

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

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Product identifier MAS™ Omni-Core™ Liquid Assayed Integrated Chemistry Control

Synonyms OCR-101 MAS™ Omni•CORE™ Level 1 (6 x 5 mL)
OCR-202 MAS™ Omni•CORE™ Level 2 (6 x 5 mL)
OCR-303 MAS™ Omni•CORE™ Level 3 (6 x 5 mL)
OCR-SP MAS™ Omni•CORE™ Sample Pack (3 x 5 mL)

Trade names Liquid Assayed Integrated Chemistry Control

Chemical family Mixture

Relevant identified uses of the substance or mixture and uses advised against *In vitro* diagnostic kit.

Note The pharmacological, toxicological, and ecological properties of this product/mixture have not been fully characterized. This data sheet will be updated as more data become available.

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SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Regulation (EC) 1272/2008 [GHS] Respiratory Sensitizer - Category 1. Skin Sensitizer - Category 1. Mixture not yet fully tested

Directive 67/548/EEC or 1999/45/EC Xn - R42 (Respiratory Sens.)/R43 (Skin Sens.) Mixture not yet fully tested.

Label elements

SECTION 2 - HAZARDS IDENTIFICATION ...continued

CLP/GHS hazard pictogram



CLP/GHS signal word Danger

CLP/GHS hazard statements H317 - May cause allergic skin reaction. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

CLP/GHS precautionary statements P261 - Avoid breathing mist or vapor. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/eye protection/ face protection. P285 - In case of inadequate ventilation wear respiratory protection. P302 + P352 - If on skin: Wash with plenty of soap and water. P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. P363 - Wash contaminated clothing before reuse. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

EU symbol/indication of danger



Xn - Harmful

Risk (R) Phrase(s) R42/43 - May cause sensitization by inhalation and skin contact.

Safety Advice S2 - Keep out of reach of children. S23 - Do not breathe spray. S24 - Avoid contact with skin. S37 - Wear suitable protective gloves. S63 - In case of accident by inhalation: remove casualty to fresh air and keep at rest.

Other hazards No data specific for the mixture were identified. The mixture does contain bovine serum albumin, which has been associated with occupational sensitization. Material produced in compliance with USDA and/or CPMP/BWP/1230/98 (Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products). This is a CPMP/ BWP/1230/98 Category IV material: it does not contain nor is it derived from specified risk materials as defined in Commission decision 97/534/EC (or successive amendments).

Because the mixture contains a protein, it may cause an allergic skin or respiratory reaction (e.g., potential to cause anaphylaxis). In a workplace setting, the likelihood of systemic effects following accidental ingestion is low, due to the rapid breakdown of proteins in the digestive tract.

SECTION 2 - HAZARDS IDENTIFICATION ...continued

Other hazards ...continued The mixture contains human source material (human plasma) and should be treated/ handled as a potential biohazard. All such human source material has been derived from donors tested individually and shown by FDA approved methods to be free from antibodies to Human Immune Deficiency Virus and Hepatitis B and C. As no test method can offer complete assurance that these or other infectious agents are not present, this product should be handled using standard biosafety precautions.

US Signal word Danger

US Hazard overview May cause allergic respiratory reaction. May cause allergic skin reaction. Contains human source material. Mixture should be treated/handled as a potential biohazard. Mixture not yet fully tested.

Note This mixture is classified as hazardous according to Directive 1999/45/EC, Regulation EC No 1272/2008 (EU CLP) and applicable US regulations. The pharmacological, toxicological, and ecological properties of this mixture have not been fully characterized. See Section 16 for full text of EU and GHS classifications. The CLP/GHS classifications are based on Regulation (EC) 1272/2008. The EU symbol/indicator of danger, R Phrases and Safety Advice are based on Directive 1999/45/EC.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ELIN CS#</u>	<u>Amount</u>	<u>EU Classification</u>	<u>GHS Classification</u>
Human Source Material	N/A	N/A	24-68%	Not classified	Not classified
Antistreptolysin	9006-92-2	N/A	3-9%	Harmful - Xn: R42/43	SS1: H317; RS1: H334
Dimethyl sulfoxide	67-68-5	200-664-3	0.5-2%	Irritant - Xi: R38	SI2: H315
Bovine serum albumin	9048-46-8	N/A	0.2-0.3%	Harmful - Xn: R42/R43	SS1: H317, RS1: H334

Note The ingredient(s) listed above are considered hazardous. Human source material (human plasma) is listed because it is a potential biohazard. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of EU and GHS classifications. Product also contains trace levels (e.g. <0.03%) of proprietary pharmaceutical ingredients. The EU classification is based on Directive 67/548/EEC and the CLP/GHS classification is based on Regulation (EC) 1272/2008.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

Immediate Medical Attention Needed Yes

SECTION 4 - FIRST AID MEASURES ...continued

Eye Contact	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
Skin Contact	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
Inhalation	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
Ingestion	If swallowed, call a physician immediately. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
Protection of first aid responders	See Section 8 for Exposure Controls/Personal Protection recommendations.
Most important symptoms and effects, both acute and delayed	See Sections 2 and 11
Indication of immediate medical attention and special treatment needed, if necessary	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

SECTION 5 - FIREFIGHTING MEASURES

Extinguishing media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Specific hazards arising from the substance or mixture	No information identified. May emit toxic gases of carbon monoxide, carbon dioxide, and oxides of nitrogen.
Flammability/Explosivity	No explosivity or flammability data identified. As product is an aqueous solution, it is not expected to be flammable or explosive.
Advice for firefighters	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.
Environmental precautions	Do not empty into drains. Avoid release to the environment.
Methods and material for containment and cleaning up	DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice with an appropriate solvent (see Section 9).
Reference to other sections	See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling	This material should be handled at the Biosafety Level 2 (BSL2) consistent with the U.S. Department of Health and Human Services, the U.S. Public Health Service, Centers for Disease Control (CDC), and National Institute of Health (NIH) Guidelines "Biosafety in Microbiological and Biomedical Laboratories" (December 2009, HHS Publication No. (CDC) 21-1112). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing mist/spray.
Conditions for safe storage including any incompatibilities	Store at 2-8 °C in a well-ventilated area, away from incompatible materials. Keep container upright and tightly closed.
Specific end use(s)	No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Note Dispose of broken vials/syringes in a sharps container.

Control

Parameters/Occupational Exposure Limit Values

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Human Source Material	--	--	--
Antistreptolysin	--	--	--
Dimethyl sulfoxide	AIHA	WEEL-TWA	250 ppm

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued

**Control
Parameters/Occupational
Exposure Limit Values
...continued**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
	Austria, Germany, Switzerland	MAK	50 ppm, 160 mg/m ³
	Estonia, Lithuania, Sweden	STEL	150 ppm, 500 mg/m ³
	Estonia, Lithuania Sweden	TWA	50 ppm, 150 mg/m ³
	Finland	TLV	50 ppm, 150 mg/m ³
	Switzerland	TWA	50 ppm
	Switzerland	STEL	100 ppm, 320 mg/m ³
	Germany	Ceiling	100 ppm, 320 mg/m ³
	Denmark	TWA	50 ppm, 160 mg/m ³
	Slovenia	TWA	160 mg/m ³
	Denmark	TWA	50 ppm, 160 mg/m ³
Bovine serum albumin	--	--	--

Exposure/Engineering controls Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at aerosol/mist-generating points.

Respiratory protection Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. An approved and properly fitted air-purifying respirator with HEPA filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls.

Hand protection Wear nitrile, rubber or other impervious gloves if skin contact is possible. If the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Skin protection Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.

Eye/face protection Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Environmental Exposure Controls Avoid release to the environment and operate within closed systems wherever practicable. Liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued

Other protective measures	Wash hands in the event of contact with this product/mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). Decontaminate all protective equipment following use.
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SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Liquid
Color	Colorless
Odor	No information identified.
Odor threshold	No information identified.
pH	6
Melting point/freezing point	No information identified.
Initial boiling point and boiling range	No information identified.
Flash point	No information identified.
Evaporation rate	No information identified.
Flammability (solid, gas)	No information identified.
Upper/lower flammability or explosive limits	No information identified.
Vapor pressure	No information identified.
Vapor density	No information identified.
Relative density	No information identified.
Water solubility	Miscible in water
Solvent solubility	No information identified.
Partition coefficient (n-octanol/water)	No information identified.
Auto-ignition temperature	No information identified.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

Decomposition temperature	No information identified.
Viscosity	No information identified.
Explosive properties	No information identified.
Oxidizing properties	No information identified.
Other information	
Molecular weight	No information identified.
Molecular formula	No information identified.

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	No information identified.
Chemical stability	Stable when stored as recommended.
Possibility of hazardous reactions	Not expected to occur.
Conditions to avoid	Avoid temperatures $\geq 25^{\circ}$ C; excess heat.
Incompatible materials	No information identified.
Hazardous decomposition products	No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Information on toxicological effects

Route of entry May be absorbed by inhalation, skin contact and ingestion.

Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Human Source Material	--	--	--	--
Antistreptolysin	--	--	--	--
Dimethyl sulfoxide	LD ₅₀	Oral	Rat	14.5 g/kg
	LD ₅₀	Oral	Rat	28.3 g/kg
	LD ₅₀	Oral	Mouse	7.9 g/kg
	LD ₅₀	Oral	Mouse	21.4 g/kg
Bovine serum albumin	--	--	--	--

Irritation/Corrosion No data on product formulation. Dimethyl sulfoxide is a skin irritant in humans and animals.

SECTION 11 - TOXICOLOGICAL INFORMATION ...continued

Sensitization	No data on product formulation. As bovine serum albumin (BSA) is derived from animal (foreign) protein, there is potential for the material to cause an allergic response in humans. Occupational exposure to BSA has caused some cases of allergic sensitization in workers handling this material.
STOT-single exposure	<p>No data on product formulation. Male rats were exposed to an aerosol of 1600 mg/m³ DMSO for 4 hr. Groups were sacrificed immediately after exposure, another 24 hours after exposure, and the third group was observed for 2 weeks after exposure before sacrifice. There was no mortality and none of the animals displayed outward signs of toxicity during and after exposure to DMSO. Organs appeared normal at necropsy.</p> <p>Single intravenous injections of undiluted DMSO were administered to groups of male and female rats. Dose levels were 2.5, 5.0, and 10 g/kg. Each dose was administered over a 1-minute interval. Animals were observed for 14 days following DMSO administration. With one exception, deaths occurred within the first 24 hours. Non-lethal doses of DMSO produced decreased motor activity and myasthenia.</p>
STOT-repeated exposure/Repeat-dose toxicity	<p>No data on product formulation. Male rats were exposed to 200 mg/m³ DMSO for 7 hours/day, 5 days a week, over 6 weeks for 30 exposures. There were no outward toxic signs noted in any of the exposed animals throughout the experimental period of 6 weeks and no effects on blood parameters were reported.</p> <p>DMSO was administered dermally to rabbits for 30 days at a dose of 1 or 5 g/kg/day. Rabbits received dermal applications of DMSO to normal and abraded skin for a period of 23 weeks, when ocular changes were observed. Treatment was withheld from animals showing ocular changes; the remaining animals continued to receive DMSO applications for the scheduled 26 weeks (6 months). Mortality was high in all groups, however there was no significant differences in mortality between groups. There were no clinical signs to suggest systemic toxicity.</p> <p>DMSO was administered as a 90% solution to rhesus monkeys by gastric intubation, 7 days a week for up to 87 weeks. Dosages administered were equivalent to 990, 2970, and 8910 mg/kg/day. The principal physical signs seen in the animals given DMSO orally included excess salivation and emesis. These signs occurred sporadically and did not appear to be related to the dose except in the group receiving higher volume of compound. Anorexia occurred at high oral doses but was not evident at the 2 lower dose levels. No DMSO-related changes were found in the treated monkeys during physical examinations.</p>
Reproductive toxicity	No data on product formulation. DMSO has been extensively used as a cryoprotectant in the freezing of early experimental animal and human embryos. The viability and apparent normalcy of frozen embryos after thawing suggests that DMSO exposure is not toxic to the early embryo.

SECTION 11 - TOXICOLOGICAL INFORMATION ...continued

Developmental toxicity	<p>No data on product formulation. Equivocal: DMSO has been associated with teratogenic and/or embryotoxic effects in the hamster, rat, mouse, and chick at high doses. In the hamster, the injection of 500 to 800 mg/kg on the 8th day of gestation was associated with a wide variety of congenital defects, including exencephaly, microphthalmia, bone and limb abnormalities, and as cleft lip. Increased frequencies of fetal death were observed when pregnant rats or rabbits were treated with doses of 5-10 or 1-3 g/kg/day, respectively.</p> <p>However, fetal death was not increased in another study after intraperitoneal treatment of pregnant rats with 6.9 g/kg/day of dimethyl sulfoxide. No malformations were observed in the offspring of rats treated with dimethyl sulfoxide at doses of 0.2-5 g/kg/day during pregnancy.</p>
Genotoxicity	<p>No data on product formulation. Dimethyl sulfoxide was negative for genotoxicity in an Ames bacterial cell mutagenicity assay and a sister chromatid exchange assay in Chinese hamster ovary cells.</p>
Carcinogenicity	<p>No data on product formulation. None of the components of the mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.</p>
Aspiration hazard	<p>No data available.</p>
Human health data	<p>See "Section 2 - Other Hazards"</p>
Additional information	<p>The toxicological properties of this mixture have not been fully characterized.</p>

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Human Source Material	--	--	--
Antistreptolysin	--	--	--
Dimethyl sulfoxide	EC ₅₀ /96h	Skeletonema costatum (Diatom)	12.35 - 25.5 g/L
	LC ₅₀ /96h	Pimephales promelas	34 g/L
	LC ₅₀ /96h	Oncorhynchus mykiss	33-37 g/L (static)
	LC ₅₀ /96h	Lepomis macrochirus	>40 g/L (static)
	LC ₅₀ /96h	Cyprinus carpio	41.7 g/L
	EC ₅₀ /24h	Daphnia magna	7 g/L
Bovine serum albumin	--	--	--

Additional toxicity information No data available.

Persistence and Degradability No data available.

SECTION 12 - ECOLOGICAL INFORMATION ...continued

Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Results of PBT and vPvB assessment	No data available.
Other adverse effects	No data available.
Note	The environmental characteristics of this product/mixture have not been fully investigated. Releases to the environment should be avoided.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods	Used product should be disposed of according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.
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SECTION 14 - TRANSPORT INFORMATION

Transport	Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
UN number	None assigned.
UN proper shipping name	None assigned.
Transport hazard classes and packing group	None assigned.
Environmental hazards	Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.
Special precautions for users	Mixture not fully tested - avoid exposure.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 15 - REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture	This SDS complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines. Consult your local or regional authorities for more information.
Chemical safety assessment	Not conducted.
OSHA Hazardous	Yes. Danger. May cause allergic respiratory reaction. May cause allergic skin reaction. Mixture should be treated/handled as a potential biohazard. Mixture not fully tested.
WHMIS classification	This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.
TSCA status	Not listed
SARA section 313	Not listed.
California proposition 65	Not listed.

SECTION 16 - OTHER INFORMATION

Full text of R phrases and EU Classifications	Xi - Irritant. Xn - Harmful. R38 - Irritating to skin. R42/43 - May cause sensitization by inhalation and skin contact.
Full text of H phrases, P phrases and GHS classification	SI2 - Skin irritant Category 2. H315 - Causes skin irritation. SS1 - Skin sensitizer Category 1. H317 - May cause an allergic skin reaction. RS1 - Respiratory Sensitizer Category 1. H334 - May cause allergic or asthmatic symptoms or breathing difficulty if inhaled.
Sources of data	Information from published literature and internal company data.
Abbreviations	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and

SECTION 16 - OTHER INFORMATION ...continued

Abbreviations ...continued Reauthorization Act; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System

Revisions This is the first version of this SDS.

Disclaimer The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical/diagnostic product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.