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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical 1 in Lumogen Black FK 4281

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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Australia Ltd (ABN 62 008 437 867)
500 Princes 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 and % Weight of Hazardous Impurities, Import Volume, Identity of Customer Sites.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Adsorption/Desorption, Hydrolysis as a function of pH, Dissociation Constant, Acute Dermal Toxicity, Bioaccumulation.

NOTIFICATION IN OTHER COUNTRIES
US, Canada, EU, Japan, Korea

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Lumogen Black FK 4281

MOLECULAR WEIGHT
<1000 Da

ANALYTICAL DATA
Reference ^{1}H NMR, IR, HPLC, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY The notified chemical will be imported in an inseparable mixture at ~50%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Black, fine crystalline powder (Lumogen Black FK 4281 containing 50% notified chemical)

Property	Value	Data Source/Justification
Melting Point	>400°C	Measured
Density	1566 kg/m^3 at 20°C	Measured
Vapour Pressure	<10^{-7} kPa at 20°C	Measured
Water Solubility	<0.1 mg/L at 20°C	Measured
Hydrolysis as a Function of pH	Not determined	The test cannot be performed as the water solubility is below the detection limit. Although hydrolysable functionality is present, this is unlikely to occur in the environmental pH range.

Partition Coefficient (n-octanol/water)	log Pow = 8.54	Calculated with EPIWIN software
Adsorption/Desorption	log K_{oc} = 11.1	Calculated with EPIWIN software
Dissociation Constant	Not determined	The notified chemical has low water solubility and contains no dissociable functionality.
Particle Size	Inhalable fraction (<100 μm): 100% Respirable fraction (≤10 μm): 94.8% MAD* = 3.61 μm	Measured
Flammability	Not highly flammable	Measured
Autoignition Temperature	374°C	Measured
Explosive Properties	Not expected to be explosive	Estimated based on chemical structure

* MAD = Mean Aerodynamic diameter

DISCUSSION OF PROPERTIES

The notified chemical is a solid, crystalline powder with negligible water solubility and a high proportion of particles (94.8%) in the respirable range.
For full details of tests on physical and chemical properties, please refer to Appendix A.

Reactivity

The notifier states that while the notified chemical is not likely to cause a dust explosion, dust accumulation should be avoided. There are no known hazardous decomposition products or incompatibility with other substances. The notified chemical is expected to be stable under normal environmental conditions.

5. INTRODUCTION AND USE INFORMATION

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

Lumogen Black FK 4281 (50% notified chemical) will be imported by sea.

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

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

PORT OF ENTRY

Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS

BASF Australia Ltd
500 Princes Highway
NOBLE PARK VIC 3174

Wattyl Australia Pty Ltd
560 Churchill Road
KILBURN SA 5084

TRANSPORTATION AND PACKAGING

Lumogen Black FK 4281 will be imported in 2x10 kg drums. From the wharf, it will be transported via road to a contracted third party warehouse in Melbourne. Distribution to numerous customers will also be by road.

USE

The notified chemical will be used as a dispersed solid pigment in coloured plastics at ~5% concentration and coatings at ~20% concentration. The introduction volume of the notified chemical will be split between end-use in industrial plastics (30%) and liquid coatings (70%). Coatings containing the notified chemical will be available for public use, however, it is anticipated that a maximum of 10% of the introduced volume will be sold to the public.

OPERATION DESCRIPTION

The notified chemical will be imported in 2x10 kg drums and transported from the wharf to a warehouse for

storage by road. From the warehouse it will be transported to various customers by road.

At the customer facility, drums containing the notified chemical will be taken to storage or production areas by forklift.

Coatings manufacture:
The notified chemical will be weighed and transferred manually and poured into a hopper and fed into an open mixer where it will be mixed with other components to form a liquid dispersion. The disperion 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 chemical will be tested by technicians. The products will be packed using automated filling and packing machines. Once the product is packaged, it will be stored before sale to a variety of customers for use in industrial and domestic applications.

Plastics manufacture:
The notified chemical 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. 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.

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.

Coatings manufacture
Inhalation of airborne particles of Lumogen Black FK 4281 (50% notified chemical) is expected to be the main route of exposure during manual weighing and transfer into the hopper and addition to mixers as part of coatings manufacture. Assuming a worst-case scenario involving dry manipulation of Lumogen Black FK 4281 (50% notified chemical) 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 4281 (50% notified chemical) would lower the predicted atmospheric particulate concentration to 2-5 mg/m^3 (EC, 2003). The notifier supplied an MSDS which recommends the use of respiratory personal protective equipment (PPE) as well as gloves, safety glasses and closed work clothes during the handling of Lumogen Black FK 4281 (50% notified chemical) in powder form.

Once the notified chemical has been mixed into a homogenous coating (~20%), 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 Lumogen Black FK 4281 (50% notified chemical) with other coating components and during manual transfer of the coating 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 Lumogen Black FK 4281 (50% notified chemical) are expected to wear PPE, such as, chemical-resistant clothing, chemical resistant gloves and protective eyewear to minimise exposure during

transfer of the liquid dispersion into filling lines and packaging equipment.

Plastics manufacture
Inhalation exposure to airborne particles of Lumogen Black FK 4281 (50% notified chemical) will 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 will wear respirators to minimise inhalation exposure. In addition, the notifier states that other PPE including splash-proof goggles, chemically resistant gloves, boots and aprons will be used to minimise any accidental dermal and ocular exposure.

Once incorporated into the finished moulded plastic article (~5%), no further exposure is anticipated as the notified chemical will be bound within the solid plastic.

Drum recyclers
Drum recyclers will be exposed to Lumogen Black FK 4281 (50% notified chemical) via inhalation, dermal and ocular routes when collecting empty import drums. LEV is expected to be in use where the empty drums are kept to minimise inhalation exposure. In addition, PPE, including a suitable respirator is expected to be used by drum recyclers to further minimise exposure.

Professional use of coating products
Professional tradesmen will experience inhalation, dermal and ocular exposure to coatings containing the notified chemical (~20%) during spray, roller and brush application. However, exposure is expected to be minimised by the use of PPE including respirator or full-face mask during spray application as well as impervious gloves, safety glasses and coveralls. Application of coating products containing the notified chemical 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 dried or cured into an inert matrix from which the notified chemical will be unavailable to cause exposure.

6.1.2. Public exposure

Do-it-yourself (DIY) users will experience inhalation, dermal and ocular exposure to coatings containing the notified chemical (~20%) during spray, roller and brush application. Exposure to coatings containing the notified chemical is expected to be similar to that experienced by professional tradesmen, however, application is expected to be significantly less frequent. DIY users are also less likely to apply coatings by spray guns, therefore reducing the potential for inhalation exposure. However, spray booths and LEV is not expected to be available to DIY users on occasions when they do apply coatings by spray. The use of PPE including impervious 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 from which the notified chemical will be unavailable to cause exposure.

6.2. Human health effects assessment

The results from toxicological investigations conducted on Lumogen Black FK 4281 (50% notified chemical) 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 >5000 mg/kg bw low toxicity
Rat, acute inhalation toxicity	LC50 >5.1 mg/L/4 hrs
Rabbit, skin irritation	slightly 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 bw/day
Mutagenicity – bacterial reverse mutation	non-mutagenic
Genotoxicity – in vitro chromosome aberration	non-genotoxic

Toxicokinetics, metabolism and distribution
The notified chemical is expected to have low potential for absorption across biological membranes due to the very low solubility of Lumogen Black FK 4281 (50% notified chemical) in water (<0.1 mg/L) and octanol (<8

mg/L). Poor oral bioavailability is supported by the observation of dark-coloured faeces and lack of systemic effects in the 28-day repeat dose oral toxicity study. In addition, the effects observed in the acute oral toxicity test did not conclusively indicate absorption as those effects may be attributed to the high volume of the dose used (see below). The dark-coloured faeces observed in the acute inhalation toxicity test also indicated that the notified chemical was not absorbed readily.

Airborne dusts of the notified chemical are expected to be inhaled readily given that 94.8% of particles are in the respirable range. However, absorption across membranes in the lung is unlikely given the low solubility of Lumogen Black FK 4281 (50% notified chemical) in water and octanol. No mucocilliary clearance is expected from the deep lung where the particles of the notified chemical are expected to deposit. Over time inhalation of high concentrations of the notified chemical may lead to accumulation of particles in the deep lung which may overwhelm the alveolar macrophage-mediated lung clearance mechanism.

Little is known about the metabolism of Lumogen Black FK 4281 (50% notified chemical). The notified chemical has some structural similarities with polycyclic aromatic hydrocarbons (PAH) which are known to undergo ring epoxidation to form mutagenic metabolites (p.142, Casarett & Doull's Toxicology: The Basic Science of Poisons, 6th edition, 2001). It is unclear whether the notified chemical is metabolised via the same pathway.

Systemic toxicity

Lumogen Black FK 4281 (50% notified chemical) was found to be of low acute toxicity (>5000 mg/kg bodyweight) via the oral route. Impaired general state, dyspnoea, staggering and piloerection were observed 3 to 5 hours after administration by oral gavage. However, the dose volume of 20 mL/kg is at the upper limit recommended in OECD TG423 and this may account for the effects observed. In an acute inhalation toxicity study, Lumogen Black FK 4281 (50% notified chemical) was found to be of low acute inhalation toxicity (>5.1 mg/L over 4 hours). One mortality occurred during the study. However, the dose at which the mortality occurred was considered suitably high to suggest that the acute inhalation toxicity of the substance containing the notified chemical (50%) was not high. Other effects observed in the study include visually accelerated respiration, pulmonary respiration sounds, squatting posture, piloerection, smeared and contaminated fur and black stained faeces. The stained faeces which was observed in all animals the day following exposure may indicate that Lumogen Black FK 4281 (50% notified chemical) was cleared from the lungs and swallowed but unable to be absorbed due to its poor oral bioavailability.

In a 28-day repeat dose oral toxicity study, no significant abnormal clinical or histopathological observations, laboratory findings or effects on the target organs were observed in animals treated with the notified chemical at 100, 300 or 1000 mg/kg bw/day. However, these findings may be indicative of poor absorption from the gastro-intestinal tract. Dark faeces, with a dose-related intensity were observed in all animals treated with the notified chemical for the duration of the study. However, this effect was absent by Day 6 of the recovery phase and was consistent with observations from the acute inhalation toxicity study. This may be indicative of poor oral bioavailability.

The 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 potential for toxicity of the notified chemical following repeated inhalation exposure were not investigated and therefore the effects on the respiratory system are unknown. However, given the particle size of Lumogen Black FK 4281 (50% notified chemical) is in the respirable range and its low solubility, repeated inhalation exposure may lead to impaired lung function.

Irritation and Sensitisation

Slight to moderate erythema was observed in all 3 animals in a skin irritation test, persisting until 72 hours in one animal. The reactions were reversible except in one animal, where scaling was observed 7 days after treatment (see Appendix B for details). These effects were not sufficient for classification according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. In addition, a modified Local Lymph Node Assay (LLNA), animals treated with Lumogen Black FK 4281 (50% notified chemical) at 30% concentration showed a statistically significant increase in ear weight indicative of irritancy potential (see Appendix B for details).

Slight eye irritation in the form of conjunctival redness, conjunctival chemosis and slight discharge were observed in all animals up to 24 hours after treatment. In addition, injected scleral vessels were observed in 2

animals, persisting to 24 hours after treatment in one (see Appendix B for details). However, these effects were not sufficient for classification according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

A modified LLNA was performed on Lumogen Black FK 4281 (50% notified chemical) at a single tested concentration of 30%. Higher concentrations were not tested due to a limited water solubility (<0.1 mg/L). This procedure has undergone validation in Europe using different mouse strains to the one used in this test but has not been validated by the OECD. Instead of using radioactive labelling, lymph node cell counts and weights were measured to indicate sensitising potential. Ear weights were measured to indicate irritant potential. There was no statistically significant increase in lymph node cell counts or weights but there was a statistically significant increase in the ear weight of treated animals. Therefore, the notified chemical is unlikely to be a sensitiser but is possibly an irritant, supported by evidence from the skin irritation test conducted in rabbits (see Appendix B for details).

Genotoxicity
The notified chemical contains some structural similarities with PAHs which are known to be metabolically activated to form carcinogens. However, given the poor oral bioavailability of Lumogen Black FK 4281 (50% notified chemical) the notified chemical is unlikely to undergo metabolic activation to a mutagenic metabolite. In support of this hypothesis, the notified chemical was found to be non-mutagenic in a bacterial reverse mutation test. There was no evidence of clastogenicity to human lymphocytes *in vitro*, either with or without metabolic activation. The results of these tests indicated the notified chemical was not clastogenic to the limits of solubility.

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

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Inhalation of Lumogen Black FK 4281 (50% notified chemical) presents the greatest risk for workers handling the notified chemical directly during formulation into coatings or incorporation into plastics. Professional tradesmen applying coatings containing the notified chemical (~20%) by spray may also encounter exposure by inhalation. Results from an acute inhalation toxicity study demonstrate that Lumogen Black FK 4281 (50% notified chemical) is of low acute inhalation toxicity and a repeat dose oral toxicity study showed that it did not cause any adverse effects up to 1000 mg/kg bw/day for 28 days. No repeat dose inhalation study was conducted but given Lumogen Black FK 4281 (50% notified chemical) consists of insoluble, respirable particles, there is potential for accumulation in the lungs following repeated inhalation. Low-dust handling techniques, LEV and the use of appropriate respirators for respirable particulates when handling the notified chemical in powder form would minimise potential inhalation exposure and minimise any potential adverse effects.

Lumogen Black FK 4281 (50% notified chemical) produced minor irritant effects in skin and eye irritation tests in rabbits. However, workers are unlikely to be at risk of irritation during use of the notified chemical.

6.3.2. Public health
While the use of coatings containing the notified chemical (~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, ocular and to a lesser extent, inhalation exposure. The extent of exposure, however, is not expected to be significant enough to present a risk of skin or eye irritation, despite minor irritation observed in animal tests on rabbits.

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.

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 chemical 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 chemical 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 ~0.2% (up to 10 kg per annum) of the notified chemical will be released through accidental spillage during reformulation of the notified chemical. The notifier also estimates that ~0.02% (up to 1 kg per annum) of the notified chemical will be released from the cleaning of formulation equipment.

Less than 0.01% (<0.5 kg) of the notified chemical is expected to remain in the original empty containers, which will be collected by approved waste contractors or drum reconditioners. The notified chemical contained therein will be disposed of via their respective waste treatment facility or incinerated in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

The introduction volume of the notified chemical will be split between end-use in industrial plastics (30%) and liquid coatings (70%). The notified chemical is expected to be stable in manufactured plastics (containing 5% notified chemical), 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 sent to landfill.

Coating products (containing 20% notified chemical) 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 disposed of to landfill or incineration. 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 chemical 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 chemical 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 5000 kg × 0.7 × 0.05 × 0.1 = 17.5 kg (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 incineration, or to the sewer from the washing of coating equipment. The MSDS recommends that contaminated packaging be disposed of in the same manner as the contents.

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

7.1.2 Environmental fate

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 chemical to the sewer during the reformulation process is not expected. Releases are expected be disposed of to landfill or by incineration,

however, landfill is more likely. Notified chemical within manufactured plastics is expected to share the fate of the plastic productand be disposed to landfill at the end of its useful life. Release of the notified chemical 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% (17.5 kg) of the notified chemical will enter sewers from the cleaning of application equipment.

The notified chemical has very low water solubility (<0.1 mg/L), and with a predicted high adsorption/desorption coefficient (log K_{OC} = 11.1) is expected to partition to sediments and soils in terrestrial and aquatic environments. The notified chemical is not readily biodegradable, and is expected to persist for some time as no apparent degradation was observed over 28 days (For the details of biodegradation study, please refer to Appendix C). Although the notified chemical has a high theoretical log K_{OW} value of 8.54, the low solubility in octanol (but higher than the water solubility) indicates a low potential for bioaccumulation.

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 chemical 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 Volume	5,000	kg/year
Proportion expected to be released to sewer	0.35	
Annual quantity of chemical released to sewer	17.5	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	0.05	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	0%	
Daily effluent production:	4,099	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 chemical are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	EC50 >100 mg/L (nominal)	Non-toxic to the limit of water solubility*
Daphnia Toxicity	EC50 >100 mg/L (WAF)	Non-toxic to the limit of water solubility
Algal Toxicity	EC50 >100 mg/L (WAF)	Non-toxic to the limit of water solubility
Inhibition of Bacterial Respiration	EC50 >996 mg/L (nominal)	Non-toxic to the limit of water solubility**

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

7.2.1 Predicted No-Effect Concentration

A predicted no effect concentration (PNEC – aquatic ecosystems) of >1 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 usable toxicity data are available for three trophic levels).

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Daphnia)	>0.1	mg/L
Assessment Factor	100	
Mitigation Factor	1.00	
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	**<0.01**
Q - Ocean	0.001	>1	**<0.001**

The Risk Quotients are well below 0.1 for both the river and ocean disposal scenarios, indicating that the notified chemical is not expected to pose an unacceptable risk to the aquatic environment based on the proposed use pattern. While the notified chemical released to the aquatic environment is 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 chemical is unlikely to be mobile in the terrestrial environment. Consequently the notified chemical is not expected to pose an unacceptable risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

and

As a comparison only, the classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Environment	Chronic category 4	May cause long lasting harmful effects to aquatic life

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 considered to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in the product Lumogen Black FK 4281:
  - *Local exhaust ventilation where manual handling of the notified chemical in powder form is carried out.*

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in the product Lumogen Black FK 4281:
  - *Dust masks (adequate for respirable particulates) wherever airborne dusts are likely to be generated.*

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

- For health concerns, the level of atmospheric dust should be maintained as low as possible. The ACGIH recommended exposure level of 3 mg/m^3 should be observed for "respirable (insoluble) particulates (not otherwise regulated)".

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

- Spray application should be carried out in accordance with the ASCC *National Guidance Material for Spray Painting* [NOHSC (1999b)].

- 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 by landfill.

Storage

- The following precautions should be taken by BASF Australia Ltd regarding storage of the notified chemical:
  - *Keep container tightly closed and dry*
  - *Store in a cool place*
  - *Avoid the generation of airborne dusts during handling*
  - *Take precautionary measures against static discharges*

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and storage for disposal via landfill, incineration or further treatment in accordance with local regulations. The notified chemical should not be discharged into drains, surface waters or groundwaters.

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 pigment in coloured plastics and coatings or is likely to change significantly;
- the amount of chemical being introduced has increased from 5 tonnes, or is likely to increase, significantly;
- if 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.

Material Safety Data Sheet
The MSDS of 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

All tests were carried out on Lumogen Black FK4281 (~50% notified chemical).

Melting Point >400°C

Method	EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Differential Scanning Calorimetry method
Test Facility	BASF AG (2005b)

Density 1566 kg/m^3 at 20°C

Method	EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Pycnometer method
Test Facility	BASF AG (2005a)

Vapour Pressure <10^{-7} kPa at 20°C

Method	EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Effusion method
Test Facility	BASF AG (2005a)

Water Solubility <0.1 mg/L at 20°C

Method	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	The water solubility of the notified chemical was determined by the Flask Method. In a preliminary test the water solubility was estimated to be <11 mg/L, based on the presence of undissolved test substance. In the definitive test, test solutions were evaporated to dryness and dissolved with concentrated sulfuric acid. Following analysis of the dried residues by UV/VIS spectrometry, the water solubility was determined to be <0.1 mg/L. The theroretical value for water solubility was calculated (with EPIWIN EPI Suite v3.10) to be 3.6×10^{-7} mg/L.
Test Facility	BASF AG (2005b)

Partition Coefficient (n-octanol/water) log Pow = 8.54

Method	Model
Remarks	The test was not conducted as the notified chemical was found to be poorly soluble in both water and 1-octanol. The notified chemical was not completely dissolved in the latter when using the OECD 107 method, resulting in a solubility of <8 mg/L. When using the ETAD method, the octanol solubility was found to be 0.065 mg/L. The theoretical value for the partition coefficient, using EPIWIN software, was calculated to be 8.54.
Test Facility	BASF AG (2005b)

Adsorption/Desorption – screening test log K_{oc} = 11.1

Method	Model
Remarks	A test was not done due to the low water solubility of the notified chemical. The theoretical value for the adsorption coefficient, using EPIWIN software, was calculated to be 11.1.
Test Facility	BASF AG (2005b)

Particle Size

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

Range (μm)	*Mass (%)*
≤10	94.82
≤20	99.96
≤22.9	100

Remarks Laser diffraction method
Inhalable fraction (<100 μm): 100 %
Respirable fraction (≤10 μm): 94.8%
MAD = 3.61 μm
Test Facility BASF AG (2005b)

Flammability Not considered highly flammable.

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

Autoignition Temperature 374°C

Method EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Test Facility BASF AG (2005c)

Stability Testing Stable at <140°C

Method OECD TG 113 Screening Test for Thermal Stability and Stability in Air.
Remarks No temperature rise of 60°C over the oven temperature was observed within 24 hours.
Test Facility BASF AG (2005c)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Lumogen Black FK 4281 (50% notified chemical) in 0.5% CMC-solution

METHOD: OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
- Species/Strain: Rat/Wistar
- Vehicle: Doubly distilled water
- Remarks - Method: No significant protocol deviations

RESULTS

Number and Sex of Animals	*Dose mg/kg bw*	*Mortality*
3F	5000	0
3F	5000	0

- LD50: >5000 mg/kg bw
- Signs of Toxicity: Impaired general state, dyspnoea, staggering and piloerection were observed from 3 to 5 hours after administration.
- Effects in Organs: None observed.
- Remarks - Results: The observed effects may reflect the large dose volume and are not necessarily indicative of absorption of the notified chemical.

CONCLUSION: The notified chemical is of low toxicity via the oral route.

TEST FACILITY: BASF AG (2005d)

B.2. Acute toxicity – inhalation

TEST SUBSTANCE: Lumogen Black FK 4281 (50% notified chemical)

METHOD: OECD TG 403 Acute Inhalation Toxicity – Limit Test.
- Species/Strain: Rat/Wistar
- Vehicle: 1% Aerosil 200
- Method of Exposure: Oro-nasal exposure.
- Exposure Period: 4 hours
- Physical Form: Solid aerosol (particulate).
- Particle Size: 1.8 and 2.1 μm (two independent samples)
- Remarks - Method: No significant protocol deviations

RESULTS

Number and Sex of Animals	*Concentration mg/L*		*Mortality*
	*Nominal**	*Actual*	
5 per sex	24.7	5.1	1/10

*The nominal concentration was calculated from the amount of the notified chemical dosed into the dust generator and the supply air flow.

- LC50: >5.1 mg/L/4 hours
- Signs of Toxicity: Mortality was observed in one female rat 3 hours after exposure. Common abnormalities noted during the study included increased respiratory rate, pulmonary respiratory sounds, hunched posture, pilo-erection, smeared fur and black coloured faeces. Fur staining persisted until and including study day 14.
  All animals attempted to escape at the very beginning of exposure.
  Normal bodyweight development was noted for all animals during the

study.

Effects in Organs	No macroscopic abnormalities were detected amongst animals at necropsy.
Remarks - Results	Although one female died during exposure, the investigators judged the high concentration tested was sufficient to demonstrate the low order acute toxicity of the notified chemical.

CONCLUSION The notified chemical is of low toxicity via inhalation.

TEST FACILITY BASF AG (2005e)

B.3. Irritation – skin

TEST SUBSTANCE Lumogen Black FK 4281 (50% notified chemical)

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	The notified chemical was moistened with a minimal amount of water
Observation Period	7 days
Type of Dressing	Semi-occlusive.
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			
Erythema/Eschar	0.67	2	1	2	72 hours	0
Oedema	0	0	0	0	-	0

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

Remarks - Results	A slight black discolouration of the application area was observed in two animals during the study. Scaling was also observed in one animal at the end of the study.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY BASF AG (2005f)

B.4. Irritation – eye

TEST SUBSTANCE Lumogen Black FK 4281 (50% notified chemical)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

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	0.33	0.33	0.33	2	24 hours	0
Conjunctiva: chemosis	0	0	0	0	-	0
Conjunctiva: discharge	0	0	0	0	-	0
Corneal opacity	0	0	0	0	-	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 or moderate conjunctival redness was observed was observed in all animals from 1 hour to 24 hours after application. Slight conjunctival chemosis and slight discharge was observed in one animal 1 hour after application only. Injected scleral vessels in a circumscribed area were observed in two animals after 1 hour, persisting in one animal up to 24 hours.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: BASF AG (2005g)

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

TEST SUBSTANCE: Lumogen Black FK 4281 (50% notified chemical)

METHOD: Adaptation of OECD TG 429: Skin Sensitisation: Local Lymph Node Assay. The modified assay is known as an Integrated Model for the Differentiation of Skin Reactions (IMDS).

Species/Strain: Female Mouse/CBA/CaOlaHsd

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

Remarks - Method: No signs of toxicity were noted during a preliminary screening test using 30% Lumogen Black FK 4281 (50% notified chemical) in acetone/olive oil 4:1 (v/v). The same concentration was used in the main test given the limited water solubility (<1 mg/L) of the substance. Historical positive control data (within 6 months of test) was provided.
Lymph node weights and cell counts and ear weights were measured instead of using radioactive labelling of lymph node cells. However, ear swelling was not measured and therefore a differentiation index (DI) could not be calculated which establishes whether a substance has irritant or sensitisation potential. The IMDS assay has undergone intralaboratory (Vohr et al., 2000, Ulrich et al., 2001) and interlaboratory (Ehling et al 2005a and 2005b) validation in Europe. However, a "positive" threshold level based on the lymph node cell count index has not been determined for the CBA mouse strain. Unlike OECD TG 429, only one test group was used in this method.

RESULTS

Concentration (% v/v)	*Proliferative response*		*Irritant response*	
	*Lymph node weight index**	*Cell count index**	*Ear weight (mg)*	*Ear weight index**
0	1.00	1.00	28.9	1.00
30	0.86	0.81	30.1†	1.04†

* Test/control ratio calculated from changes in measurements from day 4 compared to day 1.
† Statistically significant increase ($p \leq 0.05$)

Remarks - Results	There was a statistically significant increase in ear weight observed in animals treated with 30% Lumogen Black FK 4281 (50% notified chemical). This indicates the potential for Lumogen Black FK 4281 (50% notified chemical) at 30% concentration to cause irritation. However, this was not confirmed by ear swelling measurements. There was no observed increase in lymph node weights or cell counts in the treated animals which indicates Lumogen Black FK 4281 (50% notified chemical) at 30% concentration was not sensitising. No deaths or signs of systemic toxicity were noted in the test or control animals during the test. The positive control substance α-Hexylcinnamaldehyde, Tech 85% was considered to be a sensitiser under the conditions of the control experiments.
CONCLUSION	There was evidence that Lumogen Black FK 4281 (50% notified chemical) at 30% concentration caused ear swelling indicative of irritation but there was no evidence of reactions indicative of skin sensitisation under the conditions of the test.
TEST FACILITY	BASF AG (2005h)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Lumogen Black FK 4281 (50% notified chemical)
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	0.5% CMC (aqueous)
Remarks - Method	A maximum dose of 4 mL/kg bodyweight is recommended in OECD TG 407. However, a 10 mL/kg bodyweight dose was used.

RESULTS

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

Mortality and Time to Death

There were no unscheduled deaths.

Clinical Observations

Dark faeces with a dose-related intensity were observed in all animals treated with the test items for the duration of the treatment period and remained until Day 6 of the recovery phase.

No significant differences between treated animals and controls were observed in food consumption, body weight, sensory reactions or motor activity assessments.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Slight, statistically significant differences were observed in aspartate aminotransferase, glucose, triglycerides, urea, albumin, sodium and calcium levels but these were not dose-related or consistent between the sexes. Therefore the differences were considered not to be of toxicological significance.

Slight, statistically significant differences were observed in red blood cells, haemoglobin and the decrement of mean corpuscular volume in females treated with 1000 mg/kg bw/day. But these were considered incidental and not of toxicological significance as they were within historical control values.

Effects in Organs
No changes of toxicological significance were observed in the weight of organs at necropsy. No microscopic changes of toxicological significance were observed at histopathological examination.

Remarks – Results
No evidence is available to confirm unequivocally that the notified chemical has oral bioavailability.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) for oral exposure was established as 1000 mg/kg bw/day in this study, based on the results of this study.

TEST FACILITY RTC (2006)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE	Lumogen Black FK 4281 (50% notified chemical)
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure/Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA100, TA98 *E. coli*: WP2uvrA
Metabolic Activation System	10% S9 fraction derived from Aroclor-induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 0, 20, 100, 500, 2500, 5000 µg/plate b) Without metabolic activation: 0, 20, 100, 500, 2500, 5000 µg/plate
Vehicle	DMSO
Remarks - Method	The study included the standard plate test followed by another assay using the pre-incubation assay.
RESULTS	
Remarks - Results	No significant increase in the frequency of revertant colonies was observed for any of the bacterial strains at any dose level, with or without metabolic activation. The positive control chemicals induced substantial increases in revertant colony numbers, confirming the sensitivity of the cultures and activity of the S9 mix.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BASF AG (2005i)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE	Lumogen Black FK 4281 (50% notified chemical)
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain	Chinese hamster
Cell Type/Cell Line	V79
Metabolic Activation System	10% S9 fraction derived from Aroclor-induced rat liver
Vehicle	DMSO
Remarks - Method	Dose selection was limited by solubility of the test substance. At concentrations ≥12.5 µg/ml strong precipitation was observed which interfered with the evaluation of metaphases. In a pretest for dose

selection the notified chemical did not exhibit any toxic effects at a concentration of 2500 µg/ml after treatment for 4 hours.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	1.563*, 3.125*, 6.25*, 12.5, 25.0, 50.0, 75.0	4	18
Test 2a	0.781, 1.563*, 3.125*, 6.25*, 12.5	18	18
Test 2b	3.125*, 6.25*	18	28
Present			
Test 1	1.563*, 3.125*, 6.25*, 12.5, 25.0, 50.0, 75.0	4	18
Test 2	1.563*, 3.125*, 6.25*, 12.5, 25.0	4	28

*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	>2500	>6.25	≥12.5	Negative
Test 2a	-	>6.25	≥12.5	Negative
Test 2b	-	>6.25	-	Negative
Present				
Test 1	>2500	>6.25	≥12.5	Negative
Test 2	-	>6.25	≥12.5	Negative

Remarks - Results

All positive (Ethylmethanesulfonate and Cyclophosphamide) and negative control cultures displayed chromosome aberrations with the expected range, hence confirming the validity of the test method.

CONCLUSION

The notified chemical was not clastogenic to Chinese Hamster V79 cells treated in vitro to the limit of its water solubility.

TEST FACILITY

BASF AG (2006a)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Lumogen Black FK 4281 (50% notified chemical)
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Activated sludge from a wastewater treatment plant.
Exposure Period	28 days
Auxiliary Solvent	None specified
Analytical Monitoring	Respirometer
Remarks - Method	The biodegradation of the notified chemical was evaluated at a nominal test concentration of 100 mg/L. The test samples were run along with blanks, an abiotic control and aniline as the reference substance. The theoretical oxygen demand calculated for the notified chemical is 2.22 mg O_2/mg.

RESULTS

Test substance		*aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	-1	7	58
14	-2	14	69
21	-2	21	78
28	-2	28	80

Remarks - Results

The degradation of the reference substance reached the pass values of 40% and 65% within 7 and 14 days of test initiation, respectively. Oxygen demand in the blank control was <60 mg/L at the end of the exposure period. The test is therefore considered valid.

There was no indication of biodegradation of the notified chemical, remaining at ~0% after 28 days. Based on this result, the notified chemical is not classified as readily biodegradable according to the test guidelines.

CONCLUSION The notified chemical is not readily biodegradable.

TEST FACILITY BASF AG (2006b)

C.1.2. Bioaccumulation

Remarks

Although the theoretical log K_{OW} value of 8.54 for the notified chemical indicates high potential for bioaccumulation, this is more a reflection of its very low water solubility but relatively higher (but still low) solubility in octanol. The low 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 1.0 is calculated from the BCF model Oasis CATABOL model.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Lumogen Black FK 4281 (50% notified chemical)
METHOD	OECD TG 203 Fish, Acute Toxicity Test – static system over 96 hours. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish – static system over 96 hours.
Species	Zebrafish (*Danio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	None specified
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks – Method	A nominal test concentration of 100 mg/L was prepared by homogenising a mixture of the test substance and water using an ultra turrax. The test vessels were maintained at 23±1°C, with a 16 hours photoperiod, pH 8.1-8.2, and oxygen at 8.0-8.4 mg/L.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	Not measured	10	0	0	0	0	0
100	Not measured	10	0	0	0	0	0

LC50	>100 mg/L (nominal) at 96 hours.
NOEC	100 mg/L (nominal) at 96 hours.
Remarks – Results	The aqueous phase was noticeably turbid, and undissolved test substance was visible at the bottom of the test vessels. No analytical determination was carried out, since the saturation concentration of the test substance in the test water was below the analytical detection limit.
CONCLUSION	Under the study conditions the test substance is not toxic to rainbow trout up to the limit of its water solubility.
TEST FACILITY	BASF AG (2005j)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Lumogen Black FK 4281 (50% notified chemical)
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – 48 hour static test. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – 48 hour static test.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None specified
Water Hardness	238-346 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks - Method	The study was conducted as a limit test with a nominal test concentration of 100 mg/L, prepared by stirring the test substance with M4 medium for ~20 hours. A clear and colourless eluate was obtained following centrifugation and filtration to remove undissolved test substance. Therefore, a water-accommodated fraction (WAF) was prepared. The test vessels were maintained at 20.1-20.4°C, pH 8.0-8.5, and oxygen at 9.0-8.1 mg/L.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	Not measured	4 replicates of 5	0	0
100	Not measured	4 replicates of 5	0	0

LC50	>100 mg/L (WAF) at 48 hours
NOEC	100 mg/L (WAF) at 48 hours
Remarks - Results	No analytical determination was carried out, presumably because the saturation concentration of the test substance in the test water was below the analytical detection limit. The actual dissolved concentration is expected to be <0.1 mg/L. The validity criteria were met in this study.

CONCLUSION Under the study conditions the test substance is not toxic to daphnia up to the limit of its water solubility.

TEST FACILITY BASF AG (2006c)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Lumogen Black FK 4281 (50% notified chemical)

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	Green algae (*Pseudokirchneriella subcapitata*)
Exposure Period	72 hours
Concentration Range	Nominal: 0.391, 0.781, 1.56, 3.13, 6.25, 12.5, 25, 50 and 100 mg/L
Auxiliary Solvent	None specified
Water Hardness	Not specified
Analytical Monitoring	None
Remarks - Method	Three replicate cultures with an inoculation density of 1×10^4 cells/mL were exposed to nominal test concentrations of 0.391-100 mg/L, with a further 3 replicates serving as controls. Prior to inoculation, undissolved test substance was removed from individually prepared test suspensions by filtration, producing clear and colourless test solutions (WAFs). No analytical determination was carried out, since the saturation concentration of the test substance in the test water was below the analytical detection limit. The test vessels were maintained at 21-25°C, pH 7.9-9.1 and a light intensity of 60-120 µE/(m^2s). Fluoresence (measure of cell density) was measured at 0, 24, 48 and 72 hours after exposure.

RESULTS

Biomass		*Growth*	
EC50	*NOEC*	*EC50*	*NOEC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
>100 (WAF)	100 (WAF)	>100 (WAF)	100 (WAF)

Remarks - Results	As the cell multiplication factor in the untreated control was 101 after 72 hours, and pH did not vary by more than 2 units, the test was considered valid. The actual dissolved concentration is expected to be <0.1 mg/L.

CONCLUSION	Under the study conditions the test substance is not toxic to algae up to the limit of its water solubility.
TEST FACILITY	BASF AG (2006d)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Lumogen Black FK 4281 (50% 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 sludge from a municipal wastewater treatment plant.
Exposure Period	3 hours
Concentration Range	Nominal: 996 mg/L Actual: not tested
Remarks – Method	The potential inhibitory effects of the notified chemical on the activity of sewage microbes were assessed as a limit test with a single nominal concentration of 996 mg/L, prepared by stirring the notified chemical with water for 22 hours, followed by addition of synthetic medium and inoculum. The sensitivity of the sewage sludge microorganisms used in the test was assessed using the reference substance, 3,5-dichlorophenol, at nominal concentrations of 1, 10 and 100 mg/L. The pH remained between 7.2-7.6 throughout the study.
RESULTS	
IC50	>996 mg/L (nominal)
NOEC	996 mg/L (nominal)
Remarks – Results	The test concentration produced <10% reduction in the respiration rate of activated sludge in this test. Deviation of the blank controls was <15% and the EC50 of the reference substance in the range of 5-30 mg/L thus validating the test procedure.
CONCLUSION	The notified chemical cannot be classed as inhibiting microbial activity.
TEST FACILITY	BASF AG (2006f)

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