

## REPORT OF THE SCIENTIFIC COMMITTEE FOR ANIMAL NUTRITION ON THE USE OF MANGANOMANGANIC OXIDE IN FEEDINGSTUFFS

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### 1. BACKGROUND

A request for authorising manganomanganic oxide under the following conditions as a trace element has been submitted. (Table 1)

#### Table 1 : Trace element

EEC	Element	Additive	Chemical	Maximum content of	Other	Period of
No.			Formula,	the element	Provisions	Authorisation
			Description	mg/ kg complete		
				feedingstuff		
E 5	Manganese Mn	Manganomanganic oxide synthetic hausmannite)	MnO.Mn <sub>2</sub> O <sub>3</sub>	250 (total)	_	Without a time limit

#### **2. TERMS OF REFERENCE**

Scientific Committee for Animal Nutrition (SCAN) is requested to answer the following questions:

2.1. Does the use of manganomanganic oxide (MnO.Mn<sub>2</sub>O<sub>3</sub>) under the conditions proposed in the feedingstuffs satisfy the nutritional needs of the animals?

What would be the maximum content for the different animal species satisfying those requirements?

- 2.2. Does the use of manganomanganic oxide impair the characteristics of animal products?
- 2.3. On the basis of the toxicological data provided by the company, is the use of manganomanganic oxide safe:
  - For the animals?

- For the users (workers exposure)?
- For the consumers, taking into account total dietary exposure?

In assessing the safety of the product for the consumer, the Committee should in particular address the following aspects:

- The metabolic fate of manganomanganic oxide in animals
- The presence of residues in animal tissues, and their qualitative and quantitative composition
- 2.4. What are the nature and the persistence of the excreted products derived manganomanganic oxide? Can these products be prejudicial to the environment?

#### **3. OPINION OF THE COMMITTEE**

#### 3.1. Introduction

Manganese (Mn) is an essential trace element for plants and animals. It is almost 70 years since manganese was first shown to be essential for growth and fertility in mice and rats.

Normal feeds contain between 5 (fish meal and other feeds of animal origin) and more than 100 mg Mn per kg dry matter (DM) (some roughages). Recommendations of Manganese requirements of animals (from National Research Council 1989, 1993, 1994, 1998, 2000, 2001; Gesellschaft für Ernährungsphysiologie 1994, 1995, 1999, 2001; in mg/kg DM) are :

Ruminants	30-50
Pigs	15-25
Poultry	17-60
Horses	40
Fish (trout)	13

Manganese deficiency can occur naturally on diets composed of normal feed ingredients in ruminants (problems of reproduction) and poultry (perosis). Therefore, Mn supplementation of some diets is necessary to meet the requirements of animals.

Presently  $MnCO_3$ ,  $MnCl_2$ ,  $MnHPO_4$ ,  $MnSO_4$ , MnO,  $Mn_2O_3$  and amino acid Mn chelates are permitted as feed additives in the EU. The SCAN is requested to evaluate the use of manganomanganic oxide (MnO.Mn<sub>2</sub>O<sub>3</sub>, synthetic hausmannite) as feed additive.

## 3.2. Specification of the substance (brand name: Elkem Agrimax®)

The specification of the substance, its physico-chemical, technological and biological properties are described in the dossier. The Mn content of the product  $Mn(II)O-Mn(III)_2O_3$  or  $MnO.Mn_2O_3$  is given as 68-70%, and is higher than those of the other currently authorised Mn feed additives.

Elkem Agrimax® may contain some other elements (As: max 50 mg/kg; Cd, F and Hg below detection limit; detection limits: Cd: 10 mg/kg, F: 100

mg/kg, Hg: 0.2 mg/kg; Pb: max 3000 mg/kg). Remarkable is the high concentration of lead. The manganese ore always contains lead although most is removed during the smelting process. The only practical measure which can be applied is to monitor the amount of lead in the manganese oxide product. A strict quality control program for monitoring lead and other undesirable substances has been established by the company. The company claims that only products that constantly meet the quality specification (max. 3000 mg/kg lead) are used.

In regard to the formation and content of dioxins there is no report about any content of halogen compounds in the product. Fluorine could not be detected (detection limit: 100 mg/kg). The product is manufactured at temperatures between 1600 and 2000 °C, considerably higher than the temperature (250 to 450°C) at which the formation of PCDD and PCDF can occur. The analytical values of PCDD and PCDF are far below the EU limits for comparable compounds.

#### 3.3. Manganomanganic oxide in animal nutrition

Four feeding experiments (one with rats, three with chicks) were carried out to compare various amounts of  $MnO.Mn_2O_3$  with unsupplemented control mixtures and other Mn sources (MnSO<sub>4</sub>, MnO).

Important results of the experiments 1 to 3 are given in Tables 2 to 4; experiment 4 was carried out as a feeding test under farm conditions in Venezuela. Information about this test are weak (e.g. no information on feed intake and weight gain of chickens etc.), therefore, data are not considered further. Availability studies were carried out with high Mn dosages. Therefore, only comparison between various Mn sources seems to be permitted.

In experiment 1 (Table 2) five to six rats per group were fed from  $\approx$ 70 to  $\approx$ 500 g body weight with unsupplemented control diet (0.48 mg Mn/kg DM) or with diets supplemented with MnSO<sub>4</sub>, MnO.Mn<sub>2</sub>O<sub>3</sub> and MnO at two different levels ( $\approx$ 33 and  $\approx$ 69 mg Mn/kg DM), respectively. No significant differences were measured between Mn sources in feed intake, body weight gain and feed efficiency. Mn from MnSO<sub>4</sub> appears to be more available than from the two oxides of the element, although there were no differences in the overall retention of Mn for rats in these diets. In general high values (21 to 35%) of apparent Mn retention are given.

	,				Mn-Content			Organ weights (g)			
Mn-source	Mn-content	Final weight	Feed per	App. Mn-	Plasma	Liver Bone		Bone	Liver	Kidney	Spleen
	of diets	(g per rat)	weight gain	retention	$(\mu g/ml)$	(µg/liver)	µg/g	$(\mu g/g \ DM)$			
	(mg/kg DM)		(g/g)	(% of intake)			wet tissue				
Unsupplemented											
control	0.48	516	5.18	-64	0.185	6.3	0.38	2.99	16.4	1.52	0.75
MnSO <sub>4</sub>	32.5	536	4.83	29	0.176	34.2	2.09	3.75	16.4	1.41	0.81
MnSO <sub>4</sub>	73.9	535	4.92	35	0.176	41.8	2.38	4.21	17.6	1.47	0.71
$MnO.Mn_2O_3^{(1)}$	31.9	561	4.70	22	0.175	39.6	2.17	3.21	18.2	1.53	0.85
MnO.Mn <sub>2</sub> O <sub>3</sub>	67.0	541	4.86	23	0.172	41.7	2.29	3.76	18.2	1.62	0.79
MnO <sup>2)</sup>	34.2	545	4.77	29	0.174	37.5	2.09	3.44	17.9	1.52	0.77
MnO	65.4	559	4.66	21	0.179	35.6	1.88	3.89	19.0	1.58	0.79
<sup>1)</sup> 68% Mn, <sup>2)</sup> 62% Mn											
Contrast											
Unsupplemented control v Rest		NS	*	***	*	***		***			
Low Mn v High Mn		NS	NS	NS	NS	NS		**			
MnSO <sub>4</sub> v Oxides		NS	NS	NS	NS	NS		**			
$MnO.\ Mn_2O_3 \ v \ MnO$		NS	NS	NS	NS	*		NS			

Table 2: Influence of various Mn-sources and -levels on feed/weight gain, weight gain and metabolic parameters of rats (initial weight: 70 g per animal; duration of experiment: 113 days, n = 5-6, Exp. 1)

NS = not significant; \* = p<0.05; \*\* = p<0.01; \*\*\* = p<0.001

In experiment 2 (Table 3) two  $MnO.Mn_2O_3$  sources were directly compared with  $MnSO_4$  and MnO in growing broilers. Highest body weight gain and best feed conversion were measured with  $MnSO_4$  (p<0.05). No significant differences were registered between control (46 mg Mn/kg DM) and Mn oxide groups (95 and 96 mg Mn/kg DM, respectively).

Table 3: Influence of various Mn sources on performance of broilers (duration of experiment: 42 days, n = 120, Mn supplementation: 50 mg/kg feed; Exp. 2)

Mn source	Mn content of diets	Body weight (g)		Feed per kg body weight gain (kg/kg)		Mortality (%)	Mn in tibia bone (mg/kg	Mn in tibia ash $(mg/kg)^1$	Relative bioavailability	
	(ing/kg DM)	3 weeks	6 weeks	3 weeks	6 weeks		$DM)^1$	(ing/kg)	(70 to WinsO <sub>4</sub> )	
Unsupplemented control	46	693	2108 <sup>ab</sup>	1.57	2.18 AB	5.8	2.98	6.62	-	
MnSO <sub>4</sub>	100	695	2146 <sup>a</sup>	1.55	2.11 <sup>A</sup>	0.8	3.25	7.38	100	
$P-70^2$ MnO.Mn <sub>2</sub> O <sub>3</sub>	95	685	2053 <sup>b</sup>	1.56	2.38 <sup>B</sup>	4.2	3.19	7.18	74	
$S-68^2$ MnO.Mn <sub>2</sub> O <sub>3</sub>	96	672	2085 <sup>b</sup>	1.70	2.41 <sup>B</sup>	8.3	3.15	7.08	61	
MnO	96	689	2089 <sup>b</sup>	1.63	2.40 <sup>B</sup>	6.7	3.19	7.17	72	

 $^{1}$  n = 6;

P-70 and S-68: preparations from two different plants (Elkem Mangan PEA, Elkem Mangan Sauda)

different superscripts in one column indicate significant differences (a, b: p<0.05; A, B: p<0.01)

Compared with the control group addition of 50 mg Mn/kg as oxides resulted in a slight, not significant increase of the Mn concentration in the tibia of broiler chicks. The relative bioavailability of Mn from oxides amounted to 74, 61 and 72%, respectively, compared with 100% of Mn from  $MnSO_4$ .

In summary  $MnO.Mn_2O_3$  is comparable to the other Mn oxides to satisfy the nutritional needs.

# 3.4. Influence of manganomanganic oxide on characteristics of animal products

Bioavailability tests, comparing the manganomanganic oxide with MnO and MnSO<sub>4</sub>, have been performed on rats and on chickens. The test results prove that the product has a bioavailability similar to MnO and about 70 % of MnSO<sub>4</sub>. The daily requirement of Mn in poultry is 40 mg/kg feedstuff, the recommended daily dietary intake of Mn as MnSO<sub>4</sub> 50 mg/kg feedstuff. The recommendation of 60 mg Mn as manganomanganic oxide seems to be adequate to meet the requirement and to avoid low levels of Mn in animal food products. In experiment 1 with rats (Table 2) fed for 16 weeks with diets without Mn supplementation (0.48 mg Mn/kg DM) or with low (32.5–34.2 mg Mn/kg DM) or high (65.4-73.9 mg Mn/kg DM) Mn supplementation as MnSO<sub>4</sub>, MnO.Mn<sub>2</sub>O<sub>3</sub> and MnO, respectively, the differences of the Mn concentrations in plasma and liver were not significant except the liver content (higher in MnO.Mn<sub>2</sub>O<sub>3</sub> than in MnO group).

From bioavailability studies in rats and chickens one can conclude that there is no change of the Mn concentration in the product. Other criteria, e.g. lead, were not tested. The SCAN, therefore, can not decide if Elkem Agrimax® impairs the characteristics of animal products.

## **3.5.** Safety of the use of manganomanganic oxide

## 3.5.1. Metabolic fate of $MnO.Mn_2O_3$ in animals

The Mn absorption is relatively poor in all animal species. Only 3 - 4% of orally administered radioactive Mn was absorbed in rats. Less than 0.1% of an oral dose was apparently absorbed by avian species. Cattle absorb about 1% of ingested Mn. Mn absorption depends on age of animals (younger animals absorb better than older ones), sources (organic sources, MnSO<sub>4</sub><sup>2-</sup>, Cl<sup>-</sup> and CO<sub>3</sub><sup>2-</sup> are better absorbed than oxides), some antagonists in the feed (e.g. Ca, P, Fe, Co etc.), physiological stage of animal (e.g. pregnancy, lactation) and other influencing factors (Männer and Bronsch, 1987).

Mn concentration in bones may increase with higher Mn intake (Tables 3 and 4), but this reserve is not readily available when dietary intake is low. Data in Table 4 overestimate normal concentrations because of the high Mn supplementation of diets. Variable absorption and excretion are major homeostasis mechanisms by which animals maintain normal health and performance over a wide range of Mn intake.

### 3.5.2. Genotoxicity

Mutagenicity studies of MnO.Mn<sub>2</sub>O<sub>3</sub> suggest that it does not possess mutagenic activity in *Salmonella typhimurium* and *Saccharomyces cerevisiae* (Simmon and Ligon, 1977). Since manganomanganic oxide dissociates into Mn(II) and Mn(III) ions when dissolved in water, the genotoxicity of compounds containing these ions can also be considered as well. The WHO (1999) reported that manganese sulphate was not mutagenic to *Salmonella typhimurium* strains TA97, TA98, TA100, TA1535 and TA1537 with or without metabolic activation in studies performed in two laboratories (Mortelmans *et al.*, 1986), but was mutagenic in strain TA97 in another study (Pagano and Zeiger, 1992). Manganese chloride was not mutagenic in strains TA98, TA100 and TA1535, but was mutagenic in TA 1537, with conflicting results for TA102 (Wong, 1988; De Meo *et al.*, 1991). Manganese sulphate was mutagenic in a fungal gene conversion/reverse mutation *Saccharomyces cerevisiae* strain D7 (Singh, 1984).

Manganese chloride produced gene mutations in a mouse lymphoma assay *in vitro* (Oberley *et al*, 1982). It also caused DNA damage in human lymphocytes, when tested *in vitro* in the single cell gel assay technique in the absence of metabolic activation (De Meo *et al.*, 1991). Manganese sulphate also induced sister chromatid exchanges in Chinese Hamster Ovary (CHO) cells with and without metabolic activation and in a separate assay induced chromosome aberrations in the absence of metabolic activation, but not in its presence (Galloway *et al.*, 1987). Manganese chloride, however, was not clastogenic in FM3A cells in the absence of metabolic activation (Umeda and Nishimura, 1979), but did cause chromosomal aberrations in the root

tips of *Vicia faba* (Glass, 1955, 1956). Potassium permanganate caused chromosomal aberrations in in FM3A cells (Umeda and Nishimura , 1979), but not in a primary culture of cells from Syrian hamster embryos without metabolic activation (Tsuda and Kato, (1997). Manganese chloride caused cell transformation in Syrian hamster embryo cells (Castro *et al.*, 1979).

In *Drosophila melanogaster* (the fruit fly), manganese chloride did not produce somatic mutations (Rasmuson, 1985) and manganese sulphate did not induce sex-linked recessive lethal mutations in the male germ cells (Valencia *et al.*, 1985).

In *in vivo* assays in mice, oral doses of manganese sulphate or potassium permanganate caused micronuclei and chromosomal aberrations in bone marrow (Joardar and Sharma, 1990). However, oral doses of manganese chloride did not cause chromosomal aberrations in the bone marrow or spermatogonia of rats (Diskith and Chandra, 1978)

Chromosomal aberrations were reported in workers exposed to manganese (WHO, 1999), but exposure to other toxic substances such as nickel, which is known to cause such abnormalities, means that a conclusion can not be drawn for manganese.

*In vitro* study results show that at least some chemical forms of manganese have mutagenic potential, but the results of *in vivo* studies are inconsistent. No clear overall conclusion about the possible genotoxic hazard to humans from exposure to manganese compounds can be made. animals and plants.

#### Toxic metabolites

There is no toxicology of metabolites since manganese is absorbed from  $MnO.Mn_2O_3$  in elemental ionised form.

#### 3.5.3. Safety for the animals

In the second experiment with broilers (Experiment 3) three different levels of Mn coming from  $MnSO_4$  or  $MnO.Mn_2O_3$  were used (Table 4). Very high dosages of  $MnO.Mn_2O_3$  decreased feed intake and body weight gain (p<0.05). The results indicate that Mn availability from  $MnO.Mn_2O_3$  was about 70% of the availability in  $MnSO_4$  measured in the Mn tibia concentration. Experiment 3 could be considered as a tolerance study because of the very high Mn supplementation (about 20 to 70 times of requirements).

Mn source	Mn content of	Feed intake	Body weight	Feed per	Tibia weight	Total tibia Mn	Bone Mn
	diets	(g/chick)	(g/chick)	weight gain	(g)	(µg)	(mg/kg)
	(mg/kg DM)			(kg per kg))			
Control	78	515	188 <sup>ab</sup>	3.66 <sup>b</sup>	0.707 <sup>a</sup>	7 °	9 <sup>a</sup>
MnSO <sub>4</sub>	1024	505	190 <sup>ab</sup>	3.77 <sup>ab</sup>	0.704 <sup>a</sup>	15 °	21 <sup>b</sup>
MnSO <sub>4</sub>	1809	510	195 <sup>a</sup>	3.83 <sup>a</sup>	0.695 <sup>ab</sup>	23 <sup>b</sup>	33 °
MnSO <sub>4</sub>	3368	518	184 <sup>ab</sup>	3.56 °	$0.662^{ab}$	29 <sup>a</sup>	43 <sup>d</sup>
$MnO.Mn_2O_3^{(1)}$	1077	528	192 <sup>a</sup>	3.64 <sup>bc</sup>	0.695 <sup>ab</sup>	10 °	15 <sup>a</sup>
$MnO.Mn_2O_3^{(1)}$	1592	531	180 <sup>b</sup>	3.38 <sup>d</sup>	0.632 <sup>b</sup>	14 <sup>c</sup>	22 <sup>b</sup>
$MnO.Mn_2O_3^{(1)}$	2585	456	163 °	3.58 °	0.545 <sup>c</sup>	16 <sup>c</sup>	31 °

Table 4: Influence of various Mn sources and levels on performance of broilers (duration of experiment: 21 days, n = 24, Exp. 3; kind of tolerance study)

<sup>1)</sup> 31% MnO and 69% Mn<sub>2</sub>O<sub>3</sub>;

different superscripts in one column indicate significant differences (p<0.05)

The lead content of Elkem Agrimax® up to 3000 mg/kg has to be considered. In the Council Directive 1999/29/EC, Annex I the maximum content of lead in Complete feedingstuffs is 5 mg/kg (moisture content 12 %) and in mineral feedingstuffs 30 mg/kg. If Elkem Agrimax® is added to complete feedingstuffs at the highest level of 250 mg Mn/kg it contributes about 1 mg Pb/kg (20 % of the tolerable lead concentration) in complete feedingstuffs. Mineral feedingstuffs may contain 10 g Mn/kg. The lead concentration in these feedingstuffs exceeds the tolerable lead concentration of 30 mg/kg if Elkem Agrimax® is used as Mn source.

The SCAN, therefore, is of the opinion that the use of Elkem Agrimax® as feed additive in the proposed dosage is safe for the animals concerning Mn supplementation, but the content of lead must be considered as harmful. No experiments were performed in this regard.

#### *3.5.4. Safety for the users*

Around 90% of the product particles have a diameter of 5  $\mu$ m or less, suggesting that inhalation exposure for operators is therefore likely if a dust is being formed. The small particle size indicates that a dust made up of such particles is respirable and may be inhaled deep into the lungs to reach the alveoli. There is a common understanding that fine particles have more potential to be airborne than coarser particles.

The UK has set one Occupational Exposure Standard (OES) for dust from manganese and its compounds and two OESs for manganese fumes (HSE, 1999). The OES for dust is a long-term limit (8 hr time-weighted average) of 5 mg/m<sup>3</sup>, expressed as manganese. For fumes there is long-term limit (8 hr time-weighted average) of 1 mg/m<sup>3</sup> and a short-term exposure limit (15 mins) of 3 mg/m<sup>3</sup>.

The company has decided to apply the stricter limit used for fumes and to keep dust concentration in the workplace air below  $1 \text{mg Mn} / \text{m}^3$  (an 8 hour average time limit) in order to protect workers' health As Elkem Agrimax® is composed of manganomanganic oxide, the limits set for manganese and its

compounds are considered relevant upper limits for occupational exposure of people who work with Elkem Agrimax®.

According to the Manufacturer's Safety Data Sheet (MSDS), long-term inhalation (years) of manganese oxides may cause chronic manganese intoxication (manganism) affecting the central nervous system (CNS) and lead to extensive disablement, that cannot be cured. The company is aware that it is necessary to know what level of manganese can be inhaled throughout a lifetime without causing any distortion of workers' health (chronic exposure) and research is continuing in this area.

Tetravalent manganese-Mn[IV]) is classified as harmful to health, but Elkem Agrimax® contains only divalent (Mn[II]) and trivalent manganese (Mn[III]). Tetravalent manganese has not been detected in the product. The dust may cause mechanical irritation of mucous membranes, but there are no records to date describing respiratory effects in humans as a result of oral exposure. Inhalation of high concentrations of Mn vapour or Mn oxide fumes can result in chemical pneumonia, bronchitis, coughing and minor reductions of lung function. The MSDS also states that for skin and eye contact, the dust may cause mechanical irritation. The company claimed that the product did not affect Elkem workers, however it did not provide any information on sensitisation or irritation.

Preparing premixes and mixing feedingstuff for Mn homogeneity are performed in "closed systems", thus reducing to a minimum dusting from the feedingstuff itself. However, for workers handling premixes, during the process of mixing Elkem Agrimax® into feed, there may be a potential for dust to be formed and a dust made up of fine particles will be respirable. Consequently, there should be data presented on the potential for dust formation during mixing by workers.

However, in support of the human data, the animal data in rats and mice showed no significant respiratory effect. Lung inflammation from single inhalation exposures to  $2.8-43 \text{mg/m}^3$  for manganese dioxide or manganese tetroxide particles has been reported in rodent species (Bergstrom, 1977; Adkins *et al.*, 1980; Shiotsuka, 1984). However, an inflammation response is characteristic of nearly all inhalable particulate matter (US EPA, 1985) and is not exclusive to manganese.

Effects from chronic inhalation exposure to manganese in experimental animals occurs at levels higher (30-70 mg manganese/m<sup>3</sup>) than those at which effects have been reported in humans (0.14-1mg total manganese dust/m<sup>3</sup> for preclinical neurological alterations and 2-22 mg total manganese dust/m<sup>3</sup> for overt neurological alterations and 2-22 mg total manganese dust/m<sup>3</sup> for overt neurological disease). This evidence suggests that laboratory animals, especially rodents, might not be as sensitive as humans, to the neurological effects of inhalation exposure to manganese (WHO, 1999).

No studies were located by the company concerning cardiovascular, gastrointestinal, musculoskeletal, dermal or occular effects after inhalation exposure to manganese. However, there are also presently discussions and further studies in which the company and various occupational health and

research institutes are trying to assess if there are sub-clinical effects due to inhalation exposure. In recognition of the fact that inhalation exposure is probable, the company is encouraged to finish developing the new formulation (Grade A-69) containing agglomerated particles to combat the problem of inhaled dust,

Considering the above, the toxicology data to date, suggest that precautions in terms of exposure control and personal protection are needed (eye protection, eye flushing facilities and protective gloves; good ventilation; wearing of a particulate respirator according to EN 149 FFP 2S in areas of adequate ventilation).

### 3.5.5. Safety for the consumers

Mn concentration in various tissues and body fluids are very similar in man and rats. In the experiments with rats mentioned in 3.3 all types of Mn sources as well as low and high supplementation gave liver concentrations between 1.88 and 2.38 mg/kg fresh tissue. These studies show that Mn homeostasis is well regulated so that within certain limits different sources of Mn and variation in Mn intake does not significantly influence tissue concentrations.

In 1993, the SCF identified a range of safe and adequate doses as 1-10 mg Mn/person/day. In terms of consumer safety, normal homeostasis would ensure that tissue manganese concentrations remain fairly constant irrespective of dietary concentrations. Both of the manganese oxides have been permitted for oral use in veterinary medicines under Annex II of Regulation (EEC) 2377/90, requiring no Maximum Residue Limits to be set. Mn(II)O and Mn(III)<sub>2</sub>O<sub>3</sub> are poorly absorbed from the gut lumen, so Elkem Agrimax<sup>®</sup> as a feed additive is unlikely to cause harmful manganese residues to occur in edible tissues from treated animals.

In view of the absence of a NOEL for the toxicity of Mn and the uncertainty about its in vivo genotoxicity, no entirely safe upper limit of exposure to Mn can be recommended. However, given its ubiquitous nature and its role as an essential element, some exposure to Mn is unavoidable. SCAN is convinced that the recommended use of manganomanganic oxide in animal feed will not lead to unacceptable levels of exposure of human consumers to Manganese.

#### *3.5.6. Safety for the environment*

If introduced to market, manganomanganic oxide would substitute for other manganese sources and consequently no important change to the overall impact of manganese on the environment would be expected.

However, the lead content of the product, if substantially higher than other manganic oxides, may be a specific cause for concerns for the environment.

The environmental impact of manganese itself should be considered as a generic issue.

### **3.6.** Conclusions

In regard to the formation and content of dioxins there is no report about any content of halogen compounds in the product. The analytical values of PCDD and PCDF are below the EU limit for comparable compounds.

 $MnO.Mn_2O_3$  was compared with MnO and  $MnSO_4$  in one experiment with rats and two experiments with broiler chickens. Results were comparable with MnO, but Mn availability was only 70% compared with  $MnSO_4$ .

No adverse effects in man, animals and environment can be expected if  $MnO.Mn_2O_3$  is used as Mn source concerning Mn.

MnO.Mn<sub>2</sub>O<sub>3</sub> contains about 69% Mn and traces of other minerals. Remarkable is the high content of lead up to 3000 mg/kg Pb which can not be reduced as it is caused by the lead concentration in the raw material and a purification process does not exist. If Elkem Agrimax® is added to feedingstuffs at the level of (250 : 0.69 =) 362 mg/kg the contribution of Elkem Agrimax® to the allowed lead content of 5 mg/kg of complete feedingstuffs (Council Directive 1999/29/EC of 22 April 1999) is about 1.1 mg. Therefore, it has to be considered that Elkem Agrimax® contributes more than 20% to the maximum concentration of lead in these feedingstuffs. In mineral feedingstuffs the maximum content of lead is 30 mg/kg (see Directive mentioned above). Mineral feedingstuffs may contain up to10 g Mn/kg. Therefore the lead concentration in these feedingstuffs would exceed the tolerable lead concentration of 30 mg/kg if Elkem Agrimax® would be used as Mn source.

Although SCAN does not consider manganese as a problem for animal health, human health or environment, it would not recommend the use of  $Agrimax^{(R)}$  in feed due to its lead contamination.

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