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DECLARATION OF COMPLIANCE

According to Commission Directive 2007/19/EC
of 2nd April 2007

amending Directive 2007/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs.

(1) Identity and Address of the Business Operator which Manufactures the Article

Identity: **RG Mineral AS** (a Rana Gruber Group company)
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(2) Identity of Materials

**Product-ID.: COLORANA® CRM-20D, CRM-50D, CRM-60D, CRM-70D,
CRM-1075D, CRM-1080D**

Material: Red Iron Oxide Pigment.
Chem. Designation: Fe₂O₃
CAS No.: 1309-37-1, 1317-60-8
EINECS-no.: 215-168-2, 215-275-4
Color Index: Pigment Red 101, 77491
Synonyms: Hematite, ferric oxide, calcinated red iron oxide,
iron oxide red.

(3) Date of Declaration

First issued: 18th September 2007
Date issued: 18th September 2007 **Issue:** 000



(4) Confirmation that the Article meets relevant requirements acc. to 1935/2004/EC

Because of the low solubility in aqueous and organic media no migration into food is expected from iron oxides incorporated in plastics (subject to article 3 of 1935/2004/EC).

The products meet the requirements set out in Commission Directive 1935/2004/EC.

(5) Information relative to the article with respect to restrictions and/or specifications

Iron Oxides are listed and accepted as articles intended to come into contact with foodstuffs acc. to Commission Directive 2002/72/EC.

Annex III: Incomplete list of additives which may be used in the manufacture of plastic materials and articles,

Section A: Incomplete list of additives fully harmonized at community level.

Ref.no.: 62240.

CAS No.: 001332-37-2* (* see Annex III General Introduction, article 7) corresponding to EINECS 215-570-8.

Name: Iron oxide.

Restrictions and/or Specifications: **non.**

Council of Europe, Committee of Ministers, Resolution AP(89) of 12th September 1989 on the use of colourants in plastic materials coming into contact with food defines the migration from the final plastic material or article intended to come into contact with food.

Appendix I, II General principles, article 2.1: Metals and metalloids.

Other migration limits for metals and metalloids are set out in other European national provisions (COLORANA® information: IP-E-083).

The COLORANA® products **comply with the requirements.**

(6) Information relative to the article which is subject to a restriction in food

Commission Directive 95/45/EC of 26th July 1995 defines the specific purity criteria concerning colours for use in foodstuffs.

Iron Oxides are listed in the Annex, Section B: Specific criteria of purity.

E 172: Iron Oxides and Iron Hydroxides.

Definition: Iron Oxides and Iron Hydroxides are produced synthetically.

The above COLORANA® red iron oxides originate from natural magnetite and are produced by calcination at elevated temperatures. The natural magnetite is altered to hematite which includes a change in the crystal structure and chemical formula.. The products are thus defined as “chemically modified substances” according to 1907/2006/EEC, the REACH directive.



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The products are intended for use in foodstuffs.

(7) Specification on the use of the article or substance

Not relevant.

Iron Oxides are additives for colouring of plastic material intended to come into contact with foodstuffs and as such are fully harmonized and comply with the relevant European Community provisions on food contact applications.

(8) Compliance with the requirements of Article 7a(2), (3) and (4) of 2007/19/EC

Not relevant.

Iron Oxides are additives for colouring of plastic material intended to come into contact with foodstuffs and as such are fully harmonized and comply with the relevant European Community provisions on food contact applications.

(9) Authorisation and disclaimer

The Declaration of Compliance is believed to be correct but does not purport to be all inclusive. The information is based on RG Mineral AS`s present knowledge and experience. The declaration will be renewed when new scientific data are available and/or changes in the regulatory system make it necessary.

For any further information contact Rana Gruber AS/RG Mineral AS.

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