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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION  
AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

**BM3**

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Director  
Chemicals Notification and Assessment

**Full Public Report****BM3****1. IMPORTER**

Agfa-Gevaert Limited, 372 Whitehorse Road, Nunawading, Victoria  
3131

**2. IDENTITY OF THE CHEMICAL**

**Trade Name:** BM3

The notifier has requested and received exemption from publication for the chemical name, CAS number, other names identifying the compound, molecular and structural formula, molecular weight and spectral data.

**3. PHYSICAL AND CHEMICAL PROPERTIES**

BM3 is an odourless yellow powder at room temperature and atmospheric pressure. Its physical and chemical properties include:

**Vapour pressure:**  $2.72 \times 10^{-4}$  kPa at 20°C.

$1.44 \times 10^{-3}$  kPa at 50°C

$2.35 \times 10^{-3}$  kPa at 60°C

**Melting Point:** Not determined, BM3 decomposes before melting

**Density** 1.74

**Stability** Stable at room temperature. Decomposes at temperatures above 90°C. Decomposition products have not been determined, but are expected to include

carbon dioxide, water, iron oxide and toxic fumes such as oxides of nitrogen and carbon monoxide.

**Water solubility:** 29.2 g/L at 20°C, pH = 2.4.

**Hydrolytic stability:** stable under neutral and acid conditions, half life ~ 1 hr at pH 9 and 50°C.

**Partition coefficient** log P = -3.2  
(*n*-octanol/water)

**Soil adsorption/desorption:** Test not conducted. As a highly soluble metal salt, BM3 can be expected to prove mobile in soils.

**Dissociation constant** BM3 is expected to dissociate in water.

#### 4. METHODS OF DETECTION AND DETERMINATION

The chemical can be identified by infra-red spectrophotometry and the degree of purity can be estimated by high performance liquid chromatography (HPLC). Atomic absorption spectrophotometry is used to determine the metallic content.

#### 5. PURITY OF THE CHEMICAL

**Degree of Purity:** The substance is a trihydrate and as such is 98-100% pure. Crystal water content is 16-18% and BM3 is 80-85%.

**Toxic or Hazardous Impurities:** None

#### 6. INDUSTRIAL USES

BM3 is intended for use as a photographic bleaching substance. It will be marketed in Australia as an ingredient of liquid photographic bleach solution for use in photographic laboratories for developing and fixing films and papers.

The chemical will be imported as an ingredient in a concentrate which will later be mixed to make a working solution. During 1991, it is intended to import 1-2 tonnes of BM3 rising to 2-3 tonnes per year in 1992-95.

## **7. OCCUPATIONAL EXPOSURE**

Workers involved in the transport and storage of concentrates containing BM3 will be exposed only in the event of an accident causing spillage. The time spent in situations where exposure may occur is 30 minutes/day, 40 days/year/site. The most likely route of exposure is dermal.

Photographic processing will involve mixing the concentrate and loading into machines. For these processes, goggles, gloves and protective clothing are recommended.

BM3 will either be discharged to drainage or collected by a waste company. Workers involved in waste disposal may be exposed infrequently.

## **8. PUBLIC EXPOSURE**

Under normal conditions of use, the potential for public exposure is low. The chemical is imported as a concentrate and will be transported and stored in tightly closed, small plastic bottles inside outer fibreboard cartons. The product will not be marketed for domestic use and is confined to an estimated 50 photographic laboratory sites. Under normal conditions of use, there are no vapours given off from BM3 and atmospheric contamination is unlikely.

The applicant states that during photographic processing, a small portion of the bleach solution containing BM3 is carried over into the wash water and discharged into drains in accordance with local water authority regulations. BM3 is stated to be biodegradable in most sewerage plants.

For photo laboratories processing an average of 100 films per day, the estimated amount of BM3 to be released to the sewer varies from  $0.1 \text{ g.L}^{-1}$  -  $10 \text{ g.L}^{-1}$  of effluent (34g - 340g/day), depending on the method of processing and whether BM3 is

reconditioned for reuse. Alternatively, the used bleach may be collected for waste disposal or land fill.

## 9. ENVIRONMENTAL EXPOSURE

### Environmental Release

#### . Formulation, handling and disposal

BM3 will be imported as an ingredient of the bleach solutions 70 BL-Light and 94 BL-Light, and will not be subject to any reformulation until it reaches the user, where it will be diluted with water to make a working solution. Barring accidents during transport, formulation and handling are not expected to release significant amounts of BM3 to the environment. The principal route of environmental exposure will be through disposal of spent solutions, either directly to sewer or to landfill following collection.

#### . Use

The taking of photographs involves photoreduction of silver halide microcrystals in the film coating, with the resultant silver atoms migrating to the microcrystal surface where they become attached to impurities (eg silver sulphide) to form a latent image. A visible image is then produced by reducing the silver ions exposed at the microcrystal surface to metallic silver using a developer. Microcrystals containing no latent image remain unaffected by development, and the silver halide they contain is removed by subsequent treatment with fix (usually a solution of sodium thiosulphate).

Colour film processing typically involves the following sequence of steps: developing, bleaching, washing, fixing, washing and stabilising. Colour films incorporate different colour couplers in the various layers of the film coating, which form image dyes on development. It then becomes necessary to remove the metallic silver also formed during development, using a process known as bleaching. Typically this involves treatment with the ferric salt of ethylenediaminetetraacetic acid (EDTA), a mild oxidising and strong complexing agent, between the development and fix

stages of processing. BM3 performs the same function as ferric EDTA in colour processing.

The bleach concentrate containing BM3 will be diluted with water and loaded into a film or paper processing machine. Approximately ninety five photographic laboratories will use the bleach, each processing an average of 30 rolls of film daily and consuming 22 mL of the bleach per film. The concentration of BM3 in the bleach is 65 g.L<sup>-1</sup>, except for those laboratories which practice recycling, in which case the concentration used is 34 g.L<sup>-1</sup>. Release to the sewer may then occur through discharge of spent bleach solutions or wash water, or both, depending on the process involved. Bleach solution overflows (20.5 mL per film) may be discharged directly to sewer, collected for disposal, or continuously recycled. Wash water (a total of 4.2 L per film, containing 1.5 mL bleach solution) will be discharged directly to sewer, except in laboratories using a super stabiliser which does not require preliminary washes following bleaching and fixing. Releases from the various processes are tabulated below.

No of labs	Overflow	Wash water	Release to sewer
20-25	Collected	To sewer	45 mL/lab/day
3	To sewer	To sewer	660 mL/lab/day
30-35	Recycled	To sewer	45 mL/lab/day
20-25	Recycled	None	Nil
12-15	Collected	None	Nil

### **Environmental Fate**

The notifier provided the results from two biodegradability tests, the Zahn-Wellens test and the EEC test. Only the former result was supported by details of the test procedure, with the nature of the latter test being unclear. However, it returned a negative result (no degradation in 28 days).

Biodegradability testing in the EEC is conducted using a tiered approach (1). At the base or screening level, ready biodegradability is tested using relatively high concentrations of substrate (2-100 ppm). The tests are artificially stringent because the high concentrations used may inhibit biodegradation by exerting toxic effects on the inoculant. Test results exhibit

poor reproducibility, with highly variable lag periods as the main disturbing factor. These lag periods may exceed the test duration, leading to negative results. This may explain the negative result obtained in the EEC test. Such negatives do not preclude biodegradability, but indicate that further testing is required.

At the next level, inherent biodegradability is investigated using the Zahn-Wellens or semicontinuous activated sludge tests. The former method uses relatively high concentrations of substrate (50-400 ppm dissolved organic carbon) and prewashed activated sludge ( $1 \text{ g.L}^{-1}$ ). The high biomass favours biodegradation, but slow microbial adaptation can again lead to false negatives. In such cases, simulation tests using adapted microorganisms and lower substrate concentrations are required.

Exposure of BM3 to activated sludge in a Zahn-Wellens test resulted in little degradation during the initial 2 weeks, but complete removal of dissolved organic carbon in 3 weeks. This pattern of rapid degradation following an initial period of microbial adaptation is typical of a closely related chemical. Removal efficiencies for this chemical in full scale wastewater treatment plants at low ppm concentrations are typically of the order of 90%, although transient decreases in efficiency are observed when loadings are increased (2).

Solutions of BM3 will also enter the environment when they are landfilled. The high water solubility and low partition coefficient indicate that BM3 is likely to leach readily from less secure landfill sites and enter the wider environment in solution. However, significant accumulation of residues is not expected as the closely related chemical and its salts are rapidly biodegraded in a variety of aquatic and terrestrial ecosystems, including wastewater treatment systems, soils, surface waters, groundwater aquifers and both aerobic and anaerobic subsurface soil systems. Bioaccumulation is similarly unlikely because of the high water solubility and low partition coefficient.

In contrast to the related chemical (and by analogy BM3), the standard bleaching agent ferric EDTA depends on photochemical transformation rather than metabolism for its degradation in the environment, and passes through sewage works essentially unchanged (3).

## 10. EVALUATION OF TOXICOLOGICAL DATA

### 10.1 Acute toxicology

test	species	result	Reference
oral	rat	>2000mg/kg	(4)
dermal	rat	>2000mg/kg	(5)
skin irritation	rabbit	non-irritant	(6)
eye irritation	rabbit	moderate irritant	(7)
skin sensitisation	guinea pig	non sensitising	(8)

#### 10.1.1 Acute oral toxicity (4)

Groups of five male and five female rats received 2000 mg/kg BM3 as a suspension in 1,2 propanediol, by gavage. An additional group of five males received 1000 mg/kg. No control group was included in the test. Animals were observed for fourteen days and sacrificed.

Two males in the 2000 mg/kg dose group died on days 2 and day 3 after dosing. Symptoms observed were ruffled fur, increased salivation and discoloured faeces and urine in all animals. All animals receiving the higher dose had polyuria and up to two animals in each group were described as 'apathetic'. Animals which received 1000 mg/kg were asymptomatic after three days and those receiving 2000 mg/kg which survived were asymptomatic after 8 days. The oral LD 50 was assessed at being greater than 2000 mg/kg.

#### 10.1.2 Acute dermal toxicity (5)

Five male and five female Wistar Bor WISW (SPF Cpb) rats were administered 2000 mg/kg BM3 as a suspension in 1,2 propanediol to the dorsal skin 24 hours after shaving. No control group was used. Animals were observed for a period of 15 days. No deaths occurred. No local signs of skin irritation or of systemic toxicity were observed. Necropsy, after the study was



completed, showed no compound related effects. The dermal LD 50 of BM3 was estimated to be >2000 mg/kg.

#### **10.1.3 Skin Irritation (6)**

Five hundred mg BM3, moistened with water , was applied to the dorsal area of each of three healthy adult albino rabbits, strain HC:NZW twenty four hours after an area of the back was shaved and covered by a semioclusive dressing for a period of 4 hours. The shaved skin on the other side served as control. After removal of the dressing the skin was washed and the area inspected at 24, 48 and 72 hours, 7 days and 14 days after application of BM3. No signs of redness or inflammation were observed. BM3 was considered non-irritant to skin in this test.

#### **10.1.4 Eye Irritation (6)**

One hundred ul of a solution containing approx 80 mg BM3 was instilled into the conjunctival sac of one eye of each of three rabbits. The treated eye was rinsed with saline after 24 hours. The untreated eye served as a control. Effects persisting for 24 hours and longer were included in the scoring.

All animals showed some immediate effects of the test substance to the conjunctiva, iris and cornea. One animal had significant corneal opacity lasting for 72 hours, another exhibited slight effects for 24 hours and the third for 1 hour only. Conjunctival effects were slight to moderate and lasted for up to 72 hours. The effects were fully reversed within 7 days of application of the test substance. The chemical was considered a moderate eye irritant.

#### **10.1.5 Skin sensitisation (7)**

A maximisation test according to Magnusson and Kligman was carried out using male Bor: DHPW, SPF Bred guinea pigs.

Dose finding tests determined that a 1% injectable solution was the highest concentration that could easily be used and that topical applications of concentrations up to 50% of the test substance did not cause redness or swelling of the skin. Accordingly a 1% solution in propylene glycol was used for the

intradermal induction and a 50% solution in propylene glycol was used for the topical induction and challenge.

A test group of twenty animals received intradermal injections of complete Freund's adjuvant, diluted with saline, of 50% BM3 diluted with propylene glycol, and of a mixture of 50% BM3 in propylene glycol and Freund's adjuvant in equal parts. Two control groups of ten animals received identical treatment except that the second and third injections did not contain BM3. No positive control groups were included. Injections were made at three pairs of shaved dorsal sites.

One week later 10% sodium lauryl sulphate in paraffin oil was placed on the treatment sites followed by application of hypoallergenic plasters soaked in 50% BM3 in propylene glycol to the left flank sites. A plaster soaked only in solvent was applied to the right flank. Plasters were covered with an adhesive dressing and remained in place for 48 hours. Plasters soaked only in propylene glycol were applied to the control group.

Challenge took place three weeks after intradermal induction (two weeks after topical induction). A plaster soaked in 50% BM3 was applied to the left flank of animals in the control and test groups and held in place for 24 hours. Plasters soaked in saline were applied to the right side for comparison. After removal the skin was washed and the test area shaved.

No redness or swelling was noted at the challenge site in any animals in either the test or control group. BM3 was considered not to be a sensitiser in this test.

## **10.2 Mutagenicity**

### **10.2.1 Salmonella typhimurium reverse mutation assay (8)**

BM3 was assessed for mutagenicity in four strains of *Salmonella typhimurium*, TA 1535, TA 100, TA 1357, TA 98, with and without metabolic activation.

Concentrations of 8, 40, 200, 1000 and 5000 ug/plate BM3 in deionised water were tested. Deionised water served as the negative control. The following positive controls in dimethyl sulfoxide (DMSO) were used

sodium azide;  
nitrofurantoin; and  
4-nitro-1,2-phenylene diamine (4-NPDA);

without metabolic activation and

2-aminoanthracene (2-AA)

with metabolic activation

Concentrations greater than 200 ug of BM3/plate were weakly bacteriotoxic in some strains, without affecting the ability to assess mutagenicity. Positive controls produced a marked increase in revertant counts. No increase in revertant counts was noted in any test concentrations up to 5000 ug/plate.

BM3 was found not to be mutagenic to *Salmonella typhimurium* in this test.

#### 10.2.2 Micronucleus test in mice (9)

A dose ranging study for the mouse micronucleus assay tested the effects of intraperitoneal (ip) administration of 25, 35, 50 and 100 mg/kg BM3 in groups of five mixed male and female animals. Animals in all dosage groups showed ruffled fur, staggering gait, spasms and difficulty breathing. Deaths occurred in the three highest dose groups:

dose	mortality
35 mg/kg	1/5 animals
50 mg/kg	2/5 animals
100 mg/kg	3/5 animals

As a result of this study, 35 mg/kg was selected as the dose level for the micronucleus assay.

Three groups of 5 male and 5 female mice [strain Bor: nmri (spf Han)] received intraperitoneal (ip) doses of 35 mg/kg BM3, as a solution in deionised water. A fourth group was similarly treated and provided reserve animals.

In a parallel study, negative control groups of 5 male and 5 female mice received (ip) deionised water. Positive controls received cyclophosphamide, 20 mg/kg.

Both control groups were sacrificed at 24 hours, test groups were sacrificed at 16, 24 and 48 hours and bone marrow examined.

Five of 40 animals treated with 35 mg/kg died during the test period. No change in the ratio of polychromatic to normochromatic erythrocytes (PCE/NCE) was noted in any of the test groups.

The rate of micronucleated PCEs in the test groups did not differ from the negative control group in a statistically significant fashion. The positive control group had a marked statistically significant increase. However, but the result in the test group sacrificed at 16 hours differed from historical, although not parallel, controls.

The test was, therefore, classified as inconclusive and was repeated to assess the effects of graded doses at the most sensitive time interval (16 hours).

The repeat study used ip doses of 10, 20 and 40 mg/kg BM3 and cyclophosphamide, 20 mg/kg as positive control. The negative control group received deionised water. All groups were sacrificed at 16 hours and the bone marrow examined.

In the repeat test, no groups treated with BM3 were found to have increased micronucleated PCEs, ie the original finding was not reproducible. Cyclophosphamide produced a clear and distinct increase in micronucleated PCEs.

Based on the results of repeat testing, BM3 was not considered clastogenic in the micronucleus test in mice.

### **10.3        repeated Dose Toxicology**

#### **10.3.1     28 day repeated oral dose (10)**

BM3 was formulated daily as a solution in distilled water and administered, by gavage, to groups of 5 male and 5 female rats in

doses of 12, 100 and 850 mg/kg/day for 28 days. An additional group of rats received distilled water as a control.

Animals were observed daily. At the conclusion of the study the following tests were performed:

haematology;

blood chemistry; and

urinalysis.

After sacrifice on day 29, histopathology was carried out on the animal which died during collection of blood samples on day 27, the control group and the high dose group. If effects were noted in the high dose group then intermediate group tissues were examined.

Diarrhoea was noted in the high dose group during the first, third and fourth weeks of treatment. No other clinical signs were observed. Males receiving 100 and 850 mg/kg/day showed a decreased gain in body weight.

There were some indications of increased water consumption in males receiving 100 and 850 mg/kg/day.

Male and female rats receiving 850 BM3 mg/kg/day had significantly lowered blood glucose levels. Males in this dosage group also demonstrated decreased alkaline phosphatase levels. These changes were considered secondary to the chronic diarrhoea which occurred in high dose animals.

Intermediate and high dose groups had increased liver and kidney weight (adjusted to allow for variations in body weight). The change was only statistically significant in the high dose group.

Histopathological changes noted were minor kidney changes in 2/5 high dose males and minimal hepatocyte enlargement in 3/5 high dose males.

Changes seen during the study included diarrhoea and effects which could be considered secondary to it such as a slight reduction in weight gain and an increase in water consumption. Changes in blood glucose and alkaline phosphatase were considered secondary to diarrhoea.

#### 10.4 overall assessment of toxicological data

BM3 shows low acute toxicity in testing. The oral LD<sub>50</sub> was determined to be >2000 mg/kg. Dermal LD<sub>50</sub> was >2000 mg/kg. BM3 was not found to be a skin sensitiser or a skin irritant but was shown to be a moderate eye irritant. It was not found to be mutagenic in *Salmonella typhimurium* or clastogenic in the micronucleus test in the mouse. In a 28 day repeated oral dose study diarrhoea was noted in high dose animals with some changes which could be considered secondary to the diarrhoea.

#### 11. ENVIRONMENTAL EFFECTS

As BM3 is highly soluble in water and will be imported in solution, environmental exposure will mainly involve the aquatic compartment. The following test results for aquatic species were supplied.

Test	Species	Result
96 h acute	Zebra fish ( <i>Brachydanio rerio</i> )	LC <sub>50</sub> = 2500 mg.L <sup>-1</sup>
24 hr immobilisation	<i>Daphnia magna</i>	EC <sub>50</sub> = 350 mg.L <sup>-1</sup>

Both tests employed static conditions, but HPLC analysis of the test medium for the fish test confirmed that concentrations did not depart significantly from nominal over the course of the experiment. The results indicate BM3 to be practically nontoxic to fish and daphnids. While reproduction tests on daphnids were not performed, adverse effects appear unlikely in view of the lack of maternal toxicity. Predicted chronic concentrations would remain in the ppm range following application of a safety factor of 100.

Algal growth inhibition tests were also not submitted. However, in the present case of a highly water soluble chemical which is unlikely to be significantly absorbed by biota, algal toxicity is not expected at the concentrations likely to reach receiving waters (see below).

The aquatic toxicological profile of a related chemical has been studied for a wide range of freshwater and marine species, including algae, with EC<sub>50</sub>s obtained in acute tests ranging between 10<sup>2</sup> and 10<sup>4</sup> mg.L<sup>-1</sup> (2). Toxicity is reduced in hard water, and especially in sea water, because of complexation with metal ions. In view of the close structural similarity, BM3 is

not expected to have any significant aquatic toxicological characteristics.

## **12 environmental Hazard**

Under worst case conditions in the three laboratories which discharge spent BM3 directly to sewer, the daily release from the processing machine will amount to about 43 g in around 120 L of wash water, or a concentration in the region of 350 ppm in machine effluent. Assuming this becomes part of an influent stream to sewage treatment works of 5 ML (typical of smaller inland facilities), the concentration will be reduced below 10 ppb. Dilution by receiving waters, and microbial degradation during sewage treatment, would be expected to reduce this concentration further, to sub ppb levels. As noted above, the other ninety or so laboratories will discharge BM3 to sewer at much lower levels, if at all. BM3 has low acute toxicity and minimal bioaccumulation potential in the aquatic environment, and the analogous chemical is readily biodegraded in a variety of environmental systems. Accordingly, the environmental hazard arising from the proposed use of BM3 appears minimal.

BM3 performs the same function as EDTA in photographic processing. In view of the resistance of EDTA to microbial degradation, its substitution by BM3 may entail a reduction in environmental hazard. As the use of EDTA in Australia is not subject to any specific controls, except when used for human therapy, there appears to be no need to apply restrictions on the use of BM3 in photographic processing.

## **13. RECOMMENDATIONS FOR THE CONTROL OF PUBLIC AND WORKER EXPOSURE**

To minimise public and worker exposure to BM3, the following guidelines and precautions should be observed:

- . good housekeeping practices should be used and precautions taken to minimise splashes and spills.
- . workers involved with the storage and handling of BM3 should be familiarised with emergency procedures.
- . workers diluting, mixing or loading the products containing BM3 should wear PVC gloves conforming to Australian Standard 2161 - 1978 (11), goggles which surround and completely protect the eyes and conform to Australian Standard 1337 - 1984 (12) and a PVC apron.
- . MSDS for all products containing BM3 should be readily available to workers.

- . areas where either BM3 or products which contain it are handled should have good general ventilation or local ventilation.

#### **14. MATERIAL SAFETY DATA SHEET**

The Material Safety Data Sheet for BM3 and products containing BM3 are in the Worksafe Australia format (13).

#### **15. SECONDARY NOTIFICATION**

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, (the Act) secondary notification of BM3 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. If conditions of use are varied, and the effluent discharges are increased, further information may be required to assess the hazards to public health due to increased environmental levels. If, in the future, this product is to be sold to the general public, further information may be required.

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