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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical 1 in Lumogen Black FK 4280
Chemical 2 in Lumogen Black FK 4280

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 the Environment, Water, Heritage and the Arts.

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 334-336 Illawarra Road, Marrickville NSW 2204.

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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FULL PUBLIC REPORT

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Australia Ltd (ABN 62 008 437 867)
500 Princess Highway, Noble Park VIC 3174

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Chemical name, Other names, CAS number, Molecular formula, Structural formula, Molecular weight, Spectral data, Purity, Identity of Manufacturer/recipients, Introduction volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Acute Dermal Toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA, TSCA
Canada, DSL
EU, ELINCS

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Chemical 1 in Lumogen Black FK 4280
Chemical 2 in Lumogen Black FK 4280

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference NMR, IR, HPLC,UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 99 % (inseparable mixture of Chemical 1 and Chemical 2)

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Fine black powder

Property	Value	Data Source/Justification
Melting Point	No melting temperature observed between 20ºC and 400ºC	Measured
Boiling Point	Not determined	Could not be measured because the vapour pressure is too low
Density	1515 kg/m^3 at 20ºC	Measured
Vapour Pressure	< 1 x 10^{-7} kPa at 20ºC	Technical Report (BASF, 2005a)
Water Solubility	< 0.1 mg/L at 20ºC	Measured.
Hydrolysis as a Function of pH	Not determined	Measurement unfeasible due to the low water solubility.
Partition Coefficient (n-octanol/water)	Log K_{OW} = 7.52	Estimated.
Adsorption/Desorption	Log K_{OC} = 7.29	Estimated.
Dissociation Constant	Not determined	Measurement unfeasible due to the low water solubility.
Particle Size	0.9 – 2.6 μm Inhalable fraction (<100 μm): 100% Respirable fraction (<10 μm): ~50%	Measured
Flash Point	Not determined	Notified chemicals are a solid
Flammability (solid)	Not highly flammable	Measured
Autoignition Temperature	No self-heating detected	Measured
Explosive Properties	Not determined	Not expected to be explosive based on chemical structure
Surface Tension	Not determined	Measurement unfeasible due to the low water solubility.

DISCUSSION OF PROPERTIES

The inseparable mixture of the notified chemicals is a solid powder with low water solubility, low vapour pressure and high proportion of particles in the respirable range. The MSDS recommends to avoid dust formation and to take precautionary measures against static discharges.

The notified chemicals are not expected to be ionisable, surface active and hydrolysable in the environmental pH range of 4 – 9 based on the structure. Based on the estimated log K_{OC}, the notified chemicals are expected to absorb to soil or sediment from water. For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity

Stable under normal environmental and usage conditions.

5. INTRODUCTION AND USE INFORMATION

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

The notified chemicals will be imported by sea as a powder (Lumogen Black FK 4280), which is a mixture of 50% Chemical 1 and 50% Chemical 2.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0-1	0-1	1-2	1-3	1-5

PORT OF ENTRY

Melbourne

TRANSPORTATION AND PACKAGING

The notified chemicals will be imported in 20 kg (2 x 10 kg) packs and transported from the wharf on trucks to the contracted warehouse for storage until required for delivery to customers. They will be distributed by road to customers for handling and processing.

USE

The notified chemicals are used as a colouring agent for the plastics (~ 5%) and coatings industries (~ 20%).

OPERATION DESCRIPTION
At the customer facility, drums containing the notified chemicals will be taken to storage or production areas by forklift. The following description has been provided by the notifier and outlines the typical scenario involved in formulation:

Coatings manufacture:
The notified chemicals will be weighed and transferred manually into a hopper and fed into an open mixer where they will be mixed with other components to form a liquid dispersion. The dispersion will be fed into a bead or sand mill where it will be blended with other components into a homogenous liquid coating. Coating products containing the notified chemicals will be tested by technicians. The products will be packed using automated filling and packing machines.

Plastics manufacture:
The notified chemicals will be weighed manually and transferred to a blending vessel with other components. The blend will then be transferred to a hopper and fed into an extruder and the products tested by technicians. There it will enter a heat chamber before being mixed with other components and injected into a mould to form the shape of the finished plastic article.

End use
Pallets of packed products will be stored and sold to customers for use in a variety of industrial and domestic applications e.g. automotive, building and electronics. Around 30% of the introduced volume will be used in industrial plastics and 70% in liquid coatings. A maximum of 10% will be sold to the public.

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 Warehouse Workers	2-4	2	20
Plant Operators – Weighing and Compounding	4-6	8	48
Plant Operators – Filling and Packaging	2-4	2	48
Quality Assurance Technicians	1-2	1	48
Drum Recyclers	1	0.5	48
Professional Tradesmen	>500	~5	~300

EXPOSURE DETAILS
Transport and warehouse workers are unlikely to be exposed to the notified chemical except in case of handling damaged drums. Should this occur, workers are expected to wear suitable PPE and contain and collect the spill using absorbent material for recovery or disposal.

Coatings manufacture
Inhalation of airborne particles of the notified chemicals is expected to be the main route of exposure during manual weighing and transfer into the hopper and addition to mixers. Assuming a worst-case scenario involving dry manipulation of Lumogen Black FK 4280 in the absence of local exhaust ventilation (LEV), the EASE model predicts an atmospheric particulate concentration of 5-50 mg/m^3 (EC, 2003). However, the implementation of LEV while handling Lumogen Black FK 4280 would lower the predicted atmospheric particulate concentration to 2-5 mg/m^3 (EC, 2003). The MSDS supplied by the notifier recommends the use of respiratory personal protective equipment (PPE) with a particle filter during handling of powdered notified chemicals.

Once the notified chemical has been mixed into a homogenous coating, it is expected that filling of product packages will take place using closed, automated filling and packing equipment and no further inhalation exposure is anticipated.

Dermal and ocular exposure is also possible from spills, drips and splashes during the blending of the notified

chemicals with other coating components and during product sampling. Although filling and packing is expected to take place using closed, automated equipment, accidental dermal and/or ocular exposure could occur. The notifier states that process workers handling the notified chemicals are expected to wear PPE such as chemical-resistant gloves and safety glasses with side shields to minimise exposure.

Plastics manufacture
Inhalation exposure to airborne particles of the notified chemicals could occur during manual weighing and transfer into blending vessels and extruders. Inhalation exposure is expected to be similar to that described above for coatings manufacture. However, it is anticipated that LEV will be in use and workers at particular risk will wear respirators to minimise inhalation exposure. In addition, the notifier states that other PPE including safety glasses with side shields and chemical-resistant gloves should be used to minimise any accidental dermal and ocular exposure.

Once incorporated into the finished moulded plastic article, no further exposure is anticipated as the notified chemicals will be bound within the solid plastic.

Drum recyclers
Drum recyclers will be exposed to the notified chemicals via inhalation, dermal and ocular routes when collecting empty import drums. LEV and PPE, including a suitable respirator is expected to be in use to minimise inhalation exposure.

Professional use of coating products
Professional tradesmen will experience dermal and ocular exposure to coatings containing the notified chemicals (~20%) during spray, roller and brush application. However, exposure is expected to be minimised by the use of PPE during spray application such as safety glasses, gloves and coveralls. Application of coating products may also take place in a spray booth which would further minimise the potential for exposure.

After application and once dried, the coatings will be cured into an inert matrix and the notified chemicals will be unavailable for exposure.

6.1.2. Public exposure
Do-it-yourself (DIY) users could experience dermal, ocular and inhalation exposure to coatings containing ~20% notified chemicals during spray, roller or brush applications in a similar way to tradesmen, however the frequency of exposure is expected to be less than professional tradesmen. DIY users are not likely to access spray booths and LEV when applying coatings by spray application but are more likely to use roller or brush methods to apply the coatings, thereby reducing exposure. The use of PPE including gloves, safety glasses and coveralls would minimise dermal and ocular exposure. After application and once dried, the coating will be cured into an inert matrix and the notified chemicals will not be available for exposure.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemicals (as an inseparable mixture) 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	oral LD50 > 5000 mg/kg bw low toxicity
Rat, acute inhalation toxicity	LC50 > 5.2 mg/L/4 hour low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 1000 mg/kg/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* mammalian chromosome aberration	non genotoxic

Toxicokinetics, metabolism and distribution
The notified chemicals are expected to have low potential for absorption across biological membranes due to the very low solubility in water (< 0.1 mg/L) and the high estimated partition coefficient (Log P = 7.52). In oral toxicity studies the presence of dark-coloured faeces indicate that the main route of excretion is via the faeces.

Airborne dusts of the notified chemical will be easily inhaled given that 100% are within the inhalable size range and 50% of the particles are respirable. Inhaled particles will deposit in the nose, throat and upper respiratory tract, and a large proportion is likely to be cleared by muco-ciliary action and orally ingested. Respirable particles that deposit in the lower respiratory tract cannot be cleared by mucous and ciliary mechanisms and may be retained deep in the lungs, with long-term inhalation possibly leading to particle accumulation.

Acute toxicity
The notified chemicals were found to be of low toxicity via the oral route in a study conducted on rats. An inhalation test on rats resulted in obvious signs of respiratory distress and all ten animals displayed accelerated respiration for several days after exposure. Squatting posture and piloerection was noted in all animals and fur contamination was evident up to the end of the study period. However as no animals died, the notified chemicals are not considered toxic by inhalation. The respiratory effects observed may be due to lung overloading or irritation of the respiratory tract.

Irritation and Sensitisation
Slight conjunctival swelling and discharge and some scleral reddening was initially observed in an eye irritation test on rabbits, but all symptoms resolved by 72 hours. There was no staining of treated eyes by the notified chemicals.

Slight to marked black staining was noted in all rabbits in the skin irritation test and remained as slight staining in one animal until day 10 but cleared by the end of the study on day 14. Skin staining was also observed at dosing sites in the local lymph node assay and persisted in all animals throughout the study period however no evidence of lymphocyte proliferation was observed. The notified chemicals are therefore not considered to be irritating or sensitising to the skin of rabbits.

Repeated Dose Toxicity (sub acute, sub chronic, chronic)
In a 28-day repeat dose oral toxicity study, no significant adverse effects were observed in animals treated with the notified chemicals up to 1000 mg/kg bw/day. Black faeces and black pigment deposits in the gastro-intestinal tract were prominent but resolved at the end of the recovery phase and did not appear to cause adverse changes in the tissue. These findings may be indicative of poor absorption from the gastro-intestinal tract.

The oral No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study, based on the absence of observed adverse effects at the highest dose level.

The effects after repeated inhalation exposure were not investigated. As respiratory effects were observed for several days after a single exposure, the potential for the chemicals to cause respiratory effects after repeated exposure cannot be ruled out.

Mutagenicity and Carcinogenicity
Poor solubility was a limiting factor and doses were restricted to relatively low concentrations due to precipitation, particularly in the chromosome aberration test. The notified chemicals did not cause significant cytotoxicity in bacterial and mammalian cells and was not mutagenic or clastogenic at the doses tested.

Health hazard classification
The notified chemicals are not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The notified chemicals contain a high proportion of inhalable and respirable particles that are likely to cause respiratory effects if airborne dusts are inhaled. No repeat dose inhalation study was conducted however given the high level of insoluble respirable particles, there is potential for accumulation in the lungs following repeated exposure. Dust exposure could also pose a greater health risk for individuals with pre-existing respiratory conditions such as asthma or allergies. Exposure is most likely to occur during manual weighing and transfer of the powder and workers are expected to be trained in low dust handling techniques and engineering controls in place to prevent dust generation, such as local exhaust ventilation, dust collectors or wet dust suppression systems. Workers that are directly exposed are expected to wear suitable respiratory protection as stated in the MSDS. Further, fine dust particles could land on the mucous membranes of the eyes and cause eye irritation, therefore eye protection is expected to be worn. Australia has no exposure standard for respirable

dust, however, the ACGIH TLV of 3 mg/m^3 TWA is recommended. The notified chemicals are not expected to pose an inhalation risk when mixed with aqueous components based on the low vapour pressure, but workers could experience dermal and eye exposure through splashes and spills, therefore PPE (gloves, coveralls and safety glasses) should be worn to avoid skin and eye contact. No exposure is expected once the notified chemicals have been applied as a coating and dried or become incorporated into finished plastic articles.

The risk to workers during coatings and plastics manufacture is not unacceptable if the proposed engineering controls are in place and PPE is worn.

6.3.2. Public health

While the use of coatings containing the notified chemicals (~20%) by DIY users is expected to be considerably less frequent than professional tradesmen, the use of appropriate PPE is also thought to be less common, leading to greater potential for dermal and ocular exposure during roller and brush applications. However, the extent of exposure and risk is not expected to be significant.

Application of coatings containing the notified chemical (~20%) by spray, although expected to be uncommon, presents the greatest potential for inhalation exposure. Some risk of adverse respiratory effects following repeated inhalation exposure via spray application cannot be excluded, therefore the use of appropriate respiratory protection should be recommended on the product labels.

Overall, coatings containing the notified chemical are not expected to present an unacceptable risk to the health of DIY users.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemicals will not be manufactured in Australia. Release to the environment during shipping, transport and warehousing will only occur in the unlikely event of accidental spills or leaks from the import drums.

The notified chemicals will either be reformulated into liquid coatings or used in the manufacture of plastic products. As these processes do not occur in a closed system, there is potential for spillage during the weighing, loading and product transfer stages. The notifier estimates that approximately 0.2% of the notified chemicals will be released through accidental spillage during reformulation of the notified chemicals. The notifier also estimates that approximately 0.02% of the notified chemicals will be released from the cleaning of formulation equipment. Spills or release will be picked up with suitable appliance for re-use or disposal to landfill.

Less than 0.01% of the notified chemicals are expected to remain in the original empty containers, which will be collected by approved waste contractors or drum reconditioners. The notified chemicals contained therein will be disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The introduction volume of the notified chemicals will be split between end-use in industrial plastics (30%) and liquid coatings (70%). The notified chemicals are expected to be stable in manufactured plastics, given the extrusion and injection moulding processes used during manufacture. Losses during manufacture are expected to be low, with some off-cuts and rejects most likely to be recycled and a small proportion to be sent to landfill.

Coating products will be used predominantly for industrial applications but some DIY use is also expected. The end-use products will be applied externally by means of spray guns, brushes or rollers, but limited use of the former is expected from DIY users. Release from indoor applications will be captured on drop sheets, which will be most likely disposed of to landfill. For outdoor applications, droplets from brushing, rolling or spraying will either be captured and bound to sheets or paper forming an inert matrix, or will be allowed to settle on the ground where the paint will form dry inert surface coatings or agglomerations.

The major potential route of release is from the cleaning of application equipment, and it is expected that 5% of the import volume of the notified chemicals in liquid coatings will be disposed of predominantly to effluent systems via washings or alternatively immobilised to landfill (in the case of dried coatings on unwashed brushes and empty paint tins). For industrial applications, the rinsings are expected to pass to the trade waste

system where the residual coating product would be filtered out before discharge of the waste water to the sewer. The amount of the notified chemicals used by DIY users remains unclear but would not be expected to exceed 10% of the import volume. Therefore, the predicted amount entering sewers from DIY use is 0.7 × 0.05 × 10% = 0.35% of the total import volume.

RELEASE OF CHEMICAL FROM DISPOSAL

It is expected that wastes generated during formulation and coating application would be disposed to landfill, or to the sewer from the washing of coating equipment. The contaminated packaging will be disposed of to landfill.

In the case of plastics, it is expected that these will be disposed to landfill at the end of their useful life.

7.1.2 Environmental fate

Based on the provided environmental fate studies, the notified chemical is not readily biodegradable, and is expected to have low potential to bioaccumulate. For the details of the studies, please refer to Appendix C.

Given the proposed measures for containing and disposing of spillages, washings from the cleaning of formulation equipment and container residues, loss of the imported notified chemicals to the sewer during the reformulation process is not expected. Releases are expected to be disposed of to landfill. Notified chemicals within manufactured plastics are expected to share the fate of the plastic product and be disposed of to landfill at the end of its useful life. Release of the notified chemicals from coatings applications (drips, splashes and overspray) are most likely to form an inert matrix with protective sheeting or the ground, with the former likely to be directed to landfill. It is expected that 0.35% of the notified chemicals will enter sewers from the cleaning of application equipment.

The notified chemicals have very low water solubility (<0.1 mg/L), and with a predicted high adsorption/desorption coefficient (log K_{OC} = 7.29) are expected to partition to sediments and soils in terrestrial and aquatic environments. In soils, the notified chemicals will undergo slow degradation processes via biotic and abiotic pathways, forming small molecules of water and oxides of carbon and nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

The Predicted Environmental Concentration arising from the use pattern has been modelled for the worst case in which none of the notified chemicals released in aqueous wastes from the application of end-use products is removed by or degrades in, on-site waste water treatment and sewage treatment plants. The details of the calculation based on these parameters are presented below:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	4,000	kg/year
Proportion expected to be released to sewer	0.35%	
Annual quantity of chemical released to sewer	14	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	0.04	kg/day
Water use	200	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:	0.01	µg/L
PEC - Ocean:	0.001	µg/L

7.2. Environmental effects assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LL50 > 100 mg/L	Not toxic to fish above the limit of solubility*
Daphnia Toxicity	EL50 > 100 mg/L	Not toxic to daphnia up to the limit of solubility
Algal Toxicity	EL50 > 100 mg/L	Not toxic to algae up to the limit of solubility**
Inhibition of Bacterial Respiration	EC50 >1000 mg/L	Not toxic to micro-organisms

* Nominal 100 mg/L solution was very turbid. ** Less than the detection limit of 0.1 mg/L.

The notified chemicals are not toxic to the aquatic life up to the limit of solubility.

7.2.1 Predicted No-Effect Concentration

A predicted no effect concentration (PNEC – aquatic ecosystems) of > 1.0 µg/L has been derived by dividing the end point value of > 0.1 mg/L by a worst-case scenario uncertainty (safety) factor of 100 (as toxicity studies are available for four trophic levels).

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Invertebrates).	> 0.10	mg/L
Assessment Factor	100	
PNEC:	> 1.0	µg/L

7.3. Environmental risk assessment

Based on the above PEC and PNEC values, the following Risk Quotients (Qs) have been calculated:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.01	> 1.0	< 0.01
Q - Ocean	0.001	> 1.0	« 0.01

The Risk Quotients are well below 0.01 for both the river and ocean disposal scenarios, indicating that the notified chemicals are not expected to pose an unacceptable risk to the aquatic environment based on the proposed use pattern. While the notified chemicals released to the aquatic environment are expected to persist in association with sediment (due to its low biodegradability potential), its poor solubility in octanol and its relatively high molecular weight indicate low potential for bioaccumulation. In addition, the notified chemicals are unlikely to be mobile in the terrestrial environment. Consequently the notified chemicals are not expected to pose an unacceptable risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemicals are not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human health risk assessment

Under the conditions of the occupational settings described, the notified chemicals are not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified chemicals are 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 chemicals are not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemicals during manual weighing and powder transfer:
  - Local exhaust ventilation and/or appropriate dust extraction systems

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemicals during manual weighing and transfer:
  - Use of low-dust handling techniques

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemicals:
  - Eye protection
  - Gloves
  - Respiratory devices

  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 chemicals 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 chemicals should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemicals 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 chemicals has changed from a component of coatings and plastics, or is likely to change significantly;
  - the amount of chemicals being introduced has increased from 5 tonnes, or is likely to increase, significantly;
  - the chemicals have begun to be manufactured in Australia;

- additional information has become available to the person as to an adverse effect of the chemicals 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.

Material Safety Data Sheet
The MSDS of the notified chemicals 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

Melting Point No melting temperature observed between 20ºC and 400ºC

Method EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Differential Scanning Calorimetry was used to measure the melting temperature. Decomposition was not observed. Some different endothermic peaks with a maximum at about 80ºC and 120ºC were observed in the first heating and may be attributed to loss of volatile components. A small endothermic peak followed by an exothermic peak was observed at 350 - 380ºC.
Test Facility BASF (2005a)

Density 1515 kg/m^3 at 20ºC

Method EC Directive 92/69/EEC A.3 Relative Density.
Remarks Density was determined using a pycnometer and oscillating density meter with petroleum as the displacement liquid.
Test Facility BASF (2005a)

Vapour Pressure < 1 x 10^{-7} kPa at 20ºC

Method EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks The vapour pressure was determined by effusion method, weight loss, according to the test guideline. The vapour pressure decreased steadily when subjected to a constant temperature of about 153˚C and reached the detection limit. The test item was solid under the test temperature.
Test Facility BASF (2005a)

Water Solubility < 0.1 mg/L at 20ºC

Method EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Flask Method. After a preliminary test, mixtures of the notified chemicals/water were prepared at three different nominal concentrations, and solutions were obtained after filtration (0.2 µm). Aliquots of these solutions were evaporated to dryness, dissolved with concentrated sulphuric acid and analysed by means of UV/VIS spectrometry (with external calibration). All results showed a concentration below the detection limit of 0.1 mg/L. Estimation by EPIWIN (EPISuite v3.10) showed a solubility of 1.2 x 10^{-5} mg/L (at 25ºC).

Therefore, the solubility of the notified chemicals is believed to be < 0.1 mg/L.
Test Facility BASF (2005a)

Partition Coefficient (n-octanol/water) log K_{OW} = 7.52

Method EPI Suite v3.10. modelling
Remarks Measurement unfeasible due to the low solubility in both water and n-octanol.
Test Facility BASF (2005a)

Adsorption/Desorption log K_{OC} = 7.29

Method EPI Suite v3.10. modelling
Remarks Measurement unfeasible due to the low solubility in water.
Test Facility BASF (2005a)

Particle Size 0.9 - 26.31 µm

Method Determination of the particle size distribution by laser diffraction according to the Fraunhofer model. 1 g of the test item was mixed with 1ml of Trion-X solution and filled up to 100 ml with filtered water. The mixture was stirred then the suspension was stirred

in the wet disperser for 5 minutes and measured by laser diffraction method.

Range (μm)	*Cumulative Mass (%)*
< 26	100
< 16	90
< 8	50
< 3	10

Remarks None
Test Facility BASF (2005a)

Flammability Not considered to be highly flammable.

Method EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks Brief burning and rapid extinction was observed.
Test Facility BASF (2005b)

Autoignition Temperature No self-heating detected up to 400°C

Method EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks None
Test Facility BASF (2005b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Lumogen Black FK 4280
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 2004/73/EC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/HanRcc:WIST (SPF)
Vehicle	0.5% w/v carboxymethyl cellulose solution
Observation Period	15 days
Remarks - Method	Three animals were each given a single dose of 5000 mg/kg bw by oral gavage administration.
RESULTS	
LD50	> 5000 mg/kg bw
Signs of Toxicity	All animals showed slightly ruffled fur from 30 minutes to 2 hours after administration, but appeared normal by day 6. Black faeces was seen in the cage of one animal from the 5-hour reading to day 4 but was no longer evident from day 6 to the end of the observation period.
Effects in Organs	No macroscopic findings were recorded.
Remarks - Results	No deaths occurred and all animals showed normal body weight gain.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	RCC (2005a)

B.2. Acute toxicity – inhalation

TEST SUBSTANCE	Lumogen Black FK 4280
METHOD	OECD TG 403 Acute Inhalation Toxicity – Limit Test. EC Directive 92/69/EEC, 93/21/EEC B.2 Acute Toxicity (Inhalation) – Limit Test.
Species/Strain	Rats/HanRcc:WIST (SPF)
Vehicle	2% w/w Aerosil 200
Method of Exposure	Head-nose exposure
Exposure Period	4 hours
Physical Form	Solid aerosol (particulate)
Particle Size	3.0 and 3.1 μm (MMAD)
Remarks - Method	The test substance was stirred in its container before a sample was taken. It was deagglomerated in a mixer under Aerosil 200 prior to introduction in the dust generator to improve dust aerosol formation. The oxygen content in the inhalation system was not measured as the air exchange rate was judged to be sufficient and the test substance concentration was not expected to have a substantial influence on oxygen partial pressure. The results from the particle size analysis were not corrected for the additive. A total of ten animals (5 male, 5 female) were exposed to a measured concentration of 5.2 mg/l of the test substance mixed with 2% Aerosil 200.

RESULTS

LC50	> 5.2 mg/L/ 4 hours
Signs of Toxicity	Clinical signs include visually accelerated respiration in 10/10 animals up to day 3 of the study. Pulmonary respiration sounds were noted in 1/10 rats post-exposure on the exposure day. All ten animals showed squatting posture and piloerection after exposure until day 1 and two animals showed smeared fur. Fur contamination was detected in all animals up to day 14 (end of the study).
Effects in Organs	No pathological abnormalities were observed. Contaminated fur was noted during necropsy in all animals.
Remarks - Results	No deaths occurred at the tested concentration of 5.2 mg/l during the 14-day study period.

CONCLUSION The notified chemicals are of low toxicity via inhalation.

TEST FACILITY BASF (2005c)

B.3. Irritation – skin

TEST SUBSTANCE Lumogen Black FK 4280

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Moistened with purified water
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations. The remnants of the test item prevented scoring of all animals at the 1-hour observation.

RESULTS

Remarks - Results	There was no mortality and no clinical signs of toxicity or irritation (score 0) in any animal during the study. The test item caused a slight to marked black staining at the test site of all animals up to the 48-hour reading and persisted as slight staining in two animals until the 72-hour and 10-day observation periods, respectively, but cleared by the end of the study.

CONCLUSION The notified chemicals are non-irritating to the skin.

TEST FACILITY RCC (2005b)

B.4. Irritation – eye

TEST SUBSTANCE Lumogen Black FK 4280

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
Observation Period	72 hours
Remarks - Method	No significant protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0.67	0.33	0.67	1	< 72 hours	0
Conjunctiva: chemosis	0	0	0	0	0	0
Conjunctiva: discharge	0	0	0	0	0	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks - Results: No signs of systemic toxicity were observed in any animal during the study. Slight swelling (chemosis) of the conjunctivae was observed in one animal at the 1-hour reading and slight to moderate reddening of the sclerae was noted in two animals at the 1-hour reading and persisted as slight reddening up to the 24 or 48-hour readings, respectively. These signs cleared by 72 hours. Slight conjunctival discharge was observed in two animals at the 1-hour reading but had resolved by day 1. Slight black remnants of the test item were observed in the eye or conjunctival sac of two animals at the 1-hour reading but no remnants were evident thereafter. No staining of the treated eyes by the test item was observed.

CONCLUSION: The notified chemicals are slightly irritating to the eye.

TEST FACILITY: RCC (2005c)

B.5. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE: Lumogen Black FK 4280

METHOD: OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
EC Directive 2004/73/EC B.42 Skin sensitisation: Local Lymph Node Assay

Species/Strain: Mouse/CBA/CaHsdRcc(SPF)

Vehicle: Acetone/olive oil (4:1, v/v)

Remarks - Method: 25% was the highest technically applicable concentration of the test substance in the vehicle. This concentration was found to be non-irritating in the preliminary test.

RESULTS

Concentration (% w/v)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	516	-
5	604	1.2
10	629	1.2
25	404	0.8
Positive Control		
0 (vehicle control)	314	-
5	910	2.9
10	1223	3.9
25	2725	8.7

Remarks - Results: After the first topical application, residual test item was found at both dosing skin sites in all test animals, which persisted for the remainder of the study. No clinical or local signs of irritation were observed in any animal.

CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the test substance concentrations up to 25%.
TEST FACILITY	RCC (2006)

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B.6. Repeat dose toxicity

TEST SUBSTANCE	Lumogen Black FK 4280
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/Wistar Crl: (WI) BR
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 5/7 days per week Post-exposure observation period: 14 days
Vehicle	Purified water
Remarks - Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5M, 5F	0	0
low dose	5M, 5F	100	0
mid dose	5M, 5F	300	0
high dose	5M, 5F	1000	0
control recovery	5M, 5F	0	0
high dose recovery	5M, 5F	1000	0

Clinical Observations

No toxicologically relevant signs were observed. Black faeces were evident at 1000 mg/kg/day from week 3 of the treatment onwards and occasional black staining of the fur was considered to be due to the staining properties of the test substance. These observations resolved during the recovery phase. Incidental findings in the treatment group include alopecia and scabs during the treatment and broken tail apex in a number of animals during the recovery phase. The investigators noted that these types of findings are occasionally observed in rats of this strain and age under the conditions of this study and are not viewed as toxicologically significant. No clinical signs were noted in control animals, males at 300 mg/kg and females at 100 and 300 mg/kg/day.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Haematology

A small but statistically significant decrease was observed in mean corpuscular haemoglobin (MCH) levels in males at 300 mg/kg/day, although this occurred in the absence of a dose-related response. There was a lower prothrombin time (PT) of females at 1000 mg/kg/day at the end of the treatment phase but this was well within the historical control range. These changes were not considered to be toxicologically relevant.

Clinical biochemistry

Incidental changes were: a lower aspartate aminotransferase (ASAT) levels in males at 100 mg/kg/day, increased albumin in females at 300 and 1000 mg/kg/day, higher sodium levels in females at 300 mg/kg/day and slightly higher chloride levels in females at 100, 300 and 1000 mg/kg/day. These changes were within the historical control range levels and occurred without a clear dose-related response, and are not considered to be of toxicological significance.

Urinalysis

Statistically significant changes in females at 300 mg/kg/day were: higher specific gravity, lower urine volume, higher sodium levels and increased potassium levels, which were absent when corrected for urinary volume. These changes were not considered to be toxicologically significant.

Effects in Organs

Macroscopic examinations revealed black contents in the gastro-intestinal tract (GIT) in animals of both sexes dosed at 1000 mg/kg/day and in one male at 300 mg/kg/day at the end of the treatment, which is attributed to the black powder test substance. Microscopic examinations showed black pigment deposits in the lumen or on the mucosal surface of the GIT in all 5 males and 4/5 females at 1000 mg/kg/day. However the pigmentation occurred in the absence of any histopathological changes in the tissue and the pigmentation had resolved at the end of the recovery period. There were no toxicologically significant changes in organ weights of treated rats. Incidental findings include: renal pelvic dilation in males at 100 and 1000 mg/kg/day, fluid in the uterus in females treated at 1000 mg/kg/day and bone fractures of the tail apex in two females dosed at 1000 mg/kg/day. The study authors commented that these findings were occasionally seen among rats in these types of studies and that in the absence of treatment-related distribution were considered to be of no toxicological significance.

Remarks – Results

There were no unscheduled deaths and rats did not show any significant toxicologically related changes when treated with doses up to 1000 mg/kg/day.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as 1000 mg/kg bw/day in this study.

TEST FACILITY NOTOX (2006)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE	Lumogen Black FK 4280
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Pre incubation procedure & plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Aroclor-induced rat liver S9 preparation
Concentration Range in Main Test	a) With metabolic activation: 4-5000 µg/plate b) Without metabolic activation: 4-5000 µg/plate
Vehicle	DMSO
Remarks - Method	A standard plate test and preincubation test were both carried out with and without metabolic activation using concentrations of 20 – 5000 µg and 4-2500 µg, respectively. Colony counting was not possible in the first experiment due to contamination of the test substance. Subsequently, all tests were performed with autoclaved test substances.

RESULTS

Remarks - Results	Precipitation was observed in all plates, at and above 100 µg. The bacterial titre levels at the highest doses (500 and 2500 µg) were lower than the vehicle control plates. There were no significant increases in the frequency of revertant colonies at any dose either with or without S9 when compared to the concurrent control and historical control values.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BASF (2006a)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE	Lumogen Black FK 4280
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test. EC Directive 2000/32/EC B.10 Mutagenicity - In vitro Mammalian Chromosome Aberration Test.
Cell Type/Cell Line	Chinese hamster/V79
Metabolic Activation System	Aroclor-induced rat liver S9 preparation
Vehicle	DMSO
Remarks - Method	Samples were taken at 18 hours and 28 hours to cover possible cell cycle delay. Dose selection for metaphase analysis was based on the solubility limits of the notified chemicals. In the preliminary range-finding tests, doses > 12.5 μg/ml both with and without metabolic activation resulted in strong test substance precipitation, which interfered with evaluation of metaphases. Doses > 3000 μg/ml led to an inhomogenous mass that could not be administered.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period (hours)*	*Harvest Time (hours)*
Absent			
Test 1	1.56, 3.13*, 6.25*, 12.50*, 25.0, 50.0, 75.0, 100.0	4	18
Test 2	0.78, 1.56, 3.13*, 6.25*, 12.50*, 25.0	18	18
Test 3	3.13, 6.25, 12.50*	18	28
Present			
Test 1	1.56, 3.13*, 6.25*, 12.50*, 25.0, 50.0, 75.0, 100.0	4	18
Test 2	1.56, 3.13*, 6.25*, 12.50*, 25.0	4	28

*Cultures selected for metaphase analysis.

RESULTS

Remarks - Results	There was no evidence of cytotoxicity although a slight decrease in cell count was observed in test groups with metabolic activation. There was no significant increase in the number of structural and numerical chromosomal aberrations either with or without S9 compared to the vehicle control. The control values were within the expected range.
CONCLUSION	The notified chemical was not clastogenic at concentrations up to 12.5 μg/ml in Chinese hamster V79 cells treated *in vitro* under the conditions of the test.
TEST FACILITY	BASF (2006b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemicals
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	The biochemical oxygen demand (BOD) was measured; The dissolved organic carbon (DOC) was measured at the beginning and the end of the test.
Remarks - Method	Test was conducted in triplicates at 22 ± 1˚C for up to 28 days. Aniline was used as the reference substance for reference control test.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	0	7	58
28	0	28	80

Remarks - Results	All criteria for test validity were met. The reference control test for aniline reached a biodegradation degree of 69% after 14 days.
CONCLUSION	The notified chemicals are not considered readily biodegradable.
TEST FACILITY	BASF (2006c)

C.1.2. Bioaccumulation

Remarks	Although the theoretical log K_{OW} value of 7.52 for the notified chemicals indicates high potential for bioaccumulation, this is more a reflection of its very low water solubility but relatively higher (but still low) solubility in n-octanol. The low n-octanol solubility indicates low potential for the notified chemical to dissolve and accumulate significantly in fish tissue. The notifier supports this argument with reference to the Critical Body Burden concept, which establishes that the octanol solubility is well below a critical concentration (0.002×Molecular weight (g/mol)) below which a reduced uptake of the substance can be expected and toxicity is not likely. As a further supporting argument, a low bioconcentration factor (BCF) of 1.6 is calculated from the BCF model Oasis CATABOL model.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemicals
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – Static.
Species	*Danio rerio*

Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks – Method	The test was conducted at 23˚C by exposing fish (10 for each concentration) to the notified chemical at a loading rate of 100 mg/L. Test medium was observed to have undissolved test substance at the bottom of the test vessel throughout the test, strong turbidity until 72 hours, and was observed to be homogeneous dispersion with turbidity after 96 hours. A blank control test was also conducted. The study was performed without concentration control analysis because the water solubility was below the detection limit.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0		10	0	0	0	0	0
100		10	0	0	0	0	0

LL50	> 100 mg/L at 96 hours.
NOEL	100 mg/L at 96 hours.
Remarks – Results	Neither morality nor sub-lethal effects were observed from the fish exposed to the notified chemicals.

CONCLUSION The notified chemicals are not toxic to fish above the limit of solubility.

TEST FACILITY BASF (2005d)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified Chemicals

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static.
EC Directive 92/32EEC, Annex part C.2: Acute Toxicity for Daphnia – Static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	
Water Hardness	2.2 – 3.2 mmol $CaCO_3$/L
Analytical Monitoring	
Remarks - Method	The study was performed at a loading rate of 100 mg/L, 18 – 22˚C, in 4 replicates with 5 animals in each test vessel. Test solutions were centrifuged and filtered resulting in clear and colourless solutions. The study was performed without concentration control analysis because the water solubility was below the detection limit. A blank control test was also conducted without the presence of the notified chemicals.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0		20	0	0
100		20	0	0

EL50	> 100 mg/L at 48 hours
NOEL	100 mg/L at 48 hours

Remarks - Results	No immobilization of the daphnids that were exposed to the notified chemicals was observed at the loading rate of 100 mg/L.
CONCLUSION	The notified chemicals are not toxic to daphnids up to the limit of solubility.
TEST FACILITY	BASF (2005e)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemicals
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 0, 100, 50, 25, 12.5, 6.25, 3.13, 1.56, 0.781, 0.391 mg/L
Auxiliary Solvent	
Water Hardness	Not reported
Analytical Monitoring	
Remarks - Method	The study was conducted at a series of loading rates in triplicate at 21 – 25˚C and pH 8.1. For test solution preparation, undissolved test substance was removed from the stock solution by filtration with a membrane filter (pore width 0.2 µm). A blank test (in triplicate) was also conducted under identical conditions except that without the notified chemicals. A control test using potassium dichromate as the reference substance was conducted 17 months before the study.

RESULTS

Biomass		*Growth*	
E_bC50 mg/L at 72 h	*NOEC mg/L*	*E_rC50 mg/L at 72h*	*NOEC mg/L*
> 100	100	> 100	100

Remarks - Results	The E_rC50 for the potassium dichromate was determined to be 1.37 mg/L by the control test which is within the validity range of 0.92 – 1.46 mg/L. Test results indicate that the notified chemicals are not toxic to algae up to the limit of the solubility.
CONCLUSION	The notified chemicals are not toxic to algae up to the limit of the solubility.
TEST FACILITY	BASF (2006e)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemicals
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: 1000 mg/L
Remarks – Method	The study was performed at 20 ± 2˚C and pH of 7.5± 0.5. A blank control test was conducted in 3 replicates. A control test was also conducted using 3,5-dichlorophenole as the reference substance at concentrations of 1, 10 and 100 mg/L.

RESULTS

IC50	> 1000 mg/L (nominal)
NOEC	1000 mg/L (nominal)
Remarks – Results	The IC50 for the reference substance was determined to be 5.675 mg/L (with a p-value of 0.8909) which is within the valid range on 5 – 30 mg/L. No adverse effect was observed for the respiration of micro-organisms in the tested activated sludge at the loading rate of 1000 mg/L.
CONCLUSION	The notified chemicals are not toxic to the micro-organisms in activated sludge.
TEST FACILITY	BASF (2006d)

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