

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
 Product name : OsteoRAL R
 Product code : 320715

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category : For professional use only
 Use of the substance/mixture : In vitro diagnostic medical device.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

RAL DIAGNOSTICS
 Site Montesquieu
 33650 MARTILLAC
 FRANCE
 T 33 05 57 96 04 04 - F 33 05 57 96 04 05
commercial@cellavision.com - www.cellavision.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD 2090 Msida	+356 2545 6508	
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	Only for healthcare professionals

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin corrosion/irritation, Category 1, Sub-Category 1B H314
 Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Causes severe skin burns and eye damage.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS05

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Signal word (CLP)	: Danger
Contains	: Formic acid 80%
Hazard statements (CLP)	: H314 - Causes severe skin burns and eye damage.
Precautionary statements (CLP)	: P280 - Wear protective gloves, protective clothing, eye protection. P301+P330+P331+P310 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor. P303+P361+P353+P310 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.. Immediately call a POISON CENTER or doctor. P305+P351+P338+P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor.

2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Formic acid 80% substance with a Community workplace exposure limit	CAS-No.: 64-18-6 EC-No.: 200-579-1 EC Index-No.: 607-001-00-0 REACH-no: 01-2119491174-37	10-20	Acute Tox. 4 (Oral), H302 Skin Corr. 1B, H314
Hydrochloric acid $\geq 25\%$	CAS-No.: 7647-01-0 EC-No.: 231-595-7 EC Index-No.: 017-002-00-X REACH-no: 01-2119484862-27	1-5	Skin Corr. 1, H314 STOT SE 3, H335

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Formic acid 80%	CAS-No.: 64-18-6 EC-No.: 200-579-1 EC Index-No.: 607-001-00-0 REACH-no: 01-2119491174-37	(2 \leq C < 10) Eye Irrit. 2, H319 (2 \leq C < 10) Skin Irrit. 2, H315 (10 \leq C < 90) Skin Corr. 1B, H314 (90 \leq C < 100) Skin Corr. 1A, H314

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Call a physician immediately.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Rinse skin with water/shower. Take off immediately all contaminated clothing. Call a physician immediately.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician immediately.
First-aid measures after ingestion	: Rinse mouth. Do not induce vomiting. Call a physician immediately.

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4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact : Burns.
Symptoms/effects after eye contact : Serious damage to eyes.
Symptoms/effects after ingestion : Burns.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes. Do not breathe dust/fume/gas/mist/vapours/spray.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Do not breathe dust/fume/gas/mist/vapours/spray. Wear personal protective equipment.
Hygiene measures : Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store locked up. Store in a well-ventilated place.
Storage temperature : 15 – 25 °C

7.3. Specific end use(s)

No additional information available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Formic acid 80% (64-18-6)	
EU - Indicative Occupational Exposure Limit (IOEL)	
Local name	Formic acid
IOEL TWA	9 mg/m ³
Regulatory reference	COMMISSION DIRECTIVE 2006/15/EC

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

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8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colourless.
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: 1.045
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity (oral) : Not classified

Acute toxicity (dermal) : Not classified

Acute toxicity (inhalation) : Not classified

Hydrochloric acid ≥ 25 % (7647-01-0)	
LD50 oral rat	238 – 277 mg/kg (3.3%)
Formic acid 80% (64-18-6)	
LD50 oral rat	730 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 401 (Acute Oral Toxicity), 95% CL: 618 - 863
LC50 Inhalation - Rat	7.85 mg/l air Animal: rat, Guideline: OECD Guideline 403 (Acute Inhalation Toxicity)

Skin corrosion/irritation : Causes severe skin burns.

Serious eye damage/irritation : Assumed to cause serious eye damage

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

Hydrochloric acid ≥ 25 % (7647-01-0)	
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	: Not classified

Formic acid 80% (64-18-6)	
LOAEL (oral, rat, 90 days)	2000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 453 (Combined Chronic Toxicity / Carcinogenicity Studies)
NOAEL (oral, rat, 90 days)	400 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 453 (Combined Chronic Toxicity / Carcinogenicity Studies)
NOAEC (inhalation, rat, dust/mist/fume, 90 days)	0.244 mg/l air Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study)

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Before neutralisation, the product may represent a danger to aquatic organisms.

Hazardous to the aquatic environment, short-term (acute) : Not classified

Hazardous to the aquatic environment, long-term (chronic) : Not classified

Formic acid 80% (64-18-6)	
LC50 - Fish [1]	130 mg/l (freshwater)
LC50 - Fish [2]	1.7 g/l (marine water)
EC50 - Crustacea [1]	365 mg/l (freshwater)
EC50 - Crustacea [2]	531 (marine water)

12.2. Persistence and degradability

No additional information available

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12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other adverse effects : Not release to the environment.






SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions. Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
UN 1760	UN 1760	UN 1760	UN 1760	UN 1760
14.2. UN proper shipping name				
CORROSIVE LIQUID, N.O.S. (Formic acid 80% ; Hydrochloric acid ≥ 25 %)	CORROSIVE LIQUID, N.O.S. (Formic acid 80% ; Hydrochloric acid ≥ 25 %)	Corrosive liquid, n.o.s. (Formic acid 80% ; Hydrochloric acid ≥ 25 %)	CORROSIVE LIQUID, N.O.S. (Formic acid 80% ; Hydrochloric acid ≥ 25 %)	CORROSIVE LIQUID, N.O.S. (Formic acid 80% ; Hydrochloric acid ≥ 25 %)
Transport document description				
UN 1760 CORROSIVE LIQUID, N.O.S. (Formic acid 80% ; Hydrochloric acid ≥ 25 %), 8, II, (E)	UN 1760 CORROSIVE LIQUID, N.O.S. (Formic acid 80% ; Hydrochloric acid ≥ 25 %), 8, II	UN 1760 Corrosive liquid, n.o.s. (Formic acid 80% ; Hydrochloric acid ≥ 25 %), 8, II	UN 1760 CORROSIVE LIQUID, N.O.S. (Formic acid 80% ; Hydrochloric acid ≥ 25 %), 8, II	UN 1760 CORROSIVE LIQUID, N.O.S. (Formic acid 80% ; Hydrochloric acid ≥ 25 %), 8, II
14.3. Transport hazard class(es)				
8	8	8	8	8
				
14.4. Packing group				
II	II	II	II	II
14.5. Environmental hazards				
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No	Dangerous for the environment: No	Dangerous for the environment: No	Dangerous for the environment: No
No supplementary information available				

14.6. Special precautions for user

Overland transport

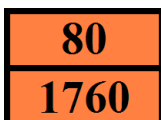
Classification code (ADR) : C9
Special provisions (ADR) : 274
Limited quantities (ADR) : 11

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Excepted quantities (ADR)	: E2
Packing instructions (ADR)	: P001, IBC02
Mixed packing provisions (ADR)	: MP15
Portable tank and bulk container instructions (ADR)	: T11
Portable tank and bulk container special provisions (ADR)	: TP2, TP27
Tank code (ADR)	: L4BN
Vehicle for tank carriage	: AT
Transport category (ADR)	: 2
Hazard identification number (Kemler No.)	: 80
Orange plates	:



Tunnel restriction code (ADR)	: E
EAC code	: 2X
APP code	: B

Transport by sea

Special provisions (IMDG)	: 274
Limited quantities (IMDG)	: 1 L
Excepted quantities (IMDG)	: E2
Packing instructions (IMDG)	: P001
IBC packing instructions (IMDG)	: IBC02
Tank instructions (IMDG)	: T11
Tank special provisions (IMDG)	: TP2, TP27
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-B
Stowage category (IMDG)	: B
Stowage and handling (IMDG)	: SW2
Properties and observations (IMDG)	: Causes burns to skin, eyes and mucous membranes.
MFAG-No	: 154

Air transport

PCA Excepted quantities (IATA)	: E2
PCA Limited quantities (IATA)	: Y840
PCA limited quantity max net quantity (IATA)	: 0.5L
PCA packing instructions (IATA)	: 851
PCA max net quantity (IATA)	: 1L
CAO packing instructions (IATA)	: 855
CAO max net quantity (IATA)	: 30L
Special provisions (IATA)	: A3, A803
ERG code (IATA)	: 8L

Inland waterway transport

Classification code (ADN)	: C9
Special provisions (ADN)	: 274
Limited quantities (ADN)	: 1 L
Excepted quantities (ADN)	: E2
Equipment required (ADN)	: PP, EP
Number of blue cones/lights (ADN)	: 0

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Rail transport

Classification code (RID)	: C9
Special provisions (RID)	: 274
Limited quantities (RID)	: 1L
Excepted quantities (RID)	: E2
Packing instructions (RID)	: P001, IBC02
Mixed packing provisions (RID)	: MP15
Portable tank and bulk container instructions (RID)	: T11
Portable tank and bulk container special provisions (RID)	: TP2, TP27
Tank codes for RID tanks (RID)	: L4BN
Transport category (RID)	: 2
Colis express (express parcels) (RID)	: CE6
Hazard identification number (RID)	: 80

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Contains substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

Name	CN designation	CAS-No.	CN code	Category	Threshold	Annex
Hydrochloric acid	Hydrogen chloride	7647-01-0	2806 10 00	Catégorie 3		Annexe I

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	Revision date	Modified	
	Supersedes	Modified	
14.4	Packing group (ADN)	Modified	
14.4	Packing group (IATA)	Modified	

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Indication of changes			
Section	Changed item	Change	Comments
14.4	Packing group (IMDG)	Modified	
14.4	Packing group (ADR)	Modified	
14.6	Packing instructions (IMDG)	Modified	
14.6	Transport category (ADR)	Modified	
14.6	Excepted quantities (ADR)	Modified	
14.6	Limited quantities (ADR)	Modified	

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number

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Abbreviations and acronyms:	
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Skin Corr. 1	Skin corrosion/irritation, Category 1
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.