concentrations there is a possibility of eye irritation effects. However, given the measures in place to lower exposure (use of PPE), the risk of eye irritation is not expected to be unacceptable.

Beauty care professionals will handle the notified chemical at up to 3% concentration, similar to public use. Therefore, the risk for beauty care professionals who regularly use products containing the notified chemical is expected to be of a similar or perhaps higher level than that experienced by members of the public who use such products on a regular basis. This is because the duration of exposure will be longer for workers applying products in many clients.

6.3.2. Public health

As stated above, the main acute risk associated with the notified chemical is its potential to cause eye irritation. However, at the proposed use concentration of up to 3% notified chemical in rinse-off and leave-on cosmetic products, eye irritation effects are unlikely to occur. Therefore, acute toxicity risk from the use of the notified chemical in rinse-off and leave-on cosmetic products is not expected to be unacceptable.

Repeat dose toxicity potential was estimated by calculation of the margin of exposure (MoE) of the notified chemical using the worst case exposure scenario, as estimated in the table of Section 6.1.2. A NOAEL of 1000 mg/kg bw/day, established in the repeat dose toxicity study for Sensanov WR, was used. A MoE value greater than or equal to 100 is considered acceptable to account for intra- and inter-species differences. Using the abovementioned NOAEL, a MoE of 139 was estimated, and hence is considered to be acceptable. However, it should be noted that the NOAEL was established for a preparation containing 50-60% notified chemical. The NOAEL for 100% notified chemical may be different to the NOAEL used in the calculation. However, it is not possible to correctly adjust this NOAEL to 100% notified chemical.

When used in the proposed manner, the risk to the public associated with the use of the notified chemical at up to 3% concentration in rinse-off and leave-on cosmetic products is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

Release of the notified chemical to the environment may occur in an accident during transport or an accidental spill during handling. The notified chemical will be blended with other ingredients and packaged into plastic or glass consumer bottles. Spills of raw notified chemical are expected to be vacuumed and reused in formulation, or if contaminated, disposed to landfill. Release (< 1%) from cleaning and maintenance operations of the blending and bottling equipment may occur, with rinsings being disposed of to sewer after onsite treatment of the wastewater.

RELEASE OF CHEMICAL FROM USE

As the notified chemical is used in cosmetics and personal care products such as lipsticks, shampoos, facial cleansers and shower gels, it is expected that effectively the entire annual import volume will be released to sewer through consumer use. A small proportion (estimated to be ≤ 2%) may remain as residues within the end-use containers.

RELEASE OF CHEMICAL FROM DISPOSAL

It is expected that end use containers containing residues of the notified chemical will either be recycled or disposed of as domestic garbage and end up in landfill sites.

7.1.2 Environmental fate

Most of the notified chemical is expected to be released to the sewerage system. In the waste water treatment processes in sewage treatment plants, some of the notified chemical is expected to partition to sludge or to suspended solids due to its low water solubility and its surface activity, where it will be removed for disposal to landfill or used on land for soil remediation (Painter, 1992). In soil, it is expected to slowly decompose by abiotic and biotic processes to form water and oxides of carbon and phosphorus.

In surface waters, the notified chemical will partition to suspended solids and organic matter. It is not readily biodegradable but is expected to slowly hydrolyse. Based on its surface activity, the notified chemical is not expected to bioaccumulate.

For the details of the environmental fate studies refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

A PEC for discharge of the notified chemical to surface waters has been calculated assuming that all of the imported quantity of the chemical is discharged to sewers nation wide and that no removal occurs in sewage treatment. The details of this worst case scenario are as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	5,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	5,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	13.70	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor – River	1.0	
Dilution Factor – Ocean	10.0	
PEC - River:	3.24	µg/L
PEC - Ocean:	0.32	µg/L

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on filtered water accommodated fractions of Sensanov WR (which comprises 50-60% notified chemical) are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (96 hour)	LL50 > 100 mg/L	Not harmful up to fish
Daphnia Toxicity (48 hour)	EL50 > 100 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity (72 hour)	E_rL50 > 100 mg/L	Not harmful to algae
Inhibition of Bacterial Respiration (3 hour)	IL50 > 1000 mg/L	Does not inhibit respiration of waste water microorganisms

The test substance, and by inference the notified chemical, is not harmful to fish, aquatic invertebrates and algae up to its limit of solubility in water. The notified chemical is therefore not classified for acute or long-term aquatic hazards under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009).

7.2.1 Predicted No-Effect Concentration

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Fish (LL50)	> 100	mg/L
Assessment Factor	100	
PNEC:	> 1000	µg/L

An assessment factor of 100 has been used to derive a PNEC as acute toxicity endpoints are available for the effects of the notified chemical on aquatic species from three trophic levels.

7.3. Environmental risk assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	3.24	> 1000	< 0.0032
Q - Ocean	0.32	> 1000	< 0.0003

The Risk Quotients (Q = PEC/PNEC) for the worst case discharge scenario have been calculated to be << 1 for both river and ocean compartments. This indicates the notified chemical is not expected to pose an unacceptable risk to the aquatic environment based on its reported use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the data provided the notified chemical is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemical is not expected to pose a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical, as introduced for the formulation of end-use products:
  - Avoid contact with eyes

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical, as introduced for the formulation of end-use products:
  - Goggles

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

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component in rinse-off and leave-on cosmetic products at concentrations ≤3%, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 5 tonnes per annum, or is likely to increase, significantly;
  - the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet

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

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

The following information on the physical and chemical properties is for Sensanov WR, containing 50-60% notified chemical. No data were submitted for the notified chemical as it has not been isolated.

Vapour Pressure 6.66 x 10^{-5} Pa at 25 °C (for Sensanov WR)

Method Calculated using EPI Suite WPIWINNT software
Remarks The vapour pressure of Sensanov WR was defined as the highest calculated value of the component substances.
Test Facility Unpublished (2008a)

Water Solubility ≤ 1 × 10^{-3} g/L at 20°C (for Sensanov WR)

Method OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks A preliminary flask test indicated that the solubility of the test substance (which contains 50-60% of the notified chemical) was < 10 mg/L after 24 h at 20°C. The definitive test was conducted by a column elution method with analysis of eluted components by GC-FID after chemical derivitisation of the dried eluates. The concentration of eluted material was less than the limit of quantification of the analytical method (LOQ = 0.5 mg/L) after 29 hours of elution. The water solubility of the test substance was taken to be ≤ 1 × 10^{-3} g/L (≤ 2 × LOQ). It was not indicated whether the analytical method used to quantify the eluted compounds in the column elution method was able to quantify the levels of the notified chemical in the eluate. However, based on the use of the notified chemical as an anionic emulsifier and its chemical structure, this chemical would be expected to be only slightly soluble in water at ambient temperature. The water solubility of the test substance is therefore considered indicative for the notified chemical.
Test Facility Unpublished (2008b)

Hydrolysis as a Function of pH

Remarks The hydrolytic stability of the notified chemical was not determined by OECD TG 111 due to the low estimated water solubility of the constituent long chain alkyl phosphate esters. The study author argued that phosphate esters will hydrolyse in aqueous media, although hydrolysis of the notified chemical may be limited in the environmental pH range of 4 to 9 and 25°C due to the low solubility of these chemicals and possible formation of micelles. The hydrolysis half lives for phosphoric acid esters in water at pH 7 and 25°C are in the range of minutes to years (Mabey and Mill, 1978).
Test Facility Unpublished (2008c)

Particle Size

Method Similar to OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range	*Mass (%)*
4.0 - 2.8 mm	21.8%
2.8 - 2.0 mm	32.1%
2.0 - 1.4 mm	33.8%
<1.4 mm	12.2%

Remarks Preliminary mechanical sieving was performed (4 mm, 1 mm and 100 µm test sieves). The principal sieving was made between 1 and 4 mm as the majority of particles was situated in this range. In the preliminary test, if no significant amount of particles is obtained under 100 µm, the test is completed.
Test Facility Unpublished (2008d)

Solid Flammability Not considered as highly flammable

Method	EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks	Only a preliminary test was performed (in duplicate). The following observation is noted: The test item melted under the effect of the flame to form a colourless limpid liquid which evaporated. Neither inflammation nor propagation was observed.
Test Facility	Unpublished (2008e)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Sensanov WR (50-60% notified chemical)
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test. EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test.
Species/Strain	Rat/Sprague-Dawley, 10M/10F
Vehicle	Paraffin oil
Remarks - Method	No significant protocol deviations. Animals received an effective dose of 2000 mg/kg bw of Sensanov WR. Control animals (5M, 5F) were treated with the vehicle.
RESULTS	
Remarks - Results	There were no mortalities observed
LD50	>2000 mg/kg bw
Signs of Toxicity	No clinical abnormalities were noted.
Effects in Organs	None
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	Unpublished (2000a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Sensanov WR (50-60% notified chemical)
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Directive 92/69/EEC B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Sprague-Dawley, 10M/10F
Vehicle	Parrafin oil
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. Animals received an effective dose of 2000 mg/kg bw of Sensanov WR. Control animals (5M, 5F) were treated with distilled water.
RESULTS	
Remarks - Results	There were no mortalities observed
LD50	>2000 mg/kg bw
Signs of Toxicity	No clinical abnormalities were noted.
Effects in Organs	None
CONCLUSION	The test substance is of low toxicity via the dermal route.
TEST FACILITY	Unpublished (2008f)

B.3. Irritation – skin

TEST SUBSTANCE	Sensanov WR (50-60% notified chemical)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 Female
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. Skin treated with distilled water served as the control.

RESULTS

Remarks - Results: No cutaneous reactions were noted in any animal up to 72 hours.

CONCLUSION: The test substance is non-irritating to the skin.

TEST FACILITY: Unpublished (2000b)

B.4. Irritation – eye

TEST SUBSTANCE: Sensanov WR (50-60% notified chemical)

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain: Rabbit/New Zealand White
Number of Animals: 3 Female
Observation Period: ≤7 Days
Remarks - Method: No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Observed Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1.7	1.7	1.3	2	6 days	0
Conjunctiva: chemosis	1	1	1.3	2	3 days	0
Conjunctiva: discharge	1.3	1	1	3	2 days	0
Corneal opacity	1	0	1.3	2	4 days	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results: Slight to moderate corneal reaction was noted in 2/3 animals 24-hours after instillation and was reversible by Day-5.

CONCLUSION: The test substance with 50-60% notified chemical is irritating to the eye. The irritation scores were not high enough to classify the chemical as an eye irritant. However, it is possible that at 100% concentration, classification as an eye irritant may be warranted.

TEST FACILITY: Unpublished (2000c)

B.5. Skin sensitisation

TEST SUBSTANCE: Sensanov WR (50-60% notified chemical)

METHOD: OECD TG 406 Skin Sensitisation - Magnusson and Kligman guinea pig maximisation test.

Species/Strain: Guinea pig/Dunkin-Hartley

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: 3.125%
topical: 100%

MAIN STUDY

Number of Animals: Test Group: 11 F Control Group: 6 F

INDUCTION PHASE: Induction Concentration:
intradermal: 3.125
topical: 100%

Signs of Irritation: No cutaneous reactions were noted following intradermal induction. Dryness and a scab (3/11 animals) were noted 24 hours post-removal of the occlusive dressing following topical induction.

CHALLENGE PHASE

1st challenge	topical: 100% and 50% (in paraffin oil)
Remarks - Method	No significant protocol deviations. Control group induction phase: intradermal injection of olive oil and topical application of liquid paraffin

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	100%	1/11	1/11
	50%	0	0
Control Group	100%	0	0
	50%	0	0

Remarks - Results	Slight erythema was noted in 1/11 animals following the challenge phase, on the area treated at 100%. Otherwise dermal scores were limited to zero at the 24 and 48 h scoring intervals.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.
TEST FACILITY	Unpublished (2009a)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Sensanov WR (50-60% notified chemical)
METHOD	OECD TG 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test.
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: i) Males: ≥4 weeks [including 15 days before mating, during the mating period (≤3 weeks)] ; ii) Females: 15 days before mating, during the mating period (≤3 weeks), during pregnancy and during lactation (until day 5 post-partum) Dose regimen: 7 days per week Post-exposure observation period: not specified
Vehicle	Olive oil
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	10M/10F	0	1
low dose	10M/11F	100	1*
mid dose	10M/10F	300	1**
high dose	10M/10F	1000	2***

*Sacrificed on day 3 due to clinical condition, which was not related to treatment.
**Sacrificed as female was not pregnant.
***Dosing-related deaths (method).

Mortality and Time to Death
No treatment-related deaths were reported.

1 female in the control group was found dead on day 12 post-coitum. This death was considered to be dosing related.

1 female in the 100 mg/kg bw/day group was sacrificed on day 3 due to clinical condition and marked weight loss. The effects were thought unlikely to be related to the treatment. This female was replaced in the study and is excluded from the conclusion of the study.

1 female in the 300 mg/kg bw/day group was sacrificed on day 25 post-coitum because of no delivery. The female was found to not be pregnant. No abnormalities were found at macroscopic post-mortem examination.

1 female in the 1000 mg/kg bw/day group was found dead on day 11. This death was considered to be due to a gavage error. In addition, 1 male was sacrificed on day 28 due to clinical conditions. This was considered as a dosing-related death.

Clinical Observations

Hypersalivation was observed in 7/20, 12/20, 15/20 and 19/20 animals treated at 0, 100, 300 and 1000 mg/kg bw/day groups, respectively. This is noted to have occurred mostly in the first week, except for the high dose group.

Reflux was observed in 2/20, 2/20, 4/20 and 7/20 animals treated at 0, 100, 300 and 1000 mg/kg bw/day groups, respectively. This is noted to have occurred towards the end of the dosing period.

Hypersalivation and reflux effects were considered to be related to the vehicle and/or test substance but were not considered to be adverse by the study author.

All treated female groups gained less weight during the premating stage. As this did not continue during gestation/lactation, this was considered to be non-adverse.

The functional observation battery and motor activity assessment revealed no treatment-related effects.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

There were no significant findings in blood biochemistry.

Mean packed cell volume and mean cell volume were statistically significantly decreased in males (1000 mg/kg bw/day group). A relationship between this and the test substance was considered unlikely.

Effects in Organs

No treatment-related macroscopic or microscopic findings were noted and there were no-treatment related organ weight changes.

Reproductive Toxicity: Effects on Dams

There were no differences from controls for pairing, mating and fertility parameters.

Reproductive Toxicity: Effects on Foetus

The number of pups found dead or cannibalized was slightly higher for the 300 and 1000 mg/kg bw/day treatment groups due to mortalities in one litter in each group. As mortalities were mostly in one litter within each group, these were not considered to be representative of the group, and were deemed to be not treatment-related. Other parameters (including isolated clinical signs/sex ratio) and necropsy findings were deemed to not be treatment related.

CONCLUSION

Considering some non-adverse effects were reported at 1000 mg/kg bw/day (hypersalivation, reflux, changes in clinical chemistry parameters), the No Observed (Adverse) Effect Level (NO(A)EL) was established as 1000 mg/kg bw/day in this study for parental toxicity. The NOEL was established as 1000 mg/kg bw/day in this study for reproductive performance and toxic effects on progeny, based on no effects observed at this level.

TEST FACILITY Unpublished (2009b)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Sensanov WR (50-60% notified chemical)

METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Phenobarbitone/β-naphthoflavone-induced rat liver (S9 homogenate)
Concentration Range in Main Test	a) With metabolic activation: 50, 150, 500, 1500 and 5000 µg/plate b) Without metabolic activation: 50, 150, 500, 1500 and 5000 µg/plate
Vehicle	Acetone
Remarks - Method	A preliminary toxicity test (0.15-5000 µg/plate) was performed to define the dose levels for the main test. Vehicle and positive controls were used in parallel with the test material. Positive controls: i) without S9: N-ethyl-N'-nitro-N-nitrosoguanidine (TA100, TA1535, WP2uvrA), 9-aminoacridine (TA1537) and 4-nitroquinoline-1-oxide (TA98); ii) with S9: 2-aminoanthracene and benzo(a)pyrene. Test 2 was conducted on separate day to Test 1 using fresh cultures of the bacterial strains and fresh test material formulations.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5,000	>5,000	≥500	Negative
Test 2		>5,000	≥500	Negative
Present				
Test 1	>5,000	>5,000	≥500	Negative
Test 2	>5,000	>5,000	≥500	Negative

Remarks - Results	No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains up to and including the maximum dose of 5000 µg/plate, either with or without metabolic activation. The positive controls gave satisfactory responses, confirming the validity of the test system.
CONCLUSION	The test substance was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Unpublished (2001)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE	Sensanov WR (50-60% notified chemical)
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Human
Cell Type/Cell Line	Lymphocytes
Metabolic Activation System	Aroclor 1254-induced rat liver (S9 homogenate)
Vehicle	Ethanol
Remarks - Method	A preliminary range finding study (0.41-1 µg/mL) was performed to define the dose levels for the main test. Poor solubility of the substance in the vehicle is noted. Vehicle and positive controls (cyclophosphamide and mitomycin C) were used in parallel with the test material.

Metabolic Activation	*Test Substance Concentration (µg/mL)**	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0.0625, 0.125, 0.25, 0.5, 1	4 h	32 h
Test 2	0.0625, 0.125, 0.25, 0.5, 1	36 h	
Present			
Test 1	0.0625, 0.125, 0.25, 0.5, 1	4 h	32 h

*All cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 1	>1	>1	Negative
Test 2		>1	>1	Negative
Present				
Test 1	>1	>1	>1	Negative

Remarks - Results: The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system. No apparent induction of structural or numerical aberrations was noted at any test level, with and without metabolic activation.

CONCLUSION: The test substance was not clastogenic to human lymphocytes treated in vitro under the conditions of the test.

TEST FACILITY: Unpublished (2008g)

B.9. Genotoxicity – in vitro

TEST SUBSTANCE: Sensanov WR (50-60% notified chemical)

METHOD: OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.

Species: Mouse

Cell Type/Cell Line: L5178Y TK+/-

Metabolic Activation System: Aroclor 1254-induced rat liver (S9 homogenate)

Vehicle: Ethanol

Remarks - Method: A preliminary range finding study (0.09-0.5 µg/mL) was performed to define the dose levels for the main test. Poor solubility of the substance in the vehicle is noted.

Vehicle and positive controls (benzo[a]pyrene and methylmethanesulfonate) were used in parallel with the test material.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	0.0313, 0.0625, 0.125, 0.25, 0.5	3 h	2 days	2 weeks
Test 2	0.0313, 0.0625, 0.125, 0.25, 0.5	24 h	2 days	2 weeks
Present				
Test 1	0.0313, 0.0625, 0.125, 0.25, 0.5	3h	2 days	2 weeks

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				

Test 1	>0.5	>0.5	>0.5	Negative
Test 2	>0.5	>0.5	>0.5	Negative
Present				
Test 1	>0.5	>0.5	>0.5	Negative

Remarks - Results

The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system. The test material did not induce any statistically significant increases in the mutant frequency at any dose level, either with or without metabolic activation.

CONCLUSION

The test substance was not clastogenic to mouse L5178Y TK+/- cells treated in vitro under the conditions of the test.

TEST FACILITY

Unpublished (2008h)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Sensanov WR (50-60% notified chemical)
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test
Inoculum	Aerobic activated sludge from a domestic wastewater treatment plant
Exposure Period	28 days
Auxiliary Solvent	None reported
Analytical Monitoring	Pressure decrease measured by a BSB sensomat system, Aqualytic Langen
Remarks - Method	The test substance was stirred into the test flasks to achieve a homogenous solution at a nominal loading level of 100 mg test substance per litre. The test vessels were incubated in the dark at 22ºC. The theoretical oxygen demand for the test substance ($ThOD_{NH4}$) was calculated as 2.916 mg O_2 / mg. The calculation was based on molecular weights for the heaviest molecular components of the test substance (i.e. docosyl phosphate and docosyl alcohol) which was stated to provide a worst case estimate of the oxygen demand for the substance. The contribution of the alkyl phosphate di-ester component of the notified chemical was apparently not included in this calculation.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation**	*Day*	*% Degradation*
7	5	7	82
14	10.5	14	88
21	13	21	89
28	16.5	28	92

* Average of two replicates

Remarks - Results	The reference substance was degraded > 60% by the 10th day, indicating a suitable aerobic activated sludge inoculum was used. All validity criteria for the test were satisfied. The test substance did not reach the pass level of 60% degradation for this test and cannot be classified as readily biodegradable.
CONCLUSION	The test substance, and by inference the notified chemical, is not readily biodegradable
TEST FACILITY	Unpublished (2008i)

C.1.2. Bioaccumulation

REMARKS	No experimental data were submitted for bioaccumulation. The notified chemical is expected to concentrate at phase boundaries due to its surfactant properties and hence is not anticipated to bioconcentrate in aquatic organisms. The concentration of notified chemical in surface water is also expected to be very low due to its tendency to partition to suspended solids and hydrolysis of the chemical.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Sensanov WR (50-60% notified chemical)
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Semi static
Species	Zebra fish *(Danio rerio)*
Exposure Period	96 hours
Auxiliary Solvent	None reported
Water Hardness	240 mg $CaCO_3$/L (theoretical)
Analytical Monitoring	ICP/OES (total P)
Remarks – Method	The test substance was stirred into the fish dilution water and filtered after 24 hours to produce filtered water accommodated fractions (filtered WAFs) at nominal concentrations of 1, 10 and 100 mg/L. Test solutions were renewed every 24 h. To monitor the test substance solubilisation and stability, analysis of total phosphorus was performed on the 100 mg/L test substance concentration at the start and the end of the study.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*[a]		*24 h*	*48 h*	*72 h*	*96 h*
Unfiltered dilution water control	Not determined	7	0	0	0	0
Filtered dilution water control	< 0.272[b]	7	0	0	0	0
1	Not determined	7	0	0	0	0
10	Not determined	7	0	0	0	0
100	1.633	7	0	0	0	0

[a] At 0 h
[b] Limit of Detection

LL50	> 100 mg/L at 96 hours (based on loading rates)
NOEL	100 mg/L at 96 hours (based on loading rates)
Remarks – Results	All validity criteria for the test were satisfied. No signs of stress were observed in the fish over the 96 h of the study. The toxic response of fish to the reference compound $K_2Cr_2O_7$ gave an LC50 (24 h) of 220 mg/L which was consistent with the historical data for the laboratory. The concentration of the test substance (determined by analysis of total phosphorus) in the nominal 100 mg/L test sample was 3.231 mg/L at 72 h compared to 1.633 mg/L at the start of the test. The increase was explained by phosphorus originating from the fish faeces. Although the notified chemical comprises 50-60% of the test substance, this does not affect the hazard conclusion since the notified chemical was expected to have been at saturating levels in the 10 and 100 mg/L test solutions. This is supported by the low total phosphorus levels measured in test solutions.
CONCLUSION	The test substance, and by inference the notified chemical, is not harmful to fish
TEST FACILITY	Unpublished (2008j)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Sensanov WR (50-60% notified chemical)
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Semi static
Species	*Daphnia magna*

Exposure Period	48 hours
Auxiliary Solvent	None reported
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	ICP/OES (total P)
Remarks - Method	As for the fish test, this test was conducted as a semi-static range finding test using filtered WAFs at loading rates of 1, 10 and 100 mg/L. Test solutions were renewed every 24 h. The dilution water was not supplemented with phosphate salts.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Unfiltered control	Not determined	20	0	0
Filtered control	< 0.272[a]	20	0	0
1	Not determined	20	0	0
10	Not determined	20	0	0
100	1.67 – 1.90[b]	22	0	0

[a] Limit of Detection
[b] Measured at the start of the study and at 48 h respectively

EL50	> 100 mg/L at 48 hours (based on loading rates)
NOEL	100 mg/L at 48 hours (based on loading rates)
Remarks - Results	All validity criteria for the test were satisfied. No signs of stress were observed in the daphnids after 48 h. The toxic response of daphnia to the reference compound $K_2Cr_2O_7$ gave an EC50 (24 h) of 1.09 mg/L which was consistent with the historical data for the laboratory. Although the notified chemical comprises 50-60% of the test substance, this does not affect the hazard conclusion since the notified chemical was expected to have been at saturating levels in the 10 and 100 mg/L test solutions. This is again supported by measurements of total phosphorus which are consistent with a solubility limit of phosphate esters in dilution water of < 2 mg/L.

CONCLUSION The test substance, and by inference the notified chemical, is not harmful to aquatic invertebrates

TEST FACILITY Unpublished (2008k)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Sensanov WR (50-60% notified chemical)

METHOD OECD TG 201 Alga, Growth Inhibition Test.

Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 1, 10, 100 mg/L
Auxiliary Solvent	None reported
Water Hardness	Not reported
Analytical Monitoring	ICP/OES (total P)
Remarks - Method	The test was conducted as a static range finding test using filtered WAFs at loading rates of 1, 10 and 100 mg/L. As for the fish and invertebrate toxicity tests, attempts were made to monitor the concentration of the notified chemical in test media indirectly by measurement of total phosphorus levels. However, in this case, the measured levels of total phosphorus were close to the Limit of Quantification for total phosphorus (0.05 mg/L) for the test sample and less than the Limit of Detection (0.015 mg/L) for the unfiltered controls at test initiation. The latter finding was not reconciled with the fact that the culture medium was supplemented with a significant concentration of KH_2PO_4 (1.6 mg/L,

equivalent to 0.36 mg total P/L). The analytical monitoring results for the notified chemical in this study are therefore not considered reliable for regulatory purposes.

RESULTS

Growth	*Biomass*
E_rL_{50} mg/L at (0-72)h	*E_bL_{50}*
> 100 mg/L (based on loading rates)	Not determined

Remarks - Results: All validity criteria for the test were satisfied. The toxic response of algae to the reference compound $K_2Cr_2O_7$ gave an E_rC50 (0 - 72 h) of 0.69 mg/L which was consistent with the historical data for the laboratory. The maximum inhibition of algal growth observed for the test substance was 6.9% hence the E_rL_{50} lies above the maximum loading rate of 100 mg/L. The statistical significance of the observed inhibition of growth rate was not calculated, hence the NOE_rL could not be reliably reported. However, the inhibition of average specific growth rate was not dose responsive and was in a low range between -3.6 and 2.7%.

CONCLUSION: The test substance, and by inference the notified chemical, is not harmful to algae

TEST FACILITY: Unpublished (2008l)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE: Sensanov WR (50-60% notified chemical)

METHOD: OECD TG 209 Activated Sludge, Respiration Inhibition Test.
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test

Inoculum: Activated sewage sludge microorganisms from a sewage treatment plant treating predominantly domestic sewage

Exposure Period: 3 hours

Concentration Range: Nominal: 1000 mg/L
Actual: Not reported

Remarks – Method: After a range finding test, the definitive test was conducted according to the guidelines above at a test substance loading level of 1000 mg/L dispersed in dechlorinated tap water with the addition of a synthetic sewage as a respiratory substrate. A blank control and reference (3,5-dichlorophenol) control were run in parallel.
The rate of respiration was determined after 3 h contact time and compared to the results from the control and reference material. Test conditions: 21°C, pH 7.6-7.9.

RESULTS

IL50: > 1000 mg/L

NOEL: 1000 mg/L

Remarks – Results: All validity criteria for the test were satisfied. Some dissolved oxygen concentrations were below those recommended in the test guideline but this was not considered to adversely affect the results of the study given that in all the cases the oxygen consumption was determined over the linear portion of the oxygen consumption trace.

CONCLUSION: The test substance, and by inference the notified chemical, does not inhibit the respiration of waste-water microorganisms

TEST FACILITY	Unpublished (2009c)

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