Fraunhofer
ITEM

Environmental Assessment for Microtracer® Particles

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Content

1 Description and Use of the Products

Microtracers® are iron particles coated with food grade colours which are used to code premixes added to formula feeds or the feeds themselves as well as to validate the mixing and cross-contamination control procedures used in manufacturing feeds. Thus, they are used to assure the quality and identity of formula feeds. Microtracers® are added to the feed batches via a premix or as a pure ingredient, by hand or automatically via a micro-dosing system. Afterwards, for validating mixing and cross-contamination control procedures, the particles are counted by developing coloured spots from each tracer particle.

Where Microtracers® are used for the qualitative and quantitative identification of premixes in final feeds, they are added to feeds at not more than 5 g/t.

The procedure of using Microtracers® for screening the feed and food quality is performed every two years if the production companies are working according to GMP-System for feed and food quality of the PDV in the Netherlands which is widely the standard in Europe. The Microtracers® are used with a maximum addition of 10 g/t of the final produced feed, for special coarse feed or food mixtures this concentration may rarely increase up to 100 g/t. Usually, 1 to 3 tons or 6 tons of feed mixtures are controlled every two years in each feed mixer by Microtracers®.

Four products of Microtracers® are available: Microtracers® F, FS, FSS and RF are colored iron grits, stainless steel grits and reduced elemental iron powder with different particle sizes (for details see Table 1). The coating food dyes are primarily Allura Red AC (E129), Brilliant Blue FCF (E133) or Sunset Yellow FCF (E 110) or other food colours as described in Commission Directive 95/45/EC, 1995 laying down specific purity criteria concerning colours for use in foodstuffs.

All information concerning composition, use and concentrations of Microtracers® were given by MTSE GmbH.

Table 1: Composition of Microtracers®

	Microtracer F®	**Microtracer FS®**	**Microtracer FSS®**	**Microtracer RF®**
Elementary iron	> 98 % „iron grit"	≥ 98 % „stainless steel grit"	≥ 98 % „stainless steel grit"	-
Hydrogen reduced elemental iron	-	-	-	≥ 98 %
Elementary chromium	-	≤ 20 %	≤ 20 %	-
Particles per gram	25.000	50.000	300.000	> 2.000.000
Particle size	75 – 425 µm	75 – 500 µm	75 – 150 µm	< 150 µm
Coating	Authorised (EU) food dyes* with maximum concentration of > 0.7 – 2 %			
Trace amounts	Trace amounts (< 1%) of sodium carbonate, shellac (< 1 %)			

*) Commission Directive 95/45/EC, 1995 laying down specific purity criteria concerning colours for use in foodstuffs

2 Environmental Risk Potential

According to Regulation (EC) No 1831/2003 on additives for use in animal nutrition, Microtracers® are regarded as being "processing aids" since they are "...not consumed as a feedingstuff by itself, intentionally used in the processing of feedingstuffs or feed materials to fulfil a technological purpose during treatment or processing which may result in the unintentional but technologically unavoidable presence of residues of the substance or its derivates in the final product...". Therefore, Microtracers® are exempted from the authorisation process of food additives as outlined in Regulation (EC) No 1831/2003.

2.1 Estimation of Predicted Environmental Concentration in Soil (PEC_{soil})

Although Microtracers® are regarded as being "processing aids" and are exempted from the authorisation process of food additives an estimation of a worst case maximum entry of Microtracers® into the soil is performed acc. to the Technical Guidance (TGD) for assessing the safety of feed additives for the environment, 2008. This estimation is based on the assumption that 100 % of the dose ingested is excreted as the parent compound.
The result implies a worst case PEC_{soil} since:
1) The final concentration of 10 g/t is chosen since this concentration is generally used for the inspection of feed mixers, which is done every two years for each feed mixer with a maximum of a final feed batch of 6 tons. However, in case of using Microtracers® for the identification and content determination of particular constituents in animal feed mixtures a final concentration of only up to 5 g/t occurs. The very rarely used concentration of 100 g/t is not considered since this concentration is only used for the inspection of feed mixers with special coarse feed.
2) A mixing soil depth of 5 cm for grassland is chosen.

The following equations are used to calculate the PEC in manure and soil:

$$PEC_{manure} = \frac{C_{add} \times FI_{total}}{N_{excreted}}$$

$$PEC_{soil\,dw} = \frac{PEC_{manure} \times Q}{RHO_{soil} \times CONV_{area\,field} \times DEPTH_{field}}$$

with values:

Symbol	Parameter	Value	Unit
C_{add}	Concentration of Microtracers® in feed	10	mg/kg complete feed
FI_{total}	Total feed intake (DM) per year	33-6700*	kg feed
$N_{excreted}$	Total N excretion per year	0.36-114*	kg N
RHO_{soil}	Bulk density of soil	1500	kg/m^3
$DEPTH_{field}$	Mixing depth with soil	5	cm
$CONV_{area\ field}$	Conversion factor for the area of the agricultural field	10000	m^2/ha
Q	Annual nitrogen immission standard	170	kg N/ha

*) range for all animal groups, exact data were used for calculation based on TGD for assessing the safety of feed additives for the environment, 2008.

The calculation results in:

Animal group	PEC_{manure} [mg/kg N]	$PEC_{soil\ dw}$ [mg/kg soil dw]
Pigs for fattening	792.079208	0.00179538
Sows	494.296578	0.00112041
Dairy cows	587.719298	0.00133216
Cattle for fattening	579.245283	0.00131296
Veal calves	700.000000	0.00158667
Sheep-goats	725.490196	0.00164444
Lambs for fattening	941.176471	0.00213333
Broilers	916.666667	0.00207778
Laying hens	892.857143	0.00202381
Turkeys	818.181818	0.00185455

The maximum predicted environmental concentration in soil is:
$PEC_{soil\ dw}$ = 0.00213 mg/kg soil dw = 2.13 µg/kg soil dw

Thus, the $PEC_{soil\ dw}$ is significantly below the trigger value of 10 µg/kg soil (acc. to TGD for assessing the safety of feed additives for the environment, 2008).
Still, it must be kept in mind, that this reflects the worst-case of permanent use of Microtracers® in animal food.

2.2 Natural iron in the environment

Iron is one of the most abundant metals in the earth's crust (ca. 4.2 to 5 %) and therefore is a regular component of the environmental compartments soil and water (Scheffer & Schachtschabel, 1989; Worch, 1997). It exists predominantly in two valence states - the relatively water-soluble Fe^{2+} (ferrous iron) and the highly water-insoluble Fe^{3+} (ferric iron), with the latter being a stable form in aerobic environments under neutral to alkaline pH conditions (Cundy et al., 2008). Also, zero-valent/elemental iron (Fe(0)) occurs under specific environmental and geological conditions, but it is rarely stable at the earth's surface due to its high reactivity (Cundy et al., 2008). The total iron content of soils varies between approximately 0.2 and 5 % and is dependant upon the source rocks from which the soil is derived, transport mechanisms and overall geochemical history (Blume, 1990; Scheffer & Schachtschabel, 1989; Vance, 1994). In aerobic soils ferric iron is the predominant state and is usually strongly bound to soil compounds. Therefore, and due to its low water solubility, it is hardly abundant in the liquid soil phase (< 0.01-0.5 mg/L) (Scheffer & Schachtschabel, 1989). Under anaerobic conditions or in very acidic soils ferric iron is reduced to water soluble ferrous iron resulting in high iron concentrations in the liquid soil phase (up to > 1000 mg/L) (Scheffer & Schachtschabel, 1989).

Iron can be disclocated from soils into the surface- and groundwater compartments where it is a common constituent (Vance, 1994). In groundwater and rivers a relatively high iron concentration of 0.1 – 100 mg/L can be found (Hülpke et al., 1993; Scheffer & Schachtschabel, 1989). In well aerated waters very stable ferric iron complexes are usually dispersed in the water or enter the sediment compartment (Worch, 1997). In case of an oxygen deficiency, water also contains the soluble ferrous iron (Worch, 1997) which particularly occurs in deeper zones of the water body, but usually not in surface waters (Höll, 1986).

2.3 Natural chromium in the environment

Chromium occurs ubiquitously in all environmental compartments. Naturally, chromium enters the soil, water and air compartments by volcanic emissions, weathering of rocks or soils and forest fires (Blume, 1990; Hülpke et al., 1993; Merian, 1984). The concentration of chromium in rocks varies from 5 mg/kg (granitic rocks) to 1800 mg/kg (ultramafic/basic and serpentine rocks) (IPCS Inchem, 1988; Ma & Hoda, 2010). The most important natural deposits are either in the elemental or the trivalent oxidation state (IPCS Inchem, 1988; Ma & Hoda, 2010). In european soils, natural chromium occurs in complexes, that are almost exclusively in the trivalent state, in concentrations between 0 to 100 mg/kg (Blume, 1990; Ma & Hoda, 2010; Scheffer & Schachtschabel, 1989). Due to the strong adsorbance to soil complexes chromium displays a very low mobility in soils (Hülpke et al., 1993; Ma & Hoda, 2010; Scheffer & Schachtschabel, 1989). In uncontaminated fresh water, chromium appears in concentrations of 1-10 µg/L (Hülpke et al., 1993). Usually, chromium in water is adsorbed to water sediments resulting in natural concentrations of 60 mg/kg (Hülpke et al., 1993; Scheffer & Schachtschabel, 1989).

Due to industrialization the appearance of hexavalent chromium in the environment arose from human activities (IPCS Inchem, 1988; Proctor, 2008). In this oxidation state, chromium is relatively stable in air and pure water, but in the environment it is usually reduced to the trivalent chromium (Ma & Hoda, 2010; von Burg & Liu, 1993). Whereas zero- and trivalent chromium is not known to be harmful to the environment in the naturally occurring concentrations, hexavalent chromium displays toxic effects on aquatic organisms (Ma & Hoda, 2010; von Burg & Liu, 1992).

2.4 Environmental risk potential of Microtracers®

As extensively shown above the main components of Microtracers®, i.e. elemental iron and partly elemental chromium (Microtracers® FS, FSS), are inherent parts in soil and water compartments. Microtracers® are excreted by the fed animals presumably with a 100 % excretion as parent compound and thus will reach agricultural soils via manure application. Based on the chemical background of iron and chromium it is presumed that either the original zero-valent or other naturally occurring valence states (as two- and trivalent iron or trivalent chromium) will enter the soil cycle. Due to the aerobic conditions of arable land this will finally result in the formation of trivalent iron and trivalent chromium. Both elements in these valence states are known to be strongly adsorbed to soil complexes, but in special cases they may be dislocated into aquatic compartments. Rather than any toxic effects of iron and chromium (with exception of the man made hexavalent chromium) the scientific literature commonly discusses their deficiencies in organisms. Iron is an essential micronutrient in plants, animals and humans and severe symptoms are caused by limited external supply situations (Graham & Stangoulis, 2003; Hock & Elstner, 1984; Muñoz et al., 2009;). For humans and animals, the trivalent chromium is an essential nutrient which is often under-supplied (Hambidge, 1974; Lindemann, 1999; Kegley & Spears, 1999; Mertz, 1993; von Burg & Liu, 1993). In contrast, it is not known whether chromium is an essential nutrient for plants, but all plants contain the element and in particular cases chromium promotes plant growth (von Burg & Liu, 1993). Even, to reduce iron deficiencies in plants the usage of iron fertilizers (Finck, 1992) or livestock manure, which itself contains some iron (ca. 0.2 to 2 kg/t) (Schulte, 2008), is regularly performed either as soil or leave application (only fertilizers) (Finck, 1992). Also, zero-valent iron is a common fertilizer and is usually applied to the soil surface as powder (Finck, 1992). A range of environmental clean-up technologies have been proposed or developed which utilise iron to remediate contaminated land and surface and subsurface waters (Cundy et al., 2008). For example, the use of zero-valent iron serves for the reduction or elimination of hazardous pesticide residues, chlorinated hydrocarbon compounds or arsenic water contamination (Cantrell et al., 1995; Cundy et al., 2008; Navarro et al., 2007).

Chromium, but not iron, is mentioned in European regulations considering limit values for amounts of heavy metals which may be added annually on agricultural land via sewage sludge. Whereas the European council directive 86/278/EEC, 1986 only lists chromium, but does not give a limit for chromium, the German sewage sludge regulation from 1992 defines a limit value of 100 mg/kg dry mass.

3 Conclusion

Microtracers® consist of elemental iron and partly elemental chromium (Microtracers® FS, FSS). Both elements are inherently abundant in soil and water compartments as clearly shown above. Natural concentrations of total iron in soils range between 2 and 50 g/kg, natural concentrations of trivalent chromium are between 0 and 100 mg/kg. Moreover, iron and most probably also chromium are essential micronutrients in most living organisms. The estimation of the worst case maximum predicted environmental concentration in soil shows that the $PEC_{soil\ dw}$ is 2.13 µg/kg soil dw which is significantly below the trigger value of 10 µg/kg soil and also far below or within natural concentrations of iron and chromium in the environment. Therefore, it can be concluded that Microtracers®, as described here, are not expected to pose any risk for terrestrial and aquatic organisms and thus will exhibit no adverse effects on the environment.

4 References

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5 Information on the expert

Kristin Krome, born on June 18, 1978 in Celle, Germany.

Education / Certification

1998 – 2004	Studies of Agricultural Science, University of Kiel (Germany)
2004	Master of Agricultural Science
2004 – 2008	Doctoral Thesis in Biology, Technical University of Darmstadt (Germany)
2008	Graduation as Dr. rer. nat. (Zoological Ecology)

Position / Work Experience

2008 – 2011	Study Director for ecotoxicological studies under GLP, Dr.U.Noack Laboratories, Sarstedt, Germany
2011 –	Scientific research assistant at the Fraunhofer Institute for Toxicology and Experimental Medicine, Dept. Chemical Risk Assessment, Hannover, Germany. Working experience: Author / co-author of scientific publications in journals and conference proceedings Preparation of reports about effects of chemicals on terrestrial organisms Preparation of environmental risk assessments of chemicals and pharmaceuticals

6 Signature of the expert

The undersigned expert has written and approved the content of this document and declares that he has no professional or other interests that could in any way influence his independent expert judgement.

	Hanover	January 23, 2012
.....	.....	.....
Signature of expert	Place	Date

MICROTRACERS, INC.

1370 Van Dyke Avenue, San Francisco, California 94124 U.S.A
Tel: 415-822-1100 Fax: 415-822-6615
Website: www.microtracers.com

PRODUCT DATA SHEET

PRODUCT: Microtracer™ F-Blue #1

DESCRIPTION: A non-nutrient "marker" used to identify premixes in finished feeds.

FORMULATION: A uniform product consisting of over 98% elemental iron grit with FD&C Blue #1 food color (Brilliant blue) and traces of sodium carbonate adsorbed on the iron.

GUARANTEES: Brilliant Blue 0.7% minimum

COLOR: Dark grey, dark blue, or reddish blue.

ODOR: None to very slight metallic odor

Bulk Density: Approximately 2.6
Specific Gravity: Approximately 7.8

STABILITY: In original packing, this product has a storage stability of 3 years under ambient conditions. In most premixes and in finished feeds containing less than 14% moisture, this product will be stable for at least 6 months. Stability in specific premixes should be confirmed.

PARTICLE SIZE: 99% passes 40 mesh (USA Standard) and less than 3% passes 200 mesh.

PARTICLE COUNT: Nominally 25/mg but with product considered to meet specification if the average value for three of four sub-samples tested is in the range of 22 to 32 particles/mg.

PACKAGING: 50 lbs in plastic pails with food-grade linings or as specified.

STORAGE: Store in a cool, dry place. Securely reseal partially used containers.

TOXICITY: The product is non-toxic. The food color is water soluble and may be washed from skin.

HANDLING: The product should not be added as the first ingredient to an empty mixer as it may settle at the bottom of the mixer due to its relatively fine particle size and its density. Once mixed in a premix, it will not settle out unless the premix contains widely divergent particle sizes, in which case the product may settle with the finer material.

Updated by NB 01-12-12

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PRODUCT DATA SHEET

PRODUCT: Microtracer™ FS-Blue #1

DESCRIPTION: A non-nutrient "marker" used to identify premixes in finished feeds.

FORMULATION: A uniform product consisting of over 98% stainless steel grit with FD&C Blue #1 food color, and traces of a sodium carbonate adsorbed on the iron. The color is legal for use in foods in the USA.

GUARANTEES: Brilliant Blue (FD&C Blue#1) 0.7% minimum

COLOR: Grayish Blue. Color may vary.

ODOR: Slight metallic odor.

Bulk Density: Approximately 2.6
Specific Gravity: Approximately 7.8

STABILITY: In original packing, this product has a storage stability of 3 years under ambient conditions. Stability in specific premixes should be confirmed.

PARTICLE SIZE: 99% passes 35 mesh (USA Standard) and less than 3% passes 200 mesh.

PARTICLE COUNT: Nominally 50/mg but with product considered to meet specification if the average value for three of four subsamples tested is in the range of 45 to 65 particles/mg.

PACKAGING: 50 lbs in plastic pails with food-grade linings or as specified.

STORAGE: Store in a cool, dry place. Securely reseal partially used containers.

TOXICITY: This product is non-toxic. The food color is soluble in dilute sodium carbonate or bleach and may be easily washed from skin.

HANDLING: This product should not be added as the first ingredient to an empty mixer as it may settle at the bottom of the mixer due to its relatively fine particle size and its density. Once mixed in a premix, it will not settle out unless the premix contains widely divergent particle sizes, in which case the product may settle with the finer material.

Updated by NB 01-12-12

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PRODUCT DATA SHEET

PRODUCT: Microtracer™ FSS-Blue #1

DESCRIPTION: A non-nutrient "marker" used to identify premixes in finished feeds.

FORMULATION: A uniform product consisting of over 98% stainless steel grit with FD&C Blue #1 food color, and traces of a sodium carbonate adsorbed on the iron. The color is legal for use in foods in the USA.

GUARANTEES: Brilliant Blue (FD&C Blue#1) 0.7% minimum

COLOR: Grayish Blue. Color may vary.

ODOR: Slight metallic odor.

Bulk Density: Approximately 2.8
Specific Gravity: Approximately 7.8

STABILITY: In original packing, this product has a storage stability of 3 years under ambient conditions. Stability in specific premixes should be confirmed.

PARTICLE SIZE: 99% passes 100 mesh (USA Standard) and less than 3% passes 200 mesh.

PARTICLE COUNT: Nominally 150/mg but with product considered to meet specification if the average value for three of four subsamples tested is in the range of 100 to 200 particles/mg.

PACKAGING: 50 lbs in plastic pails with food-grade linings or as specified.

STORAGE: Store in a cool, dry place. Securely reseal partially used containers.

TOXICITY: This product is non-toxic. The food color is soluble in dilute sodium carbonate or bleach and may be easily washed from skin.

HANDLING: This product should not be added as the first ingredient to an empty mixer as it may settle at the bottom of the mixer due to its relatively fine particle size and its density. Once mixed in a premix, it will not settle out unless the premix contains widely divergent particle sizes, in which case the product may settle with the finer material.

Updated by NB 01-12-12

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PRODUCT DATA SHEET

PRODUCT: Microtracer RF-Blue #1

DESCRIPTION: A non-nutrient marker used to identify premixes in finished feeds.

FORMULATION: A uniform product consisting of over 98% reduced iron (-100 mesh) grit with FD&C Blue #1 (Brilliant Blue FCF) food color, and traces of sodium carbonate adsorbed on the surface of the tracer. The color is legal for use in foods in the USA.

GUARANTEES: Brilliant Blue 0.7% minimum

COLOR: Dark grey or dark blue. Color may vary.

ODOR: Slight metallic odor.

Bulk Density: Approximately 2.8-3.0
Specific Gravity: Approximately 7.8

STABILITY: In original packing, this product has a storage stability of 3 years under ambient conditions. In most premixes and in finished feeds containing less than 14% moisture, this product will be stable for at least 6 months. Stability in specific premixes should be confirmed.

PARTICLE SIZE: 90% passes 100 mesh (USA Standard).

PACKAGING: 50 lbs in plastic pails with food-grade linings or as specified.

STORAGE: Store in a cool, dry place. Securely reseal partially used containers.

TOXICITY: This product is non-toxic. The food color is soluble in dilute sodium carbonate or bleach and may be easily washed from skin.

HANDLING: This product should not be added as the first ingredient to an empty mixer as it may settle at the bottom of the mixer due to its relatively fine particle size and its density. Once mixed in a premix, it will not settle out unless the premix contains widely divergent particle sizes, in which case the product may settle with the finer material.
Updated by NB 01-12-12