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APPROVED

Deputy Director  
of FSBI “NMRC RB” of the Ministry of  
Health of Russia

A.D. Fesyun

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/Stamp/

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To your Ref. No. \_\_\_\_\_

**Special Medical Assessment Report for Therapeutic Sulfide Silt Muds of the  
Dzharylgachsky Subsoil Block in the Chernomorsky Region**

**Republic of Crimea**

This special medical assessment report has been issued for the “Geominvod Firm for Exploration, Protection and Application Technology of Natural Therapeutic Resources” Limited Liability Company (Geominvod LLC (INN 7726314313, OGRN 1027739676568), apt. 225, bldg. 2, 8 Sumskaya Str., Moscow, 117208).

**1. List of Documents and Information Used under the Development of the Special Medical Assessment Report**

- 1.1 License for the subsoil use SMF 00212 MR with amendments (the License is valid till January 17, 2025).
- 1.2 Test Report No. 8235-GR dated 20.07.2022 as per the flowchart of complete physical and chemical analysis of mud with the results of measuring the mass fraction of metals active form by the atomic-absorption flame spectrometry and content of radionuclides, issued by the Test and Expertise Centre for Natural Healing Resources of the FSBI “NMRC RB” of the Ministry of Health of Russia.
- 1.3 Test Report No. 8217-GR dated 04.07.2022 as per the flowchart of brief physical and chemical analysis of mud and content of radionuclides, issued by the Test and Expertise Centre for Natural Healing Resources of the FSBI “NMRC RB” of the Ministry of Health of Russia.
- 1.4 Test Report No. 8218-GR dated 04.07.2022 as per the flowchart of brief physical and chemical analysis of mud and content of radionuclides, issued by the Test and Expertise Centre for Natural Healing Resources of the FSBI “NMRC RB” of the Ministry of Health of Russia.
- 1.5 Reports of the reduced physical and chemical analysis of therapeutic mud No. 444, 446, 451, 454, issued by the State Unitary Research and Production Enterprise of the Republic of Crimea "Crimean Hydrogeological Monitoring and Operational Station" (SURPE RC “Crimean HMOS”), sampling date: 14.05.2022.
- 1.6 Results of the brief physical and chemical analysis of therapeutic mud No. 456-463, 465-467, 469, 764, issued by the SURPE RC “Crimean HMOS”, sampling date: 13.05.2022.
- 1.7 Results of the brief physical and chemical analysis of therapeutic mud (understratum) No. 471, 472, issued by the SURPE RC “Crimean HMOS”, sampling date: 14.05.2022
- 1.8 Test Report No. 8224-GR dated 04.07.2022 for the surface brine as per the flowchart of brief chemical analysis, issued by the Test and Expertise Centre for Natural Healing Resources of the FSBI “NMRC RB” of the Ministry of Health of Russia.
- 1.9 Reports of the reduced chemical analysis of water No. 475, 477, 478, issued by the SURPE RC “Crimean HMOS”, sampling date: 12.05.2022.

- 1.10 Results of the brief chemical analysis of brine No. 479 (water from the sea surface), issued by the SURPE RC “Crimean HMOS”, sampling date: 19.05.2022
- 1.11 Results of the brief chemical analysis of brine No. 480-482 (brine from the surface), issued by the SURPE RC “Crimean HMOS”, sampling date: 12.05.2022
- 1.12 Results of the sanitary and bacteriological analysis of mud No. 415-419, 421-426, issued by the SURPE RC “Crimean HMOS”, test dates: 16.05.2022 – 18.05.2022.
- 1.13 Results of the sanitary and bacteriological analysis of brine No. 405-414, issued by the SURPE RC “Crimean HMOS”, test dates: 16.05.2022 – 18.05.2022.
- 1.14 Content of residual quantities of pesticides in therapeutic mud, issued by the SURPE RC “Crimean HMOS”, sampling date: 14.05.2022.
- 1.15 Report on the detailed exploration of Lake Dzharylgach mud field, Crimean Region, Moscow-1977, prepared by the Specialized Complex Hydrogeological Party, Geominvod, Central Institute of Balneology and Physiotherapy of the Ministry of Health of the USSR (database of hydrogeological funds of FSBI “NMRC RB” of the Ministry of Health of Russia).

## **2 List of Regulatory Documentation Used to Develop the Special Medical Assessment Report**

- 2.1 Federal Law No. 26-FZ dated February 23, 1995 “On Natural Therapeutic Resources, Health and Recreation Areas and Resorts”.
- 2.2 Order of the Ministry of Health of the Russian Federation No. 557n dated May 31, 2021 “On Approval of the Classification of Natural Therapeutic Resources, Medical Indications and Contraindications for Their Use with Treatment and Prophylactic Purposes” (hereinafter referred to as the “Classification of natural therapeutic resources”).
- 2.3 Order of the Ministry of Health of the Russian Federation No. 558n dated May 31, 2021 “On Approval of the Rules and Regulations for the Use of Natural Therapeutic Resources, Health and Recreation Areas and Resorts”.
- 2.4 Guidelines of the Ministry of Health of the USSR No. 10-11/40 dated March 11, 1987. Guidelines. Criteria for assessing the quality of therapeutic muds in the course of their exploration, use and protection.

## **3 Description of the Point of Extraction (Location) of Therapeutic Sulfide Silt Mud**

The Dzharylgachsky subsoil block is located in the Chernomorsky Region of the Republic of Crimea and is confined to Lake Dzharylgach. Lake Dzharylgach is located in the northwestern part of the Tarkhankut peninsula, 15 km from Chernomorskoe regional center, 65 km from Yevpatoria.

According to its genetic type, Lake Dzharylgach is a coastal lake. The lake kettle is composed of clays, loams, limestone and is almost completely filled with lacustrine deposits.

The lake is separated from the Black Sea by a 500-700 m wide and up to 2 m high sand-and-shingle baybar. The lakefront is composed of inequigranular sand with gravel and broken shell. The water surface area is 8.3 km<sup>2</sup>, the lake maximum depth is 0.85 m in the western part, 0.4 to 0.5 m in the eastern part.

Lake Dzharylgach is drainless and salt. The lake is fed by sodium chloride sea waters with 18 g/l mineralization, underground sulfate-chloride waters of Meotian-Pontian deposits with 3.3-3.7 g/l a mineralization, and atmospheric precipitation. According to their chemical composition, the waters of Lake Dzharylgach are sodium chloride type with 101 to 185 g/l mineralization and bromine content up to 260 mg/l.

Therapeutic muds of Lake Dzharylgach rest from the surface of bottom deposits, at a distance of 25 to 75 m from the shore. In the western part of the lake, on an area of 3.1 km<sup>2</sup>, black slimes with the smell of hydrogen sulfide and thickness of up to 15 cm rest from the surface. In the eastern part of the lake, soft contaminant-free dark grey silts with the smell of hydrogen sulfide rest from the surface. The area of dark grey silt deposit is 6.8 km<sup>2</sup>, their maximum thickness is 0.5-0.6 m.

Dark grey silts are overlaid by light grey silts with a slight smell of hydrogen sulfide, with inclusions and thin (up to 3 cm) interlayers of large shells, heavily sanded and compacted in the base in some locations. The penetrated thickness of light grey silts is approximately 6.0 m.

The lake black slimes are liquefiable. Their moisture content is 48-51%, bulk density is 1.4-1.5 g/cm<sup>3</sup>, contamination is 0.8-1.4%, pH is 7.1-7.4, organic matter content is up to 1.5 %, sulfides content is 0.2-0.3%. The mud solution mineralization is 170.0-177.0 g/l, the solution is sodium chloride according to the ionic content, contains up to 127.0 mg/l of bromine.

The chemical composition of dark grey silts differs from that of the black slimes insignificantly. Their moisture content is 48-50%, bulk density is 1.4-1.5 g/cm<sup>3</sup>, contamination is 0.2-0.7%, pH is 7.3-7.5, organic matter content decreases to 0.13%, sulfides contents decreases to 0.05-0.08%. The mud solution mineralization is 128.0-150.0 g/l.

In light grey silts, the mud solution mineralization decreases to 88-103 g/l, organic matter content - to 0.1%. The sulfides content is 0.01-0.03%.

The therapeutic mud reserves of Lake Dzharylgach were determined in 1976 using an edge-based approach. The total therapeutic mud reserves include black salt-saturated medium sulfide and dark grey highly mineralized low sulfide therapeutic muds.

The balance reserves include a mud deposit with a total seam thickness (black slimes and dark grey silts) exceeding 0.2 m.

The therapeutic mud balance reserves amounted to 3.0 mln m<sup>3</sup> with an area of mud deposit distribution ranging from 0.2 to 6.0 km<sup>2</sup> and an average thickness of 0.45 m, including the balance reserves of black salt-saturated medium sulfide mud of 0.3 mln m<sup>3</sup> and dark grey highly mineralized low sulfide mud of 2.7 mln m<sup>3</sup>.

In 1976, the Dzharylgach field was classified as a reserve one. The therapeutic mud reserves were classified as category B reserves.

Additional exploration of the Dzharylgach field in 1987 showed that the lake mud deposit is relatively simple in its structure, thin and consistent in area. No significant changes in the nature of the mud deposit structure were found. The therapeutic mud reserves were classified as C<sub>1</sub> category due to the poorly investigated hydrological and hydrochemical conditions, lack of monitoring data and data on the recovery and self-purification period.

In 2012, a feasibility study and a calculation of commercial reserves of therapeutic mud and brine of the Dzharylgach field of the Chernomorsky Region of the Autonomous Republic of Crimea were carried out, and the following balance reserves were identified: 248.12 thousand m<sup>3</sup> of category B (first-priority development area) and 1,527.63 thousand m<sup>3</sup> of category C<sub>1</sub>.

The maximum annual level of therapeutic mud extraction is set to be 4,000 tons per year.

#### **4 Characteristics of the Effective Data of Analytical Studies of the Natural Therapeutic Mud under Consideration in Accordance with the Analysis of Data on Observations over the Natural Therapeutic Mud Composition and Quality**

The mud characteristics are given based on the results of processing the provided materials, mud samples test results and data of archive materials of the FSBI "NMRC RB" of the Ministry of Health of Russia.

The main indicators of the natural mud therapeutic significance are as follows:

4.1 organic matter content (percentage of dry matter) - 2.70;

4.2 mud solution mineralization value (g/dm<sup>3</sup>) - 80.37 to 138.02. The basic ionic content according to the data obtained (in g/dm<sup>3</sup>) and the formula for the mud extraction chemical composition (test report for

native mud with an explanatory note) given below, the nature of the mud extraction composition: sulfate chloride (sometimes chloride) magnesium sodium:

Cl <sup>-</sup>	42.6 – 75.94	(Na <sup>+</sup> + K <sup>+</sup> )	22.4 – 42.55
SO <sub>4</sub> <sup>2-</sup>	8.38 – 11.44	Ca <sup>2+</sup>	1.21 – 1.6
HCO <sub>3</sub> <sup>-</sup>	0.21 – 0.93	Mg <sup>2+</sup>	4.13 – 5.83
		Cl 86 SO <sub>4</sub> 13	
M <sub>80,37</sub>	<hr/>		
		(Na + K) 70 Mg 24	

- 4.3 content of iron sulfides in natural mud (%) - 0.07 to 0.74;
- 4.4 ash content value (percentage on dry matter) - 87.1 to 87.5;
- 4.5 value of medium reaction index pH (pH units) for native mud - 6.4 to 7.14;
- 4.6 biologically active components (g/dm<sup>3</sup>): bromine - 0.22 to 0.28, iodine – N/D, boron (calculated with reference to orthoboric acid) - 0.091.
- 4.7 organoleptic properties – uneven colour, from light grey to dark grey, the consistency is visually even, soft, tactilely uneven, sticky, plastic, adheres to the skin well, stains the skin superficially, has a distinct hydrogen sulfide smell, with 10% hydrochloric acid (HCl) boils violently, evolves a strong smell of hydrogen sulfide;
- 4.8 indicators of therapeutic mud application ability normalization: shear resistance (dyne/cm<sup>2</sup>) varies according to the data presented from 2,862.3 to 7,717, contamination with mineral inclusions exceeding 0.25 mm is 0.03 to 4.6% to native mud, contamination with mineral inclusions exceeding 5 mm is 0 to 3.78% to native mud, humidity is 48.42 to 54.7% to native mud.
- 4.9 content of components harmful (toxic) to humans in therapeutic mud (mg/kg) is as follows: Zn (zinc) – N/D, Cu (copper) – 0.35, Pb (lead) – N/D, Cd (cadmium) – 0,16 (test report for native mud with an explanatory note).

In accordance with the Classification of Natural Therapeutic Resources, therapeutic muds of the Dzharylgachsky subsoil block include the following:

- by origin (type) – mineral (sulfide) silt (silt deposits of mainly saline water bodies containing less than 10% of organic matter (percentage of dry matter), and usually enriched with water-soluble salts and sulfides);
- by mud solution mineralization value (subtype) – highly mineralized - over 35 g/dm<sup>3</sup>, but not exceeding 150 g/dm<sup>3</sup> (average value of the mud extraction mineralization is 114.86 g/dm<sup>3</sup>);
- by the content of iron sulfides in natural mud (variety) – medium sulfide - over 0.15%, but not exceeding 0.50% (average value of the content of iron sulfides in natural mud is 0.21%);
- by ash content value (percentage on dry matter) (subvariety) – high-ash-content (all sulfide silt);
- by the value of medium reaction index (pH) (sort) – weakly acid - over 5.0 units, but not exceeding 7.0 units (average value of medium reaction index pH (pH units) is 6.88).

The comparison of the analysis results obtained with the data of observations over the physical and chemical composition of the Dzharylgachsky subsoil block sulfide silt muds, as well as the correspondence of indicators of the quantitative composition of previously conducted studies allow to conclude that they are stable. Minor variations of quality indicators changing the classification of mud are allowable, if they correspond to the related mud variety. Thus, the sulfide silt mud of the Dzharylgachskoe field is described by almost identical classifying parameters and formulas for the mud extraction chemical composition (Table 1):

Table 1

By origin and organic matter content (% of dry matter)	By iron sulfides content (% to natural mud)	By mud solution mineralization value and mud extraction chemical composition formula	By medium reaction index value (pH)	Study conducted in (year)
Sulfide silt Up to 1.30	Medium sulfide 0.20-0.36	Salt-saturated M 170-177 <u>Cl</u> 91 SO4 9 (Na + K)78-79 Mg 20-19	Weakly alkaline 7.1-7.4	Data from the report dated 1977
Sulfide silt 2.70	Highly sulfide 0,74	Highly mineralized M 80,37 <u>Cl</u> 86 SO4 13 (Na + K)70 Mg 20-19	Weakly acid 6.5	2022
Sulfide silt -	Medium sulfide 0.239	Highly mineralized M 120,8 <u>Cl</u> 89 (Na + K)76 Mg 21	Weakly alkaline 7.14	2022
Sulfide silt -	Medium sulfide 0.07	Highly mineralized M 117,1 <u>Cl</u> 89 (Na + K)75 Mg 21	Weakly alkaline 7.04	2022
Sulfide silt -	Medium sulfide 0.241	Highly mineralized M 122,4 <u>Cl</u> 89 (Na + K)76 Mg 21	Weakly alkaline 7.08	2022
Sulfide silt -	Medium sulfide 0.13	Highly mineralized M 138,0 <u>Cl</u> 89 (Na + K)77 Mg 20	Weakly alkaline 7.06	2022

## 5 Conditioned Content of Components Harmful to Humans in a Natural Therapeutic Resource

Chemical safety indicators include the content of 1 and 2 hazard class heavy metals: lead (Pb), cadmium (Cd), zinc (Zn), mercury (Hg), copper (Cu), nickel (Ni) and arsenic (As).

Table 2

### Chemical Safety Indicators

Name of a toxic element (substance)	Content (mg/kg) corresponding to the pollution level 2 (low level)
Lead (Pb)	125
Cadmium (Cd)	3
Zinc (Zn)	500
Mercury (Hg)	3
Copper (Cu)	200
Nickel (Ni)	150
Arsenic (As)	20

The results obtained in terms of the chemical safety indicators do not exceed the standard (conditioned) content of elements harmful to humans, specified in Table 2.

Microbiological safety indicators for therapeutic muds are given in Table 3.

Table 3

Indicators	Standard levels
TMC (CFU/g)	500,000
Titer of lactose-positive <i>Bacillus coli</i>	10
Titer of <i>Clostridium</i>	0.1
<i>P. aeruginosa</i> (blue pus bacillus)	N/D in 10 g
<i>S. aureus</i> (pathogenic staphylococci)	N/D in 10 g
Enterococci	N/D in 10 g
Fecal coliform	N/D in 10 g

The results obtained in terms of the microbiological safety indicators do not exceed the standard content of microorganisms pathogenic to humans, specified in Table 3.

Radiation safety indicators are given in Table 4.

Table 4

Indicator name	Units of measurement	Standard level
Radium-226	Bq/kg	$A_{\text{eff}} = A_{\text{Ra}} + 1.3A_{\text{Th}} + 0.09A_{\text{K}}$ $A_{\text{eff}} \leq 370$
Thorium-232	Bq/kg	
Potassium-40	Bq/kg	

The results obtained in terms of the radiation safety indicators are below the standard level.

## 6 Conditioned Content of Components Useful to Humans in a Natural Therapeutic Resource

The organic matter content is below 10% (percentage of dry matter).

The mud solution mineralization is over 35 g/dm<sup>3</sup>, but does not exceed 150 g/dm<sup>3</sup>

Basic ionic content of the mud solution (g/dm<sup>3</sup>):

Cl <sup>-</sup>	40-90	(Na <sup>+</sup> + K <sup>+</sup> )	20-50
SO <sub>4</sub> <sup>2-</sup>	8-13	Mg <sup>2+</sup>	1.1-1.8
HCO <sub>3</sub> <sup>-</sup>	0.20-1.0	Ca <sup>2+</sup>	4.0-6.0

The content of iron sulfides in natural mud is above 0.15%, but does not exceed 0.50%.

## 7 Conclusion on a Natural Resource Allocation to Natural Therapeutic Resources, Quality of a Natural Therapeutic Resource and its Safety for Human Life and Health

In accordance with the Classification of Natural Therapeutic Resources, the Dzharylgachskoye field mud is a sulfide silt, highly mineralized, medium sulfide, weakly acid therapeutic mud.

The mud extraction composition is chloride (sometimes sulfate chloride) magnesium sodium.

The comparison of the analysis results obtained with the data of observations over the condition of the Dzharylgachsky field sulfide silt muds, as well as the correspondence of indicators of the quantitative composition of previously conducted and submitted studies allow to conclude that they are stable. Minor variations of quality indicators changing the classification of mud are allowable, if they correspond to the related mud variety.

The Dzharylgachskoye field therapeutic sulfide silt mud meets the requirements of chemical, radiological, sanitary and microbiological safety and can be used for treatment and prophylactic purposes and in health resort practice while maintaining its characteristics.

## 8 List of Medical Indications for the Application of Therapeutic Sulfide Silt Mud for Treatment and Prophylactic Purposes

8.1 Diseases of the nervous system:

- disorders of individual nerves, nerve roots and plexi; polyneuropathies; diseases of myoneural junction and muscle; consequences of injuries to the roots, plexi, nerve trunks, spinal cord and brain (G 50-C 50.8, G 51.0-0 51.8, G 54- G 54.7, G 55.1- G 56.3, G 57- G 57.6, G 58, G 60- G 62.8, G 71- G 71.2), (T 90-T 95.2); consequences of surgical removal of the nervous system benign tumors, poliomyelitis; cerebral palsy (G 80); disorders of the autonomic nervous system (G 90- G 90.8).

8.2. Diseases of the musculoskeletal system: arthropathies, osteoarthritis; systemic connective tissue lesions; dorsopathies and spondylopathies; soft tissue diseases; osteopathies and chondropathies (M 02.0- M 02.8, M 05-M 08, M 07.0-M 07.6, M10.0, M 15.0-M 19.8, M 41.0-M 42.1, M 45, M 54, M 60.1-M

60.8, M 65.2-M 65.8, M 70, M 70.2-M 70.4, M 72.8-M 72.8, M 75-M 77.8, M 81.0-M 81.8, M 84.0-M 85.1, M 86.3-M 86.8).

8.3. Diseases of the genitourinary system:

- diseases of male genital organs (chronic prostatitis (N 41.1, N 41.3), orchitis, epididymitis (N 45.9), trigonitis (N 30.1-N 30.3));

- inflammatory diseases of female genital organs (N 70, N 70.1, N 71.1, N 73-M 73.6).

## **9 Methodology for the Therapeutic Sulfide Silt Mud Application for Treatment and Prophylactic Purposes**

Therapeutic sulfide silt muds are intended for external application and / or intracavitary use to treat and prevent diseases in the course therapy according to special differentiated techniques, considering various nosological entities.

Therapeutic sulfide silt muds are allowed for self-controlled periodic external applications.

### **10 List of Medical Contraindications for the Use of Sulfide Silt Muds for Treatment and Prophylactic Purposes**

10.1 Acute and subacute diseases, including acute infectious diseases before the end of quarantine period.

10.2 Chronic diseases in the acute stage.

### **11 Period of Special Medical Assessment Report Validity**

The validity period for this special medical assessment report is 5 (five) years starting from the date of its issuance (approval).

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